Food and Agriculture Organization of the United Nations

World Health Organization

CODEX ALIMENTARIUS
INTERNATIONAL FOOD STANDARDS

CCPR52

CODEX COMMITTEE ON PESTICIDE RESIDUES

Pre-meeting EWG on review of the IESTI equations
23 July 2021, 13:00 – 15:00

What is the purpose of the pre-meeting?

EWG to agree on recommendations to be presented to CCPR plenary for endorsement, based on the

- Conclusions and recommendations presented in the discussion paper,
- Comments submitted in response to the CL 2021/42 and
- Additional comments provided in the current pre-meeting.

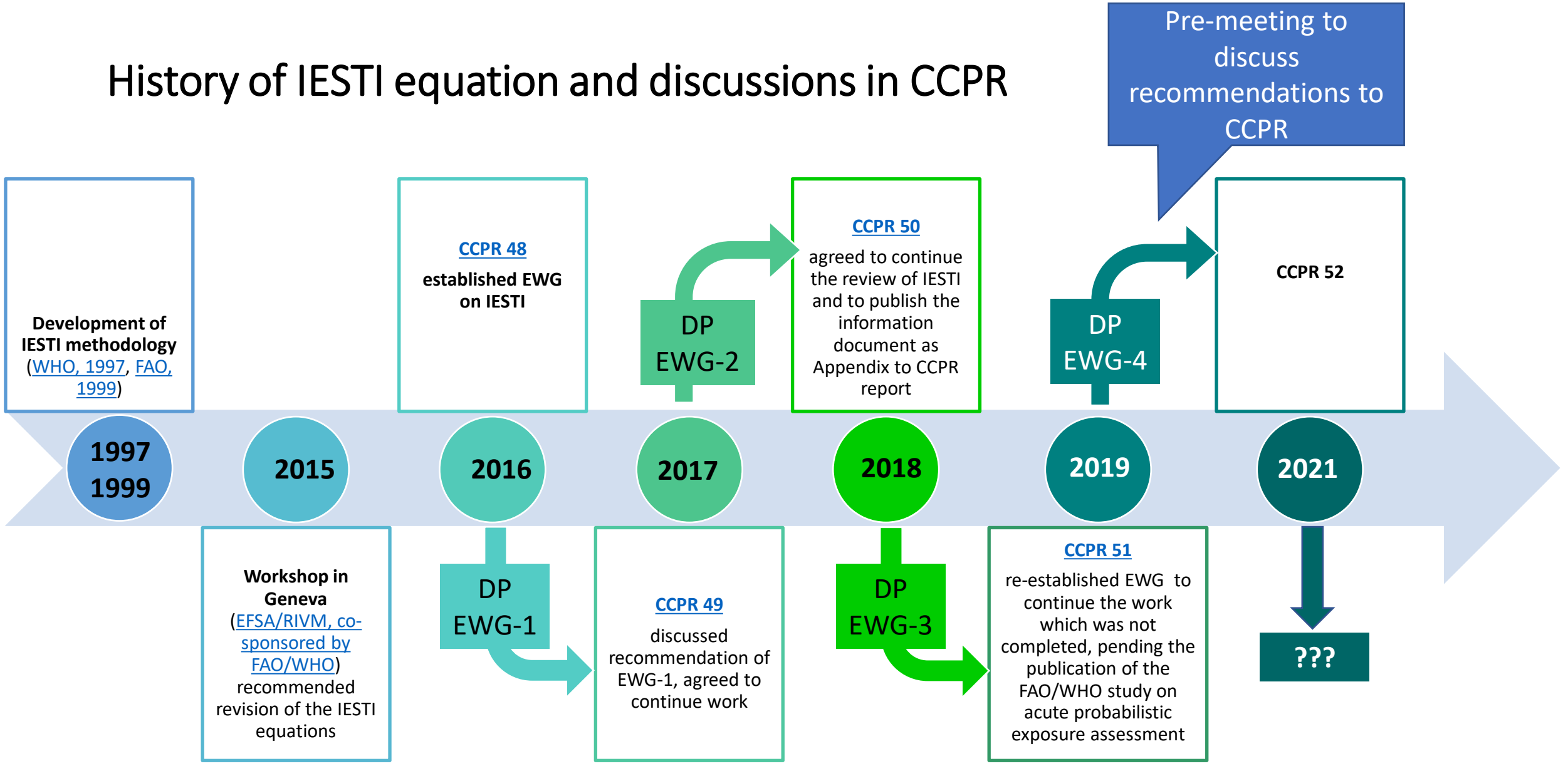
1. EWG to conclude whether the TOR (i) and (ii) are sufficiently addressed
2. The EWG should agree on proposals for follow-up actions to be endorsed by CCPR plenary, i.e.
   - to continue the work and re-establish the EWG
     - if this is agreed, define the TOR for EWG
   - there is no need to continue the work on IESTI under an EWG;
   - other follow-up actions, e.g.
     - to request JMPR to follow-up on the discussion paper or certain sections of the discussion paper,
     - to publish the discussion paper or certain sections of the discussion paper.
   - other recommendations to CCPR resulting from the work of the EWG and the discussion paper

AOB

What is not intended to be discussed in the pre-meeting

- Modifications of the discussion document;
- Discuss or revise the TOR for EWG-4;
- Discuss if and how the IESTI methodology should be changed;
- The content of the study on acute probabilistic dietary exposure assessment for pesticides (Crepet et al, 2021, https://doi.org/10.1016/j.foodcont.2020.107563, available online since 20 August 2020)
  - Note: draft versions of the study were shared with CCPR 51 (CX/PR 19/51/3-Add.2) and with JMPR and EWG (version of August 2019, 'Final results')

History of IESTI equation and discussions in CCPR



DP EWG-x: Discussion paper of electronic working group

Full TOR for EWG-4

(i) Build on discussion of the **benefits and challenges** identified in the discussion paper submitted to CCPR51 (CX/PR 19/51/14 Appendix I "Advantages and challenges that arise from the current IESTI equations") to reflect on the findings of FAO/WHO on its **review on the basis and the parameters of the IESTI equations**, and a **benchmark of the outcomes of the IESTI equations to a probabilistic distribution of actual exposures**. In addition to information provided by FAO/WHO, the EWG should consider recent publications on acute dietary exposure assessment in the peer-reviewed literature.

(ii) Gather **bulking and blending** information and prepare an overview that will be discussed at CCPR52 and distributed to the 2020 JMPR after completion. The Codex Secretariat will issue a CL that will request information on bulking and blending.

(iii) Prepare a **discussion paper** and recommendations for deliberation at CCPR52 that take into account TORs i-ii.

CP/PR 21/52/15

DISCUSSION DOCUMENT ON THE REVIEW OF THE INTERNATIONAL ESTIMATE OF SHORT-TERM INTAKE EQUATIONS (IESTI)

Prepared by the Electronic Working Group chaired by the European Union and co-chaired by Brazil and Uganda

Submitted to Codex Secretariate in February 2020

TOR for EWG-4

TOR (i)

Build on discussion of the **benefits and challenges** identified in the discussion paper submitted to CCPR51 (CX/PR 19/51/14 Appendix I "Advantages and challenges that arise from the current IESTI equations")

Discussion paper of EWG

Section 1:

Advantages/benefits and challenges arising from the current IESTI equations;

TOR for EWG-4

TOR (i)

Build on discussion of the **benefits and challenges** identified in the discussion paper submitted to CCPR51 (CX/PR 19/51/14 Appendix I "Advantages and challenges that arise from the current IESTI equations")

to reflect on the findings of FAO/WHO on its **review on the basis and the parameters of the IESTI equations**,

Discussion paper of EWG

Section 1:

Advantages/benefits and challenges arising from the current IESTI equations;

Section 3:

Review on the parameters of the IESTI equations;

TOR for EWG-4

TOR (i)

Build on discussion of the **benefits and challenges** identified in the discussion paper submitted to CCPR51 (CX/PR 19/51/14 Appendix I "Advantages and challenges that arise from the current IESTI equations")

to reflect on the findings of FAO/WHO on its **review on the basis and the parameters of the IESTI equations**,

and a **benchmark of the outcomes of the IESTI equations** to a **probabilistic distribution of actual exposures**. In addition to information provided by FAO/WHO, the EWG should consider **recent publications** on **acute dietary exposure assessment** in the peer-reviewed literature.

Discussion paper of EWG

Section 1:

Advantages/benefits and challenges arising from the current IESTI equations;

Section 3:

Review on the parameters of the IESTI equations;

Section 2:

Benchmark of the outcomes of the IESTI equations to probabilistic distribution of actual exposures;

TOR of EWG-4

TOR (ii)

Gather **bulking and blending** information and prepare an overview that will be discussed at CCPR52 and distributed to the 2020 JMPR after completion. The Codex Secretariat will issue a CL that will request information on bulking and blending .

Discussion paper of EWG

Section 4 and Appendix I:

Information on bulking and blending relevant for IESTI case 3

submitted in response to the CL 2019/73-PR

Section 5:
Conclusion and recommendations for deliberations at CCPR 52

CL 2021/42-PR Request for comments on the review of the International Estimate of Short-Term Intake equations (IESTI) (May 2021)

Section 1 to 3:

General Comments

- 1. Whether the **information and analysis provided in sections 1-3** still **provide room for further improvements** and if so, (i) indicate whether **further follow-up actions would be appropriate** and so (ii) which would be the **areas for improvements** (e.g. explore the challenges identified in Section 3, Table 3 or discuss whether the FAO/WHO study allows benchmarking the outcomes of IESTI equations to a probabilistic distribution of actual exposures).
- 2. Whether the information and analysis provided in **sections 1-3 sufficiently address TOR(i)** and if so, whether **work on this item should be concluded**.
- 3. In case the information and analysis provided in sections 1-3 sufficiently address TOR(i) indicate **where the information provided in sections 1 – 3 should reside** (either the three sections or some of them) e.g. remain available in the working document, make them available as an appendix to the report, make them available as an information document available on the Codex website, forward to JMPR for information or for further discussion, etc.

- **Specific Comments**
- 4. **Any other comments** on the recommendations concerning TOR(i) that could assist CCPR52 to decide on how to conclude on or follow-up to this matter.

CL 2021/42-PR Request for comments on the review of the International Estimate of Short-Term Intake equations (IESTI)

Section 4:

General Comments

- 5. Whether the information and analysis provided in section 4 and Appendix I **sufficiently address TOR(ii)** and if so whether **Appendix I can be forwarded to JMPR** for information or for further discussion/consideration.
- 6. Whether the **information and analysis** provided in section 4 and Appendix I still **provide room for further improvements** and if so, indicate which would be the areas for improvements.

- **Specific Comments**
- 7. **Any other comments** on the recommendation concerning TOR(ii) that could assist CCPR52 to decide on how to conclude on or follow-up to this matter.

Deadline for submitting comments: **30 June 2021**

Comments submitted by **Canada, Chile, Egypt, European Union, Iraq, Japan, Kenya, Philippines, Thailand, Uruguay, USA and CropLife International**

Comments submitted within deadline are compiled in **CX/PR 21/52/15-Add.1 (July 2021)**

Additional comments: **Kenya (CRD 5), IFU (CRD 12)**

Proposed working methodology for the pre-meeting

Discuss the main questions presented on slide 2 for the TOR (ii) and (i), i.e.

- TOR sufficiently addressed?
- Follow-up actions to be endorsed by CCPR plenary,

considering the responses submitted to CL 2021/42-PR (summarised in tabular form in slide 14, 16 to 18, 20, 22, 23, 25 and 26) and oral contributions made in the pre-meeting,

to derive final recommendations of EWG (shared on the screen, slide 15, 19, 20, 21, 24, 25, 26 and 29).

Need to finalise the discussions at 14:50 (CET)

Summary of feedback on TOR (ii)
Information on bulking and blending, Section 4 and Appendix I of discussion document

Codex Members/ observers	TOR sufficiently addressed?	Details, comments
Canada, EU, Kenya, USA, CropLife International	Yes	No Codex Member/observer requested continuation of the work on TOR (ii) under EWG

Codex Members/ observers	Follow-up actions	Details, comments
Canada, Chile, EU, Kenya, Uruguay	Forward Section 4 and Appendix I to JMPR for further considerations/information	Canada proposed to ask JMPR to provide feedback to CCPR on the usefulness of the data. Chile notes that collecting more information would be complex and time consuming.
Chile	Make the discussion paper available to Members and observers on Codex website as information document	Link
USA	This work is complete and should be submitted to JMPR for evaluation of the degree to which commodities are bulked and blended before entering international trade	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.

Recommendations of EWG on TOR (ii)
Information on bulking and blending, Section 4 and Appendix I of discussion document

- The EWG considered that the ToR (ii) is sufficiently addressed. Further work to collect further data on bulking and blending practices would be very time consuming. Before undertaking additional efforts, the information should be assessed by JMPR to decide on the usefulness of the data.
- The EWG recommends that Section 4 and Appendix I of the discussion paper is submitted to JMPR for further evaluation/consideration. The information should support discussions in JMPR to decide whether the list of commodities for which the exposure calculation is performed according to IESTI case 3 needs to be revised.

To be finalised during the pre-meeting

Summary of feedback on EWG on TOR (i) (part 1, 2 and 3), Section 1 to 3 of DD

Codex Members/ observers	TOR sufficiently addressed?	Details, comments
Canada, Chile, Iraq, Kenya, USA	Yes	Kenya notes that there is still need for further work to address the risk management and risk communication challenges and also acknowledges that quantitative consumer protection goals have not been clearly formulated by CCPR; information on actual level of protection from the current IESTI equation has not been available in the past.
EU	Yes (Section 1 and 3) No (Section 2, benchmarking of the IESTI against probabilistic exposure estimates)	EU strongly supports the re-establishment of the eWG; reasoning reported in slide 22.
Uruguay	No (Section 1 and Section 3)	Based on final report from FAO/WHO and its analysis by the JMPR, to assess the need to further explore the challenges identified in Table 2 of section 1 and Table 3 in section 3.
CropLife International	Yes (Section 1 and 3) ? (Section 2)	The current document does not reflect the point that the FAO/WHO benchmarking paper by Crepet et al (2021) is now published. The paper answers the original call for WHO benchmarking of JMPR IESTI relative to real world exposure requested by CCPR in 2017. The WHO Benchmarking is completed with the Crepet publication in 2021.

Summary of feedback on TOR (i), part 1, Advantages/benefits and challenges arising from the current IESTI equations, Section 1 of discussion document

Codex Members/ observers	Follow-up actions	Details, comments
Canada	Keep Section 1 available in the working document	Section 1 is useful to CCPR members and observers for informational purposes only.
EU	Make the document publicly available, but no strong views where the document should be shared	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.
Chile	Make the discussion paper available to Members and observers on Codex website as information document	Link
Uruguay	JMPR to assess the need to further explore challenges identified in Table 2 of section 1	

Summary of feedback on TOR (i), part 1, Advantages/benefits and challenges arising from the current IESTI equations, Section 1 of discussion document

Codex Members/ observers	Follow-up actions	Details, comments
USA	?	The discussion paper provides a complete summary of the EWG discussion of the advantages and challenges of the current IESTI equations.
CropLife International	Keep information accessible, transparent and useful to CCPR and JMPR if future questions arise	

Recommendations of EWG on TOR (i) part 1, Advantages/benefits and challenges arising from the current IESTI equations, Section 1 of discussion document

- The EWG considerd that ToR (i) on the analysis of benefits and challenges of the current IESTI equations is sufficiently addressed.
- The EWG recommends to make this summary of the discussion paper (Section 1) publicly available on the Codex website as information document. In addition, this section of the discussion paper should be forwarded to JMPR to further discuss the challenges identified in Table 2 of the discussion document and consider a possible way forward to address the challenges on issues that fall under the remit of JMPR.

To be finalised during the pre-meeting

Summary of feedback on TOR (i), part 2, Review on the parameters of the IESTI equations, Section 3 of discussion document

Codex Members/ observers	Follow-up actions	Details, comments
Canada	To be made available to JMPR	The information will be useful in providing context to the dietary risk assessment results conducted by JMPR
EU	JMPR to follow up on the work presented in discussion paper; Make the document publicly available, but no strong views where the document should be shared	
Chile	Make the discussion paper available to Members and observers on Codex website as information document	Link
Uruguay	JMPR to assess the need to further explore challenges identified in Table 3 of section 3	Table 3: Parameters used in the current IESTI equations
CropLife International	Keep information accessible, transparent and useful to CCPR and JMPR if future questions arise.	If more work for JMPR is requested (Table 3), it needs additional justification by CCPR because there is no agreement to modify the current IESTI equation.

Recommendations of EWG on TOR (i) part 2, Review on the parameters of the IESTI equations, Section 3 of discussion document

- The EWG agreed that Section 3 of the discussion document in which a comprehensive review of the parameters of the IESTI equations addresses sufficiently the second part of the ToR (i).
- The EWG recommends making this review available to JMPR for further follow-up to support the discussion on the need for a possible review of the IESTI equations (e.g. development of further guidance on how to derive certain input values such as LP, U, Ue, VF). In addition, Section 3 of the discussion document should be made available on the Codex website as information document.

To be finalised during the pre-meeting

Summary of feedback on TOR (i), part 3,
Benchmark of the outcomes of the IESTI equations to probabilistic distribution of actual exposures, Section 2 of the discussion document

Codex Members/ observers	Follow-up actions	Details, comments
Canada	Keep Section 2 available in the working document	Section 2 provides a summary and discussion of the results of the FAO/WHO benchmarking exercise; it was used by the EWG to discuss the degree to which the current IESTI equations are protective.
Chile	Make the discussion paper available to Members and observers on Codex website as information document	Link
EU	The EU supports the re-establishment of the eWG.	The study design and the methodology used in the (WHO/FAO) study had some serious deficiencies, which compromise the validity of the study (exposure calculation was based on a limited subset of food products, which does not sufficiently represent for the total food intake, results underestimate the overall exposure). Risk communication remains an issue that can only be addressed with a more substantial change of the existing equations.

Summary of feedback on TOR (i), part 3,

Benchmark of the outcomes of the IESTI equations to probabilistic distribution of actual exposures, Section 2 of the discussion document

Codex Members/ observers	Follow-up actions	Details, comments
Kenya	Kenya takes note of the recommendation of the EWG that there was need to review the WHO/FAO final published paper.	Kenya agrees with the conclusion by JMPR that benchmarking assessment of the current deterministic IESTI equation to the probabilistic exposure assessment from all countries and population of interest has characterised conservatism of the current equation and allows exposure to actual distribution.
USA	The USA proposes that this topic be concluded at CCPR52 and removed from future CCPR agenda.	The exploratory work of the EWG and FAO/WHO sponsored publication (Crépet et al., 2021) have identified no benefit to consumer health of considering modifications to the IESTI equations and have concluded that the current approach is highly protective.
CropLife International	Information should be stored in a way that is accessible, transparent and useful to CCPR and JMPR, if future questions arise. Crépet paper to be provided to CCPR members.	The WHO Benchmarking is completed with the Crepet publication in 2021.

Recommendations of EWG on TOR (i) part 3,
Benchmark of the outcomes of the IESTI equations to probabilistic distribution of actual exposures, Section 2 of the discussion document

- While some participants of the pre-meeting considered the ToR (i) (benchmarking of the outcomes of the IESTI equations to a probabilistic distribution of actual exposures and considering recent publications on acute dietary exposure assessment in the peer-reviewed literature) was sufficiently addressed, others are of the opinion that due to late publication of the final paper of Crépet et al (published on 20 August 2020), the current discussion paper does not adequately reflect the final FAO/WHO benchmarking paper. In addition, some participants expressed their concern that the study design of the acute probabilistic exposure assessment was not appropriate to derive definitive conclusions whether the IESTI methodology is sufficiently protective.

To be finalised during the pre-meeting

Cont. recommendations of EWG on TOR (i) part 3,
Benchmark of the outcomes of the IESTI equations to probabilistic distribution of actual exposures, Section 2 of the discussion document

- **Option 1**: The EWG recommends re-establishing the EWG to finalise the analysis of the benchmarking as requested in ToR (i), taking into account the results and the discussion of the acute probabilistic exposure assessments published in the paper of Crépet et al. The following ToR are proposed for the re-established EWG:
  - To update Section 2 of the discussion document, taking into account the final paper of Crépet et al on the acute probabilistic exposure assessment;
  - To finalise the benchmarking, comparing the estimated exposure derived with the currently used IESTI equation with the distribution of the exposure derived in the FAO/WHO study on the acute probabilistic exposure assessment (Crépet et al).

Cont. recommendations of EWG on TOR (i) part 3, Benchmark of the outcomes of the IESTI equations to probabilistic distribution of actual exposures, Section 2 of the discussion document

- **Option 2**: The EWG recommends that Section 2 of the discussion document together with the final version of the acute probabilistic exposure assessment published in the paper of Crépet et al should be forwarded to JMPR for further consideration to support the discussion on the need for a possible revision of the IESTI equations.

Other comments submitted

Codex Members/observers	Other proposals
Chile	**CCPR to define the level of protection** for the risk assessments carried out by the JMPR.
Chile	CCPR to encourage **improvements** to be made to the process of **collecting data on consumption** in the countries, so that the GEMS system has more comprehensive and representative information
Cuba	Indifferent position
Egypt	appreciates the approach taken by the CCPR, and would like emphasize the previous comments sent before.
Iraq	expressed its agreement
Japan	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**.
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.

Other comments submitted

Codex Members/observers	Other proposals
Thailand	The **technical revision of IESTI equations** should be considered by **JMPR** a risk assessor. CCPR should consider advantages and challenges in TOR (i) such as including the economy and consumer confidence in Codex standards. In case Codex MRLs have to be cancelled 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
Thailand	1. Thailand is of the view that using MRL instead of HR and STMR, adjusting the variability factor, (….) are a double overestimation. 2. For the processing factor and conversion factor used in the new IESTI equation, (…), there is not enough scientific data to assess. 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). 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 4. Thailand agrees with the use of case 3 for homogenous processed commodities or processed products of which their raw materials derived from various farms.

Other recommendations of EWG on TOR (i) part 3,

The EWG recommends

- CCPR should define the level of protection of the risk assessment carried out by the JMPR (for this point it might be necessary to establish an EWG to elaborate the detailed requirements on the definition of the protection level);
- CCPR should encourage improvements to be made to collect food consumption data in a wider range of countries, so that the GEMS system has more comprehensive and representative information.

To be completed during the pre-meeting

Thanks to all for your constructive collaboration!

Additional comments to be sent to ccpr@agri.gov.cn