10th December 2015

# Endocrine disrupting criteria development

# Selected substances for impact assessment

In the framework of the EU's work programme for developing regulatory criteria for endocrine disruptors (ED), the Commission has decided to undertake an impact assessment of the four policy options identified in the 2014 roadmap for that purpose. To this effect, the Commission's Joint Research Centre (JRC) has developed a methodology by which each policy option can be assessed using some 700 selected substances.

The identity of these substances selected to help guide the choice of the final criteria has been published today. The purpose of the Commission's work programme is to examine, across this selection of substances, how well the four policy options can distinguish substances of potential regulatory concern from those of low relevance. The purpose of the screening exercise is not to evaluate whether a substance should, or should not, be considered an ED. The Commission has clearly stated that screening process using these substances does not replace an in-depth regulatory assessment and has no direct regulatory implications (see Commission´s disclaimer[1]). Therefore, the selection of these substances constitutes a supportive element in the process and, as the Commission has stated, it is most definitely not a list of recognised EDs.

It is vital to avoid unfounded conclusions as to the nature of the selected substances, as this could unintentionally result in beneficial substances being subject to stigmatisation and market pressure. Many of these substances, and all those under the Crop Protection and Biocides Regulations have already undergone a full regulatory assessment, and the presence of a substance in the Commission's impact assessment does not imply any change to current uses.

The final criteria are intended to be applied across the European chemicals regulatory framework that encompasses these 700 substances; i.e., the Plant Protection Products Regulation, the Biocidal Products Regulation, the REACH (Registration, Evaluation, Authorisation and Restriction of Chemicals) Regulation, the Cosmetic Products Regulation and the Water Framework Directive. Amongst the selected substances are most crop protection products, all approved biocidal products and some substances regulated according to REACH and the Cosmetics Regulation.

[1] The Commission's disclaimer for this methodology, as presented on 6th November 2015 meeting, reads as follows: "The screening methodology was developed in the context of an impact assessment and cannot replace the regulatory decision-making process of determining the chemicals considered as having endocrine-disrupting properties. The methodology aims at estimating which substances may fall under the different endocrine disruptors impact assessment policy options. The methodology is based on a screening of existing evidence (desk work). No additional experimental data, experimental screening or discussion in scientific committees is foreseen. The screening does not substitute full evaluations of individual substances to be carried out in the context of chemical legislation. Therefore, the screening does not pre-empt the regulatory conclusions that may eventually be made on the basis of such evaluations."

Once this part of the impact assessment is finalised, a second study will evaluate the socio-economic consequences of the four policy options with regards to Plant Protection Products and Biocides. This work shall be completed during 2016, allowing the Commission to then recommend and adopt criteria for identifying EDs.

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About Cefic

Cefic, the European Chemical Industry Council, founded in 1972, is the voice of 29,000 large, medium and small chemical companies in Europe, which provide 1.2 million jobs and account for 17% of world chemicals production.