

Experts Discuss Methods for Setting Maximum Residue Levels for Biocides

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Maximum residue levels (MRL) in foods and feeds should be coordinated and established in a cross-procedural manner. In the view of the Federal Institute for Risk Assessment (BfR), this is one result of the international “European Conference on MRL-Setting for Biocides”, which the BfR organised jointly with the European Commission (DG Environment and DG Health and Consumers) on 18 and 19 March 2014. At the conference, it became apparent that there are a number of good reasons to set maximum residue levels for biocides in certain applications. One of the many options discussed was to integrate maximum residue levels for biocides into existing legal regulations, such as those for plant protection products and veterinary drugs. Other options are also being considered, however. Among the more than 70 participants were representatives of the European Commission, European Food Safety Authority (EFSA), European Chemicals Agency (ECHA) and European Medicines Agency (EMA), the Federal German Ministry of Food and Agriculture (BMEL), the responsible authorising and evaluating authorities of the member states, as well as European associations of the relevant stakeholders.

MRLs must be set at levels that do not pose an acute or a chronic health risk to consumers. Since the new biocide regulation (Regulation (EU) No 528/2012) has come into force in 2013, it must now also be checked prior to the approval of a biocidal product whether maximum residue levels in foods may have to be established for the active substances contained in the biocidal product. At the conference, the experts discussed fundamental questions on the process of establishing possible maximum levels.

As only certain biocide uses may cause residues in foods, various methods were discussed with which these can be identified as efficiently as possible, methods for the establishment of suitable control measures were also examined.

In addition to exclusive use in biocidal products, biocidal active substances are also used in plant protection products and veterinary drugs (“dual use” substances). Some MRLs have already been established for these applications.

A number of preparatory tasks must be completed before a decision can be met as to whether maximum residue levels for biocides can be integrated into already existent legislation. This legislation includes plant protection product and veterinary drug legislation, as well as the regulation for limiting contaminants in food. For example, it is necessary to clarify for which foods and food groups the setting of MRLs is necessary based on actual biocide use applications. Special consideration should be given to the fact that unlike pesticides and veterinary drugs, biocidal products often come into contact with processed foods only, such as ice-cream or juice, if they are used as disinfectants during the food production process, for example. For this reason, the previously customary practice of establishing maximum residue levels for raw products such as milk, oranges and meat may not be suitable for biocides.

In the opinion of the BfR, the conference produced three essential results:

1. The development of a suitable procedure for the harmonised setting of maximum residue levels for biocides appears to be important for uses which can lead to relevant residues in foods.
2. It should be checked whether and under which circumstances maximum residue levels are necessary for biocides and whether they could possibly be integrated into already existent MRL regulations, such as those for plant protection products and veterinary drugs. In this

way, synergy effects can be used when structuring the procedure. A solution adapted to the unique properties of biocides could also be considered.

3. Cross-process coordination would be helpful in order to guarantee that already existing maximum residue levels as well as those for which an application has been made in each of the various regulatory fields are taken into account in the cumulative evaluation.

A workshop report will soon be published on the BfR homepage in co-ordination with the European Commission. It is intended to serve as a basis for discussion so that additional measures can be agreed upon between the European member states. The presentations given at the event can be found at

http://www.bfr.bund.de/de/veranstaltung/european_conference_on_mrl_setting_for_biocides-189183.html