

Experts discuss how to further standardise the assessment for safe use of plant protection products

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Assessment of the health risks posed to operators and uninvolved third parties during and after application of plant protection products is to be further standardised in the zonal authorisation procedure within the European Union. In the opinion of the Federal Institute for Risk Assessment (BfR), this is an important outcome of the “European Conference on Safe Use of Plant Protection Products”, which the BfR organised together with the European Commission, Directorate General for Health and Consumers in Berlin on 18 and 19 June 2014. As an important step towards harmonisation, the new draft of the European Food Safety Authority (EFSA) “Guidance on the Assessment of Exposure for Operators, Workers, Residents and Bystanders in Risk Assessment of Plant Protection Products” was discussed during the conference. In addition to exposure, i.e. type and extent of absorption of active substances, the experts exchanged views on additional aspects relevant to the assessment such as standardised derivation of the amount of active substance potentially absorbed through the skin and better harmonised measures to minimise risks. The more than 50 participants represented the European Commission, EFSA, and the competent authorities from the Member States and European associations.

Estimating the exposure of operators and uninvolved third parties (workers, bystanders and residents) constitutes an important part of health risk assessment, especially in the approval procedure of plant protection products. For the assessment, conducted as part of the approval procedure and the subsequent mutual recognition, EU competent authorities currently still use differing strategies and models. This may result in different outcomes of the assessment. Additionally, the underlying data are partially out of date, meaning that they do not always completely reflect the current application technique and practice of the use of plant protection products. With the new document “Guidance on the Assessment of Exposure for Operators, Workers, Residents and Bystanders in Risk Assessment of Plant Protection Products”, EFSA presented a harmonised guidance for all Member States. This guidance also contains a new model for exposure estimation for the use of plant protection products, which is based on extensive and current study results and to which the BfR made a major contribution. In addition, the guidance describes how exposure can be better estimated according to uniform criteria for re-entry tasks and for uninvolved persons. To ensure further harmonisation in the zonal authorisation of plant protection products, it is also important to further standardise the derivation of dermal absorption values to be used in risk assessment and the assignment of risk mitigation measures within the European Union.

In the view of the BfR, the conference yielded the following essential results:

1. There was broad consensus among the experts that the new EFSA draft “Guidance on the Assessment of Exposure for Operators, Workers, Residents and Bystanders in Risk Assessment of Plant Protection Products” should be accepted by the Member States. In order to achieve harmonisation, applicants and competent authorities should use this guidance in future zonal approval procedures.
2. There was also agreement that the guidance should be regularly revised and expanded in regard to implementing additional exposure scenarios such as greenhouse applications.
3. It was considered very important that in the future a uniform standard should be used to estimate values derived from dermal absorption studies conducted on plant protection products. Therefore, the latest study findings must be taken into account for this purpose.

4. Representatives of EU Member States emphasised the necessity of more uniformly defined risk mitigation measures as part of zonal approval processes.

Further strategies for the exchange of information between the experts even for other relevant fields of plant protection product assessment are to be developed and coordinated by the European Member States. In coordination with the European Commission, a conference report will be published soon on the BfR website. The presentations given during the conference are available at

http://www.bfr.bund.de/en/overview_of_the_presentations_at_the_european_conference_on_safe_use_of_plant_protection_products_on_18_and_19_june_2014-190878.html