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Sent: 28 May 2013 08:46
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Subject: German comments Endocrine Disruptors / ED-AD-HOC-6/2013/02
Attachments: 11-DE Positionspapier zu ED(final).pdf

Dear colleagues,

At the last ad-hoc meeting of Commission Services, European Agencies and Member States under the Community Strategy for Endocrine Disruptors in February, Member State competent authorities (MSCAs) have been invited to provide comments to the document ED-AD-HOC-6/2013/02, which proposes possible elements for criteria for identification of Endocrine Disruptors.

Considering the far-reaching impact of such criteria on the management of biocides, plant protection products and chemicals, Germany considered it more appropriate to respond at ministerial level.

Please find attached a paper setting out the view of the Federal Government of Germany on criteria for grouping of endocrine disruptors for regulatory purposes.

Kind regards

By order

,
Bundesministerium für Umwelt, Naturschutz und Reaktorsicherheit
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DE Position Paper on Endocrine Disruptors

This paper presents common principles for the evaluation and grouping of substances with effects on the endocrine system. It is designed to be applied in various fields of regulation (plant protection products, biocides, chemicals) for the management of substances (including approval/authorisation).

The approach ensures a high level of protection of human health and the environment and is based on a scientific evaluation of available data. Legal and administrative decisions arising from this evaluation would be proportionate, consistent and predictable, as appropriate. However, categorization and specific and legally binding rules will be set out under the relevant EU-Regulations for the aforementioned groups of substances.

Principles

For management purposes, substances with effects on the endocrine system should be allocated to one of the following three groups:

- Group 1: Endocrine disruptors
- Group 2: Endocrine effective substances
- Group 3: Suspected endocrine effective substances

The identification of a substance as Endocrine Disruptor should be based on the WHO/IPCS (2002) definition in general.

Considering the complexity of the matter, it appears generally inappropriate to base grouping on the outcome of individual tests. Rather, weight of evidence considerations and expert judgement should be used case-by-case to decide on the grouping.

The allocation of a substance into any of the groups mentioned should consider differences regarding the assessment for human health and the environment:

- Provided substances have undergone comprehensive evaluation, current testing and assessment methodologies are generally suitable to derive dose/concentration levels which can be considered safe. While absolute certainty regarding safe dose/concentration levels for substances are generally not achievable, there is no convincing evidence to assume that levels of uncertainty are generally different regarding endocrine disruptors as compared to other toxic substances. Based on considerations on potency in combination with specificity, severity, reversibility and consistency of effect it is possible to allocate substances falling under the WHO/IPCS definition to group 1 or 2 or even dispense such substances from grouping.
- For the environmental assessment the situation is different. First, as also pointed out by the Scientific Committee of EFSA, for major taxa there exists no adequate testing methods and strategies to derive safe dose/concentration level. Second, standard testing methods normally only monitor very severe adverse effects. Third, interspecies variation appears to be higher for substances with effects on the endocrine system as for other toxic substances. As a consequence, substances meeting the WHO/IPCS definition should be allocated to group 1 in general.

Substances should **not be considered endocrine disruptors** when

- the endocrine-mediated adverse effects are only caused as secondary effects of other (non endocrine-mediated) adverse effects;
- the endocrine mediated effects are not decisive for the overall ecotoxicological profile of the substance (as other non-endocrine mediated effects are predominating and/or the observed endocrine mediated effects have been observed under clearly unrealistic exposure conditions).

Criteria for grouping

Group 1: Endocrine disruptors

Substances are placed into group 1 if their intrinsic properties comply with the WHO/IPCS definition (2002) and if they are of **high regulatory concern** because they meet one or both of the conditions below:

- There is sufficient weight of evidence information leading to the assumption that the substances have caused or may cause endocrine-mediated **adverse effects in humans** at generally **low dose levels** taking into account specificity, severity, reversibility and consistency;
- There is reliable and good-quality evidence that the substances cause population-relevant endocrine-mediated **adverse effects in wildlife – animals**.

Substances allocated to this group should generally be subject to a **hazard-based management approach**.

Group 2: Endocrine effective substances

Substances are placed into group 2 if their intrinsic properties comply with the WHO/IPCS definition (2002) and if they meet the following condition:

- There is sufficient weight of evidence information leading to the assumption that the substances have caused or may cause endocrine-mediated **effects in humans** at generally **moderate dose levels** taking into account specificity, severity, reversibility and consistency;

Substances allocated to this group should generally be subject to a **risk-based management approach**.

Group 3: Suspected endocrine effective substances

Substances are placed into group 3 when there is some evidence that they affect the endocrine system but where such evidence is insufficient to decide whether the WHO/IPCS definition is met.

Further examination of the substances (e.g. substance evaluation) may eventually lead to allocation into group 1 or group 2 or even dispense such substances from grouping.

Exemptions

By way of derogation, active ingredients of plant protection products and biocidal products which meet the criteria of group 1 but are intended endocrine disruptors to the target organisms should be subject to a risk-based management approach. While a hazard for phylogenetically closely related non-target organisms (from the group of invertebrates or plants) due to the endocrine disrupting action is

obvious, these pesticides typically show a rather low toxic potential for vertebrates (including humans).
