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European Union Comments

CODEX COMMITTEE ON PESTICIDE RESIDUES

46th Session

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AGENDA ITEM 5a

Report on items of general consideration by the 2013 JMPR

(Section 2 of the 2013 JMPR Report)

European Union Competence.

European Union Vote.

The European Union (EU) would like to provide the following comments on section 2 of the 2013 JMPR Report:

2.1 Guidance Document for WHO Monographs

The EU welcomes the announced updates of the WHO guidance documents for WHO monographs.

2.2 Hazard assessments in the 21st Century: Incorporating data from new mechanistic-based approaches in JMPR evaluations

The EU supports the discussion on incorporation of new mechanistic-based approaches.

2.3 Risk Assessment of Metabolites and Degradates of Pesticides

The EU welcomes this activity and appreciates that the recent opinion of the European Food Safety Authority (EFSA) is taken into account when providing further guidance on this matter.

2.4 Review of the need to update the Principles and methods for the risk assessment of chemicals in food (EHC 240)

The EU welcomes the announced update of EHC 240 on a routine basis.

2.5 Identification of Pesticides to be Included in Cumulative Assessment Groups on the Basis of Their Toxicological Profile

The EU welcomes the comments from JMPR on the recent EFSA opinions on cumulative assessment groups and appreciates that JMPR agreed to explore the possible application of cumulative risk assessment to its evaluation of pesticides, for example through conducting a case-study.

2.6 Guidance for the preparation and processing of large commodities for analysis of pesticide residues

The EU welcomes that guidance how to handle large commodities is provided by JMPR. The EU agrees that a pragmatic solution is needed, but cautions that any cutting or reducing the size of the sample in the field and transporting at room temperature should be avoided as much as possible. This is necessary not only to avoid degradation of the pesticides but also to maintain the physical and chemical integrity of the sample, so that the sample does not start decomposing. Samples should be transported under cold, dark conditions and any segmentation or coarse cutting should be done preferably in the laboratory where analysis will take place or in any other facility that is suitably equipped to allow immediate freeze-out of the cut material. Where this is not possible and a sample is segmented or coarsely cut before transporting it to the final laboratory, it should remain in frozen state throughout the transport. Only in exceptional cases, the transport of cut material in non-frozen state should be possible under the condition that pre-tests have confirmed the stability of the residue in the cut commodity. Still the time interval between sampling and analysis should be minimised by appropriate time planning.

2.7 Principles for assessing the performance of analytical methods based on few recovery tests

The EU does not support the proposed approach and deems it not acceptable that for incompletely validated studies higher relative standard deviations are tolerated than for completely validated studies.

The EU is of the view that in line with the Codex Guidelines on Good Laboratory Practice for Pesticide Residue Analysis (GL 40-1993) a minimum of five recovery tests¹ is needed to generate reliable data and that less than five tests are not acceptable.

Based on experiences from results from several EU proficiency tests, the RSD_R (reproducibility conditions) are relatively stable for residue levels between 0.01 mg/kg and 1 mg/kg. EU proficiency tests have shown that 20% RSD_r (within laboratory, repeatability conditions) and 25% RSD_R (between laboratories, reproducibility conditions) are suitable². This is in line with findings of Thompson and Lowthian (1997)³. Levels below 0.01 mg/kg are not considered to be relevant for most pesticide residues in food of plant origin. For levels above 1 mg/kg, 20% RSD within laboratories is also appropriate, because the high level often requires dilution and measuring at lower level.

¹ Codex Guidelines on Good Laboratory Practice for pesticide residue analysis (GL 40-1993), point 1.3 of Table 2, p. 15/16.

² Medina-Pastor, P., Fernández-Alba, A.R., Andersson, A., Rodríguez-Torreblanca, C.: European Commission proficiency tests for pesticide residues in fruits and vegetables. TrAC - Trends in Analytical Chemistry Volume 29, Issue 1, January 2010, Pages 70-83.

³ M. Thompson and P. J. Lowthian: The Horwitz Function Revisited. JAOAC International, Vol. 80, No 3, pages 676-679

The following relative standard deviations (repeatability conditions - RSDr) are therefore proposed for a minimum of five replicates:

Concentration	RSDr
	Nmin = 5
0.01 mg/kg - ≤ 0.1 mg/kg	20 %
> 0.1 mg/kg - ≤ 1 mg/kg	20%
> 1 mg/kg	20%

Furthermore, the EU does not agree that the experimental coefficient of variation (CVexp) is tolerated to be higher than the reference coefficient of variation. On the contrary, CVexp should always remain below or equal CVref. It is not appropriate to use an F-Test to weaken clear performance criteria.

2.8 Guidance for Use of Residue Trial Data from Different Geographical Locations for Estimation of Pesticide Residue Levels

The EU cannot support the guidance laid down in chapter 2.8 without having further evidence that the data from residue trials combined according to the procedure outlined are reliable and comparable.

The EU refers to the agreed "Principles and guidance for application of the proportionality concept for estimation of maximum residue limits for pesticides" stating that residue data from different geographical regions in combination with the proportionality principle can be used only on a case by case basis, to prevent an increased overall uncertainty.

Combining data from different geographical regions and data collected with different application rates may be appropriate in some cases, but evidence is needed that the combined datasets are comparable and the overall uncertainty is not increased. Appropriate statistical analysis is therefore needed as well as a comparison with measured analytical data from the concerned region for confirmation.

The rationale for the proposed step procedure is not clear. In particular, it is not clear why in case of insufficient data from a country or region, data generated in the same region (but with a different GAP) will be considered first and only in a second step data from other regions that meet the GAP (or can be adjusted using the proportionality principle) will be taken on board.

As regards the paragraph "Where the spread of residues exceeds the 7 times median range, the suitability of the dataset for estimation of residue levels would then need further careful examination, taking into account all relevant information" the EU believes this is a rather vague statement, giving considerable room for interpretation. Before taking a position on the approach, the EU would like to see some worked out examples on how the procedure is intended to be applied in practice. The announcement to further elaborate the principles is therefore highly welcomed.

2.9 Guidance for Estimating Pesticide Residue Levels for Commodity Groups

The EU cannot support the proposed approach as the overall approach to establish group maximum residue levels is not in line with the ALARA principle. The EU believes that where sufficient data are available for single crops, the MRLs should be always derived for the specific crop without considering group maximum residue levels.

The EU agrees that where insufficient data are available for single commodities, results from residue trials from different crops belonging to the same crop group or sub-group can be considered. Combination of data sets is possible for some crop groups on a case by case basis provided that the active substance is applied according to the same GAP (within the 25% rule) and statistical evidence is provided that the data are comparable. However, the EU notes that for minor crops the number of residue trials in support of the GAP is normally rather small, frequently too small for doing a statistical test.

Where the data sets are statistically different the data should not be combined. In this case further residue trials data are necessary to derive a MRL.

The EU questions the basis and need for using the "5 times range" and would like to get information on the scientific basis for this concept and the uncertainties related to it. If appropriate statistical tests are used to compare datasets, the concept would not be needed.

Furthermore, the EU would like clarification on the minimum number of trials mentioned under bullet point 2 (iii.) of the 2013 JMPR report where it is mentioned that "If the dataset identified under (ii) does not contain sufficient data points (preferably ≥ 8) required to estimate a group maximum residue level, the commodity should be considered as an exception." The EU understands that "the dataset identified under (ii.)" mentioned in bullet point 2 (iii.) refers to the dataset leading to the highest maximum residue level. However, it is not clear what would be the procedure for cases where according to (iii.) insufficient data points would be available for setting a group MRL and the commodity would be considered as an exception. Would the consequence be that no group MRL could be established at all, or would the proposed group MRL then be based on the commodity leading to the second highest residues (provided that sufficient trial data would be available)?

2.10 Update of GEMS/Food diets for the estimation of the IEDI

The EU supports the initiative to collect further consumption data in order to better match the 17 Cluster diets with the Codex Classification of Foods and Animal Feeds with a view to getting more refined exposure estimates.

2.11 Revision of the Codex Classification of Foods and Animal Feeds

The EU has no particular comments on this point.