

- Take out general reference to mixtures; mixture toxicity is relevant when considering exposure aspects. The WHO definition of an ED refers to “defined mixtures”, which is not the same thing.
- Remove reference to “equivalent level of concern to CMR” – need exposure considerations, i.e. out of this mandate
- Make it clear that potency should not be used as a single criteria for hazard characterisation; the whole body of evidence should be considered for the latter. Avoid using potency considerations in the absence of exposure data
- Irreversibility consideration allows for judgement on severity, which is part of hazard characterisation - Consider relevant text from the “windows of exposure” section – already partly

Action:

- [REDACTED] *with his example on bird seeds (no potency without exposure considerations)*
- [REDACTED] *to draft a paragraph on irreversibility and severity*
- [REDACTED] *to update the section on severity/potency*

- **Thresholds (Section 5.3):**

The endocrine system in humans works with thresholds. However the rationale for the advocated hazard-based approach proposed for the assessment of EDs is that no threshold exist for these substances

Acknowledge that this issue is still under discussion; the Scientific Committee is not in position to explore this issue deeper

Action: - [REDACTED] *to draft a short section on thresholds*

i. Conclusions / recommendations

Repeat that this document focussed on the hazard assessment of chemical substances in terms of their endocrine disrupting properties, and therefore does cover the full risk assessment paradigm. As a consequence, risk managers should take further information from exposure scenarios in order to discuss possible levels of concern and decide on risk based management options. [proposal inserted in conclusion section of version 2

The WHO/IPCS definition is very unspecific in some way; given existing knowledge, can only identify EDs working via EATC mode of action. However the Scientific Committee agrees that the same criteria for identification should apply to all endocrine systems.

Discussion in relation to hazard characterisation of lead effect, or potency require also to consider exposure aspects; which implies to move from a hazard based approach to risk assessment considerations. The Scientific Committee is of the opinion that **endocrine disruptors and their adverse effects should be treated just like any other chemical of concern for the human health or the environment, i.e. be subject to a risk assessment.** As such, endocrine effect should be considered secondary to serious toxicity. The definition of two criteria (mode of action and adversity) to characterise an ED is a poor substitute to a risk assessment. It is suggested, when reporting the hazard assessment to the risk manager, to