EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Safety of the Food Chain
Pesticides and Biocides

Brussels, 13 May 2015

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

Brussels, 12 May 2015, 15:00-17:00

List of participants:

- MEP Jens Gieseke (EPP/DE); MEP Julie Girling (ECR/ UK); MEP Françoise Grossetête (EPP/FR); MEP Karin Kadenbach (S&D/AT); MEP Anthea McIntyre (ECR/UK); MEP Pavel Poc (S&D/CZ); MEP Michèle Rivasi (Greens/FR);
- EP secretariat, political advisors, MEP assistants
- European Commission: Commissioner Andriukaitis, DG SANTE, DG AGRI, DG ENV, JRC, SG

Summary:

On 12 May 2015, Commissioner Andriukaitis chaired a round table with Members of the European Parliament to inform them about the on-going impact assessment (IA) on criteria to identify endocrine disruptors (EDs).

Commissioner Andriukaitis welcomed the MEPs and started by stressing that the Endocrine Disruptors file is a collegial one. While Commissioner Vella is in charge of the overall strategy, Commissioner Andriukaitis defends the public health part in defining endocrine disruptors in particular in the context of the plant protection products and biocidal products regulations.

He recalled the promise he made during the March plenary session of the European Parliament that the impact assessment on criteria to identify endocrine disruptors would be a transparent process and would involve all interested parties. He highlighted that a first round table was organised in March 2015 and gathered NGOs, trade associations, trade union confederations, industry associations and scientists. A second round table with EU Member States and members of the European Economic Area was organised in April 2015. A public conference on the subject is also scheduled for the 1st of June in Brussels.

I/ Information on the regulatory framework and the content of the roadmap

Commissioner Andriukaitis outlined the state of play on the regulatory framework and the roadmap: the EU legislation includes provisions on endocrine disruptors under the Regulations on plant protection products, biocidal products, chemicals (REACH), cosmetics and under the water framework directive. The biocidal products Regulation requires adoption of a Commission measure setting scientific criteria to identify endocrine disruptors by

December 2013. The plant protection products Regulation obliges the Commission to present, by December 2013, draft measures to the Standing Committee. Pending this, interim criteria are in place. Due to the diverging views in science about how to set scientific criteria to identify EDs and due to the possible significant impacts which may arise following implementation of these criteria, an IA was started in 2013. As a first step of the IA , a roadmap was published in June 2014. It defines 4 options for setting scientific criteria to identify EDs, including the baseline, meaning the current interim criteria. It also defines 3 options for regulatory decision making, including the baseline. How the 4 options for the criteria (Aspect I) and the 3 options for regulatory decision making (Aspect II) interact was explained via a presentation (*see powerpoint presentation in annex for more details*).

MEP RIVASI asked why the IA was carried out, as the legislation requires to establish scientific criteria for EDs and not to consider the regulatory consequences of the criteria. She also asked why this decision to have an IA was taken so late in the process of establishing criteria and stressed that, in addition to impacts on economy, also health benefits and environmental impacts should be considered. She stressed the need to focus on the scientific definition of EDs.

The Greens group political advisor indicated that the Commission proposed itself in 2006 the cut-off criteria in the Regulation on Plant Protection Products. It is at that time that an IA should have been carried out.

The Commission representative answered that, during its preparatory work to set the scientific criteria, the Commission noticed that there are divergences within the scientific community (science has different views on the appropriate criteria). There were also discussions among services of the Commission and among Member States because of the varying provisions in the different applicable legislations, which imply different impacts on the sectors depending on the definition of the criteria. The Commission finally decided to first do an IA to be able to better explore the diverging scientific views and to have a picture of the socio-economic impacts linked to the various options for the criteria. It was also clarified that all impacts, positive and negative, would be considered in the IA (including health and environment and not only economic aspects). It was also explained that the EU had strengthened its practice of impact assessment of its major initiatives. In the recent years, an IA is a standard procedure for all the proposals done by the Commission and this is needed in order to make informed decisions. Besides, in 2006 it would have been difficult to carry out an IA also because the scientific criteria were not set. Still in 2009 science was not ready and interim criteria were set, postponing the decision to 2013, when the expectation was to have some scientific clarity and consensus, which unfortunately is not yet there. All this is important and the Commission is as transparent as possible on the process.

MEP RIVASI asked in which of the four options proposed in the roadmap, the highest number of chemicals would be identified as EDs.

The Commission representative answered that options 2 and 3 are expected to be the ones where the highest number of EDs could be identified. In option 3, the list may be longer because of the additional categories with respect to option 2. However, the regulatory impact of option 2 and 3 will be the same, as there will be regulatory consequences only for substances belonging to category 1. Option 4 would likely identify a lower number of EDs.

II/ State of play on the public consultation

Commissioner Andriukaitis then gave information on the state of play of the ongoing IA, including the public consultation (PC) that was carried out from September 2014 till January 2015.

It was made clear that the objective of the public consultation was to gather information relevant for the IA and not to gather opinions. More than 27,000 responses were received. They were published in February on SANTE's website, except those where confidentiality was claimed. From the total responses received, over 25 000 replies were received via NGO campaigns. There were 863 answers submitted via the online survey on behalf of an organisation. Out of these, the majority (57%) were provided by agricultural producers. Public authorities and private companies also answered to the PC. It was highlighted that the PC report will not evaluate in detail the responses received. The report will give statistics and report facts, and the objective is to publish it before the summer break. The information received is already used, for instance in the preparatory work for the second set of studies.

MEPs GIRLING and GIESEKE wanted to know why it takes the Commission so long to produce a report.

The Commission representative answered that the analysis of the answers takes time because this consultation asked for data rather than opinions. Data are complex to analyse and difficult to aggregate in simple statistics. In other words, there is the need to identify what is similar or not in the data provided, which are formulated and described in different ways.

MEP RIVASI and GROSSETETE asked for more details about the stakeholders who had answered and asked to see their positions. MEP GROSSETETE asked the Commission to take into account in drawing its conclusions that health professionals usually do not have time to answer to a PC.

The Commission representative indicated that the report will indicate which kind of answers was given from which side.

MEP GROSSETETE pointed out that, in the process of the IA, the impacts on health and environment should be considered as first priorities.

The Commissioner underlined that his portfolio is about health and he would not compromise on health.

The Greens group political advisor asked why the roadmap for the IA on the criteria was set up in a sectorial approach i.e. in the context of the plant protection products and the biocidal products regulation, while the Commission has a specific mandate to set horizontal criteria for EDs. He also wanted to know why the Commission requested information on substitutability of substances identified as EDs. Finally, he argued that the public consultation organised by the Commission did not consult on the specific benefits of the options for the criteria.

The Commission representative indicated that the roadmap for the IA on the criteria was set up in the context of the plant protection products and the biocidal products regulations because the Commission has a legal requirement in these two pieces of legislation to set criteria for EDs. The Commission has to balance the length of the IA process and the scope and its content. Carrying out the IA for all sectors would take significantly more time. He then explained that the impacts in the different sectors (health, environment, trade, agriculture, industry) are all looked at to inform decision-makers. The Commission is also in contact with

various stakeholders, including scientists (both internal and external) and will consult these experts to see how to do a proper assessment, in particular as regards the difficulty to determine health impacts. Both the negative and positive sides will be considered in the IA.

MEP KADENBACH asked to look at the cocktail effect of substances.

MEP GROSSETETE indicated we should not oppose health and industry. If studies show that a substance should be banned, then new actors will intervene on the market to find alternatives. Although there is currently high sensitivity about employment in the EU, in any case, there should be no compromise on health.

MEP RIVASI said the industry wants definitive criteria to be set (they are not satisfied with the interim ones). Therefore, both consumers and industry ask for new criteria soon. On the contrary, if there is a second study assessing the socio economic impacts, the setting of the criteria will be again delayed.

The Commission representative indicated that the IA should provide facts and estimate impacts for the political debate. In some cases, further action will be needed (for instance to find alternatives). He also mentioned that there is for the moment no agreed methodology available to assess the cocktail effect, but the Commission is aware of the importance of this issue.

The Greens group political advisor asked how derogations would be assessed (for instance in the plant protection products legislation).

The Commission representative said that, if a list of potential ED substances is established, the impact of derogations need to be assessed on a case by case basis. For biocides probably there are more workable solutions than in pesticides concerning derogations. It was also clarified that "socio-economic impacts" should be interpreted in the wider sense, as they also cover health and environment and not only economy. For the derogations, it was specified there should be a derogation request (under the plant protection products Regulation the Commission does not grant derogations without request by the applicant).

III/ State of play on the on-going impact assessment

Commissioner Andriukaitis and the Commission representatives then updated participants on the two set of sequential studies, which are needed in the context of the impact assessment. The first study is an estimation of the chemicals falling under each option of the roadmap. This exercise is ongoing. A methodology was developed by JRC. Because of the timing of the impact assessment process, this methodology cannot be an in depth evaluation of the chemicals, nor replace a regulatory evaluation in the context of the authorisation of chemicals. The screening of chemicals (which is a desk work, done on the basis of already available data) is carried out by an external contractor, who will apply the methodology developed by the JRC to screen about 700 chemicals (all relevant plant protection and biocidal active substances and a subset of REACH, Cosmetics and Water Framework Directive substances). The JRC methodology will be presented at the June conference.

The second study is the assessment of impacts, which can only start once the first study is ready. It is in an early planning phase and will have a wide scope (health, environment, agriculture, trade, SMEs, industry, administrative burden, etc.) and will assess both pros and cons. To speed up the process some studies are planned to run in parallel and more human resources have been dedicated to the ED team.

MEP KADENBACH asked whether the list of substances falling under each of the four options would be publicly available.

The Commission representative confirmed it would be the case and stressed that this list could not be used for regulatory purposes because it is not done according to the regulatory context. The JRC methodology cannot replace a risk assessment/hazard assessment.

Commissioner Andriukaitis stressed transparency is crucial and the Commission is ready to organise some debates, inviting interested parties to exchange views on all these issues.

MEP POC put an emphasis on the need to use science and not economy as a basis for establishing scientific criteria to identify endocrine disruptors.

The Commission representative indicated that four options are considered in the roadmap and for each of them, impacts need to be assessed. In order to provide as much as possible relevant information about the impacts, a screening method is needed. It is a compromise between an IA as accurate as possible and the timescale available.

MEP RIVASI asked about the general timeline. MEP GIRLING asked for an updated planning at the June conference and MEP McINTYRE asked when people would be given the possibility to give their views.

The Commission representative replied that according to the current planning, the studies should be concluded in the third quarter of 2016. A timeline in written form will be provided at the June conference and people may be consulted on the draft texts once they are final.

Commissioner Andriukaitis concluded thanking all participants for attending the meeting and inviting them to attend and give their views at the June conference.