The BfR publishes workshop report based on the expert meeting on endocrine disruptors

BfR communication No. 11/2016, 4 May 2016

On the occasion of an expert meeting organised by the Federal Institute for Risk Assessment (BfR) held in Berlin on 11 and 12 April 2016, a consensus was reached on the identification of endocrine disruptors. The BfR has now published the workshop report from the conference. It contains, among other things, the consensus paper agreed by all participants. The report is published at http://www.bfr.bund.de/cm/349/scientific-principles-for-the-identification-of-endocrine-disrupting-chemicals.pdf

The presentations given at the meeting as well as a preliminary conclusion from the conference are available as videos on the website of the BfR: http://www.bfr.bund.de/en/international_expert_meeting_on_endocrine_disruptors-197246.html

The consensus paper was published in the scientific journal Archives of Toxicology http://link.springer.com/article/10.1007/s00204-016-1866-9.

Twenty-three internationally renowned scientists took part in the meeting. In addition, four observers from the European Commission, the European Food Safety Authority (EFSA) and the European Chemicals Agency (ECHA) were present. Among other things, the consensus paper lists the criteria for identifying endocrine disrupting substances. The scientific principles are an important precondition for creating uniform criteria at EU level as a basis for future human health assessments of substances and products with endocrine disrupting properties. The results of the meeting may therefore support the European Commission in developing regulatory criteria for the identification of endocrine disruptors in pesticides and other chemicals and products.

The expert meeting was designed as a discussion platform for scientists. Hosting the event, the BfR sought to facilitate the exchange of ideas between scientists viewing the issue from different standpoints. As a scientific institution for risk assessment in Germany, the BfR began developing and publicising its own scientific position on the identification and characterisation of endocrine disrupting substances a few years ago: http://link.springer.com/article/10.1007/s00003-016-1016-6.

The current discussion focuses on substances or substance mixtures which alter the function of the endocrine system and consequently causes adverse health effects in an ntact organism, or its progeny, or in (sub)populations. Such substances referred to as “endocrine disruptors” include, for example, industrial chemicals or active ingredients in biocides or pesticides. Some endocrine active substances naturally occur in plants, however, for example as ingredients (phytoestrogens). Since such substances in principle play a role in all regulatory areas, it was emphasised that in all regulatory domains procedures and assessment should adopt the “*one substance - one assessment*” principle.

An inalienable condition for legal regulation is, however, that substances with endocrine disrupting effects that adversely affect the health of an organism or its progeny can be identified with certainty within the regulatory framework. Unfortunately, endocrine disruptors are not a clearly defined group of substances which may be identified as such on the basis of

their structural characteristics. Scientific criteria for identifying endocrine-disrupting substances have been the subject of controversial discussion among experts for several years.

At the end of 2014, the European Commission instructed DG Health and Food Safety, to define conclusive criteria for the regulation of endocrine disruptors, so that they could in future be used in European pesticide and biocide legislation. Due to the globally increasing concern with regard to possible adverse effects of endocrine disruptors, active substances used in biocide and pesticide products subject to approval within the EU are in future to be tested more rigorously for endocrine disrupting properties.

The expert meeting held in Berlin on 11 and 12 April 2016 was attended by 23 scientists from Europe, the USA and Japan. They discussed the foundations as well as open questions relating to the identification of endocrine disruptors. The two-day expert conference notably focused on the following questions:

- How should endocrine disruptors be defined in the regulatory context of health **assessment?**
- What are the general principles of endocrine effects from a toxicological, pharmacological and endocrinological viewpoint?
- Which sources of uncertainty influence the identification of endocrine disrupting substances in terms of regulatory decision-making?
- Which adverse effects caused by endocrine disruptors can already be determined using existing testing methods?
- Which scientific research activities should be initiated to ensure better identification of endocrine disruptors?

The goal of the scientific discourse was to discuss questions and, where possible, find solutions to current scientific divergences. Hosting the event, the BfR facilitated the discussion.

Independently from this expert conference, the BfR began developing and publicising its own scientific position on the identification and characterisation of endocrine disrupting substances a few years ago. This concept suggested by the BfR provides for the characterisation of endocrine disruptors by means of a decision matrix based on the principles of toxicological assessment. This characterisation should include:

- the severity of adverse health effects
- the question whether the observed adverse effects are reversible
- the potency of the substance
- and other aspects such as consistency.

These decision criteria should help to categorise substances into one of three groups: ((1) “Endocrine disruptor”, (2) “Suspected endocrine disruptor” or (3) “Endocrine-active substances”). This categorisation is in line with the recommendation of the EU Commission roadmap (European Commission 2014). On the basis of these categories, regulatory decisions could be made, for example in the form of an exclusion from authorisation of endocrine disruptors in plant protection products and biocidal products.

Further information is available on the BfR website under “endocrine disruptors”:
http://www.bfr.bund.de/de/a-z_index/endokrine_disruptoren-32448.html#fragment-2

European Commission 2014: Defining criteria for identifying Endocrine Disruptors in the context of the implementation of the Plant Protection Product Regulation and Biocidal Products Regulation
http://ec.europa.eu/smart-regulation/impact/planned_ia/docs/2014_env_009_endocrine_disruptors_en.pdf