From: (SANTE)
Sent: 17 March 2016 08:39
To: JUELICHER Sabine (SANTE); MIKO Ladislav (SANTE)
Cc: (SANTE)
Subject: FW: BTO of meeting Commissioner/SANTE with toxicologist SCCS) on 10 March 2016

Please see below the minutes of the meeting between and Commissioner Andriukaitis, as prepared by .

Participants
(Scientific Committee For Consumer Safety, SCCS)
Commission: V. Andriukaitis, N. Chaze,

- The Commissioner thanked for accepting to meet, asked his views on how to assess endocrine disruptors (EDs) and how to possibly approach toxicologists and endocrinologists on this topic.
- suggested to set a high level of precaution for EDs by considering early *in vivo* hormonal effects (e.g. results from uterotrophic assay). On the other hand, insisted that a risk based approach is vital, since exposure and hazard characterization need to be considered when assessing EDs, like for any other chemical. The relative potency and exposure levels of phytoestrogens contained in food should also be taken into account when assessing risk from EDs.
- mentioned the importance of considering potency. Even the drug diethylstilbestrol (DES), probably the most potent ED ever known, shows a dose-response curve and has no adverse effects below a certain threshold. Banning many EDs based on in vitro studies makes no sense. An in vivo effect should be observed to confirm the hazard and then case-by-case risk assessment should be the base for any risk management decision.
- stressed the importance to have a full set of studies. This is the case for pesticides and biocides, while often not the case for cosmetics and chemicals under REACH. For cosmetics, it will be necessary to rely on available information, due to the ban of animal testing. In general, management decisions should also consider data available on feasible alternatives when banning a chemical.
- When asked views on option 3 of the roadmap, indicated that consumers need clear messages, particularly in such a complex topic: criteria should differentiate whether a chemical is an ED or not, avoiding intermediate categories which would raise confusion (a suspected or potential ED could be often interpreted as an ED).

- [redacted] pointed out that the dispute about risk-versus-hazard is similar in the case of glyphosate: while IARC only assessed hazard (suggesting it is a probable carcinogen), EFSA concluded that the risk assessment (considering hazard AND exposure) is acceptable for this substance. As an example, [redacted] reminded that formaldehyde is a known carcinogen formed in humans from endogenous production (e.g. due to metabolisms of amino acids) but at doses posing no risk to our bodies (i.e. exposure is low enough to pose no risk).
- The Commissioner asked whether [redacted] would be available for another meeting before summer.