EU Commission discusses critical issues in the assessment of the active substances in plant protection products

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The EU Commission invited experts from EFSA, ECHA, member states, and interested parties from industry and non-government organisations to a “Dialogue event on risk assessment of active substances in plant protection products” on 24 April 2015 in order to discuss critical issues in the assessment of the active substances contained in plant protection products. The eight expert panels with moderation discussed the independence of the authorities, as well as fundamental assessment criteria and procedures in the assessment of the health risks of the active substances in plant protection products.

The event had its background in critical references made in the course of public discussion of the risk assessment of plant protection products and their active substances. During public consultation on the pesticidal active substance “Glyphosate” in 2014, many comments dealt with general issues which went beyond the health-based risk assessment of the active substance. For this reason, the Federal Institute for Risk Assessment (BfR) recommended at the EU Commission’s Standing Committee on the Food Chain and Animal Health (SCOFCAH) in October 2014 that these open questions should be discussed jointly with all stakeholders.

The EU Commission’s Directorate General Health and Food Safety welcomed the lively discussion of the critical issues with interested stakeholders and the frank and critical exchange of opinions at this dialogue event which constituted the first step towards improved communication between the European assessment authorities, member states and stakeholders, as well as NGOs, producers and plant protection product manufacturers. In the opinion of the BfR, the event concept was very well suited for mapping out new solution paths for health risk assessment.

The first topic of discussion dealt with a possible conflict of interests raised by studies conducted by the industry on the authorisation of plant protection products. The experts emphasised that various measures in the assessment process have a conflicting influence. These include transparency in the authorisation process of the active substances and the peer review process introduced by the European Food Safety Authority (EFSA), as well as the possibility of accepting comments from the EU member states and general public. The participants also pointed out that as the manufacturer, only the industry has to provide proof of safety. This responsibility also necessitates the preparation and funding of studies which are legally required as the basis for risk assessment and management decisions.

Another question was the extent to which the independence of the experts in the European assessment authorities in the approval of active substances is ensured. Representatives of the member states and the EFSA explained the various systems established among them to avoid conflicts of interest. It is also ensured on a European level that the EU assessment is accessible and open to scrutiny in all stages via the EFSA website.

There was consensus that studies commissioned by the applicants, as well as published literature, must be subjected to a harmonised quality and compliance test. The participants considered the so-called “Klimisch score” that is currently used to be one usable method for the assessment of reliability of toxicological studies, but they also discussed how it could be further developed in future. Some thought was also given to taking other factors, such as quality and good toxicological practice, more into account in addition to the factor *reliability*.

The use of oral toxicity studies for risk assessment of operators, workers, bystanders and residents usually constitutes a suitable basis for human health risk assessment, particularly under consideration of animal welfare provisions.

The use of historical control data must be evaluated individually on a case by case basis and must not be allowed to contribute towards counteracting indications of the adverse health effects of a toxicological study. Historical control data can also contribute towards the quality assurance of existing studies.

The participants had a lot of intensive and controversial discussion in the panel on the need for further research and data requirements on carcinogenicity and reproductive toxicity especially about the regulatory inclusion of presumed “low-dosage effects”, mainly with regard to endocrine effects. There was agreement, however, that the examination of extremely high doses in the toxicological studies is not supported. According to the current level of available knowledge, a general expansion of the test requirements for active substances is not considered necessary, but a critical review of the legal regulations including improvement and refinement of data requirements should be initiated in the next few years.

The participants ascertained that the assessment of toxicological properties of co-formulants and their relevance for residues in food can be improved. It was suggested to establish an EU-harmonized tiered approach to identify potential substances of concern routinely and define the data needed for an assessment of their residues. To do so, the applicants should address co-formulants as a matter of routine in future and use data from the REACH process in a more practicable manner.

The experts discussed finally, if more extensive toxicological investigation of co-formulants for a better assessment of cumulative and mixture effects between the active substance and the co-formulants is necessary. It was agreed that the assessment of cumulative effects between active substances and co-formulants is of immense importance. To do so, it is necessary for data from the REACH process in particular to be available in a practicable form. Technical guidelines should be prepared and in particular more research activities on the suitability of alternative methods to animal testing should be initiated in order to improve regulatory assessment.

A synoptic report by the European Commission has been published in the following website:

http://ec.europa.eu/dgs/health_food-safety/dgs_consultations/docs/dgs-consultations_working-groups_20150424_summary_en.pdf