EUROPEAN COMMISSION

ENVIRONMENT DIRECTORATE-GENERAL
The Director General

HEALTH AND CONSUMERS DIRECTORATE-GENERAL
The Director General

Brussels, 1 August 2014

Summary record

1st Meeting of the Impact Assessment Steering Group on the definition of criteria for the identification of Endocrine Disruptors (EDs)

20 January 2014

DGs present: DG ENV, DG SANCO, SG, DG AGRI, DG TRADE, DG ENTR, DG RTD, DG JRC (via videoconference).
DGs invited but not present: LS, MARE, EMPL, CLIMA, CNECT, COMP.

The meeting was co-chaired by DG ENV and DG SANCO and the participants were welcomed.

The roadmap was presented to the participants. Participants were invited to raise questions and/or views. Points raised:

Scope of the roadmap:

- SG recalled that the concrete deliverables of the PPP/Biocide Regulations are criteria to identify EDs. Therefore, the Roadmap should be focused only on PPP and Biocides. The criteria should focus on PPP and Biocides while only considering implications for other sectorial legislation.

- DG ENTR commented that it would be a missed opportunity if harmonization of criteria is not addressed now, and pointed out that there would otherwise need to be clarification as to when and how it would take place.

- DG ENV added that some legislation (in particular the Water Framework Directive, WFD) requires EDs to be identifiable according to horizontal criteria.

- DG SANCO clarified that harmonisation is needed because the identification of EDs should be consistent across sectors, while regulatory consequences may vary.

Range of options foreseen in the roadmap:

- SG questioned the need for options addressing other sectorial legislation and strength of evidence. The strength of evidence should rather be considered when implementing the legislation (e.g. applying the precautionary principle when evidence leaves doubt).

- DG AGRI, DG ENTR, DG TRADE welcomed the wide range of options presented.

- DG AGRI recommended assessing all the listed options in the IA, and welcomed the inclusion of risk/socioeconomic assessment considerations, including of potency, in decision making but it would prefer to look at the "scientific proofs" instead of the "strength of evidence".

- DG TRADE welcomed the potential inclusion of risk/socioeconomic assessment considerations into decision making in some sectorial legislation (where applicable and / or desired) and indicated that it favours the B and C options (i.e. those including possible amendments of sectorial legislation). As regards the consideration of the strength of evidence, this should be included but more details should be given as what is meant..

- DG ENTR stated that it would be a missed opportunity if the options including risk/socioeconomic assessment considerations were to be taken out.

- DG ENV pointed out that, in the light of discussions under the WFD, the Commission will soon face criticism if socio/economic considerations are not be addressed in some of the legislation regarding authorisation of substances.

- DG SANCO clarified the rationale for the options foreseeing potential amendments of some sectorial legislation: the College should be provided with a complete analysis of all the feasible options and, in this specific case, where there is sectorial legislation with different decision making, amending the legislation may represent a possible solution. DG SANCO also mentioned the potential stigmatisation of substances in category III, in combination with the ban on animal testing in the cosmetics legislation. DG SANCO also mentioned that the impact assessment on criteria should not include pharmaceuticals, although it acknowledged the need for horizontal criteria in relation to the WFD.

- DG ENV clarified that consideration of strength of evidence is needed in the criteria, as it is the best approach to consider all the available evidence. As regards Category III, DG ENV commented that the IA will serve to measure the positive and negative impacts of criteria which include this Category. DG ENV commented that no class of substances should be excluded from this work as the identification of hazard properties must be the same across legislation.

- DG TRADE mentioned that the language concerning trade issues needs to be fine-tuned in the roadmap.

Impact Assessment:

- Some questions were raised regarding the scope and details of the IA. In particular, it was clarified that the focus of the IA will be on Biocides and PPPs, but that the other sectorial legislation that explicitly mentions EDs (i.e. REACH, cosmetics, WFD and the proposal for Regulation on Medical Devices) will be also assessed at a lower level of detail. The assessment of socio economic implications is so far only intended for PPPs and Biocides.

- JRC highlighted that even the 1st study planned (aimed at identifying the substances which fulfil the ED criteria) will not be straightforward, since for some substances there are uncertainties, data gaps, and lack of information.

- Details on potential contractors for the studies supporting the IA need to be worked out in the next weeks by DG ENV and DG SANCO. The IASG will be kept informed.

Next steps:

- Participants were invited to submit to both DG ENV and DG SANCO written comments by January 27, 2014.

- Following the analysis of the written comments a 2nd IASG meeting will most likely be convened in the period 17-21 February.