BKE/001/13E

Mr Björn HANSEN
Head of Unit Chemicals, Biocides & Nanomaterials
Directorate-General for Environment,
European Commission
B-1049 Brussels

Mr Peter KORYTAR
Policy Officer Chemicals, Biocides & Nanomaterials
Directorate-General for Environment,
European Commission
B-1049 Brussels

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Dear Mr Hansen and Mr Korytar

FoodDrinkEurope represents the European food and drink industry, the largest manufacturing sector in the EU in terms of turnover and employment. FoodDrinkEurope works with European and international institutions, in order to contribute to the development of a legislative and economic framework addressing the competitiveness of the industry, food quality and safety, consumer protection, social responsibility and environmental sustainability. FoodDrinkEurope's membership consists of 25 national federations, including 3 observers, 25 European sector associations and 18 major food and drink companies.

Having been aware of your draft proposal for **criteria for classification of endocrine disruptors (ED-AD-HOC-6/2013/02)** presented to the Ad hoc group on 20 February 2013, FoodDrinkEurope would like to put forward some comments on this issue which are of central importance to the EU food and drink industry. Included immediately below are our key comments followed by more detailed ones.

Overview:
For the sake of clarity and in particular to prevent uncertainties for downstream users of substances (including food business operators) FoodDrinkEurope would like to see a single category of endocrine disruptors.

Irrespective of the eventual number of categories, FoodDrinkEurope believes that the definitions underlying the category(s) should be carefully drafted so as to include substances

where there is clear scientific evidence of adverse effects in the context of the WHO definition and to avoid the inclusion of substances where there is not clear scientific evidence nor any realistic risk of an adverse effect.

We would also like to see emphasis on the use of good quality data in decision making. For us it's extremely important to have a proof of causality, so the strengths and limitations of studies need to be part of the discussion.

Substances with endocrine disrupting properties are naturally occurring in certain foods, some of which are well known for their positive contribution for a healthy diet.

Consideration of the potency and exposure to the substance in humans and/or the environment needs to be included when assessing the causal relationship.

Detailed Comments:

FoodDrinkEurope has concerns around the statement that "where there is…information demonstrating that the effects are clearly not relevant to humans and population of animal species living in the environment, category 2 may be more appropriate". We are strongly of the opinion that if effects are clearly not relevant the substance should not be identified as an ED or suspected ED. There is no value in regulating irrelevant effects.

We broadly agree with the proposed criteria to assign a substance 'Category 1', however substances should not be assigned a class on the basis of suspicion only. There must be data and biological plausibility underpinning categorisation. We therefore suggest revising the wording for the first bullet point in Category 1 to read:

- "Evidence from humans or from animal species living in the environment where it is **probable** that the observed adverse effect is endocrine-mediated…"

The same principle should be applied to the second bullet point to read:

- "Experimental studies where it is **probable** that the observed adverse effects are caused by an endocrine mode of action"

Although we strongly believe the best approach is define one only category, if it is eventually decided to go with two categories, then we would suggest rewording Category 2 to read "…where it is **plausible** that the observed adverse effect is endocrine-mediated…"

Likewise, the statement that "experimental animal studies showing an endocrine activity in vivo which is clearly linked to adverse effects in vivo (e.g. through read across)" needs to be further clarified. Presumably this means that once in-vivo endocrine activity has been demonstrated (even if in non-intact animals and by a non-physiological route) this could result in classification. This is contrary to the WHO definition of endocrine disrupter. We are strongly of the opinion that data from non-intact animals dosed via a non-physiological route should not be used in this way.

Under section 4.6 we would suggest adding "… The evaluations shall be based on all existing **relevant** data…"

Section 4.8 mentions that lead toxicity should not be considered since this is not relevant for hazard identification. We have concerns that in a very high proportion of toxicology studies

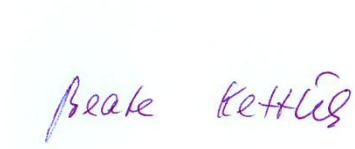
endocrine tissues are affected at high doses, which could result in a high proportion of substances identified as EDs or suspected EDs where this is not a relevant hazard for the material in question. We would propose a system analogous to identification of developmental toxicants, where only those substances considered to be primarily acting on the endocrine system are classified as EDs. Substances with adverse effects at lower doses would already be dealt with through proper risk assessment and risk management for the other, more potent, effects.

We would also like to take this opportunity to request a meeting with DG Environment in order to introduce the viewpoint and concerns of EU food and drink industry.

If you require any further information or clarification on our position, we would be most happy to oblige.

Thank you in advance for your time and consideration

Kind regards,



Beate KETTLITZ
Director Food Policy, Science and R&D