ANALYSIS OF AGENDA ITEMS IN PREPARATION FOR THE 53rd SESSION OF THE CODEX COMMITTEE ON PESTICIDE RESIDUES

4th – 8th and 13th JULY 2022 - Virtual Meeting

AGENDA ITEM 5a

Report on Items of General Consideration Arising from the 2021 JMPR Extra and Regular Meetings: International Estimate of Short-Term Intakes (IESTI) Equations

Objectives

This document offers a review and analysis of the agenda items planned for discussion at the 53rd session of the **Codex Committee on Pesticide Residues (CCPR)**, scheduled to take place virtually July 4th – 8th and 13th, 2022. This document is intended for possible use by the Codex communities of practice, promoted by GFoRSS and PARERA, as part of their contribution to enhancing awareness and supporting effective participation in international food standard setting meetings (Codex meetings) by representatives from members and observers.

The analysis provided in this document offers a factual review of agenda items, their background and a discussion of some considerations. This analysis is indicative in nature and does not represent an official position of the organizations mentioned above (PARERA and GFoRSS), their membership or their management. It provides a synthesis and analysis of the work currently under discussion by the CCPR, which may be useful for delegations from Arab countries to prepare their positions taking into account the needs and specificity of the region and the potential impact of the proposed food standards.

This analysis is prepared as part of the **Codex Initiative for the Arab Region**: ***Arab Codex Initiative***, implemented by PARERA and GFoRSS, hosted and coordinated by the Arab Industrial Development, Standardization and Mining Organization (AIDSMO) and funded by the US Codex Office, US Department of Agriculture.

The focus of the analysis of agenda item 5a of CCPR53, relates to **the report on items of general consideration arising from the 2021 JMPR extra and regular meetings (International estimate of short-term intakes (IESTI) equations).**

**It is important to note that experts – members of the Arab Expert Working Group – do not represent the organizations and / or jurisdictions to which they are affiliated. The selection and participation in the Arab Expert Working Group proceedings is based on each expert's own credentials and experience, which should not be misconstrued as the country's / delegation's / organization's position to which they belong.*

Agenda Item 5a: Report on items of general consideration arising from the 2021 JMPR extra and regular meetings: International estimate of short-term intakes (IESTI) equations.

Document

Section 2 of the JMPR Report.

At CCPR53, JMPR will present the outcome of their review related to the International Estimate of Short-Term Intakes (IESTI) equations as requested by CCPR52, which are reported in the extra and regular JMPR meeting reports (2021).

Background

Since its adoption in 1990, the estimation of the short-term dietary exposure to pesticide residues according to the equations commonly known as 'IESTI equations' (International Estimated Short-term Intake), has become an essential element in the risk assessment process of the Joint FAO/WHO Meeting on Pesticide Residues (JMPR). Since then, the IESTI methodology has been revised several times by modifying certain parameters of the equation, but the basic concept of calculating the dietary intake according to the IESTI equations has been maintained.

The exposure calculations were intended to be sufficiently conservative to cover worst-case situations that are likely to occur, which ensure that MRLs are toxicologically acceptable for consumers, as requested in CAC (CAC, 2018).

It should be noted that since 2016, CCPR initiated exploratory work on the IESTI equations and has established **four** EWGs having as term of reference to provide background on IESTI equations and to explore the advantages and challenges of the equations from risk management, risk communication, consumer protection, and trade perspectives.

The main discussions and decisions made about the methodology of IESTI are presented in the table 1 bellow:

Table 1: Work and decisions related to the review of IESTI.

Year of revision	Entity involved	Recommendation and decision
1990	JMPR	The 'IESTI equations' (International Estimated Short-term Intake) has become an essential element in the risk assessment process of the Joint FAO/WHO Meeting on Pesticide Residues (JMPR).
2006-2007	JMPR	Expression of the need to discuss several aspects of the IESTI methodology, e.g., the uncertainty and variability of the parameters used in the IESTI equations, possible ways to improve consumption, unit weight and body weight data, the practicality to use the MRL instead of the highest residue (HR) or supervised trials median residue values (STMR) in the IESTI calculations and the necessity to improve communication between risk assessors, risk managers and the public.

2015	International workshop in Geneva*	Experts on dietary exposure discussed the possible modifications of the IESTI equations considering the experience gained with IESTI equations for almost 20 years.
2016	CCPR48 (*following a proposal of the EU and Australia)*	• Support of the need to revise the IESTI; • Establishment of an Electronic Working Group (EWG-1) to identify advantages and challenges that might arise from the possible revision of the current IESTI equations and the impact on risk management, risk communication, consumer protection goals, and trade, taking into consideration the recommendations of the international EFSA/RIVM workshop cosponsored by FAO and WHO (EFSA/RIVM, 2015) and the discussions in CCPR48.
2017	CCPR49	• Considering the output of EWG-1, CCPR recommended to FAO/WHO to review the basis and the parameters of the IESTI equations, considering the technical challenges identified in the discussion paper presented by EWG-1 and to do a benchmark of the outcomes of IESTI equations comparing to the probabilistic distribution of actual exposures. • Re-establishment of the EWG (EWG-2) working to: (i) provide information on the history, background and use of the IESTI equations; (ii) review and provide illustrative comments on advantages and challenges that arise from the current IESTI equations and their impact on risk management, risk communication, consumer protection goals and trade and (iii) gather relevant information on bulking and blending, as well as other information or data relevant for the risk assessors work.
2018	CCPR50	Re-establishment of the EWG (EWG-3) to continue the work on: (i) To review and provide illustrative comments on advantages and challenges that arise from the current IESTI equations and their impact on risk management, risk communication, consumer protection goals and trade, (ii) To gather relevant information on bulking and blending, in order to feed into the risk assessors' work through the JMPR Secretariat.
2019	CCPR51	• The Representative of WHO presented the draft report on the acute probabilistic dietary exposure assessment for 47 pesticides. • The EWG-3 also drafted a circular letter to be used by CCPR for gathering relevant information on bulking and blending practices. • CCPR decided to continue the work on the IESTI in a new EWG (EWG-4), considering that the work of the previous EWG was dependent on the final FAO/WHO study on acute probabilistic dietary exposure assessment for pesticides.

2021	CCPR52	Make available, as information documents on the Codex website, the reports provided by the EWGs notably the sections about the benefits/advantages and challenges of the current IESTI methodology; review of the parameters of the IESTI equations: findings of FAO/WHO and of published in peer reviewed literature.
		Forward to JMPR the report of EWGs for further investigation as follows: **a)** ***Benefits/advantages and challenges of the current IESTI methodology***: to further discuss of the challenges and consider a possible way forward to address the challenges on issues that fall under the remit of JMPR. **b)** ***Benchmarking of IESTI calculations against probabilistic exposure estimates (comments submitted in response to CL 2021/42-PR (CX/PR 21/52/15-Add. 1)):*** for further consideration to support the discussion on the need for a possible revision of the IESTI equations and to consider the final version of the acute probabilistic exposure assessment published in the paper of Crépet et al (2021). **c)** ***Review of the parameters of the IESTI equations: findings of FAO/WHO and of published in peer reviewed literature***: for further follow-up discussions (e.g. to discuss the need for developing further guidance on how to derive certain input values such as large portion, unit weight and the variability factors (LP, U, Ue, VF). **d)** ***Information on bulking and blending relevant for IESTI Case 3***: 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.
		Request JMPR to report their considerations **to CCPR53** on the benchmarking of the IESTI equations to the probabilistic distribution of actual exposures presented in Crépet et al [1]
		Suspend the work of the EWG awaiting the feedback from JMPR. Based on the feedback from JMPR a decision should be taken **at CCPR53** if the EWG needs to continue the work.

Organised by the European Food Safety Authority (EFSA) and the National Institute for Public Health and the Environment (RIVM) co-sponsored by FAO and WHO (2015)

[1] Crépet, A., Luong, T. M., Baines, J., Boon, P. E., Ennis, J., Kennedy, M., ... & 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, 107563.

Analysis

Within the framework of the establishment of MRLs for pesticides, JMPR performs a dietary exposure (both acute and long-term) in relation to the relevant acceptable daily intake (ADI) and where necessary, the acute reference dose (ARfD) and recommended MRLs related to the commodities considered.

For the estimation of Long-term dietary exposure, an International Estimated Daily Intake (IEDI) is calculated for each compound for which an acceptable daily intake (ADI) was established.

The IEDI was calculated by multiplying the median concentrations of residues by the average daily per capita consumption of treated commodities. The concentrations were supervised trials median residues [STMRs] and/or supervised trials median residues in a processed commodity [STMR-Ps].

The per capita food consumption amounts were estimated using the Global Environment Monitoring System – Food Contamination Monitoring and Assessment Programme (GEMS/Food) cluster diets.

A detailed description of the method is included in the Environmental Health Criteria 240 (EHC 240) monograph. These IEDIs were expressed as a percentage of the upper bound of the ADIs for a 55 kg or 60 kg person, depending on the region covered by each cluster diet.

For the estimation of the Acute dietary exposure, an International Estimate of Short-Term Intake (IESTI), considered as an essential element in the risk assessment process of the Joint FAO/WHO Meeting on Pesticide Residues (JMPR), is calculated for compounds for which an acute reference dose (ARfD) was established.

For each relevant food commodity, the highest expected residue (highest residue in the edible portion of a commodity [HR] or highest residue in a processed commodity [HR-P]) and the highest large portion (LP) data for the general population (all ages) and children (6 years and under) were used for the calculation of the IESTI.

The LP data are derived from national dietary survey data collated by the WHO. For mixed commodities the STMR is used as the residue level in the IESTI calculation. In the case where a separate ARfD was established for women of childbearing age, the IESTI was calculated for this population group only. A description of the method is included in EHC 240.

Considering the conclusion and recommendation done by the EWGs, CCPR52 addressed a request to JMPR to address the questions still raised related to advantage/challenges of the approach and benchmarking of the IESTI equations against to the probabilistic distribution.

In their last report, posted in 2021, JMPR confirmed that IESTI equations used as part of JMPR risk assessments are fit for the purpose to ensure consumer protection and provide confidence that adoption of recommended MRLs is not expected to result in a public health concern.

The Meeting proposed that FAO/WHO establish an EWG to develop guidance that ensures the most appropriate and scientifically robust data for the input parameters is available for use in IESTI equations, and to further consider the impact of possible modifications to the IESTI equations in relation to the unit weight and residue level parameters.

The modifications to the IESTI equations discussed at the 2015 EFSA/FAO/WHO meeting are not expected to change the conclusions of the risk assessment in terms of consumer protection but introduce an additional degree of conservatism based on the benchmarking analysis.

The absence of quantitative consumer protection goals clearly General considerations formulated by CCPR does pose a challenge for determining the appropriate level of conservatism of the IESTI equation.

Impacts on the Arab Region

In the framework of the estimation of long-term and acute dietary exposure related to pesticides (IEDI/IESTI) and for the determination of MLRs, JMPR uses consumption data extracted from (GEMS/Food) cluster diets, which probably doesn't represent the real consumption habits prevalent in the Arab region.

Moreover, in its approaches, the meeting defined (STMR) and (HR) Levels considering the application of Good Agricultural Practices. The applicability of such approach for the Arab region, and the relevance of the resulting MRLs, will be highly dependent on the availability of consumption data.

Conclusion Considerations for the Arab Region

The conclusions reached by the EWG are informative and continue to support the evolutionary nature of risk assessment methodologies. The Risk Assessment Community in the Arab region supports these developments which will continue to enhance its own approaches in risk assessment to enable the development of MRLs relevant for the region, based on trial data, when they are available.

It would be important for Arab countries to generate consumption and occurrence data for food products and to submit them to GEMS/Food, in order to be considered by JMPR for the determination of MRLs.

It may be also recommended that the Arab region considers:

- Examining monitoring data related to pesticides in food products sold and produced in the region;
- Reviewing current risk management measures, in particular regulatory measures related to the use of pesticides in agriculture, specifically related to the application of a Good Agriculture Practices;
- Developing the approaches established for the assessment of acute and long-term dietary exposure to pesticides in the Arab region by using occurrence and consumption data generated from the region;
- Establishing a regional Expert Working Group to examine the above proposal and perform a risk analysis for pesticides in food, in the Arab region.