

# CODEX ALIMENTARIUS COMMISSION



Food and Agriculture  
Organization of the  
United Nations



World Health  
Organization

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**Agenda Item 11**

**CX/PR 21/52/15-Add.1**

**July 2021**

**ORIGINAL LANGUAGE ONLY**

## JOINT FAO/WHO FOOD STANDARDS PROGRAMME

### CODEX COMMITTEE ON PESTICIDE RESIDUES

52<sup>nd</sup> Session

(Virtual)

26-30 July and 3 August 2021

### REVIEW OF THE INTERNATIONAL ESTIMATE OF SHORT-TERM INTAKE EQUATIONS (IESTI)

*Comments of Canada, Chile, Cuba, Egypt,  
European Union, Iraq, Japan, Thailand, The Philippines, Uruguay,  
United States of America. CropLife International,*

#### Background

1. This document compiles comments received through the Codex Online Commenting System (OCS) in response to CL 2021/42-PR issued in May 2021. Under the OCS, comments are compiled in the following order: general comments are listed first, followed by comments on specific paragraphs.
2. The comments submitted through the OCS are, hereby attached as an Annex and are presented in table format.

**TOR(ii)****GENERAL/SPECIFIC COMMENTS**

COMMENTS/RATIONALE	MEMBER/OBSERVER
<p>The discussion paper clearly identifies the benefits and challenges of the current IESTI methodology from various perspectives including risk management, risk communication, consumer protection and trade. The results of the FAO/WHO's benchmarking assessment of the IESTI Equations indicated that the methodology used by JMPR to assess acute risk, is an appropriate model for consumer protection. Although only a final draft report by FAO/WHO was available to the EWG for consideration, this same report was also provided/presented to JMPR at its meeting in September, 2019. JMPR reaffirmed FAO/WHO's conclusions. In addition, Table 3 of the discussion paper provides an extensive and thorough assessment of the input parameters used in the current IESTI equations identifying both the advantages and challenges of each parameter.</p> <p>Canada commends the working group on the quality and completeness of the discussion document which summarizes the work completed by the EWG. Canada considers that the information and analysis provided in the document sufficiently addresses TOR(i) and work on this item should be considered completed.</p> <p>With respect to the question as to where the information provided in Sections 1-3 should reside, Canada recommends that Sections 1(Benefit/advantages and challenges of the current IESTI methodology) and 2(Benchmarking of IESTI calculations against probabilistic exposure estimates) should remain available in the working document. Section 1 is useful to CCPR members and observers for informational purposes only. Section 2 provides a summary and discussion of the results of the FAO/WHO benchmarking exercise and was used by the EWG to aid in their discussions on the degree to which the current IESTI equations are protective. As such, it is appropriate to keep these sections in the working document. Canada recommends that Section 3 (Review of the parameters of the IESTI equations; findings of FAO/WHO and of published in peer reviewed literature) be made available to JMPR as the information will be useful in providing context to the dietary risk assessment results conducted by JMPR.</p>	Canada
Se considera que las secciones 1 a 3 contienen la información necesaria y que no es necesario llevar a cabo mejoras ni medidas de seguimiento.	Chile
Las información y análisis desarrollado para las secciones 1 a 3 dan respuesta a lo mandado en el TDR(i), por lo tanto, este tema debe concluirse.	Chile
La información proporcionada en el documento de debate y sus apéndices son de gran interés y utilidad, por lo cual se considera que lo más adecuado, para facilitar el acceso, es ponerla a disposición de los Miembros y observadores en el sitio web del Codex como un documento de información.	Chile
<p>Hay dos temas que se levantaron en el documento de debate y que pueden requerir mayor atención del CCPR, pero fuera de los márgenes de este grupo de trabajo electrónico,</p> <p>Los temas que pueden ser abordados por el Comité son los siguientes:</p> <ul style="list-style-type: none"> <li>• Definir el "Nivel de Protección" para las evaluaciones de riesgos que lleva a cabo la JMPR, dado que es parte de la gestión de riesgos, la cual corresponde al CCPR.</li> <li>• Alentar a que se busquen mejoras al proceso de levantamiento de datos de consumo de los países, para que el sistema SIMUVIMA cuente con información más amplia y representativa.</li> </ul>	Chile

COMMENTS/RATIONALE	MEMBER/OBSERVER
Cuba agradece la oportunidad de expresar sus comentarios a la CL 2021/42-PR y en principio no apoya y no tiene consideraciones al respecto.	Cuba
Egypt appreciates the approach taken by the CCPR, and would like emphasize the previous comments sent before.	Egypt
<p>European Union Competence European Union Vote</p> <p>Sections 1-3 (Benefits/advantages and challenges of the current IESTI methodology; Benchmarking of IESTI calculations against probabilistic exposure estimates; Review of the parameters of the IESTI equation)</p> <p>Conclusions (paragraph 58, bullets 1 and 3).</p> <p>The EU agrees with the conclusions set out in paragraph 58, bullets 1 and 2 and the related presentation of the details in sections 1 and 3 of the discussion paper. The analysis of the benefits and challenges of the current IESTI methodology reflects the challenges identified in the EU, in particular the challenges for risk communication and the lack of data to verify the level of protection achieved with the IESTI methodology. The review of the parameters of the IESTI equations is clear and comprehensive. The EU considers that TOR (i) are sufficiently addressed in this regard. The EU has no strong views on where the information should reside, it should however be publicly available and easy to retrieve from the Codex website.</p> <p>Conclusions (paragraph 58, bullet 2).</p> <p>However, as regards the Conclusion in the second bullet of paragraph 58, the EU considers that the benchmarking of the IESTI calculations against probabilistic exposure estimates, as presented in section 2 of the discussion paper, does not sufficiently address TOR (i).</p> <p>The EU is of the view that the study design and the methodology used in the study had some serious deficiencies, which compromise the validity of the study. In particular, the EU questions the representativeness of the exposure calculation, which was based on a limited subset of food products, which does not sufficiently represent for the total food intake and therefore is likely to underestimate the overall exposure.</p> <p>Recommendations (paragraph 59, bullets 1-3).</p> <p>The EU strongly support the follow up by JMPR on the work presented in the discussion paper analysing the strengths and weaknesses of the parameters of the IESTI equations.</p> <p>The EU regrets that due to the late publication of the FAO/WHO study on the probabilistic exposure assessment, the eWG was not able to derive final conclusions on the benchmarking of the outcomes of the IESTI equations to probabilistic distributions of actual exposures. The EU is of the view that risk communication remains an issue that can only be addressed with a more substantial change of the existing equations. The EU therefore strongly supports the re-establishment of the eWG and is willing to continue its work as chair of this eWG to drive this work forward. The EU will however also reflect on its own way forward on this important topic, should it become clear that continuation of the eWG or follow up by JMPR is not supported by the CCPR.</p>	European Union
Agree	Iraq
Since the current IESTI calculation established by FAO/WHO experts results in good estimation of short-term dietary exposure, Japan is of the view that the current IESTI calculation is still valid for risk assessment.	Japan

COMMENTS/RATIONALE	MEMBER/OBSERVER
<p>The Philippines supports the Agenda Item 11 Review of the IESTI equations. This review activity is necessary to address usefulness of the existing parameters of the IESTI equations; gather relevant information, identify challenges and advantages from the information; and if needed harmonize the risk assessment approaches used in the equations.</p>	<p><b>Philippines</b></p>
<p>Thailand is of the view that the technical revision of IESTI equations should be considered by JMPR a risk assessor. CCPR, as a risk manager, should consider advantages and challenges in TOR (i) such as including the economy and consumer confidence in Codex standards. Especially, In case Codex MRLs have to be canceled because they are unsafe for consumers, according to the new formula which is overestimated, the confidence in Codex standard might be affected. Moreover, the lack of Codex MRL may increase and create greater trade barrier.</p>	<p><b>Thailand</b></p>
<ol style="list-style-type: none"> <li>1. Thailand is of the view that using MRL instead of HR and STMR, adjusting the variability factor, hypothesizing that all agricultural products weighing more than 25 g and the variability factor at 3 times of MRL are a double overestimation. It should be carefully considered by the JMPR. HR is the highest residue reflecting the practical situation from pesticide application according to critical GAP.</li> <li>2. For the processing factor and conversion factor used in the new IESTI equation, JMPR currently has a few of evidence of processing factors and conversion factors for each pesticide residue/agricultural product. Therefore, if this equation is used in the calculations, there is not enough scientific data to assess. We also noted that processing factors and conversion factors of a product/processed food (products) might be varied among countries due to the difference of production, processing and size (e.g. size of fruit).</li> <li>3. Thailand proposes that case studies should be added to illustrate the effects of adjusting IESTI more clearly, in particular the effect on the change of existing Codex MRLs.</li> </ol>	<p><b>Thailand</b></p>
<p>Apoya la recomendación de que FAO/OMS provea un informe final a CCPR acerca de la comparación de los resultados de las ecuaciones de la IESTI con una distribución probabilística de las exposiciones reales. Asimismo, apoya el envío del informe final a la JMPR.</p> <p>En virtud de la escasez de tiempo de la JMPR, el subcomité sugiere esperar a contar con el informe final de FAO/OMS y su análisis por parte de la JMPR para evaluar la necesidad de explorar más los desafíos identificados en la Tabla 2 de la sección 1 y la Tabla 3 de la sección 3.</p> <p>Una vez cumplidas estas etapas, se considera que el TDR (i) quedaría cubierto.</p>	<p><b>Uruguay</b></p>
<p>The United States appreciates the efforts of the Electronic Working Group (EWG), chaired by the European Union (EU) and co-chaired by Brazil and Uganda, to review the International Estimate of Short-Term Intake Equations (IESTI). The United States has been an active participant on the exploratory EWG and appreciates the efforts of the chair and co-chairs to complete the EWG evaluation of the advantages and challenges of the current IESTI equations. While there were divergent views on the conservatism of the IESTI calculations, the United States believes that the EWG discussion paper provides a complete summary of the EWG discussion of the advantages and challenges of the current IESTI equations.</p> <p>The EWG was also able to collect information to help substantiate the degree of bulking and blending of commodities that are evaluated by JMPR using the Case 3 IESTI Equation. This work is also complete and should be submitted to the FAO/WHO Joint Meeting on Pesticide Residues (JMPR) for their evaluation of the degree to which commodities are bulked and blended before entering international trade.</p> <p>The United States would also like to call attention to an FAO/WHO sponsored publication by Crépet et al. (2021) entitled, “An international probabilistic risk assessment of acute dietary exposure to pesticide residues in relation to codex maximum residue limits for pesticides in food.” [1] This published work was the culmination of the United Nations Food and Agriculture Organization (FAO)/World Health Organization's (WHO) benchmarking assessment of the IESTI equations and was supported by an international group of dietary exposure assessment experts.</p>	<p><b>USA</b></p>

COMMENTS/RATIONALE	MEMBER/OBSERVER
<p>Crépet et al. (2021) was published after the completion of the EWG's work, but supports the draft FAO/WHO findings that were discussed at CCPR51 (2019), concluding, "our results indicate that, with only a few exceptions, most of the Codex Maximum Residue Limits (CXLs) established by the Codex Alimentarius Commission would provide a high level of protection even if risk managers do not request a specific level of protection from risk assessors." This finding is also supported by an additional publication by Cleveland et al. (2019) that was incorporated in the EWG discussion paper. [2]</p> <p>Given that the exploratory EWG has completed its terms of reference and that FAO/WHO's published findings conclude that the current equations provide a high level of protection, the United States believes that additional exploratory work on the IESTI equations is not necessary at this time. The exploratory work and FAO/WHO evaluations have identified no benefit to consumer health of considering modifications to the IESTI equations and have concluded that the current approach is highly protective. Therefore, further exploratory work by CCPR is not warranted. The United States proposes that this topic be concluded at CCPR52 and removed from future CCPR agenda.</p> <p>References</p> <p>[1] Crépet, A., Luong, T. Minh, Baines, J., Boon, P. E, Ennis, J., Kennedy, M., Massarelli, I., Miller, D., Nako, S., Reuss, R., Yoon, H. Jung, &amp; Verger, P. (2021). An international probabilistic risk assessment of acute dietary exposure to pesticide residues in relation to codex maximum residue limits for pesticides in food. Food control, 121, . doi: 10.1016/j.foodcont.2020.107563</p> <p>[2] Cleveland CB, Fleming CR, Johnston JE, Klemens AS, Young BM. Benchmarking the Current Codex Alimentarius International Estimated Short-Term Intake Equations and the Proposed New Equations. J Agric Food Chem. 2019 Mar 27;67(12):3432-3447. doi: 10.1021/acs.jafc.8b05547. Epub 2019 Mar 14. PMID: 30869887.</p>	
<p>First, we note a key point of clarification. Item 16 of CX/PR 21/52/15 (May 2021) currently states: In the meantime, the study of FAO/WHO study was finalised (August 2019) . . . The publication is still pending. The final published report on the FAO/WHO assessment was not available. Likewise, Conclusion Bullet point 3 says: FAO/WHO's study has not yet been published . . . CropLife International notes a further explanation is needed. CRD Paper CX/PR 21/52/15 (May 2021) was finalized by eWG4 in February 2020. There was no activity afterwards thru 2021. As a result, the current CRD does not reflect the point that the FAO/WHO benchmarking paper by Crepet et al paper is now published in Food Control 121 (2021) 107563. The paper answers the original call for WHO benchmarking of JMPR IESTI relative to real world exposure requested by CCPR in 2017.</p> <p>The Crepet et al paper reconfirms previous JMPR conclusions that the current IESTI equation is protective. It includes a set of comprehensive probabilistic risk assessments for real-world exposures using monitoring data for 38 pesticides and 8 countries. Very low real-world exposure to pesticides are demonstrated. Absence of appreciable risk is noted for all considered scenarios. In addition, an assessment of the high "level of protection" provided by existing CXLs is given.</p> <p>CropLife International's response to the Circular Letter CL 2021/42-PR questions follows:</p> <ol style="list-style-type: none"> <li>1. After 4 eWGs, the importance of the IESTI equation is well documented, the parameters are more universally understood. Regarding Table 3, if more work for JMPR is requested, it needs additional justification by CCPR because there is no agreement to modify the current IESTI equation. The WHO Benchmarking is completed with the Crepet publication in 2021.</li> <li>2. The existing work of the 4 eWGs is well reflected in the with the CRD CX/PR 21/52/15. With the addition of the Crepet paper, the eWG(s) have addressed the stated Terms of Reference (TOR i), and no additional eWG work is envisioned.</li> <li>3. Information should be stored in a way that is accessible, transparent and useful to CCPR and JMPR, if future questions arise.</li> <li>4. The Crepet paper could be provided to CCPR 52 members.</li> </ol>	<p><b>CropLife International</b></p>

COMMENTS/RATIONALE	MEMBER/OBSERVER
<p>5. TOR (ii) is addressed. Appendix 1 is an important compilation collected from multiple national authorities and trade organizations and should be valuable to JMPR as a resource.</p> <p>6. While all processes can always be improved, additional work on Appendix 1 is not warranted at this time.</p> <p>7. The effort to collect information on bulking and blending was significant and spanned two years between the initial and final calls for international data. Networking outside the CCPR membership was needed to explain the CL and then engage a full set of trade organizations that held the data requested.</p>	

**TOR(ii)****GENERAL/SPECIFIC COMMENTS**

COMMENTS/RATIONALE	MEMBER/OBSERVER
<p>Canada considers the information and analysis provided in Section 4 and Appendix I of the discussion paper regarding the bulking and blending of commodities sufficiently robust to forward to JMPR at this time. Considerable time and effort was required to obtain this information. Prior to exploring further improvements, it is recommended that JMPR provide feedback to CCPR as to the usefulness of the data to inform their decisions on the appropriate use of bulking and blending.</p>	<b>Canada</b>
<p>Nos parece adecuado remitir a la JMPR la información del Apéndice I para información.</p>	<b>Chile</b>
<p>Recoger mayor información sería complejo y podría prolongarse por mucho tiempo.</p>	<b>Chile</b>
<p>European Union Competence European Union Vote Section 4 (Information on bulking and blending) Conclusions (paragraph 58, bullet 4) The EU appreciates the information on bulking and blending compiled in the Appendix of the Discussion Paper and considers that TOR (ii) are sufficiently addressed. Recommendations (paragraph 59, bullet 4) The EU considers that JMPR should follow up on the compiled information on bulking and blending when reviewing case 3 of the IESTI methodology.</p>	<b>European Union</b>
<p>In principle, we agree with the use of case 3 for homogenous processed commodities or processed products of which their raw materials derived from various farms.</p>	<b>Thailand</b>
<p>Uruguay agradece el trabajo del EWG y apoya el envío de información sobre los productos a granel o mezcla a la JMPR para su estudio.</p>	<b>Uruguay</b>