CODEX ALIMENTARIUS COMMISSION

Food and Agriculture Organization of the United Nations

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Agenda Item 9	**CRD13** **April 2019** <u>**ORIGINAL LANGUAGE**</u>

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

51th Session
Macao SAR, P.R. China, 8-13 April 2019

DISCUSSION PAPER ON THE REVIEW OF THE
INTERNATIONAL ESTIMATE OF SHORT-TERM INTAKE EQUATIONS

Comments submitted by European Union, Kenya and CropLife international

European Union

European Union Competence
European Union Vote

The European Union (EU) would like to thank the Electronic Working Group (eWG) on the review of the IESTI equations chaired by the Netherlands and co-chaired by Brazil and Uganda for the preparation of the discussion paper with reference CX/PR 19/51/14.

The EU considers that progress has been achieved by the eWG, but that further work is necessary, as indicated in the discussion paper.

The EU hence supports the recommendations of the eWG:

- to further develop the document on advantages and challenges that arise from the current IESTI equations;
- to distribute the document on gathering data on bulking and blending by means of a Codex CL;
- to re-establish the eWG.

Kenya

Comment: Kenya appreciates the electronic working group chaired by the Netherlands and co-chaired by Uganda and Brazil, for the coming up with the document, showing the advantages and challenges that arise from the current IESTI equations and their impact on risk management, risk communication, consumer protection goals and trade. Kenya takes note that more data on bulking and blending, in order to feed into the risk assessors work through the JMPR Secretariat is still required. We therefore supports the 3 proposed recommendations in document.

CropLife international

Regarding the eWG-3 (2018-2019): CropLife International (CLI) appreciated the opportunity to participate in the eWG for IESTI over this year. We note that the chair's arrangement of the two workgroup phone calls was helpful to answer initial group questions and advance collective understanding of this year's eWG plan. We support this phone call practice, if a future eWG is formed.

Regarding the ToR(i) of 2018: The draft paper on advantages and challenges evolved over the course of the eWG-3 to arrive at a better balance of viewpoints, than the initial draft. We concur that the draft remains open for additional work and input from other countries in the future proposed eWG, next year.

Regarding the ToR(ii) of 2018: We generally support the draft circulation letter requesting data on the bulking and blending. Because the letter will be distributed within the food chain, the letter could still be improved to avoid issues of confidential business information (CBI). For example, default blending across transport that supports averaging of residues within the food matrix may need to be understood differently than proprietary blending for taste, or commercial consistency. Also, the letter should focus more on the CCPR priority of internationally traded food.

Benchmarking: A journal article relating to the IESTI topic was recently published which provides valuable information for the benchmarking initiative: *Benchmarking the Current Codex Alimentarius International Estimated Short-Term Intake Equations and the Proposed New Equations* at link:

http://pubs.acs.org/doi/abs/10.1021/acs.jafc.8b05547. The article presents case studies at 5 levels of tiered risk assessment to place the current and proposed IESTI equations into context relative to real-world exposures. Use of publicly available data (JMPR and USDA PDP) and models (WHO-GEMS and NG CARES) provide transparency. The highest refined tier made use of large data sets of public data from USDA PDP monitoring data from the US. It is projected that a similar order of magnitude observed across the 5 tiers of risk assessment would be found in other countries, if similar refined dietary monitoring was available and used. This point is a key aspect to this benchmarking – use of the refined data sets (available from US websites) as context for the broader international conversation. This publication provides supporting details for the previous IESTI presentation at the 2017 Global Minor Use Summit: http://gmup.org/Presentations/IESTI%20Side%20Event.pdf.The derived assessments relate to the 2016 CLI CCPR side event which raised concern that the proposed changes could unnecessarily result in losses of CODEX MRLs. For further information contact lead author Cheryl Cleveland.

Regarding the CX/PR 19/51/3-Add.2 document dated March 2019 for CCPR 51 Agenda Item 9. CLI acknowledges this acute probabilistic assessment as an important contribution to the overall IESTI conversation. We concur with the general conclusions from the report:

- *According to the principles for international dietary exposure assessment, the international exposure models should be conservative in order to ensure that actual exposure of consumers in each country is lower than the international estimate and therefore that there is no appreciable risk for the population worldwide. The results of the probabilistic assessment do confirm the conservativeness of the model when compared with national assessments based on accurate data and the absence of appreciable risk for the population.*

- *The assessments performed for 8 countries are consistent and robust and the overall exercise confirms that the methodology used by the Meeting to assess the acute risk, including the IESTI equation, is an appropriate model for consumer protection.*

We also offer the following observations on the report content and approaches:

- A review of the LOQ assumptions employed is needed; milk appears to be an unrealistic driver food for many assessments, including those for the US, where the public PDP monitoring data shows an exceedingly small number of actual observed residues in milk.
- Details of the LoP assessment conducted are sparse and unclear. Is there international agreement to adopt the term LoP as defined by EFSA for use at CCPR; do other countries define this differently?
- The report should clarify how it relates to the original Terms of reference from CCPR 49 17/REP: Point 162. ii requested FAO/WHO: *To benchmark the outcomes of the IESTI equations to a probabilistic distribution of actual exposure*s.
- The original Terms of Reference (above) request a comparison of the IESTI <u>exposures</u> with realistic probabilistic <u>exposures</u>. In the CX/PR 19/51/3-Add.2 document, the authors included the ARfD for a <u>risk</u> assessment and thus have answered a different question; ARfD values can vary widely between active ingredients, and that variation depends on the toxicology of an active ingredient and not the <u>exposure</u> pattern.
- Also, ARfD values for a given active ingredient can vary between countries and JMPR. If Table 15 is supported, then the national ARfD values should be included for comparison.

In conclusion, while the methodology chosen by the WHO differs from CLI's benchmarking analysis, both studies conclude that there is a high level of protection offered by the current IESTI equations for consumers around the globe. A revision of the IESTI equations for reasons of improving consumer's safety is not necessary.