

## **What does the future hold for harmonised human health risk assessment of plant protection products?**

### **Workshop on the optimisation and harmonisation of the risk assessment procedure at the BfR**

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What strategies exist to ensure independent and transparent risk assessment? How can the scientific dialogue be improved between the various stakeholders? These and other questions were discussed by representatives of the EU Commission, the European Food Safety Authority (EFSA), the EU member states, the industry and non-governmental organisations (NGOs) at a workshop on the harmonisation and further development of the risk assessment of plant protection products. The workshop was held at the German Federal Institute for Risk Assessment (BfR) in Berlin, Germany on 23 and 24 November 2017. About 100 participants followed an invitation of the Federal Ministry of Food and Agriculture (BMEL) and the EU Commission to mainly discuss topics that triggers controversial debates within the society. The workshop was a follow-up event organised by the EU Commission in 2015.

In Europe, a highly effective and scientifically based regulatory system has been established for the approval of active substances in plant protection products since 1991. This system should evolve, be optimised and further harmonised. In particular and in view of the recent public debate over the potential health risks of plant protection products more efforts are needed to make the regulatory process of risk assessment even more transparent. Currently, the scientific assessment authorities are only able to make data publicly available to a limited degree due to the legal regulations. Therefore one of the future-orientated outcomes of the workshop was the recommendation that applicants should publish their scientific data so that the details of the assessment process can be fully understood.

The conference report and the presentations given at the workshop are available at [www.bfr.bund.de/en/workshop-203543.html](http://www.bfr.bund.de/en/workshop-203543.html).

The first session focused on the question of how to ensure independent and reliable risk assessment. The experts underlined that various measures are already in place, such as the public commenting phase within the framework of active substance evaluations on EU level. Moreover, information on all stages of the EU assessment process is available to the public in an easy-to-understand format on the EFSA website. There was general agreement that both the studies of the applicants as well as the published literature must be subject to a standardised quality review, and that the underlying study findings must be easily accessible in both cases.

A further question looked at ways of improving the scientific dialogue between assessment authorities and other stakeholders, in particular non-governmental organisations. Experts from NGOs proposed even closer involvement of scientists from civil society and the universities in the process of risk assessment. The assessment authorities called for more intensive participation in the corresponding expert bodies of the authorities. There was general agreement that greater transparency substantiates trust in the assessment process.

The second part of the workshop looked at the implementation of new concepts for the assessment of mixtures as well as the assessment of degradation products of the active substances in plant protection products. The workshop participants agreed that the assessment

process should take greater account of the cumulative effects of active substances and co-formulants.

The representative of the Directorate-General for Health and Food Safety (DG SANTE) of the EU Commission welcomed the open, frank and critical exchange of opinions, saying that it was an important step towards improved communication between the European assessment authorities, member states and stakeholders. The discussions and proposed solutions will also be taken into consideration in the forthcoming review of European legislation in the area of plant protection products.

The workshop "What does the future hold for harmonised human health risk assessment of plant protection products ?" was a follow-up event connected to a dialogue event on the risk assessment of active substances in plant protection products organised by the EU Commission in 2015.

<http://www.bfr.bund.de/cm/343/eu-kommission-diskutiert-kritische-fragen-bei-der-bewertung-von-pflanzenschutzmittelwirkstoffen.pdf> – in German)

**You can find more information on the topic of plant protection products on the BfR website:**

[http://www.bfr.bund.de/en/a-z\\_index/plant\\_protection\\_products-130188.html](http://www.bfr.bund.de/en/a-z_index/plant_protection_products-130188.html)



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### **About the BfR**

The German 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.

*This text version is a translation of the original German text which is the only legally binding version.*