EUROPEAN COMMISSION

HEALTH AND FOOD SAFETY DIRECTORATE-GENERAL

Brussels, 18 July 2016

MINUTES

Place: Conference Centre A. Borschette	Date: 30 June 2016, 9.30-12.30
Subject: Ad-hoc Working Group meeting of the Advisory Group on the Food Chain, Animal and Plant Health on criteria to identify endocrine disruptors	

The Commission presented to interested parties the draft Commission acts setting scientific criteria for identifying endocrine disruptors in the context of the EU legislation on plant protection products and biocidal products, as well as the Communication from the Commission to the European Parliament and the Council on endocrine disruptors, which is accompanied by an Impact Assessment Report[1].

The Commission representative thanked interested parties for their views and highlighted that the draft regulations are subject to the new procedure of the feedback mechanism, implying that parties can provide comments to the draft regulations on the better regulation portal for a period of 4 weeks, starting on 30 June 2016[2].

It was stressed that the regulations will be adopted under their relevant procedures and it is the intention to adopt the draft delegated act on biocidal products (BPs) after the vote in the Standing Committee on the draft implementing act on plant protection products (PPPs). The next discussion in the Standing Committee and the expert group on the relevant acts is scheduled after the summer break.

Following this introduction a technical presentation was given (see presentation) explaining in detail the draft acts and summarising the impact assessment. It was pointed out that the methodology to screen active substances for endocrine disrupting properties and the results of the contractor would be published soon[3].

In response to HEAL who asked whether ECHA had provided feedback on the criteria, it was indicated that the European Chemicals Agency (ECHA) and the European Food Safety Authority (EFSA) were consulted on the draft acts in the internal consultation procedure of the Commission services and are

[1] These documents are publicly available on http://ec.europa.eu/health/endocrine_disruptors/policy/index_en.htm.

[2] See links: http://ec.europa.eu/info/law/better-regulation/initiatives/isc201602700_en; http://ec.europa.eu/info/law/better-regulation/initiatives/isc201602695_en

[3] The documents are currently available on: http://ec.europa.eu/health/endocrine_disruptors/impact_assessment/index_en.htm.

asked to prepare themselves for the setting of ED criteria. This should help the decision making process after adoption of the criteria.

Several questions focussed on the impact of the prosed draft acts on other legislation. It was pointed out that the criteria only apply immediately to PPPs and BPs and no direct consequences occur for other legislation.

Amcham EU and ECPA asked why the Commission was not proposing draft acts following the results of the impact assessment. The Commission representative indicated that the impact assessment had the objective to provide information for the decision making by the Commission; in particular the Commission had to know the consequences of any given option. The Commission also considered other information in the decision making process, for example, according to scientists, potency, as included in option 4, should not be taken into account for the hazard identification of an ED.

Greenpeace stated that the draft acts are not based on any of the options outlined in the roadmap. CHEMTRUST pointed out that it is being proposed to change the derogation for approving ED substances from negligible exposure to negligible risk in the context of the PPP regulation. However, according to this organisation, risk assessment will not take into account low dose and mixture effects, non-monotonic dose responses on which, according to the outcome of the expert meeting organised by the German Federal Institute for Risk Assessment (BfR-statement)[4], no scientific agreement exists. ClientEarth highlighted that the change in the derogation is not based on the empowerment of the Commission for establishing ED criteria. CHEMTRUST and Greenpeace were of the opinion that the Commission is exceeding its mandate by changing the derogation as it would imply that the Commission proposal is moving away from a hazard approach.

The Commission representative pointed out that the draft acts are reflecting option 2 of the impact assessment. It was stressed that the derogation proposed is not a new one but represents an adjustment of an existing derogation to the latest state of science. The draft act on PPPs does not affect the hazard approach as enshrined in the basic legislation. It was stressed that scientific progress is happening continuously and that at any time the information on science can be considered and evaluated with regards to the use of the empowerment given to the Commission in the PPP legislation.

Several organisations indicated that option 2 in the roadmap has a different wording than the draft ED acts as it is referring to 'known or presumed' and 'read across'. It was also referred to the wording on EDs included in the current basic acts of "may cause effects'. It was also indicated that the WHO established two definitions: one on ED and one on potential ED. The requirement to have information on the mode of action was considered not to be consistent with the precautionary principle included in the basic acts as it is putting the level of proof too high. It was pointed out that academic research is generating most of the data. It is unclear how the relevant information could be developed for evaluating ED properties of active substances. PAN EUROPE proposed to have the same approach as for carcinogenicity for which one study showing effects is sufficient. UEAPME pointed out that in the different language versions of the basic acts 'may' has different meanings.

[4] For further information see:
http://www.bfr.bund.de/en/international_expert_meeting_on_endocrine_disruptors-197246.html.

This stakeholder underlined that competitiveness is also one of the objectives of the basic regulations which should also be taken into account.

COPA-COGECA stressed the impacts on SMEs of setting ED criteria and asked that the impacts are kept to a minimum. ECPA noted that potency is not part of hazard identification but hazard is not just hazard identification. As a consequence potency, which is an element of hazard characterisation, should also be considered in the ED criteria.

ECCA stressed that the proposal could lead to many false positives. CEFIC referred to the results of the screening of biocidal active substances. Under option 2, iodine is identified as a potential ED. This implies that this substance can no longer be used by the general public. This is considered not appropriate for this well-known substance especially given that under option 4 (when potency is considered), this substance would not be identified as ED. CEFIC emphasised that it supports the inclusion of hazard characterisation in the criteria. CEPE pointed out that, even in the case of negligible exposure, a biocidal substance identified as ED, cannot be put in consumer goods, for example paints. AmCham EU pointed out that a risk approach can be more protective, as a chemical with low hazard and a high exposure could be restricted. The organisation also highlighted that the WHO-definition does not state that ED-substances should be banned based on hazard. COCERAL pointed out that not including potency in the criteria would imply the banning of chemicals that are not posing a risk. These chemicals could be important to fight issues of concern, like preventing the occurrence of mycotoxins in food.

The Commission representative pointed out that EFSA considers that risk assessment of substances at low doses is possible and that a 'negligible risk' approach is expected to provide more protection than 'negligible exposure'. The representative clarified that the draft acts are not an exact copy of the option 2 as included in the roadmap and the wording in the draft act seems to be leading to some misunderstandings, for example the type of data that could be considered in the evaluation of active substances. It was pointed out that in vitro and in vivo studies could be considered and also read-across could be applied. Another point of discussion is the interpretation of the word “may” in the basic acts. According to the Commission representative this wording implies that there should be an indication of an ED effect. However, it is noted that there is a different understanding about the implications of 'may' in the basic acts.

The Commission representative emphasised that the setting of ED criteria is pioneering work as up to now no another administration in the world has set ED criteria in legislation. The Commission looked at all relevant information before presenting the draft acts. The consultation of stakeholders will help further the decision making and also shows the different views of interested parties. It is important to recognise that the draft acts developed need to obtain the agreement of both EP and Council before being able to be applied. On the generation of data it was pointed out that enacting the ED definition will ensure the development of the relevant data in the future. It was proposed not to start evaluating the potential impacts of the proposed criteria on specific substances, for example iodine, but to focus on the proposed criteria. The Commission representative also underlined that the Commission has to respect what the legislators have decided on the hazard approach and the regulatory consequences for substances identified as EDs. It was indicated that no review of PPP or BP legislation is foreseen in the short term.

ECPA stressed there was a huge amount of funding available for research on EDs. The main conclusion of the scientists was that there exists uncertainty and there is a need for further research. ECPA underlined that setting ED criteria imply more animal testing.

Several interested parties indicated the similarities between the classification of substances with ED properties and CMR-substances. It was pointed out that the proposed change from negligible exposure to negligible risk could set a precedent for the derogations foreseen for CMR-substances. The Commission representative stressed that the drafts under discussion were about setting of criteria for the identification of EDs and not the classification of CMR-substances. UEAPME stressed that CLP-legislation on classification of CMR-substances is a totally different type of legislation with very stable criteria.

The Chair stressed he valued very much the contributions provided by interested parties. He hoped that the process would result in practical ED criteria that will help to protect the health of people and the environment. He informed the participants that the minutes of the meeting would be prepared and would be publicly available.

Annex 1: Presentation

Annex 2: List of participants

Members of the Advisory Group

Organisation
BEUC **Bureau européen des unions de consommateurs**
CEFIC **European Chemical Industry Council**
COCERAL **European association representing the trade in cereals, rice, feedstuffs, oilseeds, olive oil, oils and fats and agrosupply**
COPA-COGECA **Comité des organisations professionnelles agricoles de l'UE**
ECCA **European Crop Care Association**
ECPA **European Crop Protection Association**
EUROGROUP for ANIMALS
FEFAC **European Feed Manufacturers' Federation**
FOODDRINK EUROPE **Confédération des industries agroalimentaires**
FRESHFEL EUROPE **The forum for the fresh produce industry**
PAN EUROPE **Pesticides Action Network Europe**
PFP **Primary Food Processors**
UEAPME **The European Craft and SME Employer's Association**

Non-members of the Advisory Group

A.I.S.E. **International Association for Soaps, Detergents and Maintenance Products**
AmCham EU **American Chamber of Commerce to the EU**
Bee Life **European Beekeeping Coordination**
CEPA **Certified Professional Pest Management**
CEPE **European Association of Paints, printing inks and artists' colours industry**
CHEMSEC **International Chemical Secretariat**
CHEMTRUST
CIEL **Center for International Environmental Law**
ClientEarth
COSMETICS EUROPE **European association of the cosmetics and personal care industry**
EDANA **International association for the nonwovens and related industries**
EUCOFEL **European Fruit and Vegetables Trade Association**
EurEau **European Federation of Water Services**
FECC **European Association of Chemical Distributors**
FRUCOM **European Federation of the Trade in Dried Fruit, Edible Nuts, Processed Fruit & Vegetables, Processed Fishery Products, Spices, Honey and Similar Foodstuffs**
Greenpeace European Unit
HEAL **Health & Environment Alliance**
JBCE **Japan Business Council in Europe**
SAFE **Safe Food Advocacy Europe**