CODEX ALIMENTARIUS COMMISSION

Food and Agriculture Organization of the United Nations

World Health Organization

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Agenda Item 5(a)

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

56th Session

Santiago, Chile
8-13 September 2025

Comments submitted by CropLife International

Agenda Item 5(a) **Section 2 of the 2024 JMPR Report**

Report on items of general consideration arising from the 2024 JMPR meeting

DEVELOPMENTS IN DIETARY EXPOSURE METHODOLOGY FOR PESTICIDES RESIDUES IN FOOD

BACKGROUND

1. As summarized in the 'General Considerations' chapter of the Report from the 2024 Joint Meeting on Pesticide Residues (JMPR), the JMPR continued its work on Global Estimate of Chronic Dietary Exposure (GECDE) based dietary exposure methodologies to address the request by CCPR55 "about the uncertainty associated with the degree of conservatism and transparency of the GECDE methodology by comparison to the IEDI". The following recommendations were presented in the JMPR 2024 report:

   a. the evaluation undertaken for the 2024 meeting had shown good concordance between the GECDE and estimates of dietary exposure derived using food consumption data for individuals, for both the GECDE-mean and GECDE-high, when comparing boscalid, iprodione and piperonyl butoxide,

   b. the degree of overestimation in estimates of dietary exposure based on two days of food consumption data is relatively modest, compared to estimates based on longer survey durations, when comparing Romania, Mozambique and Italy,

   c. the meeting recommends the adoption of the GECDE-high in addition to the GECDE-mean as part of the exposure assessment methodologies used by the JMPR,

   d. the meeting recommends the GECDE-mean estimates replace the IEDI estimates and concluded that the GECDE methodology has been sufficiently well validated to establish its fitness for purpose for use by the JMPR in estimating chronic and less-than-lifetime dietary exposure to residues of pesticides.

2. However, there is no consensus in JMPR with the pesticide residue experts expressing a dissenting opinion in Annex 10 of the JMPR report:

   a. the GECDE-high methodology results in long-term exposure estimates which are significantly higher than the current IEDI model, and may result in an unrealistic overestimation of the long-term dietary risk, and

   b. more detailed information is needed to clearly describe the documentation on the model, data sources, underlying assumptions, model output, and how these were applied within the GECDE model.

COMMENT

<u>Agreement on exposure assessment methodology</u>

3. CropLife International is of the opinion that given the dissenting opinion of the pesticide residue experts outlined in Annex 10 of the report, the GECDE topic should not be under consideration for use in dietary risk assessment for pesticides until the JMPR has reached consensus on its use and benefits.

4. CropLife International recommends that this topic should be brought back to CCPR for consideration and further discussion only when there is agreement within the JMPR.

The need for change has not been addressed

5. CropLife International supports the statement of a Member State also reflected in the CCPR Report (REP24/PR55) paragraph 31 "... the need to change from IEDI to GECDE-mean was not clear ...". CropLife International also raised this concern at CCPR55 and has not seen evidence as to why there is a need to move away from existing dietary risk assessment model, the IEDI.

Impact analysis

6. CropLife International proposes that before CCPR and the Codex Alimentarius Commission make risk management decisions based on the GECDE methodology, a thorough assessment and comparison should be conducted on the conservatism and protection between the current chronic exposure assessment methodology IEDI, the proposed GECDE mean, and the proposed GECDE high methodologies. Further analysis needs to be undertaken, including:

   a. For external comparison, a benchmarking to other chronic assessment methodologies used by various regulatory bodies, e.g. the EU, Japan, USA, and other countries.

   b. An impact assessment on how many of the approximately 230 pesticides which currently have Codex MRLs, would be significantly impacted by or fail a current GECDE-mean and GECDE-high risk assessment. The assessment of a few pesticides in the last two years is a valuable start, but a full analysis needs to be performed.

   c. For each pesticide, how many Codex MRLs would be lost or would need a lower GAP to pass the risk assessment and how would that limit the availability of tools for farmers?

   d. How could a risk assessment be refined if it fails one of the population sub-groups?

   e. Providing a complete plan with an expected timeline and necessary resources to adjust exposure assessment for all existing Codex MRLs to the newly proposed methodology.

PROCEDURAL MATTERS

7. CropLife International has several open questions on how the procedural transition to the proposed chronic exposure assessment needs to occur.

8. The Codex Alimentarius Commission Procedural Manual (2025) paragraph 166 of the Risk Analysis Principles states "In addressing pesticide residue issues in Codex, providing advice and taking decisions on risk management is the responsibility of the CAC and CCPR, while conducting risk assessment is the responsibility of JMPR." CropLife International would recommend that if JMPR decides to use the GECDE for their risk assessments, JMPR should also provide the traditional IEDI dietary assessments in parallel to aid CCPR in their risk management decision making.

9. Also from the CAC Manual, paragraph 172 states "CCPR and JMPR should ensure that their respective contributions to the risk analysis process result in outputs that are scientifically based, fully transparent, thoroughly documented and available in a timely manner to Members." The need for full transparency and thorough documentation is reiterated in paragraph 267 which states "In accordance with Section 4: Working principles for risk analysis for application in the framework of the Codex Alimentarius, the CCPR, in cooperation with JMPR, shall ensure that the risk analysis process is fully transparent and thoroughly documented and that results are made available in a timely manner to Members and Observers." CropLife International, as an Observer representing stakeholders responsible for a large number of dossier submissions, seeks more detailed information on data sources, information and validation of data with respect to data accuracy and representativeness of data sets, the "decomposite" composite foods, preparation of underlying data for input, and an Excel or web-based tool to conduct the exposure assessment.

10. Paragraph 213 states "CCPR shall base its recommendations on the GEMS/food diets used to identify consumption patterns. The GEMS/food diets are used to assess the risk of chronic exposure. The acute exposure calculations are not based on those diets, but available consumption data provided by Members and compiled by GEMS/food." CropLife International suggests that this paragraph would need to be changed in the CAC manual before different dietary information other than GEMS/food can be used.

TECHNICAL ASPECTS

11. CropLife International has reviewed the assessments and information provided so far by JMPR and has various technical questions, some are highlighted below.

12. Quality of surveys: CropLife International would like to ensure that the consumption surveys used in the GECDE method have been conducted following the minimum international standards regarding number of participants and appropriate statistical weighting to represent the underlying population. While it is recognized that there is value in having the granularity of exposure information for consumer groups such as infants and children, the consumption data for these consumer groups from each country in the database must be robustly reliable. The standard for verifying these data is

crucial for these groups as they consistently result in the highest exposure by body weight. CropLife International is concerned that the data quality for these consumer groups is not reliable enough or fit-for-purpose for a global consumer risk assessment.

13. Insufficient validation of the GECDE methodology: In the 2024 JMPR Report, the dietary exposure estimates derived using food consumption data for individuals from nutrition surveys were compared with the GECDE estimates for three pesticides and 61 surveys. It was concluded that there is good concordance (i.e. high correlation coefficient) between the GECDE (mean and high) and the estimates of dietary exposure from the individual dietary records. Overall, there is good concordance between the GECDE-mean and the mean of the dietary exposure from the respective individual dietary records ($R^2 = 0.9447$). However, it must also be noted that in some cases there is a significant difference between the two values. The reasons for that need to be better understood. CropLife International also questions the alleged good concordance between the GECDE-high and the high percentiles of the dietary exposure from the respective individual dietary records ($R^2 = 0.7688$ for the 95th percentile and 0.6979 for the 97.5th percentile) since many points are far from the correlation line. Furthermore, a good correlation between the GECDE and the estimates of dietary exposure from the individual dietary records would not suffice to demonstrate that GECDE is an appropriate and reliable tool to estimate the exposure of consumers to pesticide residues. As mentioned earlier, quality and reliability of the underlying dietary surveys needs to be assessed first.

14. Need for transparent disaggregation of consumption data: In preparation for exposure assessment, it is necessary to "disaggregate" the data collected from dietary survey data. People report eating such items as "dumplings" or "pizza"; they do not report eating wheat grain or soybean seeds. Therefore, it is necessary to "disaggregate" these composite foods into the elements needed to conduct the dietary risk assessment. A lot of information is needed to decomposite these composite foods. CropLife International has currently no information on this disaggregation step that was used for the GECDE method.

15. Underrepresentation of the global population: Currently 179 countries are represented in the JMPR IEDI approach based on 17 clusters, but only 46 countries are represented in the GECDE approach (Appendix 1). Cluster 2, 4, 12, 14 and 17 from the IEDI approach, a total of 44 countries, have no representation at all. Of the remaining 12 clusters, 10 of them have less than 50% of the countries represented by GECDE.

16. The currently proposed GECDE methodology is not fit-for-purpose for evaluation of pesticide residues: The GECDE model and supporting consumption data have been used by JECFA to evaluate veterinary drug and biocide uses on livestock or livestock premises since 2011. While this speaks for the method, it is necessary to point out that dietary exposures derived from such livestock uses are generally much lower than those from the combination of pesticide application to crops and consumption of treated crops by livestock. CropLife International believes that the current IEDI chronic risk assessment is already conservative with regard to exposure calculation for all regions of the world. As the GECDE model has shown to be significantly more conservative, CropLife International is of the opinion that in its current state is not appropriate for evaluating the higher exposures from crop protection uses.

NEXT STEPS

17. It is CropLife International's opinion that for evaluating the need for change, addressing the procedural and technical aspects, and assessing the impact of a proposed transition to GECDE mean, the establishment of an EWG would be beneficial.

Appendix 1: Comparison of countries which are covered by GEMS/Food Consumption Cluster diets used in the current IEDI calculation and consumption data in the CIFOCOSS database used in the GECDE calculation

Figure 1: Map of countries covered by GEMS/Food Consumption Cluster diets used in the current IEDI calculation

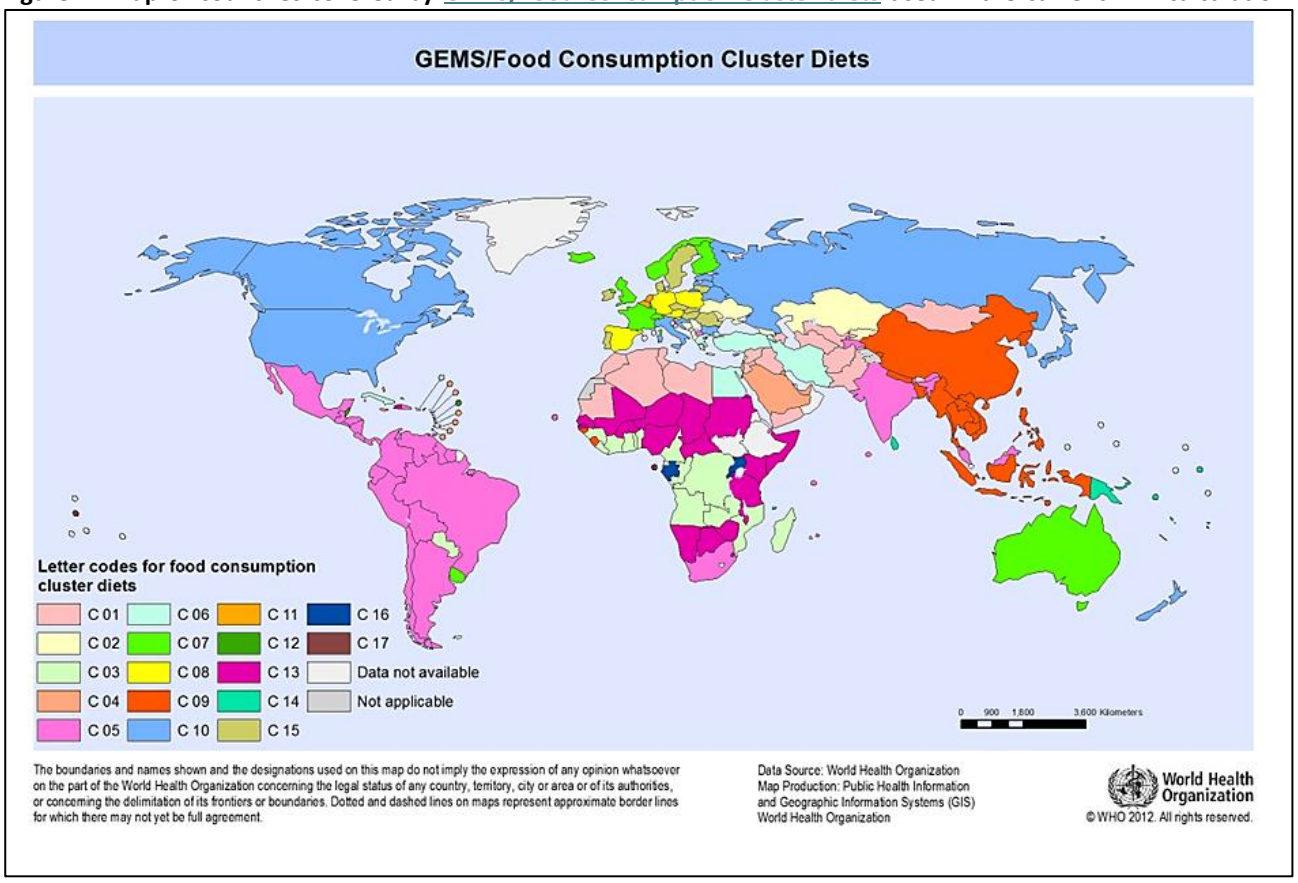

Figure 2: Map of the countries with consumption data in the CIFOCOSS database used in the GECDE calculation