

CODEX ALIMENTARIUS COMMISSION



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Organization of the
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World Health
Organization

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Agenda Item 8

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ORIGINAL LANGUAGE

JOINT FAO/WHO FOOD STANDARDS PROGRAMME CODEX COMMITTEE ON PESTICIDE RESIDUES

50th Session

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Comments on Agenda Item 8, submitted by CropLife

Technical Background:

The discussion continues regarding the 2015 Geneva workshop proposal to change the JMPR version of the IESTI by replacing field trial STMR and HR by MRL values, while maintaining the use of a variability factor of 3 and to add a conversion factor for differences between the Residue Definition (DoR) for risk assessment and monitoring. As well, the Geneva proposal removes the unit weight from the equation, assuming the full food commodity portion consumed contain residue levels at the 3 times MRL level for case 2a commodities.

eWG - Ways of working

CropLife International actively participated in the 2017-2018 eWG on the review of the IESTI equation. We summarize some key points relative to the eWG in this CRD.

1. We repeat our concerns that the 2015 Geneva proposed changes would result in a JMPR risk assessment that is always more conservative, and will result in an unnecessary loss of CXLs. All dietary intake assessments at the JMPR are currently inflated by the proposed changes. Fewer CXLs result in loss of crop protection tools for the grower and product alternatives for resistance management.
2. We share the concern's expressed by other members that the eWG's final focus is only on the JMPR version of the IESTI and not the EU IESTI equation. In the last 2 years of eWG discussions, the EU form of the IESTI was often cited as an example, instead of the JMPR form. Distinctions of the IESTI equation are critical to maintain.
 - The use of a higher EU variability factor for some commodities leads to a higher intake estimate for the EU IESTI relative to the JMPR version of the IESTI.
 - There has been a intermingling of arguments for change based on EU version with higher $v = 5$ and 7 , but JMPR IESTI ($v = 3$) is the focus at CCPR. Going forward, all specific examples should clarify when they use the EU variability factors of 5 , and 7 , and should include contrast to the lower value of 3 used at the JMPR.
 - The choice to put the MRL in the EU version of the IESTI by EU food inspection units is not understood as common practice in other countries and is not in scope at JMPR/CCPR.
 - The cited EU examples of using the MRL in the EU IESTI equation for food inspection, means for certain commodities, the EU intake estimates are based on residues in food at $7X$ the MRL. In contrast such high levels are not reflective of values in food monitoring programs.
3. CropLife International supports the proposal to benchmark the deterministic IESTI approach with additional refined exposure methodologies - point 40 of CX/PR 17/49/12. Case studies exploring 5 levels of refinement in dietary risk assessment have been developed to explore general benchmark methodology and results were shared in the 2017 IESTI discussion at the Global Minor Use Summit 3. Information can be shared further with the eWG, upon request. Probabilistic models coupled with refined dietary exposure data from dietary monitoring programs at the consumer level provide more realistic outcomes at the dinner plate. The demonstrated protective nature of the deterministic approach could be highly relevant when discussing risk with the public; we look forward to WHO's report on benchmarking expected for 2019.
4. CropLife International challenges the interpretation that direct use of the MRL within the IESTI equation is the only way to interpret an MRL as "safe" for humans. There is not agreement across the eWG that the proposed deterministic equations using the MRL as input are the only appropriate way to calculate consumer exposure. The IESTI by design is based on several worst case assumptions. We reiterate our previous comment:

One of the biggest challenges that arises from the current IESTI equations is that these simple deterministic exposure calculations multiply several upper percentile values resulting in a high level of conservatism corresponding to a very high percentile exposure value. With the existing IESTI equations, this is already a challenge, because there are limited options for refinement to more realistic exposures. However, proposed changes to the JMPR IESTI equation use even higher percentile values for exposure (with exposure estimates higher than current HR and STMR from field data), and will further aggravate the situation. (by raising the threshold of approval for some CXLs).

5. Current MRLs are established based on approved use patterns (GAPs), the OECD calculator and an understanding that current IESTI equations contain enough conservatism relative to realistic exposures at the consumer dinner plate, to cover any typical variation in residues from approved uses.

6. Evaluation of trade impact of proposed equation changes is in the remit of the eWG. But, to date no discussion of an agreed methodology and appropriate metrics for assessing trade impact of CXLs has occurred yet within the eWG. Recent publications by EU/Australia are proposed as a starting point for the CCPR discussions. We appreciate the essential work. We reiterate our comments regarding these and need for understanding impact on trade:

The planned publications by scientists from France, Australia, Germany, Hungary, the Netherlands, UK and EFSA may serve as a starting point for the discussion among risk managers on the impact on risk management, risk communication, consumer protection goals and impact on global trade that indeed need to take place. The importance of global trade to food security and nutrition should be reflected. The extra focus on economies of developing countries and minor crops will need to be addressed in these discussions. Full impact assessments need to include information on revised LPbw data and a focus on the JMPR version of the IESTI.

7. Improved risk communication continues to be cited as a reason for the Geneva 2015 proposed equations. CropLife International does not believe the use of the MRL instead of the HR is an effective instrument to improve risk communication and build trust with the general public. The challenge of estimating acute dietary exposure to satisfy global requirements is a challenge related more with risk communication for the non-scientist, rather than a pressing need to revise the IESTI equations.

8. The topic of secondary standards re-emerged this year as justification for change at the JMPR. The previous agreement to remove text on secondary standards was not adhered to in 2018. We reiterate:

- Changing the IESTI equation will not address secondary standards set by retailers.
- Secondary standards are not set using the IESTI equation but instead originate outside any regulatory process as a marketing strategy by conflating risk with detectable residues.
- Secondary standards focus on a scaling of the regulatory MRL (typically 1/2 or 1/3). But the numeric value of the MRL is set through use of the OECD calculator not the IESTI equation.

9. The Terms of Reference iii document has focused on bulking and blending – which is indeed important. However, other technical challenges for the Geneva 2015 equations were part of the Table 2 discussion for the Terms of Reference iii, but the eWG has not yet explicitly addressed them. They remain important and include:

- improper use of the current variability factor with an MRL;
- misapplication of 3X the MRL for the full portion in Case 2a;
- lack of internationally agreed sources for the proposed LPbw data; and,
- there is not agreed JMPR/CCPR methodology on the conversion factors (CF) between MRL and risk assessment definitions – will they be derived most realistically from ratios in field data on an individual crop basis or conservatively generalized based on available metabolism studies (which are fewer in number)?

10. Increased harmonization is cited as a key reason for the Geneva 2015 proposed equations. For transparency to the international community, the eWG document should acknowledge the fact that adoption of the variability factor of 3 by the EU (while maintaining the current inputs of STMR and HR for residues) is an alternate path to harmonization, in place of changing the equation at the international JMPR level.