European Union Comments

CODEX COMMITTEE ON PESTICIDE RESIDUES

49th Session

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AGENDA ITEM 5 a)

Report on items of general consideration by the 2016 JMPR

(**Section 2 of the May and September 2016 JMPR Reports**)

European Union Competence

European Union Vote

The European Union (EU) would like to provide the following comments on section 2 of the **September 2016 JMPR Report:**

2.1 Update on the revision of the Principles and Methods for the Risk Assessment of Chemicals in Food (EHC 240)

2.1.1. Benchmark dose

For deriving the toxicological reference values for teflubenzuron, JMPR used the concept of benchmark does (BMD) modelling.

The EU would like to inform about ongoing scientific developments in the EU on this issue. On 24 January 2017, EFSA published the updated EFSA guidance on the use of the BMD approach in risk assessment (http://www.efsa.europa.eu/en/efsajournal/pub/4658). EFSA reconfirmed that the BMD approach is a scientifically more advanced method compared to the NOAEL approach for deriving a Reference Point. The main changes with regard to the previous (2009) EFSA guidance (http://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2009.1150/epdf) refer to the way of applying the BMD. The preferred method for calculation the BMD interval is Model Averaging. The set of default models to be used for BMD analysis has been reviewed and a new criterion has been introduced to characterise the goodness of fit of the models considered. The guidance has been discussed during a workshop in Brussels in March 2017. This workshop confirmed a broad consensus of the experts on the overarching principles regarding dose-response modelling and a number of issues were discussed where further agreement among modellers is still needed. The approach is currently applied only in specific cases in the EFSA peer review of pesticides.

As explained in the EFSA guidance document, ideally, the relationship between dose and response would be described by a biologically based model that describes the toxicokinetic and –dynamic processes related to the specific compound. For most compounds, such models are not available, and therefore, the BMD approach uses mathematical curve fitting models that do not describe the underlying biology, and should be treated as purely statistical models. Any model that fits adequately the dataset (in the range of observation) is acceptable.
The issue of biological relevance is important in the following steps:

- the selection of the dataset / endpoint to be subject to BMD analysis,
- the choice of the BMR (benchmark response) value: the effect size selected should be biologically relevant.

2.1.2. Chemical specific adjustment factors (CSAFs)

The EU would like to inform that in 2012, EFSA published a guidance on selected default values to be used by the EFSA Scientific Committee, Scientific panels and Units in the absence of actual measured data (http://www.efsa.europa.eu/en/efsajournal/pub/2579) which also addresses the use of chemical specific adjustment factors: Substance-specific data for one particular aspect of uncertainty should be used when available to replace the relevant part of the overall default uncertainty factor.

2.1.3. Guidance on the use and interpretation of statistical evaluations and historical control data

The EU fully supports an update of EHC 240 as regards the use and interpretation of statistical evaluations and historical control data within the evaluation of toxicological data of compounds. The interpretation of statistical evaluations and historical control data often is a reason for discussion leading to divergent views of experts and it would be desirable to find a common approach.

2.2. JMPR guidance document for WHO monographers and reviewers

The EU fully supports the JMPR recommendation to update the guidance document for WHO monographers and reviewers in accordance with the recommendations derived for benchmark dose, chemical-specific adjustment factors and use and interpretation of statistical evaluations and historical control data as highlighted in our comments to sections 2.1.1. – 2.1.3. JMPR recommends to harmonise the approaches, in particular regarding the BMD approach. The EU fully supports such an update on the use and interpretation of statistical evaluations and historical control data as well as to further harmonise the BMD approach.

2.3 Evaluations of genotoxicty data

In 2011, EFSA published a Scientific Opinion on genotoxicity strategies applicable to food and feed safety assessment (http://www.efsa.europa.eu/en/efsajournal/pub/2379).

The Scientific Committee of EFSA was mandated by the European Commission to review some aspects of the genotoxicity assessment. Following this assessment, the Scientific Opinion of EFSA may be revised.

The update proposed is appreciated insofar it intends to clarify how to balance data from regulatory dossiers and published studies.

2.4 Update of the OECD Livestock Animal Burden Table

The use of the updated dietary burden feed table published in the OECD guidance document on residues in livestock is appreciated. It is noted that the same source of information is used

at EU level for the calculation of the EU dietary burden of livestock. Thus, the use of the same data are an important step for harmonisation of the risk assessment methodologies.

In addition the European Union (EU) would like to provide the following comments on section 2 of the **May 2016 JMPR Report:**

2.1. General considerations on the evaluation of genotoxicity studies:
The item was covered under section 2.3. of the September 2016 JMPR report, see above.

2.2. Methods for the evaluation of epidemiological evidence for risk assessment:
Epidemiological studies are a source of information complementing the standard toxicological package, providing additional information relevant for the hazard characterisation. The development of a common approach for the use of epidemiological studies in risk assessment is therefore of high relevance.
The EU would like to inform the Committee that EFSA currently works on a Scientific Opinion that will give guidance on how to integrate epidemiological studies in the risk assessment of pesticides. A public consultation on the draft opinion will be launched in May 2017. A harmonisation of the approach at international level would be desirable.