

# CODEX COMMITTEE ON PESTICIDE RESIDUES (CCPR53)

## European Union Comments

### AGENDA ITEM 5 (a)

Report on items of general consideration arising from the 2021 JMPR extra and regular meetings (Section 2 of the 2021 JMPR Report)

**European Union Competence**  
**European Union Vote**

The EU would like to provide the following comments on section 2 of the 2021 JMPR Report:

#### **2.1 BENEFITS AND CHALLENGES TO VIRTUAL JMPR MEETINGS**

The European Union (EU) would like to thank JMPR for all the effort dedicated to organising an extra meeting in order to reduce the backlog of the number of new use evaluations. The EU acknowledges the difficult conditions in virtual meetings, which despite some benefits, are less efficient compared to face-to-face meetings. The EU welcomes further discussion under relevant agenda items on how to enhance operational procedures of JMPR and CCPR to eliminate the backlog of evaluations and meet the future demand of establishment Codex MRLs. The regular review of Codex MRLs established more than 15 years ago is of utmost importance in order to ensure that the Codex MRLs comply with the current scientific standards.

#### **2.2 INTERNATIONAL ESTIMATE OF SHORT-TERM INTAKES (IESTI) EQUATIONS**

The EU welcomes the continuation on the discussion on the parameters of the IESTI equation and would like to request additional information on the FAO/WHO expert group in charge of this work. The EU has long experience in this particular topic and EU experts are willing to actively participate and contribute to the work of the FAO/WHO expert group.

The EU does not share the conclusion of JMPR that the benchmarking study by Crépet et al. (2021) demonstrates that “IESTI equations are protective for acute risk”. The EU considers that the study design and the data used to perform the exposure calculations were not appropriate to answer the question whether the IESTI equation is protective. Beyond this, the impact of the different parameters and modification of the equation should rather be

assessed in regard of the objectives of updating the methodology with the most recent scientific knowledge, and using the MRL in the equation for communication purpose.

As noted by the JMPR the replacement of the STMR by the MRL is a major challenge and the data collected about bulking and blending should be reviewed and incorporated into dietary risk assessment practices to refine the impact of this replacement.

As announced during the 52nd CCPR session, further work will be performed at EU level to compile all the existing knowledge on IESTI and prepare a scientific output consolidating the existing work.

CCPR will be kept informed on the findings and the subsequent risk management discussions

### **2.3 FIRST CONSIDERATIONS ON A POSSIBLE NEED FOR AMENDMENTS TO EHC 240 GUIDANCE ON APPROPRIATE USE OF TOXICOLOGICAL HISTORICAL CONTROL DATA (HCD)**

The EU is currently working on a project on the appropriate use of toxicological historical control data, as this is a topic of high importance for the EU. The EU welcomes the involvement of JMPR in the survey and subsequent workshop performed in May 2022. A final report of this project is expected to be published in September 2022, which will be followed by the publication of a Scientific Opinion in 2023.

### **2.4 GUIDANCE ON THE ASSESSMENT AND INTERPRETATION OF NON-LINEAR DISPOSITIONAL KINETICS**

The EU agrees with the need of more guidance on the integration of the kinetically-derived maximum dose (KMD) approach as an alternative to maximum tolerated dose (MTD), in particular with the interpretation of non-linearity in the dispositional kinetics of pesticides. At EU level, the hazard classification is an important element to decide on the approval of an active substance and the KMD approach is not appropriate to fulfil the legislative needs for classification and labelling; The EU considers that MTD approach, with complementary information on non-linear kinetics, is the most appropriate methodology to derive the selection of the high dose level for toxicological studies.

### **2.5 RECOMMENDATIONS FOR USE OF LEAFY VEGETABLES TO EXTRAPOLATE RESIDUES TO THE SUBGROUP 027A HERBS (HERBACEOUS PLANTS).**

The EU appreciates the detailed analysis and agrees with JMPR that the initial spray deposit is an important factor to be considered for extrapolations. However, the EU considers that some additional factors, such as the overall distribution/heterogeneity of the residue trials, should be taken into account to decide on the appropriateness of extrapolations.

The EU notes that in the case of afidopyropen, the statistical test on the data set for mustard greens was significantly different from the data sets for spinach and leafy lettuce. Moreover, for certain herbs (parsley, dill and coriander leaves), JMPR derived the MRL proposal based on the residue trials in mustard greens although this extrapolation is not a standard extrapolation agreed previously. However, the EU considers that Codex MRL proposals are acceptable, noting that the data set on mustard greens lead to a higher MRL proposal than the data set on other leafy crops and that the herbs under consideration are very minor in terms of consumption and production.

JMPR is recurrently extrapolating datasets from blueberries to elderberries, which is not foreseen in the Codex extrapolation rules. Therefore, the EU considers that the extrapolation from blueberries to elderberries (and guelder rose) should be also discussed to determine whether such extrapolation is appropriate.