



Screening of available evidence on chemical substances for the identification of endocrine disruptors according to different options in the context of an Impact Assessment

Specific Contract SANTE/2015/E3/SI2.706218

Final report



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The present screening was carried out in the context of an impact assessment to evaluate the impacts associated to options for criteria to identify endocrine disruptors under the regulations on plant protection products and biocidal products. The screening was based on available evidence (no additional testing) and needed to be carried out in a limited time. The screening methodology was developed for the purpose of the screening exercise.

The results of the screening therefore do not constitute evaluations of individual substances to be carried out under the respective chemical legislations [in particular, Regulation (EC) No 1107/2009 on plant protection products, Regulation (EU) No 528/2012 on biocidal products, Regulation (EC) No 1907/2006 REACH, Regulation (EC) No 1223/2009 on cosmetic products and the Water Framework Directive (EC) No 2000/60] and in no way prejudge future decisions on active substances to be taken pursuant to these pieces of the EU legislation.

It would thus be erroneous to consider that the substances listed in the results of this study (SANTE/2015/E3/SI2.706218) are considered as endocrine disruptors within the meaning of the EU legislation.

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Abbreviations

AOP: Adverse Outcome Pathways

ATP: Adaptation to Technical Progress

AVK: Anti-vitamin K

BPC: Biocidal Products Committee

BPC: Biocidal Products Committee

BPI: Benaki Phytopathological Institute

BPR: Biocides Product Regulation

BPs: Biocidal Products

C & L: Classification and Labelling

CAR: Competent Authority Report

CIRCABC: Communication and Information Resource Centre for Administrations, Businesses and Citizens

CLH: Harmonised classification and labelling

CLP: Classification, Labelling and Packaging Regulation

CoRAP: Community rolling action plan

CosIng: Cosmetic Ingredient Database

DAR: Draft Assessment Report

DBB: Di- μ -oxo-di-n-butylstanniohydroxyborane/Dibutyltin hydrogen borate C₈H₁₉BO₃Sn

DBT: Dibutyltin

DBTDL: Dibutyltin dilaurate

DG GROW: Directorate General for Internal Market, Industry, Entrepreneurship and SMEs

DG SANTE: Directorate General for Health and Food Safety

DOTe: 2-ethylhexyl 10-ethyl-4,4-dioctyl-7-oxo-8-oxa-3,5-dithia-4-stannatetradecanoate

EASIS: Endocrine Active Substances Information System

EATS: Estrogen, Androgen, Thyroid, Steroidogenesis

The results of the screening do not constitute evaluations of individual substances to be carried out under the respective chemical legislations [[in particular, Regulation (EC) No 1107/2009 on plant protection products, Regulation (EU) No 528/2012 on biocidal products, Regulation (EC) No 1907/2006 REACH, Regulation (EC) No 1223/2009 on cosmetic products and the Water Framework Directive (EC) No 2000/60] and in no way prejudice future decisions on active substances to be taken pursuant to these pieces of the EU legislation.

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EC: European Commission

ECB: European Chemicals Bureau

ECHA: European Chemicals Agency

ED(s): Endocrine disruptor(s)

EDSP: Endocrine Disruptor Screening Program

EFSA: European Food Safety Authority

ER: Estrogen Receptor

EU: European Union

GLP: Good Laboratory Practice

IA: Impact Assessment

JRC: Joint Research Centre

LOAEL: Lowest Observed Adverse effect Level

LoEPs: List of Endpoints

MoA: Mode of Action

MOTE: 2-Ethylhexyl 10 ethyl-4-((2-((2-ethylhexyl)oxy)-2-oxoethyl)thio)-4-octyl-7-oxo-8-oxa-3,5-dithia-4-stannatetradecanoate

Muta.: Mutagenicity

NOAEL: No Observed Adverse Effect Level

OECD: Organisation for Economic Co-operation and Development

OTC: Organotin compounds

PPAR: Peroxisome proliferator-activated receptor

PPPR: Plant Protection Product Regulation

PPPs: Plant Protection Products

QSAR: Quantitative Structure-Activity Relationship

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RAC: Committee for Risk Assessment

RAR: Renewal Assessment Report

REACH: Registration, Evaluation, Authorisation and Restriction of Chemicals

Repr. Cat.: Reproductive toxicity Category

SCCP: Scientific Committee on Consumer Products

SCCS: Scientific Committee on Consumer Safety

SIN: Substitute It Now

STOT-RE: Specific Target Organ Toxicity-Repeated Exposure

SVHC: Substance of Very High Concern

T3: Triiodothyronine

T4: Thyroxine

TBT: Tributyltin

TBTBr: Tributyltin bromide

TBTCl: Tributyltin chloride

TEDX: The Endocrine Disruption Exchange

ToxCast: EPA's Toxicity Forecaster

TPT or TPhT: Triphenyltin

TPTCl: Triphenyltin chloride

TSH: Thyroid Stimulating Hormone

VAR: Voluntary Risk Assessment Report

WFD: Water Frame Directive

WHO: World Health Organization

WoE: Weight of Evidence

EXECUTIVE SUMMARY

Screening of available evidence on chemical substances for the identification of endocrine disruptors according to different options in the context of an Impact Assessment

**Specific Contract
SANTE/2015/E3/SI2.706218**

Introduction

At the EU level, specific legislative provisions on endocrine disruptors (EDs) have been included in the Regulation on Plant Protection Products (PPPR), the Regulation on Biocidal Products (BPR), the Regulation on Chemicals (REACH), the Cosmetic Products Regulation (CPR), the Water Framework Directive (WFD) and the Commission Proposal for a Regulation on Medical Devices. However, scientific criteria allowing for the identification of EDs have not been set so far. Under the PPP and BP Regulations, the European Commission was legally required to proposed scientific criteria to identify EDs.

In this context, the European Commission carried out an impact assessment to estimate the potential impacts associated to different options for criteria to identify EDs. As a first step of this impact assessment, a Roadmap for defining criteria for identifying EDs has been published by the European Commission in 2014 (EC, 2014). Four options for identifying EDs were proposed in the Roadmap: beside the current status quo (the interim criteria set in both the PPPR and BPR), there were three options based on a definition proposed in 2002 by the World Health Organisation via its International Programme for Chemical Safety (WHO/IPCS). This WHO/IPCS definition of an endocrine disruptor is: "an exogenous substance or mixture that alters function(s) of the endocrine system and consequently causes adverse health effects in an intact organism, or its progeny, or (sub)populations" ¹ and it is widely accepted amongst scientists.

The present study was carried out for compiling supporting evidence for the impact assessment with the aim to estimate the number and identity of the chemicals which would be identified under each of the four options outlined in the Roadmap. The methodology for the screening was developed by the European Commission's Joint Research Centre (JRC). The available toxicological evidence on approximately 600 substances was screened, estimating which substances would be potentially identified as EDs when applying the different options for the criteria detailed in the Roadmap.

The screening started in May 2015 and lasted until June 2016. It covered sequentially almost all active substances authorized in the EU for use in PPPs, almost all authorized BPs, as well as a selection of substances falling under the REACH Regulation, the CPR and WFD. The list of screened substances was published in November 2015 (EC, 2015): http://ec.europa.eu/health/endocrine_disruptors/docs/impactassessment_chemicalsubstancesselection_en.pdf. The screening was a desk-based work evaluating existing evidence and toxicological data, *i.e.* no additional data were generated for the purpose of this work.

The specific objectives and results of the study are reflected in the deliverable reports, which constitute chapters of this final report.

Chapter 1. Initial feedback on the practical applicability of the screening methodology developed by JRC: Pilot study (report D1).

Chapter 2. Screening of a pre-defined set of 348 active substances approved for their use in plant protection products (PPPs) (report D2).

¹ WHO/IPCS (World Health Organization/International Programme on Chemical Safety), 2002. Global Assessment of the State-of-the-science of Endocrine Disruptors. WHO/PCS/EDC/02.2, publicly available at http://www.who.int/ipcs/publications/new_issues/endocrine_disruptors/en/.

The results of the screening do not constitute evaluations of individual substances to be carried out under the respective chemical legislations [[in particular, Regulation (EC) No 1107/2009 on plant protection products, Regulation (EU) No 528/2012 on biocidal products, Regulation (EC) No 1907/2006 REACH, Regulation (EC) No 1223/2009 on cosmetic products and the Water Framework Directive (EC) No 2000/60] and in no way prejudice future decisions on active substances to be taken pursuant to these pieces of the EU legislation.

It would thus be erroneous to consider that the substances listed in the results of this study (SANTE/2015/E3/SI2.706218) are considered as endocrine disruptors within the meaning of the EU legislation.

Chapter 3. Screening of a pre-defined set of 96 active substances approved for their use in biocidal products (BPs) (report D3).

Chapter 4. Revision of 51 PPPs and 18 BPs after inclusion of additional data and JRC's comments (Addendum to D2 and D3 reports)

Chapter 5. Screening of a miscellaneous set of 186 substances within the scope of REACH, the CPR and the WFD (report D4).

Materials & Methods

The screening of the available information for each substance was focused on adverse effects relevant to endocrine disruption and mechanistic data indicative of an endocrine mode of action (MoA). All mammalian toxicity data, unless stated otherwise, were regarded as being relevant to humans. For ecotoxicological assessment, effects from mammalian data were used, as well as data from wildlife vertebrates (i.e. fish, amphibians and to a limited degree birds and reptiles). For ecotoxicological assessment, only the adverse effects that were considered to be population relevant were taken into account for potential categorization as ED. For the extraction of the data the following data sources were used:

1. EU Pesticides Database
2. European Chemicals Agency (ECHA)
3. CIRCABC²; Groups: Health and Food Safety-PLANT PROTECTION PRODUCTS AND THEIR RESIDUES & European Chemicals Agency-Biocides TM
4. European Food Safety Authority (EFSA)
5. Cosmetic Ingredient Database (CosIng)
6. Substitute It Now (SIN) list
7. Endocrine Disruptor Screening Program (EDSP, US EPA)
8. The Endocrine Disruption Exchange (TEDX) list
9. Endocrine Active Substances Information System (EASIS, JRC)
10. US EPA's Toxicity Forecaster (ToxCast, US EPA)
11. Open literature

More specifically, this screening procedure considered the effects on the estrogenic, androgenic, thyroid and steroidogenesis (EATS) pathways, which are those for which internationally agreed study protocols are available. Guidance on the ED relevance of the reported effects was based on OECD Guidance Document 1503.

² CIRCABC: Communication and Information Resource Centre for Administrations, Businesses and Citizens.

³ OECD (2012), Guidance Document on standardised test guidelines for evaluating chemicals for endocrine disruption. Series on Testing and Assessment No. 150

The results of the screening do not constitute evaluations of individual substances to be carried out under the respective chemical legislations [[in particular, Regulation (EC) No 1107/2009 on plant protection products, Regulation (EU) No 528/2012 on biocidal products, Regulation (EC) No 1907/2006 REACH, Regulation (EC) No 1223/2009 on cosmetic products and the Water Framework Directive (EC) No 2000/60] and in no way prejudice future decisions on active substances to be taken pursuant to these pieces of the EU legislation.

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The relevant information for each substance was captured in an Excel template provided by JRC. Within the first months of the study (pilot phase, report D1), several changes/adjustments to the template were agreed with the JRC. The data captured were classified in 5 different groups depending on the type of information they provide to indicate whether a substance causes adverse effects via an endocrine MoA:

1. General adversity
2. Non-specific adversity (may or may not be indicative of EATS)
3. EATS specific adversity
4. *In vivo* mechanistic information
5. *In vitro* mechanistic information

When capturing ED-related adverse effects, special attention was given to exclude effects that were considered as non-specific secondary consequence of systemic toxicity.

Subsequently, the evaluation of each substance under each Option of the Roadmap was performed. The overall scope of the evaluation was to assess all collected data by applying a limited Weight of Evidence approach and determine whether a plausible link between adversity and MoA could be established. Based on the decision tree provided by JRC as part of the screening methodology, the potential categorization of each substance under "Option 3" of the Roadmap was either "Cat I" (ED), "Cat II" (Suspected ED), "Cat III" (Endocrine Active Substance) or "Unclassified". "Cat I" under "Option 3" was equivalent to categorization as "ED" under "Option 2", whilst all the other categories were considered as "Unclassified" under "Option 2". "Option 1" refers to the interim criteria currently in place, while "Option 4" introduces a "potency cut-off" value to characterize EDs identified from "Options 2 and 3".

For summarizing the combined/overall potential categorization, a worst case approach was used, i.e. the more conservative outcome was considered. In particular, the most recent/strict classification was chosen for the classification under "Option 1" and the most severe categorization between human health and vertebrate wildlife was chosen for the results under "Option 2, 3 & 4".

The results of the screening do not constitute evaluations of individual substances to be carried out under the respective chemical legislations [[in particular, Regulation (EC) No 1107/2009 on plant protection products, Regulation (EU) No 528/2012 on biocidal products, Regulation (EC) No 1907/2006 REACH, Regulation (EC) No 1223/2009 on cosmetic products and the Water Framework Directive (EC) No 2000/60] and in no way prejudice future decisions on active substances to be taken pursuant to these pieces of the EU legislation.

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Results & Conclusion

Detailed results are available in the respective chapters of this report. The results of the combined potential categorization for human health and vertebrate wildlife for all PPPs, BPs and Miscellaneous chemicals screened is presented (absolute numbers and in percentage) in Table 1 below:

Table 1. Combined potential categorization results for the 348 PPPs, 96 BPs and 186 miscellaneous chemicals screened.

Human health and vertebrate wildlife	Combined Potential Categorization (% of substances screened)									
	Option 1 (Most recent/strict)		Option 2		Option 3				Option 4	
	ED	Unclassified/Inconclusive	ED	Unclassified/Inconclusive	Cat I	Cat II	Cat III	Unclassified/Inconclusive	ED	Unclassified/Inconclusive
PPPs (n=348)	51 (14.7%)	297 (85.3%)	32 (9.2%)	316 (90.8%)	32 (9.2%)	96 (27.6%)	53 (15.2%)	167 (48.0%)	15 (4.3%)	333 (95.7%)
BPs (n=96)	16 (16.6%)	80 (83.4%)	6 (6.25%)	90 (93.75%)	6 (6.25%)	27 (28.1%)	9 (9.4%)	54 (56.25%)	5 (5.2%)	91 (94.8%)
Miscellaneous chemicals (n=186*)	89 (47.8%)	97 ^a (52.2%)	38 (20.4%)	148 (79.6%)	38 (20.4%)	82 (44.1%)	2 (1.1%)	64 (34.4%)	32 (17.2%)	154 (82.8%)

*Incomplete population due to lack of data for 15 substances

^a For 8 substances the categorization outcome under "Option 1" was inconclusive due to lack of data

For all three groups of substances screened, the same trend is observed across the four Options. "Option 1" (interim criteria currently in place) appears as the most conservative approach for ED categorization, since it leads to the highest percentage of substances potentially categorized as EDs. Considering "Option 2 and 3", the percentage of substances potentially categorized as EDs is lower, which derives from a more refined evaluation according to specific criteria based on the WHO/IPCS definition of an ED. Finally, an even lower percentage of substances is potentially categorized as EDs under "Option 4", which was expected since option 4 is a subset of option 2. In this study, the significantly higher percentage of miscellaneous substances identified as EDs compared with PPPs or BPs is likely to be related to the selection criteria which focused on substances with potential ED concerns (i.e. substances already identified as EDs under REACH, or classified as Repr Cat1A/B, or subjected to restrictions or included in CoRAP4 list because of ED concerns etc).

The results regarding PPPs and BPs presented in Table 1 were used as input for the impact assessment performed by the European Commission. Additionally, the results regarding 51 PPPs (out of the overall

⁴ CoRAP List: Community rolling action plan List; If a substance is on this list, it means that a Member State **has evaluated or will** evaluate it over the coming years, <http://echa.europa.eu/information-on-chemicals/evaluation/community-rolling-action-plan/corap-table>

348 PPPs) and 18 BPs (out of the overall 96 BPs) were further revised in collaboration with JRC, by including additional information (which became available later in the course of the project) from:

1. The Endocrine Disruptor Screening Program (EDSP, US EPA)
2. The ToxCast ER prediction model value which replaced the Individual ToxCast ER assays
3. Additional EASIS references
4. JRC recommendations on data capture and evaluation

The revised results are presented in Table 2 below and appear not to be significantly different compared to the ones presented in Table 1. This can be explained because the inclusion of additional data and consequent revision of the evaluation caused a decrease in the percentage of substances characterized as EDs for human health, but an increase in the percentage of substances characterized as EDs for wildlife vertebrates (see chapter 4).

Table 2. Combined revised potential categorization results (absolute numbers and percentage of screened substances) for the 348 PPPs and 96 BPs.

Human health and vertebrate wildlife	Revised Combined Potential Categorization (% of substances screened)									
	Option 1 (Most recent/strict)		Option 2		Option 3				Option 4	
	ED	Un-classified	ED	Un-classified	Cat I	Cat II	Cat III	Un-classified	ED	Un-classified
PPPs (n=348)	50 (14.4%)	298 (85.6%)	27 (7.8%)	321 (92.2%)	27 (7.75%)	104 (29.9%)	47 (13.5%)	170 (48.85%)	19 (5.5%)	329 (94.5%)
BPs (n=96)	16 (16.7%)	80 (83.3%)	6 (6.25%)	90 (93.75%)	6 (6.25%)	27 (28.1%)	6 (6.25%)	57 (59.4%)	5 (5.2%)	91 (94.8%)

Table 3 reports the number of substances (based on the summary results including the revised substances), out of those categorized as EDs under Option 1, which remained categorized as “ED” under Option 2 (equal to Cat I under Option 3) and Option 4 or became categorized as Cat II or III under Option 3. Table 3 shows that Option 1 represents a rough estimation in the identification of EDs, since only 20% of PPPs identified as EDs under Option 1 remain categorized as “ED” under Option 2. Moreover, 63% of PPPs identified as EDs under Option 2 were not identified as EDs under Option 1. Therefore, Option 1 identifies a high number of substances as EDs, but it does not identify many of those that are categorized as EDs according to the WHO/IPCS definition (Options 2 & 3). This is also illustrated in the Venn diagram below (Fig. 1).

The results of the screening do not constitute evaluations of individual substances to be carried out under the respective chemical legislations [[in particular, Regulation (EC) No 1107/2009 on plant protection products, Regulation (EU) No 528/2012 on biocidal products, Regulation (EC) No 1907/2006 REACH, Regulation (EC) No 1223/2009 on cosmetic products and the Water Framework Directive (EC) No 2000/60] and in no way prejudice future decisions on active substances to be taken pursuant to these pieces of the EU legislation.

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Table 3. Subset number of substances (based on the summary results including the revised substances) identified as EDs under Option 1 that remained EDs under Option 2 (equal to Cat I under Option 3) or categorized as Cat II or Cat III under Option 3.

Human health and vertebrate wildlife	Combined Potential Categorization for substances categorized as ED under Option 1								
	Option 1 (Most recent/strict)	Option 2		Option 3				Option 4*	
	ED	ED	Unclassified	Cat I	Cat II	Cat III	Unclassified	ED	Unclassified
PPPs	50	10	40	10	29	1	10	8	42
BPs	16	3	13	3	11	0	2	2	14
Miscellaneous chemicals	89	16	73	16	71	-	2	12	77

*Option 4 is a subset of Option 2

The results of the screening do not constitute evaluations of individual substances to be carried out under the respective chemical legislations [[in particular, Regulation (EC) No 1107/2009 on plant protection products, Regulation (EU) No 528/2012 on biocidal products, Regulation (EC) No 1907/2006 REACH, Regulation (EC) No 1223/2009 on cosmetic products and the Water Framework Directive (EC) No 2000/60] and in no way prejudice future decisions on active substances to be taken pursuant to these pieces of the EU legislation.

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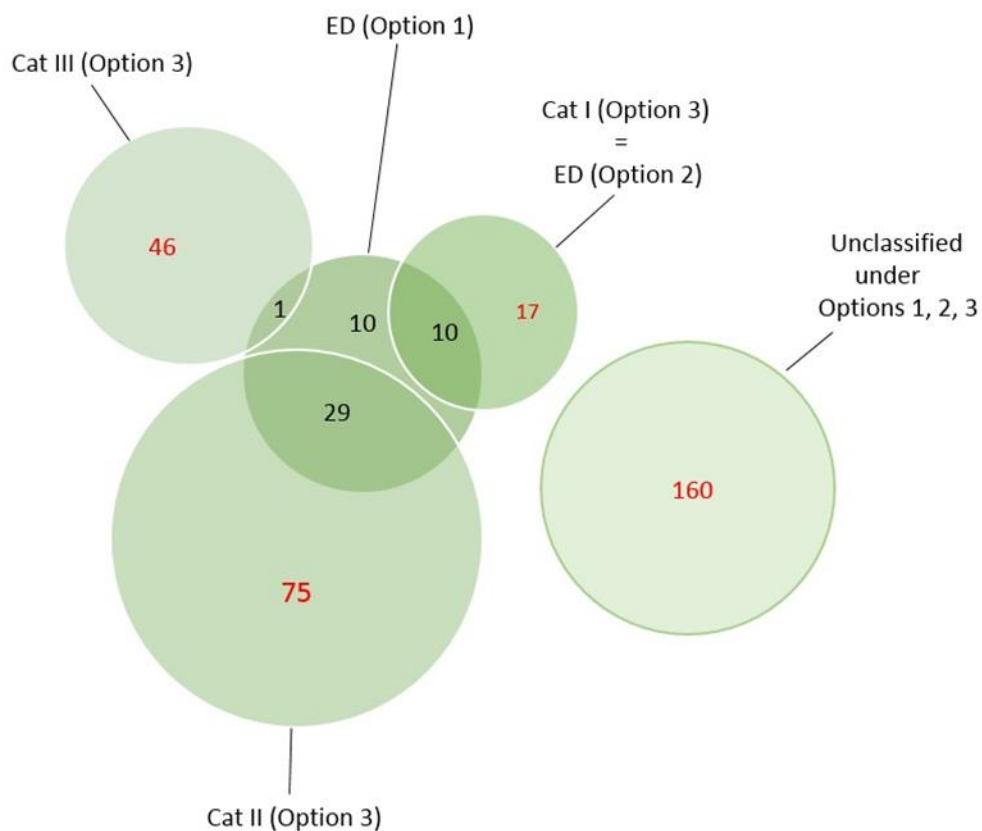


Figure 1. Schematic representation of the number of substances (based on the summary results including the revised substances) identified as EDs under Option 1 (in black) which remained EDs under Option 2 (equal to Cat I under Option 3) or categorized as Cat II or Cat III under Option 3. In red is the number of substances that were considered as "Unclassified" under Option 1.

The results of the screening do not constitute evaluations of individual substances to be carried out under the respective chemical legislations [in particular, Regulation (EC) No 1107/2009 on plant protection products, Regulation (EU) No 528/2012 on biocidal products, Regulation (EC) No 1907/2006 REACH, Regulation (EC) No 1223/2009 on cosmetic products and the Water Framework Directive (EC) No 2000/60] and in no way prejudice future decisions on active substances to be taken pursuant to these pieces of the EU legislation.

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General conclusions on the application of the screening methodology

The screening method applied was designed to take into account the relevant information currently available in regulatory documents complemented with existing relevant databases, and to the extent possible, other scientific literature. The methodology provided by the JRC has been applied consistently and scrupulously, nevertheless, a number of limitations in the application of the screening process are described below and were largely due to the amount and type of data available.

A highly variable number of studies were available for each screened chemical category (PPP, BP and miscellaneous chemicals).

A) Regulatory documents.

For most substances covered by PPP and BP Regulations, a minimum of ten *in vivo* studies [i.e. five short term toxicity/neurotoxicity studies, two chronic toxicity/carcinogenicity, one reproductive and two developmental toxicity studies] were available as part of the standard data requirements for approval/authorization. In some cases, mechanistic data were also part of the available information. The evaluation of all these studies was included in the respective regulatory document and the information captured in this screening is largely based on the peer review process at EFSA/ECHA/ EC level. For some substances covered by miscellaneous chemicals, no regulatory documents with relevant data could be retrieved.

In particular, for some of the miscellaneous chemicals selected for the screening because there is a harmonised classification for reproductive toxicity (either fertility or development) under CLP005, limited relevant data could be identified. This was due to the fact that the harmonised classification has been concluded before the implementation of Regulation (EC) 1272/2008 and the ECHA establishment, i.e. at ECB (European Chemicals Bureau) level under Directive 67/548/EEC. Thus, no opinion on the harmonised classification and labelling of the substance by the Committee for Risk Assessment (RAC) was available or any other relevant regulatory document was accessible.

B) Data retrieved from sources other than the available regulatory documents.

The availability of data from sources other than the regulatory documents - i.e. data retrieved from the TEDX, EASIS and ToxCast databases, from the SIN and EDSP reports and from open literature - differs significantly among substances of the three chemical categories (see Table 4).

⁵ Substances included in Annex VI of EC Regulation 1272/2008 (CLP00) for which a harmonised classification has been concluded under the Directive 67/548/EEC.

Table 4. Number and percentage of substances for each class of chemicals (PPP, BP, MISC) with available data in the different sources.

Data sources	Number of substances with available data		
	PPPs (n= 348)	BPs (n= 96)	MISC (n= 186)
TEDX	78 (22.4%)	19 (19.8%)	61 (32.8%)
SIN	2 (0.6%)	1 (1.04%)	59 (31.7%)
EASIS	47 (13.5%)	14 (14.6%)	18 (9.7%)
ToxCast	164 (47.1%)	35 (36.5%)	47 (25.3%)
EDSP	27 (7.8%)	9 (9.4%)	1 (0.5 %)

- In cases where no or limited relevant data had been identified, especially in case of miscellaneous chemicals, the challenge was to investigate whether read-across from chemicals with structural similarities and/or sharing common chemical groups, was possible. For consistency reasons, a read-across was applied only in cases where supportive evidence for grouping the substances was available in the regulatory documents. In these cases, the substances were grouped and the overall evaluation was based on the same data.
- The outcome of the evaluation when applying the decision tree was the same either in the absence of mechanistic information (lack of data) or because no effects were reported in the available studies. Even for the data "rich" substances, i.e. PPPs and BPs, the final outcome of categorization was very much dependent on the existence of specific *in vivo/in vitro* mechanistic data (not always included in the regulatory documents).
- To this respect, it should be noted that, in case of PPPs and BPs, most of the regulatory documents - although in accordance with the standard data requirements of the specific regulations - might not include studies performed to specifically identify ED effects. On the contrary, for miscellaneous chemicals, since most of the substances to be screened were selected from a wide pool of chemicals based on their known ED concerns, there were cases for which numerous studies examining potential ED effects were available.
- When evaluating the overall data for a substance in order to conclude on its potential categorization, a higher weight of evidence was given to assays that are specifically designed to provide information on EATS specific effects (estrogen, androgen or thyroid pathway). Examples of such assays are the Uterotrophic assay, the Hershberger assay, the Male pubertal assay, the Female pubertal assay, the Fish Short-term Reproduction assay and the Fish Sexual Development test.

The results of the screening do not constitute evaluations of individual substances to be carried out under the respective chemical legislations [[in particular, Regulation (EC) No 1107/2009 on plant protection products, Regulation (EU) No 528/2012 on biocidal products, Regulation (EC) No 1907/2006 REACH, Regulation (EC) No 1223/2009 on cosmetic products and the Water Framework Directive (EC) No 2000/60] and in no way prejudice future decisions on active substances to be taken pursuant to these pieces of the EU legislation.

It would thus be erroneous to consider that the substances listed in the results of this study (SANTE/2015/E3/SI2.706218) are considered as endocrine disruptors within the meaning of the EU legislation.

- The methodology that was applied to this screening is considered robust and suitable as a screening tool provided that the minimum data requirements for a substance (regarding both the number and the type of available studies) are met. Additionally, expertise was essential for the identification and evaluation of relevant data among the different sources, for the grouping and the use of read-across for substances with structural similarities and/or common chemical groups, as well as the establishment of a plausible link between the adverse effects observed and mechanistic data under "Option 2 & 3". Expert judgement was also required for the application of Weight of Evidence.
- It is important to emphasise that the screening methodology used was not intended to result in a full assessment of the selected substances. Existing data on the EATS pathway were found to be scarce for some substances and the available test guidelines do not consider all relevant species, pathways, or timeframes of exposure. Moreover, within the time constraints of the project, it was not possible to assess in detail the quality of individual studies, nor to carry out an in depth weight of evidence assessment across all available data for each substance.

Due to all these limitations, this study should be considered neither equivalent to nor intended to replace an in-depth assessment process as usually carried out for regulatory purposes. Hence, the outcome of the screening does not prejudice in any way the formal regulatory conclusions that may eventually be made under different pieces of EU legislation.

The results of the screening do not constitute evaluations of individual substances to be carried out under the respective chemical legislations [[in particular, Regulation (EC) No 1107/2009 on plant protection products, Regulation (EU) No 528/2012 on biocidal products, Regulation (EC) No 1907/2006 REACH, Regulation (EC) No 1223/2009 on cosmetic products and the Water Framework Directive (EC) No 2000/60] and in no way prejudice future decisions on active substances to be taken pursuant to these pieces of the EU legislation.

It would thus be erroneous to consider that the substances listed in the results of this study (SANTE/2015/E3/SI2.706218) are considered as endocrine disruptors within the meaning of the EU legislation.

CHAPTER 1

Screening of available evidence on chemical substances for the identification of endocrine disruptors according to different options in the context of an Impact Assessment

Specific Contract SANTE/2015/E3/SI2.706218

Report on the general observation on screening methodology application & on the pilot data entry

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The results of the screening do not constitute evaluations of individual substances to be carried out under the respective chemical legislations [[in particular, Regulation (EC) No 1107/2009 on plant protection products, Regulation (EU) No 528/2012 on biocidal products, Regulation (EC) No 1907/2006 REACH, Regulation (EC) No 1223/2009 on cosmetic products and the Water Framework Directive (EC) No 2000/60] and in no way prejudge future decisions on active substances to be taken pursuant to these pieces of the EU legislation.

It would thus be erroneous to consider that the substances listed in the results of this study (SANTE/2015/E3/SI2.706218) are considered as endocrine disruptors within the meaning of the EU legislation.

A. Introduction & Objectives

The aim of this report is to describe the procedure followed for the pilot implementation of the EDs screening methodology provided by JRC and the population of the database for the 35 substances (19 PPPs, 5 BPs, 11 miscellaneous chemicals) selected for the pilot study as agreed in the kick-off meeting on 4-5 May 2015 in Ispra. The procedure for the categorization of each substance is also described.

B. Materials & Methods

Selection of the pilot substances

The “*Chemical Inventory*” file, provided by JRC, was the tool used for the selection of the substances to be screened during the pilot phase of the project.

During the kick-off meeting and based on the draft *Substance Inventory Excel* file provided by JRC, BPI had selected 19 PPP and 5 BP substances to be screened within the pilot data entry (Table 1.1; the substance number is the one mentioned in the *Chemical Inventory* file provided on 14th of May 2015).

Table 1.1: PPP and BP substances selected for the pilot data entry.

No	Chemical Name	CAS	pesticides approved DG-SANTE	biocides	cosmetics	REACH	WFD
1	Carbon dioxide	124-38-9	1	1			
20	Cyproconazole	94361-06-5	1	1			
27	Aluminium sulphate	10043-01-3	1			1	
29	Quizalofop-P-ethyl	100646-51-3	1				
52	Clodinafop	114420-56-3	1				
57	Quizalofop-P-tefuryl	119738-06-6	1				
85	Captan	133-06-2	1				
113	Emamectin	155569-91-8	1				
159	Diuron	330-54-1	1			1	1
175	Bifenox	42576-02-3	1				1
188	Triadimenol	55219-65-3	1				
192	Urea	57-13-6	1			1	
216	Triflumizole	68694-11-1	1				
220	Chlormequat	7003-89-6	1				
264	2,4-D	94-75-7	1				

25

The results of the screening do not constitute evaluations of individual substances to be carried out under the respective chemical legislations [[in particular, Regulation (EC) No 1107/2009 on plant protection products, Regulation (EU) No 528/2012 on biocidal products, Regulation (EC) No 1907/2006 REACH, Regulation (EC) No 1223/2009 on cosmetic products and the Water Framework Directive (EC) No 2000/60] and in no way prejudge future decisions on active substances to be taken pursuant to these pieces of the EU legislation.

It would thus be erroneous to consider that the substances listed in the results of this study (SANTE/2015/E3/SI.706218) are considered as endocrine disruptors within the meaning of the EU legislation.

No	Chemical Name	CAS	pesticides approved DG-SANTE	biocides	cosmetics	REACH	WFD
270	Sulcotrione	99105-77-8	1				
299	Lauric acid	143-07-7	1	1		1	
331	Tribasic copper sulfate	1333-22-8	1				
336	Thiram	137-26-8	1			1	
374	Chlorpyrifos	2921-88-2	1				1
394	Sucrose	57-50-1	1				
403	Mancozeb	8018-01-7	1				
412	Quizalofop-P	94051-08-8	1				
413	MCPA	94-74-6	1				
435	Boric acid	10043-35-3		1		1	
441	Zineb	12122-67-7		1			

JRC provided BPI with the list of the 11 miscellaneous chemicals (drawn from the pool of REACH, WFD and cosmetic substances) to be screened within the pilot data entry (Table 1.2).

Table 1.2: Miscellaneous chemicals selected for the pilot data entry.

No	Chemical Name	CAS	pesticides approved DG-SANTE	biocides	cosmetics	REACH	WFD
337	Ziram	137-30-4	1			1	
1080	Resorcinol	108-46-3			1	1	
1436	Triphenyl phosphate	115-86-6				1	
2081	Benzophenone-3	131-57-7			1	1	
2813	Tert-butyl methyl ether	1634-04-4				1	
4280	Triclosan	3380-34-5			1	1	
5033	2-(2-Butoxyethoxy)ethyl 6-propylpiperonyl ether	51-03-6				1	
6817	Carbon disulphide	75-15-0				1	
7281	4,4'-Sulphonyldiphenol	80-09-1				1	
7505	Diethyl phthalate	84-66-2			1	1	
8296	nitrobenzene	98-95-3				1	

As it was already noted during the kick-off meeting, there were substances included in more than one category of chemicals.

Source of information & Data collection

The “*Chemical Inventory*” file, provided by JRC, was the tool used for the identification of the sources of information of all chemicals selected to be screened during the pilot phase of the project.

The Chemical Inventory includes information with regard to the EU approval of each chemical, i.e. within which Legislative framework(s) the chemical has been approved [PPPR, BPR, REACH, Cosmetics]. This was the key information in order to retrieve any regulatory assessment report available at EU level.

With regard to the hazard classification of each chemical the Chemical Inventory states whether a substance is classified as a CMR (Carcinogenic, Mutagenic or toxic to Reproduction) category 1 A/B or 2 or a STOT RE (Specific Target Organ Toxicity – Repeated Exposure) category 1 or 2.

Moreover, the Chemical Inventory provides information on whether a chemical has been identified with a possible ED concern (CoRAP) within REACH or a priority substance in the field of water policy (WFD).

In addition, for each chemical it is stated whether it is included in the following lists/databases:

1. Substitute It Now (SIN) list: substances that have been identified by the NGO ChemSec as being substances of concern. Endocrine disrupting activity is included as a category for reason of concern.
2. The Endocrine Disruption Exchange (TEDX) list: potential Endocrine Disruptors; developed by the US Organisation TEDX.
3. Endocrine Active Substances Information System (EASIS): JRC Database of study reports on substances related to endocrine activity.
4. Toxicity Reference Database (ToxRefDB)⁶: *in vivo* animal toxicity studies; developed by the US-EPA.
5. ToxCast Database: data for substances tested in one of the 26 *in vitro* assays that are considered to be relevant for the EATS pathways; developed by US EPA.

It is noted that in case it was identified that the information included in the Chemical Inventory provided are incorrect (because of problems in the data transfer or other reasons), this was clearly stated in the “Other information” cell included in the “Data” sheet. The steps taken for the retrieval of all relevant documents/information for each chemical are presented in detail for the different categories of substances as follows.

⁶ After the pilot phase, the use of ToxRefDB was discontinued since the time gained in database population was lost in relation to the need to quality check the data for inaccuracies and duplications (see also D. Conclusions section of chapter 1)

Plant Protection Products

1. For each PPP substance first the EU Pesticide Database (http://ec.europa.eu/sanco_pesticides/) was visited in order to check the exact approval status of the substance (http://ec.europa.eu/sanco_pesticides/public/?event=activesubstance.selection&language=EN)
 - In cases where the "Risk Assessment" had been performed by the Commission, the Draft Assessment Report (DAR) - i.e. the EU evaluation of the substance - is not publically available in the EFSA website. Then a specific search was performed to see whether the DAR and any related Addenda are available in the confidential area of CIRCABC for PPPs. The Review Report (RR), containing the final List of EndPoints (LoEPs), was downloaded from the EU Pesticide Database.
 - In case where the "Risk Assessment" had been performed by EFSA, then the EFSA website (<http://www.efsa.europa.eu/>) was visited and a specific search was performed in order to retrieve the EFSA Conclusion, containing the final List of EndPoints (LoEPs), the DAR or RAR (Re-registration Assessment Report) and the Final Addendum for the substance.
2. For an approved PPP substance, the first source of information regarding the existence of a harmonised classification (Reg. 1272/2008) is the EU Pesticide Database which is shown below.

EU Pesticides database

Plants > Pesticides > EU Pesticides Database > Search active substances > Active substance detail

ANIMALS PLANTS

Mancozeb Approved

Status under Reg. (EC) No 1107/2009 (repealing Directive 91/414/EEC)		Classification Reg. 1272/2008	
Legislation	05/72/EC , Reg. (EU) No 540/2011 , Reg. (EU) No 528/2012	Skin Sens. 1 - H317	Repr. 2 - H361d
		Aquatic Acute 1 - H400	

This classification is expected to be consistent with the one retrieved from the ECHA "C&L Inventory" (<http://echa.europa.eu/information-on-chemicals/cl-inventory-database>) which is shown below.

The results of the screening do not constitute evaluations of individual substances to be carried out under the respective chemical legislations [[in particular, Regulation (EC) No 1107/2009 on plant protection products, Regulation (EU) No 528/2012 on biocidal products, Regulation (EC) No 1907/2006 REACH, Regulation (EC) No 1223/2009 on cosmetic products and the Water Framework Directive (EC) No 2000/60] and in no way prejudge future decisions on active substances to be taken pursuant to these pieces of the EU legislation. It would thus be erroneous to consider that the substances listed in the results of this study (SANTE/2015/E3/SI2.706218) are considered as endocrine disruptors within the meaning of the EU legislation.

Summary of Classification and Labelling

Harmonised classification - Annex VI of Regulation (EC) No 1272/2008 (CLP Regulation)

General Information

Index Number	EC Number	CAS Number	International Chemical Identification
006-076-00-1		8018-01-7	mancozeb (ISO) manganese ethylenebis(dithiocarbamate) (polymeric) complex with zinc salt

ATP Inserted / Updated: CLP00/ATP01
CLP Classification (Table 3.1)

Classification		Labelling			Specific Concentration limits, M-Factors	Notes
Hazard Class and Category Code(s)	Hazard Statement Code(s)	Hazard Statement Code(s)	Supplementary Hazard Statement Code(s)	Pictograms, Signal Word Code(s)		
Skin Sens. 1	H317	H317		GHS07 GHS09 GHS08 Wng	M=10	
Repr. 2	H361d ***	H361d ***				
Aquatic Acute 1	H400	H400				

Signal Words	Pictograms		
Warning			
	Exclamation mark	Environment	Health hazard

When reporting the harmonised classification the field "ATP (Adaptation to Technical Progress) Inserted / Updated" was reported as well.

In case there was no harmonised classification for a PPP substance, the DAR/EFSA Conclusion proposal has been included. For PPP substances included in more than one category of chemicals any other classification proposal (apart from self-classification) has been reported. For example, in case of substances screened both as PPP and BP substances the proposed classification in the CAR/Assessment Report has been reported as well and any differences were noted.

Even in cases where there was a harmonised classification introduced in Reg. 1272/2008 with CLP00, i.e. the adaptation from the last ATP to Dir. 67/548/EEC, it was checked whether the proposal in the assessment report as a PPP or BP was more recent. In these cases, the proposed classification is also reported stating the date of the assessment. Otherwise, there is no entry in the "Proposed classification" cell in the "Data" sheet; the phrase "Not relevant" should have been included.

In case of substances with a harmonised classification inserted in Reg. 1272/2008 or updated with an ATP other than CLP00, the RAC opinion was retrieved from ECHA website.

The results of the screening do not constitute evaluations of individual substances to be carried out under the respective chemical legislations [[in particular, Regulation (EC) No 1107/2009 on plant protection products, Regulation (EU) No 528/2012 on biocidal products, Regulation (EC) No 1907/2006 REACH, Regulation (EC) No 1223/2009 on cosmetic products and the Water Framework Directive (EC) No 2000/60] and in no way prejudge future decisions on active substances to be taken pursuant to these pieces of the EU legislation. It would thus be erroneous to consider that the substances listed in the results of this study (SANTE/2015/E3/SI2.706218) are considered as endocrine disruptors within the meaning of the EU legislation.

For substances with no harmonised classification, a specific search was performed in the ECHA website in order to identify any recent CLH report-proposed classification.

For any PPP substance included in more than one category of chemicals a specific search has been performed in order to capture all available information (see below the text for BP substances and Miscellaneous chemicals).

Among the pilot PPP substances there was one substance, thiram, approved before EFSA was founded and for which the DAR was not available (not even in CIRCABC) but was found via the webpage <http://www.fytoweb.be/FR/doc/monographie.htm>.

For another PPP substance, chlorpyrifos, the DAR was found in CIRCABC, but the file was corrupted and therefore it was not possible to have access in the evaluation. Thus, this was excluded from the pilot.

For quizalofop-p in the EU Pesticide Database there are 2 entries, i.e. for quizalofop-P-ethyl [CAS No 100646-51-3, No 29] & quizalofop-P-tefuryl [CAS No 119738-06-6, No 57].

The screenshot shows the EU Pesticides database entry for Quizalofop-P. The page is titled "Quizalofop-P" with a green "Approved" badge. The left sidebar contains navigation options like "EU Pesticides database", "Search active substances", "Search products", "Search pesticide residues", "Download MRLs data", "Sustainable use of pesticides", "Approval of active substances", "Authorisation of Plant Protection Products", and "Maximum Residue levels".

The main content area is divided into several sections:

- Status under Reg. (EC) No 1107/2009** (repealing Directive 91/414/EEC):

Legislation	2009/37 ↗ , Reg. (EU) No 540/2011 ↗
Date of approval	01/12/2009
Expiration of approval	30/11/2019
RMS	FI
Risk Assessment	EFSA ↗
Category	HB
Review Report	↗ Specification 2010 ↗ Confirmatory data 2012
Remarks	The classification of the tefuryl variant is reported in the specific entry Quilofop-P-tefuryl
- Classification Reg. 1272/2008**: No classification
- Toxicological information**:

Reference values	Source	Remark	
ADI	0.009	EFSA 08	Tox Info for Quizalofop-P-ethyl
ARfD	Not applicable	EFSA 08	Tox Info for Quizalofop-P-ethyl
AOEL	0.01	EFSA 08	Tox Info for Quizalofop-P-ethyl
ADI	0.013	EFSA 08	Tox Info for Quizalofop-P-tefuryl
ARfD	0.1	EFSA 08	Tox Info for Quizalofop-P-tefuryl
AOEL	0.01	EFSA 08	Tox Info for Quizalofop-P-tefuryl
Other			
- Authorisation at national level**:

Authorised in	In progress for
AT, BE, BG, CY, CZ, DE, EE, EL, ES, FI, FR, HR, HU, IE, IT, LT, LU, LV, MT, NL, PL, PT, RO, SI, SK, UK	

The results of the screening do not constitute evaluations of individual substances to be carried out under the respective chemical legislations [[in particular, Regulation (EC) No 1107/2009 on plant protection products, Regulation (EU) No 528/2012 on biocidal products, Regulation (EC) No 1907/2006 REACH, Regulation (EC) No 1223/2009 on cosmetic products and the Water Framework Directive (EC) No 2000/60] and in no way prejudge future decisions on active substances to be taken pursuant to these pieces of the EU legislation. It would thus be erroneous to consider that the substances listed in the results of this study (SANTE/2015/E3/SI2.706218) are considered as endocrine disruptors within the meaning of the EU legislation.

This is in accordance with the approval Regulation (EU) No 540/2011.

284	Quizalofop-P:			1 December 2009	30 November 2019	PART A
	Quizalofop-P-ethyl CAS No 100646-51-3 CIPAC No 641.202	ethyl (R)-2-[4-(6-chloroquinoxalin-2-yloxy)phenoxy] propionate	≥ 950 g/kg			Only uses as herbicide may be authorised. PART B
	Quizalofop-P-tefuryl CAS No 119738-06-6 CIPAC No 641.226	(RS)-Tetrahydrofurfuryl (R)-2-[4-(6-chloroquinoxalin-2-yloxy)phenoxy] propionate	≥ 795 g/kg			For the implementation of the uniform principles of Annex VI, the conclusions of the review report on quizalofop-P, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 23 January 2009 shall be taken into account. In this overall assessment Member States must pay particular attention to: — the specification of the technical material as commercially manufactured which must be confirmed and supported by appropriate analytical data. The test material used in the toxicity dossiers should be compared and verified against this specification of the technical material.

Moreover, the respective EFSA Conclusion regarding the peer review of the pesticide risk assessment of the active substance quizalofop-P considers the two variants quizalofop-P-ethyl and quizalofop-P-tefuryl).

Thus, instead of one substance "quizalofop-P", two different substances, quizalofop-P-ethyl [No 29] & quizalofop-P-tefuryl [No 57] were included in the pilot.

Specific comments with regard to the DAR/RAR availability or any other problems encountered for each PPP substance that was to be screened within the pilot phase are included in Table 1.3.

Table 1.3: PPP substances: Source of Information & Data Collection comments.

No	Chemical Name	CAS	pesticides approved DG-SANTE	biocides	cosmetics	REACH	WFD	Source of Information & Data Collection Comments
27	Aluminium sulphate	10043-01-3	1			1		DAR available in EFSA. Information also available from ECHA/Reach Registrant but the main source was considered to be the evaluation report (DAR) and the EFSA Conclusion as PPP.
29	Quizalofop-P-ethyl	100646-51-3	1					Variant of Quizalofop-P [No 412] DAR available in EFSA.
52	Clodinafop	114420-56-3	1					DAR available in EFSA.
57	Quizalofop-P-tefuryl	119738-06-6	1					Variant of Quizalofop-P [No 412] DAR available in EFSA.

The results of the screening do not constitute evaluations of individual substances to be carried out under the respective chemical legislations [[in particular, Regulation (EC) No 1107/2009 on plant protection products, Regulation (EU) No 528/2012 on biocidal products, Regulation (EC) No 1907/2006 REACH, Regulation (EC) No 1223/2009 on cosmetic products and the Water Framework Directive (EC) No 2000/60] and in no way prejudge future decisions on active substances to be taken pursuant to these pieces of the EU legislation. It would thus be erroneous to consider that the substances listed in the results of this study (SANTE/2015/E3/SI2.706218) are considered as endocrine disruptors within the meaning of the EU legislation.

No	Chemical Name	CAS	pesticides approved DG-SANTE	biocides	cosmetics	REACH	WFD	Source of Information & Data Collection Comments
85	Captan	133-06-2	1					DAR available in EFSA.
113	Emamectin	155569-91-8	1					DAR available in EFSA.
159	Diuron	330-54-1	1			1	1	DAR available in EFSA.
175	Bifenox	42576-02-3	1				1	DAR available in EFSA.
188	Triadimenol	55219-65-3	1					DAR available in EFSA.
192	Urea	57-13-6	1			1		DAR available in EFSA.
216	Triflumizole	68694-11-1	1					DAR available in EFSA.
220	Chlormequat	7003-89-6	1					DAR available in EFSA.
264	2,4-D	94-75-7	1					RAR publically available in EFSA
270	Sulcotrione	99105-77-8	1					DAR publically available in EFSA
331	Tribasiccopper sulfate	1333-22-8	1					DAR available in EFSA.
336	Thiram	137-26-8	1			1		DAR available in the webpage http://www.fytoweb.be/FR/doc/mongraphie.htm
374	Chlorpyrifos	2921-88-2	1				1	Excluded from the pilot study due to corruption of the DAR file; DAR available only in CIRCABC; to be screened later and included in the Deliverable D2 for PPPs
394	Sucrose	57-50-1	1					No DAR available. BSA (Basic Substance Application) found in CIRCABC In the "chemical inventory" it is written that sucrose has data in TOXCast however we could not confirm this information (no data found in TOXCast).
403	Mancozeb	8018-01-7	1					DAR available in CIRCABC
412	Quizalofop-P	94051-08-8	1					Not considered as an individual substance. Covered by Quizalofop-P-ethyl [No 29] &Quizalofop-P-tefuryl [No 57]
413	MCPA	94-74-6	1					DAR available in CIRCABC. The data presented in ToxRefDB database are not for MCPA (Cas No 94-74-6), but for MCPA dimethylamine salt (Cas No 2039-46-5). Therefore, the ToxRefDB data was not included in MCPA Datasheet.

The individual excel sheets for PPP substances have been uploaded to the specific project area in CIRCABC.

The results of the screening do not constitute evaluations of individual substances to be carried out under the respective chemical legislations [[in particular, Regulation (EC) No 1107/2009 on plant protection products, Regulation (EU) No 528/2012 on biocidal products, Regulation (EC) No 1907/2006 REACH, Regulation (EC) No 1223/2009 on cosmetic products and the Water Framework Directive (EC) No 2000/60] and in no way prejudge future decisions on active substances to be taken pursuant to these pieces of the EU legislation. It would thus be erroneous to consider that the substances listed in the results of this study (SANTE/2015/E3/SI2.706218) are considered as endocrine disruptors within the meaning of the EU legislation.

Biocides

1. For each BP substance first the ECHA “Biocidal Active Substances” website (<http://echa.europa.eu/web/guest/information-on-chemicals/biocidal-active-substances>) was visited in order to check the exact approval status of the substance and the retrieval of the appropriate data, i.e. Assessment Report (including the Final List of Endpoints) and the Doc IIIA of the Final Competent Assessment Report (CAR), where the detailed evaluation of the study is reported.

There were cases of BP substances where the approval concerned different Product Types (PT) and thus there were different CARs available. For example, in case of carbon dioxide a CAR was available for PT14, PT15 & PT18 while the Assessment Report was available only for PT14 & PT18.

Substance Name	EC Number	CAS Number	Type	Legal Act	Date of Approval	Expiry Date	Evaluating Competent Authority	Approval Status	Data	Related Authorised Products
Carbon dioxide	204-696-9	124-38-9	14 - Rodenticides	Directive 2008/75/EC	01/11/2009	01/11/2019	FR	Approved		
Carbon dioxide	204-696-9	124-38-9	15 - Avicides	(EU) 2015/292	01/06/2015	01/06/2025	NL	Approved		
Carbon dioxide	204-696-9	124-38-9	18 - Insecticides, acaricides and products to control other arthropods	Directive 2010/74/EU	01/11/2012	01/11/2022	FR	Approved		

In all cases the different files were downloaded and the reported data were compared in order to identify any differences.

2. For an approved BP substance, the first source of information regarding the existence of a harmonised classification (Reg. 1272/2008) is the ECHA “C&L Inventory” (<http://echa.europa.eu/information-on-chemicals/cl-inventory-database>). In case the substance is also approved as a PPP, then the EU Pesticide Database should be checked as well (see above for PPP substances). When reporting the harmonised classification, the field “ATP Inserted / Updated” was reported as well.

In case there was no harmonised classification for a BP substance, the Assessment Report classification proposal has been included. For BP substances included in more than one category of chemicals, any other classification proposal (apart from self-classification) has been reported. For example, in case of substances screened both as BP and PPP substances, the proposed classification in the EFSA Conclusion/Review Report has been reported as well and any differences were noted.

Even in cases where there was a harmonised classification introduced in Reg. 1272/2008 with CLP00, i.e. the adaptation from the last ATP to Dir. 67/548/EEC, it was checked whether the proposal in the Assessment Report as BP or PPP was more recent. In these cases, the proposed classification is also reported stating the date of the assessment. Otherwise, there is no entry in the "Proposed classification" cell in the "Data" sheet; the phrase "Not relevant" should have been included.

In case of substances with a harmonised classification inserted in Reg. 1272/2008 or updated with an ATP other than CLP00, the RAC opinion was retrieved from ECHA website.

For substances with no harmonised classification, a specific search was performed in the ECHA website in order to identify any recent CLH report-proposed classification.

- For any BP substance included in more than one category of chemicals a specific search has been performed in order to capture all available information (see also text for PPP substances and Miscellaneous chemicals).

Three out of the five selected BP substances are also PPP substances. Thus, the respective documents for PPPs have been retrieved. When reporting the available data in the "Data" excel sheet the specific source document was mentioned, e.g. CAR, CAR/DAR or DAR.

Specific comments with regard to the CAR availability or any other problems encountered for each BP substance that was to be screened within the pilot phase are included in Table 1.4.

Table 1.4: BP substances: Source of Information & Data Collection comments.

No	Chemical Name	CAS	pesticides approved DG-SANTE	biocides	cosmetics	REACH	WFD	Source of Information & Data Collection Comments
1	Carbon dioxide	124-38-9	1	1				Both DAR & CAR were publically available.
20	Cyproconazole	94361-06-5	1	1				Although DAR was publically available <i>via</i> EFSA specific ecotox studies were not presented either in the publically available DAR or in the Final Addendum and were retrieved from CIRCABC. CAR only available in CIRCABC.
299	Lauric acid	143-07-7	1	1		1		Both DAR & CAR were publically available. As a REACH registered chemical, data from a "Full Joint Submission; 10,000 - 100,000

No	Chemical Name	CAS	pesticides approved DG-SANTE	biocides	cosmetics	REACH	WFD	Source of Information & Data Collection Comments
								tonnes per annum" were retrieved from ECHA website.
435	Boric acid	10043-35-3		1		1		CAR publically available. As a REACH registered chemical, data from a "100,000 - 1,000,000 tonnes per annum" submission were retrieved from ECHA website.
441	Zineb	12122-67-7		1				CAR publically available.

Miscellaneous chemicals

All substances selected for the pilot implementation of the screening methodology for Miscellaneous chemicals were REACH registered substances.

1. For each substance first the ECHA "REACH Registered substances" website (<http://echa.europa.eu/information-on-chemicals/registered-substances>) is visited in order to check the exact approval status of the substance and the retrieval of the appropriate data.
2. For registered REACH chemicals, the first source of information regarding the existence of a harmonised classification (Reg. 1272/2008) is the ECHA "C&L Inventory" (<http://echa.europa.eu/information-on-chemicals/cl-inventory-database>). In case the substance is also approved as a PPP or a BP, then the EU Pesticide Database should be checked as well (see above for PPP and BP substances).
When reporting the harmonised classification, the field "ATP Inserted / Updated" was reported as well.

In case there was no harmonised classification, the registrant's classification proposal was captured.

In case of substances with a harmonised classification inserted in Reg. 1272/2008 or updated with an ATP other than CLP00, the RAC opinion was retrieved from ECHA website.



For substances with no harmonised classification, a specific search was performed in the ECHA website in order to identify any recent CLH report-proposed classification.

3. For any registered REACH chemical included in more than one category of chemicals, a specific search has been performed in order to capture all available information (see also text for PPP & BP substances above). For the substances that are also

registered as Cosmetics, the relevant regulatory information was retrieved from EC Cosmetics (European Commission Health and Consumers CosIng) website <http://ec.europa.eu/consumers/cosmetics/cosing/index.cfm?fuseaction=search.simple>. Information with regard to any available "Substance evaluation CoRAP" was retrieved from ECHA website (<http://echa.europa.eu/information-on-chemicals/evaluation/community-rolling-action-plan/corap-table>). However, in most cases only a CoRAP justification has been found.

It is noted that, as also discussed during the kick-off meeting, in the ECHA website the Information on Registered Substances comes from registration dossiers which have been assigned a registration number, but this information has not been reviewed or verified by the Agency or any other authority. The content is subject to change without prior notice. Following JRC recommendation, these data were used only where there were no regulatory assessments available.

Moreover, for most REACH chemicals, more than one result is found when searching in the Registered substances website, e.g. 2-(2-butoxyethoxy) ethyl 6-propylpiperonyl ether (CAS No 51-03-6):

EC / List No.	CAS No.	Name	Registration Type	Submission Type	Tonnage Band	View
200-076-7	51-03-6	2-(2-butoxyethoxy)ethyl 6-propylpiperonyl ether	Full	Joint Submission	Tonnage Data Confidential	
200-076-7	51-03-6	2-(2-butoxyethoxy)ethyl 6-propylpiperonyl ether	Full	Individual Submission	0 - 10 tonnes per annum	

Showing 2 results.

Following the JRC advice regarding multiple submissions, focus was on joint submissions first, where available, and on higher tonnage submissions where data requirements are at least Annex IX or higher. The date of the data download was also reported.

Considering the current structure of the database, in case the data reported in both submissions are filled in the only way to make the distinction is to mention the "Registrants / Suppliers" name in the remarks column.

Specific comments for each Miscellaneous chemical that was to be screened within the pilot phase with regard to the EU Evaluation Report (e.g. Cosmetics Report) or the ECHA/REACH Registrant's dossier availability or any other problems encountered are included in Table 1.5.

The results of the screening do not constitute evaluations of individual substances to be carried out under the respective chemical legislations [[in particular, Regulation (EC) No 1107/2009 on plant protection products, Regulation (EU) No 528/2012 on biocidal products, Regulation (EC) No 1907/2006 REACH, Regulation (EC) No 1223/2009 on cosmetic products and the Water Framework Directive (EC) No 2000/60] and in no way prejudge future decisions on active substances to be taken pursuant to these pieces of the EU legislation. It would thus be erroneous to consider that the substances listed in the results of this study (SANTE/2015/E3/SI2.706218) are considered as endocrine disruptors within the meaning of the EU legislation.

Table 1.5: Miscellaneous chemicals: Source of Information & Data Collection comments.

No	Chemical Name	CAS	pesticides approved DG-SANTE	biocides	cosmetics	REACH	WFD	Source of Information & Data Collection Comments
337	Ziram	137-30-4	1			1		Data from a "Full Joint Submission; 100 - 1,000 tonnes per annum" were retrieved from ECHA website. As a PPP substance the DAR is available at CIRCABC.
1080	Resorcinol	108-46-3			1	1		Data from a "Full Joint Submission; 10,000 - 100,000 tonnes per annum" were retrieved from ECHA website. Cosmetics-CosIng Report available.
1436	Triphenyl phosphate	115-86-6				1		Data from a "Full Joint Submission; 1,000 - 10,000 tonnes per annum" were retrieved from ECHA website.
2081	Benzophenone-3	131-57-7			1	1		Referred as oxybenzone. Data from a "Full Joint Submission; 100 - 1,000 tonnes per annum" were retrieved from ECHA website. Cosmetics-CosIng Report available.
2813	Tert-butyl methyl ether	1634-04-4				1		Data from a "Joint Submission; 1,000,000 - 10,000,000 tonnes per annum" were retrieved from ECHA website.
4280	Triclosan	3380-34-5			1	1		Data from a "Joint Submission; 100 - 1,000 tonnes per annum" were retrieved from ECHA website. Cosmetics-CosIng Report available.
5033	2-(2-Butoxyethoxy)ethyl 6-propylpiperonyl ether	51-03-6				1		Data from a "Joint Submission; Tonnage data confidential" and an "Individual submission; 0-10 tonnes per annum" were retrieved from ECHA website. PBO is a BP substance for which the First draft CAR has been just submitted to ECHA.
6817	Carbon disulphide	75-15-0				1		Data from a "Joint Submission; 100,000 - 1,000,000 tonnes per annum" were retrieved from ECHA website.
7281	4,4'-Sulphonyldiphenol	80-09-1				1		Data from a "Joint Submission; 1,000 - 10,000 tonnes per annum" were retrieved from ECHA website.
7505	Diethyl phthalate	84-66-2			1	1		Data from a "Joint Submission; 1,000 - 10,000 tonnes per annum"

The results of the screening do not constitute evaluations of individual substances to be carried out under the respective chemical legislations [[in particular, Regulation (EC) No 1107/2009 on plant protection products, Regulation (EU) No 528/2012 on biocidal products, Regulation (EC) No 1907/2006 REACH, Regulation (EC) No 1223/2009 on cosmetic products and the Water Framework Directive (EC) No 2000/60] and in no way prejudge future decisions on active substances to be taken pursuant to these pieces of the EU legislation. It would thus be erroneous to consider that the substances listed in the results of this study (SANTE/2015/E3/SI2.706218) are considered as endocrine disruptors within the meaning of the EU legislation.

								were retrieved from ECHA website. Cosmetics-CosIng Report available.
8296	Nitrobenzene	98-95-3				1		Data from a "Joint Submission; 100,000 - 1,000,000 tonnes per annum" were retrieved from ECHA website.

In general, for the introductory information (template version 1.08) in the "Data" sheet the following instructions have been considered:

Compound:	xxx
CAS:	xxx
CLP (harmonised): CLP/ATP inserted:	If available, enter the respective classification as in the ECHA website and the CLP/ATP inserted. If not available, enter "No CLH" or 'self classification" by the registrant. In the "Evaluation" sheet put " No " or " No CLH " in the respective cells.
CLP (proposed):	Enter the classification proposal (if different from CLP) with distinction to: - EFSA (date) - CAR (date) - REACH (submission information), e.g. REACH Registrant (Joint submission; 100 - 1,000 tonnes per annum): Aquatic Acute 1 H400, Aquatic Chronic 2 H411 In case there is a harmonised C&L for which the decision has been taken following the DAR/RAR/EFSA Conclusion, enter " Not relevant ". In the "Evaluation" sheet put also " Not relevant " in the respective cells.
Co-RAP (concern - justification):	e.g. The potential of the substance for being an endocrine disruptor was evaluated by the Danish Centre for Endocrine Disruptors in 2012 on contract for the Danish EPA. The study concluded that oxybenzone is a potential endocrine disruptor. In case the substance is not labelled as "Co-RAP" in the Chemical Inventory, enter " Not relevant ".

<p>Reason for inclusion in the SIN List:</p>	<p>e.g. Benzophenone-3 (BP-3) is an endocrine disruptor with estrogenic, antiandrogen and thyroid activity, affecting several body functions including development and immune function. The substance has been found in biomonitoring studies and in human milk and urine. It is categorized as an endocrine disruptor in the EU Commission EDC database.</p> <p>In case the substance is not labelled as "SIN" in the Chemical Inventory, enter "Not relevant".</p>
<p>Other information/comments</p>	<p>e.g. Cosmetics: OPINION ON BENZOPHENONE-3 COLIPA N° S38 EASIS: Not included in the available excel file STOT RE: In the chemical inventory this was identified as a STOT RE substance BUT this has not been confirmed.</p>

Database Population

For the substances selected for the pilot implementation of the screening methodology, all relevant mammalian, ecotoxicological and mechanistic data were gathered from the respective databases as described in detail in the previous section based on what has been indicated in the "Chemical Inventory". For substances that fall into more than one regulatory category, the information from all relevant databases and regulatory documents was captured. In particular, for REACH substances, it is noted that in the ECHA website the Information on Registered Substances comes from registration dossiers which have been assigned a registration number, but not yet been reviewed or verified by the Agency or any other authority, and the content is subject to change without prior notice. Following JRC recommendation, these data were used only where there were no regulatory assessments available. Supplementary data with additional mechanistic information from established databases, as described above, were also captured.

All relevant information was collected in the reporting template (initially in the "Data summary template version 1.03_(26-5-15)_data matrix" excel file and finally in the template version 1.08_(2-7-15)) provided by JRC. The most recent version of the database file, uploaded in CIRCABC by JRC on 06/7/2015 following BPI's questions and recommendations, was used for the final data entry.

The relevant information on the test system (e.g. type of toxicity and category, study design, source/reference, species used in case of *in vivo*, test system used in case of *in vitro*, doses tested, method of application, duration of exposure, NOAEL/NOEC and LOAEL/LOEC including endpoints, other endocrine-related effects) and any other required information was captured from the source documents (either provided by JRC or retrieved by BPI). During the kick-off meeting, a discussion was held with regard to the approach to

The results of the screening do not constitute evaluations of individual substances to be carried out under the respective chemical legislations [[in particular, Regulation (EC) No 1107/2009 on plant protection products, Regulation (EU) No 528/2012 on biocidal products, Regulation (EC) No 1907/2006 REACH, Regulation (EC) No 1223/2009 on cosmetic products and the Water Framework Directive (EC) No 2000/60] and in no way prejudge future decisions on active substances to be taken pursuant to these pieces of the EU legislation. It would thus be erroneous to consider that the substances listed in the results of this study (SANTE/2015/E3/SI2.706218) are considered as endocrine disruptors within the meaning of the EU legislation.

be followed for the database population (see kick-off Minutes). In addition, during the pilot study any further questions, clarifications and recommendations were discussed with JRC via e-mail. The main points discussed during the pilot study are presented in Appendix 1.1.

In addition, several points have been identified during the pilot phase leading to the need for revising the Data entry & Evaluation/Categorization template from the version 1.03 to 1.08.

The procedure followed for the population of the database has been developed by BPI during the pilot phase and is presented below:

1. For each active substance presented in ToxRefDB, all information illustrated in ToxRefDB was copied to the "Data summary template" to columns A to Z and AB to AD. If some of the studies presented in ToxRefDB were also available in DAR, the relevant information from ToxRefDB was kept in the "Data summary template". Cross-check of the studies was conducted only for the data related to the study protocol and study design (Column A to U). Furthermore, the NOAEL/NOEL/NOEC and LOAEL/LOEL/LOEC values were added and in column AM (Additional Remarks) it is stated whether the study is also mentioned in another Source, e.g. "NOAEL source: DAR or Study also in CAR".
2. All data presented in other databases (e.g. ToxCast, EASIS, TedX) are included in the "Data summary template". In certain cases, the EASIS data are not adequate enough to be included in the datasheet and the original publication was retrieved. Moreover, not all the publications mentioned in the TedX database have been considered relevant for data entry, due to not relevant type of toxicity or species or in the case that it is a review paper possibly examining many substances and it is not easy to extract any data for the substance under examination. This has been stated in the "Other Information" cell for each chemical.
3. Any major deviations from the study protocol and the study limitations, as presented in the regulatory documents (DAR/RAR, Assessment Reports, etc), are presented in column AM: Additional Remarks.
4. The range-finding studies are not included in the "Data summary template".
5. The studies that have been evaluated and considered to be not acceptable are not included in the "Data summary template". In the case of ToxRefDB, all studies are captured in the "Data summary template", since this information was not available in the ToxRefDB database.
6. All the observed effects that have been used for the establishment of NOAEL/NOEL/NOEC values were captured in the database. For higher doses, only the ED-related effects not being a basis for NOAEL were captured.
7. In each source document (DAR/RAR, etc.), the data used for the database population were highlighted in yellow in order to check and trace back the origin of the data entered. Originally, the studies that are common in DAR and ToxRefDB database were highlighted in purple. However, this was not possible for all the file types and decision was made not to do it considering the time constraints.

The results of the screening do not constitute evaluations of individual substances to be carried out under the respective chemical legislations [[in particular, Regulation (EC) No 1107/2009 on plant protection products, Regulation (EU) No 528/2012 on biocidal products, Regulation (EC) No 1907/2006 REACH, Regulation (EC) No 1223/2009 on cosmetic products and the Water Framework Directive (EC) No 2000/60] and in no way prejudge future decisions on active substances to be taken pursuant to these pieces of the EU legislation.

It would thus be erroneous to consider that the substances listed in the results of this study (SANTE/2015/E3/SI2.706218) are considered as endocrine disruptors within the meaning of the EU legislation.

8. All relevant studies are included in the database. If no effects are observed in a study, this is reflected as 'No relevant effect observed' (Col. Y in "Data summary template") – 'No relevant effects' (Col. Z) – 'No effect' (Col. AD). In case more than one NOAEL/LOAEL values are set in a study for different parameters, as it is the case for developmental and multigeneration studies, these are reported in separate lines (see screenshot below).

Study principle	Generation/Life stage	Sex (effect)	Lowest Effect	Effect type	Effect target	Effect classification	Effect description	Eff direction	Effect	NOAEL/LOAEL
Multigenerational reproductive	Adult (P1)	M + F	50	In life observation	Growth	General adversity	Body weight gain	Decrease		20 50
Multigenerational reproductive	Adult (P1)	M + F	50	In life observation	Food consumption	General adversity		Decrease		20 50
Multigenerational reproductive	Adult (F1)	F		No relevant effect observed	No relevant effects	[Not in list]	No effects on reproduction	No effect		50
Multigenerational reproductive	Offspring (F1+F2)	M + F	100	In life observation	Litter/pup weight	ED related adversity	Body weight gain in pups	Decrease		40 100

More specifically, the population of each cell of the database excel file was conducted in accordance with the description presented in the Table below:

Table 1.6: Miscellaneous chemicals: Source of Information & Data Collection comments.

Column	Title	Description
Column A	Type of toxicity	Type of toxicity study (<i>in vitro</i> , mammalian <i>in vivo</i> or wildlife <i>in vivo</i>)
Column B	Study principle	The type of protocol used for the toxicity study is selected from pull down menu. It is noted that there were study principles missing, e.g. Developmental Neurotoxicity Study, Subchronic inhalation, Subchronic dermal in the pull down menu of template version 1.08.
Column C	Study ID	Number to identify study for further data-analysis within this methodology
Column D	Study Reference ID	Study ID, only if given in the source. The Report No should be reported preferably, if available. In case there is no specific Study ID the approach followed was to state in the "Additional remarks" the exact reference to the source document/information and leave Column D empty. For REACH Chemicals where the information is taken from the ECHA website, as a STUDY ID the reference title is included, e.g. <i>Exp Key Repeated dose toxicity: oral.001</i> .
Column E	Study guideline (OECD/US EPA) or remarks	The guideline used for the study design, if given. The OECD guideline is reported preferably, if available (e.g. OECD 416). Also other remarks regarding the guideline can be given here.
Column F	Source	Source used for the toxicity data (e.g. DAR, ToxCast, DAR/CAR etc).
Column G	Reference	Name of the 1 st study author only, e.g. Smith <i>et al</i> .

The results of the screening do not constitute evaluations of individual substances to be carried out under the respective chemical legislations [[in particular, Regulation (EC) No 1107/2009 on plant protection products, Regulation (EU) No 528/2012 on biocidal products, Regulation (EC) No 1907/2006 REACH, Regulation (EC) No 1223/2009 on cosmetic products and the Water Framework Directive (EC) No 2000/60] and in no way prejudge future decisions on active substances to be taken pursuant to these pieces of the EU legislation. It would thus be erroneous to consider that the substances listed in the results of this study (SANTE/2015/E3/SI2.706218) are considered as endocrine disruptors within the meaning of the EU legislation.

Column	Title	Description
	(citation)	
Column H	Reporting date	Reporting date of the study when available. If the reference is a scientific paper, this can be the year of publishing.
Column I	Species	Species used for the toxicity study.
Column J	Strain or <i>in vitro</i> model	The specific strain used for the toxicity study, when applicable. For <i>in vitro</i> test systems, this field can be used to further specify the cell system model.
Column K	Animals/sex/group	Number of animals per sex that are used for the specific dose or concentration.
Column L	Sex (administration)	The sex of the treated animals
Column M	Purity (%)	Purity of the compound (% of active ingredient) that is used within the study
Column N	Route of administration	The route of exposure that is used for exposing the animals is to be selected from the pull down menu: oral, inhalation, dermal, direct or other [not in list]. If other, this should be specified in the "Additional Remarks" Column. For fish and amphibian studies "uptake from water" is chosen.
Column O	Method of administration	The method that is used to expose the animal or cells to the test compound is to be selected from the pull down menu (feed, gavage, whole-body, capsules, water, topical, subcutaneous, intravenous or other [not in list]). If not in the list, then this should be specified in the "Additional Remarks" Column. For fish and amphibian studies "water" is chosen.
Column P	Doses tested	The list of doses applied within the test (e.g. 1, 3, 5, 10 mg/kg bw/day), excluding the 0 or control concentration.
Column Q	Lowest dose tested	The lowest dose used within the test (excluding the 0 exposure or control)
Column R	Highest dose tested	The highest dose used within the test.
Column S	Dose unit	The unit for the dose applied in the test is to be selected from the pull down menu. For feeding studies the values in ppm should be converted to "mg/kg bw/day" according to the conversion factor indicated by FAO/WHO (2000) ⁷ . In case of avians, the conversion factor for chick was used. In case of studies with rats, the conversion factor for young rats was used for all studies except for chronic, combined

⁷FAO/WHO, 2000. Guidelines for the preparation of toxicological working papers for the Joint FAO/WHO Expert Committee on Food Additives. Appendix F: Approximate relation of parts per million in the diet to mg/kg of body weight per day, page 18.

The results of the screening do not constitute evaluations of individual substances to be carried out under the respective chemical legislations [[in particular, Regulation (EC) No 1107/2009 on plant protection products, Regulation (EU) No 528/2012 on biocidal products, Regulation (EC) No 1907/2006 REACH, Regulation (EC) No 1223/2009 on cosmetic products and the Water Framework Directive (EC) No 2000/60] and in no way prejudge future decisions on active substances to be taken pursuant to these pieces of the EU legislation. It would thus be erroneous to consider that the substances listed in the results of this study (SANTE/2015/E3/SI2.706218) are considered as endocrine disruptors within the meaning of the EU legislation.

Column	Title	Description
		chronic/carcinogenicity and carcinogenicity studies when the conversion factor for older rats was used. In case food consumption and body weight data of the species used were provided in the study, these data were used for the conversion.
Column T	Duration of exposure	Duration of exposure. In order to achieve a harmonised description of the studies specific values might be agreed for guideline studies. For example the duration of guideline compliant two-generation studies has been assumed to be 26 weeks, if not otherwise stated.
Column U	Duration unit	The unit for the duration of exposure is to be selected from pull down menu.
Column V	Generation/Life stage	The generation or life stage for which the reported effect is given is selected from a pull down list.
Column W	Sex (effect dose)	The sex for which the observed effect is reported is to be selected from a pull down menu. Options are M (male), F (female) and F + M (male + female).
Column X	Lowest Effect dose	The actual dose at which the effect (see Effect type and Effect target) is observed. The units are assumed to be the same as defined under "Dose unit".
Column Y	Effect type	The type of effect (broad categories) is to be selected from a pull down menu. The option "No reproductive effect" was proposed to be added in the pull down list in order to assist clarity in multigeneration studies where NOAEL for reproductive effects is set at the highest dose.
Column Z	Effect target	Selected from a pull down menu.
Column AA	Effect classification	Automatically filled in.
Column AB	Effect description	A more detailed description of what is actually observed, as free text as these can be difficult to predefine.
Column AC	Effect determination	Field to state whether the determination (e.g. weight gain) was relative or absolute.
Column AD	Effect direction	Selected from a pull down menu
Column AE	NOAEL/NOEL/NOEC	The NOAEL/NOEL/NOEC values of the study.
Column AF	LOAEL/LOEL/LOEC	The LOAEL/LOEL/LOEC values of the study.
Column AG	Unit	The unit for the NOAEL/NOEL/NOEC, LOAEL/LOEL/LOEC and EC50 values
Column AH	Effect generally indicative of	Automatically filled
Column AI	Indicated in OECD GD 150	Automatically filled
Column AJ	OECD level	Automatically filled
Column AK	Human relevance	Data are considered human relevant unless it is otherwise

The results of the screening do not constitute evaluations of individual substances to be carried out under the respective chemical legislations [[in particular, Regulation (EC) No 1107/2009 on plant protection products, Regulation (EU) No 528/2012 on biocidal products, Regulation (EC) No 1907/2006 REACH, Regulation (EC) No 1223/2009 on cosmetic products and the Water Framework Directive (EC) No 2000/60] and in no way prejudge future decisions on active substances to be taken pursuant to these pieces of the EU legislation. It would thus be erroneous to consider that the substances listed in the results of this study (SANTE/2015/E3/SI2.706218) are considered as endocrine disruptors within the meaning of the EU legislation.

Column	Title	Description
	Yes/No	indicated in the study or other report e.g. EFSA Conclusion, Assessment Report (AR)
Column AL	Reasoning	Any reasoning presented in the study or other report.
Column AM	Additional remarks	Additional remarks about the study and the results that cannot be given under any of the other free text options and not covered by the information in the pick lists.

It should be noted that, although there has been a huge effort for harmonizing the data entry, there might be cases where the above mentioned data population "rules" might not have been followed for all the pilot substances, since these rules refer to the outcome of the pilot data entry. Especially, for the cases where non ED-related effects have been captured, since these are the basis for the NOAEL derivation in a study, the approaches might differ, i.e.

These effects are captured:

- as "No relevant effect observed" in Column Y and "No relevant effect" in Column Z, while the exact effects are described in Column AB "Effect description".

OR

- as shown below for a specific effect that is not included in the pick lists:

Effect type	Effect target	Effect classification	Effect description	Effect determination	Effect direction
Organ histopathology	[Not in list]	[Not in list]	not in OECD 150; used to derive NOAEL: abnormalities in duodenum.	duodenal findings: crypt cell hyperplasia, shortening of villi and general disorganisation of villus enterocytes	Change

- Another approach would be to put all these findings as "In life observation" (Column Y) & "Systemic toxicity" (Column Z).

Based on the experience gained during the pilot phase in the version 1.09 template for the "Data" excel file all the non ED-related effects, which are the NOAEL basis, will be entered as "not in OECD150-used to derive NOAEL". Thus, there will be no confusion.

Another point of difficulty in data entry is related to tumor incidence. In case of tumour occurrence in non-endocrine organs, if the options "abnormalities" (in column Y) and "tumour types" (in column Z) are selected, "ED-related adversity" will appear automatically in Column AA, which is not correct.

In order to overcome this issue we have adopted the following approach:

In case of tumors in endocrine organs:

Column Y: "abnormalities" is selected.

The results of the screening do not constitute evaluations of individual substances to be carried out under the respective chemical legislations [[in particular, Regulation (EC) No 1107/2009 on plant protection products, Regulation (EU) No 528/2012 on biocidal products, Regulation (EC) No 1907/2006 REACH, Regulation (EC) No 1223/2009 on cosmetic products and the Water Framework Directive (EC) No 2000/60] and in no way prejudge future decisions on active substances to be taken pursuant to these pieces of the EU legislation.

It would thus be erroneous to consider that the substances listed in the results of this study (SANTE/2015/E3/SI2.706218) are considered as endocrine disruptors within the meaning of the EU legislation.

Column Z: "tumor types" is selected.

Column AB: "effect description" the endocrine organ affected is reported.

In case of non-endocrine organs:

In Column Y: "organ histopathology" is selected.

In Column Z: the exact organ is selected from the pull down list e.g. "liver histopathology", "not in list".

In Column AB: the word "tumors" is included.

Categorization of substances

Following the population of the Data summary template version 1.08 provided by JRC on 6th July 2015, the procedure followed for the categorization of the 35 substances examined is illustrated in Figure 1.1 below:

The results of the screening do not constitute evaluations of individual substances to be carried out under the respective chemical legislations [[in particular, Regulation (EC) No 1107/2009 on plant protection products, Regulation (EU) No 528/2012 on biocidal products, Regulation (EC) No 1907/2006 REACH, Regulation (EC) No 1223/2009 on cosmetic products and the Water Framework Directive (EC) No 2000/60] and in no way prejudge future decisions on active substances to be taken pursuant to these pieces of the EU legislation.

It would thus be erroneous to consider that the substances listed in the results of this study (SANTE/2015/E3/SI2.706218) are considered as endocrine disruptors within the meaning of the EU legislation.

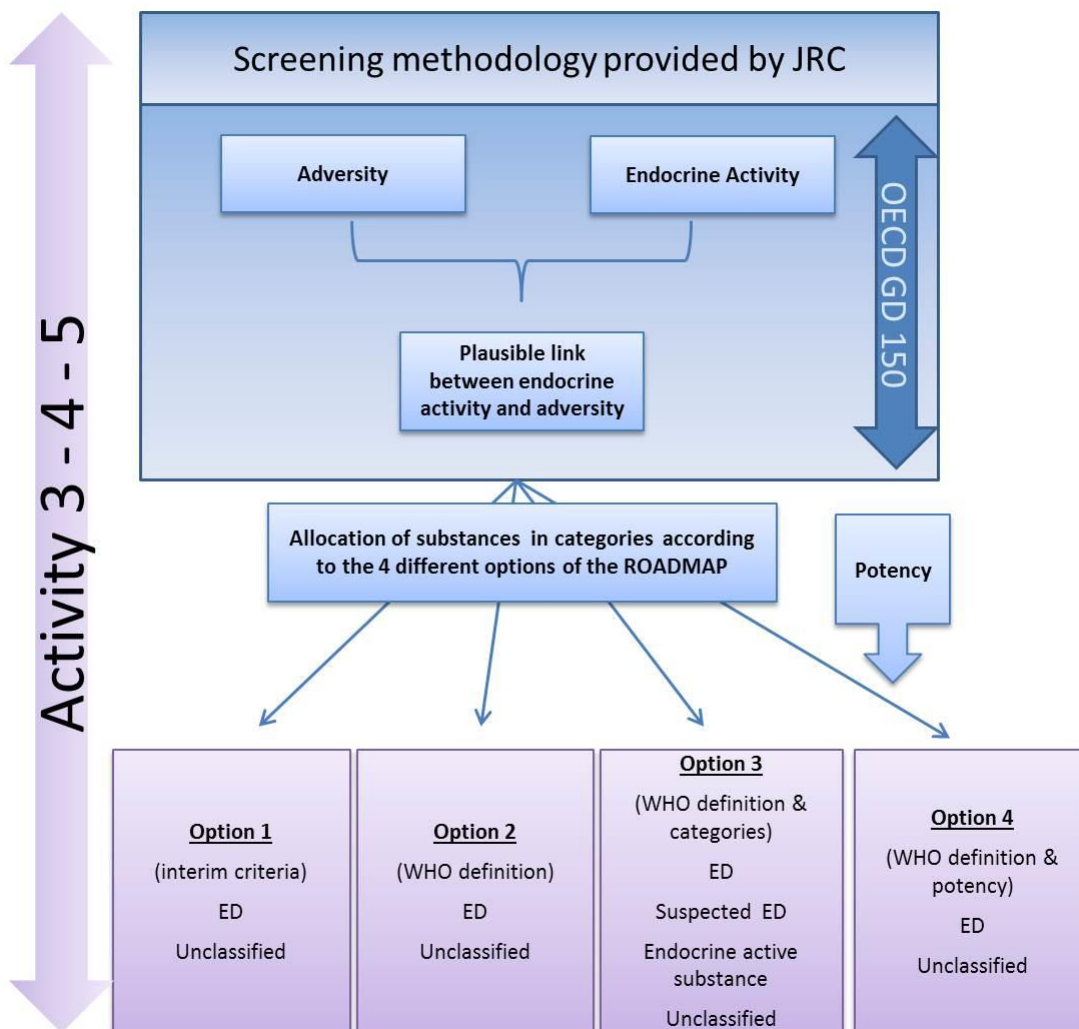
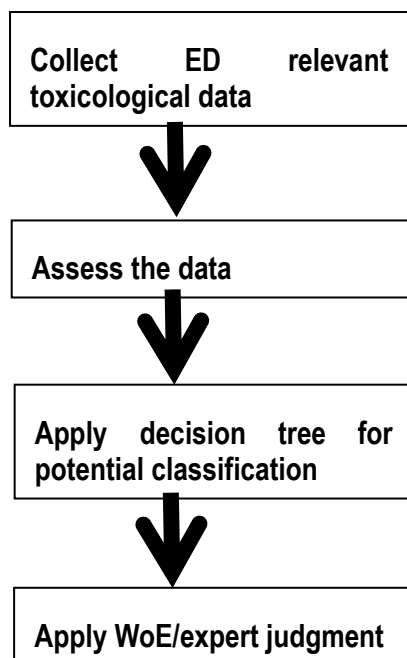


Figure 1.2. Outline of the procedure followed for the IT-database population and the categorization of the screened substances according to the four "Options" of the Roadmap within WPs 3, 4 & 5.

Categorization of effects was applied according to the instructions provided by JRC on 30.6.2015 (Appendix 1.2).

The results of the screening do not constitute evaluations of individual substances to be carried out under the respective chemical legislations [[in particular, Regulation (EC) No 1107/2009 on plant protection products, Regulation (EU) No 528/2012 on biocidal products, Regulation (EC) No 1907/2006 REACH, Regulation (EC) No 1223/2009 on cosmetic products and the Water Framework Directive (EC) No 2000/60] and in no way prejudge future decisions on active substances to be taken pursuant to these pieces of the EU legislation. It would thus be erroneous to consider that the substances listed in the results of this study (SANTE/2015/E3/SI2.706218) are considered as endocrine disruptors within the meaning of the EU legislation.



Before beginning with the evaluation of all relevant data, we exclude from human health assessment all effects that are not relevant to humans. According to this refined methodology, the first step was the collection of the ED-related and EATS-specific adverse effects as presented in the Data summary, excluding from the evaluation these ED adverse effects that were a secondary effect of general systemic toxicity. This is also consistent with the criteria described under "Options 2, 3, 4" of the published Roadmap (point b at page 5 of the Roadmap). For example, the "Data summary template" (in version 1.08, as used during the pilot phase) categorizes reduction of body weight as ED-related adversity and food consumption as "General adversity". However, if the overall weight of data suggests that decreased body weight is always accompanied by decreased food consumption, then the reduction of body weight is considered secondary to general systemic toxicity and it is not taken into account in the evaluation process. Similarly, if thyroid hypertrophy in the rat is observed, then we always check whether this is accompanied by liver weight increase or liver histopathology at a dose lower or equal to the one where thyroid effects are observed. If this is the case, then thyroid effects are considered secondary to liver toxicity and not mediated by an endocrine MoA. This is noted in the relevant part of the "Evaluation" sheet of the "Data summary template" version 1.08 and it is not considered relevant for the evaluation of the substance.

The results of the screening do not constitute evaluations of individual substances to be carried out under the respective chemical legislations [[in particular, Regulation (EC) No 1107/2009 on plant protection products, Regulation (EU) No 528/2012 on biocidal products, Regulation (EC) No 1907/2006 REACH, Regulation (EC) No 1223/2009 on cosmetic products and the Water Framework Directive (EC) No 2000/60] and in no way prejudge future decisions on active substances to be taken pursuant to these pieces of the EU legislation. It would thus be erroneous to consider that the substances listed in the results of this study (SANTE/2015/E3/SI2.706218) are considered as endocrine disruptors within the meaning of the EU legislation.

C10				
	A	B	C	D
1				
2	Note: the assessment is made by using the matrix in the "Data Summary" sheet			
3				
4		List Study ID Matrix	Reasoning	
	Study/ies not used for the evaluation because the ED adversity (ED-related and/or EATS-specific) is a secondary	Thyroid histopathology in rat - ID: 2, 8, 15	Liver histopathology in rat has been observed in 10 studies. Therefore the thyroid effects due to liver toxicity cannot be excluded.	

After the exclusion of secondary ED-related adverse effects, we proceed with the categorization of substances according to the four "Options" of the Roadmap.

More specifically, according to "Option 1", the interim criteria set in Plant Protection Product Regulation (EC) 1107/2009 and Biocides Product Regulation (EU) 528/2012 were used to characterize a substance as ED.

The "Option 1" categorization of a substance as ED or not is based mainly on its classification. Since not all substances have been discussed at ECHA level (even if there is a harmonised classification based on CLP00⁸), two different cases have been examined, i.e.:

1. The categorization based on the harmonised classification if this is available for the substance.
2. The categorization based on the available proposed classification, i.e. the most recent classification proposal on EU level has been considered (EFSA conclusion, Assessment Reports or in case of REACH Registered substances the proposal of the Registrant).

It is noted that it was not possible to have both classifications (harmonised and proposed) recorded for all pilot substances since there were cases where no harmonised classification was available or cases where the proposed classification refers to a document older than the decision for the harmonised classification. The final categorization considering the available harmonised and/or proposed classification for each substance as ED or not ("Unclassified") was decided based on the scheme shown in Figure 1.2 below.

⁸The approach followed for the retrieval of all the supporting documentation with regard to the classification of a substance is included in the "Source of Information & Data Collection" section.

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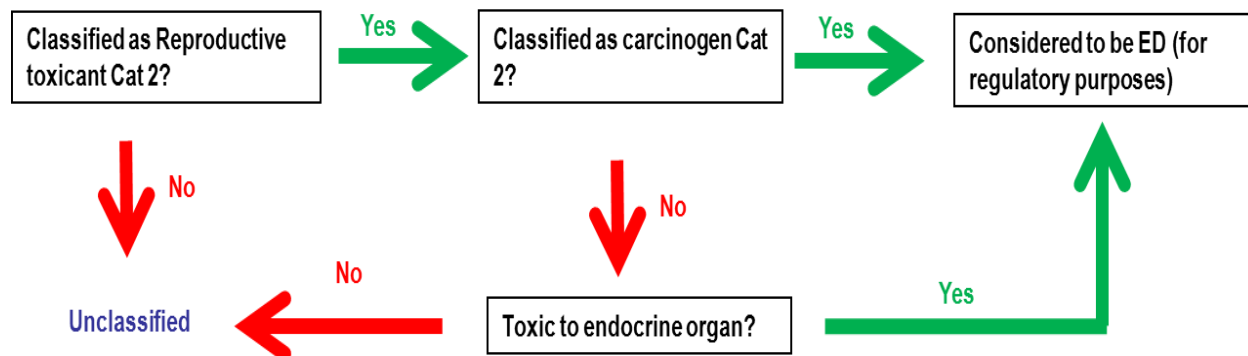


Figure 1.2. Decision tree, leading to the different ED classifications according to the interim criteria as stated in the PPPR and the BPR.

Regarding endocrine organs, for the purpose of this project, endocrine organs will be considered those that secrete hormones as well as the target organs that express the receptors for the sex hormones and thyroid hormones and are included in the OECD GD 150. The list of endocrine organs, for the purpose of this project, will then be the following:

mammary gland, accessory sex glands (e.g. Cowper's gland, seminal vesicles, prostate gland, bulbourethral glands, Glans penis), testis, epididymis, penis, cervix, uterus (endometrium), vagina, hypothalamus, pituitary, thyroid, adrenals, ovaries, placenta, Levator ani/bulbocavernosus muscles (LABC).

We have noted that in the datasheet "penis histopathology" (Column Z) is classified as "General adversity" in Column AA, whilst BPI suggests that (also for consistency with the list of "endocrine organs") it is classified as "EATS specific adversity" as it is the case for "Mammary gland histopathology".

According to "Option 2" of the Roadmap, the WHO/IPCS definition is used to identify endocrine disruptors. The Roadmap goes on to identify endocrine disruptors as substances which are (i) known or presumed to have caused endocrine-mediated adverse effects in humans or population-relevant endocrine-mediated adverse effects in animal species living in the environment or (ii) where there is evidence from experimental studies (*in vivo*), possibly supported with other information (e.g. (Q)SAR, analogue and category approaches) to provide a strong presumption that the substance has the capacity to cause endocrine-mediated adverse effects in humans or population-relevant endocrine-mediated adverse effects in animal species living in the environment.

Special attention was given on whether a clear evidence of endocrine-mediated adverse effects is present in the absence of other toxic effects or not. The endocrine-mediated adverse effects should not be a non-specific secondary consequence of toxic effects.

In "Option 3" of Roadmap, the WHO/IPCS definition was used to identify endocrine disruptors, but the substances were allocated in one of the three different categories based on the different weight of evidence for fulfilling the WHO/IPCS definition.

These categories are the following:

- Endocrine Disruptor (Category I)
- Suspected Endocrine Disruptor (Category II)
- Endocrine active substance (Category III)

Based on the collected data, a set of categorization rules were applied for the allocation of each substance to one of the aforementioned categories.

In the "Evaluation" sheet of the "Data summary template", version 1.08 excel sheet, provided by JRC, "Options 2&3" are presented together, since all substances classified as Cat I under "Option 3" are classified as EDs under "Option 2". Cat II and Cat III substances under "Option 3" are classified as "Unclassified" under "Option 2". The decision tree provided by JRC, as shown below, was used in order to allocate the chemicals in each category.

For ecotoxicological assessment, under "Option 2&3", only population relevant endpoints used for human health assessment were taken into consideration, i.e. effects on reproduction (e.g. litter size, pup and litter weight, embryo/fetal toxicity, etc), effects on all endocrine organs that could possibly affect reproduction (e.g. ovaries, testis, etc) and other effects with potential to disrupt reproduction. Effects on other endpoints that are considered not relevant for reproductive performance (e.g. tumors in non-reproductive organs) were not considered population relevant and were excluded from the ecotoxicological assessment. In case there were no relevant studies in birds, fish or amphibians, only mammalian studies were used. *In vitro* studies from ToxCast, EASIS, Tedx used for human health assessment were also used for ecotoxicological assessment. In case additional data from wildlife were available, those data were assessed and the categorization of the substance was amended accordingly. The categorisation of the substances was performed according to the different Paths (1 to 11, as indicated and numbered by BPI) of the decision tree provided by JRC on 30th June 2015, as described below.

The results of the screening do not constitute evaluations of individual substances to be carried out under the respective chemical legislations [[in particular, Regulation (EC) No 1107/2009 on plant protection products, Regulation (EU) No 528/2012 on biocidal products, Regulation (EC) No 1907/2006 REACH, Regulation (EC) No 1223/2009 on cosmetic products and the Water Framework Directive (EC) No 2000/60] and in no way prejudge future decisions on active substances to be taken pursuant to these pieces of the EU legislation.

It would thus be erroneous to consider that the substances listed in the results of this study (SANTE/2015/E3/SI2.706218) are considered as endocrine disruptors within the meaning of the EU legislation.

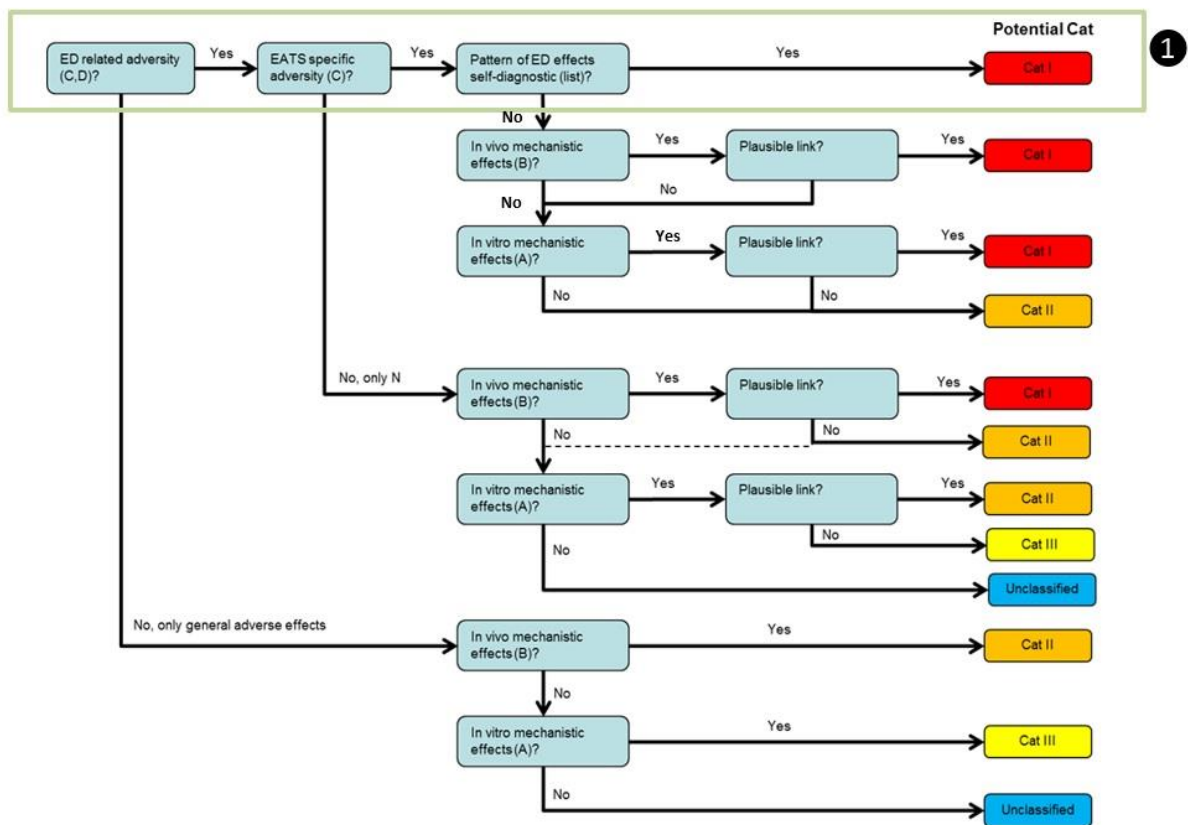


Figure 1.3.1. Decision tree (Path 1), leading to ED classification Cat I, according to “Option 3”. Substances that are classified as ED Cat I are considered to be EDs under “Option 2” (A: *In vitro* mechanistic, B: *In vivo* mechanistic & *in vivo* hormone levels, C: Adversity-EATS specific, D: Non-specific adversity (may or may not be indicative of EATS), E: Adversity-General [see Appendix 1.2]).

As shown by the green border above, Path 1 is the pathway leading a substance to be classified as Category I even if there is no mechanistic data available, provided there are adverse effects that are not only EATS specific according to OECD GD 150 but also considered diagnostic of an endocrine disrupting MoA. Two examples of such effects have been provided by JRC; one for ecotoxicological assessment and one for human health assessment as were also presented in the *Report of the Endocrine Disruptors Expert Advisory Group* entitled “*Key scientific issues relevant to the identification and characterisation of endocrine disrupting substances*” published in 2013. In ecotoxicological assessment “a change in sex ratio of fish was seen as both adverse and, according to the majority of the experts, highly likely to be a marker of endocrine disruption”. In humans “a pattern of effects known as testicular dysgenesis syndrome including hypospadias,

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cryptorchidism and decreased sperm quality which can also be replicated in laboratory mammals by certain chemicals (including hypo- and a-spermatogenesis, atrophy of the seminal vesicles and prostate, nipple retention, hypospadias, penis malformations, vaginal pouches, ectopic testes and decreased anogenital distance), was seen as highly likely to be mediated by an anti-androgenic mode of action”.

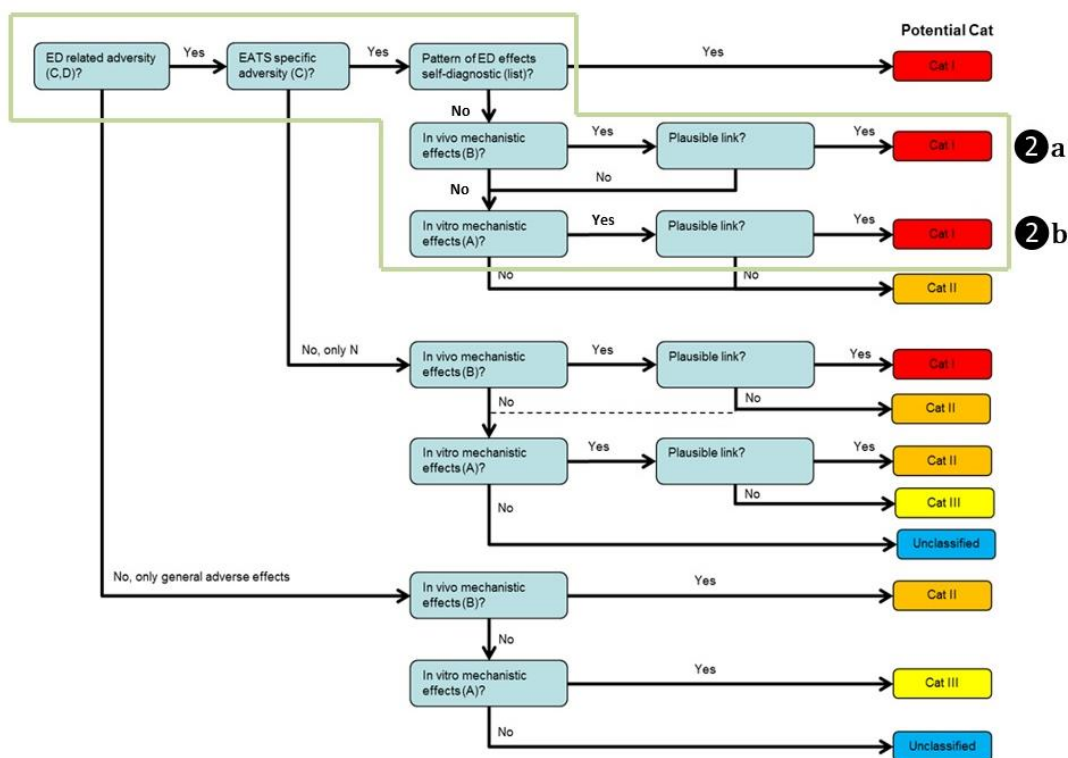


Figure 1.3.2. Decision tree (Paths 2a and 2b), leading to ED classification Cat I, according to “Option 3”. Substances that are classified as ED Cat I are considered to be EDs under “Option 2” (A: *In vitro* mechanistic, B: *In vivo* mechanistic & *in vivo* hormone levels, C: Adversity-EATS specific, D: Non-specific adversity (may or may not be indicative of EATS), E: Adversity-General [see Appendix 1.2]).

Paths 2a, 2b describe the pathways leading to classification as Cat I of a substance. If there are sufficient ED-related adversity data, which are also EATS specific, and there is mechanistic evidence of endocrine activity/mode of action and evidence of a plausible link between the endocrine activity and the observed adverse effect, then the substance is classified as Category I. This is shown above through Path 2a, in case of *in vivo* mechanistic data and through Path 2b, in case of *in vitro* mechanistic data. As JRC also notes, “Because we have captured all the effects that are thought to be relevant for ED and applied the decision tree in such a way that any evidence regarding adversity and MoA can lead to potential Cat I, we believe that the decision tree is overly protective, i.e. we expect false

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positives (rather than false negative classifications)". Consequently, as JRC also suggested, in cases of compounds that could be identified as Cat I by using the decision tree, a weight of evidence approach was followed to assess the pattern of effects observed, including severity of effects and the biological plausibility of a causal relationship between the induced endocrine activity and the adverse effects. After further discussions with JRC & SANTE it was agreed to apply, as far as possible in the short timeframe of this project, a limited weight of evidence approach to assess the consistency and strength of evidence available for observed adverse effects and endocrine activity, as well as to establish a biologically plausible link between the two in all cases and not just in the case of an initial Cat I conclusion. The flow chart in Figure 1.1 above was amended accordingly.

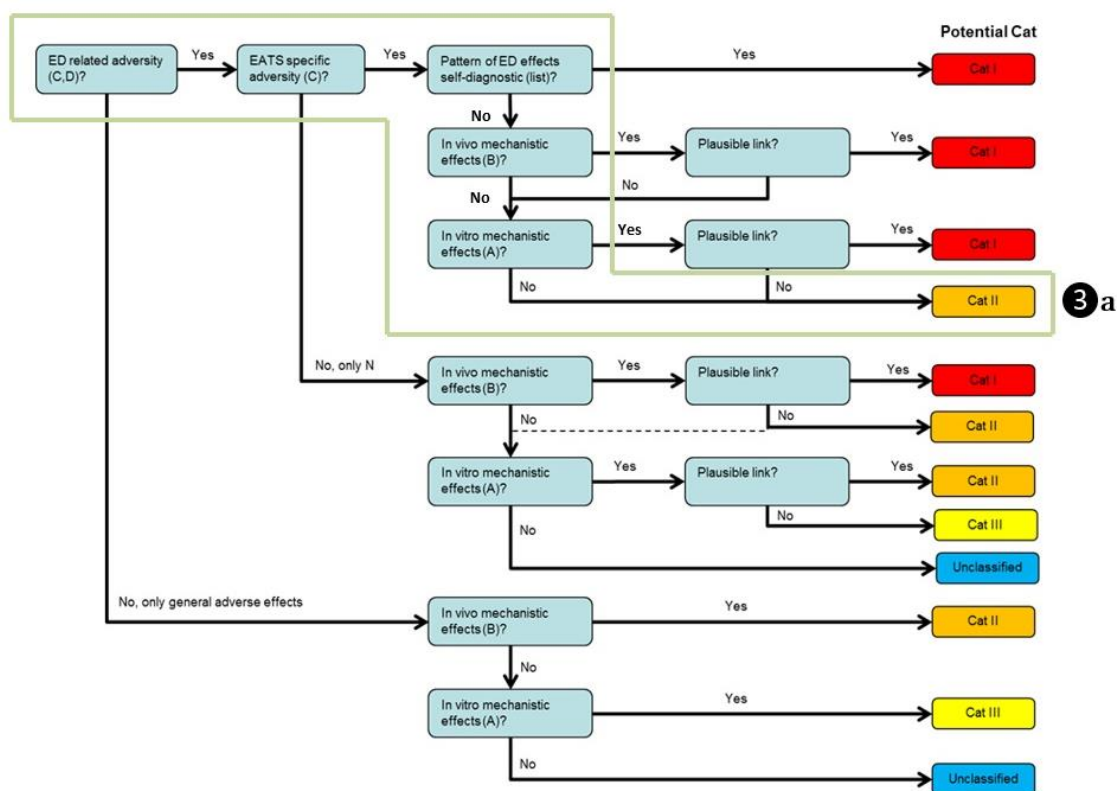


Figure 1.3.3. Decision tree (Path 3a), leading to ED classification Cat II, according to "Option 3". Substances that are classified as ED Cat II are considered to be "Unclassified" under "Option 2" (A: *In vitro* mechanistic, B: *In vivo* mechanistic & *in vivo* hormone levels, C: Adversity-EATS specific, D: Non-specific adversity (may or may not be indicative of EATS), E: Adversity-General [see Appendix 1.2]).

Path 3a describes the pathway leading to Category II where there is strong evidence of EATS-specific adverse effect data but there are neither *in vivo* mechanistic nor *in vitro* data

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available, either because no studies were performed (lack of data) or because the available mechanistic data include negative results.

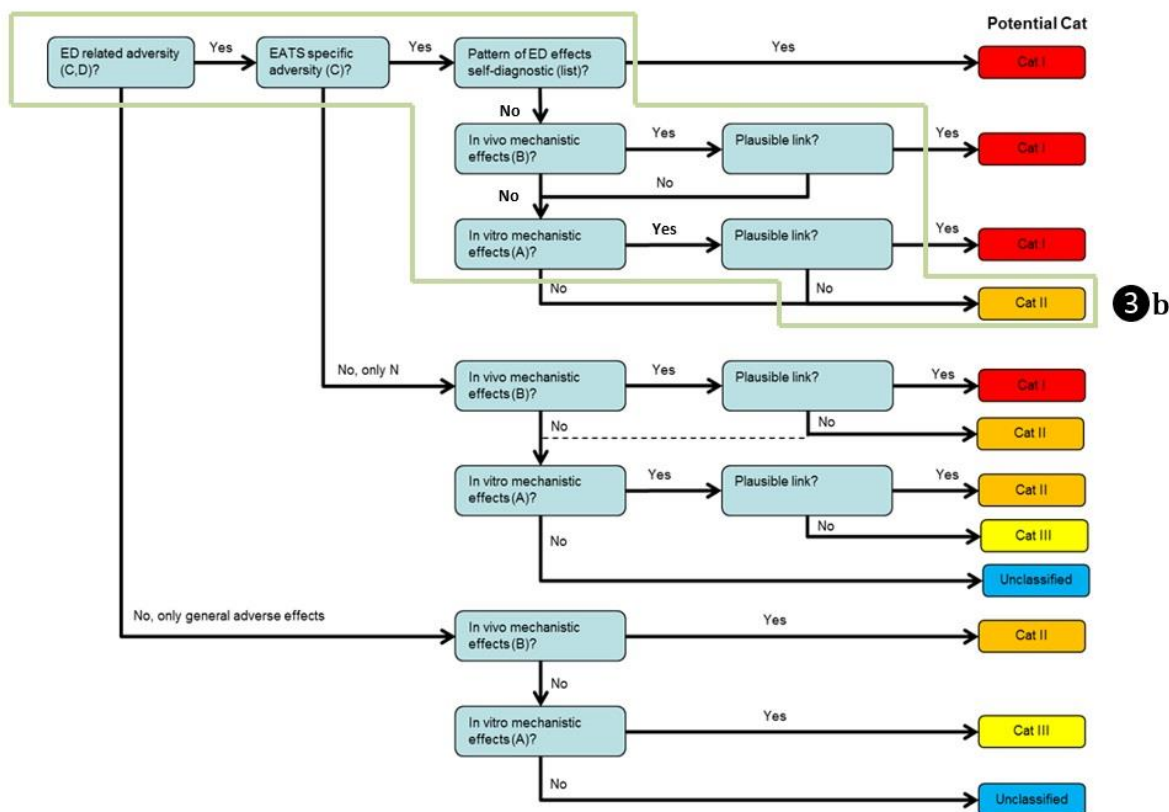


Figure 1.3.4. Decision tree (Path 3b), leading to ED classification Cat II according to “Option 3”. Substances that are classified as ED Cat II are considered to be “Unclassified” under “Option 2” (A: *In vitro* mechanistic, B: *In vivo* mechanistic & *in vivo* hormone levels, C: Adversity-EATS specific, D: Non-specific adversity (may or may not be indicative of EATS), E: Adversity-General [see Appendix 1.2]).

The next Path (3b) of the decision tree leading to Category II involves the case where there are sufficient adversity data that are EATS specific (but not self-diagnostic of EDs), and there are (or there are not) available *in vivo* mechanistic data, but with no plausible link between the endocrine activity and the observed adverse effect, and also there are *in vitro* mechanistic data but with no plausible link.

The results of the screening do not constitute evaluations of individual substances to be carried out under the respective chemical legislations [[in particular, Regulation (EC) No 1107/2009 on plant protection products, Regulation (EU) No 528/2012 on biocidal products, Regulation (EC) No 1907/2006 REACH, Regulation (EC) No 1223/2009 on cosmetic products and the Water Framework Directive (EC) No 2000/60] and in no way prejudge future decisions on active substances to be taken pursuant to these pieces of the EU legislation. It would thus be erroneous to consider that the substances listed in the results of this study (SANTE/2015/E3/SI2.706218) are considered as endocrine disruptors within the meaning of the EU legislation.

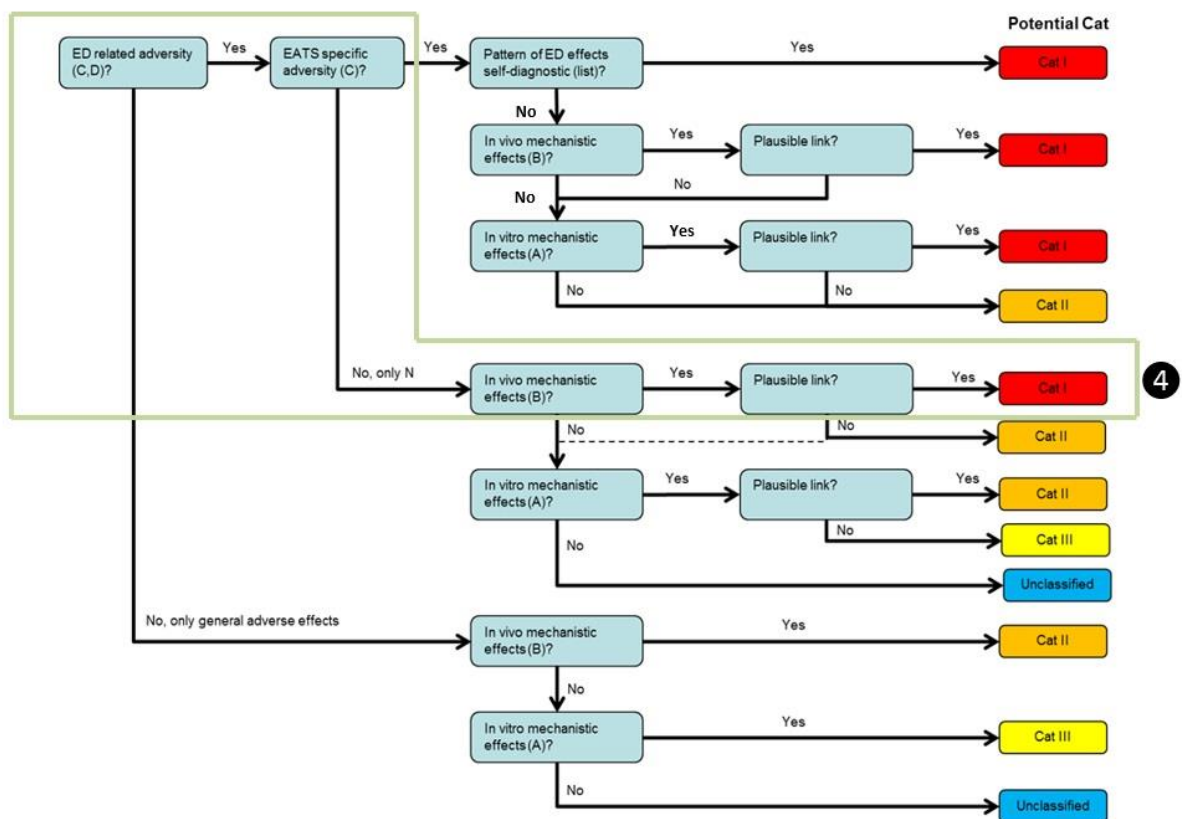


Figure 1.3.5. Decision tree (Path 4), leading to ED classification Cat I according to “Option 3”. Substances that are classified as ED Cat I are considered to be ED under “Option 2” (A: *In vitro* mechanistic, B: *In vivo* mechanistic & *in vivo* hormone levels, C: Adversity-EATS specific, D: Non-specific adversity (may or may not be indicative of EATS), E: Adversity-General [see Appendix 1.2]).

In this case (Path 4), there is only evidence of non-specific adverse effects, which may or may not be indicative of EATS mode of action. If available *in vivo* mechanistic data allow the establishment of a plausible link to the adverse effects, then it may be possible to conclude Cat I. However, although hypothetically possible, it is more likely that a plausible link to non-specific effects cannot be established and Path 5 (as indicated below) leading to Cat II would be more appropriate.

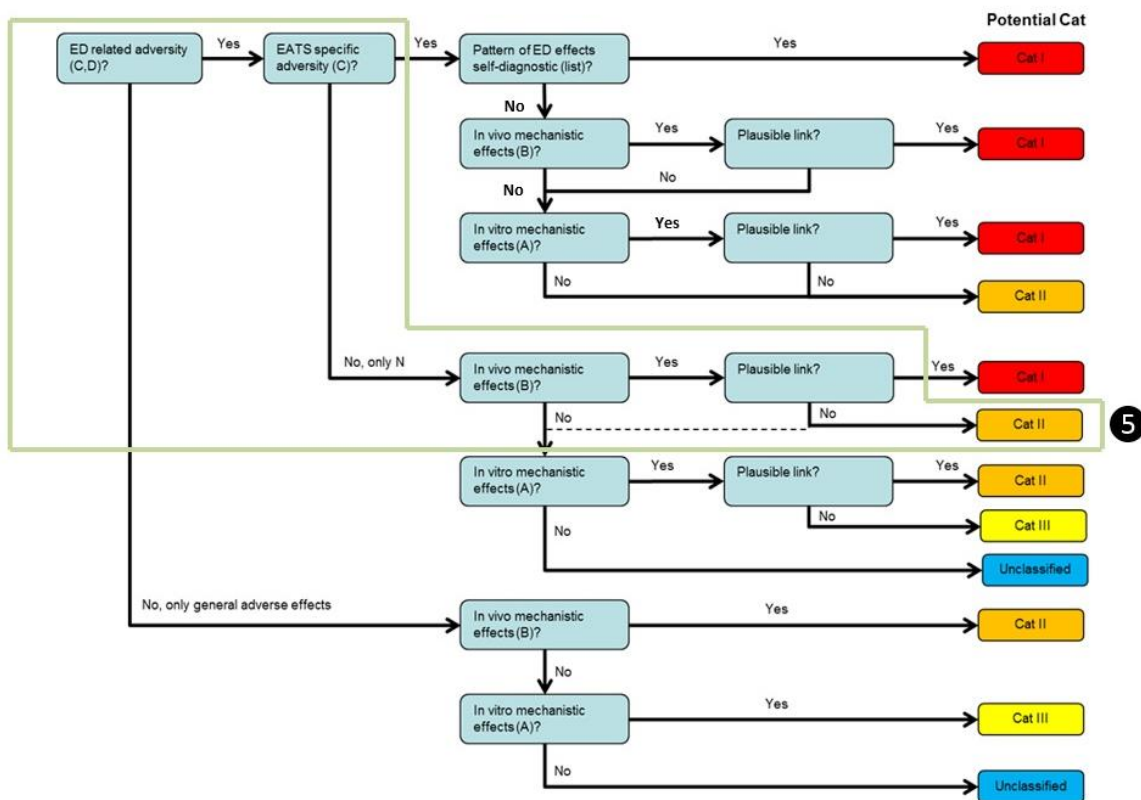


Figure 1.3.6. Decision tree (Path 5), leading to ED classification Cat II according to “Option 2 or 3”. Substances that are classified as ED Cat II are considered to be “Unclassified” under “Option 2” (A: *In vitro* mechanistic, B: *In vivo* mechanistic & *in vivo* hormone levels, C: Adversity-EATS specific, D: Non-specific adversity (may or may not be indicative of EATS), E: Adversity-General [see Appendix 1.2]).

The results of the screening do not constitute evaluations of individual substances to be carried out under the respective chemical legislations [[in particular, Regulation (EC) No 1107/2009 on plant protection products, Regulation (EU) No 528/2012 on biocidal products, Regulation (EC) No 1907/2006 REACH, Regulation (EC) No 1223/2009 on cosmetic products and the Water Framework Directive (EC) No 2000/60] and in no way prejudice future decisions on active substances to be taken pursuant to these pieces of the EU legislation. It would thus be erroneous to consider that the substances listed in the results of this study (SANTE/2015/E3/SI2.706218) are considered as endocrine disruptors within the meaning of the EU legislation.

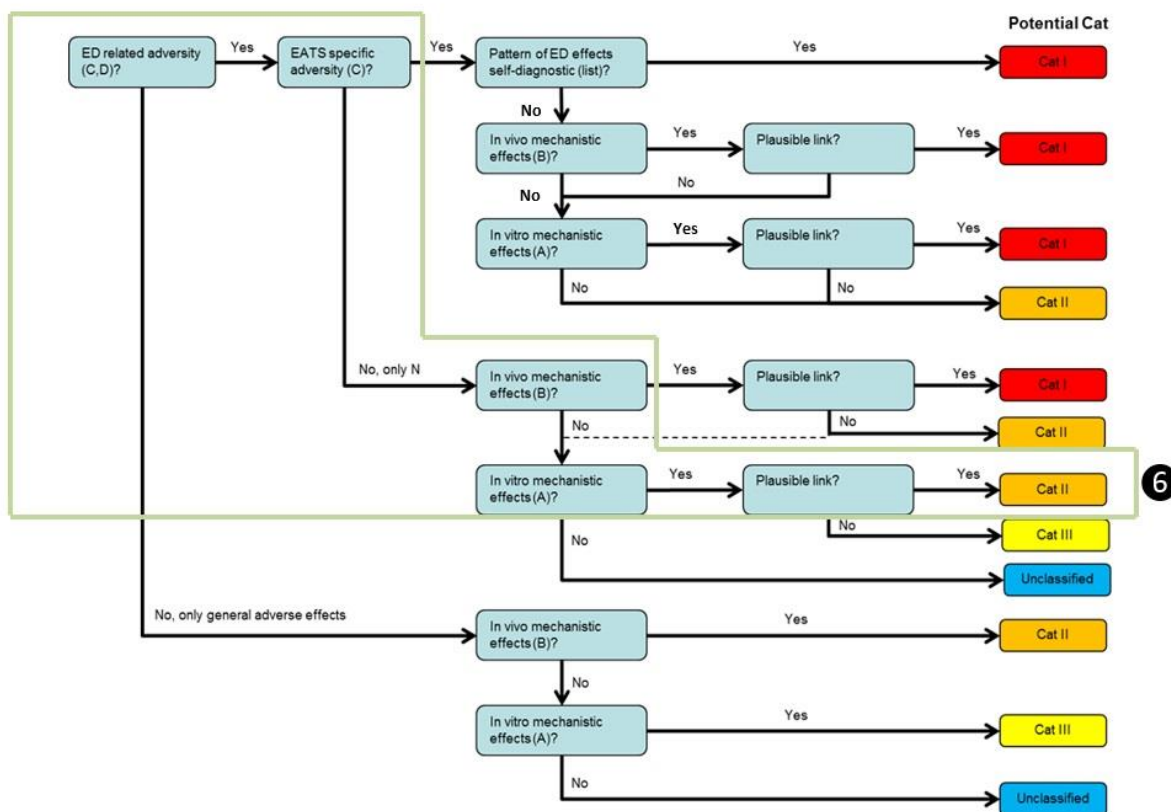


Figure 1.3.7. Decision tree (Path 6), leading to ED classification Cat II according to “Option 3”. Substances that are classified as ED Cat II are considered to be “Unclassified” under “Option 2” (A: *In vitro* mechanistic, B: *In vivo* mechanistic & *in vivo* hormone levels, C: Adversity-EATS specific, D: Non-specific adversity (may or may not be indicative of EATS), E: Adversity-General [see Appendix 1.2]).

The results of the screening do not constitute evaluations of individual substances to be carried out under the respective chemical legislations [[in particular, Regulation (EC) No 1107/2009 on plant protection products, Regulation (EU) No 528/2012 on biocidal products, Regulation (EC) No 1907/2006 REACH, Regulation (EC) No 1223/2009 on cosmetic products and the Water Framework Directive (EC) No 2000/60] and in no way prejudice future decisions on active substances to be taken pursuant to these pieces of the EU legislation. It would thus be erroneous to consider that the substances listed in the results of this study (SANTE/2015/E3/SI2.706218) are considered as endocrine disruptors within the meaning of the EU legislation.

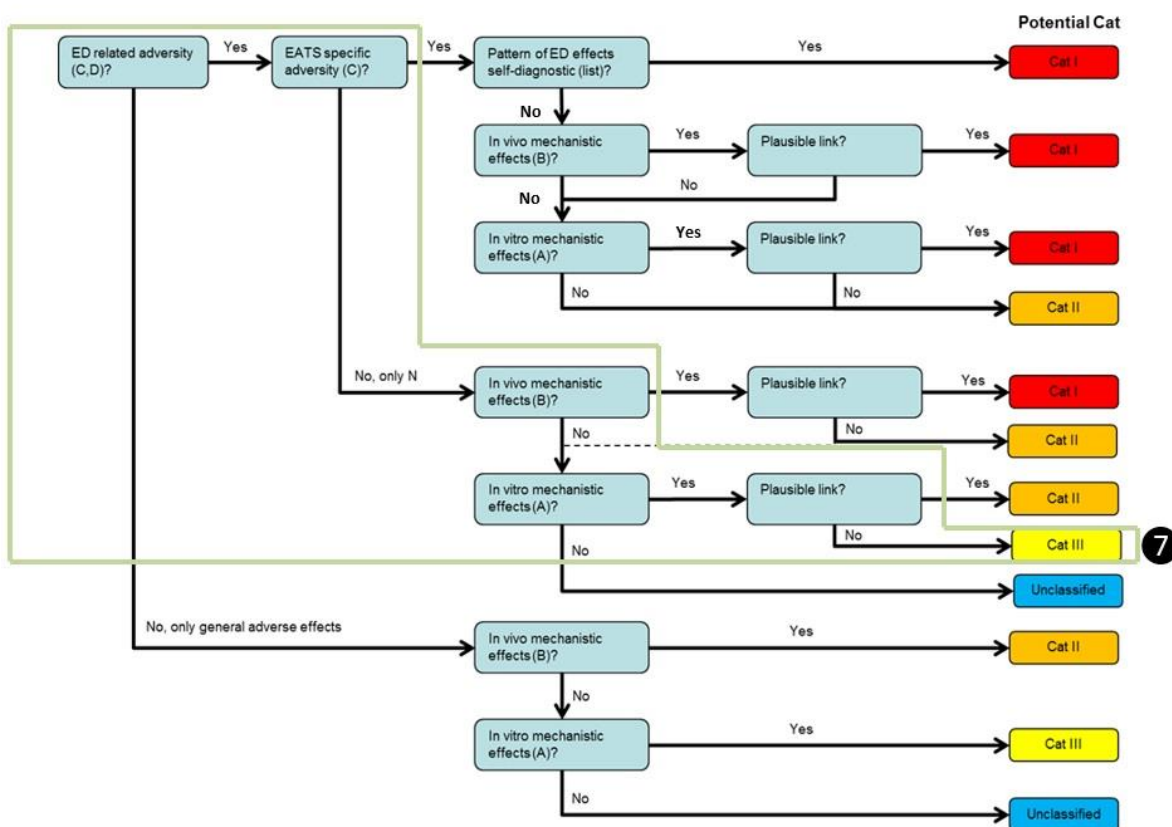


Figure 1.3.8. Decision tree (Path 7), leading to ED classification Cat III according to “Option 3”. Substances that are classified as ED Cat II are considered to be “Unclassified” under “Option 2” (A: *In vitro* mechanistic, B: *In vivo* mechanistic & *in vivo* hormone levels, C: Adversity-EATS specific, D: Non-specific adversity (may or may not be indicative of EATS), E: Adversity-General [see Appendix 1.2]).

In other words, substances are allocated in Category I if there are enough ED-related adversity data which are not EATS specific, but there is enough *in vivo* mechanistic evidence of endocrine activity/mode of action and there is also evidence of a plausible link between the endocrine activity and the observed adverse effects (Fig. 1.3.5, Path 4). In case no plausible link is identified, the substance is categorised as Category II (Fig. 1.3.6, Path 5). If there are enough ED-related adversity data which are nevertheless not EATS specific but there is only *in vitro* mechanistic evidence of endocrine activity/mode of action and evidence

The results of the screening do not constitute evaluations of individual substances to be carried out under the respective chemical legislations [[in particular, Regulation (EC) No 1107/2009 on plant protection products, Regulation (EU) No 528/2012 on biocidal products, Regulation (EC) No 1907/2006 REACH, Regulation (EC) No 1223/2009 on cosmetic products and the Water Framework Directive (EC) No 2000/60] and in no way prejudice future decisions on active substances to be taken pursuant to these pieces of the EU legislation. It would thus be erroneous to consider that the substances listed in the results of this study (SANTE/2015/E3/SI2.706218) are considered as endocrine disruptors within the meaning of the EU legislation.

of a plausible link between the endocrine activity and the observed adverse effects, then the substance is classified as Category II (Fig. 1.3.7, Path 6). In case there is no plausible link, the substance is classified as Category III (Fig. 1.3.8, Path 7).

In other words, in the case of Path 6, there is only evidence of non-specific adverse effects, which may or may not be indicative of EATS mode of action. If available *in vitro* mechanistic data allows the establishment of a plausible link to the adverse effects then it may be possible to conclude Cat II. However, although hypothetically possible, it is more likely that a plausible link to non-specific effects cannot be established and Path 7 (as indicated above) leading to Cat III would be more appropriate.

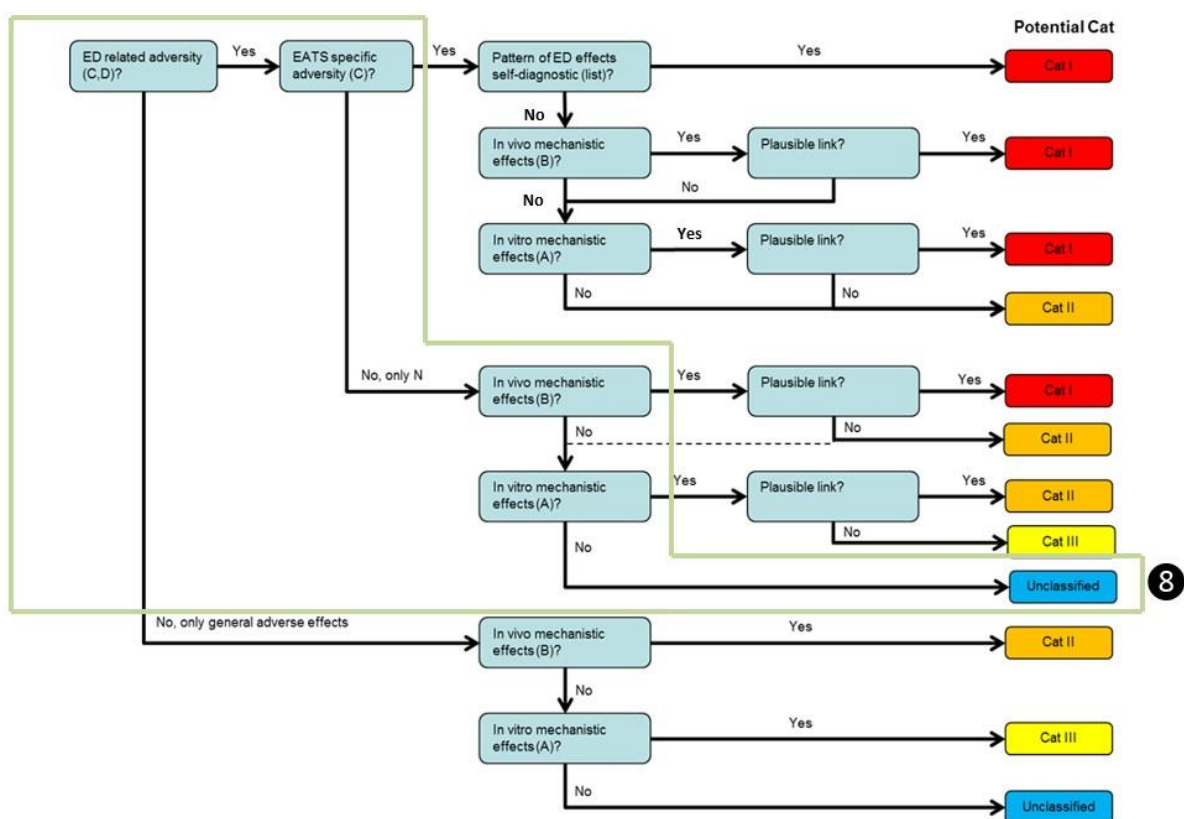


Figure 1.3.9. Decision tree (Path 8), leading to “Unclassified” substances according to “Option 2&3” (A: *In vitro* mechanistic, B: *In vivo* mechanistic & *in vivo* hormone levels, C: Adversity-EATS specific, D: Non-specific adversity (may or may not be indicative of EATS), E: Adversity-General [see Appendix 1.2]).

The results of the screening do not constitute evaluations of individual substances to be carried out under the respective chemical legislations [[in particular, Regulation (EC) No 1107/2009 on plant protection products, Regulation (EU) No 528/2012 on biocidal products, Regulation (EC) No 1907/2006 REACH, Regulation (EC) No 1223/2009 on cosmetic products and the Water Framework Directive (EC) No 2000/60] and in no way prejudice future decisions on active substances to be taken pursuant to these pieces of the EU legislation. It would thus be erroneous to consider that the substances listed in the results of this study (SANTE/2015/E3/SI2.706218) are considered as endocrine disruptors within the meaning of the EU legislation.

Path 8 is the pathway leading to “Unclassified” substances where there are ED-related adverse effects that are not EATS-specific and there are neither *in vivo* nor *in vitro* mechanistic data available (lack of data) or data including negative results. The distinction between cases where data are lacking and cases where results are negative is kept in the evaluation table.

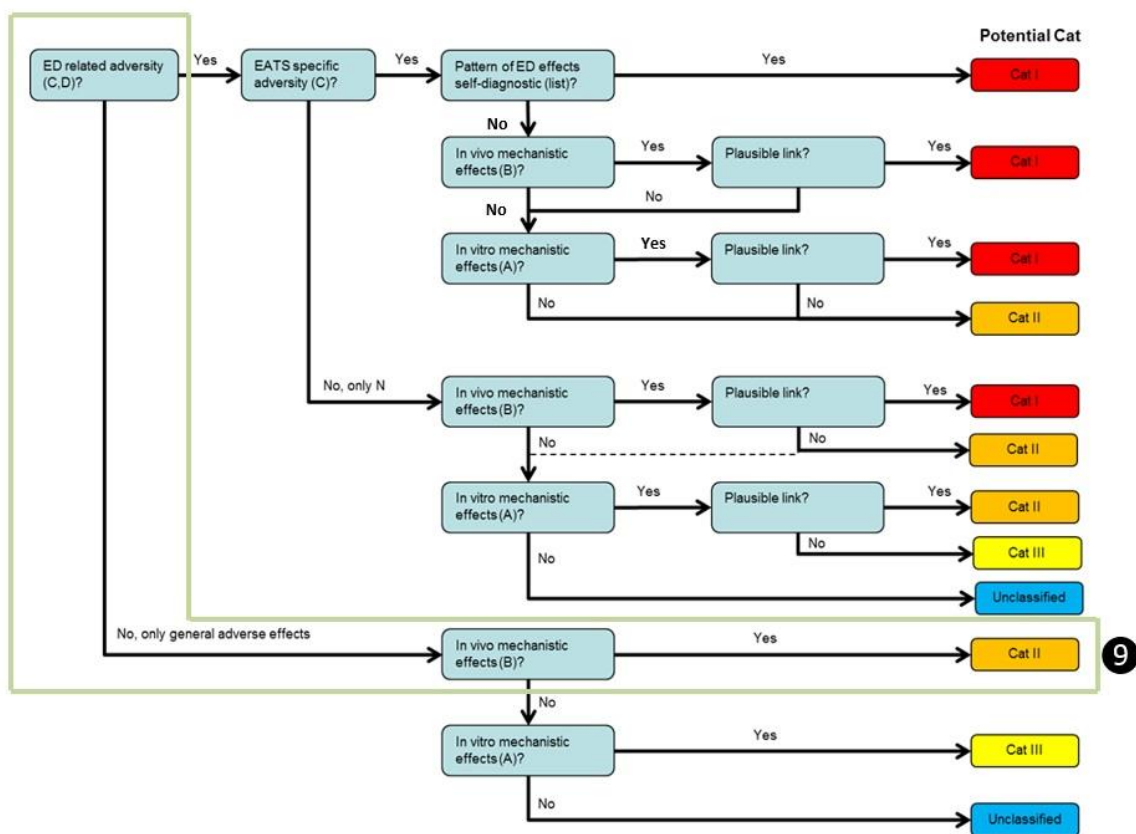


Figure 1.3.10. Decision tree (Path 9), leading to ED classification Cat II according to “Option 3”. Substances that are classified as ED Cat II are considered to be “Unclassified” under “Option 2” (A: *In vitro* mechanistic, B: *In vivo* mechanistic & *in vivo* hormone levels, C: Adversity-EATS specific, D: Non-specific adversity (may or may not be indicative of EATS), E: Adversity-General [see Appendix 1.2]).

The results of the screening do not constitute evaluations of individual substances to be carried out under the respective chemical legislations [[in particular, Regulation (EC) No 1107/2009 on plant protection products, Regulation (EU) No 528/2012 on biocidal products, Regulation (EC) No 1907/2006 REACH, Regulation (EC) No 1223/2009 on cosmetic products and the Water Framework Directive (EC) No 2000/60] and in no way prejudge future decisions on active substances to be taken pursuant to these pieces of the EU legislation. It would thus be erroneous to consider that the substances listed in the results of this study (SANTE/2015/E3/SI2.706218) are considered as endocrine disruptors within the meaning of the EU legislation.

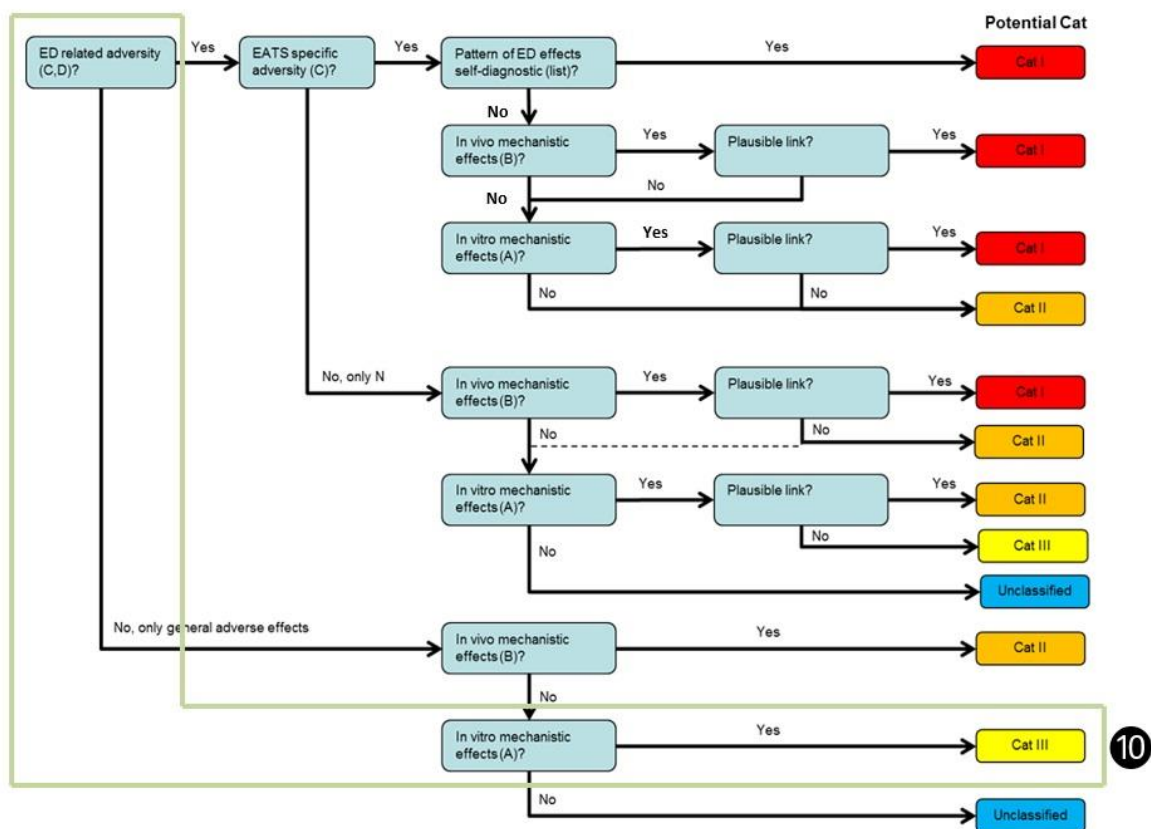


Figure 1.3.11. Decision tree (Path 10), leading to ED classification Cat III according to "Option 3". Substances that are classified as ED Cat III are considered to be "Unclassified" under "Option 2" (A: *In vitro* mechanistic, B: *In vivo* mechanistic & *in vivo* hormone levels, C: Adversity-EATS specific, D: Non-specific adversity (may or may not be indicative of EATS), E: Adversity-General [see Appendix 1.2]).

In case there are no ED-related adversity data or no general adverse effects at all, but there are *in vivo* mechanistic data indicative of an endocrine mediated MoA, then the substance is characterised as Category II (Fig. 1.3.10, Path 9). If instead of *in vivo* mechanistic data only *in vitro* mechanistic data are available, then the substance is classified as Category III (Fig. 1.3.11, Path 10).

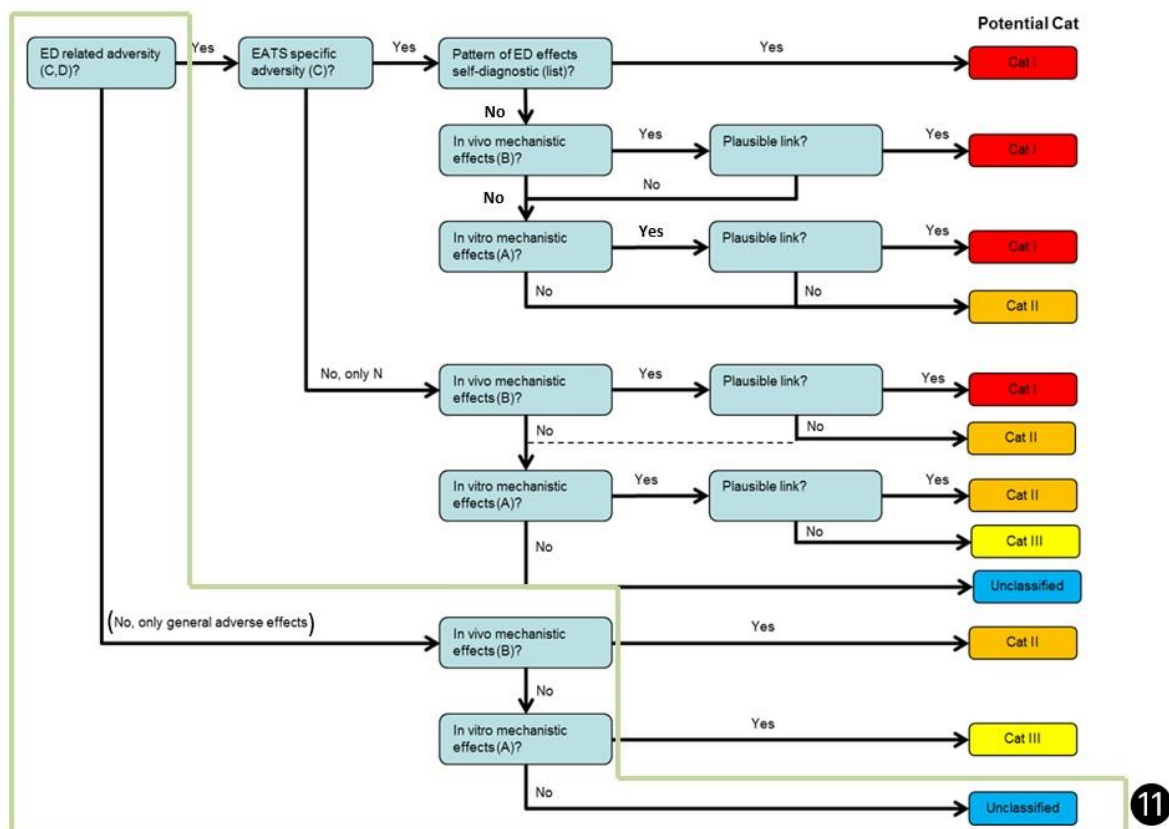


Figure 1.3.12. Decision tree (Path 11), leading to “Unclassified” substances according to “Option 2&3” (A: *In vitro* mechanistic, B: *In vivo* mechanistic & *in vivo* hormone levels, C: Adversity-EATS specific, D: Non-specific adversity (may or may not be indicative of EATS), E: Adversity-General [see Appendix 1.2]).

It should be noted that although the information included in the available ToxCast database, is not always sufficient to characterize a substance as agonist or antagonist, it is considered as relevant mechanistic data for the categorization of the substance. For example, the “ATG_ER α _TRANS” assay (column A) examines a possible “Receptor (trans)activation” (column G). If this is positive, a plausible link might be identified in combination with e.g. increased uterine weight, estrus cycle etc. However, a positive result in one ToxCast assay would not be sufficient to conclude on endocrine activity. A qualitative assessment of number of positive and negative assays, concordance between results and some judgment

The results of the screening do not constitute evaluations of individual substances to be carried out under the respective chemical legislations [[in particular, Regulation (EC) No 1107/2009 on plant protection products, Regulation (EU) No 528/2012 on biocidal products, Regulation (EC) No 1907/2006 REACH, Regulation (EC) No 1223/2009 on cosmetic products and the Water Framework Directive (EC) No 2000/60] and in no way prejudge future decisions on active substances to be taken pursuant to these pieces of the EU legislation. It would thus be erroneous to consider that the substances listed in the results of this study (SANTE/2015/E3/SI2.706218) are considered as endocrine disruptors within the meaning of the EU legislation.

of potency relative to the natural ligand would be useful to judge the strength of evidence. In other words, a WoE approach needs to be used in all Paths, as far as possible in the short timeframe of this project. As a minimum, the following are generally checked: assessment of positive and negative results, concordance between results, severity of adverse effects and biological plausibility of a possible link.

Finally, in case there are no ED-related adverse effects or no general adverse effects at all and neither *in vivo* nor *in vitro* mechanistic data, the substance is categorised as “Unclassified” (Fig. 1.3.12, Path 11).

As agreed at the 1st interim meeting on 15-6-2015, substances identified as Cat I under Option 3 should be classified as ED under “Option 2”.

According to “Option 4” of Roadmap the WHO/IPCS definition was applied to identify endocrine disruptors while potency was used as an element of hazard characterization.

Potency depends on the endpoint, but also on the dose, on the duration and timing of exposure⁹. For categorizing a substance under “Option 4”, a trigger value as cut-off value is required. Potency-based STOT-RE Cat 1 trigger values (from CLP) were proposed by JRC as cut-off criteria for endocrine disruptors of regulatory concern (see below). The following decision tree is proposed by JRC for all substances indicated as ED (Cat I only).

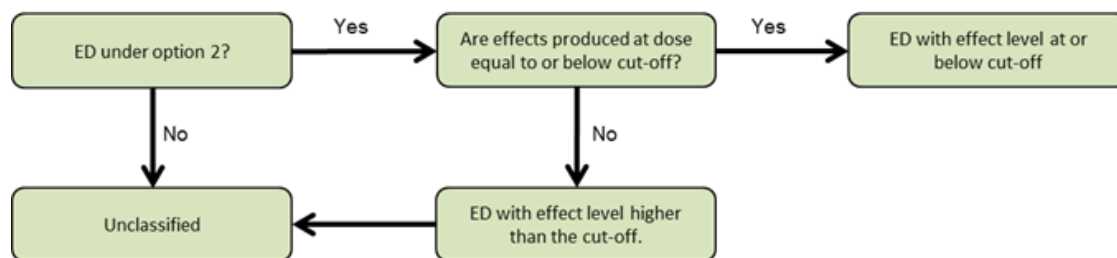


Figure 1.4. Decision tree, leading to the different ED classifications according to “Option 4”.

⁹EFSA Scientific Committee; Scientific Opinion on the hazard assessment of endocrine disruptors: scientific criteria for identification of endocrine disruptors and appropriateness of existing test methods for assessing effects mediated by these substances on human health and the environment. EFSA Journal 2013;11(3):3132. [84 pp.]doi: 10.2903/j.efsa.2013.3132. Available online: www.efsa.europa.eu/efsajournal

Table 1.7. Guidance values for STOT-RE Cat I for sub chronic and other medium-term studies.

Route of exposure	STOT-RE Cat 1
Oral (rat)	10 mg/kg bw/day
Dermal (rat or rabbit)	20 mg/kg bw/day
Inhalation (rat) gas	50 ppmV/6h/day
Inhalation (rat) vapour	0.2 mg/l/6h/day
Inhalation (rat) (dust/mist/fume)	0.02 mg/l/6h/day

As it is known, the guidance values presented in Table 1.7 refer to effects seen in a standard 90-day toxicity study in rats. They were used as a basis to extrapolate equivalent guidance values for toxicity studies of greater or lesser duration, using dose/exposure time extrapolation similar to Haber's rule for inhalation, which states essentially that the effective dose is directly proportional to the exposure concentration and the duration of exposure. The assessment was done on a case-by-case basis; for a 28-day study the guidance values above are increased by a factor of three; for a 2-year study the guidance values are decreased by a factor of eight. Based on the approach followed by the RAC the same guidance values for rat, mouse and dog studies have been used (RAC Opinion ECHA/RAC/CLH-O-0000002970-73-01/F, September 2012). Only the substances categorized as EDs Cat I were assessed under "Option 4" of the Roadmap. The ED-related and EATS specific adverse effects used for the categorization of the chemical as ED Cat I were checked as to whether the relevant effect doses were below or above the STOT-RE guidance values as shown in Table 1.7.

C. Results

The results of the potential categorization for all 35 substances of the pilot study according to the four "Options" of the Roadmap, are presented in tables 1.8 and 1.9 of Appendix II. However, based on the experience gained during the pilot phase of the project (see Conclusions of this chapter and Appendix 1.1, 1.2, 1.3 and 1.4), several amendments to the methodology with regard to both data population and categorisation were proposed and discussed with JRC in a very intense and demanding process. Therefore, the substances used for the pilot study were re-assessed during the screening phase using the revised methodology and the results are included in the respective sections of this report.

The results of the screening do not constitute evaluations of individual substances to be carried out under the respective chemical legislations [[in particular, Regulation (EC) No 1107/2009 on plant protection products, Regulation (EU) No 528/2012 on biocidal products, Regulation (EC) No 1907/2006 REACH, Regulation (EC) No 1223/2009 on cosmetic products and the Water Framework Directive (EC) No 2000/60] and in no way prejudge future decisions on active substances to be taken pursuant to these pieces of the EU legislation. It would thus be erroneous to consider that the substances listed in the results of this study (SANTE/2015/E3/SI2.706218) are considered as endocrine disruptors within the meaning of the EU legislation.

D. Conclusions

After completion of the pilot phase the following conclusions have been derived:

- a. The use of ToxRefDB as a source should be discontinued since after discussion with JRC it was concluded that *"the time gained in database population is lost in relation to the need to quality check the data for inaccuracies and duplications"*. Also, ToxRefDB reports additional observations to those reported by the DAR for the same study and represents the evaluation performed by EPA and not the one performed by EU Member States. The databases of substances already populated with entries from the ToxRefDB database will not be amended (because this would require too much time, with no significant added value), but from this point forward it will be stopped.
- b. The way of presenting ToxCast data has been changed. After the email sent on 6.8.2015 by JRC, all assays are recorded in the database irrespectively of positive or negative results. This is also helpful for the application of weight of evidence approach that needs to be followed for the evaluation and categorization of the substances. Also, a new AR assay has been added (OT_AR_ARE_LUC_Agonist_1440) (email sent by JRC on 7.8.2015). Assessment of the pilot substances will be updated accordingly by BPI.
- c. In Column B, there were study principles (missing, e.g. Developmental Neurotoxicity Study, Subchronic inhalation, Subchronic dermal) in the pull down menu that were added in template version 1.09.
- d. In Column N "Route of administration", for fish and amphibian studies "uptake from water" is chosen. In Column O "Method of administration", for fish and amphibian studies "water" is chosen. This was decided during the 1st Interim meeting of 15.6.2015 and it will be applied to all substances.
- e. In Column Z "Effect target", the option "No reproductive effect" was added to the pull down menu which in Column AA, "Effect classification" is interpreted as "Non-specific adversity (may or may not be indicative of EATS)", as it includes EATS specific and non- specific effects.
- f. In Column Z "Effect target", "penis histopathology" is now classified (Data summary template version 1.09) as "EATS specific adversity" in Column AA with (EAS) between parenthesis in Column AH "Effect indicative of", indicating it is not mentioned specifically in the OECD GD 150 document.
- g. JRC proposed (email sent on 4.8.2015) not to introduce the new term "not in OECD150-used to derive NOAEL", but rather simply add to the pick list for mammalian toxicity new terms referring to endpoints frequently reported for the 35 pilot substances (see Appendix 1.4). However, since not all the "non ED-related" organs are present in the drop down list and if we consider that an effect must be recorded (if e.g. basis for NOAEL), then the term "not in OECD150-used to derive NOAEL" is still used.
- h. When an ED-related effect present at higher doses is recorded then we also report effects now moved to general adversity (i.e. decreased body weight, increased liver weight or histopathology) and these are taken into account in the evaluation.

- i. "ED-related adversity" has been renamed to "Non-specific adversity (may or may not be indicative of EATS)" after the email sent by JRC on 4.8.2015 (see Appendix 1.4).
- j. In the new template version 1.09 and 1.10 "body weight" is classified as "General adversity" after the email sent on 4.8.2015 by JRC (see Appendix 1.4).
- k. In the "Evaluation" sheet, headings will be introduced between data copied from human health assessment and additional data from ecotoxicological assessment.
- l. It was agreed on the need for addition of information from open literature search for the substances where data from TEDX, SIN and EASIS are not available. The outcome of the literature search performed by JRC will be added by BPI in Data summary template of the substances under screening. Pilot substances will be updated accordingly with open literature data provided by JRC in due time (by 15th October 2015 for PPPs).
- m. EDSP Weight of Evidence Conclusions on the Tier 1 Screening Assays for the List 1 Chemicals (52 chemicals), developed by US EPA (June 2015), will also be considered as an additional source of information where available; a relevant comment will be added in the introductory section by BPI. Pilot substances will be amended accordingly.
- n. The weight of evidence will be applied in each step of the decision tree. Especially for a Cat I classification strong evidence of both adversity and related MoA should be available.

All pilot substance datasheets will be transferred from Data summary template version 1.08 to version 1.10 by BPI and the categorisations will be revised in line with the currently agreed principles, as concluded during the pilot phase.

Appendix 1.1

Main points discussed during the pilot study regarding the reporting template "Data summary template".

- 1. BPI:** Row 3 "CLP": It is proposed to have two entries, i.e. one for the Harmonised classification (ECHA Inventory, reference to the CLP No, i.e. CLP00) –if available- and one for the classification proposed following the Peer Review of the substance (based on the EFSA Conclusion for pesticides or the CAR AR for biocides, or any other available report for miscellaneous chemicals) – in case this is more recent than the CLP decision.

JRC: *Added*

- 2. BPI:** Columns A & B: For all "Mammalian in vivo –ToxRefDB" type studies except from "Reproduction/developmental toxicity screening test" the "OECD Level " categorization appears to be "#N/A" which might not be true. This is related to the description of the study in Column B "Study Principle".

JRC: *Added now. This was because not all studies in ToxRefDB are according to OECD guideline. However, in updated version of template 1.03, these studies are added with corresponding OECD CF level for the OECD equivalent studies. Note that some of the studies do have an OECD equivalent, but are not in the OECD CF list.*

- 3. BPI:** Column B: Add the option "Developmental toxicity" at the drop down list.

JRC: *Added*

- 4. BPI:** Column N: The description should be changed to "doses tested". The range is already given when filling in the Columns O & P (Lowest & Highest dose tested, respectively).

JRC: *Done*

- 5. BPI:** Column J: The description should be changed to "animals/sex/group".

JRC: *Done*

- 6. BPI:** Column T "Generation/Life stage": Add the option "Adult" & "Adult F1" at the drop down list. We assume that the option "Adult P1" stands for "Adult F1" in case of the Two-generation Reproduction Study, while "Adult F0" refers to the initial parental generation.

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It would thus be erroneous to consider that the substances listed in the results of this study (SANTE/2015/E3/SI2.706218) are considered as endocrine disruptors within the meaning of the EU legislation.

JRC: *P1 and F0 are the same generation (i.e. synonymous terms). They are there because they are used in the different protocols/lists from which data are to be extracted.*

In column T 'generation' applies to mammalian studies and the 'lifestage' to ecotox studies. If the effect described is for a specific lifestage, e.g. mature (adult) lifestage versus immature (pups/juveniles) in the mammalian studies, we think this should be captured in the remarks column, otherwise we could add an additional column for lifestage.

BPI: The JRC response does not resolve the issue of how to report F1 effects (when this is specific for that generation). The fact that there is a choice just for "Adults" should be noted again.

- 7. BPI:** Column AF "Values based on sex": Is this related to the NOAEL/LOAEL/EC50?? For each effect (row) the Gender information is already given in Column U.

JRC: *Sometimes in the summary regulatory documents, the NOAEL was only given for both F and M together, while effects were described differently per sex in the underlying documents. That is why we included this additional column in which to indicate the basis of the NOAEL (which could be F+M, M or F). Please proceed in the pilot phase to fill in both columns and we can see if it proves to be redundant when we review the pilot phase at our meeting on 15 June.*

- 8. BPI:** Column W and X: The pick lists in columns W (effect type) and X (effect target) are not active for "Avian reproduction test" (column B).

JRC: *They were not added because it was still unclear which test to include. We added the following avian parameters (all non-specific for ED indication) to the revised data template v1.03:*

<i>In life observation</i>	<i>Gross pathology</i>
<i>In life observation</i>	<i>Body weight</i>
<i>Reproductive</i>	<i>Hatchability</i>
<i>Reproductive</i>	<i>Eggshell thickness</i>
<i>Reproductive</i>	<i>Egg viability</i>
<i>Reproductive</i>	<i>Egg production</i>
<i>Reproductive</i>	<i>Cracked eggs</i>

Similarly, the endpoints for the amphibian assay have now been added. We may need to revisit this point after the pilot study to decide if these assays are interpretable in the context of being linked to endocrine disruption.

- 9. BPI:** In most cases when 'copying-pasting' from ToxRefDB file to the individual Data summary files the equations at Columns from AI are not functional (they actually disappear).

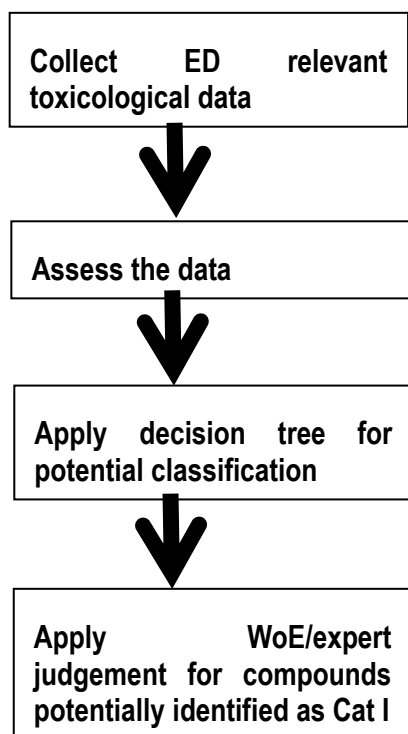
JRC: It does work when we try it, however, make sure to only copy the columns up to AA in the ToxRefDB file, otherwise the formulas for the indications are overwritten. Note that also the columns from AD are for filtering out the relevant compounds etc.

- 10. BPI:** The decision tree for the categorization of the substances (as presented in the kick-off meeting) has not been included in the Data summary EXCEL file.

JRC: We have adapted the Excel template by adding an Evaluation sheet as presented at the kick off meeting. In the Evaluation sheet, please apply the decision tree in the draft methodology report to reach your conclusions and indicate the Path taken through the decision tree in the reasoning column.

Appendix 1.2

Process



Collect ED relevant data

As indicated in the ED IA screening methodology report, collect all endpoints that are known to be relevant, which should all be in the pick list in the template (Excel file). The endpoints in the template are based on OECD GD 150, supplemented with frequently reported effects, e.g. systemic toxicity (including body weight and food intake), that may either form the basis of the derived NOAEL and/or are informative of the relevance of ED-related effects in light of other effects occurring within the same study.

Quick assessment of the overall data

To ensure that all relevant data are collected, all data that is reported in the regulatory documents are assumed to be assessed and to be relevant by default. Still, effects reported can be regarded to be not relevant when seen in combination with the other effects in the study. Generally, endocrine-related effects that are observed secondary to marked toxicity (caused by a non-endocrine mode of action), should not be considered specific, genuine endocrine disrupting effects. Even though, it is important that these effects are captured in the datasheet, but such effects should not be the sole effect(s) driving the ED classification.

Apply the decision tree

The decision tree allows for a potential classification, to quickly identify the compounds which are potentially classified as Cat I, II or III, and to identify the compounds for which not enough data is available to reliably conclude anything related to ED (Inconclusive).

Apply WoE/expert judgement

Because we have captured all the effects that are thought to be relevant for ED and applied the decision tree in such a way that any evidence regarding adversity and MoA can lead to potential cat I, we believe that the decision tree is overly protective, i.e. we expect false positives (rather than false negative classifications).

Some effects on their own might not be sufficient to conclude ED, but the overall pattern within a study or the concordance between studies might still lead to an ED classification if sufficient evidence is available. Therefore, for the compounds that are identified as potential Cat I, a weight of evidence approach is still needed to assess the pattern of effects, including severity of the effects, dose-concentration dependence and the biological plausibility of a causal relationship between the induced endocrine activity and the adverse effect(s). As the type and amount of information needed at the different levels depends on the mode of action considered as well as the type of effect observed, the required case-by-case decision we believe cannot be captured by a simple decision tree, but would always require expert judgement.

Categorization of effects

To assist in applying the decision tree and in the weight of evidence approach for the final classification, we propose to use the following categorization of ED-related effects:

The results of the screening do not constitute evaluations of individual substances to be carried out under the respective chemical legislations [[in particular, Regulation (EC) No 1107/2009 on plant protection products, Regulation (EU) No 528/2012 on biocidal products, Regulation (EC) No 1907/2006 REACH, Regulation (EC) No 1223/2009 on cosmetic products and the Water Framework Directive (EC) No 2000/60] and in no way prejudge future decisions on active substances to be taken pursuant to these pieces of the EU legislation.

It would thus be erroneous to consider that the substances listed in the results of this study (SANTE/2015/E3/SI2.706218) are considered as endocrine disruptors within the meaning of the EU legislation.

- A. *In vitro* mechanistic
- B. *In vivo* mechanistic & *in vivo* hormone levels
- C. Adversity – EATS specific
- D. Adversity – ED-related
- E. Adversity – General

A. ***In vitro* mechanistic information**

This category captures all *in vitro* information, e.g. from ToxCast and *in vitro* assays from literature, including binding assays, transactivation assays, dimerization assays etc. Also gene expression results from literature can be captured here. When evaluating these data, more value can be given to specific (combinations of) assays.

B. ***In vivo* mechanistic information**

Level 3 assays in the OECD conceptual framework are designed to be informative on a specific mode of action and they are regarded as stronger evidence of an ED mode of action, compared to *in vitro* assays. However, the data of these assays is mostly informative on the estrogenic and androgenic pathway.

In vivo hormone levels can also be regarded as informative on the mode of action, as they indicate perturbations of specific endocrine pathways. But because fluctuations in hormone levels can be also observed within certain limits without adverse consequences, the changes cannot be considered adverse on their own. The point at which these fluctuations become significant cannot be generally defined and would in an actual risk assessment always require a case-by-case decision which goes beyond the scope of this methodology. Therefore, for the purpose of this screening methodology, all changes are regarded as biomarkers informative of a specific mode of action.

C. **EATS specific adversity**

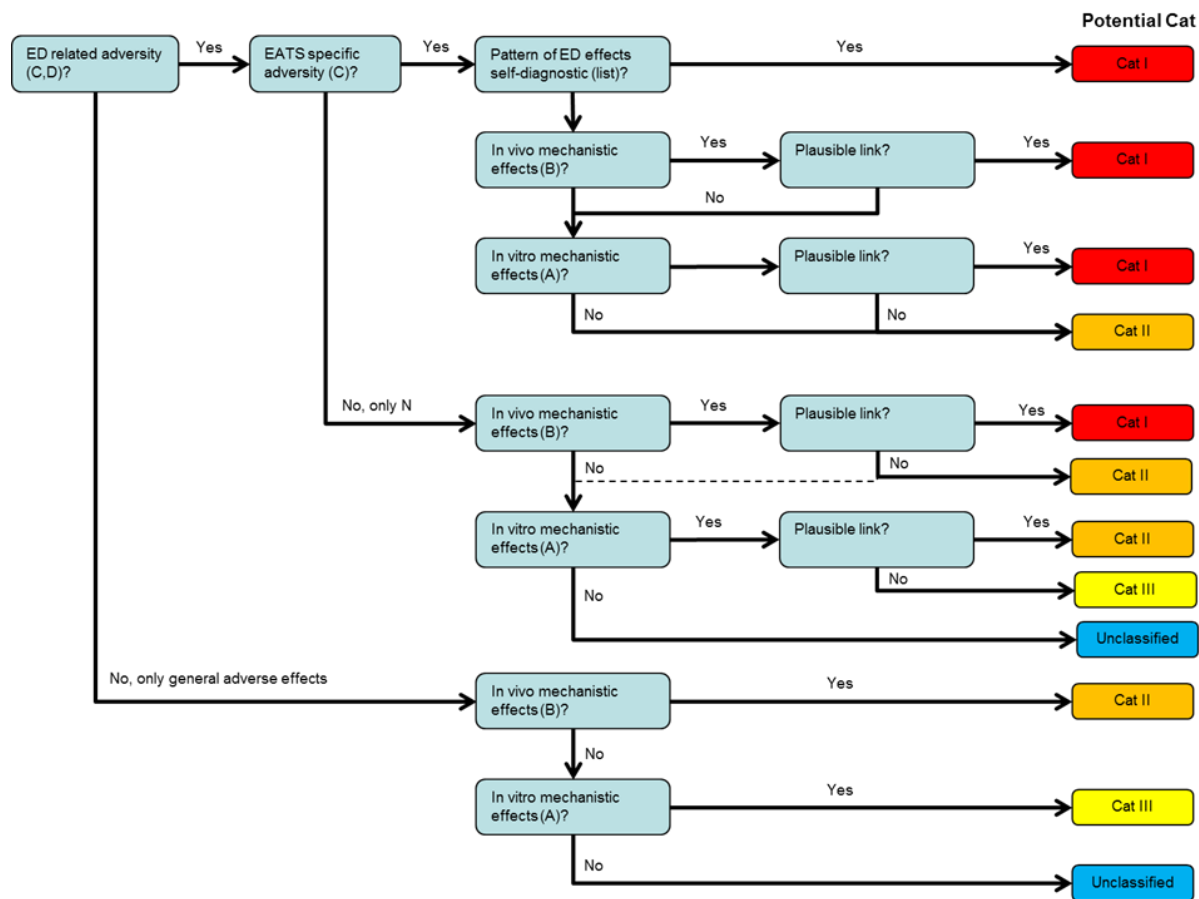
The question whether an observed effect can be considered adverse requires an assessment of data that goes beyond the methodology applied here. From a practical point of view, it is much easier and straight forward to conclude a change in e.g. morphology as directly adverse, without the requirement to assess in addition whether the change would actually lead to an impairment of function. Consequently, for the purpose of this first screen, all effects on the *in vivo* endpoints listed in the OECD GD 150 are regarded to be adverse, including all *in vivo* effects (except *in vivo* hormone levels) that are reported as indicative for a specific mode of action (so effects labelled E, A, T or S), are considered to be adverse effects.

D. ED-related adversity (later changed **to Non-specific adversity (may or may not be indicative of EATS)**)

Similar to above, all effects that are labelled N (i.e. endpoints potentially sensitive to, but not diagnostic of, EATS modalities) are considered to be adverse and potentially related to ED.

E. General adversity

Some effects are captured in the sheet that do not inform about the ED mode of action, but are needed to put the observed effects into perspective, such as food intake, systemic toxicity, body weight changes etc. This data is not used within the decision tree.



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Appendix 1.3

Guidance to fill the template in "Data" sheet

Important notes:

1. Never add or delete columns
2. Never add additional rows above row number 11
3. The row marked in green (number 10) should never be deleted and no data should ever be entered into it.

Start to fill the template:

1. Fill all columns, except for columns AA, AH, AI and AJ, which are then filled automatically.
2. To fill columns AA, AH, AI and AJ, press the button called "fill formula"

- **Reporting of "no relevant effect observed"**

When in column Y the term "no relevant effect observed" is selected, then always select in column Z the term "No relevant effects" and in column AD the term "No effect".

- **Minimise the use of the term "[Not in list]" in column Z**

Regarding the first 10 pilot chemicals screened and captured in the template version 1.03, BPI selected, in column Z, quite often the term "[Not in list]" to report effects that are either not listed in the pick-list or related to systemic toxicity. **Now, in version 1.07, there is a new endpoint added which is called Systemic Toxicity and they should use it instead of [Not in list].** If they cannot place a specific effect under the term Systemic Toxicity, then they can select "[Not in list]". However, JRC advice is that they **try to avoid selecting "[Not in list]"**. If BPI feels they need to report a specific effect for which they do not find a term in column Z, **it is better to ask us to insert this term to avoid as much as possible the selection of "[Not in list]"**.

- **Meaning of Clinical Chemistry category**

In column Y, the term "Clinical Chemistry" is present and in this category only information on hormones should be reported in column Z. No any other type of information should be reported. For clarity, although we could change the heading to 'hormone levels' we decided to use the term "Clinical Chemistry" because this is the name of the heading used in ToxRef DB from where the data on hormone levels is taken.

- **Meaning of Fetal development**

In column Y, you can select "Developmental" and then in column Z "Fetal Development".

We noticed that the contractor, for the first 10 pilot chemicals screened, frequently reported effects as skeletal malformation in column AB and/or AC. We now recommend that effects as "Skeletal and visceral malformation" are always captured by selecting in column Z "Fetal development" and then in column AB/AC providing the more detailed description.

- **Type of information to be grouped under the term "Systemic Toxicity" in column Z**

Following previous bullet-point, we have identified the following descriptors of general animal stress (found by going through the first 10 pilot chemicals screened by BPI), which should be captured by selecting the term "Systemic Toxicity" in column Z. Then, the more detailed description of these descriptors of general animal stress can be captured in column AD/AC. The descriptors are: emesis, desquamation, alopecia/hair loss, lack of grooming, anorexia, reduced faecal output and water intake, weakness/emaciation, nasal discharge, sensitivity to noise, salivation, diarrhoea, erythema, tremors and hypersensitivity, salivation, ventral or lateral recumbency, tremor, tachypnea and rhinorrhea.

In case BPI identifies more descriptors they need to report, they can still place them under the term "Systemic Toxicity" and let the JRC know on these new additions.

As a remark, although the descriptors of general animal stress are not related to ED-MoA, it is important to capture them in order to describe high dose non ED-related generalised systemic toxicity as a way of identifying endocrine effects secondary to systemic toxicity.

- **Reporting haematological changes**

We noticed that the contractor, for the first 10 pilot chemicals screened, frequently reported haematological changes (e.g. leucocyte numbers) by selecting in column Z "Clinical Chemistry" or "Not in List" and then providing the details in column AB and/or AC.

This endpoint is not in OECD 150 but, if the contractor believes it is important to capture it, we recommend that they report it, by selecting in column Y "In life observation" and in column Z "Systemic Toxicity". Although it might fit under 'Clinical Chemistry', we ask that this is not used as this column should be reserved for effects on hormone levels (see above).

- **Reporting of effects that are not in the pick-list of column Z and that are not grouped under Systemic Toxicity**

We noticed, from the first 10 pilot chemicals screened, that BPI reported in column Z/AB and/or AC changes in kidney-, brain-, lung-weight, malformation of the eye, histopathological changes of duodenum, etc., which are all effects that do not appear in GD 150 and thus appear as "Not in List" in column Z. Unless BPI believes these effects are relevant for the evaluation, (i.e. relevant to ED assessment or relevant to high dose systemic toxicity or they are the basis for the NOAEL), we suggest that BPI does not record these changes. In case BPI considers it important to capture this information, they should let us know and then we can add these terms to the pick-list of endpoints in column Z.

- **Studies with more than one species/dosing regimes**

In cases where there are, within the same study, more than one species used and/or more than one exposure scheme applied (column I and T), the study ID number should be different. To achieve this, it is proposed that studies be numbered sequentially 1,2,3,4 etc, but for the first set of experimental conditions, where e.g. the Study ID Matrix 1 is assigned, then if the species and/or exposure change, the Study ID Matrix 1a, b, c, etc, is assigned.

It is also important when you assign a study ID number as 1a, 1b, etc., that there should NOT be any space between the number and the letter.

Species names should also be standardised, e.g. mouse NOT mice, dog NOT dogs.

- **Filling ToxCast data in the template**

In order to properly capture in the excel file ToxCast data, these are reported as follows:

- The following columns in the template (File name: *Data Summary template version 1.04 (22-6-15).xlsm*) have to be filled: Columns A, B C, F, H, I, S, T, X, Y, and Z
- In column A, just select "*In vitro* ToxCast"
- In column B, select the name of the ToxCast assay
- In column C, assign ID number (only numbers)

- In column F, just write "ToxCast database"
- In column H, always enter "2013"
- In column I, take the information for each specific ToxCast Assay from column F of the excel file called "ToxCast information on assays"
- In column S, always select μM
- In column T, take the information for each specific ToxCast Assay from column E of the excel file called "ToxCast information on assays"
- In column X, enter the AC50 concentration from the heat-map with ToxCast data (file already given to the contractor)
- In column Y, take the information for each specific ToxCast Assay from column G of the excel file called "ToxCast information on assays"
- In column Z, take the information for each specific ToxCast Assay from column H of the excel file called "ToxCast information on assays"

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Appendix 1.4

List of updates made to the template version 1.09 and related guidance (implemented after finalization of the pilot phase)

When any *in vitro* study is selected in **Type of toxicity** (column A), it is important to always fill **Effect type** (column Y), **Effect target** (column Z) and **Effect direction** (column AD). Regarding ToxCast data, select in column AD the term "induction" every time an effect is observed and "no effect" if there are no changes observed.

Under **Additional remarks** (column AM), the contractor sometimes indicates if a study from ToxRef is also present in the DAR/CAR or vice versa. In some other cases, the contractor reports this information under **Source** (column F).

We would suggest to put always all reporting information on the sources in which a study is present under **Source** (column F).

At the moment, regarding the endpoints' categorisation, body-weight is categorised as "ED-related adversity", liver weight as "EATS specific adversity" and liver histopathology as "General adversity".

We propose to categorise all these three effects as "General adversity", since they are more often a sign of systemic toxicity. A remark has been added to the template [* = increase in liver weight could help interpret decrease in hormone levels, including T3 & T4] referring to liver weight increase as informative in the context of interpreting changes in hormone levels.

We discussed with the contractor the need to add to the pick-list in columns Y the new term "not in OECD150-used to derive NOAEL". The reason for this is that very often effects on organs not listed in OECD 150 (as spleen, kidney, lung, brain, etc.) were being reported by selecting in column Y "no relevant effects observed", in column Z "not in list" and then providing the detailed information of relevant organ in column AB. However, since these endpoints are often used as a basis of the NOAEL, it was recognised that it may be necessary to report them. However, after further considerations, we propose not to introduce the new term "not in OECD150-used to derive NOAEL", but rather simply add to the pick list for mammalian toxicity new terms referring to endpoints frequently reported for the 35 pilot substances. The new endpoints in column Z are: spleen-, brain-, lung- and kidney-weight (by selecting in column Y "organ weight"); spleen-, brain-, lung- and kidney-histopathology (by selecting in column Y "organ histopathology") and haematological parameters (by selecting in column Y "in life observation"). These terms will be categorised under 'general adversity'.

The results of the screening do not constitute evaluations of individual substances to be carried out under the respective chemical legislations [[in particular, Regulation (EC) No 1107/2009 on plant protection products, Regulation (EU) No 528/2012 on biocidal products, Regulation (EC) No 1907/2006 REACH, Regulation (EC) No 1223/2009 on cosmetic products and the Water Framework Directive (EC) No 2000/60] and in no way prejudge future decisions on active substances to be taken pursuant to these pieces of the EU legislation.

It would thus be erroneous to consider that the substances listed in the results of this study (SANTE/2015/E3/SI2.706218) are considered as endocrine disruptors within the meaning of the EU legislation.

We found the term 'ED-related adversity' (which corresponds to the 'N' in the GD 150 classification) somewhat misleading, so we have renamed it 'Non-specific adversity (may or may not be indicative of EATS)'.

As asked by the contractor, add for wildlife studies, the term "no relevant effects observed" in column Y and "no relevant effect" in column Z.

As asked by the contractor, add in column B the terms "Developmental Neurotoxicity Study", "Subchronic inhalation" and "Subchronic dermal".

Update the formula in column AA for the following endpoints in column Z "Luteinizing Hormone (LH) level" and "Follicle Stimulating Hormone (FSH) level".

We have added a button to the template to replicate the study details from the last study in the "Data" sheet, to facilitate entering different effects from the same study.

Documents sent to the contractor on 4.08.2015

Version 1.09 of data template [Data Summary template version 1 09 (4-8-15).xlsm]

A MS WORD-file [Description of pick lists in template v1.0_03-08-2015.docx] listing all the **Effect target** endpoints (column Z) for each **Effect type** group (column Y). to facilitate the collection of the most relevant terms to report a specific endpoint. The WORD document simply reflects the pick-lists for **Effect target** and **Effect type** (columns Y and Z).

Updated guidance on how to fill the data template v1.09 [Guidance to the template v.2_04-08-2015.docx].

CHAPTER 2

Screening of available evidence on chemical substances for the identification of endocrine disruptors according to different options in the context of an Impact Assessment

Specific Contract SANTE/2015/E3/SI2.706218

General observations and conclusions for
the screened PPPs substances

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A. Introduction & Objectives

The aim of this report is (a) to describe the methodology followed and (b) to present the final outcome for the identification of 348 active substances used in Plant Protection Products (PPPs) as potential Endocrine Disruptors (EDs) under four different Policy Options (EC, 2014). The methodology applied includes the identification of ED-related adverse effects and Mode of Action (MoA) as well as the application of the Weight of Evidence (WoE) approach for the categorization of the substances.

B. Materials & Methods

The method followed was based on the JRC draft methodology provided in May 2015, as amended and described in chapter 1 supplemented by further WoE considerations as described, below.

Screened substances and data sources

The “*Chemical Inventory*” file provided by JRC was the initial tool used for identifying sources of information to be considered in data population of each substance under the screening process, as described in chapter 1. The “*Chemical Inventory*” file originally provided by JRC included 431 PPPs (Plant Protection Product active substances). Finally, a total of 348 active substances used in PPPs were screened, following a prioritization by Commission (EC, 2015). This includes 22 PPP active substances already included in the pilot phase of the project.

Categorization of substances and WoE approach

A WoE approach was applied in the evaluation of both adverse effects and MoA as described in the JRC Report of the Endocrine Disruptors Expert Advisory Group (2013). WoE approach refers to weighing all available evidence, both positive and negative, including animal experimental (eco)toxicology studies as well as *in vitro* data in order to reach a conclusion. More specifically, in the frame of this screening methodology a limited WoE analysis was carried out, while applying the decision-tree, in order to find the right balance between a fast screening of substances (due to time constraints) and the need to evaluate all available information to a reasonably high standard. Human epidemiological, (Q)SAR and other *in silico* data were not considered.

Factors that were identified as important in a WoE approach to ED identification for either adverse effect or endocrine disrupting MoA include the quality, reliability and relevance of the individual studies, as well as consistency and reproducibility of reported effects, the pattern of effects across and within studies, number of species showing the same or similar effects, time of onset of effects and life stage affected. These factors are not specific to assessment of endocrine disruption, *per se*, but relevant for any toxicological end-point assessment. With respect to reproducibility, it was recognized that, due to animal welfare reasons, it is often difficult to require repetition of *in vivo* vertebrate studies (e.g. multigeneration reproductive toxicity studies in rats).

In the WoE approach only reliable studies were considered, according to the following points:

- According to Klimisch *et al.* (1997), a study is reliable without restrictions if it is generated according to generally valid and/or internationally accepted testing guidelines (preferably performed according to GLP) or in which the test parameters documented are based on a specific (national) testing guideline

(preferably performed according to GLP) or in which all parameters described are closely related/comparable to a guideline method.

- Studies evaluated by EU regulatory bodies (EFSA, BPC/ECHA, RAC/ECHA) and considered to be reliable and scientifically sound were considered acceptable in the frame of this project. In this case, the critical effect(s), target organ(s) and tissue(s) identified, the dose-response relationship(s) and NOAEL(s) and/or LOAEL(s) for the critical effect(s) were adopted. The relevance for human health and/or vertebrate wildlife was determined as described below.
- "Non-guideline data" (e.g. from academic laboratories) following good scientific principles in design, conduct and reporting and employing appropriate statistics, were judged on their scientific merit and not automatically considered of lower quality to a Test Guideline conducted by a GLP accredited facility. This approach was adopted to the extent possible in the context of this project for scientific data available in the open literature, EASIS and TEDX databases. However, due to the time constraints of this project, the quality of "non-guideline data" could only be assessed to a limited extent (e.g. the results of poorly presented papers were given a lower weight of evidence).

The WoE approach has been applied to all studies considered in the context of this project, in order to achieve a balanced integrated assessment of available data on all endpoints relevant for endocrine toxicity, taking into account the following concepts:

- The nature of the effect (e.g. histopathological change versus organ weight change; impaired function versus change in hormone levels) (see also point 1 under section B.ii. "Option 2 & 3").
- The coherence of the effect observed at different doses in the same study (dose-response curve), across different studies or in relation to other effects.
- The reproducibility of results across the *in vivo* repeated dose studies that were conducted using the same species, route of administration and measure the same endpoints. For example, organ weight in rat that was measured in both oral subchronic and oral chronic studies but was only found to change in the subchronic study, was assigned a low weight of evidence. (see also point 7 and point 9 under section B.ii. "Option 2 & 3").
- *In vivo* mechanistic data were considered to provide stronger evidence than *in vitro* studies, in the identification of an endocrine-related MoA (see also point 10 under section B.ii. "Option 2 & 3").
- The WoE of *in vitro* mechanistic data was based on the nature of the measured endpoints (data on protein expression e.g. cell proliferation weighed more than data on gene expression e.g. receptor transactivation) and the strength of the effect. The latter was assessed considering the relative potency of a compound as compared to the respective positive control of the study (e.g. the EC₅₀ or IC₅₀ values). (see also point 10 under section B.ii." Option 2 & 3").
- MoA data have been used to conclude on the relevance of certain adverse effects (e.g. data on liver enzyme induction may be useful to conclude on the relevance of changes in thyroid hormone levels and related adverse effects with respect to an endocrine mode of action) (see also point 3 under section B.ii. "Option 2 & 3").

- The coherence of the pathway from the biochemical/cellular effect to the adverse outcome in the organ/organisms was considered to the extent possible considering the current scientific knowledge. Where available, proposed Adverse Outcome Pathways (AOP) were used (see, for example, point 11 under section B.ii. "Option 2 & 3").
- In substance characterisation, potency has also been considered in addition to the aforementioned concepts, as described below under section B.iii "Option 4".

In the context of this screening, several assumptions regarding the evaluation/assessment of specific effects have been made. These are described in detail under points 14 and 15 under section B.ii. "Option 2 & 3", further in the text.

The Categorization scheme of the 348 PPPs according to the four different "options" proposed in the EC Roadmap (EC, 2014) is illustrated in Figure 2.1 below:

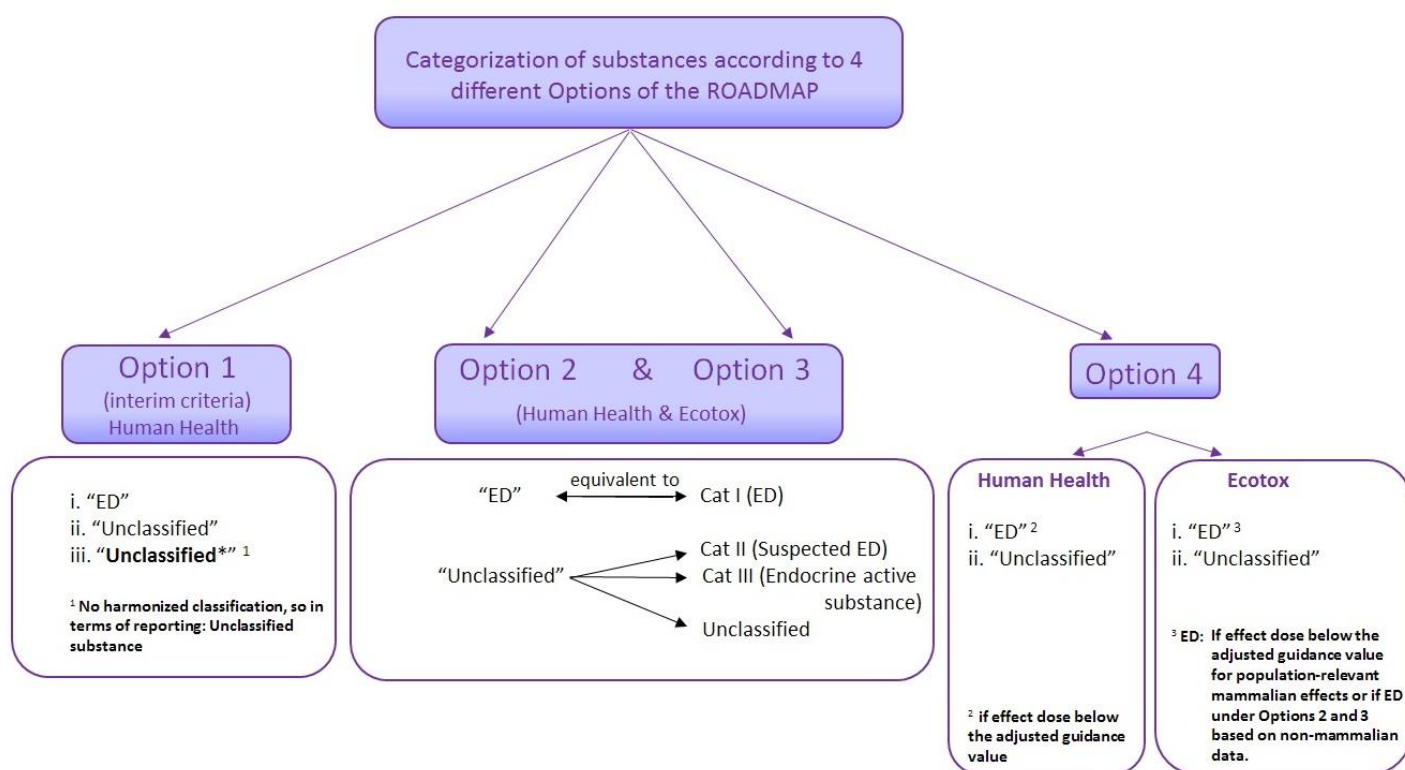


Figure 2.1. Categorization of substances according to four different "Options" of the Roadmap.

Details on the steps followed for the categorisation of all substances according to each of the four "options" are presented below. The WoE approach described above was employed in all steps.

i. Option 1

For "Option 1" the interim criteria set out in the Plant Protection Products Regulation (EC) 1107/2009 (PPPR) and Biocidal Products Regulation (EU) 528/2012 (BPR) were used to characterize a substance as ED (Fig. 2.2), i.e.:

- substances that are or have to be classified as carcinogenic category 2 and toxic for reproduction category 2, shall be considered to have endocrine disrupting properties.
- substances such as those that are or have to be classified as toxic for reproduction category 2 and which have toxic effects on the endocrine organs, may be considered to have such endocrine disrupting properties. The WoE approach described under "Option 2 & 3" below was also applied for judging whether the substance exhibited toxic effects on endocrine organs.

Since classification of a substance as carcinogenic or toxic for reproduction is only relevant to human health according to the criteria set out in CLP (Regulation (EC) 1272/2008), "Option 1" is not applicable for vertebrate wildlife.

As described in detail in chapter 1, both the harmonised classification (when available) and the proposed classification (when relevant) have been considered for the categorization, i.e.:

3. The harmonised classification for the substances (when available), i.e. the harmonised classification as it has been included in Annex VI of Regulation (EC) 1272/2008 (CLP Regulation) and obtained from the C&L inventory of ECHA website (<http://echa.europa.eu/web/guest/information-on-chemicals/cl-inventory-database>); the harmonised classification is the outcome of discussions held at ECHA/ECB level.
4. The proposed classification (when the proposal is more recent than the decision for the harmonised C&L), i.e. the classification proposal concluded during the peer review process under Regulation (EC) 1107/2009 (EFSA Conclusion or DAR/RAR) and/or under Regulation (EU) 528/2012 (ECHA Assessment Report/CAR).

The final categorization considering the available harmonised and/or proposed classification for each substance as ED or not ("Unclassified") was based on the scheme shown in Figure 2.2 below:

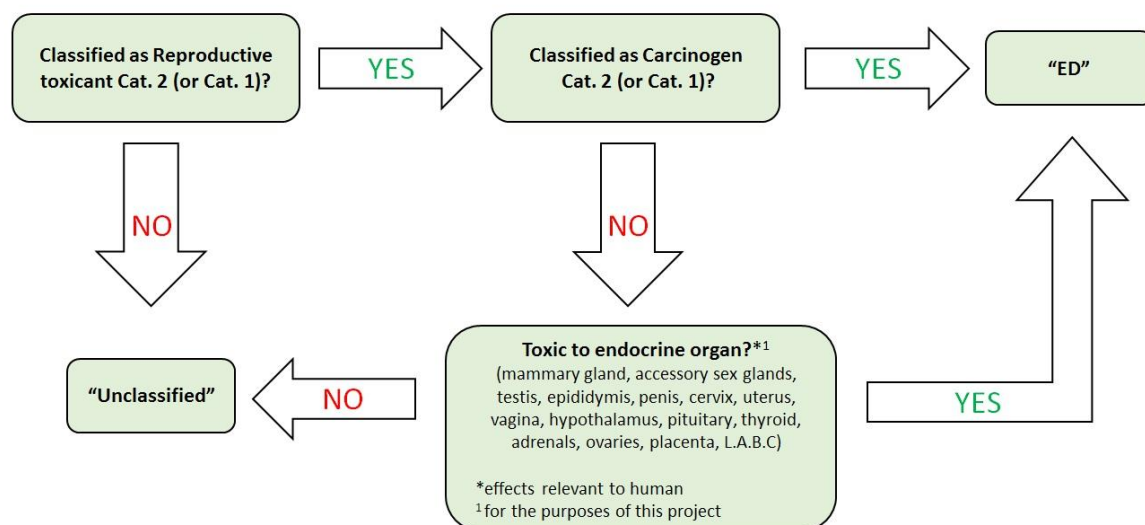


Figure 2.2. Decision tree, leading to the different ED classifications according to the interim criteria as stated in the PPPR and the BPR.

Since there were a few substances classified as Repr/Carc Cat 1A/B based on Harmonised or proposed classification and although the interim criteria refer only to classification as Repr/Carc Cat 2 for the categorization under "Option 1", classification as Repr/Carc Cat 1A/B was dealt with in the same way as Cat.2

Substances with a harmonised classification available

For substances with a harmonised classification available, a reference is made to the ATP Inserted / Updated in Annex VI of Regulation (EC) 1272/2008 (CLP Regulation) stating also the date of the original inclusion; the relevant information have been captured in column C of the "Evaluation" sheet of the Data Summary template version 1.10 excel sheet provided by JRC. For these substances and when the interim criteria are not fulfilled the term "Unclassified" has been used as an outcome.

Substances with no harmonised classification available

For substances with no harmonised classification available, thus not included in Annex VI of Regulation (EC) 1272/2008 (CLP Regulation), the phrase "Not relevant" has been entered in column B, when no discussion was made for those substances.

In terms of reporting, the "Not relevant" in case of the "Harmonised C&L" is interpreted as "Unclassified*" (Fig. 2.3).

ii. Option 2 & Option 3

Categorization of the 348 PPPs under "Option 2 & 3" has been performed after completion of the data population for each substance in the "Data summary template version 1.10" excel file.

The general principles of the WoE, used to categorise substances under "Option 2 & 3", are presented below:

1. Only adverse effects have been captured in the "Evaluation" sheet (e.g. organ histopathology, impaired fertility). Studies reporting "No relevant effects", on measured biological parameters coloured in green in the "Data summary" sheet, have not been captured in detail in the "Evaluation" sheet but they have been considered for the WoE during substance evaluation.
2. Effects that were considered to be secondary to general systemic toxicity rather than ED-related or EATS (Estrogen, Androgen, Thyroid, Steroidogenesis) specific, as well as developmental and reproductive adverse effects recorded in dose levels equal and/or higher than the maternal LOAEL, have not been considered for the evaluation/categorization procedure. These effects, the respective study IDs as well as the reasoning for non consideration in the evaluation were captured in cells B5 and C5 of the "Evaluation" sheet. An example is provided in Figure 2.4.
3. Histopathological findings in rat thyroid and increased thyroid weight in presence of liver histopathology could be attributed to a specific liver mediated mechanism which is not considered to be an ED-mediated mechanism since in the frames of this project enhancement of the metabolism and excretion of thyroid hormones by the liver has not been considered as an endocrine MoA. Therefore, such effects have not been considered for the evaluation since they are not informative to conclude on ED. In that case, the thyroid effect and the study ID were mentioned in cells B5 and C5, together with the respective reasoning (Fig. 2.4).

	A	B	C
1			
2	Note: the assessment is made by using the matrix in the "Data Summary" sheet		
3			
4		List Study ID Matrix	Reasoning
5	Study/ies not used for the evaluation because the ED adversity (ED-related and/or EATS-specific) is a secondary effect of general-systemic toxicity.	ID: 1, 6, 7, 8, 9, 10	<p>*Changes in fetal development in rat (visceral and skeletal minor variations) and decreased fetal weight are observed at the top dose, in presence of maternal toxicity [ID: 9].</p> <p>*Age at preputial separation and decreased litter/pup weight (rat) are considered by RAC (2014) secondary effects to maternal toxicity [ID: 8].</p> <p>*Effects on thyroid weight, thyroid histopathology in rat [ID: 1, 6] and mouse [ID: 7], as well as thyroid tumors in male mice [ID: 7] are due to liver enzyme induction, which is a CAR mediated MoA. (RAC 2014) This mechanism is not considered to be an ED-mediated mechanism. Therefore, these effects have not been considered for the evaluation as not informative to conclude on ED.</p> <p>* Decreased fetal weight (rabbit) [ID: 10] at maternal toxic dose</p>

Figure 2.4. Example of effects not used for the evaluation due to occurrence at maternally toxic doses or due to the absence of ED-mediated mechanism of the observed thyroid effects.

- For vertebrate wildlife evaluation, only the adverse effects that are considered to be population relevant have been taken into account for the categorization. Considering studies in mammals, these effects include (but are not limited to) the following: effects on reproductive organs (ovaries, testis, etc.), developmental effects (litter size, litter weight, sex ratio, teratological effects, etc.), reproductive effects (abortions, pre- and post-implantation losses, gestation length, embryo/fetal viability etc.), effects on survival, sexual maturity, etc. As regards the thyroid effects observed in mammalian studies and since it is scientifically accepted that the thyroid dysfunction can adversely affect reproduction and development, for the purpose of this project, the thyroid effects are considered to be population relevant only when they are accompanied by reproductive/developmental effects in the same species.
- In case of substances showing reproductive and/or developmental adverse effects but not classified as "Repr. Cat. 2 or 1B or 1A" (see CLP, EC Regulation 1272/2008), these effects have been considered in most cases to be secondary to maternal toxicity and have therefore not been used in the evaluation/categorization procedure. However, there were cases of adverse effects on pup/foetus (e.g. resorptions, reduced pup/foetal viability or total litter loss) which have not been disregarded, although not considered adequate for classification, since a causal link with maternal toxicity was not proved (based on what was concluded in the available regulatory documents).

When the same adverse effects were observed in different studies both in the absence and presence of maternal toxicity they have been considered relevant independently of maternal toxicity e.g. substance No 240.

In addition, histopathological/reproductive effects such as testicular atrophy or degeneration and small and flaccid testis in mice, testicular atrophy and suppression of spermatogenesis in rats that might be related to an endocrine mode of action have been considered as positive evidence in the "Evaluation" sheet, although not considered adequate evidence for classification as reproductive toxicant.

6. In case of substances showing reproductive and/or developmental adverse effects and classified as "Repr. Cat. 2 or 1B or 1A", effects have been used in the evaluation procedure even if they have been observed in the presence of maternal toxicity. (e.g No. 230 and 14). This was because a priority is given, as part of the WoE approach, to the outcome of EU official regulatory bodies (EFSA, RAC, BPC) on a specific endpoint which is in line with the criteria set out in the CLP Regulation. According to these criteria, a substance is classified as toxic for reproduction, only when the reproductive/developmental adverse effects are considered not to be a secondary non-specific consequence of maternal/parental toxicity.
7. When the same adverse effect was observed only in short term studies (e.g. 13-week) and not in any of the available chronic studies (e.g. 52-week or 104-week) conducted in the same species, using the same route of administration and relevant doses, this effect has been disregarded or at least considered as weak evidence. In other words, these effects have not been considered reproducible and this was clearly mentioned in the "Evaluation" sheet e.g. *"This effect appears only in a short-term study and not in longer duration studies, so it is disregarded due to low weight of evidence (Fig. 2.5).* It should be noted that this applies to endpoints measured in both short term and long term studies.

OPTION 2 & 3		
	Mammalian	
Question	Answer (Yes/No)	Reasoning
Is there <u>evidence of adversity that may or may not be caused by an ED-related effect in an intact organism, or its progeny, or in a (sub)population?</u> <i>If yes, please indicate in the reasoning, each adverse effect and the corresponding "Study ID Matrix". If no, in the reasoning, please explain if the no is due to lack of data or because no effects were reported in a particular study/ies (always report "Study ID Matrix")</i>	NO	<p>Increased adrenals weight (dog) [ID: 4] Adrenals histopathology: slight hypertrophy/hyperplasia (dog) [ID: 4]</p> <p>These effects appear only in one 90-day study in dog [ID: 4] and not in the respective 1-year study and not in another species. Due to low weight of evidence they are disregarded. Furthermore, effects in adrenals without other endpoints related to ED MoA cannot provide information on ED MoA.</p>
Is there <u>evidence of Adversity – EATS specific</u> in an intact organism, or its progeny, or in a (sub)population? <i>If yes, please indicate in the reasoning, each specific adverse effect and the corresponding "Study ID Matrix". If no, in the reasoning, please explain if the no is due to lack of data or because no effects were reported in a particular study/ies (always report "Study ID Matrix")</i>	YES	<p>Thyroid histopathology: diffuse follicular cell hypertrophy [ID: 5 (dog)]; follicular cell hyperplasia: [ID: 8 (mouse)]</p>
Is there evidence of <u>in vivo mechanistic and/or in vivo hormone levels information?</u> <i>If yes, please indicate in the reasoning, each in vivo mechanistic effect and the corresponding "Study ID"</i>	NO	No in vivo mechanistic data
Is there evidence of <u>in vitro mechanistic information?</u> <i>If yes, please indicate in the reasoning, each in vitro mechanistic effect and the corresponding "Study ID Matrix". If no, in the reasoning,</i>	NO	No relevant effects
Is there evidence of a <u>plausible link between in vitro/in vivo mechanistic information and the observed EATS-specific/ED-related adversity?</u> <i>If yes, please indicate in the reasoning, the link between in vitro/in vivo mechanistic</i>	NO	No plausible link due to absence of mechanistic data
	Path 3a of the decision tree	Cat II

Figure 2.5. "Option 2 & 3" of human health assessment of the substance No 179. The non specific adverse effects (may or may not be ED- related) were disregarded due to low weight of evidence.

8. During the evaluation procedure, tumours in endocrine organs were considered as "EATS specific adversity" to be consistent with the consideration of histopathological findings in the same organs. This approach overrides the general approach of classifying tumours as "Non-specific adversity (may or may not be indicative of EATS)" in the "Data summary template" (see Fig. 2.6), by considering them as EATS specific when occurring in an endocrine organ.

Effect type	Effect target	Effect classification	Effect description	Effect determination	Effect direction
Organ histopathology	Thyroid histopathology	EATS specific adversity	follicular cell hyperplasia		Change
Abnormalities	Tumour types	Non-specific adversity (may or may not be indicative of EATS)	thyroid tumors		Increase

Figure 2.6. Inconsistency between 'Effect classification' of histopathological findings in thyroid and thyroid tumours.

- In cases where the only relevant adverse effects were observed in a unique study in one species and there was no study of longer duration with the same species available (e.g. 2-year rat or 52-week dog study) or no other study of the same type of investigation (e.g. a unique multigenerational reproductive study in rat), these effects could not be disregarded in the framework of this project, where in case of limited evidence a worst case approach is generally followed. In the case of substance No 255 (Fig. 2.7), the substance was classified as Cat II based on increased anogenital distance derived from a two-generation study in rat. No other ED-related/ EATS-specific adverse effects or mechanistic data were reported. Other examples: Substance No 25.

OPTION 2 & 3				
	Mammalian		Ecotox	
Question	Answer (Yes/No)	Reasoning	Answer (Yes/No)	Reasoning
Is there evidence of Adversity – ED related in an intact organism, or its progeny, or in a (sub)population? <i>If yes, please indicate in the reasoning, each ED-related adverse effect and the corresponding "Study ID Matrix". If no, in the reasoning, please explain if the no is due to lack of data or because no effects were reported in a particular study/lies (always report "Study ID Matrix")</i>	No	No relevant effects reported	No	No relevant effects reported
Is there evidence of Adversity – EATS specific in an intact organism, or its progeny, or in a (sub)population? <i>If yes, please indicate in the reasoning, each specific adverse effect and the corresponding "Study ID Matrix". If no, in the reasoning, please explain if the no is due to lack of data or because no effects were reported in a particular study/lies (always report "Study ID Matrix")</i>	Yes	Increased Ano-Genital distance noted [rat, ID: 8] (EFSA conclusion (2013): could be interpreted as potential endocrine effect occurring at high doses). Testis weight [mouse, ID:2] - mentioned as target organ in the LoEPs (EFSA Conclusion). However, no similar effect is noted in the longer duration study in mouse and thus considered as low evidence.	Yes	Mammalian: Increased Ano-Genital distance noted [rat, ID: 8] (EFSA conclusion (2013): could be interpreted as potential endocrine effect occurring at high doses). Histopathological effects on thyroid [rat, ID: 1, 6, 8], Increased thyroid weight [rat, ID: 8] Testis weight [mouse, ID:2] - mentioned as target organ in the LoEPs (EFSA Conclusion). However, no similar effect is noted in the longer duration study in mouse and thus considered as low evidence.
Is there evidence of in vivo mechanistic and/or in vivo hormone levels information? <i>If yes, please indicate in the reasoning, each in vivo mechanistic effect and the corresponding "Study ID Matrix". If no, in the reasoning, please explain if the no is due to lack of data or because no</i>	No	No data	No	No data
Is there evidence of in vitro mechanistic information? <i>If yes, please indicate in the reasoning, each in vitro mechanistic effect and the corresponding "Study ID Matrix". If no, in the reasoning, please explain if the</i>	No	No data	No	No data
Is there evidence of a plausible link between in vitro/in vivo mechanistic information and the observed EATS-specific/ED-related adversity? <i>If yes, please indicate in the reasoning, the link between in vitro/in vivo mechanistic information and the observed adversity.</i>	No	Not relevant	No	Not relevant
	path 3a of the decision tree	Cat II	path 3a of the decision tree	Cat II

Figure 2.7. Evaluation of substance No 255 under "Option 2 & 3" as Cat II based on one EATS-specific adverse effect.

10. The weight of evidence approach applied for the observed adversity was also applied for the available *in vitro/in vivo* mechanistic data. If an effect was observed only in one mechanistic study, but it was the only mechanistic study available, then it could not be disregarded in the framework of this project, where in case of limited evidence a worst case approach is generally followed. In the case for example of substance No 106 high potency antagonistic activity through ER alpha and ER beta could not be disregarded, since they were the only estrogen receptor antagonistic assays available. If there were more than one *in vivo* or *in vitro* mechanistic effects reported but with different effect direction (e.g. Increase/Decrease), then they were considered equivocal and were not used in the evaluation process. For the *in vitro* mechanistic ToxCast data (*ToxCast data for ED IA_05-08-2015*" file), the following interpretation was given to the respective color coding in terms of potency:

red colour: high potency
orange colour: medium to high potency
yellow colour: medium potency
light green colour: low to medium potency

The results of the screening do not constitute evaluations of individual substances to be carried out under the respective chemical legislations [[in particular, Regulation (EC) No 1107/2009 on plant protection products, Regulation (EU) No 528/2012 on biocidal products, Regulation (EC) No 1907/2006 REACH, Regulation (EC) No 1223/2009 on cosmetic products and the Water Framework Directive (EC) No 2000/60] and in no way prejudice future decisions on active substances to be taken pursuant to these pieces of the EU legislation. It would thus be erroneous to consider that the substances listed in the results of this study (SANTE/2015/E3/SI2.706218) are considered as endocrine disruptors within the meaning of the EU legislation.

green colour: low potency

The potency of the available *in vitro* mechanistic data was taken into consideration for the evaluation/categorization procedure and for the possibility to establish a plausible link between them and the adverse effects observed (e.g. in case the only *in vitro* mechanistic data available was a signal of low potency in an agonist assay, then this information would be disregarded or at least considered as weak evidence for a plausible link).

11. In the frame of this project, although in the "Evaluation" sheet a distinction was made between negative results (no effects observed) and lack of data e.g. no effects on androgen receptor or no data on androgen receptor, the outcome was the same i.e. "No" in the respective question in Column D "Is there evidence of *in vitro* mechanistic information?" in the "Evaluation" sheet (Fig. 2.8).

<p>"Study ID Matrix")</p> <p>Is there evidence of <i>in vitro</i> mechanistic information? <i>If yes, please indicate in the reasoning, each in vitro mechanistic effect and the corresponding "Study ID Matrix". If no, in the reasoning, please explain if the no is due to lack of data or because no effects were reported in a particular study/ies (always report "Study ID Matrix")</i></p>	<p>No</p>	<p>The compound was inactive in all ToxCast assays [ID: 21-30]</p>	<p>"Study ID Matrix")</p> <p>Is there evidence of <i>in vitro</i> mechanistic information? <i>If yes, please indicate in the reasoning, each in vitro mechanistic effect and the corresponding "Study ID Matrix". If no, in the reasoning, please explain if the no is due to lack of data or because no effects were reported in a particular study/ies (always report "Study ID Matrix")</i></p>	<p>No</p>	<p>Lack of data</p>
<p>Is there evidence of a plausible link</p>			<p>Is there evidence of a plausible link</p>		

Figure 2.8. Lack of data or negative results produce the same outcome during evaluation of a substance.

12. It should be noted that, where possible, a plausible link was established between the available mechanistic data and the adverse effects observed based on the proposed Adverse Outcome Pathways (AOPs) in the OECD AOP Knowledge Base i.e.:
- i. Androgen receptor agonism leading to reproductive dysfunction (e.g. substance No 46, substance No 132)
 - ii. Aromatase inhibition leading to reproductive dysfunction (in fish)
 - iii. Estrogen receptor antagonism leading to reproductive dysfunction (e.g. substance No 46, substance No 132, substance No 216, substance No 106, substance No 336)
 - iv. PPAR α activation leading to impaired fertility upon utero exposure in rodent males
 - v. PPAR γ activation leading to impaired fertility in adult female rodents
 - vi. Xenobiotic Induced Inhibition of Thyroperoxidase and Subsequent Adverse Neurodevelopmental Outcomes in Mammals

In case a plausible link was established according to a specific AOP this AOP was referenced in cell F14 of the "Evaluation" sheet.

13. In other cases, a plausible link was established only in the presence of a certain correlation between the available mechanistic data and the adverse effects observed. The EDSP conclusion for PPPs that are included in the EDSP Weight of Evidence list (i.e. tebuconazole, imidacloprid, abamectin, bifenthrin, pyriproxyfen, folpet, 2-phenylphenol, glyphosate, malathion, captan, methomyl, benfluralin, metribuzin, oxamyl, dimethoate, esfenvalerate, flutolanil, phosmet, myclobutanil, 2,4-D, propiconazole, cypermethrin, chlorothalonil, chlorpyrifos, linuron, iprodione, metalaxyl, beta-cyfluthrin, ethoprophos and propyzamide) was also taken into consideration for the overall assessment of the compound. The EDSP conclusion is mentioned in cell B7 of the "Data" sheet of the template e.g. *"the conclusion of the EPA WoE evaluation is that substance X demonstrates no convincing evidence of potential interaction with the estrogen, androgen or thyroid pathways"* (Fig. 2.9). JRC, at a later stage, will add in the "Data" sheet of the aforementioned compounds, all the individual studies included in the EDSP WoE evaluation.

Compound:	[REDACTED]
CAS:	[REDACTED]
CLP (harmonized): CLP00	Acute Tox. 4 - H302 Skin Sens. 1 - H317 Eye Dam. 1 - H318 STOT SE 3 - H335 Aquatic Chronic 3 - H412
CLP (proposed):	EFSA [REDACTED] Acute Tox. 4 - H302 Eye Dam. 1 - H318 STOT SE 3 - H335 (respiratory irritant) EUH066 Aquatic Chronic 3 - H412
Co-RAP (concern - justification):	-
Reason for inclusion on the SIN List:	not relevant
Other information/comments	[REDACTED] The conclusion of the EPA WoE evaluation is that [REDACTED] demonstrates no convincing evidence of potential interaction with the estrogen, androgen or thyroid pathways.

Figure 2.9. EDSP weight of evidence for substance No 264 reported in the "Other information/comments" (cell B7) of the "Data summary template version 1 10" excel file.

14. In cases where more than one Path was involved in the categorization of a substance this was clearly indicated in the "Evaluation". For example, if both *in vivo* and *in vitro* mechanistic data can be used to establish a plausible link with the adverse effects reported, Paths 2a/2b of the decision tree may be followed at the same time (e.g. substance No 2, substance No 52, substance No 68, substance No 87, substance No 196, substance No 258, substance No 304, substance No 335, substance No 379, substance No 403).
15. A rather restrictive approach has been followed for the evaluation of adrenal effects. Adrenal gland weight and the morphology of the adrenal cortex are often altered in response to subacute and chronic stress. These alterations

include increases in adrenal weight and hypertrophy of the cortex. In toxicity studies where there is an increase in adrenal gland weights, it is important to differentiate adrenal gland hypertrophy (due to stress) from degenerative changes of the adrenal cortex that are often characterized by cellular hypertrophy and vacuolation due to disruption of steroidogenesis (Everds *et al.*, 2013). Therefore, particular emphasis was given to degenerative effects on adrenal gland, whilst changes in adrenal weights were disregarded or at least considered of low weight of evidence. Moreover, effects in adrenal gland observed in the absence of other effects on endocrine organs or at high dose levels accompanied by generalized toxicity were in most cases disregarded in the evaluation (Fig. 2.5).

16. The organ weight values were reported, if available, as both absolute weights and relative weights (organ-to-body-weight ratios). However, only absolute testis weight was used for the evaluation since testis weight, like brain weight, is normally conserved despite body weight loss (Holson *et al.*, 2011). Also, the evaluation was based on the principle that organ-to-body weight ratio is predictive for evaluating liver and thyroid gland weights, and organ-to-brain weight ratio is predictive for evaluating ovary and adrenal gland weights (Bailey *et al.*, 2004).
17. Finally, all substances classified as Cat I under "Option 3" are classified as EDs under "Option 2". Cat II and Cat III substances under "Option 3" are classified as "Unclassified" under "Option 2".

iii. Option 4

According to "Option 4" of the Roadmap (EC, 2014), the WHO/IPCS definition was applied to identify endocrine disruptors while potency was used as an element of hazard characterization.

Potency depends on the endpoint, but also on the dose, on the duration and timing of exposure¹⁰. For categorizing a substance under "Option 4", a trigger value as cut-off value was used. Potency-based STOT-RE Cat. 1 trigger values (from CLP) were proposed by JRC as cut-off criteria for endocrine disruptors of regulatory concern. The following decision tree (Fig. 2.10) is proposed by JRC for all substances indicated as ED (Cat I only).

¹⁰EFSA Scientific Committee; Scientific Opinion on the hazard assessment of endocrine disruptors: scientific criteria for identification of endocrine disruptors and appropriateness of existing test methods for assessing effects mediated by these substances on human health and the environment. EFSA Journal 2013; 11(3):3132. [84 pp.] doi: 10.2903/j.efsa.2013.3132. Available online: www.efsa.europa.eu/efsajournal

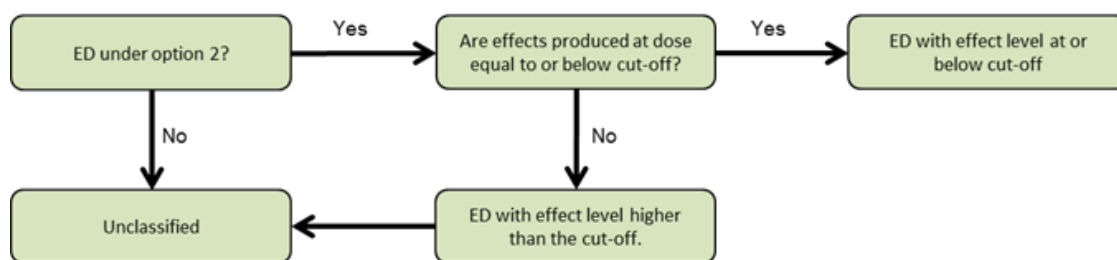


Figure 2.10. Decision tree, leading to the different ED classifications according to “Option 4”.

Table 2.1. Guidance values for STOT-RE Cat I for sub-chronic and other medium-term studies.

Route of exposure	STOT-RE Cat 1
Oral (rat)	10 mg/kg bw/day
Dermal (rat or rabbit)	20 mg/kg bw/day
Inhalation (rat) gas	50 ppmV/6h/day
Inhalation (rat) vapour	0.2 mg/l/6h/day
Inhalation (rat) (dust/mist/fume)	0.02 mg/l/6h/day

It is noted that the guidance values presented in Table 2.1 refer to effects seen in a standard 90-day toxicity study in rats. They were used as a basis to extrapolate equivalent guidance values for toxicity studies of longer or shorter duration. In particular, dose/exposure time extrapolation was conducted by using an approach similar to Haber’s rule for inhalation, which states essentially that the effective dose is directly proportional to the exposure concentration and the duration of exposure.

Overall, the assessment was done on a case-by-case basis: e.g. for a 28-day study the guidance values reported in Table 2.1 are increased by a factor of three; for a 2-year study, the guidance values are decreased by a factor of eight. Based on the approach followed by the RAC, the same guidance values for rat, mouse and dog studies have been used (RAC Opinion ECHA/RAC/CLH-O-0000002970-73-01/F, September 2012).

Having used such extrapolations, substances categorized as ED under “Option 2” or Cat 1 under “Option 3” on the basis of mammalian evaluation remained classified as EDs for human health under “Option 4” if the effect used for the plausible link was observed at dose levels at or below the adjusted potency cut-off value (Fig. 2.11) or characterized as “Unclassified” if the effect used for the plausible link was observed at dose levels above the adjusted potency cut-off value (Fig. 2.12).

For vertebrate wildlife evaluation and based on what has been agreed with JRC, substances categorized as ED under “Option 2” or Cat 1 under “Option 3” on basis of vertebrate wildlife other than mammalian data (avian, fish, amphibians), were classified as ED under “Option 4” by applying a virtual very high potency cut-off value (Fig. 2.12). If the plausible link was established on the basis of mammalian data only, then the same cut-off values as in human health assessment were also used under “Option 4” for vertebrate wildlife (Fig. 2.11).

Screening of available evidence on chemical substances for the identification of endocrine disruptors according to different options in the context of an Impact Assessment

OPTION 2 & 3			Ecotox		OPTION 4		
Question	Answer (Yes/No)	Reasoning	Answer (Yes/No)	Reasoning	Question	Answer (Yes/No)	Reasoning
Is there evidence of a plausible link between in vitro/in vivo mechanistic information and the observed EATS-specific/ED-related adversity? If yes, please indicate in the reasoning, the link between in vitro/in vivo mechanistic information and the observed adversity (both ED-related and/or EATS-specific). Also explain if there is concordance (i.e. biological concordance) between mechanistic and adversity information. If no, in the reasoning, please explain if the no is due to lack of data or because no effects were reported in a particular studies (always report "Study ID Matrix").	YES	The available in vivo mechanistic data (i.e. decreased FSH, LH and testosterone levels) are in concordance with the observed adverse effects on male reproductive system (e.g. decreased testis weigh, testis histopathology findings, decreased sperm motility and sperm numbers, etc)	YES	The available in vivo mechanistic data (i.e. decreased FSH, LH and testosterone levels) are in concordance with the observed adverse effects on male reproductive system (e.g. decreased testis weigh, testis histopathology findings, decreased sperm motility and sperm numbers, etc)	In case the substance is an ED (Cat I), are the endocrine-related adverse effects produced at a dose at or below a relevant guidance value ?	YES	The most sensitive endpoint is the following: Decreased FSH, LH and testosterone levels; testis histopathology findings, decreased sperm motility and sperm numbers levels ID: 49 (27 mg/kg bw/day, 4 weeks, rat) Guidance value for STOT-RE Cat 1 for oral administration in rat is 10 mg/kg bw/ day for standard 90-day toxicity study. The extrapolated guidance value for 4 weeks study is 32.25 (= 10/0.31). Therefore guidance value > most sensitive endpoint.
	Path 2a of the decision tree	CAT I	Path 2a of the decision tree	CAT I	Human ED	Ecotox ED	

Figure 2.11. Classification of substance No 65 under "Option 4" for human health and vertebrate wildlife. For vertebrate wildlife, the substance is classified as ED and the plausible link is established on basis of mammalian data alone, by applying the same cut-off value as for human health assessment.

OPTION 2 & 3			Ecotox		OPTION 4		
Question	Answer (Yes/No)	Reasoning	Answer (Yes/No)	Reasoning	Question	Answer (Yes/No)	Reasoning
Is there evidence of a plausible link between in vitro/in vivo mechanistic information and the observed EATS-specific/ED-related adversity? If yes, please indicate in the reasoning, the link between in vitro/in vivo mechanistic information and the observed adversity (both ED-related and/or EATS-specific). Also explain if there is concordance (i.e. biological concordance) between mechanistic and adversity information. If no, in the reasoning, please explain if the no is due to lack of data or because no effects were reported in a particular studies (always report "Study ID Matrix").	No	No plausible link could be established	Yes	Decreased fecundity in fish could be attributed to aromatase inhibition as exhibited by decreased Vitellogenin (VTG) levels in female fish and by <i>in vitro</i> studies. (AOP 25: aromatase inhibition leading to reproductive dysfunction in fish)	In case the substance is an ED (Cat I), are the endocrine-related adverse effects produced at a dose at or below a relevant guidance value ?	Not applicable	
	Path 3b of the decision tree	CAT II	Path 2a & 2b of the decision tree	CAT I	Human Unclassified	Ecotox ED	

Figure 2.12. Classification of substance No 20 under "Option 4" for human health and vertebrate wildlife. For vertebrate wildlife, the substance is classified automatically as ED since the plausible link is established on basis of vertebrate wildlife data only (and guidance values are relevant for mammalian data only).

The results of the screening do not constitute evaluations of individual substances to be carried out under the respective chemical legislations [[in particular, Regulation (EC) No 1107/2009 on plant protection products, Regulation (EU) No 528/2012 on biocidal products, Regulation (EC) No 1907/2006 REACH, Regulation (EC) No 1223/2009 on cosmetic products and the Water Framework Directive (EC) No 2000/60] and in no way prejudice future decisions on active substances to be taken pursuant to these pieces of the EU legislation. It would thus be erroneous to consider that the substances listed in the results of this study (SANTE/2015/E3/SI2.706218) are considered as endocrine disruptors within the meaning of the EU legislation.

C. Case studies

Below are presented some representative substances that are considered of particular interest and are noteworthy.

i. Substance No 87

The substance No 87 proved to function as an endocrine disruptor as it affects steroidogenesis by inhibiting aromatase activity. As a result, hormonal alteration leads to reproductive dysfunction and changes in foetal development in mammals. Moreover, the substance affected the sex ratio in fish, which is considered self-diagnostic of ED. Taking into consideration the whole toxicological profile of Substance No 87, it was categorized as ED (Cat I) under "Option 2 & 3" and under "Option 4" on basis of both mammalian and wildlife data (Fig. 2.13-16).

Compound:	██████████
CAS:	██████████
CLP (harmonized): CLP00/ATP05	Carc. 2; H351 Repr. 1B; H360Df Aquatic Chronic 2; H411
CLP (proposed):	Not relevant (EFSA Conclusion older than CLP harmonized)
Co-RAP (concern - justification):	Not relevant
Reason for inclusion in the SIN List:	Not relevant
Other information/comments	EFSA Conclusion 2008: Overall, the results from the new in vitro studies and the new developmental study in rats confirm that ██████████ has endocrine disrupting properties and added that already in previous studies on ██████████ the occurrence of impaired reproductive/developmental parameters had been attributed to the interference of the substance with hormonal substances. RAC Opinion 2012: For post implantation losses and late resorptions, taking into account the similar effect seen in rats and for another ██████████ ██████████ in non-human primates, the common mode of action to all test species, as well as the relevance to humans, a classification as Repr. 1B (CLP) is proposed for this effect. The presence of cleft palates in the rat fetuses in the presence or absence of overt maternal toxicity, the presence of skeletal findings in guinea pigs (e.g. fusion of thoracic centrum and arch) in the absence of a clear mechanism of action explaining the induction of anomalies, all support classification as Repr. 1B (CLP).

Figure 2.13. Main information captured in the Data summary template version 1.10 about the substance No 87.

OPTION 2 & 3		
	Mammalian	
Question	Answer (Yes/No)	Reasoning
<p>Is there evidence of adversity that may or may not be caused by an ED related effect in an intact organism, or its progeny, or in a (sub)population? <i>If yes, please indicate in the reasoning, each adverse effect and the corresponding "Study ID Matrix". If no, in the reasoning, please explain if the no is due to lack of data or because no effects were reported in a particular studies (always report "Study ID Matrix")</i></p>	YES	<ul style="list-style-type: none"> *Dystocia (rat) [ID: 11, 25] *Decreased fertility (rat) [ID: 11] *Increased gestation length (rat) [ID: 11, 25] *Decreased lactation index (rat) [ID: 11] *Decreased litter/pup weight (rat) [ID: 11] *Decreased number of live births (rat) [ID: 11] *Increased time to mating (rat) [ID: 11] *Vaginal haemorrhage (rat) [ID: 11] *Post implantation loss [ID: 16 (rabbit); ID: 12, 14a, 14b, 25, 26 (rat)] *Resorptions [ID: 16 (rabbit); ID: 12, 14a, 14b, 26 (rat)] *Ovarian theca granulosa cell tumours (rat) [ID: 9] *Adrenal gland cortex tumours (rat) [ID: 9] *Changes in fetal development: skeletal variations (rudimentary cervical and/or accessory 14th ribs); cleft palate; absent or small tuberositas deltoidea (rat) [ID: 12, 15, 14a] *Increased placental weight (rat) [ID: 12, 15, 14a, 14b] *Decreased fetal weight (rat) [ID: 25]; Increased fetal weight (rat) [ID: 26] *Decreased number of live births (rat) [ID: 25] *Pup mortality (rat) [ID: 25] *Decreased number of live fetuses (rat) [ID: 14a, 14b] *Decreased adrenals weight (rat) [ID: 11]: This effect is disregarded since it is not reproduced in longer duration studies.
<p>Is there evidence of Adversity – EATS specific in an intact organism, or its progeny, or in a (sub)population? <i>If yes, please indicate in the reasoning, each specific adverse effect and the corresponding "Study ID Matrix". If no, in the reasoning, please explain if the no is due to lack of data or because no effects were reported in a particular studies</i></p>	YES	<ul style="list-style-type: none"> *Increased anogenital distance in rat: observed in fetuses of both sexes and in newborn female but not male offsprings [ID: 25] *Increased estrus cyclicity (rat) [ID: 18c, 18d] *Ovary histopathology: deposition of amyloid (mouse) [ID: 10b] *Ovary histopathology: ovarian cysts (rat) [ID: 8, 9] *Testis histopathology: deposition of amyloid (mouse) [ID: 10a]
<p>Is there evidence of in vivo mechanistic and/or in vivo hormone levels information? <i>If yes, please indicate in the reasoning, each in vivo mechanistic effect</i></p>	YES	<ul style="list-style-type: none"> *Decreased estradiol levels (rat) [ID: 26, 14a, 14b, 18c] *Increased FSH levels (rat) [ID: 18a, 18c] *Increased testosterone levels (rat) [ID: 25, 26]
<p>Is there evidence of in vitro mechanistic information? <i>If yes, please indicate in the reasoning, each in vitro mechanistic effect and the corresponding "Study ID Matrix". If no, in the reasoning, please explain if the no is due to lack of data or because no effects were reported in a particular studies</i></p>	YES	<ul style="list-style-type: none"> *High inhibition of aromatase activity [ID: 19a (rat granulosa cells)] *Low inhibition of aromatase activity [ID: 19f (human granulosa cells)] *Inhibition of aromatase activity [ID: 20b (human granulosa cells)] *Inhibition of aromatase activity [ID: 20a (rat granulosa cells)] *Inhibition of aromatase activity [ID: 19d (pig luteal cells)]
<p>Is there evidence of a plausible link between in vitro/in vivo mechanistic information and the observed EATS-specific/ED-related adversity? <i>If yes, please indicate in the reasoning, the link between in vitro/in vivo mechanistic information and the observed adversity (both ED-related and/or EATS-specific).</i></p>	YES	<p>Decreased estradiol levels accompanied by increased testosterone levels indicate an inhibition of aromatase activity, as indicated by all the available in vitro studies. This alteration of steroidogenesis may be responsible for the adverse effects observed i.e. increased anogenital distance in females, increased estrus cyclicity, increased time to mating, decreased fertility and increased fetal weight (an increased fetal weight might be related to the up-regulated levels of testosterone observed in the dams; [REDACTED]).</p>
	Path 2a/2b of the decision tree	Cat I

Figure 2.14. Categorization of the substance No 87 under “Option 2 & 3” on basis of mammalian data.

The results of the screening do not constitute evaluations of individual substances to be carried out under the respective chemical legislations [[in particular, Regulation (EC) No 1107/2009 on plant protection products, Regulation (EU) No 528/2012 on biocidal products, Regulation (EC) No 1907/2006 REACH, Regulation (EC) No 1223/2009 on cosmetic products and the Water Framework Directive (EC) No 2000/60] and in no way prejudice future decisions on active substances to be taken pursuant to these pieces of the EU legislation. It would thus be erroneous to consider that the substances listed in the results of this study (SANTE/2015/E3/SI.706218) are considered as endocrine disruptors within the meaning of the EU legislation.

Screening of available evidence on chemical substances for the identification of endocrine disruptors according to different options in the context of an Impact Assessment

Question	Ecotox Answer (Yes/No)	Reasoning
<p>Is there evidence of adversity that may or may not be caused by an ED related effect in an intact organism, or its progeny, or in a (sub)population? <i>If yes, please indicate in the reasoning, each adverse effect and the corresponding "Study ID Matrix". If no, in the reasoning, please explain if the no is due to lack of data or because no effects were reported in a particular study/ies (always report "Study ID Matrix")</i></p>	YES	<p>Mammalian</p> <ul style="list-style-type: none"> *Dystocia (rat) [ID: 11, 25] *Decreased fertility (rat) [ID: 11] *Increased gestation length (rat) [ID: 11, 25] *Decreased lactation index (rat) [ID: 11] *Decreased litter/pup weight (rat) [ID: 11] *Decreased number of live births (rat) [ID: 11] *Increased time to mating (rat) [ID: 11] *Vaginal haemorrhage (rat) [ID: 11] *Post implantation loss [ID: 16 (rabbit); ID: 12, 14a, 14b, 25, 26 (rat)] *Resorptions [ID: 16 (rabbit); ID: 12, 14a, 14b, 26 (rat)] *Ovarian theca granulosa cell tumours (rat) [ID: 9] *Adrenal gland cortex tumours (rat) [ID: 9] *Changes in fetal development: skeletal variations (rudimentary cervical and/or accessory 14th ribs); cleft palate; absent or small tuberositas deltoidea (rat) [ID: 12, 15, 14a] *Increased placental weight (rat) [ID: 12, 15, 14a, 14b] *Decreased fetal weight (rat) [ID: 25]; Increased fetal weight (rat) [ID: 26] *Decreased number of live births (rat) [ID: 25] *Pup mortality (rat) [ID: 25] *Decreased number of live fetuses (rat) [ID: 14a, 14b] *Decreased adrenals weight (rat) [ID: 11]: This effect is disregarded since it is not reproduced in longer duration studies. <p>Ecotox</p> <ul style="list-style-type: none"> *Decreased length (Pimephales promelas) [ID: 22] *Decreased survival of embryos during the first days until hatch (Danio rerio) [ID: 21] *Increased time to maturity (time to first spawn) (Danio rerio) [ID: 23a] *Decreased fecundity (Danio rerio) [ID: 21]
<p>Is there evidence of Adversity – EATS specific in an intact organism, or its progeny, or in a (sub)population? <i>If yes, please indicate in the reasoning, each specific adverse effect and the corresponding "Study ID Matrix". If no, in the reasoning, please explain if the no is due to lack of data or because no effects were reported in a particular study/ies (always report "Study ID Matrix")</i></p>	YES	<p>Mammalian</p> <ul style="list-style-type: none"> *Increased anogenital distance in rat: observed in fetuses of both sexes and in newborn female but not male offsprings [ID: 25] *Increased estrus cyclicity (rat) [ID: 18c, 18d] *Ovary histopathology: deposition of amyloid (mouse) [ID: 10b] *Ovary histopathology: ovarian cysts (rat) [ID: 8, 9] *Testis histopathology: deposition of amyloid (mouse) [ID: 10a] <p>Ecotox</p> <ul style="list-style-type: none"> *Sex ratio (reduced % females) [ID: (21), 23a, 23b, 23c] *Testis histopathology: reduced number of germ cells and spermatids present in the testicular tubules (Coturnix coturnix japonica) [ID: 24]
<p>Is there evidence of in vivo mechanistic and/or in vivo hormone levels information? <i>If yes, please indicate in the reasoning, each in vivo mechanistic effect and the corresponding "Study ID Matrix". If no, in the reasoning, please explain if the no is due to lack of data or because no effects were reported in a particular study/ies (always report "Study ID Matrix")</i></p>	YES	<p>Mammalian</p> <ul style="list-style-type: none"> *Decreased estradiol levels (rat) [ID: 26, 14a, 14b, 18c] *Increased FSH levels (rat) [ID: 18a, 18c] *Increased testosterone levels (rat) [ID: 25, 26] <p>Ecotox</p> <ul style="list-style-type: none"> *Decreased vitellogenin (VTG) in females (Danio rerio) [ID: 23c]
<p>Is there evidence of in vitro mechanistic information? <i>If yes, please indicate in the reasoning, each in vitro mechanistic effect and the corresponding "Study ID Matrix". If no, in the reasoning, please explain if the no is due to lack of data or because no effects were reported in a particular study/ies (always report "Study ID Matrix")</i></p>	YES	<ul style="list-style-type: none"> *High inhibition of aromatase activity [ID: 19a (rat granulosa cells)] *Low inhibition of aromatase activity [ID: 19f (human granulosa cells)] *Inhibition of aromatase activity [ID: 20b (human granulosa cells)] *Inhibition of aromatase activity [ID: 20a (rat granulosa cells)] *Inhibition of aromatase activity [ID: 19d (pig luteal cells)]
<p>Is there evidence of a plausible link between in vitro/in vivo mechanistic information and the observed EATS-specific/ED-related adversity? <i>If yes, please indicate in the reasoning, the link between in vitro/in vivo mechanistic information and the observed adversity (both ED-related and/or EATS-specific). Also explain if there is concordance (i.e. biological concordance)</i></p>	YES	<p>Decreased estradiol levels accompanied by increased testosterone levels indicate an inhibition of aromatase activity, as indicated by all the available in vitro studies. This alteration of steroidogenesis may be responsible for the adverse effects observed i.e. increased anogenital distance in females, increased estrus cyclicity, increased time to mating, decreased fertility and increased fetal weight (an increased fetal weight might be related to the up-regulated levels of testosterone observed in the dams; [REDACTED]).</p> <p>In addition, the ecotox studies demonstrated altered sex ratio in fish i.e. decreased % females which is self-diagnostic of ED. This is further demonstrated by decreased VTG in females resulting from aromatase inhibition, as indicated by all the available in vitro studies.</p>
	Path 1f2a/2b of the decision tree	Cat I

Figure 2.15. Categorization of the substance No 87 under "Option 2 & 3" on basis of vertebrate wildlife data.

The results of the screening do not constitute evaluations of individual substances to be carried out under the respective chemical legislations [[in particular, Regulation (EC) No 1107/2009 on plant protection products, Regulation (EU) No 528/2012 on biocidal products, Regulation (EC) No 1907/2006 REACH, Regulation (EC) No 1223/2009 on cosmetic products and the Water Framework Directive (EC) No 2000/60] and in no way prejudice future decisions on active substances to be taken pursuant to these pieces of the EU legislation. It would thus be erroneous to consider that the substances listed in the results of this study (SANTE/2015/E3/SI2.706218) are considered as endocrine disruptors within the meaning of the EU legislation.

OPTION 4		
Question	Answer (Yes/No)	Reasoning
In case the substance is an ED (Cat I), are the endocrine-related adverse effects produced at a dose at or below a relevant guidance value ?	YES	The effect doses of the adverse effects used for the plausible link are below the adjusted guidance value of 10 mg/kg bw/day.
Human	Ecotox	
ED	ED	

Figure 2.16. Categorization of the substance No 87 under “Option 4”. Categorization under “Option 4” for vertebrate wildlife was based on mammalian data only.

ii. Substance No 403

The substance No 403 proved to function as an endocrine disruptor as it interacts with the thyroid pathway. Taking into consideration the whole toxicological profile of substance No 383, it was categorized as ED (Cat I) under “Option 2 & 3” and under “Option 4” (Fig. 2.17-18).

	A	B	C	D
1	Compound:	██████████		
2	CAS:	██████████		
	C&L (harmonized):	Skin Sens. 1 - H317		
	ATP Inserted: CLP00/ATP01	Repr. 2 - H361d***		
3		Aquatic Acute 1 - H400		
	C&L (proposed):	Not relevant DAR older than harmonised C&L		
4				
5	Co-RAP (concern - justification):	Not relevant		
6	Reason for inclusion on the SIN List:	Not relevant		
	Other information/comments:	██████████ was considered irrelevant - investigation of neurodegenerative effects of ██████████ on C. elegans.		
7				

Figure 2.17. Main information captured in the Data summary template version 1.10 about the substance No 403.

The results of the screening do not constitute evaluations of individual substances to be carried out under the respective chemical legislations [[in particular, Regulation (EC) No 1107/2009 on plant protection products, Regulation (EU) No 528/2012 on biocidal products, Regulation (EC) No 1907/2006 REACH, Regulation (EC) No 1223/2009 on cosmetic products and the Water Framework Directive (EC) No 2000/60] and in no way prejudice future decisions on active substances to be taken pursuant to these pieces of the EU legislation. It would thus be erroneous to consider that the substances listed in the results of this study (SANTE/2015/E3/SI2.706218) are considered as endocrine disruptors within the meaning of the EU legislation.

Screening of available evidence on chemical substances for the identification of endocrine disruptors according to different options in the context of an Impact Assessment

OPTION 2 & 3			OPTION 4		
Question	Mammalian		Question	Answer (Yes/No)	Reasoning
	Answer (Yes/No)	Reasoning			
Is there evidence of adversity that may or may not be caused by an ED related effect in an intact organism, or its progeny, or in a (sub)population? <i>If yes, please indicate in the reasoning, each adverse effect and the corresponding "Study ID Matrix". If no, in the reasoning, please explain if the no is due to lack of data or because no effects were reported in a particular study/ies (always report "Study ID Matrix")</i>	YES	<p>Abortions: ID: 6 (rabbit), 14 (rat)</p> <p>Adrenals histopathology: hypertrophy of the cells of the adrenal zona glomerulosa [ID: 5, rat]; pallor of the adrenal zona fasciculata [ID: 7, dog]</p> <p>Increased adrenal weight [ID: 34, 35 (rat); rat (dog)]</p> <p>Thyroid tumors: thyroid follicular cell carcinomas, adenomas, nodular hyperplasia and hypertrophy/hyperplasia [rat, ID: 10, 31]</p> <p>Fetal development: effects basis for classification [rat, ID: 9, 13, 14]</p> <p>Decreased number of live fetuses & increased resorptions [rat, 14]</p>	In case the substance is an ED (Cat I), are the endocrine-related adverse effects produced at a dose at or below a relevant guidance value ?	Yes	The most sensitive endpoint is the following: Thyroid histopathology ID: 36 (5.7 mg/kg bw/day, 13 weeks, dog) Guidance value for STOT - RE Cat 1 for oral administration in rat is 10 mg/kg bw/ day for standard 90-day toxicity study. Therefore guidance value > most sensitive endpoint.
Is there evidence of Adversity – EATS specific in an intact organism, or its progeny, or in a (sub)population? <i>If yes, please indicate in the reasoning, each specific adverse effect and the corresponding "Study ID Matrix". If no, in the reasoning, please explain if the no is due to lack of data or because no effects were reported in a particular study/ies (always report "Study ID Matrix")</i>	YES	<p>Thyroid histopathology: Follicular hyperplasia, colloid pallor and accumulation of colloid, Hypothyroidism [dog, ID: 7, 24, 33, 36]; follicular cell hypertrophy [mouse, ID: 22] [rat, ID: 2, 5, 8, 10, 20, 31, 35, 27a]</p> <p>Increased Thyroid weight [dog, ID: 24, 25, 36] [mouse, ID: 22, 57] [rat, ID: 2, 5, 8, 10, 35]</p> <p>Epididymis histopathology: hypoplastic changes in the reproductive systems (a - or hypospermatogenesis, hypogenesis of the epididymis, prostate, ovaries and / or uteri) [dog, ID /], damaged epithelial cells in the tubules of epididymis with loss of sperms & decreased weight [rat, ID 55 - Tedx]</p> <p>Histopathology effects on ovaries and prostate: hypoplastic</p>			
Is there evidence of in vivo mechanistic and/or in vivo hormone levels information? <i>If yes, please</i>	YES	<p>Decreased T3 & T4 levels [ID: 7, 24, 25 (dog); 5, 10, 20, 26, 58, 27a, 27b, 27c (rat); 12 (mouse)]</p> <p>Increased TSH in rats [ID: 5, 10, 27c]</p>			
Is there evidence of in vitro mechanistic information? <i>If yes, please indicate in the reasoning, each in vitro mechanistic effect and the corresponding "Study ID Matrix". If no, in the reasoning, please explain if the no is due to lack of data or because no effects were reported in a</i>	YES	<p>Androgenic receptor</p> <p>- Receptor binding: high potency [ID 40]</p> <p>- antagonistic effects on AR transactivity (in the absence of an AR agonist, [redacted] also elicited a down regulating effect at 10uM)) [ID 59c-EASIS]</p> <p>CYP 19: inactive (no effects on aromatase activity) [ID: 59c]</p>			
Is there evidence of a plausible link between in vitro/in vivo mechanistic information and the observed EATS-specific/ED-related adversity? <i>If yes, please indicate in the reasoning, the link between in vitro/in vivo mechanistic information and the observed adversity (both ED-related and/or EATS-specific). Also explain if there is concordance (i.e biological</i>	YES	<p>The available <i>in vivo</i> and <i>in vitro</i> mechanistic data (e.g. decreased T4 and T3 levels, increased TSH levels, proliferation and (trans)activation of thyroid receptor) are in concordance with the observed thyroid effects (increased thyroid weight, thyroid hypertrophy and hyperplasia)</p> <p>Furthermore, the available <i>in vitro</i> mechanistic data (e.g. AR receptor binding and antagonistic effects on AR) could be</p>			
Path 2a, 2b of the decision tree		CAT I	Human ED	Ecotox ED	

Figure 2.18. Categorization of the substance No 403 under "Option 2, 3 & 4" on basis of mammalian data.

The results of the screening do not constitute evaluations of individual substances to be carried out under the respective chemical legislations [[in particular, Regulation (EC) No 1107/2009 on plant protection products, Regulation (EU) No 528/2012 on biocidal products, Regulation (EC) No 1907/2006 REACH, Regulation (EC) No 1223/2009 on cosmetic products and the Water Framework Directive (EC) No 2000/60] and in no way prejudice future decisions on active substances to be taken pursuant to these pieces of the EU legislation. It would thus be erroneous to consider that the substances listed in the results of this study (SANTE/2015/E3/SI2.706218) are considered as endocrine disruptors within the meaning of the EU legislation.

iii. Substance No 375

The substance No 375 proved to function as an endocrine disruptor as it affects the androgen pathway since it acts as an anti-androgen. However substance No 375 was not categorized as ED under "Option 4" (Fig. 2.19-20).

	A	B
1	Compound:	██████████
2	CAS:	██████████
3	C&L (harmonized): ATP Inserted / Updated: CLP00	Acute Tox. 4 * H302 Carc. 2 H351 Repr. 1B H360Df STOT RE 2 * H373 Aquatic Acute 1 H400 Aquatic Chronic 1 H410
4	C&L (proposed):	<u>DAR (1996):</u> Carcinogen Category 3: R40 (Possible risk of irreversible effects) R22 (Harmful if swallowed) R50 (Very toxic to aquatic organisms) R53 (May cause long-term adverse effects in the aquatic environment)
5	Co-RAP (concern - justification):	Not applicable
6	Reason for inclusion on the SIN List:	Not applicable
7	Other information/comments:	CMR CLP classification STOT-RE CLP classificaton Included in EDSP weight of evidence conclusions of EPA: For the estrogen pathway, the available data suggests that ██████████ does not interact with the estrogen pathway. For the androgen pathway, ██████████ appears to act as an anti-androgen both in vitro and in vivo. For the thyroid pathway, there was evidence of potential interaction in mammals characterized by changes in thyroid hormone levels in the absence of changes in thyroid weight or histopathology in multiple studies.

Figure 2.19. Main information captured in the Data summary template version 1.10 about the substance No 375.

Screening of available evidence on chemical substances for the identification of endocrine disruptors according to different options in the context of an Impact Assessment

OPTION 2 & 3			OPTION 4		
Mammalian					
Question	Answer (Yes/No)	Reasoning	Question	Answer (Yes/No)	Reasoning
Is there evidence of adversity that may or may not be caused by an ED related effect in an intact organism, or its progeny, or in a population? <i>If yes, please indicate in the reasoning, each specific adverse effect and the corresponding "Study ID Matrix". If no, in the reasoning, please explain if the no is due to lack of data or because no effects were reported in a particular study/ies (always report "Study ID Matrix").</i>	YES	Increased abortion, ID: 20 (rabbit) Increased adrenal weights, IDs: 10 (rat), 23 (rat), 58c (rat) Increased fetal mortality, IDs: 20 (rabbit) Pituitary weight: Increased in ID:10 (rat) and decreased in ID: 11 ((rat) Pituitary histopathology: Decreased incidence of adenomas/carcinomas, ID: 13 (rat)	In case the substance is an ED (Cat I), are the endocrine-related adverse effects produced at a dose at or below a relevant	NO	The most sensitive endpoint is the following: Epididymis histopathology, testis histopathology, testis weight: ID: 12 (6.25 mg/kg bw/day, 24 months, rat) Guidance value for STOT - RE Cat 1 for oral administration in rat is 10 mg/kg bw/ day for standard 90-day toxicity study. The extrapolated guidance value for 2 years study is 1,25 (= 10/8). Therefore guidance value < most sensitive endpoint.
Is there evidence of Adversity - FATS specific in an intact organism, or its progeny, or in a (sub)population? <i>If yes, please indicate in the reasoning, each specific adverse effect and the corresponding "Study ID Matrix". If no, in the reasoning, please explain if the no is due to lack of data or because no effects were reported in a particular study/ies (always report "Study ID Matrix").</i>	YES	Decreased accessory sex glands, IDs: 56a (rat) Epididymis histopathology findings, IDs: 12 (rat), 58g (rat) Decreased epididymis weight, IDs: 23 (rat), 58a (rat), 59a (rat) Decreased LABC weight, ID: 58e (rat) Induction of ovarian tumors, ID: 13 (rat) Decreased ovary weight, ID: 10 (rat) Decreased prostate weight, IDs: 23 (rat), 58a (rat), 59a (rat) Testis histopathology findings, IDs: 12 (rat), 13 (rat), 17 (rat), 21 (rat), 53c (rat), 58g (rat) Increased testis weight, IDs: 12 (rat), 21 (rat), 59a (rat) Uterus histopathology, IDs: 12 (rat), 13 (rat), 53c (rat) Decreased seminal vesicles weight, ID: 59a (rat)			
Is there evidence of in vivo mechanistic and/or in vivo hormone levels information? <i>If yes, please indicate in the reasoning, each in vivo mechanistic effect and the</i>	YES	Increased estradiol and LH levels, IDs: 56a, 59a, 59b Decreased LABC weight (Hershberger), ID:58c (rat) Decreased seminal vesicles weight (Hershberger), ID: 58c (rat) Serum testosterone levels decreased, ID: 23 Testicular testosterone secreting capacity and testicular testosterone content increased, ID: 23			
Is there evidence of in vitro mechanistic information? <i>If yes, please indicate in the reasoning, each in vitro mechanistic effect and the corresponding "Study ID Matrix". If no, in the reasoning, please explain if the no is due to lack of data or because no effects were reported in a particular study/ies (always report "Study ID Matrix").</i>	YES	Androgen receptor: Receptor binding induction, IDs: 1 (high potency), 56b, 57a, 58a, 58b, 59c No effects on androgen receptor, IDs: 27, 28, 29, 30, 31 (On receptor binding: ID 28) Estrogen receptor: Receptor binding induction, ID: 57a No effects on estrogen receptor, IDs: 33-49 (On receptor binding, IDs: 36-38) Testosterone synthesis: Reduced aromatase activity, ID: 53a Decreased 17-20 desmolase activity, ID: 53a Other: Decreased LHRH binding in the pituitary, ID: 22 Reduced response of interstitial cells to LH, ID: 53b inhibition of dihydrotestosterone (DHT)-hAR induced gene expression in CV-1 and MDA-MB-453-KB2 cells, ID: 58d De-repression (increase) of TRPM2 and decrease of C3 mRNA levels, ID: 58f No effects on estrogen related receptor, IDs: 50, 51 No effects on CYP19, ID: 32 No effects on thyroid receptor, ID: 52			
Is there evidence of a plausible link between in vitro/in vivo mechanistic information and the	YES	The available <i>in vivo</i> and <i>in vitro</i> mechanistic data (e.g. hAR antagonist, decreased testosterone level) are in concordance with the observed adverse effects (e.g. at testis, epididymis, prostate) [REDACTED] appears to exhibit an anti-androgen activity.			
			Human	Ecotox	
Path 2a of the decision tree		CAT I	Unclassified	Unclassified	

Figure 2.20. Categorization of the substance No 375 under "Option 2, 3 & 4" on basis of mammalian data. The same data have been used also for the vertebrate wildlife evaluation.

The results of the screening do not constitute evaluations of individual substances to be carried out under the respective chemical legislations [[in particular, Regulation (EC) No 1107/2009 on plant protection products, Regulation (EU) No 528/2012 on biocidal products, Regulation (EC) No 1907/2006 REACH, Regulation (EC) No 1223/2009 on cosmetic products and the Water Framework Directive (EC) No 2000/60] and in no way prejudice future decisions on active substances to be taken pursuant to these pieces of the EU legislation. It would thus be erroneous to consider that the substances listed in the results of this study (SANTE/2015/E3/SI2.706218) are considered as endocrine disruptors within the meaning of the EU legislation.

iv. Substance No 344

The substance No 344 was classified as Cat II under "Option 2 & 3" for human health and vertebrate wildlife. The substance No 344 induced a well conserved pattern of adverse effects on male reproductive system (degenerative changes in testes, decreased spermatogenic activity, oligospermia and accumulation of atypical spermatogenic cells) in two different species (rat and dog). However, there was insufficient evidence from the available mechanistic studies to support a plausible link (Fig. 2.21-22).

	A	B
1	Compound:	[REDACTED]
2	CAS:	[REDACTED]
3	C&L (harmonized): ATP Inserted / Updated: CLP00	STOT RE 2 * H373 ** (nervous system) Aquatic Acute 1 H400 Aquatic Chronic 1 H410
4	C&L (proposed):	Not relevant DAR (2000) older than CLP harmonized
5	Co-RAP (concern - justification):	Not relevant
6	Reason for inclusion on the SIN List:	Not relevant
7	Other information/comments:	-

Figure 2.21. Main information captured in the Data summary template version 1.10 about the substance No 344.

OPTION 2 & 3		
	Mammalian	
Question	Answer (Yes/No)	Reasoning
Is there <u>evidence of adversity that may or may not be caused by an ED related effect in an intact organism, or its progeny, or in a (sub)population?</u> <i>If yes, please indicate in the reasoning, each adverse effect and the corresponding</i>	No	No ED related adverse effects
Is there <u>evidence of Adversity – EATS specific in an intact organism, or its progeny, or in a (sub)population?</u> <i>If yes, please indicate in the reasoning, each specific adverse effect and the corresponding "Study ID Matrix". If no, in the reasoning, please explain if the no is due to lack of data or because no effects were reported in a particular studies (always report "Study ID Matrix")</i>	Yes	Testis histopathology: Bilateral treatment-related lesions (spermatogenic degeneration and atypical spermatogenic cells) (dog 90 days) [ID: 3], Decreased spermatogenic activity, accumulation of atypical cells in the lumen of the seminiferous tubules, oligospermia (dog 1 years) [ID: 4], Degeneration and mineralisation in the testes (rat 2 years) [ID: 7] Degenerative changes in the seminiferous tubules and atypical spermatogenic cell sequences (rat) [ID: 8] Acinar atrophy in mammary glands (rat 2 years) [ID: 7]
Is there <u>evidence of in vivo mechanistic and/or in vivo hormone levels information?</u> <i>If yes, please indicate in the reasoning, each in vivo mechanistic effect and the corresponding "Study ID Matrix". If no, in the reasoning,</i>	No	Lack of data
Is there <u>evidence of in vitro mechanistic information?</u> <i>If yes, please indicate in the reasoning, each in vitro mechanistic effect and the corresponding "Study ID Matrix". If no, in the reasoning, please explain if the no is due to lack of</i>	No	Estrogen receptor transactivation properties of low potency [ID: 13] Only 5 out of 27 ToxCast assays conducted. No androgenic effects [ID: 11], no estrogenic effects [ID: 12, 14, 15]
Is there <u>evidence of a plausible link between in vitro/in vivo mechanistic information and the observed EATS-specific/ED-related adversity?</u> <i>If yes, please indicate in the reasoning, the link</i>	No	Insufficient evidence from the available mechanistic studies to support a plausible link
	Path 3a of the decision tree	Cat II

Figure 2.22. Categorization of the substance No 344 under "Option 2 & 3" on basis of mammalian data. The same data were use also for the vertebrate wildlife assessment.

v. Substance No 175

The substance No 175 was classified as Cat III under “Option 2 & 3” for human health and vertebrate wildlife. No ED-related/EATS-specific effects were reported and the categorization was based only on *in vitro* mechanistic data (Fig. 2.23-24).

	A	B
1	Compound:	
2	CAS:	
3	C&L (harmonized): ATP Inserted / Updated:	No harmonized classification available
4	C&L (proposed):	EFSA (2007): Acute Tox. 4; H302 Aquatic Acute 1; H400 Aquatic Chronic 1; H410
5	Co-RAP (concern - justification):	-
6	Reason for inclusion on the SIN List:	-
7	Other information/comments:	WFD substance

Figure 2.23. Main information captured in the Data summary template version 1.10 about the substance No 175.

OPTION 2 & 3		
Mammalian		
Question	Answer (Yes/No)	Reasoning
Is there <u>evidence of adversity that may or may not be caused by an ED related effect in an intact organism, or its progeny, or in a (sub)population?</u> <i>If yes, please indicate in the reasoning, each adverse effect and the corresponding "Study ID Matrix". If no, in the reasoning, please explain if the no is due to lack of</i>	No	No effects were reported
Is there <u>evidence of Adversity – EATS specific</u> in an intact organism, or its progeny, or in a (sub)population? <i>If yes, please indicate in the reasoning, each specific adverse effect and the corresponding "Study ID Matrix". If no, in the reasoning, please explain if the no is due to lack of data or because no effects</i>	No	No effects were reported
Is there evidence of <u>in vivo mechanistic and/or in vivo hormone levels information?</u> <i>If yes, please indicate in the reasoning, each in vivo mechanistic effect and the corresponding "Study ID Matrix". If no, in the reasoning, please explain if the no is due to lack of</i>	No	Lack of data
Is there evidence of <u>in vitro mechanistic information?</u> <i>If yes, please indicate in the reasoning, each in vitro mechanistic effect and the corresponding "Study ID Matrix". If no, in the reasoning, please explain if the no is due to lack of data or because no effects were reported in a particular studies (always report "Study ID Matrix")</i>	Yes	Androgen receptor (significant displacement of [3H]-DHT binding) - ID: 11, Antiandrogenic activity in the presence of DHT - ID: 10, androgen receptor (pure AR antagonistic activity) - ID: 14, hPXR agonistic activity - ID: 12
Is there evidence of a <u>plausible link between in vitro/in vivo mechanistic information and the observed EATS-specific/ED-related adversity?</u> <i>If yes, please indicate in the reasoning, the link between in vitro/in vivo mechanistic</i>	No	Not relevant
	Path 10 of the decision tree	CAT III

Figure 2.24. Categorization of the substance No 175 under "Option 2 & 3" on basis of mammalian data. The same data were used also for the vertebrate wildlife evaluation.

vi. Substance No 189

This substance is proposed for classification as Repr. 1B; H360Fd and is proved to cause several effects which may be ED- related, such as fertility impairment and changes in foetal development. However, in absence of EATS specific effects or mechanistic data, this substance is classified as "Unclassified" under "Option 2 & 3" (Fig. 2.25-26).

	A	B
1	Compound:	[REDACTED]
2	CAS:	[REDACTED]
3	CLP (harmonized):	No CLP harmonized available
4	CLP (proposed):	EFSA Conclusion 2005: Acute Tox. 4; H302 Eye Irrit. 2; H319 Skin Sens. 1; H317 Repr. 1B; H360Fd Aquatic Chronic 4; H413 Aquatic Chronic 3; H412
5	Co-RAP (concern - justification):	Not relevant
6	Reason for inclusion in the SIN List:	Not relevant
7	Other information/comments	EFSA Conclusion 2005: Due to the fact that the [REDACTED], a variant of [REDACTED] is used in the formulated product, it should be noted that the evaluated data belong to [REDACTED] unless otherwise specified [REDACTED]. The CAS No. reported in the Chemical inventory excel file ([REDACTED]) refers to the variant [REDACTED].

Figure 2.25. Main information captured in the Data summary template version 1.10 about the substance No 189.

Screening of available evidence on chemical substances for the identification of endocrine disruptors according to different options in the context of an Impact Assessment

OPTION 2 & 3				OPTION 4		
Mammalian		Ecotox		Address same questions as for mammalian, including population relevant mammalian data plus data for fish, bird and amphibians studies		
Question	Answer (Yes/No)	Reasoning	Answer (Yes/No)	Reasoning	Question	Answer (Yes/No)
Is there evidence of adversity that may or may not be caused by an ED-related effect in an intact organism, or its progeny, or in a (sub)population? <i>If yes, please indicate in the reasoning, each adverse effect and the corresponding "Study ID Matrix". If no, in the reasoning, please explain if the no is due to lack of data or because no effects were reported in a particular studies (always report "Study ID Matrix").</i>	YES	Changes in fetal development: skeletal anomalies, retarded or reduced ossification; (cleft palate observed only in maternal toxic dose in two preliminary studies) [ID: 9 (rabbit); ID: 8, 11, 13, 14 (rat)] Decreased fertility [ID: 7a, 7b (rat)] Fetal mortality [ID: 9 (rabbit)] Post implantation loss [ID: 9 (rabbit); ID: 8, 11 (rat)] Decreased litter size [ID: 7a (rat)] Decreased fetal weight [ID: 8 (rat)]	YES	<u>Data copied from mammalian assessment:</u> Changes in fetal development: skeletal anomalies, retarded or reduced ossification; (cleft palate observed only in maternal toxic dose in two preliminary studies) [ID: 9 (rabbit); ID: 8, 11, 13, 14 (rat)] Decreased fertility [ID: 7a, 7b (rat)] Fetal mortality [ID: 9 (rabbit)] Post implantation loss [ID: 9 (rabbit); ID: 8, 11 (rat)] Decreased litter size [ID: 7a (rat)] Decreased fetal weight [ID: 8 (rat)]	In case the substance is an ED (Cat I), are the endocrine-related adverse effects produced at a dose at or below a relevant guidance value ?	
Is there evidence of Adversity – EATS specific in an intact organism, or its progeny, or in a (sub)population? <i>If yes, please indicate in the reasoning, each specific adverse effect and the corresponding "Study ID Matrix". If no, in the reasoning, please explain if the no is due to lack of data or because no</i>	NO	No EATS specific effects reported	NO	No EATS specific effects reported		
Is there evidence of in vivo mechanistic and/or in vivo hormone levels information? <i>If yes, please indicate in the reasoning, each in vivo mechanistic effect and the</i>	NO	No data	NO	No data		
Is there evidence of in vitro mechanistic information? <i>If yes, please indicate in the reasoning, each in vitro mechanistic effect and the</i>	NO	No data	NO	No data		
Is there evidence of a plausible link between in vitro/in vivo mechanistic information and the observed EATS-specific/ED-related adversity? <i>If yes, please indicate in the reasoning, the link between in vitro/in vivo mechanistic information and the observed adversity</i>	NO	No mechanistic data available	NO	No mechanistic data available		
					Human	Ecotox
Path 8 of the decision tree		Unclassified	Path 8 of the decision tree	Unclassified	Unclassified	Unclassified

Figure 2.26. Categorization of the substance No 189 under "Option 2 & 3" on basis of mammalian data.

Types of Adversity and MoA in the categorization outcome

1. "EATS specific adversity"

In the frame of this project, "EATS specific adversity" has been considered as strong indication (or evidence) to support that the substance causes adversity through an ED-MoA. Therefore, this consideration leads to the most strict categorization of the substance as "Endocrine Disruptors (Cat I) or "Suspected Endocrine Disruptors" (Cat II) (Fig. 2.27). EATS specific adverse effects may or may not be supported by "Non-specific adversity (may or may not be indicative of EATS)". Moreover, certain pattern of effects, mostly related to EATS-specific adversity (e.g. testicular dysgenesis syndrome in mammals or change in sex ratio in fish), can provide strong indication of ED-MoA and therefore their observation is considered sufficient and self-diagnostic to directly lead to classification as Cat I.

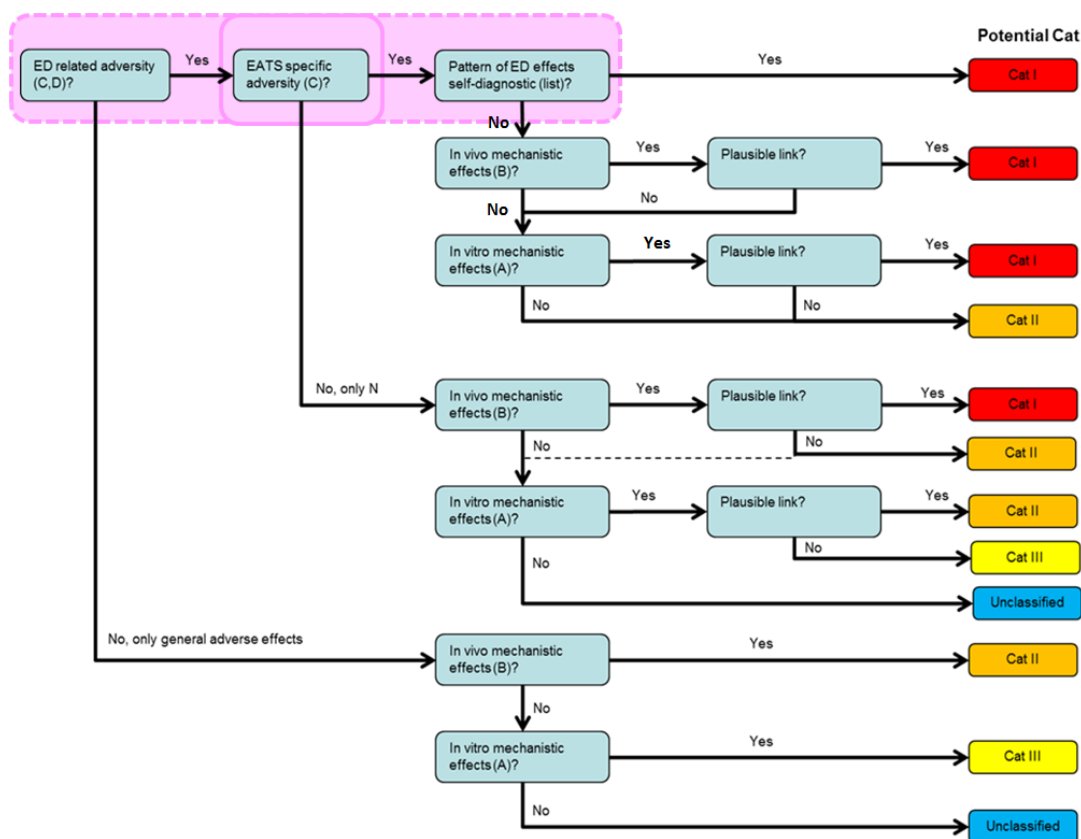


Figure 2.27. Presence of “EATS specific effects” - strong indication of ED- related adversity.

Example: Substance No 344 exhibits a well-conserved pattern of “EATS specific” adverse effects on the male reproductive system in two different species (degenerative effects in testes, decreased spermatogenic activity, oligospermia and accumulation of atypical spermatogenic cells in sub-chronic and chronic studies in rat and dog). In the absence of a plausible link due to lack of any mechanistic data this substance was eventually classified as Cat II for both human health and vertebrate wildlife assessment.

2. “Non-specific adversity (may or may not be indicative of EATS)”

In the frame of this project, “Non-specific adversity (may or may not be indicative of EATS)” leads to a much wider spectrum of potential categories, mostly Cat II, III and “Unclassified”, depending on the assessment of the *in vivo/in vitro* mechanistic information available (Fig. 2.28). In rare cases presence of non-specific adversity can lead to Cat I. It is noted that only one substance (No 91) was classified as Cat I based on non-specific adversity in the absence of EATS specific effects.

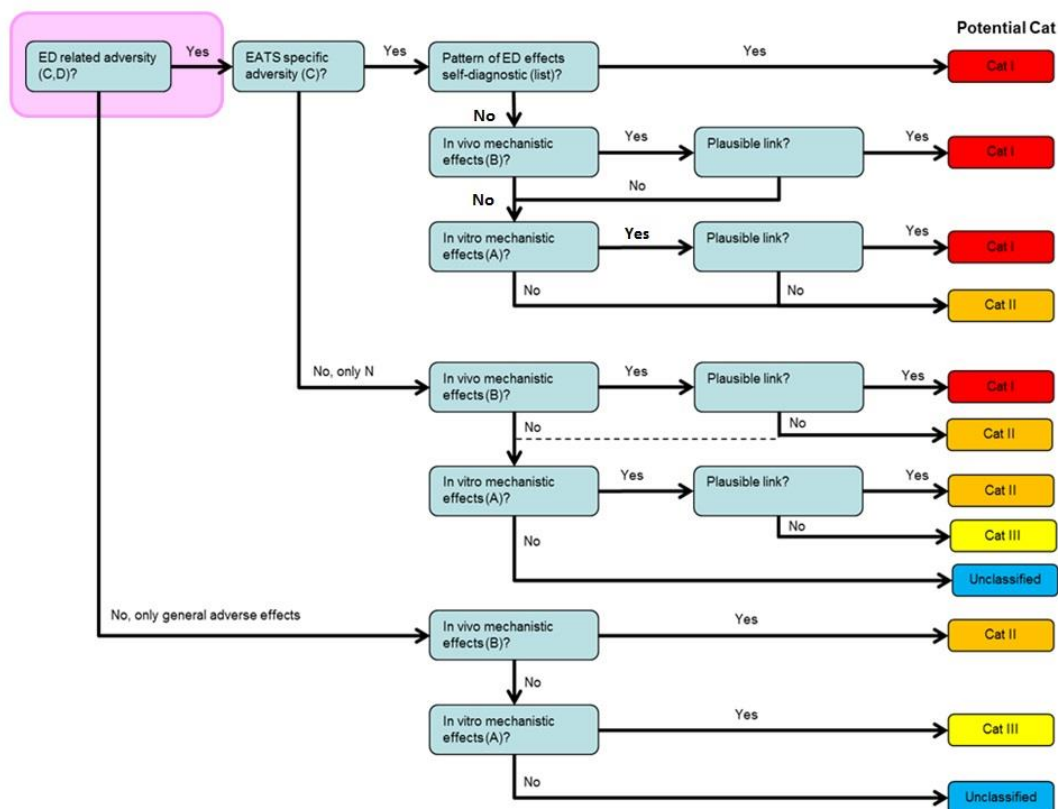


Figure 2.28. “Non-specific adverse effects (may or may not be indicative of EATS)” are considered no indication of ED- related adversity in the absence of any supporting mechanistic data.

Example: Substance No 50 caused a variety of “Non-specific adverse effects (may or may not be indicative of EATS)” related to fetal and pup development (abortions, fetal development findings, increased fetal mortality, decreased fetal weight, increased gestation length, decreased pup weight gain, decreased number of live fetuses, deregulated pup development, increased number of resorptions) which in total absence of “EATS specific” adverse effects but in presence of *in vitro* mechanistic data was eventually categorized as Cat III for both human health and vertebrate wildlife assessment.

3. *In vivo* mechanistic data

In the frame of this project, *in vivo* mechanistic data (which may or may not be supported by *in vitro* mechanistic data) are considered as a strong indication of an endocrine MoA. In case a plausible link is determined with either “EATS specific” or “Non-specific adversity (may or may not be indicative of EATS)”, then the substance is classified as Cat I. In case a plausible link is not established or *in vivo* mechanistic effects are not accompanied by any ED-related adversity, then the categorization is Cat II (Fig. 2.29).

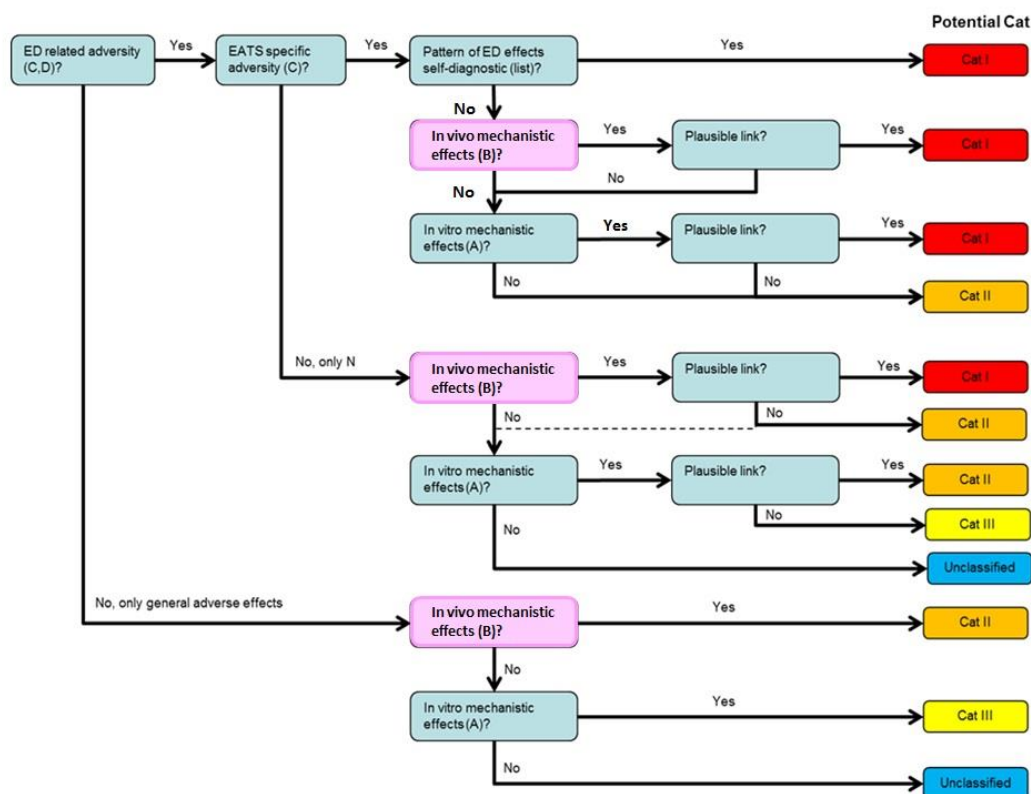


Figure 2.29. *In vivo* mechanistic information considered as strong indication of ED MoA leads to the categorization of a substance as Cat I or Cat II.

Example: Substance No 408 caused changes in thyroid hormone levels (T3 & T4) and TSH levels in four different species (rat, mouse, dog and monkey) which is a clear indication of hypothalamic-pituitary-thyroid (HPT) axis disruption. This substance was eventually categorized as Cat I in presence of strong evidence of adversity (EATS-specific and non-specific adversity).

4. *In vitro* mechanistic data

In the frame of this project, *in vitro* mechanistic data, in the absence of *in vivo* mechanistic data, are generally considered as weak indications of an endocrine MoA. In this case, a substance could be categorized as Cat I, Cat II or Cat III depending on the type of adversity observed ("EATS specific adversity" or "Non-specific adversity (that may or may not be indicative of EATS)") and on whether or not a plausible link to the observed adversity is established. The possibility that a substance is categorized as Cat I on the basis of *in vitro* mechanistic data is limited to the cases where there is clear and strong evidence of EATS specific adversity and a plausible link with equally clear *in vitro* mechanistic data is established. However, it was acknowledged that it would often be difficult to establish a direct plausible link to adverse effects and thus a Cat II in case of presence of EATS specific effects or Cat III in presence of non-specific effects was more likely (Fig. 2.30).

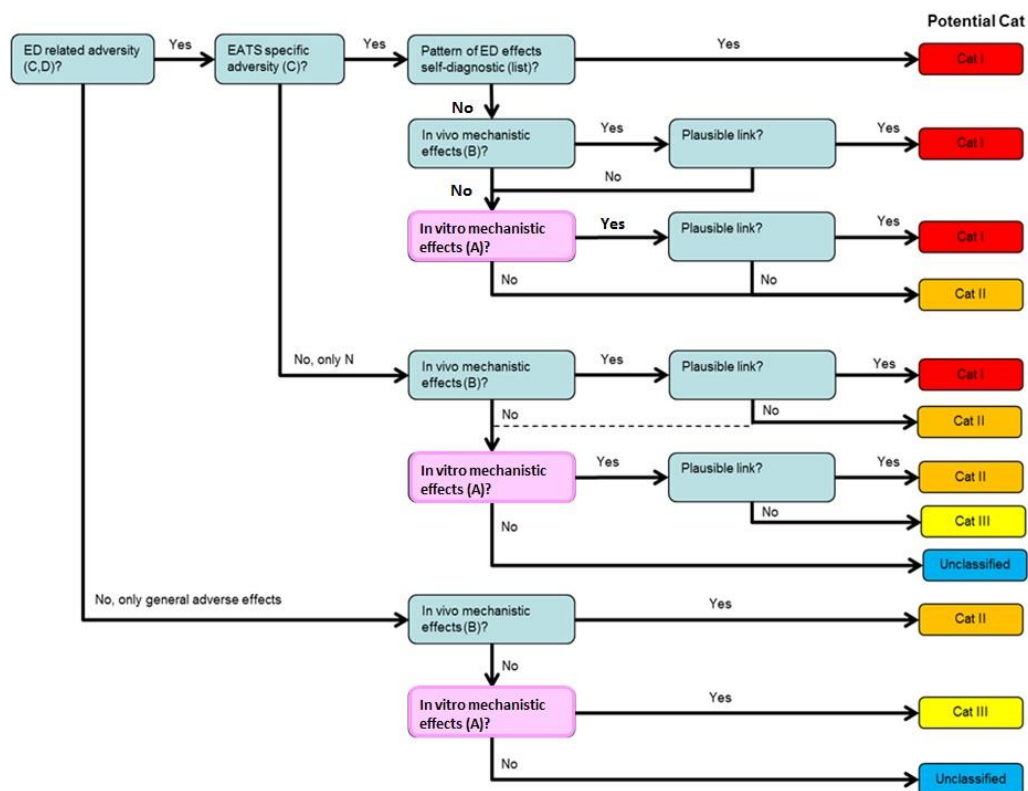


Figure 2.30. *In vitro* mechanistic information considered as weak indication of ED MoA leads to the categorization of a substance as Cat I, Cat II or Cat III.

Example: Substance No 350 exhibited strong antagonistic effects and weak agonistic activity on ER alpha and ER beta in the absence of *in vivo* mechanistic effects and adversity which resulted in categorization as Cat III.

It should be mentioned that when applying the decision tree for each substance the weight of evidence of the observed types of adversity and MoA was taken into account in each step followed. When the weight of evidence of the observed effects has been considered inadequate the Path followed was similar to cases where no effects were observed.

D. Results

As agreed during the 2nd Interim meeting, the overall summary tables with the potential categorization results for all 348 PPPs screened for human health (Table 2.2) and vertebrate wildlife (Table 2.3) as well as an overall/combined table for human health and vertebrate wildlife (Table 2.4) and a summary table for "Option 3" results and the different Paths leading to the different categories for human health (Table 2.5) and vertebrate wildlife (Table 2.6), are presented below.

The results of the categorization for each of the 348 PPP substances according to the four "Options" of the Roadmap for human health and vertebrate wildlife assessment based on the above methodology are presented in the Appendix 2.1.

Under "Option 1" and since both the harmonised C&L (when available) and the proposed C&L (when relevant) have been considered for the categorization of the substances, the results are reported in order for it to be possible to make a distinction between the substances with a harmonised classification, which have been included in Annex VI of Regulation (EC) 1272/2008 (CLP Regulation), i.e. their classification has been agreed, and those substances for which no harmonised classification is available because discussions have not yet been concluded on a classification proposal.

In the Categorization Results Table (Appendix 2.1), when there is no harmonised C&L available, "Not relevant" is reported. However, when concluding for the categorization under "Option 1", this is interpreted as "Unclassified*", since certain Stakeholders may consider only the official classification as relevant for the application of the interim criteria. The "*" has been added in order to make the distinction from the substances which are categorized as "Unclassified" considering the harmonised C&L included in Annex VI of CLP Regulation.

For all substances where there is no harmonised C&L available (141 out of the 348 PPPs screened) the categorization was concluded considering the proposed classification since this is the most recent one. It is noted that for 11 substances with no harmonised classification i.e. categorized as "Unclassified*", the categorization is different when considering the most recent proposed C&L.

Moreover, for 103 out of the 207 PPPs for which there is a harmonised classification, a more recent C&L proposal in the respective evaluation report has been identified. In these cases, the "Most Recent" "Option 1" outcome is the one based on the proposed C&L (more severe in most cases); it is noted that only for 13 substances the categorization is different when considering the most recent proposed C&L instead of the available harmonised C&L. In cases where the proposed classification has been questioned in the evaluation report, i.e. a question mark (?) has been added since it has been considered that the issue should be flagged to ECHA. This question mark has been maintained when populating the relevant data and reporting the outcome in the Categorization Results Table.

As presented in the summary tables, out of 348 PPPs screened, 51 PPPs were classified as EDs under "Option 1" (Table 2.2). Of these 51 PPPs, 9 PPPs (No 201, 202, 296, 375, 20, 87, 216 and 13) are classified as Repr. Cat. 1A/B and, thus for these substances the cut-off criteria¹¹ of Regulation (EC) 1107/2009 are also applicable.

¹¹ The term "cut-off criteria" is not used in the legislation. It is used in common language to refer to *approval criteria* in Reg. 1107/2009 and *exclusion criteria* in Reg. 528/2012.

In Reg. 1107/2009, *approval criteria* are:

- purely based on hazard considerations for certain classes of substances (*mutagens, PBT = persistent, bioaccumulative and toxic, vPvB= very persistent and very bioaccumulative, POP= persistent organic pollutants*);
- based on a strong hazard component for other classes of substances (*carcinogens, toxic for reproduction, endocrine disruptors*).

In Reg. 528/2012, *exclusion criteria* are:

- purely based on hazard considerations for certain classes of substances (*mutagens, PBT = persistent, bioaccumulative and toxic, vPvB= very persistent and very bioaccumulative, carcinogens, toxic for reproduction, endocrine disruptors*) when used by consumers;

based on a strong hazard component for the same classes of substances when used by professional users.

The results of the screening do not constitute evaluations of individual substances to be carried out under the respective chemical legislations [[in particular, Regulation (EC) No 1107/2009 on plant protection products, Regulation (EU) No 528/2012 on biocidal products, Regulation (EC) No 1907/2006 REACH, Regulation (EC) No 1223/2009 on cosmetic products and the Water Framework Directive (EC) No 2000/60] and in no way prejudice future decisions on active substances to be taken pursuant to these pieces of the EU legislation. It would thus be erroneous to consider that the substances listed in the results of this study (SANTE/2015/E3/SI2.706218) are considered as endocrine disruptors within the meaning of the EU legislation.

Table 2.2. Potential categorization results for human health for the 348 PPPs screened.

Human health	Potential Categorization										
	Option 1*		Option 2		Option 3				Option 4		
	ED	Unclassified	ED	Unclassified	Cat I	Cat II	Cat III	Unclassified	ED	Unclassified	
Number of PPPs	Harmonised C&L	27	321*	31	317	31	88	59	170	13	335
	Most recent C&L proposal**	51	297								

* For 141 substances there is no harmonised C & L available which is interpreted as "Unclassified".

** Taking into account the proposed classification i.e. the classification proposal concluded during the peer review process under Regulation (EC) 1107/2009 (EFSA Conclusion or DAR/RAR) and/or under Regulation (EU) 528/2012 (ECHA Assessment Report/CAR) when this is more recent than the decision for the harmonised C&L.

Regarding vertebrate wildlife 28 PPPs were classified as EDs under "Option 2" (equivalent to Cat I under "Option 3"), whilst only 13 PPPs were classified as EDs under "Option 4" (Table 2.3).

Table 2.3. Potential categorization results for vertebrate wildlife* for the 348 PPPs screened.

Vertebrate wildlife	Potential Categorization							
	Option 2		Option 3				Option 4	
	ED	Unclassified	Cat I	Cat II	Cat III	Unclassified	ED	Unclassified
Number of PPPs	28	320	28	89	55	176	13	335

Regarding "Option 4", out of 13 substances classified as ED only one was solely based on non-mammalian data (fish, avian, amphibian) whilst the other 12 substances were based on mammalian data by using the same potency cut-off value as for mammals.

For combined/overall potential categorization the more conservative outcome has been considered i.e. the most recent classification in case of "Option 1", the most severe categorization between human health and vertebrate wildlife in case of "Option 2, 3 & 4" (Table 2.4). Consequently, 51 PPPs were classified as EDs under "Option 1", 32 PPPs were classified as EDs under "Option 2" (equivalent to Cat I under "Option 3") whilst only 15 PPPs were classified as EDs under "Option 4".

Table 2.4. Combined potential categorization results for human health and vertebrate wildlife for the 348 PPPs screened.

Human health and vertebrate wildlife	Potential Categorization									
	Option 1 (Most recent)		Option 2		Option 3				Option 4	
	ED	Unclassified	ED	Unclassified	Cat I	Cat II	Cat III	Unclassified	ED	Unclassified
Number of PPPs	51	297	32	316	32	96	53	167	15	333

For “Option 3”, the Paths of the decision tree (please refer to Appendix I) leading to each categorization are presented in Table 2.5 for human health assessment and in Table 2.6 for vertebrate wildlife assessment. As it is shown in Table 2.5, 17 out of 31 PPPs categorized as Cat I are through Path 2a resulting from strong evidence of adversity and strong MoA. 7 PPPs categorized as Cat I are using Path 2b resulting from EATS-specific adversity and *in vitro* mechanistic data whilst 6 PPPs are concluded as Cat I through combined Paths 2a,2b (EATS-specific adversity and both *in vitro* and *in vivo* mechanistic data). Only one PPP was categorized as Cat I by using Path 4 resulting from non-specific adversity and *in vivo* mechanistic data, which confirms the notion that it is extremely difficult to reach classification as Cat I in the absence of EATS-specific adversity. Regarding classification as Cat II, out of 88 PPPs classified as Cat II, 55 PPPs used Path 3a resulting from evidence of EATS specific adversity but absence of *in vivo/in vitro* mechanistic data (either results showed no effects or there were no data available). This practically means that some of those 55 PPPs could potentially be classified as Cat I in case additional mechanistic data were provided capable of forming a plausible link with observed adversity. Out of 59 substances classified as Cat III under “Option 3”, this resulted from positive evidence of *in vitro* mechanistic data (in the absence of any adversity in 34 cases (via Path 10) and in the presence of non-specific adversity in 25 cases (Path 7). Finally, out of 170 substances categorised as “Unclassified” 121 PPPs reached this conclusion using Path 11 resulting from absence of adversity and mechanistic data. For the other 49 there were adverse effects but these may or may not have been ED-related and in the absence of any mechanistic data either *in vitro* or *in vivo* to indicate an endocrine mode of action or, alternatively, in the presence of negative mechanistic data the substances were designated “Unclassified” (Path 8).

Table 2.5. Presentation of the results for “Option 3” and the different Paths leading to the different categories or to “Unclassified” for human health.

PPPs	Potential Categorization - Option 3 (human health)							
	Number of substances							
	Cat I		Cat II		Cat III		Unclassified	
Total number	31		88		59		170	
	Path 1	-	Path 3a	55	Path 7	25	Path 8	49
	Path 2a	17	Path 3b	19	Path 10	34	Path 11	121
	Path 2b	7	Path 3a, 3b	4				
	Path 2a, 2b	6	Path 5	6				
	Path 4	1	Path 6	1				
			Path 5 & 6	2				
			Path 9	1				

Similar results were obtained for the classification of vertebrate wildlife under “Option 3” (Table 2.6). Most of the PPPs (13 out of 28) used Path 2a in order to be classified as Cat I, 55 out of 89 PPPs were classified as Cat II through Path 3a, 31 out of 55 PPPs reached Cat III through Path 10 and finally 119 out of 176 PPPs were concluded as “Unclassified” through Path 11.

Table 2.6. Presentation of the results for “Option 3” and the different Paths leading to the different categories or to “Unclassified” for vertebrate wildlife.

PPPs	Potential Categorization - Option 3 (vertebrate wildlife)							
	Number of substances							
	Cat I		Cat II		Cat III		Unclassified	
Total number	28		89		55		176	
	Path 1	-	Path 3a	55	Path 7	24	Path 8	57
	Path 2a	13	Path 3b	18	Path 10	31	Path 11	119
	Path 2b	7	Path 3a, 3b	4				
	Path 2a, 2b	6	Path 5	7				
	Path 1,2a,2b	1	Path 6	3				
	Path 4	1	Path 5 & 6	2				
			Path 9	-				

E. References

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Appendix 2.1

The results of potential categorization for each of the 348 PPP substances according to the four "Options" of the Roadmap (EC, 2014) for human health and vertebrate wildlife assessment are presented below:

Potential categorization results of the 348 PPPs under "Option 1"

	Chemical Name	Carc Cat. 2 (C&L Harmonised)	Carc Cat. 2 (C&L Proposed)	Repr. Cat. 2 (C&L Harmonised)	Repr. Cat. 2 (C&L Proposed)	Carc Cat. 1A or 1B (C&L Harmonised)	Carc Cat. 1A or 1B (C&L Proposed)	Repr. Cat. 1A or 1B (C&L Harmonised)	Repr. Cat. 1A or 1B (C&L Proposed)	Effects on Endocrine organs (YES/NO)	OPTION 1 Harmonized	OPTION 1 Proposed	OPTION 1 Most recent
1	Carbon dioxide	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	No	Unclassified*	Unclassified	Unclassified
2	Tebuconazole	No	Not relevant	Yes	Not relevant	No	Not relevant	No	No	Yes	ED	Not relevant	ED
3	Methyl nonyl ketone	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	No	Unclassified*	Unclassified	Unclassified
4	Fipronil	No	No	No	No	No	No	No	No	Yes	Unclassified	Unclassified	Unclassified
5	Magnesium phosphide	No	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	Unclassified	Not relevant	Unclassified
6	Imidacloprid	No	No	No	No	No	No	No	No	No	Unclassified	Unclassified	Unclassified
7	Thiabendazole	No	No	No	No	No	No	No	No	Yes	Unclassified	Unclassified	Unclassified
8	Aluminium phosphide	No	No	No	No	No	No	No	No	No	Unclassified	Unclassified	Unclassified
9	Sulfuryl fluoride	No	No	No	No	No	No	No	No	No	Unclassified	Unclassified	Unclassified
10	Bromadiolone	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	Yes	No	Unclassified*	Cut off criteria are applicable / Repr Cat 1A/B	Cut off criteria are applicable / Repr Cat 1A/B
11	Diflubenzuron	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	No	Unclassified*	Unclassified	Unclassified
12	Dazomet	No	No	No	Yes	No	No	No	No	Yes	Unclassified	ED	ED

The results of the screening do not constitute evaluations of individual substances to be carried out under the respective chemical legislations [[in particular, Regulation (EC) No 1107/2009 on plant protection products, Regulation (EU) No 528/2012 on biocidal products, Regulation (EC) No 1907/2006 REACH, Regulation (EC) No 1223/2009 on cosmetic products and the Water Framework Directive (EC) No 2000/60] and in no way prejudge future decisions on active substances to be taken pursuant to these pieces of the EU legislation.

It would thus be erroneous to consider that the substances listed in the results of this study (SANTE/2015/E3/SI2.706218) are considered as endocrine disruptors within the meaning of the EU legislation.

	Chemical Name	Carc Cat. 2 (C&L Harmonised)	Carc Cat. 2 (C&L Proposed)	Repr. Cat. 2 (C&L Harmonised)	Repr. Cat. 2 (C&L Proposed)	Carc Cat. 1A or 1B (C&L Harmonised)	Carc Cat. 1A or 1B (C&L Proposed)	Repr. Cat. 1A or 1B (C&L Harmonised)	Repr. Cat. 1A or 1B (C&L Proposed)	Effects on Endocrine organs (YES/NO)	OPTION 1 Harmonized	OPTION 1 Proposed	OPTION 1 Most recent
13	Difenacoum	No	No	No	No	No	No	No	Yes	Yes	Unclassified	ED / Cut off criteria are applicable / Repr Cat 1A/B	ED / Cut off criteria are applicable / Repr Cat 1A/B
14	Fenpropimorph	No	No	Yes	Yes	No	No	No	No	Yes	ED	ED	ED
15	Abamectin (aka avermectin)	No	No	Yes	Yes	No	No	No	No	Yes	ED	ED	ED
16	Fenoxycarb	Yes	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	Yes	Unclassified	Not relevant	Unclassified
17	Etofenprox	No	Not relevant	Yes	Not relevant	No	Not relevant	No	No	No	Unclassified	Not relevant	Unclassified
18	Bifenthrin	Yes	Yes	No	No	No	No	No	No	Yes	Unclassified	Unclassified	Unclassified
19	lambda-Cyhalothrin	No	No	No	No	No	No	No	No	Yes	Unclassified	Unclassified	Unclassified
20	Cyproconazole	No	Not relevant	No	Not relevant	No	Not relevant	Yes	Not relevant	Yes	ED - Cut off criteria are applicable / Repr Cat 1A/B	Not relevant	ED - Cut off criteria are applicable / Repr Cat 1A/B
21	Pyriproxyfen	No	No	No	No	No	No	No	No	Yes	Unclassified	Unclassified	Unclassified
22	Folpet	Yes	Yes	No	No	No	No	No	No	No	Unclassified	Unclassified	Unclassified
23**	Triflumuron	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	No	Unclassified*	Unclassified	Unclassified
24**	2-Phenylphenol (incl. sodium salt orthophenyl phenol)	No	Yes	No	No	No	No	No	No	No	Unclassified	Unclassified	Unclassified
25	Hymexazol	No	No	No	Yes	No	No	No	No	Yes	Unclassified	ED	ED
27	Aluminium sulphate	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	No	Unclassified*	Unclassified	Unclassified
28	Ferric phosphate	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	No	Unclassified*	Unclassified	Unclassified

The results of the screening do not constitute evaluations of individual substances to be carried out under the respective chemical legislations [[in particular, Regulation (EC) No 1107/2009 on plant protection products, Regulation (EU) No 528/2012 on biocidal products, Regulation (EC) No 1907/2006 REACH, Regulation (EC) No 1223/2009 on cosmetic products and the Water Framework Directive (EC) No 2000/60] and in no way prejudice future decisions on active substances to be taken pursuant to these pieces of the EU legislation.

It would thus be erroneous to consider that the substances listed in the results of this study (SANTE/2015/E3/SI2.706218) are considered as endocrine disruptors within the meaning of the EU legislation.

	Chemical Name	Carc Cat. 2 (C&L Harmonised)	Carc Cat. 2 (C&L Proposed)	Repr. Cat. 2 (C&L Harmonised)	Repr. Cat. 2 (C&L Proposed)	Carc Cat. 1A or 1B (C&L Harmonised)	Carc Cat. 1A or 1B (C&L Proposed)	Repr. Cat. 1A or 1B (C&L Harmonised)	Repr. Cat. 1A or 1B (C&L Proposed)	Effects on Endocrine organs (YES/NO)	OPTION 1 Harmonized	OPTION 1 Proposed	OPTION 1 Most recent
29****	Quizalofop-P-ethyl	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	Yes	Unclassified*	Unclassified	Unclassified
30	Halosulfuron methyl	Not relevant	No	Not relevant	Yes	Not relevant	No	Not relevant	No	Yes	Unclassified*	ED	ED
31	Acrinathrin	Not relevant	Yes	Not relevant	No	Not relevant	No	Not relevant	No	Yes	Unclassified*	Unclassified	Unclassified
32	Cycloxydim	No	Not relevant	Yes	Not relevant	No	Not relevant	No	Not relevant	Yes	ED	Not relevant	ED
34	tau-Fluvalinate	No	No	No	No	No	No	No	No	No	Unclassified	Unclassified	Unclassified
35	Lufenuron	No	No	No	No	No	No	No	No	No	Unclassified	Unclassified	Unclassified
36	Flumioxazin	No	Not relevant	No	Not relevant	No	Not relevant	Yes	Not relevant	No	Cut off criteria are applicable / Repr Cat 1A/B	Not relevant	Cut off criteria are applicable / Repr Cat 1A/B
37	Tribenuron (aka metometuron)	No	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	Yes	Unclassified	Not relevant	Unclassified
38	Geraniol	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	No	Unclassified*	Unclassified	Unclassified
39	Glyphosate (incl trimesium aka sulfosate)	No	No	No	No	No	No	No	No	No	Unclassified	Unclassified	Unclassified
40	Metaldehyde	No	No	No	No	No	No	No	No	Yes	Unclassified	Unclassified	Unclassified
41	Dimethomorph	No	No	No	No	No	No	No	No	Yes	Unclassified	Unclassified	Unclassified
42***	Putrescine (1,4-Diaminobutane)	Not relevant	No	Not relevant	Yes	Not relevant	No	Not relevant	No	No	Unclassified*	Unclassified	Unclassified
43	Azadirachtin	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	Yes	Unclassified*	Unclassified	Unclassified
44	Propaquizafop	Not relevant	Yes	Not relevant	No	Not relevant	No	Not relevant	No	Yes	Unclassified*	Unclassified	Unclassified
45	Nicosulfuron	No	No	No	No	No	No	No	No	No	Unclassified	Unclassified	Unclassified
46	Tetraconazole	No	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	Yes	Unclassified	Not relevant	Unclassified
47	1-Decanol	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	No	Unclassified*	Unclassified	Unclassified
48	Tebufenozide	No	No	No	No	No	No	No	No	No	Unclassified	Unclassified	Unclassified

The results of the screening do not constitute evaluations of individual substances to be carried out under the respective chemical legislations [[in particular, Regulation (EC) No 1107/2009 on plant protection products, Regulation (EU) No 528/2012 on biocidal products, Regulation (EC) No 1907/2006 REACH, Regulation (EC) No 1223/2009 on cosmetic products and the Water Framework Directive (EC) No 2000/60] and in no way prejudge future decisions on active substances to be taken pursuant to these pieces of the EU legislation.

It would thus be erroneous to consider that the substances listed in the results of this study (SANTE/2015/E3/SI2.706218) are considered as endocrine disruptors within the meaning of the EU legislation.

	Chemical Name	Carc Cat. 2 (C&L Harmonised)	Carc Cat. 2 (C&L Proposed)	Repr. Cat. 2 (C&L Harmonised)	Repr. Cat. 2 (C&L Proposed)	Carc Cat. 1A or 1B (C&L Harmonised)	Carc Cat. 1A or 1B (C&L Proposed)	Repr. Cat. 1A or 1B (C&L Harmonised)	Repr. Cat. 1A or 1B (C&L Proposed)	Effects on Endocrine organs (YES/NO)	OPTION 1 Harmonized	OPTION 1 Proposed	OPTION 1 Most recent
49	Dodine	No	No	No	No	No	No	No	No	No	Unclassified	Unclassified	Unclassified
50	Fenoxaprop-P	Not relevant	No	Not relevant	Yes	Not relevant	No	Not relevant	No	No	Unclassified*	Unclassified	Unclassified
51	Fenbuconazole	No	No	No	Yes	No	No	No	No	Yes	Unclassified	ED	ED
52	Clodinafop	No	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	Yes	Unclassified	Not relevant	Unclassified
53	Bromuconazole	Not relevant	No	Not relevant	Yes	Not relevant	No	Not relevant	No	Yes	Unclassified*	Unclassified	Unclassified
54	Spiroxamine	No	No	No	Yes	No	No	No	No	Yes	Unclassified	ED	ED
55	Tebufenpyrad	No	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	Unclassified	Not relevant	Unclassified
56	Difenoconazole	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	Yes	Unclassified*	Unclassified	Unclassified
57****	Quizalofop-P-tefuryl	Yes	Yes	Yes	Yes	No	No	No	No	Yes	ED	ED	ED
59	Azimsulfuron	No	No	No	No	No	No	No	No	Yes	Unclassified	Unclassified	Unclassified
60	Amidosulfuron	No	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	Unclassified	Not relevant	Unclassified
61	Fenazaquin	No	No	No	No	No	No	No	No	Yes	Unclassified	Unclassified	Unclassified
62	Pyrethrins	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	No	Unclassified*	Unclassified	Unclassified
63	6-Benzyladenine	Not relevant	No	Not relevant	Yes	Not relevant	No	Not relevant	No	No	Unclassified*	Unclassified	Unclassified
64	Cyprodinil	No	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	Unclassified	Not relevant	Unclassified
65	Malathion	No	No	No	No	No	No	No	No	Yes	Unclassified	Unclassified	Unclassified
66	Cyhalofop-butyl	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	No	Unclassified*	Unclassified	Unclassified
67	Rimsulfuron (aka renriduron)	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	Yes	Unclassified*	Unclassified	Unclassified
68	Pymetrozine	Yes	Yes	No	Yes	No	No	No	No	Yes	Unclassified	ED	ED
69	Metconazole	No	Not relevant	Yes	Not relevant	No	Not relevant	No	Not relevant	Yes	ED	Not relevant	ED
70	Ipconazole	Not relevant	No	Not relevant	Yes	Not relevant	No	Not relevant	No	Yes	Unclassified*	ED	ED
71	Bispyribac	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	Yes	Unclassified*	Unclassified	Unclassified
72	Fenhexamid	No	No	No	No	No	No	No	No	Yes	Unclassified	Unclassified	Unclassified
73	Prohexadione	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	Yes	Unclassified*	Unclassified	Unclassified

The results of the screening do not constitute evaluations of individual substances to be carried out under the respective chemical legislations [[in particular, Regulation (EC) No 1107/2009 on plant protection products, Regulation (EU) No 528/2012 on biocidal products, Regulation (EC) No 1907/2006 REACH, Regulation (EC) No 1223/2009 on cosmetic products and the Water Framework Directive (EC) No 2000/60] and in no way prejudice future decisions on active substances to be taken pursuant to these pieces of the EU legislation.

It would thus be erroneous to consider that the substances listed in the results of this study (SANTE/2015/E3/SI2.706218) are considered as endocrine disruptors within the meaning of the EU legislation.

	Chemical Name	Carc Cat. 2 (C&L Harmonised)	Carc Cat. 2 (C&L Proposed)	Repr. Cat. 2 (C&L Harmonised)	Repr. Cat. 2 (C&L Proposed)	Carc Cat. 1A or 1B (C&L Harmonised)	Carc Cat. 1A or 1B (C&L Proposed)	Repr. Cat. 1A or 1B (C&L Harmonised)	Repr. Cat. 1A or 1B (C&L Proposed)	Effects on Endocrine organs (YES/NO)	OPTION 1 Harmonized	OPTION 1 Proposed	OPTION 1 Most recent
74	Pyraflufen-ethyl	No	No	No	No	No	No	No	No	Yes	Unclassified	Unclassified	Unclassified
75	Sintofen (aka Cintofen)	Not relevant	Yes?	Not relevant	No	Not relevant	No	Not relevant	No	No	Unclassified*	Unclassified	Unclassified
76	Calcium phosphide	No	No	No	No	No	No	No	No	No	Unclassified	Unclassified	Unclassified
77	Fludioxonil	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	No	Unclassified*	Unclassified	Unclassified
78	Zinc phosphide	No	No	No	No	No	No	No	No	No	Unclassified	Unclassified	Unclassified
79	zeta-Cypermethrin	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	No	Unclassified*	Unclassified	Unclassified
80	Limestone	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	No	Unclassified*	Unclassified	Unclassified
81	Famoxadone	No	No	No	No	No	No	No	No	No	Unclassified	Unclassified	Unclassified
82	Azoxystrobin	No	No	No	No	No	No	No	No	No	Unclassified	Unclassified	Unclassified
83	Ethoprophos	No	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	Unclassified	Not relevant	Unclassified
84	Triticonazole	No	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	Yes	Unclassified	Not relevant	Unclassified
85	Captan	Yes	Yes	No	Yes (?)	No	No	No	No	No	Unclassified	ED (?)	ED (?)
86	Indolybutyric acid	Not relevant	No	Not relevant	Yes	Not relevant	No	Not relevant	No	Yes	Unclassified*	ED	ED
87	Epoxiconazole	Yes	Not relevant	No	Not relevant	No	Not relevant	Yes	Not relevant	Yes	ED - Cut off criteria are applicable / Repr Cat 1A/B	Not relevant	ED - Cut off criteria are applicable / Repr Cat 1A/B
88	Fenpyroximate	No	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	Unclassified	Not relevant	Unclassified
90	Acibenzolar-S-methyl (benzothiadiazole)	No	No	No	No	No	No	No	No	No	Unclassified	Unclassified	Unclassified
91	Triflurosulfuron	Not relevant	Yes	Not relevant	Yes	Not relevant	No	Not relevant	No	Yes	Unclassified*	Unclassified	Unclassified
92	Fluquinconazole	No	Yes	No	No	No	No	No	No	No	Unclassified	Unclassified	Unclassified
93	Disodium phosphonate	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	No	Unclassified*	Unclassified	Unclassified

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94	Picolinafen	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	Yes	Unclassified*	Unclassified	Unclassified
95	Metosulam	Not relevant	Yes	Not relevant	No	Not relevant	No	Not relevant	No	No	Unclassified*	Unclassified	Unclassified
96***	Potassium phosphonates (formerly potassium phosphite)	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	No	Unclassified*	Unclassified	Unclassified
97	Metaflumizone	Not relevant	No	Not relevant	Yes	Not relevant	No	Not relevant	No	No	Unclassified*	Unclassified	Unclassified
98	Iprovalicarb	Not relevant	Yes	Not relevant	No	Not relevant	No	Not relevant	No	Yes	Unclassified*	Unclassified	Unclassified
99	Sulfosulfuron	No	No	No	No	No	No	No	No	No	Unclassified	Unclassified	Unclassified
100	Trinexapac (aka cimeta carb ethyl)	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	No	Unclassified*	Unclassified	Unclassified
101	Kresoxim-methyl	Yes	Yes	No	No	No	No	No	No	No	Unclassified	Unclassified	Unclassified
102	Chromafenozide	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	No	Unclassified*	Unclassified	Unclassified
103	Metam (incl. - potassium and - sodium)	No	Yes	No	Yes	No	No	No	No	No	Unclassified	ED	ED
104	Flupyrsulfuron-methyl (DPX KE 459)	No	Yes	No	Yes	No	No	No	No	No	Unclassified	ED	ED
105	Florasulam	No	No	No	No	No	No	No	No	No	Unclassified	Unclassified	Unclassified
106	8-Hydroxyquinoline incl. oxyquinoleine	No	Not relevant	Yes	Not relevant	No	Not relevant	No	Not relevant	Yes	ED	Not relevant	ED
107	Spirodiclofen	Not relevant	Yes	Not relevant	No	Not relevant	No	Not relevant	No	Yes	Unclassified*	Unclassified	Unclassified
108	Dimoxystrobin	Yes	Not relevant	Yes	Not relevant	No	Not relevant	No	Not relevant	Yes	ED	Not relevant	ED
109	Aminopyralid	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	No	Unclassified*	Unclassified	Unclassified

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110	Dichlorprop-P	No	No	No	No	No	No	No	No	No	Unclassified	Not relevant	Unclassified
111	Napropamide	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	No	Unclassified*	Unclassified	Unclassified
112	Mepiquat	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	No	Unclassified*	Unclassified	Unclassified
113	Emamectin	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	No	Unclassified*	Unclassified	Unclassified
115	Flonicamid (IKI-220)	No	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	Yes	Unclassified	Not relevant	Unclassified
116	Dodemorph	No	Not relevant	Yes	Not relevant	No	Not relevant	No	Not relevant	No	Unclassified	Not relevant	Unclassified
117	Carbetamide	Yes	Not relevant	No	Not relevant	No	Not relevant	Yes	Not relevant	Yes	ED - Cut off criteria are applicable / Repr Cat 1A/B	Not relevant	ED
118	Ethephon	No	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	Unclassified	Not relevant	Unclassified
119	Methomyl	No	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	Unclassified	Not relevant	Unclassified
120	Chloridazon (aka pyrazone)	No	No	No	No	No	No	No	No	No	Unclassified	Unclassified	Unclassified
121	Clopyralid	No	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	Unclassified	Not relevant	Unclassified
123	Prothioconazole	Not relevant	No	Not relevant	Yes	Not relevant	No	Not relevant	No	Yes	Unclassified*	ED	ED
124	Cyflufenamid	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	No	Unclassified*	Unclassified	Unclassified
125	Penthiopyrad	Not relevant	Yes	Not relevant	No	Not relevant	No	Not relevant	No	Yes	Unclassified*	Unclassified	Unclassified
126	Benfluralin	Not relevant	Yes	Not relevant	No	Not relevant	No	Not relevant	No	No	Unclassified*	Unclassified	Unclassified
127	Spinetoram	Not relevant	No	Not relevant	Yes	Not relevant	No	Not relevant	No	No	Unclassified*	Unclassified	Unclassified
128	Proquinazid	Yes	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	Yes	Unclassified	Not relevant	Unclassified
129	Oryzalin	Not relevant	Yes	Not relevant	No	Not relevant	No	Not relevant	No	Yes	Unclassified*	Unclassified	Unclassified
130	Dicamba	No	No	No	No	No	No	No	No	No	Unclassified	Unclassified	Unclassified
131	Picloram	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	No	Unclassified*	Unclassified	Unclassified

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132	Oxadiazon	No	No	No	Yes	No	No	No	No	No	Unclassified	Unclassified	Unclassified
134	Spirotetramat	No	Not relevant	Yes	Not relevant	No	Not relevant	No	Not relevant	Yes	ED	Not relevant	ED
135	Metribuzin	No	No	No	Yes (?)	No	No	No	No	Yes	Unclassified	ED (?)	ED (?)
137	Lenacil	Not relevant	Yes	Not relevant	No	Not relevant	No	Not relevant	No	Yes	Unclassified*	Unclassified	Unclassified
138	Fluometuron	Not relevant	Yes	Not relevant	No	Not relevant	No	Not relevant	No	No	Unclassified*	Unclassified	Unclassified
139	Penoxsulam	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	No	Unclassified*	Unclassified	Unclassified
140	Metrafenone	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	No	Unclassified*	Unclassified	Unclassified
141	Fenamiphos (aka phenamiphos)	No	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	Unclassified	Not relevant	Unclassified
142	Formetanate	No	No	No	No	No	No	No	No	No	Unclassified	Unclassified	Unclassified
143	Tri-allate	No	No	No	No	No	No	No	No	No	Unclassified	Unclassified	Unclassified
144	Pirimicarb	No	No	No	No	No	No	No	No	No	Unclassified	Unclassified	Unclassified
145	Oxamyl	No	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	Unclassified	Not relevant	Unclassified
146	Fluopicolide	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	No	Unclassified*	Unclassified	Unclassified
147	Propamocarb	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	No	Unclassified*	Unclassified	Unclassified
148	Bentazone	No	No	No	No	No	No	No	No	No	Unclassified	Unclassified	Unclassified
149	Etridiazole	Yes	Yes	No	No	No	No	No	No	Yes	Unclassified	Unclassified	Unclassified
150	Quinoclamine	Not relevant	No	Not relevant	Yes	Not relevant	No	Not relevant	No	Yes	Unclassified*	ED	ED
151	Valifenalate (formerly Valiphenal)	Not relevant	Yes	Not relevant	No	Not relevant	No	Not relevant	No	Yes	Unclassified*	Unclassified	Unclassified
152	Spiromesifen	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	Yes	Unclassified*	Unclassified	Unclassified
153	2,5-Dichlorobenzoic acid methylester	No	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	Unclassified	Not relevant	Unclassified
154	Pirimiphos-methyl	No	Yes	No	No	No	No	No	No	No	Unclassified	Unclassified	Unclassified

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156	Metobromuron	Not relevant	Yes	Not relevant	No	Not relevant	No	Not relevant	No	Yes	Unclassified*	Unclassified	Unclassified
157	1-Methyl-cyclopropene	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	No	Unclassified*	Unclassified	Unclassified
158	Thiencarbazon	Not relevant	Yes(?)	Not relevant	No	Not relevant	No	Not relevant	No	No	Unclassified*	Unclassified	Unclassified
159	Diuron	Yes	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	Yes	Unclassified	Not relevant	Unclassified
160	Dithianon	No	Yes	No	No	No	No	No	No	No	Unclassified	Unclassified	Unclassified
161	Tembotrione	No	Not relevant	Yes	Not relevant	No	Not relevant	No	Not relevant	Yes	ED	Not relevant	ED
162	Isoproturon	Yes	Yes	No	Yes	No	No	No	No	Yes	Unclassified	ED	ED
163	Amisulbrom	Yes	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	Unclassified	Not relevant	Unclassified
164	Imazalil (aka enilconazole)	Yes	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	Yes	Unclassified	Not relevant	Unclassified
165	Fluoxastrobin	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	No	Unclassified*	Unclassified	Unclassified
167	Mandipropamid	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	No	Unclassified*	Unclassified	Unclassified
168	Fuberidazole	Yes	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	Unclassified	Not relevant	Unclassified
169	Fosetyl [same as Fosetyl-Al]	No	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	Unclassified	Not relevant	Unclassified
170	Cyflumetofen	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	Yes	Unclassified*	Unclassified	Unclassified
171	Benthiavalicarb [same as benthiavalicarb-isopropyl CAS No. 177406-68-7]	Not relevant	Yes	Not relevant	Yes (?)	Not relevant	No	Not relevant	No	Yes	Unclassified*	ED (?)	ED (?)
172	Metamitron	No	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	Yes	Unclassified	Not relevant	Unclassified
173	Bupirimate	Yes	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	Unclassified	Not relevant	Unclassified
174	Pyroxulam	No	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	Unclassified	Not relevant	Unclassified
175	Bifenox	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	No	Unclassified*	Unclassified	Unclassified
176	Oxyfluorfen	Not relevant	Yes	Not relevant	No	Not relevant	No	Not relevant	No	No	Unclassified*	Unclassified	Unclassified

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178	Fenpyrazamine	No	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	Unclassified	Not relevant	Unclassified
179	Penflufen	Not relevant	Yes	Not relevant	No	Not relevant	No	Not relevant	No	Yes	Unclassified*	Cut off criteria are applicable / Carc Cat 2	Cut off criteria are applicable / Carc Cat 2
180	Chlorantraniliprole	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	No	Unclassified*	Unclassified	Unclassified
181	Dimethachlor	No	Yes	No	No	No	No	No	No	No	Unclassified	Unclassified	Unclassified
182	Ascorbic acid	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	No	Unclassified*	Unclassified	Unclassified
183	Glufosinate [same as glufosinate ammonium CAS No. 77182-82-2]	No	Not relevant	No	Not relevant	No	Not relevant	Yes	Not relevant	No	Cut off criteria are applicable / Repr Cat 1A	Not relevant	Cut off criteria are applicable / Repr Cat 1A
184	Diclofop [same as diclofop-methyl CAS No.257-141-8]	No	No	No	No	No	No	No	No	No	Unclassified	Unclassified	Unclassified
185	Carboxin	Not relevant	Yes	Not relevant	No	Not relevant	No	Not relevant	No	Yes	Unclassified*	Unclassified	Unclassified
186	Prosulfocarb	No	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	Unclassified	Not relevant	Unclassified
187	Pyrimethanil	No	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	Unclassified	Not relevant	Unclassified
188	Triadimenol	Not relevant	No	Not relevant	Yes	Not relevant	No	Not relevant	No	Yes	Unclassified*	ED	ED
189	Triclopyr [a second variant of Triclopyr: 3,5,6-trichloro-2-pyridyloxy-2-butoxyethyl ester CAS No:]	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	Yes	No	Unclassified*	Cut off criteria are applicable / Repr Cat 1A/B	Cut off criteria are applicable / Repr Cat 1A/B

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	064700-56-7]												
190	Pyridate	No	No	No	No	No	No	No	No	No	Unclassified	Unclassified	Unclassified
191	Tolclofos-methyl	No	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	Yes	Unclassified	Not relevant	Unclassified
192	Urea	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	No	Unclassified*	Unclassified	Unclassified
193	1,4-Dimethylnaphthalene	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	No	Unclassified*	Unclassified	Unclassified
194	Acequinocyl	No	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	Unclassified	Not relevant	Unclassified
195	Cymoxanil	No	Not relevant	Yes	Not relevant	No	Not relevant	No	Not relevant	Yes	ED	Not relevant	ED
196	Bixafen	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	Yes	Unclassified*	Unclassified	Unclassified
197	Terbutylazine	Yes	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	Yes	Unclassified	Not relevant	Unclassified
198	Trimethylamine hydrochloride	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	No	Unclassified*	Unclassified	Unclassified
199	Dimethoate	No	No	No	No	No	No	No	No	No	Unclassified	Unclassified	Unclassified
200	Meptyldinocap [same as DE-126]	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	Yes	Unclassified*	Unclassified	Unclassified
201	Flurochloridone	Not relevant	No	Not relevant	Yes	Not relevant	No	Not relevant	Yes	Yes	Unclassified*	ED - Cut off criteria are applicable / Repr Cat 1A/B	ED - Cut off criteria are applicable / Repr Cat 1A/B
202	Amitrole (aminotriazole)	No	No	Yes	No	No	No	No	Yes	Yes	ED	ED - Cut off criteria are applicable / Repr Cat 1A/B	ED - Cut off criteria are applicable / Repr Cat 1A/B

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206	Chlorsulfuron	No	Yes	No	No	No	No	No	No	Yes	Unclassified	Unclassified	Unclassified
207	Fluopyram	No	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	Yes	Unclassified	Not relevant	Unclassified
208	Pencycuron	No	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	Unclassified	Not relevant	Unclassified
209	Cyromazine	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	No	Unclassified*	Unclassified	Unclassified
210	Esfenvalerate	No	Yes	No	No	No	No	No	No	Yes	Unclassified	Unclassified	Unclassified
211	Penconazole	No	Not relevant	Yes	Not relevant	No	Not relevant	No	Not relevant	No	Unclassified	Not relevant	Unclassified
212	Flutolanil	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	No	Unclassified*	Unclassified	Unclassified
213	Metazachlor	Yes	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	Yes	Unclassified	Not relevant	Unclassified
214	Fenpropidin	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	No	Unclassified*	Unclassified	Unclassified
215	Prochloraz	No	Yes	No	Yes	No	No	No	No	Yes	Unclassified	ED	ED
216	Triflumizole	No	Not relevant	No	Not relevant	No	Not relevant	Yes	Not relevant	Yes	ED - Cut off criteria are applicable / Repr Cat 1A/B	Not relevant	ED - Cut off criteria are applicable / Repr Cat 1A/B
217	Pyriofenone	Not relevant	Yes	Not relevant	No	Not relevant	No	Not relevant	No	No	Unclassified*	Unclassified	Unclassified
218	Buprofezin	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	Yes	Unclassified*	Unclassified	Unclassified
219	Fluroxypyr	No	No	No	No	No	No	No	No	No	Unclassified	Unclassified	Unclassified
220	Chlormequat	No	No	No	No	No	No	No	No	No	Unclassified	Unclassified	Unclassified
221	Metalaxyl-M	No	No	No	No	No	No	No	No	Yes	Unclassified	Unclassified	Unclassified
222	Triazoxide	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	No	Unclassified*	Unclassified	Unclassified
224	Phosmet	No	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	Unclassified	Not relevant	Unclassified
225	Aclonifen	Yes	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	Unclassified	Not relevant	Unclassified
226	Clofentezine	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	No	Unclassified*	Unclassified	Unclassified
227	Metsulfuron-methyl	No	No	No	No	No	No	No	No	No	Unclassified	Unclassified	Unclassified
230	Flutriafol	Not relevant	No	Not relevant	Yes	Not relevant	No	Not relevant	No	No	Unclassified*	Unclassified	Unclassified

The results of the screening do not constitute evaluations of individual substances to be carried out under the respective chemical legislations [[in particular, Regulation (EC) No 1107/2009 on plant protection products, Regulation (EU) No 528/2012 on biocidal products, Regulation (EC) No 1907/2006 REACH, Regulation (EC) No 1223/2009 on cosmetic products and the Water Framework Directive (EC) No 2000/60] and in no way prejudice future decisions on active substances to be taken pursuant to these pieces of the EU legislation.

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231	Gamma-cyhalothrin	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	No	Unclassified*	Unclassified	Unclassified
232	Paclobotrazol	Not relevant	No	Not relevant	Yes	Not relevant	No	Not relevant	No	No	Unclassified*	Unclassified	Unclassified
237***	Phosphane	No	No	No	No	No	No	No	No	No	Unclassified	Unclassified	Unclassified
238	Hexythiazox	No	No	No	No	No	No	No	No	Yes	Unclassified	Unclassified	Unclassified
239	Thifensulfuron-methyl	No	No	No	Yes	No	No	No	No	Yes	Unclassified	ED	ED
240	Tefluthrin	No	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	Unclassified	Not relevant	Unclassified
241	Fluazinam	No	Not relevant	Yes	Not relevant	No	Not relevant	No	Not relevant	Yes	ED	Not relevant	ED
243	Imazaquin	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	No	Unclassified*	Unclassified	Unclassified
244	Clomazone	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	No	Unclassified*	Unclassified	Unclassified
245	Triasulfuron	No	No	No	No	No	No	No	No	No	Unclassified	Unclassified	Unclassified
246	Isoxaben	No	No	No	No	No	No	No	No	No	Unclassified	Unclassified	Unclassified
247	Bensulfuron methyl	No	No	No	No	No	No	No	No	No	Unclassified	Unclassified	Unclassified
248	Fluazifop-P	No	No	Yes	Yes	No	No	No	No	Yes	ED	ED	ED
249	Teflubenzuron	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	No	Unclassified*	Unclassified	Unclassified
250	Diflufenican	No	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	Yes	Unclassified	Not relevant	Unclassified
251	1-Naphthylacetamide (1-NAD)	Not relevant	No	Not relevant	Yes	Not relevant	No	Not relevant	No	Yes	Unclassified*	ED	ED
252	1-Naphthylacetic acid (1-NAA)	Not relevant	No	Not relevant	Yes	Not relevant	No	Not relevant	No	Yes	Unclassified*	ED	ED
253	Heptamaloxylog lucan	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	No	Unclassified*	Unclassified	Unclassified
254	Diethofencarb	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	Yes	Unclassified*	Unclassified	Unclassified
255	Sedaxane	Not relevant	Yes	Not relevant	No	Not relevant	No	Not relevant	No	No	Unclassified*	Unclassified	Unclassified
256	Tralkoxydim	Yes	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	Yes	Unclassified	Not relevant	Unclassified
257	Isopyrazam	Not relevant	Yes	Not relevant	Yes	Not relevant	No	Not relevant	No	Yes	Unclassified*	ED	ED

The results of the screening do not constitute evaluations of individual substances to be carried out under the respective chemical legislations [[in particular, Regulation (EC) No 1107/2009 on plant protection products, Regulation (EU) No 528/2012 on biocidal products, Regulation (EC) No 1907/2006 REACH, Regulation (EC) No 1223/2009 on cosmetic products and the Water Framework Directive (EC) No 2000/60] and in no way prejudice future decisions on active substances to be taken pursuant to these pieces of the EU legislation.

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258	Myclobutanil	No	No	Yes	Yes	No	No	No	No	Yes	ED	ED	ED
259	Thymol	No	No	No	No	No	No	No	No	No	Unclassified	Unclassified	Unclassified
261	Quinmerac	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	No	Unclassified*	Unclassified	Unclassified
262	Fluxapyroxad	Not relevant	Yes	Not relevant	No	Not relevant	No	Not relevant	No	No	Unclassified*	Unclassified	Unclassified
263	Prosulfuron	No	No	No	No	No	No	No	No	Yes	Unclassified	Unclassified	Unclassified
264	2,4-D	No	No	No	No	No	No	No	No	Yes	Unclassified	Unclassified	Unclassified
265	Haloxypop-P (Haloxypop-R)	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	No	Unclassified*	Unclassified	Unclassified
266	Pyridaben	No	No	No	No	No	No	No	No	Yes	Unclassified	Unclassified	Unclassified
267	Eugenol	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	No	Unclassified*	Unclassified	Unclassified
269	Benalaxyl-M	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	No	Unclassified*	Unclassified	Unclassified
270	Sulcotrione	No	Not relevant	Yes	Not relevant	No	Not relevant	No	Not relevant	No	Unclassified	Not relevant	Unclassified
271	Clethodim	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	Yes	Unclassified*	Unclassified	Unclassified
290	Repellents by smell of animal or plant origin/ sheep fat	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	No	Unclassified*	Unclassified	Unclassified
291	Repellents by smell of animal or plant origin/ tall oil crude	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	No	Unclassified*	Unclassified	Unclassified
292	Repellents by smell of animal or plant origin/ tall oil pitch	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	No	Unclassified*	Unclassified	Unclassified
293	Sea-algae extract (formerly sea-algae extract and seaweeds)	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	No	Unclassified*	Unclassified	Unclassified
294	Clothianidin	No	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	Yes	Unclassified	Not relevant	Unclassified

The results of the screening do not constitute evaluations of individual substances to be carried out under the respective chemical legislations [[in particular, Regulation (EC) No 1107/2009 on plant protection products, Regulation (EU) No 528/2012 on biocidal products, Regulation (EC) No 1907/2006 REACH, Regulation (EC) No 1223/2009 on cosmetic products and the Water Framework Directive (EC) No 2000/60] and in no way prejudge future decisions on active substances to be taken pursuant to these pieces of the EU legislation.

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295	Propiconazole	No	No	No	No	No	No	No	No	No	Unclassified	Unclassified	Unclassified
296	Thiacloprid	Yes	Not relevant	No	Not relevant	No	Not relevant	Yes	Not relevant	Yes	ED - Cut off criteria are applicable / Repr Cat 1A/B	Not relevant	ED - Cut off criteria are applicable / Repr Cat 1A/B
297	Pelargonic acid (Nonanoic acid)	No	No	No	No	No	No	No	No	No	Unclassified	Unclassified	Unclassified
298	Caprylic acid (Octanoic acid)	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	No	Unclassified*	Unclassified	Unclassified
299	Lauric acid	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	No	Unclassified*	Unclassified	Unclassified
300	Thiamethoxam	No	No	No	No	No	No	No	No	Yes	Unclassified	Unclassified	Unclassified
301	Spinosad	No	No	No	No	No	No	No	No	No	Unclassified	Unclassified	Unclassified
302	Copper hydroxide	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	No	Unclassified*	Unclassified	Unclassified
303	Capric acid (Decanoic acid)	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	No	Unclassified*	Unclassified	Unclassified
304	Cypermethrin	No	No	No	No	No	No	No	No	Yes	Unclassified	Unclassified	Unclassified
305	Deltamethrin	No	No	No	No	No	No	No	No	Yes	Unclassified	Unclassified	Unclassified
306	Benzoic acid	No	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	Yes	Unclassified	Not relevant	Unclassified
307	Alpha-Cypermethrin (aka alphamethrin)	No	No	No	No	No	No	No	No	No	Unclassified	Unclassified	Unclassified
308	Chlorpropham	Yes	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	Yes	Unclassified	Not relevant	Unclassified
309	Flazasulfuron	No	No	No	No	No	No	No	No	No	Unclassified	Unclassified	Unclassified
310	Mesotrione	No	No	No	No	No	No	No	No	No	Unclassified	Unclassified	Unclassified
311	Pethoxamid	No	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	Yes	Unclassified	Not relevant	Unclassified
312	Mepanipyrim	Yes	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	Unclassified	Not relevant	Unclassified
313	Methyl decanoate	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	No	Unclassified*	Unclassified	Unclassified

The results of the screening do not constitute evaluations of individual substances to be carried out under the respective chemical legislations [[in particular, Regulation (EC) No 1107/2009 on plant protection products, Regulation (EU) No 528/2012 on biocidal products, Regulation (EC) No 1907/2006 REACH, Regulation (EC) No 1223/2009 on cosmetic products and the Water Framework Directive (EC) No 2000/60] and in no way prejudge future decisions on active substances to be taken pursuant to these pieces of the EU legislation.

It would thus be erroneous to consider that the substances listed in the results of this study (SANTE/2015/E3/SI2.706218) are considered as endocrine disruptors within the meaning of the EU legislation.

	Chemical Name	Carc Cat. 2 (C&L Harmonised)	Carc Cat. 2 (C&L Proposed)	Repr. Cat. 2 (C&L Harmonised)	Repr. Cat. 2 (C&L Proposed)	Carc Cat. 1A or 1B (C&L Harmonised)	Carc Cat. 1A or 1B (C&L Proposed)	Repr. Cat. 1A or 1B (C&L Harmonised)	Repr. Cat. 1A or 1B (C&L Proposed)	Effects on Endocrine organs (YES/NO)	OPTION 1 Harmonized	OPTION 1 Proposed	OPTION 1 Most recent
314	Methyl octanoate	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	No	Unclassified*	Unclassified	Unclassified
319	Beflubutamid	No	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	Unclassified	Not relevant	Unclassified
320	Imazamox	No	No	No	No	No	No	No	No	No	Unclassified	Unclassified	Unclassified
321	Picoxystrobin	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	No	Unclassified*	Unclassified	Unclassified
322	Cyazofamid	No	No	No	No	No	No	No	No	No	Unclassified	Unclassified	Unclassified
323	Propineb	No	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	Yes	Unclassified	Not relevant	Unclassified
324	Imazosulfuron	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	No	Unclassified*	Unclassified	Unclassified
325	Maleic hydrazide	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	No	Unclassified*	Unclassified	Unclassified
326	Maneb	No	Not relevant	Yes	Not relevant	No	Not relevant	No	Not relevant	Yes	ED	Not relevant	ED
327	Quinoxifen	No	No	No	No	No	No	No	No	No	Unclassified	Unclassified	Unclassified
328	Carfentrazone-ethyl	No	No	No	No	No	No	No	No	No	Unclassified	Unclassified	Unclassified
331	Tribasic copper sulfate	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	No	Unclassified*	Unclassified	Unclassified
332	Acetamiprid	No	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	Unclassified	Not relevant	Unclassified
334	Desmedipham	No	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	Yes	Unclassified	Not relevant	Unclassified
335	Phenmedipham	No	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	Yes	Unclassified	Not relevant	Unclassified
336	Thiram	No	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	Yes	Unclassified	Not relevant	Unclassified
337	Ziram	No	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	Yes	Unclassified	Not relevant	Unclassified
338	Profoxydim	Yes	Not relevant	Yes	Not relevant	No	Not relevant	No	Not relevant	Yes	ED	Not relevant	ED
339	Isoxaflutole	No	No	Yes	Yes (?)	No	No	No	No	Yes	ED	ED (?)	ED (?)
340	Trifloxystrobin	No	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	Unclassified	Not relevant	Unclassified
341	Flufenacet (formerly fluthiamide)	No	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	Yes	Unclassified	Not relevant	Unclassified
342	Tritosulfuron	No	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	Yes	Unclassified	Not relevant	Unclassified

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343	Indoxacarb	No	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	Unclassified	Not relevant	Unclassified
344	Oxasulfuron	No	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	Yes	Unclassified	Not relevant	Unclassified
345	Propoxycarbazone	No	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	Unclassified	Not relevant	Unclassified
346	Bifenazate	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	No	Unclassified*	Unclassified	Unclassified
347	Tepaloxymidim	Yes	Not relevant	Yes	Not relevant	No	Not relevant	No	Not relevant	Yes	ED	Not relevant	ED
348	Etoxazole	No	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	Yes	Unclassified	Not relevant	Unclassified
349	Chlorotoluron	Yes	Not relevant	Yes	Not relevant	No	Not relevant	No	Not relevant	No	ED	Not relevant	ED
350	Zoxamide	No	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	Unclassified	Not relevant	Unclassified
351	Daminozide	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	No	Unclassified*	Unclassified	Unclassified
352	Methoxyfenozide	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	No	Unclassified*	Unclassified	Unclassified
353	Fenamidone	No	No	No	No	No	No	No	No	Yes	Unclassified	Unclassified	Unclassified
354	Dimethenamid-P	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	No	Unclassified*	Unclassified	Unclassified
355	Mecoprop-P	No	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	Unclassified	Not relevant	Unclassified
357	Bromoxynil	No	Not relevant	Yes	Not relevant	No	Not relevant	No	Not relevant	Yes	ED	Not relevant	ED
359	Foramsulfuron	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	No	Unclassified*	Unclassified	Unclassified
360	Pyraclostrobin	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	No	Unclassified*	Unclassified	Unclassified
361	Silthiofam	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	Yes	Unclassified*	Unclassified	Unclassified
362	S-Metolachlor	No	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	Unclassified	Not relevant	Unclassified
363	Pyridalyl	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	Yes	Unclassified*	Unclassified	Unclassified
364	Iodosulfuron	No	No	No	No	No	No	No	No	No	Unclassified	Unclassified	Unclassified
365	Boscalid (formerly nicobifen)	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	Yes	Unclassified*	Unclassified	Unclassified
366	Chlorothalonil	Yes	No	No	No	No	No	No	No	Yes	Unclassified	Unclassified	Unclassified
368	Thiophanate-methyl	No	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	Yes	Unclassified	Not relevant	Unclassified

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369	Propyzamide	No	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	Yes	Unclassified	Not relevant	Unclassified
370	Ethofumesate	No	No	No	No	No	No	No	No	Yes	Unclassified	Unclassified	Unclassified
371	Flubendiamide	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	Yes	Unclassified*	Unclassified	Unclassified
372	Diquat (dibromide)	Not relevant	No	Not relevant	Yes	Not relevant	No	Not relevant	No	No	Unclassified*	Unclassified	Unclassified
374	Chlorpyrifos	No	No	No	No	No	No	No	No	No	Unclassified	Unclassified	Unclassified
375	Linuron	Yes	Not relevant	No	Not relevant	No	Not relevant	Yes	Not relevant	Yes	ED - Cut off criteria are applicable / Repr Cat 1A/B	Not relevant	ED - Cut off criteria are applicable / Repr Cat 1A/B
379	Iprodione	Yes	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	Yes	Unclassified	Not relevant	Unclassified
382	Mesosulfuron	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	Yes	Unclassified*	Unclassified	Unclassified
383	Pendimethalin	No	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	Yes	Unclassified	Not relevant	Unclassified
384 [†]	Denathonium benzoate	-	-	-	-	-	-	-	-	-	-	-	-
385	Milbemectin	No	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	Yes	Unclassified	Not relevant	Unclassified
390	Chlorpyrifos-methyl	No	No	No	No	No	No	No	No	Yes	Unclassified	Unclassified	Unclassified
394	Sucrose	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	No	Unclassified*	Unclassified	Unclassified
395	Metalaxyl	No	No	No	No	No	No	No	No	Yes	Unclassified	Unclassified	Unclassified
398	Sodium 5-nitroguaiacolate	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	No	Unclassified*	Unclassified	Unclassified
400	Forchlorfenuron	Yes	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	Unclassified	Not relevant	Unclassified
401	Beta-Cyfluthrin	No	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	Yes	Unclassified	Not relevant	Unclassified
402	Benalaxyl	No	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	Unclassified	Not relevant	Unclassified
403	Mancozeb	No	Not relevant	Yes	Not relevant	No	Not relevant	No	Not relevant	Yes	Unclassified	Not relevant	Unclassified
404	Sodium o-	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	No	Unclassified*	Unclassified	Unclassified

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	nitrophenolate												
405	Sodium p-nitrophenolate	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	No	Unclassified*	Unclassified	Unclassified
407	Ametoctradin	Not relevant	No	Not relevant	Yes	Not relevant	No	Not relevant	No	No	Unclassified*	Unclassified	Unclassified
408	Metiram	Not relevant	No	Not relevant	Yes	Not relevant	No	Not relevant	No	Yes	Unclassified*	Unclassified	Unclassified
409	Laminarin	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	No	Unclassified*	Unclassified	Unclassified
411	Mecoprop	No	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	Unclassified	Not relevant	Unclassified
413	MCPA	No	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	Yes?	Unclassified	Not relevant	Unclassified
414	MCPB	No	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	Unclassified	Not relevant	Unclassified
415	2,4-DB	No	No	No	No	No	No	No	No	Yes	Unclassified	Unclassified	Unclassified
416	Flurtamone	No	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	Unclassified	Not relevant	Unclassified
417	Fosthiazate	No	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	yes	Unclassified	Not relevant	Unclassified
418	Carvone	No	No	No	No	No	No	No	No	No	Unclassified	Unclassified	Unclassified
426	Bordeaux mixture	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	No	Unclassified*	Unclassified	Unclassified
428	n-Tetradecylacetate	Not relevant	No	Not relevant	Yes	Not relevant	No	Not relevant	No	No	Unclassified*	Unclassified	Unclassified

Unclassified*: No harmonized classification available

**This substance was incorrectly marked also as a BP in the published list of substances to be screened.

*** This substance had been already screened when “list of substances to be screened” was published.

****This substance covers also the substance Quizalofop-P.

† This substance was initially included in the list of substances to be screened, but following the rational it was decided that the substance was not to be screened.

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Potential categorization results of the 348 PPPs under “Option 2, 3 & 4” for human health & vertebrate wildlife and combined potential categorization under all Options

	Chemical Name	Potential Categorization Human Health				Potential Categorization Wildlife				Combined Potential Categorization (HH & Wildlife Vertebrates)			
		OPTION 2	OPTION 3	Path of decision tree	OPTION 4	OPTION 2	OPTION 3	Path of decision tree	OPTION 4	OPTION 1 Most recent	OPTION 2	OPTION 3	OPTION 4
1	Carbon dioxide	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
2	Tebuconazole	ED	Cat I	2a, 2b	Unclassified	ED	Cat I	2a, 2b	Unclassified	ED	ED	Cat I	Unclassified
3	Methyl nonyl ketone	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
4	Fipronil	Unclassified	Cat II	5	Unclassified	Unclassified	Cat II	3b	Unclassified	Unclassified	Unclassified	Cat II	Unclassified
5	Magnesium phosphide	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
6	Imidacloprid	Unclassified	Cat III	10	Unclassified	Unclassified	Cat III	10	Unclassified	Unclassified	Unclassified	Cat III	Unclassified
7	Thiabendazole	Unclassified	Cat II	3b	Unclassified	Unclassified	Cat II	3b	Unclassified	Unclassified	Unclassified	Cat II	Unclassified
8	Aluminium phosphide	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
9	Sulfuryl fluoride	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
10	Bromadiolone	Unclassified	Unclassified	8	Unclassified	Unclassified	Unclassified	8	Unclassified	Cut off criteria are applicable / Repr Cat 1A/B	Unclassified	Unclassified	Unclassified
11	Diflubenzuron	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
12	Dazomet	Unclassified	Cat II	3b	Unclassified	Unclassified	Cat II	3b	Unclassified	ED	Unclassified	Cat II	Unclassified
13	Difenacoum	Unclassified	Cat II	3a	Unclassified	Unclassified	Cat II	3a	Unclassified	ED / Cut off criteria are applicable / Repr Cat 1A/B	Unclassified	Cat II	Unclassified
14	Fenpropimorph	Unclassified	Unclassified	8	Unclassified	Unclassified	Unclassified	8	Unclassified	ED	Unclassified	Unclassified	Unclassified

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		Potential Categorization Human Health				Potential Categorization Wildlife				Combined Potential Categorization (HH & Wildlife Vertebrates)			
	Chemical Name	OPTION 2	OPTION 3	Path of decision tree	OPTION 4	OPTION 2	OPTION 3	Path of decision tree	OPTION 4	OPTION 1 Most recent	OPTION 2	OPTION 3	OPTION 4
15	Abamectin (aka avermectin)	Unclassified	Cat II	3a	Unclassified	Unclassified	Cat II	3a	Unclassified	ED	Unclassified	Cat II	Unclassified
16	Fenoxycarb	Unclassified	Cat III	7	Unclassified	Unclassified	Cat III	7	Unclassified	Unclassified	Unclassified	Cat III	Unclassified
17	Etofenprox	Unclassified	Cat III	7	Unclassified	Unclassified	Cat III	7	Unclassified	Unclassified	Unclassified	Cat III	Unclassified
18	Bifenthrin	Unclassified	Cat III	7	Unclassified	Unclassified	Cat II	5	Unclassified	Unclassified	Unclassified	Cat II	Unclassified
19	lambda-Cyhalothrin	Unclassified	Cat II	5 & 6	Unclassified	Unclassified	Cat II	5 & 6	Unclassified	Unclassified	Unclassified	Cat II	Unclassified
20	Cyproconazole	Unclassified	Cat II	3b	Unclassified	ED	Cat I	2a & 2b	ED	ED - Cut off criteria are applicable / Repr Cat 1A/B	ED	Cat I	ED
21	Pyriproxyfen	Unclassified	Cat II	3b	Unclassified	Unclassified	Cat II	3b	Unclassified	Unclassified	Unclassified	Cat II	Unclassified
22	Folpet	Unclassified	Cat III	7	Unclassified	Unclassified	Cat III	7	Unclassified	Unclassified	Unclassified	Cat III	Unclassified
23**	Triflumuron	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
24**	2-Phenylphenol (incl. sodium salt orthophenyl phenol)	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	8	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
25	Hymexazol	Unclassified	Cat II	3a	Unclassified	Unclassified	Cat II	3a	Unclassified	ED	Unclassified	Cat II	Unclassified
27	Aluminium sulphate	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
28	Ferric phosphate	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
29****	Quizalofop-P-ethyl	Unclassified	Cat II	3a	Unclassified	Unclassified	Cat II	3a	Unclassified	Unclassified	Unclassified	Cat II	Unclassified

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30	Halosulfuron methyl	Unclassified	Unclassified	8	Unclassified	Unclassified	Unclassified	8	Unclassified	ED	Unclassified	Unclassified	Unclassified
31	Acrinathrin	Unclassified	Cat II	3a	Unclassified	Unclassified	Cat II	3a	Unclassified	Unclassified	Unclassified	Cat II	Unclassified
32	Cycloxydim	Unclassified	Cat II	3a	Unclassified	Unclassified	Cat II	3a	Unclassified	ED	Unclassified	Cat II	Unclassified
34	tau-Fluvalinate	Unclassified	Cat III	10	Unclassified	Unclassified	Cat III	10	Unclassified	Unclassified	Unclassified	Cat III	Unclassified
35	Lufenuron	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
36	Flumioxazin	Unclassified	Cat III	7	Unclassified	Unclassified	Cat III	7	Unclassified	Cut off criteria are applicable / Repr Cat 1A/B	Unclassified	Cat III	Unclassified
37	Tribenuron (aka metometuron)	Unclassified	Cat III	7	Unclassified	Unclassified	Cat III	7	Unclassified	Unclassified	Unclassified	Cat III	Unclassified
38	Geraniol	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
39	Glyphosate (incl trimesium aka sulfosate)	Unclassified	Cat II	3a	Unclassified	Unclassified	Cat II	3a	Unclassified	Unclassified	Unclassified	Cat II	Unclassified
40	Metaldehyde	Unclassified	Cat II	3a	Unclassified	Unclassified	Cat II	3a	Unclassified	Unclassified	Unclassified	Cat II	Unclassified
41	Dimethomorph	Unclassified	Cat II	3a	Unclassified	Unclassified	Cat II	3a	Unclassified	Unclassified	Unclassified	Cat II	Unclassified
42***	Putrescine (1,4-Diaminobutane)	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
43	Azadirachtin	Unclassified	Cat II	3a	Unclassified	Unclassified	Cat II	3a	Unclassified	Unclassified	Unclassified	Cat II	Unclassified
44	Propaquizafop	Unclassified	Cat II	3a	Unclassified	Unclassified	Cat II	3a	Unclassified	Unclassified	Unclassified	Cat II	Unclassified
45	Nicosulfuron	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
46	Tetraconazole	ED	Cat I	2b	Unclassified	ED	Cat I	2b	ED	Unclassified	ED	Cat I	ED

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		Potential Categorization Human Health				Potential Categorization Wildlife				Combined Potential Categorization (HH & Wildlife Vertebrates)			
	Chemical Name	OPTION 2	OPTION 3	Path of decision tree	OPTION 4	OPTION 2	OPTION 3	Path of decision tree	OPTION 4	OPTION 1 Most recent	OPTION 2	OPTION 3	OPTION 4
47	1-Decanol	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
48	Tebufenozide	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
49	Dodine	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
50	Fenoxaprop-P	Unclassified	Cat III	7	Unclassified	Unclassified	Cat III	7	Unclassified	Unclassified	Unclassified	Cat III	Unclassified
51	Fenbuconazole	Unclassified	Cat II	5 & 6	Unclassified	Unclassified	Cat II	5 & 6	Unclassified	ED	Unclassified	Cat II	Unclassified
52	Clodinafop	Unclassified	Cat II	3a, 3b	Unclassified	Unclassified	Cat II	3a, 3b	Unclassified	Unclassified	Unclassified	Cat II	Unclassified
53	Bromuconazole	Unclassified	Cat II	3a	Unclassified	Unclassified	Cat II	3a	Unclassified	Unclassified	Unclassified	Cat II	Unclassified
54	Spiroxamine	Unclassified	Cat II	3a	Unclassified	Unclassified	Cat II	3a	Unclassified	ED	Unclassified	Cat II	Unclassified
55	Tebufenpyrad	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
56	Difenoconazole	Unclassified	Cat III	10	Unclassified	Unclassified	Cat III	10	Unclassified	Unclassified	Unclassified	Cat III	Unclassified
57****	Quizalofop-P-tefuryl	Unclassified	Cat II	3a	Unclassified	Unclassified	Cat II	3a	Unclassified	ED	Unclassified	Cat II	Unclassified
59	Azimsulfuron	Unclassified	Cat II	3a	Unclassified	Unclassified	Cat II	3a	Unclassified	Unclassified	Unclassified	Cat II	Unclassified
60	Amidosulfuron	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
61	Fenazaquin	Unclassified	Cat II	3a	Unclassified	Unclassified	Cat II	3a	Unclassified	Unclassified	Unclassified	Cat II	Unclassified
62	Pyrethrins	Unclassified	Unclassified	8	Unclassified	Unclassified	Unclassified	8	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
63	6-Benzyladenine	Unclassified	Unclassified	8	Unclassified	Unclassified	Unclassified	8	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
64	Cyprodinil	Unclassified	Cat III	10	Unclassified	Unclassified	Cat III	10	Unclassified	Unclassified	Unclassified	Cat III	Unclassified
65	Malathion	ED	Cat I	2a	ED	ED	Cat I	2a	ED	Unclassified	ED	Cat I	ED
66	Cyhalofop-butyl	Unclassified	Cat III	10	Unclassified	Unclassified	Cat III	10	Unclassified	Unclassified	Unclassified	Cat III	Unclassified
67	Rimsulfuron (aka renriduron)	Unclassified	Cat II	3a	Unclassified	Unclassified	Cat II	3a	Unclassified	Unclassified	Unclassified	Cat II	Unclassified
68	Pymetrozine	Unclassified	Cat II	3a, 3b	Unclassified	Unclassified	Cat II	3a, 3b	Unclassified	ED	Unclassified	Cat II	Unclassified

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	Chemical Name	Potential Categorization Human Health				Potential Categorization Wildlife				Combined Potential Categorization (HH & Wildlife Vertebrates)			
		OPTION 2	OPTION 3	Path of decision tree	OPTION 4	OPTION 2	OPTION 3	Path of decision tree	OPTION 4	OPTION 1 Most recent	OPTION 2	OPTION 3	OPTION 4
69	Metconazole	Unclassified	Unclassified	8	Unclassified	Unclassified	Unclassified	8	Unclassified	ED	Unclassified	Unclassified	Unclassified
70	Ipconazole	Unclassified	Cat II	3a	Unclassified	Unclassified	Cat II	3a	Unclassified	ED	Unclassified	Cat II	Unclassified
71	Bispyribac	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
72	Fenhexamid	Unclassified	Cat II	3b	Unclassified	Unclassified	Cat II	3b	Unclassified	Unclassified	Unclassified	Cat II	Unclassified
73	Prohexadione	Unclassified	Cat II	3a	Unclassified	Unclassified	Cat II	3a	Unclassified	Unclassified	Unclassified	Cat II	Unclassified
74	Pyraflufen-ethyl	Unclassified	Cat II	3b	Unclassified	Unclassified	Cat II	3b	Unclassified	Unclassified	Unclassified	Cat II	Unclassified
75	Sintofen (aka Cintofen)	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
76	Calcium phosphide	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
77	Fludioxonil	Unclassified	Cat III	10	Unclassified	Unclassified	Cat III	10	Unclassified	Unclassified	Unclassified	Cat III	Unclassified
78	Zinc phosphide	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
79	zeta-Cypermethrin	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
80	Limestone	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
81	Famoxadone	Unclassified	Cat III	10	Unclassified	Unclassified	Cat III	10	Unclassified	Unclassified	Unclassified	Cat III	Unclassified
82	Azoxystrobin	Unclassified	Cat III	10	Unclassified	Unclassified	Cat III	10	Unclassified	Unclassified	Unclassified	Cat III	Unclassified
83	Ethoprophos	Unclassified	Unclassified	8	Unclassified	Unclassified	Unclassified	8	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
84	Triticonazole	Unclassified	Cat II	3a	Unclassified	Unclassified	Cat II	3a	Unclassified	Unclassified	Unclassified	Cat II	Unclassified
85	Captan	Unclassified	Cat III	7	Unclassified	Unclassified	Cat III	7	Unclassified	ED (?)	Unclassified	Cat III	Unclassified
86	Indolylbutyric acid	Unclassified	Cat II	3a	Unclassified	Unclassified	Cat II	3a	Unclassified	ED	Unclassified	Cat II	Unclassified

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	Chemical Name	Potential Categorization Human Health				Potential Categorization Wildlife				Combined Potential Categorization (HH & Wildlife Vertebrates)			
		OPTION 2	OPTION 3	Path of decision tree	OPTION 4	OPTION 2	OPTION 3	Path of decision tree	OPTION 4	OPTION 1 Most recent	OPTION 2	OPTION 3	OPTION 4
87	Epoxiconazole	ED	Cat I	2a/2b	ED	ED	Cat I	1/2a/2b	ED	ED - Cut off criteria are applicable / Repr Cat 1A/B	ED	Cat I	ED
88	Fenpyroximate	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
90	Acibenzolar-S-methyl (benzothiadiazole)	Unclassified	Unclassified	8	Unclassified	Unclassified	Unclassified	8	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
91	Triflurosulfuron	ED	Cat I	4	Unclassified	ED	Cat I	4	Unclassified	Unclassified	ED	Cat I	Unclassified
92	Fluquinconazole	Unclassified	Unclassified	8	Unclassified	Unclassified	Unclassified	8	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
93	Disodium phosphonate	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
94	Picolinafen	Unclassified	Cat II	3a	Unclassified	Unclassified	Unclassified	8	Unclassified	Unclassified	Unclassified	Cat II	Unclassified
95	Metosulam	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
96***	Potassium phosphonates (formerly potassium phosphite)	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
97	Metaflumizone	Unclassified	Unclassified	8	Unclassified	Unclassified	Unclassified	8	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
98	Iprovalicarb	Unclassified	Unclassified	8	Unclassified	Unclassified	Unclassified	8	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
99	Sulfosulfuron	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
100	Trinexapac (aka cimeta carb ethyl)	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified

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	Chemical Name	OPTION 2	OPTION 3	Path of decision tree	OPTION 4	OPTION 2	OPTION 3	Path of decision tree	OPTION 4	OPTION 1 Most recent	OPTION 2	OPTION 3	OPTION 4
101	Kresoxim-methyl	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
102	Chromafenozide	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
103	Metam (incl. -potassium and -sodium)	Unclassified	Unclassified	8	Unclassified	Unclassified	Unclassified	8	Unclassified	ED	Unclassified	Unclassified	Unclassified
104	Flupyrsulfuron-methyl (DPX KE 459)	Unclassified	Unclassified	8	Unclassified	Unclassified	Unclassified	8	Unclassified	ED	Unclassified	Unclassified	Unclassified
105	Florasulam	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
106	8-Hydroxyquinoline incl. oxyquinoleine	ED	Cat I	2b	ED	ED	Cat I	2b	ED	ED	ED	Cat I	ED
107	Spirodiclofen	ED	Cat I	2a	ED	ED	Cat I	2a	ED	Unclassified	ED	Cat I	ED
108	Dimoxystrobin	Unclassified	Unclassified	8	Unclassified	Unclassified	Unclassified	8	Unclassified	ED	Unclassified	Unclassified	Unclassified
109	Aminopyralid	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
110	Dichlorprop-P	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
111	Napropamide	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
112	Mepiquat	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
113	Emamectin	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
115	Fonicamid (IKI-220)	Unclassified	Cat II	3a	Unclassified	Unclassified	Cat II	3a	Unclassified	Unclassified	Unclassified	Cat II	Unclassified
116	Dodemorph	Unclassified	Unclassified	8	Unclassified	Unclassified	Unclassified	8	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified

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	Chemical Name	OPTION 2	OPTION 3	Path of decision tree	OPTION 4	OPTION 2	OPTION 3	Path of decision tree	OPTION 4	OPTION 1 Most recent	OPTION 2	OPTION 3	OPTION 4
117	Carbetamide	Unclassified	Cat II	3a	Unclassified	Unclassified	Cat II	3a	Unclassified	ED	Unclassified	Cat II	Unclassified
118	Ethephon	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
119	Methomyl	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	8	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
120	Chloridazon (aka pyrazone)	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
121	Clopyralid	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
123	Prothioconazole	Unclassified	Cat II	3b	Unclassified	Unclassified	Cat II	3b	Unclassified	ED	Unclassified	Cat II	Unclassified
124	Cyflufenamid	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
125	Penthiopyrad	Unclassified	Cat II	3a	Unclassified	Unclassified	Cat II	3a	Unclassified	Unclassified	Unclassified	Cat II	Unclassified
126	Benfluralin	Unclassified	Cat III	10	Unclassified	Unclassified	Cat III	7	Unclassified	Unclassified	Unclassified	Cat III	Unclassified
127	Spinetoram	Unclassified	Unclassified	8	Unclassified	Unclassified	Unclassified	8	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
128	Proquinazid	Unclassified	Cat II	3a	Unclassified	Unclassified	Cat II	3a	Unclassified	Unclassified	Unclassified	Cat II	Unclassified
129	Oryzalin	Unclassified	Cat II	3a	Unclassified	Unclassified	Cat II	3b	Unclassified	Unclassified	Unclassified	Cat II	Unclassified
130	Dicamba	Unclassified	Unclassified	11	Unclassified	Unclassified	Cat II	3ab	Unclassified	Unclassified	Unclassified	Cat II	Unclassified
131	Picloram	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
132	Oxadiazon	ED	Cat I	2b	Unclassified	ED	Cat I	2b	Unclassified	Unclassified	ED	Cat I	Unclassified
134	Spirotetramat	Unclassified	Cat II	3a	Unclassified	Unclassified	Unclassified	8	Unclassified	ED	Unclassified	Cat II	Unclassified
135	Metribuzin	Unclassified	Unclassified	8	Unclassified	Unclassified	Unclassified	8	Unclassified	ED (?)	Unclassified	Unclassified	Unclassified
137	Lenacil	ED	Cat I	2a	Unclassified	Unclassified	Cat II	3a	Unclassified	Unclassified	ED	Cat I	Unclassified

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	Chemical Name	OPTION 2	OPTION 3	Path of decision tree	OPTION 4	OPTION 2	OPTION 3	Path of decision tree	OPTION 4	OPTION 1 Most recent	OPTION 2	OPTION 3	OPTION 4
138	Fluometuron	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
139	Penoxsulam	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
140	Metrafenone	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
141	Fenamiphos (aka phenamiphos)	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
142	Formetanate	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
143	Tri-allate	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
144	Pirimicarb	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
145	Oxamyl	Unclassified	Cat III	10	Unclassified	Unclassified	Cat III	10	Unclassified	Unclassified	Unclassified	Cat III	Unclassified
146	Fluopicolide	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
147	Propamocarb	Unclassified	Cat III	7	Unclassified	Unclassified	Cat III	7	Unclassified	Unclassified	Unclassified	Cat III	Unclassified
148	Bentazone	Unclassified	Unclassified	8	Unclassified	Unclassified	Unclassified	8	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
149	Etridiazole	Unclassified	Cat II	3b	Unclassified	Unclassified	Cat II	3a	Unclassified	Unclassified	Unclassified	Cat II	Unclassified
150	Quinoclamine	Unclassified	Unclassified	8	Unclassified	Unclassified	Unclassified	8	Unclassified	ED	Unclassified	Unclassified	Unclassified
151	Valifenalate (formerly Valiphenal)	Unclassified	Cat II	3a	Unclassified	Unclassified	Cat II	3a	Unclassified	Unclassified	Unclassified	Cat II	Unclassified
152	Spiromesifen	Unclassified	Cat II	5	Unclassified	Unclassified	Unclassified	8	Unclassified	Unclassified	Unclassified	Cat II	Unclassified
153	2,5-Dichlorobenzoic acid methylester	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
154	Pirimiphos-methyl	Unclassified	Cat III	10	Unclassified	Unclassified	Cat III	10	Unclassified	Unclassified	Unclassified	Cat III	Unclassified
156	Metobromuron	Unclassified	Unclassified	8	Unclassified	Unclassified	Unclassified	8	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified

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	Chemical Name	Potential Categorization Human Health				Potential Categorization Wildlife				Combined Potential Categorization (HH & Wildlife Vertebrates)			
		OPTION 2	OPTION 3	Path of decision tree	OPTION 4	OPTION 2	OPTION 3	Path of decision tree	OPTION 4	OPTION 1 Most recent	OPTION 2	OPTION 3	OPTION 4
157	1-Methyl-cyclopropene	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
158	Thiencarbazone	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
159	Diuron	Unclassified	Cat III	7	Unclassified	Unclassified	Cat III	7	Unclassified	Unclassified	Unclassified	Cat III	Unclassified
160	Dithianon	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
161	Tembotrione	Unclassified	Cat II	3a	Unclassified	Unclassified	Cat II	3a	Unclassified	ED	Unclassified	Cat II	Unclassified
162	Isoproturon	Unclassified	Cat II	3b	Unclassified	Unclassified	Cat II	3b	Unclassified	ED	Unclassified	Cat II	Unclassified
163	Amisulbrom	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
164	Imazalil (aka enilconazole)	Unclassified	Cat III	7	Unclassified	Unclassified	Cat III	7	Unclassified	Unclassified	Unclassified	Cat III	Unclassified
165	Fluoxastrobin	Unclassified	Cat III	10	Unclassified	Unclassified	Cat III	10	Unclassified	Unclassified	Unclassified	Cat III	Unclassified
167	Mandipropamid	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
168	Fuberidazole	Unclassified	Unclassified	8	Unclassified	Unclassified	Unclassified	8	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
169	Fosetyl [same as Fosetyl-AI]	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
170	Cyflumetofen	Unclassified	Cat II	3a	Unclassified	Unclassified	Cat II	3a	Unclassified	Unclassified	Unclassified	Cat II	Unclassified
171	Benthiavalicarb [same as benthiavalicarb-isopropyl CAS No. 177406-68-7]	Unclassified	Cat II	3a	Unclassified	Unclassified	Cat II	3a	Unclassified	ED (?)	Unclassified	Cat II	Unclassified
172	Metamitron	Unclassified	Unclassified	8	Unclassified	Unclassified	Unclassified	8	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
173	Bupirimate	Unclassified	Cat III	10	Unclassified	Unclassified	Cat III	10	Unclassified	Unclassified	Unclassified	Cat III	Unclassified
174	Pyroxsulam	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified

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		OPTION 2	OPTION 3	Path of decision tree	OPTION 4	OPTION 2	OPTION 3	Path of decision tree	OPTION 4	OPTION 1 Most recent	OPTION 2	OPTION 3	OPTION 4
175	Bifenox	Unclassified	Cat III	10	Unclassified	Unclassified	Cat III	10	Unclassified	Unclassified	Unclassified	Cat III	Unclassified
176	Oxyfluorfen	Unclassified	Cat III	10	Unclassified	Unclassified	Cat III	10	Unclassified	Unclassified	Unclassified	Cat III	Unclassified
178	Fenpyrazamine	Unclassified	Unclassified	8	Unclassified	Unclassified	Unclassified	8	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
179	Penflufen	Unclassified	Cat II	3a	Unclassified	Unclassified	Unclassified	8	Unclassified	Cut off criteria are applicable / Carc Cat 1A	Unclassified	Cat II	Unclassified
180	Chlorantraniliprole	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
181	Dimethachlor	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
182	Ascorbic acid	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
183	Glufosinate [same as glufosinate ammonium CAS No. 77182-82-2]	Unclassified	Unclassified	8	Unclassified	Unclassified	Unclassified	8	Unclassified	Cut off criteria are applicable / Repr Cat 1A	Unclassified	Unclassified	Unclassified
184	Diclofop [same as diclofop-methyl CAS No.257-141-8]	Unclassified	Cat III	10	Unclassified	Unclassified	Cat II	6	Unclassified	Unclassified	Unclassified	Cat II	Unclassified
185	Carboxin	Unclassified	Cat II	3a	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Cat II	Unclassified
186	Prosulfocarb	Unclassified	Unclassified	8	Unclassified	Unclassified	Unclassified	8	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
187	Pyrimethanil	Unclassified	Cat III	10	Unclassified	Unclassified	Cat III	10	Unclassified	Unclassified	Unclassified	Cat III	Unclassified
188	Triadimenol	Unclassified	Cat II	3b	Unclassified	Unclassified	Cat III	7	Unclassified	ED	Unclassified	Cat II	Unclassified

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189	Triclopyr [a second variant of Triclopyr: 3,5,6-trichloro-2-pyridyloxy-2-butoxyethyl ester CAS No: 064700-56-7]	Unclassified	Unclassified	8	Unclassified	Unclassified	Unclassified	8	Unclassified	Cut off criteria are applicable / Repr Cat 1A/B	Unclassified	Unclassified	Unclassified
190	Pyridate	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
191	Tolclofos-methyl	Unclassified	Cat III	7	Unclassified	Unclassified	Cat III	7	Unclassified	Unclassified	Unclassified	Cat III	Unclassified
192	Urea	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
193	1,4-Dimethylnaphthalene	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
194	Acequinocyl	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
195	Cymoxanil	Unclassified	Cat II	3a	Unclassified	Unclassified	Cat II	3a	Unclassified	ED	Unclassified	Cat II	Unclassified
196	Bixafen	Unclassified	Cat II	3a, 3b	Unclassified	Unclassified	Cat II	3b	Unclassified	Unclassified	Unclassified	Cat II	Unclassified
197	Terbuthylazine	Unclassified	Cat III	7	Unclassified	Unclassified	Cat II	6	Unclassified	Unclassified	Unclassified	Cat II	Unclassified
198	Trimethylamine hydrochloride	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
199	Dimethoate	Unclassified	Cat II	5	Unclassified	Unclassified	Cat II	5	Unclassified	Unclassified	Unclassified	Cat II	Unclassified
200	Meptyldinocap [same as DE-126]	Unclassified	Cat II	3a	Unclassified	Unclassified	Cat II	3a	Unclassified	Unclassified	Unclassified	Cat II	Unclassified

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	Chemical Name	OPTION 2	OPTION 3	Path of decision tree	OPTION 4	OPTION 2	OPTION 3	Path of decision tree	OPTION 4	OPTION 1 Most recent	OPTION 2	OPTION 3	OPTION 4
201	Flurochloridone	ED	Cat I	2a	Unclassified	ED	Cat I	2a	Unclassified	ED - Cut off criteria are applicable / Repr Cat 1A/B	ED	Cat I	Unclassified
202	Amitrole (aminotriazole)	ED	Cat I	2a	ED	ED	Cat I	2a	ED	ED - Cut off criteria are applicable / Repr Cat 1A/B	ED	Cat I	ED
206	Chlorsulfuron	Unclassified	Cat II	3a	Unclassified	Unclassified	Cat II	3a	Unclassified	Unclassified	Unclassified	Cat II	Unclassified
207	Fluopyram	Unclassified	Unclassified	8	Unclassified	Unclassified	Unclassified	8	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
208	Pencycuron	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
209	Cyromazine	Unclassified	Unclassified	8	Unclassified	Unclassified	Unclassified	8	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
210	Esfenvalerate	Unclassified	Cat III	7	Unclassified	Unclassified	Cat II	6	Unclassified	Unclassified	Unclassified	Cat II	Unclassified
211	Penconazole	Unclassified	Cat III	7	Unclassified	Unclassified	Cat III	7	Unclassified	Unclassified	Unclassified	Cat III	Unclassified
212	Flutolanil	Unclassified	Cat III	10	Unclassified	Unclassified	Cat III	10	Unclassified	Unclassified	Unclassified	Cat III	Unclassified
213	Metazachlor	Unclassified	Unclassified	8	Unclassified	Unclassified	Cat II	5	Unclassified	Unclassified	Unclassified	Cat II	Unclassified
214	Fenpropidin	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
215	Prochloraz	Unclassified	Cat II	3b	Unclassified	Unclassified	Cat II	3b	Unclassified	ED	Unclassified	Cat II	Unclassified
216	Triflumizole	ED	Cat I	2b	ED	ED	Cat I	2b	ED	ED - Cut off criteria are applicable / Repr Cat 1A/B	ED	Cat I	ED

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	Chemical Name	OPTION 2	OPTION 3	Path of decision tree	OPTION 4	OPTION 2	OPTION 3	Path of decision tree	OPTION 4	OPTION 1 Most recent	OPTION 2	OPTION 3	OPTION 4
217	Pyriofenone	Unclassified	Unclassified	8	Unclassified	Unclassified	Unclassified	8	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
218	Buprofezin	Unclassified	Cat II	3b	Unclassified	Unclassified	Cat II	3a	Unclassified	Unclassified	Unclassified	Cat II	Unclassified
219	Fluroxypyr	Unclassified	Cat III	10	Unclassified	Unclassified	Cat III	10	Unclassified	Unclassified	Unclassified	Cat III	Unclassified
220	Chloromequat	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
221	Metalaxyl-M	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
222	Triazoxide	Unclassified	Unclassified	8	Unclassified	Unclassified	Unclassified	8	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
224	Phosmet	Unclassified	Cat III	10	Unclassified	Unclassified	Cat III	10	Unclassified	Unclassified	Unclassified	Cat III	Unclassified
225	Aclonifen	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
226	Clofentezine	Unclassified	Cat III	10	Unclassified	Unclassified	Cat III	10	Unclassified	Unclassified	Unclassified	Cat III	Unclassified
227	Metsulfuron-methyl	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
230	Flutriafol	Unclassified	Unclassified	8	Unclassified	Unclassified	Unclassified	8	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
231	Gamma-cyhalothrin	Unclassified	Unclassified	8	Unclassified	Unclassified	Unclassified	8	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
232	Paclobutrazol	Unclassified	Cat III	7	Unclassified	Unclassified	Cat II	3a	Unclassified	Unclassified	Unclassified	Cat II	Unclassified
237***	Phosphane	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
238	Hexythiazox	Unclassified	Cat III	7	Unclassified	Unclassified	Cat III	7	Unclassified	Unclassified	Unclassified	Cat III	Unclassified
239	Thifensulfuron-methyl	Unclassified	Cat II	6	Unclassified	Unclassified	Cat III	7	Unclassified	ED	Unclassified	Cat II	Unclassified
240	Tefluthrin	Unclassified	Cat III	7	Unclassified	Unclassified	Cat III	7	Unclassified	Unclassified	Unclassified	Cat III	Unclassified
241	Fluazinam	Unclassified	Cat II	3a	Unclassified	Unclassified	Cat II	3a	Unclassified	ED	Unclassified	Cat II	Unclassified
243	Imazaquin	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
244	Clomazone	Unclassified	Cat III	10	Unclassified	Unclassified	Cat III	10	Unclassified	Unclassified	Unclassified	Cat III	Unclassified
245	Triasulfuron	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified

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		OPTION 2	OPTION 3	Path of decision tree	OPTION 4	OPTION 2	OPTION 3	Path of decision tree	OPTION 4	OPTION 1 Most recent	OPTION 2	OPTION 3	OPTION 4
246	Isoxaben	Unclassified	Cat III	10	Unclassified	Unclassified	Cat III	10	Unclassified	Unclassified	Unclassified	Cat III	Unclassified
247	Bensulfuron methyl	Unclassified	Unclassified	8	Unclassified	Unclassified	Unclassified	8	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
248	Fluazifop-P	Unclassified	Cat II	3b	Unclassified	Unclassified	Cat II	3b	Unclassified	ED	Unclassified	Cat II	Unclassified
249	Teflubenzuron	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
250	Diflufenican	Unclassified	Cat II	3a	Unclassified	Unclassified	Cat II	3a	Unclassified	Unclassified	Unclassified	Cat II	Unclassified
251	1-Naphthylacetamide (1-NAD)	Unclassified	Cat II	3a	Unclassified	Unclassified	Cat II	3a	Unclassified	ED	Unclassified	Cat II	Unclassified
252	1-Naphthylacetic acid (1-NAA)	Unclassified	Cat II	3a	Unclassified	Unclassified	Cat II	3a	Unclassified	ED	Unclassified	Cat II	Unclassified
253	Heptamaloxylog lucan	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
254	Diethofencarb	Unclassified	Cat II	3a	Unclassified	Unclassified	Cat II	3a	Unclassified	Unclassified	Unclassified	Cat II	Unclassified
255	Sedaxane	Unclassified	Cat II	3a	Unclassified	Unclassified	Cat II	3a	Unclassified	Unclassified	Unclassified	Cat II	Unclassified
256	Tralkoxydim	ED	Cat I	2a	Unclassified	ED	Cat I	2a	Unclassified	Unclassified	ED	Cat I	Unclassified
257	Isopyrazam	Unclassified	Unclassified	8	Unclassified	Unclassified	Unclassified	8	Unclassified	ED	Unclassified	Unclassified	Unclassified
258	Myclobutanil	ED	Cat I	2a, 2b	Unclassified	ED	Cat I	2a, 2b	Unclassified	ED	ED	Cat I	Unclassified
259	Thymol	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
261	Quinmerac	Unclassified	Unclassified	8	Unclassified	Unclassified	Unclassified	8	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
262	Fluxapyroxad	Unclassified	Unclassified	8	Unclassified	Unclassified	Unclassified	8	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
263	Prosulfuron	Unclassified	Cat II	3a	Unclassified	Unclassified	Cat II	3a	Unclassified	Unclassified	Unclassified	Cat II	Unclassified
264	2,4-D	ED	Cat I	2a	Unclassified	ED	Cat I	2a	Unclassified	Unclassified	ED	Cat I	Unclassified
265	Haloxyfop-P (Haloxyfop-R)	Unclassified	Cat III	10	Unclassified	Unclassified	Cat III	10	Unclassified	Unclassified	Unclassified	Cat III	Unclassified

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266	Pyridaben	Unclassified	Cat II	5	Unclassified	Unclassified	Cat II	5	Unclassified	Unclassified	Unclassified	Cat II	Unclassified
267	Eugenol	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
269	Benalaxyl-M	Unclassified	Unclassified	8	Unclassified	Unclassified	Unclassified	8	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
270	Sulcotrione	Unclassified	Unclassified	8	Unclassified	Unclassified	Unclassified	8	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
271	Clethodim	Unclassified	Cat II	3a	Unclassified	Unclassified	Cat II	3a	Unclassified	Unclassified	Unclassified	Cat II	Unclassified
290	Repellents by smell of animal or plant origin/ sheep fat	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
291	Repellents by smell of animal or plant origin/ tall oil crude	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
292	Repellents by smell of animal or plant origin/ tall oil pitch	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
293	Sea-algae extract (formerly sea-algae extract and seaweeds)	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
294	Clothianidin	Unclassified	Cat II	3a	Unclassified	Unclassified	Cat II	3a	Unclassified	Unclassified	Unclassified	Cat II	Unclassified
295	Propiconazole	Unclassified	Cat II	5	Unclassified	Unclassified	Cat II	5	Unclassified	Unclassified	Unclassified	Cat II	Unclassified
296	Thiacloprid	Unclassified	Cat II	3b	Unclassified	Unclassified	Cat II	3b	Unclassified	ED - Cut off criteria are applicable / Repr Cat 1A/B	Unclassified	Cat II	Unclassified

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297	Pelargonic acid (Nonanoic acid)	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
298	Caprylic acid (Octanoic acid)	Unclassified	Cat III	10	Unclassified	Unclassified	Cat III	10	Unclassified	Unclassified	Unclassified	Cat III	Unclassified
299	Lauric acid	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
300	Thiamethoxam	Unclassified	Cat II	3a	Unclassified	Unclassified	Cat II	3a	Unclassified	Unclassified	Unclassified	Cat II	Unclassified
301	Spinosad	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
302	Copper hydroxide	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
303	Capric acid (Decanoic acid)	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
304	Cypermethrin	ED	Cat I	2a, 2b	ED	ED	Cat I	2a, 2b	ED	Unclassified	ED	Cat I	ED
305	Deltamethrin	Unclassified	Cat II	3b	Unclassified	Unclassified	Cat II	3b	Unclassified	Unclassified	Unclassified	Cat II	Unclassified
306	Benzoic acid	Unclassified	Unclassified	8	Unclassified	Unclassified	Unclassified	8	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
307	Alpha-Cypermethrin (aka alphamethrin)	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
308	Chlorpropham	Unclassified	Cat II	3b	Unclassified	Unclassified	Cat II	3b	Unclassified	Unclassified	Unclassified	Cat II	Unclassified
309	Flazasulfuron	Unclassified	Unclassified	8	Unclassified	Unclassified	Unclassified	8	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
310	Mesotrione	Unclassified	Unclassified	8	Unclassified	Unclassified	Unclassified	8	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
311	Pethoxamid	Unclassified	Cat II	3a	Unclassified	Unclassified	Unclassified	8	Unclassified	Unclassified	Unclassified	Cat II	Unclassified
312	Mepanipyrim	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
313	Methyl decanoate	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
314	Methyl octanoate	Unclassified	Cat III	10	Unclassified	Unclassified	Cat III	10	Unclassified	Unclassified	Unclassified	Cat III	Unclassified

The results of the screening do not constitute evaluations of individual substances to be carried out under the respective chemical legislations [[in particular, Regulation (EC) No 1107/2009 on plant protection products, Regulation (EU) No 528/2012 on biocidal products, Regulation (EC) No 1907/2006 REACH, Regulation (EC) No 1223/2009 on cosmetic products and the Water Framework Directive (EC) No 2000/60] and in no way prejudice future decisions on active substances to be taken pursuant to these pieces of the EU legislation.

It would thus be erroneous to consider that the substances listed in the results of this study (SANTE/2015/E3/SI2.706218) are considered as endocrine disruptors within the meaning of the EU legislation.

		Potential Categorization Human Health				Potential Categorization Wildlife				Combined Potential Categorization (HH & Wildlife Vertebrates)			
	Chemical Name	OPTION 2	OPTION 3	Path of decision tree	OPTION 4	OPTION 2	OPTION 3	Path of decision tree	OPTION 4	OPTION 1 Most recent	OPTION 2	OPTION 3	OPTION 4
319	Beflubutamid	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
320	Imazamox	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
321	Picoxystrobin	Unclassified	Cat III	10	Unclassified	Unclassified	Cat III	10	Unclassified	Unclassified	Unclassified	Cat III	Unclassified
322	Cyazofamid	Unclassified	Cat III	10	Unclassified	Unclassified	Cat III	10	Unclassified	Unclassified	Unclassified	Cat III	Unclassified
323	Propineb	Unclassified	Cat II	3b	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Cat II	Unclassified
324	Imazosulfuron	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
325	Maleic hydrazide	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
326	Maneb	ED	Cat I	2a	Unclassified	ED	Cat I	2a	Unclassified	ED	ED	Cat I	Unclassified
327	Quinoxifen	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
328	Carfentrazone-ethyl	Unclassified	Cat III	10	Unclassified	Unclassified	Cat III	10	Unclassified	Unclassified	Unclassified	Cat III	Unclassified
331	Tribasic copper sulfate	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
332	Acetamiprid	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
334	Desmedipham	ED	Cat I	2a	Unclassified	Unclassified	Unclassified	8	Unclassified	Unclassified	ED	Cat I	Unclassified
335	Phenmedipham	Unclassified	Cat II	3a, 3b	Unclassified	Unclassified	Cat II	3a, 3b	Unclassified	Unclassified	Unclassified	Cat II	Unclassified
336	Thiram	ED	Cat I	2b	Unclassified	ED	Cat I	2b	Unclassified	Unclassified	ED	Cat I	Unclassified
337	Ziram	ED	Cat I	2b	ED	ED	Cat I	2b	ED	Unclassified	ED	Cat I	ED
338	Profoxydim	Unclassified	Cat II	3a	Unclassified	Unclassified	Cat II	3a	Unclassified	ED	Unclassified	Cat II	Unclassified
339	Isoxaflutole	Unclassified	Cat II	3a	Unclassified	Unclassified	Cat II	3a	Unclassified	ED (?)	Unclassified	Cat II	Unclassified
340	Trifloxystrobin	Unclassified	Cat III	10	Unclassified	Unclassified	Cat III	10	Unclassified	Unclassified	Unclassified	Cat III	Unclassified
341	Flufenacet (formerly	Unclassified	Cat II	9	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Cat II	Unclassified

The results of the screening do not constitute evaluations of individual substances to be carried out under the respective chemical legislations [[in particular, Regulation (EC) No 1107/2009 on plant protection products, Regulation (EU) No 528/2012 on biocidal products, Regulation (EC) No 1907/2006 REACH, Regulation (EC) No 1223/2009 on cosmetic products and the Water Framework Directive (EC) No 2000/60] and in no way prejudice future decisions on active substances to be taken pursuant to these pieces of the EU legislation.

It would thus be erroneous to consider that the substances listed in the results of this study (SANTE/2015/E3/SI2.706218) are considered as endocrine disruptors within the meaning of the EU legislation.

		Potential Categorization Human Health				Potential Categorization Wildlife				Combined Potential Categorization (HH & Wildlife Vertebrates)			
	Chemical Name	OPTION 2	OPTION 3	Path of decision tree	OPTION 4	OPTION 2	OPTION 3	Path of decision tree	OPTION 4	OPTION 1 Most recent	OPTION 2	OPTION 3	OPTION 4
	fluthiamide)												
342	Tritosulfuron	Unclassified	Cat II	3a	Unclassified	Unclassified	Cat II	3a	Unclassified	Unclassified	Unclassified	Cat II	Unclassified
343	Indoxacarb	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
344	Oxasulfuron	Unclassified	Cat II	3a	Unclassified	Unclassified	Cat II	3a	Unclassified	Unclassified	Unclassified	Cat II	Unclassified
345	Propoxycarbazone	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
346	Bifenazate	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
347	Tepraloxydim	ED	Cat I	2b	Unclassified	ED	Cat I	2b	Unclassified	ED	ED	Cat I	Unclassified
348	Etoazole	Unclassified	Cat II	3b	Unclassified	Unclassified	Cat II	3b	Unclassified	Unclassified	Unclassified	Cat II	Unclassified
349	Chlorotoluron	Unclassified	Unclassified	8	Unclassified	Unclassified	Unclassified	8	Unclassified	ED	Unclassified	Unclassified	Unclassified
350	Zoxamide	Unclassified	Cat III	10	Unclassified	Unclassified	Cat III	7	Unclassified	Unclassified	Unclassified	Cat III	Unclassified
351	Daminozide	Unclassified	Cat III	10	Unclassified	Unclassified	Cat III	10	Unclassified	Unclassified	Unclassified	Cat III	Unclassified
352	Methoxyfenozide	Unclassified	Cat II	3a	Unclassified	Unclassified	Cat II	3a	Unclassified	Unclassified	Unclassified	Cat II	Unclassified
353	Fenamidone	ED	Cat I	2a	ED	Unclassified	Cat II	3b	Unclassified	Unclassified	ED	Cat I	ED
354	Dimethenamid-p	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
355	Mecoprop-P	Unclassified	Cat III	7	Unclassified	Unclassified	Cat III	7	Unclassified	Unclassified	Unclassified	Cat III	Unclassified
357	Bromoxynil	Unclassified	Cat II	3b	Unclassified	Unclassified	Cat II	3b	Unclassified	ED	Unclassified	Cat II	Unclassified
359	Foramsulfuron	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
360	Pyraclostrobin	Unclassified	Cat III	7	Unclassified	Unclassified	Cat III	7	Unclassified	Unclassified	Unclassified	Cat III	Unclassified
361	Silthiofam	Unclassified	Unclassified	8	Unclassified	Unclassified	Cat II	3a	Unclassified	Unclassified	Unclassified	Cat II	Unclassified
362	S-Metolachlor	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	8	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
363	Pyridalyl	Unclassified	Cat II	3a	Unclassified	Unclassified	Cat II	3a	Unclassified	Unclassified	Unclassified	Cat II	Unclassified

The results of the screening do not constitute evaluations of individual substances to be carried out under the respective chemical legislations [[in particular, Regulation (EC) No 1107/2009 on plant protection products, Regulation (EU) No 528/2012 on biocidal products, Regulation (EC) No 1907/2006 REACH, Regulation (EC) No 1223/2009 on cosmetic products and the Water Framework Directive (EC) No 2000/60] and in no way prejudice future decisions on active substances to be taken pursuant to these pieces of the EU legislation.

It would thus be erroneous to consider that the substances listed in the results of this study (SANTE/2015/E3/SI2.706218) are considered as endocrine disruptors within the meaning of the EU legislation.

		Potential Categorization Human Health				Potential Categorization Wildlife				Combined Potential Categorization (HH & Wildlife Vertebrates)			
	Chemical Name	OPTION 2	OPTION 3	Path of decision tree	OPTION 4	OPTION 2	OPTION 3	Path of decision tree	OPTION 4	OPTION 1 Most recent	OPTION 2	OPTION 3	OPTION 4
364	Iodosulfuron	Unclassified	Unclassified	8	Unclassified	Unclassified	Unclassified	8	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
365	Boscalid (formerly nicobifen)	ED	Cat I	2a	Unclassified	ED	Cat I	2a	Unclassified	Unclassified	ED	Cat I	Unclassified
366	Chlorothalonil	Unclassified	Cat III	7	Unclassified	Unclassified	Cat II	5	Unclassified	Unclassified	Unclassified	Cat II	Unclassified
368	Thiophanate-methyl	ED	Cat I	2a	Unclassified	ED	Cat I	2a	Unclassified	Unclassified	ED	Cat I	Unclassified
369	Propyzamide	ED	Cat I	2a	Unclassified	ED	Cat I	2a	Unclassified	Unclassified	ED	Cat I	Unclassified
370	Ethofumesate	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	8	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
371	Flubendiamide	ED	Cat I	2a	ED	ED	Cat I	2a	ED	Unclassified	ED	Cat I	ED
372	Diquat (dibromide)	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
374	Chlorpyrifos	Unclassified	Cat III	10	Unclassified	Unclassified	Cat III	10	Unclassified	Unclassified	Unclassified	Cat III	Unclassified
375	Linuron	ED	Cat I	2a	Unclassified	ED	Cat I	2a	Unclassified	ED - Cut off criteria are applicable / Repr Cat 1A/B	ED	Cat I	Unclassified
379	Iprodione	ED	Cat I	2a, 2b	Unclassified	ED	Cat I	2a, 2b	Unclassified	Unclassified	ED	Cat I	Unclassified
382	Mesosulfuron	Unclassified	Unclassified	8	Unclassified	Unclassified	Unclassified	8	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
383	Pendimethalin	ED	Cat I	2a	ED	ED	Cat I	2a	ED	Unclassified	ED	Cat I	ED
384 [†]	Denatonium benzoate	-	-	-	-	-	-	-	-	-	-	-	-
385	Milbemectin	Unclassified	Unclassified	8	Unclassified	Unclassified	Unclassified	8	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified

The results of the screening do not constitute evaluations of individual substances to be carried out under the respective chemical legislations [[in particular, Regulation (EC) No 1107/2009 on plant protection products, Regulation (EU) No 528/2012 on biocidal products, Regulation (EC) No 1907/2006 REACH, Regulation (EC) No 1223/2009 on cosmetic products and the Water Framework Directive (EC) No 2000/60] and in no way prejudge future decisions on active substances to be taken pursuant to these pieces of the EU legislation.

It would thus be erroneous to consider that the substances listed in the results of this study (SANTE/2015/E3/SI2.706218) are considered as endocrine disruptors within the meaning of the EU legislation.

		Potential Categorization Human Health				Potential Categorization Wildlife				Combined Potential Categorization (HH & Wildlife Vertebrates)			
	Chemical Name	OPTION 2	OPTION 3	Path of decision tree	OPTION 4	OPTION 2	OPTION 3	Path of decision tree	OPTION 4	OPTION 1 Most recent	OPTION 2	OPTION 3	OPTION 4
390	Chlorpyrifos-methyl	Unclassified	Cat II	5	Unclassified	Unclassified	Cat II	5	Unclassified	Unclassified	Unclassified	Cat II	Unclassified
394	Sucrose	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
395	Metalaxyl	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
398	Sodium 5-nitroguaiacolate	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
400	Forchlorfenuron	Unclassified	Cat III	10	Unclassified	Unclassified	Cat III	10	Unclassified	Unclassified	Unclassified	Cat III	Unclassified
401	Beta-Cyfluthrin	Unclassified	Cat III	7	Unclassified	Unclassified	Cat III	7	Unclassified	Unclassified	Unclassified	Cat III	Unclassified
402	Benalaxyl	Unclassified	Unclassified	8	Unclassified	Unclassified	Unclassified	8	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
403	Mancozeb	ED	Cat I	2a, 2b	ED	ED	Cat I	2a, 2b	ED	Unclassified	ED	Cat I	ED
404	Sodium o-nitrophenolate	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
405	Sodium p-nitrophenolate	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
407	Ametoctradin	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
408	Metiram	ED	Cat I	2a	ED	Unclassified	Cat II	3a	Unclassified	Unclassified	ED	Cat I	ED
409	Laminarin	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
411	Mecoprop	Unclassified	Cat III	7	Unclassified	Unclassified	Cat III	7	Unclassified	Unclassified	Unclassified	Cat III	Unclassified
413	MCPA	Unclassified	Cat III	7	Unclassified	Unclassified	Cat III	7	Unclassified	Unclassified	Unclassified	Cat III	Unclassified
414	MCPB	Unclassified	Cat III (?)	7	Unclassified	Unclassified	Cat III (?)	7	Unclassified	Unclassified	Unclassified	Cat III (?)	Unclassified
415	2,4-DB	Unclassified	Cat II	3a	Unclassified	Unclassified	Cat II	3a	Unclassified	Unclassified	Unclassified	Cat II	Unclassified
416	Flurtamone	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
417	Fosthiazate	Unclassified	Unclassified	8	Unclassified	Unclassified	Unclassified	8	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
418	Carvone	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
426	Bordeaux	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified

The results of the screening do not constitute evaluations of individual substances to be carried out under the respective chemical legislations [[in particular, Regulation (EC) No 1107/2009 on plant protection products, Regulation (EU) No 528/2012 on biocidal products, Regulation (EC) No 1907/2006 REACH, Regulation (EC) No 1223/2009 on cosmetic products and the Water Framework Directive (EC) No 2000/60] and in no way prejudice future decisions on active substances to be taken pursuant to these pieces of the EU legislation.

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		Potential Categorization Human Health				Potential Categorization Wildlife				Combined Potential Categorization (HH & Wildlife Vertebrates)			
	Chemical Name	OPTION 2	OPTION 3	Path of decision tree	OPTION 4	OPTION 2	OPTION 3	Path of decision tree	OPTION 4	OPTION 1 Most recent	OPTION 2	OPTION 3	OPTION 4
	mixture												
428	n-Tetradecylacetate	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified

**This substance was incorrectly marked also as a BP in the published list of substances to be screened.

*** This substance had been already screened when “list of substances to be screened” was published.

****This substance covers also the substance Quizalofop-P.

† This substance was initially included in the list of substances to be screened, but following the rational it was decided that the substance was not to be screened.

The results of the screening do not constitute evaluations of individual substances to be carried out under the respective chemical legislations [[in particular, Regulation (EC) No 1107/2009 on plant protection products, Regulation (EU) No 528/2012 on biocidal products, Regulation (EC) No 1907/2006 REACH, Regulation (EC) No 1223/2009 on cosmetic products and the Water Framework Directive (EC) No 2000/60] and in no way prejudge future decisions on active substances to be taken pursuant to these pieces of the EU legislation.

It would thus be erroneous to consider that the substances listed in the results of this study (SANTE/2015/E3/SI2.706218) are considered as endocrine disruptors within the meaning of the EU legislation.

CHAPTER 3

Screening of available evidence on chemical substances for the identification of endocrine disruptors according to different options in the context of an Impact Assessment

Specific Contract SANTE/2015/E3/SI2.706218

General observations and conclusions for the screened
BPs substances

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A. Introduction & Objectives

The aim of this report is to present the final outcome for the identification of 96 active substances used in Biocidal Products (BPs) as potential Endocrine Disruptors (EDs) under four different Policy "Options" of the Roadmap (EC, 2014).

B. Materials & Methods

The methodology applied was based on the JRC draft methodology provided in May 2015 as amended and described in chapter 1 and supplemented by further WoE considerations as described in chapter 2. Additional minor modifications have been introduced during the screening of the BPs. These are presented below together with any identified issues which were specific for BPs.

Screened substances and data sources

The "Chemical Inventory" file provided by JRC was the initial tool used for identifying sources of information to be considered in data population of each substance under the screening process, as described in chapter 1. The "Chemical Inventory" file originally provided by JRC included 101 BPs (Biocidal Product active substances), 88 approved and 13 not yet approved. Finally, considering the change in the approval status of certain substances and following consultation with DG SANTE, a total of 96 BPs were screened. Only 1 BP is not yet approved but this was included following consultation with DG SANTE since the opinion for approval has already been adopted by the BPC while the Assessment Report has been published on the ECHA website.

It is noted that 37 BPs are also approved as PPPs; all of these substances have already been screened in the frames of Deliverable 2 for PPPs (chapter 2).

It is noted that for all BPs screened, the Competent Authority Report (CAR) documents used to retrieve the required data/information were those available in the restricted CIRCABC area.

Data Summary template version 1.11

A revised Data Summary template excel workbook was provided by JRC on the 14th of January 2016. Data Summary template 1.11 includes the following amendments:

- Additional inhalation exposure categories have been added to the "Route of administration" pick list.
- The text in cell A5 of the evaluation sheet has been changed to "Effect/s not considered for the evaluation as not informative to conclude on ED since the effect (ED-related and/or EATS-specific) is considered to be secondary to general-systemic toxicity".
- A new sheet called "information note" has been added in order to capture any comments or changes made to the file.
- New columns (AN, AO, AP and AQ) have been added in the "Data" sheet in order to automatically calculate a potency cut-off value to be used for "Option 4".

C. Case studies

i. **Anti-Vitamin K (AVK) rodenticides**

AVK rodenticides are a group of structurally similar compounds also known as anticoagulant rodenticides. All AVK rodenticides, including warfarin and other anticoagulant coumarin pharmaceuticals share the same MoA, namely inhibition of vitamin K epoxide reductase (an enzyme involved with blood coagulation and foetal tissues development, including bone formation, CNS development and angiogenesis).

Carcinogenicity and fertility studies have been waived and thus not carried out due to technical difficulties resulting from the anticoagulant properties of these substances and the use of the target species (rodents) as test species. Moreover, warfarin has been used in the prevention of thrombosis and thromboembolism in humans for many decades and there is no evidence of it being carcinogenic or toxic to fertility. However, based on read across from human data for warfarin, it is concluded that these substances have the capacity to adversely affect the human *in utero* development and therefore, a classification as Repr. Cat 1A or 1B is proposed by RAC for each substance. With regard to the evaluation of these substances, human data for warfarin have not been captured in the Datasheet due to lack of details but have been considered as evidence of adversity in the evaluation sheet (Figure 3.11).

D	E	F	G
OPTION 2 & 3			
	Mammalian		Ecotox
Question	Answer (Yes/No)	Reasoning	Answer (Yes/No)
Is there evidence of adversity that might potentially be caused by an ED related effect in an intact organism, or its progeny, or in a (sub)population? If yes, please indicate in the reasoning, each adverse effect and the corresponding "Study ID Matrix". If no, in the reasoning, please explain if the no is due to lack of data or because no effects were reported in a particular study/ies (always report "Study ID Matrix")	Yes	Human data for warfarin: Stillbirth or abortion, microcephaly, hydrocephaly, nasal hypoplasia, bone anomalies, growth retardation in human (dose level \cong 0.04 – 0.2 mg/kg bw/day): These data are not captured in the Data Summary due to lack of further details in CAR.	Yes
Is there evidence of Adversity – EATS specific in an intact organism, or its progeny, or in a (sub)population? If yes, please indicate in the reasoning, each specific adverse effect and the corresponding "Study ID Matrix". If no, in the reasoning, please explain if the no is due to lack of data or because no effects were reported in a particular study/ies (always report "Study ID Matrix")	No	No relevant adverse effects reported	No
Is there evidence of in vivo mechanistic and/or in vivo hormone levels information? If yes, please indicate in the reasoning, each in vivo mechanistic effect and the corresponding "Study ID Matrix". If no, in the reasoning, please explain if the no is due to lack of data or because no effects were reported in a particular study/ies (always report "Study ID Matrix")	No	No data	No
Is there evidence of in vitro mechanistic information? If yes, please indicate in the reasoning, each in vitro mechanistic effect and the corresponding "Study ID Matrix". If no, in the reasoning, please explain if the no is due to lack of data or	Yes	Aromatase inhibition (high potency) [ID: 6] Cofactor recruitment on AR (medium and medium	Yes

Figure 3.1. No ED-related adversity was reported for substance no 460, an AVK rodenticide. However, human data for Warfarin, a structurally and functionally similar compound, have been captured in the evaluation sheet.

ii. Boric acid and borates

Most of the simple inorganic borates such as boric acid, boric oxide, disodium tetraborate and disodium octaborate tetrahydrate exist predominantly as undissociated boric acid in dilute aqueous solution at physiological pH, leading to the conclusion that the main species in the plasma of mammals is un-dissociated boric acid. Since other borates dissociate to form boric acid in aqueous solutions, they too can be considered to exist as un-dissociated boric acid under physiological conditions. For the assessment of substances 446, 444 (boric oxide, disodium octaborate tetrahydrate) and 443-447-449

The results of the screening do not constitute evaluations of individual substances to be carried out under the respective chemical legislations [[in particular, Regulation (EC) No 1107/2009 on plant protection products, Regulation (EU) No 528/2012 on biocidal products, Regulation (EC) No 1907/2006 REACH, Regulation (EC) No 1223/2009 on cosmetic products and the Water Framework Directive (EC) No 2000/60] and in no way prejudice future decisions on active substances to be taken pursuant to these pieces of the EU legislation. It would thus be erroneous to consider that the substances listed in the results of this study (SANTE/2015/E3/SI2.706218) are considered as endocrine disruptors within the meaning of the EU legislation.

(disodium tetraborates) studies have been conducted with boric acid or sodium tetraborate decahydrate. All studies have been captured in the database while doses were recorded as mg boron/kg bw/day.

For substance 435 (boric acid), studies in REACH database conducted with Disodium tetraborate decahydrate where the equivalence in boric acid was not reported, have not been captured since they did not provide any additional information. Doses were recorded in the database as mg boric acid/kg bw/day (whenever possible).

D. Examples of adversity/MoA in the different Paths of the decision tree

As already mentioned in chapter 2, in the frame of this project, "EATS specific adversity" has been considered as strong indication of adversity caused by an ED-MoA, leading to the most strict categorization of the substances as "Endocrine Disruptors" (Cat I) or "Suspected Endocrine Disruptors" (Cat II). "Non-specific adversity (may or may not be indicative of EATS)" was considered weak evidence of adversity caused by an ED-MoA, which may lead to "lower" potential categories, mostly Cat II, III and "Unclassified" in the absence of "EATS specific adversity". *In vivo* mechanistic data (which may or may not be supported by *in vitro* mechanistic data) were considered as strong indication of endocrine mode of action (MoA). In case *in vivo* mechanistic data are available and a plausible link is determined with either "EATS specific adversity" or "Non-specific adversity (may or may not be indicative of EATS)" the substance is classified as Cat I. *In vitro* mechanistic data, in the absence of *in vivo* mechanistic data, were generally considered as weak indication of endocrine mode of action (MoA). In this case, a substance could be categorized as Cat I, Cat II or Cat III depending on the type of adversity observed (EATS specific adversity or ED-related adversity) and on whether or not a plausible link to the observed adversity is established (see Appendix I). The possibility that a substance is categorized as Cat I on the basis of *in vitro* mechanistic data is limited to the cases where there is clear and strong evidence of EATS specific adversity and a plausible link with equally clear *in vitro* mechanistic data is established. However, it was acknowledged that it would often be difficult to establish a direct plausible link to adverse effects and thus a Cat II in case of presence of EATS specific effects or Cat III in presence of non-specific effects was more likely.

It should be mentioned that when applying the decision tree for each substance, the weight of evidence of the observed types of adversity and endocrine MoA was taken into account for each step followed. When the weight of evidence of the observed effects has been considered inadequate the Path followed was similar to cases where no effects were observed.

Examples:

Categorization as Cat I via Path 2a or Path 2b of the decision tree

Substance No 441 exhibits adverse effects on thyroid weight and histopathology (EATS specific adversity) in three different species. *In vivo* mechanistic information on thyroid hormone levels (decreased T3 and T4, increased TSH) allow the establishment of a plausible link leading to classification of the substance as Cat I through Path 2a.

Substance No 304 causes adverse effects on male reproductive system as well as on fertility and reproductive performance. These effects can be linked to either *in vivo*

mechanistic or *in vitro* mechanistic data indicating antagonistic effects on AR, reduced expression levels of enzymes catalyzing testosterone production (3 β -HSD, 17 β -HSD), reduced AR expression, increased expression levels of aromatase, induction of aromatase activity as well as decreased testosterone synthesis. Consequently, substance No 304 is classified as Cat I through Path 2a and 2b.

Categorization as Cat II via Path 5 of the decision tree

Substance No 4 causes a variety of "Non-specific adverse effects (may or may not be indicative of EATS)" related to reproduction and fetal development (decreased fertility, delays in fetal development, decreased fetal weight, decreased litter viability, decreased pup weight, increased post-implantation loss, decreased pup survival index) which are considered a weak indication of ED-related adversity, in total absence of "EATS specific" adverse effects but in presence of *in vivo* mechanistic data. Thus, it is categorized as Cat II through Path 5 since no plausible link can be established.

Categorization as Cat II via Path 3a of the decision tree

Substance No 435 exhibits a variety of adverse effects on reproductive organs and fertility parameters some of which are EATS-specific. However in the absence of any *in vivo* or *in vitro* mechanistic data, it is classified as Cat II through Path 3a.

Categorization as Cat III via Path 10 of the decision tree

Substance No 431 causes no adverse effects. However, based solely on *in vitro* mechanistic information on hAR, it is classified as Cat III through Path 10.

E. Results

In this section, the overall summary tables with the potential categorization results for all 96 BPs (including also the 32 BPs/PPPs already assessed for Deliverable 2) screened for human health (Table 3.1) and vertebrate wildlife (Table 3.2) are presented. Moreover, an overall/combined table for human health and vertebrate wildlife (Table 3.3) and a summary table for "Option 3" results and the different Paths leading to the different categories for human health (Table 3.4) and vertebrate wildlife (Table 3.5), are presented below.

The results of the categorization for each of the 96 BP substances according to the four "Options" of the Roadmap (EC, 2014) for human health and ecotoxicological assessment based on the methodology described in chapter 2 are presented in the Appendix 3.1.

Under "Option 1", since both the harmonised C&L (when available) and the proposed C&L (when relevant) have been considered for the categorization of the substances, the results are reported in order to allow making a distinction between the substances with a harmonised classification (which have been included in Annex VI of Regulation (EC) 1272/2008 (CLP Regulation), i.e. their classification has been agreed) and those substances for which no harmonised classification is available because they have not yet been discussed.

In the Categorization Results Table (Appendix 3.1), when there is no harmonised C&L available, "Not relevant" is reported. However, when concluding for the categorization under "Option 1", this is interpreted as "Unclassified*". The "*" has been added in order to make the distinction from the substances which are categorized as "Unclassified" after discussion, i.e. considering the harmonised C&L included in Annex VI of CLP Regulation.

For all substances where there is no harmonised C&L available (27 out of the 96 BPs screened) the categorization was concluded considering the proposed classification since this is the most recent one. It is noted that for 1 substance with no harmonised classification (i.e. categorized as "Unclassified*") the categorization is different when considering the most recent proposed C&L, while for 1 substance (rodenticide) the cut-off¹² are applicable, based on the proposed C&L as Repr Cat 1A.

Moreover, for 52 out of the 69 BPs for which there is a harmonised classification, a more recent C&L proposal in the respective evaluation report has been identified. In these cases, the "Option 1" outcome is the one based on the "Most Recent" proposed C&L (more severe in most cases); it is noted that only for 5 substances the categorization under "Option 1" is different when considering the most recent proposed C&L instead of the available harmonised C&L.

¹² The term "cut-off criteria" is not used in the legislation. It is used in common language to refer to *approval criteria* in Reg. 1107/2009 and *exclusion criteria* in Reg. 528/2012.

In Reg. 1107/2009, *approval criteria* are:

- purely based on hazard considerations for certain classes of substances (*mutagens, PBT = persistent, bioaccumulative and toxic, vPvB= very persistent and very bioaccumulative, POP= persistent organic pollutants*);
- based on a strong hazard component for other classes of substances (*carcinogens, toxic for reproduction, endocrine disruptors*).

In Reg. 528/2012, *exclusion criteria* are:

- purely based on hazard considerations for certain classes of substances (*mutagens, PBT = persistent, bioaccumulative and toxic, vPvB= very persistent and very bioaccumulative, carcinogens, toxic for reproduction, endocrine disruptors*) when used by consumers;

based on a strong hazard component for the same classes of substances when used by professional users.

The results of the screening do not constitute evaluations of individual substances to be carried out under the respective chemical legislations [[in particular, Regulation (EC) No 1107/2009 on plant protection products, Regulation (EU) No 528/2012 on biocidal products, Regulation (EC) No 1907/2006 REACH, Regulation (EC) No 1223/2009 on cosmetic products and the Water Framework Directive (EC) No 2000/60] and in no way prejudice future decisions on active substances to be taken pursuant to these pieces of the EU legislation. It would thus be erroneous to consider that the substances listed in the results of this study (SANTE/2015/E3/SI2.706218) are considered as endocrine disruptors within the meaning of the EU legislation.

As presented in the Categorization Results Table (see Appendix 3.1), out of 96 BPs screened, 16 BPs were classified as EDs and 80 as "Unclassified" under "Option 1". Of these 80 BPs, one BP (No 10) is classified as Repr. Cat. 1A and, thus for this substance the exclusion/cut-off criteria of Article 5 of Regulation (EC) 528/2012 are also applicable. Under "Option 2", 5 substances were classified as EDs (equivalent to Cat I under "Option 3"), and 4 substances were classified as EDs under "Option 4" (Table 3.1).

Table 3.1. Potential categorization results for human health for the 96 BPs screened.

Human health		Potential Categorization									
		Option 1*		Option 2		Option 3				Option 4	
		ED***	Unclassified	ED	Unclassified	Cat I	Cat II	Cat III	Unclassified	ED	Unclassified
Number of BPs	Harmonised C&L	11	85*	5	91	5	26	11	54	4	92
	Most recent C&L proposal**	16	80								

* For 27 substances there is no harmonised C & L available, which is interpreted as "Unclassified".
 ** Taking into account the proposed classification - i.e. the classification proposal concluded during the peer review process under Regulation (EC) 1107/2009 (EFSA Conclusion or DAR/RAR) and/or under Regulation (EU) 528/2012 (ECHA Assessment Report/CAR) - when this is more recent than the decision for the harmonised C&L.
 *** The substances categorized as EDs under "Option 1" are significantly higher in number because they include groups of related substances (i.e. 6 borate compounds that have a harmonised classification as Repr Cat 1A or 1B and are toxic to endocrine organs)

Regarding vertebrate wildlife, 6 BPs were classified as EDs under "Option 2" (equivalent to Cat I under "Option 3"), whilst 5 BPs were classified as EDs under "Option 4" (Table 3.2).

Table 3.2. Potential categorization results for vertebrate wildlife for the 96 BPs screened.

Vertebrate wildlife		Potential Categorization							
		Option 2		Option 3				Option 4	
		ED	Unclassified	Cat I	Cat II	Cat III	Unclassified	ED	Unclassified
Number of BPs		6	90	6	26	9	55	5	91

For combined/overall potential categorization, the more conservative outcome has been considered i.e. the most recent classification in case of "Option 1", the most severe categorization between human health and vertebrate wildlife in case of "Option 2, 3 & 4" (Table 3.3). Consequently, 16 BPs were classified as EDs under "Option 1", 6 BPs were classified as EDs under "Option 2" (equivalent to Cat I under "Option 3") whilst 5 BPs were classified as EDs under "Option 4".

Table 3.3. Combined potential categorization results for human health and vertebrate wildlife for the 96 BPs screened.

Human health and vertebrate wildlife	Potential Categorization									
	Option 1 (Most recent)		Option 2		Option 3				Option 4	
	ED	Unclassified	ED	Unclassified	Cat I	Cat II	Cat III	Unclassified	ED	Unclassified
Number of BPs	16	80	6	90	6	27	9	54	5	91

For "Option 3", the Paths of the decision tree (please refer to Appendix I) leading to each categorization are presented in Table 3.4 for human health assessment and in Table 3.5 for vertebrate wildlife assessment. As it is shown in Table 3.4, 1 out of 5 BPs categorized as Cat I are through Path 2a resulting from EATS specific adversity and *in vivo* mechanistic data, 2 BPs are concluded as Cat I through combined Paths 2a, 2b (EATS specific adversity and a plausible link with *in vivo/in vitro* mechanistic data) and 2 BPs are categorized as Cat I through Path 4 (Non-specific adversity (may or may not be indicative of EATS) and *in vivo* mechanistic information). Regarding classification as Cat II, out of 26 BPs classified as Cat II, 14 BPs were classified through Path 3a resulting from evidence of EATS specific adversity but absence of *in vivo/in vitro* mechanistic effects (either results showed no effects or there were no data available). Out of 11 substances classified as Cat III under "Option 3", 7 BPs reached this classification through Path 7 resulting from Non-specific adversity (may or may not be indicative of EATS) and positive *in vitro* mechanistic data but with no plausible link. Finally, out of 54 substances categorized as "Unclassified", 39 BPs reached this conclusion through Path 11 resulting from absence of adversity and mechanistic data. For the other 15 there were adverse effects but these were non-specific and in the absence of any mechanistic data either *in vitro* or *in vivo* to indicate an endocrine mode of action or, alternatively, in the presence of negative mechanistic data the substances were designated "Unclassified" (Path 8).

Table 3.4. Presentation of the results for “Option 3” and the different Paths leading to the different categories or to “Unclassified” for human health.

BPs	Potential Categorization - Option 3 (human health) Number of substances							
	Cat I		Cat II		Cat III		Unclassified	
Total number	5		26		11		54	
	Path 1	-	Path 3a	14	Path 7	7	Path 8	15
	Path 2a	1	Path 3b	7	Path 10	4	Path 11	39
	Path 2b	-	Path 3a, 3b	2				
	Path 2a, 2b	2	Path 5	2				
	Path 4	2	Path 6	-				
			Path 5 & 6	1				
			Path 9	-				

Similar results were obtained for the classification of vertebrate wildlife under “Option 3” (Table 3.5). For 4 BPs, Path 2a was used in order to be classified as Cat I, whilst for the 3 of them Path 2b was also used. 2 BPs were classified as Cat I through Path 4. 14 out of 26 BPs were classified as Cat II through Path 3a (EATS specific adversity and absence of endocrine MoA data), 5 out of 9 BPs reached Cat III through Path 7 (Non-specific adversity (may or may not be indicative of EATS) and *in vitro* mechanistic data) and finally 39 out of 55 BPs were concluded as “Unclassified” through Path 11.

Table 3.5. Presentation of the results for "Option 3" and the different Paths leading to the different categories or to "Unclassified" for vertebrate wildlife.

BPs	Potential Categorization - Option 3 (vertebrate wildlife*)							
	Cat I		Cat II		Cat III		Unclassified	
Total number	6		26		9		55	
	Path 1	-	Path 3a	14	Path 7	5	Path 8	16
	Path 2a	1	Path 3b	8	Path 10	4	Path 11	39
	Path 2b	-	Path 3a, 3b	1				
	Path 2a, 2b	3	Path 5	2				
	Path 1,2a,2b	-	Path 6	-				
	Path 4	2	Path 5 & 6	1				
			Path 9	-				

Out of the 6 BPs that were classified as Cat I under "Option 3" for wildlife vertebrates, only one substance reached this categorization based solely on non-mammalian ecotoxicity data.

F. References

- JRC, 2016. Screening methodology to identify endocrine disruptors according to different options in the context of an impact assessment.
- EC, 2014. Defining criteria for identifying Endocrine Disruptors in the context of the implementation of the Plant Protection Product Regulation and Biocidal Products Regulation. DG ENV.A.3, DG SANCO.E.3. http://ec.europa.eu/smart-regulation/impact/planned_ia/docs/2014_env_009_endocrine_disruptors_en.pdf
- EC, 2015. Selection of chemical substances to be screened in the context of the impact assessment on criteria to identify endocrine disruptors. http://ec.europa.eu/health/endocrine_disruptors/policy/index_en.htm
- EC, 2009. Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC. OJ L 309, 24.11.2009, p. 1–50
- EC, 2012. Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products Text with EEA relevance. OJ L 167, 27.6.2012, p. 1–123
- EC, 2008. Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006. OJ L 353, 31.12.2008, p. 1–1355

Appendix 3.1

The results of potential categorization for each the 96 BP substances according to the four "Options" of the Roadmap (EC, 2014) for human health and vertebrate wildlife assessment are presented below:

The results of the screening do not constitute evaluations of individual substances to be carried out under the respective chemical legislations [[in particular, Regulation (EC) No 1107/2009 on plant protection products, Regulation (EU) No 528/2012 on biocidal products, Regulation (EC) No 1907/2006 REACH, Regulation (EC) No 1223/2009 on cosmetic products and the Water Framework Directive (EC) No 2000/60] and in no way prejudge future decisions on active substances to be taken pursuant to these pieces of the EU legislation. It would thus be erroneous to consider that the substances listed in the results of this study (SANTE/2015/E3/SI2.706218) are considered as endocrine disruptors within the meaning of the EU legislation.

Potential categorization results of the 96 BPs under "Option 1"

	Chemical Name	Carc Cat. 2 (C&L Harmonised)	Carc Cat. 2 (C&L Proposed)	Repr. Cat. 2 (C&L Harmonised)	Repr. Cat. 2 (C&L Proposed)	Carc Cat. 1A or 1B (C&L Harmonised)	Carc Cat. 1A or 1B (C&L Proposed)	Repr. Cat. 1A or 1B (C&L Harmonised)	Repr. Cat. 1A or 1B (C&L Proposed)	Effects on Endocrine organs (YES/NO)	OPTION 1 Harmonized	OPTION 1 Proposed	OPTION 1 Most recent
1	Carbon dioxide	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	No	Unclassified*	Unclassified	Unclassified
2	Tebuconazole	No	Not relevant	Yes	Not relevant	No	Not relevant	No	No	Yes	ED	Not relevant	ED
3	Methyl nonyl ketone	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	No	Unclassified*	Unclassified	Unclassified
4	Fipronil	No	No	No	No	No	No	No	No	Yes	Unclassified	Unclassified	Unclassified
5	Magnesium phosphide	No	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	Unclassified	Not relevant	Unclassified
6	Imidacloprid	No	No	No	No	No	No	No	No	No	Unclassified	Unclassified	Unclassified
7	Thiabendazole	No	No	No	No	No	No	No	No	Yes	Unclassified	Unclassified	Unclassified
8	Aluminium phosphide	No	No	No	No	No	No	No	No	No	Unclassified	Unclassified	Unclassified
9	Sulfuryl fluoride	No	No	No	No	No	No	No	No	No	Unclassified	Unclassified	Unclassified
10	Bromadiolone	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	Yes	No	Unclassified*	Cut off criteria are applicable / Repr Cat 1A/B	Cut off criteria are applicable / Repr Cat 1A/B
11	Diflubenzuron	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	No	Unclassified*	Unclassified	Unclassified
12	Dazomet	No	No	No	Yes	No	No	No	No	Yes	Unclassified	ED	ED
13	Difenacoum	No	No	No	No	No	No	No	Yes	Yes	Unclassified	ED / Cut off criteria are applicable / Repr Cat 1A/B	ED / Cut off criteria are applicable / Repr Cat 1A/B

The results of the screening do not constitute evaluations of individual substances to be carried out under the respective chemical legislations [[in particular, Regulation (EC) No 1107/2009 on plant protection products, Regulation (EU) No 528/2012 on biocidal products, Regulation (EC) No 1907/2006 REACH, Regulation (EC) No 1223/2009 on cosmetic products and the Water Framework Directive (EC) No 2000/60] and in no way prejudice future decisions on active substances to be taken pursuant to these pieces of the EU legislation.

It would thus be erroneous to consider that the substances listed in the results of this study (SANTE/2015/E3/SI2.706218) are considered as endocrine disruptors within the meaning of the EU legislation.

Screening of available evidence on chemical substances for the identification of endocrine disruptors according to different options in the context of an Impact Assessment

	Chemical Name	Carc Cat. 2 (C&L Harmonised)	Carc Cat. 2 (C&L Proposed)	Repr. Cat. 2 (C&L Harmonised)	Repr. Cat. 2 (C&L Proposed)	Carc Cat. 1A or 1B (C&L Harmonised)	Carc Cat. 1A or 1B (C&L Proposed)	Repr. Cat. 1A or 1B (C&L Harmonised)	Repr. Cat. 1A or 1B (C&L Proposed)	Effects on Endocrine organs (YES/NO)	OPTION 1 Harmonized	OPTION 1 Proposed	OPTION 1 Most recent
14	Fenpropimorph	No	No	Yes	Yes	No	No	No	No	Yes	ED	ED	ED
15	Abamectin (aka avermectin)	No	No	Yes	Yes	No	No	No	No	Yes	ED	ED	ED
16	Fenoxycarb	Yes	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	Yes	Unclassified	Not relevant	Unclassified
17	Etofenprox	No	Not relevant	Yes	Not relevant	No	Not relevant	No	No	No	Unclassified	Not relevant	Unclassified
18	Bifenthrin	Yes	Yes	No	No	No	No	No	No	Yes	Unclassified	Unclassified	Unclassified
19	lambda-Cyhalothrin	No	No	No	No	No	No	No	No	Yes	Unclassified	Unclassified	Unclassified
20	Cyproconazole	No	Not relevant	No	Not relevant	No	Not relevant	Yes	Not relevant	Yes	ED - Cut off criteria are applicable / Repr Cat 1A/B	Not relevant	ED - Cut off criteria are applicable / Repr Cat 1A/B
21	Pyriproxyfen	No	No	No	No	No	No	No	No	Yes	Unclassified	Unclassified	Unclassified
22	Folpet	Yes	Yes	No	No	No	No	No	No	No	Unclassified	Unclassified	Unclassified
294	Clothianidin	No	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	Yes	Unclassified	Not relevant	Unclassified
295	Propiconazole	No	No	No	No	No	No	No	No	No	Unclassified	Unclassified	Unclassified
296	Thiacloprid	Yes	Not relevant	No	Not relevant	No	Not relevant	Yes	Not relevant	Yes	ED - Cut off criteria are applicable / Repr Cat 1A/B	Not relevant	ED - Cut off criteria are applicable / Repr Cat 1A/B
297	Pelargonic acid (Nonanoic acid)	No	No	No	No	No	No	No	No	No	Unclassified	Unclassified	Unclassified
298	Caprylic acid (Octanoic acid)	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	No	Unclassified*	Unclassified	Unclassified
299	Lauric acid	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	No	Unclassified*	Unclassified	Unclassified

The results of the screening do not constitute evaluations of individual substances to be carried out under the respective chemical legislations [[in particular, Regulation (EC) No 1107/2009 on plant protection products, Regulation (EU) No 528/2012 on biocidal products, Regulation (EC) No 1907/2006 REACH, Regulation (EC) No 1223/2009 on cosmetic products and the Water Framework Directive (EC) No 2000/60] and in no way prejudice future decisions on active substances to be taken pursuant to these pieces of the EU legislation.

It would thus be erroneous to consider that the substances listed in the results of this study (SANTE/2015/E3/SI2.706218) are considered as endocrine disruptors within the meaning of the EU legislation.

Screening of available evidence on chemical substances for the identification of endocrine disruptors according to different options in the context of an Impact Assessment

	Chemical Name	Carc Cat. 2 (C&L Harmonised)	Carc Cat. 2 (C&L Proposed)	Repr. Cat. 2 (C&L Harmonised)	Repr. Cat. 2 (C&L Proposed)	Carc Cat. 1A or 1B (C&L Harmonised)	Carc Cat. 1A or 1B (C&L Proposed)	Repr. Cat. 1A or 1B (C&L Harmonised)	Repr. Cat. 1A or 1B (C&L Proposed)	Effects on Endocrine organs (YES/NO)	OPTION 1 Harmonized	OPTION 1 Proposed	OPTION 1 Most recent
300	Thiamethoxam	No	No	No	No	No	No	No	No	Yes	Unclassified	Unclassified	Unclassified
301	Spinosad	No	No	No	No	No	No	No	No	No	Unclassified	Unclassified	Unclassified
302	Copper hydroxide	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	No	Unclassified*	Unclassified	Unclassified
303	Capric acid (Decanoic acid)	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	No	Unclassified*	Unclassified	Unclassified
304	Cypermethrin	No	No	No	No	No	No	No	No	Yes	Unclassified	Unclassified	Unclassified
305	Deltamethrin	No	No	No	No	No	No	No	No	Yes	Unclassified	Unclassified	Unclassified
306	Benzoic acid	No	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	Yes	Unclassified	Not relevant	Unclassified
307	Alpha-Cypermethrin (aka alphamethrin)	No	No	No	No	No	No	No	No	No	Unclassified	Unclassified	Unclassified
343	Indoxacarb	No	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	Unclassified	Not relevant	Unclassified
429	tolyfluanid	No	No	No	No	No	No	No	No	Yes	Unclassified	Unclassified	Unclassified
430	flufenoxuron	No	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	Unclassified	Not relevant	Unclassified
431	Didecyldimethylammonium chloride; DDAC	No	No	No	No	No	No	No	No	No	Unclassified	Unclassified	Unclassified
432	Tralopyril	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	No	Unclassified*	Unclassified	Unclassified
433	Permethrin	No	No	No	No	No	No	No	No	Yes	Unclassified	Unclassified	Unclassified
434	IPBC	No	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	Unclassified	Not relevant	Unclassified
435	Boric acid	No	No	No	No	No	No	Yes	Yes	Yes	ED	ED	ED
436	Difethialone	No	Not relevant	No	Not relevant	No	Not relevant	Yes	Not relevant	No	Unclassified	Not relevant	Unclassified
437	Acrolein	No	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	Unclassified	Not relevant	Unclassified
438	dichlofluanid	No	No	No	No	No	No	No	No	Yes	Unclassified	Unclassified	Unclassified
439	Transfluthrin	No	No	No	No	No	No	No	No	No	Unclassified	Unclassified	Unclassified
440	Basic Copper carbonate	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	No	Unclassified*	Unclassified	Unclassified

The results of the screening do not constitute evaluations of individual substances to be carried out under the respective chemical legislations [[in particular, Regulation (EC) No 1107/2009 on plant protection products, Regulation (EU) No 528/2012 on biocidal products, Regulation (EC) No 1907/2006 REACH, Regulation (EC) No 1223/2009 on cosmetic products and the Water Framework Directive (EC) No 2000/60] and in no way prejudice future decisions on active substances to be taken pursuant to these pieces of the EU legislation.

It would thus be erroneous to consider that the substances listed in the results of this study (SANTE/2015/E3/SI2.706218) are considered as endocrine disruptors within the meaning of the EU legislation.

Screening of available evidence on chemical substances for the identification of endocrine disruptors according to different options in the context of an Impact Assessment

	Chemical Name	Carc Cat. 2 (C&L Harmonised)	Carc Cat. 2 (C&L Proposed)	Repr. Cat. 2 (C&L Harmonised)	Repr. Cat. 2 (C&L Proposed)	Carc Cat. 1A or 1B (C&L Harmonised)	Carc Cat. 1A or 1B (C&L Proposed)	Repr. Cat. 1A or 1B (C&L Harmonised)	Repr. Cat. 1A or 1B (C&L Proposed)	Effects on Endocrine organs (YES/NO)	OPTION 1 Harmonized	OPTION 1 Proposed	OPTION 1 Most recent
	(mentioned in ECHA as Copper(II) Carbonate)												
441	Zineb	No	No	No	Yes	No	No	No	No	Yes	Unclassified	ED	ED
442	Chlorfenapyr	No	No	No	No	No	No	No	No	No	Unclassified	Unclassified	Unclassified
443	Disodium tetraborate pentahydrate	No	No	No	No	No	No	Yes	Yes	Yes	ED	ED	ED
444	Disodium octaborate tetrahydrate	No	Not relevant	No	Not relevant	No	Not relevant	Yes	Not relevant	Yes	ED	Not relevant	ED
445	Warfarin sodium	No	Not relevant	No	Not relevant	No	Not relevant	Yes	Not relevant	No	Unclassified	Not relevant	Unclassified
446	Boric oxide	No	No	No	No	No	No	Yes	Yes	Yes	ED	ED	ED
447	Disodium tetraborate decahydrate	No	No	No	No	No	No	Yes	Yes	Yes	ED	ED	ED
448	Copper (II) oxide	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	No	Unclassified*	Unclassified	Unclassified
449	Disodium tetraborate	No	No	No	No	No	No	Yes	Yes	Yes	ED	ED	ED
450	N,N-diethyl-meta-toluamide (DEET)	No	No	No	No	No	No	No	No	No	Unclassified	Unclassified	Unclassified
451	alphachloralose (chloralose)	No	No	No	No	No	No	No	No	No	Unclassified	Unclassified	Unclassified
453	Bendiocarb	No	No	No	No	No	No	No	No	No	Unclassified	Unclassified	Unclassified
454	Metofluthrin	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	No	Unclassified*	Unclassified	Unclassified
455	Polyvinylpyrrolidone iodine	No	No	No	No	No	No	No	No	No	Unclassified	Unclassified	Unclassified
456	1R-trans phenothrin	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	Yes	Unclassified*	Unclassified	Unclassified
457	cis-tricos-9-ene (Muscalure)	No	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	Unclassified	Not relevant	Unclassified
459	Cu-HDO	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	No	Unclassified*	Unclassified	Unclassified
460	Chlorophacinone	No	No	No	No	No	No	No	Yes	No	Unclassified	Unclassified	Unclassified

The results of the screening do not constitute evaluations of individual substances to be carried out under the respective chemical legislations [[in particular, Regulation (EC) No 1107/2009 on plant protection products, Regulation (EU) No 528/2012 on biocidal products, Regulation (EC) No 1907/2006 REACH, Regulation (EC) No 1223/2009 on cosmetic products and the Water Framework Directive (EC) No 2000/60] and in no way prejudice future decisions on active substances to be taken pursuant to these pieces of the EU legislation.

It would thus be erroneous to consider that the substances listed in the results of this study (SANTE/2015/E3/SI2.706218) are considered as endocrine disruptors within the meaning of the EU legislation.

Screening of available evidence on chemical substances for the identification of endocrine disruptors according to different options in the context of an Impact Assessment

	Chemical Name	Carc Cat. 2 (C&L Harmonised)	Carc Cat. 2 (C&L Proposed)	Repr. Cat. 2 (C&L Harmonised)	Repr. Cat. 2 (C&L Proposed)	Carc Cat. 1A or 1B (C&L Harmonised)	Carc Cat. 1A or 1B (C&L Proposed)	Repr. Cat. 1A or 1B (C&L Harmonised)	Repr. Cat. 1A or 1B (C&L Proposed)	Effects on Endocrine organs (YES/NO)	OPTION 1 Harmonized	OPTION 1 Proposed	OPTION 1 Most recent
461	Ethyl butylacetylaminopropionate (IR3535)	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	No	Unclassified*	Unclassified	Unclassified
462	Brodifacoum	No	No	No	No	No	No	No	Yes	No	Unclassified	Unclassified	Unclassified
463	Coumatetralyl	No	No	No	No	No	No	No	Yes	No	Unclassified	Unclassified	Unclassified
464	4,5-Dichloro-2-octylisothiazol-3(2H)-one (DCOIT)	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	No	Unclassified*	Unclassified	Unclassified
465	S-Methoprene	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	No	Unclassified*	Unclassified	Unclassified
466	K-HDO	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	No	Unclassified*	Unclassified	Unclassified
467	Alkyl (C12-16) dimethylbenzyl ammonium chloride; C 12-16-ADBAC	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	No	Unclassified*	Unclassified	Unclassified
468	hydrogen cyanide	No	No	No	No	No	No	No	No	Yes	Unclassified	Unclassified	Unclassified
469	Iodine	No	No	No	No	No	No	No	No	No	Unclassified	Unclassified	Unclassified
470	Hydrochloric acid [same as Hydrogen chloride]	No	No	No	No	No	No	No	No	No	Unclassified	Unclassified	Unclassified
471	Nitrogen	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	No	Unclassified*	Unclassified	Unclassified
472	Copper sulphate pentahydrate	No	No	No	No	No	No	No	No	No	Unclassified	Unclassified	Unclassified
473	Bromoacetic acid	No	No	No	No	No	No	No	No	No	Unclassified	Unclassified	Unclassified
474	Creosote	No	No	No	Yes (developmental)	Yes	Yes	No	Yes (fertility)	No	Unclassified	ED	ED
475	Warfarin	No	Not relevant	No	Not relevant	No	Not relevant	Yes	Not relevant	No	Unclassified	Not relevant	Unclassified
476	DDACarbonate	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	No	Unclassified*	Unclassified	Unclassified

The results of the screening do not constitute evaluations of individual substances to be carried out under the respective chemical legislations [[in particular, Regulation (EC) No 1107/2009 on plant protection products, Regulation (EU) No 528/2012 on biocidal products, Regulation (EC) No 1907/2006 REACH, Regulation (EC) No 1223/2009 on cosmetic products and the Water Framework Directive (EC) No 2000/60] and in no way prejudice future decisions on active substances to be taken pursuant to these pieces of the EU legislation.

It would thus be erroneous to consider that the substances listed in the results of this study (SANTE/2015/E3/SI2.706218) are considered as endocrine disruptors within the meaning of the EU legislation.

Screening of available evidence on chemical substances for the identification of endocrine disruptors according to different options in the context of an Impact Assessment

	Chemical Name	Carc Cat. 2 (C&L Harmonised)	Carc Cat. 2 (C&L Proposed)	Repr. Cat. 2 (C&L Harmonised)	Repr. Cat. 2 (C&L Proposed)	Carc Cat. 1A or 1B (C&L Harmonised)	Carc Cat. 1A or 1B (C&L Proposed)	Repr. Cat. 1A or 1B (C&L Harmonised)	Repr. Cat. 1A or 1B (C&L Proposed)	Effects on Endocrine organs (YES/NO)	OPTION 1 Harmonized	OPTION 1 Proposed	OPTION 1 Most recent
477	Flocoumafen	No	No	No	No	No	No	No	Yes	No	Unclassified	Unclassified	Unclassified
480	Glutaraldehyde	No	No	No	No	No	No	No	No	Yes	Unclassified	Unclassified	Unclassified
481	Copper pyrithione	Not relevant	No	Not relevant	Yes (development)	Not relevant	No	Not relevant	No	Yes	Unclassified*	ED	ED
482	Dinotefuran	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	No	Unclassified*	Unclassified	Unclassified
483	Potassium sorbate	No	No	No	No	No	No	No	No	Yes	Unclassified	Unclassified	Unclassified
484	MIT	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	No	Unclassified*	Unclassified	Unclassified
485	D CPP	No	No	No	No	No	No	No	No	No	Unclassified	Unclassified	Unclassified
486	C(M)IT/MIT	No	No	No	No	No	No	No	No	No	Unclassified	Unclassified	Unclassified
487	MBM	Not relevant	No	Not relevant	No	Not relevant	Yes	Not relevant	No	No	Unclassified*	Unclassified	Unclassified
488	Propan-2-ol	No	No	No	No	No	No	No	No	Yes	Unclassified	Unclassified	Unclassified
489	Hydrogen peroxide	No	No	No	No	No	No	No	No	No	Unclassified	Unclassified	Unclassified
490	Medetomidine	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	No	Unclassified*	Unclassified	Unclassified
491	Hexaflumuron	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	No	Unclassified*	Unclassified	Unclassified

Unclassified*: No harmonized classification available

The results of the screening do not constitute evaluations of individual substances to be carried out under the respective chemical legislations [[in particular, Regulation (EC) No 1107/2009 on plant protection products, Regulation (EU) No 528/2012 on biocidal products, Regulation (EC) No 1907/2006 REACH, Regulation (EC) No 1223/2009 on cosmetic products and the Water Framework Directive (EC) No 2000/60] and in no way prejudice future decisions on active substances to be taken pursuant to these pieces of the EU legislation.

It would thus be erroneous to consider that the substances listed in the results of this study (SANTE/2015/E3/SI2.706218) are considered as endocrine disruptors within the meaning of the EU legislation.

Potential categorization results of the 96 BPs under "Option 2, 3 & 4" for human health & vertebrate wildlife and combined potential categorization under all Options

		Potential Categorization Human Health				Potential Categorization Wildlife Vertebrates				Combined Potential Categorization (HH & Wildlife Vertebrates)			
	Chemical Name	OPTION 2	OPTION 3	Path of decision tree	OPTION 4	OPTION 2	OPTION 3	Path of decision tree	OPTION 4	OPTION 1 Most recent	OPTION 2	OPTION 3	OPTION 4
1	Carbon dioxide	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
2	Tebuconazole	ED	Cat I	2a, 2b	Unclassified	ED	Cat I	2a, 2b	Unclassified	ED	ED	Cat I	Unclassified
3	Methyl nonyl ketone	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
4	Fipronil	Unclassified	Cat II	5	Unclassified	Unclassified	Cat II	3b	Unclassified	Unclassified	Unclassified	Cat II	Unclassified
5	Magnesium phosphide	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
6	Imidacloprid	Unclassified	Cat III	10	Unclassified	Unclassified	Cat III	10	Unclassified	Unclassified	Unclassified	Cat III	Unclassified
7	Thiabendazole	Unclassified	Cat II	3b	Unclassified	Unclassified	Cat II	3b	Unclassified	Unclassified	Unclassified	Cat II	Unclassified
8	Aluminium phosphide	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
9	Sulfuryl fluoride	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
10	Bromadiolone	Unclassified	Unclassified	8	Unclassified	Unclassified	Unclassified	8	Unclassified	Cut off criteria are applicable / Repr Cat 1A/B	Unclassified	Unclassified	Unclassified
11	Diflubenzuron	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
12	Dazomet	Unclassified	Cat II	3b	Unclassified	Unclassified	Cat II	3b	Unclassified	ED	Unclassified	Cat II	Unclassified
13	Difenacoum	Unclassified	Cat II	3a	Unclassified	Unclassified	Cat II	3a	Unclassified	ED / Cut off	Unclassified	Cat II	Unclassified

The results of the screening do not constitute evaluations of individual substances to be carried out under the respective chemical legislations [[in particular, Regulation (EC) No 1107/2009 on plant protection products, Regulation (EU) No 528/2012 on biocidal products, Regulation (EC) No 1907/2006 REACH, Regulation (EC) No 1223/2009 on cosmetic products and the Water Framework Directive (EC) No 2000/60] and in no way prejudice future decisions on active substances to be taken pursuant to these pieces of the EU legislation.

It would thus be erroneous to consider that the substances listed in the results of this study (SANTE/2015/E3/SI2.706218) are considered as endocrine disruptors within the meaning of the EU legislation.

Screening of available evidence on chemical substances for the identification of endocrine disruptors according to different options in the context of an Impact Assessment

		Potential Categorization Human Health				Potential Categorization Wildlife Vertebrates				Combined Potential Categorization (HH & Wildlife Vertebrates)			
	Chemical Name	OPTION 2	OPTION 3	Path of decision tree	OPTION 4	OPTION 2	OPTION 3	Path of decision tree	OPTION 4	OPTION 1 Most recent	OPTION 2	OPTION 3	OPTION 4
										criteria are applicable / Repr Cat 1A/B			
14	Fenpropimorph	Unclassified	Unclassified	8	Unclassified	Unclassified	Unclassified	8	Unclassified	ED	Unclassified	Unclassified	Unclassified
15	Abamectin (aka avermectin)	Unclassified	Cat II	3a	Unclassified	Unclassified	Cat II	3a	Unclassified	ED	Unclassified	Cat II	Unclassified
16	Fenoxycarb	Unclassified	Cat III	7	Unclassified	Unclassified	Cat III	7	Unclassified	Unclassified	Unclassified	Cat III	Unclassified
17	Etofenprox	Unclassified	Cat III	7	Unclassified	Unclassified	Cat III	7	Unclassified	Unclassified	Unclassified	Cat III	Unclassified
18	Bifenthrin	Unclassified	Cat III	7	Unclassified	Unclassified	Cat II	5	Unclassified	Unclassified	Unclassified	Cat II	Unclassified
19	lambda-Cyhalothrin	Unclassified	Cat II	5 & 6	Unclassified	Unclassified	Cat II	5 & 6	Unclassified	Unclassified	Unclassified	Cat II	Unclassified
20	Cyproconazole	Unclassified	Cat II	3b	Unclassified	ED	Cat I	2a & 2b	ED	ED - Cut off criteria are applicable / Repr Cat 1A/B	ED	Cat I	ED
21	Pyriproxyfen	Unclassified	Cat II	3b	Unclassified	Unclassified	Cat II	3b	Unclassified	Unclassified	Unclassified	Cat II	Unclassified
22	Folpet	Unclassified	Cat III	7	Unclassified	Unclassified	Cat III	7	Unclassified	Unclassified	Unclassified	Cat III	Unclassified
294	Clothianidin	Unclassified	Cat II	3a	Unclassified	Unclassified	Cat II	3a	Unclassified	Unclassified	Unclassified	Cat II	Unclassified
295	Propiconazole	Unclassified	Cat II	5	Unclassified	Unclassified	Cat II	5	Unclassified	Unclassified	Unclassified	Cat II	Unclassified

The results of the screening do not constitute evaluations of individual substances to be carried out under the respective chemical legislations [[in particular, Regulation (EC) No 1107/2009 on plant protection products, Regulation (EU) No 528/2012 on biocidal products, Regulation (EC) No 1907/2006 REACH, Regulation (EC) No 1223/2009 on cosmetic products and the Water Framework Directive (EC) No 2000/60] and in no way prejudice future decisions on active substances to be taken pursuant to these pieces of the EU legislation.

It would thus be erroneous to consider that the substances listed in the results of this study (SANTE/2015/E3/SI2.706218) are considered as endocrine disruptors within the meaning of the EU legislation.

Screening of available evidence on chemical substances for the identification of endocrine disruptors according to different options in the context of an Impact Assessment

		Potential Categorization Human Health				Potential Categorization Wildlife Vertebrates				Combined Potential Categorization (HH & Wildlife Vertebrates)			
	Chemical Name	OPTION 2	OPTION 3	Path of decision tree	OPTION 4	OPTION 2	OPTION 3	Path of decision tree	OPTION 4	OPTION 1 Most recent	OPTION 2	OPTION 3	OPTION 4
296	Thiacloprid	Unclassified	Cat II	3b	Unclassified	Unclassified	Cat II	3b	Unclassified	ED - Cut off criteria are applicable / Repr Cat 1A/B	Unclassified	Cat II	Unclassified
297	Pelargonic acid (Nonanoic acid)	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
298	Caprylic acid (Octanoic acid)	Unclassified	Cat III	10	Unclassified	Unclassified	Cat III	10	Unclassified	Unclassified	Unclassified	Cat III	Unclassified
299	Lauric acid	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
300	Thiamethoxam	Unclassified	Cat II	3a	Unclassified	Unclassified	Cat II	3a	Unclassified	Unclassified	Unclassified	Cat II	Unclassified
301	Spinosad	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
302	Copper hydroxide	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
303	Capric acid (Decanoic acid)	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
304	Cypermethrin	ED	Cat I	2a, 2b	ED	ED	Cat I	2a, 2b	ED	Unclassified	ED	Cat I	ED
305	Deltamethrin	Unclassified	Cat II	3b	Unclassified	Unclassified	Cat II	3b	Unclassified	Unclassified	Unclassified	Cat II	Unclassified
306	Benzoic acid	Unclassified	Unclassified	8	Unclassified	Unclassified	Unclassified	8	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
307	Alpha-Cypermethrin (aka alphamethrin)	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
343	Indoxacarb	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
429	tolylfluanid	Unclassified	Unclassified	8	Unclassified	Unclassified	Unclassified	8	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
430	flufenoxuron	Unclassified	Unclassified	8	Unclassified	Unclassified	Unclassified	8	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
431	Didecyldimethylammonium chloride; DDAC	Unclassified	Cat III	10	Unclassified	Unclassified	Cat III	10	Unclassified	Unclassified	Unclassified	Cat III	Unclassified

The results of the screening do not constitute evaluations of individual substances to be carried out under the respective chemical legislations [[in particular, Regulation (EC) No 1107/2009 on plant protection products, Regulation (EU) No 528/2012 on biocidal products, Regulation (EC) No 1907/2006 REACH, Regulation (EC) No 1223/2009 on cosmetic products and the Water Framework Directive (EC) No 2000/60] and in no way prejudice future decisions on active substances to be taken pursuant to these pieces of the EU legislation.

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Screening of available evidence on chemical substances for the identification of endocrine disruptors according to different options in the context of an Impact Assessment

		Potential Categorization Human Health				Potential Categorization Wildlife Vertebrates				Combined Potential Categorization (HH & Wildlife Vertebrates)			
	Chemical Name	OPTION 2	OPTION 3	Path of decision tree	OPTION 4	OPTION 2	OPTION 3	Path of decision tree	OPTION 4	OPTION 1 Most recent	OPTION 2	OPTION 3	OPTION 4
432	Tralopyril	Unclassified	Unclassified	8	Unclassified	Unclassified	Unclassified	8	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
433	Permethrin	Unclassified	Cat II	3a/b	Unclassified	Unclassified	Cat II	3b	Unclassified	Unclassified	Unclassified	Cat II	Unclassified
434	IPBC	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
435	Boric acid	Unclassified	Cat II	3a	Unclassified	Unclassified	Cat II	3a	Unclassified	ED	Unclassified	Cat II	Unclassified
436	Difethialone	Unclassified	Unclassified	8	Unclassified	Unclassified	Unclassified	8	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
437	Acrolein	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
438	dichlofluanid	Unclassified	Cat II	3a	Unclassified	Unclassified	Cat II	3a	Unclassified	Unclassified	Unclassified	Cat II	Unclassified
439	Transfluthrin	Unclassified	Unclassified	8	Unclassified	Unclassified	Unclassified	8	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
440	Basic Copper carbonate (mentioned in ECHA as Copper(II) Carbonate)	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
441	Zineb	ED	Cat I	2a	ED	ED	Cat I	2a	ED	ED	ED	Cat I	ED
442	Chlorfenapyr	Unclassified	Cat III	10	Unclassified	Unclassified	Cat III	10	Unclassified	Unclassified	Unclassified	Cat III	Unclassified
443	Disodium tetraborate pentahydrate	Unclassified	Cat II	3a	Unclassified	Unclassified	Cat II	3a	Unclassified	ED	Unclassified	Cat II	Unclassified
444	Disodium octaborate tetrahydrate	Unclassified	Cat II	3a	Unclassified	Unclassified	Cat II	3a	Unclassified	ED	Unclassified	Cat II	Unclassified
445	Warfarin sodium	Unclassified	Unclassified	8	Unclassified	Unclassified	Unclassified	8	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
446	Boric oxide	Unclassified	Cat II	3a	Unclassified	Unclassified	Cat II	3a	Unclassified	ED	Unclassified	Cat II	Unclassified
447	Disodium tetraborate decahydrate	Unclassified	Cat II	3a	Unclassified	Unclassified	Cat II	3a	Unclassified	ED	Unclassified	Cat II	Unclassified
448	Copper (II) oxide	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
449	Disodium tetraborate	Unclassified	Cat II	3a	Unclassified	Unclassified	Cat II	3a	Unclassified	ED	Unclassified	Cat II	Unclassified

The results of the screening do not constitute evaluations of individual substances to be carried out under the respective chemical legislations [[in particular, Regulation (EC) No 1107/2009 on plant protection products, Regulation (EU) No 528/2012 on biocidal products, Regulation (EC) No 1907/2006 REACH, Regulation (EC) No 1223/2009 on cosmetic products and the Water Framework Directive (EC) No 2000/60] and in no way prejudice future decisions on active substances to be taken pursuant to these pieces of the EU legislation.

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Screening of available evidence on chemical substances for the identification of endocrine disruptors according to different options in the context of an Impact Assessment

		Potential Categorization Human Health				Potential Categorization Wildlife Vertebrates				Combined Potential Categorization (HH & Wildlife Vertebrates)			
	Chemical Name	OPTION 2	OPTION 3	Path of decision tree	OPTION 4	OPTION 2	OPTION 3	Path of decision tree	OPTION 4	OPTION 1 Most recent	OPTION 2	OPTION 3	OPTION 4
450	N,N-diethyl-meta-toluamide (DEET)	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
451	alphachloralose (chloralose)	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
453	Bendiocarb	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
454	Metofluthrin	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
455	Polyvinylpyrrolidone iodine	ED	Cat I	4	ED	ED	Cat I	4	ED	Unclassified	ED	Cat I	ED
456	1R-trans phenothrin	Unclassified	Cat III	7	Unclassified	Unclassified	Cat III	7	Unclassified	Unclassified	Unclassified	Cat III	Unclassified
457	cis-tricos-9-ene (Muscalure)	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
459	Cu-HDO	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
460	Chlorophacinone	Unclassified	Cat III	7	Unclassified	Unclassified	Cat III	7	Unclassified	Unclassified	Unclassified	Cat III	Unclassified
461	Ethyl butylacetylaminopropionate (IR3535)	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
462	Brodifacoum	Unclassified	Unclassified	8	Unclassified	Unclassified	Unclassified	8	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
463	Coumatetralyl	Unclassified	Unclassified	8	Unclassified	Unclassified	Unclassified	8	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
464	4,5-Dichloro-2-octylisothiazol-3(2H)-one (DCOIT)	Unclassified	Cat III	7	Unclassified	Unclassified	Cat II	3a/3b	Unclassified	Unclassified	Unclassified	Cat II	Unclassified
465	S-Methoprene	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
466	K-HDO	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
467	Alkyl (C12-16) dimethylbenzyl ammonium chloride; C 12-16-ADBAC	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
468	hydrogen cyanide	Unclassified	Cat II	3a/b	Unclassified	Unclassified	Unclassified	8	Unclassified	Unclassified	Unclassified	Cat II	Unclassified

The results of the screening do not constitute evaluations of individual substances to be carried out under the respective chemical legislations [[in particular, Regulation (EC) No 1107/2009 on plant protection products, Regulation (EU) No 528/2012 on biocidal products, Regulation (EC) No 1907/2006 REACH, Regulation (EC) No 1223/2009 on cosmetic products and the Water Framework Directive (EC) No 2000/60] and in no way prejudice future decisions on active substances to be taken pursuant to these pieces of the EU legislation.

It would thus be erroneous to consider that the substances listed in the results of this study (SANTE/2015/E3/SI2.706218) are considered as endocrine disruptors within the meaning of the EU legislation.

Screening of available evidence on chemical substances for the identification of endocrine disruptors according to different options in the context of an Impact Assessment

		Potential Categorization Human Health				Potential Categorization Wildlife Vertebrates				Combined Potential Categorization (HH & Wildlife Vertebrates)			
	Chemical Name	OPTION 2	OPTION 3	Path of decision tree	OPTION 4	OPTION 2	OPTION 3	Path of decision tree	OPTION 4	OPTION 1 Most recent	OPTION 2	OPTION 3	OPTION 4
469	Iodine	ED	Cat I	4	ED	ED	Cat I	4	ED	Unclassified	ED	Cat I	ED
470	Hydrochloric acid [same as Hydrogen chloride]	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
471	Nitrogen	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
472	Copper sulphate pentahydrate	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
473	Bromoacetic acid	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
474	Creosote	Unclassified	Unclassified	8	Unclassified	Unclassified	Unclassified	8	Unclassified	ED	Unclassified	Unclassified	Unclassified
475	Warfarin	Unclassified	Unclassified	8	Unclassified	Unclassified	Unclassified	8	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
476	DDACarbonate	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
477	Flocoumafen	Unclassified	Unclassified	8	Unclassified	Unclassified	Unclassified	8	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
480	Glutaraldehyde	Unclassified	Cat II	3b	Unclassified	Unclassified	Cat II	3b	Unclassified	Unclassified	Unclassified	Cat II	Unclassified
481	Copper pyrithione	Unclassified	Cat II	3a	Unclassified	Unclassified	Cat II	3a	Unclassified	ED	Unclassified	Cat II	Unclassified
482	Dinotefuran	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
483	Potassium sorbate	Unclassified	Unclassified	8	Unclassified	Unclassified	Unclassified	8	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
484	MIT	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
485	DCPP	Unclassified	Cat II	3a	Unclassified	Unclassified	Cat II	3a	Unclassified	Unclassified	Unclassified	Cat II	Unclassified
486	C(M)IT/MIT	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
487	MBM	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
488	Propan-2-ol	Unclassified	Cat II	3a	Unclassified	Unclassified	Cat II	3a	Unclassified	Unclassified	Unclassified	Cat II	Unclassified
489	Hydrogen peroxide	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
490	Medetomidine	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified

The results of the screening do not constitute evaluations of individual substances to be carried out under the respective chemical legislations [[in particular, Regulation (EC) No 1107/2009 on plant protection products, Regulation (EU) No 528/2012 on biocidal products, Regulation (EC) No 1907/2006 REACH, Regulation (EC) No 1223/2009 on cosmetic products and the Water Framework Directive (EC) No 2000/60] and in no way prejudice future decisions on active substances to be taken pursuant to these pieces of the EU legislation.

It would thus be erroneous to consider that the substances listed in the results of this study (SANTE/2015/E3/SI2.706218) are considered as endocrine disruptors within the meaning of the EU legislation.

Screening of available evidence on chemical substances for the identification of endocrine disruptors according to different options in the context of an Impact Assessment

		Potential Categorization Human Health				Potential Categorization Wildlife Vertebrates				Combined Potential Categorization (HH & Wildlife Vertebrates)			
	Chemical Name	OPTION 2	OPTION 3	Path of decision tree	OPTION 4	OPTION 2	OPTION 3	Path of decision tree	OPTION 4	OPTION 1 Most recent	OPTION 2	OPTION 3	OPTION 4
491	Hexaflumuron	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified

The results of the screening do not constitute evaluations of individual substances to be carried out under the respective chemical legislations [[in particular, Regulation (EC) No 1107/2009 on plant protection products, Regulation (EU) No 528/2012 on biocidal products, Regulation (EC) No 1907/2006 REACH, Regulation (EC) No 1223/2009 on cosmetic products and the Water Framework Directive (EC) No 2000/60] and in no way prejudge future decisions on active substances to be taken pursuant to these pieces of the EU legislation.

It would thus be erroneous to consider that the substances listed in the results of this study (SANTE/2015/E3/SI2.706218) are considered as endocrine disruptors within the meaning of the EU legislation.

CHAPTER 4

Screening of available evidence on chemical substances for the identification of endocrine disruptors according to different options in the context of an Impact Assessment

**Specific Contract
SANTE/2015/E3/SI2.706218**

Addendum to Chapter 2 and Chapter 3

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A. Introduction & Objectives

This addendum to chapters 2 and 3 aims to report amendments to the categorization results of PPPs and BPs following the delivery of the categorization results used for the impact assessment which were included in chapter 2 and chapter 3.

B. Materials & Methods

The excel files of a total of 69 substances were revised in collaboration with JRC in order to include:

1. Additional information from the Endocrine Disruptor Screening Program (EDSP, US EPA) that became available later in the course of this project
2. The ToxCast ER prediction model value which replaced the Individual ToxCast ER assays
3. Additional EASIS references
4. JRC recommendations on data capture and evaluation

The methodology applied was based on the JRC draft methodology provided in May 2015 as amended and described in chapter 1 and supplemented by further WoE considerations as described in chapter 2. Additional minor modifications which have been introduced during the screening of the BPs (chapter 3) were considered.

i. Additional data

ToxCast ER prediction model

All the individual estrogenic assays have been removed and replaced by the ToxCast ER prediction model value. More specifically the following assays have been replaced:

ACEA_T47D_80hr_Positive; ATG_ERa_TRANS; ATG_ERE_CIS; ATG_ERRa_TRANS; ATG_ERRg_TRANS; NVS_NR_bER; NVS_NR_hER; NVS_NR_mERa; OT_ER_ERaERa_1440; OT_ER_ERaERb_0480; OT_ER_ERaERb_1440; OT_ER_ERbERb_0480; OT_ERa_ERE_LUC_Agonist_1440; OT_ERa_ERE_LUC_Antagonist_1440; OT_ERa_GFPERaERE_0120; OT_ERa_GFPERaERE_0480; OT_ERb_ERE_LUC_Antagonist_1440; OT_ER_ERaERa_0480; OT_ER_ERbERb_1440. ER prediction model scores range from 0 (no activity) to 1 (bioactivity of 17- β -estradiol).

Scores above or equal to 0.1 are considered positive for estrogenic activity, scores below 0.001 are considered inactive while scores between 0.001 and 0.1 are considered inconclusive (Browne et al., 2015). In the latter case, the individual ER assays were used. This was applied to 50 PPPs and 18 BPs (Table 4.1 & 4.2).

EDSP Weight of Evidence

EDSP data were available for 29 PPPs as well as for 1 BP (433) (Table 4.1 & 4.2). The "Weight of evidence analysis" from EDSP was used as an additional source document. All Tier 1 assays were captured in the Data summary template version 1.11 using the information provided in Appendix 1 of the aforementioned document. Other Scientifically Relevant Information (OSRI) available in Appendix 2 of the EDSP "Weight of evidence analysis" document, was not systematically captured, although it may have already been reported from other sources. Negative effects were also reported whilst equivocal results were not reported. Studies that had already been captured from other sources (e.g. EASIS, TEDX) were not captured again. For those studies the "Source" Column of the template was modified to indicate that they were also available in EDSP. The EDSP conclusion was also mentioned in cell B7 (Other information/Comments) of the "Data" sheet of the template as was also done in the case of PPPs for Deliverable D2 (chapter 2).

ii. Revised Substances

In total 51 PPPs, 18 BPs (including 4 substances which are approved as both PPPs and BPs) have been revised following inclusion of additional data (Table 4.1 and Table 4.2, respectively).

Table 4.1: Revised PPPs following inclusion of additional data.

PPP #	Chemical Name	CAS	Individual ToxCast ER assays replaced by ER model	EDSP data included	Additional EASIS references
1	Carbon dioxide	124-38-9	1	1	1
2	Tebuconazole	107534-96-3	1	1	
6	Imidacloprid	138261-41-3	1	1	
15	Abamectin (aka avermectin)	71751-41-2	1	1	
18	Bifenthrin	82657-04-3	1	1	1
20	Cyproconazole	94361-06-5	1		
21	Pyriproxyfen	95737-68-1	1	1	
22	Folpet	133-07-3	1	1	
24	2-Phenylphenol (incl. sodium salt orthophenyl phenol)	90-43-7	1	1	
39	Glyphosate (incl. trimesium aka sulfosate)	1071-83-6		1	
46	Tetraconazole	112281-77-3	1		
65	Malathion	121-75-5	1	1	
83	Ethoprophos	13194-48-4	1	1	
85	Captan	133-06-2	1	1	
87	Epoxiconazole	133855-98-8	1		1
106	8-Hydroxyquinoline incl. oxyquinoleine	148-24-3	1		

The results of the screening do not constitute evaluations of individual substances to be carried out under the respective chemical legislations [[in particular, Regulation (EC) No 1107/2009 on plant protection products, Regulation (EU) No 528/2012 on biocidal products, Regulation (EC) No 1907/2006 REACH, Regulation (EC) No 1223/2009 on cosmetic products and the Water Framework Directive (EC) No 2000/60] and in no way prejudice future decisions on active substances to be taken pursuant to these pieces of the EU legislation. It would thus be erroneous to consider that the substances listed in the results of this study (SANTE/2015/E3/SI2.706218) are considered as endocrine disruptors within the meaning of the EU legislation.

PPP #	Chemical Name	CAS	Individual ToxCast ER assays replaced by ER model	EDSP data included	Additional EASIS references
107	Spirodiclofen	148477-71-8	1		
119	Methomyl	16752-77-5	1	1	
126	Benfluralin	1861-40-1	1	1	
132	Oxadiazon	19666-30-9	1		
135	Metribuzin	21087-64-9	1	1	
145	Oxamyl	23135-22-0	1	1	
159	Diuron	330-54-1	1		1
199	Dimethoate	60-51-5	1	1	1
202	Amitrole (aminotriazole)	61-82-5	1		1
210	Esfenvalerate	66230-04-4	1	1	
212	Flutolanil	66332-96-5	1	1	
215	Prochloraz	67747-09-5	1		1
216	Triflumizole	68694-11-1	1		
224	Phosmet	732-11-6	1	1	
256	Tralkoxydim	87820-88-0	1		
258	Myclobutanil	88671-89-0	1	1	
264	2,4-D	94-75-7	1	1	
295	Propiconazole	60207-90-1	1	1	1
304	Cypermethrin	52315-07-8	1	1	1
326	Maneb	12427-38-2	1		
334	Desmedipham	13684-56-5	1		
336	Thiram	137-26-8	1		
337	Ziram	137-30-4	1		
347	Tepraloxydim	149979-41-9	1		
353	Fenamidone	161326-34-7	1		
365	Boscalid (formerly nicobifen)	188425-85-6	1		
366	Chlorothalonil	1897-45-6	1	1	
368	Thiophanate-methyl	23564-05-8	1		
369	Propyzamide	23950-58-5	1	1	
374	Chlorpyrifos	2921-88-2	1	1	1
375	Linuron	330-55-2	1	1	1
379	Iprodione	36734-19-7	1	1	
383	Pendimethalin	40487-42-1	1		
395	Metalaxyl	57837-19-1	1	1	
403	Mancozeb	8018-01-7	1		
408	Metiram	9006-42-2	1		

The results of the screening do not constitute evaluations of individual substances to be carried out under the respective chemical legislations [[in particular, Regulation (EC) No 1107/2009 on plant protection products, Regulation (EU) No 528/2012 on biocidal products, Regulation (EC) No 1907/2006 REACH, Regulation (EC) No 1223/2009 on cosmetic products and the Water Framework Directive (EC) No 2000/60] and in no way prejudice future decisions on active substances to be taken pursuant to these pieces of the EU legislation. It would thus be erroneous to consider that the substances listed in the results of this study (SANTE/2015/E3/SI2.706218) are considered as endocrine disruptors within the meaning of the EU legislation.

Table 4.2: Revised BPs following inclusion of additional data.

BP #	Chemical Name	CAS	Individual ToxCast ER assays replaced by ER model	EDSP data included
435	Boric acid	10043-35-3	1	
430	flufenoxuron	101463-69-8	1	
480	Glutaraldehyde	111-30-8	1	
442	Chlorfenapyr	122453-73-0	1	
450	N,N-diethyl-meta-toluamide	134-62-3	1	
482	Dinotefuran	165252-70-0	1	
453	Bendiocarb	22781-23-3	1	
460	Chlorophacinone	3691-35-8	1	
433	Permethrin	52645-53-1	1	1
434	IPBC	55406-53-6	1	
464	4,5-Dichloro-2-octylisothiazol-3(2H)-one	64359-81-5	1	
431	Didecyldimethylammonium chloride; DDAC	7173-51-5 (68424-95-3)	1	
475, 445	Warfarin, Warfarin sodium	81-81-2, 129-06-6	1	
491	Hexaflumuron	86479-06-3	1	
297	Pelargonic acid (Nonanoic acid)*	112-05-0	1	
298	Caprylic acid (Octanoic acid)*	124-07-2	1	
303	Capric acid (Decanoic acid)*	334-48-5	1	
306	Benzoic acid*	65-85-0	1	
435	Boric acid	10043-35-3	1	

Substances with * are also approved as PPPs

C. Examples of revised substances

Examples of PPPs re-evaluated on the basis of additional EDSP/EASIS/ToxCast ER prediction model data and JRC's recommendations, are presented below:

- Flutolanil was initially categorized as Cat III under "Option 3" for human health based only on *in vitro* data indicating ER antagonistic activity deriving from the individual ToxCast ER assays (Path 10 of the decision tree). Those assays were replaced by the ER prediction model showing lack of estrogenic or anti-estrogenic activity which was further supported by *in vitro* EDSP data. Therefore, the categorization of flutolanil changed to "Unclassified" under "Option 3" (Path 11 of the decision tree). Regarding evaluation of vertebrate wildlife, EDSP data from a Fish short-term reproduction assay (FSTRA) were added leading to a shift in categorization from Cat III (Path 10) to Cat I (Path 2a) under "Option 3" and to ED under "Option 4" for vertebrate wildlife. More specifically, the plausible link suggested was the following: "*In vivo* mechanistic data for female fish (decrease in VTG) can be linked to the observed EATS specific effects in the gonads (ootresia) and the consequent decrease in egg production. *In vivo* mechanistic data for male fish (reduced male 2nd sec characteristics) can be linked to the observed EATS specific effects - gonad abnormalities".
- Malathion was categorized as Cat I under "Option 3" and ED under "Option 2" for human health based on a plausible link established between *in vivo* mechanistic (decreased FSH, LH and testosterone levels) and EATS-specific effects (decreased testis weigh, testis histopathology findings, decreased sperm motility and sperm numbers). However, EDSP data captured, included four studies (Hershberger, Female pubertal, Male pubertal and Uterotrophic assay) which showed no effect. As EDSP data are more informative to conclude on ED activity, EATS-specific adverse effects were considered of low WoE. As a result, categorization was changed to Cat II under "Option 3" and "Unclassified" under "Option 2" for human health. The same data was used for vertebrate wildlife evaluation since EDSP data did not provide any additional information and so the categorization outcome was the same as for human health.
- Ziram was categorized as Cat I under "Option 3" and ED under "Option 2" for human health following the establishment of a link between *in vitro* mechanistic data (indicating ER antagonism) and EATS specific effects on reproductive/ endocrine organs (decreased uterus weight, increased testis weight, increased ovary weight and increased epididymis weight). However, the replacement of individual ToxCast ER assays with the ER prediction model showing no anti-estrogenic activity, rendered the previously established link not further plausible. As a result, the categorization for human health was changed to Cat II under "Option 3" and "Unclassified" under "Option 2". The same was applied for vertebrate wildlife evaluation since the same data as for human health were used.

- 8-hydroxyquinoline was initially classified as ED under "Option 2" (equal to Cat I under "Option 3" via Path 2b) as well as under "Option 4" for both human health and vertebrate wildlife. This was based on a plausible link between estrogen receptor antagonism and reproductive dysfunction in female rats and rabbits (demonstrated as abortions, decreased number of live foetuses and estrus cyclicity). After inclusion of the ToxCast ER prediction model value indicating no (anti)estrogenic activity and following JRC's recommendation to consider EATS-specific effects as low WoE (alterations in the number and duration of the oestrus cycle and decreased ovary weight in rat in the presence of maternal toxicity), 8-hydroxyquinoline was re-evaluated as "Unclassified" under "Option 2 & 3" (Path 8 of the decision tree), for both human health and vertebrate wildlife.

D. Results

In this section, and following the inclusion of additional data, the overall summary tables with the revised potential categorization results for (i) 348 PPPs and (ii) 96 BPs (including also the 32 BPs/PPPs) screened for human health and vertebrate wildlife are presented¹³.

Tables 4.3 and 4.4 below show the revised potential categorization under "Option 3" for the 51 PPPs and 18 BPs respectively, after the inclusion of the additional data (see also Appendix 4.1).

Table 4.3. Number of PPPs in each potential category under "Option 3" before and after inclusion of the additional data for human health and vertebrate wildlife.

	Human health		Vertebrate wildlife	
	Previous potential categorization	Revised potential categorization	Previous potential categorization	Revised potential categorization
Cat I	27	16	25	19
Cat II	7	14	11	18
Cat III	12	6	9	3
Unclassified	5	15	6	11

Table 4.4. Number of BPs in each potential category under "Option 3" before and after inclusion of the additional data for human health and vertebrate wildlife.

	Human health		Vertebrate wildlife	
	Previous potential categorization	Revised potential categorization	Previous potential categorization	Revised potential categorization
Cat I	0	0	0	0
Cat II	3	3	4	4
Cat III	5	1	4	1
Unclassified	10	14	10	13

¹³ 347 PPPs and 98 BPs are reported in the impact assessment report because:

- three substances had been already screened when the list of substances to be screened was published (i.e. putrescine, potassium phosphonates and phosphane);
- one substance was covered by others (i.e. quizalofop-P was covered by the variants quizalofop-P-ethyl and quizalofop-P-tefuryl);
- two substances were initially incorrectly reported as being both PPPs and BPs, while they are only PPPs (i.e. triflururon and 2-phenylphenol).

The six substances mentioned above were not identified as EDs in the results of the screening used for the impact assessment (reported in Appendix 2.1 and Appendix 3.1). Therefore the results of the impact assessment are not affected.

The results of the screening do not constitute evaluations of individual substances to be carried out under the respective chemical legislations [[in particular, Regulation (EC) No 1107/2009 on plant protection products, Regulation (EU) No 528/2012 on biocidal products, Regulation (EC) No 1907/2006 REACH, Regulation (EC) No 1223/2009 on cosmetic products and the Water Framework Directive (EC) No 2000/60] and in no way prejudice future decisions on active substances to be taken pursuant to these pieces of the EU legislation. It would thus be erroneous to consider that the substances listed in the results of this study (SANTE/2015/E3/SI2.706218) are considered as endocrine disruptors within the meaning of the EU legislation.

i. PPPs

As agreed during the 2nd Interim meeting, the overall summary tables with the potential categorization results for all 348 PPPs screened for human health (Table 4.5) and vertebrate wildlife (Table 4.6) as well as an overall/combined table for human health and vertebrate wildlife (Table 4.7) and a summary table for "Option 3" results and the different Paths leading to the different categories for human health (Table 4.8) and vertebrate wildlife (Table 4.9), are presented below.

Following the inclusion of additional data, the revised categorization results for each of the 348 PPPs according to the four "Options" of the Roadmap for human health and vertebrate wildlife assessment are presented in Appendix 4.2.

Under "Option 1" and since both the harmonised C&L (when available) and the proposed C&L (when relevant) have been considered for the categorization of the substances, the results are reported in order to allow making a distinction between the substances with a harmonised classification, which have been included in Annex VI of Regulation (EC) 1272/2008 (CLP Regulation), i.e. their classification has been agreed, and those substances for which no harmonised classification is available because discussions have not yet been concluded on a classification proposal.

In the Categorization Results Table (Appendix 4.2), when there is no harmonised C&L available, "Not relevant" is reported. However, when concluding for the categorization under "Option 1", this is interpreted as "Unclassified*", since certain Stakeholders may consider only the official classification as relevant for the application of the interim criteria. The "*" has been added in order to make the distinction from the substances which are categorized as "Unclassified" considering the harmonised C&L included in Annex VI of CLP Regulation.

For all substances where there is no harmonised C&L available (141 out of the 348 PPPs screened) the categorization was concluded considering the proposed classification since this is the most recent one. It is noted that for 11 substances with no harmonised classification i.e. categorized as "Unclassified*", the categorization is different when considering the most recent proposed C&L.

Moreover, for 103 out of the 207 PPPs for which there is a harmonised classification, a more recent C&L proposal in the respective evaluation report has been identified. In these cases, the "Most Recent" "Option 1" outcome is the one based on the proposed C&L (more severe in most cases); it is noted that only for 13 substances the categorization is different when considering the most recent proposed C&L instead of the available harmonised C&L. In cases where the proposed classification has been questioned in the evaluation report, i.e. a question mark (?) has been added since it has been considered that the issue should be flagged to ECHA. This question mark has been maintained when populating the relevant data and reporting the outcome in the Categorization Results Table.

As presented in the Categorization Results Table (Appendix 4.2), out of 348 PPPs screened, 50 PPPs were classified as EDs under "Option 1". Of these 50 PPPs, 9 PPPs (No 201, 202, 296, 375, 20, 87, 216, 117 and 13) are classified as Repr. Cat. 1A/B and, thus

for these substances the cut-off criteria¹⁴ of Regulation (EC) 1107/2009 are also applicable.

Table 4.5. Potential categorization results for human health for the 348 PPPs screened after inclusion of the additional data.

Human health	Potential Categorization										
	Option 1*			Option 2		Option 3				Option 4	
		ED	Unclassified	ED	Unclassified	Cat I	Cat II	Cat III	Unclassified	ED	Unclassified
Number of PPPs (348)	Harmonised C&L	27	321*	20	328	20	95	53	180	9	339
	Most recent C&L proposal**	50	298								

*For 141 substances there is no harmonised C & L available which is interpreted as "Unclassified".

**Taking into account the proposed classification i.e. the classification proposal concluded during the peer review process under Regulation (EC) 1107/2009 (EFSA Conclusion or DAR/RAR) and/or under Regulation (EU) 528/2012 (ECHA Assessment Report/CAR) when this is more recent than the decision for the harmonised C&L.

Regarding vertebrate wildlife, 22 PPPs were classified as EDs under "Option 2" (equivalent to Cat I under "Option 3"), whilst only 16 PPPs were classified as EDs under "Option 4" (Table 4.6).

¹⁴ The term "cut-off criteria" is not used in the legislation. It is used in common language to refer to *approval criteria* in Reg. 1107/2009 and *exclusion criteria* in Reg. 528/2012.

In Reg. 1107/2009, *approval criteria* are:

- purely based on hazard considerations for certain classes of substances (*mutagens, PBT = persistent, bioaccumulative and toxic, vPvB= very persistent and very bioaccumulative, POP= persistent organic pollutants*);
- based on a strong hazard component for other classes of substances (*carcinogens, toxic for reproduction, endocrine disruptors*).

In Reg. 528/2012, *exclusion criteria* are:

- purely based on hazard considerations for certain classes of substances (*mutagens, PBT = persistent, bioaccumulative and toxic, vPvB= very persistent and very bioaccumulative, carcinogens, toxic for reproduction, endocrine disruptors*) when used by consumers;

based on a strong hazard component for the same classes of substances when used by professional users.

The results of the screening do not constitute evaluations of individual substances to be carried out under the respective chemical legislations [[in particular, Regulation (EC) No 1107/2009 on plant protection products, Regulation (EU) No 528/2012 on biocidal products, Regulation (EC) No 1907/2006 REACH, Regulation (EC) No 1223/2009 on cosmetic products and the Water Framework Directive (EC) No 2000/60] and in no way prejudice future decisions on active substances to be taken pursuant to these pieces of the EU legislation. It would thus be erroneous to consider that the substances listed in the results of this study (SANTE/2015/E3/SI2.706218) are considered as endocrine disruptors within the meaning of the EU legislation.

Table 4.6. Potential categorization results for vertebrate wildlife* for the 348 PPPs screened after inclusion of the additional data.

Vertebrate wildlife	Potential Categorization							
	Option 2		Option 3				Option 4	
	ED	Unclassified	Cat I	Cat II	Cat III	Unclassified	ED	Unclassified
Number of PPPs (348)	22	326	22	95	49	182	16	332

Regarding "Option 4", out of sixteen substances classified as ED, ten (No 2, 20, 21, 24, 212, 215, 258, 295, 375, 395) were solely based on non-mammalian data (fish, avian, amphibian) whilst three were based on both mammalian and non-mammalian data (No 87, 304, 369) and the other three substances (No 202, 371, 403) were based on mammalian data by using the same potency cut-off value as for mammals.

For combined/overall potential categorization the more conservative outcome has been considered, i.e. the most recent classification in case of "Option 1", the most severe categorization between human health and vertebrate wildlife in case of "Option 2, 3 & 4" (Table 4.7). Consequently, 50 PPPs were classified as EDs under "Option 1", 27 PPPs were classified as EDs under "Option 2" (equivalent to Cat I under "Option 3"), whilst only 19 PPPs were classified as EDs under "Option 4".

Table 4.7. Combined potential categorization results for human health and vertebrate wildlife for the 348 PPPs screened after inclusion of the additional data.

Human health and vertebrate wildlife	Potential Categorization									
	Option 1 (Most recent)		Option 2		Option 3				Option 4	
	ED	Unclassified	ED	Unclassified	Cat I	Cat II	Cat III	Unclassified	ED	Unclassified
Number of PPPs (348)	50	298	27	321	27	104	47	170	19	329

For "Option 3", the Paths of the decision tree (please refer to Appendix I) leading to each categorization are presented in Table 4.8 for human health assessment and in Table 4.9 for vertebrate wildlife assessment. As it is shown in Table 4.8, 14 out of 20 PPPs categorized as Cat I are through Path 2a resulting from strong evidence of adversity and strong MoA. 5 PPPs are concluded as Cat I through combined Paths 2a, 2b (EATS-specific adversity and both *in vitro* and *in vivo* mechanistic data). Only one PPP was categorized as Cat I by using Path 4 resulting from non-specific adversity and *in vivo* mechanistic data, which confirms the notion that it is extremely difficult to reach classification as Cat I in the absence of EATS-specific adversity. Regarding classification as Cat II, out of 95

PPPs classified as Cat II, 61 PPPs used Path 3a resulting from evidence of EATS specific adversity but absence of *in vivo/in vitro* mechanistic data (either results showed no effects or there were no data available). Out of 53 substances classified as Cat III under "Option 3", 31 cases reached this categorization based on positive evidence of *in vitro* mechanistic data in the absence of any adversity (via Path 10) while 22 of them reached this categorization in the presence of non-specific adversity (Path 7). Finally, out of 180 substances categorised as "Unclassified", 127 PPPs reached this conclusion using Path 11 resulting from absence of adversity and mechanistic data. For the other 53, there were adverse effects but these may or may not have been ED-related and in the absence of any mechanistic data either *in vitro* or *in vivo* to indicate an endocrine mode of action or, alternatively, in the presence of negative mechanistic data, the substances were designated "Unclassified" (Path 8).

Table 4.8. Presentation of the results for "Option 3" and the different Paths leading to the different categories or to "Unclassified" for human health.

PPPs	Potential Categorization - Option 3 (human health) Number of substances							
	Cat I		Cat II		Cat III		Unclassified	
Total number (348)	20		95		53		180	
	Path 1	-	Path 3a	61	Path 7	22	Path 8	53
	Path 2a	14	Path 3b	20	Path 10	31	Path 11	127
	Path 2b	-	Path 3a, 3b	5				
	Path 2a, 2b	5	Path 5	5				
	Path 4	1	Path 6	1				
			Path 5/6	2				
			Path 9	1				

Similar results were obtained for the classification of vertebrate wildlife under "Option 3" (Table 4.9). Most of the PPPs (12 out of 22) were classified as Cat I through Path 2a. 58 out of 95 PPPs were classified as Cat II through Path 3a, 28 out of 49 PPPs reached Cat III through Path 10 and finally 124 out of 182 PPPs were concluded as "Unclassified" through Path 11.

Table 4.9. Presentation of the results for "Option 3" and the different Paths leading to the different categories or to "Unclassified" for vertebrate wildlife.

PPPs	Potential Categorization - Option 3 (vertebrate wildlife) Number of substances							
	Cat I		Cat II		Cat III		Unclassified	
Total number (348)	22		95		49		182	
	Path 1	-	Path 3a	58	Path 7	21	Path 8	58
	Path 1/2a	1	Path 3b	19	Path 10	28	Path 11	124
	Path 2a	12	Path 3a/3b	7				
	Path 2b	-	Path 5	6				
	Path 2a/2b	6	Path 6	2				
	Path 1/2a/2b	1	Path 5/6	2				
	Path 4	2	Path 9	1				

ii. BPs

Following the inclusion of additional data, the revised categorization results for each of the 96 BPs according to the four "Options" of the Roadmap for human health and vertebrate wildlife assessment are presented in Appendix 4.2.

Under "Option 1", since both the harmonised C&L (when available) and the proposed C&L (when relevant) have been considered for the categorization of the substances, the results are reported in order to allow making a distinction between the substances with a harmonised classification (which have been included in Annex VI of Regulation (EC) 1272/2008 (CLP Regulation), i.e. their classification has been agreed) and those substances for which no harmonised classification is available because they have not yet been discussed.

In the Categorization Results Table (Appendix 4.2), when there is no harmonised C&L available, "Not relevant" is reported. However, when concluding for the categorization under "Option 1", this is interpreted as "Unclassified*". The "*" has been added in order to make the distinction from the substances which are categorized as "Unclassified" after discussion, i.e. considering the harmonised C&L included in Annex VI of CLP Regulation.

For all substances where there is no harmonised C&L available (27 out of the 96 BPs screened), the categorization was concluded considering the proposed classification since this is the most recent one. It is noted that for 1 substance with no harmonised classification (i.e. categorized as "Unclassified*") the categorization is different when

considering the most recent proposed C&L, while for 1 substance (rodenticide) the cut-off¹⁵ is applicable, based on the proposed C&L as Repr Cat 1A.

Moreover, for 52 out of the 69 BPs for which there is a harmonised classification, a more recent C&L proposal in the respective evaluation report has been identified. In these cases, the "Option 1" outcome is the one based on the "Most Recent" proposed C&L (more severe in most cases); it is noted that only for 4 substances the categorization is different when considering the most recent proposed C&L instead of the available harmonised C&L.

As presented in the Categorization Results Table (see Appendix 4.2), out of 96 BPs screened, 16 BPs were classified as EDs and 80 as "Unclassified" under "Option 1". Of these 80 BPs, one BP (No 10) is classified as Repr. Cat. 1A and, thus for this substance the exclusion/cut-off criteria of Article 5 of Regulation (EC) 528/2012 are also applicable. Under "Option 2", 5 substances were classified as ED (equivalent to Cat I under "Option 3"), and 4 substances were classified as ED under "Option 4" (Table 4.10).

Table 4.10. Potential categorization results for human health for the 96 BPs screened.

Human health	Potential Categorization										
	Option 1*			Option 2		Option 3				Option 4	
		ED***	Unclassified	ED	Unclassified	Cat I	Cat II	Cat III	Unclassified	ED	Unclassified
Number of BPs (96)	Harmonised C&L	11	85*	5	91	5	26	7	58	4	92
	Most recent C&L proposal**	16	80								

* For 27 substances there is no harmonised C & L available, which is interpreted as "Unclassified".

** Taking into account the proposed classification - i.e. the classification proposal concluded during the peer review process under Regulation (EC) 1107/2009 (EFSA Conclusion or DAR/RAR) and/or under Regulation (EU) 528/2012 (ECHA Assessment Report/CAR) - when this is more recent than the decision for the harmonised C&L.

*** The substances categorized as ED under "Option 1" are significantly higher in number because they include groups of related substances (i.e. 6 borate compounds that have a harmonised classification as Repr Cat 1A or 1B and are toxic to endocrine organs)

¹⁵ The term "cut-off criteria" is not used in the legislation. It is used in common language to refer to approval criteria in Reg. 1107/2009 and exclusion criteria in Reg. 528/2012.

In Reg. 1107/2009, approval criteria are:

- purely based on hazard considerations for certain classes of substances (*mutagens, PBT = persistent, bioaccumulative and toxic, vPvB= very persistent and very bioaccumulative, POP= persistent organic pollutants*);
- based on a strong hazard component for other classes of substances (*carcinogens, toxic for reproduction, endocrine disruptors*).

In Reg. 528/2012, exclusion criteria are:

- purely based on hazard considerations for certain classes of substances (*mutagens, PBT = persistent, bioaccumulative and toxic, vPvB= very persistent and very bioaccumulative, carcinogens, toxic for reproduction, endocrine disruptors*) when used by consumers;

based on a strong hazard component for the same classes of substances when used by professional users.

The results of the screening do not constitute evaluations of individual substances to be carried out under the respective chemical legislations [[in particular, Regulation (EC) No 1107/2009 on plant protection products, Regulation (EU) No 528/2012 on biocidal products, Regulation (EC) No 1907/2006 REACH, Regulation (EC) No 1223/2009 on cosmetic products and the Water Framework Directive (EC) No 2000/60] and in no way prejudice future decisions on active substances to be taken pursuant to these pieces of the EU legislation. It would thus be erroneous to consider that the substances listed in the results of this study (SANTE/2015/E3/SI2.706218) are considered as endocrine disruptors within the meaning of the EU legislation.

Regarding vertebrate wildlife, 6 BPs were classified as EDs under "Option 2" (equivalent to Cat I under "Option 3"), whilst 5 BPs were classified as EDs under "Option 4" (Table 4.11).

Table 4.11. Potential categorization results for vertebrate wildlife for the 96 BPs screened.

Vertebrate wildlife	Potential Categorization							
	Option 2		Option 3				Option 4	
	ED	Unclassified	Cat I	Cat II	Cat III	Unclassified	ED	Unclassified
Number of BPs (96)	6	90	6	26	6	58	5	91

For combined/overall potential categorization, the more conservative outcome has been considered i.e. the most recent classification in case of "Option 1", the most severe categorization between human health and vertebrate wildlife in case of "Option 2, 3 & 4" (Table 4.12). Consequently, 16 BPs were classified as EDs under "Option 1", 6 BPs were classified as EDs under "Option 2" (equivalent to Cat I under "Option 3") whilst 5 BPs were classified as EDs under "Option 4".

Table 4.12. Combined potential categorization results for human health and vertebrate wildlife for the 96 BPs screened.

Human health and vertebrate wildlife	Potential Categorization									
	Option 1 (Most recent)		Option 2		Option 3				Option 4	
	ED	Unclassified	ED	Unclassified	Cat I	Cat II	Cat III	Unclassified	ED	Unclassified
Number of BPs (96)	16	80	6	90	6	27	6	57	5	91

For "Option 3", the Paths of the decision tree (please refer to Appendix I) leading to each categorization are presented in Table 4.13 for human health assessment and in Table 4.14 for vertebrate wildlife assessment. As it is shown in Table 4.13, 1 out of 5 BPs categorized as Cat I are through Path 2a resulting from EATS specific adversity and *in vivo* mechanistic data, 2 BPs are concluded as Cat I through combined Paths 2a, 2b (EATS specific adversity and a plausible link with *in vivo/in vitro* mechanistic data) and 2 BPs are categorized as Cat I through Path 4 (Non-specific adversity (may or may not be indicative of EATS) and *in vivo* mechanistic information). Regarding classification as Cat II, out of 26 BPs classified as Cat II, 14 BPs were classified through Path 3a resulting from evidence of EATS specific adversity but absence of *in vivo/in vitro* mechanistic

effects (either results showed no effects or there were no data available). Out of 7 substances classified as Cat III under "Option 3", 6 BPs reached this classification through Path 7 resulting from Non-specific adversity (may or may not be indicative of EATS) and positive *in vitro* mechanistic data but with no plausible link. Finally, out of 58 substances categorized as "Unclassified", 42 BPs reached this conclusion through Path 11 resulting from absence of adversity and mechanistic data. For the other 16 there were adverse effects but these were non-specific and in the absence of any mechanistic data either *in vitro* or *in vivo* to indicate an endocrine mode of action or, alternatively, in the presence of negative mechanistic data the substances were designated "Unclassified" (Path 8).

Table 4.13. Presentation of the results for "Option 3" and the different Paths leading to the different categories or to "Unclassified" for human health.

BPs	Potential Categorization - Option 3 (human health)							
	Number of substances							
	Cat I		Cat II		Cat III		Unclassified	
Total number (96)	5		26		7		58	
	Path 1	-	Path 3a	14	Path 7	6	Path 8	16
	Path 2a	1	Path 3b	8	Path 10	1	Path 11	42
	Path 2b	-	Path 3a/3b	1				
	Path 2a/2b	2	Path 5	2				
	Path 4	2	Path 6	-				
			Path 5/6	1				
			Path 9	-				

Similar results were obtained for the classification of vertebrate wildlife under "Option 3" (Table 4.14). For one BP, Path 2a was used in order to be classified as Cat I, whilst for three of them Path 2a/b was used. 2 BPs were classified as Cat I through Path 4. 14 out of 26 BPs were classified as Cat II through Path 3a (EATS specific adversity and absence of endocrine MoA data), 5 out of 6 BPs reached Cat III through Path 7 (Non-specific adversity (may or may not be indicative of EATS) and *in vitro* mechanistic data) and finally 42 out of 58 BPs were concluded as "Unclassified" through Path 11.

Table 4.14. Presentation of the results for “Option 3” and the different Paths leading to the different categories or to “Unclassified” for vertebrate wildlife.

BPs	Potential Categorization - Option 3 (vertebrate wildlife*) Number of substances							
	Cat I		Cat II		Cat III		Unclassified	
Total number (96)	6		26		6		58	
	Path 1	-	Path 3a	14	Path 7	5	Path 8	16
	Path 2a	1	Path 3b	8	Path 10	1	Path 11	42
	Path 2b	-	Path 3a/3b	1				
	Path 2a/2b	3	Path 5	2				
	Path 1/2a/2b	-	Path 6	-				
	Path 4	2	Path 5/6	1				
			Path 9	-				

Out of the 6 BPs that were classified as Cat I under “Option 3” for vertebrate wildlife, only one substance (No 20) reached this categorization based solely on non-mammalian ecotoxicity data.

E. References

- EC, 2014. Defining criteria for identifying Endocrine Disruptors in the context of the implementation of the Plant Protection Product Regulation and Biocidal Products Regulation. DG ENV.A.3, DG SANCO.E.3 (http://ec.europa.eu/smart-regulation/impact/planned_ia/docs/2014_env_009_endocrine_disruptors_en.pdf).
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- EC, 2009. Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC. OJ L 309, 24.11.2009, p. 1–50
- EC, 2012. Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products Text with EEA relevance. OJ L 167, 27.6.2012, p. 1–123
- EC, 2008. Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006. OJ L 353, 31.12.2008, p. 1–1355

Appendix 4.1

Revision of 51 PPPs after the inclusion of additional data and potential categorization under "Option 3" for human health and vertebrate wildlife.

PPP #	Chemical Name	CAS No	Human health		Vertebrate wildlife	
			Previous Potential Categorization	Revised Potential Categorization	Previous Potential Categorization	Revised Potential Categorization
2	Tebuconazole	107534-96-3	Cat I	Cat I	Cat I	Cat I
6	Imidacloprid	138261-41-3	Cat III	Unclassified	Cat III	Unclassified
15	Abamectin (aka avermectin)	71751-41-2	Cat II	Cat II	Cat II	Cat II
18	Bifenthrin	82657-04-3	Cat III	Unclassified	Cat II	Cat II
20	Cyproconazole	94361-06-5	Cat II	Cat II	Cat I	Cat I
21	Pyriproxyfen	95737-68-1	Cat II	Unclassified	Cat II	Cat I
22	Folpet	133-07-3	Cat III	Unclassified	Cat III	Cat II
24	2-Phenylphenol (incl. sodium salt orthophenyl phenol)	90-43-7	Unclassified	Unclassified	Unclassified	Cat I
39	Glyphosate (incl. trimesium aka sulfosate)	1071-83-6	Cat II	Cat II	Cat II	Cat II
46	Tetraconazole	112281-77-3	Cat I	Cat II	Cat I	Cat II
65	Malathion	121-75-5	Cat I	Cat II	Cat I	Cat II
83	Ethoprophos	13194-48-4	Unclassified	Unclassified	Unclassified	Unclassified
85	Captan	133-06-2	Cat III	Unclassified	Cat III	Unclassified
87	Epoxiconazole	133855-98-8	Cat I	Cat I	Cat I	Cat I
106	8-Hydroxyquinoline incl. oxyquinoleine	148-24-3	Cat I	Unclassified	Cat I	Unclassified
107	Spirodiclofen	148477-71-8	Cat I	Cat I	Cat I	Cat I

The results of the screening do not constitute evaluations of individual substances to be carried out under the respective chemical legislations [[in particular, Regulation (EC) No 1107/2009 on plant protection products, Regulation (EU) No 528/2012 on biocidal products, Regulation (EC) No 1907/2006 REACH, Regulation (EC) No 1223/2009 on cosmetic products and the Water Framework Directive (EC) No 2000/60] and in no way prejudice future decisions on active substances to be taken pursuant to these pieces of the EU legislation. It would thus be erroneous to consider that the substances listed in the results of this study (SANTE/2015/E3/SI2.706218) are considered as endocrine disruptors within the meaning of the EU legislation.

PPP #	Chemical Name	CAS No	Human health		Vertebrate wildlife	
			Previous Potential Categorization	Revised Potential Categorization	Previous Potential Categorization	Revised Potential Categorization
119	Methomyl	16752-77-5	Unclassified	Unclassified	Unclassified	Unclassified
126	Benfluralin	1861-40-1	Cat III	Cat II	Cat III	Unclassified
132	Oxadiazon	19666-30-9	Cat I	Cat III	Cat I	Cat III
135	Metribuzin	21087-64-9	Unclassified	Unclassified	Unclassified	Unclassified
145	Oxamyl	23135-22-0	Cat III	Cat III	Cat III	Cat III
159	Diuron	330-54-1	Cat III	Cat III	Cat III	Cat II
199	Dimethoate	60-51-5	Cat II	Cat II	Cat II	Cat II
202	Amitrole (aminotriazole)	61-82-5	Cat I	Cat I	Cat I	Cat I
210	Esfenvalerate	66230-04-4	Cat III	Unclassified	Cat II	Unclassified
212	Flutolanil	66332-96-5	Cat III	Unclassified	Cat III	Cat I
215	Prochloraz	67747-09-5	Cat II	Cat I	Cat II	Cat I
216	Triflumizole	68694-11-1	Cat I	Cat III	Cat I	Cat III
224	Phosmet	732-11-6	Cat III	Unclassified	Cat III	Unclassified
256	Tralkoxydim	87820-88-0	Cat I	Cat II	Cat I	Cat II
258	Myclobutanil	88671-89-0	Cat I	Cat III	Cat I	Cat I
264	2,4-D	94-75-7	Cat I	Cat II	Cat I	Cat II
295	Propiconazole	60207-90-1	Cat II	Cat III	Cat II	Cat I
304	Cypermethrin	52315-07-8	Cat I	Cat I	Cat I	Cat I
326	Maneb	12427-38-2	Cat I	Cat I	Cat I	Cat I
334	Desmedipham	13684-56-5	Cat I	Cat I	Unclassified	Unclassified
336	Thiram	137-26-8	Cat I	Cat II	Cat I	Cat II
337	Ziram	137-30-4	Cat I	Cat II	Cat I	Cat II

PPP #	Chemical Name	CAS No	Human health		Vertebrate wildlife	
			Previous Potential Categorization	Revised Potential Categorization	Previous Potential Categorization	Revised Potential Categorization
347	Tepraloxydim	149979-41-9	Cat I	Cat II	Cat I	Cat II
353	Fenamidone	161326-34-7	Cat I	Cat I	Cat II	Cat II
365	Boscalid (formerly nicobifen)	188425-85-6	Cat I	Cat II	Cat I	Cat II
366	Chlorothalonil	1897-45-6	Cat III	Unclassified	Cat II	Cat II
368	Thiophanate-methyl	23564-05-8	Cat I	Cat I	Cat I	Cat I
369	Propyzamide	23950-58-5	Cat I	Cat I	Cat I	Cat I
374	Chlorpyrifos	2921-88-2	Cat III	Cat II	Cat III	Cat II
375	Linuron	330-55-2	Cat I	Cat I	Cat I	Cat I
379	Iprodione	36734-19-7	Cat I	Cat I	Cat I	Cat I
383	Pendimethalin	40487-42-1	Cat I	Cat I	Cat I	Cat II
395	Metalaxyl	57837-19-1	Unclassified	Unclassified	Unclassified	Cat I
403	Mancozeb	8018-01-7	Cat I	Cat I	Cat I	Cat I
408	Metiram	9006-42-2	Cat I	Cat I	Cat II	Unclassified

Revision of 18 BPs after the inclusion of additional data and potential categorization under "Option 3" for human health and vertebrate wildlife.

BP #	Chemical Name	CAS No	Human health		Vertebrate wildlife	
			Previous Potential Categorization	Revised Potential Categorization	Previous Potential categorization	Revised Potential Categorization
435	Boric acid	10043-35-3	Cat II	Cat II	Cat II	Cat II
430	flufenoxuron	101463-69-8	Unclassified	Unclassified	Unclassified	Unclassified
480	Glutaraldehyde	111-30-8	Cat II	Cat II	Cat II	Cat II
442	Chlorfenapyr	122453-73-0	Cat III	Unclassified	Cat III	Unclassified
450	N,N-diethyl-meta-toluamide	134-62-3	Unclassified	Unclassified	Unclassified	Unclassified
482	Dinotefuran	165252-70-0	Unclassified	Unclassified	Unclassified	Unclassified
453	Bendiocarb	22781-23-3	Unclassified	Unclassified	Unclassified	Unclassified
460	Chlorophacino ne	3691-35-8	Cat III	Cat III	Cat III	Cat III
433	Permethrin	52645-53-1	Cat II	Cat II	Cat II	Cat II
434	IPBC	55406-53-6	Unclassified	Unclassified	Unclassified	Unclassified
464	4,5-Dichloro-2-octylisothiazol-3(2H)-one	64359-81-5	Cat III	Unclassified	Cat II	Cat II
431	Didecyldimethylammonium chloride; DDAC	7173-51-5 (68424-95-3)	Cat III	Unclassified	Cat III	Unclassified
475, 445	Warfarin, Warfarin sodium	81-81-2, 129-06-6	Unclassified	Unclassified	Unclassified	Unclassified
491	Hexaflumuron	86479-06-3	Unclassified	Unclassified	Unclassified	Unclassified

			Human health		Vertebrate wildlife	
BP #	Chemical Name	CAS No	Previous Potential Categorization	Revised Potential Categorization	Previous Potential categorization	Revised Potential Categorization
297	Pelargonic acid (Nonanoic acid)*	112-05-0	Unclassified	Unclassified	Unclassified	Unclassified
298	Caprylic acid (Octanoic acid)*	124-07-2	Cat III	Unclassified	Cat III	Unclassified
303	Capric acid (Decanoic acid)*	334-48-5	Unclassified	Unclassified	Unclassified	Unclassified
306	Benzoic acid*	65-85-0	Unclassified	Unclassified	Unclassified	Unclassified

The results of the screening do not constitute evaluations of individual substances to be carried out under the respective chemical legislations [[in particular, Regulation (EC) No 1107/2009 on plant protection products, Regulation (EU) No 528/2012 on biocidal products, Regulation (EC) No 1907/2006 REACH, Regulation (EC) No 1223/2009 on cosmetic products and the Water Framework Directive (EC) No 2000/60] and in no way prejudice future decisions on active substances to be taken pursuant to these pieces of the EU legislation. It would thus be erroneous to consider that the substances listed in the results of this study (SANTE/2015/E3/SI2.706218) are considered as endocrine disruptors within the meaning of the EU legislation.

Appendix 4.2

The results of the revised potential categorization of each of the 348 PPP and 96 BP substances according to the four "Options" of the Roadmap (EC, 2014) for human health and vertebrate wildlife assessment are presented below:

The results of the screening do not constitute evaluations of individual substances to be carried out under the respective chemical legislations [[in particular, Regulation (EC) No 1107/2009 on plant protection products, Regulation (EU) No 528/2012 on biocidal products, Regulation (EC) No 1907/2006 REACH, Regulation (EC) No 1223/2009 on cosmetic products and the Water Framework Directive (EC) No 2000/60] and in no way prejudge future decisions on active substances to be taken pursuant to these pieces of the EU legislation. It would thus be erroneous to consider that the substances listed in the results of this study (SANTE/2015/E3/SI2.706218) are considered as endocrine disruptors within the meaning of the EU legislation.

Revised potential categorization results for 348 PPPs under "Option 1"

	Chemical Name	Carc Cat. 2 (C&L Harmonised)	Carc Cat. 2 (C&L Proposed)	Repr. Cat. 2 (C&L Harmonised)	Repr. Cat. 2 (C&L Proposed)	Carc Cat. 1A or 1B (C&L Harmonised)	Carc Cat. 1A or 1B (C&L Proposed)	Repr. Cat. 1A or 1B (C&L Harmonised)	Repr. Cat. 1A or 1B (C&L Proposed)	Effects on Endocrine organs (YES/NO)	OPTION 1 Harmonized	OPTION 1 Proposed	OPTION 1 Most recent
1	Carbon dioxide	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	No	Unclassified*	Unclassified	Unclassified
2	Tebuconazole	No	Not relevant	Yes	Not relevant	No	Not relevant	No	No	Yes	ED	Not relevant	ED
3	Methyl nonyl ketone	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	No	Unclassified*	Unclassified	Unclassified
4	Fipronil	No	No	No	No	No	No	No	No	Yes	Unclassified	Unclassified	Unclassified
5	Magnesium phosphide	No	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	Unclassified	Not relevant	Unclassified
6	Imidacloprid	No	No	No	No	No	No	No	No	No	Unclassified	Unclassified	Unclassified
7	Thiabendazole	No	No	No	No	No	No	No	No	Yes	Unclassified	Unclassified	Unclassified
8	Aluminium phosphide	No	No	No	No	No	No	No	No	No	Unclassified	Unclassified	Unclassified
9	Sulfuryl fluoride	No	No	No	No	No	No	No	No	No	Unclassified	Unclassified	Unclassified
10	Bromadiolone	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	Yes	No	Unclassified*	Cut off criteria are applicable / Repr Cat 1A/B	Cut off criteria are applicable / Repr Cat 1A/B
11	Diflubenzuron	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	No	Unclassified*	Unclassified	Unclassified
12	Dazomet	No	No	No	Yes	No	No	No	No	Yes	Unclassified	ED	ED
13	Difenacoum	No	No	No	No	No	No	No	Yes	Yes	Unclassified	ED / Cut off criteria are applicable / Repr Cat 1A/B	ED / Cut off criteria are applicable / Repr Cat 1A/B
14	Fenpropimorph	No	No	Yes	Yes	No	No	No	No	Yes	ED	ED	ED

The results of the screening do not constitute evaluations of individual substances to be carried out under the respective chemical legislations [[in particular, Regulation (EC) No 1107/2009 on plant protection products, Regulation (EU) No 528/2012 on biocidal products, Regulation (EC) No 1907/2006 REACH, Regulation (EC) No 1223/2009 on cosmetic products and the Water Framework Directive (EC) No 2000/60] and in no way prejudice future decisions on active substances to be taken pursuant to these pieces of the EU legislation.

It would thus be erroneous to consider that the substances listed in the results of this study (SANTE/2015/E3/SI2.706218) are considered as endocrine disruptors within the meaning of the EU legislation.

Screening of available evidence on chemical substances for the identification of endocrine disruptors according to different options in the context of an Impact Assessment

	Chemical Name	Carc Cat. 2 (C&L Harmonised)	Carc Cat. 2 (C&L Proposed)	Repr. Cat. 2 (C&L Harmonised)	Repr. Cat. 2 (C&L Proposed)	Carc Cat. 1A or 1B (C&L Harmonised)	Carc Cat. 1A or 1B (C&L Proposed)	Repr. Cat. 1A or 1B (C&L Harmonised)	Repr. Cat. 1A or 1B (C&L Proposed)	Effects on Endocrine organs (YES/NO)	OPTION 1 Harmonized	OPTION 1 Proposed	OPTION 1 Most recent
15	Abamectin (aka avermectin)	No	No	Yes	Yes	No	No	No	No	Yes	ED	ED	ED
16	Fenoxycarb	Yes	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	Yes	Unclassified	Not relevant	Unclassified
17	Etofenprox	No	Not relevant	Yes	Not relevant	No	Not relevant	No	No	No	Unclassified	Not relevant	Unclassified
18	Bifenthrin	Yes	Yes	No	No	No	No	No	No	No	Unclassified	Unclassified	Unclassified
19	lambda-Cyhalothrin	No	No	No	No	No	No	No	No	Yes	Unclassified	Unclassified	Unclassified
20	Cyproconazole	No	Not relevant	No	Not relevant	No	Not relevant	Yes	Not relevant	Yes	ED - Cut off criteria are applicable / Repr Cat 1A/B	Not relevant	ED - Cut off criteria are applicable / Repr Cat 1A/B
21	Pyriproxyfen	No	No	No	No	No	No	No	No	No	Unclassified	Unclassified	Unclassified
22	Folpet	Yes	Yes	No	No	No	No	No	No	No	Unclassified	Unclassified	Unclassified
23**	Triflumuron	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	No	Unclassified*	Unclassified	Unclassified
24**	2-Phenylphenol (incl. sodium salt orthophenyl phenol)	No	Yes	No	No	No	No	No	No	No	Unclassified	Unclassified	Unclassified
25	Hymexazol	No	No	No	Yes	No	No	No	No	Yes	Unclassified	ED	ED
27	Aluminium sulphate	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	No	Unclassified*	Unclassified	Unclassified
28	Ferric phosphate	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	No	Unclassified*	Unclassified	Unclassified
29****	Quizalofop-P-ethyl	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	Yes	Unclassified*	Unclassified	Unclassified
30	Halosulfuron methyl	Not relevant	No	Not relevant	Yes	Not relevant	No	Not relevant	No	Yes	Unclassified*	ED	ED
31	Acrinathrin	Not relevant	Yes	Not relevant	No	Not relevant	No	Not relevant	No	Yes	Unclassified*	Unclassified	Unclassified
32	Cycloxydim	No	Not relevant	Yes	Not relevant	No	Not relevant	No	Not relevant	Yes	ED	Not relevant	ED
34	tau-Fluvalinate	No	No	No	No	No	No	No	No	No	Unclassified	Unclassified	Unclassified
35	Lufenuron	No	No	No	No	No	No	No	No	No	Unclassified	Unclassified	Unclassified

The results of the screening do not constitute evaluations of individual substances to be carried out under the respective chemical legislations [[in particular, Regulation (EC) No 1107/2009 on plant protection products, Regulation (EU) No 528/2012 on biocidal products, Regulation (EC) No 1907/2006 REACH, Regulation (EC) No 1223/2009 on cosmetic products and the Water Framework Directive (EC) No 2000/60] and in no way prejudice future decisions on active substances to be taken pursuant to these pieces of the EU legislation.

It would thus be erroneous to consider that the substances listed in the results of this study (SANTE/2015/E3/SI2.706218) are considered as endocrine disruptors within the meaning of the EU legislation.

Screening of available evidence on chemical substances for the identification of endocrine disruptors according to different options in the context of an Impact Assessment

	Chemical Name	Carc Cat. 2 (C&L Harmonised)	Carc Cat. 2 (C&L Proposed)	Repr. Cat. 2 (C&L Harmonised)	Repr. Cat. 2 (C&L Proposed)	Carc Cat. 1A or 1B (C&L Harmonised)	Carc Cat. 1A or 1B (C&L Proposed)	Repr. Cat. 1A or 1B (C&L Harmonised)	Repr. Cat. 1A or 1B (C&L Proposed)	Effects on Endocrine organs (YES/NO)	OPTION 1 Harmonized	OPTION 1 Proposed	OPTION 1 Most recent
36	Flumioxazin	No	Not relevant	No	Not relevant	No	Not relevant	Yes	Not relevant	No	Cut off criteria are applicable / Repr Cat 1A/B	Not relevant	Cut off criteria are applicable / Repr Cat 1A/B
37	Tribenuron (aka metometuron)	No	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	Yes	Unclassified	Not relevant	Unclassified
38	Geraniol	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	No	Unclassified*	Unclassified	Unclassified
39	Glyphosate (incl trimesium aka sulfosate)	No	No	No	No	No	No	No	No	No	Unclassified	Unclassified	Unclassified
40	Metaldehyde	No	No	No	No	No	No	No	No	Yes	Unclassified	Unclassified	Unclassified
41	Dimethomorph	No	No	No	No	No	No	No	No	Yes	Unclassified	Unclassified	Unclassified
42***	Putrescine (1,4-Diaminobutane))	Not relevant	No	Not relevant	Yes	Not relevant	No	Not relevant	No	No	Unclassified*	Unclassified	Unclassified
43	Azadirachtin	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	Yes	Unclassified*	Unclassified	Unclassified
44	Propaquizafop	Not relevant	Yes	Not relevant	No	Not relevant	No	Not relevant	No	Yes	Unclassified*	Unclassified	Unclassified
45	Nicosulfuron	No	No	No	No	No	No	No	No	No	Unclassified	Unclassified	Unclassified
46	Tetraconazole	No	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	Yes	Unclassified	Not relevant	Unclassified
47	1-Decanol	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	No	Unclassified*	Unclassified	Unclassified
48	Tebufenozide	No	No	No	No	No	No	No	No	No	Unclassified	Unclassified	Unclassified
49	Dodine	No	No	No	No	No	No	No	No	No	Unclassified	Unclassified	Unclassified
50	Fenoxaprop-P	Not relevant	No	Not relevant	Yes	Not relevant	No	Not relevant	No	No	Unclassified*	Unclassified	Unclassified
51	Fenbuconazole	No	No	No	Yes	No	No	No	No	Yes	Unclassified	ED	ED
52	Clodinafop	No	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	Yes	Unclassified	Not relevant	Unclassified

The results of the screening do not constitute evaluations of individual substances to be carried out under the respective chemical legislations [[in particular, Regulation (EC) No 1107/2009 on plant protection products, Regulation (EU) No 528/2012 on biocidal products, Regulation (EC) No 1907/2006 REACH, Regulation (EC) No 1223/2009 on cosmetic products and the Water Framework Directive (EC) No 2000/60] and in no way prejudice future decisions on active substances to be taken pursuant to these pieces of the EU legislation.

It would thus be erroneous to consider that the substances listed in the results of this study (SANTE/2015/E3/SI2.706218) are considered as endocrine disruptors within the meaning of the EU legislation.

Screening of available evidence on chemical substances for the identification of endocrine disruptors according to different options in the context of an Impact Assessment

	Chemical Name	Carc Cat. 2 (C&L Harmonised)	Carc Cat. 2 (C&L Proposed)	Repr. Cat. 2 (C&L Harmonised)	Repr. Cat. 2 (C&L Proposed)	Carc Cat. 1A or 1B (C&L Harmonised)	Carc Cat. 1A or 1B (C&L Proposed)	Repr. Cat. 1A or 1B (C&L Harmonised)	Repr. Cat. 1A or 1B (C&L Proposed)	Effects on Endocrine organs (YES/NO)	OPTION 1 Harmonized	OPTION 1 Proposed	OPTION 1 Most recent
53	Bromuconazole	Not relevant	No	Not relevant	Yes	Not relevant	No	Not relevant	No	Yes	Unclassified*	Unclassified	Unclassified
54	Spiroxamine	No	No	No	Yes	No	No	No	No	Yes	Unclassified	ED	ED
55	Tebufenpyrad	No	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	Unclassified	Not relevant	Unclassified
56	Difenoconazole	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	Yes	Unclassified*	Unclassified	Unclassified
57****	Quizalofop-P-tefuryl	Yes	Yes	Yes	Yes	No	No	No	No	Yes	ED	ED	ED
59	Azimsulfuron	No	No	No	No	No	No	No	No	Yes	Unclassified	Unclassified	Unclassified
60	Amidosulfuron	No	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	Unclassified	Not relevant	Unclassified
61	Fenazaquin	No	No	No	No	No	No	No	No	Yes	Unclassified	Unclassified	Unclassified
62	Pyrethrins	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	No	Unclassified*	Unclassified	Unclassified
63	6-Benzyladenine	Not relevant	No	Not relevant	Yes	Not relevant	No	Not relevant	No	No	Unclassified*	Unclassified	Unclassified
64	Cyprodinil	No	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	Unclassified	Not relevant	Unclassified
65	Malathion	No	No	No	No	No	No	No	No	Yes	Unclassified	Unclassified	Unclassified
66	Cyhalofop-butyl	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	No	Unclassified*	Unclassified	Unclassified
67	Rimsulfuron (aka renniduron)	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	Yes	Unclassified*	Unclassified	Unclassified
68	Pymetrozine	Yes	Yes	No	Yes	No	No	No	No	Yes	Unclassified	ED	ED
69	Metconazole	No	Not relevant	Yes	Not relevant	No	Not relevant	No	Not relevant	Yes	ED	Not relevant	ED
70	Ipconazole	Not relevant	No	Not relevant	Yes	Not relevant	No	Not relevant	No	Yes	Unclassified*	ED	ED
71	Bispyribac	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	Yes	Unclassified*	Unclassified	Unclassified
72	Fenhexamid	No	No	No	No	No	No	No	No	Yes	Unclassified	Unclassified	Unclassified
73	Prohexadione	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	Yes	Unclassified*	Unclassified	Unclassified
74	Pyraflufen-ethyl	No	No	No	No	No	No	No	No	Yes	Unclassified	Unclassified	Unclassified
75	Sintofen (aka Cintofen)	Not relevant	Yes?	Not relevant	No	Not relevant	No	Not relevant	No	No	Unclassified*	Unclassified	Unclassified

The results of the screening do not constitute evaluations of individual substances to be carried out under the respective chemical legislations [[in particular, Regulation (EC) No 1107/2009 on plant protection products, Regulation (EU) No 528/2012 on biocidal products, Regulation (EC) No 1907/2006 REACH, Regulation (EC) No 1223/2009 on cosmetic products and the Water Framework Directive (EC) No 2000/60] and in no way prejudice future decisions on active substances to be taken pursuant to these pieces of the EU legislation.

It would thus be erroneous to consider that the substances listed in the results of this study (SANTE/2015/E3/SI2.706218) are considered as endocrine disruptors within the meaning of the EU legislation.

Screening of available evidence on chemical substances for the identification of endocrine disruptors according to different options in the context of an Impact Assessment

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76	Calcium phosphide	No	No	No	No	No	No	No	No	No	Unclassified	Unclassified	Unclassified
77	Fludioxonil	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	No	Unclassified*	Unclassified	Unclassified
78	Zinc phosphide	No	No	No	No	No	No	No	No	No	Unclassified	Unclassified	Unclassified
79	zeta-Cypermethrin	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	No	Unclassified*	Unclassified	Unclassified
80	Limestone	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	No	Unclassified*	Unclassified	Unclassified
81	Famoxadone	No	No	No	No	No	No	No	No	No	Unclassified	Unclassified	Unclassified
82	Azoxystrobin	No	No	No	No	No	No	No	No	No	Unclassified	Unclassified	Unclassified
83	Ethoprophos	No	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	Unclassified	Not relevant	Unclassified
84	Triticonazole	No	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	Yes	Unclassified	Not relevant	Unclassified
85	Captan	Yes	Yes	No	Yes (?)	No	No	No	No	No	Unclassified	ED (?)	ED (?)
86	Indolylbutyric acid	Not relevant	No	Not relevant	Yes	Not relevant	No	Not relevant	No	Yes	Unclassified*	ED	ED
87	Epoxiconazole	Yes	Not relevant	No	Not relevant	No	Not relevant	Yes	Not relevant	Yes	ED - Cut off criteria are applicable / Repr Cat 1A/B	Not relevant	ED - Cut off criteria are applicable / Repr Cat 1A/B
88	Fenpyroximate	No	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	Unclassified	Not relevant	Unclassified
90	Acibenzolar-S-methyl (benzothiadiazole)	No	No	No	No	No	No	No	No	No	Unclassified	Unclassified	Unclassified
91	Triflurosulfuron	Not relevant	Yes	Not relevant	Yes	Not relevant	No	Not relevant	No	Yes	Unclassified*	Unclassified	Unclassified
92	Fluquinconazole	No	Yes	No	No	No	No	No	No	No	Unclassified	Unclassified	Unclassified
93	Disodium phosphonate	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	No	Unclassified*	Unclassified	Unclassified
94	Picolinafen	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	Yes	Unclassified*	Unclassified	Unclassified
95	Metosulam	Not relevant	Yes	Not relevant	No	Not relevant	No	Not relevant	No	No	Unclassified*	Unclassified	Unclassified

The results of the screening do not constitute evaluations of individual substances to be carried out under the respective chemical legislations [[in particular, Regulation (EC) No 1107/2009 on plant protection products, Regulation (EU) No 528/2012 on biocidal products, Regulation (EC) No 1907/2006 REACH, Regulation (EC) No 1223/2009 on cosmetic products and the Water Framework Directive (EC) No 2000/60] and in no way prejudice future decisions on active substances to be taken pursuant to these pieces of the EU legislation.

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Screening of available evidence on chemical substances for the identification of endocrine disruptors according to different options in the context of an Impact Assessment

	Chemical Name	Carc Cat. 2 (C&L Harmonised)	Carc Cat. 2 (C&L Proposed)	Repr. Cat. 2 (C&L Harmonised)	Repr. Cat. 2 (C&L Proposed)	Carc Cat. 1A or 1B (C&L Harmonised)	Carc Cat. 1A or 1B (C&L Proposed)	Repr. Cat. 1A or 1B (C&L Harmonised)	Repr. Cat. 1A or 1B (C&L Proposed)	Effects on Endocrine organs (YES/NO)	OPTION 1 Harmonized	OPTION 1 Proposed	OPTION 1 Most recent
96***	Potassium phosphonates (formerly potassium phosphite)	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	No	Unclassified*	Unclassified	Unclassified
97	Metaflumizone	Not relevant	No	Not relevant	Yes	Not relevant	No	Not relevant	No	No	Unclassified*	Unclassified	Unclassified
98	Iprovalicarb	Not relevant	Yes	Not relevant	No	Not relevant	No	Not relevant	No	Yes	Unclassified*	Unclassified	Unclassified
99	Sulfosulfuron	No	No	No	No	No	No	No	No	No	Unclassified	Unclassified	Unclassified
100	Trinexapac (aka cimetary ethyl)	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	No	Unclassified*	Unclassified	Unclassified
101	Kresoxim-methyl	Yes	Yes	No	No	No	No	No	No	No	Unclassified	Unclassified	Unclassified
102	Chromafenozide	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	No	Unclassified*	Unclassified	Unclassified
103	Metam (incl. potassium and sodium)	No	Yes	No	Yes	No	No	No	No	No	Unclassified	ED	ED
104	Flupyrsulfuron-methyl (DPX KE 459)	No	Yes	No	Yes	No	No	No	No	No	Unclassified	ED	ED
105	Florasulam	No	No	No	No	No	No	No	No	No	Unclassified	Unclassified	Unclassified
106	8-Hydroxyquinoline incl. oxyquinoleine	No	Not relevant	Yes	Not relevant	No	Not relevant	No	Not relevant	No	Unclassified	Not relevant	Unclassified
107	Spirodiclofen	Not relevant	Yes	Not relevant	No	Not relevant	No	Not relevant	No	Yes	Unclassified*	Unclassified	Unclassified
108	Dimoxystrobin	Yes	Not relevant	Yes	Not relevant	No	Not relevant	No	Not relevant	Yes	ED	Not relevant	ED
109	Aminopyralid	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	No	Unclassified*	Unclassified	Unclassified
110	Dichlorprop-P	No	No	No	No	No	No	No	No	No	Unclassified	Not relevant	Unclassified
111	Napropamide	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	No	Unclassified*	Unclassified	Unclassified
112	Mepiquat	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	No	Unclassified*	Unclassified	Unclassified
113	Emamectin	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	No	Unclassified*	Unclassified	Unclassified

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Screening of available evidence on chemical substances for the identification of endocrine disruptors according to different options in the context of an Impact Assessment

	Chemical Name	Carc Cat. 2 (C&L Harmonised)	Carc Cat. 2 (C&L Proposed)	Repr. Cat. 2 (C&L Harmonised)	Repr. Cat. 2 (C&L Proposed)	Carc Cat. 1A or 1B (C&L Harmonised)	Carc Cat. 1A or 1B (C&L Proposed)	Repr. Cat. 1A or 1B (C&L Harmonised)	Repr. Cat. 1A or 1B (C&L Proposed)	Effects on Endocrine organs (YES/NO)	OPTION 1 Harmonized	OPTION 1 Proposed	OPTION 1 Most recent
115	Flonicamid (IKI-220)	No	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	Yes	Unclassified	Not relevant	Unclassified
116	Dodemorph	No	Not relevant	Yes	Not relevant	No	Not relevant	No	Not relevant	No	Unclassified	Not relevant	Unclassified
117	Carbetamide	Yes	Not relevant	No	Not relevant	No	Not relevant	Yes	Not relevant	Yes	ED - Cut off criteria are applicable / Repr Cat 1A/B	Not relevant	ED - Cut off criteria are applicable / Repr Cat 1A/B
118	Ethephon	No	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	Unclassified	Not relevant	Unclassified
119	Methomyl	No	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	Unclassified	Not relevant	Unclassified
120	Chloridazon (aka pyrazone)	No	No	No	No	No	No	No	No	No	Unclassified	Unclassified	Unclassified
121	Clopyralid	No	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	Unclassified	Not relevant	Unclassified
123	Prothioconazole	Not relevant	No	Not relevant	Yes	Not relevant	No	Not relevant	No	Yes	Unclassified*	ED	ED
124	Cyflufenamid	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	No	Unclassified*	Unclassified	Unclassified
125	Penthiopyrad	Not relevant	Yes	Not relevant	No	Not relevant	No	Not relevant	No	Yes	Unclassified*	Unclassified	Unclassified
126	Benfluralin	Not relevant	Yes	Not relevant	No	Not relevant	No	Not relevant	No	No	Unclassified*	Unclassified	Unclassified
127	Spinetoram	Not relevant	No	Not relevant	Yes	Not relevant	No	Not relevant	No	No	Unclassified*	Unclassified	Unclassified
128	Proquinazid	Yes	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	Yes	Unclassified	Not relevant	Unclassified
129	Oryzalin	Not relevant	Yes	Not relevant	No	Not relevant	No	Not relevant	No	Yes	Unclassified*	Unclassified	Unclassified
130	Dicamba	No	No	No	No	No	No	No	No	No	Unclassified	Unclassified	Unclassified
131	Picloram	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	No	Unclassified*	Unclassified	Unclassified
132	Oxadiazon	No	No	No	Yes	No	No	No	No	No	Unclassified	Unclassified	Unclassified

The results of the screening do not constitute evaluations of individual substances to be carried out under the respective chemical legislations [[in particular, Regulation (EC) No 1107/2009 on plant protection products, Regulation (EU) No 528/2012 on biocidal products, Regulation (EC) No 1907/2006 REACH, Regulation (EC) No 1223/2009 on cosmetic products and the Water Framework Directive (EC) No 2000/60] and in no way prejudice future decisions on active substances to be taken pursuant to these pieces of the EU legislation.

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	Chemical Name	Carc Cat. 2 (C&L Harmonised)	Carc Cat. 2 (C&L Proposed)	Repr. Cat. 2 (C&L Harmonised)	Repr. Cat. 2 (C&L Proposed)	Carc Cat. 1A or 1B (C&L Harmonised)	Carc Cat. 1A or 1B (C&L Proposed)	Repr. Cat. 1A or 1B (C&L Harmonised)	Repr. Cat. 1A or 1B (C&L Proposed)	Effects on Endocrine organs (YES/NO)	OPTION 1 Harmonized	OPTION 1 Proposed	OPTION 1 Most recent
134	Spirotetramat	No	Not relevant	Yes	Not relevant	No	Not relevant	No	Not relevant	Yes	ED	Not relevant	ED
135	Metribuzin	No	No	No	Yes (?)	No	No	No	No	No	Unclassified	Unclassified	Unclassified
137	Lenacil	Not relevant	Yes	Not relevant	No	Not relevant	No	Not relevant	No	Yes	Unclassified*	Unclassified	Unclassified
138	Fluometuron	Not relevant	Yes	Not relevant	No	Not relevant	No	Not relevant	No	No	Unclassified*	Unclassified	Unclassified
139	Penoxsulam	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	No	Unclassified*	Unclassified	Unclassified
140	Metrafenone	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	No	Unclassified*	Unclassified	Unclassified
141	Fenamiphos (aka phenamiphos)	No	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	Unclassified	Not relevant	Unclassified
142	Formetanate	No	No	No	No	No	No	No	No	No	Unclassified	Unclassified	Unclassified
143	Tri-allate	No	No	No	No	No	No	No	No	No	Unclassified	Unclassified	Unclassified
144	Pirimicarb	No	No	No	No	No	No	No	No	No	Unclassified	Unclassified	Unclassified
145	Oxamyl	No	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	Unclassified	Not relevant	Unclassified
146	Fluopicolide	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	No	Unclassified*	Unclassified	Unclassified
147	Propamocarb	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	No	Unclassified*	Unclassified	Unclassified
148	Bentazone	No	No	No	No	No	No	No	No	No	Unclassified	Unclassified	Unclassified
149	Etridiazole	Yes	Yes	No	No	No	No	No	No	Yes	Unclassified	Unclassified	Unclassified
150	Quinoclamine	Not relevant	No	Not relevant	Yes	Not relevant	No	Not relevant	No	Yes	Unclassified*	ED	ED
151	Valifenalate (formerly Valiphenal)	Not relevant	Yes	Not relevant	No	Not relevant	No	Not relevant	No	Yes	Unclassified*	Unclassified	Unclassified
152	Spiromesifen	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	Yes	Unclassified*	Unclassified	Unclassified
153	2,5-Dichlorobenzoic acid methylester	No	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	Unclassified	Not relevant	Unclassified
154	Pirimiphos-methyl	No	Yes	No	No	No	No	No	No	No	Unclassified	Unclassified	Unclassified
156	Metobromuron	Not relevant	Yes	Not relevant	No	Not relevant	No	Not relevant	No	Yes	Unclassified*	Unclassified	Unclassified

The results of the screening do not constitute evaluations of individual substances to be carried out under the respective chemical legislations [[in particular, Regulation (EC) No 1107/2009 on plant protection products, Regulation (EU) No 528/2012 on biocidal products, Regulation (EC) No 1907/2006 REACH, Regulation (EC) No 1223/2009 on cosmetic products and the Water Framework Directive (EC) No 2000/60] and in no way prejudice future decisions on active substances to be taken pursuant to these pieces of the EU legislation.

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157	1-Methyl-cyclopropene	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	No	Unclassified*	Unclassified	Unclassified
158	Thiocarbazon	Not relevant	Yes(?)	Not relevant	No	Not relevant	No	Not relevant	No	No	Unclassified*	Unclassified	Unclassified
159	Diuron	Yes	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	Yes	Unclassified	Not relevant	Unclassified
160	Dithianon	No	Yes	No	No	No	No	No	No	No	Unclassified	Unclassified	Unclassified
161	Tembotrione	No	Not relevant	Yes	Not relevant	No	Not relevant	No	Not relevant	Yes	ED	Not relevant	ED
162	Isoproturon	Yes	Yes	No	Yes	No	No	No	No	Yes	Unclassified	ED	ED
163	Amisulbrom	Yes	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	Unclassified	Not relevant	Unclassified
164	Imazalil (aka enilconazole)	Yes	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	Yes	Unclassified	Not relevant	Unclassified
165	Fluoxastrobin	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	No	Unclassified*	Unclassified	Unclassified
167	Mandipropamid	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	No	Unclassified*	Unclassified	Unclassified
168	Fuberidazole	Yes	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	Unclassified	Not relevant	Unclassified
169	Fosetyl [same as Fosetyl-AI]	No	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	Unclassified	Not relevant	Unclassified
170	Cyflumetofen	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	Yes	Unclassified*	Unclassified	Unclassified
171	Benthiavalicarb [same as benthiavalicarb-isopropyl CAS No. 177406-68-7]	Not relevant	Yes	Not relevant	Yes (?)	Not relevant	No	Not relevant	No	Yes	Unclassified*	ED (?)	ED (?)
172	Metamitron	No	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	Yes	Unclassified	Not relevant	Unclassified
173	Bupirimate	Yes	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	Unclassified	Not relevant	Unclassified
174	Pyroxsulam	No	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	Unclassified	Not relevant	Unclassified
175	Bifenox	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	No	Unclassified*	Unclassified	Unclassified

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176	Oxyfluorfen	Not relevant	Yes	Not relevant	No	Not relevant	No	Not relevant	No	No	Unclassified*	Unclassified	Unclassified
178	Fenpyrazamine	No	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	Unclassified	Not relevant	Unclassified
179	Penflufen	Not relevant	Yes	Not relevant	No	Not relevant	No	Not relevant	No	Yes	Unclassified*	Cut off criteria are applicable / Carc Cat 2	Cut off criteria are applicable / Carc Cat 2
180	Chlorantraniliprole	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	No	Unclassified*	Unclassified	Unclassified
181	Dimethachlor	No	Yes	No	No	No	No	No	No	No	Unclassified	Unclassified	Unclassified
182	Ascorbic acid	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	No	Unclassified*	Unclassified	Unclassified
183	Glufosinate [same as glufosinate ammonium CAS No. 77182-82-2]	No	Not relevant	No	Not relevant	No	Not relevant	Yes	Not relevant	No	Cut off criteria are applicable / Repr Cat 1A	Not relevant	Cut off criteria are applicable / Repr Cat 1A
184	Diclofop [same as diclofop-methyl CAS No.257-141-8]	No	No	No	No	No	No	No	No	No	Unclassified	Unclassified	Unclassified
185	Carboxin	Not relevant	Yes	Not relevant	No	Not relevant	No	Not relevant	No	Yes	Unclassified*	Unclassified	Unclassified
186	Prosulfocarb	No	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	Unclassified	Not relevant	Unclassified
187	Pyrimethanil	No	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	Unclassified	Not relevant	Unclassified
188	Triadimenol	Not relevant	No	Not relevant	Yes	Not relevant	No	Not relevant	No	Yes	Unclassified*	ED	ED

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189	Triclopyr [a second variant of Triclopyr: 3,5,6-trichloro-2-pyridyloxy-2-butoxyethylester CAS No: 064700-56-7]	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	Yes	No	Unclassified*	Cut off criteria are applicable / Repr Cat 1A/B	Cut off criteria are applicable / Repr Cat 1A/B
190	Pyridate	No	No	No	No	No	No	No	No	No	Unclassified	Unclassified	Unclassified
191	Tolclofos-methyl	No	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	Yes	Unclassified	Not relevant	Unclassified
192	Urea	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	No	Unclassified*	Unclassified	Unclassified
193	1,4-Dimethylnaphthalene	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	No	Unclassified*	Unclassified	Unclassified
194	Acequinocyl	No	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	Unclassified	Not relevant	Unclassified
195	Cymoxanil	No	Not relevant	Yes	Not relevant	No	Not relevant	No	Not relevant	Yes	ED	Not relevant	ED
196	Bixafen	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	Yes	Unclassified*	Unclassified	Unclassified
197	Terbutylazine	Yes	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	Yes	Unclassified	Not relevant	Unclassified
198	Trimethylamine hydrochloride	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	No	Unclassified*	Unclassified	Unclassified
199	Dimethoate	No	No	No	No	No	No	No	No	Yes	Unclassified	Unclassified	Unclassified
200	Meptyldinocap [same as DE-126]	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	Yes	Unclassified*	Unclassified	Unclassified
201	Flurochloridone	Not relevant	No	Not relevant	Yes	Not relevant	No	Not relevant	Yes	Yes	Unclassified*	ED - Cut off criteria are applicable / Repr Cat 1A/B	ED - Cut off criteria are applicable / Repr Cat 1A/B

The results of the screening do not constitute evaluations of individual substances to be carried out under the respective chemical legislations [[in particular, Regulation (EC) No 1107/2009 on plant protection products, Regulation (EU) No 528/2012 on biocidal products, Regulation (EC) No 1907/2006 REACH, Regulation (EC) No 1223/2009 on cosmetic products and the Water Framework Directive (EC) No 2000/60] and in no way prejudice future decisions on active substances to be taken pursuant to these pieces of the EU legislation.

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Screening of available evidence on chemical substances for the identification of endocrine disruptors according to different options in the context of an Impact Assessment

	Chemical Name	Carc Cat. 2 (C&L Harmonised)	Carc Cat. 2 (C&L Proposed)	Repr. Cat. 2 (C&L Harmonised)	Repr. Cat. 2 (C&L Proposed)	Carc Cat. 1A or 1B (C&L Harmonised)	Carc Cat. 1A or 1B (C&L Proposed)	Repr. Cat. 1A or 1B (C&L Harmonised)	Repr. Cat. 1A or 1B (C&L Proposed)	Effects on Endocrine organs (YES/NO)	OPTION 1 Harmonized	OPTION 1 Proposed	OPTION 1 Most recent
202	Amitrole (aminotriazole)	No	No	Yes	No	No	No	No	Yes	Yes	ED	ED - Cut off criteria are applicable / Repr Cat 1A/B	ED - Cut off criteria are applicable / Repr Cat 1A/B
206	Chlorsulfuron	No	Yes	No	No	No	No	No	No	Yes	Unclassified	Unclassified	Unclassified
207	Fluopyram	No	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	Yes	Unclassified	Not relevant	Unclassified
208	Pencycuron	No	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	Unclassified	Not relevant	Unclassified
209	Cyromazine	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	No	Unclassified*	Unclassified	Unclassified
210	Esfenvalerate	No	Yes	No	No	No	No	No	No	Yes	Unclassified	Unclassified	Unclassified
211	Penconazole	No	Not relevant	Yes	Not relevant	No	Not relevant	No	Not relevant	No	Unclassified	Not relevant	Unclassified
212	Flutolanil	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	No	Unclassified*	Unclassified	Unclassified
213	Metazachlor	Yes	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	Yes	Unclassified	Not relevant	Unclassified
214	Fenpropidin	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	No	Unclassified*	Unclassified	Unclassified
215	Prochloraz	No	Yes	No	Yes	No	No	No	No	Yes	Unclassified	ED	ED
216	Triflumizole	No	Not relevant	No	Not relevant	No	Not relevant	Yes	Not relevant	Yes	ED - Cut off criteria are applicable / Repr Cat 1A/B	Not relevant	ED - Cut off criteria are applicable / Repr Cat 1A/B
217	Pyriofenone	Not relevant	Yes	Not relevant	No	Not relevant	No	Not relevant	No	No	Unclassified*	Unclassified	Unclassified
218	Buprofezin	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	Yes	Unclassified*	Unclassified	Unclassified
219	Fluroxypyr	No	No	No	No	No	No	No	No	No	Unclassified	Unclassified	Unclassified
220	Chlormequat	No	No	No	No	No	No	No	No	No	Unclassified	Unclassified	Unclassified
221	Metalaxyl-M	No	No	No	No	No	No	No	No	Yes	Unclassified	Unclassified	Unclassified

The results of the screening do not constitute evaluations of individual substances to be carried out under the respective chemical legislations [[in particular, Regulation (EC) No 1107/2009 on plant protection products, Regulation (EU) No 528/2012 on biocidal products, Regulation (EC) No 1907/2006 REACH, Regulation (EC) No 1223/2009 on cosmetic products and the Water Framework Directive (EC) No 2000/60] and in no way prejudice future decisions on active substances to be taken pursuant to these pieces of the EU legislation.

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	Chemical Name	Carc Cat. 2 (C&L Harmonised)	Carc Cat. 2 (C&L Proposed)	Repr. Cat. 2 (C&L Harmonised)	Repr. Cat. 2 (C&L Proposed)	Carc Cat. 1A or 1B (C&L Harmonised)	Carc Cat. 1A or 1B (C&L Proposed)	Repr. Cat. 1A or 1B (C&L Harmonised)	Repr. Cat. 1A or 1B (C&L Proposed)	Effects on Endocrine organs (YES/NO)	OPTION 1 Harmonized	OPTION 1 Proposed	OPTION 1 Most recent
222	Triazoxide	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	No	Unclassified*	Unclassified	Unclassified
224	Phosmet	No	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	Unclassified	Not relevant	Unclassified
225	Aclonifen	Yes	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	Unclassified	Not relevant	Unclassified
226	Clofentezine	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	No	Unclassified*	Unclassified	Unclassified
227	Metsulfuron-methyl	No	No	No	No	No	No	No	No	No	Unclassified	Unclassified	Unclassified
230	Flutriafol	Not relevant	No	Not relevant	Yes	Not relevant	No	Not relevant	No	No	Unclassified*	Unclassified	Unclassified
231	Gamma-cyhalothrin	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	No	Unclassified*	Unclassified	Unclassified
232	Paclobutrazol	Not relevant	No	Not relevant	Yes	Not relevant	No	Not relevant	No	No	Unclassified*	Unclassified	Unclassified
237***	Phosphane	No	No	No	No	No	No	No	No	No	Unclassified	Unclassified	Unclassified
238	Hexythiazox	No	No	No	No	No	No	No	No	Yes	Unclassified	Unclassified	Unclassified
239	Thifensulfuron-methyl	No	No	No	Yes	No	No	No	No	Yes	Unclassified	ED	ED
240	Tefluthrin	No	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	Unclassified	Not relevant	Unclassified
241	Fluazinam	No	Not relevant	Yes	Not relevant	No	Not relevant	No	Not relevant	Yes	ED	Not relevant	ED
243	Imazaquin	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	No	Unclassified*	Unclassified	Unclassified
244	Clomazone	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	No	Unclassified*	Unclassified	Unclassified
245	Triasulfuron	No	No	No	No	No	No	No	No	No	Unclassified	Unclassified	Unclassified
246	Isoxaben	No	No	No	No	No	No	No	No	No	Unclassified	Unclassified	Unclassified
247	Bensulfuron methyl	No	No	No	No	No	No	No	No	No	Unclassified	Unclassified	Unclassified
248	Fluazifop-P	No	No	Yes	Yes	No	No	No	No	Yes	ED	ED	ED
249	Teflubenzuron	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	No	Unclassified*	Unclassified	Unclassified
250	Diflufenican	No	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	Yes	Unclassified	Not relevant	Unclassified
251	1-Naphthylacetamide	Not relevant	No	Not relevant	Yes	Not relevant	No	Not relevant	No	Yes	Unclassified*	ED	ED

The results of the screening do not constitute evaluations of individual substances to be carried out under the respective chemical legislations [[in particular, Regulation (EC) No 1107/2009 on plant protection products, Regulation (EU) No 528/2012 on biocidal products, Regulation (EC) No 1907/2006 REACH, Regulation (EC) No 1223/2009 on cosmetic products and the Water Framework Directive (EC) No 2000/60] and in no way prejudice future decisions on active substances to be taken pursuant to these pieces of the EU legislation.

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	(1-NAD)												
252	1-Naphthylacetic acid (1-NAA)	Not relevant	No	Not relevant	Yes	Not relevant	No	Not relevant	No	Yes	Unclassified*	ED	ED
253	Heptamaloxyglucan	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	No	Unclassified*	Unclassified	Unclassified
254	Diethofencarb	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	Yes	Unclassified*	Unclassified	Unclassified
255	Sedaxane	Not relevant	Yes	Not relevant	No	Not relevant	No	Not relevant	No	No	Unclassified*	Unclassified	Unclassified
256	Tralkoxydim	Yes	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	Yes	Unclassified	Not relevant	Unclassified
257	Isopyrazam	Not relevant	Yes	Not relevant	Yes	Not relevant	No	Not relevant	No	Yes	Unclassified*	ED	ED
258	Myclobutanil	No	No	Yes	Yes	No	No	No	No	Yes	ED	ED	ED
259	Thymol	No	No	No	No	No	No	No	No	No	Unclassified	Unclassified	Unclassified
261	Quinmerac	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	No	Unclassified*	Unclassified	Unclassified
262	Fluxapyroxad	Not relevant	Yes	Not relevant	No	Not relevant	No	Not relevant	No	No	Unclassified*	Unclassified	Unclassified
263	Prosulfuron	No	No	No	No	No	No	No	No	Yes	Unclassified	Unclassified	Unclassified
264	2,4-D	No	No	No	No	No	No	No	No	No	Unclassified	Unclassified	Unclassified
265	Haloxypop-P (Haloxypop-R)	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	No	Unclassified*	Unclassified	Unclassified
266	Pyridaben	No	No	No	No	No	No	No	No	Yes	Unclassified	Unclassified	Unclassified
267	Eugenol	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	No	Unclassified*	Unclassified	Unclassified
269	Benalaxyl-M	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	No	Unclassified*	Unclassified	Unclassified
270	Sulcotrione	No	Not relevant	Yes	Not relevant	No	Not relevant	No	Not relevant	No	Unclassified	Not relevant	Unclassified
271	Clethodim	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	Yes	Unclassified*	Unclassified	Unclassified
290	Repellents by smell of animal or plant origin/ sheep fat	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	No	Unclassified*	Unclassified	Unclassified

The results of the screening do not constitute evaluations of individual substances to be carried out under the respective chemical legislations [[in particular, Regulation (EC) No 1107/2009 on plant protection products, Regulation (EU) No 528/2012 on biocidal products, Regulation (EC) No 1907/2006 REACH, Regulation (EC) No 1223/2009 on cosmetic products and the Water Framework Directive (EC) No 2000/60] and in no way prejudice future decisions on active substances to be taken pursuant to these pieces of the EU legislation.

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Screening of available evidence on chemical substances for the identification of endocrine disruptors according to different options in the context of an Impact Assessment

	Chemical Name	Carc Cat. 2 (C&L Harmonised)	Carc Cat. 2 (C&L Proposed)	Repr. Cat. 2 (C&L Harmonised)	Repr. Cat. 2 (C&L Proposed)	Carc Cat. 1A or 1B (C&L Harmonised)	Carc Cat. 1A or 1B (C&L Proposed)	Repr. Cat. 1A or 1B (C&L Harmonised)	Repr. Cat. 1A or 1B (C&L Proposed)	Effects on Endocrine organs (YES/NO)	OPTION 1 Harmonized	OPTION 1 Proposed	OPTION 1 Most recent
291	Repellents by smell of animal or plant origin/ tall oil crude	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	No	Unclassified*	Unclassified	Unclassified
292	Repellents by smell of animal or plant origin/ tall oil pitch	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	No	Unclassified*	Unclassified	Unclassified
293	Sea-algae extract (formerly sea-algae extract and seaweeds)	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	No	Unclassified*	Unclassified	Unclassified
294	Clothianidin	No	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	Yes	Unclassified	Not relevant	Unclassified
295	Propiconazole	No	No	No	No	No	No	No	No	No	Unclassified	Unclassified	Unclassified
296	Thiacloprid	Yes	Not relevant	No	Not relevant	No	Not relevant	Yes	Not relevant	Yes	ED - Cut off criteria are applicable / Repr Cat 1A/B	Not relevant	ED - Cut off criteria are applicable / Repr Cat 1A/B
297	Pelargonic acid (Nonanoic acid)	No	No	No	No	No	No	No	No	No	Unclassified	Unclassified	Unclassified
298	Caprylic acid (Octanoic acid)	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	No	Unclassified*	Unclassified	Unclassified
299	Lauric acid	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	No	Unclassified*	Unclassified	Unclassified
300	Thiamethoxam	No	No	No	No	No	No	No	No	Yes	Unclassified	Unclassified	Unclassified
301	Spinosad	No	No	No	No	No	No	No	No	No	Unclassified	Unclassified	Unclassified
302	Copper hydroxide	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	No	Unclassified*	Unclassified	Unclassified
303	Capric acid (Decanoic acid)	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	No	Unclassified*	Unclassified	Unclassified
304	Cypermethrin	No	No	No	No	No	No	No	No	Yes	Unclassified	Unclassified	Unclassified

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305	Deltamethrin	No	No	No	No	No	No	No	No	Yes	Unclassified	Unclassified	Unclassified
306	Benzoic acid	No	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	Unclassified	Not relevant	Unclassified
307	Alpha-Cypermethrin (aka alphamethrin)	No	No	No	No	No	No	No	No	No	Unclassified	Unclassified	Unclassified
308	Chlorpropham	Yes	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	Yes	Unclassified	Not relevant	Unclassified
309	Flazasulfuron	No	No	No	No	No	No	No	No	No	Unclassified	Unclassified	Unclassified
310	Mesotrione	No	No	No	No	No	No	No	No	No	Unclassified	Unclassified	Unclassified
311	Pethoxamid	No	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	Yes	Unclassified	Not relevant	Unclassified
312	Mepanipyrim	Yes	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	Unclassified	Not relevant	Unclassified
313	Methyl decanoate	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	No	Unclassified*	Unclassified	Unclassified
314	Methyl octanoate	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	No	Unclassified*	Unclassified	Unclassified
319	Beflubutamid	No	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	Unclassified	Not relevant	Unclassified
320	Imazamox	No	No	No	No	No	No	No	No	No	Unclassified	Unclassified	Unclassified
321	Picoxystrobin	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	No	Unclassified*	Unclassified	Unclassified
322	Cyazofamid	No	No	No	No	No	No	No	No	No	Unclassified	Unclassified	Unclassified
323	Propineb	No	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	Yes	Unclassified	Not relevant	Unclassified
324	Imazosulfuron	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	No	Unclassified*	Unclassified	Unclassified
325	Maleic hydrazide	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	No	Unclassified*	Unclassified	Unclassified
326	Maneb	No	Not relevant	Yes	Not relevant	No	Not relevant	No	Not relevant	Yes	ED	Not relevant	ED
327	Quinoxifen	No	No	No	No	No	No	No	No	No	Unclassified	Unclassified	Unclassified
328	Carfentrazone-ethyl	No	No	No	No	No	No	No	No	No	Unclassified	Unclassified	Unclassified
331	Tribasic copper	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	No	Unclassified*	Unclassified	Unclassified

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	sulfate												
332	Acetamiprid	No	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	Unclassified	Not relevant	Unclassified
334	Desmedipham	No	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	Yes	Unclassified	Not relevant	Unclassified
335	Phenmedipham	No	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	Yes	Unclassified	Not relevant	Unclassified
336	Thiram	No	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	Yes	Unclassified	Not relevant	Unclassified
337	Ziram	No	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	Yes	Unclassified	Not relevant	Unclassified
338	Profoxydim	Yes	Not relevant	Yes	Not relevant	No	Not relevant	No	Not relevant	Yes	ED	Not relevant	ED
339	Isoxaflutole	No	No	Yes	Yes (?)	No	No	No	No	Yes	ED	ED (?)	ED (?)
340	Trifloxystrobin	No	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	Unclassified	Not relevant	Unclassified
341	Flufenacet (formerly fluthiamide)	No	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	Yes	Unclassified	Not relevant	Unclassified
342	Tritosulfuron	No	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	Yes	Unclassified	Not relevant	Unclassified
343	Indoxacarb	No	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	Unclassified	Not relevant	Unclassified
344	Oxasulfuron	No	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	Yes	Unclassified	Not relevant	Unclassified
345	Propoxycarbazone	No	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	Unclassified	Not relevant	Unclassified
346	Bifenazate	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	No	Unclassified*	Unclassified	Unclassified
347	Tepraloxydim	Yes	Not relevant	Yes	Not relevant	No	Not relevant	No	Not relevant	Yes	ED	Not relevant	ED
348	Etoazole	No	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	Yes	Unclassified	Not relevant	Unclassified
349	Chlorotoluron	Yes	Not relevant	Yes	Not relevant	No	Not relevant	No	Not relevant	No	ED	Not relevant	ED
350	Zoxamide	No	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	Unclassified	Not relevant	Unclassified
351	Daminozide	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	No	Unclassified*	Unclassified	Unclassified
352	Methoxyfenozide	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	No	Unclassified*	Unclassified	Unclassified
353	Fenamidone	No	No	No	No	No	No	No	No	Yes	Unclassified	Unclassified	Unclassified

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354	Dimethenamid-P	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	No	Unclassified*	Unclassified	Unclassified
355	Mecoprop-P	No	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	Unclassified	Not relevant	Unclassified
357	Bromoxynil	No	Not relevant	Yes	Not relevant	No	Not relevant	No	Not relevant	Yes	ED	Not relevant	ED
359	Foramsulfuron	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	No	Unclassified*	Unclassified	Unclassified
360	Pyraclostrobin	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	No	Unclassified*	Unclassified	Unclassified
361	Silthiofam	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	Yes	Unclassified*	Unclassified	Unclassified
362	S-Metolachlor	No	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	Unclassified	Not relevant	Unclassified
363	Pyridalyl	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	Yes	Unclassified*	Unclassified	Unclassified
364	Iodosulfuron	No	No	No	No	No	No	No	No	No	Unclassified	Unclassified	Unclassified
365	Boscalid (formerly nicobifen)	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	Yes	Unclassified*	Unclassified	Unclassified
366	Chlorothalonil	Yes	No	No	No	No	No	No	No	Yes	Unclassified	Unclassified	Unclassified
368	Thiophanate-methyl	No	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	Yes	Unclassified	Not relevant	Unclassified
369	Propyzamide	No	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	Yes	Unclassified	Not relevant	Unclassified
370	Ethofumesate	No	No	No	No	No	No	No	No	Yes	Unclassified	Unclassified	Unclassified
371	Flubendiamide	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	Yes	Unclassified*	Unclassified	Unclassified
372	Diquat (dibromide)	Not relevant	No	Not relevant	Yes	Not relevant	No	Not relevant	No	No	Unclassified*	Unclassified	Unclassified
374	Chlorpyrifos	No	No	No	No	No	No	No	No	Yes	Unclassified	Unclassified	Unclassified
375	Linuron	Yes	Not relevant	No	Not relevant	No	Not relevant	Yes	Not relevant	Yes	ED - Cut off criteria are applicable / Repr Cat	Not relevant	ED - Cut off criteria are applicable / Repr Cat

The results of the screening do not constitute evaluations of individual substances to be carried out under the respective chemical legislations [[in particular, Regulation (EC) No 1107/2009 on plant protection products, Regulation (EU) No 528/2012 on biocidal products, Regulation (EC) No 1907/2006 REACH, Regulation (EC) No 1223/2009 on cosmetic products and the Water Framework Directive (EC) No 2000/60] and in no way prejudice future decisions on active substances to be taken pursuant to these pieces of the EU legislation.

It would thus be erroneous to consider that the substances listed in the results of this study (SANTE/2015/E3/SI2.706218) are considered as endocrine disruptors within the meaning of the EU legislation.

Screening of available evidence on chemical substances for the identification of endocrine disruptors according to different options in the context of an Impact Assessment

	Chemical Name	Carc Cat. 2 (C&L Harmonised)	Carc Cat. 2 (C&L Proposed)	Repr. Cat. 2 (C&L Harmonised)	Repr. Cat. 2 (C&L Proposed)	Carc Cat. 1A or 1B (C&L Harmonised)	Carc Cat. 1A or 1B (C&L Proposed)	Repr. Cat. 1A or 1B (C&L Harmonised)	Repr. Cat. 1A or 1B (C&L Proposed)	Effects on Endocrine organs (YES/NO)	OPTION 1 Harmonized	OPTION 1 Proposed	OPTION 1 Most recent
											1A/B		1A/B
379	Iprodione	Yes	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	Yes	Unclassified	Not relevant	Unclassified
382	Mesosulfuron	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	Yes	Unclassified*	Unclassified	Unclassified
383	Pendimethalin	No	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	Yes	Unclassified	Not relevant	Unclassified
384 [†]	Denathonium benzoate	-	-	-	-	-	-	-	-	-	-	-	-
385	Milbemectin	No	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	Yes	Unclassified	Not relevant	Unclassified
390	Chlorpyrifos-methyl	No	No	No	No	No	No	No	No	Yes	Unclassified	Unclassified	Unclassified
394	Sucrose	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	No	Unclassified*	Unclassified	Unclassified
395	Metalaxyl	No	No	No	No	No	No	No	No	Yes	Unclassified	Unclassified	Unclassified
398	Sodium 5-nitroguaiacolate	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	No	Unclassified*	Unclassified	Unclassified
400	Forchlorfenuron	Yes	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	Unclassified	Not relevant	Unclassified
401	Beta-Cyfluthrin	No	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	Yes	Unclassified	Not relevant	Unclassified
402	Benalaxyl	No	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	Unclassified	Not relevant	Unclassified
403	Mancozeb	No	Not relevant	Yes	Not relevant	No	Not relevant	No	Not relevant	Yes	ED	Not relevant	ED
404	Sodium o-nitrophenolate	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	No	Unclassified*	Unclassified	Unclassified
405	Sodium p-nitrophenolate	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	No	Unclassified*	Unclassified	Unclassified
407	Ametoctradin	Not relevant	No	Not relevant	Yes	Not relevant	No	Not relevant	No	No	Unclassified*	Unclassified	Unclassified
408	Metiram	Not relevant	No	Not relevant	Yes	Not relevant	No	Not relevant	No	Yes	Unclassified*	Unclassified	Unclassified
409	Laminarin	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	No	Unclassified*	Unclassified	Unclassified

The results of the screening do not constitute evaluations of individual substances to be carried out under the respective chemical legislations [[in particular, Regulation (EC) No 1107/2009 on plant protection products, Regulation (EU) No 528/2012 on biocidal products, Regulation (EC) No 1907/2006 REACH, Regulation (EC) No 1223/2009 on cosmetic products and the Water Framework Directive (EC) No 2000/60] and in no way prejudice future decisions on active substances to be taken pursuant to these pieces of the EU legislation.

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Screening of available evidence on chemical substances for the identification of endocrine disruptors according to different options in the context of an Impact Assessment

	Chemical Name	Carc Cat. 2 (C&L Harmonised)	Carc Cat. 2 (C&L Proposed)	Repr. Cat. 2 (C&L Harmonised)	Repr. Cat. 2 (C&L Proposed)	Carc Cat. 1A or 1B (C&L Harmonised)	Carc Cat. 1A or 1B (C&L Proposed)	Repr. Cat. 1A or 1B (C&L Harmonised)	Repr. Cat. 1A or 1B (C&L Proposed)	Effects on Endocrine organs (YES/NO)	OPTION 1 Harmonized	OPTION 1 Proposed	OPTION 1 Most recent
411	Mecoprop	No	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	Unclassified	Not relevant	Unclassified
413	MCPA	No	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	Yes?	Unclassified	Not relevant	Unclassified
414	MCPB	No	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	Unclassified	Not relevant	Unclassified
415	2,4-DB	No	No	No	No	No	No	No	No	Yes	Unclassified	Unclassified	Unclassified
416	Flurtamone	No	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	Unclassified	Not relevant	Unclassified
417	Fosthiazate	No	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	yes	Unclassified	Not relevant	Unclassified
418	Carvone	No	No	No	No	No	No	No	No	No	Unclassified	Unclassified	Unclassified
426	Bordeaux mixture	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	No	Unclassified*	Unclassified	Unclassified
428	n-Tetradecylacetate	Not relevant	No	Not relevant	Yes	Not relevant	No	Not relevant	No	No	Unclassified*	Unclassified	Unclassified

Unclassified*: No harmonized classification available

**This substance was incorrectly marked also as a BP in the published list of substances to be screened.

*** This substance had been already screened when "list of substances to be screened" was published.

****This substance covers also the substance Quizalofop-P.

† This substance was initially included in the list of substances to be screened, but following the rational it was decided that the substance was not to be screened.

The results of the screening do not constitute evaluations of individual substances to be carried out under the respective chemical legislations [[in particular, Regulation (EC) No 1107/2009 on plant protection products, Regulation (EU) No 528/2012 on biocidal products, Regulation (EC) No 1907/2006 REACH, Regulation (EC) No 1223/2009 on cosmetic products and the Water Framework Directive (EC) No 2000/60] and in no way prejudice future decisions on active substances to be taken pursuant to these pieces of the EU legislation.

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Revised potential categorization results for 348 PPPs under “Option 2, 3 & 4” for human health & vertebrate wildlife and combined potential categorization under all Options

	Chemical Name	Potential Categorization Human Health				Potential Categorization Wildlife				Combined Potential Categorization (HH & Wildlife Vertebrates)			
		OPTION 2	OPTION 3	Path of decision tree	OPTION 4	OPTION 2	OPTION 3	Path of decision tree	OPTION 4	OPTION 1 Most recent	OPTION 2	OPTION 3	OPTION 4
1	Carbon dioxide	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
2	Tebuconazole	ED	Cat I	2a/2b	Unclassified	ED	Cat I	2a/2b	ED	ED	ED	Cat I	ED
3	Methyl nonyl ketone	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
4	Fipronil	Unclassified	Cat II	5	Unclassified	Unclassified	Cat II	3b	Unclassified	Unclassified	Unclassified	Cat II	Unclassified
5	Magnesium phosphide	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
6	Imidacloprid	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
7	Thiabendazole	Unclassified	Cat II	3b	Unclassified	Unclassified	Cat II	3b	Unclassified	Unclassified	Unclassified	Cat II	Unclassified
8	Aluminium phosphide	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
9	Sulfuryl fluoride	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
10	Bromadiolone	Unclassified	Unclassified	8	Unclassified	Unclassified	Unclassified	8	Unclassified	Cut off criteria are applicable / Repr Cat 1A/B	Unclassified	Unclassified	Unclassified
11	Diflubenzuron	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
12	Dazomet	Unclassified	Cat II	3b	Unclassified	Unclassified	Cat II	3b	Unclassified	ED	Unclassified	Cat II	Unclassified

The results of the screening do not constitute evaluations of individual substances to be carried out under the respective chemical legislations [[in particular, Regulation (EC) No 1107/2009 on plant protection products, Regulation (EU) No 528/2012 on biocidal products, Regulation (EC) No 1907/2006 REACH, Regulation (EC) No 1223/2009 on cosmetic products and the Water Framework Directive (EC) No 2000/60] and in no way prejudice future decisions on active substances to be taken pursuant to these pieces of the EU legislation.

It would thus be erroneous to consider that the substances listed in the results of this study (SANTE/2015/E3/SI2.706218) are considered as endocrine disruptors within the meaning of the EU legislation.

Screening of available evidence on chemical substances for the identification of endocrine disruptors according to different options in the context of an Impact Assessment

	Chemical Name	Potential Categorization Human Health				Potential Categorization Wildlife				Combined Potential Categorization (HH & Wildlife Vertebrates)			
		OPTION 2	OPTION 3	Path of decision tree	OPTION 4	OPTION 2	OPTION 3	Path of decision tree	OPTION 4	OPTION 1 Most recent	OPTION 2	OPTION 3	OPTION 4
13	Difenacoum	Unclassified	Cat II	3a	Unclassified	Unclassified	Cat II	3a	Unclassified	ED / Cut off criteria are applicable / Repr Cat 1A/B	Unclassified	Cat II	Unclassified
14	Fenpropimorph	Unclassified	Unclassified	8	Unclassified	Unclassified	Unclassified	8	Unclassified	ED	Unclassified	Unclassified	Unclassified
15	Abamectin (aka avermectin)	Unclassified	Cat II	3a	Unclassified	Unclassified	Cat II	3a	Unclassified	ED	Unclassified	Cat II	Unclassified
16	Fenoxycarb	Unclassified	Cat III	7	Unclassified	Unclassified	Cat III	7	Unclassified	Unclassified	Unclassified	Cat III	Unclassified
17	Etofenprox	Unclassified	Cat III	7	Unclassified	Unclassified	Cat III	7	Unclassified	Unclassified	Unclassified	Cat III	Unclassified
18	Bifenthrin	Unclassified	Unclassified	11	Unclassified	Unclassified	Cat II	9	Unclassified	Unclassified	Unclassified	Cat II	Unclassified
19	lambda-Cyhalothrin	Unclassified	Cat II	5 & 6	Unclassified	Unclassified	Cat II	5 & 6	Unclassified	Unclassified	Unclassified	Cat II	Unclassified
20	Cyproconazole	Unclassified	Cat II	3b	Unclassified	ED	Cat I	2a/2b	ED	ED - Cut off criteria are applicable / Repr Cat 1A/B	ED	Cat I	ED
21	Pyriproxyfen	Unclassified	Unclassified	11	Unclassified	ED	Cat I	2a	ED	Unclassified	ED	Cat I	ED
22	Folpet	Unclassified	Unclassified	8	Unclassified	Unclassified	Cat II	5	Unclassified	Unclassified	Unclassified	Cat II	Unclassified
23**	Triflumuron	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
24**	2-Phenylphenol (incl. sodium salt orthophenyl phenol)	Unclassified	Unclassified	11	Unclassified	ED	Cat I	4	ED	Unclassified	ED	Cat I	ED
25	Hymexazol	Unclassified	Cat II	3a	Unclassified	Unclassified	Cat II	3a	Unclassified	ED	Unclassified	Cat II	Unclassified

The results of the screening do not constitute evaluations of individual substances to be carried out under the respective chemical legislations [[in particular, Regulation (EC) No 1107/2009 on plant protection products, Regulation (EU) No 528/2012 on biocidal products, Regulation (EC) No 1907/2006 REACH, Regulation (EC) No 1223/2009 on cosmetic products and the Water Framework Directive (EC) No 2000/60] and in no way prejudice future decisions on active substances to be taken pursuant to these pieces of the EU legislation.

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Screening of available evidence on chemical substances for the identification of endocrine disruptors according to different options in the context of an Impact Assessment

	Chemical Name	Potential Categorization Human Health				Potential Categorization Wildlife				Combined Potential Categorization (HH & Wildlife Vertebrates)			
		OPTION 2	OPTION 3	Path of decision tree	OPTION 4	OPTION 2	OPTION 3	Path of decision tree	OPTION 4	OPTION 1 Most recent	OPTION 2	OPTION 3	OPTION 4
27	Aluminium sulphate	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
28	Ferric phosphate	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
29****	Quizalofop-P-ethyl	Unclassified	Cat II	3a	Unclassified	Unclassified	Cat II	3a	Unclassified	Unclassified	Unclassified	Cat II	Unclassified
30	Halosulfuron methyl	Unclassified	Unclassified	8	Unclassified	Unclassified	Unclassified	8	Unclassified	ED	Unclassified	Unclassified	Unclassified
31	Acrinathrin	Unclassified	Cat II	3a	Unclassified	Unclassified	Cat II	3a	Unclassified	Unclassified	Unclassified	Cat II	Unclassified
32	Cycloxydim	Unclassified	Cat II	3a	Unclassified	Unclassified	Cat II	3a	Unclassified	ED	Unclassified	Cat II	Unclassified
34	tau-Fluvalinate	Unclassified	Cat III	10	Unclassified	Unclassified	Cat III	10	Unclassified	Unclassified	Unclassified	Cat III	Unclassified
35	Lufenuron	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
36	Flumioxazin	Unclassified	Cat III	7	Unclassified	Unclassified	Cat III	7	Unclassified	Cut off criteria are applicable / Repr Cat 1A/B	Unclassified	Cat III	Unclassified
37	Tribenuron (aka metometuron)	Unclassified	Cat III	7	Unclassified	Unclassified	Cat III	7	Unclassified	Unclassified	Unclassified	Cat III	Unclassified
38	Geraniol	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
39	Glyphosate (incl aka trimesium sulfosate)	Unclassified	Cat II	3a	Unclassified	Unclassified	Cat II	3a/3b	Unclassified	Unclassified	Unclassified	Cat II	Unclassified
40	Metaldehyde	Unclassified	Cat II	3a	Unclassified	Unclassified	Cat II	3a	Unclassified	Unclassified	Unclassified	Cat II	Unclassified
41	Dimethomorph	Unclassified	Cat II	3a	Unclassified	Unclassified	Cat II	3a	Unclassified	Unclassified	Unclassified	Cat II	Unclassified
42****	Putrescine (1,4-	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified

The results of the screening do not constitute evaluations of individual substances to be carried out under the respective chemical legislations [[in particular, Regulation (EC) No 1107/2009 on plant protection products, Regulation (EU) No 528/2012 on biocidal products, Regulation (EC) No 1907/2006 REACH, Regulation (EC) No 1223/2009 on cosmetic products and the Water Framework Directive (EC) No 2000/60] and in no way prejudice future decisions on active substances to be taken pursuant to these pieces of the EU legislation.

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		Potential Categorization Human Health				Potential Categorization Wildlife				Combined Potential Categorization (HH & Wildlife Vertebrates)			
	Chemical Name	OPTION 2	OPTION 3	Path of decision tree	OPTION 4	OPTION 2	OPTION 3	Path of decision tree	OPTION 4	OPTION 1 Most recent	OPTION 2	OPTION 3	OPTION 4
	Diaminobutane))												
43	Azadirachtin	Unclassified	Cat II	3a	Unclassified	Unclassified	Cat II	3a	Unclassified	Unclassified	Unclassified	Cat II	Unclassified
44	Propaquizafop	Unclassified	Cat II	3a	Unclassified	Unclassified	Cat II	3a	Unclassified	Unclassified	Unclassified	Cat II	Unclassified
45	Nicosulfuron	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
46	Tetraconazole	Unclassified	Cat II	3b	Unclassified	Unclassified	Cat II	3b	Unclassified	Unclassified	Unclassified	Cat II	Unclassified
47	1-Decanol	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
48	Tebufenozide	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
49	Dodine	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
50	Fenoxaprop-P	Unclassified	Cat III	7	Unclassified	Unclassified	Cat III	7	Unclassified	Unclassified	Unclassified	Cat III	Unclassified
51	Fenbuconazole	Unclassified	Cat II	5 & 6	Unclassified	Unclassified	Cat II	5 & 6	Unclassified	ED	Unclassified	Cat II	Unclassified
52	Clodinafop	Unclassified	Cat II	3a/3b	Unclassified	Unclassified	Cat II	3a/3b	Unclassified	Unclassified	Unclassified	Cat II	Unclassified
53	Bromuconazole	Unclassified	Cat II	3a	Unclassified	Unclassified	Cat II	3a	Unclassified	Unclassified	Unclassified	Cat II	Unclassified
54	Spiroxamine	Unclassified	Cat II	3a	Unclassified	Unclassified	Cat II	3a	Unclassified	ED	Unclassified	Cat II	Unclassified
55	Tebufenpyrad	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
56	Difenoconazole	Unclassified	Cat III	10	Unclassified	Unclassified	Cat III	10	Unclassified	Unclassified	Unclassified	Cat III	Unclassified
57****	Quizalofop-P-tefuryl	Unclassified	Cat II	3a	Unclassified	Unclassified	Cat II	3a	Unclassified	ED	Unclassified	Cat II	Unclassified
59	Azimsulfuron	Unclassified	Cat II	3a	Unclassified	Unclassified	Cat II	3a	Unclassified	Unclassified	Unclassified	Cat II	Unclassified
60	Amidosulfuron	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
61	Fenazaquin	Unclassified	Cat II	3a	Unclassified	Unclassified	Cat II	3a	Unclassified	Unclassified	Unclassified	Cat II	Unclassified
62	Pyrethrins	Unclassified	Unclassified	8	Unclassified	Unclassified	Unclassified	8	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified

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Screening of available evidence on chemical substances for the identification of endocrine disruptors according to different options in the context of an Impact Assessment

	Chemical Name	Potential Categorization Human Health				Potential Categorization Wildlife				Combined Potential Categorization (HH & Wildlife Vertebrates)			
		OPTION 2	OPTION 3	Path of decision tree	OPTION 4	OPTION 2	OPTION 3	Path of decision tree	OPTION 4	OPTION 1 Most recent	OPTION 2	OPTION 3	OPTION 4
63	6-Benzyladenine	Unclassified	Unclassified	8	Unclassified	Unclassified	Unclassified	8	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
64	Cyprodinil	Unclassified	Cat III	10	Unclassified	Unclassified	Cat III	10	Unclassified	Unclassified	Unclassified	Cat III	Unclassified
65	Malathion	Unclassified	Cat II	5	Unclassified	Unclassified	Cat II	5	Unclassified	Unclassified	Unclassified	Cat II	Unclassified
66	Cyhalofop-butyl	Unclassified	Cat III	10	Unclassified	Unclassified	Cat III	10	Unclassified	Unclassified	Unclassified	Cat III	Unclassified
67	Rimsulfuron (aka renriduron)	Unclassified	Cat II	3a	Unclassified	Unclassified	Cat II	3a	Unclassified	Unclassified	Unclassified	Cat II	Unclassified
68	Pymetrozine	Unclassified	Cat II	3a/3b	Unclassified	Unclassified	Cat II	3a/3b	Unclassified	ED	Unclassified	Cat II	Unclassified
69	Metconazole	Unclassified	Unclassified	8	Unclassified	Unclassified	Unclassified	8	Unclassified	ED	Unclassified	Unclassified	Unclassified
70	Ipconazole	Unclassified	Cat II	3a	Unclassified	Unclassified	Cat II	3a	Unclassified	ED	Unclassified	Cat II	Unclassified
71	Bispyribac	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
72	Fenhexamid	Unclassified	Cat II	3b	Unclassified	Unclassified	Cat II	3b	Unclassified	Unclassified	Unclassified	Cat II	Unclassified
73	Prohexadione	Unclassified	Cat II	3a	Unclassified	Unclassified	Cat II	3a	Unclassified	Unclassified	Unclassified	Cat II	Unclassified
74	Pyraflufen-ethyl	Unclassified	Cat II	3b	Unclassified	Unclassified	Cat II	3b	Unclassified	Unclassified	Unclassified	Cat II	Unclassified
75	Sintofen (aka Cintofen)	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
76	Calcium phosphide	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
77	Fludioxonil	Unclassified	Cat III	10	Unclassified	Unclassified	Cat III	10	Unclassified	Unclassified	Unclassified	Cat III	Unclassified
78	Zinc phosphide	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
79	zeta-Cypermethrin	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
80	Limestone	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
81	Famoxadone	Unclassified	Cat III	10	Unclassified	Unclassified	Cat III	10	Unclassified	Unclassified	Unclassified	Cat III	Unclassified

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Screening of available evidence on chemical substances for the identification of endocrine disruptors according to different options in the context of an Impact Assessment

	Chemical Name	Potential Categorization Human Health				Potential Categorization Wildlife				Combined Potential Categorization (HH & Wildlife Vertebrates)			
		OPTION 2	OPTION 3	Path of decision tree	OPTION 4	OPTION 2	OPTION 3	Path of decision tree	OPTION 4	OPTION 1 Most recent	OPTION 2	OPTION 3	OPTION 4
82	Azoxystrobin	Unclassified	Cat III	10	Unclassified	Unclassified	Cat III	10	Unclassified	Unclassified	Unclassified	Cat III	Unclassified
83	Ethoprophos	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
84	Triticonazole	Unclassified	Cat II	3a	Unclassified	Unclassified	Cat II	3a	Unclassified	Unclassified	Unclassified	Cat II	Unclassified
85	Captan	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	ED (?)	Unclassified	Unclassified	Unclassified
86	Indolylbutyric acid	Unclassified	Cat II	3a	Unclassified	Unclassified	Cat II	3a	Unclassified	ED	Unclassified	Cat II	Unclassified
87	Epoxiconazole	ED	Cat I	2a/2b	ED	ED	Cat I	1/2a/2b	ED	ED - Cut off criteria are applicable / Repr Cat 1A/B	ED	Cat I	ED
88	Fenpyroximate	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
90	Acibenzolar-S-methyl (benzothiadiazole)	Unclassified	Unclassified	8	Unclassified	Unclassified	Unclassified	8	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
91	Triflusalufuron	ED	Cat I	4	Unclassified	ED	Cat I	4	Unclassified	Unclassified	ED	Cat I	Unclassified
92	Fluquinconazole	Unclassified	Unclassified	8	Unclassified	Unclassified	Unclassified	8	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
93	Disodium phosphonate	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
94	Picolinafen	Unclassified	Cat II	3a	Unclassified	Unclassified	Unclassified	8	Unclassified	Unclassified	Unclassified	Cat II	Unclassified
95	Metosulam	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
96***	Potassium phosphonates (formerly potassium phosphite)	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
97	Metaflumizone	Unclassified	Unclassified	8	Unclassified	Unclassified	Unclassified	8	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified

The results of the screening do not constitute evaluations of individual substances to be carried out under the respective chemical legislations [[in particular, Regulation (EC) No 1107/2009 on plant protection products, Regulation (EU) No 528/2012 on biocidal products, Regulation (EC) No 1907/2006 REACH, Regulation (EC) No 1223/2009 on cosmetic products and the Water Framework Directive (EC) No 2000/60] and in no way prejudice future decisions on active substances to be taken pursuant to these pieces of the EU legislation.

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Screening of available evidence on chemical substances for the identification of endocrine disruptors according to different options in the context of an Impact Assessment

	Chemical Name	Potential Categorization Human Health				Potential Categorization Wildlife				Combined Potential Categorization (HH & Wildlife Vertebrates)			
		OPTION 2	OPTION 3	Path of decision tree	OPTION 4	OPTION 2	OPTION 3	Path of decision tree	OPTION 4	OPTION 1 Most recent	OPTION 2	OPTION 3	OPTION 4
98	Iprovalicarb	Unclassified	Unclassified	8	Unclassified	Unclassified	Unclassified	8	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
99	Sulfosulfuron	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
100	Trinexapac (aka cimetacarb ethyl)	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
101	Kresoxim-methyl	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
102	Chromafenozide	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
103	Metam (incl. - potassium and - sodium)	Unclassified	Unclassified	8	Unclassified	Unclassified	Unclassified	8	Unclassified	ED	Unclassified	Unclassified	Unclassified
104	Flupyrulfuron-methyl (DPX KE 459)	Unclassified	Unclassified	8	Unclassified	Unclassified	Unclassified	8	Unclassified	ED	Unclassified	Unclassified	Unclassified
105	Florasulam	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
106	8-Hydroxyquinoline incl. oxyquinoleine	Unclassified	Unclassified	8	Unclassified	Unclassified	Unclassified	8	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
107	Spirodiclofen	ED	Cat I	2a	Unclassified	ED	Cat I	2a	Unclassified	Unclassified	ED	Cat I	Unclassified
108	Dimoxystrobin	Unclassified	Unclassified	8	Unclassified	Unclassified	Unclassified	8	Unclassified	ED	Unclassified	Unclassified	Unclassified
109	Aminopyralid	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
110	Dichlorprop-P	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
111	Napropamide	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
112	Mepiquat	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
113	Emamectin	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
115	Flonicamid (IKI-220)	Unclassified	Cat II	3a	Unclassified	Unclassified	Cat II	3a	Unclassified	Unclassified	Unclassified	Cat II	Unclassified

The results of the screening do not constitute evaluations of individual substances to be carried out under the respective chemical legislations [[in particular, Regulation (EC) No 1107/2009 on plant protection products, Regulation (EU) No 528/2012 on biocidal products, Regulation (EC) No 1907/2006 REACH, Regulation (EC) No 1223/2009 on cosmetic products and the Water Framework Directive (EC) No 2000/60] and in no way prejudice future decisions on active substances to be taken pursuant to these pieces of the EU legislation.

It would thus be erroneous to consider that the substances listed in the results of this study (SANTE/2015/E3/SI2.706218) are considered as endocrine disruptors within the meaning of the EU legislation.

Screening of available evidence on chemical substances for the identification of endocrine disruptors according to different options in the context of an Impact Assessment

	Chemical Name	Potential Categorization Human Health				Potential Categorization Wildlife				Combined Potential Categorization (HH & Wildlife Vertebrates)			
		OPTION 2	OPTION 3	Path of decision tree	OPTION 4	OPTION 2	OPTION 3	Path of decision tree	OPTION 4	OPTION 1 Most recent	OPTION 2	OPTION 3	OPTION 4
116	Dodemorph	Unclassified	Unclassified	8	Unclassified	Unclassified	Unclassified	8	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
117	Carbetamide	Unclassified	Cat II	3a	Unclassified	Unclassified	Cat II	3a	Unclassified	ED	Unclassified	Cat II	Unclassified
118	Ethephon	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
119	Methomyl	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
120	Chloridazon (aka pyrazone)	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
121	Clopyralid	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
123	Prothioconazole	Unclassified	Cat II	3b	Unclassified	Unclassified	Cat II	3b	Unclassified	ED	Unclassified	Cat II	Unclassified
124	Cyflufenamid	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
125	Penthiopyrad	Unclassified	Cat II	3a	Unclassified	Unclassified	Cat II	3a	Unclassified	Unclassified	Unclassified	Cat II	Unclassified
126	Benfluralin	Unclassified	Cat II	3b	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Cat II	Unclassified
127	Spinetoram	Unclassified	Unclassified	8	Unclassified	Unclassified	Unclassified	8	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
128	Proquinazid	Unclassified	Cat II	3a	Unclassified	Unclassified	Cat II	3a	Unclassified	Unclassified	Unclassified	Cat II	Unclassified
129	Oryzalin	Unclassified	Cat II	3a	Unclassified	Unclassified	Cat II	3b	Unclassified	Unclassified	Unclassified	Cat II	Unclassified
130	Dicamba	Unclassified	Unclassified	11	Unclassified	Unclassified	Cat II	3a/3b	Unclassified	Unclassified	Unclassified	Cat II	Unclassified
131	Picloram	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified

The results of the screening do not constitute evaluations of individual substances to be carried out under the respective chemical legislations [[in particular, Regulation (EC) No 1107/2009 on plant protection products, Regulation (EU) No 528/2012 on biocidal products, Regulation (EC) No 1907/2006 REACH, Regulation (EC) No 1223/2009 on cosmetic products and the Water Framework Directive (EC) No 2000/60] and in no way prejudice future decisions on active substances to be taken pursuant to these pieces of the EU legislation.

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	Chemical Name	Potential Categorization Human Health				Potential Categorization Wildlife				Combined Potential Categorization (HH & Wildlife Vertebrates)			
		OPTION 2	OPTION 3	Path of decision tree	OPTION 4	OPTION 2	OPTION 3	Path of decision tree	OPTION 4	OPTION 1 Most recent	OPTION 2	OPTION 3	OPTION 4
132	Oxadiazon	Unclassified	Cat III	10	Unclassified	Unclassified	Cat III	10	Unclassified	Unclassified	Unclassified	Cat III	Unclassified
134	Spirotetramat	Unclassified	Cat II	3a	Unclassified	Unclassified	Unclassified	8	Unclassified	ED	Unclassified	Cat II	Unclassified
135	Metribuzin	Unclassified	Unclassified	8	Unclassified	Unclassified	Unclassified	8	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
137	Lenacil	ED	Cat I	2a	Unclassified	Unclassified	Unclassified	8	Unclassified	Unclassified	ED	Cat I	Unclassified
138	Fluometuron	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
139	Penoxsulam	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
140	Metrafenone	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
141	Fenamiphos (aka phenamiphos)	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
142	Formetanate	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
143	Tri-allate	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
144	Pirimicarb	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
145	Oxamyl	Unclassified	Cat III	10	Unclassified	Unclassified	Cat III	10	Unclassified	Unclassified	Unclassified	Cat III	Unclassified
146	Fluopicolide	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
147	Propamocarb	Unclassified	Cat III	7	Unclassified	Unclassified	Cat III	7	Unclassified	Unclassified	Unclassified	Cat III	Unclassified
148	Bentazone	Unclassified	Unclassified	8	Unclassified	Unclassified	Unclassified	8	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
149	Etridiazole	Unclassified	Cat II	3b	Unclassified	Unclassified	Cat II	3a	Unclassified	Unclassified	Unclassified	Cat II	Unclassified
150	Quinoclamine	Unclassified	Unclassified	8	Unclassified	Unclassified	Unclassified	8	Unclassified	ED	Unclassified	Unclassified	Unclassified
151	Valifenalate (formerly Valiphenal)	Unclassified	Cat II	3a	Unclassified	Unclassified	Cat II	3a	Unclassified	Unclassified	Unclassified	Cat II	Unclassified
152	Spiromesifen	Unclassified	Cat II	5	Unclassified	Unclassified	Unclassified	8	Unclassified	Unclassified	Unclassified	Cat II	Unclassified

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Screening of available evidence on chemical substances for the identification of endocrine disruptors according to different options in the context of an Impact Assessment

	Chemical Name	Potential Categorization Human Health				Potential Categorization Wildlife				Combined Potential Categorization (HH & Wildlife Vertebrates)			
		OPTION 2	OPTION 3	Path of decision tree	OPTION 4	OPTION 2	OPTION 3	Path of decision tree	OPTION 4	OPTION 1 Most recent	OPTION 2	OPTION 3	OPTION 4
153	2,5-Dichlorobenzoic acid methylester	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
154	Pirimiphos-methyl	Unclassified	Cat III	10	Unclassified	Unclassified	Cat III	10	Unclassified	Unclassified	Unclassified	Cat III	Unclassified
156	Metobromuron	Unclassified	Unclassified	8	Unclassified	Unclassified	Unclassified	8	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
157	1-Methyl-cyclopropene	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
158	Thiocarbazono	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
159	Diuron	Unclassified	Cat III	7	Unclassified	Unclassified	Cat II	3b	Unclassified	Unclassified	Unclassified	Cat II	Unclassified
160	Dithianon	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
161	Tembotrione	Unclassified	Cat II	3a	Unclassified	Unclassified	Cat II	3a	Unclassified	ED	Unclassified	Cat II	Unclassified
162	Isoproturon	Unclassified	Cat II	3b	Unclassified	Unclassified	Cat II	3b	Unclassified	ED	Unclassified	Cat II	Unclassified
163	Amisulbrom	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
164	Imazalil (aka enilconazole)	Unclassified	Cat III	7	Unclassified	Unclassified	Cat III	7	Unclassified	Unclassified	Unclassified	Cat III	Unclassified
165	Fluoxastrobin	Unclassified	Cat III	10	Unclassified	Unclassified	Cat III	10	Unclassified	Unclassified	Unclassified	Cat III	Unclassified
167	Mandipropamid	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
168	Fuberidazole	Unclassified	Unclassified	8	Unclassified	Unclassified	Unclassified	8	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
169	Fosetyl [same as Fosetyl-Al]	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
170	Cyflumetofen	Unclassified	Cat II	3a	Unclassified	Unclassified	Cat II	3a	Unclassified	Unclassified	Unclassified	Cat II	Unclassified

The results of the screening do not constitute evaluations of individual substances to be carried out under the respective chemical legislations [[in particular, Regulation (EC) No 1107/2009 on plant protection products, Regulation (EU) No 528/2012 on biocidal products, Regulation (EC) No 1907/2006 REACH, Regulation (EC) No 1223/2009 on cosmetic products and the Water Framework Directive (EC) No 2000/60] and in no way prejudice future decisions on active substances to be taken pursuant to these pieces of the EU legislation.

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	Chemical Name	Potential Categorization Human Health				Potential Categorization Wildlife				Combined Potential Categorization (HH & Wildlife Vertebrates)			
		OPTION 2	OPTION 3	Path of decision tree	OPTION 4	OPTION 2	OPTION 3	Path of decision tree	OPTION 4	OPTION 1 Most recent	OPTION 2	OPTION 3	OPTION 4
171	Benthiavalicarb [same as benthiavalicarb-isopropyl CAS No. 177406-68-7]	Unclassified	Cat II	3a	Unclassified	Unclassified	Cat II	3a	Unclassified	ED (?)	Unclassified	Cat II	Unclassified
172	Metamitron	Unclassified	Unclassified	8	Unclassified	Unclassified	Unclassified	8	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
173	Bupirimate	Unclassified	Cat III	10	Unclassified	Unclassified	Cat III	10	Unclassified	Unclassified	Unclassified	Cat III	Unclassified
174	Pyroxsulam	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
175	Bifenox	Unclassified	Cat III	10	Unclassified	Unclassified	Cat III	10	Unclassified	Unclassified	Unclassified	Cat III	Unclassified
176	Oxyfluorfen	Unclassified	Cat III	10	Unclassified	Unclassified	Cat III	10	Unclassified	Unclassified	Unclassified	Cat III	Unclassified
178	Fenpyrazamine	Unclassified	Unclassified	8	Unclassified	Unclassified	Unclassified	8	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
179	Penflufen	Unclassified	Cat II	3a	Unclassified	Unclassified	Unclassified	8	Unclassified	Cut off criteria are applicable / Carc Cat 1A	Unclassified	Cat II	Unclassified
180	Chlorantraniliprole	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
181	Dimethachlor	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
182	Ascorbic acid	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified

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		OPTION 2	OPTION 3	Path of decision tree	OPTION 4	OPTION 2	OPTION 3	Path of decision tree	OPTION 4	OPTION 1 Most recent	OPTION 2	OPTION 3	OPTION 4
183	Glufosinate [same as glufosinate ammonium CAS No. 77182-82-2]	Unclassified	Unclassified	8	Unclassified	Unclassified	Unclassified	8	Unclassified	Cut off criteria are applicable / Repr Cat 1A	Unclassified	Unclassified	Unclassified
184	Diclofop [same as diclofop-methyl CAS No.257-141-8]	Unclassified	Cat III	10	Unclassified	Unclassified	Cat II	6	Unclassified	Unclassified	Unclassified	Cat II	Unclassified
185	Carboxin	Unclassified	Cat II	3a	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Cat II	Unclassified
186	Prosulfocarb	Unclassified	Unclassified	8	Unclassified	Unclassified	Unclassified	8	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
187	Pyrimethanil	Unclassified	Cat III	10	Unclassified	Unclassified	Cat III	10	Unclassified	Unclassified	Unclassified	Cat III	Unclassified
188	Triadimenol	Unclassified	Cat II	3b	Unclassified	Unclassified	Cat III	7	Unclassified	ED	Unclassified	Cat II	Unclassified
189	Triclopyr [a second variant of Triclopyr: 3,5,6-trichloro-2-pyridyloxy-2-butoxyethylester CAS No: 064700-56-7]	Unclassified	Unclassified	8	Unclassified	Unclassified	Unclassified	8	Unclassified	Cut off criteria are applicable / Repr Cat 1A/B	Unclassified	Unclassified	Unclassified
190	Pyridate	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
191	Tolclofos-methyl	Unclassified	Cat III	7	Unclassified	Unclassified	Cat III	7	Unclassified	Unclassified	Unclassified	Cat III	Unclassified
192	Urea	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified

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	Chemical Name	OPTION 2	OPTION 3	Path of decision tree	OPTION 4	OPTION 2	OPTION 3	Path of decision tree	OPTION 4	OPTION 1 Most recent	OPTION 2	OPTION 3	OPTION 4
193	1,4-Dimethylnaphthalene	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
194	Acequinocyl	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
195	Cymoxanil	Unclassified	Cat II	3a	Unclassified	Unclassified	Cat II	3a	Unclassified	ED	Unclassified	Cat II	Unclassified
196	Bixafen	Unclassified	Cat II	3a/3b	Unclassified	Unclassified	Cat II	3b	Unclassified	Unclassified	Unclassified	Cat II	Unclassified
197	Terbuthylazine	Unclassified	Cat III	7	Unclassified	Unclassified	Cat II	6	Unclassified	Unclassified	Unclassified	Cat II	Unclassified
198	Trimethylamine hydrochloride	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
199	Dimethoate	Unclassified	Cat II	3a	Unclassified	Unclassified	Cat II	3a	Unclassified	Unclassified	Unclassified	Cat II	Unclassified
200	Meptyldinocap [same as DE-126]	Unclassified	Cat II	3a	Unclassified	Unclassified	Cat II	3a	Unclassified	Unclassified	Unclassified	Cat II	Unclassified
201	Flurochloridone	ED	Cat I	2a	Unclassified	ED	Cat I	2a	Unclassified	ED - Cut off criteria are applicable / Repr Cat 1A/B	ED	Cat I	Unclassified
202	Amitrole (aminotriazole)	ED	Cat I	2a	ED	ED	Cat I	2a	ED	ED - Cut off criteria are applicable / Repr Cat 1A/B	ED	Cat I	ED
206	Chlorsulfuron	Unclassified	Cat II	3a	Unclassified	Unclassified	Cat II	3a	Unclassified	Unclassified	Unclassified	Cat II	Unclassified
207	Fluopyram	Unclassified	Unclassified	8	Unclassified	Unclassified	Unclassified	8	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
208	Pencycuron	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified

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		OPTION 2	OPTION 3	Path of decision tree	OPTION 4	OPTION 2	OPTION 3	Path of decision tree	OPTION 4	OPTION 1 Most recent	OPTION 2	OPTION 3	OPTION 4
209	Cyromazine	Unclassified	Unclassified	8	Unclassified	Unclassified	Unclassified	8	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
210	Esfenvalerate	Unclassified	Unclassified	8	Unclassified	Unclassified	Unclassified	8	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
211	Penconazole	Unclassified	Cat III	7	Unclassified	Unclassified	Cat III	7	Unclassified	Unclassified	Unclassified	Cat III	Unclassified
212	Flutolanil	Unclassified	Unclassified	11	Unclassified	ED	Cat I	2a	ED	Unclassified	ED	Cat I	ED
213	Metazachlor	Unclassified	Unclassified	8	Unclassified	Unclassified	Cat II	5	Unclassified	Unclassified	Unclassified	Cat II	Unclassified
214	Fenpropidin	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
215	Prochloraz	ED	Cat I	2a/2b	Unclassified	ED	Cat I	1/2a	ED	ED	ED	Cat I	ED
216	Triflumizole	Unclassified	Cat III	7	Unclassified	Unclassified	Cat III	7	Unclassified	ED - Cut off criteria are applicable / Repr Cat 1A/B	Unclassified	Cat III	Unclassified
217	Pyriofenone	Unclassified	Unclassified	8	Unclassified	Unclassified	Unclassified	8	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
218	Buprofezin	Unclassified	Cat II	3b	Unclassified	Unclassified	Cat II	3a	Unclassified	Unclassified	Unclassified	Cat II	Unclassified
219	Fluroxypyr	Unclassified	Cat III	10	Unclassified	Unclassified	Cat III	10	Unclassified	Unclassified	Unclassified	Cat III	Unclassified
220	Chlormequat	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
221	Metalaxyl-M	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
222	Triazoxide	Unclassified	Unclassified	8	Unclassified	Unclassified	Unclassified	8	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
224	Phosmet	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
225	Aclonifen	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
226	Clofentezine	Unclassified	Cat III	10	Unclassified	Unclassified	Cat III	10	Unclassified	Unclassified	Unclassified	Cat III	Unclassified

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	Chemical Name	Potential Categorization Human Health				Potential Categorization Wildlife				Combined Potential Categorization (HH & Wildlife Vertebrates)			
		OPTION 2	OPTION 3	Path of decision tree	OPTION 4	OPTION 2	OPTION 3	Path of decision tree	OPTION 4	OPTION 1 Most recent	OPTION 2	OPTION 3	OPTION 4
227	Metsulfuron-methyl	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
230	Flutriafol	Unclassified	Unclassified	8	Unclassified	Unclassified	Unclassified	8	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
231	Gamma-cyhalothrin	Unclassified	Unclassified	8	Unclassified	Unclassified	Unclassified	8	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
232	Pacloutrazol	Unclassified	Cat III	7	Unclassified	Unclassified	Cat II	3a	Unclassified	Unclassified	Unclassified	Cat II	Unclassified
237***	Phosphane	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
238	Hexythiazox	Unclassified	Cat III	7	Unclassified	Unclassified	Cat III	7	Unclassified	Unclassified	Unclassified	Cat III	Unclassified
239	Thifensulfuron-methyl	Unclassified	Cat II	6	Unclassified	Unclassified	Cat III	7	Unclassified	ED	Unclassified	Cat II	Unclassified
240	Tefluthrin	Unclassified	Cat III	7	Unclassified	Unclassified	Cat III	7	Unclassified	Unclassified	Unclassified	Cat III	Unclassified
241	Fluazinam	Unclassified	Cat II	3a	Unclassified	Unclassified	Cat II	3a	Unclassified	ED	Unclassified	Cat II	Unclassified
243	Imazaquin	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
244	Clomazone	Unclassified	Cat III	10	Unclassified	Unclassified	Cat III	10	Unclassified	Unclassified	Unclassified	Cat III	Unclassified
245	Triasulfuron	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
246	Isoxaben	Unclassified	Cat III	10	Unclassified	Unclassified	Cat III	10	Unclassified	Unclassified	Unclassified	Cat III	Unclassified
247	Bensulfuron methyl	Unclassified	Unclassified	8	Unclassified	Unclassified	Unclassified	8	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
248	Fluazifop-P	Unclassified	Cat II	3b	Unclassified	Unclassified	Cat II	3b	Unclassified	ED	Unclassified	Cat II	Unclassified
249	Teflubenzuron	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
250	Diflufenican	Unclassified	Cat II	3a	Unclassified	Unclassified	Cat II	3a	Unclassified	Unclassified	Unclassified	Cat II	Unclassified
251	1-Naphthylacetamide (1-NAD)	Unclassified	Cat II	3a	Unclassified	Unclassified	Cat II	3a	Unclassified	ED	Unclassified	Cat II	Unclassified
252	1-Naphthylacetic acid	Unclassified	Cat II	3a	Unclassified	Unclassified	Cat II	3a	Unclassified	ED	Unclassified	Cat II	Unclassified

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Screening of available evidence on chemical substances for the identification of endocrine disruptors according to different options in the context of an Impact Assessment

		Potential Categorization Human Health				Potential Categorization Wildlife				Combined Potential Categorization (HH & Wildlife Vertebrates)			
	Chemical Name	OPTION 2	OPTION 3	Path of decision tree	OPTION 4	OPTION 2	OPTION 3	Path of decision tree	OPTION 4	OPTION 1 Most recent	OPTION 2	OPTION 3	OPTION 4
	(1-NAA)												
253	Heptamaloxyloglucan	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
254	Diethofencarb	Unclassified	Cat II	3a	Unclassified	Unclassified	Cat II	3a	Unclassified	Unclassified	Unclassified	Cat II	Unclassified
255	Sedaxane	Unclassified	Cat II	3a	Unclassified	Unclassified	Cat II	3a	Unclassified	Unclassified	Unclassified	Cat II	Unclassified
256	Tralkoxydim	Unclassified	Cat II	3a	Unclassified	Unclassified	Cat II	3a	Unclassified	Unclassified	Unclassified	Cat II	Unclassified
257	Isopyrazam	Unclassified	Unclassified	8	Unclassified	Unclassified	Unclassified	8	Unclassified	ED	Unclassified	Unclassified	Unclassified
258	Myclobutanil	Unclassified	Cat III	7	Unclassified	ED	Cat I	2a/2b	ED	ED	ED	Cat I	ED
259	Thymol	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
261	Quinmerac	Unclassified	Unclassified	8	Unclassified	Unclassified	Unclassified	8	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
262	Fluxapyroxad	Unclassified	Unclassified	8	Unclassified	Unclassified	Unclassified	8	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
263	Prosulfuron	Unclassified	Cat II	3a	Unclassified	Unclassified	Cat II	3a	Unclassified	Unclassified	Unclassified	Cat II	Unclassified
264	2,4-D	Unclassified	Cat II	3a/3b	Unclassified	Unclassified	Cat II	3a/3b	Unclassified	Unclassified	Unclassified	Cat II	Unclassified
265	Haloxypop-P (Haloxypop-R)	Unclassified	Cat III	10	Unclassified	Unclassified	Cat III	10	Unclassified	Unclassified	Unclassified	Cat III	Unclassified
266	Pyridaben	Unclassified	Cat II	5	Unclassified	Unclassified	Cat II	5	Unclassified	Unclassified	Unclassified	Cat II	Unclassified
267	Eugenol	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
269	Benalaxyl-M	Unclassified	Unclassified	8	Unclassified	Unclassified	Unclassified	8	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
270	Sulcotrione	Unclassified	Unclassified	8	Unclassified	Unclassified	Unclassified	8	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
271	Clethodim	Unclassified	Cat II	3a	Unclassified	Unclassified	Cat II	3a	Unclassified	Unclassified	Unclassified	Cat II	Unclassified

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	Chemical Name	Potential Categorization Human Health				Potential Categorization Wildlife				Combined Potential Categorization (HH & Wildlife Vertebrates)			
		OPTION 2	OPTION 3	Path of decision tree	OPTION 4	OPTION 2	OPTION 3	Path of decision tree	OPTION 4	OPTION 1 Most recent	OPTION 2	OPTION 3	OPTION 4
290	Repellents by smell of animal or plant origin/ sheep fat	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
291	Repellents by smell of animal or plant origin/ tall oil crude	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
292	Repellents by smell of animal or plant origin/ tall oil pitch	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
293	Sea-algae extract (formerly sea-algae extract and seaweeds)	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
294	Clothianidin	Unclassified	Cat II	3a	Unclassified	Unclassified	Cat II	3a	Unclassified	Unclassified	Unclassified	Cat II	Unclassified
295	Propiconazole	Unclassified	Cat III	10	Unclassified	ED	Cat I	2a/2b	ED	Unclassified	ED	Cat I	ED
296	Thiacloprid	Unclassified	Cat II	3b	Unclassified	Unclassified	Cat II	3b	Unclassified	ED - Cut off criteria are applicable / Repr Cat 1A/B	Unclassified	Cat II	Unclassified
297	Pelargonic acid (Nonanoic acid)	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
298	Caprylic acid (Octanoic acid)	Unclassified	Cat III	10	Unclassified	Unclassified	Cat III	10	Unclassified	Unclassified	Unclassified	Cat III	Unclassified
299	Lauric acid	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
300	Thiamethoxam	Unclassified	Cat II	3a	Unclassified	Unclassified	Cat II	3a	Unclassified	Unclassified	Unclassified	Cat II	Unclassified

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		OPTION 2	OPTION 3	Path of decision tree	OPTION 4	OPTION 2	OPTION 3	Path of decision tree	OPTION 4	OPTION 1 Most recent	OPTION 2	OPTION 3	OPTION 4
301	Spinosad	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
302	Copper hydroxide	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
303	Capric acid (Decanoic acid)	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
304	Cypermethrin	ED	Cat I	2a/2b	ED	ED	Cat I	2a/2b	ED	Unclassified	ED	Cat I	ED
305	Deltamethrin	Unclassified	Cat II	3b	Unclassified	Unclassified	Cat II	3b	Unclassified	Unclassified	Unclassified	Cat II	Unclassified
306	Benzoic acid	Unclassified	Unclassified	8	Unclassified	Unclassified	Unclassified	8	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
307	Alpha-Cypermethrin (aka alphamethrin)	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
308	Chlorpropham	Unclassified	Cat II	3b	Unclassified	Unclassified	Cat II	3b	Unclassified	Unclassified	Unclassified	Cat II	Unclassified
309	Flazasulfuron	Unclassified	Unclassified	8	Unclassified	Unclassified	Unclassified	8	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
310	Mesotrione	Unclassified	Unclassified	8	Unclassified	Unclassified	Unclassified	8	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
311	Pethoxamid	Unclassified	Cat II	3a	Unclassified	Unclassified	Unclassified	8	Unclassified	Unclassified	Unclassified	Cat II	Unclassified
312	Mepanipyrim	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
313	Methyl decanoate	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
314	Methyl octanoate	Unclassified	Cat III	10	Unclassified	Unclassified	Cat III	10	Unclassified	Unclassified	Unclassified	Cat III	Unclassified
319	Beflubutamid	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
320	Imazamox	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
321	Picoxystrobin	Unclassified	Cat III	10	Unclassified	Unclassified	Cat III	10	Unclassified	Unclassified	Unclassified	Cat III	Unclassified
322	Cyazofamid	Unclassified	Cat III	10	Unclassified	Unclassified	Cat III	10	Unclassified	Unclassified	Unclassified	Cat III	Unclassified
323	Propineb	Unclassified	Cat II	3b	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Cat II	Unclassified

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		Potential Categorization Human Health				Potential Categorization Wildlife				Combined Potential Categorization (HH & Wildlife Vertebrates)			
	Chemical Name	OPTION 2	OPTION 3	Path of decision tree	OPTION 4	OPTION 2	OPTION 3	Path of decision tree	OPTION 4	OPTION 1 Most recent	OPTION 2	OPTION 3	OPTION 4
324	Imazosulfuron	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
325	Maleic hydrazide	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
326	Maneb	ED	Cat I	2a	Unclassified	ED	Cat I	2a	Unclassified	ED	ED	Cat I	Unclassified
327	Quinoxifen	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
328	Carfentrazone-ethyl	Unclassified	Cat III	10	Unclassified	Unclassified	Cat III	10	Unclassified	Unclassified	Unclassified	Cat III	Unclassified
331	Tribasic copper sulfate	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
332	Acetamiprid	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
334	Desmedipham	ED	Cat I	2a	Unclassified	Unclassified	Unclassified	8	Unclassified	Unclassified	ED	Cat I	Unclassified
335	Phenmedipham	Unclassified	Cat II	3a/3b	Unclassified	Unclassified	Cat II	3a/3b	Unclassified	Unclassified	Unclassified	Cat II	Unclassified
336	Thiram	Unclassified	Cat II	3a	Unclassified	Unclassified	Cat II	3a	Unclassified	Unclassified	Unclassified	Cat II	Unclassified
337	Ziram	Unclassified	Cat II	3a	Unclassified	Unclassified	Cat II	3a	Unclassified	Unclassified	Unclassified	Cat II	Unclassified
338	Profoxydim	Unclassified	Cat II	3a	Unclassified	Unclassified	Cat II	3a	Unclassified	ED	Unclassified	Cat II	Unclassified
339	Isoxaflutole	Unclassified	Cat II	3a	Unclassified	Unclassified	Cat II	3a	Unclassified	ED (?)	Unclassified	Cat II	Unclassified
340	Trifloxystrobin	Unclassified	Cat III	10	Unclassified	Unclassified	Cat III	10	Unclassified	Unclassified	Unclassified	Cat III	Unclassified
341	Flufenacet (formerly fluthiamide)	Unclassified	Cat II	9	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Cat II	Unclassified
342	Tritosulfuron	Unclassified	Cat II	3a	Unclassified	Unclassified	Cat II	3a	Unclassified	Unclassified	Unclassified	Cat II	Unclassified
343	Indoxacarb	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified

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		Potential Categorization Human Health				Potential Categorization Wildlife				Combined Potential Categorization (HH & Wildlife Vertebrates)			
	Chemical Name	OPTION 2	OPTION 3	Path of decision tree	OPTION 4	OPTION 2	OPTION 3	Path of decision tree	OPTION 4	OPTION 1 Most recent	OPTION 2	OPTION 3	OPTION 4
344	Oxasulfuron	Unclassified	Cat II	3a	Unclassified	Unclassified	Cat II	3a	Unclassified	Unclassified	Unclassified	Cat II	Unclassified
345	Propoxycarbazone	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
346	Bifenazate	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
347	Tepraloxydim	Unclassified	Cat II	3a	Unclassified	Unclassified	Cat II	3a	Unclassified	ED	Unclassified	Cat II	Unclassified
348	Etoxazole	Unclassified	Cat II	3b	Unclassified	Unclassified	Cat II	3b	Unclassified	Unclassified	Unclassified	Cat II	Unclassified
349	Chlorotoluron	Unclassified	Unclassified	8	Unclassified	Unclassified	Unclassified	8	Unclassified	ED	Unclassified	Unclassified	Unclassified
350	Zoxamide	Unclassified	Cat III	10	Unclassified	Unclassified	Cat III	7	Unclassified	Unclassified	Unclassified	Cat III	Unclassified
351	Daminozide	Unclassified	Cat III	10	Unclassified	Unclassified	Cat III	10	Unclassified	Unclassified	Unclassified	Cat III	Unclassified
352	Methoxyfenozide	Unclassified	Cat II	3a	Unclassified	Unclassified	Cat II	3a	Unclassified	Unclassified	Unclassified	Cat II	Unclassified
353	Fenamidone	ED	Cat I	2a	ED	Unclassified	Cat II	3b	Unclassified	Unclassified	ED	Cat I	ED
354	Dimethenamid-P	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
355	Mecoprop-P	Unclassified	Cat III	7	Unclassified	Unclassified	Cat III	7	Unclassified	Unclassified	Unclassified	Cat III	Unclassified
357	Bromoxynil	Unclassified	Cat II	3b	Unclassified	Unclassified	Cat II	3b	Unclassified	ED	Unclassified	Cat II	Unclassified
359	Foramsulfuron	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
360	Pyraclostrobin	Unclassified	Cat III	7	Unclassified	Unclassified	Cat III	7	Unclassified	Unclassified	Unclassified	Cat III	Unclassified
361	Silthiofam	Unclassified	Unclassified	8	Unclassified	Unclassified	Cat II	3a	Unclassified	Unclassified	Unclassified	Cat II	Unclassified
362	S-Metolachlor	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	8	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
363	Pyridalyl	Unclassified	Cat II	3a	Unclassified	Unclassified	Cat II	3a	Unclassified	Unclassified	Unclassified	Cat II	Unclassified
364	Iodosulfuron	Unclassified	Unclassified	8	Unclassified	Unclassified	Unclassified	8	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified

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	Chemical Name	Potential Categorization Human Health				Potential Categorization Wildlife				Combined Potential Categorization (HH & Wildlife Vertebrates)			
		OPTION 2	OPTION 3	Path of decision tree	OPTION 4	OPTION 2	OPTION 3	Path of decision tree	OPTION 4	OPTION 1 Most recent	OPTION 2	OPTION 3	OPTION 4
365	Boscalid (formerly nicobifen)	Unclassified	Cat II	3a	Unclassified	Unclassified	Cat II	3a	Unclassified	Unclassified	Unclassified	Cat II	Unclassified
366	Chlorothalonil	Unclassified	Unclassified	8	Unclassified	Unclassified	Cat II	5	Unclassified	Unclassified	Unclassified	Cat II	Unclassified
368	Thiophanate-methyl	ED	Cat I	2a	Unclassified	ED	Cat I	2a	Unclassified	Unclassified	ED	Cat I	Unclassified
369	Propyzamide	ED	Cat I	2a	ED	ED	Cat I	2a	ED	Unclassified	ED	Cat I	ED
370	Ethofumesate	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	8	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
371	Flubendiamide	ED	Cat I	2a	ED	ED	Cat I	2a	ED	Unclassified	ED	Cat I	ED
372	Diquat (dibromide)	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
374	Chlorpyrifos	Unclassified	Cat II	3b	Unclassified	Unclassified	Cat II	3b	Unclassified	Unclassified	Unclassified	Cat II	Unclassified
375	Linuron	ED	Cat I	2a	Unclassified	ED	Cat I	2a	ED	ED - Cut off criteria are applicable / Repr Cat 1A/B	ED	Cat I	ED
379	Iprodione	ED	Cat I	2a	Unclassified	ED	Cat I	2a	Unclassified	Unclassified	ED	Cat I	Unclassified
382	Mesosulfuron	Unclassified	Unclassified	8	Unclassified	Unclassified	Unclassified	8	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
383	Pendimethalin	ED	Cat I	2a	ED	Unclassified	Cat II	3a/3b	Unclassified	Unclassified	ED	Cat I	ED
384 ⁺	Dentathonium benzoate	-	-	-	-	-	-	-	-	-	-	-	-
385	Milbemectin	Unclassified	Unclassified	8	Unclassified	Unclassified	Unclassified	8	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified

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		OPTION 2	OPTION 3	Path of decision tree	OPTION 4	OPTION 2	OPTION 3	Path of decision tree	OPTION 4	OPTION 1 Most recent	OPTION 2	OPTION 3	OPTION 4
390	Chlorpyrifos-methyl	Unclassified	Cat II	5	Unclassified	Unclassified	Cat II	5	Unclassified	Unclassified	Unclassified	Cat II	Unclassified
394	Sucrose	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
395	Metalaxyl	Unclassified	Unclassified	8	Unclassified	ED	Cat I	2a	ED	Unclassified	ED	Cat I	ED
398	Sodium nitroguaiacolate ⁵⁻	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
400	Forchlorfenuron	Unclassified	Cat III	10	Unclassified	Unclassified	Cat III	10	Unclassified	Unclassified	Unclassified	Cat III	Unclassified
401	Beta-Cyfluthrin	Unclassified	Cat III	7	Unclassified	Unclassified	Cat III	7	Unclassified	Unclassified	Unclassified	Cat III	Unclassified
402	Benalaxyl	Unclassified	Unclassified	8	Unclassified	Unclassified	Unclassified	8	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
403	Mancozeb	ED	Cat I	2a/2b	ED	ED	Cat I	2a/2b	ED	ED	ED	Cat I	ED
404	Sodium nitrophenolate ^{o-}	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
405	Sodium nitrophenolate ^{p-}	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
407	Ametoctradin	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
408	Metiram	ED	Cat I	2a	ED	Unclassified	Unclassified	8	Unclassified	Unclassified	ED	Cat I	ED
409	Laminarin	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
411	Mecoprop	Unclassified	Cat III	7	Unclassified	Unclassified	Cat III	7	Unclassified	Unclassified	Unclassified	Cat III	Unclassified
413	MCPA	Unclassified	Cat III	7	Unclassified	Unclassified	Cat III	7	Unclassified	Unclassified	Unclassified	Cat III	Unclassified
414	MCPB	Unclassified	Cat III (?)	7	Unclassified	Unclassified	Cat III (?)	7	Unclassified	Unclassified	Unclassified	Cat III (?)	Unclassified
415	2,4-DB	Unclassified	Cat II	3a	Unclassified	Unclassified	Cat II	3a	Unclassified	Unclassified	Unclassified	Cat II	Unclassified
416	Flurtamone	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified

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		OPTION 2	OPTION 3	Path of decision tree	OPTION 4	OPTION 2	OPTION 3	Path of decision tree	OPTION 4	OPTION 1 Most recent	OPTION 2	OPTION 3	OPTION 4
417	Fosthiazate	Unclassified	Unclassified	8	Unclassified	Unclassified	Unclassified	8	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
418	Carvone	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
426	Bordeaux mixture	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
428	n-Tetradecylacetate	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified

**This substance was incorrectly marked also as a BP in the published list of substances to be screened.

*** This substance had been already screened when “list of substances to be screened” was published.

****This substance covers also the substance Quizalofop-P.

† This substance was initially included in the list of substances to be screened, but following the rational it was decided that the substance was not to be screened.

The results of the screening do not constitute evaluations of individual substances to be carried out under the respective chemical legislations [[in particular, Regulation (EC) No 1107/2009 on plant protection products, Regulation (EU) No 528/2012 on biocidal products, Regulation (EC) No 1907/2006 REACH, Regulation (EC) No 1223/2009 on cosmetic products and the Water Framework Directive (EC) No 2000/60] and in no way prejudice future decisions on active substances to be taken pursuant to these pieces of the EU legislation.

It would thus be erroneous to consider that the substances listed in the results of this study (SANTE/2015/E3/SI2.706218) are considered as endocrine disruptors within the meaning of the EU legislation.

Revised potential categorization results for 96 BPs under "Option 1"

	Chemical Name	Carc Cat. 2 (C&L Harmonised)	Carc Cat. 2 (C&L Proposed)	Repr. Cat. 2 (C&L Harmonised)	Repr. Cat. 2 (C&L Proposed)	Carc Cat. 1A or 1B (C&L Harmonised)	Carc Cat. 1A or 1B (C&L Proposed)	Repr. Cat. 1A or 1B (C&L Harmonised)	Repr. Cat. 1A or 1B (C&L Proposed)	Effects on Endocrine organs (YES/NO)	OPTION 1 Harmonized	OPTION 1 Proposed	OPTION 1 Most recent
1	Carbon dioxide	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	No	Unclassified*	Unclassified	Unclassified
2	Tebuconazole	No	Not relevant	Yes	Not relevant	No	Not relevant	No	No	Yes	ED	Not relevant	ED
3	Methyl nonyl ketone	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	No	Unclassified*	Unclassified	Unclassified
4	Fipronil	No	No	No	No	No	No	No	No	Yes	Unclassified	Unclassified	Unclassified
5	Magnesium phosphide	No	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	Unclassified	Not relevant	Unclassified
6	Imidacloprid	No	No	No	No	No	No	No	No	No	Unclassified	Unclassified	Unclassified
7	Thiabendazole	No	No	No	No	No	No	No	No	Yes	Unclassified	Unclassified	Unclassified
8	Aluminium phosphide	No	No	No	No	No	No	No	No	No	Unclassified	Unclassified	Unclassified
9	Sulfuryl fluoride	No	No	No	No	No	No	No	No	No	Unclassified	Unclassified	Unclassified
10	Bromadiolone	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	Yes	No	Unclassified*	Cut off criteria are applicable / Repr Cat 1A/B	Cut off criteria are applicable / Repr Cat 1A/B
11	Diflubenzuron	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	No	Unclassified*	Unclassified	Unclassified
12	Dazomet	No	No	No	Yes	No	No	No	No	Yes	Unclassified	ED	ED
13	Difenacoum	No	No	No	No	No	No	No	Yes	Yes	Unclassified	ED / Cut off criteria are applicable /	ED / Cut off criteria are applicable /

The results of the screening do not constitute evaluations of individual substances to be carried out under the respective chemical legislations [[in particular, Regulation (EC) No 1107/2009 on plant protection products, Regulation (EU) No 528/2012 on biocidal products, Regulation (EC) No 1907/2006 REACH, Regulation (EC) No 1223/2009 on cosmetic products and the Water Framework Directive (EC) No 2000/60] and in no way prejudice future decisions on active substances to be taken pursuant to these pieces of the EU legislation.

It would thus be erroneous to consider that the substances listed in the results of this study (SANTE/2015/E3/SI2.706218) are considered as endocrine disruptors within the meaning of the EU legislation.

Screening of available evidence on chemical substances for the identification of endocrine disruptors according to different options in the context of an Impact Assessment

	Chemical Name	Carc Cat. 2 (C&L Harmonised)	Carc Cat. 2 (C&L Proposed)	Repr. Cat. 2 (C&L Harmonised)	Repr. Cat. 2 (C&L Proposed)	Carc Cat. 1A or 1B (C&L Harmonised)	Carc Cat. 1A or 1B (C&L Proposed)	Repr. Cat. 1A or 1B (C&L Harmonised)	Repr. Cat. 1A or 1B (C&L Proposed)	Effects on Endocrine organs (YES/NO)	OPTION 1 Harmonized	OPTION 1 Proposed	OPTION 1 Most recent
												Repr Cat 1A/B	Repr Cat 1A/B
14	Fenpropimorph	No	No	Yes	Yes	No	No	No	No	Yes	ED	ED	ED
15	Abamectin (aka avermectin)	No	No	Yes	Yes	No	No	No	No	Yes	ED	ED	ED
16	Fenoxycarb	Yes	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	Yes	Unclassified	Not relevant	Unclassified
17	Etofenprox	No	Not relevant	Yes	Not relevant	No	Not relevant	No	No	No	Unclassified	Not relevant	Unclassified
18	Bifenthrin	Yes	Yes	No	No	No	No	No	No	Yes	Unclassified	Unclassified	Unclassified
19	lambda-Cyhalothrin	No	No	No	No	No	No	No	No	Yes	Unclassified	Unclassified	Unclassified
20	Cyproconazole	No	Not relevant	No	Not relevant	No	Not relevant	Yes	Not relevant	Yes	ED - Cut off criteria are applicable / Repr Cat 1A/B	Not relevant	ED - Cut off criteria are applicable / Repr Cat 1A/B
21	Pyriproxyfen	No	No	No	No	No	No	No	No	Yes	Unclassified	Unclassified	Unclassified
22	Folpet	Yes	Yes	No	No	No	No	No	No	No	Unclassified	Unclassified	Unclassified
294	Clothianidin	No	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	Yes	Unclassified	Not relevant	Unclassified
295	Propiconazole	No	No	No	No	No	No	No	No	No	Unclassified	Unclassified	Unclassified
296	Thiacloprid	Yes	Not relevant	No	Not relevant	No	Not relevant	Yes	Not relevant	Yes	ED - Cut off criteria are applicable / Repr Cat 1A/B	Not relevant	ED - Cut off criteria are applicable / Repr Cat 1A/B
297	Pelargonic acid (Nonanoic acid)	No	No	No	No	No	No	No	No	No	Unclassified	Unclassified	Unclassified

The results of the screening do not constitute evaluations of individual substances to be carried out under the respective chemical legislations [[in particular, Regulation (EC) No 1107/2009 on plant protection products, Regulation (EU) No 528/2012 on biocidal products, Regulation (EC) No 1907/2006 REACH, Regulation (EC) No 1223/2009 on cosmetic products and the Water Framework Directive (EC) No 2000/60] and in no way prejudice future decisions on active substances to be taken pursuant to these pieces of the EU legislation.

It would thus be erroneous to consider that the substances listed in the results of this study (SANTE/2015/E3/SI2.706218) are considered as endocrine disruptors within the meaning of the EU legislation.

Screening of available evidence on chemical substances for the identification of endocrine disruptors according to different options in the context of an Impact Assessment

	Chemical Name	Carc Cat. 2 (C&L Harmonised)	Carc Cat. 2 (C&L Proposed)	Repr. Cat. 2 (C&L Harmonised)	Repr. Cat. 2 (C&L Proposed)	Carc Cat. 1A or 1B (C&L Harmonised)	Carc Cat. 1A or 1B (C&L Proposed)	Repr. Cat. 1A or 1B (C&L Harmonised)	Repr. Cat. 1A or 1B (C&L Proposed)	Effects on Endocrine organs (YES/NO)	OPTION 1 Harmonized	OPTION 1 Proposed	OPTION 1 Most recent
298	Caprylic acid (Octanoic acid)	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	No	Unclassified*	Unclassified	Unclassified
299	Lauric acid	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	No	Unclassified*	Unclassified	Unclassified
300	Thiamethoxam	No	No	No	No	No	No	No	No	Yes	Unclassified	Unclassified	Unclassified
301	Spinosad	No	No	No	No	No	No	No	No	No	Unclassified	Unclassified	Unclassified
302	Copper hydroxide	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	No	Unclassified*	Unclassified	Unclassified
303	Capric acid (Decanoic acid)	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	No	Unclassified*	Unclassified	Unclassified
304	Cypermethrin	No	No	No	No	No	No	No	No	Yes	Unclassified	Unclassified	Unclassified
305	Deltamethrin	No	No	No	No	No	No	No	No	Yes	Unclassified	Unclassified	Unclassified
306	Benzoic acid	No	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	Yes	Unclassified	Not relevant	Unclassified
307	Alpha-Cypermethrin (aka alphamethrin)	No	No	No	No	No	No	No	No	No	Unclassified	Unclassified	Unclassified
343	Indoxacarb	No	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	Unclassified	Not relevant	Unclassified
429	tolylfluanid	No	No	No	No	No	No	No	No	Yes	Unclassified	Unclassified	Unclassified
430	flufenoxuron	No	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	Unclassified	Not relevant	Unclassified
431	Didecyldimethylammonium chloride; DDAC	No	No	No	No	No	No	No	No	No	Unclassified	Unclassified	Unclassified
432	Tralopyril	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	No	Unclassified*	Unclassified	Unclassified
433	Permethrin	No	No	No	No	No	No	No	No	Yes	Unclassified	Unclassified	Unclassified
434	IPBC	No	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	Unclassified	Not relevant	Unclassified
435	Boric acid	No	No	No	No	No	No	Yes	Yes	Yes	ED	ED	ED
436	Difethialone	No	Not relevant	No	Not relevant	No	Not relevant	Yes	Not relevant	No	Unclassified	Not relevant	Unclassified
437	Acrolein	No	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	Unclassified	Not relevant	Unclassified
438	dichlofluanid	No	No	No	No	No	No	No	No	Yes	Unclassified	Unclassified	Unclassified

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The results of the screening do not constitute evaluations of individual substances to be carried out under the respective chemical legislations [[in particular, Regulation (EC) No 1107/2009 on plant protection products, Regulation (EU) No 528/2012 on biocidal products, Regulation (EC) No 1907/2006 REACH, Regulation (EC) No 1223/2009 on cosmetic products and the Water Framework Directive (EC) No 2000/60] and in no way prejudice future decisions on active substances to be taken pursuant to these pieces of the EU legislation.

It would thus be erroneous to consider that the substances listed in the results of this study (SANTE/2015/E3/SI2.706218) are considered as endocrine disruptors within the meaning of the EU legislation.

Screening of available evidence on chemical substances for the identification of endocrine disruptors according to different options in the context of an Impact Assessment

	Chemical Name	Carc Cat. 2 (C&L Harmonised)	Carc Cat. 2 (C&L Proposed)	Repr. Cat. 2 (C&L Harmonised)	Repr. Cat. 2 (C&L Proposed)	Carc Cat. 1A or 1B (C&L Harmonised)	Carc Cat. 1A or 1B (C&L Proposed)	Repr. Cat. 1A or 1B (C&L Harmonised)	Repr. Cat. 1A or 1B (C&L Proposed)	Effects on Endocrine organs (YES/NO)	OPTION 1 Harmonized	OPTION 1 Proposed	OPTION 1 Most recent
439	Transfluthrin	No	No	No	No	No	No	No	No	No	Unclassified	Unclassified	Unclassified
440	Basic Copper carbonate (mentioned in ECHA as Copper(II) Carbonate)	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	No	Unclassified*	Unclassified	Unclassified
441	Zineb	No	No	No	Yes	No	No	No	No	Yes	Unclassified	ED	ED
442	Chlorfenapyr	No	No	No	No	No	No	No	No	No	Unclassified	Unclassified	Unclassified
443	Disodium tetraborate pentahydrate	No	No	No	No	No	No	Yes	Yes	Yes	ED	ED	ED
444	Disodium octaborate tetrahydrate	No	Not relevant	No	Not relevant	No	Not relevant	Yes	Not relevant	Yes	ED	Not relevant	ED
445	Warfarin sodium	No	Not relevant	No	Not relevant	No	Not relevant	Yes	Not relevant	No	Unclassified	Not relevant	Unclassified
446	Boric oxide	No	No	No	No	No	No	Yes	Yes	Yes	ED	ED	ED
447	Disodium tetraborate decahydrate	No	No	No	No	No	No	Yes	Yes	Yes	ED	ED	ED
448	Copper (II) oxide	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	No	Unclassified*	Unclassified	Unclassified
449	Disodium tetraborate	No	No	No	No	No	No	Yes	Yes	Yes	ED	ED	ED
450	N,N-diethyl-meta-toluamide (DEET)	No	No	No	No	No	No	No	No	No	Unclassified	Unclassified	Unclassified
451	alphachloralose (chloralose)	No	No	No	No	No	No	No	No	No	Unclassified	Unclassified	Unclassified
453	Bendiocarb	No	No	No	No	No	No	No	No	No	Unclassified	Unclassified	Unclassified
454	Metofluthrin	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	No	Unclassified*	Unclassified	Unclassified
455	Polyvinylpyrrolidone iodine	No	No	No	No	No	No	No	No	No	Unclassified	Unclassified	Unclassified
456	1R-trans phenothrin	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	Yes	Unclassified*	Unclassified	Unclassified
457	cis-tricos-9-ene (Muscalure)	No	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	Unclassified	Not relevant	Unclassified

The results of the screening do not constitute evaluations of individual substances to be carried out under the respective chemical legislations [[in particular, Regulation (EC) No 1107/2009 on plant protection products, Regulation (EU) No 528/2012 on biocidal products, Regulation (EC) No 1907/2006 REACH, Regulation (EC) No 1223/2009 on cosmetic products and the Water Framework Directive (EC) No 2000/60] and in no way prejudice future decisions on active substances to be taken pursuant to these pieces of the EU legislation.

It would thus be erroneous to consider that the substances listed in the results of this study (SANTE/2015/E3/SI2.706218) are considered as endocrine disruptors within the meaning of the EU legislation.

Screening of available evidence on chemical substances for the identification of endocrine disruptors according to different options in the context of an Impact Assessment

	Chemical Name	Carc Cat. 2 (C&L Harmonised)	Carc Cat. 2 (C&L Proposed)	Repr. Cat. 2 (C&L Harmonised)	Repr. Cat. 2 (C&L Proposed)	Carc Cat. 1A or 1B (C&L Harmonised)	Carc Cat. 1A or 1B (C&L Proposed)	Repr. Cat. 1A or 1B (C&L Harmonised)	Repr. Cat. 1A or 1B (C&L Proposed)	Effects on Endocrine organs (YES/NO)	OPTION 1 Harmonized	OPTION 1 Proposed	OPTION 1 Most recent
459	Cu-HDO	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	No	Unclassified*	Unclassified	Unclassified
460	Chlorophacinone	No	No	No	No	No	No	No	Yes	No	Unclassified	Unclassified	Unclassified
461	Ethyl butylacetylaminopropionate (IR3535)	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	No	Unclassified*	Unclassified	Unclassified
462	Brodifacoum	No	No	No	No	No	No	No	Yes	No	Unclassified	Unclassified	Unclassified
463	Coumatetralyl	No	No	No	No	No	No	No	Yes	No	Unclassified	Unclassified	Unclassified
464	4,5-Dichloro-2-octylisothiazol-3(2H)-one (DCOIT)	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	No	Unclassified*	Unclassified	Unclassified
465	S-Methoprene	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	No	Unclassified*	Unclassified	Unclassified
466	K-HDO	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	No	Unclassified*	Unclassified	Unclassified
467	Alkyl (C12-16) dimethylbenzyl ammonium chloride; C 12-16-ADBAC	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	No	Unclassified*	Unclassified	Unclassified
468	hydrogen cyanide	No	No	No	No	No	No	No	No	Yes	Unclassified	Unclassified	Unclassified
469	Iodine	No	No	No	No	No	No	No	No	No	Unclassified	Unclassified	Unclassified
470	Hydrochloric acid [same as Hydrogen chloride]	No	No	No	No	No	No	No	No	No	Unclassified	Unclassified	Unclassified
471	Nitrogen	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	No	Unclassified*	Unclassified	Unclassified
472	Copper sulphate pentahydrate	No	No	No	No	No	No	No	No	No	Unclassified	Unclassified	Unclassified
473	Bromoacetic acid	No	No	No	No	No	No	No	No	No	Unclassified	Unclassified	Unclassified
474	Creosote	No	No	No	Yes (developmental)	Yes	Yes	No	Yes (fertility)	No	Unclassified	ED	ED

The results of the screening do not constitute evaluations of individual substances to be carried out under the respective chemical legislations [[in particular, Regulation (EC) No 1107/2009 on plant protection products, Regulation (EU) No 528/2012 on biocidal products, Regulation (EC) No 1907/2006 REACH, Regulation (EC) No 1223/2009 on cosmetic products and the Water Framework Directive (EC) No 2000/60] and in no way prejudice future decisions on active substances to be taken pursuant to these pieces of the EU legislation.

It would thus be erroneous to consider that the substances listed in the results of this study (SANTE/2015/E3/SI2.706218) are considered as endocrine disruptors within the meaning of the EU legislation.

Screening of available evidence on chemical substances for the identification of endocrine disruptors according to different options in the context of an Impact Assessment

	Chemical Name	Carc Cat. 2 (C&L Harmonised)	Carc Cat. 2 (C&L Proposed)	Repr. Cat. 2 (C&L Harmonised)	Repr. Cat. 2 (C&L Proposed)	Carc Cat. 1A or 1B (C&L Harmonised)	Carc Cat. 1A or 1B (C&L Proposed)	Repr. Cat. 1A or 1B (C&L Harmonised)	Repr. Cat. 1A or 1B (C&L Proposed)	Effects on Endocrine organs (YES/NO)	OPTION 1 Harmonized	OPTION 1 Proposed	OPTION 1 Most recent
475	Warfarin	No	Not relevant	No	Not relevant	No	Not relevant	Yes	Not relevant	No	Unclassified	Not relevant	Unclassified
476	DDACarbonate	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	No	Unclassified*	Unclassified	Unclassified
477	Flocoumafen	No	No	No	No	No	No	No	Yes	No	Unclassified	Unclassified	Unclassified
480	Glutaraldehyde	No	No	No	No	No	No	No	No	Yes	Unclassified	Unclassified	Unclassified
481	Copper pyrithione	Not relevant	No	Not relevant	Yes (development)	Not relevant	No	Not relevant	No	Yes	Unclassified*	ED	ED
482	Dinotefuran	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	No	Unclassified*	Unclassified	Unclassified
483	Potassium sorbate	No	No	No	No	No	No	No	No	Yes	Unclassified	Unclassified	Unclassified
484	MIT	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	No	Unclassified*	Unclassified	Unclassified
485	DCPP	No	No	No	No	No	No	No	No	No	Unclassified	Unclassified	Unclassified
486	C(M)IT/MIT	No	No	No	No	No	No	No	No	No	Unclassified	Unclassified	Unclassified
487	MBM	Not relevant	No	Not relevant	No	Not relevant	Yes	Not relevant	No	No	Unclassified*	Unclassified	Unclassified
488	Propan-2-ol	No	No	No	No	No	No	No	No	Yes	Unclassified	Unclassified	Unclassified
489	Hydrogen peroxide	No	No	No	No	No	No	No	No	No	Unclassified	Unclassified	Unclassified
490	Medetomidine	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	No	Unclassified*	Unclassified	Unclassified
491	Hexaflumuron	Not relevant	No	Not relevant	No	Not relevant	No	Not relevant	No	No	Unclassified*	Unclassified	Unclassified

Unclassified*: No harmonized classification available

The results of the screening do not constitute evaluations of individual substances to be carried out under the respective chemical legislations [[in particular, Regulation (EC) No 1107/2009 on plant protection products, Regulation (EU) No 528/2012 on biocidal products, Regulation (EC) No 1907/2006 REACH, Regulation (EC) No 1223/2009 on cosmetic products and the Water Framework Directive (EC) No 2000/60] and in no way prejudice future decisions on active substances to be taken pursuant to these pieces of the EU legislation.

It would thus be erroneous to consider that the substances listed in the results of this study (SANTE/2015/E3/SI2.706218) are considered as endocrine disruptors within the meaning of the EU legislation.

Revised potential categorization results for 96 BPs under “Option 2, 3 & 4” for human health and vertebrate wildlife and combined potential categorization under all Options

	Chemical Name	Potential Categorization Human Health				Potential Categorization Wildlife Vertebrates				Combined Potential Categorization (HH & Wildlife Vertebrates)			
		OPTION 2	OPTION 3	Path of decision tree	OPTION 4	OPTION 2	OPTION 3	Path of decision tree	OPTION 4	OPTION 1 Most recent	OPTION 2	OPTION 3	OPTION 4
1	Carbon dioxide	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
2	Tebuconazole	ED	Cat I	2a, 2b	Unclassified	ED	Cat I	2a, 2b	Unclassified	ED	ED	Cat I	Unclassified
3	Methyl nonyl ketone	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
4	Fipronil	Unclassified	Cat II	5	Unclassified	Unclassified	Cat II	3b	Unclassified	Unclassified	Unclassified	Cat II	Unclassified
5	Magnesium phosphide	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
6	Imidacloprid	Unclassified	Cat III	10	Unclassified	Unclassified	Cat III	10	Unclassified	Unclassified	Unclassified	Cat III	Unclassified
7	Thiabendazole	Unclassified	Cat II	3b	Unclassified	Unclassified	Cat II	3b	Unclassified	Unclassified	Unclassified	Cat II	Unclassified
8	Aluminium phosphide	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
9	Sulfuryl fluoride	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
10	Bromadiolone	Unclassified	Unclassified	8	Unclassified	Unclassified	Unclassified	8	Unclassified	Cut off criteria are applicable / Repr Cat 1A/B	Unclassified	Unclassified	Unclassified
11	Diflubenzuron	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
12	Dazomet	Unclassified	Cat II	3b	Unclassified	Unclassified	Cat II	3b	Unclassified	ED	Unclassified	Cat II	Unclassified
13	Difenacoum	Unclassified	Cat II	3a	Unclassified	Unclassified	Cat II	3a	Unclassified	ED / Cut off	Unclassified	Cat II	Unclassified

The results of the screening do not constitute evaluations of individual substances to be carried out under the respective chemical legislations [[in particular, Regulation (EC) No 1107/2009 on plant protection products, Regulation (EU) No 528/2012 on biocidal products, Regulation (EC) No 1907/2006 REACH, Regulation (EC) No 1223/2009 on cosmetic products and the Water Framework Directive (EC) No 2000/60] and in no way prejudice future decisions on active substances to be taken pursuant to these pieces of the EU legislation.

It would thus be erroneous to consider that the substances listed in the results of this study (SANTE/2015/E3/SI2.706218) are considered as endocrine disruptors within the meaning of the EU legislation.

Screening of available evidence on chemical substances for the identification of endocrine disruptors according to different options in the context of an Impact Assessment

		Potential Categorization Human Health				Potential Categorization Wildlife Vertebrates				Combined Potential Categorization (HH & Wildlife Vertebrates)			
	Chemical Name	OPTION 2	OPTION 3	Path of decision tree	OPTION 4	OPTION 2	OPTION 3	Path of decision tree	OPTION 4	OPTION 1 Most recent	OPTION 2	OPTION 3	OPTION 4
										criteria are applicable / Repr Cat 1A/B			
14	Fenpropimorph	Unclassified	Unclassified	8	Unclassified	Unclassified	Unclassified	8	Unclassified	ED	Unclassified	Unclassified	Unclassified
15	Abamectin (aka avermectin)	Unclassified	Cat II	3a	Unclassified	Unclassified	Cat II	3a	Unclassified	ED	Unclassified	Cat II	Unclassified
16	Fenoxycarb	Unclassified	Cat III	7	Unclassified	Unclassified	Cat III	7	Unclassified	Unclassified	Unclassified	Cat III	Unclassified
17	Etofenprox	Unclassified	Cat III	7	Unclassified	Unclassified	Cat III	7	Unclassified	Unclassified	Unclassified	Cat III	Unclassified
18	Bifenthrin	Unclassified	Cat III	7	Unclassified	Unclassified	Cat II	5	Unclassified	Unclassified	Unclassified	Cat II	Unclassified
19	lambda-Cyhalothrin	Unclassified	Cat II	5 & 6	Unclassified	Unclassified	Cat II	5 & 6	Unclassified	Unclassified	Unclassified	Cat II	Unclassified
20	Cyproconazole	Unclassified	Cat II	3b	Unclassified	ED	Cat I	2a & 2b	ED	ED - Cut off criteria are applicable / Repr Cat 1A/B	ED	Cat I	ED
21	Pyriproxyfen	Unclassified	Cat II	3b	Unclassified	Unclassified	Cat II	3b	Unclassified	Unclassified	Unclassified	Cat II	Unclassified
22	Folpet	Unclassified	Cat III	7	Unclassified	Unclassified	Cat III	7	Unclassified	Unclassified	Unclassified	Cat III	Unclassified
294	Clothianidin	Unclassified	Cat II	3a	Unclassified	Unclassified	Cat II	3a	Unclassified	Unclassified	Unclassified	Cat II	Unclassified
295	Propiconazole	Unclassified	Cat II	5	Unclassified	Unclassified	Cat II	5	Unclassified	Unclassified	Unclassified	Cat II	Unclassified

The results of the screening do not constitute evaluations of individual substances to be carried out under the respective chemical legislations [[in particular, Regulation (EC) No 1107/2009 on plant protection products, Regulation (EU) No 528/2012 on biocidal products, Regulation (EC) No 1907/2006 REACH, Regulation (EC) No 1223/2009 on cosmetic products and the Water Framework Directive (EC) No 2000/60] and in no way prejudice future decisions on active substances to be taken pursuant to these pieces of the EU legislation.

It would thus be erroneous to consider that the substances listed in the results of this study (SANTE/2015/E3/SI2.706218) are considered as endocrine disruptors within the meaning of the EU legislation.

Screening of available evidence on chemical substances for the identification of endocrine disruptors according to different options in the context of an Impact Assessment

		Potential Categorization Human Health				Potential Categorization Wildlife Vertebrates				Combined Potential Categorization (HH & Wildlife Vertebrates)			
	Chemical Name	OPTION 2	OPTION 3	Path of decision tree	OPTION 4	OPTION 2	OPTION 3	Path of decision tree	OPTION 4	OPTION 1 Most recent	OPTION 2	OPTION 3	OPTION 4
296	Thiacloprid	Unclassified	Cat II	3b	Unclassified	Unclassified	Cat II	3b	Unclassified	ED - Cut off criteria are applicable / Repr Cat 1A/B	Unclassified	Cat II	Unclassified
297	Pelargonic acid (Nonanoic acid)	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
298	Caprylic acid (Octanoic acid)	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
299	Lauric acid	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
300	Thiamethoxam	Unclassified	Cat II	3a	Unclassified	Unclassified	Cat II	3a	Unclassified	Unclassified	Unclassified	Cat II	Unclassified
301	Spinosad	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
302	Copper hydroxide	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
303	Capric acid (Decanoic acid)	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
304	Cypermethrin	ED	Cat I	2a, 2b	ED	ED	Cat I	2a, 2b	ED	Unclassified	ED	Cat I	ED
305	Deltamethrin	Unclassified	Cat II	3b	Unclassified	Unclassified	Cat II	3b	Unclassified	Unclassified	Unclassified	Cat II	Unclassified
306	Benzoic acid	Unclassified	Unclassified	8	Unclassified	Unclassified	Unclassified	8	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
307	Alpha-Cypermethrin (aka alphamethrin)	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
343	Indoxacarb	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
429	tolyfluanid	Unclassified	Unclassified	8	Unclassified	Unclassified	Unclassified	8	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
430	flufenoxuron	Unclassified	Unclassified	8	Unclassified	Unclassified	Unclassified	8	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
431	Didecyldimethylammonium chloride; DDAC	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified

The results of the screening do not constitute evaluations of individual substances to be carried out under the respective chemical legislations [[in particular, Regulation (EC) No 1107/2009 on plant protection products, Regulation (EU) No 528/2012 on biocidal products, Regulation (EC) No 1907/2006 REACH, Regulation (EC) No 1223/2009 on cosmetic products and the Water Framework Directive (EC) No 2000/60] and in no way prejudice future decisions on active substances to be taken pursuant to these pieces of the EU legislation.

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Screening of available evidence on chemical substances for the identification of endocrine disruptors according to different options in the context of an Impact Assessment

		Potential Categorization Human Health				Potential Categorization Wildlife Vertebrates				Combined Potential Categorization (HH & Wildlife Vertebrates)			
	Chemical Name	OPTION 2	OPTION 3	Path of decision tree	OPTION 4	OPTION 2	OPTION 3	Path of decision tree	OPTION 4	OPTION 1 Most recent	OPTION 2	OPTION 3	OPTION 4
432	Tralopyril	Unclassified	Unclassified	8	Unclassified	Unclassified	Unclassified	8	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
433	Permethrin	Unclassified	Cat II	3b	Unclassified	Unclassified	Cat II	3b	Unclassified	Unclassified	Unclassified	Cat II	Unclassified
434	IPBC	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
435	Boric acid	Unclassified	Cat II	3a	Unclassified	Unclassified	Cat II	3a	Unclassified	ED	Unclassified	Cat II	Unclassified
436	Difethialone	Unclassified	Unclassified	8	Unclassified	Unclassified	Unclassified	8	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
437	Acrolein	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
438	dichlofluanid	Unclassified	Cat II	3a	Unclassified	Unclassified	Cat II	3a	Unclassified	Unclassified	Unclassified	Cat II	Unclassified
439	Transfluthrin	Unclassified	Unclassified	8	Unclassified	Unclassified	Unclassified	8	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
440	Basic Copper carbonate (mentioned in ECHA as Copper(II) Carbonate)	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
441	Zineb	ED	Cat I	2a	ED	ED	Cat I	2a	ED	ED	ED	Cat I	ED
442	Chlorfenapyr	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
443	Disodium tetraborate pentahydrate	Unclassified	Cat II	3a	Unclassified	Unclassified	Cat II	3a	Unclassified	ED	Unclassified	Cat II	Unclassified
444	Disodium octaborate tetrahydrate	Unclassified	Cat II	3a	Unclassified	Unclassified	Cat II	3a	Unclassified	ED	Unclassified	Cat II	Unclassified
445	Warfarin sodium	Unclassified	Unclassified	8	Unclassified	Unclassified	Unclassified	8	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
446	Boric oxide	Unclassified	Cat II	3a	Unclassified	Unclassified	Cat II	3a	Unclassified	ED	Unclassified	Cat II	Unclassified
447	Disodium tetraborate decahydrate	Unclassified	Cat II	3a	Unclassified	Unclassified	Cat II	3a	Unclassified	ED	Unclassified	Cat II	Unclassified
448	Copper (II) oxide	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
449	Disodium tetraborate	Unclassified	Cat II	3a	Unclassified	Unclassified	Cat II	3a	Unclassified	ED	Unclassified	Cat II	Unclassified

The results of the screening do not constitute evaluations of individual substances to be carried out under the respective chemical legislations [[in particular, Regulation (EC) No 1107/2009 on plant protection products, Regulation (EU) No 528/2012 on biocidal products, Regulation (EC) No 1907/2006 REACH, Regulation (EC) No 1223/2009 on cosmetic products and the Water Framework Directive (EC) No 2000/60] and in no way prejudice future decisions on active substances to be taken pursuant to these pieces of the EU legislation.

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Screening of available evidence on chemical substances for the identification of endocrine disruptors according to different options in the context of an Impact Assessment

		Potential Categorization Human Health				Potential Categorization Wildlife Vertebrates				Combined Potential Categorization (HH & Wildlife Vertebrates)			
	Chemical Name	OPTION 2	OPTION 3	Path of decision tree	OPTION 4	OPTION 2	OPTION 3	Path of decision tree	OPTION 4	OPTION 1 Most recent	OPTION 2	OPTION 3	OPTION 4
450	N,N-diethyl-meta-toluamide (DEET)	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
451	alphachloralose (chloralose)	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
453	Bendiocarb	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
454	Metofluthrin	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
455	Polyvinylpyrrolidone iodine	ED	Cat I	4	ED	ED	Cat I	4	ED	Unclassified	ED	Cat I	ED
456	1R-trans phenothrin	Unclassified	Cat III	7	Unclassified	Unclassified	Cat III	7	Unclassified	Unclassified	Unclassified	Cat III	Unclassified
457	cis-tricos-9-ene (Muscalure)	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
459	Cu-HDO	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
460	Chlorophacinone	Unclassified	Cat III	7	Unclassified	Unclassified	Cat III	7	Unclassified	Unclassified	Unclassified	Cat III	Unclassified
461	Ethyl butylacetylaminopropionate (IR3535)	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
462	Brodifacoum	Unclassified	Unclassified	8	Unclassified	Unclassified	Unclassified	8	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
463	Coumatetralyl	Unclassified	Unclassified	8	Unclassified	Unclassified	Unclassified	8	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
464	4,5-Dichloro-2-octylisothiazol-3(2H)-one (DCOIT)	Unclassified	Unclassified	8	Unclassified	Unclassified	Cat II	3a/3b	Unclassified	Unclassified	Unclassified	Cat II	Unclassified
465	S-Methoprene	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
466	K-HDO	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
467	Alkyl (C12-16) dimethylbenzyl ammonium chloride; C 12-16-ADBAC	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified

The results of the screening do not constitute evaluations of individual substances to be carried out under the respective chemical legislations [[in particular, Regulation (EC) No 1107/2009 on plant protection products, Regulation (EU) No 528/2012 on biocidal products, Regulation (EC) No 1907/2006 REACH, Regulation (EC) No 1223/2009 on cosmetic products and the Water Framework Directive (EC) No 2000/60] and in no way prejudice future decisions on active substances to be taken pursuant to these pieces of the EU legislation.

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Screening of available evidence on chemical substances for the identification of endocrine disruptors according to different options in the context of an Impact Assessment

		Potential Categorization Human Health				Potential Categorization Wildlife Vertebrates				Combined Potential Categorization (HH & Wildlife Vertebrates)			
	Chemical Name	OPTION 2	OPTION 3	Path of decision tree	OPTION 4	OPTION 2	OPTION 3	Path of decision tree	OPTION 4	OPTION 1 Most recent	OPTION 2	OPTION 3	OPTION 4
468	hydrogen cyanide	Unclassified	Cat II	3a/b	Unclassified	Unclassified	Unclassified	8	Unclassified	Unclassified	Unclassified	Cat II	Unclassified
469	Iodine	ED	Cat I	4	ED	ED	Cat I	4	ED	Unclassified	ED	Cat I	ED
470	Hydrochloric acid [same as Hydrogen chloride]	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
471	Nitrogen	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
472	Copper sulphate pentahydrate	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
473	Bromoacetic acid	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
474	Creosote	Unclassified	Unclassified	8	Unclassified	Unclassified	Unclassified	8	Unclassified	ED	Unclassified	Unclassified	Unclassified
475	Warfarin	Unclassified	Unclassified	8	Unclassified	Unclassified	Unclassified	8	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
476	DDACarbonate	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
477	Flocoumafen	Unclassified	Unclassified	8	Unclassified	Unclassified	Unclassified	8	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
480	Glutaraldehyde	Unclassified	Cat II	3b	Unclassified	Unclassified	Cat II	3b	Unclassified	Unclassified	Unclassified	Cat II	Unclassified
481	Copper pyrithione	Unclassified	Cat II	3a	Unclassified	Unclassified	Cat II	3a	Unclassified	ED	Unclassified	Cat II	Unclassified
482	Dinotefuran	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
483	Potassium sorbate	Unclassified	Unclassified	8	Unclassified	Unclassified	Unclassified	8	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
484	MIT	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
485	DCPP	Unclassified	Cat II	3a	Unclassified	Unclassified	Cat II	3a	Unclassified	Unclassified	Unclassified	Cat II	Unclassified
486	C(M)IT/MIT	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
487	MBM	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
488	Propan-2-ol	Unclassified	Cat II	3a	Unclassified	Unclassified	Cat II	3a	Unclassified	Unclassified	Unclassified	Cat II	Unclassified
489	Hydrogen peroxide	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified

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The results of the screening do not constitute evaluations of individual substances to be carried out under the respective chemical legislations [[in particular, Regulation (EC) No 1107/2009 on plant protection products, Regulation (EU) No 528/2012 on biocidal products, Regulation (EC) No 1907/2006 REACH, Regulation (EC) No 1223/2009 on cosmetic products and the Water Framework Directive (EC) No 2000/60] and in no way prejudice future decisions on active substances to be taken pursuant to these pieces of the EU legislation.

It would thus be erroneous to consider that the substances listed in the results of this study (SANTE/2015/E3/SI2.706218) are considered as endocrine disruptors within the meaning of the EU legislation.

		Potential Categorization Human Health				Potential Categorization Wildlife Vertebrates				Combined Potential Categorization (HH & Wildlife Vertebrates)			
	Chemical Name	OPTION 2	OPTION 3	Path of decision tree	OPTION 4	OPTION 2	OPTION 3	Path of decision tree	OPTION 4	OPTION 1 Most recent	OPTION 2	OPTION 3	OPTION 4
490	Medetomidine	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
491	Hexaflumuron	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified

The results of the screening do not constitute evaluations of individual substances to be carried out under the respective chemical legislations [[in particular, Regulation (EC) No 1107/2009 on plant protection products, Regulation (EU) No 528/2012 on biocidal products, Regulation (EC) No 1907/2006 REACH, Regulation (EC) No 1223/2009 on cosmetic products and the Water Framework Directive (EC) No 2000/60] and in no way prejudge future decisions on active substances to be taken pursuant to these pieces of the EU legislation.

It would thus be erroneous to consider that the substances listed in the results of this study (SANTE/2015/E3/SI2.706218) are considered as endocrine disruptors within the meaning of the EU legislation.

CHAPTER 5

Screening of available evidence on chemical substances for the identification of endocrine disruptors according to different options in the context of an Impact Assessment

Specific Contract SANTE/2015/E3/SI2.706218

General observations and conclusions for the screened miscellaneous chemicals

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A. Introduction & Objectives

The aim of this report is to present the final outcome of the screening of 186 substances within the scope of REACH, the Cosmetic Products Regulation and the WFD (hereinafter called miscellaneous chemicals) as potential Endocrine Disruptors (ED) under four different Policy Options of the Roadmap (EC, 2014: Roadmap on defining criteria for identifying endocrine disruptors in the context of the implementation of the Plant Protection Product Regulation and Biocidal Products Regulation).

B. Materials & Methods

The methodology applied was based on the JRC draft methodology provided in May 2015, amended as described in chapter 1 and supplemented by further WoE considerations as described in chapter 2, minor modifications which have been introduced during the screening of the BPs (chapter 3) and finally published by JRC (JRC, 2016).

Screened substances

The original plan, as described in the Terms of Reference of the specific call, was to screen about 220 substances within the scope of REACH, the Cosmetic Products Regulation and the WFD (miscellaneous chemicals). In November 2015, DG SANTE provided BPI with a list of 181 chemical substances to be screened. Since in some cases instead of a unique substance the reference concerned a chemical group, e.g. parabens, further clarifications were requested. Finally, a total of 186 substances (drawn from the pool of substances regulated under REACH, WFD and the Cosmetic Regulation) were screened as miscellaneous chemicals.

Substances were selected for the screening exercise according to the following stepwise rationale:

- (1) All substances on the Candidate List already identified as Substances of Very High Concern (SVHC) because of ED concerns under Art. 57(f)
- (2) All substances for which an SVHC opinion on the identification of the substance as SVHC due to its endocrine disrupting properties was provided by the Member State Committee at ECHA ;
- (3) All substances on the Candidate list identified as SVHC because of reprotoxicity 1A/1B;
- (4) All substances listed in Annex XVII for restrictions due to an ED concern or because of having a harmonised classification as reprotoxic 1A/1B;
- (5) All substances placed on the community rolling action plan (CoRAP) due to ED concern;

More information regarding the selection of chemical substances to be screened in the context of the impact assessment on criteria to identify endocrine disruptors can be found in the relevant document published by the European Commission (EC, 2015):

http://ec.europa.eu/health/endocrine_disruptors/docs/impactassessment_chemicalsubst_ancesselecion_en.pdf.

Data sources

Regarding the identification of the relevant source documents the following data retrieval scheme was developed in discussion with the Commission services taking into account the selection criteria:

Criterion 1 or 2: The MSC opinion and SVHC support document were used as the main source of data. The evaluation was made directly from these documents with reference to the available tables without extracting all the study details into the "Data" sheet [link to the MSC documents: <http://echa.europa.eu/role-of-the-member-state-committee-in-the-authorisation-process/svhc-opinions-of-the-member-state-committee>].

Criterion 3: The relevant CLH report of RAC opinion on CLP harmonised was used. However, this was available only in limited cases since the harmonised classification was concluded before the implementation of Regulation (EC) 1272/2008 (CLP). As additional sources, EASIS, SIN, TEDX, EDSP, ToxCast were used (when applicable). Moreover, the key studies on relevant toxicological endpoints (when available) - as given in the REACH dossier submitted by the registrant - were consulted for the assessment.

The background CLH dossier and/or the RAC opinion on the CLH dossier (when available) were found in the ECHA website; <http://echa.europa.eu/web/guest/opinions-of-the-committee-for-risk-assessment-on-proposals-for-harmonised-classification-and-labelling>.

The support documents for the identification of the substance as substance of very high concern (i.e., for listing it on the candidate list) were retrieved from the ECHA website (checking both the candidate list -<http://echa.europa.eu/candidate-list-table>- and the information available in the ECHA brief profile of each substance. However, in most cases the support document simply refers to the harmonised classification of the substance).

The ECHA website (<http://echa.europa.eu/en/information-on-chemicals/information-from-existing-substances-regulation>) was checked for any available Risk Assessment Reports carried out and finalised under the Existing Substance Regulation (EEC 793/93).

The Annex XV transitional reports (for those substances where the work was started under the Regulation 793/93, but wasn't finalised before REACH came into force) were found following the link: <http://echa.europa.eu/information-on-chemicals/transitional-measures/annex-xv-transitional-reports>.

Criterion 4: The restriction dossiers were used when provided by Commission Services. Background information on restrictions adopted under REACH was available following the link: <http://echa.europa.eu/previous-consultations-on-restriction-proposals>.

As for criterion 3 substances, the ECHA website was checked for any available Risk Assessment Reports carried out and finalised under the Existing Substance Regulation (EEC 793/93) and for the availability of any Annex XV transitional reports.

Criterion 5: Since in the CoRAP justification in most cases only the concern is indicated, the REACH registrant's submission data have been used to identify the key studies. In case there has been a reference to the key studies leading to the concerns raised, these have been considered for the evaluation. Moreover, the additional sources of EASIS, SIN, TEDX, EDSP, ToxCast were used (when applicable). For limited cases a CoRAP decision was found. The CoRAP relevant documents were found in the ECHA website, <http://echa.europa.eu/information-on-chemicals/evaluation/community-rolling-action-plan/corap-table>. For specific substances, documents/presentations/factsheets prepared by the MSCA and presented to ECHA ED EG were provided by JRC.

It is noted that a search was conducted for miscellaneous chemicals screened in the ECHA website (Information on Chemicals ,<http://echa.europa.eu/information-on-chemicals>) in order to identify all available information/source documents. For those substances marked as "Cosmetics" in the Chemical Inventory the CosIng database (<http://ec.europa.eu/growth/sectors/cosmetics/cosing/>) was also used in order to identify (when available) the relevant regulatory documents [Scientific Committee on Consumer Products (SCCP) and Scientific Committee on Consumer Safety (SCCP) Opinions]. However, there were substances for which limited or no data were included in the available regulatory documents and/or in the REACH registrant's dossier (publicly available data in the relevant ECHA website).

Taking into account all the above the "*Chemical Inventory*" file provided by JRC as the initial tool to be used for identifying sources of information, was updated for the 186 miscellaneous chemicals screened. Web links or references of the exact sources of data identified for each chemical are mentioned in the Chemical Inventory file "*Chemical Inventory_Miscellaneous_31-05-2016*", updated by BPI.

The results of the screening do not constitute evaluations of individual substances to be carried out under the respective chemical legislations [[in particular, Regulation (EC) No 1107/2009 on plant protection products, Regulation (EU) No 528/2012 on biocidal products, Regulation (EC) No 1907/2006 REACH, Regulation (EC) No 1223/2009 on cosmetic products and the Water Framework Directive (EC) No 2000/60] and in no way prejudice future decisions on active substances to be taken pursuant to these pieces of the EU legislation. It would thus be erroneous to consider that the substances listed in the results of this study (SANTE/2015/E3/SI2.706218) are considered as endocrine disruptors within the meaning of the EU legislation.

Chemical Inventory of miscellaneous chemicals (Part 1)

Criteria for selection of REACH Chemicals:

1. All substances on the Candidate List already identified as SVHCs because of ED concerns under Art. 57(f)
2. All substances for which an SVHC opinion on the identification of the substance as SVHC due to its endocrine disrupting properties was provided by the Member State Committee at ECHA
3. All substances on the Candidate list identified as SVHC because of reprotoxicity 1A/1B
4. Select all substances listed in Annex XVII for restrictions due to a ED concern or because of having a harmonised classification as reprotoxic 1A/1B
5. All substances placed on CoRAP due to ED concern

1 EASIS data available; to be considered

(1) EASIS data available; not to be considered

[±] EASIS data not available although originally marked as such

[1] Found in SIN List; Reason for inclusion is captured in the Data sheet.

*Information represents what was valid in the beginning of the project. This information may have changed.

	Chemical Name	CAS	Miscellaneous to be screened	Criteria for Selection for ED IA (REACH Chemicals) - as provided by JRC	EFSA (no approved/pending)	biocides not yet approved	cosmetics	REACH tonnage band*	REACH*	CMR CLP classification	STOT-RE CLP classification
450	propargite	2312-35-8	YES	5	1 (Not approved; EFSA Conclusion available)			100 - 1,000 tonnes per annum	1	1	
557	Oligomerisation and alkylation reaction products of 2-phenylpropene and phenol [Previously registered as Phenol, methylstyrenated - EC N. 270-966-8 and CAS N.	700-960-7	YES	5							

The results of the screening do not constitute evaluations of individual substances to be carried out under the respective chemical legislations [[in particular, Regulation (EC) No 1107/2009 on plant protection products, Regulation (EU) No 528/2012 on biocidal products, Regulation (EC) No 1907/2006 REACH, Regulation (EC) No 1223/2009 on cosmetic products and the Water Framework Directive (EC) No 2000/60] and in no way prejudice future decisions on active substances to be taken pursuant to these pieces of the EU legislation.

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	Chemical Name	CAS	Miscellaneous to be screened	Criteria for Selection for ED IA (REACH Chemicals) - as provided by JRC	EFSA (no approved/pending	biocides not yet approved	cosmetics	REACH tonnage band*	REACH*	CMR CLP classification	STOT-RE CLP classification
	68512-30-1]										
558	2,2',6,6'-Tetrabromo-4,4'-isopropylidenediphenol, oligomeric reaction products with Propylene oxide and n-butyl glycidyl ether		YES	5							
559	reaction mass of 1-(1,2,3,4,5,6,7,8-octahydro-2,3,8,8-tetramethyl-2-naphthyl)ethan-1-one and 1-(1,2,3,4,6,7,8,8a-octahydro-2,3,8,8-tetramethyl-2-naphthyl)ethan-1-one and 1-(1,2,3,5,6,7,8,8a-octahydro-2,3,8,8-tetramethyl-2-naphthyl)ethan-1-one		YES	5							
560	reaction mass of 2-ethylhexyl 10-ethyl-4,4-dioctyl-7-oxo-8-oxa-3,5-dithia-4-stannatetradecanoate and 2-ethylhexyl 10-ethyl-4-[[2-[[2-ethylhexyl)oxy]-2-		YES	3							

The results of the screening do not constitute evaluations of individual substances to be carried out under the respective chemical legislations [[in particular, Regulation (EC) No 1107/2009 on plant protection products, Regulation (EU) No 528/2012 on biocidal products, Regulation (EC) No 1907/2006 REACH, Regulation (EC) No 1223/2009 on cosmetic products and the Water Framework Directive (EC) No 2000/60] and in no way prejudice future decisions on active substances to be taken pursuant to these pieces of the EU legislation.

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	Chemical Name	CAS	Miscellaneous to be screened	Criteria for Selection for ED IA (REACH Chemicals) - as provided by JRC	EFSA (no approved/pending	biocides not yet approved	cosmetics	REACH tonnage band*	REACH*	CMR CLP classification	STOT-RE CLP classification
	oxoethyl]thio]-4-octyl-7-oxo-8-oxa-3,5-dithia-4-stannatetradecanoate (reaction mass of DOTE and MOTE)										
561	4-Nonylphenol, branched and linear, ethoxylated [substances with a linear and/or branched alkyl chain with a carbon number of 9 covalently bound in position 4 to phenol, ethoxylated covering UVCB- and well-defined substances, polymers and homologues, which include any of the individual isomers and/or combinations thereof]		YES	1							
562	4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated [covering well-defined substances and UVCB substances, polymers and homologues]	9036-19-5	YES	1							
563	4-Nonylphenol, branched and linear [substances with		YES	1							

The results of the screening do not constitute evaluations of individual substances to be carried out under the respective chemical legislations [[in particular, Regulation (EC) No 1107/2009 on plant protection products, Regulation (EU) No 528/2012 on biocidal products, Regulation (EC) No 1907/2006 REACH, Regulation (EC) No 1223/2009 on cosmetic products and the Water Framework Directive (EC) No 2000/60] and in no way prejudice future decisions on active substances to be taken pursuant to these pieces of the EU legislation.

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Screening of available evidence on chemical substances for the identification of endocrine disruptors according to different options in the context of an Impact Assessment

	Chemical Name	CAS	Miscellaneous to be screened	Criteria for Selection for ED IA (REACH Chemicals) - as provided by JRC	EFSA (no approved/pending	biocides not yet approved	cosmetics	REACH tonnage band*	REACH*	CMR CLP classification	STOT-RE CLP classification
	a linear and/or branched alkyl chain with a carbon number of 9 covalently bound in position 4 to phenol, covering also UVCB- and well-defined substances which include any of the individual isomers or a combination thereof]										
580	Dibutyltin (DBT) (Dibutyl stannane)	1002-53-5	YES (Dibutyltin salts)	3 (chloride), 4							
651	lead dinitrate	10099-74-8	YES	3				10 - 100 tonnes per annum	1	1	1
656	triphenyl phosphite	101-02-0	YES	5				1,000 - 10,000 tonnes per annum	1		
659	cadmium chloride	10108-64-2	YES	3				1 - 10 tonnes per annum	1	1	1
670	cadmium sulphate	10124-36-4; Additional CAS No: 31119-53-6	YES	3				Intermediate Use Only	1	1	1
673	cobalt sulphate [Cobalt(II)]	10124-43-3	YES	3				multiple	1	1	1

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	sulphate]							tonnage bands because multiple submissions			
682	cobalt dinitrate [Cobalt(II) dinitrate]	10141-05-6	YES	3				multiple tonnage bands because multiple submissions	1	1	1
687	N-Phenyl-P-Phenylenediamine [N-(4-aminophenyl)aniline]	101-54-2	YES	not included in the "Selection REACH chemicals" List			1	100 - 1,000 tonnes per annum	1		1
912	sodium dichromate	10588-01-9 (Additional CAS No: 7789-12-0)	YES	3				10,000 - 100,000 tonnes per annum	1	1	1
952	p-cresol	106-44-5	YES	5				10,000+ tonnes per annum	1		
960	p-phenylenediamine	106-50-3	YES	not included in the "Selection REACH chemicals" List			1	multiple tonnage bands	1		1

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								because multiple submissions			
989	1-bromopropane (n-propyl bromide)	106-94-5	YES	3				multiple tonnage bands because multiple submissions	1	1	1
1080	Resorcinol (1,3-benzenediol)	108-46-3	YES	5			1	10,000 - 100,000 tonnes per annum	1		1 self classification
1151	2-methoxyethanol (ethylene glycol monomethyl ether)	109-86-4	YES	3			1	1,000 - 10,000 tonnes per annum	1	1	1
1182	2-methoxyethyl acetate	110-49-6	YES				1			1	
1196	1,2-dimethoxyethane	110-71-4	YES	3				100 - 1,000 tonnes per annum	1	1	
1202	2-ethoxyethanol	110-80-5	YES	3			1	100 - 1,000 tonnes per annum	1	1	

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1228	2-ethoxyethyl acetate	111-15-9	YES	3			1			1	
1234	Silicic acid, lead salt	11120-22-2	YES	3				1 - 10 tonnes per annum	1	1	1
1280	Ethylene Glycol Monobutyl Ether (2-Butoxyethanol)	111-76-2	YES				1	100,000 - 1,000,000 tonnes per annum	1	1	1
1281	2-(2-methoxyethoxy)ethanol (DEGME)	111-77-3	YES					10,000 - 100,000 tonnes per annum	1	1	
1298	Diethylene glycol monobutyl ether (ethoxydiglycol)	111-90-0	YES				1	10,000 - 100,000 tonnes per annum	1	1	1
1303	dimethyl glutarate	1119-40-0	YES	5				100 - 1,000 tonnes per annum	1		1
1305	bis(2-methoxyethyl) ether	111-96-6	YES	3				100 - 1,000 tonnes per annum	1	1	
1350	1,2-bis(2-methoxyethoxy)ethane	112-49-2	YES	3				10 - 100 tonnes per annum	1	1	

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1436	triphenyl phosphate	115-86-6	YES	5				1,000 - 10,000 tonnes per annum	1		
1439	tris(2-chloroethyl) phosphate (TCEP)	115-96-8	YES	3				10 - 100 tonnes per annum	1	1	
1484	bis(2-ethylhexyl) phthalate (DEHP)	117-81-7	YES	1, 2, 3, 4				multiple tonnage bands because multiple submissions	1	1	
1486	Bis(2-methoxyethyl) phthalate	117-82-8	YES	3						1	
1519	2,2',6,6'-tetra-tert-butyl-4,4'-methylenediphenol	118-82-1	YES	5				100 - 1,000 tonnes per annum	1		
1611	lead oxide sulfate (basic lead sulphate)	12036-76-9	YES	3				1 - 10 tonnes per annum	1	1	1
1631	lead titanium trioxide	12060-00-3	YES	3				10 - 100 tonnes per annum	1	1	1
1637	pentalead tetraoxide	12065-90-6	YES	3				10,000 -	1	1	1

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	sulphate (tetrabasic lead sulphate)							100,000 tonnes per annum			
1678	trilead dioxide phosphonate (dibasic lead phosphite)	12141-20-7	YES	3				10,000 - 100,000 tonnes per annum	1	1	1
1719	tetralead trioxide sulphate (tribasic lead sulphate)	12202-17-4	YES	3				1,000,000 - 10,000,000 tonnes per annum	1	1	1
1737	Low temperature tar oil, alkaline, extract residues (coal), low temperature coal tar alkaline	122384-78-5	YES	4						1	
1778	p-aminophenol	123-30-8	YES				1	multiple tonnage bands because multiple submissions	1	1	1
1870	dioxobis(stearato)trilead (dibasic lead stearate)	12578-12-0	YES	3				10,000 - 100,000 tonnes per annum	1	1	1

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1884	Lead titanium zirconium oxide	12626-81-2	YES	3				100 - 1,000 tonnes per annum	1	1	1
1892	lead chromate molybdate sulfate red	12656-85-8	YES	3				1,000 - 10,000 tonnes per annum	1	1	1
1925	N,N-dimethylacetamide	127-19-5	YES	3				10,000 - 100,000 tonnes per annum	1	1	
2042	Dipentyl phthalate (DPP)	131-18-0	YES	3						1	
2061	orange lead (lead tetroxide)	1314-41-6	YES	3				10,000 - 100,000 tonnes per annum	1	1	1
2081	Benzophenone-3 (oxybenzone)	131-57-7	YES	5			1	10 - 100 tonnes per annum	1		1
2091	lead monoxide (lead oxide)	1317-36-8	YES	3				100,000 - 1,000,000 tonnes per annum	1	1	1
2105	trilead bis(carbonate) dihydroxide (basic lead carbonate)	1319-46-6	YES	3				10 - 100 tonnes per annum	1	1	1

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2191	lead diazide	13424-46-9	YES	3				10 - 100 tonnes per annum	1	1	1
2202	lead sulfochromate yellow	1344-37-2	YES	3				1,000 - 10,000 tonnes per annum	1	1	1
2324	lead bis(tetrafluoroborate)	13814-96-5	YES	3				10 - 100 tonnes per annum	1	1	1
2391	4-(1,1,3,3-tetramethylbutyl)phenol	140-66-9	YES	1				10,000 - 100,000 tonnes per annum	1		1
2491	3-ethyl-2-methyl-2-(3-methylbutyl)-1,3-oxazolidine	143860-04-2	YES	3						1	
2527	3-methylpyrazole	1453-58-3	YES	5				10 - 100 tonnes per annum	1	1	1
2543	tributyltin chloride	1461-22-9	YES (Tributyltin salts)					Intermediate Use Only	1	1	1
2544	tributyltin bromide	1461-23-0	YES (Tributyltin salts)								1

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2594	2-Mercaptobenzothiazole (Benzothiazole-2-thiol)	149-30-4	YES				1	multiple tonnage bands because multiple submissions	1	1	
2625	3-Benzylidene camphor (1,7,7-trimethyl-3-(phenylmethylene)bicyclo[2.2.1]heptan-2-one)	15087-24-8	YES				1			1	
2633	Sodium perborate,perboric acid, sodium salt	15120-21-5 (11138-47-9)	YES	3						1	
2657	lead 2,4,6-trinitro-m-phenylene dioxide (Lead styphnate)	15245-44-0	YES	3				10 - 100 tonnes per annum	1	1	1
2701	2-ethylhexyl 10-ethyl-4,4-dioctyl-7-oxo-8-oxa-3,5-dithia-4-stannatetradecanoate (DOTE)	15571-58-1	YES	3				1,000 - 10,000 tonnes per annum	1	1	1
2813	tert-butyl methyl ether	1634-04-4	YES	5				1,000,000 - 10,000,000 tonnes per annum	1		
2863	2-Amino-3-hydroxypyridine	16867-03-1	YES				1				1

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	(2-aminopyridin-3-ol)										
2940	Lead(II) bis(methanesulfonate)	17570-76-2	YES	3						1	1
2945	ammonium thiocyanate	1762-95-4	YES	5				1,000 - 10,000 tonnes per annum	1		
3040	octabenzene	1843-05-6	YES	5				1,000 - 10,000 tonnes per annum	1		
3152	p-METHYLAMINOPHENOL sulphate	1936-57-8	YES				1				1
3269	tributyltin	20763-88-6	YES (Tributyltin salts)	4 (tributyltin compounds)							
3278	lead cyanamidate	20837-86-9	YES	3				10 - 100 tonnes per annum	1	1	1
3588	tert-butyl-4-methoxyphenol	25013-16-5	YES	5				100 - 1,000 tonnes per annum	1	1	
3590	Bisphenol-A-Epichlorhydrin Epoxy resin Average MW < 700 [4,4'-Isopropylidenediphenol,	25068-38-6	YES	5				100,000 - 1,000,000 tonnes per annum	1		

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	oligomeric reaction products with 1-chloro-2,3-epoxypropane]										
3600	Phenol, nonyl- (Nonylphenol)	25154-52-3	YES				1			1	
3601	trixyllyl phosphate	25155-23-1	YES	3				100 - 1,000 tonnes per annum	1	1	1
3708	bis(2-ethylhexyl) tetrabromophthalate (BEH-TEBP)	26040-51-7	YES	5				100 - 1,000 tonnes per annum	1		
3824	Polyhexamethylene biguanide hydrochloride	27083-27-8	YES			1	1			1	1
4051	lead di(acetate) (also mentioned as lead acetate)	301-04-2	YES	3				1 - 10 tonnes per annum	1	1	1
4087	Paraformaldehyde	30525-89-4	YES							1	
4270	Pentadecafluorooctanoic acid (PFOA)	335-67-1	YES	3						1	1
4280	Triclosan	3380-34-5	YES	5		1	1	1,000 - 10,000 tonnes per annum	1		
4449	tributyltin-cation (same as tributyltin hydride, CAS: 688-73-3)	36643-28-4	YES (Tributyltin salts)								

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4462	trilead diarsenate	3687-31-8	YES	3				Intermediate Use Only	1		
4537	4-Methylbenzylidene camphor (3-(4'-Methylbenzylidene)-dl-camphor / Enzacamene)	38102-62-4 (36861-47-9)	YES				1				
4548	Ammonium pentadecafluorooctanoate (APFO)	3825-26-1	YES	3						1	1
4960	Kojic Acid (5-hydroxy-2-hydroxymethyl-4-pyrone)	501-30-4	YES				1			1	
4975	Benzo[a]pyrene	50-32-8	YES	4						1	
5033	2-(2-butoxyethoxy)ethyl 6-propylpiperonyl ether (PBO)	51-03-6	YES	5		1		multiple tonnage bands because multiple submissions	1	1	
5047	Quaternium-15 (cis-isomer)	51229-78-8	YES				1			1	1 (self classification)
5065	cobalt carbonate	513-79-1	YES	3				multiple tonnage bands because	1	1	1

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								multiple submissions			
5067	Acetic acid, lead salt, basic	51404-69-4	YES	3				multiple tonnage bands because multiple submissions	1	1	1
5160	Camphor benzalkonium methosulfate (Methyl N,N,N-trimethyl-4-[(4,7,7-trimethyl-3-oxobicyclo[2.2.1]hept-2-ylidene)methyl]anilinium sulphate)	52793-97-2	YES				1				
5202	bis(2-propylheptyl) phthalate	53306-54-0	YES	5				10,000 - 100,000 tonnes per annum	1		
5209	1,2,4-trihydroxybenzene (Benzene-1,2,4-triol)	533-73-3	YES				1				
5272	Decamethylcyclopentasiloxane (mentioned as Cyclomethicone and	541-02-6 (all 69430-24-6 / 556-67-2 /	YES				1	10,000 - 100,000 tonnes per	1		

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	Cyclopentasiloxane)	541-02-6 / 540-97-6)						annum			
5324	2-Ethylhexyl-4-methoxycinnamate (Oxtinoxate or Ethylhexyl Methoxycinnamate)	5466-77-3	YES	5			1				
5382	Cyclomethicone Octamethylcyclotetrasiloxane	556-67-2	YES				1	100,000 - 1,000,000 tonnes per annum	1	1	
5443	Tributyltin (tributyltin chloride?)	56573-85-4	YES (Tributyltin salts)	4 (tributyltin compounds)							
5706	diisopentyl phthalate	605-50-5	YES	3				10 - 100 tonnes per annum	1	1	
5760	toluene-2,5-diamine sulfate (2-methyl-p-phenylenediamine sulfate)	615-50-9	YES				1	100 - 1,000 tonnes per annum	1	1	1
5786	Phenol, styrenated	61788-44-1	YES	5				multiple tonnage bands because multiple submissions	1		

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	Chemical Name	CAS	Miscellaneous to be screened	Criteria for Selection for ED IA (REACH Chemicals) - as provided by JRC	EFSA (no approved/pending	biocides not yet approved	cosmetics	REACH tonnage band*	REACH*	CMR CLP classification	STOT-RE CLP classification
5822	Sulfurous acid, lead salt, dibasic (basic lead sulphate)	62229-08-7	YES	3				100 - 1,000 tonnes per annum	1	1	1
5851	methoxyacetic acid	625-45-6	YES	3				Intermediate Use Only	1	1	
5880	1,2-Diethoxyethane	629-14-1	YES	3						1	
5962	Triphenyltin chloride	639-58-7	YES (Triphenyltin salts)	4						1	
6014	Lead dipicrate	6477-64-1	YES	3						1	1
6071	Tar acids, coal, crude, crude phenols	65996-85-2	YES	4						1	1
6132	Triphenyltin	668-34-8	YES (Triphenyltin salts)	4							
6223	N,N-dimethylformamide	68-12-2	YES	3				multiple tonnage bands because multiple submissions	1	1	1
6277	dibutyltin dichloride (DBTCI2)	683-18-1	YES (Dibutyltin salts)	3, 4 (dibutyltin)				10 - 100 tonnes per	1	1	1

The results of the screening do not constitute evaluations of individual substances to be carried out under the respective chemical legislations [[in particular, Regulation (EC) No 1107/2009 on plant protection products, Regulation (EU) No 528/2012 on biocidal products, Regulation (EC) No 1907/2006 REACH, Regulation (EC) No 1223/2009 on cosmetic products and the Water Framework Directive (EC) No 2000/60] and in no way prejudice future decisions on active substances to be taken pursuant to these pieces of the EU legislation.

It would thus be erroneous to consider that the substances listed in the results of this study (SANTE/2015/E3/SI2.706218) are considered as endocrine disruptors within the meaning of the EU legislation.

	Chemical Name	CAS	Miscellaneous to be screened	Criteria for Selection for ED IA (REACH Chemicals) - as provided by JRC	EFSA (no approved/pending	biocides not yet approved	cosmetics	REACH tonnage band*	REACH*	CMR CLP classification	STOT-RE CLP classification
								annum			
6325	1,2-Benzenedicarboxylic acid, di-C7-11-branched and linear alkyl esters	68515-42-4	YES	3						1	
6330	1,2-Benzenedicarboxylic acid, dihexylester, branched and linear (Diisohexyl phthalate -DIHP)	68515-50-4	YES	3						1	
6331	1,2-Benzenedicarboxylic acid, di-C6-10-alkyl esters	68515-51-5 (Additional Cas No: 68648-93-1)	YES	3				100 - 1,000 tonnes per annum	1		
6369	2,2'-dimethyl-4,4'-methylenebis(cyclohexylamine)	6864-37-5	YES	5				1000-10000 tonnes per annum	1		1
6384	Silicic acid (H ₂ Si ₂ O ₅), barium salt (1:1), lead-doped	68784-75-8	YES	3				10 - 100 tonnes per annum	1	1	1
6440	[phthalato(2-)]dioxotrilead (dibasic lead phthalate)	69011-06-9	YES	3				100 - 1,000 tonnes per annum	1	1	1
6518	3-amino-2,6-dimethylphenol	6994-64-5	YES				1				1

The results of the screening do not constitute evaluations of individual substances to be carried out under the respective chemical legislations [[in particular, Regulation (EC) No 1107/2009 on plant protection products, Regulation (EU) No 528/2012 on biocidal products, Regulation (EC) No 1907/2006 REACH, Regulation (EC) No 1223/2009 on cosmetic products and the Water Framework Directive (EC) No 2000/60] and in no way prejudice future decisions on active substances to be taken pursuant to these pieces of the EU legislation.

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	Chemical Name	CAS	Miscellaneous to be screened	Criteria for Selection for ED IA (REACH Chemicals) - as provided by JRC	EFSA (no approved/pending	biocides not yet approved	cosmetics	REACH tonnage band*	REACH*	CMR CLP classification	STOT-RE CLP classification
6593	cobalt di(acetate) [Cobalt(II) diacetate]	71-48-7	YES	3				multiple tonnage bands because multiple submissions	1	1	1
6600	Isopentyl-p-Methoxycinnamate (Amiloxate)	71617-10-2	YES	5			1	100 - 1,000 tonnes per annum	1		
6618	1,2-Benzenedicarboxylic acid, di-C6-8-branched alkyl esters, C7-rich	71888-89-6	YES	3						1	
6731	mercury	7439-97-6	YES	4				100 - 1,000 tonnes per annum	1	1	1
6789	chloromethane (Methyl chloride)	74-87-3	YES	5				multiple tonnage bands because multiple submissions	1	1	1
6810	Acetaldehyde	75-07-0	YES				1	multiple tonnage bands	1	1	

The results of the screening do not constitute evaluations of individual substances to be carried out under the respective chemical legislations [[in particular, Regulation (EC) No 1107/2009 on plant protection products, Regulation (EU) No 528/2012 on biocidal products, Regulation (EC) No 1907/2006 REACH, Regulation (EC) No 1223/2009 on cosmetic products and the Water Framework Directive (EC) No 2000/60] and in no way prejudice future decisions on active substances to be taken pursuant to these pieces of the EU legislation.

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	Chemical Name	CAS	Miscellaneous to be screened	Criteria for Selection for ED IA (REACH Chemicals) - as provided by JRC	EFSA (no approved/pending	biocides not yet approved	cosmetics	REACH tonnage band*	REACH*	CMR CLP classification	STOT-RE CLP classification
								because multiple submissions			
6812	Dichloromethane	75-09-2	YES				1	multiple tonnage bands because multiple submissions	1	1	1
6814	Di- μ -oxo-di-n-butylstanniohydroxyborane/ Dibutyltin hydrogen borate C8H19BO3Sn (DBB)	75113-37-0	YES	4						1	1
6815	formamide	75-12-7	YES	3				multiple tonnage bands because multiple submissions	1	1	1
6817	carbon disulphide	75-15-0	YES	5				multiple tonnage bands because	1	1	1

The results of the screening do not constitute evaluations of individual substances to be carried out under the respective chemical legislations [[in particular, Regulation (EC) No 1107/2009 on plant protection products, Regulation (EU) No 528/2012 on biocidal products, Regulation (EC) No 1907/2006 REACH, Regulation (EC) No 1223/2009 on cosmetic products and the Water Framework Directive (EC) No 2000/60] and in no way prejudice future decisions on active substances to be taken pursuant to these pieces of the EU legislation.

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Screening of available evidence on chemical substances for the identification of endocrine disruptors according to different options in the context of an Impact Assessment

	Chemical Name	CAS	Miscellaneous to be screened	Criteria for Selection for ED IA (REACH Chemicals) - as provided by JRC	EFSA (no approved/pending	biocides not yet approved	cosmetics	REACH tonnage band*	REACH*	CMR CLP classification	STOT-RE CLP classification
								multiple submissions			
6900	sodium perchlorate	7601-89-0	YES	5				1,000 - 10,000 tonnes per annum	1		1
6932	Sodium peroxometaborate	7632-04-4	YES	3						1	
6941	Cobalt dichloride	7646-79-9	YES	3					1	1	1
7051	Lead chromate	7758-97-6	YES	3						1	1
7055	N-pentyl-isopentylphthalate	776297-69-9	YES	3							
7065	sodium chromate	7775-11-3	YES	3				1 - 10 tonnes per annum	1	1	1
7076	potassium dichromate	7778-50-9	YES	3				multiple tonnage bands because multiple submissions	1	1	1
7108	Lead hydrogen arsenate	7784-40-9	YES	3						1	1
7129	ammonium dichromate	7789-09-5	YES	3				Intermediate Use Only	1	1	1

The results of the screening do not constitute evaluations of individual substances to be carried out under the respective chemical legislations [[in particular, Regulation (EC) No 1107/2009 on plant protection products, Regulation (EU) No 528/2012 on biocidal products, Regulation (EC) No 1907/2006 REACH, Regulation (EC) No 1223/2009 on cosmetic products and the Water Framework Directive (EC) No 2000/60] and in no way prejudice future decisions on active substances to be taken pursuant to these pieces of the EU legislation.

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Screening of available evidence on chemical substances for the identification of endocrine disruptors according to different options in the context of an Impact Assessment

	Chemical Name	CAS	Miscellaneous to be screened	Criteria for Selection for ED IA (REACH Chemicals) - as provided by JRC	EFSA (no approved/pending	biocides not yet approved	cosmetics	REACH tonnage band*	REACH*	CMR CLP classification	STOT-RE CLP classification
7147	Cadmium fluoride	7790-79-6	YES	3						1	1
7150	ammonium perchlorate	7790-98-9	YES	5				1,000 - 10,000 tonnes per annum	1		1
7157	tetraethyllead	78-00-2	YES	3				1,000 - 10,000 tonnes per annum	1	1	1
7215	2-Chloroacetamide	79-07-2	YES				1	100 - 1,000 tonnes per annum	1	1	
7222	N-methylacetamide	79-16-3	YES	3				Tonnage Data Confidential	1	1	
7261	2,2',6,6'-tetrabromo-4,4'-isopropylidenediphenol (TBBPA)	79-94-7	YES	5				1,000 - 10,000 tonnes per annum	1		
7274	4,4'-isopropylidenediphenol (Bisphenol A)	80-05-7	YES	5				1,000,000+ tonnes per annum	1	1	
7279	dapsone (TETRAHYDROMYRCENYL ACETATE)	80-08-0	YES	5				multiple tonnage bands	1		1

The results of the screening do not constitute evaluations of individual substances to be carried out under the respective chemical legislations [[in particular, Regulation (EC) No 1107/2009 on plant protection products, Regulation (EU) No 528/2012 on biocidal products, Regulation (EC) No 1907/2006 REACH, Regulation (EC) No 1223/2009 on cosmetic products and the Water Framework Directive (EC) No 2000/60] and in no way prejudice future decisions on active substances to be taken pursuant to these pieces of the EU legislation.

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	Chemical Name	CAS	Miscellaneous to be screened	Criteria for Selection for ED IA (REACH Chemicals) - as provided by JRC	EFSA (no approved/pending	biocides not yet approved	cosmetics	REACH tonnage band*	REACH*	CMR CLP classification	STOT-RE CLP classification
								because multiple submissions			
7281	4,4'-sulphonyldiphenol (Bisphenol S)	80-09-1	YES	5				1,000 - 10,000 tonnes per annum	1		
7285	pyrochlore, antimony lead yellow	8012-00-8	YES	3				10 - 100 tonnes per annum	1	1	1
7298	p-(1,1-dimethylpropyl)phenol	80-46-6	YES	5				100 - 1,000 tonnes per annum	1		
7322	Musk Ketone (also as 4'-tert-Butyl-2',6'-dimethyl-3',5'-dinitroacetophenone)	81-14-1	YES				1			1	
7323	Musk Xylene (also as 5-tert-Butyl-2,4,6-trinitro-m-xylene)	81-15-2	YES				1			1	
7369	1-Methyl-2,6-diaminobenzene (also as 2-Methyl-m-phenylenediamine OR Toluene-2,6-diamine)	823-40-5	YES				1			1	
7437	2-amino-4-hydroxyethylaminoanisol	83763-48-8 (relevant	YES				1				1

The results of the screening do not constitute evaluations of individual substances to be carried out under the respective chemical legislations [[in particular, Regulation (EC) No 1107/2009 on plant protection products, Regulation (EU) No 528/2012 on biocidal products, Regulation (EC) No 1907/2006 REACH, Regulation (EC) No 1223/2009 on cosmetic products and the Water Framework Directive (EC) No 2000/60] and in no way prejudice future decisions on active substances to be taken pursuant to these pieces of the EU legislation.

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	Chemical Name	CAS	Miscellaneous to be screened	Criteria for Selection for ED IA (REACH Chemicals) - as provided by JRC	EFSA (no approved/pending	biocides not yet approved	cosmetics	REACH tonnage band*	REACH*	CMR CLP classification	STOT-RE CLP classification
	sulfate	also for 83763-47-7)									
7503	Distillates (coal tar), naphthalene oils,naphthalene oil	84650-04-4	YES	4						1	
7505	Diethyl phthalate	84-66-2	YES	5			1	multiple tonnage bands because multiple submissions	1	1	1
7507	diisobutyl phthalate (BIPB)	84-69-5	YES	2, 3				multiple tonnage bands because multiple submissions	1	1	
7511	dibutyl phthalate	84-74-2	YES	2, 3, 4				multiple tonnage bands because multiple submissions	1	1	

The results of the screening do not constitute evaluations of individual substances to be carried out under the respective chemical legislations [[in particular, Regulation (EC) No 1107/2009 on plant protection products, Regulation (EU) No 528/2012 on biocidal products, Regulation (EC) No 1907/2006 REACH, Regulation (EC) No 1223/2009 on cosmetic products and the Water Framework Directive (EC) No 2000/60] and in no way prejudice future decisions on active substances to be taken pursuant to these pieces of the EU legislation.

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	Chemical Name	CAS	Miscellaneous to be screened	Criteria for Selection for ED IA (REACH Chemicals) - as provided by JRC	EFSA (no approved/pending	biocides not yet approved	cosmetics	REACH tonnage band*	REACH*	CMR CLP classification	STOT-RE CLP classification
7512	Dihexyl phthalate	84-75-3	YES	3						1	
7516	1,2-Benzenedicarboxylic acid, dipentylester, branched and linear	84777-06-0	YES	3						1	
7578	6,6'-di-tert-butyl-4,4'-butylidenedi-m-cresol	85-60-9	YES	5				100 - 1,000 tonnes per annum	1		1
7581	benzyl butyl phthalate	85-68-7	YES	2, 3, 4				1,000 - 10,000 tonnes per annum	1	1	1
7645	dioctyltin oxide	870-08-6	YES	5				1,000 - 10,000 tonnes per annum	1	1	1
7657	N-Methyl-2-pyrrolidone (Methyl Pyrrolidone)	872-50-4 (also relevant for 51013-18-4)	YES	3			1	10,000 - 100,000 tonnes per annum	1	1	1
7740	dinoseb	88-85-7	YES	3				1,000 - 10,000 tonnes per annum	1	1	1
7749	triphenyltin hydride (based on the CAS No)	892-20-6	YES (Triphenyltin salts)	4							

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Screening of available evidence on chemical substances for the identification of endocrine disruptors according to different options in the context of an Impact Assessment

	Chemical Name	CAS	Miscellaneous to be screened	Criteria for Selection for ED IA (REACH Chemicals) - as provided by JRC	EFSA (no approved/pending	biocides not yet approved	cosmetics	REACH tonnage band*	REACH*	CMR CLP classification	STOT-RE CLP classification
7870	Fatty acids, C16-18, lead salts	91031-62-8	YES	3						1	1
8027	Hydroxyethyl-p-phenylenediamine sulfate (3-(2-Hydroxyethyl)-p-phenylenediammonium sulphate)	93841-25-9	YES				1				1
8046	propyl 4-hydroxybenzoate (propylparaben)	94-13-3	YES	5				100 - 1,000 tonnes per annum	1		
8049	Hydroxyethyl-3,4-methylenedioxyaniline HCl	94158-14-2	YES				1				1
8099	benzotriazole	95-14-7	YES	5				1,000 - 10,000 tonnes per annum	1	1	
8119	o-Aminophenol (also relevant for o-Aminophenol (o-Aminophenol; CI 76520) and its salts)	95-55-6 (also relevant for 67845-79-8 & 51-19-4)	YES				1	Intermediate Use Only	1	1	
8170	1,2,3-trichloropropane	96-18-4	YES	3				1,000 - 10,000 tonnes per annum	1	1	1
8185	imidazolidine-2-thione (ETU)	96-45-7	YES	3				100 - 1,000	1	1	1

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	Chemical Name	CAS	Miscellaneous to be screened	Criteria for Selection for ED IA (REACH Chemicals) - as provided by JRC	EFSA (no approved/pending	biocides not yet approved	cosmetics	REACH tonnage band*	REACH*	CMR CLP classification	STOT-RE CLP classification
								tonnes per annum			
8194	6,6'-di-tert-butyl-4,4'-thiodi-m-cresol	96-69-5	YES	5				100 - 1,000 tonnes per annum	1		
8196	2,4-di-tert-butylphenol	96-76-4	YES	5				multiple tonnage bands because multiple submissions	1		1
8250	Furfural	98-01-1	YES				1	10,000 - 100,000 tonnes per annum	1	1	
8276	4-tert-butylphenol	98-54-4	YES	5				multiple tonnage bands because multiple submissions	1	1	1
8296	nitrobenzene	98-95-3	YES					multiple tonnage bands	1	1 Repr. 1B (F) Carc. 2	1 (blood)

The results of the screening do not constitute evaluations of individual substances to be carried out under the respective chemical legislations [[in particular, Regulation (EC) No 1107/2009 on plant protection products, Regulation (EU) No 528/2012 on biocidal products, Regulation (EC) No 1907/2006 REACH, Regulation (EC) No 1223/2009 on cosmetic products and the Water Framework Directive (EC) No 2000/60] and in no way prejudice future decisions on active substances to be taken pursuant to these pieces of the EU legislation.

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	Chemical Name	CAS	Miscellaneous to be screened	Criteria for Selection for ED IA (REACH Chemicals) - as provided by JRC	EFSA (no approved/pending	biocides not yet approved	cosmetics	REACH tonnage band*	REACH*	CMR CLP classification	STOT-RE CLP classification
								because multiple submissions			
8331	methyl 4-hydroxybenzoate (methylparaben)	99-76-3	YES	5				1,000 - 10,000 tonnes per annum	1	1	
8341	4-hydroxybenzoic acid (p-hydroxybenzoic acid)	99-96-7	YES	5				1,000 - 10,000 tonnes per annum	1		
8372a	Ethylparaben	120-47-8	YES		1						1 (Butylparaben Propylparaben Methylparaben Ethylparaben)
8372b	Isopropylparaben (Isopropyl 4-hydroxybenzoate)	4191-73-5	YES								
8372c	Butylparaben (Butyl 4-hydroxybenzoate)	94-26-8	YES								
8372d	Isobutyl paraben (Isobutyl 4-hydroxybenzoate (INCI:	4247-02-3 (224-208-8)	YES								

The results of the screening do not constitute evaluations of individual substances to be carried out under the respective chemical legislations [[in particular, Regulation (EC) No 1107/2009 on plant protection products, Regulation (EU) No 528/2012 on biocidal products, Regulation (EC) No 1907/2006 REACH, Regulation (EC) No 1223/2009 on cosmetic products and the Water Framework Directive (EC) No 2000/60] and in no way prejudice future decisions on active substances to be taken pursuant to these pieces of the EU legislation.

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	Chemical Name	CAS	Miscellaneous to be screened	Criteria for Selection for ED IA (REACH Chemicals) - as provided by JRC	EFSA (no approved/pending	biocides not yet approved	cosmetics	REACH tonnage band*	REACH*	CMR CLP classification	STOT-RE CLP classification
	Isobutylparaben) /Sodium salt or Salts of Isobutylparaben)										

The results of the screening do not constitute evaluations of individual substances to be carried out under the respective chemical legislations [[in particular, Regulation (EC) No 1107/2009 on plant protection products, Regulation (EU) No 528/2012 on biocidal products, Regulation (EC) No 1907/2006 REACH, Regulation (EC) No 1223/2009 on cosmetic products and the Water Framework Directive (EC) No 2000/60] and in no way prejudice future decisions on active substances to be taken pursuant to these pieces of the EU legislation.

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Chemical Inventory of miscellaneous chemicals (Part 2)

Criteria for selection of REACH Chemicals:

1. All substances on the Candidate List already identified as SVHCs because of ED concerns under Art. 57(f)
2. All substances for which an SVHC opinion on the identification of the substance as SVHC due to its endocrine disrupting properties was provided by the Member State Committee at ECHA
3. All substances on the Candidate list identified as SVHC because of reprotoxicity 1A/1B
4. Select all substances listed in Annex XVII for restrictions due to a ED concern or because of having a harmonised classification as reprotoxic 1A/1B
5. All substances placed on CoRAP due to ED concern

1 EASIS data available; to be considered

(1) EASIS data available; not to be considered

[±] EASIS data not available although originally marked as such

[1] Found in SIN List; Reason for inclusion is captured in the Data sheet.

	Chemical Name	CAS	WFD	CoRAP with ED label	SIN ED label	ECHA ED EG	Tedx	EASIS	ToxCast	REACH candidate list	REACH restriction list	REACH authorisation list	EDSP
450	propargite	2312-35-8		1					1				1
557	Oligomerisation and alkylation reaction products of 2-phenylpropene and phenol [Previously registered as Phenol, methylstyrenated - EC N. 270-966-8 and CAS N. 68512-30-1]	700-960-7		1									
558	2,2',6,6'-Tetrabromo-4,4'-isopropylidenediphenol,			1									

The results of the screening do not constitute evaluations of individual substances to be carried out under the respective chemical legislations [[in particular, Regulation (EC) No 1107/2009 on plant protection products, Regulation (EU) No 528/2012 on biocidal products, Regulation (EC) No 1907/2006 REACH, Regulation (EC) No 1223/2009 on cosmetic products and the Water Framework Directive (EC) No 2000/60] and in no way prejudice future decisions on active substances to be taken pursuant to these pieces of the EU legislation.

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	Chemical Name	CAS	WFD	CoRAP with ED label	SIN ED label	ECHA ED EG	Tedx	EASIS	ToxCast	REACH candidate list	REACH restriction list	REACH authorisation list	EDSP
	oligomeric reaction products with Propylene oxide and n-butyl glycidyl ether												
559	reaction mass of 1-(1,2,3,4,5,6,7,8-octahydro-2,3,8,8-tetramethyl-2-naphthyl)ethan-1-one and 1-(1,2,3,4,6,7,8,8a-octahydro-2,3,8,8-tetramethyl-2-naphthyl)ethan-1-one and 1-(1,2,3,5,6,7,8,8a-octahydro-2,3,8,8-tetramethyl-2-naphthyl)ethan-1-one			1									
560	reaction mass of 2-ethylhexyl 10-ethyl-4,4-dioctyl-7-oxo-8-oxa-3,5-dithia-4-stannatetradecanoate and 2-ethylhexyl 10-ethyl-4-[[2-[(2-ethylhexyl)oxy]-2-oxoethyl]thio]-4-octyl-7-oxo-8-oxa-3,5-dithia-4-stannatetradecanoate (reaction mass of DOTE and MOTE)									1			
561	4-Nonylphenol, branched and linear, ethoxylated [substances with a linear and/or branched alkyl chain with a carbon number of 9 covalently bound in position 4 to phenol, ethoxylated covering									1			

The results of the screening do not constitute evaluations of individual substances to be carried out under the respective chemical legislations [[in particular, Regulation (EC) No 1107/2009 on plant protection products, Regulation (EU) No 528/2012 on biocidal products, Regulation (EC) No 1907/2006 REACH, Regulation (EC) No 1223/2009 on cosmetic products and the Water Framework Directive (EC) No 2000/60] and in no way prejudice future decisions on active substances to be taken pursuant to these pieces of the EU legislation.

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	Chemical Name	CAS	WFD	CoRAP with ED label	SIN ED label	ECHA ED EG	Tedx	EASIS	ToxCast	REACH candidate list	REACH restriction list	REACH authorisation list	EDSP
	UVCB- and well-defined substances, polymers and homologues, which include any of the individual isomers and/or combinations thereof]												
562	4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated [covering well-defined substances and UVCB substances, polymers and homologues]	9036-19-5			[1]					1			
563	4-Nonylphenol, branched and linear [substances with a linear and/or branched alkyl chain with a carbon number of 9 covalently bound in position 4 to phenol, covering also UVCB- and well-defined substances which include any of the individual isomers or a combination thereof]									1			
580	Dibutyltin (DBT) (Dibutyl stannane)	1002-53-5			1		1	1					
651	lead dinitrate	10099-74-8			[1]		1			1			
656	triphenyl phosphite	101-02-0		1					1				
659	cadmium chloride	10108-64-2					1			1			
670	cadmium sulphate	10124-36-4; Additional CAS								1			

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It would thus be erroneous to consider that the substances listed in the results of this study (SANTE/2015/E3/SI2.706218) are considered as endocrine disruptors within the meaning of the EU legislation.

Screening of available evidence on chemical substances for the identification of endocrine disruptors according to different options in the context of an Impact Assessment

	Chemical Name	CAS	WFD	CoRAP with ED label	SIN ED label	ECHA ED EG	Tedx	EASIS	ToxCast	REACH candidate list	REACH restriction list	REACH authorisation list	EDSP
		No: 31119-53-6											
673	cobalt sulphate [Cobalt(II) sulphate]	10124-43-3								1			
682	cobalt dinitrate [Cobalt(II) dinitrate]	10141-05-6								1			
687	N-Phenyl-P-Phenylenediamine [N-(4-aminophenyl)aniline]	101-54-2							1				
912	sodium dichromate	10588-01-9 (Additional CAS No: 7789-12-0)											
952	p-cresol	106-44-5		1			1	{1}	1				
960	p-phenylenediamine	106-50-3											
989	1-bromopropane (n-propyl bromide)	106-94-5						1		1			
1080	Resorcinol (1,3-benzenediol)	108-46-3		1	1		1	1	1				
1151	2-methoxyethanol (ethylene glycol monomethyl ether)	109-86-4					1		1	1			
1182	2-methoxyethyl acetate	110-49-6											
1196	1,2-dimethoxyethane	110-71-4								1			
1202	2-ethoxyethanol	110-80-5					1		1	1			
1228	2-ethoxyethyl acetate	111-15-9							1	1			
1234	Silicic acid, lead salt	11120-22-2			[1]					1			

The results of the screening do not constitute evaluations of individual substances to be carried out under the respective chemical legislations [[in particular, Regulation (EC) No 1107/2009 on plant protection products, Regulation (EU) No 528/2012 on biocidal products, Regulation (EC) No 1907/2006 REACH, Regulation (EC) No 1223/2009 on cosmetic products and the Water Framework Directive (EC) No 2000/60] and in no way prejudice future decisions on active substances to be taken pursuant to these pieces of the EU legislation.

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Screening of available evidence on chemical substances for the identification of endocrine disruptors according to different options in the context of an Impact Assessment

	Chemical Name	CAS	WFD	CoRAP with ED label	SIN ED label	ECHA ED EG	Tedx	EASIS	ToxCast	REACH candidate list	REACH restriction list	REACH authorisation list	EDSP
1280	Ethylene Glycol Monobutyl Ether (2-Butoxyethanol)	111-76-2							1				
1281	2-(2-methoxyethoxy)ethanol (DEGME)	111-77-3							1		1		
1298	Diethylene glycol monobutyl ether (ethoxydiglycol)	111-90-0							1				
1303	dimethyl glutarate	1119-40-0		1					1				
1305	bis(2-methoxyethyl) ether	111-96-6							1	1		1	
1350	1,2-bis(2-methoxyethoxy)ethane	112-49-2							1	1			
1436	triphenyl phosphate	115-86-6		1	1		1		1				
1439	tris(2-chloroethyl) phosphate (TCEP)	115-96-8							1	1		1	
1484	bis(2-ethylhexyl) phthalate (DEHP)	117-81-7	1				1	(1)	1	1	1	1	
1486	Bis(2-methoxyethyl) phthalate	117-82-8								1			
1519	2,2',6,6'-tetra-tert-butyl-4,4'-methylenediphenol	118-82-1		1		1							
1611	lead oxide sulfate (basic lead sulphate)	12036-76-9			[1]					1			
1631	lead titanium trioxide	12060-00-3			[1]					1			
1637	pentalead tetraoxide sulphate (tetrabasic lead sulphate)	12065-90-6			[1]					1			
1678	trilead dioxide phosphonate (dibasic lead phosphite)	12141-20-7			[1]					1			

The results of the screening do not constitute evaluations of individual substances to be carried out under the respective chemical legislations [[in particular, Regulation (EC) No 1107/2009 on plant protection products, Regulation (EU) No 528/2012 on biocidal products, Regulation (EC) No 1907/2006 REACH, Regulation (EC) No 1223/2009 on cosmetic products and the Water Framework Directive (EC) No 2000/60] and in no way prejudice future decisions on active substances to be taken pursuant to these pieces of the EU legislation.

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	Chemical Name	CAS	WFD	CoRAP with ED label	SIN ED label	ECHA ED EG	Tedx	EASIS	ToxCast	REACH candidate list	REACH restriction list	REACH authorisation list	EDSP
1719	tetralead trioxide sulphate (tribasic lead sulphate)	12202-17-4			[1]					1			
1737	Low temperature tar oil, alkaline, extract residues (coal), low temperature coal tar alkaline	122384-78-5									1		
1778	p-aminophenol	123-30-8											
1870	dioxobis(stearato)trilead (dibasic lead stearate)	12578-12-0			[1]					1			
1884	Lead titanium zirconium oxide	12626-81-2			[1]					1			
1892	lead chromate molybdate sulfate red	12656-85-8								1		1	
1925	N,N-dimethylacetamide	127-19-5								1			
2042	Dipentyl phthalate (DPP)	131-18-0					1	1	1	1			
2061	orange lead (lead tetroxide)	1314-41-6			[1]					1			
2081	Benzophenone-3 (oxybenzone)	131-57-7		1	1		1	1					
2091	lead monoxide (lead oxide)	1317-36-8			[1]					1			
2105	trilead bis(carbonate) dihydroxide (basic lead carbonate)	1319-46-6			[1]					1	1		
2191	lead diazide	13424-46-9			[1]					1			
2202	lead sulfochromate yellow	1344-37-2								1		1	
2324	lead bis(tetrafluoroborate)	13814-96-5			[1]					1			
2391	4-(1,1,3,3-tetramethylbutyl)phenol	140-66-9	1		1		1	[1]	1	1			

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	Chemical Name	CAS	WFD	CoRAP with ED label	SIN ED label	ECHA ED EG	Tedx	EASIS	ToxCast	REACH candidate list	REACH restriction list	REACH authorisation list	EDSP
2491	3-ethyl-2-methyl-2-(3-methylbutyl)-1,3-oxazolidine	143860-04-2								1			
2527	3-methylpyrazole	1453-58-3		1									
2543	tributyltin chloride	1461-22-9			1		1	(1)	1				
2544	tributyltin bromide	1461-23-0					1						
2594	2-Mercaptobenzothiazole (Benzothiazole-2-thiol)	149-30-4							1				
2625	3-Benzylidene camphor (1,7,7-trimethyl-3-(phenylmethylene)bicyclo[2.2.1]heptan-2-one)	15087-24-8			1		1	1					
2633	Sodium perborate,perboric acid, sodium salt	15120-21-5 (11138-47-9)			[1]					1			
2657	lead 2,4,6-trinitro-m-phenylene dioxide (Lead styphnate)	15245-44-0			[1]					1			
2701	2-ethylhexyl 10-ethyl-4,4-dioctyl-7-oxo-8-oxa-3,5-dithia-4-stannatetradecanoate (DOTE)	15571-58-1								1			
2813	tert-butyl methyl ether	1634-04-4		1	1	1	1	{1}					
2863	2-Amino-3-hydroxypyridine (2-aminopyridin-3-ol)	16867-03-1											
2940	Lead(II) bis(methanesulfonate)	17570-76-2			[1]					1			
2945	ammonium thiocyanate	1762-95-4		1									
3040	octabenzene	1843-05-6		1					1				

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Screening of available evidence on chemical substances for the identification of endocrine disruptors according to different options in the context of an Impact Assessment

	Chemical Name	CAS	WFD	CoRAP with ED label	SIN ED label	ECHA ED EG	Tedx	EASIS	ToxCast	REACH candidate list	REACH restriction list	REACH authorisation list	EDSP
3152	p-METHYLAMINOPHENOL sulphate	1936-57-8											
3269	tributyltin	20763-88-6					1						
3278	lead cyanamidate	20837-86-9			[1]					1			
3588	tert-butyl-4-methoxyphenol	25013-16-5		1	1	1	1	1					
3590	Bisphenol-A-Epichlorhydrin Epoxy resin Average MW < 700 [4,4'-Isopropylidenediphenol, oligomeric reaction products with 1-chloro-2,3-epoxypropane]	25068-38-6		1				{1}					
3600	Phenol, nonyl- (Nonylphenol)	25154-52-3	1		1			{1}			1		
3601	trixyl phosphate	25155-23-1		1						1			
3708	bis(2-ethylhexyl) tetrabromophthalate (BEH-TEBP)	26040-51-7		1	[1]								
3824	Polyhexamethylene biguanide hydrochloride	27083-27-8											
4051	lead di(acetate) (also mentioned as lead acetate)	301-04-2			[1]		1			1			
4087	Paraformaldehyde	30525-89-4											
4270	Pentadecafluorooctanoic acid (PFOA)	335-67-1					1	(1)	1	1			
4280	Triclosan	3380-34-5		1	1		1	(1)	1				
4449	tributyltin-cation (same as tributyltin hydride, CAS: 688-73-3)	36643-28-4	1										

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	Chemical Name	CAS	WFD	CoRAP with ED label	SIN ED label	ECHA ED EG	Tedx	EASIS	ToxCast	REACH candidate list	REACH restriction list	REACH authorisation list	EDSP
4462	trilead diarsenate	3687-31-8			[1]					1			
4537	4-Methylbenzylidene camphor (3-(4'-Methylbenzylidene)-dl-camphor / Enzacamene)	38102-62-4 (36861-47-9)											
4548	Ammonium pentadecafluorooctanoate (APFO)	3825-26-1					1		1	1			
4960	Kojic Acid (5-hydroxy-2-hydroxymethyl-4-pyrone)	501-30-4											
4975	Benzo[a]pyrene	50-32-8	1				1	(1)			1		
5033	2-(2-butoxyethoxy)ethyl 6-propylpiperonyl ether (PBO)	51-03-6		1			1	{1}	1				
5047	Quaternium-15 (cis-isomer)	51229-78-8						{1}					
5065	cobalt carbonate	513-79-1								1			
5067	Acetic acid, lead salt, basic	51404-69-4			[1]					1			
5160	Camphor benzalkonium methosulfate (Methyl N,N,N-trimethyl-4-[(4,7,7-trimethyl-3-oxobicyclo[2.2.1]hept-2-ylidene)methyl]anilinium sulphate)	52793-97-2											
5202	bis(2-propylheptyl) phthalate	53306-54-0		1									
5209	1,2,4-trihydroxybenzene (Benzene-1,2,4-triol)	533-73-3					1	{1}					
5272	Decamethylcyclopentasiloxane (mentioned as Cyclomethicone	541-02-6 (all 69430-24-6 /					1						

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	Chemical Name	CAS	WFD	CoRAP with ED label	SIN ED label	ECHA ED EG	Tedx	EASIS	ToxCast	REACH candidate list	REACH restriction list	REACH authorisation list	EDSP
	and Cyclopentasiloxane)	556-67-2 / 541-02-6 / 540-97-6)											
5324	2-Ethylhexyl-4-methoxycinnamate (Oxtinoxate or Ethylhexyl Methoxycinnamate)	5466-77-3		1	1		1	1					
5382	Cyclomethicone Octamethylcyclotetrasiloxane	556-67-2			1		1	{1}	1				
5443	Tributyltin (tributyltin chloride?)	56573-85-4			1								
5706	diisopentyl phthalate	605-50-5								1			
5760	toluene-2,5-diamine sulfatate (2-methyl-p-phenylenediamine sulfatate)	615-50-9											
5786	Phenol, styrenated	61788-44-1		1									
5822	Sulfurous acid, lead salt, dibasic (basic lead sulphate)	62229-08-7			[1]					1			
5851	methoxyacetic acid	625-45-6					1			1			
5880	1,2-Diethoxyethane	629-14-1								1			
5962	Triphenyltin chloride	639-58-7			1		1	{1}					
6014	Lead dipicrate	6477-64-1			[1]					1			
6071	Tar acids, coal, crude, crude phenols	65996-85-2									1		
6132	Triphenyltin	668-34-8			1			1					

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	Chemical Name	CAS	WFD	CoRAP with ED label	SIN ED label	ECHA ED EG	Tedx	EASIS	ToxCast	REACH candidate list	REACH restriction list	REACH authorisation list	EDSP
6223	N,N-dimethylformamide	68-12-2			[1]		1	{1}	1	1			
6277	dibutyltin dichloride (DBTCl ₂)	683-18-1			1		1	1		1			
6325	1,2-Benzenedicarboxylic acid, di-C7-11-branched and linear alkyl esters	68515-42-4								1			
6330	1,2-Benzenedicarboxylic acid, dihexylester, branched and linear (Diisohexyl phthalate -DIHP)	68515-50-4								1			
6331	1,2-Benzenedicarboxylic acid, di-C6-10-alkyl esters	68515-51-5 (Additional Cas No: 68648-93-1)											
6369	2,2'-dimethyl-4,4'-methylenebis(cyclohexylamine)	6864-37-5		1									
6384	Silicic acid (H ₂ Si ₂ O ₅), barium salt (1:1), lead-doped	68784-75-8			[1]					1			
6440	[phthalato(2-)]dioxotrilead (dibasic lead phthalate)	69011-06-9			[1]					1			
6518	3-amino-2,6-dimethylphenol	6994-64-5											
6593	cobalt di(acetate) [Cobalt(II) diacetate]	71-48-7								1			
6600	Isopentyl-p-Methoxycinnamate (Amiloxate)	71617-10-2		1									
6618	1,2-Benzenedicarboxylic acid, di-	71888-89-6								1			

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	Chemical Name	CAS	WFD	CoRAP with ED label	SIN ED label	ECHA ED EG	Tedx	EASIS	ToxCast	REACH candidate list	REACH restriction list	REACH authorisation list	EDSP
	C6-8-branched alkyl esters, C7-rich												
6731	mercury	7439-97-6					1	{4}			1		
6789	chloromethane (Methyl chloride)	74-87-3		1									
6810	Acetaldehyde	75-07-0											
6812	Dichloromethane	75-09-2	1				1				1		
6814	Di- μ -oxo-di-n-butylstanniohydroxyborane/ Dibutyltin hydrogen borate C ₈ H ₁₉ BO ₃ Sn (DBB)	75113-37-0									1		
6815	formamide	75-12-7								1			
6817	carbon disulphide	75-15-0		1	1		1	1					
6900	sodium perchlorate	7601-89-0		1			1						
6932	Sodium peroxometaborate	7632-04-4								1			
6941	Cobalt dichloride	7646-79-9					1			1			
7051	Lead chromate	7758-97-6								1		1	
7055	N-pentyl-isopentylphthalate	776297-69-9								1			
7065	sodium chromate	7775-11-3								1			
7076	potassium dichromate	7778-50-9								1		1	
7108	Lead hydrogen arsenate	7784-40-9			[1]					1			
7129	ammonium dichromate	7789-09-5								1		1	
7147	Cadmium fluoride	7790-79-6								1			

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Screening of available evidence on chemical substances for the identification of endocrine disruptors according to different options in the context of an Impact Assessment

	Chemical Name	CAS	WFD	CoRAP with ED label	SIN ED label	ECHA ED EG	Tedx	EASIS	ToxCast	REACH candidate list	REACH restriction list	REACH authorisation list	EDSP
7150	ammonium perchlorate	7790-98-9		1			1						
7157	tetraethyllead	78-00-2			[1]					1			
7215	2-Chloroacetamide	79-07-2											
7222	N-methylacetamide	79-16-3							1	1			
7261	2,2',6,6'-tetrabromo-4,4'-isopropylidenediphenol (TBBPA)	79-94-7		1	1		1	(1)	1				
7274	4,4'-isopropylidenediphenol (Bisphenol A)	80-05-7		1	1		1	(1)	1				
7279	dapsone (TETRAHYDROMYRCENYL ACETATE)	80-08-0		1					1				
7281	4,4'-sulphonyldiphenol (Bisphenol S)	80-09-1		1	1	1	1	1					
7285	pyrochlore, antimony lead yellow	8012-00-8			[1]					1			
7298	p-(1,1-dimethylpropyl)phenol	80-46-6		1		1	1	1	1				
7322	Musk Ketone (also as 4'-tert-Butyl-2',6'-dimethyl-3',5'-dinitroacetophenone)	81-14-1					1	{1}					
7323	Musk Xylene (also as 5-tert-Butyl-2,4,6-trinitro-m-xylene)	81-15-2					1			1		1	
7369	1-Methyl-2,6-diamino-benzene (also as 2-Methyl-m-phenylenediamine OR Toluene-2,6-diamine)	823-40-5											
7437	2-amino-4-	83763-48-8											

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	Chemical Name	CAS	WFD	CoRAP with ED label	SIN ED label	ECHA ED EG	Tedx	EASIS	ToxCast	REACH candidate list	REACH restriction list	REACH authorisation list	EDSP
	hydroxyethylaminoanisole sulfate	(relevant also for 83763-47-7)											
7503	Distillates (coal tar), naphthalene oils, naphthalene oil	84650-04-4									1		
7505	Diethyl phthalate	84-66-2		1	1		1	1	1				
7507	diisobutyl phthalate (BIPB)	84-69-5					1	{1}	1	1		1	
7511	dibutyl phthalate	84-74-2					1	(1)	1	1	1	1	
7512	Dihexyl phthalate	84-75-3			1		1	1	1	1			
7516	1,2-Benzenedicarboxylic acid, dipentylester, branched and linear	84777-06-0								1			
7578	6,6'-di-tert-butyl-4,4'-butylidenedi-m-cresol	85-60-9		1									
7581	benzyl butyl phthalate	85-68-7					1	(1)	1	1	1	1	
7645	dioctyltin oxide	870-08-6		1									
7657	N-Methyl-2-pyrrolidone (Methyl Pyrrolidone)	872-50-4 (also relevant for 51013-18-4)							1	1			
7740	dinoseb	88-85-7					1	{1}	1	1			
7749	triphenyltin hydride (based on the CAS No)	892-20-6					1						
7870	Fatty acids, C16-18, lead salts	91031-62-8								1			
8027	Hydroxyethyl-p-phenylenediamine sulfate (3-(2-Hydroxyethyl)-p-	93841-25-9											

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Screening of available evidence on chemical substances for the identification of endocrine disruptors according to different options in the context of an Impact Assessment

	Chemical Name	CAS	WFD	CoRAP with ED label	SIN ED label	ECHA ED EG	Tedx	EASIS	ToxCast	REACH candidate list	REACH restriction list	REACH authorisation list	EDSP
	phenylenediammonium sulphate)												
8046	propyl 4-hydroxybenzoate (propylparaben)	94-13-3		1	1		1	1	1				
8049	Hydroxyethyl-3,4-methylenedioxyaniline HCl	94158-14-2											
8099	benzotriazole	95-14-7		1									
8119	o-Aminophenol (also relevant for o-Aminophenol (o-Aminophenol; CI 76520) and its salts)	95-55-6 (also relevant for 67845-79-8 & 51-19-4)											
8170	1,2,3-trichloropropane	96-18-4								1			
8185	imidazolidine-2-thione (ETU)	96-45-7					1	1	1	1			
8194	6,6'-di-tert-butyl-4,4'-thiodi-m-cresol	96-69-5		1									
8196	2,4-di-tert-butylphenol	96-76-4		1					1				
8250	Furfural	98-01-1							1				
8276	4-tert-butylphenol	98-54-4		1	1	1	1	{1}	1				
8296	nitrobenzene	98-95-3					1		1				
8331	methyl 4-hydroxybenzoate (methylparaben)	99-76-3		1	1 (evaluated)	1	1	1	1				
8341	4-hydroxybenzoic acid (p-hydroxybenzoic acid)	99-96-7		1			1	{1}					
8372 a	Ethylparaben	120-47-8			1 (evaluated)		1						

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The results of the screening do not constitute evaluations of individual substances to be carried out under the respective chemical legislations [[in particular, Regulation (EC) No 1107/2009 on plant protection products, Regulation (EU) No 528/2012 on biocidal products, Regulation (EC) No 1907/2006 REACH, Regulation (EC) No 1223/2009 on cosmetic products and the Water Framework Directive (EC) No 2000/60] and in no way prejudice future decisions on active substances to be taken pursuant to these pieces of the EU legislation.

It would thus be erroneous to consider that the substances listed in the results of this study (SANTE/2015/E3/SI2.706218) are considered as endocrine disruptors within the meaning of the EU legislation.

	Chemical Name	CAS	WFD	CoRAP with ED label	SIN ED label	ECHA ED EG	Tedx	EASIS	ToxCast	REACH candidate list	REACH restriction list	REACH authorisation list	EDSP
8372 b	Isopropylparaben (Isopropyl 4-hydroxybenzoate)	4191-73-5					1						
8372 c	Butylparaben (Butyl 4-hydroxybenzoate)	94-26-8			[1]		1						
8372 d	Isobutyl paraben (Isobutyl 4-hydroxybenzoate (INCI: Isobutylparaben) /Sodium salt or Salts of Isobutylparaben)	4247-02-3 (224-208-8)					1						

The results of the screening do not constitute evaluations of individual substances to be carried out under the respective chemical legislations [[in particular, Regulation (EC) No 1107/2009 on plant protection products, Regulation (EU) No 528/2012 on biocidal products, Regulation (EC) No 1907/2006 REACH, Regulation (EC) No 1223/2009 on cosmetic products and the Water Framework Directive (EC) No 2000/60] and in no way prejudice future decisions on active substances to be taken pursuant to these pieces of the EU legislation.

It would thus be erroneous to consider that the substances listed in the results of this study (SANTE/2015/E3/SI2.706218) are considered as endocrine disruptors within the meaning of the EU legislation.

Chemical Inventory of miscellaneous chemicals (Part 3)

Criteria for selection of REACH Chemicals:

1. All substances on the Candidate List already identified as SVHCs because of ED concerns under Art. 57(f)
2. All substances for which an SVHC opinion on the identification of the substance as SVHC due to its endocrine disrupting properties was provided by the Member State Committee at ECHA
3. All substances on the Candidate list identified as SVHC because of reprotoxicity 1A/1B
4. Select all substances listed in Annex XVII for restrictions due to a ED concern or because of having a harmonised classification as reprotoxic 1A/1B
5. All substances placed on CoRAP due to ED concern

1 EASIS data available; to be considered

(1) EASIS data available; not to be considered

[±] EASIS data not available although originally marked as such

[1] Found in SIN List; Reason for inclusion is captured in the Data sheet.

	Chemical Name	CAS	ECHA C&L Inventory - ATP Inserted/Updated	ECHA - Substance brief profile/Substance information	REACH - Registered substance: Data availability	CoRAP justification/decision availability	CAR availability
450	propargite	2312-35-8	CLP00	http://echa.europa.eu/brief-profile/-/briefprofile/100.017.279	1 active registrations under REACH, 1 Joint Submission(s) and 0 Individual Submission(s)	http://www.echa.europa.eu/documents/10162/13628/corap_justification_219-006-1_nl_en_2888_en.pdf	n.a.
557	Oligomerisation and alkylation reaction products of 2-phenylpropene and phenol [Previously registered as Phenol, methylstyrenated - EC N. 270-966-8 and CAS N. 68512-30-1]	700-960-7	No C&L harmonized	http://echa.europa.eu/brief-profile/-/briefprofile/100.228.163	3 active registrations under REACH, 1 Joint Submission(s) and 0 Individual Submission(s)	http://echa.europa.eu/information-on-chemicals/evaluation/community-rolling-action-plan/corap-table/-/dislist/details/0b0236e18	n.a.

The results of the screening do not constitute evaluations of individual substances to be carried out under the respective chemical legislations [[in particular, Regulation (EC) No 1107/2009 on plant protection products, Regulation (EU) No 528/2012 on biocidal products, Regulation (EC) No 1907/2006 REACH, Regulation (EC) No 1223/2009 on cosmetic products and the Water Framework Directive (EC) No 2000/60] and in no way prejudice future decisions on active substances to be taken pursuant to these pieces of the EU legislation.

It would thus be erroneous to consider that the substances listed in the results of this study (SANTE/2015/E3/SI2.706218) are considered as endocrine disruptors within the meaning of the EU legislation.

	Chemical Name	CAS	ECHA C&L Inventory - ATP Inserted/Updated	ECHA - Substance brief profile/Substance information	REACH - Registered substance: Data availability	CoRAP justification/decision availability	CAR availability
						07e432f	
558	2,2',6,6'-Tetrabromo-4,4'-isopropylidenediphenol, oligomeric reaction products with Propylene oxide and n-butyl glycidyl ether		No C&L harmonized	http://echa.europa.eu/brief-profile/-/briefprofile/100.108.129	1 active registrations under REACH, 0 Joint Submission(s) and 1 Individual Submission(s)	http://echa.europa.eu/information-on-chemicals/evaluation/community-rolling-action-plan/corap-table/-/dislist/details/0b0236e1807ece86	n.a.
559	reaction mass of 1-(1,2,3,4,5,6,7,8-octahydro-2,3,8,8-tetramethyl-2-naphthyl)ethan-1-one and 1-(1,2,3,4,6,7,8,8a-octahydro-2,3,8,8-tetramethyl-2-naphthyl)ethan-1-one and 1-(1,2,3,5,6,7,8,8a-octahydro-2,3,8,8-tetramethyl-2-naphthyl)ethan-1-one		No C&L harmonized	http://echa.europa.eu/brief-profile/-/briefprofile/100.144.093	11 active registrations under REACH, 1 Joint Submission(s) and 0 Individual Submission(s)	http://echa.europa.eu/documents/10162/b460ac94-c0ca-4de8-b59c-3ad52a7b3314	n.a.
560	reaction mass of 2-ethylhexyl 10-ethyl-4,4-dioctyl-7-oxo-8-oxa-3,5-dithia-4-stannatetradecanoate and 2-ethylhexyl 10-ethyl-4-[[2-[(2-ethylhexyl)oxy]-2-oxoethyl]thio]-4-octyl-7-oxo-8-oxa-3,5-dithia-4-stannatetradecanoate (reaction mass of DOTE and MOTE)		No C&L harmonized	http://echa.europa.eu/substance-information/-/substanceinfo/other/6ea2db4b069c36dff70ea171fb102fefca53693509924345c682718ea6efe2f8	n.a.	n.a.	n.a.
561	4-Nonylphenol, branched and linear, ethoxylated [substances with a linear and/or branched alkyl chain with a carbon		No C&L harmonized	http://echa.europa.eu/substance-information/-	n.a.	n.a.	n.a.

The results of the screening do not constitute evaluations of individual substances to be carried out under the respective chemical legislations [[in particular, Regulation (EC) No 1107/2009 on plant protection products, Regulation (EU) No 528/2012 on biocidal products, Regulation (EC) No 1907/2006 REACH, Regulation (EC) No 1223/2009 on cosmetic products and the Water Framework Directive (EC) No 2000/60] and in no way prejudice future decisions on active substances to be taken pursuant to these pieces of the EU legislation.

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	Chemical Name	CAS	ECHA C&L Inventory - ATP Inserted/Updated	ECHA - Substance brief profile/Substance information	REACH - Registered substance: Data availability	CoRAP justification/decision availability	CAR availability
	number of 9 covalently bound in position 4 to phenol, ethoxylated covering UVCB- and well-defined substances, polymers and homologues, which include any of the individual isomers and/or combinations thereof]			/substanceinfo/100.105.797			
562	4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated [covering well-defined substances and UVCB substances, polymers and homologues]	9036-19-5	No C&L harmonized	http://echa.europa.eu/substance-information/-/substanceinfo/100.120.858	Pre-Registration process	n.a.	n.a.
563	4-Nonylphenol, branched and linear [substances with a linear and/or branched alkyl chain with a carbon number of 9 covalently bound in position 4 to phenol, covering also UVCB- and well-defined substances which include any of the individual isomers or a combination thereof]		CLP00 (4-nonylphenol, branched); CAS No. 84852-15-3	http://echa.europa.eu/substance-information/-/substanceinfo/100.239.149	n.a.	n.a.	n.a.
580	Dibutyltin (DBT) (Dibutyl stannane)	1002-53-5	No C&L harmonized	http://echa.europa.eu/substance-information/-/substanceinfo/100.150.199	No REACH registered substance	n.a.	n.a.
651	lead dinitrate	10099-74-8	No C&L harmonized for this specific compound;	http://echa.europa.eu/brief-profile/	7 active registrations under REACH, 1 Joint	n.a.	n.a.

The results of the screening do not constitute evaluations of individual substances to be carried out under the respective chemical legislations [[in particular, Regulation (EC) No 1107/2009 on plant protection products, Regulation (EU) No 528/2012 on biocidal products, Regulation (EC) No 1907/2006 REACH, Regulation (EC) No 1223/2009 on cosmetic products and the Water Framework Directive (EC) No 2000/60] and in no way prejudice future decisions on active substances to be taken pursuant to these pieces of the EU legislation.

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	Chemical Name	CAS	ECHA C&L Inventory - ATP Inserted/Updated	ECHA - Substance brief profile/Substance information	REACH - Registered substance: Data availability	CoRAP justification/decision availability	CAR availability
			See also Index No. 082-001-00-6 (CLP00) for "lead compounds with the exception of those specified elsewhere in this Annex" & Index No. 082-007-00-9 for "lead acetate, basic" CAS No. 1335-32-6.	/briefprofile/100.030.210	<u>Submission(s) and 0 Individual Submission(s)</u>		
656	triphenyl phosphite	101-02-0	CLP00	http://echa.europa.eu/brief-profile/-/briefprofile/100.002.645	7 active registrations under REACH, 1 Joint Submission(s) and 0 Individual Submission(s)	http://echa.europa.eu/documents/10162/13628/corap_justification_202-908-4_uk_2715_en.pdf	n.a.
659	cadmium chloride	10108-64-2	CLP00	http://echa.europa.eu/brief-profile/-/briefprofile/100.030.256	<u>2 active registrations under REACH, 1 Joint Submission(s) and 0 Individual Submission(s)</u>	n.a.	n.a.
670	cadmium sulphate	10124-36-4; Additional CAS No: 31119-53-6	CLP00	http://echa.europa.eu/brief-profile/-/briefprofile/100.030.288	<u>2 active registrations under REACH, 1 Joint Submission(s) and 0 Individual Submission(s)</u>	n.a.	n.a.
673	cobalt sulphate [Cobalt(II) sulphate]	10124-43-3	ATP01	http://echa.europa.eu/brief-profile/-/briefprofile/100.030.291	<u>14 active registrations under REACH, 1 Joint Submission(s) and 1 Individual Submission(s)</u>	n.a.	n.a.
682	cobalt dinitrate [Cobalt(II) dinitrate]	10141-05-6	ATP01corr	http://echa.europa.eu	<u>9 active registrations under</u>	n.a.	n.a.

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	Chemical Name	CAS	ECHA C&L Inventory - ATP Inserted/Updated	ECHA - Substance brief profile/Substance information	REACH - Registered substance: Data availability	CoRAP justification/decision availability	CAR availability
				u/brief-profile/-/briefprofile/100.030.353	REACH, 1 Joint Submission(s) and 1 Individual Submission(s)		
687	N-Phenyl-P-Phenylenediamine [N-(4-aminophenyl)aniline]	101-54-2	No C&L harmonized	http://echa.europa.eu/brief-profile/-/briefprofile/100.002.684	8 active registrations under REACH, 1 Joint Submission(s) and 0 Individual Submission(s)	n.a.	n.a.
912	sodium dichromate	10588-01-9 (Additional CAS No: 7789-12-0)	ATP01corr	http://echa.europa.eu/brief-profile/-/briefprofile/100.031.070	17 active registrations under REACH, 1 Joint Submission(s) and 0 Individual Submission(s)	n.a.	n.a.
952	p-cresol	106-44-5	CLP00	http://echa.europa.eu/brief-profile/-/briefprofile/100.003.090	8 active registrations under REACH, 1 Joint Submission(s) and 0 Individual Submission(s)	http://echa.europa.eu/documents/10162/7505ce07-d1cc-467e-bf7a-b9c0f324b9fd	n.a.
960	p-phenylenediamine	106-50-3	CLP00	http://echa.europa.eu/brief-profile/-/briefprofile/100.003.096	7 active registrations under REACH, 1 Joint Submission(s) and 3 Individual Submission(s)	n.a.	n.a.
989	1-bromopropane (n-propyl bromide)	106-94-5	CLP00	http://echa.europa.eu/brief-profile/-/briefprofile/100.003.133	10 active registrations under REACH, 1 Joint Submission(s) and 3 Individual Submission(s)	n.a.	n.a.
1080	Resorcinol (1,3-benzenediol)	108-46-3	CLP00	http://echa.europa.eu/brief-profile/-/briefprofile/100.003	4 active registrations under REACH, 1 Joint Submission(s) and 0	http://echa.europa.eu/information-on-chemicals/evaluation/com	n.a.

The results of the screening do not constitute evaluations of individual substances to be carried out under the respective chemical legislations [[in particular, Regulation (EC) No 1107/2009 on plant protection products, Regulation (EU) No 528/2012 on biocidal products, Regulation (EC) No 1907/2006 REACH, Regulation (EC) No 1223/2009 on cosmetic products and the Water Framework Directive (EC) No 2000/60] and in no way prejudice future decisions on active substances to be taken pursuant to these pieces of the EU legislation.

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	Chemical Name	CAS	ECHA C&L Inventory - ATP Inserted/Updated	ECHA - Substance brief profile/Substance information	REACH - Registered substance: Data availability	CoRAP justification/decision availability	CAR availability
				.260	Individual Submission(s)	munity-rolling-action-plan/corap-table/-/dislist/details/0b0236e1807eaff8	
1151	2-methoxyethanol (ethylene glycol monomethyl ether)	109-86-4	CLP00	http://echa.europa.eu/brief-profile/-/briefprofile/100.003.377	8 active registrations under REACH, 1 Joint Submission(s) and 0 Individual Submission(s)	n.a.	n.a.
1182	2-methoxyethyl acetate	110-49-6	CLP00	http://echa.europa.eu/substance-information/-/substanceinfo/100.003.431	Pre-registered substances	n.a.	n.a.
1196	1,2-dimethoxyethane	110-71-4	CLP00	http://echa.europa.eu/brief-profile/-/briefprofile/100.003.451	6 active registrations under REACH, 1 Joint Submission(s) and 0 Individual Submission(s)	n.a.	n.a.
1202	2-ethoxyethanol	110-80-5	ATP03	http://echa.europa.eu/brief-profile/-/briefprofile/100.003.459	7 active registrations under REACH, 1 Joint Submission(s) and 0 Individual Submission(s)	n.a.	n.a.
1228	2-ethoxyethyl acetate	111-15-9	CLP00/ATP01	http://echa.europa.eu/substance-information/-/substanceinfo/100.003.491	Pre-Registration process	n.a.	n.a.

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	Chemical Name	CAS	ECHA C&L Inventory - ATP Inserted/Updated	ECHA - Substance brief profile/Substance information	REACH - Registered substance: Data availability	CoRAP justification/decision availability	CAR availability
1234	Silicic acid, lead salt	11120-22-2	No C&L harmonized for this specific compound; See also Index No. 082-001-00-6 (CLP00) for "lead compounds with the exception of those specified elsewhere in this Annex" & Index No. 082-007-00-9 for "lead acetate, basic" CAS No. 1335-32-6.	http://echa.europa.eu/brief-profile/-/briefprofile/100.031.227	0 active registrations under REACH, 1 Joint Submission(s) and 0 Individual Submission(s)	n.a.	n.a.
1280	Ethylene Glycol Monobutyl Ether (2-Butoxyethanol)	111-76-2	CLP00	http://echa.europa.eu/brief-profile/-/briefprofile/100.003.550	19 active registrations under REACH, 1 Joint Submission(s) and 0 Individual Submission(s)	n.a.	n.a.
1281	2-(2-methoxyethoxy)ethanol (DEGME)	111-77-3	CLP00	http://echa.europa.eu/brief-profile/-/briefprofile/100.003.551	6 active registrations under REACH, 1 Joint Submission(s) and 0 Individual Submission(s)	n.a.	n.a.
1298	Diethylene glycol monobutyl ether (ethoxydiglycol)	111-90-0	No C&L harmonized	http://echa.europa.eu/brief-profile/-/briefprofile/100.003.563	10 active registrations under REACH, 1 Joint Submission(s) and 0 Individual Submission(s)	n.a.	n.a.
1303	dimethyl glutarate	1119-40-0	No C&L harmonized	http://echa.europa.eu/brief-profile/-/briefprofile/100.012	2 active registrations under REACH, 1 Joint Submission(s) and 0	http://echa.europa.eu/documents/10162/13eda1a8-4f68-4b6e-8559-	n.a.

The results of the screening do not constitute evaluations of individual substances to be carried out under the respective chemical legislations [[in particular, Regulation (EC) No 1107/2009 on plant protection products, Regulation (EU) No 528/2012 on biocidal products, Regulation (EC) No 1907/2006 REACH, Regulation (EC) No 1223/2009 on cosmetic products and the Water Framework Directive (EC) No 2000/60] and in no way prejudice future decisions on active substances to be taken pursuant to these pieces of the EU legislation.

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	Chemical Name	CAS	ECHA C&L Inventory - ATP Inserted/Updated	ECHA - Substance brief profile/Substance information	REACH - Registered substance: Data availability	CoRAP justification/decision availability	CAR availability
				.980	Individual Submission(s)	9bb66c1018bc	
1305	bis(2-methoxyethyl) ether	111-96-6	CLP00	http://echa.europa.eu/brief-profile/-/briefprofile/100.003.568	4 active registrations under REACH, 1 Joint Submission(s) and 0 Individual Submission(s)	n.a.	n.a.
1350	1,2-bis(2-methoxyethoxy)ethane	112-49-2	CLP00	http://echa.europa.eu/brief-profile/-/briefprofile/100.003.616	1 active registrations under REACH, 1 Joint Submission(s) and 0 Individual Submission(s)	n.a.	n.a.
1436	triphenyl phosphate	115-86-6	No C&L harmonized	http://echa.europa.eu/brief-profile/-/briefprofile/100.003.739	1 active registrations under REACH, 1 Joint Submission(s) and 0 Individual Submission(s)	http://echa.europa.eu/information-on-chemicals/evaluation/community-rolling-action-plan/corap-table/-/dislist/details/0b0236e1807eb287	n.a.
1439	tris(2-chloroethyl) phosphate (TCEP)	115-96-8	ATP01	http://echa.europa.eu/brief-profile/-/briefprofile/100.003.744	0 active registrations under REACH, 1 Joint Submission(s) and 0 Individual Submission(s)	n.a.	n.a.
1484	bis(2-ethylhexyl) phthalate (DEHP)	117-81-7	CLP00	http://echa.europa.eu/brief-profile/-/briefprofile/100.003.829	18 active registrations under REACH, 2 Joint Submission(s) and 0 Individual Submission(s)	n.a.	n.a.
1486	Bis(2-methoxyethyl) phthalate	117-82-8	CLP00	http://echa.europa.eu/substance-	Pre-Registration process	n.a.	n.a.

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	Chemical Name	CAS	ECHA C&L Inventory - ATP Inserted/Updated	ECHA - Substance brief profile/Substance information	REACH - Registered substance: Data availability	CoRAP justification/decision availability	CAR availability
				information/-/substanceinfo/100.003.830			
1519	2,2',6,6'-tetra-tert-butyl-4,4'-methylenediphenol	118-82-1	No C&L harmonized	http://echa.europa.eu/brief-profile/-/briefprofile/100.003.891	3 active registrations under REACH, 1 Joint Submission(s) and 0 Individual Submission(s)	http://echa.europa.eu/information-on-chemicals/evaluation/community-rolling-action-plan/corap-table/-/dislist/details/0b0236e180695054	n.a.
1611	lead oxide sulfate (basic lead sulphate)	12036-76-9	No C&L harmonized for this specific compound; See also Index No. 082-001-00-6 (CLP00) for "lead compounds with the exception of those specified elsewhere in this Annex" & Index No. 082-007-00-9 for "lead acetate, basic" CAS No. 1335-32-6.	http://echa.europa.eu/brief-profile/-/briefprofile/100.031.672	1 active registrations under REACH, 1 Joint Submission(s) and 0 Individual Submission(s)	n.a.	n.a.
1631	lead titanium trioxide	12060-00-3	No C&L harmonized for this specific compound; See also Index No. 082-001-00-6 (CLP00) for "lead compounds with	http://echa.europa.eu/brief-profile/-/briefprofile/100.031.841	1 active registrations under REACH, 1 Joint Submission(s) and 0 Individual Submission(s)	n.a.	n.a.

The results of the screening do not constitute evaluations of individual substances to be carried out under the respective chemical legislations [[in particular, Regulation (EC) No 1107/2009 on plant protection products, Regulation (EU) No 528/2012 on biocidal products, Regulation (EC) No 1907/2006 REACH, Regulation (EC) No 1223/2009 on cosmetic products and the Water Framework Directive (EC) No 2000/60] and in no way prejudice future decisions on active substances to be taken pursuant to these pieces of the EU legislation.

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	Chemical Name	CAS	ECHA C&L Inventory - ATP Inserted/Updated	ECHA - Substance brief profile/Substance information	REACH - Registered substance: Data availability	CoRAP justification/decision availability	CAR availability
			the exception of those specified elsewhere in this Annex" & Index No. 082-007-00-9 for "lead acetate, basic" CAS No. 1335-32-6.				
1637	pentalead tetraoxide sulphate (tetrabasic lead sulphate)	12065-90-6	No C&L harmonized for this specific compound; See also Index No. 082-001-00-6 (CLP00) for "lead compounds with the exception of those specified elsewhere in this Annex" & Index No. 082-007-00-9 for "lead acetate, basic" CAS No. 1335-32-6.	http://echa.europa.eu/brief-profile/-/briefprofile/100.031.867	34 active registrations under REACH, 1 Joint Submission(s) and 0 Individual Submission(s)	n.a.	n.a.
1678	trilead dioxide phosphonate (dibasic lead phosphite)	12141-20-7	No C&L harmonized for this specific compound; See also Index No. 082-001-00-6 (CLP00) for "lead compounds with the exception of those specified elsewhere in this Annex" & Index No. 082-007-00-9 for "lead	http://echa.europa.eu/brief-profile/-/briefprofile/100.032.035	7 active registrations under REACH, 1 Joint Submission(s) and 0 Individual Submission(s)	n.a.	n.a.

The results of the screening do not constitute evaluations of individual substances to be carried out under the respective chemical legislations [[in particular, Regulation (EC) No 1107/2009 on plant protection products, Regulation (EU) No 528/2012 on biocidal products, Regulation (EC) No 1907/2006 REACH, Regulation (EC) No 1223/2009 on cosmetic products and the Water Framework Directive (EC) No 2000/60] and in no way prejudice future decisions on active substances to be taken pursuant to these pieces of the EU legislation.

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	Chemical Name	CAS	ECHA C&L Inventory - ATP Inserted/Updated	ECHA - Substance brief profile/Substance information	REACH - Registered substance: Data availability	CoRAP justification/decision availability	CAR availability
			acetate, basic" CAS No. 1335-32-6.				
1719	tetralead trioxide sulphate (tribasic lead sulphate)	12202-17-4	No C&L harmonized for this specific compound; See also Index No. 082-001-00-6 (CLP00) for "lead compounds with the exception of those specified elsewhere in this Annex" & Index No. 082-007-00-9 for "lead acetate, basic" CAS No. 1335-32-6.	http://echa.europa.eu/brief-profile/-/briefprofile/100.032.152	44 active registrations under REACH, 1 Joint Submission(s) and 0 Individual Submission(s)	n.a.	n.a.
1737	Low temperature tar oil, alkaline, extract residues (coal), low temperature coal tar alkaline	122384-78-5	ATP01	http://echa.europa.eu/substance-information/-/substanceinfo/100.100.105	Pre-Registration process	n.a.	n.a.
1778	p-aminophenol	123-30-8	CLP00	http://echa.europa.eu/brief-profile/-/briefprofile/100.004.198	5 active registrations under REACH, 1 Joint Submission(s) and 2 Individual Submission(s)	n.a.	n.a.
1870	dioxobis(stearato)trilead (dibasic lead stearate)	12578-12-0	No C&L harmonized for this specific compound; See also Index No. 082-001-00-6 (CLP00) for	http://echa.europa.eu/brief-profile/-/briefprofile/100.032.444	6 active registrations under REACH, 1 Joint Submission(s) and 0 Individual Submission(s)	n.a.	n.a.

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	Chemical Name	CAS	ECHA C&L Inventory - ATP Inserted/Updated	ECHA - Substance brief profile/Substance information	REACH - Registered substance: Data availability	CoRAP justification/decision availability	CAR availability
			"lead compounds with the exception of those specified elsewhere in this Annex" & Index No. 082-007-00-9 for "lead acetate, basic" CAS No. 1335-32-6.				
1884	Lead titanium zirconium oxide	12626-81-2	No C&L harmonized for this specific compound; See also Index No. 082-001-00-6 (CLP00) for "lead compounds with the exception of those specified elsewhere in this Annex" & Index No. 082-007-00-9 for "lead acetate, basic" CAS No. 1335-32-6.	http://echa.europa.eu/brief-profile/-/briefprofile/100.032.467	5 active registrations under REACH, 1 Joint Submission(s) and 0 Individual Submission(s)	n.a.	n.a.
1892	lead chromate molybdate sulfate red	12656-85-8	ATP01	http://echa.europa.eu/brief-profile/-/briefprofile/100.032.496	8 active registrations under REACH, 1 Joint Submission(s) and 0 Individual Submission(s)	n.a.	n.a.
1925	N,N-dimethylacetamide	127-19-5	CLP00	http://echa.europa.eu/brief-profile/-/briefprofile/100.004.389	13 active registrations under REACH, 1 Joint Submission(s) and 0 Individual Submission(s)	n.a.	n.a.

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	Chemical Name	CAS	ECHA C&L Inventory - ATP Inserted/Updated	ECHA - Substance brief profile/Substance information	REACH - Registered substance: Data availability	CoRAP justification/decision availability	CAR availability
2042	Dipentyl phthalate (DPP)	131-18-0	CLP00	http://echa.europa.eu/substance-information/-/substanceinfo/100.004.563	<u>Pre-Registration process</u>	n.a.	n.a.
2061	orange lead (lead tetroxide)	1314-41-6	No C&L harmonized for this specific compound; See also Index No. 082-001-00-6 (CLP00) for "lead compounds with the exception of those specified elsewhere in this Annex" & Index No. 082-007-00-9 for "lead acetate, basic" CAS No. 1335-32-6.	http://echa.europa.eu/brief-profile/-/briefprofile/100.013.851	10 active registrations under REACH, 1 Joint Submission(s) and 0 Individual Submission(s)	n.a.	n.a.
2081	Benzophenone-3 (oxybenzone)	131-57-7	No C&L harmonized	http://echa.europa.eu/brief-profile/-/briefprofile/100.004.575	<u>2 active registrations under REACH, 1 Joint Submission(s) and 0 Individual Submission(s)</u>	n.a.	n.a.
2091	lead monoxide (lead oxide)	1317-36-8	No C&L harmonized for this specific compound; See also Index No. 082-001-00-6 (CLP00) for "lead compounds with the exception of those	http://echa.europa.eu/brief-profile/-/briefprofile/100.013.880	59 active registrations under REACH, 1 Joint Submission(s) and 0 Individual Submission(s)	n.a.	n.a.

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	Chemical Name	CAS	ECHA C&L Inventory - ATP Inserted/Updated	ECHA - Substance brief profile/Substance information	REACH - Registered substance: Data availability	CoRAP justification/decision availability	CAR availability
			specified elsewhere in this Annex" & Index No. 082-007-00-9 for "lead acetate, basic" CAS No. 1335-32-6.				
2105	trilead bis(carbonate) dihydroxide (basic lead carbonate)	1319-46-6	No C&L harmonized for this specific compound; See also Index No. 082-001-00-6 (CLP00) for "lead compounds with the exception of those specified elsewhere in this Annex" & Index No. 082-007-00-9 for "lead acetate, basic" CAS No. 1335-32-6.	http://echa.europa.eu/brief-profile/-/briefprofile/100.013.901	1 active registrations under REACH, 1 Joint Submission(s) and 0 Individual Submission(s)	n.a.	n.a.
2191	lead diazide	13424-46-9	CLP00	http://echa.europa.eu/brief-profile/-/briefprofile/100.033.206	5 active registrations under REACH, 1 Joint Submission(s) and 0 Individual Submission(s)	n.a.	n.a.
2202	lead sulfochromate yellow	1344-37-2	ATP01	http://echa.europa.eu/brief-profile/-/briefprofile/100.014.267	<u>7 active registrations under REACH, 1 Joint Submission(s) and 0 Individual Submission(s)</u>	n.a.	n.a.
2324	lead bis(tetrafluoroborate)	13814-96-5	No C&L harmonized for this specific compound;	http://echa.europa.eu/brief-profile/-	2 active registrations under REACH, 1 Joint	n.a.	n.a.

The results of the screening do not constitute evaluations of individual substances to be carried out under the respective chemical legislations [[in particular, Regulation (EC) No 1107/2009 on plant protection products, Regulation (EU) No 528/2012 on biocidal products, Regulation (EC) No 1907/2006 REACH, Regulation (EC) No 1223/2009 on cosmetic products and the Water Framework Directive (EC) No 2000/60] and in no way prejudice future decisions on active substances to be taken pursuant to these pieces of the EU legislation.

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	Chemical Name	CAS	ECHA C&L Inventory - ATP Inserted/Updated	ECHA - Substance brief profile/Substance information	REACH - Registered substance: Data availability	CoRAP justification/decision availability	CAR availability
			See also Index No. 082-001-00-6 (CLP00) for "lead compounds with the exception of those specified elsewhere in this Annex" & Index No. 082-007-00-9 for "lead acetate, basic" CAS No. 1335-32-6.	/briefprofile/100.034.064	Submission(s) and 0 Individual Submission(s)		
2391	4-(1,1,3,3-tetramethylbutyl)phenol	140-66-9	ATP01	http://echa.europa.eu/brief-profile/-/briefprofile/100.004.934	11 active registrations under REACH, 1 Joint Submission(s) and 0 Individual Submission(s)	n.a.	n.a.
2491	3-ethyl-2-methyl-2-(3-methylbutyl)-1,3-oxazolidine	143860-04-2	CLP00	http://echa.europa.eu/brief-profile/-/briefprofile/100.101.975	<u>Substance pre-registered under REACH</u>	n.a.	n.a.
2527	3-methylpyrazole	1453-58-3	No C&L harmonized	http://echa.europa.eu/brief-profile/-/briefprofile/100.014.478	1 active registrations under REACH, 0 Joint Submission(s) and 1 Individual Submission(s)	http://echa.europa.eu/information-on-chemicals/evaluation/community-rolling-action-plan/corap-table/-/dislist/details/0b0236e1807ed474	n.a.
2543	tributyltin chloride	1461-22-9	No C&L harmonized	http://echa.europa.eu/en/brief-profile/-	3 active registrations under REACH, 1 Joint	n.a.	n.a.

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	Chemical Name	CAS	ECHA C&L Inventory - ATP Inserted/Updated	ECHA - Substance brief profile/Substance information	REACH - Registered substance: Data availability	CoRAP justification/decision availability	CAR availability
				/briefprofile/100.014.508	Submission(s) and 0 Individual Submission(s)		
2544	tributyltin bromide	1461-23-0	No C&L harmonized	http://echa.europa.eu/en/substance-information/-/substanceinfo/100.014.509	<u>Pre-Registration process</u>	n.a.	n.a.
2594	2-Mercaptobenzothiazole (Benzothiazole-2-thiol)	149-30-4	CLP00	http://echa.europa.eu/brief-profile/-/briefprofile/100.005.216	<u>4 active registrations under REACH, 1 Joint Submission(s) and 1 Individual Submission(s)</u>	http://echa.europa.eu/information-on-chemicals/evaluation/community-rolling-action-plan/corap-table/-/dislist/details/0b0236e1807e5b5a	n.a.
2625	3-Benzylidene camphor (1,7,7-trimethyl-3-(phenylmethylene)bicyclo[2.2.1]heptan-2-one)	15087-24-8	No C&L harmonized	http://echa.europa.eu/substance-information/-/substanceinfo/100.035.567	<u>Pre-Registration process</u>	n.a.	n.a.
2633	Sodium perborate,perboric acid, sodium salt	15120-21-5 (11138-47-9)	ATP01/ATP01corr	http://echa.europa.eu/substance-information/-/substanceinfo/100.035.597	<u>Pre-Registration process</u>	n.a.	n.a.
2657	lead 2,4,6-trinitro-m-phenylene dioxide (Lead styphnate)	15245-44-0	CLP00	http://echa.europa.eu/brief-profile/-	9 active registrations under REACH, 1 Joint	n.a.	n.a.

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	Chemical Name	CAS	ECHA C&L Inventory - ATP Inserted/Updated	ECHA - Substance brief profile/Substance information	REACH - Registered substance: Data availability	CoRAP justification/decision availability	CAR availability
				/briefprofile/100.035.703	Submission(s) and 0 Individual Submission(s)		
2701	2-ethylhexyl 10-ethyl-4,4-dioctyl-7-oxo-8-oxa-3,5-dithia-4-stannatetradecanoate (DOTE)	15571-58-1	ATP05	http://echa.europa.eu/brief-profile/-/briefprofile/100.036.005	4 active registrations under REACH, 1 Joint Submission(s) and 0 Individual Submission(s)	n.a.	n.a.
2813	tert-butyl methyl ether	1634-04-4	CLP00	http://echa.europa.eu/brief-profile/-/briefprofile/100.015.140	81 active registrations under REACH, 1 Joint Submission(s) and 0 Individual Submission(s)	http://echa.europa.eu/information-on-chemicals/evaluation/community-rolling-action-plan/corap-table/-/dislist/details/0b0236e18068d70b	n.a.
2863	2-Amino-3-hydroxypyridine (2-aminopyridin-3-ol)	16867-03-1	No C&L harmonized	http://echa.europa.eu/substance-information/-/substanceinfo/100.037.154	Pre-Registration process	n.a.	n.a.
2940	Lead(II) bis(methanesulfonate)	17570-76-2	CLP00	http://echa.europa.eu/brief-profile/-/briefprofile/100.100.365	5 active registrations under REACH, 0 Joint Submission(s) and 1 Individual Submission(s)	n.a.	n.a.
2945	ammonium thiocyanate	1762-95-4	No C&L harmonized	http://echa.europa.eu/brief-profile/-/briefprofile/100.015.614	1 active registrations under REACH, 1 Joint Submission(s) and 0 Individual Submission(s)	http://echa.europa.eu/information-on-chemicals/evaluation/community-rolling-action-	n.a.

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	Chemical Name	CAS	ECHA C&L Inventory - ATP Inserted/Updated	ECHA - Substance brief profile/Substance information	REACH - Registered substance: Data availability	CoRAP justification/decision availability	CAR availability
						plan/corap-table/-/dislist/details/0b0236e1807e8b57	
3040	octabenzene	1843-05-6	No C&L harmonized	http://echa.europa.eu/brief-profile/-/briefprofile/100.015.838	3 active registrations under REACH, 1 Joint Submission(s) and 0 Individual Submission(s)	http://echa.europa.eu/information-on-chemicals/evaluation/community-rolling-action-plan/corap-table/-/dislist/details/0b0236e1807e6a8b	n.a.
3152	p-METHYLAMINOPHENOL sulphate	1936-57-8	No C&L harmonized	http://echa.europa.eu/substance-information/-/substanceinfo/100.016.097	Pre-Registration process	n.a.	n.a.
3269	tributyltin	20763-88-6	No C&L harmonized	Only documents for Bis(tributyltin) oxide with reference to CAS No. 20763-88-6 (tributyltin) were found	http://echa.europa.eu/documents/10162/13640/svhc_axvrep_norway_pbt_tdto_20083006_en.pdf ; http://echa.europa.eu/documents/10162/52f3fc94-c78f-436f-98ca-e0f845f37a9a	n.a.	n.a.
3278	lead cyanamidate	20837-86-9	No C&L harmonized for this specific compound; See also Index No. 082-	http://echa.europa.eu/brief-profile/-/briefprofile/100.040	4 active registrations under REACH, 1 Joint Submission(s) and 0	n.a.	n.a.

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	Chemical Name	CAS	ECHA C&L Inventory - ATP Inserted/Updated	ECHA - Substance brief profile/Substance information	REACH - Registered substance: Data availability	CoRAP justification/decision availability	CAR availability
			001-00-6 (CLP00) for "lead compounds with the exception of those specified elsewhere in this Annex" & Index No. 082-007-00-9 for "lead acetate, basic" CAS No. 1335-32-6.	.052	Individual Submission(s)		
3588	tert-butyl-4-methoxyphenol	25013-16-5	No C&L harmonized	http://echa.europa.eu/brief-profile/-/briefprofile/100.042.315	2 active registrations under REACH, 1 Joint Submission(s) and 0 Individual Submission(s)	http://echa.europa.eu/information-on-chemicals/evaluation/community-rolling-action-plan/corap-table/-/dislist/details/0b0236e1807ea5c9	n.a.
3590	Bisphenol-A-Epichlorhydrin Epoxy resin Average MW < 700 [4,4'-Isopropylidenediphenol, oligomeric reaction products with 1-chloro-2,3-epoxypropane]	25068-38-6	CLP00	http://echa.europa.eu/brief-profile/-/briefprofile/100.105.541	38 active registrations under REACH, 1 Joint Submission(s) and 1 Individual Submission(s)	http://echa.europa.eu/information-on-chemicals/evaluation/community-rolling-action-plan/corap-table/-/dislist/details/0b0236e1807e9666	n.a.
3600	Phenol, nonyl- (Nonylphenol)	25154-52-3	CLP00	http://echa.europa.eu/substance-information/-/substanceinfo/100.0	<u>Pre-Registration process</u>	n.a.	n.a.

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	Chemical Name	CAS	ECHA C&L Inventory - ATP Inserted/Updated	ECHA - Substance brief profile/Substance information	REACH - Registered substance: Data availability	CoRAP justification/decision availability	CAR availability
				42.414			
3601	trixylyl phosphate	25155-23-1	ATP03	http://echa.europa.eu/brief-profile/-/briefprofile/100.042.419	2 active registrations under REACH, 1 Joint Submission(s) and 0 Individual Submission(s)	http://echa.europa.eu/information-on-chemicals/evaluation/community-rolling-action-plan/corap-table/-/dislist/details/0b0236e180686bab	n.a.
3708	bis(2-ethylhexyl) tetrabromophthalate (BEH-TEBP)	26040-51-7	No C&L harmonized	http://echa.europa.eu/brief-profile/-/briefprofile/100.043.099	1 active registrations under REACH, 1 Joint Submission(s) and 0 Individual Submission(s)	http://echa.europa.eu/information-on-chemicals/evaluation/community-rolling-action-plan/corap-table/-/dislist/details/0b0236e1807ed6f6	n.a.
3824	Polyhexamethylene biguanide hydrochloride	27083-27-8	ATP05	http://echa.europa.eu/substance-information/-/substanceinfo/100.124.672	<u>Pre-Registration process</u>	n.a.	n.a.
4051	lead di(acetate) (also mentioned as lead acetate)	301-04-2	CLP00	http://echa.europa.eu/brief-profile/-/briefprofile/100.005.551	4 active registrations under REACH, 1 Joint Submission(s) and 0 Individual Submission(s)	n.a.	n.a.
4087	Paraformaldehyde	30525-89-4	No C&L harmonized	http://echa.europa.eu/substance-		n.a.	n.a.

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	Chemical Name	CAS	ECHA C&L Inventory - ATP Inserted/Updated	ECHA - Substance brief profile/Substance information	REACH - Registered substance: Data availability	CoRAP justification/decision availability	CAR availability
				information/-/substanceinfo/100.108.270			
4270	Pentadecafluorooctanoic acid (PFOA)	335-67-1	ATP05	http://echa.europa.eu/substance-information/-/substanceinfo/100.005.817		n.a.	n.a.
4280	Triclosan	3380-34-5	CLP00	http://echa.europa.eu/substance-information/-/substanceinfo/100.020.167	Pre-Registration process	http://echa.europa.eu/information-on-chemicals/evaluation/community-rolling-action-plan/corap-table/-/dislist/details/0b0236e1807e4774	Draft CAR available in Circabc
4449	tributyltin-cation (same as tributyltin hydride, CAS: 688-73-3)	36643-28-4	No C&L harmonized	n.a.	n.a.	n.a.	n.a.
4462	trilead diarsenate	3687-31-8	No C&L harmonized for this specific compound; See also Index No. 082-001-00-6 (CLP00) for "lead compounds with the exception of those specified elsewhere in this Annex" & Index No. 082-007-00-9 for "lead	http://echa.europa.eu/brief-profile/-/briefprofile/100.020.890	0 active registrations under REACH, 1 Joint Submission(s) and 0 Individual Submission(s)	n.a.	n.a.

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	Chemical Name	CAS	ECHA C&L Inventory - ATP Inserted/Updated	ECHA - Substance brief profile/Substance information	REACH - Registered substance: Data availability	CoRAP justification/decision availability	CAR availability
			acetate, basic" CAS No. 1335-32-6.				
4537	4-Methylbenzylidene camphor (3-(4'-Methylbenzylidene)-dl-camphor / Enzacamene)	38102-62-4 (36861-47-9)	No C&L harmonized	http://echa.europa.eu/substance-information/-/substanceinfo/100.048.386	<u>Pre-Registration process</u>	n.a.	n.a.
4548	Ammonium pentadecafluorooctanoate (APFO)	3825-26-1	ATP05	http://echa.europa.eu/substance-information/-/substanceinfo/100.021.202	<u>Pre-Registration process</u>	n.a.	n.a.
4960	Kojic Acid (5-hydroxy-2-hydroxymethyl-4-pyrone)	501-30-4	No C&L harmonized	http://echa.europa.eu/substance-information/-/substanceinfo/100.007.203	<u>Pre-Registration process</u>	n.a.	n.a.
4975	Benzo[a]pyrene	50-32-8	CLP00	http://echa.europa.eu/substance-information/-/substanceinfo/100.000.026	<u>re-Registration process</u>	n.a.	n.a.
5033	2-(2-butoxyethoxy)ethyl 6-propylpiperonyl ether (PBO)	51-03-6	No C&L harmonized	http://echa.europa.eu/brief-profile/-/briefprofile/100.000.070	<u>2 active registrations under REACH, 1 Joint Submission(s) and 1 Individual Submission(s).</u>	http://echa.europa.eu/information-on-chemicals/evaluation/community-rolling-action-	Draft CAR available in Circabc

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	Chemical Name	CAS	ECHA C&L Inventory - ATP Inserted/Updated	ECHA - Substance brief profile/Substance information	REACH - Registered substance: Data availability	CoRAP justification/decision availability	CAR availability
						plan/corap-table/-/dislist/details/0b0236e1807ea6a1	
5047	Quaternium-15 (cis-isomer)	51229-78-8	ATP01	http://echa.europa.eu/brief-profile/-/briefprofile/100.102.448	2 active registrations under REACH, 0 Joint Submission(s) and 1 Individual Submission(s)	n.a.	n.a.
5065	cobalt carbonate	513-79-1	ATP01	http://echa.europa.eu/brief-profile/-/briefprofile/100.007.428	11 active registrations under REACH, 1 Joint Submission(s) and 2 Individual Submission(s)	n.a.	n.a.
5067	Acetic acid, lead salt, basic	51404-69-4	No C&L harmonized for this specific compound; See also Index No. 082-001-00-6 (CLP00) for "lead compounds with the exception of those specified elsewhere in this Annex" & Index No. 082-007-00-9 for "lead acetate, basic" CAS No. 1335-32-6.	http://echa.europa.eu/brief-profile/-/briefprofile/100.051.960	4 active registrations under REACH, 2 Joint Submission(s) and 0 Individual Submission(s)	n.a.	n.a.
5160	Camphor benzalkonium methosulfate (Methyl N,N,N-trimethyl-4-[(4,7,7-trimethyl-3-oxobicyclo[2.2.1]hept-2-ylidene)methyl]anilinium sulphate)	52793-97-2	No C&L harmonized	http://echa.europa.eu/substance-information/-/substanceinfo/100.0	Pre-Registration process	n.a.	n.a.

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	Chemical Name	CAS	ECHA C&L Inventory - ATP Inserted/Updated	ECHA - Substance brief profile/Substance information	REACH - Registered substance: Data availability	CoRAP justification/decision availability	CAR availability
				52.883			
5202	bis(2-propylheptyl) phthalate	53306-54-0	No C&L harmonized	http://echa.europa.eu/brief-profile/-/briefprofile/100.053.137	5 active registrations under REACH, 1 Joint Submission(s) and 0 Individual Submission(s)	http://echa.europa.eu/information-on-chemicals/evaluation/community-rolling-action-plan/corap-table/-/dislist/details/0b0236e1807ec010	n.a.
5209	1,2,4-trihydroxybenzene (Benzene-1,2,4-triol)	533-73-3	No C&L harmonized	http://echa.europa.eu/substance-information/-/substanceinfo/100.007.797	<u>Pre-Registration process</u>	n.a.	n.a.
5272	Decamethylcyclopentasiloxane (mentioned as Cyclomethicone and Cyclopentasiloxane)	541-02-6 (all 69430-24-6 / 556-67-2 / 541-02-6 / 540-97-6)	No C&L harmonized	http://echa.europa.eu/brief-profile/-/briefprofile/100.007.969	<u>15 active registrations under REACH, 1 Joint Submission(s) and 0 Individual Submission(s)</u>	n.a.	n.a.
5324	2-Ethylhexyl-4-methoxycinnamate (Oxtinoxate or Ethylhexyl Methoxycinnamate)	5466-77-3	No C&L harmonized	http://echa.europa.eu/substance-information/-/substanceinfo/100.024.341	<u>Pre-Registration process</u>	http://echa.europa.eu/information-on-chemicals/evaluation/community-rolling-action-plan/corap-table/-/dislist/details/0b0236e1807eb946	n.a.

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5382	Cyclomethicone Octamethylcyclotetrasiloxane	556-67-2	CLP00	http://echa.europa.eu/brief-profile/-/briefprofile/100.008.307	16 active registrations under REACH, 1 Joint Submission(s) and 0 Individual Submission(s)	n.a.	n.a.
5443	Tributyltin (tributyltin chloride?)	56573-85-4	No C&L harmonized	In documents for Bis(tributyltin) oxide with reference to CAS No. 56573-85-4 as tributyltin chloride was found	http://echa.europa.eu/documents/10162/13640/svhc_axvrep_norway_pbt_tbto_20083006_en.pdf ; http://echa.europa.eu/documents/10162/52f3fc94-c78f-436f-98ca-e0f845f37a9a	n.a.	n.a.
5706	diisopentyl phthalate	605-50-5	CLP00	http://echa.europa.eu/brief-profile/-/briefprofile/100.009.172	1 active registrations under REACH, 0 Joint Submission(s) and 1 Individual Submission(s)	n.a.	n.a.
5760	toluene-2,5-diamine sulfate (2-methyl-p-phenylenediamine sulfate)	615-50-9	CLP00	http://echa.europa.eu/en/brief-profile/-/briefprofile/100.009.484	http://echa.europa.eu/registration-dossier/-/registered-dossier/13667	n.a.	n.a.
5786	Phenol, styrenated	61788-44-1	No C&L harmonized	http://echa.europa.eu/brief-profile/-/briefprofile/100.057.232	5 active registrations under REACH, 2 Joint Submission(s) and 1 Individual Submission(s)	http://echa.europa.eu/information-on-chemicals/evaluation/community-rolling-action-plan/corap-table/-/dislist/details/0b0236e18	n.a.

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	Chemical Name	CAS	ECHA C&L Inventory - ATP Inserted/Updated	ECHA - Substance brief profile/Substance information	REACH - Registered substance: Data availability	CoRAP justification/decision availability	CAR availability
						06974de	
5822	Sulfurous acid, lead salt, dibasic (basic lead sulphate)	62229-08-7	No C&L harmonized for this specific compound; See also Index No. 082-001-00-6 (CLP00) for "lead compounds with the exception of those specified elsewhere in this Annex" & Index No. 082-007-00-9 for "lead acetate, basic" CAS No. 1335-32-6.	http://echa.europa.eu/brief-profile/-/briefprofile/100.057.680	1 active registrations under REACH, 1 Joint Submission(s) and 0 Individual Submission(s)	n.a.	n.a.
5851	methoxyacetic acid	625-45-6	CLP00	http://echa.europa.eu/brief-profile/-/briefprofile/100.009.904	<u>2 active registrations under REACH, 1 Joint Submission(s) and 0 Individual Submission(s).</u>	n.a.	n.a.
5880	1,2-Diethoxyethane	629-14-1	ATP01	http://echa.europa.eu/substance-information/-/substanceinfo/100.010.070	<u>Pre-Registration process</u>	n.a.	n.a.
5962	Triphenyltin chloride	639-58-7	No C&L harmonized	http://echa.europa.eu/substance-information/-/substanceinfo/100.010.327	n.a	n.a	n.a

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6014	Lead dipicrate	6477-64-1	No C&L harmonized for this specific compound; See also Index No. 082-001-00-6 (CLP00) for "lead compounds with the exception of those specified elsewhere in this Annex" & Index No. 082-007-00-9 for "lead acetate, basic" CAS No. 1335-32-6.	http://echa.europa.eu/substance-information/-/substanceinfo/100.026.669	Pre-Registration process	n.a.	n.a.
6071	Tar acids, coal, crude,crude phenols	65996-85-2	CLP00/ATP01	http://echa.europa.eu/brief-profile/-/briefprofile/100.059.999	2 active registrations under REACH, 1 Joint Submission(s) and 0 Individual Submission(s)	n.a.	n.a.
6132	Triphenyltin	668-34-8	No C&L harmonized	http://echa.europa.eu/substance-information/-/substanceinfo/100.223.038	n.a	n.a.	n.a.
6223	N,N-dimethylformamide	68-12-2	CLP00	http://echa.europa.eu/brief-profile/-/briefprofile/100.000.617	13 active registrations under REACH, 1 Joint Submission(s) and 1 Individual Submission(s)	n.a.	n.a.

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	Chemical Name	CAS	ECHA C&L Inventory - ATP Inserted/Updated	ECHA - Substance brief profile/Substance information	REACH - Registered substance: Data availability	CoRAP justification/decision availability	CAR availability
6277	dibutyltin dichloride (DBTCl ₂)	683-18-1	ATP01	http://echa.europa.eu/brief-profile/-/briefprofile/100.010.610	5 active registrations under REACH, 1 Joint Submission(s) and 0 Individual Submission(s)	n.a.	n.a.
6325	1,2-Benzenedicarboxylic acid, di-C7-11-branched and linear alkyl esters	68515-42-4	No C&L harmonized	http://echa.europa.eu/substance-information/-/substanceinfo/100.064.602	<u>Pre-Registration process</u>	http://echa.europa.eu/information-on-chemicals/evaluation/community-rolling-action-plan/corap-table/-/dislist/details/0b0236e1806974de	n.a.
6330	1,2-Benzenedicarboxylic acid, dihexylester, branched and linear (Diisohexyl phthalate -DHP)	68515-50-4	No C&L harmonized	http://echa.europa.eu/substance-information/-/substanceinfo/100.064.610	<u>Pre-Registration process</u>	n.a.	n.a.
6331	1,2-Benzenedicarboxylic acid, di-C6-10-alkyl esters	68515-51-5 (Additional Cas No: 68648-93-1)	No C&L harmonized	http://echa.europa.eu/brief-profile/-/briefprofile/100.064.611	1 active registrations under REACH, 1 Joint Submission(s) and 0 Individual Submission(s)	n.a.	n.a.
6369	2,2'-dimethyl-4,4'-methylenebis(cyclohexylamine)	6864-37-5	CLP00	http://echa.europa.eu/brief-profile/-/briefprofile/100.027.238	3 active registrations under REACH, 1 Joint Submission(s) and 0 Individual Submission(s)	http://echa.europa.eu/information-on-chemicals/evaluation/community-rolling-action-plan/corap-table/-/dislist/details/0b0236e18	n.a.

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	Chemical Name	CAS	ECHA C&L Inventory - ATP Inserted/Updated	ECHA - Substance brief profile/Substance information	REACH - Registered substance: Data availability	CoRAP justification/decision availability	CAR availability
						07e81c7	
6384	Silicic acid (H ₂ Si ₂ O ₅), barium salt (1:1), lead-doped	68784-75-8	No C&L harmonized for this specific compound; See also Index No. 082-001-00-6 (CLP00) for "lead compounds with the exception of those specified elsewhere in this Annex" & Index No. 082-007-00-9 for "lead acetate, basic" CAS No. 1335-32-6.	http://echa.europa.eu/brief-profile/-/briefprofile/100.065.681	<u>2 active registrations under REACH, 1 Joint Submission(s) and 0 Individual Submission(s)</u>	n.a.	n.a.
6440	[phthalato(2-)]dioxotrilead (dibasic lead phthalate)	69011-06-9	No C&L harmonized for this specific compound; See also Index No. 082-001-00-6 (CLP00) for "lead compounds with the exception of those specified elsewhere in this Annex" & Index No. 082-007-00-9 for "lead acetate, basic" CAS No. 1335-32-6.	http://echa.europa.eu/brief-profile/-/briefprofile/100.066.970	<u>1 active registrations under REACH, 1 Joint Submission(s) and 0 Individual Submission(s)</u>	n.a.	n.a.
6518	3-amino-2,6-dimethylphenol	6994-64-5	No C&L harmonized	http://echa.europa.eu/substance-information/-	<u>Pre-Registration process</u>	n.a.	n.a.

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				/substanceinfo/100.027.517			
6593	cobalt di(acetate) [Cobalt(II) diacetate]	71-48-7	ATP01/ATP01corr	http://echa.europa.eu/brief-profile/-/briefprofile/100.000.687	10 active registrations under REACH, 1 Joint Submission(s) and 1 Individual Submission(s)	n.a.	n.a.
6600	Isopentyl-p-Methoxycinnamate (Amiloxate)	71617-10-2	No C&L harmonized	http://echa.europa.eu/brief-profile/-/briefprofile/100.068.798	1 active registrations under REACH, 1 Joint Submission(s) and 0 Individual Submission(s)	http://echa.europa.eu/information-on-chemicals/evaluation/community-rolling-action-plan/corap-table/-/dislist/details/0b0236e1807ec45b	n.a.
6618	1,2-Benzenedicarboxylic acid, di-C6-8-branched alkyl esters, C7-rich	71888-89-6	ATP01	http://echa.europa.eu/substance-information/-/substanceinfo/100.069.214	Pre-Registration process	n.a.	n.a.
6731	mercury	7439-97-6	ATP01	http://echa.europa.eu/brief-profile/-/briefprofile/100.028.278	2 active registrations under REACH, 1 Joint Submission(s) and 0 Individual Submission(s)	n.a.	n.a.
6789	chloromethane (Methyl chloride)	74-87-3	CLP00	http://echa.europa.eu/brief-profile/-/briefprofile/100.000.744	29 active registrations under REACH, 1 Joint Submission(s) and 5 Individual Submission(s)	http://echa.europa.eu/information-on-chemicals/evaluation/community-rolling-action-	n.a.

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	Chemical Name	CAS	ECHA C&L Inventory - ATP Inserted/Updated	ECHA - Substance brief profile/Substance information	REACH - Registered substance: Data availability	CoRAP justification/decision availability	CAR availability
						plan/corap-table/-/dislist/details/0b0236e1807e3a06	
6810	Acetaldehyde	75-07-0	CLP00	http://echa.europa.eu/brief-profile/-/briefprofile/100.000.761	6 active registrations under REACH, 2 Joint Submission(s) and 0 Individual Submission(s)	n.a.	n.a.
6812	Dichloromethane	75-09-2	CLP00	http://echa.europa.eu/brief-profile/-/briefprofile/100.000.763	11 active registrations under REACH, 1 Joint Submission(s) and 1 Individual Submission(s)	http://echa.europa.eu/inf-ormation-on-chemicals/evaluation/community-rolling-action-plan/corap-table/-/dislist/details/0b0236e180b89717	n.a.
6814	Di- μ -oxo-di-n-butylstanniohydroxyborane/ Dibutyltin hydrogen borate C ₈ H ₁₉ BO ₃ Sn (DBB)	75113-37-0	ATP01/ATP01corr	http://echa.europa.eu/brief-profile/-/briefprofile/100.100.300	2 active registrations under REACH, 0 Joint Submission(s) and 1 Individual Submission(s).	n.a.	n.a.
6815	formamide	75-12-7	CLP00	http://echa.europa.eu/brief-profile/-/briefprofile/100.000.766	10 active registrations under REACH, 1 Joint Submission(s) and 2 Individual Submission(s)	n.a.	n.a.
6817	carbon disulphide	75-15-0	CLP00	http://echa.europa.eu/brief-profile/-/briefprofile/100.000.767	6 active registrations under REACH, 1 Joint Submission(s) and 1 Individual Submission(s).	http://echa.europa.eu/inf-ormation-on-chemicals/evaluation/community-rolling-action-	n.a.

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						plan/corap-table/-/dislist/details/0b0236e1807e60af	
6900	sodium perchlorate	7601-89-0	CLP00	http://echa.europa.eu/brief-profile/-/briefprofile/100.028.647	3 active registrations under REACH, 1 Joint Submission(s) and 0 Individual Submission(s)	http://echa.europa.eu/information-on-chemicals/evaluation/community-rolling-action-plan/corap-table/-/dislist/details/0b0236e1807ea4f2	n.a.
6932	Sodium peroxometaborate	7632-04-4	No C&L harmonized	http://echa.europa.eu/substance-information/-/substanceinfo/100.028.688	Pre-Registration process	n.a.	n.a.
6941	Cobalt dichloride	7646-79-9	ATP01	http://echa.europa.eu/brief-profile/-/briefprofile/100.028.718	6 active registrations under REACH, 1 Joint Submission(s) and 0 Individual Submission(s)	n.a.	n.a.
7051	Lead chromate	7758-97-6	ATP01	http://echa.europa.eu/substance-information/-/substanceinfo/100.028.951	Pre-Registration process	n.a.	n.a.
7055	N-pentyl-isopentylphthalate	776297-69-9	CLP00	http://echa.europa.eu/substance-	n.a.	n.a.	n.a.

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	Chemical Name	CAS	ECHA C&L Inventory - ATP Inserted/Updated	ECHA - Substance brief profile/Substance information	REACH - Registered substance: Data availability	CoRAP justification/decision availability	CAR availability
				information/- /substanceinfo/other/4a086aeaedaf3a9deb78fe8564ff9239fc527f6e3a08a485f0d8bbcab713c7c0			
7065	sodium chromate	7775-11-3	CLP00	http://echa.europa.eu/brief-profile/-/briefprofile/100.028.990	<u>1 active registrations under REACH, 1 Joint Submission(s) and 0 Individual Submission(s)</u>	n.a.	n.a.
7076	potassium dichromate	7778-50-9	CLP00	http://echa.europa.eu/brief-profile/-/briefprofile/100.029.005	<u>12 active registrations under REACH, 1 Joint Submission(s) and 1 Individual Submission(s)</u>	n.a.	n.a.
7108	Lead hydrogen arsenate	7784-40-9	CLP00	http://echa.europa.eu/substance-information/-/substanceinfo/100.029.149	<u>Pre-Registration process</u>	n.a.	n.a.
7129	ammonium dichromate	7789-09-5	CLP00	http://echa.europa.eu/brief-profile/-/briefprofile/100.029.221	<u>0 active registrations under REACH, 1 Joint Submission(s) and 0 Individual Submission(s)</u>	n.a.	n.a.
7147	Cadmium fluoride	7790-79-6	CLP00	http://echa.europa.eu/en/substance-information/-	<u>Pre-Registration process</u>	n.a.	n.a.

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	Chemical Name	CAS	ECHA C&L Inventory - ATP Inserted/Updated	ECHA - Substance brief profile/Substance information	REACH - Registered substance: Data availability	CoRAP justification/decision availability	CAR availability
				/substanceinfo/100.029.293			
7150	ammonium perchlorate	7790-98-9	ATP01	http://echa.europa.eu/brief-profile/-/briefprofile/100.029.305	<u>2 active registrations under REACH, 1 Joint Submission(s) and 0 Individual Submission(s)</u>	http://echa.europa.eu/information-on-chemicals/evaluation/community-rolling-action-plan/corap-table/-/dislist/details/0b0236e1807e9ab1	n.a.
7157	tetraethyllead	78-00-2	No C&L harmonized for this specific compound; See also Index No. 082-001-00-6 (CLP00) for "lead compounds with the exception of those specified elsewhere in this Annex" & Index No. 082-007-00-9 for "lead acetate, basic" CAS No. 1335-32-6.	http://echa.europa.eu/brief-profile/-/briefprofile/100.000.979	<u>1 active registrations under REACH, 0 Joint Submission(s) and 1 Individual Submission(s)</u>	n.a.	n.a.
7215	2-Chloroacetamide	79-07-2	CLP00	http://echa.europa.eu/brief-profile/-/briefprofile/100.001.068	<u>1 active registrations under REACH, 1 Joint Submission(s) and 0 Individual Submission(s)</u>	n.a.	n.a.
7222	N-methylacetamide	79-16-3	CLP00	http://echa.europa.eu/brief-profile/-/briefprofile/100.001.068	<u>1 active registrations under REACH, 1 Joint Submission(s) and 0 Individual Submission(s)</u>	n.a.	n.a.

The results of the screening do not constitute evaluations of individual substances to be carried out under the respective chemical legislations [[in particular, Regulation (EC) No 1107/2009 on plant protection products, Regulation (EU) No 528/2012 on biocidal products, Regulation (EC) No 1907/2006 REACH, Regulation (EC) No 1223/2009 on cosmetic products and the Water Framework Directive (EC) No 2000/60] and in no way prejudice future decisions on active substances to be taken pursuant to these pieces of the EU legislation.

It would thus be erroneous to consider that the substances listed in the results of this study (SANTE/2015/E3/SI2.706218) are considered as endocrine disruptors within the meaning of the EU legislation.

	Chemical Name	CAS	ECHA C&L Inventory - ATP Inserted/Updated	ECHA - Substance brief profile/Substance information	REACH - Registered substance: Data availability	CoRAP justification/decision availability	CAR availability
				/briefprofile/100.001.075	<u>Submission(s) and 0 Individual Submission(s)</u>		
7261	2,2',6,6'-tetrabromo-4,4'-isopropylidenediphenol (TBBPA)	79-94-7	ATP01	http://echa.europa.eu/brief-profile/-/briefprofile/100.001.125	<u>9 active registrations under REACH, 1 Joint Submission(s) and 0 Individual Submission(s)</u>	http://echa.europa.eu/information-on-chemicals/evaluation/community-rolling-action-plan/corap-table/-/dislist/details/0b0236e1807e837f	n.a.
7274	4,4'-isopropylidenediphenol (Bisphenol A)	80-05-7	ATP01corr	http://echa.europa.eu/brief-profile/-/briefprofile/100.001.133	<u>49 active registrations under REACH, 1 Joint Submission(s) and 0 Individual Submission(s)</u>	http://echa.europa.eu/information-on-chemicals/evaluation/community-rolling-action-plan/corap-table/-/dislist/details/0b0236e1807e375d	n.a.
7279	dapsone (TETRAHYDROMYRCENYL ACETATE)	80-08-0	CLP00	http://echa.europa.eu/brief-profile/-/briefprofile/100.001.136	<u>5 active registrations under REACH, 1 Joint Submission(s) and 1 Individual Submission(s)</u>	http://echa.europa.eu/information-on-chemicals/evaluation/community-rolling-action-plan/corap-table/-/dislist/details/0b0236e1807eaa8	n.a.
7281	4,4'-sulphonyldiphenol (Bisphenol S)	80-09-1	No C&L harmonized	http://echa.europa.eu/brief-profile/-/briefprofile/100.001	<u>7 active registrations under REACH, 1 Joint Submission(s) and 0</u>	http://echa.europa.eu/information-on-chemicals/evaluation/com	n.a.

The results of the screening do not constitute evaluations of individual substances to be carried out under the respective chemical legislations [[in particular, Regulation (EC) No 1107/2009 on plant protection products, Regulation (EU) No 528/2012 on biocidal products, Regulation (EC) No 1907/2006 REACH, Regulation (EC) No 1223/2009 on cosmetic products and the Water Framework Directive (EC) No 2000/60] and in no way prejudice future decisions on active substances to be taken pursuant to these pieces of the EU legislation.

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	Chemical Name	CAS	ECHA C&L Inventory - ATP Inserted/Updated	ECHA - Substance brief profile/Substance information	REACH - Registered substance: Data availability	CoRAP justification/decision availability	CAR availability
				.137	Individual Submission(s)	munity-rolling-action-plan/corap-table/-/dislist/details/0b0236e180686aaf	
7285	pyrochlore, antimony lead yellow	8012-00-8	No C&L harmonized for this specific compound; See also Index No. 082-001-00-6 (CLP00) for "lead compounds with the exception of those specified elsewhere in this Annex" & Index No. 082-007-00-9 for "lead acetate, basic" CAS No. 1335-32-6.	http://echa.europa.eu/brief-profile/-/briefprofile/100.029.436	2 active registrations under REACH, 1 Joint Submission(s) and 0 Individual Submission(s)	n.a.	n.a.
7298	p-(1,1-dimethylpropyl)phenol	80-46-6	No C&L harmonized	http://echa.europa.eu/brief-profile/-/briefprofile/100.001.165	4 active registrations under REACH, 1 Joint Submission(s) and 0 Individual Submission(s)	http://echa.europa.eu/information-on-chemicals/evaluation/community-rolling-action-plan/corap-table/-/dislist/details/0b0236e18069485d	n.a.
7322	Musk Ketone (also as 4'-tert-Butyl-2',6'-dimethyl-3',5'-dinitroacetophenone)	81-14-1	ATP01	http://echa.europa.eu/substance-information/-/substanceinfo/100.0	Pre-Registration process	n.a.	n.a.

The results of the screening do not constitute evaluations of individual substances to be carried out under the respective chemical legislations [[in particular, Regulation (EC) No 1107/2009 on plant protection products, Regulation (EU) No 528/2012 on biocidal products, Regulation (EC) No 1907/2006 REACH, Regulation (EC) No 1223/2009 on cosmetic products and the Water Framework Directive (EC) No 2000/60] and in no way prejudice future decisions on active substances to be taken pursuant to these pieces of the EU legislation.

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	Chemical Name	CAS	ECHA C&L Inventory - ATP Inserted/Updated	ECHA - Substance brief profile/Substance information	REACH - Registered substance: Data availability	CoRAP justification/decision availability	CAR availability
				01.209			
7323	Musk Xylene (also as 5-tert-Butyl-2,4,6-trinitro-m-xylene)	81-15-2	CLP00	http://echa.europa.eu/substance-information/-/substanceinfo/100.001.210		n.a.	n.a.
7369	1-Methyl-2,6-diamino-benzene (also as 2-Methyl-m-phenylenediamine OR Toluene-2,6-diamine)	823-40-5	CLP00	http://echa.europa.eu/en/substance-information/-/substanceinfo/100.011.376	Pre-Registration process	n.a.	n.a.
7437	2-amino-4-hydroxyethylaminoanisole sulfate	83763-48-8 (relevant also for 83763-47-7)	No C&L harmonized	http://echa.europa.eu/substance-information/-/substanceinfo/100.073.374	Pre-Registration process	n.a.	n.a.
7503	Distillates (coal tar), naphthalene oils, naphthalene oil	84650-04-4	ATP01	http://echa.europa.eu/brief-profile/-/briefprofile/100.075.869	15 active registrations under REACH, 1 Joint Submission(s) and 0 Individual Submission(s)	n.a.	n.a.
7505	Diethyl phthalate	84-66-2	No C&L harmonized	http://echa.europa.eu/brief-profile/-/briefprofile/100.001.409	12 active registrations under REACH, 2 Joint Submission(s) and 1 Individual Submission(s)	http://echa.europa.eu/information-on-chemicals/evaluation/community-rolling-action-plan/corap-table/-/dislist/details/0b0236e18	n.a.

The results of the screening do not constitute evaluations of individual substances to be carried out under the respective chemical legislations [[in particular, Regulation (EC) No 1107/2009 on plant protection products, Regulation (EU) No 528/2012 on biocidal products, Regulation (EC) No 1907/2006 REACH, Regulation (EC) No 1223/2009 on cosmetic products and the Water Framework Directive (EC) No 2000/60] and in no way prejudice future decisions on active substances to be taken pursuant to these pieces of the EU legislation.

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	Chemical Name	CAS	ECHA C&L Inventory - ATP Inserted/Updated	ECHA - Substance brief profile/Substance information	REACH - Registered substance: Data availability	CoRAP justification/decision availability	CAR availability
						<u>071b6bc</u>	
7507	diisobutyl phthalate (BIPB)	84-69-5	ATP01	http://echa.europa.eu/brief-profile/-/briefprofile/100.001.412	8 active registrations under REACH, 2 Joint Submission(s) and 4 Individual Submission(s)	n.a.	n.a.
7511	dibutyl phthalate	84-74-2	CLP00	http://echa.europa.eu/brief-profile/-/briefprofile/100.001.416	10 active registrations under REACH, 2 Joint Submission(s) and 2 Individual Submission(s)	n.a.	n.a.
7512	Dihexyl phthalate	84-75-3	ATP05	http://echa.europa.eu/substance-information/-/substanceinfo/100.001.417		n.a.	n.a.
7516	1,2-Benzenedicarboxylic acid, dipentylester, branched and linear	84777-06-0	CLP00	http://echa.europa.eu/substance-information/-/substanceinfo/100.001.417	Pre-Registration process	n.a.	n.a.
7578	6,6'-di-tert-butyl-4,4'-butylidenedi-m-cresol	85-60-9	No C&L harmonized	http://echa.europa.eu/brief-profile/-/briefprofile/100.001.471	3 active registrations under REACH, 1 Joint Submission(s) and 0 Individual Submission(s)	http://echa.europa.eu/information-on-chemicals/evaluation/community-rolling-action-plan/corap-table/-/dislist/details/0b0236e1807ed549	n.a.

The results of the screening do not constitute evaluations of individual substances to be carried out under the respective chemical legislations [[in particular, Regulation (EC) No 1107/2009 on plant protection products, Regulation (EU) No 528/2012 on biocidal products, Regulation (EC) No 1907/2006 REACH, Regulation (EC) No 1223/2009 on cosmetic products and the Water Framework Directive (EC) No 2000/60] and in no way prejudice future decisions on active substances to be taken pursuant to these pieces of the EU legislation.

It would thus be erroneous to consider that the substances listed in the results of this study (SANTE/2015/E3/SI2.706218) are considered as endocrine disruptors within the meaning of the EU legislation.

	Chemical Name	CAS	ECHA C&L Inventory - ATP Inserted/Updated	ECHA - Substance brief profile/Substance information	REACH - Registered substance: Data availability	CoRAP justification/decision availability	CAR availability
7581	benzyl butyl phthalate	85-68-7	CLP00	http://echa.europa.eu/brief-profile/-/briefprofile/100.001.475	1 active registrations under REACH, 1 Joint Submission(s) and 0 Individual Submission(s)	n.a.	n.a.
7645	dioctyltin oxide	870-08-6	No C&L harmonized	http://echa.europa.eu/brief-profile/-/briefprofile/100.011.629	6 active registrations under REACH, 1 Joint Submission(s) and 0 Individual Submission(s)	http://echa.europa.eu/documents/10162/0e54874d-2718-424f-8779-d151273368b7	n.a.
7657	N-Methyl-2-pyrrolidone (Methyl Pyrrolidone)	872-50-4 (also relevant for 51013-18-4)	ATP01	http://echa.europa.eu/brief-profile/-/briefprofile/100.011.662	35 active registrations under REACH, 1 Joint Submission(s) and 0 Individual Submission(s)	n.a.	n.a.
7740	dinoseb	88-85-7	CLP00	http://echa.europa.eu/brief-profile/-/briefprofile/100.001.692	1 active registrations under REACH, 1 Joint Submission(s) and 0 Individual Submission(s)	n.a.	n.a.
7749	triphenyltin hydride (based on the CAS No)	892-20-6	No C&L harmonized	http://echa.europa.eu/substance-information/-/substanceinfo/100.011.789	Pre-Registration process	n.a.	n.a.
7870	Fatty acids, C16-18, lead salts	91031-62-8	No C&L harmonized for this specific compound; See also Index No. 082-001-00-6 (CLP00) for "lead compounds with	http://echa.europa.eu/brief-profile/-/briefprofile/100.084.483	8 active registrations under REACH, 1 Joint Submission(s) and 0 Individual Submission(s)	n.a.	n.a.

The results of the screening do not constitute evaluations of individual substances to be carried out under the respective chemical legislations [[in particular, Regulation (EC) No 1107/2009 on plant protection products, Regulation (EU) No 528/2012 on biocidal products, Regulation (EC) No 1907/2006 REACH, Regulation (EC) No 1223/2009 on cosmetic products and the Water Framework Directive (EC) No 2000/60] and in no way prejudice future decisions on active substances to be taken pursuant to these pieces of the EU legislation.

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	Chemical Name	CAS	ECHA C&L Inventory - ATP Inserted/Updated	ECHA - Substance brief profile/Substance information	REACH - Registered substance: Data availability	CoRAP justification/decision availability	CAR availability
			the exception of those specified elsewhere in this Annex" & Index No. 082-007-00-9 for "lead acetate, basic" CAS No. 1335-32-6.				
8027	Hydroxyethyl-p-phenylenediamine sulfate (3-(2-Hydroxyethyl)-p-phenylenediammonium sulphate)	93841-25-9	No C&L harmonized	http://echa.europa.eu/en/substance-information/-/substanceinfo/100.089.952	Pre-Registration process	n.a.	n.a.
8046	propyl 4-hydroxybenzoate (propylparaben)	94-13-3	No C&L harmonized	http://echa.europa.eu/brief-profile/-/briefprofile/100.002.098	3 active registrations under REACH, 1 Joint Submission(s) and 0 Individual Submission(s)	http://echa.europa.eu/information-on-chemicals/evaluation/community-rolling-action-plan/corap-table/-/dislist/details/0b0236e1807ea411	n.a.
8049	Hydroxyethyl-3,4-methylenedioxyaniline HCl	94158-14-2	No C&L harmonized	http://echa.europa.eu/substance-information/-/substanceinfo/100.093.671	Pre-Registration process	n.a.	n.a.
8099	benzotriazole	95-14-7	No C&L harmonized	http://echa.europa.eu/brief-profile/-/briefprofile/100.002	5 active registrations under REACH, 1 Joint Submission(s) and 0	http://echa.europa.eu/information-on-chemicals/evaluation/com	n.a.

The results of the screening do not constitute evaluations of individual substances to be carried out under the respective chemical legislations [[in particular, Regulation (EC) No 1107/2009 on plant protection products, Regulation (EU) No 528/2012 on biocidal products, Regulation (EC) No 1907/2006 REACH, Regulation (EC) No 1223/2009 on cosmetic products and the Water Framework Directive (EC) No 2000/60] and in no way prejudice future decisions on active substances to be taken pursuant to these pieces of the EU legislation.

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	Chemical Name	CAS	ECHA C&L Inventory - ATP Inserted/Updated	ECHA - Substance brief profile/Substance information	REACH - Registered substance: Data availability	CoRAP justification/decision availability	CAR availability
				.177	Individual Submission(s)	munity-rolling-action-plan/corap-table/-/dislist/details/0b0236e1807eac85	
8119	o-Aminophenol (also relevant for o-Aminophenol (o-Aminophenol; CI 76520) and its salts)	95-55-6 (also relevant for 67845-79-8 & 51-19-4)	CLP00	http://echa.europa.eu/brief-profile/-/briefprofile/100.002.211	1 active registrations under REACH, 0 Joint Submission(s) and 1 Individual Submission(s)	n.a.	n.a.
8170	1,2,3-trichloropropane	96-18-4	CLP00	http://echa.europa.eu/brief-profile/-/briefprofile/100.002.261	4 active registrations under REACH, 1 Joint Submission(s) and 0 Individual Submission(s)	n.a.	n.a.
8185	imidazolidine-2-thione (ETU)	96-45-7	CLP00	http://echa.europa.eu/brief-profile/-/briefprofile/100.002.280	3 active registrations under REACH, 1 Joint Submission(s) and 0 Individual Submission(s)	n.a.	n.a.
8194	6,6'-di-tert-butyl-4,4'-thiodi-m-cresol	96-69-5	No C&L harmonized	http://echa.europa.eu/brief-profile/-/briefprofile/100.002.297	2 active registrations under REACH, 1 Joint Submission(s) and 0 Individual Submission(s)	http://echa.europa.eu/information-on-chemicals/evaluation/community-rolling-action-plan/corap-table/-/dislist/details/0b0236e1807e87d7	n.a.
8196	2,4-di-tert-butylphenol	96-76-4	No C&L harmonized	http://echa.europa.eu/brief-profile/-/briefprofile/100.002	9 active registrations under REACH, 1 Joint Submission(s) and 2	http://echa.europa.eu/information-on-chemicals/evaluation/com	n.a.

The results of the screening do not constitute evaluations of individual substances to be carried out under the respective chemical legislations [[in particular, Regulation (EC) No 1107/2009 on plant protection products, Regulation (EU) No 528/2012 on biocidal products, Regulation (EC) No 1907/2006 REACH, Regulation (EC) No 1223/2009 on cosmetic products and the Water Framework Directive (EC) No 2000/60] and in no way prejudice future decisions on active substances to be taken pursuant to these pieces of the EU legislation.

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	Chemical Name	CAS	ECHA C&L Inventory - ATP Inserted/Updated	ECHA - Substance brief profile/Substance information	REACH - Registered substance: Data availability	CoRAP justification/decision availability	CAR availability
				.303	<u>Individual Submission(s)</u>	munity-rolling-action-plan/corap-table/-/dislist/details/0b0236e1807ead67	
8250	Furfural	98-01-1	CLP00/ATP01	http://echa.europa.eu/brief-profile/-/briefprofile/100.002.389	http://echa.europa.eu/registration-dossier/-/registered-dossier/14883	n.a.	n.a.
8276	4-tert-butylphenol	98-54-4	ATP06	http://echa.europa.eu/brief-profile/-/briefprofile/100.002.436	<u>13 active registrations under REACH, 1 Joint Submission(s) and 1 Individual Submission(s)</u>	http://echa.europa.eu/information-on-chemicals/evaluation/community-rolling-action-plan/corap-table/-/dislist/details/0b0236e18069f586	n.a.
8296	nitrobenzene	98-95-3	ATP05	http://echa.europa.eu/brief-profile/-/briefprofile/100.002.469	<u>9 active registrations under REACH, 1 Joint Submission(s) and 1 Individual Submission(s)</u>	n.a.	n.a.
8331	methyl 4-hydroxybenzoate (methylparaben)	99-76-3	No C&L harmonized	http://echa.europa.eu/brief-profile/-/briefprofile/100.002.532	<u>5 active registrations under REACH, 1 Joint Submission(s) and 1 Individual Submission(s)</u>	http://echa.europa.eu/information-on-chemicals/evaluation/community-rolling-action-plan/corap-table/-/dislist/details/0b0236e180686b0e	n.a.

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	Chemical Name	CAS	ECHA C&L Inventory - ATP Inserted/Updated	ECHA - Substance brief profile/Substance information	REACH - Registered substance: Data availability	CoRAP justification/decision availability	CAR availability
8341	4-hydroxybenzoic acid (p-hydroxybenzoic acid)	99-96-7	No C&L harmonized	http://echa.europa.eu/brief-profile/-/briefprofile/100.002.550	5 active registrations under REACH, 1 Joint Submission(s) and 0 Individual Submission(s)	http://echa.europa.eu/information-on-chemicals/evaluation/community-rolling-action-plan/corap-table/-/dislist/details/0b0236e18070bbe3	n.a.
8372a	Ethylparaben	120-47-8	No C&L harmonized	http://echa.europa.eu/brief-profile/-/briefprofile/100.004.000	3 active registrations under REACH, 1 Joint Submission(s) and 0 Individual Submission(s)		n.a.
8372b	Isopropylparaben (Isopropyl 4-hydroxybenzoate)	4191-73-5	No C&L harmonized	http://echa.europa.eu/substance-information/-/substanceinfo/100.021.882	Pre-Registration process	n.a.	n.a.
8372c	Butylparaben (Butyl 4-hydroxybenzoate)	94-26-8	No C&L harmonized	http://echa.europa.eu/substance-information/-/substanceinfo/100.021.882	Pre-Registration process	n.a.	n.a.
8372d	Isobutyl paraben (Isobutyl 4-hydroxybenzoate (INCI: Isobutylparaben) /Sodium salt or Salts of Isobutylparaben)	4247-02-3 (224-208-8)	No C&L harmonized	http://echa.europa.eu/substance-information/-/substanceinfo/100.022.008	Pre-Registration process	n.a.	n.a.

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Chemical Inventory of miscellaneous chemicals (Part 4)

Criteria for selection of REACH Chemicals:

1. All substances on the Candidate List already identified as SVHCs because of ED concerns under Art. 57(f)
2. All substances for which an SVHC opinion on the identification of the substance as SVHC due to its endocrine disrupting properties was provided by the Member State Committee at ECHA
3. All substances on the Candidate list identified as SVHC because of reprotoxicity 1A/1B
4. Select all substances listed in Annex XVII for restrictions due to a ED concern or because of having a harmonised classification as reprotoxic 1A/1B
5. All substances placed on CoRAP due to ED concern

1 EASIS data available; to be considered

(1) EASIS data available; not to be considered

[±] EASIS data not available although originally marked as such

[1] Found in SIN List; Reason for inclusion is captured in the Data sheet.

	Chemical Name	CAS	Final Risk Assessment report - Existing Substances Regulation (ESR)	Candidate List of substances of very high concern for Authorisation	Dossier Evaluation Decisions/Annex XV transitional reports/SVHC opinions of the MS Committee (MSC)	DAR availability	Cosmetics-CosIng report availability	Additional documents sent by JRC	Remarks/Additional source documents
450	propargite	2312-35-8	n.a.	n.a.	n.a.	Circabc/EF SA	n.a.		ECHA- Prior Informed Consent (PIC): This substance is subject to the Prior Informed Consent regulation and to export notification procedure from 31-Jan-2005
557	Oligomerisation and alkylation reaction products of 2-phenylpropene and phenol [Previously	700-960-7	n.a.	n.a.	http://echa.europa.eu/information-on-chemicals/dossier-evaluation-	n.a.	n.a.	CoRAP Decision document provided by JRC same as	EC No 700-960-7: Grounds for concern seem to meet the prioritisation criteria for inclusion into the CoRAP; MSC is of the opinion that should be prioritized for substance evaluation

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	Chemical Name	CAS	Final Risk Assessment report - Existing Substances Regulation (ESR)	Candidate List of substances of very high concern for Authorisation	Dossier Evaluation Decisions/Annex XV transitional reports/SVHC opinions of the MS Committee (MSC)	DAR availability	Cosmetics-CosIng report availability	Additional documents sent by JRC	Remarks/Additional source documents
	registered as Phenol, methylstyrenated - EC N. 270-966-8 and CAS N. 68512-30-1]				<u>decisions/-dislist/substance/100.228.163</u>			the one downloaded from ECHA website	
558	2,2',6,6'-Tetrabromo-4,4'-isopropylidenediphenol, oligomeric reaction products with Propylene oxide and n-butyl glycidyl ether		n.a	n.a	n.a.	n.a.	n.a.		See also No. 7261 [2,2',6,6'-tetrabromo-4,4'-isopropylidenediphenol]
559	reaction mass of 1-(1,2,3,4,5,6,7,8-octahydro-2,3,8,8-tetramethyl-2-naphthyl)ethan-1-one and 1-(1,2,3,4,6,7,8,8a-octahydro-2,3,8,8-tetramethyl-2-naphthyl)ethan-1-one and 1-(1,2,3,5,6,7,8,8a-octahydro-2,3,8,8-tetramethyl-2-naphthyl)ethan-1-one		n.a	n.a	n.a.	n.a.	n.a.		
560	reaction mass of 2-ethylhexyl 10-ethyl-4,4-		n.a.	<u>http://echa.europa.eu/candi</u>	<u>http://echa.europa.eu/documents/</u>	n.a.	n.a.		The Member State Committee has agreed on identification of the following substances as

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	dioctyl-7-oxo-8-oxa-3,5-dithia-4-stannatetradecanoate and 2-ethylhexyl 10-ethyl-4-[[2-[(2-ethylhexyl)oxy]-2-oxoethyl]thio]-4-octyl-7-oxo-8-oxa-3,5-dithia-4-stannatetradecanoate (reaction mass of DOTE and MOTE)			date-list-table/-/dislist/details/0b0236e1805908e3	10162/e26bf5ada61e-4f5b-afb8-ff5745fa75d9				Substances of Very High Concern [http://echa.europa.eu/documents/10162/3555188c-537b-4f3d-b03a-9143cb64a02e] RMOA (risk management option analysis)- Austria: http://echa.europa.eu/documents/10162/95a89428-1dbc-4a20-97e5-c4b004977d3d
561	4-Nonylphenol, branched and linear, ethoxylated [substances with a linear and/or branched alkyl chain with a carbon number of 9 covalently bound in position 4 to phenol, ethoxylated covering UVCB- and well-defined substances, polymers and homologues, which include any of the individual isomers and/or		n.a.	http://echa.europa.eu/candidate-list-table/-/dislist/details/0b0236e1807df0ea	n.a.	n.a.	n.a.		http://echa.europa.eu/documents/10162/8bd40dc-1367-480e-8d81-b5d308bc5f81 ; http://echa.europa.eu/documents/10162/f28b5c79-11e0-4ce2-91db-e53f7daa4d5a

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	combinations thereof]								
562	4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated [covering well-defined substances and UVCB substances, polymers and homologues]	9036-19-5		http://echa.europa.eu/candidate-list-table/-/dislist/details/0b0236e1807db570	n.a	n.a.	n.a.		Although selected as "criterion 1" No MSC Opinion was found in the link provided by JRC, i.e. http://echa.europa.eu/role-of-the-member-state-committee-in-the-authorisation-process/svhc-opinions-of-the-member-state-committee
563	4-Nonylphenol, branched and linear [substances with a linear and/or branched alkyl chain with a carbon number of 9 covalently bound in position 4 to phenol, covering also UVCB- and well-defined substances which include any of the individual isomers or a combination thereof]		http://echa.europa.eu/en/information-on-chemicals/information-from-existing-substances-regulation/-/substance-rev/2553/term	http://echa.europa.eu/candidate-list-table/-/dislist/details/0b0236e1807db370	n.a.	n.a.	n.a.		http://echa.europa.eu/documents/10162/8bd440dc-1367-480e-8d81-b5d308bc5f81 ; http://echa.europa.eu/documents/10162/f28b5c79-11e0-4ce2-91db-e53f7daa4d5a
580	Dibutyltin (DBT) (Dibutyl stannane)	1002-53-5	n.a	n.a	n.a	n.a.	n.a.		CAS Nos Grouped: 1002-53-5 (580_Dibutyltin); 683-18-1 (6277_dibutyltin dichloride)
651	lead dinitrate	10099-74-8	n.a	http://echa.europa.eu/candidate-list-table/-/dislist/details/0b0236e1807db370	n.a	n.a.	n.a.	none	REACH: Mainly read-across from supporting substance (structural analogue or surrogate)

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				date-list-table/-/dislist/details/0b0236e1807dc7f6					such as "Acetic acid, lead salt, basic" - RAC Opinion/CLH dossier available for LEAD
656	triphenyl phosphite	101-02-0	n.a	n.a	n.a	n.a.	n.a.	Substance Evaluation Report (UK, March 2014)	
659	cadmium chloride	10108-64-2	n.a	http://echa.europa.eu/en/candidate-list-table/-/dislist/details/0b0236e1807df243	n.a.	n.a.	n.a.		<u>Some uses of this substance are restricted under Annex XVII of REACH; Agreements of the MSC on identification of Substances of Very High Concern</u>
670	cadmium sulphate	10124-36-4; Additional CAS No: 31119-53-6	n.a	http://echa.europa.eu/candidate-list-table/-/dislist/details/0b0236e18058c1d0	n.a.	n.a.	n.a.		
673	cobalt sulphate [Cobalt(II)]	10124-43-3	n.a	http://echa.eu	n.a.	n.a.	n.a.		

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Screening of available evidence on chemical substances for the identification of endocrine disruptors according to different options in the context of an Impact Assessment

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	sulphate]			ropa.eu/candidate-list-table/-/dislist/details/0b0236e1807daa34					
682	cobalt dinitrate [Cobalt(II) dinitrate]	10141-05-6	n.a	http://echa.europa.eu/candidate-list-table/-/dislist/details/0b0236e1807da983	n.a.	n.a.	n.a.		
687	N-Phenyl-P-Phenylenediamine [N-(4-aminophenyl)aniline]	101-54-2	n.a	n.a	n.a	n.a.	YES (0991/06 - Opinion on N-Phenyl-p-phenylene diamine)		
912	sodium dichromate	10588-01-9 (Additional CAS No: 7789-12-0)	n.a.	http://echa.europa.eu/candidate-list-table/-	n.a.	n.a.	n.a.		

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				/dislist/details/Ob0236e1807d8a93					
952	p-cresol	106-44-5	n.a.	n.a.	n.a.	n.a.	n.a.	UK (2015): SUBSTANCE EVALUATION CONCLUSION as required by REACH Article 48 and EVALUATION REPORT	
960	p-phenylenediamine	106-50-3	n.a.	n.a.	n.a.	n.a.	YES (0989/06 - Opinion on p-Phenylene diamine)		
989	1-bromopropane (n-propyl bromide)	106-94-5	n.a.	http://echa.europa.eu/candidate-list-	http://echa.europa.eu/information-on-	n.a.	n.a.		

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				table/-/dislist/details/0b0236e1807dbbed	chemicals/dossier-evaluation-decisions/-/dislist/substance/100.003.133				
1080	Resorcinol (1,3-benzenediol)	108-46-3	n.a.	n.a.	n.a.	n.a.	YES (SCCP/111 7/07; SCCS/1270 /09)	Nordic Working Papers: Suspected endocrine disrupting substances (2013)	The Nordic Working paper includes data also for PBO
1151	2-methoxyethanol (ethylene glycol monomethyl ether)	109-86-4	n.a.	http://echa.europa.eu/candidate-list-table/-/dislist/details/0b0236e1807d99e2	n.a.	n.a.	YES (SCCNFP/0 663/03, final; SCCNFP04 7401, final; SCCNFP/08 25/04)		same CosIng reports for Nos 1151, 1182, 1202, 1228
1182	2-methoxyethyl acetate	110-49-6	Not yet available [http://echa.e	n.a.	n.a.	n.a.	YES (SCCNFP/0 663/03,		same CosIng reports for Nos 1151, 1182, 1202, 1228

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			uropa.eu/en/information-on-chemicals/information-from-existing-substances-regulation/-/substance-rev/2519/term]				final; SCCNFP04 7401, final; SCCNFP/08 25/04)		
1196	1,2-dimethoxyethane	110-71-4	n.a.	http://echa.europa.eu/candidate-list-table/-/dislist/details/0b0236e1807daf82	n.a.	n.a.	n.a.		
1202	2-ethoxyethanol	110-80-5	http://echa.europa.eu/en/information-on-chemicals/information-from-existing-	http://echa.europa.eu/candidate-list-table/-/dislist/details/0b0236e1807	http://echa.europa.eu/information-on-chemicals/transitional-measures/annex-	n.a.	YES (SCCNFP/0663/03, final; SCCNFP04 7401, final;		same CosIng reports for Nos 1151, 1182, 1202, 1228

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			substances-regulation/-/substance-rev/2496/term	d9911	xv-transitional-reports		SCCNFP/08 25/04)		
1228	2-ethoxyethyl acetate	111-15-9	http://echa.europa.eu/en/information-on-chemicals/information-from-existing-substances-regulation/-/substance-rev/2560/term	http://echa.europa.eu/candidate-list-table/-/dislist/details/0b0236e1807daec7	n.a.	n.a.	YES (SCCNFP/0663/03, final; SCCNFP047401, final; SCCNFP/0825/04)		same Cosing reports for Nos 1151, 1182, 1202, 1228
1234	Silicic acid, lead salt	11120-22-2	n.a.	http://echa.europa.eu/candidate-list-table/-/dislist/details/0b0236e1807de27d	n.a.	n.a.	n.a.	none	No REACH registered substance - RAC Opinion/CLH dossier available for LEAD
1280	Ethylene Glycol	111-76-2	http://echa.eu	n.a.	n.a.	n.a.	YES		

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	Monobutyl Ether (2-Butoxyethanol)		ropa.eu/en/information-on-chemicals/information-from-existing-substances-regulation/-/substance-rev/2513/term				(SCCP/1045/06)		
1281	2-(2-methoxyethoxy)ethanol (DEGME)	111-77-3	http://echa.europa.eu/en/information-on-chemicals/information-from-existing-substances-regulation/-/substance-rev/2512/term	n.a.	n.a.	n.a.	n.a.		http://echa.europa.eu/addressing-chemicals-of-concern/restrictions/substances-restricted-under-reach/-/dislist/details/0b0236e1807e2db3
1298	Diethylene glycol monobutyl ether (ethoxydiglycol)	111-90-0	n.a	n.a	n.a.	n.a.	YES (SCCP/1044/06;		

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							SCCP/1200/08; SCCS/1316/10; SCCS/1507/13)		
1303	dimethyl glutarate	1119-40-0	n.a.	n.a.	n.a.	n.a.	n.a.		
1305	bis(2-methoxyethyl) ether	111-96-6	n.a.	http://echa.europa.eu/candidate-list-table/-/dislist/details/0b0236e1807d9a5c	n.a.	n.a.	n.a.		
1350	1,2-bis(2-methoxyethoxy)ethane	112-49-2	n.a.	http://echa.europa.eu/candidate-list-table/-/dislist/details/0b0236e1807db01b	n.a.	n.a.	n.a.		
1436	triphenyl phosphate	115-86-6	n.a.	n.a.	n.a.	n.a.	n.a.	Environmental risk evaluation	

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								report: Triphenyl phosphate; England, Wales	
1439	tris(2-chloroethyl) phosphate (TCEP)	115-96-8	http://echa.europa.eu/en/information-on-chemicals/information-from-existing-substances-regulation/-/substance-rev/2568/term	http://echa.europa.eu/candidate-list-table/-/dislist/details/0b0236e1807d8417	n.a.	n.a.	n.a.		No relevant information available in REACH Registered substances website; http://echa.europa.eu/registration-dossier/-/registered-dossier/5193
1484	bis(2-ethylhexyl) phthalate (DEHP)	117-81-7	http://echa.europa.eu/en/information-on-chemicals/information-from-existing-substances-regulation/	http://echa.europa.eu/candidate-list-table/-/dislist/details/0b0236e1807d8dc8	http://echa.europa.eu/role-of-the-member-state-committee-in-the-authorisation-process/svhc-opinions-of-the	n.a.	n.a.		ECHA RAC-SEAC Background document to the Opinion on the Annex XV dossier proposing restrictions on four phthalates (December, 2012)

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			/substance-rev/2575/term		member-state-committee/-/substance-rev/6704/term				
1486	Bis(2-methoxyethyl) phthalate	117-82-8	n.a.	http://echa.europa.eu/candidate-list-table/-/dislist/details/0b0236e1807db0cc	http://echa.europa.eu/proposals-to-identify-substances-of-very-high-concern-previous-consultations/-/substance-rev/3473/term?_viewsubstances_WAR_echarevsubstanceportlet_SE_ARCH_CRITERIA_EC_NUMBER=204-212-6&_viewsubstances_WAR_echarevsubstanceportlet_DISS=true	n.a.	n.a.		<u>Recommendation for inclusion in the authorisation list - previous consultation</u>
1519	2,2',6,6'-tetra-tert-butyl-	118-82-1	n.a.	n.a.	n.a.	n.a.	n.a.		

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	4,4'-methylenediphenol								
1611	lead oxide sulfate (basic lead sulphate)	12036-76-9	n.a.	http://echa.europa.eu/candidate-list-table/-/dislist/details/0b0236e1807ddb0b	Voluntary RAR for lead compounds	n.a.	n.a.	none	REACH: Mainly read-across from supporting substance (structural analogue or surrogate) - Lead acetate, Lead etc - RAC Opinion/CLH dossier available for LEAD
1631	lead titanium trioxide	12060-00-3	n.a.	http://echa.europa.eu/candidate-list-table/-/dislist/details/0b0236e1807ddf0b	n.a.	n.a.	n.a.	none	REACH: Mainly read-across from supporting substance (structural analogue or surrogate) - Lead acetate, Lead etc
1637	pentalead tetraoxide sulphate (tetrabasic lead sulphate)	12065-90-6	n.a.	http://echa.europa.eu/candidate-list-table/-/dislist/details/0b0236e1807ddc58	Voluntary RAR for lead compounds	n.a.	n.a.	none	REACH: Mainly read-across from supporting substance (structural analogue or surrogate) such as Lead acetate - RAC Opinion/CLH dossier available for LEAD
1678	trilead dioxide phosphonate (dibasic lead	12141-20-7	n.a.	http://echa.europa.eu/candidate-list-table/-/dislist/details/0b0236e1807ddc58	Voluntary RAR for lead compounds	n.a.	n.a.	none	REACH: Mainly read-across from supporting substance (structural analogue or surrogate)

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Screening of available evidence on chemical substances for the identification of endocrine disruptors according to different options in the context of an Impact Assessment

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	phosphite)			date-list-table/-/dislist/details/0b0236e1807ddda6					such as Lead acetate - RAC Opinion/CLH dossier available for LEAD
1719	tetralead trioxide sulphate (tribasic lead sulphate)	12202-17-4	n.a.	http://echa.europa.eu/candidate-list-table/-/dislist/details/0b0236e1807ddbbf	Voluntary RAR for lead compounds	n.a.	n.a.	none	REACH: Mainly read-across from supporting substance (structural analogue or surrogate) such as Lead acetate - RAC Opinion/CLH dossier available for LEAD
1737	Low temperature tar oil, alkaline, extract residues (coal), low temperature coal tar alkaline	122384-78-5	n.a.	n.a.	n.a.	n.a.	n.a.		<u>Restriction list (annex XVII)</u>
1778	p-aminophenol	123-30-8	n.a.	n.a.	n.a.	n.a.	YES (0867/05 - Opinion on p-Aminophenol)		
1870	dioxobis(stearato)trilead (dibasic lead stearate)	12578-12-0	n.a.	http://echa.europa.eu/candidate-list-table/-/dislist/details/0b0236e1807ddbbf	Voluntary RAR for lead compounds	n.a.	n.a.	none	REACH: Mainly read-across from supporting substance (structural analogue or surrogate)

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				date-list-table/-/dislist/details/0b0236e1807ddd17					such as Lead acetate - RAC Opinion/CLH dossier available for LEAD
1884	Lead titanium zirconium oxide	12626-81-2	n.a.	http://echa.europa.eu/candidate-list-table/-/dislist/details/0b0236e1807de11b	n.a.	n.a.	n.a.	none	REACH: Mainly read-across from supporting substance (structural analogue or surrogate) such as Lead acetate - RAC Opinion/CLH dossier available for LEAD
1892	lead chromate molybdate sulfate red	12656-85-8	n.a.	http://echa.europa.eu/candidate-list-table/-/dislist/details/0b0236e1807d967c	n.a.	n.a.	n.a.		
1925	N,N-dimethylacetamide	127-19-5	n.a.	http://echa.europa.eu/candidate-list-table/-/dislist/details	n.a.	n.a.	n.a.		

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				/0b0236e1807dbb5e					
2042	Dipentyl phthalate (DPP)	131-18-0	n.a.	http://echa.europa.eu/candidate-list-table/-/dislist/details/0b0236e1807dcfb2	<u>Agreements of the MSC on identification of Substances of Very High Concern</u>	n.a.			<u>Identification of Substances of Very High Concern - previous consultation</u>
2061	orange lead (lead tetroxide)	1314-41-6	n.a.	http://echa.europa.eu/candidate-list-table/-/dislist/details/0b0236e1807dc54f	Voluntary RAR for lead compounds	n.a.	n.a.	none	REACH: Mainly read-across from supporting substance (structural analogue or surrogate) such as Lead acetate - RAC Opinion/CLH dossier available for LEAD
2081	Benzophenone-3 (oxybenzone)	131-57-7	n.a.	n.a.	n.a.	n.a.	YES (SCCP/1069/06; SCCP/1201/08) & <i>Opinion on the Evaluation</i>		

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							<i>of Potentially Estrogenic Effects of UV-filters adopted by the SCCNFP during the 17th Plenary meeting of 12 June 2001 (available online only; see remarks)</i>		
2091	lead monoxide (lead oxide)	1317-36-8	n.a.	http://echa.europa.eu/candidate-list-table/-/dislist/details/0b0236e1807	Voluntary RAR for lead compounds	n.a.	n.a.	none	REACH: Mainly read-across from supporting substance (structural analogue or surrogate) such as Lead acetate - RAC Opinion/CLH dossier available for LEAD

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				dc49b					
2105	trilead bis(carbonate) dihydroxide (basic lead carbonate)	1319-46-6	n.a.	http://echa.europa.eu/candidate-list-table/-/dislist/details/0b0236e1807dc62b	Voluntary RAR for lead compounds	n.a.	n.a.	none	REACH: Also read-across from supporting substance (structural analogue or surrogate) such as Lead acetate
2191	lead diazide	13424-46-9	n.a.	http://echa.europa.eu/candidate-list-table/-/dislist/details/0b0236e1807dbf52	n.a.	n.a.	n.a.	none	REACH: No relevant toxicity/ecotoxicity data; justification: "study technically not feasible". However, classification for fertility and organ toxicity is proposed - RAC Opinion/CLH dossier available for LEAD
2202	lead sulfochromate yellow	1344-37-2	n.a.	http://echa.europa.eu/candidate-list-table/-/dislist/details/0b0236e1807d95e1	n.a.	n.a.	n.a.		<u>Substance of very high concern requiring authorisation before it is used (Annex XIV of REACH).</u>
2324	lead bis(tetrafluoroborate)	13814-96-5	n.a.	http://echa.europa.eu/candidate-list-table/-/dislist/details/0b0236e1807d95e1	n.a.	n.a.	n.a.	none	REACH: Also read-across from supporting substance (structural analogue or surrogate)

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Screening of available evidence on chemical substances for the identification of endocrine disruptors according to different options in the context of an Impact Assessment

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				date-list-table/-/dislist/details/0b0236e1807dc6a7					such as Lead acetate - RAC Opinion/CLH dossier available for LEAD
2391	4-(1,1,3,3-tetramethylbutyl)phenol	140-66-9	n.a.	http://echa.europa.eu/candidate-list-table/-/dislist/details/0b0236e1807d9e89	http://echa.europa.eu/information-on-chemicals/dossier-evaluation-decisions/-/dislist/substance/100.004.934	n.a.	n.a.		
2491	3-ethyl-2-methyl-2-(3-methylbutyl)-1,3-oxazolidine	143860-04-2	n.a.	http://echa.europa.eu/candidate-list-table/-/dislist/details/0b0236e1807de5e6	n.a.	n.a.	n.a.		
2527	3-methylpyrazole	1453-58-3	n.a.	n.a.	n.a.	n.a.	n.a.		
2543	tributyltin chloride	1461-22-9	n.a.	n.a.	n.a.	n.a.	n.a.		
2544	tributyltin bromide	1461-23-0	n.a.	n.a.	n.a.	n.a.	n.a.		

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2594	2-Mercaptobenzothiazole (Benzothiazole-2-thiol)	149-30-4	n.a.	n.a.	n.a.	n.a.	No matching results found when searching by CAS No	http://ec.europa.eu/health/ph_risk/committees/04_sccp/docs/sccp_o_001.pdf	
2625	3-Benzylidene camphor (1,7,7-trimethyl-3-(phenylmethylene)bicyclo[2.2.1]heptan-2-one)	15087-24-8	n.a.	n.a.	<u>Identification of Substances of Very High Concern - current consultation</u>	n.a.	YES (1513/13 - Opinion on 3-Benzylidene camphor, 1374/96 - Opinion on 3-Benzylidenebornan-2-one)		
2633	Sodium perborate,perboric acid, sodium salt	15120-21-5 (11138-47-9)	n.a.	http://echa.europa.eu/candidate-list-table/-	<u>Agreements of the MSC on identification of Substances of</u>	n.a.	http://ec.europa.eu/growth/tools-	n.a.	http://echa.europa.eu/substance-information/-/substanceinfo/100.031.251

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				/dislist/details/0b0236e1807df1ae	Very High Concern		databases/cosing/index.cfm?fuseaction=search.details_v2&id=38025		
2657	lead 2,4,6-trinitro-m-phenylene dioxide (Lead styphnate)	15245-44-0	n.a.	http://echa.europa.eu/candidate-list-table/-/dislist/details/0b0236e1807dc006	n.a.	n.a.	http://ec.europa.eu/growth/tools-databases/cosing/index.cfm?fuseaction=search.details_v2&id=80948	none	REACH: Also read-across from supporting substance (structural analogue or surrogate) such as Lead acetate - RAC Opinion/CLH dossier available for LEAD
2701	2-ethylhexyl 10-ethyl-4,4-dioctyl-7-oxo-8-oxa-3,5-dithia-4-stannatetradecanoate (DOTE)	15571-58-1	n.a.	http://echa.europa.eu/candidate-list-table/-/dislist/details/0b0236e1805	n.a.	n.a.	n.a.		

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				908a5					
2813	tert-butyl methyl ether	1634-04-4	http://echa.europa.eu/en/information-on-chemicals/information-from-existing-substances-regulation?p_p_id=viewsubstances_WAR_echarevsubstanceportlet&p_p_lifecycle=0&p_p_state=normal&p_p_mode=view&p_p_col_id=column-1&p_p_col_pos=1&p_p_col_count=2&viewsubstances_WAR_echarev	n.a.	n.a.	n.a.	n.a.		

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			substanceportlet keywords=& viewsubstances WAR echarevsubstanceportlet advancedSearch=false& viewsubstances WAR echarevsubstanceportlet andOperator=true& viewsubstances WAR echarevsubstanceportlet orderByCol=staticField - 105& viewsubstances WAR echarevsubstanceportlet orderByType=asc& viewsubstances WAR						

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			_echarevsubst anceportlet_delta=200						
2863	2-Amino-3-hydroxypyridine (2-aminopyridin-3-ol)	16867-03-1	n.a.	n.a.	n.a.	n.a.	YES (1126/07 - Opinion on 2-Amino-3-hydroxypyridine)		
2940	Lead(II) bis(methanesulfonate)	17570-76-2	n.a.	http://echa.europa.eu/candidate-list-table/-/dislist/details/0b0236e1807dccc4	n.a.	n.a.	http://ec.europa.eu/growth/tools-databases/cosing/index.cfm?fuseaction=search.details_v2&id=80945	none	REACH: No relevant toxicity/ecotoxicity data - RAC Opinion/CLH dossier available for LEAD
2945	ammonium thiocyanate	1762-95-4	n.a.	n.a.	n.a.	n.a.	n.a.		
3040	octabenzene	1843-05-6	n.a.	n.a.	n.a.	n.a.	n.a.		
3152	p-METHYLAMINOPHENOL	1936-57-8	n.a.	n.a.	n.a.	n.a.	YES		http://ec.europa.eu/growth/tools-

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	sulphate						(0484/01 - Opinion on the Use of Permanent Hair Dyes and Bladder Cancer Risk, 0553/02 - Assessment Strategies for Hair Dyes, 0635/03 - Request for a Re-evaluation of hair dyes listed in Annex III to Directive 76/768/EE		databases/cosing/index.cfm?fuseaction=search_details_v2&id=84439

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							C on Cosmetic Products, 0797/04 - Opinion concerning Use of Permanent Hair Dyes and Bladder Cancer - Updated 2004, 0930/05 - Opinion on Personal Use of Hair Dyes and Cancer Risk, 0963/05 - Opinion on p-Methylami		

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							nophenol sulfate, 1054/06 - Memorandum on Hair Dye Substances and their Skin Sensitising Properties, 0179/99 - Opinion concerning p-Methylaminophenol		
3269	tributyltin	20763-88-6	n.a.	n.a.	n.a.	n.a.	n.a.		No results have been found using the specific CAS No; Tributyltin compounds include numerous substances not possible to group (see http://echa.europa.eu/en/substance-information/-/substanceinfo/100.240.865). Final selection and grouping was done following JRC instructions.

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3278	lead cyanamidate	20837-86-9	n.a.	http://echa.europa.eu/candidate-list-table/-/dislist/details/0b0236e1807dc75a	n.a.	n.a.	n.a.	none	REACH: No relevant toxicity/ecotoxicity data. However, classification for fertility and organ toxicity is proposed. - RAC Opinion/CLH dossier available for LEAD
3588	tert-butyl-4-methoxyphenol	25013-16-5	n.a.	n.a.	n.a.	n.a.	n.a.		
3590	Bisphenol-A-Epichlorhydrin Epoxy resin Average MW < 700 [4,4'-Isopropylidenediphenol, oligomeric reaction products with 1-chloro-2,3-epoxypropane]	25068-38-6	n.a.	n.a.	n.a.	n.a.	http://ec.europa.eu/growth/tools-databases/cosing/index.cfm?fuseaction=search_v2&id=54206	DE presentation : Assessment of Bisphenol A as an Endocrine Disrupter for the Environment	
3600	Phenol, nonyl- (Nonylphenol)	25154-52-3	http://echa.europa.eu/information-on-chemicals/info	n.a.	http://echa.europa.eu/en/information-on-chemicals/inform	n.a.	YES (0888/05; 0913/05)		http://ec.europa.eu/growth/tools-databases/cosing/index.cfm?fuseaction=search_details_v2&id=29388

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			rmation-from-existing-substances-regulation?dis= true&search criteria ecnumber=246-672-0&search criteria casnumber=25154-52-3&search criteria name=Nonylphenol		ation-from-existing-substances-regulation/-/substance-rev/2554/term				
3601	trixylol phosphate	25155-23-1	n.a.	http://echa.europa.eu/candidate-list-table/-/dislist/details/0b0236e1807dd3a3	n.a.	n.a.	n.a.		
3708	bis(2-ethylhexyl) tetrabromophthalate (BEH-TEBP)	26040-51-7	n.a.	n.a.	n.a.	n.a.	n.a.		

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3824	Polyhexamethylene biguanide hydrochloride	27083-27-8	n.a.	n.a.	n.a.	n.a.	YES (1534/14 - Opinion on Hydrolysed wheat proteins (Sensitisation only), 0125/99 - Opinion concerning Restrictions on Materials listed in annex VI of Directive 76/768/EEC on Cosmetic Products)		
4051	lead di(acetate) (also mentioned as lead acetate)	301-04-2	n.a.	http://echa.europa.eu/candidate-list-	n.a.	n.a.	n.a.	none	REACH: No relevant toxicity/ecotoxicity data - RAC Opinion/CLH dossier available for LEAD

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				table/-/dislist/details/0b0236e1807dead0					
4087	Paraformaldehyde	30525-89-4	n.a.	n.a.	n.a.	n.a.	http://ec.europa.eu/growth/tools-databases/cosing/index.cfm?fuseaction=search_detail_s_v2&id=28127		
4270	Pentadecafluorooctanoic acid (PFOA)	335-67-1	n.a.	http://echa.europa.eu/candidate-list-table/-/dislist/details/0b0236e1807db2ba	n.a.	n.a.	n.a.		http://echa.europa.eu/documents/10162/e7f15a22-ba28-4ad6-918a-6280392fa5ae
4280	Triclosan	3380-34-5	n.a.	http://echa.europa.eu/address	n.a.	n.a.	YES (0600/02 -		BPC Opinion ECHA/BPC/066/2015 [http://echa.europa.eu/regulations/biocidal-

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				ssing-chemicals-of-concern/biocidal-products-regulation/potential-candidates-for-substitution-previous-consultations?diss=true&search_criteria_ecnumber=222-182-2&search_criteria_casnumber=3380-34-5&search_criteria_name=Triclosan			Opinion concerning Triclosan, 1040/06 - Opinion on Triclosan, 1192/08 - Opinion on Triclosan, 1251/09 - Opinion on Triclosan Anti-microbial Resistance, 1414/11 - Opinion on Triclosan Addendum to the SCCP opinion on Triclosan)		products-regulation/approval-of-active-substances/bpc-opinions-on-active-substance-approval?diss=true&search_criteria_ecnumber=222-182-2&search_criteria_casnumber=3380-34-5&search_criteria_name=Triclosan]
4449	tributyltin-cation (same as	36643-28-4	n.a.	n.a.	n.a.	n.a.	n.a.		The document

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	tributyltin hydride, CAS: 688-73-3)								"30_Tributyltin_EQSdatasheet_150105" regarding the Common Implementation Strategy for the WFD is available. No results have been found using the specific CAS No in the ECHA website; Tributyltin compounds include numerous substances not possible to group (see http://echa.europa.eu/en/substance-information/-/substanceinfo/100.240.865)
4462	trilead diarsenate	3687-31-8	n.a.	http://echa.europa.eu/candidate-list-table/-/dislist/details/0b0236e1807dac26	n.a.	n.a.	n.a.	none	No REACH registered substance - RAC Opinion/CLH dossier available for LEAD
4537	4-Methylbenzylidene camphor (3-(4'-Methylbenzylidene)-dl-camphor / Enzacamene)	38102-62-4 (36861-47-9)	n.a.	n.a.	http://echa.europa.eu/documents/10162/a9e12f40-872c-4096-8141-f379b57f2037	n.a.	YES (0483/01 - Evaluation of Potentially Estrogenic Effects of UV-filters,		http://ec.europa.eu/health/scientific_committees/consumer_safety/opinions/sccnfp_opinions_97_04/sccp_out145_en.htm

The results of the screening do not constitute evaluations of individual substances to be carried out under the respective chemical legislations [[in particular, Regulation (EC) No 1107/2009 on plant protection products, Regulation (EU) No 528/2012 on biocidal products, Regulation (EC) No 1907/2006 REACH, Regulation (EC) No 1223/2009 on cosmetic products and the Water Framework Directive (EC) No 2000/60] and in no way prejudice future decisions on active substances to be taken pursuant to these pieces of the EU legislation.

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							0779/04 - Opinion on 4-Methylbenzylidene camphor, 1042/06 - Opinion on 4-Methylbenzylidene Camphor, 1184/08 - Opinion on 4-Methylbenzylidene camphor (4-MBC), 1377/96 - 3-(4-Methylbenzylidene)-d,l camphor)		

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4548	Ammonium pentadecafluorooctanoate (APFO)	3825-26-1	n.a.	http://echa.europa.eu/candidate-list-table/-/dislist/details/0b0236e1807db956	http://echa.europa.eu/proposals-to-identify-substances-of-very-high-concern-previous-consultations/-/substance-rev/3447/term?viewsubstances_WAR_echarevsubstanceportlet_SE_ARCH_CRITERIA_EC_NUMBER=223-320-4&viewsubstances_WAR_echarevsubstanceportlet_DISS=true	n.a.	n.a.		http://echa.europa.eu/documents/10162/4d9637d4-a066-4bdb-a014-9ee5fcb0b676
4960	Kojic Acid (5-hydroxy-2-hydroxymethyl-4-pyrone)	501-30-4	n.a.	n.a.	n.a.	n.a.	YES (SCCP/1182/06; SCCP/1481/12)		

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4975	Benzo[a]pyrene	50-32-8	n.a.	n.a.	http://echa.europa.eu/addressing-chemicals-of-concern/authorisation/substances-of-very-high-concern-identification/-/substance-rev/12639/term?viewsubstances_WAR_echarevsubstanceportlet_SEARCH_CRITERIA_EC_NUMBER=200-028-5&viewsubstances_WAR_echarevsubstanceportlet_DISS=true	n.a.	http://ec.europa.eu/growth/tools-databases/cosing/index.cfm?fuseaction=search.details_v2&id=29010		
5033	2-(2-butoxyethoxy)ethyl 6-propylpiperonyl ether (PBO)	51-03-6	n.a.	n.a.	n.a.	n.a.	n.a.	Nordic Working Papers: Suspected	The Nordic Working paper includes data also for resorcinol

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								endocrine disrupting substances (2013)	
5047	Quaternium-15 (cis-isomer)	51229-78-8	n.a.	n.a.	n.a.	n.a.	YES (SCCC/128 4/09; SCCS/1344 /10)		
5065	cobalt carbonate	513-79-1	n.a.	http://echa.europa.eu/candidate-list-table/-/dislist/details/0b0236e1807da8cf	n.a.	n.a.	n.a.		
5067	Acetic acid, lead salt, basic	51404-69-4	n.a.	http://echa.europa.eu/candidate-list-table/-/dislist/details/0b0236e1807de1ec	http://echa.europa.eu/documents/10162/13638/SVHC_AXVREP_EC_257-175-3_AceticAcidLeadSalt_en.pdf	n.a.	n.a.	none	REACH: No relevant toxicity/ecotoxicity data. However, data for lead acetate are used (read across) for other REACH registered lead compounds - RAC Opinion/CLH dossier available for LEAD
5160	Camphor benzalkonium	52793-97-2	n.a.	n.a.	n.a.	n.a.	YES		SCCP & SCCP documents for N,N,N-Trimethyl-

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	methosulfate (Methyl N,N,N-trimethyl-4-[(4,7,7-trimethyl-3-oxobicyclo[2.2.1]hept-2-ylidene)methyl]anilinium sulphate)						(SCCP/1015/06; SCCP/1202/08)		4-(2-oxoborn-3-ylidenemethyl) anilinium methyl sulphate (idenified ingredient of Camphor benzalkonium methosulfate)
5202	bis(2-propylheptyl) phthalate	53306-54-0	n.a.	n.a.	n.a.	n.a.	n.a.		
5209	1,2,4-trihydroxybenzene (Benzene-1,2,4-triol)	533-73-3	n.a.	n.a.	n.a.	n.a.	YES (SCCP/0962/05)		
5272	Decamethylcyclopentasiloxane (mentioned as Cyclomethicone and Cyclopentasiloxane)	541-02-6 (all 69430-24-6 / 556-67-2 / 541-02-6 / 540-97-6)	n.a.	n.a.	n.a.	n.a.	YES (SCCP/0893/05; SCCP/1241/10)		same Cosing reports for Nos 5272 & 5382
5324	2-Ethylhexyl-4-methoxycinnamate (Oxtinoxate or Ethylhexyl Methoxycinnamate)	5466-77-3	n.a.	n.a.	n.a.	n.a.	YES (0483/01 - Evaluation of Potentially Estrogenic Effects of UV-filters,	UV-filters in cosmetics – prioritisation for environmental assessment (England &	http://ec.europa.eu/health/scientific_committees/consumer_safety/opinions/sccnfp_opinions_97_04/sccp_out145_en.htm

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5382	Cyclomethicone Octamethylcyclotetrasiloxane	556-67-2	n.a.	n.a.	n.a.	n.a.	YES (SCCP/089 3/05; SCCP/1241 /10)		same CosIng reports for Nos 5272 & 5382
5443	Tributyltin (tributyltin chloride?)	56573-85-4	n.a.	n.a.	n.a.	n.a.	n.a.		No results have been found using the specific CAS No; Tributaltin compounds include numerous substances not possible to group (see http://echa.europa.eu/en/substance-information/-/substanceinfo/100.240.865)
5706	diisopentyl phthalate	605-50-5	n.a.	http://echa.europa.eu/candidate-list-table/-/dislist/details/0b0236e1807dad78	n.a.	n.a.	n.a.		
5760	toluene-2,5-diamine sulfate (2-methyl-p-phenylenediamine sulfate)	615-50-9	n.a.	n.a.	n.a.	n.a.	YES (SCCP/108 4/07; SCCP/1054 /06)	Draft Substance Evaluation Report (UK, 2014)	
5786	Phenol, styrenated	61788-44-1	n.a.	n.a.	n.a.	n.a.	n.a.		
5822	Sulfurous acid, lead salt,	62229-08-7	n.a.	http://echa.eu	Voluntary RAR for	n.a.	n.a.	none	REACH: Mainly read-across from supporting

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	dibasic (basic lead sulphate)			ropa.eu/candidate-list-table/-/dislist/details/0b0236e1807dde61	lead compounds				substance (structural analogue or surrogate) such as Lead acetate - RAC Opinion/CLH dossier available for LEAD
5851	methoxyacetic acid	625-45-6	n.a.	http://echa.europa.eu/documents/10162/e2dffe7e-49be-4dc6-b155-ecf3b91f42b7		n.a.	n.a.		
5880	1,2-Diethoxyethane	629-14-1	n.a.	http://echa.europa.eu/candidate-list-table/-/dislist/details/0b0236e1807def64	n.a.	n.a.			
5962	Triphenyltin chloride	639-58-7	n.a.	n.a.	n.a.	n.a.	n.a.		No CLP harmonized available
6014	Lead dipicrate	6477-64-1	n.a.	http://echa.europa.eu/candidate-list-table/-/dislist/details/0b0236e1807def64	http://echa.europa.eu/documents/10162/ff595229-	n.a.	n.a.	none	No REACH registered substance - RAC Opinion/CLH dossier available for LEAD

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				table/-/dislist/details/0b0236e1807dc1fa	79d7-45fe-bc4a-8af25445a8f1				
6071	Tar acids, coal, crude, crude phenols	65996-85-2	n.a.	n.a.	n.a.	n.a.	n.a.		<u>Some uses of this substance are restricted under Annex XVII of REACH.</u>
6132	Triphenyltin	668-34-8	n.a.	n.a.	n.a.	n.a.	n.a.		
6223	N,N-dimethylformamide	68-12-2	n.a.	http://echa.europa.eu/candidate-list-table/-/dislist/details/0b0236e1807dec94		n.a.	n.a.		
6277	dibutyltin dichloride (DBTCI2)	683-18-1		http://echa.europa.eu/candidate-list-table/-/dislist/details/0b0236e1807dede8		n.a.	n.a.		CAS Nos Grouped: 1002-53-5 (580_Dibutyltin); 683-18-1 (6277_dibutyltin dichloride)
6325	1,2-Benzenedicarboxylic acid, di-C7-11-branched and linear alkyl esters	68515-42-4	n.a.	http://echa.europa.eu/candidate-list-table/-/dislist/details/0b0236e1807dede8	<u>Agreements of the MSC on identification of</u>	n.a.	YES (0888/05; 0913/05)		http://ec.europa.eu/growth/tools-databases/cosing/index.cfm?fuseaction=search_details_v2&id=29373

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				table/-/dislist/details/0b0236e1807da06c	Substances of Very High Concern				
6330	1,2-Benzenedicarboxylic acid, dihexylester, branched and linear (Diisohexyl phthalate - DIHP)	68515-50-4	n.a.	http://echa.europa.eu/candidate-list-table/-/dislist/details/0b0236e1807deea6	Agreements of the MSC on identification of Substances of Very High Concern	n.a.	n.a.		http://echa.europa.eu/opinions-of-the-committee-for-risk-assessment-on-proposals-for-harmonised-classification-and-labelling/-/substance-rev/2084/term
6331	1,2-Benzenedicarboxylic acid, di-C6-10-alkyl esters	68515-51-5 (Additional Cas No: 68648-93-1)	n.a.	http://echa.europa.eu/candidate-list-table/-/dislist/details/0b0236e1806e6ac6	n.a.	n.a.	n.a.		CAS no.: 68648-93-1: http://echa.europa.eu/substance-information/-/substanceinfo/100.065.447
6369	2,2'-dimethyl-4,4'-methylenebis(cyclohexylamine)	6864-37-5	n.a.	n.a.	n.a.	n.a.	n.a.	DE Presentation : 5th Endocrine Disrupter Expert	

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								Group Meeting Closed Session	
6384	Silicic acid (H ₂ Si ₂ O ₅), barium salt (1:1), lead-doped	68784-75-8	n.a	http://echa.europa.eu/candidate-list-table/-/dislist/details/0b0236e1807de416	n.a	n.a.	n.a.	none	The relevant toxicity REACH Registrant data refer to a "combined repeated dose and reproduction / developmental screening" conducted with the substance. Due to the limited data available and since the substance is grouped regarding C&L to other lead compounds it has been considered most appropriate to include in the Data sheet the data for lead as included in the regulatory documents.
6440	[phthalato(2-)]dioxotrilead (dibasic lead phthalate)	69011-06-9	n.a	http://echa.europa.eu/candidate-list-table/-/dislist/details/0b0236e1807dda72	http://echa.europa.eu/information-on-chemicals/dossier-evaluation-decisions/-/dislist/substance/100.066.970;	n.a.	n.a.	none	Voluntary RAR for lead compounds; REACH: Mainly read-across from supporting substance (structural analogue or surrogate) such as Lead acetate - RAC Opinion/CLH dossier available for LEAD
6518	3-amino-2,6-dimethylphenol	6994-64-5	n.a.	n.a.	n.a.	n.a.	YES (SCCS/152		

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							9/14)		
6593	cobalt di(acetate) [Cobalt(II) diacetate]	71-48-7	n.a.	http://echa.europa.eu/candidate-list-table/-/dislist/details/0b0236e1807da7c1	n.a.	n.a.	n.a.		<u>REACH Dossier Evaluation Decision available</u>
6600	Isopentyl-p-Methoxycinnamate (Amiloxate)	71617-10-2	n.a.	n.a.	n.a.	n.a.	YES (SCCP/164 1/97)	UV-filters in cosmetics – prioritisation for environmental assessment (England & Wales)	
6618	1,2-Benzenedicarboxylic acid, di-C6-8-branched alkyl esters, C7-rich	71888-89-6	n.a.	http://echa.europa.eu/candidate-list-table/-/dislist/details/0b0236e1807da12b	http://echa.europa.eu/proposals-to-identify-substances-of-very-high-concern-previous-consultations/	n.a.	n.a.		<u>Agreements of the MSC on identification of Substances of Very High Concern</u>

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					/substance-rev/3486/term?viewsubstancesWAR_echarevsubstanceportlet_SE_ARCH_CRITERIA_EC_NUMBER=276-158-1&viewsubstancesWAR_echarevsubstanceportlet_DISS=true				
6731	mercury	7439-97-6	n.a.	n.a.	n.a.	n.a.	n.a.		<u>Some uses of this substance are restricted under Annex XVII of REACH.</u>
6789	chloromethane (Methyl chloride)	74-87-3	n.a.	n.a.	n.a.	n.a.	http://ec.europa.eu/growth/tools-databases/cosing/index.cfm?fuseaction=search.details_v2&id=3		

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							0122		
6810	Acetaldehyde	75-07-0	n.a.	n.a.	n.a.	n.a.	YES (SCCNFP/0821/04)		
6812	Dichloromethane	75-09-2	n.a.	n.a.	http://echa.europa.eu/information-on-chemicals/dossier-evaluation-decisions-/dislist/substance/100.000.763	n.a.	http://ec.europa.eu/growth/tools-databases/cosing/index.cfm?fuseaction=search.detail_s_v2&id=28242	http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/scsco_170.pdf	
6814	Di-μ-oxo-di-n-butylstanniohydroxyborane/ Dibutyltin hydrogen borate C ₈ H ₁₉ B ₃ O ₃ Sn (DBB)	75113-37-0	n.a.	n.a.	n.a.	n.a.	n.a.		
6815	formamide	75-12-7	n.a.	http://echa.europa.eu/candidate-list-table-/dislist/details	n.a.	n.a.	http://ec.europa.eu/growth/tools-databases/		n.a.

The results of the screening do not constitute evaluations of individual substances to be carried out under the respective chemical legislations [[in particular, Regulation (EC) No 1107/2009 on plant protection products, Regulation (EU) No 528/2012 on biocidal products, Regulation (EC) No 1907/2006 REACH, Regulation (EC) No 1223/2009 on cosmetic products and the Water Framework Directive (EC) No 2000/60] and in no way prejudice future decisions on active substances to be taken pursuant to these pieces of the EU legislation.

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				/0b0236e1807db500			cosing/index.cfm?fuseaction=search.details_v2&id=29211		
6817	carbon disulphide	75-15-0	n.a.	n.a.	n.a.	n.a.	http://ec.europa.eu/cosing/index.cfm?fuseaction=search.details_v2&id=28909		
6900	sodium perchlorate	7601-89-0	n.a.	n.a.	n.a.	n.a.	n.a.	DE presentation : 5th Endocrine Disrupter Expert Group	

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								Meeting Closed Session	
6932	Sodium peroxometaborate	7632-04-4	n.a.	http://echa.europa.eu/candidate-list-table/-/dislist/details/0b0236e1807defee	<u>Identification of Substances of Very High Concern - previous consultation</u>	n.a.	<u>YES (790/2009 - CMR 1B)</u>		http://ec.europa.eu/growth/tools-databases/cosing/index.cfm?fuseaction=search.details_v2&id=38025
6941	Cobalt dichloride	7646-79-9	n.a.	http://echa.europa.eu/candidate-list-table/-/dislist/details/0b0236e1807d888d	n.a.	n.a.	n.a.		
7051	Lead chromate	7758-97-6	n.a.	http://echa.europa.eu/candidate-list-table/-/dislist/details/0b0236e1807d972b	http://echa.europa.eu/proposals-to-identify-substances-of-very-high-concern-previous-consultations/	n.a.	http://ec.europa.eu/growth/tools-databases/cosing/index.cfm?fuseaction=search.details_v2&id=38025		

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					/substance-rev/3515/term?_viewsubstances_WAR_echarevsubstanceportlet_SEARCH_CRITERIA_EC_NUMBER=231-846-0&_viewsubstances_WAR_echarevsubstanceportlet_DISS=true		eaction=search.detail_s_v2&id=80941		
7055	N-pentyl-isopentylphthalate	776297-69-9	n.a.	http://echa.europa.eu/candidate-list-table/-/dislist/details/0b0236e1807db637	Identification of Substances of Very High Concern - previous consultation	n.a.	n.a.		
7065	sodium chromate	7775-11-3				n.a.	n.a.		
7076	potassium dichromate	7778-50-9				n.a.	n.a.		
7108	Lead hydrogen arsenate	7784-40-9	n.a.	http://echa.europa.eu/candidate-list-	http://echa.europa.eu/proposals-to-identify-	n.a.	http://ec.europa.eu/growth/tool	none	No REACH registered substance - RAC Opinion/CLH dossier available for LEAD

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				table/-/dislist/details/0b0236e1807d8c75	substances-of-very-high-concern-previous-consultations/-/substance-rev/3547/term?viewsubstancesWAR_echarevsubstanceportlet_SE_ARCH_CRITERIA_EC_NUMBER=232-064-2&viewsubstancesWAR_echarevsubstanceportletDISS=true		s-databases/cosing/index.cfm?function=search.details_v2&id=80942		
7129	ammonium dichromate	7789-09-5	http://echa.europa.eu/en/information-on-chemicals/information-from-existing-substances-regulation/-	http://echa.europa.eu/candidate-list-table/-/dislist/details/0b0236e1807da522	n.a.	n.a.	n.a.		Reference to data relevant for other chromates has been made.

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			/substance-rev/2565/term						
7147	Cadmium fluoride	7790-79-6	n.a.	http://echa.europa.eu/candidate-list-table/-/dislist/details/0b0236e18059092a	n.a.	n.a.	n.a.		
7150	ammonium perchlorate	7790-98-9	n.a.	n.a.	n.a.	n.a.	n.a.	DE presentation : 5th Endocrine Disrupter Expert Group Meeting Closed Session	
7157	tetraethyllead	78-00-2	n.a.	http://echa.europa.eu/candidate-list-table/	http://echa.europa.eu/information-on-chemicals/dossier	n.a.	http://ec.europa.eu/growth/tools	none	REACH: Also read-across from other Lead compounds - RAC Opinion/CLH dossier available for LEAD

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				/dislist/details/0b0236e1807de06e	-evaluation-decisions/-dislist/substance/100.000.979		databases/cosing/index.cfm?fuseaction=search.details_v2&id=80946		
7215	2-Chloroacetamide	79-07-2	n.a.	n.a.	n.a.	n.a.	YES (SCCS/1360/10; SCCS/1414/11)		
7222	N-methylacetamide	79-16-3	n.a.	http://echa.europa.eu/candidate-list-table/-dislist/details/0b0236e1807de488	n.a.	n.a.	http://ec.europa.eu/growth/tools-databases/cosing/index.cfm?fuseaction=search.details_v2&id=29212		
7261	2,2',6,6'-tetrabromo-4,4'-	79-94-7	http://echa.eu	n.a.	http://echa.europ	n.a.	n.a.		EFSA Opinions available; See also No. 558

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	isopropylidenediphenol (TBBPA)		ropa.eu/en/information-on-chemicals/information-from-existing-substances-regulation/-/substance-rev/2506/term		a.eu/information-on-chemicals/dossier-evaluation-decisions/-/dislist/substance/100.001.125				[2,2',6,6'-Tetrabromo-4,4'-isopropylidenediphenol, oligomeric reaction products with Propylene oxide and n-butyl glycidyl ether]
7274	4,4'-isopropylidenediphenol (Bisphenol A)	80-05-7	http://echa.europa.eu/en/information-on-chemicals/information-from-existing-substances-regulation/-/substance-rev/2543/term		http://echa.europa.eu/documents/10162/13630/trd_cover_page_bisphenol_a_en.pdf	n.a.	n.a.		EFSA Opinions available
7279	dapsone (TETRAHYDROMYRCENYL ACETATE)	80-08-0	n.a.	n.a.	n.a.	n.a.	http://ec.europa.eu/growth/tool		

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							s-databases/cosing/index.cfm?function=search.details_v2&id=41042		
7281	4,4'-sulphonyldiphenol (Bisphenol S)	80-09-1	n.a.	n.a.	http://echa.europa.eu/information-on-chemicals/dossier-evaluation-decisions-/dislist/substance/100.001.137	n.a.	n.a.		
7285	pyrochlore, antimony lead yellow	8012-00-8	n.a.	http://echa.europa.eu/candidate-list-table-/dislist/details/0b0236e1807de33c	n.a.	n.a.	n.a.	none	REACH: Mainly read-across from supporting substance (structural analogue or surrogate) such as lead acetate & lead dinitrate- RAC Opinion/CLH dossier available for LEAD
7298	p-(1,1-	80-46-6	n.a.	n.a.	n.a.	n.a.	n.a.	Presentation	

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	dimethylpropyl)phenol							for 4-t-Pentylphenol	
7322	Musk Ketone (also as 4'-tert-Butyl-2',6'-dimethyl-3',5'-dinitroacetophenone)	81-14-1	http://echa.europa.eu/en/information-on-chemicals/information-from-existing-substances-regulation/-/substance-rev/2505/term	n.a.	n.a.	n.a.	YES (SCCNFP/0817/04) & SCCP/0162/99 - Opinion on Musk ketone ONLY online available (see Remarks); 0634/03 - Opinion on Musk ketone and Musk xylene NOT FOUND		http://ec.europa.eu/health/scientific_committees/consumer_safety/opinions/sccnfp_opinions_97_04/sccp_out99_en.htm

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7323	Musk Xylene (also as 5-tert-Butyl-2,4,6-trinitro-m-xylene)	81-15-2	http://echa.europa.eu/en/information-on-chemicals/information-from-existing-substances-regulation/-/substance-rev/2571/terms	http://echa.europa.eu/candidate-list-table/-/dislist/details/0b0236e1807d8b29	<u>Agreements of the MSC on identification of Substances of Very High Concern</u>	n.a.	YES (SCCNFP/0817/04; SCCNFP/0163/99); 0634/03 - Opinion on Musk ketone and Musk xylene NOT FOUND		
7369	1-Methyl-2,6-diaminobenzene (also as 2-Methyl-m-phenylenediamine OR Toluene-2,6-diamine)	823-40-5	n.a.	n.a.	n.a.	n.a.	YES (SCCP/0888/05; SCCP/0913/05)		The CosIng reports SCCP/0888/05; SCCP/0913/05 are general opinions. There is an EU RAR available for toluene-2,4 diamine; not possible to conclude on possibilities for read across.
7437	2-amino-4-hydroxyethylaminoanisole sulfate	83763-48-8 (relevant also for 83763-47-7)	n.a.	n.a.	n.a.	n.a.	YES (SCCNFP/0553/02; SCCNFP/0635/03; SCCNFP/07		http://ec.europa.eu/health/scientific_committees/consumer_safety/opinions/sccnfp_opinions_97_04/sccp_out143_en.htm

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							97/04; SCCP/0930 /05; SCCP/0958 /05; SCCP/1054 /06; SCCP/1172 /08; SCCS/1250 /09) & 0484/01 Opinion ONLY online available (see Remarks)		
7503	Distillates (coal tar), naphthalene oils,naphthalene oil	84650-04-4	n.a.	n.a.	n.a.	n.a.	http://ec.europa.eu/growth/tool-s-databases/cosing/ind		

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							ex.cfm?fuseaction=search.details_v2&id=81071		
7505	Diethyl phthalate	84-66-2	n.a	n.a	http://echa.europa.eu/information-on-chemicals/dossier-evaluation-decisions-/dislist/substance/100.001.409	n.a.	YES (SCCNFP/0411/01; SCCNFP/0767/03; SCCP/1016/06)		
7507	diisobutyl phthalate (BIPB)	84-69-5	n.a.	http://echa.europa.eu/candidate-list-table-/dislist/details/0b0236e1807d931d	http://echa.europa.eu/role-of-the-member-state-committee-in-the-authorisation-process/svhc-opinions-of-the-member-state-committee-/substance-	n.a.	n.a.		ECAH RAC-SEAC Background document to the Opinion on the Annex XV dossier proposing restrictions on four phthalates (December, 2012)

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					rev/6702/term				
7511	dibutyl phthalate	84-74-2	http://echa.europa.eu/en/information-on-chemicals/information-from-existing-substances-regulation/-/substance-rev/2557/term	http://echa.europa.eu/candidate-list-table/-/dislist/details/0b0236e1807d82a7	http://echa.europa.eu/role-of-the-member-state-committee-in-the-authorisation-process/svhc-opinions-of-the-member-state-committee/-/substance-rev/6701/term	n.a.	n.a.		
7512	Dihexyl phthalate	84-75-3	n.a.	http://echa.europa.eu/candidate-list-table/-/dislist/details/0b0236e1807dd99e	Agreements of the MSC on identification of Substances of Very High Concern	n.a.	n.a.		http://echa.europa.eu/opinions-of-the-committee-for-risk-assessment-on-proposals-for-harmonised-classification-and-labelling?diss=true&search_criteria_ecnumber=201-559-5&search_criteria_casnumber=84-75-3&search_criteria_name=Dihexyl+phthalate
7516	1,2-Benzenedicarboxylic acid, dipentylester, branched and linear	84777-06-0	n.a.	http://echa.europa.eu/candidate-list-table/	http://echa.europa.eu/proposals-to-identify-substances-of-	n.a.	http://ec.europa.eu/growth/tool		the support document for the identification of 1,2-Benzenedicarboxylic acid, dipentylester, branched and linear as a substance of very high concern is based on the harmonized

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Screening of available evidence on chemical substances for the identification of endocrine disruptors according to different options in the context of an Impact Assessment

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				/dislist/details/0b0236e1807db220	very-high-concern-previous-consultations/-/substance-rev/3443/term?viewsubstancesWAR_echarevsubstanceportlet_SEARCH_CRITERIA_EC_NUMBER=284-032-2&viewsubstancesWAR_echarevsubstanceportletDISS=true		databases/cosing/index.cfm?fuseaction=search.details_v2&id=30178		classification and does not contain any relevant data for population.
7578	6,6'-di-tert-butyl-4,4'-butylidenedi-m-cresol	85-60-9	n.a.	n.a.	n.a.	n.a.	n.a.		
7581	benzyl butyl phthalate	85-68-7	http://echa.europa.eu/en/information-on-chemicals/information-from-existing-substances-	http://echa.europa.eu/candidate-list-table/-/dislist/details/0b0236e1807d84ad	http://echa.europa.eu/role-of-the-member-state-committee-in-the-authorisation-process/svhc-	n.a.	n.a.		ECAH RAC-SEAC Background document to the Opinion on the Annex XV dossier proposing restrictions on four phthalates (December, 2012)

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			regulation/-/substance-rev/2558/term		opinions-of-the-member-state-committee/-/substance-rev/6703/term				
7645	diocetyl tin oxide	870-08-6	n.a.	n.a.	n.a.	n.a.	n.a.		
7657	N-Methyl-2-pyrrolidone (Methyl Pyrrolidone)	872-50-4 (also relevant for 51013-18-4)	n.a.	http://echa.europa.eu/candidate-list-table/-/dislist/details/0b0236e1807da281	http://echa.europa.eu/previous-consultations-on-restriction-proposals/-/substance-rev/1899/term	n.a.	YES (SCCS/1413/11)		http://echa.europa.eu/documents/10162/fa8e78f8-2096-42c7-b73e-e3cc84349e3f
7740	dinoseb	88-85-7	n.a.	http://echa.europa.eu/candidate-list-table/-/dislist/details/0b0236e1807de543	n.a.	n.a.	http://ec.europa.eu/growth/tool_s_databases/cosing/index.cfm?fuseaction=search.details_v2&id=29150		

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7749	triphenyltin hydride (based on the CAS No)	892-20-6	n.a	n.a	n.a	n.a.	n.a.		
7870	Fatty acids, C16-18, lead salts	91031-62-8	n.a.	http://echa.europa.eu/candidate-list-table/-/dislist/details/0b0236e1807ddefa	n.a.	n.a.	n.a.	none	REACH: Mainly read-across from supporting substance (structural analogue or surrogate) such as lead acetate & lead dinitrate- RAC Opinion/CLH dossier available for LEAD
8027	Hydroxyethyl-p-phenylenediamine sulfate (3-(2-Hydroxyethyl)-p-phenylenediammonium sulphate)	93841-25-9	n.a.	n.a.	n.a.	n.a.	YES (SCCP/066 6/03; SCCP/1124 /07; SCCS/1310 /10)		
8046	propyl 4-hydroxybenzoate (propylparaben)	94-13-3	n.a.	n.a.	n.a.	n.a.	http://ec.europa.eu/growth/tool-s-databases/cosing/index.cfm?fuseaction=se	none	

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							arch.details_v2&id=37312		
8049	Hydroxyethyl-3,4-methylenedioxyaniline HCl	94158-14-2	n.a.	n.a.	n.a.	n.a.	YES (SCCNFP/0553/02; SCCNFP/0635/03; SCCNFP/0797/04; SCCP/0930/05; SCCP/0951/05; SCCP/1054/06; SCCS/1269/09) & 0484/01 Opinion ONLY online available (see		http://ec.europa.eu/health/scientific_committees/consumer_safety/opinions/sccnfp_opinions_97_04/sccp_out143_en.htm

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							Remarks)		
8099	benzotriazole	95-14-7	n.a.	n.a.	http://echa.europa.eu/information-on-chemicals/dossier-evaluation-decisions/-/dislist/substance/100.002.177	n.a.	http://ec.europa.eu/growth/tool-s-databases/cosing/index.cfm?fuseaction=search.detail_s_v2&id=32149		
8119	o-Aminophenol (also relevant for o-Aminophenol (o-Aminophenol; CI 76520) and its salts)	95-55-6 (also relevant for 67845-79-8 & 51-19-4)	n.a.	n.a.	n.a.	n.a.	YES (SCCNFP/0553/02; SCCNFP/0635/03; SCCNFP/0797/04; SCCP/0930/05; SCCP/0951/05; SCCP/1054		http://ec.europa.eu/health/scientific_committees/consumer_safety/opinions/sccnfp_opinions_97_04/sccp_out143_en.htm

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							/06; SCCS/1291/10) & 0484/01 Opinion ONLY online available (see Remarks)		
8170	1,2,3-trichloropropane	96-18-4	n.a.	n.a.	http://echa.europa.eu/information-on-chemicals/dossier-evaluation-decisions/-/dislist/substance/100.002.261	n.a.	http://ec.europa.eu/growth/tool-s-databases/cosing/index.cfm?fuseaction=search_detail_s_v2&id=30168		
8185	imidazolidine-2-thione (ETU)	96-45-7	n.a.	http://echa.europa.eu/candidate-list-	n.a.	DAR for mancozeb	http://ec.europa.eu/growth/tool		

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				table/- /dislist/details /0b0236e1807 ded4f			s- databases/ cosing/ind ex.cfm?fus eaction=se arch.detail s_v2&id=2 9198		
8194	6,6'-di-tert-butyl-4,4'-thiodi-m-cresol	96-69-5	n.a.	n.a.	n.a.	n.a.	n.a.		
8196	2,4-di-tert-butylphenol	96-76-4	n.a.	n.a.	http://echa.europa.eu/information-on-chemicals/dossier-evaluation-decisions/-/dislist/substance/100.002.303	n.a.	n.a.		
8250	Furfural	98-01-1	http://echa.europa.eu/en/information-on-chemicals/information-from-existing-	n.a.	n.a.	n.a.	YES (SCCNFP/0822/04; SCCP/1461/12)		

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			substances-regulation/-/substance-rev/2517/term						
8276	4-tert-butylphenol	98-54-4	http://echa.europa.eu/en/information-on-chemicals/information-from-existing-substances-regulation/-/substance-rev/2536/term	n.a.	n.a.	n.a.	http://ec.europa.eu/growth/tools-databases/cosing/index.cfm?fuseaction=search.details_v2&id=28677		
8296	nitrobenzene	98-95-3	http://echa.europa.eu/en/information-on-chemicals/information-from-existing-substances-regulation/-	http://echa.europa.eu/candidate-list-table/-/dislist/details/0b0236e1808dad85	n.a.	n.a.	http://ec.europa.eu/growth/tools-databases/cosing/index.cfm?fuseaction=search		http://echa.europa.eu/documents/10162/58b183f8-3178-4a37-a4fe-68385af2cbf8

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			/substance-rev/2545/term				arch.details_v2&id=28468		
8331	methyl 4-hydroxybenzoate (methylparaben)	99-76-3	n.a.	n.a.	n.a.	n.a.	http://ec.europa.eu/growth/tools-databases/cosing/index.cfm?fuseaction=search.details_v2&id=92341	none (specifically for methylparaben)	Not included in the SIN List (http://sinlist.chemsec.org/). However, the Danish Centre of Endocrine Disruptors has evaluated methylparaben ("Evaluation of tebuconazole, triclosan, methylparaben and ethylparaben according to the Danish proposal for criteria for endocrine disruptors, May 2012"; report provided by JRC)
8341	4-hydroxybenzoic acid (p-hydroxybenzoic acid)	99-96-7	n.a.	n.a.	n.a.	n.a.	http://ec.europa.eu/growth/tools-databases/cosing/index.cfm?fuseaction=search.details_v2&id=92341	none	REACH: Mainly read-across from parabens

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							2341		
8372a	Ethylparaben	120-47-8	n.a.	n.a.	n.a.	n.a.	http://ec.europa.eu/growth/tools-databases/cosing/index.cfm?fuseaction=search_detail_s_v2&id=92341	none	Not included in the SIN List (http://sinlist.chemsec.org/). However, the Danish Centre of Endocrine Disruptors has evaluated methylparaben ("Evaluation of tebuconazole, triclosan, methylparaben and ethylparaben according to the Danish proposal for criteria for endocrine disruptors, May 2012"; report provided by JRC)
8372b	Isopropylparaben (Isopropyl 4-hydroxybenzoate)	4191-73-5	n.a.	n.a.	n.a.	n.a.	YES	none	
8372c	Butylparaben (Butyl 4-hydroxybenzoate)	94-26-8	n.a.	n.a.	n.a.	n.a.	http://ec.europa.eu/growth/tools-databases/cosing/index.cfm?fuseaction=search_detail_s_v2&id=31734	none	http://ec.europa.eu/growth/tools-databases/cosing/index.cfm?fuseaction=search_details_v2&id=31734

The results of the screening do not constitute evaluations of individual substances to be carried out under the respective chemical legislations [[in particular, Regulation (EC) No 1107/2009 on plant protection products, Regulation (EU) No 528/2012 on biocidal products, Regulation (EC) No 1907/2006 REACH, Regulation (EC) No 1223/2009 on cosmetic products and the Water Framework Directive (EC) No 2000/60] and in no way prejudice future decisions on active substances to be taken pursuant to these pieces of the EU legislation.

It would thus be erroneous to consider that the substances listed in the results of this study (SANTE/2015/E3/SI2.706218) are considered as endocrine disruptors within the meaning of the EU legislation.

	Chemical Name	CAS	Final Risk Assessment report - Existing Substances Regulation (ESR)	Candidate List of substances of very high concern for Authorisation	Dossier Evaluation Decisions/Annex XV transitional reports/SVHC opinions of the MS Committee (MSC)	DAR availability	Cosmetics-CosIng report availability	Additional documents sent by JRC	Remarks/Additional source documents
							s_v2&id=31734		
8372d	Isobutyl paraben (Isobutyl 4-hydroxybenzoate (INCI: Isobutylparaben) /Sodium salt or Salts of Isobutylparaben)	4247-02-3 (224-208-8)	n.a.	n.a.	n.a.	n.a.	YES	none	

The results of the screening do not constitute evaluations of individual substances to be carried out under the respective chemical legislations [[in particular, Regulation (EC) No 1107/2009 on plant protection products, Regulation (EU) No 528/2012 on biocidal products, Regulation (EC) No 1907/2006 REACH, Regulation (EC) No 1223/2009 on cosmetic products and the Water Framework Directive (EC) No 2000/60] and in no way prejudice future decisions on active substances to be taken pursuant to these pieces of the EU legislation.

It would thus be erroneous to consider that the substances listed in the results of this study (SANTE/2015/E3/SI2.706218) are considered as endocrine disruptors within the meaning of the EU legislation.

It is noted that for all miscellaneous chemicals screened, only publically available source documents/data have been considered, apart from the working documents from ECHA ED EG for which the evaluating MS CA had given explicit permission to use.

Regarding the availability of a classification proposal, in most cases the REACH Registrant's classification proposal was captured in the data sheet. However, since this refers to a self-classification, it has been captured for completeness reasons especially since the REACH registrant's data have been considered for data population as well. Whenever a proposed classification has been available by a regulatory authority both proposals have been captured. However, the more strict classification proposal has been finally considered for the overall/combined categorization outcome under Option 1. It is noted that for 183 out of the 186 substances screened the most strict classification was either the harmonised C&L or the regulatory authority's proposal. For two substances, a classification as Repr. Cat 1A/B is applied by REACH Registrants while for one substance (#2625 3-Benzylidene camphor), not REACH registered, a self-classification by the majority of notifiers as Repr. Cat 1A/B has been identified.

It is noted that in the ECHA website the information on Registered Substances comes from registration dossiers which have been assigned a registration number, but this information has not been reviewed or verified by the Agency or any other authority. The content is subject to change without prior notice. Following JRC recommendation, these data were used only where there were no regulatory assessments available.

Moreover, for any REACH chemicals where more than one submission result has been found when searching in the Registered substances website, and following JRC recommendation regarding multiple submissions, focus was on joint submissions first, where available, and on higher tonnage submissions where data requirements are at least Annex IX or higher.

All data were retrieved from the ECHA website between February and May 2016.

The Data Summary template excel workbook used for miscellaneous chemicals was the same as the one used for biocides, i.e. the Data Summary template version 1.11 provided by JRC on the 14th of January 2016.

C. Case studies

1. Grouping Of Chemicals

In cases of miscellaneous chemicals where no or limited relevant data have been identified further consideration was taken on whether read-across from chemicals with structural similarities and/or sharing common chemical/functional moieties, was possible. For consistency reasons, a read-across was applied only in cases where it was substantiated in the regulatory documents. In these cases, the substances were grouped and the overall evaluation was based on the same data.

In this section, all cases of grouping/ are presented.

i. Phthalates

In total 18 phthalates were included in the final list of miscellaneous chemicals to be screened, i.e.:

#	Substance name	CAS No
1484	bis(2-ethylhexyl) phthalate (DEHP)	117-81-7
1486	Bis(2-methoxyethyl) phthalate	117-82-8
2042	Dipentyl phthalate (DPP)	131-18-0
3708	bis(2-ethylhexyl) tetrabromophthalate (BEH-TEBP)	26040-51-7
5202	bis(2-propylheptyl) phthalate	53306-54-0
5706	diisopentyl phthalate	605-50-5
6330	1,2-Benzenedicarboxylic acid, dihexylester, branched and linear (Diisohexyl phthalate -DIHP)	68515-50-4
6331	1,2-Benzenedicarboxylic acid, di-C6-10-alkyl esters	68515-51-5 (Additional CAS No: 68648-93-1)
6440	[phthalato(2-)]dioxotrilead (dibasic lead phthalate)*	69011-06-9
6618	1,2-Benzenedicarboxylic acid, di-C6-8-branched alkyl esters, C7-rich	71888-89-6
7055	N-pentyl-isopentylphthalate	776297-69-9
7505	Diethyl phthalate	84-66-2
7507	diisobutyl phthalate (BIPB)	84-69-5
7511	dibutyl phthalate	84-74-2
7512	Dihexyl phthalate	84-75-3
7516	1,2-Benzenedicarboxylic acid, dipentylester, branched and linear	84777-06-0
7581	benzyl butyl phthalate	85-68-7
6325	1,2-Benzenedicarboxylic acid, di-C7-11-branched and linear alkyl esters	68515-42-4

* assessed as a lead compound (see next case study)

Different source documents were available for each one of these phthalates and an effort was made to see whether any grouping was possible.

The four phthalates #**1484** [bis(2-ethylhexyl) phthalate], #**7507** (diisobutyl phthalate), #**7511** (dibutyl phthalate) and #**7581** (benzyl butyl phthalate), all selected under criterion 1 and/or 2, are considered to have endocrine disrupting effects with a similar mode of action (background document to the Opinion on the Annex XV on four phthalates). Common source documents (background document to the Opinion on the Annex XV on four phthalates & MSC opinion support document for dibutyl phthalate) have been used to extract the relevant data for the evaluation. All four of them have been categorised as "Cat I" under Option 3" (equivalent to ED under Option 2) based on effects that are self-diagnostic of endocrine disruption in human health as well as in vertebrate wildlife assessment.

As described in detail in the previous section, the evaluation of substances selected under Criterion 1 and 2 has been performed without extracting all the study details into the "Data" sheets. Thus, following consultation with JRC, only critical studies (Annex XV restriction report phthalates) were used to extract the necessary data to apply "Option 4" (i.e. the lowest effect dose of the critical endpoint used for the plausible link, duration of the study, type of study and route of administration).

The categorization of the following phthalates (#**7505**, #**5202**, #**2042**, #**7512**) was based on specific data for each one of them (such as REACH registration data, TEDX, EASIS, ToxCast or SIN¹⁶):

- diethyl phthalate, #**7505**, has been categorised as "Unclassified" under Option 3 (and Option 2) for human health assessment based on CoRAP conclusion: "*The existing information on DEP is sufficient to conclude that DEP does not exhibit endocrine disrupting effects in terms of human health similar to those observed with other phthalate diesters. Predominantly negative results on the oestrogenic or antiandrogenic potency of DEP are reported and an endocrine disrupting mechanism cannot be attributed to the DEP effects on the male reproductive system*".

- phthalate #**5202** [bis(2-propylheptyl) phthalate] has been categorized as "Unclassified" due to the fact that no ED adverse effects could be demonstrated following the weight of evidence approach.

- phthalates #**2042** [dipentyl phthalate (DPP)] and #**7512** (dihexyl phthalate) have been categorised as Cat I under Option 3 (equivalent to ED under Option 2) due to adverse effects captured from the available studies. Regarding phthalate #**6330** [1,2-benzenedicarboxylic acid, dihexylester, branched and linear (diisohexyl phthalate-DIHP)], based on the CLH report (2012), although no mammalian reproductive or developmental toxicity studies are available for DIHP "the dossier submitter performed an extensive and well-conducted read-across analysis based on the existing data on reproductive and developmental toxicity of the transitional phthalates with high structural similarity to DIHP, which includes DIBP (#7507), DBP (#7511), DIPP (#5706), DPP (#2042), DnHP (#7512) and DEHP (#1484). These phthalates constitute a clear structural category that allows for read-across to fill data gaps for DIHP and supports the conclusion that DIHP is a reproductive toxicant. Adverse effects in the developing male pup, including malformations of the male reproductive system and feminisation of male sexual differentiation, appear to be the most sensitive developmental endpoints. Other relevant effects are decreased testes weight, decreased sperm production, and decreased testosterone levels". Considering the above, based on structural similarities, DIHP [#**6330**] has been also categorized as Cat I under "Option 3" (equivalent to ED under "Option 2").

¹⁶ Evaluation of 22 SIN List 2.0 substances according to the Danish proposal on criteria for endocrine disruptors, Danish Centre on Endocrine Disruptors, May 2012

Regarding DIPP [**#5706**], taking into account the above statement as well as the final conclusion in the Background document to the Opinion proposing harmonised classification and labelling at Community level of 1,2-Benzenedicarboxylic acid, dihexylester, branched and linear (RAC Annex 1, 2013) it is considered that base on structural similarities of DIPP with DIBP (#7507), DBP (#7511), DPP (#2042), DnHP (#7512) and DEHP (#1484). More specifically the following is stated in the RAC Opinion for DIHP: *"The phthalates for which most data is available are DEHP, DBP and DIBP. Less information is available for DnHP and DPP. No mammalian toxicity data is available for DIPP (see Table 18 and 19). DIPP has, however, been grouped and classified as Repr. 1B together with dipentyl phthalate esters: 1,2-benzenedicarboxylic acid, dipentylester, branched and linear (CAS no 84777-06-0), n-pentyl-isopentylphthalate, di-npentyl phthalate (131-18-0) (Annex VI; Index No. 607-426-00-1). The available data permit an assessment of the reproductive toxicity of this category of phthalates, and no further testing of the member (DIHP) with lacking data is warranted. Reproductive toxicity is concluded to be an intrinsic hazard of the phthalates in the current chemical group and consequently DIHP is anticipated to behave in a similar way as the reference chemicals. Therefore, classification of DIHP as Repr. 1B is warranted."*

Thus, DIPP has been also categorized as Cat I under "Option 3" (equivalent to ED under "Option 2").

For phthalate **#6331** (1,2-Benzenedicarboxylic acid, di-C6-10-alkyl esters) specific data have been available based on which categorization as "Cat II" under "Option 3" has been concluded. However, since classification as Repr 1B; H360FD is proposed in the SVHC Annex XV report (2015) due to the content of phthalate **#7512** (dihexyl phthalate, > 0.3%), the relevance of the categorization of 1,2-Benzenedicarboxylic acid, di-C6-10-alkyl esters as Cat I could be considered in case supportive evidence is available.

Regarding phthalates **#6325** (1,2-Benzenedicarboxylic acid, di-C7-11-branched and linear alkyl esters), **#1486** [Bis(2-methoxyethyl) phthalate], **#7055** (N-pentyl-isopentylphthalate), **#6618** [1,2-Benzenedicarboxylic acid, di-C6-8-branched alkyl esters, C7-rich] and **#7516** (1,2-Benzenedicarboxylic acid, dipentylester, branched and linear), no relevant source documents have been identified. According to the justification in the relevant MSC opinion (ECHA "Opinion of the MSC on the 6th draft recommendation of the priority substances and Annex XIV entries", adopted on 11 June 2015);

https://echa.europa.eu/documents/10162/13576/msc_opinion_draft_6th_axiv_recommen_dation_en.pdf) these phthalates show similarities in terms of structure or physico-chemical properties with other phthalates already included in Annex XIV, categorized as Cat I in the evaluation [i.e. **#2042** (dipentyl phthalate)]. As noted also in the evaluation sheet for each one of these phthalates, the issue of evaluating them taking into account the categorization of other phthalates could be considered in case supportive evidence is available.

No relevant source documents have been also identified for phthalate **#3708** [bis(2-ethylhexyl) tetrabromophthalate] and thus the screening outcome is inconclusive. Taking into account the CoRAP justification document where concerns were raised due to structural similarity with **#1484** [bis(2-ethylhexyl) phthalate], which has a harmonised classification as Repr 1B, the issue of evaluating the substance similarly as bis(2-ethylhexyl) phthalate could be considered in case supportive evidence is available.

ii. Lead compounds

In total 29 substances containing lead were included in the final Miscellaneous Chemicals List to be screened, i.e.:

#	Substance name	CAS No
651	lead dinitrate	10099-74-8
1234	Silicic acid, lead salt	11120-22-2
1611	lead oxide sulfate (basic lead sulphate)	12036-76-9
1631	lead titanium trioxide	12060-00-3
1637	pentalead tetraoxide sulphate (tetrabasic lead sulphate)	12065-90-6
1678	trilead dioxide phosphonate (dibasic lead phosphite)	12141-20-7
1719	tetralead trioxide sulphate (tribasic lead sulphate)	12202-17-4
1870	dioxobis(stearato)trilead (dibasic lead stearate)	12578-12-0
1884	Lead titanium zirconium oxide	12626-81-2
2061	orange lead (lead tetroxide)	1314-41-6
2091	lead monoxide (lead oxide)	1317-36-8
2105	trilead bis(carbonate) dihydroxide (basic lead carbonate)	1319-46-6
2191	lead diazide	13424-46-9
2324	lead bis(tetrafluoroborate)	13814-96-5
2657	lead 2,4,6-trinitro-m-phenylene dioxide (Lead styphnate)	15245-44-0
2940	Lead(II) bis(methanesulfonate)	17570-76-2
3278	lead cyanamidate	20837-86-9
4051	lead di(acetate) (also mentioned as lead acetate)	301-04-2
4462	trilead diarsenate	3687-31-8
5067	Acetic acid, lead salt, basic	51404-69-4
5822	Sulfurous acid, lead salt, dibasic (basic lead sulphate)	62229-08-7
6014	Lead dipicrate	6477-64-1
6384	Silicic acid (H ₂ Si ₂ O ₅), barium salt (1:1), lead-doped	68784-75-8
6440	[phthalato(2-)]dioxotrilead (dibasic lead phthalate)	69011-06-9
7108	Lead hydrogen arsenate	7784-40-9
7157	tetraethyllead	78-00-2
7285	pyrochlore, antimony lead yellow	8012-00-8
7870	Fatty acids, C16-18, lead salts	91031-62-8

All of these substances have been selected for screening under criterion 3, i.e. *substances listed in Annex XVII for restrictions due to an ED concern or because of having a harmonised classification as reprotoxic 1A/1B*.

In the relevant support document (SVHC Support Document) for the identification of each lead compound screened as a substance of very high concern [ECHA] reference was made to the harmonised classification, either of the specific compound (in case of lead diazide, lead 2,4,6-trinitro-m-phenylene dioxide, lead(II) bis(methanesulfonate), lead di(acetate) & lead hydrogen arsenate) or of related compounds. Thus, the harmonised

classification considered for each lead compound was the one mentioned in the SVHC document.

No individual toxicity data were included in the available support documents.

Moreover, in most cases the relevant REACH registration data concerned mainly read across from a substance referred to as lead acetate CAS No 51404-69-4 (Acetic acid, lead salt, basic - lead acetate basic).

Considering the limited data available in the REACH registration dossiers (publicly available in the ECHA website) for the specific compounds to be screened further search was performed for lead in the ECHA website and the following documents have been retrieved and used for data population and evaluation of each lead compound:

* RAC Opinion on Lead classification (Repr. 1A H360DF); Adopted 5 December 2013

* Voluntary Risk Assessment Report (VAR, 2008) for Lead Metal, Lead Oxide, Lead tetroxide and several Lead stabiliser compounds.

* The EFSA Scientific Opinion on Lead in Food [EFSA Journal 2010; 8(4):1570] has been considered in the evaluation of all lead compounds.

According to the RAC Opinion on harmonised classification of lead (2013) *"in the body, it is the actual lead ion itself that is toxic; making it unimportant which type of lead source is really causing the exposure. What matters is the actual lead concentration in blood/soft tissue/bone or whatever compartment that is of interest"*. Thus, the data included in the available regulatory documents have been considered relevant for all screened compounds. Any TEDX data available for any lead compound screened have been considered for all lead compounds as well.

Specific notes regarding REACH registration data have been included in the Data sheet for each compound. All lead compounds were categorized as Cat II under "Option 3" (equivalent to ED under "Option 2") via Path 3a/b of the decision tree for both human health and vertebrate wildlife evaluation.

iii. Compounds containing both lead & chromium

#	Substance name	CAS No
1892	lead chromate molybdate red	12656-85-8
2202	lead sulfochromate yellow	1344-37-2
7051	lead chromate	7758-97-6

Separate templates were created for lead chromate molybdate red (**#1892**), lead sulfochromate yellow (**#2202**). Data from the evaluation of lead compounds were also used in the evaluation of each substance. It is noted that the categorization outcome of these substances is in line with the categorization of other lead and chromium compounds. The evaluation of lead chromate (**#7051**) for which there were no data, was solely based on data of the lead compounds.

iv. Perchlorates

#	Substance name	CAS No
6900	sodium perchlorate	7601-89-0
7150	ammonium perchlorate	7790-98-9

Grouped data population and evaluation was performed for sodium perchlorate (**#6900**) and ammonium perchlorate (**#7150**). This was based on CoRAP (substance evaluation) that supports that there may be a (potential) joint evaluation due to structural similarities of these two substances.

v. Nonylphenols

#	Substance name	CAS No
561	4-Nonylphenol, branched and linear ethoxylated	104-35-8 7311-27-5 14409-72-4 20427-84-3 26027-38-3 27942-27-4 34166-38-6 37205-87-1 127087-87-0 156609-10-8
563	4-Nonylphenol, branched and linear	84852-15-3 26543-97-5 104-40-5 17404-66-9 30784-30-6 52427-13-1 186825-36-5 142731-63-3
3600	Nonylphenol	25154-52-3

Evaluation of **561_4-Nonylphenol, branched and linear, ethoxylated** was based on read across from **563_4-Nonylphenol, branched and linear**, according to the statement: "4-Nonylphenol, branched and linear, ethoxylated are identified as substances of very high concern in accordance with Article 57 (f) of Regulation (EC) 1907/2006 (REACH) because, due to their degradation, they are a relevant source in the environment of substances of very high concern (4-Nonylphenol, branched and linear (4-NP)). Therefore, there is scientific evidence of probable serious effects to the environment from these substances, through their degradation to 4-Nonylphenol, branched and linear" identified in one of the source documents ["Support document for identification of 4-Nonylphenol, branched and linear, ethoxylated as substances of very high concern; 2013"].

3600_ Phenol, nonyl was combined with **563_4-Nonylphenol, branched and linear**, in one excel file by maintaining the data from the most recent source (i.e. **563_4-Nonylphenol, branched and linear**). Thus, all three substances (#561, 563 & 3600) have been categorised as "Cat I" under "Option 3" (equivalent to ED under Option 2) based on effects that are self-diagnostic of endocrine disruption in vertebrate wildlife assessment.

For human health the substances were categorised as Cat I under Option 3 (equivalent to ED under Option 2) via Path 2a/2b.

vi. Octylphenols

#	Substance name	CAS No
562	4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated	9036-19-5
2391	4-(1,1,3,3-tetramethylbutyl)phenol	140-66-9

Evaluation of **562_4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated** was based on read across from **2391_4-(1,1,3,3-tetramethylbutyl)phenol**. This decision was made based on what is stated in one of the main source documents [“Support document for identification of 4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated as substances of very high concern because, due to their degradation to a substance of very high concern (4-(1,1,3,3-tetramethylbutyl)phenol) with endocrine disrupting properties, they cause probable serious effects to the environment which give rise to an equivalent level of concern to those of cmrs and pbts/vpvbs”]

Thus, both substances (#562, 2391) were categorised as “Cat I” under “Option 3” (equivalent to ED under Option 2) for human health and vertebrate wildlife, via Paths 2a/2b and 1, respectively.

vii. Dibutyltin compounds (DBT)

In total three dibutyltin compounds have been included in the list of miscellaneous chemicals to be screened, i.e.:

#	Substance name	CAS No
580	Dibutyltin (DBT) (Dibutyl stannane)	1002-53-5
6277	Dibutyltin dichloride (DBTCl ₂)	683-18-1
6814	Di-μ-oxo-di-n-butylstanniohydroxyborane/Dibutyltin hydrogen borate C ₈ H ₁₉ BO ₃ Sn (DBB)	75113-37-0

(a) DBT and DBTCl₂ are both included in the SIN List (SIN Group: tin compounds). As far as the data population is concerned, only three studies included in EASIS were captured for DBT. Due to the limited information available for the evaluation of DBT, following consultation with JRC, the two substances have been grouped and evaluated together based on the analogous decision on tributyltins that any salt can be converted to the chloride form in the stomach after oral uptake. Specifically, for DBT compounds the following is stated in the RAC Background document (2015) in the *Opinion proposing harmonised classification and labelling at EU level of Dibutyltin dilaurate*: “It is generally assumed that DBT, probably as the chloride, is the moiety (toxophore) responsible for the in vivo effects when animals are orally exposed to DBTDL. Thus, when considering classification of DBTDL for hazard classes that reside on exposure through the oral route, it is justified to take studies into account where DBTC and other rapidly acid-hydrolysable DBT substances have been administered orally (the same metabolite, DBT)”.

It is noted that a harmonised classification is available only for DBTCl₂ (including classification as Repr. 1B; H360F); this has been considered applicable for DBT as well, following the recommendation by JRC to group these two substances. Regarding the available data considered for the categorization under "Options 2 and 3", reference is made to the compound tested for each effect mentioned in the relevant cells of the evaluation sheet.

Furthermore, although no CLH report/RAC Opinion is available for dibutyltin dichloride (DBTCl₂) there is a CLH report for dibutyltin dilaurate (DBTDL) (RAC Annex 1 "Background document to the Opinion proposing harmonised classification and labelling at Community level of Dibutyltin dilaurate", 2015) where data of DBTCl₂ are considered (DBTDL can be regarded as a precursor to DBTCl₂ through the oral route since DBTDL hydrolyses into DBTCl₂ in the stomach). Although data presented in the retrieved CLH report for DBTDL were not included in the Data sheet for DBT/DBTCl₂, they have been taken into account for the weight of evidence and the evaluation of the dibutyltin compounds.

DBT and DBTCl₂ were categorized as "Cat II" under "Option 3" via Path 5 (equivalent to "Unclassified" under "Option 2") of the decision tree for both human health and vertebrate wildlife evaluation.

(b) The remaining dibutyltin compound, i.e. #6814 Di-μ-oxo-di-n-butylistanniohydroxyborane/ Dibutyltin hydrogen borate C₈H₁₉BO₃Sn (DBB), is included in the SIN List (SIN Groups: Tin compounds, Boron compounds).

Although there is a harmonised classification for DBB (ATP01/ATP01corr, including classification as Repr. 1B; H360DF and Muta. 2; H341) no CLH report is available.

No individual data have been identified for this substance in the available data sources. However, read-across from both dibutyltin compounds and other borates could be considered in case supportive evidence is available.

It is further noted that in the ECHA website DBB is included in the substances that are [*subject to the Prior Informed Consent regulation and to export notification procedure from 31-Jan-2005*](#) referring to the legislation & EFSA Text ([*Official Journal L 398 , 30/12/1989 P. 0019 - 0023*](#)). Considering the above a search has been performed in the EFSA website for dibutyltin compounds and the "**Opinion of the Scientific Panel on Contaminants in the Food Chain on a request from the Commission to assess the health risks to consumers associated with exposure to organotins in foodstuffs**" (2004) has been retrieved. The EFSA Opinion refers to many organotin compounds (OTC) focusing on dibutyltin (DBT), tributyltin (TBT) and triphenyltin (TPT) since they were considered the most toxic OTC. The following are summarized in the EFSA Opinion:

"In particular, TBT and TPT are highly toxic to aquatic organisms and show a complex toxicity profile in rodents. Furthermore, they tend to bioaccumulate through the food chain (in particular in fish and seafood). TBT and TPT cause masculinization in female snails ("imposex") and in fish at low concentrations (1 ng/L in water), suggesting that these compounds are endocrine disruptors. Reproductive and developmental toxicity in rodents at relatively low doses (around 1 mg/kg b.w./day) further supports this endocrine activity".

The results of the screening do not constitute evaluations of individual substances to be carried out under the respective chemical legislations [[in particular, Regulation (EC) No 1107/2009 on plant protection products, Regulation (EU) No 528/2012 on biocidal products, Regulation (EC) No 1907/2006 REACH, Regulation (EC) No 1223/2009 on cosmetic products and the Water Framework Directive (EC) No 2000/60] and in no way prejudice future decisions on active substances to be taken pursuant to these pieces of the EU legislation. It would thus be erroneous to consider that the substances listed in the results of this study (SANTE/2015/E3/SI2.706218) are considered as endocrine disruptors within the meaning of the EU legislation.

The EFSA opinion related to organotins in foodstuffs (2004) has been considered as supportive document, especially regarding reproductive toxicity, when concluding for each one of the "tin" compounds screened.

viii. Tributyltin (TBT) compounds

In total five (5) tributyltin (TBT) compounds have been included in the list of miscellaneous chemicals to be screened, i.e.:

#	Substance name	CAS No
2543	Tributyltin chloride (TBTCl)	1461-22-9
2544	Tributyltin bromide (TBTBr)	1461-23-0
4449	Tributyltin cation	36643-28-4
3269	Tributyltin	20763-88-6
5443	Tributyltin	56573-85-4

Adequate data for evaluation were available only for #**2543** (TBTCl). Considering that all the TBT compounds are included in the SIN List for the same reason and following consultation with JRC, all five chemicals have been evaluated together based on the same rationale as above for DBT derivatives. In addition, DBT derivatives are considered to assess the toxic properties of TBT compounds, in particular properties for adverse impairment of reproduction and development, since after oral ingestion of TBT compounds dibutyltin derivatives have been identified as common first metabolites. (RAC Background document, 2015 in the *Opinion proposing harmonised classification and labelling at EU level of Dibutyltin dilaurate*).

As already noted for DBT compounds, the EFSA opinion related to organotins in foodstuffs (2004) has been considered as a supportive document, especially regarding reproductive toxicity, when concluding for each one of the "tin" compounds screened.

Regarding "Option 1", there has not been a harmonised classification for any of the TBT compounds. All TBT compounds have been categorized as "Cat I" under "Option 3" (equivalent to ED under "Option 2") via Path 2b the decision tree for both human health and vertebrate wildlife evaluation.

ix. Triphenyltin (TPT) compounds

In total three triphenyltin (TPT) compounds have been included in the list of miscellaneous chemicals to be screened, i.e.:

#	Substance name	CAS No
5962	Triphenyltin chloride (TPTCl)	639-58-7
6132	Triphenyltin (TPT)	668-34-8
7749	Triphenyltin hydride	892-20-6

The results of the screening do not constitute evaluations of individual substances to be carried out under the respective chemical legislations [[in particular, Regulation (EC) No 1107/2009 on plant protection products, Regulation (EU) No 528/2012 on biocidal products, Regulation (EC) No 1907/2006 REACH, Regulation (EC) No 1223/2009 on cosmetic products and the Water Framework Directive (EC) No 2000/60] and in no way prejudice future decisions on active substances to be taken pursuant to these pieces of the EU legislation. It would thus be erroneous to consider that the substances listed in the results of this study (SANTE/2015/E3/SI2.706218) are considered as endocrine disruptors within the meaning of the EU legislation.

Only two of TPhT compounds, i.e. TPT and TPTCl, are included in the SIN List (Sin Group: Tin compounds)

Following consultation with JRC, the three substances were grouped and evaluated together for the same reasons as indicated for DBT and TBT salts.

As already noted for DBT and TBT compounds, the EFSA opinion related to organotins in foodstuffs (2004) has been considered as a supportive document, especially regarding reproductive toxicity, when concluding for each one of the "tin" compounds screened.

There is no harmonised classification available for TPhT compounds. The information used for the data population has been gathered only from open literature sources, i.e. EASIS and TEDX. All TPhT compounds have been categorized as "Cat I" under "Option 3" (equivalent to ED under "Option 2") *via* Path 2a/b of the decision tree for both human health and vertebrate wildlife evaluation.

x. Diocyltin oxide

Another organotin compound included in the miscellaneous chemicals to be screened is #7645 Diocyltin oxide. Limited relevant data were available in the REACH registration dossier. Moreover, no relevant regulatory documents have been identified with the exception of the EFSA opinion related to organotins in foodstuffs (2004) where a general reference to octyltins is made and no specific data or references related to diocyltin oxide are included.

Based on the above, the concluded categorization of the substance is "Unclassified" under "Option 3" for both human health and vertebrate wildlife evaluation. However the possibility for read-across from other organotin compounds could be considered in case supportive evidence is available.

xi. Musk ketone and musk xylene

#	Substance name	CAS No
7322	Musk ketone	81-14-1
7323	Musk xylene	81-15-2

According to EU RISK ASSESSMENT REPORT – 4'-TERT-BUTYL-2',6'-DIMETHYL-3',5'-DINITROACETOPHENONE (2005) "musk ketone is quite comparable to musk xylene with respect to physico-chemical and toxicokinetic properties" and "the data available on musk xylene can be safely used for the risk characterisation of musk ketone". As there are no carcinogenicity data available for #7322 musk ketone, data concerning #7323 musk xylene have been used for the evaluation of musk ketone. These compounds have been categorised as "Unclassified" under all "Options".

xii. Reaction mass of DOTE and MOTE

One of the cases for which a surrogate (possibility for read-across) has been concluded is presented:

The results of the screening do not constitute evaluations of individual substances to be carried out under the respective chemical legislations [[in particular, Regulation (EC) No 1107/2009 on plant protection products, Regulation (EU) No 528/2012 on biocidal products, Regulation (EC) No 1907/2006 REACH, Regulation (EC) No 1223/2009 on cosmetic products and the Water Framework Directive (EC) No 2000/60] and in no way prejudice future decisions on active substances to be taken pursuant to these pieces of the EU legislation. It would thus be erroneous to consider that the substances listed in the results of this study (SANTE/2015/E3/SI2.706218) are considered as endocrine disruptors within the meaning of the EU legislation.

The reaction product of 2-ethylhexyl 10-ethyl-4,4-dioctyl-7-oxo-8-oxa-3,5-dithia-4-stannatetradecanoate (DOTE) and 2-ethylhexyl 10 ethyl-4-((2-ethylhexyl)oxy)-2-oxoethylthio)-4-octyl-7-oxo-8-oxa-3,5-dithia-4-stannatetradecanoate (MOTE) is a substance for which no individual studies were identified in the available data sources. However, the substance has been classified under ATP05 as Repr. 1B; H360D. As mentioned in the Substance of Very High Concern Support Document, the classification of the reaction mass of DOTE and MOTe was based on the toxicological properties of DOTE. Therefore, in absence of individual data, the evaluation of this substance was based on the evaluation of DOTE which was "Unclassified" under "Option 3" through Path 8 of the decision tree for both human health and vertebrate wildlife assessment.

xiii. Ethoxy-/methoxy- ethanols and their acetates

#	Substance name	CAS No
1151	2-methoxyethanol	109-86-4
1182	2-methoxyethyl acetate	110-49-6
1202	2-ethoxyethanol	110-80-5
1228	2-ethoxyethyl acetate	111-15-9

In total four (4) ethoxy-/methoxy- ethanols and its acetates were included in the substances to be screened. The three of them are cosmetics (**#1151**, **#1202**, **#1228**) and have been selected for screening under criterion 3, i.e. *substances listed in Annex XVII for restrictions due to an ED concern or because of having a harmonised classification as reprotoxic 1A/1B*. The relevant SCCP Opinion (SCCNFP/0663/03) reports the following:

"The SCCNFP is of the opinion that ethoxyethanol, ethoxyethanol acetate, 2-methoxyethanol and 2-methoxyethanol acetate (i.e. glycol ethers and their acetates) do pose a health risk when used in cosmetic products."

"The toxicity of 2-methoxyethanol, 2-ethoxyethanol and their acetates has been evaluated in a number of reviews in the past 20 years (1-7). All four substances have been demonstrated to exert adverse haematological, neurological and reproduction toxic effects both in rodents and in humans. It has also been demonstrated that 2-methoxyethanol, 2-ethoxyethanol and their acetates can readily absorb through the skin (1 - 12). The concern over the use of reproduction toxic substances in the formulation of cosmetic products has been expressed in a recent Opinion of SCCNFP."

Moreover, all four chemicals have a harmonised classification as Repr. 1B; H360FD.

For **#1151** 2-methoxyethanol, data population has been completed using the REACH Registrant data available. However, no data was found in the available sources for **#1182** 2-methoxyethyl acetate. Therefore, considering the SCCNFP/0663/03, the evaluation of 2-methoxyethyl acetate was based on the evaluation of 2-methoxyethanol.

In case of **#1202** 2-ethoxyethanol the REACH registration data have been also considered. For **#1228** 2-ethoxyethyl acetate, data from the ToxCast database were available as well as the summaries of three studies included the SVHC Support Document. However, no mechanistic effects were reported for **#1228** 2-ethoxyethyl

acetate. Thus, taking into consideration the SCCNFP/0663/03, it was decided that the overall evaluation of #1228 2-ethoxyethyl acetate should be based on the evaluation of #1202 2-ethoxyethanol.

xiv. Sodium peroxometaborate

Limited data were available for #6932 sodium peroxometaborate (CAS No 7632-04-4). As stated in the "Substance information" available in the ECHA website (<http://echa.europa.eu/substance-information/-/substanceinfo/100.028.688>) "this substance has several Harmonised Classifications and Labelling's (CLH) approved by the European Union". In all entries, classification as Repr 1B with H360Df is included. However, ECB (2004) recommended classification of perborates as toxic to reproduction based on the data on boric acid and disodium tetraborate decahydrate (SCCS/1345/10). Read-across from borates and boric acid has been applied for the evaluation of sodium peroxometaborate leading to categorization as Cat II under "Option 3" (equivalent to "Unclassified" under "Option 2").

xv. Cadmium compounds

#	Substance name	CAS No
659	cadmium chloride	10108-64-2
670	cadmium sulphate	10124-36-4; 31119-53-6
7147	cadmium fluoride	7790-79-6

Based on the available SVHC support documents (2014)¹⁷ the toxic effect of all three cadmium compounds are caused by the cadmium ion. Thus, the available data for cadmium chloride (#659) and cadmium sulphate (#670) were captured together in a single template and the substances were evaluated/categorized as a group. No data were available for cadmium fluoride (#7147) and categorization under "Options 2, 3 & 4" was based on the evaluation of cadmium chloride and cadmium sulphate.

It is noted that these three cadmium compounds were selected for screening under criterion 3, i.e. there is a harmonised classification for reproductive toxicity (either fertility or development). However, since the harmonised classification was concluded before the implementation of Regulation (EC) 1272/2008 and the ECHA establishment, i.e. at ECB (European Chemicals Bureau) level under Directive 67/548/EEC, no opinion on the harmonised classification and labelling of the substance by the Committee for Risk Assessment (RAC) was available or any other relevant regulatory document was accessible. It is worth noting that a RAC opinion is available for three different cadmium compounds, i.e. cadmium carbonate, hydroxide and nitrate. In the respective RAC Opinions it is mentioned that *only harmonised classifications for carcinogenicity, mutagenicity and STOT RE are presented, since that is within the scope of the present CLH report*. Moreover the following is mentioned:

¹⁷ SVHC Support Document – Cadmium chloride, 2014; SVHC Support Document – Cadmium sulphate, 2014; SVHC Support Document – Cadmium fluoride, 2014

"The chloride, sulphate and fluoride salts are classified differently to the salts covered by the general entry, with a more severe classification for acute inhalational toxicity (Acute Tox. 2*; H330), and additional classifications for repeated oral and inhalational toxicity (STOT RE 1; H372**), germ cell mutagenicity (Muta. 1B; H340), carcinogenicity (Carc. 1B; H350) and reproductive toxicity (Repr. 1B; H360FD).

RAC agrees with the DS that the systemic toxicity of these cadmium salts will be dependent on the bioavailability of the Cd²⁺ ion following exposure. This is in line with previous regulatory decisions made in the EU in relation to the classification of these substances. As they are all very water soluble, it is anticipated that they will all have comparable bioavailability and will possess similar systemic hazards."

xvi. Cobalt compounds

#	Substance name	CAS No
673	Cobalt sulphate [Cobalt(II) sulphate]	10124-43-3
682	Cobalt dinitrate [Cobalt(II) dinitrate]	10141-05-6
5065	Cobalt carbonate	513-79-1
6593	Cobalt di(acetate) [Cobalt(II) diacetate]	71-48-7
6941	Cobalt dichloride	7646-79-9

According to the available SVHC Support documents for the screened cobalt compounds the toxicity of soluble Co(II) salt compounds is basically comparable. The following statement from the SVHC SUPPORT DOCUMENT for Cobalt (II) sulphate (2010) is given as example: *The data from soluble cobalt(II) salts compounds can be used to read across to cobalt(II) sulphate as relevant information concerning its CMR effects because these properties are mediated by the ionic form of cobalt(II).*

xvii. Water soluble Cr (VI) compounds

#	Substance name	CAS No
7065	Sodium chromate	7775-11-3
912	Sodium dichromate	10588-01-9; 7789-12-0
7129	Ammonium dichromate	7789-09-5
7076	Potassium dichromate	7778-50-9

Sodium chromate (**#7065**), Sodium dichromate (**#912**), Ammonium dichromate (**#7129**) and Potassium dichromate (**#7076**) are assessed as a group in the EU Risk Assessment Report for water soluble Cr(VI) compounds. The same data were used for data population and evaluation of these compounds but a separate template was created for each substance. The REACH registration dossiers were used instead of the Risk Assessment report since the latter was taken into consideration in the registration dossier.

2. Substances with Limited Or No Relevant Data Available

For several substances which have been selected for screening as miscellaneous chemicals, most of them under the criterion 3, i.e. substances listed in Annex XVII for restrictions due to a ED concern or because of having a harmonised classification as toxic for reproduction 1A/1B, no or limited relevant data have been identified. The evaluation of those substances, when there was no clear indication/evidence for grouping (as done for lead compounds), was finally concluded to be inconclusive/not relevant due to lack of data. For some of these substances possibilities of read-across from similar compounds have been identified and a note has been included in the respective "Evaluation" sheet.

More specifically, for 15 substances there were no relevant data available and the categorization under "Options 2, 3 and 4" was concluded to be not possible due to lack of data (Tables 5.1 and 5.2). For nine of these substances the outcome has been inconclusive under "Option 1" since the substance is classified as Repr. Cat 1A or 1B but due to lack of data no conclusion can be drawn regarding effects on endocrine organs (Table 5.1). For the remaining seven substances the categorization outcome under "Option 1" was "Unclassified" since there was no classification (harmonised or proposed) for reproductive toxicity (Table 5.2).

Table 5.1. Miscellaneous chemicals for which categorization under "Option 1" was inconclusive and categorization under "Option 2, 3 & 4" was not relevant due to lack of data.

#	Substance name	CAS No
1486*	Bis(2-methoxyethyl) phthalate	117-82-8
2491	3-ethyl-2-methyl-2-(3-methylbutyl)-1,3-oxazolidine	143860-04-2
5880	1,2-Diethoxyethane	629-14-1
6325*	1,2-Benzenedicarboxylic acid, di-C7-11-branched and linear alkyl esters	68515-42-4
6618*	1,2-Benzenedicarboxylic acid, di-C6-8-branched alkyl esters, C7-rich	71888-89-6
6814**	Di- μ -oxo-di-n-butylstanniohydroxyborane/ Dibutyltin hydrogen borate C ₈ H ₁₉ BO ₃ Sn (DBB)	75113-37-0
7055*	N-pentyl-isopentylphthalate	776297-69-9
7516*	1,2-Benzenedicarboxylic acid, dipentylester, branched and linear	84777-06-0

* According to justification by ECHA (ECHA "Opinion of the MSC on the 6th draft recommendation of the priority substances and Annex XIV entries", adopted on 11 June 2015); https://echa.europa.eu/documents/10162/13576/msc_opinion_draft_6th_axiv_recommendation_en.pdf, The marked * phthalates show similarities in terms of structure or physico-chemical properties with other phthalates already included in Annex XIV. The issue of evaluating the substance similarly to other phthalates could be considered in case supportive evidence is available.

** Read across from other organotin compounds and/or borates could be considered in case supportive evidence is available.

Table 5.2. Miscellaneous chemicals for which categorization under "Option 2, 3 & 4" was not possible due to lack of data and categorization under "Option 1" was "Unclassified" since no harmonised C&L was available

#	Substance name	CAS No
1737	Low temperature tar oil, alkaline, extract residues (coal), low temperature coal tar alkaline	122384-78-5
3708*	bis(2-ethylhexyl) tetrabromophthalate (BEH-TEBP)	26040-51-7

The results of the screening do not constitute evaluations of individual substances to be carried out under the respective chemical legislations [[in particular, Regulation (EC) No 1107/2009 on plant protection products, Regulation (EU) No 528/2012 on biocidal products, Regulation (EC) No 1907/2006 REACH, Regulation (EC) No 1223/2009 on cosmetic products and the Water Framework Directive (EC) No 2000/60] and in no way prejudice future decisions on active substances to be taken pursuant to these pieces of the EU legislation. It would thus be erroneous to consider that the substances listed in the results of this study (SANTE/2015/E3/SI2.706218) are considered as endocrine disruptors within the meaning of the EU legislation.

3824	Polyhexamethylene biguanide hydrochloride	27083-27-8
4087	Paraformaldehyde	30525-89-4
6071	Tar acids, coal, crude, crude phenols	65996-85-2
7369	1-Methyl-2,6-diamino-benzene (also as 2-Methyl-m-phenylenediamine OR Toluene-2,6-diamine)	823-40-5
7503	Distillates (coal tar), naphthalene oils, naphthalene oil	84650-04-4

* Taking into account the CoRAP justification document where concerns were raised due to structural similarity with #1484 [bis(2-ethylhexyl) phthalate], (117-81-7: harmonised classification Repr 1B) the issue of evaluating the substance as bis(2-ethylhexyl) phthalate could be considered in case supportive evidence is available.

Furthermore, there are eleven (11) substances for which only few (1 to 3) studies have been identified and based on these the categorization outcome under "Options 2, 3 and 4" is "Unclassified" (Table 5.3). A note has been added in the Categorization Results Table in order to easily identify these cases. It is noted that no harmonised C&L is available for any of these 11 substances.

Table 5.3. Miscellaneous chemicals for which only few (1 to 3) studies have been identified and based on these the categorization outcome under "Options 2, 3 and 4" is "Unclassified"

#	Substance name	CAS No
558	2,2',6,6'-Tetrabromo-4,4'-isopropylidenediphenol, oligomeric reaction products with Propylene oxide and n-butyl glycidyl ether	-
559	reaction mass of 1-(1,2,3,4,5,6,7,8-octahydro-2,3,8,8-tetramethyl-2-naphthyl)ethan-1-one and 1-(1,2,3,4,6,7,8,8a-octahydro-2,3,8,8-tetramethyl-2-naphthyl)ethan-1-one and 1-(1,2,3,5,6,7,8,8a-octahydro-2,3,8,8-tetramethyl-2-naphthyl)ethan-1-one	-
2863	2-Amino-3-hydroxypyridine (2-aminopyridin-3-ol)	16867-03-1
3152	p-methylaminophenol sulphate	1936-57-8
5160	Camphor benzalkonium methosulfate (Methyl N,N,N-trimethyl-4-[(4,7,7-trimethyl-3-oxobicyclo[2.2.1]hept-2-ylidene)methyl]anilinium sulphate)	52793-97-2
6518	3-amino-2,6-dimethylphenol	6994-64-5
7578	6,6'-di-tert-butyl-4,4'-butylidenedi-m-cresol	85-60-9
8049	Hydroxyethyl-3,4-methylenedioxyaniline HCl	94158-14-2
8099	benzotriazole	95-14-7

3. Parabens

In total six parabens as well as their common metabolite #**8341** were screened, i.e.:

#	Substance name	CAS No	Categorization result human health	Categorization result vertebrate wildlife
8046	propyl 4-hydroxybenzoate (propylparaben)	94-13-3	Cat II	Cat I

The results of the screening do not constitute evaluations of individual substances to be carried out under the respective chemical legislations [[in particular, Regulation (EC) No 1107/2009 on plant protection products, Regulation (EU) No 528/2012 on biocidal products, Regulation (EC) No 1907/2006 REACH, Regulation (EC) No 1223/2009 on cosmetic products and the Water Framework Directive (EC) No 2000/60] and in no way prejudice future decisions on active substances to be taken pursuant to these pieces of the EU legislation. It would thus be erroneous to consider that the substances listed in the results of this study (SANTE/2015/E3/SI2.706218) are considered as endocrine disruptors within the meaning of the EU legislation.

#	Substance name	CAS No	Categorization result human health	Categorization result vertebrate wildlife
8331	methyl 4-hydroxybenzoate (methylparaben)	99-76-3	Unclassified	Cat II
8372a	ethylparaben	120-47-8	Cat III	Cat II
8372b	Isopropylparaben (Isopropyl 4-hydroxybenzoate)	4191-73-5	Cat II	Cat II
8372c	Butylparaben (Butyl 4-hydroxybenzoate)	94-26-8	Cat II	Cat II
8372d	Isobutyl paraben (Isobutyl 4-hydroxybenzoate (INCI: Isobutylparaben)/Sodium salt or Salts of Isobutylparaben)	4247-02-3 (224-208-8)	Cat II	Cat II
8341	4-hydroxybenzoic acid (p-hydroxybenzoic acid)	99-96-7	Unclassified	Unclassified

The relevant regulatory documents considered as source documents for the evaluation of the selected parabens to be screened are listed below:

- SCCP/0873/05 Extended Opinion on the Safety evaluation of parabens
- SCCP/0874/05 Extended Opinion on parabens, underarm cosmetics and breast cancer
- SCCP/1017/06 Opinion on parabens
- SCCP/1183/08 Opinion on parabens
- SCCS/1348/10 Opinion on parabens
- SCCS/1446/11 Clarification on Opinion SCCS/1348/10 in the light of the Danish clause of safeguard banning of use of parabens in cosmetic products intended for children under 3 years of age
- SCCS/1514/13 Updated request for a scientific opinion on propyl- and butylparaben
- EFSA (2004), Opinion of the Scientific Panel on Food Additives, Flavourings, Processing Aids and Materials in Contact with Food on a Request from the Commission related to parahydroxybenzoates (E214-219), Question number EFAS-Q-2004-063, adopted on 13 July 2004. The EFSA Journal 83, 1-26.
- Danish Centre of Endocrine Disruptors evaluation (May 2012); "Evaluation of tebuconazole, triclosan, methylparaben and ethylparaben according to the Danish proposal for criteria for endocrine disruptors, May 2012"

It is noted that the available regulatory documents included all references found in TEDX database for each paraben.

Although most of the relevant studies performed with parabens are common (i.e. several parabens have been tested in the same studies), a different datasheet has been used for the evaluation of each paraben since they show different relative activities/potencies in

the same *in vitro* assays depending on the length and branching of their alkyl side-chains.

4. 4,4'-isopropylidenediphenol (Bisphenol A)

The following regulatory documents were available for 4,4'-isopropylidenediphenol (Bisphenol A) [#7274]:

- European Union Risk Assessment Report 4,4'-ISOPROPYLIDENEDIPHENOL (BISPHENOL-A) (2010)
- EFSA Scientific Opinion Scientific Opinion on the risks to public health related to the presence of bisphenol A (BPA) in foodstuffs (2015)¹⁸
- EFSA Scientific Opinion on Bisphenol A: evaluation of a study investigating its neurodevelopmental toxicity, review of recent scientific literature on its toxicity and advice on the Danish risk assessment of Bisphenol A (2010)¹⁹

The relevant data included in the data sheet were retrieved from European Union Risk Assessment Report for 4,4'-Isopropylidenediphenol (Bisphenol-A) (2010) while additional data were available in the TEDX and in the REACH registration dossier. The conclusions drawn in the relevant EFSA Opinions have been considered for the evaluation although no individual studies have been mentioned.

As regards human health, bisphenol A (BPA) was categorized as unclassified under "Options 1, 2 & 4" (Cat II under "Option 3"). As regards vertebrate wildlife, it was categorized as ED under "Option 2" (equivalent to Cat I under "Option 3") and unclassified under "Option 4".

For human health, several non-specific adverse effects that may or may not be indicative of EATS (effects on adrenals and pituitary as well as reproductive effects) and EATS-specific adverse effects on reproductive organs of both male and females, i.e. ovary, uterus, prostate, seminal vesicles and testis in rodents were observed. However, no plausible link could be established with the *in vitro* or *in vivo* mechanistic data available. The lack of a specific ED-related pattern is supported also by the EFSA conclusions on endocrine-mediated action of BPA where the following is mentioned: "*In addition, as it has been reviewed on a number of occasions (e.g. EFSA, 2006; EFSA CEF Panel, 2010; FAO/WHO, 2011) "Due to the complexity of BPA's interaction with different hormone receptors and signalling pathways it is challenging to establish which specific endocrine mechanism triggers a certain in vivo effect of BPA"*.

¹⁸ FSA CEF Panel (EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids), 2015. Scientific Opinion on the risks to public health related to the presence of bisphenol A (BPA) in foodstuffs: PART II – Toxicological assessment and risk characterisation. EFSA Journal 2015;13(1):3978, 621 pp. doi:10.2903/j.efsa.2015.3978

¹⁹ EFSA Panel on food contact materials, enzymes, flavourings and processing aids (CEF). Scientific Opinion on Bisphenol A: evaluation of a study investigating its neurodevelopmental toxicity, review of recent scientific literature on its toxicity and advice on the Danish risk assessment of Bisphenol A. EFSA Journal 2010;8(9):1829. [110 pp.] doi:10.2903/j.efsa.2010.1829. Available online: www.efsa.europa.eu/efsajournal.htm

The results of the screening do not constitute evaluations of individual substances to be carried out under the respective chemical legislations [[in particular, Regulation (EC) No 1107/2009 on plant protection products, Regulation (EU) No 528/2012 on biocidal products, Regulation (EC) No 1907/2006 REACH, Regulation (EC) No 1223/2009 on cosmetic products and the Water Framework Directive (EC) No 2000/60] and in no way prejudice future decisions on active substances to be taken pursuant to these pieces of the EU legislation. It would thus be erroneous to consider that the substances listed in the results of this study (SANTE/2015/E3/SI2.706218) are considered as endocrine disruptors within the meaning of the EU legislation.

With respect to vertebrate wildlife evaluation, a plausible link was established since *in vitro* and *in vivo* mechanistic data available (binding and agonistic activity to thyroid hormone receptor as well as transthyretin transactivation) were considered as likely to be responsible for the observed malformations in several frog species. Moreover, inhibition of sperm maturation in fish and skewed sex ratio in amphibians could be linked to increased vitellogenin synthesis in male fish suggesting estrogenic activity.

The results of the screening do not constitute evaluations of individual substances to be carried out under the respective chemical legislations [[in particular, Regulation (EC) No 1107/2009 on plant protection products, Regulation (EU) No 528/2012 on biocidal products, Regulation (EC) No 1907/2006 REACH, Regulation (EC) No 1223/2009 on cosmetic products and the Water Framework Directive (EC) No 2000/60] and in no way prejudge future decisions on active substances to be taken pursuant to these pieces of the EU legislation. It would thus be erroneous to consider that the substances listed in the results of this study (SANTE/2015/E3/SI2.706218) are considered as endocrine disruptors within the meaning of the EU legislation.

D. Results

The results of the potential categorization for each of the 186 miscellaneous chemicals according to the four "Options" of the Roadmap for human health and vertebrate wildlife assessment based on the above methodology are presented in the Appendix 5.1.

In this section, the overall summary tables with the potential categorization results for miscellaneous chemicals screened for human health (Table 5.4) and vertebrate wildlife (Table 5.5) are presented. Moreover, an overall/combined table for human health and vertebrate wildlife (Table 5.6) and a summary table for "option 3" results and the different Paths leading to the different categories for human health (Table 5.7) and vertebrate wildlife (Table 5.8) are presented.

Under "Option 1", since both the harmonised classification (when available) and the proposed classification (when relevant) have been considered for the categorization of the substances, the results are reported separately.

As already noted above, in most cases for miscellaneous chemicals the proposed classification represents the classification applied by REACH registrant, i.e. self-classification, not peer reviewed or checked by a regulatory authority. Although this has been captured for completeness reasons, especially since the REACH registrant's data have been considered for data population as well, this has not been considered for the overall categorization outcome under "Option 1" except from the cases where this was more strict than the harmonised classification or when no harmonised classification was available.

In the Categorization Results Table (Appendix 5.1), when there is no harmonised C&L available, "*Not relevant*" is reported. However, when concluding for the categorization under "Option 1", this is interpreted as "*Unclassified**". The "*" has been added in order to make the distinction from the substances which are categorized as "*Unclassified*" after discussion, i.e. considering the harmonised C&L included in Annex VI of CLP Regulation. For nine (9) substances the outcome has been inconclusive under "Option 1" since although these substances are classified as Repr. Cat 1A or 1B no conclusion can be drawn regarding effects on endocrine organs due to lack of data.

For 20 substances out of the 58 in total, for which there is no harmonised classification available, no relevant C&L proposal has been found.

Considering the most strict classification, 89 out of 186 miscellaneous chemicals screened were classified as EDs, 89 as "Unclassified" under "Option 1" while for 8 substances the categorization outcome under "Option 1" was inconclusive due to lack of data. Under "Option 2", 30 substances were classified as ED (equivalent to Cat I under "Option 3"), and 18 substances were classified as ED under "Option 4" (Table 5.4).

Table 5.4. Potential categorization results for human health for the miscellaneous chemicals screened.

Human health	Potential Categorization											
	Option 1			Option 2		Option 3				Option 4		Options 2, 3, 4
		ED	Unclassified /Inconclusive	ED	Unclassified ¹	Cat I	Cat II	Cat III ¹	Unclassified ¹	ED	Unclassified ¹	Inconclusive ²
Number of Miscellaneous US Chemicals	Harmonised C&L	83	95 ^a + 8 ^b	30	141	30	85	5	51	18	153	15
	Most strict C&L ^c	89	89 + 8 ^b									

^a For 58 substances there is no harmonised C & L available, which is interpreted as "Unclassified"

^b For 8 substances the categorization outcome under "Option 1" was inconclusive due to lack of data.

^c Taking into account the most strict C&L among the harmonised C&L (if available) and any relevant C&L proposal from regulatory authority or C&L applied by REACH registrants/notifiers; for 2 substances the C&L proposed by regulatory authorities is most strict than the harmonised C&L.

¹ Including substances for which population was completed only with few (up to 3) studies

² Incomplete population due to lack of data

Regarding vertebrate wildlife, 37 miscellaneous chemicals were classified as EDs under "Option 2" (equivalent to Cat I under "Option 3"), whilst 28 miscellaneous chemicals were classified as EDs under "Option 4" (Table 5.5).

Table 5.5. Potential categorization results for vertebrate wildlife for the 186 miscellaneous chemicals screened.

Vertebrate wildlife	Potential Categorization								
	Option 2		Option 3				Option 4		Options 2, 3, 4
	ED	Unclassified ¹	Cat I	Cat II ¹	Cat III	Unclassified ¹	ED	Unclassified ¹	Inconclusive ²
Number of Miscellaneous Chemicals	37	134	37	82	3	49	28	143	15

¹ Including substances for which population was completed only with few (up to 3) studies

² Incomplete population due to lack of data

For combined/overall potential categorization, the more conservative outcome has been considered, i.e. the most strict classification in case of "Option 1", the most severe categorization between human health and vertebrate wildlife in case of "Option 2, 3 & 4" (Table 5.6). Consequently, 89 miscellaneous chemicals were classified as EDs under "Option 1", 38 miscellaneous chemicals were classified as EDs under "Option 2" (equivalent to Cat I under "Option 3") whilst 32 miscellaneous chemicals were classified as EDs under "Option 4".

Table 5.6. Combined potential categorization results for human health and vertebrate wildlife for the miscellaneous chemicals screened.

Human health & vertebrate wildlife	Potential Categorization										
	Option 1		Option 2		Option 3				Option 4		Options 2, 3, 4
	ED	Unclassified/Inconclusive	ED	Unclassified ¹	Cat I	Cat II ¹	Cat III	Unclassified ¹	ED	Unclassified ¹	Inconclusive ²
Number of Miscellaneous Chemicals	89	89 + 8 ^a	38	133	38	82	2	49	32	139	15

^a For 8 substances the categorization outcome under "Option 1" was inconclusive due to lack of data.

¹ Including substances for which population was completed only with few (up to 3) studies

² Incomplete population due to lack of data

For "Option 3", the Paths of the decision tree (please refer to Appendix I) leading to each categorization are presented in Table 5.7 for human health assessment and in Table 5.8 for vertebrate wildlife assessment.

Table 5.7. Presentation of the results for "Option 3" and the different Paths leading to the different categories or to "Unclassified" for human health.

Miscellaneous Chemicals	Potential Categorization – "Option 3" (Human health)									
	Number of substances									
	Cat I		Cat II		Cat III		Unclassified		Inconclusive (incomplete population due to lack of data)	
Total number	30		85		5		51		15	
	Path 1	6	Path 3a	30	Path 7	0	Path 8	15		
	Path 2a	6	Path 3b	17	Path 10	5	Path 11	36		
	Path 2b	5	Path 3a, 3b	34						
	Path 2a, 2b	13	Path 5	2						
	Path 4	-	Path 6	-						
			Path 9	2						

Most of the substances categorized as Cat I under "Option 3" for vertebrate wildlife, reached this categorization through Path 1 based on a pattern of effects self-diagnostic of Endocrine Disruption (Table 5.8).

Table 5.8. Presentation of the results for "Option 3" and the different Paths leading to the different categories or to "Unclassified" for vertebrate wildlife.

Miscellaneous Chemicals	Potential Categorization – "Option 3" (vertebrate wildlife) Number of substances								
	Cat I		Cat II		Cat III		Unclassified		Inconclusive (incomplete population due to lack of data)
Total number	37		82		3		49		15
	Path 1	14	Path 3a	30	Path 7	-	Path 8	15	
	Path 2a	6	Path 3b	11	Path 10	3	Path 11	34	
	Path 1, 2a	2	Path 3a, 3b	36					
	Path 2a, 2b	7	Path 5	3					
	Path 2b	6	Path 6	-					
	Path 4	2	Path 9	2					

The results of the screening do not constitute evaluations of individual substances to be carried out under the respective chemical legislations [[in particular, Regulation (EC) No 1107/2009 on plant protection products, Regulation (EU) No 528/2012 on biocidal products, Regulation (EC) No 1907/2006 REACH, Regulation (EC) No 1223/2009 on cosmetic products and the Water Framework Directive (EC) No 2000/60] and in no way prejudice future decisions on active substances to be taken pursuant to these pieces of the EU legislation. It would thus be erroneous to consider that the substances listed in the results of this study (SANTE/2015/E3/SI2.706218) are considered as endocrine disruptors within the meaning of the EU legislation.

E. References

- EC, 2014. Defining criteria for identifying Endocrine Disruptors in the context of the implementation of the Plant Protection Product Regulation and Biocidal Products Regulation. DG ENV.A.3, DG SANCO.E.3. (http://ec.europa.eu/smart-regulation/impact/planned_ia/docs/2014_env_009_endocrine_disruptors_en.pdf).
- JRC, 2016. Screening methodology to identify endocrine disruptors according to different options in the context of an impact assessment. . EUR 27955 EN doi:10.2788/288320 (<http://publications.jrc.ec.europa.eu/repository/bitstream/JRC101950/jrc%20screening%20methodology%20for%20ed%20impact%20assessment%20%28online%29.pdf>)
- EC, 2015. Selection of chemical substances to be screened in the context of the impact assessment on criteria to identify endocrine disruptors. (http://ec.europa.eu/health/endocrine_disruptors/impact_assessment/index_en.htm).
- EC, 2008. Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006. OJ L 353, 31.12.2008, p. 1–135

Appendix 5.1

The results of the potential categorization of each of the 186 miscellaneous chemicals according to the four options of the Roadmap (EC, 2014) for human health and vertebrate wildlife assessment based on the methodology described in chapter 2 and chapter 3 are presented in the embedded files:.

Potential categorization results for 186 miscellaneous chemicals under “Option 1”

	Chemical Name	Carc Cat. 2 (C&L Harmonised)	Carc Cat. 2 (C&L Proposed)	Repr. Cat. 2 (C&L Harmonised)	Repr. Cat. 2 (C&L Proposed)	Carc Cat. 1A or 1B (C&L Harmonised)	Carc Cat. 1A or 1B (C&L Proposed)	Repr. Cat. 1A or 1B (C&L Harmonised)	Repr. Cat. 1A or 1B (C&L Proposed)	Effects on Endocrine organs (YES/NO)	OPTION 1 Harmonized	OPTION 1 Proposed	OPTION 1 Most strict
450	propargite	YES	YES	NO	YES	NO	NO	NO	NO	YES	Unclassified	ED	ED
557	Oligomerisation and alkylation reaction products of 2-phenylpropene and phenol [Previously registered as Phenol, methylstyrenated - EC N. 270-966-8 and CAS N. 68512-30-1]	Not relevant	NO	Not relevant	NO	Not relevant	NO	Not relevant	YES	NO	Unclassified*	Unclassified	Unclassified*
558	2,2',6,6'-Tetrabromo-4,4'-isopropylidenediphenol, oligomeric reaction products with Propylene oxide and n-butyl glycidyl ether	Not relevant	NO	Not relevant	NO	Not relevant	NO	Not relevant	NO	NO	Unclassified*	Unclassified	Unclassified*
559	reaction mass of 1-(1,2,3,4,5,6,7,8-octahydro-2,3,8,8-tetramethyl-2-naphthyl)ethan-1-one and 1-(1,2,3,4,6,7,8,8a-octahydro-2,3,8,8-tetramethyl-2-naphthyl)ethan-1-one and 1-(1,2,3,5,6,7,8,8a-octahydro-2,3,8,8-tetramethyl-2-naphthyl)ethan-1-one	Not relevant	NO	Not relevant	NO	Not relevant	NO	Not relevant	NO	NO	Unclassified*	Unclassified	Unclassified*
560	reaction mass of 2-ethylhexyl 10-ethyl-4,4-dioctyl-7-oxo-8-oxa-3,5-dithia-4-stannatetradecanoate and 2-ethylhexyl 10-ethyl-4-[[2-[[2-ethylhexyl)oxy]-2-oxoethyl]thio]-4-octyl-7-oxo-8-oxa-3,5-dithia-4-	NO	Not relevant	NO	Not relevant	NO	Not relevant	YES	Not relevant	NO	Unclassified	Not relevant	Unclassified

The results of the screening do not constitute evaluations of individual substances to be carried out under the respective chemical legislations [[in particular, Regulation (EC) No 1107/2009 on plant protection products, Regulation (EU) No 528/2012 on biocidal products, Regulation (EC) No 1907/2006 REACH, Regulation (EC) No 1223/2009 on cosmetic products and the Water Framework Directive (EC) No 2000/60] and in no way prejudice future decisions on active substances to be taken pursuant to these pieces of the EU legislation.

It would thus be erroneous to consider that the substances listed in the results of this study (SANTE/2015/E3/SI2.706218) are considered as endocrine disruptors within the meaning of the EU legislation.

Screening of available evidence on chemical substances for the identification of endocrine disruptors according to different options in the context of an Impact Assessment

	Chemical Name	Carc Cat. 2 (C&L Harmonised)	Carc Cat. 2 (C&L Proposed)	Repr. Cat. 2 (C&L Harmonised)	Repr. Cat. 2 (C&L Proposed)	Carc Cat. 1A or 1B (C&L Harmonised)	Carc Cat. 1A or 1B (C&L Proposed)	Repr. Cat. 1A or 1B (C&L Harmonised)	Repr. Cat. 1A or 1B (C&L Proposed)	Effects on Endocrine organs (YES/NO)	OPTION 1 Harmonized	OPTION 1 Proposed	OPTION 1 Most strict
	stannatetradecanoate (reaction mass of DOTE and MOTE)												
561	4-Nonylphenol, branched and linear, ethoxylated [substances with a linear and/or branched alkyl chain with a carbon number of 9 covalently bound in position 4 to phenol, ethoxylated covering UVCB- and well-defined substances, polymers and homologues, which include any of the individual isomers and/or combinations thereof]	Not relevant	NO	Not relevant	YES	Not relevant	NO	Not relevant	NO	YES	Unclassified*	ED	ED
562	4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated [covering well-defined substances and UVCB substances, polymers and homologues]	Not relevant	Not relevant	Not relevant	Not relevant	Not relevant	Not relevant	Not relevant	Not relevant	YES	Unclassified*	Not relevant	Unclassified*
563	4-Nonylphenol, branched and linear [substances with a linear and/or branched alkyl chain with a carbon number of 9 covalently bound in position 4 to phenol, covering also UVCB- and well-defined substances which include any of the individual isomers or a combination thereof]	NO	NO	YES	YES	NO	NO	NO	NO	YES	ED	ED	ED
580	Dibutyltin (DBT) (Dibutyl stannane)	NO	NO	NO	NO	NO	NO	YES	YES	YES	ED	ED	ED
651	lead dinitrate	NO	NO	NO	NO	NO	NO	YES	YES	YES	ED	ED	ED
656	triphenyl phosphite	NO	NO	NO	NO	NO	NO	NO	NO	NO	Unclassified	Unclassified	Unclassified

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The results of the screening do not constitute evaluations of individual substances to be carried out under the respective chemical legislations [[in particular, Regulation (EC) No 1107/2009 on plant protection products, Regulation (EU) No 528/2012 on biocidal products, Regulation (EC) No 1907/2006 REACH, Regulation (EC) No 1223/2009 on cosmetic products and the Water Framework Directive (EC) No 2000/60] and in no way prejudice future decisions on active substances to be taken pursuant to these pieces of the EU legislation.

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Screening of available evidence on chemical substances for the identification of endocrine disruptors according to different options in the context of an Impact Assessment

	Chemical Name	Carc Cat. 2 (C&L Harmonised)	Carc Cat. 2 (C&L Proposed)	Repr. Cat. 2 (C&L Harmonised)	Repr. Cat. 2 (C&L Proposed)	Carc Cat. 1A or 1B (C&L Harmonised)	Carc Cat. 1A or 1B (C&L Proposed)	Repr. Cat. 1A or 1B (C&L Harmonised)	Repr. Cat. 1A or 1B (C&L Proposed)	Effects on Endocrine organs (YES/NO)	OPTION 1 Harmonized	OPTION 1 Proposed	OPTION 1 Most strict
659	cadmium chloride	NO	NO	NO	YES	YES	YES	YES	NO	YES	ED	ED	ED
670	cadmium sulphate	NO	NO	NO	NO	YES	YES	YES	YES	YES	ED	ED	ED
673	cobalt sulphate [Cobalt(II) sulphate]	NO	NO	NO	NO	YES	YES	YES	YES	YES	ED	ED	ED
682	cobalt dinitrate [Cobalt(II) dinitrate]	NO	NO	NO	NO	YES	YES	YES	YES	YES	ED	ED	ED
687	N-Phenyl-P-Phenylenediamine [N-(4-aminophenyl)aniline]	Not relevant	NO	Not relevant	NO	Not relevant	NO	Not relevant	NO	NO	Unclassified*	Unclassified	Unclassified*
912	sodium dichromate	NO	NO	NO	NO	YES	YES	YES	YES	YES	ED	ED	ED
952	p-cresol	NO	NO	NO	NO	NO	NO	NO	NO	NO	Unclassified	Unclassified	Unclassified
960	p-phenylenediamine	NO	NO	NO	NO	NO	NO	NO	NO	YES	Unclassified	Unclassified	Unclassified
989	1-bromopropane (n-propyl bromide)	NO	YES	NO	NO	NO	NO	YES	YES	YES	ED	ED	ED
1080	Resorcinol (1,3-benzenediol)	NO	NO	NO	NO	NO	NO	NO	NO	YES	Unclassified	Unclassified	Unclassified
1151	2-methoxyethanol (ethylene glycol monomethyl ether)	NO	NO	NO	NO	NO	NO	YES	YES	YES	ED	ED	ED
1182	2-methoxyethyl acetate	NO	Not relevant	NO	Not relevant	NO	Not relevant	YES	Not relevant	YES	ED	Not relevant	ED
1196	1,2-dimethoxyethane	NO	YES	NO	NO	NO	NO	YES	YES	YES	ED	ED	ED
1202	2-ethoxyethanol	NO	NO	NO	NO	NO	NO	YES	YES	YES	ED	ED	ED
1228	2-ethoxyethyl acetate	NO	Not relevant	NO	Not relevant	NO	Not relevant	YES	Not relevant	YES	ED	Not relevant	ED
1234	Silicic acid, lead salt	NO	NO	NO	NO	NO	NO	YES	YES	YES	ED	ED	ED
1280	Ethylene Glycol Monobutyl Ether (2-Butoxyethanol)	NO	NO	NO	NO	NO	NO	NO	NO	NO	Unclassified	Unclassified	Unclassified
1281	2-(2-methoxyethoxy)ethanol (DEGME)	NO	NO	YES	YES	NO	NO	NO	NO	NO	Unclassified	Unclassified	Unclassified
1298	Diethylene glycol monobutyl ether (ethoxydiglycol)	Not relevant	NO	Not relevant	NO	Not relevant	NO	Not relevant	NO	NO	Unclassified*	Unclassified	Unclassified*
1303	dimethyl glutarate	Not relevant	NO	Not relevant	NO	Not relevant	NO	Not relevant	NO	NO	Unclassified*	Unclassified	Unclassified*
1305	bis(2-methoxyethyl) ether	NO	NO	NO	NO	NO	NO	YES	YES	YES	ED	ED	ED

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Screening of available evidence on chemical substances for the identification of endocrine disruptors according to different options in the context of an Impact Assessment

	Chemical Name	Carc Cat. 2 (C&L Harmonised)	Carc Cat. 2 (C&L Proposed)	Repr. Cat. 2 (C&L Harmonised)	Repr. Cat. 2 (C&L Proposed)	Carc Cat. 1A or 1B (C&L Harmonised)	Carc Cat. 1A or 1B (C&L Proposed)	Repr. Cat. 1A or 1B (C&L Harmonised)	Repr. Cat. 1A or 1B (C&L Proposed)	Effects on Endocrine organs (YES/NO)	OPTION 1 Harmonized	OPTION 1 Proposed	OPTION 1 Most strict
1350	1,2-bis(2-methoxyethoxy)ethane	NO	NO	NO	NO	NO	NO	YES	YES	YES	ED	ED	ED
1436	triphenyl phosphate	Not relevant	NO	Not relevant	NO	Not relevant	NO	Not relevant	NO	NO	Unclassified*	Unclassified	Unclassified*
1439	tris(2-chloroethyl) phosphate (TCEP)	YES	YES	NO	NO	NO	NO	YES	YES	YES	ED	ED	ED
1484	bis(2-ethylhexyl) phthalate (DEHP)	NO	NO	NO	NO	NO	NO	YES	YES	YES	ED	ED	ED
1486	Bis(2-methoxyethyl) phthalate	NO	Not relevant	NO	Not relevant	NO	Not relevant	YES	Not relevant	inconclusive ²	inconclusive ²	Not relevant	inconclusive ²
1519	2,2',6,6'-tetra-tert-butyl-4,4'-methylenediphenol	Not relevant	NO	Not relevant	NO	Not relevant	NO	Not relevant	NO	NO	Unclassified*	Unclassified	Unclassified*
1611	lead oxide sulfate (basic lead sulphate)	NO	YES	NO	NO	NO	NO	YES	YES	YES	ED	ED	ED
1631	lead titanium trioxide	NO	NO	NO	NO	NO	NO	YES	YES	YES	ED	ED	ED
1637	pentalead tetraoxide sulphate (tetrabasic lead sulphate)	NO	YES	NO	NO	NO	NO	YES	YES	YES	ED	ED	ED
1678	trilead dioxide phosphonate (dibasic lead phosphite)	NO	NO	NO	NO	NO	NO	YES	YES	YES	ED	ED	ED
1719	tetralead trioxide sulphate (tribasic lead sulphate)	NO	YES	NO	NO	NO	NO	YES	YES	YES	ED	ED	ED
1737	Low temperature tar oil, alkaline, extract residues (coal), low temperature coal tar alkaline	NO	Not relevant	NO	Not relevant	YES	Not relevant	NO	Not relevant	inconclusive ²	Unclassified	Not relevant	Unclassified
1778	p-aminophenol	NO	NO	NO	NO	NO	NO	NO	NO	NO	Unclassified	Unclassified	Unclassified
1870	dioxobis(stearato)trilead (dibasic lead stearate)	NO	YES	NO	NO	NO	NO	YES	YES	YES	ED	ED	ED
1884	Lead titanium zirconium oxide	NO	NO	NO	NO	NO	NO	YES	YES	YES	ED	ED	ED
1925	N,N-dimethylacetamide	NO	NO	NO	NO	NO	NO	YES	YES	YES	ED	ED	ED
2042	Dipentyl phthalate (DPP)	NO	Not relevant	NO	Not relevant	NO	Not relevant	YES	Not relevant	YES	ED	Not relevant	ED
2061	orange lead (lead tetroxide)	NO	YES	NO	NO	NO	NO	YES	YES	YES	ED	ED	ED
2081	Benzophenone-3 (oxybenzone)	Not relevant	NO	Not relevant	NO	Not relevant	NO	Not relevant	NO	YES	Unclassified*	Unclassified	Unclassified*

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Screening of available evidence on chemical substances for the identification of endocrine disruptors according to different options in the context of an Impact Assessment

	Chemical Name	Carc Cat. 2 (C&L Harmonised)	Carc Cat. 2 (C&L Proposed)	Repr. Cat. 2 (C&L Harmonised)	Repr. Cat. 2 (C&L Proposed)	Carc Cat. 1A or 1B (C&L Harmonised)	Carc Cat. 1A or 1B (C&L Proposed)	Repr. Cat. 1A or 1B (C&L Harmonised)	Repr. Cat. 1A or 1B (C&L Proposed)	Effects on Endocrine organs (YES/NO)	OPTION 1 Harmonized	OPTION 1 Proposed	OPTION 1 Most strict
2091	lead monoxide (lead oxide)	NO	YES	NO	NO	NO	NO	YES	YES	YES	ED	ED	ED
2105	trilead bis(carbonate) dihydroxide (basic lead carbonate)	NO	YES	NO	NO	NO	NO	YES	YES	YES	ED	ED	ED
2191	lead diazide	NO	NO	NO	NO	NO	NO	YES	YES	YES	ED	ED	ED
2391	4-(1,1,3,3-tetramethylbutyl)phenol	NO	NO	NO	NO	NO	NO	NO	NO	NO	Unclassified	Unclassified	Unclassified
2491	3-ethyl-2-methyl-2-(3-methylbutyl)-1,3-oxazolidine	NO	Not relevant	NO	Not relevant	NO	Not relevant	YES	Not relevant	inconclusive ²	inconclusive ²	Not relevant	inconclusive ²
2527	3-methylpyrazole	Not relevant	NO	Not relevant	YES	Not relevant	NO	Not relevant	NO	YES	Unclassified*	ED	ED
2543	tributyltin chloride	Not relevant	NO	Not relevant	NO	Not relevant	NO	Not relevant	NO	YES	Unclassified*	Unclassified	Unclassified*
2544	tributyltin bromide	Not relevant	NO	Not relevant	NO	Not relevant	NO	Not relevant	NO	YES	Unclassified*	Unclassified	Unclassified*
2594	2-Mercaptobenzothiazole (Benzothiazole-2-thiol)	NO	NO	NO	NO	NO	NO	NO	NO	YES	Unclassified	Unclassified	Unclassified
2625	3-Benzylidene camphor (1,7,7-trimethyl-3-(phenylmethylene)bicyclo[2.2.1]heptan-2-one)	Not relevant	NO	Not relevant	YES	Not relevant	NO	Not relevant	NO	YES	Unclassified*	ED	ED
2633	Sodium perborate, perboric acid, sodium salt	NO	NO	NO	NO	NO	NO	YES	YES	YES	ED	ED	ED
2657	lead 2,4,6-trinitro-m-phenylene dioxide (Lead styphnate)	NO	NO	NO	NO	NO	NO	YES	YES	YES	ED	ED	ED
2701	2-ethylhexyl 10-ethyl-4,4-dioctyl-7-oxo-8-oxa-3,5-dithia-4-stannatetradecanoate (DOTE)	NO	NO	NO	NO	NO	NO	YES	NO	NO	Unclassified	Unclassified	Unclassified
2813	tert-butyl methyl ether	NO	NO	NO	NO	NO	NO	NO	NO	YES	Unclassified	Unclassified	Unclassified
2863	2-Amino-3-hydroxypyridine (2-aminopyridin-3-ol)	Not relevant	Not relevant	Not relevant	Not relevant	Not relevant	Not relevant	Not relevant	Not relevant	NO	Unclassified*	Not relevant	Unclassified*
2940	Lead(II) bis(methanesulfonate)	NO	NO	NO	NO	NO	NO	YES	YES	YES	ED	ED	ED

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Screening of available evidence on chemical substances for the identification of endocrine disruptors according to different options in the context of an Impact Assessment

	Chemical Name	Carc Cat. 2 (C&L Harmonised)	Carc Cat. 2 (C&L Proposed)	Repr. Cat. 2 (C&L Harmonised)	Repr. Cat. 2 (C&L Proposed)	Carc Cat. 1A or 1B (C&L Harmonised)	Carc Cat. 1A or 1B (C&L Proposed)	Repr. Cat. 1A or 1B (C&L Harmonised)	Repr. Cat. 1A or 1B (C&L Proposed)	Effects on Endocrine organs (YES/NO)	OPTION 1 Harmonized	OPTION 1 Proposed	OPTION 1 Most strict
2945	ammonium thiocyanate	Not relevant	NO	Not relevant	NO	Not relevant	NO	Not relevant	NO	NO	Unclassified*	Unclassified	Unclassified*
3040	octabenzene	Not relevant	NO	Not relevant	NO	Not relevant	NO	Not relevant	NO	NO	Unclassified*	Unclassified	Unclassified*
3152	p-METHYLAMINOPHENOL sulphate	Not relevant	Not relevant	Not relevant	Not relevant	Not relevant	Not relevant	Not relevant	Not relevant	NO	Unclassified*	Not relevant	Unclassified*
3269	tributyltin	Not relevant	NO	Not relevant	NO	Not relevant	NO	Not relevant	NO	YES	Unclassified*	Unclassified	Unclassified*
3278	lead cyanamidate	NO	NO	NO	NO	NO	NO	YES	YES	YES	ED	ED	ED
3588	tert-butyl-4-methoxyphenol	Not relevant	NO	Not relevant	NO	Not relevant	NO	Not relevant	NO	YES	Unclassified*	Unclassified	Unclassified*
3590	Bisphenol-A-Epichlorhydrin Epoxy resin Average MW < 700 [4,4'-Isopropylidenediphenol, oligomeric reaction products with 1-chloro-2,3-epoxypropane]	NO	NO	NO	NO	NO	NO	NO	NO	NO	Unclassified	Unclassified	Unclassified
3600	Phenol, nonyl- (Nonylphenol)	NO	Not relevant	YES	Not relevant	NO	Not relevant	NO	Not relevant	YES	ED	Not relevant	ED
3601	trixyl phosphate	NO	NO	NO	NO	NO	NO	YES	YES	YES	ED	ED	ED
3708	bis(2-ethylhexyl) tetrabromophthalate (BEH-TEBP)	Not relevant	NO	Not relevant	NO	Not relevant	NO	Not relevant	NO	inconclusive ²	Unclassified*	Unclassified	Unclassified*
3824	Polyhexamethylene biguanide hydrochloride	YES	YES	NO	NO	NO	NO	NO	NO	inconclusive ²	Unclassified	Unclassified	Unclassified
4051	lead di(acetate) (also mentioned as lead acetate)	NO	NO	NO	NO	NO	NO	YES	YES	YES	ED	ED	ED
4087	Paraformaldehyde	Not relevant	Not relevant	Not relevant	Not relevant	Not relevant	Not relevant	Not relevant	Not relevant	inconclusive ²	Unclassified*	Not relevant	Unclassified*
4270	Pentadecafluorooctanoic acid (PFOA)	YES	YES	NO	NO	NO	NO	YES	YES	YES	ED	ED	ED
4280	Triclosan	NO	NO	NO	NO	NO	NO	NO	NO	YES	Unclassified	Unclassified	Unclassified
4449	tributyltin-cation (same as tributyltin hydride, CAS: 688-73-3)	Not relevant	NO	Not relevant	NO	Not relevant	NO	Not relevant	NO	YES	Unclassified*	Unclassified	Unclassified*
4462	trilead diarsenate	NO	NO	NO	NO	YES	YES	YES	YES	YES	ED	ED	ED

The results of the screening do not constitute evaluations of individual substances to be carried out under the respective chemical legislations [[in particular, Regulation (EC) No 1107/2009 on plant protection products, Regulation (EU) No 528/2012 on biocidal products, Regulation (EC) No 1907/2006 REACH, Regulation (EC) No 1223/2009 on cosmetic products and the Water Framework Directive (EC) No 2000/60] and in no way prejudice future decisions on active substances to be taken pursuant to these pieces of the EU legislation.

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Screening of available evidence on chemical substances for the identification of endocrine disruptors according to different options in the context of an Impact Assessment

	Chemical Name	Carc Cat. 2 (C&L Harmonised)	Carc Cat. 2 (C&L Proposed)	Repr. Cat. 2 (C&L Harmonised)	Repr. Cat. 2 (C&L Proposed)	Carc Cat. 1A or 1B (C&L Harmonised)	Carc Cat. 1A or 1B (C&L Proposed)	Repr. Cat. 1A or 1B (C&L Harmonised)	Repr. Cat. 1A or 1B (C&L Proposed)	Effects on Endocrine organs (YES/NO)	OPTION 1 Harmonized	OPTION 1 Proposed	OPTION 1 Most strict
4537	4-Methylbenzylidene camphor (3-(4'-Methylbenzylidene)-dl-camphor / Enzacamene)	Not relevant	Not relevant	Not relevant	Not relevant	Not relevant	Not relevant	Not relevant	Not relevant	YES	Unclassified*	Not relevant	Unclassified*
4548	Ammonium pentadecafluorooctanoate (APFO)	YES	Not relevant	NO	Not relevant	NO	Not relevant	YES	Not relevant	YES	ED	Not relevant	ED
4960	Kojic Acid (5-hydroxy-2-hydroxymethyl-4-pyrone)	Not relevant	Not relevant	Not relevant	Not relevant	Not relevant	Not relevant	Not relevant	Not relevant	YES	Unclassified*	Not relevant	Unclassified*
5033	2-(2-butoxyethoxy)ethyl 6-propylpiperonyl ether (PBO)	Not relevant	NO	Not relevant	NO	Not relevant	NO	Not relevant	NO	YES	Unclassified*	Unclassified	Unclassified*
5047	Quaternium-15 (cis-isomer)	NO	NO	YES	YES	NO	NO	NO	NO	NO	Unclassified	Unclassified	Unclassified
5065	cobalt carbonate	NO	NO	NO	NO	YES	YES	YES	YES	YES	ED	ED	ED
5067	Acetic acid, lead salt, basic	NO	NO	NO	NO	NO	NO	YES	YES	YES	ED	ED	ED
5160	Camphor benzalkonium methosulfate (Methyl N,N,N-trimethyl-4-[(4,7,7-trimethyl-3-oxobicyclo[2.2.1]hept-2-ylidene)methyl]anilinium sulphate)	Not relevant	Not relevant	Not relevant	Not relevant	Not relevant	Not relevant	Not relevant	Not relevant	NO	Unclassified*	Not relevant	Unclassified*
5202	bis(2-propylheptyl) phthalate	Not relevant	NO	Not relevant	NO	Not relevant	NO	Not relevant	NO	NO	Unclassified*	Unclassified	Unclassified*
5209	1,2,4-trihydroxybenzene (Benzene-1,2,4-triol)	Not relevant	Not relevant	Not relevant	Not relevant	Not relevant	Not relevant	Not relevant	Not relevant	NO	Unclassified*	Not relevant	Unclassified*
5272	Decamethylcyclopentasiloxane (mentioned as Cyclomethicone and Cyclopentasiloxane)	Not relevant	Not relevant	Not relevant	Not relevant	Not relevant	Not relevant	Not relevant	Not relevant	YES	Unclassified*	Not relevant	Unclassified*
5324	2-Ethylhexyl-4-methoxycinnamate (Oxtinoxate or Ethylhexyl Methoxycinnamate)	Not relevant	Not relevant	Not relevant	Not relevant	Not relevant	Not relevant	Not relevant	Not relevant	YES	Unclassified*	Not relevant	Unclassified*
5382	Cyclomethicone Octamethylcyclotetrasiloxane	NO	NO	YES	YES	NO	NO	NO	NO	YES	ED	ED	ED
5443	Tributyltin (tributyltin chloride?)	Not relevant	NO	Not relevant	NO	Not relevant	NO	Not relevant	NO	YES	Unclassified*	Unclassified	Unclassified*

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5706	diisopentyl phthalate	NO	NO	NO	NO	NO	NO	YES	YES	YES	ED	ED	ED
5760	toluene-2,5-diamine sulfate (2-methyl-p-phenylenediamine sulfate)	NO	NO	NO	NO	NO	NO	NO	NO	NO	Unclassified	Unclassified	Unclassified
5786	Phenol, styrenated	Not relevant	NO	Not relevant	NO	Not relevant	NO	Not relevant	NO	NO	Unclassified*	Unclassified	Unclassified*
5822	Sulfurous acid, lead salt, dibasic (basic lead sulphate)	NO	YES	NO	NO	NO	NO	YES	YES	YES	ED	ED	ED
5851	methoxyacetic acid	NO	NO	NO	NO	NO	NO	YES	YES	YES	ED	ED	ED
5880	1,2-Diethoxyethane	NO	Not relevant	NO	Not relevant	NO	Not relevant	YES	Not relevant	inconclusive ²	inconclusive ²	Not relevant	inconclusive ²
5962	Triphenyltin chloride	Not relevant	Not relevant	Not relevant	Not relevant	Not relevant	Not relevant	Not relevant	Not relevant	YES	Unclassified*	Not relevant	Unclassified*
6014	Lead dipicrate	NO	Not relevant	NO	Not relevant	NO	Not relevant	YES	Not relevant	YES	ED	Not relevant	ED
6071	Tar acids, coal, crude, crude phenols	NO	NO	NO	NO	NO	YES	NO	NO	inconclusive ²	Unclassified	Unclassified	Unclassified
6132	Triphenyltin	Not relevant	Not relevant	Not relevant	Not relevant	Not relevant	Not relevant	Not relevant	Not relevant	YES	Unclassified*	Not relevant	Unclassified*
6223	N,N-dimethylformamide	NO	NO	NO	NO	NO	NO	YES	YES	NO	Unclassified	Unclassified	Unclassified
6277	dibutyltin dichloride (DBTCI2)	NO	NO	NO	NO	NO	NO	YES	YES	YES	ED	ED	ED
6325	1,2-Benzenedicarboxylic acid, di-C7-11-branched and linear alkyl esters	NO	Not relevant	NO	Not relevant	NO	Not relevant	YES	Not relevant	inconclusive ²	inconclusive ²	Not relevant	inconclusive ²
6330	1,2-Benzenedicarboxylic acid, dihexylester, branched and linear (Diisohexyl phthalate - DIHP)	NO	Not relevant	NO	Not relevant	NO	Not relevant	YES	Not relevant	YES	ED	Not relevant	ED
6331	1,2-Benzenedicarboxylic acid, di-C6-10-alkyl esters	Not relevant	NO	Not relevant	NO	Not relevant	NO	Not relevant	YES	YES	Unclassified*	ED	ED
6369	2,2'-dimethyl-4,4'-methylenebis(cyclohexylamine)	NO	NO	NO	NO	NO	NO	NO	NO	NO	Unclassified	Unclassified	Unclassified
6384	Silicic acid (H2Si2O5), barium salt (1:1), lead-doped	NO	NO	NO	NO	NO	NO	YES	YES	YES	ED	ED	ED

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6440	[phthalato(2-)]dioxotrilead (dibasic lead phthalate)	NO	YES	NO	NO	NO	NO	YES	YES	YES	ED	ED	ED
6518	3-amino-2,6-dimethylphenol	Not relevant	Not relevant	Not relevant	Not relevant	Not relevant	Not relevant	Not relevant	Not relevant	NO	Unclassified*	Not relevant	Unclassified*
6593	cobalt di(acetate) [Cobalt(II) diacetate]	NO	NO	NO	NO	YES	YES	YES	YES	YES	ED	ED	ED
6600	Isopentyl-p-Methoxycinnamate (Amiloxate)	Not relevant	NO	Not relevant	NO	Not relevant	NO	Not relevant	NO	NO	Unclassified*	Unclassified	Unclassified*
6618	1,2-Benzenedicarboxylic acid, di-C6-8-branched alkyl esters, C7-rich	NO	Not relevant	NO	Not relevant	NO	Not relevant	YES	Not relevant	inconclusive ²	inconclusive ²	Not relevant	inconclusive ²
6731	mercury	NO	Not relevant	NO	Not relevant	NO	Not relevant	YES	Not relevant	YES	ED	Not relevant	ED
6789	chloromethane (Methyl chloride)	YES	YES	NO	YES	NO	NO	NO	NO	YES	Unclassified	ED	ED
6810	Acetaldehyde	YES	YES	NO	NO	NO	NO	NO	NO	NO	Unclassified	Unclassified	Unclassified
6812	Dichloromethane	YES	YES	NO	NO	NO	NO	NO	NO	YES	Unclassified	Unclassified	Unclassified
6814	Di-μ-oxo-di-n-butylstanniohydroxyborane/ Dibutyltin hydrogen borate C8H19BO3Sn (DBB)	NO	Not relevant	NO	Not relevant	NO	Not relevant	YES	Not relevant	inconclusive ²	inconclusive ²	Not relevant	inconclusive ²
6815	formamide	NO	NO	NO	NO	NO	NO	YES	YES	YES	ED	ED	ED
6817	carbon disulphide	NO	NO	YES	YES	NO	NO	NO	NO	YES	ED	ED	ED
6900	sodium perchlorate	NO	NO	NO	NO	NO	NO	NO	NO	YES	Unclassified	Unclassified	Unclassified
6932	Sodium peroxometaborate	NO	Not relevant	NO	Not relevant	NO	Not relevant	YES	Not relevant	YES	ED	Not relevant	ED
6941	Cobalt dichloride	NO	NO	NO	NO	YES	YES	YES	YES	YES	ED	ED	ED
7055	N-pentyl-isopentylphthalate	NO	Not relevant	NO	Not relevant	NO	Not relevant	YES	Not relevant	inconclusive ²	inconclusive ²	Not relevant	inconclusive ²
7065	sodium chromate	NO	NO	NO	NO	YES	YES	YES	YES	YES	ED	ED	ED
7076	potassium dichromate	NO	NO	NO	NO	YES	YES	YES	YES	YES	ED	ED	ED
7108	Lead hydrogen arsenate	YES	Not relevant	NO	Not relevant	NO	Not relevant	YES	Not relevant	YES	ED	Not relevant	ED

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7129	ammonium dichromate	NO	Not relevant	NO	Not relevant	YES	Not relevant	YES	Not relevant	YES	ED	Not relevant	ED
7147	Cadmium fluoride	NO	Not relevant	NO	Not relevant	YES	Not relevant	YES	Not relevant	YES	ED	Not relevant	ED
7150	ammonium perchlorate	NO	NO	NO	NO	NO	NO	NO	NO	YES	Unclassified	Unclassified	Unclassified
7157	tetraethyllead	NO	NO	NO	NO	NO	NO	YES	YES	YES	ED	ED	ED
7215	2-Chloroacetamide	NO	NO	YES	YES	NO	NO	NO	NO	YES	ED	ED	ED
7222	N-methylacetamide	NO	NO	NO	NO	NO	NO	YES	NO	NO	Unclassified	Unclassified	Unclassified
7261	2,2',6,6'-tetrabromo-4,4'-isopropylidenediphenol (TBBPA)	NO	YES	NO	NO	NO	NO	NO	NO	YES	Unclassified	Unclassified	Unclassified
7274	4,4'-isopropylidenediphenol (Bisphenol A)	NO	NO	YES	YES	NO	NO	NO	NO	YES	ED	ED	ED
7279	dapsone (TETRAHYDROMYRCENYL ACETATE)	NO	NO	NO	NO	NO	NO	NO	NO	YES	Unclassified	Unclassified	Unclassified
7281	4,4'-sulphonyldiphenol (Bisphenol S)	Not relevant	NO	Not relevant	NO	Not relevant	NO	Not relevant	NO	YES	Unclassified*	Unclassified	Unclassified*
7285	pyrochlore, antimony lead yellow	NO	YES	NO	NO	NO	NO	YES	YES	YES	ED	ED	ED
7298	p-(1,1-dimethylpropyl)phenol	Not relevant	NO	Not relevant	NO	Not relevant	NO	Not relevant	NO	YES	Unclassified*	Unclassified	Unclassified*
7322	Musk Ketone (also as 4'-tert-Butyl-2',6'-dimethyl-3',5'-dinitroacetophenone)	YES	Not relevant	NO	Not relevant	NO	Not relevant	NO	Not relevant	NO	Unclassified	Not relevant	Unclassified
7323	Musk Xylene (also as 5-tert-Butyl-2,4,6-trinitro-m-xylene)	YES	Not relevant	NO	Not relevant	NO	Not relevant	NO	Not relevant	NO	Unclassified	Not relevant	Unclassified
7369	1-Methyl-2,6-diamino-benzene (also as 2-Methyl-m-phenylenediamine OR Toluene-2,6-diamine)	NO	Not relevant	NO	Not relevant	NO	Not relevant	NO	Not relevant	inconclusive ²	Unclassified	Not relevant	Unclassified
7437	2-amino-4-hydroxyethylaminoanisole sulfate	Not relevant	Not relevant	Not relevant	Not relevant	Not relevant	Not relevant	Not relevant	Not relevant	NO	Unclassified*	Not relevant	Unclassified*

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7503	Distillates (coal tar), naphthalene oils, naphthalene oil	NO	NO	NO	NO	YES	YES	NO	NO	inconclusive ²	Unclassified	Unclassified	Unclassified
7505	Diethyl phthalate	Not relevant	NO	Not relevant	NO	Not relevant	NO	Not relevant	NO	YES	Unclassified*	Unclassified	Unclassified*
7507	diisobutyl phthalate (BIPB)	NO	NO	NO	NO	NO	NO	YES	YES	YES	ED	ED	ED
7511	dibutyl phthalate	NO	NO	NO	NO	NO	NO	YES	YES	YES	ED	ED	ED
7512	Dihexyl phthalate	NO	Not relevant	NO	Not relevant	NO	Not relevant	YES	Not relevant	YES	ED	Not relevant	ED
7516	1,2-Benzenedicarboxylic acid, dipentylester, branched and linear	NO	Not relevant	NO	Not relevant	NO	Not relevant	YES	Not relevant	inconclusive ²	inconclusive ²	Not relevant	inconclusive ²
7578	6,6'-di-tert-butyl-4,4'-butylidenedi-m-cresol	Not relevant	NO	Not relevant	NO	Not relevant	NO	Not relevant	NO	NO	Unclassified*	Unclassified	Unclassified*
7581	benzyl butyl phthalate	NO	NO	NO	NO	NO	NO	YES	YES	YES	ED	ED	ED
7645	diocetyl tin oxide	Not relevant	NO	Not relevant	NO	Not relevant	NO	Not relevant	NO	NO	Unclassified*	Unclassified	Unclassified*
7657	N-Methyl-2-pyrrolidone (Methyl Pyrrolidone)	NO	NO	NO	NO	NO	NO	YES	YES	NO	Unclassified	Unclassified	Unclassified
7740	dinoseb	NO	NO	NO	NO	NO	NO	YES	YES	YES	ED	ED	ED
7749	triphenyltin hydride (based on the CAS No)	Not relevant	Not relevant	Not relevant	Not relevant	Not relevant	Not relevant	Not relevant	Not relevant	YES	Unclassified*	Not relevant	Unclassified*
7870	Fatty acids, C16-18, lead salts	NO	YES	NO	NO	NO	NO	YES	YES	YES	ED	ED	ED
8027	Hydroxyethyl-p-phenylenediamine sulfate (3-(2-Hydroxyethyl)-p-phenylenediammonium sulphate)	Not relevant	Not relevant	Not relevant	Not relevant	Not relevant	Not relevant	Not relevant	Not relevant	NO	Unclassified*	Not relevant	Unclassified*
8046	propyl 4-hydroxybenzoate (propylparaben)	Not relevant	NO	Not relevant	NO	Not relevant	NO	Not relevant	NO	YES	Unclassified*	Unclassified	Unclassified*
8049	Hydroxyethyl-3,4-methylenedioxyaniline HCl	Not relevant	Not relevant	Not relevant	Not relevant	Not relevant	Not relevant	Not relevant	Not relevant	YES	Unclassified*	Not relevant	Unclassified*
8099	benzotriazole	Not relevant	NO	Not relevant	NO	Not relevant	NO	Not relevant	NO	NO	Unclassified*	Unclassified	Unclassified*

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8119	o-Aminophenol (also relevant for o-Aminophenol (o-Aminophenol; Cl 76520) and its salts)	NO	NO	NO	NO	NO	NO	NO	NO	NO	Unclassified	Unclassified	Unclassified
8170	1,2,3-trichloropropane	NO	NO	NO	NO	YES	YES	YES	YES	YES	ED	ED	ED
8185	imidazolidine-2-thione (ETU)	NO	YES	NO	NO	NO	NO	YES	YES	YES	ED	ED	ED
8194	6,6'-di-tert-butyl-4,4'-thiodi-m-cresol	Not relevant	NO	Not relevant	NO	Not relevant	NO	Not relevant	NO	YES	Unclassified*	Unclassified	Unclassified*
8196	2,4-di-tert-butylphenol	Not relevant	NO	Not relevant	NO	Not relevant	NO	Not relevant	NO	NO	Unclassified*	Unclassified	Unclassified*
8250	Furfural	YES	YES	NO	NO	NO	NO	NO	NO	NO	Unclassified	Unclassified	Unclassified
8276	4-tert-butylphenol	NO	NO	YES	YES	NO	NO	NO	NO	YES	ED	ED	ED
8296	nitrobenzene	YES	YES (depending on the benzene content)	NO	YES	NO	YES	YES	NO	YES	ED	ED	ED
8331	methyl 4-hydroxybenzoate (methylparaben)	Not relevant	NO	Not relevant	NO	Not relevant	NO	Not relevant	NO	NO	Unclassified*	Unclassified	Unclassified*
8341	4-hydroxybenzoic acid (p-hydroxybenzoic acid)	Not relevant	NO	Not relevant	NO	Not relevant	NO	Not relevant	NO	NO	Unclassified*	Unclassified	Unclassified*
1892***	lead chromate molybdate sulfate red	NO	NO	NO	NO	YES	YES	YES	YES	YES	ED	ED	ED
2202***	lead sulfochromate yellow	NO	NO	NO	NO	YES	YES	YES	YES	YES	ED	ED	ED
2324**	lead bis(tetrafluoroborate)	NO	NO	NO	NO	NO	NO	YES	YES	YES	ED	ED	ED
4975 [†]	Benzo[a]pyrene	NO	Not relevant	NO	Not relevant	YES	Not relevant	YES	Not relevant	NO	ED	Not relevant	ED
7051***	Lead chromate	NO	Not relevant	NO	Not relevant	YES	Not relevant	YES	Not relevant	YES	ED	Not relevant	ED
8372a	Ethylparaben	Not relevant	NO	Not relevant	NO	Not relevant	NO	Not relevant	NO	NO	Unclassified*	Unclassified	Unclassified*
8372b	Isopropylparaben (Isopropyl 4-hydroxybenzoate)	Not relevant	Not relevant	Not relevant	Not relevant	Not relevant	Not relevant	Not relevant	Not relevant	NO	Unclassified*	Not relevant	Unclassified*

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8372c	Butylparaben (Butyl 4-hydroxybenzoate)	Not relevant	Not relevant	Not relevant	Not relevant	Not relevant	Not relevant	Not relevant	Not relevant	YES	Unclassified*	Not relevant	Unclassified*
8372d	Isobutyl paraben (Isobutyl 4-hydroxybenzoate (INCI: Isobutylparaben) /Sodium salt or Salts of Isobutylparaben)	Not relevant	NO	Not relevant	NO	Not relevant	NO	Not relevant	NO	YES	Unclassified*	Not relevant	Unclassified*

No C&L harmonized available; In terms of reporting this substance is "Unclassified"

**The categorization outcome based on the available data for lead compounds is similar to the categorization of borates.

***The categorization outcome is similar to categorization of other lead and chromate compounds.

¹ Population completed only with few studies (1-3)

² Incomplete population due to lack of data

³ Classification may change after inclusion of additional data from EASIS

Option 1- Inconclusive: substance is classified as Repr. Cat 1A or 1B but due to lack of data no conclusion can be drawn regarding effects on endocrine organs

Option 4 - Unclassified (?): Option 4 cannot be applied since read-across analysis was based on multiple substances and dose levels cannot be specified.

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Potential categorization of 186 miscellaneous chemicals under “Option 2, 3 & 4” for human health & vertebrate wildlife and combined potential categorization under all Options

	Chemical Name	Potential Categorization Human Health				Potential Categorization Wildlife Vertebrates				Combined Potential Categorization (HH & Wildlife Vertebrates)			
		OPTION 2	OPTION 3	Path of decision tree	OPTION 4	OPTION 2	OPTION 3	Path of decision tree	OPTION 4	OPTION 1 Most strict	OPTION 2	OPTION 3	OPTION 4
450	propargite	Unclassified	Cat II	3b	Unclassified	Unclassified	Cat II	3b	Unclassified	ED	Unclassified	Cat II	Unclassified
557	Oligomerisation and alkylation reaction products of 2-phenylpropene and phenol [Previously registered as Phenol, methylstyrenated - EC N. 270-966-8 and CAS N. 68512-30-1]	Unclassified	Cat III	10	Unclassified	Unclassified	Cat III	10	Unclassified	Unclassified	Unclassified	Cat III	Unclassified
558	2,2',6,6'-Tetrabromo-4,4'-isopropylidenediphenol, oligomeric reaction products with Propylene oxide and n-butyl glycidyl ether	Unclassified ¹	Unclassified ¹	11	Unclassified ¹	Unclassified ¹	Unclassified ¹	11	Unclassified ¹	Unclassified	Unclassified ¹	Unclassified ¹	Unclassified ¹
559	reaction mass of 1-(1,2,3,4,5,6,7,8-octahydro-2,3,8,8-tetramethyl-2-naphthyl)ethan-1-one and 1-(1,2,3,4,6,7,8,8a-octahydro-2,3,8,8-tetramethyl-2-naphthyl)ethan-1-one and 1-(1,2,3,5,6,7,8,8a-octahydro-2,3,8,8-tetramethyl-2-naphthyl)ethan-1-one	Unclassified ¹	Unclassified ¹	11	Unclassified ¹	Unclassified ¹	Unclassified ¹	11	Unclassified ¹	Unclassified	Unclassified ¹	Unclassified ¹	Unclassified ¹
560	reaction mass of 2-ethylhexyl 10-ethyl-4,4-dioctyl-7-oxo-8-oxa-3,5-dithia-4-stannatetradecanoate and 2-	Unclassified	Unclassified	8	Unclassified	Unclassified	Unclassified	8	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified

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	Chemical Name	Potential Categorization Human Health				Potential Categorization Wildlife Vertebrates				Combined Potential Categorization (HH & Wildlife Vertebrates)			
		OPTION 2	OPTION 3	Path of decision tree	OPTION 4	OPTION 2	OPTION 3	Path of decision tree	OPTION 4	OPTION 1 Most strict	OPTION 2	OPTION 3	OPTION 4
	ethylhexyl 10-ethyl-4-[[2-[(2-ethylhexyl)oxy]-2-oxoethyl]thio]-4-octyl-7-oxo-8-oxa-3,5-dithia-4-stannatetradecanoate (reaction mass of DOTE and MOTE)												
561	4-Nonylphenol, branched and linear, ethoxylated [substances with a linear and/or branched alkyl chain with a carbon number of 9 covalently bound in position 4 to phenol, ethoxylated covering UVCB- and well-defined substances, polymers and homologues, which include any of the individual isomers and/or combinations thereof]	ED	Cat I	2a/2b	Unclassified	ED	Cat I	1	ED	ED	ED	Cat I	ED
562	4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated [covering well-defined substances and UVCB substances, polymers and homologues]	ED	Cat I	2a/2b	ED	ED	Cat I	1	ED	Unclassified*	ED	Cat I	ED
563	4-Nonylphenol, branched and linear [substances with a linear and/or branched alkyl chain with a carbon number of 9 covalently bound in position 4 to phenol, covering also UVCB- and well-defined substances]	ED	Cat I	2a/2b	Unclassified	ED	Cat I	1	ED	ED	ED	Cat I	ED

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		OPTION 2	OPTION 3	Path of decision tree	OPTION 4	OPTION 2	OPTION 3	Path of decision tree	OPTION 4	OPTION 1 Most strict	OPTION 2	OPTION 3	OPTION 4
	which include any of the individual isomers or a combination thereof]												
580	Dibutyltin (DBT) (Dibutyl stannane)	Unclassified	Cat II	5	Unclassified	Unclassified	Cat II	5	Unclassified	ED	Unclassified	Cat II	Unclassified
651	lead dinitrate	Unclassified	Cat II	3a/3b	Unclassified	Unclassified	Cat II	3a/3b	Unclassified	ED	Unclassified	Cat II	Unclassified
656	triphenyl phosphite	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
659	cadmium chloride	Unclassified	Cat II	3b	Unclassified	Unclassified	Cat II	3b	Unclassified	ED	Unclassified	Cat II	Unclassified
670	cadmium sulphate	Unclassified	Cat II	3b	Unclassified	Unclassified	Cat II	3b	Unclassified	ED	Unclassified	Cat II	Unclassified
673	cobalt sulphate [Cobalt(II) sulphate]	Unclassified	Cat II	3a	Unclassified	Unclassified	Cat II	3a	Unclassified	ED	Unclassified	Cat II	Unclassified
682	cobalt dinitrate [Cobalt(II) dinitrate]	Unclassified	Cat II	3a	Unclassified	Unclassified	Cat II	3a	Unclassified	ED	Unclassified	Cat II	Unclassified
687	N-Phenyl-P-Phenylenediamine [N-(4-aminophenyl)aniline]	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
912	sodium dichromate	Unclassified	Cat II	3b	Unclassified	Unclassified	Cat II	3b	Unclassified	ED	Unclassified	Cat II	Unclassified
952	p-cresol	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
960	p-phenylenediamine	Unclassified	Unclassified	8	Unclassified	Unclassified	Unclassified	8	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
989	1-bromopropane (n-propyl bromide)	Unclassified	Cat II	3a	Unclassified	Unclassified	Cat II	3a	Unclassified	ED	Unclassified	Cat II	Unclassified
1080	Resorcinol (1,3-benzenediol)	ED	Cat I	2a/2b	ED	Unclassified	Cat III	10	Unclassified	Unclassified	ED	Cat I	ED
1151	2-methoxyethanol (ethylene glycol monomethyl ether)	Unclassified	Cat II	3a	Unclassified	Unclassified	Cat II	3a	Unclassified	ED	Unclassified	Cat II	Unclassified
1182	2-methoxyethyl acetate	Unclassified	Cat II	3a	Unclassified	Unclassified	Cat II	3a	Unclassified	ED	Unclassified	Cat II	Unclassified
1196	1,2-dimethoxyethane	Unclassified	Cat II	3a	Unclassified	Unclassified	Cat II	3a	Unclassified	ED	Unclassified	Cat II	Unclassified

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		OPTION 2	OPTION 3	Path of decision tree	OPTION 4	OPTION 2	OPTION 3	Path of decision tree	OPTION 4	OPTION 1 Most strict	OPTION 2	OPTION 3	OPTION 4
1202	2-ethoxyethanol	Unclassified	Cat II	3a	Unclassified	Unclassified	Cat II	3a	Unclassified	ED	Unclassified	Cat II	Unclassified
1228	2-ethoxyethyl acetate	Unclassified	Cat II	3a	Unclassified	Unclassified	Cat II	3a	Unclassified	ED	Unclassified	Cat II	Unclassified
1234	Silicic acid, lead salt	Unclassified	Cat II	3a/3b	Unclassified	Unclassified	Cat II	3a/3b	Unclassified	ED	Unclassified	Cat II	Unclassified
1280	Ethylene Glycol Monobutyl Ether (2-Butoxyethanol)	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
1281	2-(2-methoxyethoxy)ethanol (DEGME)	Unclassified	Unclassified	8	Unclassified	Unclassified	Unclassified	8	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
1298	Diethylene glycol monobutyl ether (ethoxydiglycol)	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
1303	dimethyl glutarate	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
1305	bis(2-methoxyethyl) ether	Unclassified	Cat II	3a	Unclassified	Unclassified	Cat II	3a	Unclassified	ED	Unclassified	Cat II	Unclassified
1350	1,2-bis(2-methoxyethoxy)ethane	Unclassified	Cat II	3a	Unclassified	Unclassified	Cat II	3a	Unclassified	ED	Unclassified	Cat II	Unclassified
1436	triphenyl phosphate	Unclassified	Cat III	10	Unclassified	ED	Cat I	4	ED	Unclassified	ED	Cat I	ED
1439	tris(2-chloroethyl) phosphate (TCEP)	Unclassified	Cat II	3a	Unclassified	Unclassified	Cat II	3a	Unclassified	ED	Unclassified	Cat II	Unclassified
1484	bis(2-ethylhexyl) phthalate (DEHP)	ED	Cat I	1	ED	ED	Cat I	1	ED	ED	ED	Cat I	ED
1486	Bis(2-methoxyethyl) phthalate	inconclusive ²	inconclusive ²	inconclusive ²	inconclusive ²	inconclusive ²	inconclusive ²	inconclusive ²	inconclusive ²	inconclusive ²	inconclusive ²	inconclusive ²	inconclusive ²
1519	2,2',6,6'-tetra-tert-butyl-4,4'-methylenediphenol	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
1611	lead oxide sulfate (basic lead sulphate)	Unclassified	Cat II	3a/3b	Unclassified	Unclassified	Cat II	3a/3b	Unclassified	ED	Unclassified	Cat II	Unclassified
1631	lead titanium trioxide	Unclassified	Cat II	3a/3b	Unclassified	Unclassified	Cat II	3a/3b	Unclassified	ED	Unclassified	Cat II	Unclassified
1637	pentalead tetraoxide sulphate (tetrabasic lead sulphate)	Unclassified	Cat II	3a/3b	Unclassified	Unclassified	Cat II	3a/3b	Unclassified	ED	Unclassified	Cat II	Unclassified

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		OPTION 2	OPTION 3	Path of decision tree	OPTION 4	OPTION 2	OPTION 3	Path of decision tree	OPTION 4	OPTION 1 Most strict	OPTION 2	OPTION 3	OPTION 4
1678	trilead dioxide phosphonate (dibasic lead phosphite)	Unclassified	Cat II	3a/3b	Unclassified	Unclassified	Cat II	3a/3b	Unclassified	ED	Unclassified	Cat II	Unclassified
1719	tetralead trioxide sulphate (tribasic lead sulphate)	Unclassified	Cat II	3a/3b	Unclassified	Unclassified	Cat II	3a/3b	Unclassified	ED	Unclassified	Cat II	Unclassified
1737	Low temperature tar oil, alkaline, extract residues (coal), low temperature coal tar alkaline	inconclusive ²	inconclusive ²	inconclusive ²	inconclusive ²	inconclusive ²	inconclusive ²	inconclusive ²	inconclusive ²	Unclassified	inconclusive ²	inconclusive ²	inconclusive ²
1778	p-aminophenol	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
1870	dioxobis(stearato)trilead (dibasic lead stearate)	Unclassified	Cat II	3a/3b	Unclassified	Unclassified	Cat II	3a/3b	Unclassified	ED	Unclassified	Cat II	Unclassified
1884	Lead titanium zirconium oxide	Unclassified	Cat II	3a/3b	Unclassified	Unclassified	Cat II	3a/3b	Unclassified	ED	Unclassified	Cat II	Unclassified
1925	N,N-dimethylacetamide	Unclassified	Cat II	3a	Unclassified	Unclassified	Cat II	3a	Unclassified	ED	Unclassified	Cat II	Unclassified
2042	Dipentyl phthalate (DPP)	ED	Cat I	2a/2b	Unclassified	ED	Cat I	2a/2b	Unclassified	ED	ED	Cat I	ED
2061	orange lead (lead tetroxide)	Unclassified	Cat II	3a/3b	Unclassified	Unclassified	Cat II	3a/3b	Unclassified	ED	Unclassified	Cat II	Unclassified
2081	Benzophenone-3 (oxybenzone)	Unclassified	Cat II	3b	Unclassified	ED	Cat I	4	ED	Unclassified	ED	Cat I	ED
2091	lead monoxide (lead oxide)	Unclassified	Cat II	3a/3b	Unclassified	Unclassified	Cat II	3a/3b	Unclassified	ED	Unclassified	Cat II	Unclassified
2105	trilead bis(carbonate) dihydroxide (basic lead carbonate)	Unclassified	Cat II	3a/3b	Unclassified	Unclassified	Cat II	3a/3b	Unclassified	ED	Unclassified	Cat II	Unclassified
2191	lead diazide	Unclassified	Cat II	3a/3b	Unclassified	Unclassified	Cat II	3a/3b	Unclassified	ED	Unclassified	Cat II	Unclassified
2391	4-(1,1,1,3-tetramethylbutyl)phenol	ED	Cat I	2a/2b	ED	ED	Cat I	1	ED	Unclassified	ED	Cat I	ED
2491	3-ethyl-2-methyl-2-(3-methylbutyl)-1,3-oxazolidine	inconclusive ²	inconclusive ²	inconclusive ²	inconclusive ²	inconclusive ²	inconclusive ²	inconclusive ²	inconclusive ²	inconclusive ²	inconclusive ²	inconclusive ²	inconclusive ²
2527	3-methylpyrazole	Unclassified	Unclassified	8	Unclassified	Unclassified	Unclassified	8	Unclassified	ED	Unclassified	Unclassified	Unclassified

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		OPTION 2	OPTION 3	Path of decision tree	OPTION 4	OPTION 2	OPTION 3	Path of decision tree	OPTION 4	OPTION 1 Most strict	OPTION 2	OPTION 3	OPTION 4
2543	tributyltin chloride	ED	Cat I	2b	ED	ED	Cat I	2b	ED	Unclassified	ED	Cat I	ED
2544	tributyltin bromide	ED	Cat I	2b	ED	ED	Cat I	2b	ED	Unclassified	ED	Cat I	ED
2594	2-Mercaptobenzothiazole (Benzothiazole-2-thiol)	Unclassified	Unclassified	8	Unclassified	Unclassified	Unclassified	8	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
2625	3-Benzylidene camphor (1,7,7-trimethyl-3-(phenylmethylene)bicyclo[2.2.1]heptan-2-one)	Unclassified	Cat II	3b	Unclassified	ED	Cat I	2b	ED	ED	ED	Cat I	ED
2633	Sodium perborate, perboric acid, sodium salt	Unclassified	Cat II	3a	Unclassified	Unclassified	Cat II	3a	Unclassified	ED	Unclassified	Cat II	Unclassified
2657	lead 2,4,6-trinitro-m-phenylene dioxide (Lead styphnate)	Unclassified	Cat II	3a/3b	Unclassified	Unclassified	Cat II	3a/3b	Unclassified	ED	Unclassified	Cat II	Unclassified
2701	2-ethylhexyl 10-ethyl-4,4-dioctyl-7-oxo-8-oxa-3,5-dithia-4-stannatetradecanoate (DOTE)	Unclassified	Unclassified	8	Unclassified	Unclassified	Unclassified	8	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
2813	tert-butyl methyl ether	Unclassified	Cat II	3b	Unclassified	Unclassified	Cat II	3b	Unclassified	Unclassified	Unclassified	Cat II	Unclassified
2863	2-Amino-3-hydroxypyridine (2-aminopyridin-3-ol)	Unclassified ¹	Unclassified ¹	11	Unclassified ¹	Unclassified ¹	Unclassified ¹	11	Unclassified ¹	Unclassified*	Unclassified ¹	Unclassified ¹	Unclassified ¹
2940	Lead(II) bis(methanesulfonate)	Unclassified	Cat II	3a/3b	Unclassified	Unclassified	Cat II	3a/3b	Unclassified	ED	Unclassified	Cat II	Unclassified
2945	ammonium thiocyanate	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
3040	octabenzene	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
3152	p-METHYLAMINOPHENOL sulphate	Unclassified ¹	Unclassified ¹	11	Unclassified ¹	Unclassified ¹	Unclassified ¹	11	Unclassified ¹	Unclassified	Unclassified ¹	Unclassified ¹	Unclassified ¹
3269	tributyltin	ED	Cat I	2b	ED	ED	Cat I	2b	ED	Unclassified	ED	Cat I	ED
3278	lead cyanamidate	Unclassified	Cat II	3a/3b	Unclassified	Unclassified	Cat II	3a/3b	Unclassified	ED	Unclassified	Cat II	Unclassified
3588	tert-butyl-4-methoxyphenol	ED	Cat I	2a	Unclassified	ED	Cat I	2a	Unclassified	Unclassified	ED	Cat I	ED

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3590	Bisphenol-A-Epichlorhydrin Epoxy resin Average MW < 700 [4,4'-Isopropylidenediphenol, oligomeric reaction products with 1-chloro-2,3-epoxypropane]	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
3600	Phenol, nonyl- (Nonylphenol)	ED	Cat I	2a/2b	Unclassified	ED	Cat I	1	ED	ED	ED	Cat I	ED
3601	trixyl phosphate	Unclassified	Cat II	3a	Unclassified	Unclassified	Cat II	3a	Unclassified	ED	Unclassified	Cat II	Unclassified
3708	bis(2-ethylhexyl) tetrabromophthalate (BEH-TEBP)	inconclusive ²	inconclusive ²	inconclusive ²	inconclusive ²	inconclusive ²	inconclusive ²	inconclusive ²	inconclusive ²	Unclassified*	inconclusive ²	inconclusive ²	inconclusive ²
3824	Polyhexamethylene biguanide hydrochloride	inconclusive ²	inconclusive ²	inconclusive ²	inconclusive ²	inconclusive ²	inconclusive ²	inconclusive ²	inconclusive ²	Unclassified	inconclusive ²	inconclusive ²	inconclusive ²
4051	lead di(acetate) (also mentioned as lead acetate)	Unclassified	Cat II	3a/3b	Unclassified	Unclassified	Cat II	3a/3b	Unclassified	ED	Unclassified	Cat II	Unclassified
4087	Paraformaldehyde	inconclusive ²	inconclusive ²	inconclusive ²	inconclusive ²	inconclusive ²	inconclusive ²	inconclusive ²	inconclusive ²	Unclassified*	inconclusive ²	inconclusive ²	inconclusive ²
4270	Pentadecafluorooctanoic acid (PFOA)	Unclassified	Cat II	3a	Unclassified	Unclassified	Cat II	3a	Unclassified	ED	Unclassified	Cat II	Unclassified
4280	Triclosan	Unclassified	Cat II	3b	Unclassified	ED	Cat I	2a	ED	Unclassified	ED	Cat I	ED
4449	tributyltin-cation (same as tributyltin hydride, CAS: 688-73-3)	ED	Cat I	2b	ED	ED	Cat I	2b	ED	Unclassified	ED	Cat I	ED
4462	trilead diarsenate	Unclassified	Cat II	3a/3b	Unclassified	Unclassified	Cat II	3a/3b	Unclassified	ED	Unclassified	Cat II	Unclassified
4537	4-Methylbenzylidene camphor (3-(4'-Methylbenzylidene)-dl-camphor / Enzacamene)	ED	Cat I	2a/2b	Unclassified	ED	Cat I	2a/2b	Unclassified	Unclassified*	ED	Cat I	Unclassified
4548	Ammonium pentadecafluorooctanoate	Unclassified	Cat II	3a/3b	Unclassified	Unclassified	Cat II	3a/3b	Unclassified	ED	Unclassified	Cat II	Unclassified

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		OPTION 2	OPTION 3	Path of decision tree	OPTION 4	OPTION 2	OPTION 3	Path of decision tree	OPTION 4	OPTION 1 Most strict	OPTION 2	OPTION 3	OPTION 4
	(APFO)												
4960	Kojic Acid (5-hydroxy-2-hydroxymethyl-4-pyrone)	ED	Cat I	2a	Unclassified	ED	Cat I	2a	Unclassified	Unclassified*	ED	Cat I	Unclassified
5033	2-(2-butoxyethoxy)ethyl 6-propylpiperonyl ether (PBO)	Unclassified	Cat III	10	Unclassified	Unclassified	Cat III	10	Unclassified	Unclassified	Unclassified	Cat III	Unclassified
5047	Quaternium-15 (cis-isomer)	Unclassified	Unclassified	8	Unclassified	Unclassified	Unclassified	8	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
5065	cobalt carbonate	Unclassified	Cat II	3a	Unclassified	Unclassified	Cat II	3a	Unclassified	ED	Unclassified	Cat II	Unclassified
5067	Acetic acid, lead salt, basic	Unclassified	Cat II	3a/3b	Unclassified	Unclassified	Cat II	3a/3b	Unclassified	ED	Unclassified	Cat II	Unclassified
5160	Camphor benzalkonium methosulfate (Methyl N,N,N-trimethyl-4-[[4,7,7-trimethyl-3-oxobicyclo[2.2.1]hept-2-ylidene)methyl]anilinium sulphate)	Unclassified ¹	Unclassified ¹	11	Unclassified ¹	Unclassified ¹	Unclassified ¹	11	Unclassified ¹	Unclassified*	Unclassified ¹	Unclassified ¹	Unclassified ¹
5202	bis(2-propylheptyl) phthalate	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
5209	1,2,4-trihydroxybenzene (Benzene-1,2,4-triol)	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified*	Unclassified	Unclassified	Unclassified
5272	Decamethylcyclopentasiloxane (mentioned as Cyclomethicone and Cyclopentasiloxane)	Unclassified	Unclassified	8	Unclassified	Unclassified	Unclassified	8	Unclassified	Unclassified*	Unclassified	Unclassified	Unclassified
5324	2-Ethylhexyl-4-methoxycinnamate (Oxtinoxate or Ethylhexyl Methoxycinnamate)	Unclassified	Cat II	3b	Unclassified	Unclassified	Cat II	3a/3b	Unclassified	Unclassified*	Unclassified	Cat II	Unclassified
5382	Cyclomethicone Octamethylcyclotetrasiloxane	ED	Cat I	2a	ED	ED	Cat I	2a	ED	ED	ED	Cat I	ED
5443	Tributyltin (tributyltin chloride?)	ED	Cat I	2b	ED	ED	Cat I	2b	ED	Unclassified	ED	Cat I	ED

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Screening of available evidence on chemical substances for the identification of endocrine disruptors according to different options in the context of an Impact Assessment

	Chemical Name	Potential Categorization Human Health				Potential Categorization Wildlife Vertebrates				Combined Potential Categorization (HH & Wildlife Vertebrates)			
		OPTION 2	OPTION 3	Path of decision tree	OPTION 4	OPTION 2	OPTION 3	Path of decision tree	OPTION 4	OPTION 1 Most strict	OPTION 2	OPTION 3	OPTION 4
5706	diisopentyl phthalate	ED	Cat I	1	Unclassified (?)	ED	Cat I	1	Unclassified (?)	ED	ED	Cat I	Unclassified (?)
5760	toluene-2,5-diamine sulfate (2-methyl-p-phenylenediamine sulfate)	Unclassified	Unclassified	8	Unclassified	Unclassified	Unclassified	8	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
5786	Phenol, styrenated	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
5822	Sulfurous acid, lead salt, dibasic (basic lead sulphate)	Unclassified	Cat II	3a/3b	Unclassified	Unclassified	Cat II	3a/3b	Unclassified	ED	Unclassified	Cat II	Unclassified
5851	methoxyacetic acid	ED	Cat I	2a/2b	Unclassified	ED	Cat I	2a/2b	Unclassified	ED	ED	Cat I	Unclassified
5880	1,2-Diethoxyethane	inconclusive ²	inconclusive ²	inconclusive ²	inconclusive ²	inconclusive ²	inconclusive ²	inconclusive ²	inconclusive ²	inconclusive ²	inconclusive ²	inconclusive ²	inconclusive ²
5962	Triphenyltin chloride	ED	Cat I	2a/2b	ED	ED	Cat I	2a/2b	ED	Unclassified*	ED	Cat I	ED
6014	Lead dipicrate	Unclassified	Cat II	3a/3b	Unclassified	Unclassified	Cat II	3a/3b	Unclassified	ED	Unclassified	Cat II	Unclassified
6071	Tar acids, coal, crude, crude phenols	inconclusive ²	inconclusive ²	inconclusive ²	inconclusive ²	inconclusive ²	inconclusive ²	inconclusive ²	inconclusive ²	Unclassified	inconclusive ²	inconclusive ²	inconclusive ²
6132	Triphenyltin	ED	Cat I	2a/2b	ED	ED	Cat I	2a/2b	ED	Unclassified*	ED	Cat I	ED
6223	N,N-dimethylformamide	Unclassified	Unclassified	8	Unclassified	Unclassified	Unclassified	8	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
6277	dibutyltin dichloride (DBTCI2)	Unclassified	Cat II	5	Unclassified	Unclassified	Cat II	5	Unclassified	ED	Unclassified	Cat II	Unclassified
6325	1,2-Benzenedicarboxylic acid, di-C7-11-branched and linear alkyl esters	inconclusive ²	inconclusive ²	inconclusive ²	inconclusive ²	inconclusive ²	inconclusive ²	inconclusive ²	inconclusive ²	inconclusive ²	inconclusive ²	inconclusive ²	inconclusive ²
6330	1,2-Benzenedicarboxylic acid, dihexylester, branched and linear (Diisohexyl phthalate - DIHP)	ED	Cat I	2a	Unclassified (?)	ED	Cat I	2a	Unclassified (?)	ED	ED	Cat I	ED
6331	1,2-Benzenedicarboxylic acid, di-C6-10-alkyl esters	Unclassified	Cat II	3a	Unclassified	Unclassified	Cat II	3a	Unclassified	ED	Unclassified	Cat II	Unclassified

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	Chemical Name	Potential Categorization Human Health				Potential Categorization Wildlife Vertebrates				Combined Potential Categorization (HH & Wildlife Vertebrates)			
		OPTION 2	OPTION 3	Path of decision tree	OPTION 4	OPTION 2	OPTION 3	Path of decision tree	OPTION 4	OPTION 1 Most strict	OPTION 2	OPTION 3	OPTION 4
6369	2,2'-dimethyl-4,4'-methylenebis(cyclohexylamine)	Unclassified	Unclassified	8	Unclassified	Unclassified	Unclassified	8	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
6384	Silicic acid (H ₂ SiO ₅), barium salt (1:1), lead-doped	Unclassified	Cat II	3a/3b	Unclassified	Unclassified	Cat II	3a/3b	Unclassified	ED	Unclassified	Cat II	Unclassified
6440	[phthalato(2-)]dioxotrilead (dibasic lead phthalate)	Unclassified	Cat II	3a/3b	Unclassified	Unclassified	Cat II	3a/3b	Unclassified	ED	Unclassified	Cat II	Unclassified
6518	3-amino-2,6-dimethylphenol	Unclassified ¹	Unclassified ¹	11	Unclassified ¹	Unclassified ¹	Unclassified ¹	11	Unclassified ¹	Unclassified	Unclassified ¹	Unclassified ¹	Unclassified ¹
6593	cobalt di(acetate) [Cobalt(II) diacetate]	Unclassified	Cat II	3a	Unclassified	Unclassified	Cat II	3a	Unclassified	ED	Unclassified	Cat II	Unclassified
6600	Isopentyl-p-Methoxycinnamate (Amiloxate)	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
6618	1,2-Benzenedicarboxylic acid, di-C6-8-branched alkyl esters, C7-rich	inconclusive ²	inconclusive ²	inconclusive ²	inconclusive ²	inconclusive ²	inconclusive ²	inconclusive ²	inconclusive ²	inconclusive ²	inconclusive ²	inconclusive ²	inconclusive ²
6731	mercury	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	8	Unclassified	ED	Unclassified	Unclassified	Unclassified
6789	chloromethane (Methyl chloride)	Unclassified	Cat II	3a	Unclassified	Unclassified	Cat II	3a	Unclassified	ED	Unclassified	Cat II	Unclassified
6810	Acetaldehyde	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
6812	Dichloromethane	Unclassified	Cat II	3a	Unclassified	Unclassified	Cat II	3a	Unclassified	Unclassified	Unclassified	Cat II	Unclassified
6814	Di-μ-oxo-di-n-butylstanniohydroxyborane/ Dibutyltin hydrogen borate C ₈ H ₁₉ BO ₃ Sn (DBB)	inconclusive ²	inconclusive ²	inconclusive ²	inconclusive ²	inconclusive ²	inconclusive ²	inconclusive ²	inconclusive ²	inconclusive ²	inconclusive ²	inconclusive ²	inconclusive ²
6815	formamide	Unclassified	Cat II	3a	Unclassified	Unclassified	Cat II	3a	Unclassified	ED	Unclassified	Cat II	Unclassified
6817	carbon disulphide	Unclassified	Cat II	3a	Unclassified	Unclassified	Cat II	3a	Unclassified	ED	Unclassified	Cat II	Unclassified
6900	sodium perchlorate	ED	Cat I	2a	ED	ED	Cat I	1	ED	Unclassified	ED	Cat I	ED

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Screening of available evidence on chemical substances for the identification of endocrine disruptors according to different options in the context of an Impact Assessment

	Chemical Name	Potential Categorization Human Health				Potential Categorization Wildlife Vertebrates				Combined Potential Categorization (HH & Wildlife Vertebrates)			
		OPTION 2	OPTION 3	Path of decision tree	OPTION 4	OPTION 2	OPTION 3	Path of decision tree	OPTION 4	OPTION 1 Most strict	OPTION 2	OPTION 3	OPTION 4
6932	Sodium peroxometaborate	Unclassified	Cat II	3a	Unclassified	Unclassified	Cat II	3a	Unclassified	ED	Unclassified	Cat II	Unclassified
6941	Cobalt dichloride	Unclassified	Cat II	3a	Unclassified	Unclassified	Cat II	3a	Unclassified	ED	Unclassified	Cat II	Unclassified
7055	N-pentyl-isopentylphthalate	inconclusive ²	inconclusive ²	inconclusive ²	inconclusive ²	inconclusive ²	inconclusive ²	inconclusive ²	inconclusive ²	inconclusive ²	inconclusive ²	inconclusive ²	inconclusive ²
7065	sodium chromate	Unclassified	Cat II	3b	Unclassified	Unclassified	Cat II	3b	Unclassified	ED	Unclassified	Cat II	Unclassified
7076	potassium dichromate	Unclassified	Cat II	3b	Unclassified	Unclassified	Cat II	3b	Unclassified	ED	Unclassified	Cat II	Unclassified
7108	Lead hydrogen arsenate	Unclassified	Cat II	3a/3b	Unclassified	Unclassified	Cat II	3a/3b	Unclassified	ED	Unclassified	Cat II	Unclassified
7129	ammonium dichromate	Unclassified	Cat II	3b	Unclassified	Unclassified	Cat II	3b	Unclassified	ED	Unclassified	Cat II	Unclassified
7147	Cadmium fluoride	Unclassified	Cat II	3b	Unclassified	Unclassified	Cat II	3b	Unclassified	ED	Unclassified	Cat II	Unclassified
7150	ammonium perchlorate	ED	Cat I	2a	ED	ED	Cat I	1	ED	Unclassified	ED	Cat I	ED
7157	tetraethyllead	Unclassified	Cat II	3a/3b	Unclassified	Unclassified	Cat II	3a/3b	Unclassified	ED	Unclassified	Cat II	Unclassified
7215	2-Chloroacetamide	Unclassified	Cat II	3a	Unclassified	Unclassified	Cat II	3a	Unclassified	ED	Unclassified	Cat II	Unclassified
7222	N-methylacetamide	Unclassified	Unclassified	8	Unclassified	Unclassified	Unclassified	8	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
7261	2,2',6,6'-tetrabromo-4,4'-isopropylidenediphenol (TBBPA)	Unclassified	Cat II	3a/3b	Unclassified	Unclassified	Cat II	3a/3b	Unclassified	Unclassified	Unclassified	Cat II	Unclassified
7274	4,4'-isopropylidenediphenol (Bisphenol A)	Unclassified	Cat II ³	3b	Unclassified	ED	Cat I	2a	ED	ED	ED	Cat I	ED
7279	dapsone (TETRAHYDROMYRCENYL ACETATE)	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
7281	4,4'-sulphonyldiphenol (Bisphenol S)	Unclassified	Cat II	9	Unclassified	ED	Cat I	1/2a	ED	Unclassified	ED	Cat I	ED
7285	pyrochlore, antimony lead yellow	Unclassified	Cat II	3a/3b	Unclassified	Unclassified	Cat II	3a/3b	Unclassified	ED	Unclassified	Cat II	Unclassified

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	Chemical Name	Potential Categorization Human Health				Potential Categorization Wildlife Vertebrates				Combined Potential Categorization (HH & Wildlife Vertebrates)			
		OPTION 2	OPTION 3	Path of decision tree	OPTION 4	OPTION 2	OPTION 3	Path of decision tree	OPTION 4	OPTION 1 Most strict	OPTION 2	OPTION 3	OPTION 4
7298	p-(1,1-dimethylpropyl)phenol	Unclassified	Cat II	3a	Unclassified	ED	Cat I	1	ED	Unclassified	ED	Cat I	ED
7322	Musk Ketone (also as 4'-tert-Butyl-2',6'-dimethyl-3',5'-dinitroacetophenone)	Unclassified ¹	Unclassified ¹	11	Unclassified ¹	Unclassified ¹	Unclassified ¹	11	Unclassified ¹	Unclassified	Unclassified ¹	Unclassified ¹	Unclassified ¹
7323	Musk Xylene (also as 5-tert-Butyl-2,4,6-trinitro-m-xylene)	Unclassified ¹	Unclassified ¹	11	Unclassified ¹	Unclassified ¹	Unclassified ¹	11	Unclassified ¹	Unclassified	Unclassified ¹	Unclassified ¹	Unclassified ¹
7369	1-Methyl-2,6-diamino-benzene (also as 2-Methyl-m-phenylenediamine OR Toluene-2,6-diamine)	inconclusive ²	inconclusive ²	inconclusive ²	inconclusive ²	inconclusive ²	inconclusive ²	inconclusive ²	inconclusive ²	Unclassified	inconclusive ²	inconclusive ²	inconclusive ²
7437	2-amino-4-hydroxyethylaminoanisole sulfate	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified*	Unclassified	Unclassified	Unclassified
7503	Distillates (coal tar), naphthalene oils,naphthalene oil	inconclusive ²	inconclusive ²	inconclusive ²	inconclusive ²	inconclusive ²	inconclusive ²	inconclusive ²	inconclusive ²	Unclassified	inconclusive ²	inconclusive ²	inconclusive ²
7505	Diethyl phthalate	Unclassified	Unclassified	8	Unclassified	Unclassified	Cat II	3a	Unclassified	Unclassified	Unclassified	Cat II	Unclassified
7507	diisobutyl phthalate (BIPB)	ED	Cat I	1	Unclassified	ED	Cat I	1	Unclassified	ED	ED	Cat I	Unclassified
7511	dibutyl phthalate	ED	Cat I	1	ED	ED	Cat I	1	ED	ED	ED	Cat I	ED
7512	Dihexyl phthalate	ED	Cat I	1	ED	ED	Cat I	1	ED	ED	ED	Cat I	ED
7516	1,2-Benzenedicarboxylic acid, dipentylester, branched and linear	inconclusive ²	inconclusive ²	inconclusive ²	inconclusive ²	inconclusive ²	inconclusive ²	inconclusive ²	inconclusive ²	inconclusive ²	inconclusive ²	inconclusive ²	inconclusive ²
7578	6,6'-di-tert-butyl-4,4'-butylidenedi-m-cresol	Unclassified ¹	Unclassified ¹	11	Unclassified ¹	Unclassified ¹	Unclassified ¹	11	Unclassified ¹	Unclassified	Unclassified ¹	Unclassified ¹	Unclassified ¹
7581	benzyl butyl phthalate	ED	Cat I	1	Unclassified	ED	Cat I	1	Unclassified	ED	ED	Cat I	Unclassified
7645	dioctyltin oxide	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified

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	Chemical Name	Potential Categorization Human Health				Potential Categorization Wildlife Vertebrates				Combined Potential Categorization (HH & Wildlife Vertebrates)			
		OPTION 2	OPTION 3	Path of decision tree	OPTION 4	OPTION 2	OPTION 3	Path of decision tree	OPTION 4	OPTION 1 Most strict	OPTION 2	OPTION 3	OPTION 4
7657	N-Methyl-2-pyrrolidone (Methyl Pyrrolidone)	Unclassified	Unclassified	8	Unclassified	Unclassified	Unclassified	8	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
7740	dinoseb	Unclassified	Cat II	3a	Unclassified	Unclassified	Cat II	3a	Unclassified	ED	Unclassified	Cat II	Unclassified
7749	triphenyltin hydride (based on the CAS No)	ED	Cat I	2a/2b	ED	ED	Cat I	2a/2b	ED	Unclassified*	ED	Cat I	ED
7870	Fatty acids, C16-18, lead salts	Unclassified	Cat II	3a/3b	Unclassified	Unclassified	Cat II	3a/3b	Unclassified	ED	Unclassified	Cat II	Unclassified
8027	Hydroxyethyl-p-phenylenediamine sulfate (3-(2-Hydroxyethyl)-p-phenylenediammonium sulphate)	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified*	Unclassified	Unclassified	Unclassified
8046	propyl 4-hydroxybenzoate (propylparaben)	Unclassified	Cat II	3b	Unclassified	ED	Cat I	1/2a	ED	Unclassified*	ED	Cat I	ED
8049	Hydroxyethyl-3,4-methylenedioxyaniline HCl	Unclassified ¹	Unclassified ¹	11	Unclassified ¹	Unclassified ¹	Unclassified ¹	11	Unclassified ¹	Unclassified*	Unclassified ¹	Unclassified ¹	Unclassified ¹
8099	benzotriazole	Unclassified ¹	Unclassified ¹	11	Unclassified ¹	Unclassified ¹	Unclassified ¹	11	Unclassified ¹	Unclassified	Unclassified ¹	Unclassified ¹	Unclassified ¹
8119	o-Aminophenol (also relevant for o-Aminophenol (o-Aminophenol; CI 76520) and its salts)	Unclassified	Unclassified	8	Unclassified	Unclassified	Unclassified	8	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
8170	1,2,3-trichloropropane	Unclassified	Cat II	3a	Unclassified	Unclassified	Cat II	3a	Unclassified	ED	Unclassified	Cat II	Unclassified
8185	imidazolidine-2-thione (ETU)	ED	Cat I	2a/2b	ED	ED	Cat I	2a/2b	ED	ED	ED	Cat I	ED
8194	6,6'-di-tert-butyl-4,4'-thiodi-m-cresol	Unclassified	Cat II	3a	Unclassified	Unclassified	Cat II	3a	Unclassified	Unclassified	Unclassified	Cat II	Unclassified
8196	2,4-di-tert-butylphenol	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
8250	Furfural	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified

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		OPTION 2	OPTION 3	Path of decision tree	OPTION 4	OPTION 2	OPTION 3	Path of decision tree	OPTION 4	OPTION 1 Most strict	OPTION 2	OPTION 3	OPTION 4
8276	4-tert-butylphenol	Unclassified	Cat II	3b	Unclassified	Unclassified	Cat II	3b	Unclassified	ED	Unclassified	Cat II	Unclassified
8296	nitrobenzene	Unclassified	Cat II	3a	Unclassified	Unclassified	Cat II	3a	Unclassified	ED	Unclassified	Cat II	Unclassified
8331	methyl 4-hydroxybenzoate (methylparaben)	Unclassified	Unclassified	11	Unclassified	Unclassified	Cat II	3a/3b	Unclassified	Unclassified*	Unclassified	Cat II	Unclassified
8341	4-hydroxybenzoic acid (p-hydroxybenzoic acid)	Unclassified	Unclassified	11	Unclassified	Unclassified	Unclassified	11	Unclassified	Unclassified*	Unclassified	Unclassified	Unclassified
1892***	lead chromate molybdate sulfate red	Unclassified	Cat II	3a/3b	Unclassified	Unclassified	Cat II	3a/3b	Unclassified	ED	Unclassified	Cat II	Unclassified
2202***	lead sulfochromate yellow	Unclassified	Cat II	3a/3b	Unclassified	Unclassified	Cat II	3a/3b	Unclassified	ED	Unclassified	Cat II	Unclassified
2324**	lead bis(tetrafluoroborate)	Unclassified	Cat II	3a/3b	Unclassified	Unclassified	Cat II	3a/3b	Unclassified	ED	Unclassified	Cat II	Unclassified
4975	Benzo[a]pyrene	Unclassified ¹	Cat III ^{1,3}	10	Unclassified ¹	Unclassified ¹	Cat II ^{1,3}	5	Unclassified ¹	ED	Unclassified ¹	Cat II ^{1,3}	Unclassified ¹
7051***	Lead chromate	Unclassified	Cat II	3a/3b	Unclassified	Unclassified	Cat II	3a/3b	Unclassified	ED	Unclassified	Cat II	Unclassified
8372a	Ethylparaben	Unclassified	Cat III	10	Unclassified	Unclassified	Cat II	9	Unclassified	Unclassified*	Unclassified	Cat II	Unclassified
8372b	Isopropylparaben (Isopropyl 4-hydroxybenzoate)	Unclassified	Cat II	9	Unclassified	Unclassified	Cat II	9	Unclassified	Unclassified*	Unclassified	Cat II	Unclassified
8372c	Butylparaben (Butyl 4-hydroxybenzoate)	Unclassified	Cat II	3b	Unclassified	Unclassified	Cat II	3b	Unclassified	Unclassified*	Unclassified	Cat II	Unclassified
8372d	Isobutyl paraben (Isobutyl 4-hydroxybenzoate (INCI: Isobutylparaben) /Sodium salt or Salts of Isobutylparaben)	Unclassified	Cat II	3a/3b	Unclassified	Unclassified	Cat II	3a/3b	Unclassified	Unclassified*	Unclassified	Cat II	Unclassified

**The categorization outcome based on the available data for lead compounds is similar to the categorization of borates.

***The categorization outcome is similar to categorization of other lead and chromate compounds.

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¹ Population completed only with few studies (1-3)

² Incomplete population due to lack of data

³ Classification may change after inclusion of additional data from EASIS

Option 1- Inconclusive: substance is classified as Repr. Cat 1A or 1B but due to lack of data no conclusion can be drawn regarding effects on endocrine organs

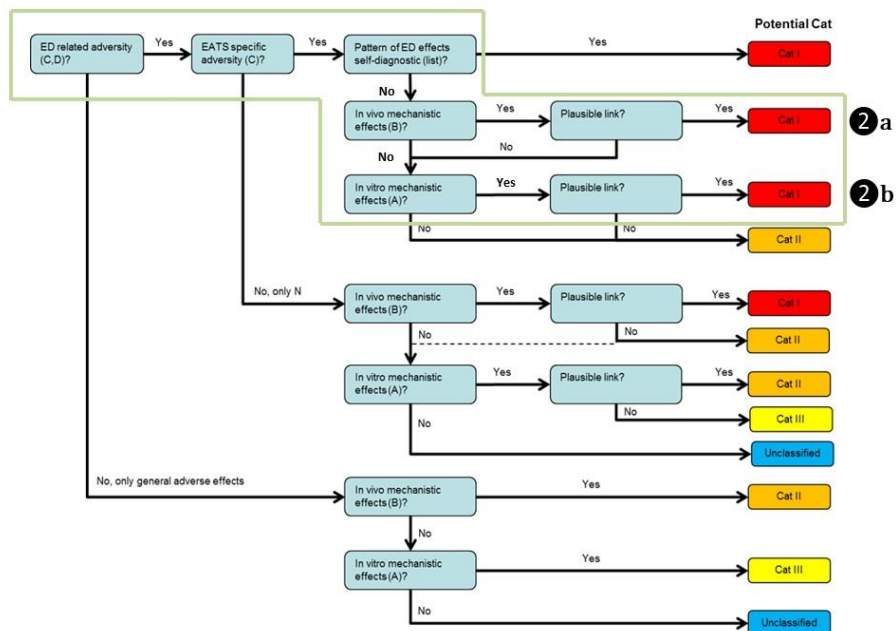
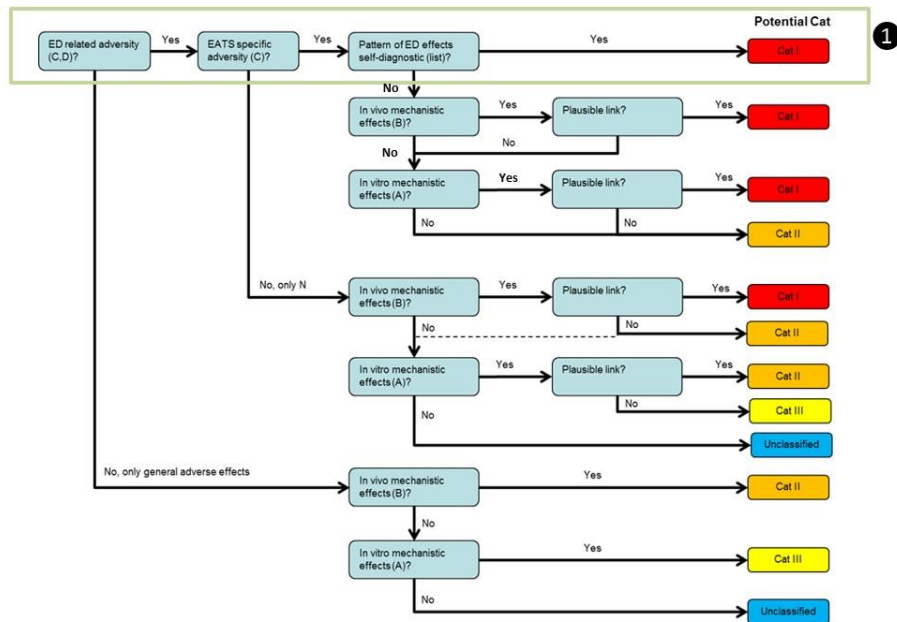
Option 4 - Unclassified (?): Option 4 cannot be applied since read-across analysis was based on multiple substances and dose levels cannot be specified.

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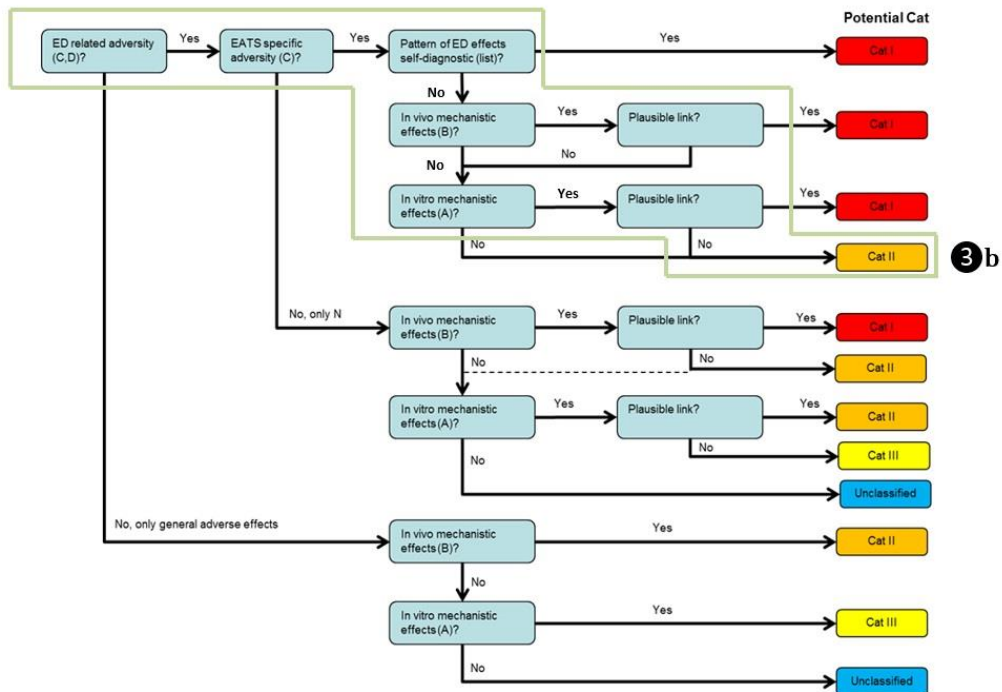
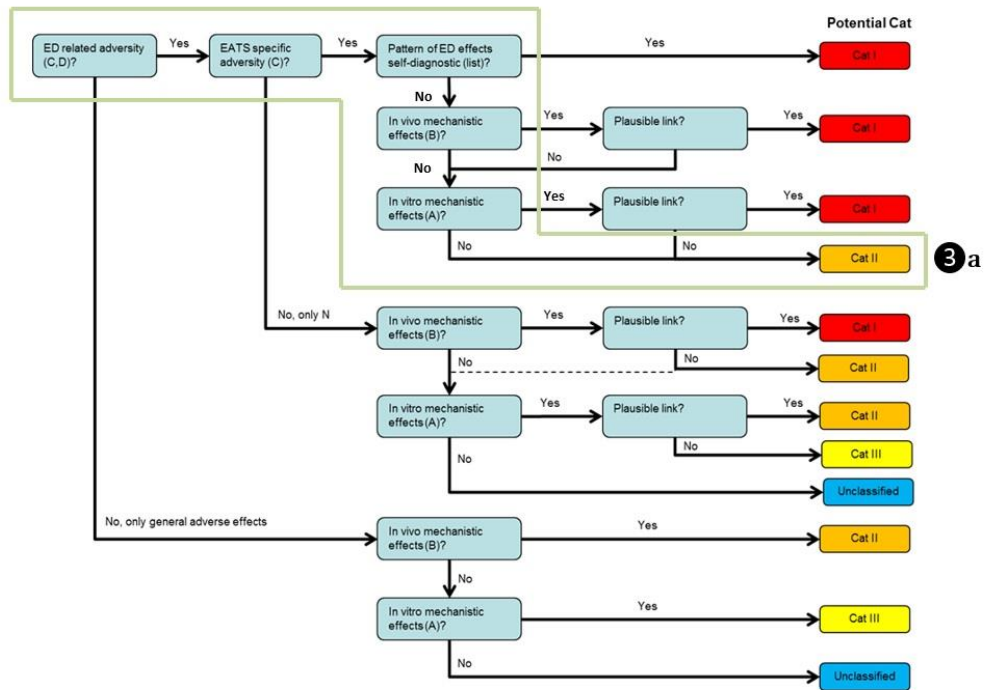
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Appendix I

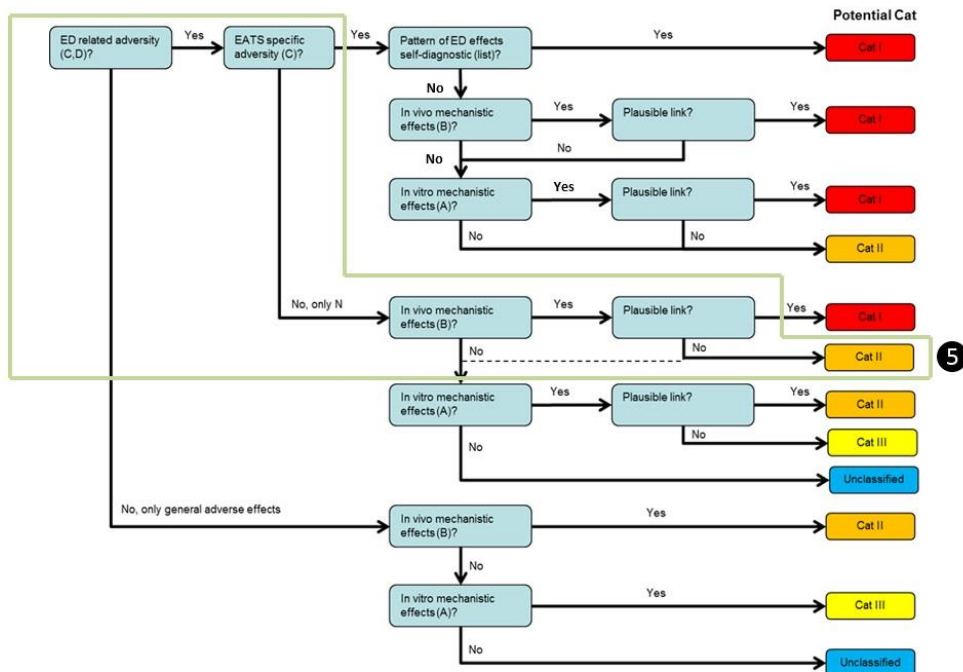
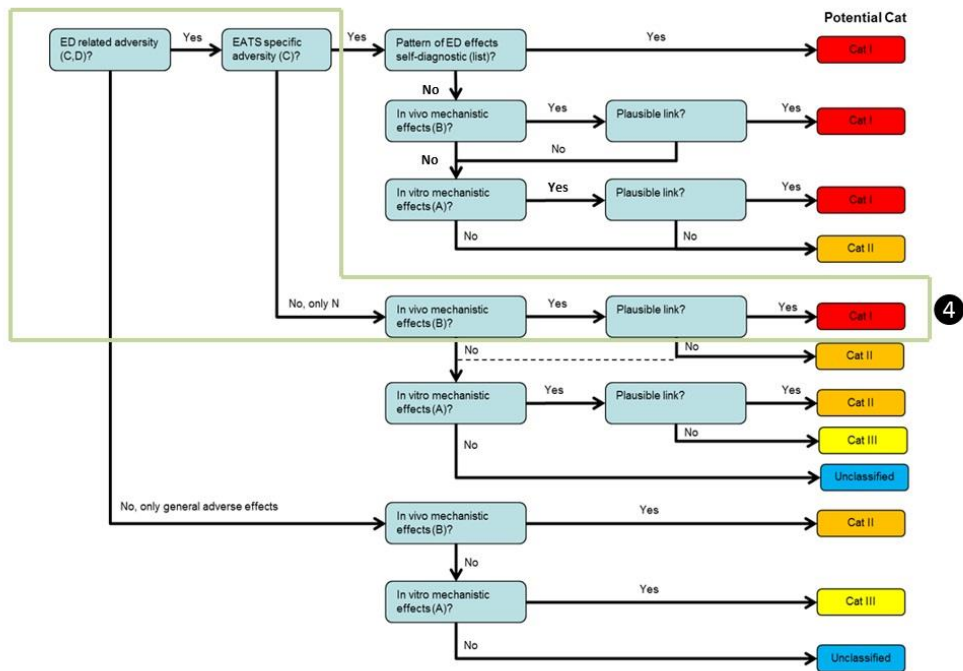
Decision tree Paths 1 to 11



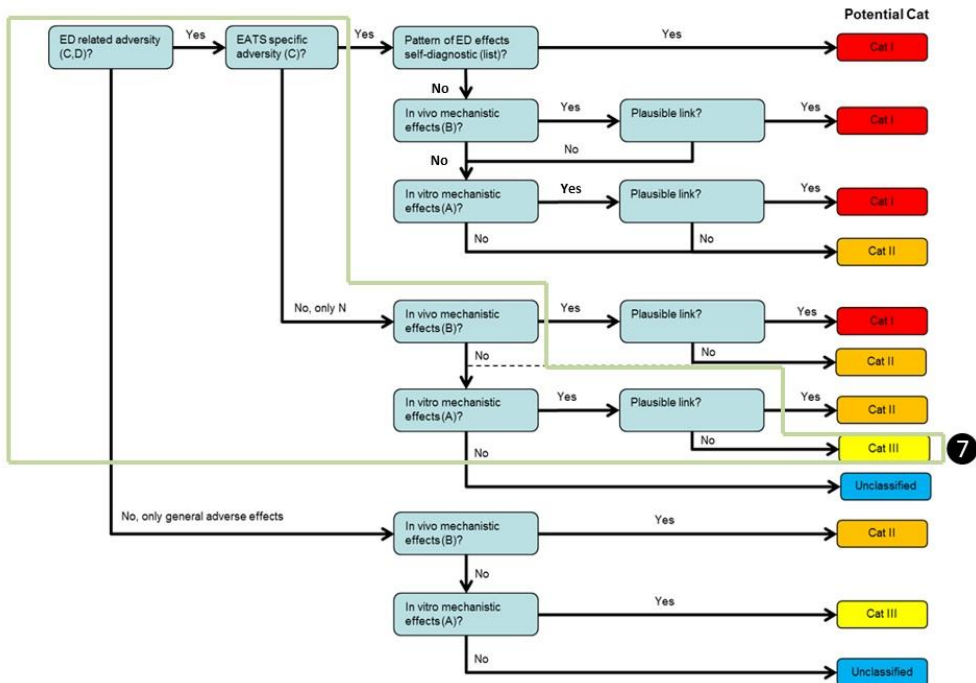
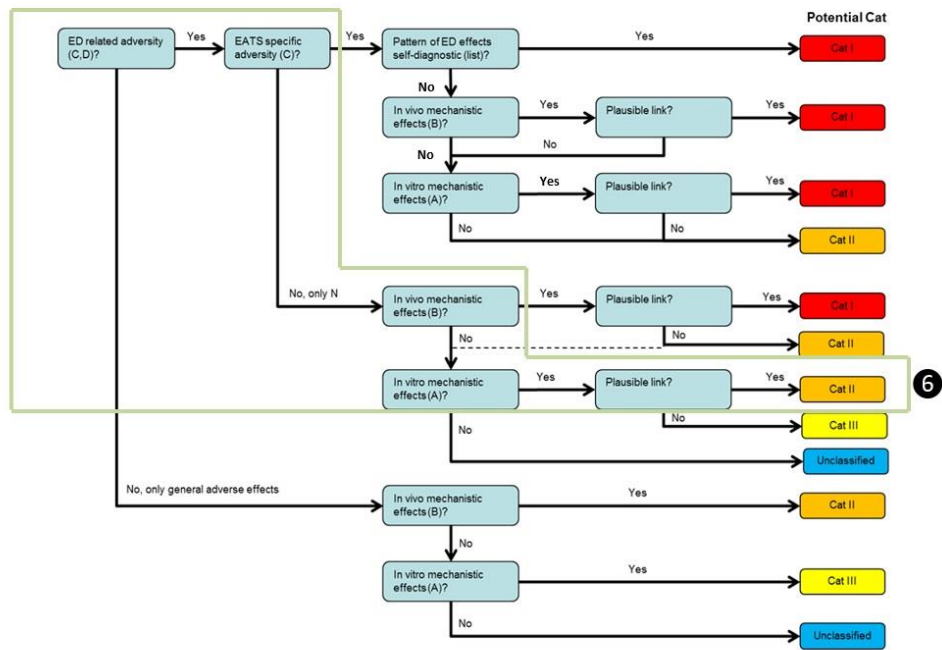
The results of the screening do not constitute evaluations of individual substances to be carried out under the respective chemical legislations [[in particular, Regulation (EC) No 1107/2009 on plant protection products, Regulation (EU) No 528/2012 on biocidal products, Regulation (EC) No 1907/2006 REACH, Regulation (EC) No 1223/2009 on cosmetic products and the Water Framework Directive (EC) No 2000/60] and in no way prejudice future decisions on active substances to be taken pursuant to these pieces of the EU legislation. It would thus be erroneous to consider that the substances listed in the results of this study (SANTE/2015/E3/SI2.706218) are considered as endocrine disruptors within the meaning of the EU legislation.



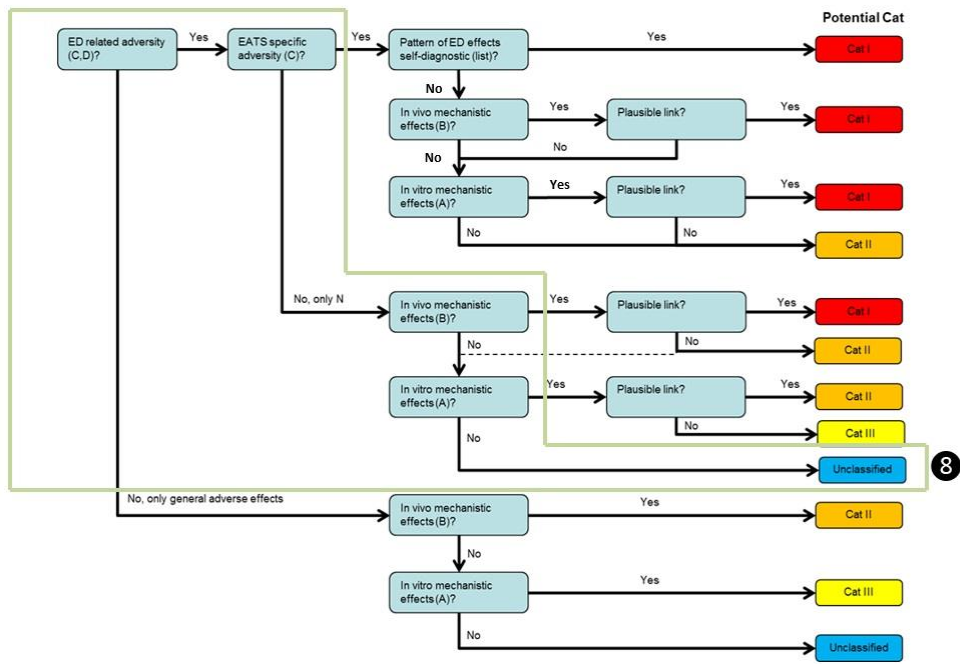
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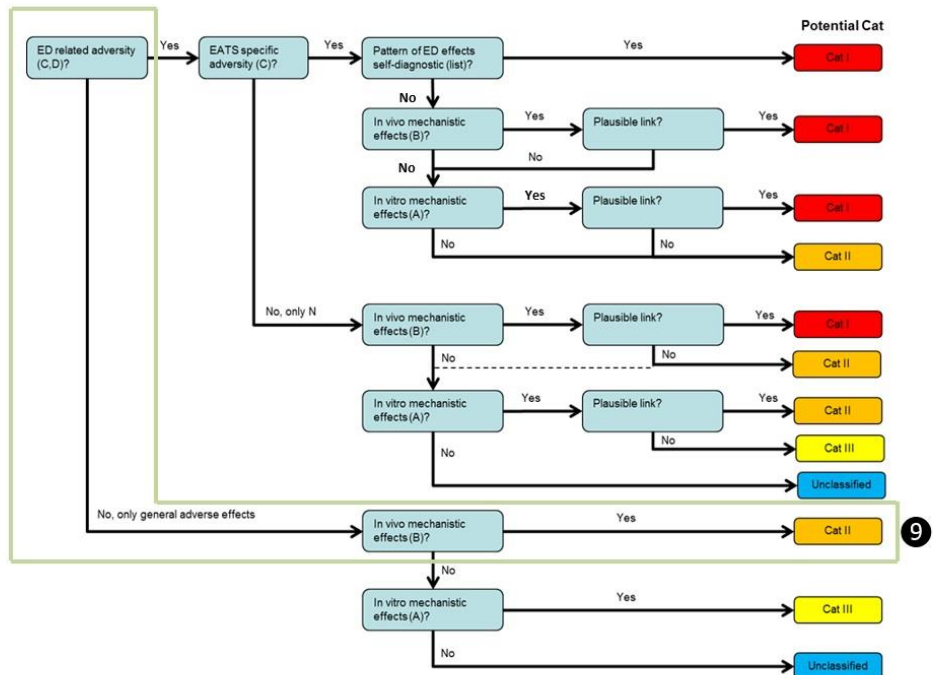
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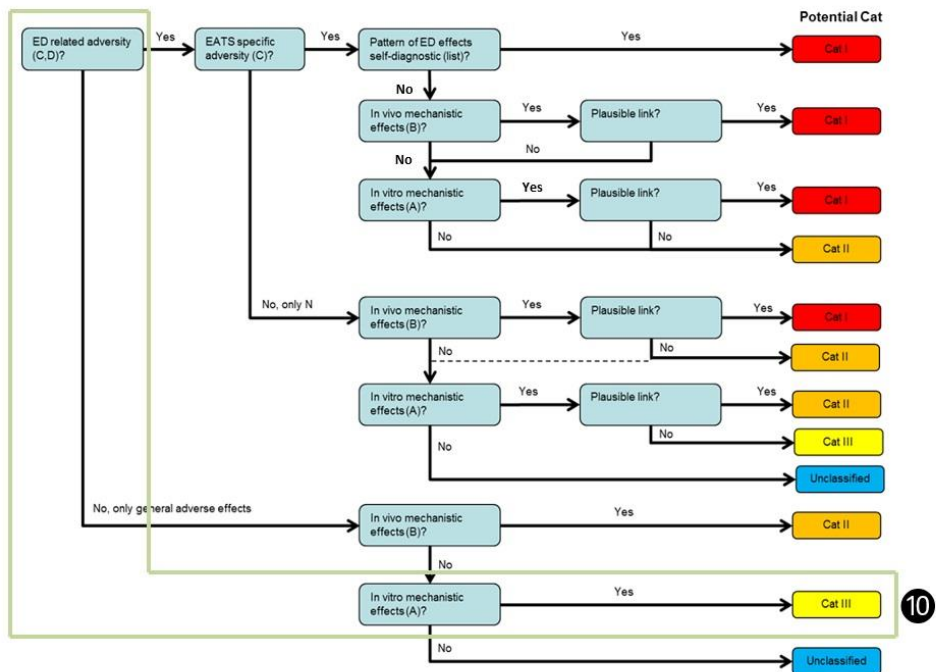


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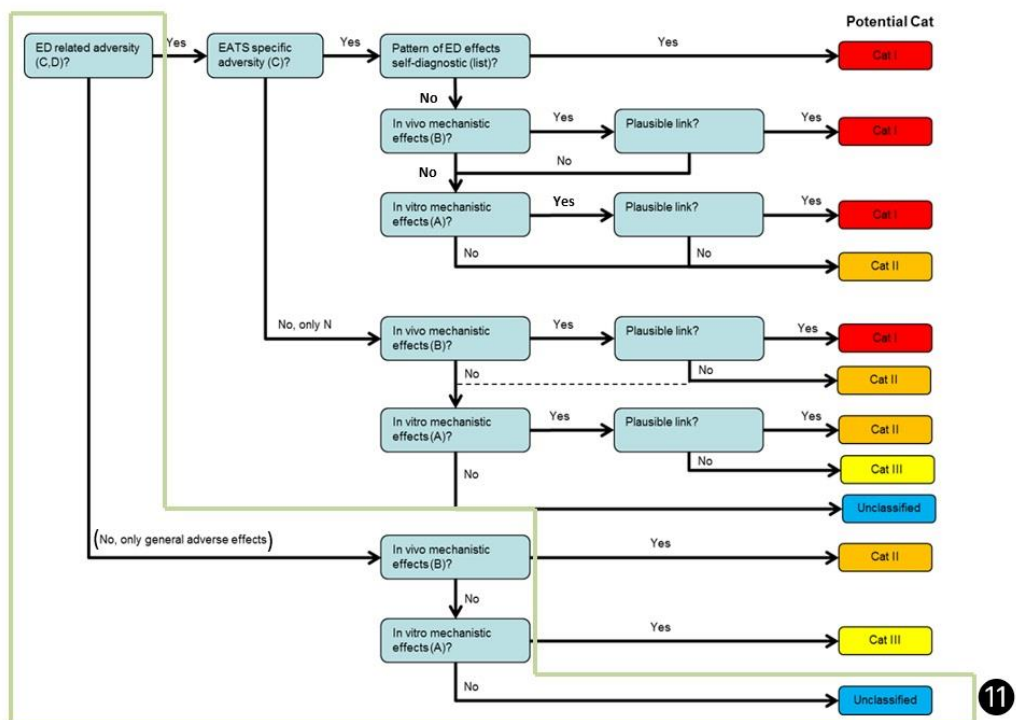


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The results of the screening do not constitute evaluations of individual substances to be carried out under the respective chemical legislations [[in particular, Regulation (EC) No 1107/2009 on plant protection products, Regulation (EU) No 528/2012 on biocidal products, Regulation (EC) No 1907/2006 REACH, Regulation (EC) No 1223/2009 on cosmetic products and the Water Framework Directive (EC) No 2000/60] and in no way prejudice future decisions on active substances to be taken pursuant to these pieces of the EU legislation. It would thus be erroneous to consider that the substances listed in the results of this study (SANTE/2015/E3/SI2.706218) are considered as endocrine disruptors within the meaning of the EU legislation.



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The results of the screening do not constitute evaluations of individual substances to be carried out under the respective chemical legislations [[in particular, Regulation (EC) No 1107/2009 on plant protection products, Regulation (EU) No 528/2012 on biocidal products, Regulation (EC) No 1907/2006 REACH, Regulation (EC) No 1223/2009 on cosmetic products and the Water Framework Directive (EC) No 2000/60] and in no way prejudice future decisions on active substances to be taken pursuant to these pieces of the EU legislation. It would thus be erroneous to consider that the substances listed in the results of this study (SANTE/2015/E3/SI2.706218) are considered as endocrine disruptors within the meaning of the EU legislation.

Potential categorization resulting from the different Paths of the decision tree

Path	ED-related adversity (non-specific) (Yes/No)	EATS- specific adversity (Yes/No)	<i>In vivo</i> MoA (Yes/No)	<i>In vitro</i> MoA	Plausible Link (Yes / No)	Potential Category
1	Yes	Yes (self diagnostic of ED effect)	-	-	-	Cat I
2a	Yes/No	Yes	Yes	Yes/No	Yes	Cat I
2b	Yes/No	Yes	Yes/No	Yes	Yes	Cat I
3a	Yes/No	Yes	No	No	-	Cat II
3b	Yes/No	Yes	Yes/No	Yes	No	Cat II
4	Yes	No	Yes	-	Yes	Cat I
5	Yes	No	Yes	-	No	Cat II
6	Yes	No	No	Yes	Yes	Cat II
7	Yes	No	No	Yes	No	Cat III
8	Yes	No	No	No	-	Unclassified
9	No	No	Yes	No	-	Cat II
10	No	No	No	Yes	-	Cat III
11	No	No	No	No	-	Unclassified

The results of the screening do not constitute evaluations of individual substances to be carried out under the respective chemical legislations [[in particular, Regulation (EC) No 1107/2009 on plant protection products, Regulation (EU) No 528/2012 on biocidal products, Regulation (EC) No 1907/2006 REACH, Regulation (EC) No 1223/2009 on cosmetic products and the Water Framework Directive (EC) No 2000/60] and in no way prejudice future decisions on active substances to be taken pursuant to these pieces of the EU legislation. It would thus be erroneous to consider that the substances listed in the results of this study (SANTE/2015/E3/SI2.706218) are considered as endocrine disruptors within the meaning of the EU legislation.

Appendix II

Pilot phase – results:

The 35 substances included in the pilot study were re-assessed during the screening phase using the revised methodology which in a number of cases led to a change in the potential categorization. The results of this re-assessment are included in the respective sections of this report (Chapters 2, 3, 4 & 5). However, for transparency reasons, the results obtained during the pilot phase are presented in this appendix.

As shown in Table 1.8 regarding human health assessment, among the 35 substances categorized under the four “Options” of the Roadmap, seven (cyproconazole, quizalofop-p-tefuryl, mancozeb, boric acid, ziram, carbon disulphide and nitrobenzene) were classified as EDs under “Option 1” according to harmonised classification system, sixteen (captan, diuron, triadimenol, thiram, mancozeb, boric acid, zineb, ziram, resorcinol, benzophenone-3, tert-butyl methyl ether, triclosan, carbon disulphide, 4,4'-sulphonyldiphenol, diethyl phthalate, nitrobenzene) were classified as ED Cat I under “Option 2&3”, and five of these substances (mancozeb, zineb, triclosan, carbon disulphide and nitrobenzene) were classified as EDs under “Option 4”.

Table 1.8. Potential categorization of pilot substances according to the four “Options” of the Roadmap for human health assessment.

No	Chemical Name	Category of chemical	Potential categorization					
			Option 1		Option 2	Option 3	Path of decision tree	Option 4
			Harmonised	Proposed				
1	Carbon dioxide	PPP/BP	Unclassified	Unclassified	Unclassified	Cat II	3a	Unclassified
20	Cyproconazole	PPP/BP	ED	ED	Unclassified	Cat II	3b	Unclassified
27	Aluminium sulphate	PPP	Unclassified	Unclassified	Unclassified	Unclassified	11	Unclassified
29	Quizalofop-P-ethyl	PPP	Unclassified	Unclassified	Unclassified	Cat II	3a	Unclassified
52	Clodinafop	PPP	Unclassified	Unclassified	Unclassified	Cat II	3a	Unclassified
57	Quizalofop-P-tefuryl	PPP	ED	ED(?)	Unclassified	Cat II	3a	Unclassified
85	Captan	PPP	Unclassified	ED(?)	ED	Cat I	2b	Unclassified
113	Emamectin	PPP	Unclassified	Unclassified	Unclassified	Cat II	3a	Unclassified
159	Diuron	PPP	Unclassified	Unclassified	ED	Cat I	2a	Unclassified
175	Bifenox	PPP	Unclassified	Unclassified	Unclassified	Cat III	7	Unclassified
188	Triadimenol	PPP	Unclassified	ED	ED	Cat I	2b	Unclassified
192	Urea	PPP	Unclassified	Unclassified	Unclassified	Unclassified	11	Unclassified
216	Triflumizole	PPP	Unclassified	ED	Unclassified	Cat II	3a	Unclassified
220	Chlormequat	PPP	Unclassified	Unclassified	Unclassified	Unclassified	8	Unclassified
264	2,4-D	PPP	Unclassified	Unclassified	Unclassified	Cat II	3a	Unclassified
270	Sulcotrione	PPP	Unclassified	Not relevant	Unclassified	Cat II	3a	Unclassified
299	Lauric acid	PPP/BP	Unclassified	Unclassified	Unclassified	Unclassified	11	Unclassified

The results of the screening do not constitute evaluations of individual substances to be carried out under the respective chemical legislations [[in particular, Regulation (EC) No 1107/2009 on plant protection products, Regulation (EU) No 528/2012 on biocidal products, Regulation (EC) No 1907/2006 REACH, Regulation (EC) No 1223/2009 on cosmetic products and the Water Framework Directive (EC) No 2000/60] and in no way prejudice future decisions on active substances to be taken pursuant to these pieces of the EU legislation. It would thus be erroneous to consider that the substances listed in the results of this study (SANTE/2015/E3/SI2.706218) are considered as endocrine disruptors within the meaning of the EU legislation.

331	Tribasic copper sulfate	PPP	Unclassified	Unclassified	Unclassified	Unclassified	8	Unclassified
336	Thiram	PPP	Unclassified	Unclassified	ED	Cat I	2a,b	Unclassified
394	Sucrose	PPP	Unclassified	Unclassified	Unclassified	Unclassified	11	Unclassified
403	Mancozeb	PPP	ED	Not relevant	ED	Cat I	2a	ED
413	MCPA	PPP	Unclassified	Unclassified	Unclassified	Cat II	3	Unclassified
435	Boric acid	BP	ED	ED	ED	Cat I	2a,b	Unclassified
441	Zineb	BP	Unclassified	ED	ED	Cat I	2a	ED
337	Ziram	MISC	ED	ED	ED	Cat I	2a	Unclassified
1080	Resorcinol	MISC	Unclassified	Unclassified	ED	Cat I	2b	Unclassified
1436	Triphenyl phosphate	MISC	Unclassified	Unclassified	Unclassified	Cat II	3a	Unclassified
2081	Benzophenone-3	MISC	Unclassified	Unclassified	ED	Cat I	2a,b	Unclassified
2813	Tert-butyl methyl ether	MISC	Unclassified	Unclassified	ED	Cat I	2a,b	Unclassified
4280	Triclosan	MISC	Unclassified	Unclassified	ED	Cat I	2a,b	ED
5033	2-(2-Butoxyethoxy)ethyl 6-propylpiperonyl ether	MISC	Unclassified	Unclassified	Unclassified	Cat II	3b	Unclassified
6817	Carbon disulphide	MISC	ED	Unclassified	ED	Cat I	2a	ED
7281	4,4'-Sulphonyldiphenol	MISC	Unclassified	Unclassified	ED	Cat I	2b, 4	Unclassified
7505	Diethyl phthalate	MISC	Unclassified	ED	ED	Cat I	2a,b	Unclassified
8296	Nitrobenzene	MISC	ED	ED	ED	Cat I	2b	ED

In the case of ecotoxicological assessment, two more compounds (cyproconazole and 2,4-D) were classified as ED Cat I under "Option 2&3" since the assessment of the additional ecotoxicological data contributed to worsen the classification of these compounds as presented in Table 1.9.

Table 1.9. Potential categorization of pilot substances according to the four "Options" of the Roadmap for ecotoxicological assessment.

No	Chemical Name	Category of chemical	Potential categorization					
			Option 1		Option 2	Option 3	Path of decision tree	Option 4*
			Harmonised	Proposed				
1	Carbon dioxide	PPP/BP	Unclassified	Unclassified	Unclassified	Cat II	3a	Unclassified
20	Cyproconazole	PPP/BP	ED	ED	ED	Cat I	2b	Unclassified
27	Aluminium sulphate	PPP	Unclassified	Unclassified	Unclassified	Unclassified	11	Unclassified

The results of the screening do not constitute evaluations of individual substances to be carried out under the respective chemical legislations [[in particular, Regulation (EC) No 1107/2009 on plant protection products, Regulation (EU) No 528/2012 on biocidal products, Regulation (EC) No 1907/2006 REACH, Regulation (EC) No 1223/2009 on cosmetic products and the Water Framework Directive (EC) No 2000/60] and in no way prejudice future decisions on active substances to be taken pursuant to these pieces of the EU legislation. It would thus be erroneous to consider that the substances listed in the results of this study (SANTE/2015/E3/SI2.706218) are considered as endocrine disruptors within the meaning of the EU legislation.

29	Quizalofop-P-ethyl	PPP	Unclassified	Unclassified	Unclassified	Cat II	3a	Unclassified
52	Clodinafop	PPP	Unclassified	Unclassified	Unclassified	Cat II	3a	Unclassified
57	Quizalofop-P-tefuryl	PPP	ED	ED(?)	Unclassified	Cat II	3a	Unclassified
85	Captan	PPP	Unclassified	Unclassified	ED	Cat I	2b	Unclassified
113	Emamectin	PPP	Unclassified	Unclassified	Unclassified	Cat II	3a	Unclassified
159	Diuron	PPP	Unclassified	Unclassified	ED	Cat I	2a	Unclassified
175	Bifenox	PPP	Unclassified	Unclassified	Unclassified	Cat III	7	Unclassified
188	Triadimenol	PPP	Unclassified	ED	ED	Cat I	2b	Unclassified
192	Urea	PPP	Unclassified	Unclassified	Unclassified	Unclassified	11	Unclassified
216	Triflumizole	PPP	Unclassified	ED	Unclassified	Cat II	3a	Unclassified
220	Chlormequat	PPP	Unclassified	Unclassified	Unclassified	Unclassified	8	Unclassified
264	2,4-D	PPP	Unclassified	Unclassified	ED	Cat I	2a	Unclassified
270	Sulcotrione	PPP	Unclassified	Not relevant	Unclassified	Cat II	3a	Unclassified
299	Lauric acid	PPP/BP	Unclassified	Unclassified	Unclassified	Unclassified	11	Unclassified
331	Tribasic copper sulfate	PPP	Unclassified	Unclassified	Unclassified	Unclassified	8	Unclassified
336	Thiram	PPP	Unclassified	Unclassified	ED	Cat I	2a,b	Unclassified
394	Sucrose	PPP	Unclassified	Unclassified	Unclassified	Unclassified	11	Unclassified
403	Mancozeb	PPP	ED	Not relevant	ED	Cat I	2a	ED
413	MCPA	PPP	Unclassified	Unclassified	Unclassified	Cat II	3	Unclassified
435	Boric acid	BP	ED	ED	ED	Cat I	2a,b	Unclassified
441	Zineb	BP	Unclassified	ED	ED	Cat I	2a	ED
337	Ziram	MISC	ED	ED	ED	Cat I	2a	Unclassified
1080	Resorcinol	MISC	Unclassified	Unclassified	ED	Cat I	2b	Unclassified
1436	Triphenyl phosphate	MISC	Unclassified	Unclassified	Unclassified	Cat II	3a	Unclassified
2081	Benzophenone-3	MISC	Unclassified	Unclassified	ED	Cat I	2a,b	Unclassified
2813	Tert-butyl methyl ether	MISC	Unclassified	Unclassified	ED	Cat I	2a,b	Unclassified
4280	Triclosan	MISC	Unclassified	Unclassified	ED	Cat I	2a,b	ED
5033	2-(2-Butoxyethoxy) ethyl 6-propyl-piperonyl ether	MISC	Unclassified	Unclassified	Unclassified	Cat II	3b	Unclassified
6817	Carbon disulphide	MISC	ED	Unclassified	ED	Cat I	2a	ED
7281	4,4'-Sulphonyldiphenol	MISC	Unclassified	Unclassified	ED	Cat I	1, 2b, 4	Unclassified
7505	Diethyl phthalate	MISC	Unclassified	ED	ED	Cat I	2a,b	Unclassified
8296	Nitrobenzene	MISC	ED	ED	ED	Cat I	2b	ED

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