CODEX ALIMENTARIUS COMMISSION

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World Health Organization

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Agenda Item 11 **CX/PR 21/52/15**

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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON PESTICIDE RESIDUES

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DISCUSSION PAPER 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)

Codex members and observers wishing to submit comments on the proposed Guidelines should do so as instructed in CL 2021/42-PR available on the Codex webpage/Circular Letters[1] or CCPR/Related Circular Letters[2]

Background

1. Since the late 1990s, 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 was 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 in reality. As such, it should be ensured that Codex maximum residue limits (MRLs) are toxicologically acceptable for consumers, as requested in CAC (CAC, 2018).

2. In 2006 and 2007, JMPR identified 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 (FAO 2006, 2007).

3. In September 2015, experts on dietary exposure discussed during an international workshop in Geneva organised by the European Food Safety Authority (EFSA) and the National Institute for Public Health and the Environment (RIVM) and co-sponsored by FAO and WHO, possible modifications of the IESTI equations (EFSA and RIVM, 2015), taking into account the experience gained with IESTI equations for almost 20 years.

4. Following a proposal of the EU and Australia, CCPR48 (2016) supported[3] the proposal to explore the potential impact of possible changes to the IESTI equations. Delegations also acknowledged that it was timely for JMPR to review the IESTI procedure and that CCPR should discuss the need to harmonise approaches for risk assessment, risk management and risk communication.

5. CCPR48 established an Electronic Working Group (EWG) (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. The recommendations of the international EFSA/RIVM workshop cosponsored by FAO and WHO (EFSA/RIVM, 2015) and the discussions in CCPR48 should be taken into account.

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1 http://www.fao.org/fao-who-codexalimentarius/resources/circular-letters/en/
2 http://www.fao.org/fao-who-codexalimentarius/committees/committee/related-circular-letters/en/?committee=CCPR
3 REP16/PR, paras. 184-194

6. CCPR49 (2017) considered the discussion paper[4] prepared by the EWG-1 on IESTI; the document elaborated the advantages and challenges from risk management perspective that might arise from the possible revision of the current IESTI equations. In addition, the discussion paper outlined a number of technical/risk assessment challenges that arise from the IESTI equations used by JMPR as well as from a possible revision of the IESTI equations.

7. CCPR49 recommended[5] that FAO/WHO should review the basis and the parameters of the IESTI equations, considering the technical challenges identified in the discussion paper; in addition, FAO/WHO should benchmark the outcomes of IESTI equations to a probabilistic distribution of actual exposures.

8. CCPR49 also agreed to re-establish an EWG (EWG-2). The focus of the EWG-2 — in contrast to the EWG-1 — was on the use of the current IESTI equations. In particular, the following points should be addressed in a discussion document:

   (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.

9. CCPR50 (2018) discussed the document prepared by the EWG-2 which summarised the history, background and use of the IESTI equations and which summarised the ongoing work on the review of IESTI, including information on activities outside the EWG.[6] Since the work on TOR (ii) and (iii) could not be finalised due to lack of scientific advice from FAO/WHO, CCPR50 agreed to re-establish the EWG (EWG-3) and continue the work on the following TOR[7]:

   (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.

10. In addition, the Committee agreed to append the following outputs prepared by the EWG-2 to the report of the CCPR50:

   - the document on the history, background and use of the IESTI equations as part of the CCPR report[8];
   - the table on technical / risk assessment challenges that either arise from the possible revision of the current IESTI equations or are current challenges.[9]

11. In the JMPR Report 2018 (FAO, 2018), preliminary results for probabilistic modelling of acute dietary exposure to evaluate the IESTI equations were presented. This work had been initiated by WHO to address the second part of the request of CCPR49 to FAO/WHO, i.e. to benchmark the outcomes of IESTI equations to a probabilistic distribution of actual exposures. The final report was expected to be ready for discussion in CCPR51.

12. In the 2019 CCPR meeting (CCPR51), the Representative of WHO presented the draft report on the acute probabilistic dietary exposure assessment for 47 pesticides.[10] Due to the late availability of the draft report, a full discussion of the draft report during the CCPR meeting was not possible. It was envisaged the final paper would be presented to JMPR in September 2019 for further discussions.

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4 CX/PR 17/49/12
5 REP 17/PR, para. 147-163
6 CX/PR 18/50/12
7 REP 18/PR, para. 130-137
8 Appendix XI to REP 18/PR
9 Appendix XII to REP 18/PR
10 CX/PR 19/51/3-Add.2

13. Considering that the draft report was not available at the time of the EWG discussions, the TOR of EWG-3 could not be finalised. Hence, the discussion document prepared by the EWG-3[11] addressed TOR (i) only partly. The EWG-3 also drafted a circular letter to be used by CCPR for gathering relevant information on bulking and blending practices; the feedback on the Circular Letter (CL) is considered relevant in consideration of the current practice of using central tendency median (STMR) values for estimating the short-term dietary exposure for products that are subject to bulking and blending. The letter also asked for information to better clarify which commodities belong to Case 3.

14. CCPR51 agreed to issue the CL prepared by the EWG-3 to collect information on bulking and blending. The CL was sent out in July 2019 (CL 2019/73-PR[12]); the deadline for submitting information was 10 November 2019.

15. In addition, CCPR 51 agreed 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.[13]

16. In the meantime, the study of FAO/WHO study was finalised (August 2019) and the results were presented and discussed in the JMPR 2019 Meeting (FAO/WHO, 2020). The publication is still pending. The final published report on the FAO/WHO assessment was not available.

Introduction

17. The discussion paper was prepared to address the TOR agreed in CCPR 51 for EWG on the IESTI equations (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.

18. In order to address the first part of TOR (i), the EWG reflected on the findings of FAO/WHO and findings published in peer reviewed literature in relation to

    - advantages/benefits and challenges arising from the current IESTI equations (**section 1**);
    - the benchmark of the outcomes of the IESTI equations to probabilistic distribution of actual exposures (**section 2**);
    - the review on the parameters of the IESTI equations (**section 3**).

19. To address TOR (ii), the EWG summarised information submitted in response to the CL 2019/73-PR in **section 4** to be provided to risk assessors through the JMPR Secretariat.

20. In order to address TOR (iii), **Section 5** contains conclusions and recommendations for deliberations at CCPR 52.

21. In EWG-4, the following members signed up: 71 members from 33 countries and 5 observers. The draft discussion paper was presented for commenting and was discussed in two web conferences (17 January 2020 and 5 February 2020). Representatives of 17 Codex members and 5 observers posted comments and/or participated on the web conferences.

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[11] CX/PR 19/51/14

[12] The Compilation of the replies to this CL can be found by clicking on this link.

[13] REP 19/PR, para. 187-197

1. Benefits/advantages and challenges of the current IESTI methodology

22. As a result of the previous EWGs, a list of benefits/advantages and challenges of the current IESTI methodology was prepared, considering the impact on the IESTI methodology on risk management, on risk communication, on consumer protection goals and on trade. Since the current discussion paper should build on the previous discussion on benefits and challenges, the tables below briefly outline the key points raised in EWG-3 (CX/PR 19/51/14 Appendix I).

Table 1: Benefits/advantages of the current IESTI equations

General benefits/advantages
The IESTI methodology is transparent. IESTI calculations require low computational capacity; the calculations can be performed easily using standard IT tools.
Benefits from risk management perspective
IESTI calculations provide clear answers to risk management questions (i.e. whether the short-term exposure is above or below the toxicological reference value (ARfD)). Because of the IESTI methodology, risk management decisions became more consistent, transparent and reproducible. IESTI methodology generally promotes global harmonisation of risk management decisions. The use of the JMPR IESTI calculation tool which is based on the IESTI equations allows to perform ad-hoc risk assessments which give answers to risk managers whether risk management actions are needed.
Benefits from risk communication perspective
The IESTI calculations are performed in a transparent way which can be shared with interested parties. The IESTI calculations are used to support the messaging that Codex MRLs are health protective. The IESTI calculation tool was proven to be beneficial not only in the framework of establishing safe Codex MRLs, but also for supporting food inspection services and national competent authorities to answer risk management questions on the safety of national MRLs or the safety of food placed on the market.[14] The input values are simple and can be generated at reasonable costs for different geographical regions.
Benefits from perspective of consumer protection
IESTI calculations are generally assumed to give conservative estimates compared to expected exposure events occurring in real life, because the methodology • combines conservative estimates for food intake (large portion covers 97.5th percent of the consumers that according to food surveys consume a certain product) with • conservative estimates for the expected residue concentration (highest residue or median residue expected on a crop for the most critical Good Agricultural Practice) and • postulates that the food item consumed may contain higher residues than the residues measured in the residue trials where composite samples were analysed which usually contains at least 12 units of the food item. This assumption is taken into account by applying a variability factor. IESTI calculations support risk-based decisions on the setting of Codex MRLs taking into account national food consumption habits.

14 It is common practice in the EU that the IESTI equations (EU version of IESTI equations with European food consumption data and agreed European variability factors) are used to take decisions on risk management actions for consignments/lots where the food control services find residue levels exceeding the MRL.

Benefits regarding impact on trade

Setting Codex MRLs promotes international trade.

Harmonised risk assessment methodologies promote the acceptance of food standards at international level, hence reducing non-tariff trade barriers.

Table 2: Challenges of the current IESTI equations

General challenges

Some countries experienced that the JMPR IESTI model is too rigid or too conservative.

Some countries question if the JMPR IESTI model is conservative enough.

Data to verify the level of protection achieved with the IESTI methodology have not been available so far. Recent studies that were performed to address this issue are reported in Section 2.

Due to the different perception of the level of conservatism, national models have been developed which implement modifications of the IESTI equations, e.g. using different variability factors, unit weight data, consumption data.

A main challenge is to find agreement on a harmonised methodology which is acceptable for all Codex member countries.

Challenges from risk management perspective

The IESTI methodology is deterministic and does not give risk managers quantitative information on:

- the distribution of the exposure across the population;
- the uncertainty of the calculations, and
- the frequency of cases where the short-term exposure exceeds the ARfD or level of protection (i.e. for a target population).

The development of this type of quantitative information requires the use of probabilistic methods and tools to assess population-based data on pesticide residue levels and food consumption. The possibility to generally link the IESTI better to the population-based exposure would benefit from further exploration.

For making IESTI calculations representative for all Codex member countries, it would be desirable to integrate a wide range of food consumption data from different regions worldwide.

Internationally agreed protocols for a harmonised approach on how to derive consumption data for the IESTI methodology are not in place.

Although the IESTI methodology leads to a high level of harmonization in acute risk assessments at international level, complete harmonisation is not realistic because countries may use differing inputs (such as national consumption data, residue definitions, variability factors, crop group extrapolation and toxicological reference points) which impacts on MRL setting.

Diverging input variables used in the national models (modified IESTI equations) by different Codex member countries lead to different exposure outcomes. This divergency may result in rejection of Codex MRLs by some Codex member countries. Consequently, the need for negotiations on acceptance of Codex MRLs increases.

Changing the currently used IESTI methodology by replacing or modifying input variables in order to find wider acceptance of the methodology would lead to different results compared to previous risk assessments performed by JMPR. Hence, Codex MRLs that were considered safe may not be safe or vice versa, if the same input values are used in a revised methodology.

Challenges from risk communication perspective

Some Codex member countries face risk communication challenges to explain that Codex MRLs are sufficiently protective because the risk assessment with IESTI equations is not performed with the Codex MRL but with the highest residue (HR) or the supervised trials median residue (STMR) obtained from residue trials; both the HR and the STMR are usually lower than the MRL. Further examination of this challenge was discussed at the international workshop in Geneva (EFSA RIVM, 2015), which proposed potential simplification of the IESTI equation. Some Codex members within the EWG suggested that simplification of the IESTI equations, particularly for case 2a and 2b, would enhance the understanding of the methodology by the general public and stakeholders and would positively impact risk communication.

In 2006 JMPR recommended to discuss the adequacy of IESTI equations to assess the safety of food containing residues at levels found in monitoring and/or enforcement programmes (FAO, 2006). Although some Codex member countries would welcome further work to develop tools/models aligned with the IESTI methodology that can be used for national enforcement programmes, previous EWG considered that the development of these risk assessment tools does not fall under the remit of CCPR/JMPR and therefore this point is not further discussed.

Challenges from perspective of consumer protection

Quantitative consumer protection goals have not been clearly formulated.

Reliable information on the actual level of protection resulting from the use of IESTI methodology at international level is not available.

The IESTI calculations case 1, 2a and 2b[15] are performed with the HR (highest residue, input value used in IESTI calculations, see Table 3 which refers to the residue definition for risk assessment and reflects the residue in the edible part of the crop. The HR is a point estimate; the variability of the residue concentrations measured in the individual residue trials and expected when the pesticide is applied in accordance with the Good Agricultural Practices approved in Codex member countries is not taken into account.

In contrast to the HR, MRLs are usually established following a statistical assessment implemented in the OECD calculator. The MRL is intended to entail at least 95% of the residue levels expected on treated crops in accordance with the Good Agricultural Practice, to ensure that agricultural products produced in accordance with the GAP are compliant with the legal limit. Since 2010, JMPR also uses to OECD calculator to derive MRL proposals. The MRL derived with the OECD calculator is usually higher than the HR. Based on synthetic residue data with 4 trials, 8 trials and 16 trials it was concluded that the ratio between MRL and HR is 2.1, 1.8 and 1.5, respectively. The ratio between MRL and STMR was calculated to account for 4.1, 4.8 and 5.3 for datasets of 4, 8 and 16 trials. The gap between MRL and HR/STMR depends to a large extent on the number of residue trials (Van der Velde-Koerts et al, 2018b). As a consequence, the phenomenon exists that the IESTI calculations exceed the ARfD if the exposure is calculated with the Codex MRL, instead of using the HR or STMR. For these cases it is difficult to communicate to the public that the MRL is safe (Richter et al, 2018).

Challenges regarding impact on trade

A change in the current JMPR IESTI model may trigger the need to lower certain CXLs, and consequently would introduce new trade barriers. For those cases, alternative Good Agricultural Practices (GAPs) need to be developed, leading to acceptable residues with regard to short-term dietary intake.

Recent publications considered the impact of modifications of IESTI variables and suggested that only a minor percentage of CXLs would be affected van der Velde et al (2018a)). However, it is not known how any of such modifications and losses of CXLs might be measured in trade value, lost pest control, or reduced abilities for growers to substitute alternate chemistries and the impact on weed or insect resistance issues.

Establishing Codex MRLs for the alternative GAPs will take time and causes additional costs.

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15 The difference between IESTI case 1 and 2a/2b is the use of a variability factor: while for case 2a/2b the HR value is multiplied by a variability factor, this is not the case for food products where the exposure calculations are performed according to case 1. More details on the calculation algorithm for the different IESTI cases can be found in section 3.

2. Benchmarking of IESTI calculations against probabilistic exposure estimates

2.1. Overview

23. FAO/WHO performed a study on a probabilistic exposure assessment to address the request of CCPR49 to FAO/WHO which specified that FAO/WHO should:

(i) review the basis and the parameters of the IESTI equations,

(ii) benchmark the outcomes of IESTI equations to a probabilistic distribution of actual exposures and

(iii) present the outcome to CCPR.

24. In general, benchmarking is a process of comparing performance metrics of a product or a process (in the given case the performance of the IESTI methodology as it is currently used by JMPR) to practices generally considered as superior or being acknowledged as the best practice. The purpose of benchmarking is to identify opportunities for improvement. A successful benchmarking process of the IESTI methodology requires a reference methodology which is generally accepted as leading to a forecast of the short-term dietary exposure of consumers that is closer to reality. The predicted exposure derived with IESTI calculations should be compared with the exposure derived with the reference methodology to identify whether the IESTI methodology fulfils its purpose, i.e.

- IESTI reliably predicts consumer health risks, and
- at the same time the calculations are not overly conservative, indicating arbitrary consumer health concern, because of overestimation of the exposure.

25. Overall, the study should validate the ability of the IESTI methodology to predict exposure events above and below the ARfD that are likely to occur within a population.

2.2. FAO/WHO Benchmarking Assessment of the IESTI Equations

26. FAO/WHO prepared a final draft assessment that was discussed at CCPR51 (CX/PR 19/51/3-Add.2); in August 2019 an updated, final analysis was provided to the EWG-4 that was subsequently presented to JMPR at its 2019 Regular Meeting on September 17-26, 2019.

27. In this study, FAO/WHO (2019) estimated acute dietary exposure for 47 pesticides using a probabilistic methodology (Monte Carlo methodology) based on real-world data on pesticide residue levels and food commodity consumption collected as a part of national pesticide monitoring programmes and food surveys. The assessment included food surveys from eight countries (Australia, Brazil, Canada, and the European countries Czech Republic, France, Italy and the Netherlands) and monitoring data on unprocessed products (RAC) from five countries/regions. For three countries food consumption data were available for both adults and children. Overall 6 scenarios for adults and 5 scenarios for children were calculated.

28. For each scenario, the matching food consumption data/pesticide monitoring data were identified which were then used to perform the probabilistic exposure calculations. The number of food items taken into account in these calculations ranged from 11 (Italian adults)[16] to 127 (Canadian adults). FAO/WHO then performed its assessment by first comparing the IESTI equation with the probabilistic exposure estimates and then performing a level of protection analysis (LoP) that assumed all foods consumed contained pesticide residue concentrations at the MRL. Each component of FAO/WHO's assessment and conclusions reported in JMPR's 2019 Summary Report are further described below.

- The first component of FAO/WHO's assessment provided exposure estimates derived with probabilistic exposure models for each of the eight countries and compared the results with the relevant Acute Reference Dose (ARfD). This comparison considered two use scenarios - 10% use of the pesticide and 100% use of the pesticide[17] – and concluded that there was a zero risk of exceeding the relevant ARfD in all countries and subpopulations of adults/children. For adults, the 97.5th percentile of acute dietary exposure was <10% ARfD, for children <50% ARfD. Based on these results, JMPR concluded that the IESTI equation was considered protective for acute risk (FAO/WHO, 2020).

16 In the Italian diet the following food items were considered in the exposure calculation which are probably not sufficiently representative for the typical Italian diet: Almonds, coconuts, ginseng, lentil (dry), milk (cattle), pine nut kernels, pistachio nuts, sunflower seed, watermelons and walnuts.

17 As reported by JMPR, two scenarios were tested: 10% use of the pesticide, i.e., only 10% of non-quantifiable samples were assumed to contain the pesticide (90% concentrations assigned a zero value; 10%, the LOQ) and 100% use (all commodities are treated and 100% of the non-quantifiables were assigned the LOQ).

- The second component of FAO/WHO's assessment was a LoP analysis that used the same consumption data as the first component, but assumed that all food consumed contained pesticide residues at the CXL for each of the 47 pesticides selected by WHO. The LoP was defined by the study authors as the percentage of person-days with intakes at or below the ARfD when the residue occurs at the level of the CXL. Based on the LoP calculations performed by FAO/WHO, a LoP of 100% indicates that no acute dietary exposure estimates exceeded the ARfD.

Based on the LoP analysis, for 4 of the 47 pesticides covered by the study, the LoP of MRLs was lower than 90% for at least 1 population in 1 country. For 7 pesticides, the LoP was found to range between 90 and 99% for all populations in all countries. For the remaining 36 pesticides, the LoP was higher than 99% (among those, for 14 pesticides the LoP was 100%).

29. The 2019 JMPR concluded that given the extremely conservative estimates produced when assuming all commodities have residues present at the MRL, a LoP of less than 100% does not necessarily indicate that approved uses will lead to an exceedance of the ARfD in practice.

30. The 2019 JMPR suggested that a more realistic assessment of the LoP could be made by assuming residues at the MRL for a single commodity and residues from monitoring data for other commodities in the assessment (FAO/WHO, 2020).

31. A final published report on the FAO/WHO assessment was not available during the development of this EWG discussion paper, but the results and conclusions are consistent with the final draft assessment that was prepared by FAO/WHO and discussed at CCPR51 (CX/PR 19/51/3-Add.2). JMPR's summary also reaffirms the preliminary assessment conclusions, which are summarized below and were further re-iterated by the WHO Representative during CCPR51 plenary discussion.[18]

> *The IESTI equation is used as a proxy for estimating the acute dietary exposure at international level. 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.* (CX/PR 19/51/3-Add.2)

32. Some EWG members felt that the unavailability of the final report, describing in detail the study design and the findings, impacted the discussions on the strength of the FAO/WHO study; this limited the ability of the EWG to fully deliberate on whether the findings were sufficiently conclusive with respect to the degree to which the current IESTI is protective.

33. Some members of the EWG were of the opinion that the study was not designed as a benchmarking exercise which compares the outcome of the currently used IESTI equation with the distribution of the exposure calculated with the Monte Carlo methodology. Others found the FAO/WHO study is congruent with many other national probabilistic assessments which have consistently demonstrated that actual exposures are far lower than those from deterministic models.

34. Given that members of the EWG had additional questions on the methodology and results, more detailed documentation of the study should be provided that could allow an improved interpretation of the results. In particular, understanding of the FAO/WHO report would benefit from further explanations of the following:

- Information whether the food products, for which the calculations were performed, were sufficiently representative for the total diet of the subgroup of the population assessed in the scenarios: The information on the study design did not allow to conclude whether the exposure calculations are reliable enough to predict the total exposure of the population subgroups covered by the study. If the probabilistic calculations cover only a small proportion of the food products consumed by the respective population group, the calculated exposure derived with the probabilistic calculation would underestimate the actual exposure and consequently, the results of the probabilistic exposure calculations cannot be used for a benchmarking exercise.

18 REP19/PR, Paragraph 190 states: "The WHO Representative informed CCPR that the FAO/WHO study on acute probabilistic dietary exposure assessment for pesticides was still a draft; found the current IESTI equation was protective as it is; and that while there might be amendments to the text, the conclusions were firm and unlikely to change during the finalization of the paper. The Representative further noted that the written comments received to date on the paper would be forwarded to the authors for their consideration when finalizing the paper."

- In general, the calculation of the acute exposure using a probabilistic methodology can provide information on the distribution of the exposure related to the food placed on the market in the respective country. However, considering the lack of full harmonisation of national MRLs with Codex MRLs, the use of national monitoring data adds uncertainty for a benchmarking exercise validating the adequacy of the IESTI methodology used by JMPR to derive Codex MRL proposals. If national MRLs are lower than the Codex MRLs, it is expected that the respective food products placed on the market would in general contain lower residues than the residue levels in countries in which the Codex MRLs were taken over in the legislation and vice versa. Hence, the exposure calculation based on these monitoring data would not allow to draw a conclusion on the risk assessment performed by JMPR using IESTI methodology for Codex MRL proposals.
- Further details on the residue definitions for MRL compliance applicable in the countries in the countries which provided pesticide monitoring data would be useful to ensure that they match with the residue definitions of Codex.

35. Without these details some members felt it would be difficult to develop a conclusion on whether the FAO/WHO study provides a reliable answer to the question of whether the IESTI methodology is fit for purpose. Hence, the EWG recommends that a more detailed information be prepared by FAO/WHO which is made available to CCPR and JMPR.

2.3. Relevant Exposure Assessments in the Peer-Reviewed Literature

36. Cleveland et al (2019) published a paper which aimed at benchmarking the outcomes of IESTI calculations (current IESTI calculations and calculations according to the recommended methodology derived in the international workshop in Geneva (EFSA/RIVM, 2015)) for strawberries (12 pesticides), tomatoes (16 pesticides) and apples (8 pesticides) against refined exposure assessments (quasi-probabilistic and probabilistic calculations). For the refined exposure assessments distributions of US consumption data were combined with (i) Codex MRLs (quasi-probabilistic calculation), (ii) distribution of field trial data and (iii) distribution of US monitoring data (both probabilistic calculations). US consumption data were used in the quasi-probabilistic and the probabilistic calculations (for apples and tomatoes: consumption data of children of the age 1-6 years, for strawberries: consumption of children age of 3-6 years). A possible unit-to-unit variability for apples and tomatoes was not taken into account. For the quasi-probabilistic calculation, the exposure was calculated for the 97.5th percentile of eaters. In the scenario with supervised field trials, the 95th percentile and for monitoring data the 99.9th percentile per capita exposure was calculated.

37. Overall, the paper gave a ranking of exposure estimates obtained for the three food products with different calculation scenarios, normalised against the currently used IESTI methodology. Using the Codex MRL in the quasi-probabilistic calculation, exposure was in general lower than the exposure calculated with the current IESTI methodology (1.1 – 3.7 times lower). Using data from supervised field trials, the exposure (95th percentile) was 8 – 120 times lower than the IESTI estimate. In the scenario using monitoring data the difference ranged from 4.1 times lower (acetamiprid/strawberries) to 1750 times lower (methoxyfenozide/tomatoes).

38. The calculation based on monitoring data might be biased for cases where the US tolerance is set at a different level than the Codex MRL (see examples in footnote[19]), since the monitoring data do not necessarily reflect the Codex MRL. The quasi-probabilistic and the probabilistic calculation with results from residue trials provide answers to a question, which is close to the question of CCPR regarding the adequacy of the IESTI equations in terms of conservatism. However, the study does not allow to conclude on the reliability of the IESTI calculations to predict or exclude consumer health risks. It would be necessary to investigate in more detail the distribution at the upper tail of the exposure calculations derived with the quasi-probabilistic and probabilistic calculation scenarios and to compare the results with the ARfD.

39. A number of additional studies are available which may provide further details to interested readers on previous discussions on the variability factors used in IESTI equations (EFSA, 2005, 2007).

[19] US tolerance for strawberries for thiamethoxam: 0.3 mg/kg; CXL: 0.5 mg/kg
US tolerance for tomatoes for sulfoxaflor: 0.7 mg/kg; CXL: 1.5 mg/kg
US tolerance for apples for pyraclostrobin: 1.5 mg/kg; CXL: 0.5 mg/kg

40. Breysse et al (2018) and van der Velde et al (2018a) investigated the impact of modifications of the IESTI equation as discussed in the international workshop in Geneva (EFSA & RIVM, 2015) on the existing EU and Codex MRLs. However, since these papers did not perform a benchmarking of IESTI calculations against a distribution of dietary exposures expected if food is consumed that complies with the Codex MRLs, they are not discussed in further detail.[20]

2.4. Summary

41. In summary, FAO/WHO has performed an assessment of the IESTI equations using probabilistic data on national pesticide residue levels and food commodity consumption. This includes a final draft FAO/WHO assessment that was discussed at CCPR51 and a presentation of these results at the 2019 JMPR Regular Meeting.

42. The results of FAO/WHO's assessment help characterize the current IESTI equation and reaffirm the conclusion reported by the WHO Representative at CCPR51 that, "found the current IESTI equation was protective." The EWG also reviewed a limited number of more recent publications in the scientific literature that provide further evaluation of the IESTI equations using probabilistic methods.

43. While information is available on the FAO/WHO assessment, the EWG was unable to review FAO/WHO's final, published report during the development of this EWG discussion paper and only brief information on results was presented to JMPR during its 2019 Regular Meeting. This limited the ability of EWG to fully deliberate on the strength of the study and whether the findings can be used to make general conclusions on the degree to which the current IESTI is protective. It is recommended that FAO/WHO provide clarifying statements to aspects raised by CCPR52. This will help inform CCPR discussion on the FAO/WHO benchmarking assessment and the more general conclusions on the IESTI methodology.

3. Review of the parameters of the IESTI equations: findings of FAO/WHO and of published in peer reviewed literature

44. For performing the short-term dietary intake calculations JMPR applies the following IESTI equations (equation 1 to 7) (FAO, 2016).

Case 1 applies for the following cases:

- for fruits and vegetables with a unit weight of the raw agricultural commodity less than 25 g (U_{RAC} < 25 g);
- for post-harvest uses of pesticides on cereal grains, oil seeds and pulses, as well as for meat, liver, kidney, edible offal and eggs):

Unprocessed products $$\mathrm{IESTI} = \frac{\mathrm{LP} \times \mathrm{HR}}{\mathrm{bw}}$$ Equation 1

Processed products $$\mathrm{IESTI} = \frac{\mathrm{LP} \times \mathrm{HR-P}}{\mathrm{bw}}$$ Equation 2

Case 2a applies for the following cases:

- for fruits, vegetables with a unit weight of the raw agricultural commodity greater than 25 g (U_{RAC}>25 g) and a unit weight of the edible part of the raw commodity less than the large portion consumed (U_e<LP)

Unprocessed products $$\mathrm{IESTI} = \frac{\mathrm{Ue} \times \mathrm{HR} \times \mathrm{v} + (\mathrm{LP} - \mathrm{Ue}) \times \mathrm{HR}}{\mathrm{bw}}$$ Equation 3

Processed products $$\mathrm{IESTI} = \frac{\mathrm{Ue} \times \mathrm{HR-P} \times \mathrm{v} + (\mathrm{LP} - \mathrm{Ue}) \times \mathrm{HR-P}}{\mathrm{bw}}$$ Equation 4

20 Even though the TOR focusses on advantages and challenges of the current IESTI methodology and not on potential IESTI changes, information from these publications might be useful to have an indication on the change in number of accepted CXLs if the input variables (and the equations) are amended according to the recommendations of the international scientific workshop in Geneva in September 2015.

Case 2b applies for the following cases:

- for fruits, vegetables with a unit weight of the raw agricultural commodity greater than 25 g (U_{RAC}>25 g) and a unit weight of the edible part of the raw commodity (U_e) greater than the large portion (U_e>LP)

Unprocessed products $$\mathrm{IESTI} = \frac{\mathrm{LP}\ \times \mathrm{HR} \times \mathrm{v}}{\mathrm{bw}}$$ Equation 5

Processed products $$\mathrm{IESTI} = \frac{\mathrm{LP}\ \times \mathrm{HR} - \mathrm{P} \times \mathrm{v}}{\mathrm{bw}}$$ Equation 6

Case 3 applies for the following cases

- for pre-harvest uses of pesticides for processed commodities where due to bulking and blending the STMR-P represents the likely highest residue;
- for cereal grains, oil seeds and pulses but also to milk.

Processed products $$\mathrm{IESTI} = \frac{\mathrm{LP}\ \times \mathrm{STMR} - \mathrm{P}}{\mathrm{bw}}$$ Equation 7

45. In the table below the individual parameters are explained, including findings on advantages and challenges that were raised in previous discussions and the resulting limitations. In this table the analysis of JMPR (JMPR Report 2006) has been integrated where JMPR concluded that IESTI and ARfD are associated with uncertainty and variability.

46. It is emphasised that the technical issues related to the model parameters (e.g. variability factor, unit weight, large portion) fall under the responsibility of the JMPR. Hence the information presented in Table 3 is primarily intended to support JMPR in future discussions on possible revisions of IESTI methodology or development of further guidance to describe how to derive the input values for IESTI calculations.

Table 3: Parameters used in the current IESTI equations

Parameter	Definition, explanations	Advantages	Challenges
LP	Highest large portion reported (97.5th percentile of eaters), expressed as kg food per day. The LP refers to the food as eaten (e.g. orange without peel). The LP are reported per person. LP data are usually derived for different subgroups of the population covered by a survey. Normally separate LP data are available for the general population and for children.	LP data can be derived easily, without sophisticated statistics. For the most frequently consumed products, LP are available, mainly for the RAC (raw agricultural commodities). LP data are also available for many processed products.	Different approaches exist how to derive a reliable LP, in particular on the aspects listed in the following bullet points: • Number of subjects (consumer days): To derive a reliable LP, the number of subjects having eaten a food product needs to be greater than 120 (Ambrus et Szenczi-Cseh, 2017). In the JMPR IESTI model, for exceptional cases, LP values were derived based on less than 120 days, if the data seem to be reliable. In this case, the LP is affected by a higher level of uncertainty. Richter et al (2018) recommended to calculate different percentiles (95th, 90th) in case the number of individuals that reported consumption of a pertinent food product is insufficient for calculating statistically reliably the 97.5th percentile consumption value (<41 individuals). In this case, the LP is also affected by a higher level of uncertainty. • Body weight in relation to LP: The body weight is not considered in the LP (LP is expressed as g per person per day). For food surveys that cover wider groups of the population with a high variability of body weights (e.g. general population including children), the LP per person may not reflect the most critical consumers (e.g. children with a higher consumption per kg body weight). The use of LP derived from the general population covering all age groups should be avoided when large portions are not expressed on an individual body weight basis (Van der Velde-Koerts et al, 2018). • Information on the method used to collect the LP consumption data are not always reported to GEMS/Food. Consequently, the LP data are considered to be affected by uncertainties (FAO, 2006).

Parameter	Definition, explanations	Advantages	Challenges
			In addition, the following challenges were identified: • For less frequently consumed food products, LP data are not available. More guidance would be desirable on how to estimate the IESTI for food items for which no or no reliable large portion can be derived, because the food items are not available in the food consumption surveys or the food items are consumed by only a few consumers in a few surveys; • LP are not available for all types of processed products (e.g. for processed products falling under IESTI case 3). • LP data are available for a limited number of Codex member countries (Richter et al, 2018); for some countries data are available for the general population only. • LP data are available for different population groups, e.g. children of 2-6 years for country A and children of 1-4 years of country B. An agreement would be desirable which population groups are relevant for the IESTI and what should be the age limits and/or bodyweight limits for that population group (e.g. infants, toddlers, young children, adults).
bw	Mean body weight It is calculated for the subgroup of the population covered by the survey for which the LP is derived	Simple parameter, biometric data of the population are usually available for most food surveys. If no survey specific body weight data are available, default values can be used.	A possible correlation of the LP and body weight is not considered in the calculations (i.e. consumption of a food item by a person with higher body weight may be higher compared to a person with a lower body weight). JMPR therefore recommended that the correlation between the LP and the body weight of each population should be established (FAO, 2006). See also challenges reported in the section on LP (body weight in relation to LP).
U	Unit weight of the whole commodity (as defined for MRL setting, including inedible parts). This parameter is required to decide if for a food commodity IESTI case 1 or IESTI case 2A/2B needs to be used.	Simple parameter. If no empirically measured unit weight data are available, approximate values derived by expert judgement are used.	Median unit weight data are not always available. It is not always clear how the U values were derived and whether it refers to the whole commodity or to the edible portion (JMPR, 2006 and Richter et al, 2018).

Parameter	Definition, explanations	Advantages	Challenges
	It is also used to derive Ue (by correcting the unit weight considering the percentage of the edible portion).		Approximate unit weight values derived by expert judgement may be questioned and can lead to disagreement. For some products it is not clear what is considered as the unit (spinach, grapes). The unit weights of food products have a high variability (depending on varieties, commercial classes, country specific requirements in trade). Using the median unit weight introduces a major source of uncertainty in the exposure assessment. Methodology how to derive the median unit weight is not standardised (e.g. defining the minimum number of units, defining how different varieties should be taken into account cherry tomatoes/medium sized tomatoes/varieties with high unit weight) (Richter et al, 2018). Lack of transparency was noted which unit weight value used in risk assessments (Richter et al, 2018).
Ue	Unit weight of the edible portion, in kg. Median value provided by the country where the trials which gave the highest residue were carried out. Ideally, the Ue should be available at country level to combine the LP with the associated Ue. Ue is calculated from unit weight whole commodity (U) by multiplying with the percentage edible portion.	Simple parameter.	See above on Unit weight (U). Methodology on how to derive the factor for percentage edible portion is not standardised.
v	Variability factor- the factor applied to the composite residue to estimate the residue level in a high-residue unit; defined as the residue level in the 97.5th percentile unit divided by the mean residue level for the lot. The default variability factor of 3 can be replaced by empirical variability factors, if data are available.	The originally used variability factors of 5, 7 and 10 were replaced in 2003 by the default variability factor of 3, following a review of data sets (2003 JMPR Report). Additional data were provided which confirmed the previous conclusion (2005 JMPR) of residue data from over 22000 crop units in single plots from different crops and different countries.	In some national/regional models developed for calculating the short-term dietary exposure, the variability factors of 5 and 7 are used, which lead to different outcomes of the short-term exposure calculations. Under certain conditions the default variability factor of 3 might even be too conservative (e.g. post-harvest treatments of fruits by dipping/drenching). A methodology how to derive empirical variability factors is lacking.

Parameter	Definition, explanations	Advantages	Challenges
HR	Highest residue in composite sample of edible portion found in the supervised trials used for estimating the maximum residue level, expressed in mg/kg It refers to the residue definition for risk assessment.	Simple parameter that can be derived from residue trials without statistical knowledge from residue trials reflecting the critical GAP. When no information is available on the residue in the edible portion, usually the HR in the whole commodity is used as a conservative surrogate (JMPR, 2007).	The HR does not reflect the distribution of the results of residue trials. Due to the high variability of residue concentrations found in residue trials and the limited number of residue trials that are usually available, the use of the HR leads to a high level of uncertainty (FAO, 2006). JMPR was concerned that conducting the assessment using the HR value instead of the MRL might not assure the safety of consumers, mainly when the MRL is much larger than the HR (JMPR, 2006). JMPR recommended to incorporate statistical calculation for deriving MRLs, which would improve the consistency in the estimations of the MRL made by the JMPR based on the available data. With the introduction of the OECD calculator a statistical methodology is used to derive MRLs. However, the gap between the HR and the MRL still exists, and hence the concerns raised by JMPR are still not fully addressed. HR data are not always available for the edible portion of the RAC; in this case the HR referring to the whole product, including the non-edible part can be used, but this leads to additional conservatism (e.g. oranges with peel) (JMPR, 2007).
HR-P	Highest residue in a processed commodity, in mg/kg, calculated by multiplying the highest residue in the raw commodity by the processing factor (PF). It also refers to the residue definition for risk assessment.	See HR and PF	In many cases, only the HR value is available, but no HR-P, due to the lack of processing studies. The use of the HR value for calculating the dietary exposure for processed products leads to additional uncertainties, as does the introduction of the processing factor. See also HR and PF.
STMR	Supervised trials median residue, in mg/kg. The STMR is the expected residue level in the edible portion of a food commodity when a pesticide has been used according to maximum GAP conditions. The STMR refers to the residue definition for risk assessment.	Simple parameter that can be derived from residue trials without statistical knowledge from residue trials reflecting the critical GAP.	See below STMR-P

Parameter	Definition, explanations	Advantages	Challenges
	The STMR is estimated as the median of the residue values (one from each trial) from supervised trials conducted according to the maximum GAP conditions. It is used for commodities where consignments are likely to be bulked and blended before they reach the consumer.		
STMR-P	Supervised trials median residue in processed commodity, in mg/kg. The STMR-P is the expected residue in a processed commodity calculated by multiplying the STMR of the raw agricultural commodity by the corresponding processing factor (PF). The STMR also refers to the residue definition for risk assessment.	In some cases, studies are available for processed products which can be used to derive the STMR-P. See also PF.	There is no clear guidance for which products mixing and bulking/blending is reasonable (Richter et al, 2018). JMPR should be requested to review the current practice of calculating the short-term exposure according to IESTI case 3 using the STMR-P for the products listed in the Appendix, taking into account the information provided in response to the CL 2019/73-PR (see section 3). In many cases, only the STMR value is available, but no STMR-P, due to the lack of processing studies. The use of the STMR value for calculating the dietary exposure for processed products leads to additional uncertainties as does the introduction of the processing factor.
PF	The processing factor for a specified combination of a pesticide residue, commodity and food process is the residue level in the processed product divided by the residue level in the starting commodity usually a raw agricultural commodity. Basically, two processing factors can be calculated: • PF ENF: this PF is based on the residue definition for enforcement. It is used to recommend maximum residue levels for processed commodities in which the residue concentrates during processing. • PF RISK: this PF is used for dietary risk assessment.	Since processing studies are usually part of the data requirements, some data are normally made available by data providers.	Different regulatory requirements exist on the number of processing studies (number of studies, extrapolation, types of processed products for which studies are required). Reliable processing factors are not available for all processed products. Processing practices may widely differ, resulting in a high variability of residues in processed products.

Parameter	Definition, explanations	Advantages	Challenges
	For recalculating the HR and the STMR to derive the HR-P and the STMR-P the processing factor that relates to the residue definition for risk assessment is required. PF is calculated according to the following equation: $PF = \frac{residue\ concentration\ in\ processed\ product}{residue\ concentration\ in\ unprocessed\ product}$		

47. Further work to address the challenges listed in Table 3 would be valuable, but considering limited resources, any future work should be carefully prioritized.

4. Information on bulking and blending relevant for IESTI case 3

48. According to FAO Manual, the short-term dietary exposure calculations for processed commodities, in which the pesticide residues result from pre-harvest uses, should be performed according to Equation 7, also referred to as IESTI case 3 (see Section 2). For this case it is assumed that different consignments of raw agricultural commodities (RACs) treated with a pesticide are bulked and blended before they are processed and reach the consumers. Therefore, the STMR-P is considered a more appropriate estimate for the residue present in the products consumed than the HR-P.

49. In the Appendix, the commodities/product groups are listed for which JMPR calculates the short-term exposure according to IESTI case 3. For pulses, cereals and oilseeds (unprocessed products, raw agricultural commodities), the calculations are performed according to case 1, where post-harvest treatment is relevant.

50. It is noted that according to the current practice of JMPR, IESTI case 3 calculations are performed not only for processed products, but also for unprocessed products, where the STMR is used instead of the STMR-P (Equation 8).

Unprocessed products $$\mathrm{IESTI} = \frac{\mathrm{LP}\ \times \mathrm{STMR}}{\mathrm{bw}}$$ Equation 8

51. The Appendix also comprises certain commodities where short-term dietary intake calculations are performed according to case 1 or 2, which may need to be reconsidered.

52. In the framework of CL 2019/73-PR information on the most common and usual bulking and blending practices should be collected in order to decide whether the currently used practices of JMPR are justified and for which a median residue (STMR or STMR-P) is appropriate for calculating the dietary risk assessment.

53. Information on bulking and blending was submitted from eight individual Member States including Australia, Canada, Egypt, Japan, Mexico, Thailand, United Kingdom, and USA. Information was also provided by thirteen trade organizations; BSDA (British Soft Drink Association), BFJA (British Fruit Juice Association), California Almond Board, California Citrus Quality Control, COCERAL (the EU traders association of cereals, grains, rice, fats, olive oil, oilseeds, feedstuff and agro-supply chain), FIVS (an international federation serving trade associations and companies in the alcohol beverage industry from around the world), GAFTA (the Grain and Feed Trade Association), IFU (International Fruit and Vegetable Juice Association), INC (International Nut and Dried Fruit Council), THIE (Tea & Herbal Infusions Europe), US Grain Council, US Wine Institute, US Wild Blueberry Commission of Maine, WPTC (World Processing Tomato Council).

54. The information received included descriptive and/or quantitative information on bulking and blending practices for several raw and processed commodities such as cereal grains, oilseeds, pulses, GM soya beans, citrus juice, apple juice, wine grapes & wine, raw & frozen blueberries, strawberry puree, frozen durian, canned pineapple, mango puree, tomato puree, tomato paste, tomato juice, dried fruits, tree nuts, sugar cane sugar, tea and herb tea.

55. Bulking and blending was shown for all commodities investigated, except for pineapples. Quantitative information on bulking and blending before and during jam/jelly/marmalade production, canning of fruits and vegetables, freezing of fruits and vegetables, oil production and milling is limited or absent and would be desirable. Codex Members are encouraged to contact trade organizations in their country to provide quantitative information on bulking and blending for these processes.

56. The compilation of information on bulking and blending shall be provided to JMPR for their review and consideration. In the Appendix, a general overview on the submitted information is given; more details on the type of information submitted in response to the Circular Letter can be found in a separate document (Annex to this discussion paper), where all contributions are compiled.

57. It is noted that the information on bulking and blending practices was collected in response to the CL which requested information for the most common practices for industrially produced products and products traded internationally. Since the data collection was not intended for speciality products (e.g. products with direct marketing by farmers, niche products) or for products that are produced at household level, these practices may not be fully representative for all products placed on the market and consumed.

5. Conclusions and recommendations

Conclusions

58. CCPR initiated exploratory work on the IESTI equations at CCPR48 (2016) and has since established four EWGs that have provided background on IESTI equations and explored the advantages and challenges of the equations from risk management, risk communication, consumer protection, and trade perspectives. The current EWG, EWG-4, builds on this previous EWG work by further evaluating the advantages and challenges of the current IESTI equations, summarizing the results of FAO/WHO's benchmarking exercise, and gathering information on bulking and blending practices. The conclusions of EWG-4 are as follows:

- The EWG completed its evaluations of the advantages and challenges of the current IESTI equations. Based on its overall evaluation, it is evident that the IESTI methodology is an important element of the dietary risk assessment process performed by JMPR in the framework of proposing Codex MRLs. The methodology allows a transparent estimation of the expected short-term dietary exposure to pesticide residues expected in food treated with pesticides and it provides the basis for risk managers to take decisions on the acceptance or non-acceptance of proposed Codex MRLs.
- While there was overall consensus on the importance of the IESTI equations and their benefits, risk management and risk communication challenges were identified. As a result, there are divergent views on the conservatism of the IESTI calculations. Some Codex member countries, for example, report facing risk communication challenges when explaining that Codex MRLs are sufficiently protective. Others do not face the same challenge because they assess and communicate risk differently in their national systems. Similarly, quantitative consumer protection goals have not been clearly formulated by CCPR and information on the actual level of protection from the current IESTI equations has not been available in the past.
- The EWG's evaluation of the advantages and challenges of the current equations was further informed by FAO/WHO's assessment of the current IESTI equations using probabilistic distribution of actual exposures. FAO/WHO's study has not yet been published, but a draft report was discussed at CCPR51 and final results were presented during JMPR's 2019 Regular Meeting in September. Based on the information available to EWG, JMPR concluded that the IESTI equation is protective based on comparison of the IESTI equation and probabilistic models from all countries and populations of interest (FAO/WHO 2020, chapter 2.4). JMPR also reviewed FAO/WHO's level of protection analysis that assessed exposure using the MRL for each pesticide-commodity combination instead of the actual pesticide residue monitoring data. JMPR concluded that this approach is extremely conservative – because it assumes "all commodities have residues present at the MRL" – and suggested an approach to perform a more realistic analysis of the level of protection.
- CL 2019/73-PR was issued by the Codex Secretariat to provide information to help substantiate the degree of bulking and blending of commodities that are evaluated by JMPR using the Case 3 IESTI Equation. A large number of organizations responded to the circular Letter on bulking and blending and provided information on cereal grains, oilseeds, pulses, GM soya beans, citrus juice, apple juice, wine grapes & wine, raw & frozen blueberries, strawberry puree, frozen durian, canned pineapple, mango puree, tomato puree, tomato paste, tomato juice, dried fruits, tree nuts, sugar cane sugar, tea and herb tea. This information will be provided to JMPR and can be used to help evaluate whether the commodities are bulked and blended before entering international trade.

Recommendations

59. Based on the information provided in this discussion document and conclusions above, the EWG recommends the forllowing for consideration by CCPR:

- Information was available on the FAO/WHO benchmarking assessment, but the EWG was unable to review FAO/WHO's final, published report and only information on summary results was presented to JMPR during its 2019 Regular Meeting in September 2019. Some EWG members felt that this limited the ability of the EWG to fully deliberate on the strength of the FAO/WHO study and whether the findings were sufficiently conclusive with respect to the degree to which the current IESTI is protective.
- For further progress, some Codex Members suggested that general conclusions on the conservatism of the current IESTI equations cannot be made because CCPR has not specified the desired protection level (e.g. by defining a percentile of the population to be protected). Other Codex Members, however, indicated that the FAO/WHO benchmarking assessment provides a quantitative comparison with population-based, probabilistic results that help characterize the conservatism of the IESTI equations. It is recommended that FAO/WHO provide a more detailed, final report to CCPR comparing the FAO/WHO benchmarking assessment and the current IESTI methodology to the desired protection levels to be set. The EWG also recommends that the final FAO/WHO report be submitted to JMPR for deliberation.
- Further work to address the challenges listed in Table 3 would be valuable, but considering limited resources, any future work should be carefully prioritized by JMPR in close collaboration with CCPR.
- JMPR will be provided the information submitted by stakeholders in response to the Circular Letter on bulking and blending practices (Annex). It is recommended that JMPR review this information and evaluate the current practices used to assess short-term dietary exposure and setting of MRLs for bulked/blending commodities (i.e. IESTI Case 3).

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Appendix I - Information on bulking and blending submitted in response to the CL 2019/73-PR (English only)

Commodities for which bulking or blending information is relevant to[(a)]			Further information on current JMPR procedures	Information submitted in response to CL 2019/73-PR
Dry pulses (RAC)	VD 0071 VD 0523 VD 0541 VD 0072 VD 0524 VD 0533	Beans (dry) Broad bean (dry) (Soya bean (dry) Peas (dry) Chick-pea (dry) Lentil (dry)	In the current JMPR IESTI model dry pulses are treated in two ways: pre-harvest treatment = case 3 post-harvest treatment = case 1	Australia Canada Japan United Kingdom (soya beans) United Kingdom (information provided by GAFTA) USA COCERAL (beans, soya beans, peas (dry))
Cereal grains (RAC)	GC 0650 GC 0654 GC 0640 GC 0641 GC 0647 GC 0649 GC 0646 GC 0651 GC 0645	Rye Wheat Barley Buckwheat Oats Rice Millet Sorghum grain Maize (corn)	In the current JMPR IESTI model cereal grains are treated in two ways: pre-harvest treatment = case 3 post-harvest treatment = case 1	Australia Canada Japan United Kingdom (information provided by GAFTA) USA COCERAL
Oilseeds (RAC)	SO 0090 SO 0495 SO 0691 SO 0693 SO 0696a SO 0696b SO 0697 SO 0698 SO 0699 SO 0700 SO 0702 - -	Mustard seed Rape seed Cotton seed Linseed (Flax-seed) Palm kernels Palm fruit Peanut, shelled Poppy seed Safflower seed Sesame seed Sunflower seed Borage seeds Cucurbitaceae seeds	In the current JMPR IESTI model oilseeds are treated in two ways: pre-harvest treatment = case 3 post-harvest treatment = case 1	Australia (rapeseed, cotton seed) Canada Japan United Kingdom (information provided by GAFTA) USA COCERAL (rape seed, sunflower seed)
Treenuts (RAC)	TN 0295 TN 0660 TN 0660 TN 0662 TN 0664 TN 0666 TN 0669 TN 0672 TN 0673 TN 0675 TN 0678	Cashew nut Almonds Almonds Brazil nut Chestnuts Hazelnut Macadamia nut Pecan Pine nut Pistachio nut Walnut	In the current JMPR IESTI model treenuts (nutmeat) are treated as case 1 commodities. The case 1 classification used by the JMPR is challenged because treenuts are industrially bulked or blended (over several farms or pesticide treatment regimes).	Japan USA (Almonds) INC
	TN 0665	Coconut	The unit weight of a coconut is much higher than 25 g, for which case 2 applies.	-
	VR 0596	Sugar beet (RAC)	The unit weight of a sugar beet is much higher than 25 g, for which case 2 applies. However, as raw sugar beets are not consumed, only the extracted sugar, sugar beets are treated as case 3 in the current JMPR IESTI model.	Japan
	GS 0659	Sugar cane (RAC)	The unit weight of a sugarcane is much higher than 25 g, for which case 2 applies.	Japan Thailand

Commodities for which bulking or blending information is relevant to[(a)]			**Further information on current JMPR procedures**	**Information submitted in response to CL 2019/73-PR**
			However, as raw sugarcanes are not consumed, only the extracted sugar, sugar cane is treated as case 3 in the current JMPR IESTI model.	
	SB 0715	Cocoa beans (RAC)	Cocoa beans (RAC) are roasted. Various products are prepared: cocoa mass, cocoa powder, cocoa butter. Cocoa beans and its products are treated as case 3 in the current JMPR IESTI model.	Japan USA
	SM 0716	Coffee beans (RAC)	Green coffee beans (RAC) are roasted. Coffee beans and its products are treated as case 3 in the current JMPR IESTI model.	Japan USA
	DH 1100	Hops, dry (RAC)	In the current JMPR IESTI model dry hops are treated as case 3 commodities.	Japan USA
Dried tea	DT 1114	Tea, green, black (RAC)	In the current JMPR IESTI model dried tea is treated as case 3 commodity.	Japan THIE
Dried herb teas	DT 0446 DT 1110 DT 1113 - -	Roselle (RAC) Camomile (RAC) Mate (RAC) Rooibos leaves (RAC) Valerian root (RAC)	In the current JMPR IESTI model dried herb teas are treated as case 3 commodities.	Japan USA THIE (camomile, mate, rooibos, valerian root, roselle hibiscus, rose hips, fruits)
Canned fruits	FC 0003 FC 0005 FT 0337 FI 0345 FI 0350 FI 0353 FI 0341	Subgroup of Mandarins Subgroup of Grapefruits Guava Mango Papaya Pineapple Kiwifruit	Canned fruits, which are divided in parts or cut to pieces before being canned, are treated as case 3 in the current JMPR IESTI model.	Japan (mandarins, strawberries, pears, peaches) Thailand (pineapple),
	DM 0305 FB 0020 FB 0021 FB 0264 FB 0265 FB 0269 FB 0272 FB 0275 FI 0343 FP 0230 FS 0013 FS 0014 FS 0240 FS 0245 FS 0247	Table olives Blueberries Currants, black, red, white Blackberries Cranberry Grapes Raspberries, red, black Strawberry Litchi Pear Subgroup of Cherries Subgroup of Plums Apricot Nectarine Peach	Canned fruits, which can be derived from a single fruit because whole fruits or fruit halves are canned, are treated as case 1 or case 2 in the current JMPR IESTI model, depending on the weight of the canned fruit units. Some of these case 1 and case 2 classifications used in the JMPR IESTI model are challenged. Canned pineapple is cut to pieces or slices before being canned and is treated as case 3 in the current JMPR IESTI model because it does not refer to the original unit weight. However, canned pineapple could also be treated as case 2, because a single pineapple can end up in a single can.	Canada (blueberries)

Commodities for which bulking or blending information is relevant to[a]		Further information on current JMPR procedures	Information submitted in response to CL 2019/73-PR
		Canned/preserved table olives and canned litchis still represent the original fruits and can still be considered as individual units (U<25 g) and hence are considered case 1 in the current JMPR IESTI model as is the RAC. However, canned/preserved table olives and canned litchis could also be treated as case 3 because the commodities are industrially bulked or blended (over several farms or pesticide treatment regimes).	
Canned vegetables	VA 0381 Garlic VA 0385 Onion, bulb VA 0384 Leek VB 0041 Cabbages, head VC 0431 Squash, Summer VC 0046 Melons VO 0440 Egg plant (Aubergine) VL 0476 Endive (i.e. Escarole) VL 0502 Spinach VL 0480 Kale VR 0574 Beetroot VR 0578 Celeriac VR 0498 Salsify (Oyster plant) VR 0497 Swede (Rutabaga) VS 0624 Celery VS 0622 Bamboo shoots GC 1275 Sweet corn kernels HH 0624 Celery leaves HS 0784 Ginger, root	Canned vegetables, which are divided in parts or cut to pieces before being canned, are treated as case 3 in the current JMPR IESTI model.	-
	VB 0402 Brussels sprouts VF 0449 Fungi, edible, except mushrooms (mainly wild) VF 0450 Mushrooms (cultivated) VL 0269 Grape leaves VO 0445 Peppers, sweet (incl. pimiento) VO 0448 Tomato VP 0061 Green beans with pods (immature) VP 0062 Green beans without pods (succulent seeds) VP 0064 Peas without pods (succulent seeds) VP 0523 Broad bean without pods (succulent seeds) VR 0577 Carrot VR 0589 Potato VS 0620 Artichoke globe VS 0621 Asparagus VS 0626 Palm hearts	Canned vegetables that can be derived from a single vegetable because whole vegetables or vegetable halves are canned are treated as case 1 or case 2 in the current JMPR IESTI model, depending on the weight of the canned vegetable. Some of these case 1 and case 2 classifications used in the JMPR IESTI model are challenged. Canned green peas without pods still represent the original seeds and can still be considered as individual units (U<25 g) and hence are considered case 1 in the current JMPR IESTI model as is the RAC. However, canned green peas without pods could also be treated as case 3 because the commodity is industrially bulked or blended (over several farms or pesticide treatment regimes).	-

Commodities for which bulking or blending information is relevant to[a]			Further information on current JMPR procedures	Information submitted in response to CL 2019/73-PR
	GC 3081	Baby corn	Canned carrots are generally small (whole) carrots and these can still be considered as individual units (U<25 g) and hence are considered case 1 in the current JMPR IESTI model. However, canned carrots could also be treated as case 3 because the commodity is industrially bulked or blended (over several farms or pesticide treatment regimes).	
Canned pulses	VD 0071 VD 0523 VD 0072 VD 0524 VD 0533	Beans (dry) Broad bean (dry) Peas (dry) (Pisum spp) Chick-pea (dry) Lentil (dry)	In the current JMPR IESTI model canned pulses are treated in two ways: pre-harvest treatment = case 3 post-harvest treatment = case 1	See dry pulses (RAC)
Dried fruits	FI 0327 FI 0345 FI 0353 FI 0350 FT 0305	Banana Mango Pineapple Papaya Table olives	Dried fruits which are divided in parts or cut to pieces before being dried are treated as case 3 in the current JMPR IESTI model.	INC
	DF 0014 DF 0226 DF 0240 DF 0269 DF 0295 DF 0297 FB 0020 FB 0021 FB 0264 FB 0265 FB 0272 FB 0275 FB 1235 FI 0343 FP 0230 FP 0307 FS 0013 FS 0245 FS 0247 FT 0289 VF 0449 VF 0450 VO 0444 VO 0448 VO 2704 VP 0061	Subgroup of Plums (i.e. prunes) Apple Apricot Grapes (i.e. raisins, currants, sultanas) Date Fig Blueberries Currants, black, red, white Blackberries Cranberry Raspberries, red, black Strawberry Table grapes (i.e. raisins, currants, sultanas) Litchi Pear Persimmon, Japanese (i.e. Kaki fruit) Subgroup of Cherries Nectarine Peach Carambola Fungi, edible, except mushrooms (mainly wild) Mushrooms (cultivated) Peppers, chili Tomato Goji berry Beans with pods	Dried fruits that can be derived from a single fruit (because the original fruit or the fruit halve is dried), are treated as case 1 or case 2 in the current JMPR IESTI model, depending on the weight of the dried fruit. Some of these case 1 and case 3 classifications used in the JMPR IESTI model are challenged. Dried grapes (raisins, currants and sultanas) are derived from grape berries and a such the berry is not cut into pieces and can still be considered an individual unit (U<25g) and hence is considered case 1 in the current JMPR IESTI model. However, dried grapes could also be treated as case 3 because the commodity is industrially bulked or blended (over several farms or pesticide treatment regimes). Dried cranberries still represent the original berries and can still be considered an individual unit (U<25g) and hence is considered case 1 in the current JMPR IESTI model as is the RAC. However, dried cranberries could also be treated as case 3 because the commodity is industrially bulked or blended (over several farms or pesticide treatment regimes).	INC (raisins)

Commodities for which bulking or blending information is relevant to[(a)]			Further information on current JMPR procedures	Information submitted in response to CL 2019/73-PR
	VP 0064	Peas without pods (succulent seeds)		
Dried vegetables	VR 0587 VA 0381 VA 0385 VA 0384 VB 0400 VB 0404 VB 0041 VC 0431 VC 0046 VO 0445 VO 0440 VL 0465 VL 0502 VL 0480 VR 0577 VR 0578 VR 0588 VR 0506 VR 0589 VS 0621 GC 0447 GC 1275	Parsley, turnip-rooted Garlic Onion, bulb Leek Broccoli Cauliflower Cabbages, head Squash, Summer Melons Peppers, sweet Egg plant Chervil Spinach Kale Carrot Celeriac Parsnip Turnip, garden Potato Asparagus Sweet corn (on-the-cob) Sweet corn (kernels)	Dried vegetables which are divided in parts or cut to pieces before being dried are treated as case 3 in the current JMPR IESTI model.	-
	VF 0449 VF 0450 VO 0444 VO 0448 VO 2704 VP 0061 VP 0064	Fungi, edible, except mushrooms (mainly wild) Mushrooms (cultivated) Peppers, chili Tomato Goji berry Beans with pods (immature pods with seeds) Peas without pods (succulent seeds)	Dried vegetables that can be derived from a single commodity (because the original vegetable is dried), are treated as case 1 or case 2 in the current JMPR IESTI model, depending on the weight of the dried commodity.	-
Dried herbs and dried spices	HH 0624 DH 0722 DH 0723 HH 0733 DH 0736 DH 0738 HH 0740 DH 0741 DH 0743 HH 0745 HH 0749 DH 0750 HH 0756 HH 0761 HS 0783 HS 0794 HS 0784	Celery leaves Basil Bay leaves Hyssop Marjoram Mints Parsley Rosemary Sage Savory, summer, winter Tarragon Thyme Coriander leaves Lemongrass Galangal, rhizomes Turmeric, root Ginger, root	Herbs and spices are divided in parts or cut to pieces before being dried and are treated as case 3 in the current JMPR IESTI model. Some dried spices are ground to powders before being traded.	THIE (mint, lemongrass, sage, ginger roots)

Commodities for which bulking or blending information is relevant to[(a)]			Further information on current JMPR procedures	Information submitted in response to CL 2019/73-PR
Fruit juices	FC 0204	Lemon	No unit weight can be assigned to fruit juices and they are treated as case 3 in the current JMPR IESTI model.	United Kingdom (information provided by BSDA and BFJA) USA IFU (orange, pome fruit juice, pineapple, mango juice)
	FC 0205	Lime		
	FC 0003	Subgroup of Mandarins		
	JF 0004	Subgroup of Oranges		
	FC 0005	Subgroup of Pummelo		
	JF 0226	Apple		
	FP 0230	Pear		
	FP 2220	Azarole		
	FS 0013	Subgroup of Cherries		
	FS 0240	Apricot		
	FS 0245	Nectarine		
	FS 0247	Peach		
	FS 0014	Subgroup of Plums		
	FB 0272	Raspberries, red, black		
	FB 0264	Blackberries		
	FB 0020	Blueberries		
	FB 0021	Currants, black,		
	FB 0273	Rose hips		
	FB 0267	Elderberries		
	JF 0269	Grapes		
	FB 1236	Wine grapes		
	FB 0275	Strawberry		
	FB 0265	Cranberry		
	FT 0287	Barbados cherry (acerola)		
	FT 0338	Guava		
	FI 0343	Litchi		
	FI 0327	Banana		
	FI 0345	Mango		
	FI 0350	Papaya		
	JF 0341	Pineapple		
	FI 0365	Soursop (Guanabana)		
	FI 0351	Passion fruit (maracuja)		
	FI 0355	Pomegranate		
	FI 0341	Kiwifruit		
	FI 2483	Cupuaçu		
Vegetable and herb juices	VA 0385	Onion, bulb	No unit weight can be assigned to vegetable and herb juices and they are treated as case 3 in the current JMPR IESTI model.	USA IFU (tomato juice) WPTC (tomato juice)
	VC 0424	Cucumber		
	VC 0429	Pumpkins		
	VC 0046	Melons		
	VC 0432	Watermelon		
	JF 0448	Tomato		
	VO 0445	Peppers, sweet		
	VL 0510	Cos lettuce		
	VL 0482	Lettuce, head		
	VL 0483	Lettuce, leaf		
	VL 0502	Spinach		
	VR 0574	Beetroot		
	VR 0577	Carrot		
	VR 0578	Celeriac		
	VS 0624	Celery		
	HH 0722	Basil		
	HH 0738	Mints		
	HH 0740	Parsley		

Commodities for which bulking or blending information is relevant to[(a)]			Further information on current JMPR procedures	Information submitted in response to CL 2019/73-PR
Jams, jellies, marmalades	FC 0204 FC 0003 FC 0004 FP 0226 FP 0231 FS 0013 FS 0014 FS 0240 FS 0245 FS 0247 FB 0264 FB 0272 FB 0020 FB 0021 FB 0273 FB 0267 FB 0265 FB 0275 FT 0297 FI 0353 HS 0784	Lemon Subgroup of Mandarins Subgroup of Oranges Apple Quince Subgroup of Cherries Subgroup of Plums Apricot Nectarine Peach Blackberries Raspberries, red, black Blueberries Currants, black, red, Rose hips Elderberries Cranberry Strawberry Fig Pineapple Ginger, root	No unit weight can be assigned to jams, jellies and marmalades and they are treated as case 3 in the current JMPR IESTI model.	USA
Essential oils	FC 0204 FC 0205 FC 0004 FC 0005	Lemon Lime Subgroup of Oranges Subgroup of Pummelo	No unit weight can be assigned to oils and they are treated as case 3 in the current JMPR IESTI model.	USA
Olive oil	OR 0305	Olives for oil extraction	No unit weight can be assigned to oils and they are treated as case 3 in the current JMPR IESTI model.	USA
Refined oils	OR 0541 GC 0649 OR 0645 TN 0295 TN 0660 OR 0665 TN 0672 TN 0678 OR 0495 OR 0691 SO 0693 OR 1240 OR 0696 OR 0697 SO 0698 OR 0699 OR 0700 OR 0702 - - - TN 0669	Soya bean (dry) Rice (bran oil) Maize (corn) Cashew nut Almonds Coconut Pecan Walnut Rape seed Cotton seed Linseed (Flax-seed) Palm kernels Palm fruit Peanut, shelled Poppy seed Safflower seed Sesame seed Sunflower seed Borage seeds Cucurbitaceae seeds Grape seed Macadamia nut	No unit weight can be assigned to oils and they are treated as case 3 in the current JMPR IESTI model.	USA

Commodities for which bulking or blending information is relevant to[(a)]			Further information on current JMPR procedures	Information submitted in response to CL 2019/73-PR
Industrially prepared sauce/puree	FP 0226 FP 0230 FS 0014 FS 0240 FB 0272 FB 0020 FB 0021 FB 0265 FB 0275 FI 0369 FI 0327 FI 0345 VS 0627 VO 0448	Apple Pear Subgroup of Plums Apricot Raspberries, red, black Blueberries Currants, black, red Cranberry Strawberry Tamarind (sweet) Banana Mango Rhubarb Tomato	The large portions derived from food surveys relate to sauce/puree that has been bought in a shop and hence represent industrial procedures. No unit weight can be assigned to sauce/puree and hence sauce/puree is treated as case 3 in the current JMPR IESTI model. The case 3 classification used in the JMPR IESTI model is challenged. Sauce/puree does not necessarily imply industrial processing, but can also relate to household processing. When household processing is taken into account, case 1 would be more appropriate.	Japan United Kingdom (information provided by BSDA and BFJA) USA
Industrially prepared paste	VO 0448 VO 0444	Tomato Peppers, chili	The large portions derived from food surveys relate to paste that has been bought in a shop and hence represent industrial procedures. No unit weight can be assigned to paste and hence paste is treated as case 3 in the current JMPR IESTI model.	USA WPTC (tomato paste)
Wine	FB 0269 FB 1236	Grapes Wine grapes	A single wine bottle does not contain the wine from a single grape bunch. No unit weight can be assigned to wine and wine is therefore treated as case 3 in the current JMPR IESTI model. The case 3 classification used in the JMPR IESTI model is challenged. Case 3 would postulate that wine grapes or wine from different producers are bulked/pooled. Wine could also be treated as case 1 because it is not unlikely that wine is coming from one vineyard, and thus, the HR would be a more appropriate estimator for the residues in wine.	USA FIVS

Commodities for which bulking or blending information is relevant to[(a)]			Further information on current JMPR procedures	Information submitted in response to CL 2019/73-PR
Industrially frozen	FS 0245 FS 0247 VA 0381 VA 0385 VA 0384 VB 0400 VB 0404 VB 0041 VC 0431 VO 0445 VL 0476 VL 0502 VL 0480 VR 0574 VR 0577 VR 0578 VR 0589 VS 0621 GC 0447 GC 1275 HH 0624 HH 0740	Nectarine Peach Garlic Onion, bulb Leek Broccoli Cauliflower Cabbages, head Squash, Summer Peppers, sweet) Endive (i.e. Escarole) Spinach Kale (Borecole, Collards) Beetroot Carrot Celeriac Potato Asparagus Sweet corn (on-the-cob) Sweet corn (kernels) Celery leaves Parsley	The large portions derived from food surveys relate to frozen commodities that have been bought in a shop and hence represent industrial procedures. Fruits and vegetables are generally cut to pieces and blanched before being frozen industrially. Units weight cannot be assigned to such frozen commodities and the listed frozen commodities are therefore treated as case 3 in the current JMPR IESTI model. Frozen commodities do not necessarily imply industrial processing, but can also relate to household processing. When household processing is taken into account, case 1 would be more appropriate.	Thailand (durian (frozen) USA (blueberries)
	FB 0020 FB 0275 VB 0402 VP 0062 VP 0063 VP 0064 VP 0523	Blueberries Strawberry Brussels sprouts VP 0061Beans with pods: (immature pods + succulent seeds) Beans without pods:(succulent seeds) Peas with pods: (immature pods + succulent seeds) Peas without pods (succulent seeds) Broad bean without pods (succulent seeds)	Frozen fruits and vegetables that can be derived from a single commodity (because the original fruit or vegetable is frozen), are treated as case 1 or case 2 in the current JMPR IESTI model, depending on the weight of the frozen commodity. The case 3 classification used in the JMPR IESTI model is challenged.	<u>High bush blueberries:</u> Canada <u>Low-bush blueberries:</u> Canada USA
Sauerkraut	VB 0041	Cabbages, head	Cabbages are cut to pieces before being transformed into sauerkraut.	
Industrial deep-fried – French fries	VR 0589	Potato	The large portions derived from food surveys relate to French fries that have been bought in a shop and hence represent industrial procedures. Potatoes are cut to pieces before being transformed into French fries.	
Industrial deep-fried – Crisps	VR 0589	Potato	The large portions derived from food surveys relate to crisps that have been bought in a shop and hence represent industrial procedures.	

Commodities for which bulking or blending information is relevant to[(a)]			Further information on current JMPR procedures	Information submitted in response to CL 2019/73-PR
			Potatoes are cut to thin slices before being transformed into crisps.	
Industrial pickled	VA 0384 VB 0041 VC 0424 VO 0445 VL 0466 VR 0574 VR 0577 VL 0468 VL 0485	Leek Cabbages, head Cucumber Peppers, sweet Chin cabbage (Pak-choi) Beetroot Carrot Flowering white cabbage Mustard greens	The large portions derived from food surveys relate to pickles that have been bought in a shop and hence represent industrial procedures.	
	HS 0773 VA 0385 VC 0425	Caper buds Onion, bulb Gherkin	Pickled vegetables which are divided in parts or cut to pieces before being dried are treated as case 3 in the current JMPR IESTI model. Pickled vegetables that can be derived from a single commodity (because the original vegetable is pickled), are treated as case 1 or case 2 in the current JMPR IESTI model, depending on the weight of the pickled commodity.	
Starch	VR 0573 VR 0463 VR 0589 VR 0504	Arrowroot Cassava (Manioc) Potato Tannia	No unit weight can be assigned to starch and starch is treated as case 3 in the current JMPR IESTI model.	
Coconut milk	TN 0665	Coconut	No unit weight can be assigned to coconut milk and it is treated as case 3 in the current JMPR IESTI model.	
Butter/paste	SO 0697 SO 0700 DM 1215	Peanut, shelled Sesame seed Cocoa beans	No unit weight can be assigned to butter/paste and it is treated as case 3 in the current JMPR IESTI model.	
Miso, soya sauce and tofu	VD 0541	Soya bean (dry)	No unit weight can be assigned to miso, soya sauce and tofu and it is treated as case 3 in the current JMPR IESTI model.	
Milk	VD 0541 GC 0650	Soya bean (dry) Rice	No unit weight can be assigned to milk and it is treated as case 3 in the current JMPR IESTI model.	
Flour of pulses and oilseeds	VD 0541 VD 0072 VD 0524 SO 0090	Soya bean (dry) Peas (dry) Chick-pea (dry) Mustard seed	No unit weight can be assigned to flour and it is treated as case 3 in the current JMPR IESTI model.	
Flour of fruits and vegetables	FT 0291 VR 0589 VR 0504 VR 0463 VR 0508	Carob Potato Tannia (Tanier, Yautia) Cassava (Manioc) Sweet potato	No unit weight can be assigned to flour and it is treated as case 3 in the current JMPR IESTI model.	

Commodities for which bulking or blending information is relevant to[(a)]			Further information on current JMPR procedures	Information submitted in response to CL 2019/73-PR
Bran, germ, grits, flour, starch	GC 0640 GC 0641 GC 0647 GC 0649 GC 0645 GC 0646 GC 0650 GC 0651 GC 0654	Barley Buckwheat Oats Rice Maize (corn) Millet Rye Sorghum grain Wheat	No unit weight can be assigned to cereal milling products and they are treated as case 3 in the current JMPR IESTI model.	See cereal grains (RAC)
Beer and malt	GC 0650 GC 0654 GC 0649 GC 0646 GC 0651 GC 0645 GC 0640	Rye Wheat Rice Millet Sorghum grain Maize (corn) Barley	No unit weight can be assigned to beer and malt and they are treated as case 3 in the current JMPR IESTI model.	See cereal grains (RAC)
Flakes	GC 0650 GC 0654 GC 0640 GC 0641 GC 0647 GC 0645	Rye Wheat Barley Buckwheat Oats Maize (corn)	In the current JMPR IESTI model flakes are treated as case 3 commodities.	See cereal grains (RAC)

General comments (not related to individual commodities listed above):

Mexico: Considering that there are many companies that sell the products listed above, they have several warehouses where they receive products from their different suppliers, it is common that these products come from various farms, warehouses, and therefore from different pre and post-harvest treatment regimes.

It is important to note that the export of agricultural products will require information requested by the exporting country, as in the case of the European Union where the directives of the European Parliament and the council indicate that one of the production level requirements to be reported It is the pre and post-harvest treatment of the product to be exported, so this information could be obtained from the quality report provided by the exporter. (Google translation of comments submitted in Spanish).

Egypt:

We think that may some internationally traded or consumed portion of the commodities can be derived from a single commodity unit, a single farm or a single storage facility or a single pesticide treatment regime. In Egypt there are no applied quality control systems to refer all single products back to their producing farms, but there is an applied control system on some commodities such as (Citrus Fruits, Strawberry, Guava and Potatoes).

The internationally traded or consumed portion of the commodities listed in Annex I of the CL are usually bulked or blended over several farms (in case of pre-harvest treatments), over several storage facilities (in case of post-harvest treatments) or over several pesticide treatment regimes (in case of large production farms) before the commodity is internationally traded or consumed.

Bulking and blending is used to fulfil the requested traded quantities for the international traded commodities, it should be derived from several farms (which will be using different pesticides with different storage facilities); to reach a degree of grade for some commodities, food operators has to mix or bulk commodities from different farms. Upon the request of buyer, to fulfil quality requirement related to sizes for instant.

In Egypt, the coded farms have records for the quantitative and quantitative description.

(a) Commodities/group of products which are calculated according to IESTI case 3 (for pre-harvest treatments) or IESTI case 1 (if post-harvest treatment is relevant) are presented without shading.
Commodities/groups of products for which it is current JMPR practice to calculate short-term dietary exposure according to case 1 or 2 are shaded in grey.

APPENDIX II: LIST OF PARTICIPANTS[21]

COUNTRY	NAME	TITLE/ORGANIZATION
ARGENTINA	Daniel Mazzarella	Technical Supervisor in the Department of Agrochemical Registration Directorate of Agrochemical and Biological products National Animal Health and Agri-food Quality Service SENASA - National Animal Health and Agri-food Quality Service
AUSTRIA	Ingo Grosssteiner	Expert Department for Residue Behaviour and Physical-Chemical Properties / Austrian Agency for Health and Food Safety (AGES)
AUSTRALIA	James Deller	Director, Residues and Trade Section Australian Pesticides and Veterinary Medicines Authority
AUSTRALIA	Karina Budd	Director - Residue Chemistry and Laboratory Performance Evaluation Section National Residue Survey | Exports Division | Department of Agriculture
BRAZIL	Amanda Bulgaro	AgroCare Latinoamerica
BRAZIL	Carlos Ramos Venancio (official representative)	Official title: General Coordinator of Pesticide Control Ministry of Agriculture, Livestock and Food Supply – MAPA
BRAZIL	Adriana Torres de Sousa Pottier	Health Regulation Expert Brazilian Health Regulatory Agency – Anvisa
BRAZIL	Antonio Batista Sanches	Health Regulation Expert Brazilian Health Regulatory Agency - Anvisa
CANADA	Jennifer Selwyn	Section Head Health Evaluation Directorate, Pest Management Regulatory Agency, Health Canada
CHINA	Zhao Huiyu	Zhejiang Academy of Agriculture Sciences
CHILE	Roxana Inés Vera Muñoz	Jefa Sub departamento de Acuerdos Internacionales y Coordinadora del Subcomité Nacional del Codex Sobre Residuos de Plaguicidas Servicio Agrícola y Ganadero Chile
CHILE	Eduardo Aylwin	Observer Organization Chilean Food Safety and Quality Agency, ACHIPIA
COSTA RICA	Veronica Picado P	Coordinator National Committee CCPR / Ministerio de Agricultura, Ganadería / Servicio fitosanitario del estado
COSTA RICA	Amanda Lasso C	Codex Secretariat / Ministerio de Economía, Industría y Comercio

[21] Please contact the focal point of the Member Country or Observer Organization for the details of the delegates. The list of Codex contact points for members and observers are available from the Codex website at:
http://www.fao.org/fao-who-codexalimentarius/about-codex/members/en/
http://www.fao.org/fao-who-codexalimentarius/about-codex/observers/observers/obs-list/en/

COUNTRY	NAME	TITLE/ORGANIZATION
COSTA RICA	Tatiana Vasquez	Pesticide Registration Officer / Ministerio de Agricultura, Ganadería / Servicio fitosanitario del Estado
DENMARK	Bodil Hamborg Jensen	Senior Advisor National Food Institute, Denmark
EGYPT	Mariam Barsoum Onsy	Food Standards Specialist/Egyptian Organization for Standardization & Quality (EOS) / Ministry of Trade and Industry
EUROPEAN COMMISSION	Volker Wachtler	
EUROPEAN COMMISSION	Marco Castellina	
EUROPEAN COMMISSION	Maria Taberno	
FRANCE	Florence Gerault	Ministry of Agriculture
FRANCE	Xavier Sarda	ANSES
FRANCE	Gaelle Vial	ANSES
FRANCE	Nicolas Breysse	ANSES
GERMANY	Christian Sieke	(Official Representative)Federal Institute for Risk Assessment (BfR) Department Pesticides Safety Unit Residues and Analytical Methods
GERMANY	Monika Schumacher	Federal Ministry of Food and Agriculture Section 313 “Residues and Contaminants in Food, Food Contact Materials” Bundesministerium für Ernährung und Landwirtschaft
HONDURAS	Juan Carlos Paguada	Coordinador del CCPR
HONDURAS	Yolandina Lambur/	Codex Honduras
INDONESIA	Asep Nugraha Ardiwinata	Researcher Indonesian Agency for Agricultural Research and Development
IRAN	Roya Noorbakhsh	ISIRI
INDIA	K.K. Sharma	Network Coordinator, AINP on Pesticide Residues, IARI, New Delhi
INDIA	VANDANA TRIPATHY	ICAR-Indian Agricultural Research Institute
INDIA	Sarita Bhalla	Consultant (Pharmacology)Medical Toxicologist, Central Insecticides Board & Registration Committee
INDIA	Vandana Tripathy	Senior Scientist ICAR-IARI, New Delhi
INDIA	Krishna Kumar Sharma	Indian Agricultural Research Institute
INDIA	National Codex Contact Point (as member)	Food Safety and Standards Authority of India Ministry of Health and Family Welfare FDA Bhawan, Kotla Road,
JAPAN	Yukiko Yamada	Senior Advisor / Ministry of Agriculture, Forestry and Fisheries of Japan

COUNTRY	NAME	TITLE/ORGANIZATION
JAPAN	Keisuke AWA	Assistant Director / Pharmaceutical Safety and Environmental Health Bureau Ministry of Health, Labour and Welfare of Japan
JAPAN	Hidetaka Kobayashi	Deputy Director, Agricultural Chemicals Office, Ministry of Agriculture, Forestry and Fisheries
Kazakhstan	Azzaryonov Alexandr	Ministry of Health of the Republic of Kazakhstan
MEXICO	Tania Daniela Fosado Soriano	Secretaría de Economía Punto de Contacto CODEX México
NETHERLANDS	Trijntje van der Velde-	Koerts RIVM, Bilthoven
NETHERLANDS	Karin Mahieu	RIVM
NEW ZEALANDS	Warren Hughes	Principal Adviser ACVM / Ministry for Primary Industries, Wellington
NIGERIA	Nwaeze Boniface Oguobi Cibueze	Chief Regulatory Officer
NORWAY	Norwegian Contact Point	
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International Council of Beverages Associations (ICBA)	Paivi Julkunen (Simone SooHoo)	ICBA Codex Policy Advisor/ International Council of Beverages Associations (ICBA)
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International Fruit & Vegetable Juice Association (IFU)	John Collins	Executive Director
International Nut and Dried Fruit Council Foundation (INC)	Ana Bermejo	Food Safety and Law Specialist
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International Organisation of Spice Trade Association (IOSTA)	Laura Shumow	Observer Organization