Risiken erkennen – Gesundheit schützen

BfR compilation of residue definitions for pesticides

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The term ‘pesticide residue’ refers to the parent active substance itself and to metabolites and/or breakdown or reaction products of the active substance, all of which may be contained in food and feed products or drinking water. The number and nature of components in the residue varies from pesticide to pesticide. In some cases only the parent compound is detected whilst in other cases numerous metabolites are formed which may have to be considered, too. For each pesticide which is intended for use on food or feed crops, the relevant residue has to be defined for both risk assessment and enforcement/monitoring. Consequently, two different residue definitions may be established, one for risk assessment and one for enforcement/monitoring purposes.

Whereas the residue definitions for enforcement/monitoring are laid down in the EU MRL (maximum residue levels) legislation for pesticides, the residue definitions for risk assessment are often only available to people who are actually involved in the authorisation of pesticides, but not to other interested parties. In response to numerous requests, BfR now provides a compilation of residue definitions for both risk assessment and enforcement/monitoring.

This tool is primarily intended for experts who are familiar with the risk assessment of pesticide residues in food and feed (e.g. experts from regulatory authorities involved in monitoring and enforcement or experts dealing with quality control or risk management).

1 How residue definitions are derived

The establishment of a residue definition is a case-by-case decision. For guidance purposes, the reader is referred to the FAO Manual [1] and to the OECD Guidance Document on the Definition of the Residue [2].

The residue definition for enforcement/monitoring is mainly restricted to compounds which would typically account for a substantial proportion of the residue (‘marker compounds’). This can be used to indicate possible misuse of the pesticide and this can be analysed and quantified easily by a broad base of national laboratories (ideally by a multi-residue method). Residue definitions for enforcement/monitoring are supposed to be as simple as possible and are ideally based on one analyte only, often the active substance itself. A monitoring method based on only one analyte can be used more easily by compliance authorities and minimizes the need to obtain expensive reference compounds. Residue definitions for enforcement/monitoring have been published together with the corresponding MRLs (maximum residue levels) in Commission Regulation (EC) No 396/2005 [3] and respective follow-up regulations. Current MRLs and corresponding residue definitions are available from the EU Pesticides Database [4].

The residue definition for dietary intake estimations and risk assessment needs to take into account all residue components of toxicological interest and usually includes the parent compound together with all toxicologically relevant metabolites and/or breakdown or reaction products. The various factors for exposure potential and relevant toxicity are considered for all these compounds. The resulting residue definition forms the basis for pesticide intake estimations and consumer risk assessment. The residue definition for enforcement/monitoring is often a subset of the definition established for risk assessment purposes. In the past, residue definitions for risk assessment were often not publicly available, with the

exception of those residue definitions which were included in annually published reports and evaluations by the FAO/WHO Joint Meeting on Pesticide Residues (JMPR) [5].

2 Data included in the BfR compilation

The compilation is based on pesticide risk assessments that have been conducted by BfR within the framework of national pesticide authorisations. All 297 active substances assessed so far have been included in the data compilation. In addition to BfR risk assessments, information was also sourced from the European Pesticide Risk Assessment Peer Review programme (PRAPER), in particular from Draft Assessment Reports, Review Reports and EFSA Scientific Reports.

The listed residue definitions for enforcement/monitoring comply with Commission Regulation (EC) No 396/2005 and respective follow-up regulations. Hence, they are legally binding. However, it should be noted that within the framework of European Pesticide Risk Assessment some residue definitions for enforcement/monitoring have since been changed but have not yet been incorporated into the Commission Regulation. As soon as these changes are made, they will be considered in the next update of the BfR compilation of residue definitions.

If the residue definition for risk assessment deviates from that for enforcement/ monitoring, this definition is given together with its reference (EU, BfR…). From the data compilation it is, therefore, obvious if a residue definition originates from a DAR proposal, if it has been confirmed by EFSA in the EFSA Conclusion Report or if it is based on BfR risk assessment conducted within the framework of a national authorisation procedure.

Since risk assessment is an ongoing process that has to be constantly adapted to the state-of-the-art, residue definitions are changed quite frequently. The BfR compilation will not, therefore, be able to reflect the status quo in all cases. BfR does not assume any ability for the accuracy or up-to-dateness of the data. Periodic updates are envisaged.

3 References

[1] FAO (2002) Submission and evaluation of pesticide residues data for the estimation of maximum residue levels in food and feed, FAO Plant Production and Protection Paper 170, Food and Agriculture Organization of the United Nations, Rome

[2] OECD (2006) Guidance Document on the Definition of Residue. OECD Environment, Health and Safety Publications. Series on Testing and Assessment No. 63 and Series on Pesticides No. 31, Environment Directorate, Organisation for Economic Co-operation and Development, Paris, 2006.
http://www.olis.oecd.org/olis/2006doc.nsf/LinkTo/NT00003E9A/$FILE/JT03215488.PDF
A revised version of this document has been drafted (November 2008) and commented on, and is now awaiting approval/publication. It can be downloaded from:
http://www.oecd.org/dataoecd/18/4/41784347.pdf

[3] Commission Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC (OJ L 70 from 16.03.2005, p. 1)

[4] EU Pesticides Database, http://ec.europa.eu/sanco_pesticides/public/index.cfm

[5] JMPR reports and evaluations, http://www.fao.org/agriculture/crops/core-themes/theme/pests/pm/jmpr/en/