

# CODEX ALIMENTARIUS COMMISSION



Food and Agriculture  
Organization of the  
United Nations



World Health  
Organization

# E

Viale delle Terme di Caracalla, 00153 Rome, Italy - Tel: (+39) 06 57051 - E-mail: [codex@fao.org](mailto:codex@fao.org) - [www.codexalimentarius.org](http://www.codexalimentarius.org)

Agenda Item 4

CX/GP 16/30/4

February 2016

## JOINT FAO/WHO FOOD STANDARDS PROGRAMME CODEX COMMITTEE ON GENERAL PRINCIPLES

Thirtieth Session

Paris, France, 11 - 15 April 2016

### CONSISTENCY OF THE RISK ANALYSIS TEXTS ACROSS THE RELEVANT COMMITTEES

(prepared by the Codex Secretariat in collaboration with FAO and WHO)

Governments and international organizations in Observer status with the Codex Alimentarius Commission wishing to submit comments on this document are invited to do so no later than **30 March 2016** as follows: Ms Geneviève Raoux, *Ministère de l'Economie, de l'Industrie et du Numérique, Direction générale de la concurrence, de la consommation et de la répression des fraudes*, 59 Boulevard Vincent Auriol, Teledoc 223, 75703 Paris Cedex 13, France (E-mail: [genevieve.raoux@dgccrf.finances.gouv.fr](mailto:genevieve.raoux@dgccrf.finances.gouv.fr)) with a copy to the Secretariat of the Codex Alimentarius Commission, Joint FAO/WHO Food Standards Programme (E-mail: [Codex@fao.org](mailto:Codex@fao.org)).

#### BACKGROUND

1. This activity was included in the Strategic Plan 2008-2013 as Activity 2.1 “*Review of the consistency of risk analysis principles elaborated by the relevant Codex Committees*” and should have been completed by 2011.
2. The matter of consistency was first considered by CCGP25; (see ALINORM 09/32/33) and the relevant document (CX/GP 09/25/5). CCGP25 requested the Secretariat to prepare a revised document and circulate it for comments. The document “*Review of the Risk Analysis policies of Codex Committees*”, (CL 2010/1-GP) and comments were considered by CCGP26 (see Appendix 1 for the discussion), which agreed that the risk analysis policies developed by Codex committees were generally consistent with the “*Working principles for risk analysis for application in the framework of the Codex Alimentarius*”, which complied with the mandate given to the Committee under Activity 2.1. CCGP26 agreed to forward the review presented in CL 2010/1-GP to the committees concerned for their consideration and review of their risk analysis policies, which would initiate Activity 2.2 of the Strategic Plan.
3. Following the decision of CCGP26 (ALINORM 10/33/33), the committees concerned, i.e. CCCF, CCFA, CCFH, CCNFSDU, CCPR and CCRVDF, started to review their documents and this work was finalized in 2014. The last committees to finalize the revision were CCPR46 and CCRVDF21.
4. In adopting revisions of the *Risk Analysis Principles Applied by CCRVDF* and of the *Risk Assessment Policy for Residues of Veterinary Drugs in Foods*, CAC35 noted that the CCGP could review these documents for consistency at its next session.
5. In completing this review, CCGP28 agreed to consider the consistency of all risk analysis texts across the relevant committees at its next session guided by a document, prepared by the Codex Secretariat, which would compare and analyse the texts of the different committees. However, such a document was not prepared for CCGP29 and it was agreed to consider this item at the next CCGP session.

#### ANALYSIS

6. The Secretariat analyzed the different texts by ordering abbreviated texts of the paragraphs of each of the principles side by side in the order of the General Principles (see Appendix 2). This was only done to facilitate the comparison and it is not proposed to reorder the texts in this manner also keeping in mind the comments made at CCGP26 (see Appendix 1, para 49).

*General Comments*

7. The texts are generally consistent with the Working Principles and in practice give Codex committees sufficient guidance on how to conduct the risk analysis. The main concepts of the working principles are contained in all texts, however the texts differ significantly in structure and the amount of procedural text contained and how they deal with risk assessment policy (separate section, integrated or separate annex). The main structural differences to the working principles have already been mentioned in CL 2010/1-GP and not much has changed since.
8. For two of the committees (CCRVDF and CCPR), FAO and WHO expert bodies are the only acceptable source of scientific advice; for three committees (CCFA, CCCF and CCFH) the main source of scientific advice are FAO and WHO expert bodies however other international scientific bodies are admitted if agreed by the Commission. For one committee (CCNFSDU) no specific expert body is mentioned, FAO and WHO are acknowledged as the primary source of nutritional risk assessment advice while other internationally recognized bodies are admitted as approved by the Commission.

*Specific Comments**CCFA*

9. The text for CCFA was derived from the Joint CCFA/CCCF text, which was split into two separate texts following the recommendation at CCGP26. The structure used is different than the working principles using as headings the bodies responsible: CCFH, JECFA and CCFA and JECFA, ordering the paragraphs by which body is responsible. The text does not contain an explicit risk assessment policy but paras 33 and 34 give indications about the priorities. The Committee decided in 2011 that the text was adequate and there was no merit in reformatting it (REP11/FA, para 14) and in 2012 finalized the text on the basis of a proposal from the Secretariat (REP12/FA, para 21).

*CCCF*

10. The Committee had revised its risk analysis principles and the exposure assessment annex to reflect the split of the CCFAC into CCFA and CCCF in 2007 (see ALINORM 07/30/41, para 18). The text is ordered in a similar way as the CCFA text but contains somewhat more structure in subheadings. The reference to the exposure assessment policy should be corrected in para 17 and para 17bis should be renumbered. The Committee decided in 2010 that no action to revise the text was necessary (see ALINORM 10/33/41, para 24).

*CCRVDF*

11. The Committee undertook extensive work on its Risk Analysis principles since 2010 (including Concern Form and extrapolation of MRL to other species as well as clarifications of other parts in the text and in the risk assessment policy). The process was completed in 2014. Most of the text is under the heading "Risk management in CCRVDF" including the risk assessment. The risk assessment policy remains in an annex. With the exception of some numbering issues in section 3 (3.1.3 and 3.1.4 could logically be sub-sections of 3.1.2), the text seems well structured and broadly follows the working principles.

*CCPR*

12. The Committee undertook extensive work on its risk analysis principles since 2008 including the integration of the previous annex on risk management policies and prioritization into the main text and the elaboration of a number of new annexes. The resulting text is the longest of all risk analysis texts. The order used in the text is a mixture of the three parts of Risk Analysis and the work procedure of the CCPR. One could argue that e.g. the prioritization process, which has been included under risk management, is rather part of the risk assessment policy or that the reference to the step procedure is procedural and should not be in the risk analysis principles. On the other hand, it may be practical for members to have all relevant information in one comprehensive document and that the order chosen is the most user-friendly even if not in line with the Working Principles. There seem to be some issues in the section numbering logic in section 5.

*CCNFSDU*

13. The text closely follows the working principles while adapting the definitions and other texts to nutritional risk analysis. There is no recognition of the *Joint FAO/WHO Expert Meetings on Nutrition* (JEMNU) as a source of scientific advice. This does not reflect current practice across Codex committees and should be corrected by the CCNFSDU.

*CCFH*

14. The CCFH text mainly follows the working principles while in addition making reference to other risk analysis texts developed by the CCFH. Since 2010 the text was revised and notably the procedural part was removed.

**CONCLUSION**

15. Overall, there do not seem to be impediments for the effective use of the present risk analysis principles of Codex committees and some of the principles have only been finalized recently. There is thus no immediate need for a revision of the Codex risk analysis section of the Procedural Manual.

**RECOMMENDATIONS***Short term*

16. CCNFSDU should revise the text on nutritional risk analysis and include JEMNU as its primary source of scientific advice.
17. Minor numbering issues in the texts for CCCF, CCRVDF and CCPR should be addressed by the Secretariat with the relevant Committee.

*Medium term*

18. A substantial review of the Codex risk analysis section of the Procedural Manual could be considered as work under the upcoming Codex Strategic Plan 2020-2025. Such work could be led by the Secretariat but should closely involve the relevant Committees as well as the joint expert committee (JEMRA, JECFA, JMPR and JEMNU) secretariats and should be based on the experience gathered with the application of the existing texts rather than on a linguistic and structural consistency review with the oldest of the texts (the working principles).
19. If deemed necessary and to take into account of new developments in risk analysis it could be considered to overhaul the *Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius*, possibly based on an FAO and WHO expert consultation.

**Appendix 1**

Discussion in CCGP26 (ALINORM 10/33/33 paras 48-55)

48. The Secretariat highlighted the main general issues that had been identified in the review and the proposals for consideration by the Committee: reordering the texts according to the three components of risk analysis; defining risk assessment policy more clearly; developing risk communication further where appropriate; integrating into a single text all provisions on risk analysis and considering the deletion of procedural elements. Some questions were also put forward for consideration by specific committees, for example whether additives and contaminants should be addressed in separate documents.

49. Several delegations noted that the main elements of risk analysis were included in the risk analysis policies developed by Codex Committees, even if they did not always follow the format of the *Working Principles for Risk Analysis*. They pointed out that if the documents were reordered, they may become less readable and more difficult to use. This would also create an additional workload for Committees which should focus on developing standards for food safety. It was also proposed to limit the recommendations to an editorial reordering of the provisions without considering substantial amendments.

50. Several proposals were put forward in the discussion: asking the views of the Committees concerned and considering their proposals before proceeding further in the CCGP; reviewing the consistency in the application of risk analysis in various committees; and asking the views of FAO and WHO especially regarding the interaction between risk managers and risk assessors.

51. The Delegation of New Zealand expressed the view that the risk analysis principles developed by various committees had mainly repeated the overarching framework of the *Working Principles* with some adjustment, and should rather concentrate on the specificities of each risk analysis process, especially through the development of an adequate risk assessment policy. The Delegation proposed that committees should explain in particular how they took into account uncertainties and other legitimate factors in the risk analysis process and that this might be assisted by a working group of CCGP.

52. The Committee noted a proposal to review the use of the term “evaluation” and to replace it with the more adequate term “assessment” throughout the risk analysis documents developed by Codex Committees.

53. Some delegations expressed the view that two separate risk analysis documents should be developed for food additives and for contaminants

54. It was noted that the Committee on Pesticide Residues (CCPR) was revising its risk analysis policies and it was suggested to forward some general recommendations to the CCPR, for consideration as part of the revision process.

**Conclusion**

55. The Committee agreed that risk analysis policies developed by Codex committees were generally consistent with the *Working Principles for Risk Analysis*, which complied with the mandate given to the Committee under Activity 2.1. The Committee also agreed to forward the review presented in CL 2010/1-GP to the committees concerned for their consideration and review of their risk analysis policies, which would initiate Activity 2.2 of the Strategic Plan.

## Appendix 2

## Comparison of Codex Risk Analysis Texts

Working Principles (WP)	CCFA (2007)	CCCF (2007)	CCRVDF (2014)	CCPR	CCNFSDU	CCFH
<p><b>1 Scope</b></p> <p>1 RA principles for Codex</p> <p>2 Guidance to Codex committees and relevant Joint FAO/WHO expert bodies and consultations</p> <p>3 Roles of Codex committees and risk assessors</p>	<p><b>1 Scope</b></p> <p>1 Applications of RA principles to CCFA and JECFA. (WP paras 1, 2)</p> <p>Does not preclude consideration recommendations of other internationally recognised bodies and ad-hoc expert consultations as approved by the Commission.</p> <p>2 Link to WP</p> <p>21 JECFA role (WP, para 3)</p> <p>7 CCFA role (WP, para 3)</p>	<p><b>1 Scope</b></p> <p>1 as CCFA, para 1</p> <p>2 as CCFA, para 2</p> <p>3 Reference to feed</p> <p>4 Role of CCCF (WP, para 3)</p> <p>5 Role of JECFA (WP, para 3)</p>	<p><b>1 Purpose/scope</b></p> <p>1 RA principles of CCRVDF. Link to WP. (WP, paras 1,2)</p> <p>2 Roles of CCRVDF and JECFA and link to WP.</p> <p>3,4 Repetition of role of CCRVDF.</p> <p>5 Repetition of role of JECFA and additional role of JECFA to give advice to governments.</p>	<p><b>1 Scope</b></p> <p>1 Application of RA principles to CCPR and JMPR and link to WP</p>	<p><b>1 Background</b></p> <p>1 as WP, para 1 (<i>could be deleted</i>)</p> <p>2 the para links risk analysis for nutritional matters to WP para 2 and the mention of "health aspects"</p> <p>3 Link to the mandate of CCNFSDU to also endorse and provide advice to other committees</p> <p><b>2 Introduction</b></p> <p>4 Explains linkage and difference to traditional risk analysis</p> <p>5 Link to WP</p> <p>6 Three components and additional part: Problem formulation (<i>this is repeated in para 14</i>)</p>	<p><b>1 Scope</b></p> <p>1 Roles of CCFH and JEMRA and link to WP (WP paras 1,2)</p> <p>7 CCFH commissions JEMRA through FAO/WHO. For matters that cannot be addressed by JEMRA this does not preclude consideration of recommendations from other internationally recognized expert bodies as approved by the Commission</p>
<p><b>2 General aspects</b></p> <p>4 Consistent application; observe the statements of principle;</p> <p>5 Structured approach: RA, RM, RC</p> <p>6 Process should be documented</p> <p>7 Communication between all parties</p> <p>8 Components should be applied under an overarching RM frame</p>	<p><b>2 CCFA and JECFA</b></p> <p>3 Communication is essential requirement (WP para 38)</p> <p>4 CCFA/JECFA continue develop procedures to improve the communication</p> <p>5 JECFA/CCFA make sure that all interested parties</p>	<p><b>2 General Principles of CCCF and JECFA</b></p> <p>6 as CCFA, paras 3 and 4</p> <p>7 as CCFA, para 5</p>	<p><b>2 Parties involved</b></p> <p><b>3 Risk Management in CCRVDF</b></p> <p>7 Structured approach of RM – (WP, para 28)</p> <p>8 Other legitimate factors - (WP, para 28)</p> <p><b>3.1 preliminary risk management activities</b></p>	<p><b>2 General aspects</b></p> <p><b>Summary of the MRL-setting process</b></p> <p>2 Roles of CCPR and JMPR (WP, para 3)</p> <p>3 Process starts with nomination of pesticide for evaluation. CCPR/JMPR secretaries prioritise and schedule</p> <p>4 WHO Core Assessment Group</p>	<p><b>3 Scope</b></p> <p>7 Some repetition with para 4 and explanation of nutritional benefit.</p> <p>8 Nutrients of interest to the NRA (those that increase risk through inadequate and those doing this through excessive intake)</p> <p>9 Consideration of food matrix for nutritional benefits</p>	

<p>9 Functional separation but iterative process</p> <p>10 Insufficient information: no standard but code of practice</p> <p>11 Precaution/ uncertainty</p> <p>12 Needs of developing countries</p>	<p>involved; transparent, documented. Respect legitimate concerns for confidentiality documentation be made available in a timely manner. (WP para 6 and 41)</p>		<p>9 List of the preliminary RMA (WP, para 32)</p>	<p>considers data to establish ADI/ARfD</p> <p>5 FAO panel of Experts on Pesticide Residues in Food and the Environment considers data on registered use patterns etc.</p> <p>6 JMPR Risk assessment includes both short-term and long-term dietary exposures...</p> <p>7 CCPR considers JMPR recommendations – those accepted are submitted to CAC for adoption. Active periodic review program.</p> <p>8 CCPR/JMPR outputs should be science based, transparent, documented and available in timely manner (WP para 6 and 41)</p>	<p>10 Quantitative NRA may guide decisions on quantitative content.</p> <p>11 NRA should be a quantitative as possible. Explanation of where qualitative can be used.</p> <p><b>6 Selection of Risk Assessor by the CCNFSDU</b></p> <p>33 FAO and WHO acknowledged as primary source – does not preclude other internationally recognised expert bodies as approved by the Commission.</p> <p>34 Requests for RA should have TOR and where appropriate NRA policy established by CCNFSDU</p> <p><b>4 Definitions</b></p> <p>12 New definitions</p> <p>13 adaptation of existing RA definitions</p> <p><b>5 Principles for NRA</b></p> <p>14 three components + problem formulation as preliminary risk management activity</p>	
<p><b>3 Risk Assessment Policy</b></p> <p>13 Component of RM</p> <p>14 Aims of RA policy</p> <p>15 Mandate to RA should be clear</p> <p>16 Risk management options and risk</p>	<p>6 Minimum quality criteria for data - priority list</p> <p>33 JECFA agenda - work closely with CCFA: three priorities</p> <p>34 Priority also to those known or expected problems,</p>	<p>8 as CCFA, para 6</p> <p><b>JECFA</b></p> <p><b>Preparation of risk assessment</b></p> <p>20 as CCFA 33 and 34</p> <p>11 as CCFA, para 18</p>	<p><b>3.1.1 Risk assessment policy for the conduct of the risk analysis</b></p> <p>10 Link to risk assessment policy</p> <p><b>3.1.2 Establishment of priority list</b></p>	<p><b>3. Risk assessment policy</b></p> <p>9 Considerations of CCPR when preparing its priority list for JMPR</p> <p>10 CCPR specify background info and reasons (WP para 15)</p>	<p><b>Preliminary NRA</b></p> <p>15 Refer to WP without citing directly.</p> <p>Nutritional problem formation</p> <p>16 Why?</p> <p>17 What to include?</p>	<p><b>2 Prioritisation of proposals for new work</b></p> <p>2 Description of prioritisation process</p> <p><b>3 Preliminary RM activities</b></p> <p>3 CCFH develop risk profile.</p>

	<p>emergency or public health risk (wonder if 33 and 34 could be combined)</p> <p>16 Communication of CCFA and JECFA to prioritise additives to achieve the best available risk assessment (<i>what does this add to 17</i>)</p> <p>17 Considerations of CCFA when prioritising for JECFA</p> <p>18 CCFA to provide background information on substances for review (WP para 15)</p>		<p>11 CCRVDF role in establishing priority list</p> <p>12 Criteria for being on the priority list</p> <p>13 CCRVDF takes into account protection of info under TRIPS - makes every effort to encourage data disclosure to JECFA – (WP, para 6)</p> <p><b>3.1.3 Establishment of a preliminary risk profile</b></p> <p>14 Member establishes dossier</p> <p>15 Requirements for extrapolating to other species</p> <p>16 CCRVDF considers preliminary risk profile and decides if to include on priority list</p> <p><i>(could this be a subsection of 3.1.2 as it belongs to establishing the priority list?)</i></p> <p><b>3.1.4 Ranking of the hazard for risk assessment and risk management</b></p> <p>17 Ad-hoc CCRVDF working group finalises priority list and develops questions to be asked to JECFA.</p>	<p>11 CCPR may refer RM options (WP para 16)</p> <p>12 CCPR to request JMPR to review RA policies, methods and guidelines considered by CCPR</p> <p>13 CCPR to clearly state when it uses other legitimate factors and why.</p> <p>14 JMPR applies transparent, science based RA process for ADI/ARfD</p> <p>15 JMPR with CCPR explore minimum data requirements.</p> <p><b>3.1 MRLs for specific groups</b></p> <p><b>3.1.1 MRLs for foods of animal origin</b></p> <p>Paras 17-19</p> <p><b>3.1.2 MRLs for fat-soluble pesticides</b></p> <p>Paras 20-22</p> <p><b>3.1.3 MRLs for spices</b></p> <p>Para 23</p> <p><b>3.1.4 MRLs for processed and ready-to-eat foods</b></p> <p>Paras 24-25</p> <p><b>3.2 Establishment of EMRLs</b></p> <p>Paras 26-30</p>	<p>18 Examples of information to be gathered.</p>	<p>4 Members wishing to include new item in priority list should prepare project document and preliminary risk profile.</p> <p>5 CCFH responsible for developing the RM questions for JEMRA</p> <p>6 When referring pathogen commodity combinations CCFH may also refer MRM options</p> <p>8 When commissioning scientific advice CCFH to follow structured approach in GL63 and WP</p> <p>9 Considerations when seeking risk assessment – sufficient knowledge/data available – expectation that results will assist RM – previously done risk assessments</p> <p>10 If the CCFH decides to seek risk assessment Will submit to FAO/WHO risk profile, risk assessment policy (as appropriate). FAO/WHO will evaluate request and either agree or not to undertake risk assessment</p>
--	--	--	--	--	---	--

			18 CCRVDF approves priority list and forwards to CAC for approval.  <i>(could this be a subsection of 3.1.2 as it belongs to establishing the priority list)</i>			
<p><b>Risk Assessment</b></p> <p>17 Scope and purpose should be clearly defined</p> <p>18 Criteria for Selection of experts</p> <p>19 RA in accordance with statements of principle and incorporate the 4 steps of RA</p> <p>20 RA based on all available scientific data - quantitative and may take into account qualitative information</p> <p>21 RA should take into account relevant production, handling and storage practices throughout food chain</p> <p>22 Relevant data from different parts of the world including developing countries</p> <p>23 Constraints, uncertainties and assumptions should be quantified as much as possible</p> <p>24 RA to be based on realistic exposure scenarios - RA policy</p> <p>25 Report should note the constraints, uncertainties and assumptions and</p>	<p><b>JECFA</b></p> <p>22 JECFA selection of experts (WP, para 18)</p> <p>23 JECFA to provide CCFA with RA including 4 steps of RA. (WP para 19) + For Food additives continue current procedure for establishing ADI</p> <p>24 JECFA to provide science based quantitative RA (WP para 20)</p> <p>25 JECFA to inform on applicability and constraints of RA and vulnerable groups (WP para 25)</p> <p>26 JECFA to assess identity and purity of FA</p> <p>27 JECFA to use global data including from developing countries, exposure studies (WP para 22)</p> <p>28 JECFA responsible for evaluating exposure to FA</p>	<p><b>Risk assessment</b></p> <p>21 as CCFA, para 22</p> <p>22 as CCFA, para 23 + Give risks associated with different levels of dietary exposure</p> <p>23 as CCFA para 27</p> <p>24 as CCFA para 29</p> <p><b>Communication with CCCF</b></p> <p>25 as CCFA para 24</p> <p>26 as CCFA para 25</p> <p>27 JECFA to provide CCCF with scientific view on validity of data used for exposure assessment (WP para 24)</p> <p>28 as CCFA, para 30</p> <p>29 as CCFA 31</p> <p>30 as CCFA 32</p>	<p>6 Selection of experts for JECFA</p> <p><b>3.1.5 Commissioning of the risk assessment</b></p> <p>19 After CAC approval CCRVDF forwards list to JECFA may also forward RM options.</p> <p><b>3.2 Consideration of the result of the risk assessment</b></p> <p>20 Detailed JECFA report indicating choices made and uncertainties.</p> <p>21 When incomplete data JECFA may propose temp MRL which sold not proceed to step 8</p> <p>22 JECFA report be made available sufficiently early.</p> <p>23 JECFA outline different RM options - clearly distinguish between risk assessment and evaluation of RMO.</p> <p>24 CCRVDF may ask additional questions</p>	<p><b>4. Risk assessment</b></p> <p><b>4.1 Role of JMPR</b></p> <p>31 JMPR description</p> <p>32 JMPR outputs</p> <p>33 JMPR provide CCCPR with RA including 4 components of RA (WP, para 19)</p> <p>34 JMPR to inform on applicability and constraints of RA and vulnerable groups (WP para 25)</p> <p>35 JMPR to communicate uncertainties (WP, para 25)</p> <p><b>4.2 Dietary intake</b></p> <p>36 JMPR responsible to evaluate exposure to pesticides; global data; developing countries; GEMS/food (PM, para 22)</p> <p>37-43 More on dietary intake</p>	<p><b>Nutritional Risk Assessment</b></p> <p>19 Reference to WP as generally applicable.</p> <p><b>Nutrient-related Hazard Identification and hazard characterization</b></p> <p>20-26 Description of assessment of situations of inadequate or excessive intake. Reference to global FAO/WHO standards and regional standards.</p> <p><b>Nutrient-related intake assessment and risk characterization</b></p> <p>27 Populations relevant</p> <p>28 Total diet context</p>	<p><b>4 Risk assessment</b></p> <p>11 FAO/WHO will ensure that selection of experts is in line with FAO/WHO framework for the provision of scientific advice on food safety and nutrition and GL30</p> <p>12 JEMRA should: base RA on data from different parts of the world including developing countries (WP para 22); Communicate to CCFH on applicability and constraints (WP para 25); communicate magnitude and source of uncertainties (WP para 25); communicate assumptions (WP para 25)</p> <p>13 FAO/WHO will provide results to CCFH in format to be decided. May provide scientific expertise on guidance on interpretation of RA (WP para 26) 14 RA carried out by JEMRA operate under framework of GL30 (duplication of 11?)</p>



<p>minority opinions - RM to resolve not RA</p> <p>26 Report of RA provided in readily readable from to RM and other risk assessors</p>	<p>29 JECFA to take into account regional/national consumption patterns (WP para 21)</p> <p>30 JECFA to communicate to CCFA any uncertainties (WP para 23, 25)</p> <p>31 JECFA to communicate basis for assumptions (WP para 23)</p> <p>32 JECFA to communicate outcome in clear manner (WP para 26) - not deal with consequences on trade - and if it give options should be in line with WP and the present text</p>		<p>25 Both JECFA and CCRVDF process should be clearly documented</p> <p>26 A delegation may ask JECFA for additional explanation (Concern form)</p> <p><b>3.3 Using the concern form</b></p> <p>27 Definition of concern form</p> <p>28 Procedure to use the concern form</p>			
<p><b>Risk Management</b></p> <p>27 Recognise dual mandate; primary objective health; avoid differences for same risk</p> <p>28 Structured approach of RM; other legitimate factors; Second statement of principle</p> <p>29 Risk assessment should be complete when taking</p>	<p><b>CCFA</b></p> <p>8 CCFA bases RM on JECFA</p> <p>9 Additional request to JECFA</p> <p>10 Relation to GFSA</p> <p>11 CCFA bases RM on JECFA and Other legitimate factors (WP para 28)</p> <p>12 CCFA to take into account uncertainty</p>	<p><b>CCCF</b></p> <p><b>Communication with JECFA</b></p> <p>9 as CCFA, para 16</p> <p>10 as CCFA, para 17</p> <p>12 as 19 for CCFA (WP para 16)</p> <p>13 as 19 for CCFA</p> <p>14 as 9 for CCFA</p> <p><b>Risk management</b></p>	<p><b>3.4 Evaluation of RMO</b></p> <p>29 Other legitimate factors..</p> <p><i>(Reference is made to a Committee report and possible amendments should the text of the committee decision be included here?)</i></p> <p>30 Options for the CCRVDF: recommend MRLs based on JECFA, recommend extrapolation to other species, modify MRLs</p>	<p><b>5. Risk Management</b></p> <p><b>5.1 Role of CCPR</b></p> <p>44 CCPR recommends RM proposals such as MRLs for CAC</p> <p>45 CCPR base on JMPR and other legitimate factors (WP, para 28)</p> <p>46 Additional request to JMPR</p> <p>47 CCPR to take into account uncertainty</p>	<p><b>Nutritional risk management</b></p> <p>29 WP apply with additions.</p> <p>30 NRM can be quantitative or qualitative should take into account impact and consumer behaviour.</p> <p>31 NRA policy should be formulated before conduct.</p>	<p><b>5 Risk management</b></p> <p>15 RM options may include provisions from Codex texts</p> <p>16 MRM option recommended to CAC should be based on the policies in the following paras and take into account JEMRA assumptions and uncertainties</p> <p>17 GL and COP can include micro criteria or other metrics as in Annex II of GL63)</p>

<p>decisions on RM refer to para 10 when uncertainty</p> <p>30 Take into account relevant practices; feasibility of enforcement; compliance; prevalence of adverse health effects</p> <p>31 RM process transparent - fully documented</p> <p>32 Outcome of preliminary RM and risk assessment combined with evaluation of available RM to reach decision.</p> <p>For the purpose of these Principles, preliminary risk management activities are taken to include: identification of a food safety problem; establishment of a risk profile; ranking of the hazard for risk assessment and risk management priority; establishment of risk assessment policy for the conduct of the risk assessment; commissioning of the risk assessment; and consideration of the result of the risk assessment.</p> <p>33 Assess RM options by level of consumer protection. Consider option of not taking action.</p> <p>34 Avoid trade barriers - RM options that lead to equal protection shall be</p>	<p>13 CCFA shall only endorse level for additives for which JEMPR has: established identity and purity specifications and completed RA (WP, para 29)</p> <p>14 CCFA takes into account regional and national food consumption differences as assessed by JECFA</p> <p>15 CCFA shall state clearly if uses other factors (<i>could this be added to 11</i>)</p> <p>19 CCFA may provide risk management options to obtain JECFA guidance (WP para 16)</p> <p>20 CCFA refers methods for assessing maximum use levels</p>	<p>15 as CCFA para 10</p> <p>16 CCCF base on JECFA + uncertainties + other factors (combines paras 8, 11, 12 and 15 of CCFA)</p> <p>17 Conditions for CCCF endorsing ML and link to</p> <p>“Codex Policy for Exposure of Contaminants and Toxins in Foods”</p> <p><i>This should probably read: “Policy of CCCF for exposure assessment of contaminants and toxins in foods or food groups”</i></p> <p>17bis Reference to MLs to distinguish food fraud (<i>should be numbered continuously</i>)</p> <p>18 as para 14 CCFA</p> <p>19 Before finalising ML CCCF to ask JECFA on method/sampling validity (similar to para 20 CCFA)</p>	<p>considering other legitimate factors, request JECFA to reconsider, decline to advance the MRLs; develop RM guidance for those without ADI and refer options to JECFA for advice</p> <p>31 Attention to availability of analytical methods for residue detection</p> <p><b>3.4 Monitoring and review of the decisions taken</b></p> <p><i>(this should probably be 3.5)</i></p> <p>32 Members may ask for review of decisions - in particular if difficulties in application of GL71</p> <p>33 CCRVDF may request JECFA to review in light of new scientific info</p> <p>34 Risk assessment policy to be reconsidered on the basis of experience</p>	<p>48 CCPR shall only endorse MRL recommended by JMPR</p> <p>49 CCPR base on global scale consumption patterns; GEMS/food for chronic exposure</p> <p>50 If there are no methods of analysis to enforce MRL then none will be established.</p> <p><b>5.2 Selection of pesticides for JMPR evaluation</b></p> <p>51 CCPR/JMPR agree on schedule each year</p> <p><b>5.2.1 Procedure for the preparation of the schedules and priority lists</b></p> <p>52-60</p> <p><b>5.2.2 Nomination requirements and criteria for the prioritisation and scheduling pesticides for evaluation by JMPR</b></p> <p><b>New pesticides</b></p> <p>Nomination/prioritisation/scheduling</p> <p>Paras 61-63</p> <p><b>5.2.3 New uses of pesticides previously reviewed by JMPR</b></p> <p>Nomination/prioritisation/Scheduling</p>	<p>18 Additional request to JEMRA</p> <p>19 CCFH decides on case by case basis if COP or GL or MC or other metrics</p> <p>20 Other legitimate factors in line with statements of principle. Clearly state when used. (WP para 28)</p> <p>21 CCFH establish MC if quantitative RA is possible taking into account regional national food consumption patterns and dietary exposure. GL21 to be used as guidance.</p> <p>22 Where MC established – methods of analysis and sampling to be provided.</p>
--	--	---	--	---	---

<p>evaluated by which is least trade restrictive</p> <p>35 RM take into account economic consequences and feasibility of RM options. Need for alternatives. Take into account situation of developing countries</p> <p>36 RM continuing process to incorporate new science.</p>				<p>Paras 64-66</p> <p><b>5.2.4 Other Evaluations</b></p> <p>Nomination/prioritisation/scheduling</p> <p>Paras 67-70</p> <p><b>5.2.5 Periodic review</b></p> <p>Paras 71-77</p> <p><b>5.2.6 Periodic review procedure</b></p> <p>Paras 78-81</p> <p><b>5.3 Elaboration procedure</b></p> <p>Paras 82-87</p> <p>5.4 Revocation of CXLs</p> <p>Paras 88-90</p> <p><b>5.5 Procedure for submitting concerns and clarifications</b></p> <p>Paras 91-102</p>		
<p><b>Risk communication</b></p> <p>37 8 goals of RC: awareness and understanding, transparency and consistency; sound basis for understanding of RM decisions; improve effectiveness and efficiency; strengthen working relations; foster public understanding; involvement of all interested parties; exchange of information of</p>			<p><b>4 Risk communication in the context of risk management</b></p> <p>35 as WP, para 38</p> <p>36 CCRVDF provides comments on risk assessment guidelines of JECFA</p>	<p><b>6 Risk communication</b></p> <p>103 CCPR and JMPR ensure transparency, documentation of RA process and timely availability of results (<i>partly duplicates 8</i>)</p> <p>104 CCPR provide comments on the guidelines related to assessment procedures by JMPR</p>	<p><b>Nutritional risk communication</b></p> <p>32 WP apply.</p>	<p><b>6 Risk communication</b></p> <p>23 Reference to WP and CCFH and JEMRA to use guidance in 24-29</p> <p>24 CCFH may provide comments on the guidelines related to assessment procedures being drafted or published by JEMRA</p> <p><b>7 Interaction between Risk manager (CCFH)</b></p>

<p>parties on risks associated to food</p> <p>38 Clear interactive and documented Communication between Risk assessors (joint FAO/WHO bodies) and risk managers (Codex) and all interested parties</p> <p>39 Make sure that all needed information and opinion is available for RM process</p> <p>40 Transparency about Risk assessment policy and uncertainty refer to para 25.</p> <p>41 Information not only for those in the process but also other interested parties while respecting concerns for confidentiality - refer to para 6.</p>				<p>105 CCPR/JMPR recognise essential need for communication (WP para 38)</p> <p>106 CCPR/JMPR continue develop procedures to enhance communication</p>		<p><b>and Risk assessor (JEMRA)</b></p> <p>25 CCFH recognises need for interactive process between RA and RM to assess feasibility of RA and that RA policy is clear and the RM questions asked by CCFH are appropriate.</p> <p>26 When benefit from interaction with other Codex committees, expert consultations and/or other international scientific bodies this should be included (shorten?)</p> <p>27 CCFH/JEMRA communications timely and effective (repetition of 23)</p> <p>28 CCFH likely to receive questions from JEMRA and vice versa. (does this add anything?)</p> <p>29 CCFH may recommend discontinuation or modify work if (a) completion of RA not feasible (b) not possible to provide MRM options</p> <p>30 CCFH and JEMRA to ensure that their respective contributions result in outputs that are scientifically based, fully transparent, documented and</p>
---	--	--	--	--	--	---

						available in timely manner
		<b>Additional text</b> Policy of CCCF for exposure assessment	<b>Additional texts</b> Template for priority list Concern form Risk assessment policy for the setting of MRL for RVDF	<b>Additional texts</b> Annex A: Concern form (advancement) Annex B: Concern form (Periodic review) Annex C: Proportionality concept Annex D: Minor crops Annex to Annex D		