BfR welcomes the scientific criteria of the European Commission for identifying endocrine disruptors

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The European Commission has presented a draft on how endocrine-disrupting chemical substances ("endocrine disruptors") contained in the active ingredients of pesticides and biocides can be identified using harmonised scientific criteria. The definition of these criteria is a binding foundation for the regulation of endocrine-disrupting substances in order to warrant a high level of protection for consumers.

The draft considers suggestions on hazard identification of endocrine-disrupting substances which scientists developed in April in the course of an international conference organised by BfR and held in Berlin. According to these suggestions, a comprehensive scientific analysis with regard to the definition of the WHO must be carried out when identifying such substances, and the insights must be weighted based on their conclusiveness, (weight-of-evidence approach).

The Federal Institute for Risk Assessment (BfR) has recommended for many years that for endocrine-disrupting substances the principle of "one substance – one assessment" must apply. The institute is of the opinion that the assessment criteria which the European Commission has recommended for pesticides and biocides should be applicable to all naturally occurring and synthetically produced substances that have a negative effect on the body's hormone system.

BfR recommends that harmonised technical guidelines are developed in order to enable transparent and safe identification of chemical substances. In order to ensure a high level of protection, a given endocrine disruptor should be identified on the basis of the weight-of-evidence approach which, among other things, takes into account the quality, reliability, reproducibility and conclusiveness of the scientific evidence.

BfR welcomes that, in addition to the mentioned criteria, the communication of the European Commission also lists a series of measures and their funding in order to support research and international cooperation, as well as the development of testing methods.

The European Commission has presented a draft on how harmonised criteria for the identification of endocrine disruptors can be defined in the areas of pesticides and biocides. The definition of such criteria is a precondition for a standardised science-based approach to the identification and regulation of endocrine-disrupting chemical substances. The draft is based on the definition of endocrine disruptors of the World Health Organisation (WHO). In its draft, the Commission took into account the scientific consensus on the definition of endocrine disruptors as well as the principles of identification of these substances. This consensus had been developed and published on the occasion of a conference attended by scientists from a range of different disciplines that had been organised by BfR and held in Berlin in April.[1]

BfR is acting on the assumption that the presented criteria based on the fundamental principle "One substance – one assessment" can be applied to all naturally occurring and

[1] The BfR publishes a workshop report on the expert meeting on endocrine disruptors: http://www.bfr.bund.de/cm/349/the-BfR-publishes-workshop-report-based-on-the-expert-meeting-on-endocrine-disruptors.pdf

synthetically produced substances in order to minimise exposure to endocrine disruptors overall. Endocrine disruptors can have severe effects on health and the environment, and they are already banned for use in pesticides and biocides. The goal now is to be able to regulate them for other products as well. For this purpose, the substances must be identified based on scientific criteria which are implemented in law.

The criteria for identifying endocrine disruptors can offer a high level of protection for human health and the environment provided that the identification of an endocrine disruptor considers all relevant scientific insights and that these insights are weighted in accordance with their conclusiveness (weight-of-evidence approach). To ensure that this is the case, the aspects of consistency, specificity or limit dose must be defined in detail. The Commission subscribes to the broad scientific consensus which states that the potency of a substance should not be considered when identifying endocrine disruptors. In contrast, its potency must be taken into account when assessing the actual risk posed by endocrine disruptors.[2]

However, for the purpose of the two legal acts in the areas of pesticides and biocides, BfR considers the development and alignment of harmonised technical guidelines for practicable decisions of all EU authorities to be essential. In line with the communication of the Commission, these guidelines can then serve as a basis for transparent and safe identification of chemical substances. In order to provide a high level of protection, the identification of endocrine disruptors should be based on the weight-of-evidence approach. This notably means that the quality, reliability, reproducibility and conclusiveness of scientific evidence must be taken into consideration in accordance with internationally agreed study protocols (*in-vivo* studies or adequately validated alternative testing systems that enable prediction of harmful effects in human and animals as well as *in-vivo*, *in-vitro* and mechanistic studies to determine endocrine effects). The specificity of the effect and the limit dose are also incorporated in this robust systematic test procedure. BfR acts on the assumption that in developing these guidelines, the consensus paper adopted at the workshop in April can offer valuable support.

BfR especially welcomes that over and above the mentioned criteria, the communication of the Commission also contains a list of measures and their funding in order to support research and international cooperation as well as the development of testing methods. The EU Commission has additionally asked the European Food Safety Authority (EFSA) and the European Chemical Agency (ECHA) to jointly investigate whether individual approved substances for which indications exist that they have endocrine disrupting properties can be identified as endocrine disruptors based on the presented criteria.

Background information on the WHO definition of endocrine disruptors and adverse effects:

The scientific criteria recommended by the European Commission are based on the definition of endocrine disruptors by the World Health Organisation (WHO), on which broad consensus exists (BfR 2016).

The WHO defines a substance as an endocrine disruptor if

- it has an adverse effect on human health,
- it has an endocrine mode of action and

[2] http://ec.europa.eu/health/endocrine_disruptors/docs/com_2016_350_en.pdf

- a causal relationship exists between the adverse and endocrine mode of action (WHO/IPCS 2002).

In 2009, adverse effects were defined which the Commission based on the definition from the International Programme on Chemical Safety (WHO 2009): *"A change in the morphology, physiology, growth, development, reproduction or lifespan of an organism, system or (sub)population that results in an impairment of functional capacity, an impairment of the capacity to compensate for additional stress or an increase in susceptibility to other influences."*

Further information on the topic of endocrine disruptors can be found on the BfR website:

http://www.bfr.bund.de/en/international_expert_meeting_on_endocrine_disruptors-197246.html

http://www.bfr.bund.de/en/a-z_index/endocrine_disruptors-130013.html

References

Press release of the European Commission: http://europa.eu/rapid/press-release_IP-16-2152_de.htm

COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT AND THE COUNCIL on endocrine disruptors and the draft Commission acts setting out scientific criteria for their determination in the context of the EU legislation on plant protection products and biocidal products:
http://ec.europa.eu/health/endocrine_disruptors/docs/com_2016_350_en.pdf

Publication of the EU Commission on the subject of "Endocrine Disruptors":
http://ec.europa.eu/health/endocrine_disruptors/key_publications/index_en.htm

WHO (2009). International Program on Chemical Safety, Principles and methods for the risk assessment of chemicals in food. (Environmental Health Criteria), 2009

BfR (2016) Workshop report from the expert meeting on endocrine disruptors:
http://www.bfr.bund.de/cm/349/the-BfR-publishes-workshop-report-based-on-the-expert-meeting-on-endocrine-disruptors.pdf

About the BfR

The Federal Institute for Risk Assessment (BfR) is a scientifically independent institution within the portfolio of the Federal Ministry of Food and Agriculture (BMEL) in Germany. It advises the Federal Government and Federal Laender on questions of food, chemical and product safety. The BfR conducts its own research on topics that are closely linked to its assessment tasks.

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