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DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Safety of the Food Chain
Pesticides and Biocides

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Summary report of round table on the impact assessment on criteria to identify endocrine disruptors

Brussels, 25 March 2015, 10:00-12:00

List of participants : PlasticsEurope; Eurogroup for Animals; Center for Alternatives to Animal Testing (CAAT); Bureau Européen des Unions de Consommateurs (BEUC); European Chemical Industry Council (CEFIC); CHEM Trust; Comité du commerce des céréales, aliments du bétail, oléagineux, huile d'olive, huiles et graisses et agrofournitures de l'UE (COCERAL); European Crop Protection Association (ECPA); Food and Drink Europe; Health and Environment Alliance (HEAL); Endocrine Society; Technical University of Munich; European Trade Union Confederation (ETUC); Standing Committee of European Doctors (CPME); Pesticide Action Network Europe (PAN); Cosmetics Europe; European Commission.

On 25 March 2015 the European Commission held a round table with stakeholders on the impact assessment (IA) on criteria to identify endocrine disruptors (EDs). The purpose of the meeting was to inform stakeholders about the process and state of play on the on-going IA and clarify possible misunderstandings.

The Commission representative indicated that the Commissioner for Health and Food Safety, Commissioner Andriukaitis, is *chef de file* for setting scientific criteria to identify endocrine disruptors in the Juncker Commission. The Commissioner considers it of utmost importance that the IA process is transparent and therefore three round tables and a conference will take place. Moreover, a new webpage on EDs is active on the SANTE website from today. It was highlighted that the minutes of this meeting will be published on the SANTE website.

Today's round table will be followed by two additional round tables with Members of Parliament and representatives of Member States in April. On the 1st of June 2015 a conference on endocrine disruptors will be organised in Brussels. The objective of this conference is to update stakeholders, Members of Parliament, Member States and third countries about the process and to provide a platform for exchange of views. Commissioner Andriukaitis will be present at the conference. Stakeholders were requested to put forward suggestions for areas to be looked at in the conference.

The Commission representative informed that the Directorate-General for Health and Food Safety (SANTE) became the lead service for the IA on the establishment of criteria to identify endocrine disruptors under the biocidal and plant protection product legislation, as a consequence of the transfer or the biocidal products legislation to SANTE. An internal task force with SANTE staff has been set up for the work on the IA. It was emphasised that the IA will be carried out following the internal standard

procedures in close collaboration with other Commission services. DG Environment remains responsible for the EU strategy on EDs.

A general introduction was provided on the IA process. It was stressed that an IA must be based on evidence. An internal Impact Assessment Steering Group is set up for each IA in which the relevant Commission services participate. This inter-service group is involved in every key step of the IA process. A public consultation and stakeholders meetings are part of the IA process which are organised to gather both views and appropriate data. In the IA process the benefits and costs of the options specified in the roadmap will be analysed. This also means assessing the impact on health and the environment. The IA report summarises the outcome of the analysis of data gathered through the public consultation and the supporting studies and will be submitted to the Impact Assessment Board, an internal Commission body checking the quality of the report. Finally, the IA Report will be published together with the legislative proposal.

The Commission representative outlined the regulatory framework of the ongoing IA and summarized the content of the roadmap for the establishment of criteria to identify endocrine disruptors. It was highlighted that according to the 7th Environmental Action Plan, adopted in 2013 by EP and Council, the EU shall develop harmonised hazard-based criteria to identify endocrine disruptors. All measures, actions and targets set out in the 7th EAP shall be proposed and implemented in accordance with the principles of smart regulation and, where appropriate, subject to a comprehensive IA. In this context, in June 2014 the Commission published a roadmap which defines four options for setting the criteria for identifying endocrine disruptors, including the baseline (current interim criteria). Moreover, in the roadmap three options for approaches to regulatory decision making are considered. The Commission representative pointed out that the European Strategy on EDs from 1999 already considers EDs in European legislation, however, the consequences of a substance being identified as an endocrine disruptor varies in the different EU legislation in force. It was emphasised that pending the decision of setting scientific criteria to identify endocrine disruptors, protective interim criteria are in place.

A public consultation was carried out as of September 2014 to January 2015. The main aim of this consultation was to collect data for the IA. In total 27,087 responses were received, most of which were published on the SANTE website on the 2nd of February. The consultation used a specific IT tool that caused some technical difficulties. It is also the objective to publish as soon as possible all the names of the respondents that did not ask for confidentiality and as well as the files attached to the responses.

The Commission representative indicated that as part of the IA process two sets of studies will take place.

The first study consists of estimating the chemicals that may fall under the different options specified in the roadmap. In a 1st instance the Joint Research Centre (JRC) of the Commission developed a method for estimating the chemicals falling under the different options in the roadmap based on available evidence. Then, an external contractor will screen the evidence available for about 700 chemicals and determine if they fall under each of the 4 options outlined in the Roadmap. The substances to be screened include most substances approved under the plant protection product and biocides legislation, plus a group of additional chemicals falling under REACH Regulation, the Cosmetics Products Regulation and the Water Framework Directive (WFD). The contractor is expected to start its activities in early May 2015.

The 2nd study consists of assessing the impacts on various aspects and will look at benefits and disadvantages of the different options. The results will feed into the overall comparison of the different policy options. The Commission representative emphasised that the studies are sequential: the 2nd study cannot start before the results of the 1st study are obtained.

Currently the 2nd study is at an early phase. The Commission pointed out that the economic impact on agriculture is likely to be assessed in cooperation with JRC while other impacts may be outsourced using a framework contract to be concluded with external contractor.

ChemTrust suggested screening only chemicals that have not been selected for other cut-off criteria and asked for the names of the substances that will fall within each of the 4 options outlined in the roadmap. ChemTrust also claimed that cost for industry has been inflated and should be reconsidered in view of benefits for alternative producers. ECPA replicated that cost for industry was calculated using data provided by Member States.

University of München asked whether it is or not still under discussion the fact that EDs will be considered substances of equivalent concern to CMRs, i.e. substances for which consumer exposure is not considered in the assessment. University of München recommended considering opinions drafted in the past from SANCO Scientific Committees on EDs.

Eurogroup for Animals noted the lack of consideration on the impact for laboratory animals.

BEUC asked in which way previous work of the Commission would be considered (e.g. the Report published by the JRC in 2013) and whether the criteria proposed by DG ENV in 2013 will be given a higher weight than other options.

HEAL indicated the importance of publishing the results of the screening process of chemicals or at least of publishing the methodology used to select them. HEAL also pointed out that the additivity of endocrine disruptors should be considered. Excluding REACH and cosmetic substances would put in place a boundary that does not exist in toxicology. Finally, HEAL asked whether the legislative proposal for the criteria will be subject to a formal inter-service consultation in the Commission.

The Endocrine Society emphasised that sufficient endocrine disruptor scientists should be involved in the process.

PAN asked how all impacts would be estimated, for example on soil erosion and resistance development and whether for the screening of substances new data would be generated. The organisation also stressed the need to select independent scientists.

CAAT asked to consider also innovation and green chemistry to design chemicals and asked about the role of the agencies (ECHA/EFSA) in the methodology developed by JRC. They also recommended considering the screening program Tox21. Finally, they pointed out that the term "screening" may be misinterpreted by toxicologists, as it is generally used to indicate in vitro laboratory test batteries.

Several stakeholders asked whether the proposed activities are in any way linked to the ongoing TTIP negotiations with the USA.

ETUC asked how the impacts on workers will be assessed.

CEFIC pointed out that it is unclear what other type of chemicals, in addition to pesticides and biocides, would be included in the IA and also claimed that also microorganisms used as pesticides and non-synthetic, natural substances (e.g. fytoestrogens in soy) should be considered. They pointed out that human exposure to natural EDs is high. CEFIC also indicated that impact on innovation should include effects on inhibition of investments in the EU. They also expressed their concern on the likely stigmatization of chemicals labelled as EDs or suspected EDs, as an outcome of the IA.

COCERAL asked how impacts on trade will be assessed and asked about expected timelines for the IA Report.

The Commission indicated it will consider all comments and suggestions of the stakeholders. All the previous work on endocrine disruptors will be considered in the process because the IA is a continuation of the work that has been done over the last years. At this moment the Commission has not concluded on how endocrine disruptors will be treated in the regulatory process, as the roadmap includes also options for decision making.

Stakeholders raised many questions on the screening methodology and the possibility to provide comments. The Commission pointed out that the JRC-methodology, based on existing evidence, is discussed in the inter-service group and will be cross-checked by the staff of the agencies ECHA and EFSA. The time line of the process does not allow having a public consultation on this methodology. It was emphasised that this approach is in line with Commission IA guidelines.

The Commission pointed out that a legal obligation to set criteria to identify EDs are in place only in the pesticides and biocides legislation. However, the criteria once established, may have repercussions on other sectors. Therefore it is agreed in the inter-service group to include substances which are addressed in other legal frameworks. However, substances under Reach, the Cosmetics Products Regulation and the WFD will be only part of the screening exercise. The socio-economic impacts for these chemicals will not be assessed.

The Commission emphasised that the evidence-screening of chemicals for the IA in the first study does not replace or pre-empty the detailed regulatory risk assessment of chemicals in the future. It is a quick evidence-screening (desk study) for the purpose of the IA for which the JRC developed a decision tree to decide which substances would fall under which option. The Commission is aware that publishing a list of selected chemicals might be misinterpreted. The way of communicating the results of the screening process of chemicals is not yet decided. The Commission confirmed that the IA is focussing on traditional chemical substances (i.e. excluding for instance microbials used as pesticides, pherohormones and natural substances present in food).

The Commission made clear that neither the current work on criteria for endocrine disruptors nor other food safety standards are subject of discussion in the TTIP negotiations.

The Commission indicated it is looking at possibilities to speed up the IA process.

The Commission thanked the participants for their participation in this meeting organised on a short notice, their contributions, and closed the meeting.