Agenda Item 8 **CRD09**

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON PESTICIDE RESIDUES

50th Session
Haikou, P.R. China, 9-14 April 2018

Draft Discussion Paper on ToR II and III of EWG on

Reviewing the International Estimate of Short-Term Intake (IESTI)

Prepared by the eWG chaired by the Netherlands and co-chaired by Australia and Uganda

READING GUIDE

CX/PR 18/50/12 states that in order to assist the Committee in considering recommendations related to TOR (ii) and (iii), Conference Rooms Documents (CRDs) will be made available in advance to the plenary meeting. This is the CRD related to TOR ii.

This draft document was initially prepared by RIVM to respond to TOR ii of the EWG that was established by CCPR49 (2017) to review the International Estimate of Short-Term Intake (IESTI).

(ii). 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.

The first draft of this document was posted on the EWG Forum on 6 November 2017. Comments were received until 5 December 2017 from the United Kingdom, Kenya, Canada, CropLife, ICBA, Chile, Brazil, Argentina, AgroCare Latin America, and USA. The combined comments are available on the EWG Forum.

In response to the comments received, a second draft of the paper was prepared as well as a 'response to comments' table. The second draft of the document, together with the table, was posted on the EWG Forum on 5 February 2018 with a request to comment by 9 February. This extremely short response time was (understandably) too challenging for most of the members of the EWG. Nevertheless comments were received from CropLife and USA. The main comment was, that TOR ii is not yet fully addressed. No changes have been made yet to the second draft document, although it is clear that substantial revisions are needed. The way forward will be discussed by CCPR50.

International Estimate of Short-Term Intake (IESTI)

ToR II: Advantages and challenges that arise from the current IESTI equations and their impact on risk management, risk communication, consumer protection goals and trade

Please note that the ToR II could not yet be fulfilled, since to complete the work of the current CCPR EWG, additional input is needed, as requested by CCPR49. From CCPR49 report para 162: The Committee agreed to request FAO/WHO:

i. To review the basis and the parameters of the IESTI equations;

ii. To benchmark the outcomes of IESTI equations to a probabilistic distribution of actual exposures; and

iii. To present the outcome to CCPR.

However, before presenting the outcome to CCPR, the work above needs to be discussed by JMPR, which meets in September. Therefore, this information will not be available in time for discussion at CCPR50. JMPR may also want to reflect on a special issue of the Journal of Environmental Science and Health, in which a series of papers will be published shortly on the impact on number of MRLs.

Therefore, this document should be considered as 'work-in-progress'.

Introduction

The MRL (Maximum Residue Level) is the maximum concentration of a pesticide residue (expressed as mg/kg) to be legally permitted in or on food commodities and animal feeds. MRLs are based on Good Agricultural Practice (GAP) data and foods derived from commodities that comply with the respective MRLs are intended to be toxicologically acceptable (CAC, 2016).

During the MRL setting, one of the aspects taken into consideration is the acute dietary intake of a pesticide. At an international level, a deterministic methodology is used to address the calculation of the acute dietary exposure to pesticides, the so-called International Estimated Short Term Intake (IESTI) of the pesticide residue (for a chronological history of the acute RA methodology see (Hamilton & Crossley, 2004; WHO, 2009). In characterizing any risks possibly related to the short-term pesticide dietary exposure, the calculated intake, i.e. the IESTI, is thereafter compared with the established toxicological threshold for acute toxicity (Acute Reference Dose-ARfD[1]) of the chemical (WHO, 2007).

In total, four different equations are distinguished for the calculations of the acute dietary exposure, depending on different factors related for instance to the size of the crop unit compared to the consumption level, how the crop is marketed (bulking/blending) or whether it is processed. The IESTI equations' history, background and use were discussed in another document (IESTI-A brief explanatory note on history and use; Appendix I to the Discussion paper). The present document is intended to put forward the advantages and challenges related to the use of the IESTI equations.

It should be mentioned here that although the IESTI methodology was initially developed for authorization and MRL-setting purposes, it is currently also employed by other end- users, such as enforcement agencies/food inspection services.

Which are the advantages?

In the past, the toxicological acceptability of the MRL was based on the comparison of only chronic exposure to the toxicological threshold of the pesticide (Acceptable Daily Intake)[2]. Nonetheless, some pesticides may exert their adverse effects after single or a few days exposure. An acute dietary risk assessment, with the IESTI equation(s), can estimate high acute dietary intakes, based on large portions and prevent adverse health effects induced by such exposures.

The main advantage of the IESTI methodology, is that it is presently utilized in different frameworks at a national and global level, thereby facilitating a partially harmonized and transparent risk assessment. In addition, when it occurs, harmonization may result in the same acceptance or rejection of MRLs worldwide and prevent possible trade barriers. Furthermore, it is easier to explain for all parties and general public that residues in concentrations up to MRL are safe. In addition to enhanced risk communication, it will be less likely that food retailers will introduce secondary standards.

Which are the challenges?

Although the IESTI equations were intended to be used by all end- users in the same manner, over time, the input values for the different parameters of the equations started to diverge between the various user groups. The main challenges regarding the use of the IESTI equations, are linked to these diverging input values for the equation parameters. The parameters are listed in Table 1 as well as the background reasoning for these differences. It is recognized that some parameters are influenced by different regional and cultural habits and will remain nation specific. It will be unrealistic to assume that one value can be achieved. However, the methods on how to retrieve those nation specific data should be harmonized (large portion and interlinked body weight, unit weight). Other parameters, such as the input variable for determining the residue (HR(-P), STMR(-P), or MRL) and for different statistical assumptions (variability factors) can be harmonized. For these parameters consensus should be reached as well as for e.g. different residue definitions or conversion factors for enforcement and risk assessment.

It is noted that differences in residue levels based on different use labels will remain, when comparing the outcomes between different national agencies. In theory, the globally set residue levels should cover the authorized uses in all Codex countries.

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[1] The ARfD of a chemical is an estimate of the amount of a substance in food and/or drinking-water, normally expressed on a body-weight basis, which can be ingested in a period of 24 hours or less without appreciable health risk to the consumer on the basis of all known facts at the time of the evaluation. (JMPR 2002).

[2] The ADI of a chemical is the daily intake which, during an entire lifetime, appears to be without appreciable risk to the health of the consumer on the basis of all the known facts at the time of the evaluation of the chemical by the Joint FAO/WHO Meeting on Pesticide Residues. It is expressed in milligrams of the chemical per kilogram of body weight. (Codex Alimentarius, Vol. 2A)

If the equations are changed partly or completely, further challenges will entail the potential loss of uses, communicating why the equations have been altered, and explaining why previously safe MRLs have been removed.

Table 1 Differences in applied input parameters in the IESTI equation.

IESTI parameter	Difference, reasons for differences
Residue (HR, HR-P, STMR, STMR-P)	Different residue values between national/regional authorities and JMPR, because of differences in the submitted data and/or differences in use (dose rate, pre-harvest interval) and because different residue definitions are used between authorities. Lack of transparency whether HR/HR-P/STMR/STMR-P used in risk assessments refers to raw edible portion or Raw Agricultural Commodity (RAC) and whether PF (peeling and/or processing factors) and/or CF (to convert from one residue definition to another) have been used.
Variability factor (v)	JMPR: variability factor v= 1 for case 1 & 3 and v= 3 for case 2a & 2b EU: v=1 for case 1 & 3, v= 5 or 7 for case 2a & 2b, depending on the unit weight, and v= 10 for granular applications.
Large portion (LP) or reliability of estimate of 97.5th percentile consumption given sample size and ambiguities associated with categorization	Different large portions between countries, EU and JMPR. These differences can be the result of different cultural habits, but also due to lack of clear guidance on how the LP data are derived from food surveys.
Unit weight (U_{RAC} and U_e)	Different unit weights between countries, EU and JMPR because of different cultural habits and trading practices, lack of guidance how to derive information on unit weight and how to define the unit (e.g. spinach)

The HR and STMR in the IESTI equation(s)

The highest residue (HR) and the Supervised Trials Median Residue (STMR) used in the IESTI calculation refer to the residue as defined by the residue definition for dietary risk assessment present in the raw edible portion of the crop. When the HR or STMR are not available for the raw edible portion, the HR or STMR of the crop (further referred to as Raw Agricultural Commodity (RAC)) is used in the dietary risk assessment, adding additional uncertainty. The HR, STMR and MRL are generally based on data from the same supervised residue trials, though sometimes different residue definitions are applicable, as the MRL is based on the residue definition for enforcement. When only limited residue data are available and the variability (standard deviation) of the residue population is significant, the resulting MRL recommendation can be substantially higher than the HR and the STMR.

MRLs leading to a dietary exposure exceeding the acute reference dose (ARfD) as calculated with the IESTI can occur. For example, two situations were identified in the 2017 JMPR report, one was for fenpyroximate on apples, pears and cucumbers (using MRLs[3] of 0.2 and 0.3 m/kg for pome fruit and cucumbers versus the HRs of 0.15, 14 and 0.24 for apples, pears and cucumbers, respectively), and one for chlormequat on oats, using the MRL of 4 mg/kg instead of the STMR of 1.3 mg/kg. In such situations, food safety inspection services cannot act because the legal limit –the MRL- is not exceeded although the dietary exposure is calculated to be above the ARfD. The situation actually becomes relevant where the acute dietary exposure calculation performed with the HR (or STMR for IESTI case 3) is close to the ARfD. Thus, a residue concentration observed in monitoring, complying with the MRL, may if inserted in the IESTI equation instead of the HR/STMR, lead to an exposure higher than the ARfD. This triggered the question whether the HR (and STMR) in the IESTI equation should be replaced by the same metric as used for enforcement; the MRL.

[3] The acute dietary risk assessment for fenpyroximate using the MRL instead of the HR did not take into account the additional metabolites that are included in the residue definition for risk assessment. Thus, ideally, a conversion factor should be calculated that needs to be included in the calculation as well. Without this conversion factor the calculated exposure may underestimate the toxicologically relevant dietary burden for consumers.

The variability factor in the IESTI equation(s)

To obtain representative samples from supervised field trials several units of the RAC are taken from a treated plot (see Table V.1 in FAO 2009). For crops with a unit weight, e.g. one tomato, of >25 g twelve to twenty-four individual units are homogenized in a composite sample and subsequently analysed. However, consumers are exposed to residues in individual units and the residue in some individual units will be much higher than the residue that was measured in the composite sample. The variability factor is the factor applied to reflect that uncertainty in the variability of residues in individual units (FAO 2009). The variability factor is intended to be the 97.5%ile ratio of the individual unit residues compared to the average unit residue: P97.5 residue in units / P50 residue in units.

Previously, the JMPR (JMPR, 2002) used variability factors of 1, 3, 5, 7 or 10 for different types of commodities. After discussing the work of IUPAC, the 2003 JMPR agreed to replace the default variability factors of 3, 5, 7 and 10 by a new default variability factor of 3 for all commodities, except for U_{RAC} < 25 g where no variability factor is used (a variability of factor of 1 in the calculation sheets) (JMPR, 2003). From 2006 onwards, JMPR has used a default variability factor of 3 while the EU has continued to use the 'old' variability factors[4] (FAO 2002), resulting in recurring disagreements on the safety of Codex MRLs between the EU and the other Codex Member States. No agreement was reached between EU Member States on a proposal made by the European Commission (EFSA, 2007) on using a default variability factor of 3 instead of 5 and 7.

In March 2005, at the request of the European Commission, the EFSA PPR Panel (EFSA, 2005) published an opinion on a variability factor to be used for acute dietary intake assessment of pesticide residues in fruit and vegetables. Following the analysis of a large dataset of residue concentrations in single units, the Panel found that the average variability factor for supervised field trials was 2.8, while it was 3.6 for market place samples. . It was estimated that the variability factors for supervised trials will exceed the proposed default value of 3 in 34% of cases, whereas the previous default value of 7 for medium-sized food items will be exceeded in 0.2% of cases. Similarly, the variability factors for market surveys averaged 3.6, and will exceed 3 in about 65% of cases and 7 in about 1% of cases.

However, the PPR Panel also noted that the assessment of acute risks from dietary exposure uses conservative assumptions for portion size and the residue concentration as well as the variability factor. It was recommended to further investigate the combined effect of these conservative assumptions on the overall level of consumer protection (EFSA 2005).

Expression of the large portion

Expression of the large portion in kg/person and/or g/kg bw/day: Large portions can be derived from Food Consumption Surveys (FCS) in different ways. The current IESTI equations use a Large Portion as kg/person divided by the mean bodyweight (LP_{person}/bw) of the population group of the dietary survey from which the LP was derived (e.g. general population, adults, children). In this way it is not possible to take into account a possible correlation between the amount consumed and the body weight and, since it is expected that the larger portions (based on kg/person) are consumed by subjects representing body weights above the average, the use of an average bodyweight can be considered as a conservative assumption. This is especially true for children due to the high variability in body weight among individuals of different ages but within the same children group in the survey. The direct use of the P97.5 from a distribution based on kg/kg bw/day would provide a more precise estimate for large portion. In addition it is noted that a P97.5 value from a distribution based on kg/kg bw/day values corresponds to babies/toddlers or children who eat a lot relative to their bodyweight. This effect is most obvious in FCS performed among the general population including a wide range of ages. A plan is needed to get consistent international data collection. Furthermore, further discussion on the impact of the added accuracy and the potential loss of the ability to detect unusual outlier values is needed.

[4] In the EU the variability factor of 10 that was recommended by JMPR in 2002 for leafy vegetables and for granular soil treatment are not used.

Expression of the large portion raw, processed or combined: The LP should be matched to the commodity to which the HR or STMR relates. In the case of commodities that are predominantly eaten as the fresh fruit or vegetable, the LP should relate to the raw agricultural commodity. However, when major portions of the commodity are eaten in a processed way (e.g. grains) and when information on the residue in the processed commodity is available, the LP should relate to the processed commodity (e.g. flour or bread). In practice, some countries derive one single large portion to cover both the raw and processed forms of a certain commodity, while other countries report the large portions for specified raw and processed commodities. For example, LPs can be derived for orange raw and orange juice separately, or for total orange products consumed on a single day (including orange raw, orange juice and other orange products). Currently, there is no clear definition of the commodities for which large portions need to be derived, leading to different interpretations and potentially very different P97.5 consumption values. Consumption of more obscure or esoteric food items might result in even greater aggregation in some countries (e.g, countries consuming less oranges might report these generically as "citrus"). Comparisons, thus, can be difficult and dangerous when reporting can vary in this way.

Different LPs in different countries: Both EU and JMPR use as large portion for a certain commodity the most critical and robust of the values reported by the individual member states. Still, since Codex has more member states than the EU, they may be working with different LP values for a given commodity.

Impact of new FCS on LPs: The 97.5th percentile consumption among consumers only (LP) can be very unstable. So it may change a lot from survey to survey. Ideally, every time a new consumption survey is conducted its impact on the existing highest LP per commodity should be assessed. A decision to change the highest LP per commodity may have impact on MRLs that were assessed before. However, re-assessing all existing MRLs for a given commodity every time the highest LP for that commodity changes, would be quite time and resource intensive. Though time and resources should not be an impediment to, it may be necessary to establish a prioritization criterion for the revision of the MRLs.

In addition, national food surveys usually may not cover certain minority populations in sufficient numbers to allow development of minority-specific consumption estimate. In the most unfavorable situations this could mean that the LP is underestimated. It is noted that minorities are not excluded from surveys and in some nations sometimes actively attempted to oversample them in the study design so that minority-specific consumption estimates are available.

The Unit weight concept

In the IESTI calculation, the unit weight value (U) affects the outcome of the IESTI equation in two ways. The U_e determines whether the LP will be composed by more than one crop unit (Case 2a) or will be a portion of the unit (Case 2b) and subsequently determines which IESTI formula is applicable. Furthermore, the U_{RAC} determines whether a variability factor is to be applied to the HR. According to JMPR procedures, no variability factor[5] is used if the U_{RAC} is smaller than 25 g and a variability factor of 3 is used if the U_{RAC} is 25 g or higher. According to EU procedures, a variability factor of 1 is used if the U_{RAC} is smaller than 25 g, a variability factor of 7 is used if the U_{RAC} is between 25 g and 250 g, and a variability factor of 5 is used if the U_{RAC} is higher than 250 g.

Several countries have provided unit weight data without specifying whether the U values provided represents the median of units consumed in a country or a different estimation. Also, it is not clear in all cases whether the value refers to the whole commodity or to the raw edible portion (JMPR, 2006). For some crops it is not so evident how the unit weight should be expressed (e.g. spinach as single leaves, as plants or as bunches; bananas as single fruit or a hand of seven fruits). This also applies to other crops (e.g. elderberries, grapes, Chinese cabbage, rucola, tomatoes). Thus, more guidance is needed on how to derive unit weight data. Without a clear rationale different unit weights are used in different parts of the world for the same crop commodities. It is noted that several commodities exist in varieties that have very different unit weights, e.g., cherry tomatoes versus flesh tomatoes. The use of different unit weights results in very different outcomes of the IESTI, even if the large portion and residue levels are the same (Van der Velde-Koerts, 2010; see Figure 1 below).

[5] Please note that 'no variability factor' equals using a variability factor of 1

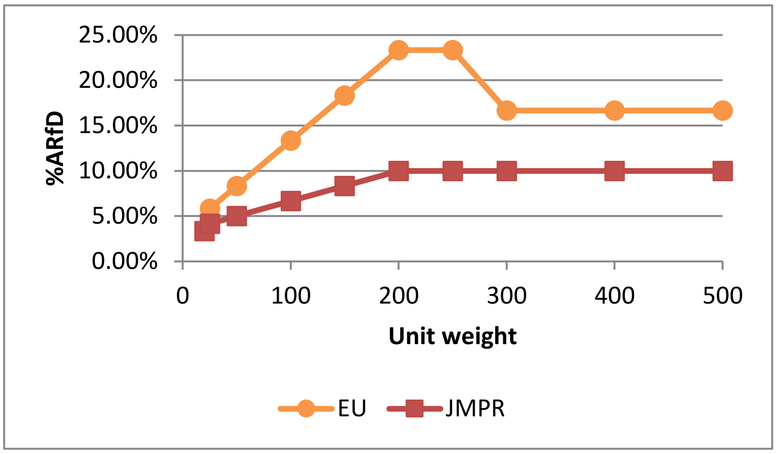

Figure 1IESTI (expressed as %ARfD) as a function of unit weight ($U_{RAC}=U_e$= 20-500 g), while all the other parameters are kept constant (HR = 0.2 mg/kg, LP = 200 g/person, bw = 60 kg, ARfD = 0.02 mg/kg bw) for 3 situations: EU (v=1,5,7), JMPR (v=1, 3).

In the IESTI equations, it is required to express the Large Portion (LP) as kg/person to compare the LP (97.5th percentile) with the unit weight to decide on the equation to be used (case 2a or case 2b). Subsequently, in the case 1, 2a, 2b and 3 equations the Large Portion as kg/person is divided by the average bodyweight (LP_{person}/bw). The drawbacks on expressing the Large Portion (LP) as kg/person were described previously in this document.

In case 2a the LP expressed as kg/person is required to calculate the exposure. So even in cases where the consumption distribution is based on kg/kg bw, this value has to be multiplied by the average bodyweight to get a kg/person value. This may result in an unrealistic high large portion, since the actual bodyweight can be much lower especially in surveys including large age differences ('general population surveys'). For case 1, case 2b and case 3 this is no problem, since the kg/person value is again divided by that same average bodyweight. However, in case 2a only part of the unrealistic high large portion is multiplied by the variability factor, while the other part is not multiplied by the variability factor. This introduces additional errors in the exposure assessment. Resolution of the point requires the raw data of the consumption survey to be transparently available.

IESTI used by food safety inspection services

Within the EU the IESTI is also used by food safety inspection services for risk assessment, when a batch is found to contain a residue level that exceeds the MRL[6]. In this case, the IESTI is used to decide whether a recall is needed, and whether the other EU member states need to be alerted. In some cases, other parties (e.g. retail, NGO) find that the exposure based on residues found by the inspection services, calculated with IESTI, exceeds the ARfD even though the MRL is not exceeded. See paragraph on HR and STMR in IESTI equations for examples. In such situations, food safety inspection services cannot act, because the legal limit is not exceeded. Therefore, a number of issues around the input parameters related to such uses shall be further considered.

One of the issues is related to the variability factors, since there is at present no consensus on what variability factor should be used with market place samples. Another important aspect is the use of the high globally harmonized large portion, which may be much higher than the national established large portion or exceedingly high or variable unit sizes derived in different countries. When discussing the challenges of the input parameters of the IESTI equation, also the use of the equations by enforcement/food inspection services should be kept in mind.

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[6] Codex MRLs are implemented in EU legislation and as such become EU MRLs, unless a reservation was made during the discussion at CCPR. EU Inspections relate to EU MRLs.

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Appendix 1

Table 1: Advantages that might arise from the possible revision of the current IESTI equations

1	It is an opportunity to define clear protection goals and to design an equation set that is "tuned" to ensure the goals are met but without being overly conservative and without adverse trade impacts.
2	It is an opportunity to explore alternatives and revise the approach to acute dietary risk assessment by establishing a transparent, credible, and unambiguous calculation approach. There is opportunity to calibrate the revised equations using the best tools and data available for estimating likely actual short-term dietary exposure, to benchmark the level of conservatism and ensure its link to the defined protection goals.
3	Using the MRL instead of the HR in the dietary risk assessment may simplify communication of risk assessment assumptions. This will help to address concerns among the general public in some regions about the safety of MRLs.
4	Using up-to-date scientific knowledge will decrease uncertainties and improve the credibility of the methodology, e.g. on how to express the Large Portion. Additional consideration of consumption for the various types of commodities within the IESTI set of equations warrants periodic review and any new data to support such revisions should be thoughtfully considered
5	Updating the IESTI methodology, including clarification of the input parameters may increase the acceptance of CXLs.
6	Uniformity of understanding the IESTI methodology world wide
7	World-wide harmonisation of the IESTI methodology including the clarification of its parameters, may allow and facilitate its use by a larger number of countries thereby helping to prevent trade barriers.
8	HRs are based on residue data from a specific GAP. Residue data from alternative GAPs may result in a higher HR values, but if the residue value is still below the MRL, the commodity can be moved in international trade. Moving from GAP specific HRs to the MRLs in consumer risk assessment reflects in a more transparent way international trade standards irrespective of the kind of treatment.
9	The unit weight of a commodity is a poorly defined parameter. Removing it from the equation may improve the practicability and understanding of the methodology.

Table 2: Challenges that might arise from the possible revision of the current IESTI equations

1	To manage executing the technical work needed in an acceptable time frame, like developing further guidance on the derivation of conversion factors, developing databases with conversion factors and processing factors, and P97.5 large portion value derived from the distribution of consumption values of dietary surveys expressed as g/kg body weight. It is noted that part of this work would also be required to underpin the current methodology.
2	To undertake a comprehensive analysis on the impacts of any proposed changes to the IESTI methodology on existing CXLs, noting that depending on the changes agreed on, some CXLs may be lost. It is noted that the loss of CXLs may have an impact on the availability of specific pesticides and hence food production.
3	To effectively communicate/explain to the consumer, the growers, importers and exporters how some CXLs currently considered to be safe are considered unacceptable if revised IESTI equations are adopted.
4	Given the possible loss of MRLs, instructions regarding how countries can use Codex MRLs as reference for their national regulations, must be considered. It is needed to generate orientation and guidelines related to the IESTI equations in an easy-to-understand document for developing and less developed countries,.. Note that this would be useful in the current situation as well
5	To provide training regarding this equation and its potential use by the countries. Note that this would be useful in the current situation as well
6	Growers need to have pest control substances with multiple Modes of Action available to prevent the development of pesticide resistance to any single pesticide. A reduction in the number of CXLs may lead to the loss of products alternative for the grower.
7	Consideration needs to be given on how to address residues in products of animal origin e.g. the different policies in the EU compared to Codex of setting MRLs for muscle and not meat.
8	The loss of some of the current CXLs may impact global trade. This potential impact may be disproportionally affecting developing countries trading in food crops and having limited access to alternative compounds
10	Reaching consensus on the protection goal. Defining the target percentile(s) of suitable probabilistic exposure distributions that are to be estimated by the IESTI equations in order to be used for regulatory decisions.

READING GUIDE

CX/PR 18/50/12 states that in order to assist the Committee in considering recommendations related to TOR (ii) and (iii), Conference Rooms Documents (CRDs) will be made available in advance to the plenary meeting. This is the CRD related to TOR iii.

This draft document was prepared by RIVM to initiate data gathering as specified by ToR iii of the EWG that was established by CCPR49 (2017) to review the International Estimate of Short-Term Intake (IESTI).

(iii). To gather relevant information on bulking and blending, as well as other information or data as outlined in Table 3 Appendix 2 of CX/PR 17/49/12 in order to feed into the risk assessors work through the JMPR Secretariat.

The document was posted on the EWG Forum on 17 November 2017. Comments were received until 5 December 2017 from CropLife, ICBA, Chile, Argentina, and USA. The combined comments are available on the eWG Forum.

The comments made clear that the drafting team did not explain the intended purpose of the ToR iii document well. This document was intended solely as call for data on bulking and blending and not as a discussion document on current practices in using these data, or on the other issues listed in Table 3 of Appendix 2 of CX/ PR 17/49/12. The comments were diverse and mostly reacted to the document itself. Little new information on bulking and blending was provided. No changes have been made yet to the draft document. The way forward will be discussed by CCPR50.

International Estimate of Short-Term Intake (IESTI)

ToR iii Additional information on bulking and blending

Introduction

In a workshop held in Geneva in 2015 the equations of the IESTI were re-evaluated (EFSA, 2015). The results were presented in a back-to-back meeting at the CCPR of 2016. At this meeting the CCPR decided to an eWG to prepare a discussion paper on the evaluation of the international estimate of short-term intake (IESTI). In this document (CX/PR 17/49/12) the advantages and challenges of revisiting the IESTI were listed taking into account the recommendations of the international workshop. This document was presented at the 49th session of the CCPR. After the meeting the eWG proceeded with a new mandate which included 4 new terms of Reference (ToR). The first ToR (i) included more information on the IESTI equations' history, background and use (reference to document, to be included when finalized). The main advantages and challenges of having an acute dietary risk assessment model based on harmonized IESTI equations are discussed in ToR ii (reference to document, to be included when finalized). This document is aimed at ToR iii, gathering of information on bulking and blending. The final ToR (iv) is a new discussion paper including the developments from ToR i-iii.

Background

As already explained in the various background documents prepared for ToR i and ii, the currently used IESTI model uses four different equations to calculate the consumer exposure to residues of plant protection products, following (good) agricultural use practices.

At the workshop in Geneva it became apparent that validated information on bulking and blending for processed products, the prerequisite for using the case 3 equation, can be taken into account if it can be demonstrated that such bulking and blending is guaranteed to occur. For that, further investigation of the processing, bulking and blending practices is needed. This paper is aimed at gathering information on processing, bulking and blending.

Case 3

Case 3
$\text{IESTI} = \dfrac{\text{LP}_{\text{person}} \times (\text{STMR or STMR - P})}{\text{bw}}$

Case 3 is applied for processed commodities for which the STMR(-P) represents the likely highest residue due to bulking or blending. This applies for instance to milk, grains, oil seeds, and pulses for which estimates are based on the pre-harvest use of the pesticide. Case 3 also applies to processed commodities such as flour, vegetable oils and fruit juices. In the current IESTI it is also applied to e.g. various dried and canned vegetables.

The current dietary risk assessment assumes bulking and blending of these commodities before they go into trade and therefore uses the STMR(-P) as best estimate for the exposure.

Why bulking and blending information?

During the workshop in Geneva it was concluded that if it can be demonstrated that bulking and blending occurs, an appropriate processing or homogenizing factor can be applied for refinement of case 3 calculations. This is specifically of importance in cases where the ARfD will be exceeded without such a factor.

At the same time, the participants agreed that there are substantial uncertainties and inconsistencies about the degrees of bulking and blending, which would not facilitate a harmonized approach. Therefore, the workshop also recommended further investigation of the bulking and blending practices.

In the list of challenges as presented in X/PR 17/49/12 it was defined as follows: "Information on bulking and blending practices needs to be gathered in order to decide on cases where a median residue instead of the MRL could be used in the dietary risk assessment, or a homogenization factor could be added." This challenge is interlinked with challenge number 13 of that list; "For blended foods (e.g. fruit juice, seed/nut oil, flour, corn meal), it is suggested to add a homogenization factor (<1) to the equation to reflect the decreased variability in pesticide residues resulting from processing."

Request to participants of eWG involved in growing, trading, and processing business

Participants of the eWG are requested to submit information on processing, bulking and blending of commodities either themselves or to forward this request to relevant parties and coordinate the bundling and submission of the data per country to the eWG.

Different types of case 3 commodities can be distinguished for which information is needed:

1. Commodities that are bulked and blended for industrial processing to e.g. juice (lemon, orange, grapefruit etc.), dried (powder) (pepper), frozen, canned, and pickled products, commodities used in wine and beer processing, and oil processing.

2. Commodities that are (also) bulked and blended before trade (e.g. raw beans, peas, cereals, nuts and seeds, teas etc.).

As it concerns a lot of different (processed) crop and animal commodities for Case 3, the commodities are not listed here. Crops eligible for providing data on processing and/or bulking and blending can be retrieved from the IESTI by putting a filter to column W and select 3. It is noted that information on bulking and blending of cereals (rice, wheat, barley), wine, dry fermented tea, and juices (oranges, apples, black berries, stone fruits) are of primary interest, since exceedances of the ARfD have been observed for these commodities on a more regular basis.

Submission and timing

As support for "guaranteed processing, bulking and blending processes", preferably provide SOPs and a good source reference.

Submission of the data can be directed at the eWG and uploaded by the participants on the shared drive (Codex Forum). Though it is expected this will be a continuous process, members are requested to indicate whether and for which crops they can provide information on processing, bulking and blending following the requirements as described above before the **first of December 2017**. The actual data can be submitted at a later stage. Pre-notification will help identifying for which crops this information is anticipated and for which crops further requests maybe issued.

References

EFSA 2015. Revisiting the International Estimate of Short-Term Intake (IESTI equations) used to estimate the acute exposure to pesticide residues via food, 8/9 September 2015, Geneva, Switzerland, EFSA Supporting publication **2015**:EN-907.

CCPR 2016. Codex Alimentarius Commission. Report of the 48th Session of the Codex Committee on Pesticide Residues, Chongquing, China, 25-30 April 2016, REP16/PR, 2016, http://www.fao.org/fao-who-codexalimentarius/meetings-reports/detail/en/?meeting=CCPR&session=48

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