EUROPEAN COMMISSION
Directorate-General for Trade

Directorate E - Neighbouring countries, USA and Canada
USA and Canada

Brussels,
USA and Canada

Meeting Report

Summary report – Conference on endocrine disruptors (EDs) – 1 June 2015

Quite interesting conference with around 200 participants from COM, MS, EP, NGOs, industry as well as the scientific community. See draft agenda enclosed.

Estefania Roncero Fernandez, Wolf-Martin Maier (both D.3) and Benjamin Musall (G.3) attended for DG TRADE. We followed most, but not all sessions of the conference.

The following points were particularly interesting for us:

- In **session 1 ("Scientific debate on criteria to identify endocrine disruptors")**, **Prof. Daniel Dietrich** (University of Konstanz, Germany) stressed that interference with the human endocrine system of any substance as such is only a "mode of action", not per se an adverse effect. As an example, Prof. Dietrich noted that also beer and coffee interfere with the endocrine system. In accordance with well-established principles of modern toxicology, potency should also be taken into consideration for the purpose of identifying EDs (in fact, potency would be included according to option 4 of the IA Roadmap which is also the favourite option of many industry associations and individual companies). Chemicals interfering with the endocrine system can and should be subject to a classical risk assessment procedure and not only hazard identification. Risk assessment also allows the determination if there are indeed adverse effects.

- In the same session 1, the statements of Prof. Dietrich were largely echoed by **Prof. Anthony Hardy**, the **Chair of EFSA's Scientific Committee**. He added that adversity has to be established in vivo in humans. However, Prof. Hardy admitted that there are certain scientific uncertainties around EDs, namely critical windows of susceptibility (e.g. during developmental phases in early childhood or pre-birth), exposure to multiple chemicals (also known as "mixture toxicity") and non-monotonic dose-response (i.e. lower doses can cause more effects than higher ones). Prof. Hardy explained that EFSA's Scientific Committee is preparing a number of guidance documents on EDs: (1) uncertainty in risk assessment (finalization planned for end-16), (2) weight of evidence (September 17) and (3) biological relevance (end-16).

- In the **Q&A session** that followed, NGO and EP representatives attacked the position of Prof. Dietrich and Prof. Hardy and claimed that there would be clear scientific evidence for an epidemic of diseases caused by EDs which required

urgent regulatory action. A representative from the Swedish Chemicals Agency also pointed to the legal action which Sweden (supported by the Council and EP) has taken against the COM for failure to adopt criteria identifying EDs before end-13. The scientists defended their position and rebutted the claims of NGOs and MEPs, but interestingly admitted that the potential cumulative effects of endocrine active substances ("mixture toxicity") is indeed an open issue which implies that the traditional "substance-by-substance" approach of classical risk assessment may face important limitations *(This is interesting also from a TTIP perspective as "mixture toxicity"* – [Art. 4.1(a) third indent] – *is an important example of a "new and emerging issue" which could be covered by a future TTIP Agreement).*

- **Session 3** was devoted to **"potential impacts on industry and consumers"**. Chair **Michèle Rivasi MEP** voiced her opinion that the whole purpose of starting an Impact Assessment was only to delay the adoption of the EDs criteria. **Beate Kettlitz** (Director Food Policy, Science and R&D) from **FoodDrinkEurope** gave an overview of potential impacts on the food industry. She stressed that it was extremely important to clearly distinguish between "endocrine actives substances" and "endocrine disruptors" (only for the latter, an adverse effect can be proven). The EU food industry believes that the Impact Assessment should also look into the question whether substitutes are available for substances identified as EDs and whether the banning of certain substances could endanger the food supply. This position was largely supported by **Jean-Charles Bocquet**, Director General of the **European Crop Protection Association (ECPA)**. Mr. Bocquet added that in his industry's view the existing regulatory framework of the EU is already very strong and enables targeted regulatory action to eliminate any possible dangers from EDs. Industry itself is heavily investing in R&D aimed at finding the least harmful, but still efficient plant protection substances. According to Mr. Bocquet, the number of pesticides substances available on the market has already declined by more than 600 over the last decades (due to voluntary industry phase-out and regulatory action) – today only around 250 of such substances remain permitted in the EU. Finally, Mr. Bocquet called on scientists working for governments, industry and NGOs to cooperate more closely to find the best possible solutions.

- Session 3 also featured a presentation by **Claus Jørgensen**, Senior Project Manager with the **Danish Consumer Council**. He presented the new "THINK Chemical" initiative which is supported by the Danish government. In Denmark, there is a strong public awareness of the dangers caused by EDs, with a clear majority of Danes in favour of banning EDs and even national action going beyond regulatory initiatives at EU level. According to studies commissioned by NGOs, EDs are everywhere to be found – in our food, toys, all kinds of consumer articles… Even industry was starting to realize that urgent action is needed (as an example, Mr. Jørgensen mentioned the case of COOP which recently had to withdraw a certain type of microwave popcorn from its supermarkets, due to EDs-related concerns). According to one study, the cost of prolonged non-action on EDs would amount to 150 billion €/year in the EU *(it would be interesting to find the source of this claim).* It is hard to understand why the principle of REACH according to which the burden of proof has shifted to industry is not also applied to EDs. Finally, Mr. Jørgensen claimed that industry would "cry wolf" by systematically exaggerating potential economic losses resulting from strong

regulatory action on EDs (a recent *ChemSec* study was provided as example – tbc).

- In **session 4**, **"Potential impacts on trade and agriculture"**, **Luc Peeters**, **Chairman of Copa-Cogeca Working Party on Phytosanitary Questions**, explained how provisions on EDs are included in several pieces of EU legislation. He stressed that food production needed proper tools to ensure food protection. To highlight the importance of plant protection, he indicated that a 30-40% of food loss due to pests and diseases would be expected (without treatment) as well as a 70% increase in food demand by 2050. Luc Peeters expressed that Risk Assessment had to take into account human and health aspects and that the Commission was doing a proper job regarding Risk Management. For him, a sustainable use of pesticides implies that active substances are used safely. Luc Peeters signalled that effective plant protection had to include enough alternatives for crop rotation and an Integrated Pest Management for all groups. A viable solution would be a higher use of Plant Protection Products. For major crops, an economical balance is needed; for minor crops and special crops, the impact would be higher. He also informed that, currently, only 3 low-risk active substances and 4 active substances had been approved at EU level.

- **Gaston Maria Funes**, **Minister Counsellor of Agricultural Affairs from the Embassy of Argentina to the EU**, thanked the Commission for the opportunity to provide comments during the public consultation on the Impact Assessment on EDs. He asked how the Commission would effectively consider the input made by third countries. Gaston Funes expressed that Argentina shared the same concerns about the protection of public health and the environment, which are political priorities. He highlighted that any regulatory decision had to be science-based and respect multilateral fora. Argentina estimates that the process would imply a significant negative impact on trade (e.g. the production of soil beans in Argentina would decrease by 20%). Gaston Funes highlighted that the principles agreed in the WTO SPS&TBT Agreements should be respected, measures should not restrict trade more than necessary and alternatives measures such as GAP, MRLs, controls, etc., had to be considered. According to him, the precautionary principle in the EU affects customary international law and basic principles of sanitary and phytosanitary policies and legislation (e.g. EU general food law-Regulation EC 178/2002, Art.7 and PPP- Regulation EC 1107/2008). He claimed that the ED initiative went beyond the criteria of the SPS Agreement (notably Art. 5.7) and restricted trade more than necessary without considering alternatives. Possible impacts could be: decrease of agricultural production, economic and environmental costs associated to the lack of replacement of substances, impact on international trade, discouragement of innovation and investment and socioeconomic impacts (job losses) in countries exporting to EU. Gaston Funes requested high transparency during the whole process, cooperation among different sectors (public and private) to encourage further developments and research and to monitor the progress of scientific evidence on this matter in international fora (OECD, WHO, FAO, Codex).

- Session 4 also included a presentation by **Michelle Cooper**, **Counsellor and Head of Section, Agriculture and Environment from the Mission of Canada to the EU**. She informed that Canada had also sent comments during the public

consultation last January. Canada claimed that the EU's approach was based solely on hazard rather than risk analysis and this was inconsistent with international accepted risk-based assessment practices. Commitments to the WTO and multilateral trading system, as well as international standard organizations should be respected. She informed that Canada uses a risk-based rather than hazard-based approach to assess pesticides safety, taking into account risk=hazard x exposure, according to international practices. Michelle Cooper indicated that the process could negatively impact how MRLs were established. The negative trade impact would be high for Canada and also for the EU, the world's biggest agricultural exporter and largest exporter overall, provoking restricted access to some products, increasing costs and reducing competitiveness. She complained that the options proposed in the roadmap did not include a risk-based approach and WTO members should not adopt measures more trade-restrictive than necessary. Any decision has to be science-based and consistent with international obligations.

- In the Q&A session, one **OECD representative** asked what Canada and Argentina were doing to help the EU with this process instead of merely criticizing and adopting the industry's position. Argentina replied that some Committees had been created to analyse the situation and how to raise this issue at international fora. Regarding IPM in Argentina, Gaston Funes indicated that there were many different strategies including agricultural and social programmes. He informed that a national Committee chaired by the Ministry of Health were investigating suspected harmful pesticides and different activities integrating stakeholders were being developed. Canada replied that their position was not the industry's views and they cooperated in international fora such as OECD.

- **Session 5**, **"Potential impacts on health and environment"**, was introduced by **Julie Girling MEP**, **Member of the EP's ENVI Committee** who indicated htat the WHO 2012 study showed that there were gaps regarding EDs. **Angeliki Lyssimachou** from **PAN (Pesticides Action Network)-Europe** stated that pesticides were deliberately made to be toxic to living organisms. She claimed that several pesticides were ED and combined with low solubility, the result was the contamination of ecosystems. She complained that the EU releases 300.000 tonnes of pesticides/year, which made it amongst others extremely important to prevent exposure of foetuses and babies to ED. According to her, EDs-related concerns included reproductive dysfunctions, as well as metabolic, neurodegenerative and neurodevelopmental diseases. Current risk assessments failed to protect human health and environment from EDs. The expert from PAN claimed that there were 50 pesticides with ED properties, 31 of them able to cause adverse effects. After the implementation of the ED roadmap, these 31 pesticides could be discarded as harmful. She stressed that alternatives to EDs were available and that the Commission should not use the IA to decide upon science-based ED criteria.

- **Génon K. Jensen**, **Executive Director from HEAL (Health and Environment Alliance)**, signalled that 70 organisations in 28 countries were promoting health and environmental policies. According to HEAL, to regulate EDs is one of the

biggest opportunities to reduce adverse effects (to tackle huge health costs, prioritise vulnerable groups and prevent chronic diseases).

- Finally, **Professor Andreas Hensel**, the **President of the German Federal Institute for Risk Assessment** made a presentation suggesting a weight of evidence strategy and expert judgement to decide case-by-case in which category a substance had to be included. The steps of the assessment largely reflect Options 2 – 4b of the 'roadmap' document: Step one would determine, if there is evidence that WHO/IPCS criteria are fulfilled. If so, a substance would be classified as an ED. If there is no clear evidence but a suspicion, additional criteria should be taken into consideration, namely potency, reversibility, reproducibility and scientific validity. On this basis, a simple decision matrix can be created that allows screening of a high number of substances. A test-run with 39 substances led to highly reproducible, consistent results. According to the German BfR, socio-economic criteria should not be used because they do not fit into a science-based concept. He indicated that they supported the option 4.b, which would be in compliance with international concepts, stop the use of interim criteria and deliver a high level of protection of human health.