From: [redacted] (SANTE)
Sent: 20 October 2016 15:42
To: [redacted] (SANTE)
Cc: [redacted] (SANTE); [redacted] (SANTE); [redacted] (SANTE); [redacted] (SANTE)
Subject: BTO - 19/10/2016 – Event organised by MEP BUSOI (EPP/RO) on how to Manage Endocrine Disruptors, 15:00-17:00, JAN 6Q2 European Parliament

[redacted]
Please find below the BTO of the meeting at EP yesterday, prepared by [redacted].
[redacted]

BTO - 19/10/2016 – Event organised by MEP BUSOI (EPP/RO) on how to Manage Endocrine Disruptors, 15:00-17:00, JAN 6Q2 European Parliament

High number of participants, which according to MEP BUSOI, reflects the interest in the topic.
MEP BUSOI indicated that there is no legal vacuum concerning EDs in the EU legislation (interim criteria in place) and that the draft criteria put forward by the Commission in June are good and balanced.

Event organised around two sessions:

I/ How to assess the proposals made by the EU Commission for PPP and BP

- MEP GIESEKE (EPP/DE)
- - stressed the need to have an objective discussion with no emotions. He recognised the complexity of the situation.
- - agrees with the WHO definition, but stressed the need to protect HH and ENV defining rules which farmers and industry can live with;
- - mentions that the concept of potency should be considered in the criteria and mentions that dose makes the poison
-
- [redacted] (Tech University of Munich)
- stressed that potency should be considered otherwise a lot of compounds which pose no risk will be banned
-
- [redacted] (Endocrine society)
- expressed concerns about the criteria presented by the Commission: they are not protective enough of HH and ENV (cf scope of the criteria); the amendment to the derogation is not in line with COM's legal mandate; categories should be included
-
- [redacted] (Bayer)
- indicated that there is consensus on: the WHO definition of an ED; the need to regulate EDs and under realistic conditions of exposure; the fact that interim EDs are not fit for purpose.
- He mentioned substances which would be identified as ED with the criteria without posing risk for certain uses for which they are needed: iodine, caffeine, vitamin D and insect growth regulators). In

particular Vitamin D, identified as ED, was not considered to pose a risk by the RMS ([redacted]) since the exposure associated to the use as a biocide would be in the range of the Vitamin D intake level.

- He mentioned that the draft criteria do not provide for exceptions for natural chemicals.
- He indicated that the amendment proposed to the PPP derogation is a step in the right direction but is not enough as regulating by derogations is not the solution (very lengthy process and very resource consuming for all parties including regulators).
- He wondered why Option 4 was not chosen given that the IA concluded that the protection of HH and environment is expected to be the same as for Option 2.

Questions from [redacted] (Greens advisor); Pan Europe; HEAL and BASF to [redacted] and [redacted] on the relevance of animal studies, the relevance of categories; at which stage potency should be considered and the link between toxicology and epidemiology.
COM ([redacted]) intervened to clarify that the criteria consider all data – including animal data and in-vitro data and this is evident if the criteria are read in their integrity and not limited to the first paragraphs. The criteria also assume that these data are relevant for humans unless proven otherwise, and seek to assess them with a weight of evidence approach. COM also gave indications about the next steps (a revised version of the draft acts will be discussed soon).

II/ What could be the forthcoming approach for Regulations such as REACH and Cosmetics products?

- MEP DANTIN (EPP/FR), on behalf of MEP GROSSETETE (EPP/FR)
- Recognised that the criteria proposed are the 1st worldwide in a regulatory context, based on science and on the WHO definition. He said the criteria put forward were balanced but needed to include the notion of "presumed".
- He recognised that the proposed amendment is interesting, but that the issue of the legal mandate of the Commission needs to be further investigated. He would welcome the Commission's comments on the opinion from the EP LS.
-
- [redacted]
- presented the conclusion of the 2014 Memorandum of the Scientific Committee on Consumer Safety supporting the use of risk assessment to assess endocrine disruptors.
- mentioned, based on her experience, that the results of animal testing are good predictors of human adverse effects
- asks to consider hazard and exposure when assessing / regulating chemicals
-
- [redacted] (ECHA) presented the comments made by ECHA to the draft criteria and explained how ECHA has already identified a few EDs under REACH using the WHO/IPCS definition.
-
- [redacted]
- made a presentation discussing how the weight of evidence approach should be interpreted. In particular a WOE should be transparent and quantifiable, and consider that mechanisms are receptor based, the existence of dose responses and thresholds, and that hormone levels are naturally fluctuating.
-
- [redacted] presented the REACH provisions on EDs, and explained the generic risk approach in the EU legislation ("cut-off"), which is a political choice.

Questions from [redacted] (Greens advisors)

MEP BUSOI concluded that, following the discussion in this meeting, further reflection should be given to the consideration of exposure and potency for the assessment of endocrine disruptors.