CODEX ALIMENTARIUS COMMISSION



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REVISITING THE INTERNATIONAL ESTIMATE OF SHORT-TERM INTAKE (IESTI)

Prepared by EU and Australia

Introduction¹

- 1. The MRL is the maximum concentration of a pesticide residue (expressed as mg/kg) to be legally permitted in or on food commodities and animal feeds. Concerning the establishment of MRLs, the Codex formulated two goals (Codex Alimentarius Vol. 2):
 - a. Codex MRLs are based on registered or approved usage of a pesticide and are intended to apply in international trade
 - b. Foods complying with the Codex MRLs should be safe for human consumption
- 2. Initially, the toxicological acceptability ('safety') of the MRL was determined by estimating a life-time daily exposure² to the residue and comparing this with the Acceptable Daily Intake (ADI). However, in the early 1990s, it became apparent that, in some cases, residues of a chemical could pose risks after a single or a few days of exposure through the diet. Research on residues of acutely toxic pesticides (organophosphates and carbamates) in individual fruits and vegetables revealed random occurrences of comparatively high residue levels. Some individuals who consume significant amounts of such foods will occasionally eat the "hot" commodity unit (Hamey and Harris, 1999³).
- 2. In a FAO/WHO consultation which took place in Geneva in 1997⁴ and at a subsequent meeting in 1999⁵, a deterministic methodology was developed to address the calculation of the acute dietary exposure to pesticides, the International Estimate of Short Term Intake (IESTI) (For a chronological history of the acute RA methodology see [Travis et al., 2004⁶; WHO, 2009⁷]). The JMPR at its meeting in 1999, performed acute dietary exposure assessments for the first time, and compared the exposure estimates to the Acute Reference Dose, ARfD⁸. The methodology has been further refined by subsequent JMPR meetings, see Appendix 1 for the current equations.

¹ Adapted from Annex A – Background document in the Event Report of the EFSA Scientific Workshop, co-sponsored by FAO and WHO, '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. http://www.efsa.europa.eu/en/supporting/pub/907e

² Calculated by multiplying the median residue from supervised field trials by the estimated average daily regional consumption for each food commodity and then summing the products.

³ Hamey PY, Harris CA (1999) The variation of pesticide residues in fruits and vegetables and associated assessment of risk. Regul. Toxicol. Pharmacol 30: S34-S41.

⁴ WHO, 1997. Food Consumption and Exposure Assessment of Chemicals. Report of the FAO/WHO Consultation, Geneva, Switzerland, 10-14 February 1997. WHO, Switzerland.

⁵ Draft report of the ad hoc Expert Meeting on Acute Dietary Intake of Pesticide Residues, 8-9 April 1999, annex V in Pesticide Residues in food 1999 – Report. FAO Plant Production and Protection Paper, 153, Rome, 1999.

⁶ Travis KZ, Hamilton D, Davies L, O'Mullane M, Mueller U, Chapter 8 Acute Intake p243-268 in Pesticide Residues in Food and Drinking Water: Human Exposure and Risks edited by Denis Hamilton, Stephen Crossley (2004) John Wiley & Sons, England

⁷ WHO (World Health Organization), 2009. EHC 240, Principles and methods for the risk assessment of chemicals in food, Chapter 6: Dietary exposure assessment of chemicals in food.

⁸ The Acute Reference Dose (ARfD) of a chemical is an estimate of the amount of a substance in food and/or drinkingwater, 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)

- 3. Codex Member States which use Codex MRLs, implicitly use the IESTI equations. In Australia and the EU, the IESTI equations are used to estimate the short term dietary intake from pesticides for both authorisation of use and MRL setting. The IESTI equations are also used by national food safety inspection services to decide whether food products analysed in national monitoring programmes can be considered safe for consumption. Although the same IESTI equations are used, the input parameters (residue values, variability factors, unit weights, large portions) differ among international bodies (JMPR, EFSA) and individual countries. Because of differences in these input parameters, the outcome of acute exposure assessments may differ for a single crop-pesticide combination in different parts of the world. The use of different input parameters potentially creates trade barriers and concerns among the general public as to whether the MRL can be considered safe. Therefore, an evaluation of the IESTI calculation is proposed.
- 4. At several of its meetings, the JMPR has indicated the need for an international meeting to revisit the IESTI equation. In 2006, inter alia, the following specific issues were identified for further discussion (JMPR, 2006⁹):
 - Uncertainty and variability of the parameters used in the estimation;
 - Ways to improve the consumption, unit weight and body weight data provided to JMPR;
 - Identification of additional subgroups of the population for which the assessment should be conducted, e.g. toddlers;
 - The adequacy of the IESTI equation when residues from monitoring/enforcement data are used or the need for specific methodology for this type of application;
 - How to improve communication between the JMPR, risk managers and the public on the output of the risk assessment conducted by JMPR.
- 5. In 2007 JMPR concluded that, "overall, the IESTI (using the HR as an input) is a satisfactory indicator for assessing the short-term dietary intake and the acceptability of MRLs. However, from the perspective of public perception there may be benefits in estimating the IESTI using the MRL, while also including adjustments for edible portion and the different residue definitions for risk assessment and enforcement." The previously made recommendation to organise an international consultation, including relevant stakeholders, was reiterated. The main objective of such an event would be the continued development of the estimation of the short-term dietary intake of pesticides and the interpretation of the outcome of short-term dietary risk assessments conducted by JMPR. Furthermore JMPR recommended discussing whether it is appropriate to use the IESTI equation for evaluating the safety of individual consignments of food (JMPR, 2007¹⁰).
- 6. The discussion on the IESTI methodology continued in 2010 (JMPR, 2010¹¹), where particular emphasis was placed on the issue of uncertainties in the calculation of the IESTI. JMPR stressed the fact that to ensure international harmonisation of the methodology, changes such as a possible replacement of HR by MRL in the IESTI equations cannot be implemented by JMPR alone, but should be discussed, as recommended previously, at the international level.

2015 International scientific workshop on IESTI¹²

7. In response to the above series of recommendations and recognizing the need to harmonize the IESTI methodology on a world-wide level, the European Food Safety Authority (EFSA) and the Dutch WHO Collaborating Centre on Chemical Food Safety (RIVM¹³) organised a 2-day international Scientific Workshop to seek the views of experts on the IESTI methodology. Individuals in the field of dietary exposure assessment of pesticide residues representing different geographic and economic regions attended.

⁹ General report item 2.4 in JMPR Report 2006; Short-term dietary intake assessment: uncertainties in the international Estimated Short-Term Intake (IESTI) calculation and its interpretation. FAO Plant Production and Protection Paper, 187, Rome, 2006

¹⁰ General report item 2.1 in JMPR Report 2007; Short-term dietary intake assessment: further considerations. FAO Plant Production and Protection Paper, 191, Rome, 2007.

¹¹ General report item 2.3 in JMPR report 2010; Dietary risk assessments conducted by the JMPR: Need for appropriate consumption data for further method development. FAO Plant Production and Protection Paper, 200, Rome, 2011.

¹² Adapted from the Event Report of the EFSA Scientific Workshop, co-sponsored by FAO and WHO, '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. http://www.efsa.europa.eu/en/supporting/pub/907e

¹³ RIVM is a Dutch acronym for the Dutch National Institute for Public Health and the Environment

The event was co-sponsored by FAO and WHO. EFSA organised a stakeholder meeting on the day before the Scientific Workshop, to provide an opportunity for all stakeholders (e.g. representatives of civil society, institutional stakeholder, industry and academia) to present their views and to identify any shortcomings on the currently used methodology for acute exposure assessment. The overall goal of the Scientific Workshop was to evaluate, and where possible harmonise, the parameters within the IESTI equations as well as the equations themselves in order to propose ways to revise the methodology. In addition, the appropriateness of the IESTI methodology in assessing residues from monitoring and enforcement programmes was considered. In preparation for the workshop, experts from the WHO Collaborating Centre on Chemical Food Safety (at RIVM) drafted a background document describing the issues to be discussed and proposals for possible ways forward.

8. During the workshop, participants recommended replacing the current IESTI equations by the following:

New IESTI equation replacing case 1 and case 3 of the current IESTI equation:

 $IESTI = LP_{hw} \times MRL \times CF \times PF$

New IESTI equation replacing case 2a and case 2b of the current IESTI equation: $IESTI = LP_{hv} \times MRL \times v \times CF \times PF$

The main changes in the proposed equations compared to the current equations are as follows:

- LP is based on individual body weights rather than average body weights;
- The MRL, multiplied by a conversion factor (CF) to correct for the residue definition for dietary risk assessment, is used instead of the HR;
- Use of an average variability factor of 3 as default;
- The unit weight was proposed to be removed from the equations, because 1) it may not be correct to assume that only one unit in the large portion has a higher residue than the average residue of the lot sampled for analysis; 2) several commodities exist in varieties that have very different unit weights, e.g., cherry tomatoes versus beefsteak tomatoes; 3) the current unit weight data are not derived in a consistent way, and much work would be needed to improve the database.
- 9. Furthermore, future work was identified as required to refine the risk assessment as follows:
 - A clear list of commodities for which the variability factor is not applicable needs to be developed.
 - Information on bulking and blending practices needs to be gathered.
 - Further guidance on the derivation of conversion factors is needed
 - Conversion factors and processing factors should be made publically available by the risk assessors in a database. If different databases are made available by different risk assessors, the design of the databases should be agreed
 - A harmonized and comprehensive list of commodities and certain pre-defined processed commodities for which large portion data need to be derived should be developed. Processing studies should be conducted by addressing the commodities that are identified in the harmonised list.
 - A harmonised list or database compiling the large portions for the different diets should be developed at global level. Data included in this database should comply with agreed input and quality criteria.
 - Further guidance on how to derive a large portion is required.
- 10. The report of the EFSA workshop, co-sponsored by FAO and WHO, was published as an EFSA event report in December 2015¹⁴. An advanced draft of the report was provided to the JMPR 2015 meeting for its consideration. It was decided that at a side-event in the framework of the 2016 CCPR meeting, CCPR members would be informed on the outcome of the Scientific workshop.
- 11. Following the workshop, an ad hoc working group of experts working in the field of risk assessment has prepared a preliminary impact assessment on the proposed changes. The assessment includes:

¹⁴ http://www.efsa.europa.eu/en/supporting/pub/907e

- impact on the number of MRLs that would be acceptable from a dietary risk assessment perspective when comparing the current equations "old" with the new methodology;
- impact of the change of methodology on exposure estimates (comparison of exposure estimates with current methodology and alternative methodology)

The working group consisted of members from ANSES (FR), APVMA (AUS), BfR (DE), CRD (UK), EFSA (EU), RIVM (NL). The results of the impact assessment will be presented in the aforementioned side-event at CCPR 48.

Conclusions and recommendations

- 12. As defined in the Codex Procedural Manual, risk analysis should follow a structured approach comprising three distinct but closely linked components: risk assessment, risk management and risk communication. Although the development of a calculation tool for assessing acute exposure is clearly a risk assessment task within the remit of JMPR, the risk managers at CCPR are requested to advise JMPR on their needs, i.e. define more clearly what the calculation tool should deliver and how conservative its calculations and outputs should be.
- 13. As a pre-condition for CCPR to accept the results of a new calculation tool, it is important that the impact of any changes in the current IESTI equations and its parameters is properly assessed, both in terms of consumer protection and MRL establishment.
- 14. A project on new work is therefore proposed (see project document) in order to follow up on the conclusions of the scientific workshop and on the preliminary assessment of the impacts conducted by the ad hoc expert group. Furthermore, the workshop identified a list of work needed to improve the methodology. The actions mentioned in this list are recommended to form the basis for further discussions and should be assessed and, if agreed, prioritised.
- 15. Since the use of different risk assessment policies for addressing short-term exposures may potentially create trade barriers and concerns among the general public as to whether the MRL can be considered safe, CCPR is invited to agree that further development and harmonisation of the IESTI methodology is desirable. Furthermore, CCPR is recommended to:
 - A Request JMPR to discuss the proposals from the Scientific workshop (Geneva, 2015) and conclude on a new set of IESTI equations taking into account these proposals and the needs from the risk managers.
 - B To establish a CCPR e-working group to discuss the issues described in para 13 and 14 in order to be able to interact with JMPR on their work in revising the IESTI.

Appendix 1¹⁵: Acute dietary exposure estimates currently used by JMPR

LP_{person} Highest large portion reported (97.5th percentile of consumers only), kg of food per person per day.

- **HR** Highest residue in composite sample¹⁶ of raw edible portion found in the supervised trials performed according to GAP used for estimating the maximum residue level (in mg/kg).
- **HR-P** Highest residue in a processed¹⁷ commodity, mg/kg, calculated by multiplying the highest residue in the raw commodity by the processing factor.
- **bw** Mean body weight, kg, provided by the country from which the LP was reported. The bodyweight represents the mean body weight of the population group of the dietary survey from which the LP was derived (e.g. general population, adults, children).
- **U**_e Unit weight of the raw edible portion, kg, provided by the country where the trials that gave the highest residue were carried out.
- **U**_{RAC} Unit weight of the raw agricultural commodity (RAC), kg, provided by the country where the trials that gave the highest residue were carried out.
- *v* Variability factor, the factor applied to the composite residue to estimate the residue level in a high-residue unit.
- **STMR** Supervised trials median residue in the raw edible portion of a food commodity (expressed as mg/kg), derived from the same set of supervised field trials as the HR.
- STMR-P Supervised trials median residue in processed commodity (in mg/kg).

Case 1

The residue in a composite sample (raw or processed) reflects the residue level in a portion of the commodity that would be consumed at one meal (whole fruit or vegetable unit weight (expressed as RAC) is below 0.025 kg). Case 1 also applies to meat, liver, kidney, edible offal and eggs, and for grains, oilseed and pulses commodities when the estimates were based on post-harvest use of the pesticide.

 $\text{IESTI} = \frac{\text{LP}_{\text{person}} \times (\text{HR or HR - P})}{\text{bw}}$

Case 2

The one meal portion, such as a single fruit or vegetable unit, might have a higher residue than the composite (whole fruit or vegetable unit weight (expressed as RAC) is equal or above 0.025 kg).

Case 2a

The unit weight (raw edible portion) of the commodity is lower than the large portion weight.

$$\text{IESTI} = \frac{\left\{ U_{e} \times (\text{HR or HR - P}) \times \nu \right\} + \left\{ (\text{LP}_{\text{person}} - U_{e}) \times (\text{HR or HR - P}) \right\}}{\text{bw}}$$

The Case 2a formula is based on the assumption that the first unit contains residues at the [HR \times *v*] level and the next ones contain residues at the HR level, which represents the residue in the composite from the same lot as the first one.

http://www.efsa.europa.eu/en/supporting/pub/907e

¹⁵ Based on Annex A – **Background document** in the Event Report of the EFSA Scientific Workshop, co-sponsored by FAO and WHO, '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.

¹⁶ Composite sample = samples composed of multiple units of the same commodity

¹⁷ 'Processing' can either relate to removing inedible parts of a commodity, e.g. peeling a banana, or to further (industrial or household) preparation, e.g. milling of grain, cooking of spinach.

Case 2b

The unit weight (raw edible portion) of the commodity exceeds the large portion weight.

$$\text{IESTI} = \frac{\text{LP}_{\text{person}} \times (\text{HR or HR - P}) \times \nu}{\text{bw}}$$

The Case 2b formula is based on the assumption that there is only one consumed unit and it contains residues at the [HR $\times v$] level.

Case 3

Case 3 is for those processed commodities where, because of bulking or blending, the STMR-P represents the likely highest residue. Case 3 also applies to milk and to grains, oilseeds and pulses for which the estimates were based on pre-harvest use of the pesticide.

$$IESTI = \frac{LP_{person} \times (STMR \text{ or } STMR \text{ - } P)}{bw}$$

The concept of a variability factor was introduced to enable residues in individual units with high concentrations to be estimated from a composite sample, which is assumed to represent the average residue concentration in the sampled lot. The variability factor (v) was defined as the 97.5th percentile of the residue concentrations present in commodity units (RAC) divided by the mean residue concentration of the sample population: P97.5 residue in units.

In the IESTI methodology, the estimates are performed for each crop individually, as it is unlikely that an individual will consume, within a meal or 24 h, a large portion of more than one food containing the highest residue level (the one that incorporates the variability factor). The IESTI calculations can be performed separately to estimate dietary exposure from consumption of the unprocessed or processed form of a food commodity, when relevant.

Appendix 2

PROJECT DOCUMENT

PROPOSAL FOR NEW WORK ON REVISITING THE INTERNATIONAL ESTIMATE OF SHORT-TERM INTAKE (IESTI)

Prepared by EU and Australia

1. Purpose and scope of revisiting the IESTI

The purpose of this new work is to revisit the parameters and equations of the International Estimate of Short-Term Intake (IESTI) methodology.

The IESTI equations were established in the late 1990's, and have been modified several times. Not all modifications have been taken up consistently across the world. Therefore, after more than 15 years of use, we feel we need an assessment of the existing methodology to harmonise internationally acute exposure assessment approaches used by different risk assessment bodies across the world. This work will facilitate trade while maintaining a high level of consumer protection and enhance consumer's trust in the safety of MRLs.

A first step to advance further discussions in an international context was taken by the European Food Safety Authority (EFSA) and the Dutch National Institute for Public Health and the Environment (RIVM) by organising a Scientific Workshop held in Geneva in September 2015. The workshop, co-sponsored by FAO and WHO, was attended by 40 participants from all over the world, including several JMPR panel members. Participants agreed upon recommendations on how to revise and harmonise the IESTI equations and its input parameters. These recommendations would need now to be adequately evaluated. This evaluation should focus on the impact that any change of the current methodology would have on consumer protection and MRL establishment for trade. The workshop also identified follow-up actions needed to better facilitate the adoption of the revised IESTI equations. This could be further discussed once new work is adopted and a working group is established.

2. Relevance and timeliness

The IESTI methodology for calculating the acute dietary exposure to pesticide residues in the context of MRLsetting was initially established in two international joint FAO/WHO meetings (WHO, 1997¹; FAO, 1999²). Subsequently, the methodology was further developed by JMPR (FAO/WHO, 2009³). In several of its meetings, JMPR has indicated the need to revisit the IESTI equations⁴. An international scientific workshop on revisiting the IESTI was held on 8 and 9 September 2015 in Geneva. The report of this event was published on 15 December 2015⁵. The scientific workshop has issued several recommendations to EU and Codex members.

Since its development, the IESTI methodology was modified several times by the JMPR, but not all modifications have been taken up consistently by those regulatory agencies across the world that use the current approach. As a consequence, the acute exposure assessment approaches are not fully harmonised. This lack of harmonisation is a contributing factor for rejection of certain Codex MRLs, which as a result may lead to the creation of trade barriers. Therefore, improving consistency in application through harmonisation of the methodologies is needed. Moreover, implementation of the proposed revised IESTI equations will help to address concerns among the general public in some regions about the safety of MRLs established for pesticide residues.

¹ WHO (1997). Food consumption and exposure assessment of chemicals. Report of a FAO/WHO consultation, Geneva, Switzerland, 10–14 February 1997. Geneva, Switzerland, WHO (WHO/FSF/FOS/97.5). Retrieved from http://apps.who.int/iris/bitstream/10665/63988/1/WHO_FSF_FOS_97.5.pdf

² FAO (1999). Pesticide residues in food—1998. Report of the Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Expert Group on Pesticide Residues. Rome, Italy, FAO. Retrieved from http://www.fao.org/fileadmin/templates/agphome/documents/Pests_Pesticides/JMPR/Reports_1991-2006/REPORT1999.pdf

³ FAO/WHO (2009) Principles and methods for the risk assessment of chemicals in food, Environmental Health Criteria 240, chapter 6 Dietary exposure assessment of chemicals in food.

⁴ General item 2.4 in JMPR Report 2006; Short-term dietary intake assessment: uncertainties in the international Estimated Short-Term Intake (IESTI) calculation and its interpretation. General report item 2.1 in JMPR Report 2007; Short-term dietary intake assessment: further considerations. General report item 2.3 in JMPR report 2010; Dietary risk assessments conducted by the JMPR: Need for appropriate consumption data for further method development.

⁵ EFSA and RIVM, 2015. EFSA Scientific Workshop, co-sponsored by FAO and WHO: Revisiting the International Estimate of Short-Term Intake (IESTI equations) used to estimate the acute exposure to pesticide residues via food. EFSA supporting publication 2015:EN-907.

3. Main aspects to be covered

The proposed new work by CCPR should cover the following aspects:

- 1. To consider the need for revision and further harmonisation of the IESTI methodology, taking into account previous recommendations of the JMPR and the aforementioned scientific workshop. For this purpose, it is recommended that an electronic working group be established.
- 2. To provide JMPR with specific information needed to prepare advice on the harmonisation of the IESTI methodology. Although the development of a calculation tool for assessing acute exposure is clearly a risk assessment task within the remit of JMPR, CCPR should address risk management issues, namely the expected level of conservativeness of the acute risk assessment methodology. The electronic working group should prepare a paper on these questions.
- 3. To decide on what type of assessment(s) would be best suited to assess the impact that any proposed change of methodology would have on consumer protection and on trade. The electronic working group should identify the types of assessment which would best inform CCPR on the impact of any proposed change of methodology. It could then either carry out such an assessment or prepare a request to JMPR to conduct the assessment.
- 4. To explore which further actions are needed, and establish a priority list for these actions, to gain a better picture of the possible impact of a change of methodology. The initial list of follow up actions established by the scientific workshop (see Discussion document, para 9) could be used as a starting point for this exercise. The electronic working group should advise CCPR on the actions needed and on a priority list for these actions. Furthermore, the electronic working group should advise how and by whom these actions could be best performed.

4. Assessment against the Criteria for the establishment of work priorities

The proposed work is consistent with the Criteria for the Establishment of work priorities.

General criterion

- It will provide clarity, consistency and certainty for the risk assessment of pesticide residues. Applying a more uniform approach may help to facilitate fair trade practices.

Criteria applicable to general subjects:

- a) Diversification of national legislations and apparent resultant or potential impediments to international trade
 - Internationally harmonizing acute exposure assessment approaches used by different risk assessment bodies will help to reduce possible trade barriers by reducing international divergences in MRL setting.
- b) Scope of work and establishment of priorities between the various sections of the work.
 - The scope of the envisaged work is outlined in section 3 of the project document.
- c) Work already undertaken by other international organizations in this field and/or suggested by the relevant international intergovernmental body(ies).
 - The event report of the international scientific workshop on revisiting the IESTI in Geneva has been published in December 2015. The workshop was jointly organised by EFSA, RIVM, and co-sponsored by FAO and WHO.
- d) Amenability of the subject of the proposal to standardization.
 - None identified.
- e) Consideration of the global magnitude of the problem or issue.
 - The IESTI equations were established by JMPR in the past, but further refinement is needed to improve harmonisation internationally of acute exposure assessment approaches used by risk assessment bodies across the world.

5. Relevance to the Codex Strategic Objectives

The proposal to develop revisit IESTI is in line with the following strategic goals of the Codex

Alimentarius Commission Strategic Plan 2014 - 2019:

- Goal 1 (Establish international food standards that address current and emerging food issues), and in
 particular objective 1.2 (Proactively identify emerging issues and Member needs and, where appropriate,
 develop relevant food standards) and objective 1.2.2 (Develop and revise international and regional
 standards as needed, in response to needs identified by Members and in response to factors that affect
 food safety, nutrition and fair practices in the food trade); and
- Goal 2 (Ensure the application of risk analysis principles in the development of Codex standards), specifically objective 2.1.2 (Encourage engagement of scientific and technical expertise of Members and their representatives in the development of Codex standards).

6. Information on the relation between the proposal and other existing Codex documents

This proposal takes into account CX/PR/05/37/4 where it is concluded that food containing residues at the level of the adopted Codex MRL must be safe for consumers. Furthermore, it is related to the Principles and methods for the risk assessment of chemicals in food, Environmental Health Criteria 240 (FAO/WHO; 2009), chapter 6 'Dietary exposure assessment of chemicals in food'.

7. Identification of any requirement for and availability of expert advice

Expert advice of JMPR and other relevant risk assessment bodies will be sought and taken into account.

8. Identification of any need for Technical Input to the Guidelines from external Bodies that can be planned for

Technical input will be sought from JMPR, national and regional risk assessment bodies for points 1) and 2) of section 3 of this project document, relating to the need for further harmonisation of the IESTI methodology, and point 3), relating to assessment of the impact that any proposed change of methodology would have. For point 4), of section 3, relating to the need to explore which further actions are needed and to the establishment of a priority list, cooperation with the OECD RCEG could be sought. Additionally for point 4), the initial list of follow up actions established by the scientific workshop should serve as a starting point (see Discussion document, para 9).

9. Proposed timeline for completion of the new work, including the start date, the Proposed Date for adoption at Step 5, and the proposed date for adoption by the Commission

- CCPR 48 Endorsement of a proposal for new work and setting up of an electronic working group on revising the IESTI and asking JMPR for advice
- CAC 39 Approval of new work
- CCPR 49 Consideration of draft advice from the electronic working group at Step 3, comments at step 4, and possible advancement to Step 5
- CAC 40 Adoption at step 5
- CCPR 50 Discussion of draft from the electronic working group at Step 6 and comments at step 7 and advancement to Step 8 for adoption.
- CAC 41 Adoption at step 8

The electronic working group should interact with JMPR during their sessions in 2016 and 2017.