EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Safety of the Food Chain
Pesticides and Biocides

Brussels, 28 April 2015

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

Brussels, 24 April 2015, 15:00-17:00

List of participants:

- 23 MS: AT Perm Rep, BE Environment Ministry, CR Perm Rep Health Attaché, CY Perm Rep Health Attache', CZ Perm Rep Health, DE Federal Environment Agency (UBA) and DE Federal Institute for risk (BfR), DK Perm Rep Environmental Counsellor, ES Ministry of Healthy, FI Perm Rep Counsellor, FR Perm Rep Industry Attache', HU Perm Rep Environment Attache', IE Department of Agriculture, Food and the Marine, IT Perm Rep Health/Pharma/Foodstuffs/Vet Attache', LT Perm Rep Environment Attache', LV Perm Rep Environment Counsellor, MT Perm Rep Phytosanitary and Veterinary Attache', NL Perm Rep, PL Perm Rep Environment Counsellor and PL Perm Rep Competitiveness and Growth Counsellor, PT perm Rep Alimentação e Veterinária, SE Swedish Chemical Agency (Kemi), SI Perm Rep Health Attaché, SK Perm Rep, UK Perm Rep
- Norway Mission to EU, Counsellor for Environment
- Council Secretariat
- European Commission: DG SANTE (04, A1, E3, E6), DG AGRI, DG EMPL, DG ENV, DG GROW, JRC, DG JUST, DG RTD, DG TRADE

Summary:

On 24 April 2015, the European Commission held a round table with Member States and EEA Members. The purpose of the meeting was to inform about the on-going impact assessment (IA) on criteria to identify endocrine disruptors (EDs).

The Commissioner for Health and Food Safety, Commissioner Andriukaitis, *chef de file* for setting scientific criteria to identify EDs, required the highest transparency on the impact assessment process. In this context, three round tables and a conference will take place. The first round table was held on 25 March 2015 with stakeholders and the third round table with MEPs will take place the 12 May 2015.

A general introduction was provided on the **impact assessment (IA) process**, which is a standard procedure for Commission initiatives for which significant impacts are expected. It supports decision making, and is not intended to substitute it. It normally starts with the publication of a roadmap, where the problem, objectives, stakeholders affected and, consultation plan are set out. Availability of data is key for an IA, as it

should be based on evidence. The data are gathered via internal/external studies plus evidence provided by stakeholders through a public consultation. All kind of impacts are considered: economic, social, environmental and health aspects. The draft IA Report prepared by the Commission Services is submitted to an IA Board, an internal Commission body, for acceptance or possible revision. The finalized IA Report accompanies the adoption of the initiative.

The Commission representative outlined the **regulatory framework** of the ongoing IA **and** summarized the content of the **roadmap** (published in June 2014) for the establishment of criteria to identify EDs. Specific provisions on EDs are included in the following EU legislation: Water Framework Directive, REACH and the Regulations on Plant Protection Products (PPP), Cosmetics and Biocidal Products (BP). Consumers are protected: e.g. food residues of PPPs identified as EDs cannot exceed the detection limit (analytical zero). Pending criteria for identification of EDs required in PPP and BP legislation, protective interim criteria are applicable. Implementation of the EU legislation is ongoing (for example, restrictive measures on uses of Bisphenol A and phthalates).
It was highlighted that an IA started in 2013 because: 1) the question as to whether and how to regulate EDs is subject to ongoing controversies amongst scientists and regulators worldwide; 2) an IA is a standard procedure for initiatives for which significant impacts are expected and this is the case for criteria to identify EDs; 3) the 7th Environmental Action Programme adopted in 2013 asked the Commission to set horizontal hazard-based criteria performing an IA if appropriate; 4) the criteria set for PPP and BP may impact also other EU legislation.
It was pointed out that the consequences of setting criteria vary significantly among sectors based on the regulatory framework: the PPP Regulation is mainly based on hazard while e.g. the BP Regulation or REACH is based on risk and allows to include socio-economic considerations in the regulatory decision process.
The roadmap outlines 4 options for scientific criteria based on hazard (including the interim criteria as baseline, plus options based on the WHO definition of an ED). Moreover, 3 options for regulatory decision making are presented foreseeing the possibility to include risk and/or socio-economic elements in the legislation, where appropriate.

A **public consultation** was carried out from September 2014 to January 2015 with the aim to collect data for the IA. In total over 27,000 responses were received, most of which were published on the SANTE website on the 2nd of February. Due to some technical difficulties with the IT tool used, the names of the respondents not asking for confidentiality, plus the files attached to the responses, were published at a second stage in March. Responses from about 20 public authorities in MS were received (of which 3 from governments), plus 6 responses from third countries' governments. More information is available at: http://wcmcom-ec-europa-eu-wip.wcm3vue.cec.eu.int:8080/health/endocrine_disruptors/stakeholders_dialogue/index_en.htm. A more analytical report will be published at a later stage.

The Commission representative indicated that as part of the IA process two **sets of studies** will take place.
The 1st study-package aims at estimating the chemicals that may fall under the different options specified in the roadmap. It started and consists of two parts. The first part, which is the development of a methodology for the screening of evidence, is almost finalised by the Joint Research Centre (JRC) of the Commission. A second part, which is the screening of chemicals based on available evidence, will start early May by an external contractor. The contractor will screen about 700 substances, starting with most

substances approved under the PPP legislation, followed by substances approved under the BP legislation and finally a subsample of substances falling under REACH, the Cosmetic Regulation and the Water Framework Directive. It was emphasised that the methodology for the screening is developed in the context of an IA and will therefore not pre-empt any regulatory assessment.
The 2nd study-package for the IA will assess the health, environment and socio-economic impacts (costs and benefits) associated with the various options for the criteria. This 2nd study-package is in a planning phase (methodology development), and it can start operationally only when the results of the 1st study-package are available. It was anticipated and highlighted that input from MS may be needed soon as regards data for the 2nd study-package for the IA (e.g. number, identity and quantity of PPP authorized in each MS).

The Commission representative provided information on the **conference** scheduled for **1st of June 2015**. Commissioner Andriukaitis will be present for the opening. A draft agenda is available at: http://wcmcom-ec-europa-eu-wip.wcm3vue.cec.eu.int:8080/health/endocrine_disruptors/events/ev_20150416_en.htm
Registration is open until 19th of May 2015. Only one person per MS/organization/third country can be accepted due to room capacity. After 19th of May, it will be reconsidered whether further participants who registered may be accepted. The objective of the conference is to update MS, MEPs, stakeholders and third countries about the on-going IA and also provide a platform for further exchange of views.

Questions:

Austria asked whether, considering the high interest for the conference, it would be possible to hold the conference in a bigger room.

Sweden expressed its disappointment with regards to the Commission's delays in setting the scientific criteria and mentioned the on-going Court of Justice case in which Sweden declared that the Commission failed to adopt delegated acts to specify scientific criteria for the determination of endocrine-disrupting properties and therefore failed to implement the Biocidal Products Regulation (supported by EP, Council and several MS). Sweden argued that the Commission had been asked to set hazard based scientific criteria and indicated the roadmap foresees non-hazard based options considering potency or risk and socio-economic aspects. Sweden stressed that the interim criteria do not cover the environmental aspect and claimed that scientific disagreement on endocrine disruptors was there even before 2013. Such a disagreement will be present in any scientific discussion. It expressed the wish that the baseline for the IA will be the current situation including integrated pest management (IPM).

Finland and Norway supported the Swedish intervention. Norway added that the participants of this meeting are mainly from the Permanent Representations with few exceptions from Agencies (e.g. Sweden) and technical discussions are difficult to be followed by Permanent Representations delegates.

The Commission representative explained that invitations for this meeting were sent to Deputy Permanent Representatives/Heads of Mission to the EU and that the Commission takes note of the comments of Sweden. The Commission representative underlined the existing scientific controversy and the fact that the consequences of setting the scientific criteria differ among sectors: PPP legislation does not allow for case-by-case analysis, as does the BP Regulation and REACH. The Commission representative indicated that the legal obligation to set criteria applies only for PPP and BP, but the criteria will have

consequences also for other areas of the chemical legislation. Although DG SANTE portfolio is focused on health matters, all concerned Commission services are involved in this process, thus ensuring that also environmental aspects are covered.

As regards the change of room to allow wider participation to the conference of 1st June, the Commission representative indicated that it will investigate whether this is possible but stressed it would likely be difficult. It was stressed that there is no intention to exclude wide participation and the event will also be web-streamed.

France welcomed the approach of highest transparency as many questions may arise during the IA process. It called for horizontal criteria and asked for more information about the JRC methodology for the IA and the contractor that will do the screening of the substances.

Germany supported the intervention of Sweden. It asked for more information about the methodology developed by the JRC. It asked how environmental impacts will be assessed and offered expertise to perform this task. It asked whether the IA will assess options A-C on the regulatory decision making and emphasized the importance of involving MS in the IA. It asked about expected timelines for finalizing the IA.

Denmark expressed satisfaction that work on the IA is progressing. It called for science-based criteria, which should be separated from socio-economic considerations. It considers transparency very important.

Italy asked whether the political approach of Mr Juncker's Commission for this IA will follow the same principles (fostering growth and innovation) as for other files (e.g. medical devices, GMOs).

The Commission representative highlighted that the decision to carry out an IA was taken before the Commission of Mr Juncker started. The IA is expected to be finalized in 2016 and there is high interest for finalizing it as soon as possible, while maintaining high quality. The limiting factor is that the main two sets of studies have to be performed sequentially and cannot be run in parallel. The Commission representative clarified that the legislative proposal may opt for criteria which are not exactly as the options described in the roadmap (e.g. other elements of hazard characterization considered).

Portugal asked which kind of data is expected from MS for this IA (e.g. only names of PPP used or also quantities). It warned that companies consider the amounts of products sold as business confidential information and may be reluctant to release it. Portugal delegate mentioned his personal support of the Commission's decision to start an IA on this complex and sensitive issue, especially given the fact that there is risk of losing essential tools in agriculture.

Spain asked when the 1st set of study is expected to be finalized and whether the methodology developed by the JRC and the results of the screening will be published.

The Commission indicated that the methodology developed by the JRC is intended to be published, but reflection is still on-going concerning the best timing to do so. The screening will start early May and the first results on PPP are expected by autumn 2015, which will enable the first socio-economic studies (e.g. on agriculture) to start.

Sweden asked whether it would be possible to continue the discussion started in the meeting via a written procedure.

Germany welcomed the feedback received during this meeting and indicated their wish to continue being updated regularly. The aim of future meetings should be clearer. It reminded that past scientific opinions (e.g. JRC, EFSA) should be considered in the IA.

Hungary indicated that the next meeting should be at technical level.

Norway supported the Hungary's intervention and asked how the answers of the public consultation would be considered in the process.

Belgium highlighted the complexity of the topic and asked whether literature data will be looked at in the screening performed by the contractor for the IA.

Germany indicated that previous scientific work had to be taken into account.

The Commission representative clarified that a written procedure for providing comments is not foreseen due to constraints on Commission resources and the need to progress on the IA, which is the priority. The new website, the several meetings held and the conference planned ensure a high level of transparency. If needed, further roundtables with MS may be envisaged at technical level. The Commission representative replied to Norway that the data provided in the public consultation would be included in the IA process. It was reminded that MS are regularly informed on the IA at the Standing Committees (PPP/BP) and Caracal meetings (REACH). To the question of Belgium the Commission representative responded that the screening will look at data in approval dossiers and at a certain extent in scientific literature. The screening will never replace a regulatory assessment.

The Commission representative thanked the participants for the discussion and questions and closed the meeting.