best wishes

[redacted]

On 21 Feb 2013, at 11:48, BOTTEX Bernard <Bernard.BOTTEX@efsa.europa.eu> wrote:

Dear All,

Thank you for all the feedback regarding the UNEP/WHO report. I attended yesterday the DG ENV ad-hoc meeting of Commission Services, EU Agencies and Member States where the report was presented by [redacted]

The WHO report was received extremely positively by most of the participants, confirming the position that there is a need to act urgently and reduce the exposure of consumers to man-made EDs. The 2002 report was focussing on a limited group of chemicals: PCBs, dioxins; the 2012 report, after reviewing over 2500 references, identified over 800 chemicals with ED properties. If a lot of work has been done for some of them, for the majority, there is no data available.

The report is on the same line as our opinion regarding definition for EDs, criteria, test methods and current limitations.

Critical windows of susceptibility was acknowledged with the remark that every chemical has the capacity to pass the placenta, which implies that you cannot prevent foetus exposure, i.e. protect your sub-population at risk (fertile/pregnant women). I.e. the only solution is a CMR approach (keep in mind that this is a risk management issue, not a risk assessment – you can still assess the risk of a genotoxic carcinogen using a margin of exposure approach)
The report also takes it for granted that some EDs show low dose effects and NMDR properties, and expand on mixtures considerations: individual EDs showing no adverse effect at low dose may show adverse effects when involved in combination with other EDs, although still at low dose.

THEREFORE we do not believe that there is a need to rewrite the opinion but we need to incorporate a couple of changes,

- Cross reference the WHO report in the sections introduction, windows of susceptibility, low dose and NMDRCs, and mixtures. And insert a summary of the WHO work in the appendix A
- reconsider our conclusions: options 2 and 3 of the current conclusions where we explain that EDs should be considered like most other chemicals, i.e. subject to a risk assessment, puts us in isolation compared to the rest of the world, and may be hard to defend considering the uncertainties, lack of data and methods identified. Any suggestion for rewording based on these new parameters will be welcomed

My suggestion would be to say that ED can be identified according to 2 criteria: endocrine activity and adversity. When it comes to levels of concern considerations and priority setting, parameters like severity or potency can be used but the SC is of the opinion that such parameters should not be used in isolation but together with exposure considerations (timing, duration etc...), which implies to move from the hazard based approach for the identification of EDs to a risk based approach for characterising levels of concern and discussing prioritisation.

The SC should acknowledge the importance of a number of issues (mixtures; low dose and NMDRCs, how to deal with human data, guidance for weight of evidence approach, need for testing strategies covering critical windows of exposure) that require urgent follow up to help with the assessment of substances for possible ED properties

Concerning the remarks below from [redacted] and as just stressed by [redacted] please note that nowhere in the document we said that we disregard academic studies; we mention that we did not considerscreen/test methods used for academic research purposes but not internationally standardised. We acknowledged that as part of the weight of evidence approach, all robust data, i.e. not only coming from internationally agreed guidelines, should be taken into consideration.

Kind regards,

Bernard