CODEX ALIMENTARIUS COMMISSION E

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World Health Organization

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Agenda Item 10 **CX/CF 19/13/8-Add. 1**

April 2019

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON CONTAMINANTS IN FOODS

13th Session
Yogyakarta, Indonesia, 29 April – 3 May 2019

DRAFT GUIDELINES FOR RISK ANALYSIS OF INSTANCES OF CONTAMINANTS IN FOOD WHERE THERE IS NO REGULATORY LEVEL OR RISK MANAGEMENT FRAMEWORK ESTABLISHED

Comments submitted by Australia, Canada, Costa Rica, Colombia, the European Union, Indonesia, Japan , Kenya, Republic of Korea, Switzerland, United States of America, ICBA, IDF, IFT and ISDI

Australia

Australia supports progression of the draft guidelines and offers the following comments:

1. Terminology used in the main document in relation to '*unregulated contaminant*' could be more aligned with the title '*contaminants in food where there is no regulatory level*'. In practice, there would be relatively few contaminants that could be considered as 'unregulated' because general food law requires that all food is safe and suitable for human consumption. On this basis, the current title '*contaminants in food where there is no regulatory level*' more accurately indicates this point and we suggest changes are made throughout the document to reflect this.

2. Section 3 - Scope, Principles:

   Australia recommends an additional bullet point to the effect that general food legislation for safety and suitability continue to apply to '*contaminants with no regulatory level*'.

   Section 3.2 Exclusion from the scope of these guidelines:

   We suggest contaminants with a health based guidance value (HBGV) are not explicitly excluded from the framework as some may not necessarily have a corresponding (enforceable) regulatory limit (i.e. ML or trigger level). The guideline may assist manage situations where a regulatory limit for a contaminant in a particular commodity does not exist but a regulatory limit is established in other commodities.

3. Given that a rapid (dietary) exposure assessment is part of the decision tree, additional commentary on what is involved in such an assessment would be useful for countries that do not routinely undertake total diet studies.

Canada

Canada wishes to express its appreciation to the chair, New Zealand, and co-chair, the Netherlands, for leading the electronic Working Group (eWG) on the *Draft Guidelines for Risk Analysis of instances of Contaminants in Food where there is No Regulatory Level or Risk Management Framework Established*. Canada would like to indicate its agreement with the revisions made to the proposed draft *Guidelines* as presented in Appendix I of this document.

Canada would also like to propose the following editorial suggestions (additions to the text in **bold/underline**):

1. Page 5: **4** Principles.
   - Numbering this section would result in renumbering the sections that follow.
2. Page 7, section 6.6, 2nd paragraph: "In the absence of sufficient toxicological data to establish a HBGV for the unregulated contaminant, dietary intake against an appropriate threshold of no **toxicological** concern or reference value for any outcome whether genotoxic or non-genotoxic, should be selected for the contaminant (Step 6)."

Costa Rica

Costa Rica thanks New Zealand and the Netherlands for their work and would like to take this opportunity to make the following comments.

Location	Original wording	Proposed wording	Justification
Page 5, first paragraph	……..Risk managers should respond to such detections to adequately protect public health and should at the same time take into consideration the practical aspects of the initial detections and equity in trade.	….. Risk managers should respond to such detections **so that** public health **is** adequately **protected** and should at the same time **take** into consideration the practical aspects of the initial detections and equity in trade.	Rewording is recommended to improve interpretation
Page 5, second paragraph, third bullet point.	"…should be able to be applied within a restricted time frame in …"	"… should be able to be applied within **no more than xx months** in…"	It should at least be possible to offer an approximate maximum for this 'restricted time frame', since it could otherwise be misinterpreted, though there is no specific proposal as to its duration, which is left to the working group to decide.
Page 6, section 3. Scope, single paragraph, second bullet point.	"… occurring only once rather than intermittently and which…"	"…occurring only once, **those that have only been detected** intermittently and which…"	The original wording appears to be contradictory in referring to contaminants 'detected once' and then going on to exclude those detected intermittently, since the opposite of intermittent is continuous, which is not consistent with being 'detected once'.
Page 7, first bullet point.	"… apply to food for human consumption placed on the market in…"	"… apply to food for human consumption **and feed** placed on the market in…"	Feed is included within the scope (see the first bullet point, which states "which are in conformity with the definitions in the General Standard for Contaminants and Toxins in Food and Feed (CXS 193-1995) for which there are no standards, recommendations or regional, national or Codex standards"), which should also be included in this section to make the document consistent. The document should clarify whether feed is excluded.

Location	Original wording	Proposed wording	Justification
Page 7, sixth bullet point.	"Where there are continuing detections of a [...] contaminant..."	"Where there are continuing **or frequent** detections of a [...] contaminant ..."	While it is understood that the greatest risk arises out of a continuing presence, it should be taken into account that there may be contaminants that are detected frequently, but not continuously, and that this could also involve a public health risk.
Page 7, 4. Roles	In many cases, the competent authority will act as risk manager responsible for the official import inspection/surveillance programmes or import control programmes, including sampling, and will subsequently receive the results from the authorised or equivalent laboratory. Decisions on the safety or otherwise of the food consignment in question will be adopted in accordance with national food safety legislation.	In many cases, the competent authority **of each country** will act as risk manager responsible for the official import inspection/surveillance programmes, including sampling, and will subsequently receive the results from the authorised or equivalent laboratory. Decisions on the safety or otherwise of the foods in question will be adopted in accordance with national food safety legislation.	Changes in wording to make it easier to understand. Doubt arises as to the word "consignment", since this refers to imports. The word "***entry***" should be used instead. It could be removed, however, without affecting the original meaning.
Page 7, 5. NOTIFICATIONS RELATING TO A DETECTION OR DETECTIONS, paragraph 1	The authorised or equivalent laboratory should provide information on all detections and measurements of contaminant concentrations from the official or officially recognised food monitoring and surveillance programmes, including those for which a regulatory framework has not been put in place, as prescribed by the risk managers. As such, the presence of the unregulated contaminants will have been validated in an approved laboratory and the samples will have been subject to quality assurance provisions as required by an official regulatory programme. The origin of samples should be unambiguous.	The authorised or equivalent laboratory **of each country** should provide information **to the regulatory authority** on all detections and measurements of contaminant concentrations from the official or officially recognised food monitoring and surveillance programmes, including those for which a regulatory framework has not been put in place, as prescribed by the risk managers. **As such, the methods of analysis for determining** whether the unregulated contaminants are present **should be validated and certified** by an approved laboratory and the samples **should be** subject to **assurance of the validity of the results** as required by **a standard or** an official regulatory programme. The origin of samples should be unambiguous **and certified as official by the competent authority**.	Change in wording to ensure greater clarity regarding the competence of the laboratories, the validity of the results and the samples.

Location	Original wording	Proposed wording	Justification
Page 7, 5. NOTIFICATIONS RELATING TO A DETECTION OR DETECTIONS, bullet point 2	Test method and its analytical performance, quantification procedure and standards used for the quantification, and whether it is a confirmatory method that provides identification information relating to the chemical structure of the analyte;	Method and analytical technique used, quantification procedure and standards used to **determine the performance parameters and validity of the results and their acceptance criteria**, and whether it is a confirmatory method that **provides** information **relating to the identification criteria used**;	Clarify the concepts used in this paragraph to ensure that the analytical determinations are reliable.
Page 7, 5. NOTIFICATIONS RELATING TO A DETECTION OR DETECTIONS , bullet points 3 and 4	-Number of detections, type of samples and total number of samples tested; -Summary statistics of occurrence data;	**- Total number of samples tested, type of samples and number of detections;** -Summary statistics of data **with** occurrence;	Change in word order so that it is consistent with the actual sequence of actions. Suggested change of preposition in the text of bullet point 4.
Page 8. 6. APPLICATION OF THE DECISION TREE FOR RAPID RISK ASSESSMENT, paragraph 1	On confirming the presence of an unregulated contaminant in foods, the risk manager should apply rapid risk assessment in a timely manner in the accompanying decision tree (see Annex 1). The TTC – one of the elements for a rapid risk assessment approach – is a science-based detection instrument that allows rapid risk characterisation when low levels of unregulated contaminants are detected in foods. The rapid risk assessment approach makes it possible to prioritise only the instances that justify subsequent exhaustive investigations.	On confirming the presence of an unregulated contaminant in foods, the risk manager should apply rapid risk assessment in a timely manner, **as laid down in Annex 1 of the Decision Tree for rapid risk assessment.** The TTC – one of the elements for a rapid risk assessment approach – is a science-based instrument that allows rapid risk characterisation when low levels of unregulated contaminants are detected in foods. The rapid risk assessment approach makes it possible to prioritise only the instances that justify subsequent exhaustive investigations.	This change in wording is recommended so that the reader understands from the beginning that they should refer to Annex 1. It is recommended that the word "detection" be eliminated, since it is regarded as redundant.
Page 8, Exclusionary categories of contaminants (Step 1 of the Decision Tree for rapid risk assessment), bullet point 3.	Metals	Toxic elements	It is recommended that the classification be closed at *toxic chemical elements*, since there could be non-metals that may affect human health. There could also be toxic metals if the non-metals are not all considered.

Location	Original wording	Proposed wording	Justification
Page 9-10	The cut-off values are derived from the consideration that, within a population, the consignment will form only a tenth of the standard daily diet, based on access to a varied diet that may contain the same food from other sources and a range of other food groups. (…)6.6. Selection of the TTC value/Establishment of a HBGV, exposure assessment and risk characterisation (Steps 6-9 of the Decision Tree for rapid risk assessment). On the basis of the toxicological information available, it should be determined whether it is feasible to establish a HBGV within the necessary time frame. (…) • Determine that the food consignment/batch is suitable for human consumption on the basis of an insignificant risk to human health; • Determine that the food consignment/batch is not suitable for human consumption on the basis of a potential risk to human health;	The cut-off values are derived from the consideration that, within a population, the consignment will form only a tenth of the standard daily diet, **based on** access to a varied diet that may contain the same food from other sources and a range of other food groups. (…) 6.6. Selection of the TTC value/Establishment of a HBGV, exposure assessment and risk characterisation (Steps 6-9 of the Decision Tree for rapid risk assessment). **On the basis of** the toxicological information available, it should be determined whether it is feasible to establish a HBGV within the necessary time frame. (…) • Determine that the food consignment/batch is suitable for human consumption **on the basis of** an insignificant risk to human health; • Determine that the food consignment/batch is not suitable for human consumption **on the basis of** a potential risk to human health;	Costa Rica recommends this change in the paragraph.
Page 10, final paragraph	Communication of the risk is therefore recommended when the risk management measures for unregulated contaminants present in food are implemented.	Communication of the risk **by the competent authority** is therefore recommended when the risk management measures for unregulated contaminants present in food are implemented.	It is recommended that the party responsible for communicating the risk be clarified.
Page 11	8. Carry out a rapid exposure assessment		It is considered important to specify the maximum time required for a rapid exposure assessment.

Location	Original wording	Proposed wording	Justification
Page 14	3-MCPD/3-MCPD esters- 4 µg/kg pc/día - 1600x lower than the HBGV		It is requested that a check be carried out on whether the protection of the TTC class is *160X lower than the HBGV* rather than *1600X lower than the HBGV*

Colombia

The proposed amendments are shown by text insertions in **bold and underlined** and deletion is in ~~strikethrough.~~

PARAGRAPHS	PROPOSED POSITION	OBSERVATIONS OR COMMENTS	CATEGORY OF [1]COMMENT			
			E	S	TE	TR
3. SCOPE 3.1 Inclusions within the scope of these guidelines. • Natural toxins, e.g. Mycotoxins and phytotoxins	We request revision of paragraph number 3, subsection 3.1, bullet point 3, about natural mycotoxins, e.g. Micro-toxins **(with the exception of aflatoxins)** or phytotoxins included in this paragraph.	Colombia suggests adjusting number 3, subsection 3.1, bullet point 3 along the lines of specifying the exceptional nature of aflatoxins, as these are natural mycotoxins which are excluded from number 6.1. Exclusionary categories of contaminants. (Step 1 of the decision tree for rapid risk assessment) – High-potency carcinogens. For example, aflatoxins, azo and N-nitroso compounds, benzidines).| The proposed wording is as follows: • Natural toxins, e.g. Mycotoxins and phytotoxins **with the exception of aflatoxins**.			***X***	

[1] - "Editorial": This type of comment explains and simplifies the text without changing its meaning. It includes corrections of spelling and grammar, suggestions for alternative but equivalent wording and for simplifying sentence structure.
- "Substantive": This type of comment involves conceptual modifications and the addition of new aspects or ideas. It includes additions and expansions, changes, reorganisation of the text or deletions which alter the content of the sentence, paragraph or section of the draft document.
- "Technical" This type of comment involves scientific corrections and technical adjustments. Its aim is to explain the standard and improve it as much as possible and, on occasion, to align it technically with other standards.
- "Translation": This type of comment corrects points where the text's translation into another language version is deemed to be inaccurate.

PARAGRAPHS	PROPOSED POSITION	OBSERVATIONS OR COMMENTS	CATEGORY OF [1]COMMENT			
			E	S	TE	TR
6. APPLICATION OF THE DECISION TREE FOR RAPID RISK ASSESSMENT 6.1. Exclusionary categories of contaminants (Step 1 of the decision tree for rapid risk assessment)	Should the contaminants listed in the exclusionary categories be detected, given that they are the source of potential concern about food safety, risk managers must observe the current regulatory frameworks, standards, recommendations and guidelines available.	It should be emphasised that it is necessary to take action when contaminants from the category of contaminants listed in the document are present, as risk assessments and maximum permitted levels are available for some categories of food which serve as models.			***X***	
6. APPLICATION OF THE DECISION TREE FOR RAPID RISK ASSESSMENT 6.2. Application of the limit (Step 2 of the decision tree for rapid risk assessment).	We suggest revising number **6.** APPLICATION OF THE DECISION TREE FOR RAPID RISK ASSESSMENT 6.2. Application of the cut-off value (Step 2 of the decision tree for rapid risk assessment), along the lines of proposing **the cut-off value as a baseline that may be revised in future.**	Colombia suggests that the cut-off value proposed by the eWG of (1µc/Kg) should be expressed as a provisional value and considered as a baseline. This is due to the possibility that it may not be a suitable cut-off value for different subpopulations, intakes by populations and/or food groups.		***X***		

The European Union

The European Union and its Member States (EUMS) welcome and appreciate the work on the draft Guidelines for risk analysis of instances of contaminants in food where there is no regulatory level or risk management framework established by the electronic Working Group chaired by New Zealand and co-chaired by the Netherlands.

The EUMS wish to make the following observations and comments on the document:

Heading **3. Scope**:

- It is noted that the three conditions outlined in the bullet points are cumulative.
- It is suggested to simplify the second bullet point as follows: “those detections have not been previously reported in the concerned food”.

Heading **3.1. Inclusions in the scope of these guidelines:**

- It is suggested to reword the first sentence as follows (with an addition): “The following non-exhaustive list of groups of contaminants would fall under the scope of this document if present in food. However, it is to be noted that within each group there are regulated contaminants, which do not fall under the scope.
- It is proposed to change the order of the points**.** The following order is proposed: natural toxins, processing induced contaminants, contaminants from materials used during processing of food, environmental contaminants and greenhouse gas mitigation technology.
- While it is acknowledged that the presence of a contaminant related to the greenhouse mitigation technology was the trigger for initiating this work, this is very specific compared to the other more general bullet points. A suggested more general description for this topic could be: “contaminants from products used in agriculture (not expected to be present in food).”

Heading **3.2. Exclusions from the scope of the guideline:**

o It is proposed to delete the footnote 2 related to the 3rd bullet point as HBGV can also be established by regional or national risk assessment bodies. The deletion of the footnote is in line with the fact that unregulated contaminants refer to contaminants for which there are no specific Codex, regional or national standards, recommendations or guidelines.

o As regards the third bullet point, it is also proposed -besides contaminants for which there are health based guidance values (HBGV)- to add contaminants for which there are Points of Departure (POD)/ Benchmark Dose (lower confidence limit) (BMDL) (for genotoxic carcinogens).

Heading **4. Roles** and **5. Reporting of detections**

o Given that there might be already rules in place at national level as regards the interactions between laboratories / competent authorities and stakeholder, it might be appropriate to include the following sentence at the beginning of heading 4 and 5: "The provisions in this section are without prejudice to existing national or regional provisions already in place".

o Reference is made to accredited laboratories: given the nature of the finding "unexpected in the food concerned", it is evident that a laboratory might not be accredited to perform that specific analysis in that food. Therefore, it should be clarified that the accreditation refers to a general accreditation for analysis in food rather than an accreditation for that specific analysis. It is suggested to mention "from a laboratory, accredited or equivalent level for performing analysis in food"

o Some of the listed information that has to be provided by the analyst to the risk manager is incompatible with the nature of the finding (unexpected finding in food), such as summary statistics of occurrence data, assessment of homogeneity of distribution for the contaminant in the food. Such information is rather related to follow-up actions etc. and should be mentioned as an additional point 6.9 or be mentioned under Heading 7. Further risk management activities.

Heading **6. Application of the Decision Tree for Rapid Risk Assessment**.

o Reference is made to "rapid risk assessment" but no reference is made to an indicative timing that this type of assessment would represent. Acknowledging that all cases might be different and certain findings might require more time than others, it is appropriate to provide an indicative timeline for the application of the Decision tree for rapid risk assessment (e.g. 1 week)

- Heading **6.1. Exclusionary contaminant categories:** It is mentioned that a risk manager should exclude applying the decision tree to the mentioned categories of contaminants. However, a risk manager might not have the sufficient knowledge to determine if an identified substance has the potential to bio-accumulate. Therefore, it is proposed to add (in bold and underlined): a risk manager, **possibly following expert advice if needed,** should exclude applying (….).

- In the **last paragraph of heading 6.1**. Besides the possibility to derive a health based guidance value if sufficient toxicological data are available, also the Margin of Exposure (MOE) could be applied for genotoxic carcinogens in case there are sufficient toxicological data to derive a point of departure (POD) and benchmark dose lower confidence limit (BMDL).

Heading **6.2 Application of the cut-off value.**

o It might be appropriate to clarify that the application of a cut-off value of 1 µg/kg does not entail an obligation for laboratories to achieve that level of sensitivity for any analysis of unregulated contaminants.

o Given the rudimentary approach followed, it might not be appropriate for the risk manager to conclude that this results in a no safety concern. It is therefore suggested to use the following wording: "No restrictive management measures to be taken" or "Low probability of adverse health effects".

Heading **6.5 Toxicological data collection**:

o It is proposed to use the word "should" instead of "may": the risk assessor **should** access any toxicological data (…)

o In line with the comment made above as regards the last paragraph of heading 6.1, it is proposed to add MOE besides HBGV in the text between brackets (i.e. TTC vs HBGV/**MOE** approach).

Heading **6.6. Selection of the TTC /establishment of a HBGV, exposure assessment and risk characterisation**

o In line with the comment made as regards the last paragraph of heading 6.1, the title of the heading 6.6. should also make reference to establishment of POD/BMDL/NOAEL besides establishment of a HBGV (idem in the first and second paragraph of heading 6.6.)

o In paragraph 12 of the document it is mentioned that the technical references in footnotes 1 and 4 will not remain in the final document. As the reference in footnote 4 is of major importance, the information contained in footnote 4 has to be included in the body of the text at the end of the paragraph 2 of heading 6.6.

o In the third paragraph when reference is made to the abbreviated exposure assessment of the food of interest, it should be explicitly mentioned that exposure to the substance from other (food) sources has to be taken into account as much as possible in this rapid exposure assessment.

- Heading **6.8. Decision by the risk manager** It is proposed to delete the last paragraph starting with "Ultimately (…). Alternatively it could be specified that the second criterion refers to a public health concern **generally or to specific subgroups of the population.** This is in line with the information provided in heading 6.2.

Annex 1, Decision Tree for Rapid Risk Assessment

o In box 1, it is appropriate to explicitly refer to 3.2 and 6.1.: 1. Is the contaminant in a TTC exclusionary category **(see 3.2 and 6.1)**?

o In order to reflect the provisions referred to in heading 6.2, it is requested to add a box 1b between box 1 and box 2 with the question: "**Could the consignment represent more than a tenth of the daily intake of a subgroup of the population?". And add right of the new box 1b: If "yes" → handle on a case-by-case basis.** If no, continue to box 2.

o In the box left to box 2, it is better to replace "no food safety concern" with "No restrictive management measures to be taken" or "Low probability of adverse health effects" (see comment on Heading 6.2).

o In box 6 it is appropriate to make reference to footnote 4 under heading 6.6. "Select appropriate TTC reference value **(see 6.6, footnote 4),** or in case the footnote 4 is deleted "Select appropriate TTC value (**see 6.6, 2nd paragraph).** (see comment under heading 6.6.)

o Box 7 and box above box 7 (see comment above as regards the last paragraph of heading 6.1)

o Box above box 7: "Sufficient data and time to establish a HBGV or POD/BMDL/NOAEL" Box 7: 7. Calculate HBGV or POD/BMDL/NOAEL

o Box 11 and the following two boxes: A reference to "risk management decision", might give the impression that this relates only to a decision as regards the fate of the lot/consignment or restrictive measures while, in addition, other actions might be undertaken (such as surveillance) in the case of potential health concern. Therefore, it is suggested to add in box 11 and in the two boxes below 11: "(…) risk management decision /appropriate follow up (…)".

Annexes 2, 3 and 4

o In paragraph 12 it is mentioned that the case studies (Annex 3) and worked examples (Annex 4) will not remain in the final document. The EUMS agree to this.

o In addition, as no reference in the draft guidelines is made to Annex 2. Derivation of the cut-off value, the EUMS are of the opinion that this Annex should also be deleted from the final document.

o In order to avoid any confusion and as these annexes are a source of information to assist CCCF with the development of the guidelines (§ 12), it is more appropriate for the Plenary discussion to integrate these annexes as annex to the BACKGROUND section of the document instead of annexes to the guidelines.

Indonesia

1. Introduction

Indonesia proposes that the Committee should carefully consider the potential negative impact of the draft guidelines on the international trade. The proposed Draft Guidelines will greatly effect on trade, and potentially could cause disruption to international trade, especially due to the differences in understanding and capacity of to apply the principles of the Draft Guidelines. Indonesia is of the view that member countries should have more time to understand and comprehend the proposed draft for better preparedness.

3. Scope

3.1 Inclusions in the scope of these guidelines

The Scope of the proposed draft guidelines is very wide open. Indonesia would like to delete the sentence of "but are not limited to" in para 3.1 in order to limit the scope of the Guidelines. If in the future there will be other groups of contaminants added then the Committee should consider revision or amendment to the Guidelines.

Principles

Related to principle "Risk assessors carrying out the rapid risk assessment should have appropriate competency and experience", Indonesia would like to propose to Codex through FAO/WHO to provide capacity building for human resources and instrumentation, especially for developing countries.

6.2 Application of the cut-off value (Step 2 of the Decision Tree for Rapid Risk Assessment)

Indonesia would like to seek a clarification regarding the cut off value of 1 µg/kg. Indonesia is of the view that the application of single cut-off value (1 ppb) which based on TTC of 0.0025 µg/kg bw/day may not be appropriate since this TTC value was actually proposed for substances with Structural Alerts (SA's) for Genotoxicity. It would be more appropriate to use tiered TTC (Kroes *et al*., 2004 Tiered TTC) for unregulated contaminant, i.e.

1. No structural alerts (FDA ToR): 0.025 µg/kg bw/day

2. Organophosphates: 0.3 µg/kg bw/day

3. Cramer Class III: 1.5 µg/kg bw/day

4. Cramer Class III: 9 µg/kg bw/day

5. Cramer Class III: 30 µg/kg bw/day

Sources: Kroes et al., 2004. Structure-based thresholds of toxicological concern (TTC): guidance for application to substances present at low levels in the diet. Food and Chemical Toxicology 42 (2004) 65–83. www.elsevier.com/locate/foodchemtox.

6.8 Decision by the risk manager

Indonesia would like to seek clarification regarding the third bullet of section 6.8 on Decision by the risk manager, and request that specific holding time may be proposed. This is very important because placing the food consignment on hold without specific timeline could cause food wastage and it could negatively impact food security.

Japan

General Comments

Title of the guidelines

The title of the guideline must reflect the contents in a succinct manner. Japan suggests the CCCF decide the title of the guidelines after discussion of the contents.

The term "**rapid risk analysis**"

Addition of the term "rapid" to "risk analysis" evokes conducting all the activities of three components of usual risk analysis in a rapid manner. These guidelines provide risk manager with an approach for quick response within a limited timeframe to the detection of unregulated contaminants in food based on principles for risk analysis for food safety in a simplified and pragmatic way. For this reason, Japan proposes replacing the word "rapid" to other words such as "simplified" or "pragmatic" throughout the document.

The term "**rapid risk assessment**" **and** "**rapid risk assessment approach**"

Japan proposes changing the word "rapid risk assessment (approach)" to

- ✓ "risk assessment (approach) of unregulated contaminants in food", or
- ✓ "risk assessment (approach) where prompt action is necessary"

as the word "rapid risk assessment" is vague and subjective.

Title of decision tree, Annex 1, "**Decision Tree for Rapid Risk Assessment**"

The decision tree in Annex 1 includes both risk manager actions and risk assessor actions. Therefore, Japan proposes replacing "Decision Tree for Rapid Risk Assessment" with "Decision tree for Risk Management and Risk Assessment" throughout the document.

Specific Comments

Japan proposes some amendments of the text: insertion is in **bold and underlined**, and deletion is in ~~strikethrough~~.

1. Introduction

Japan proposes replacing the word “a rapid risk management response” with “a quick response of risk management”.

2. Purpose

A typo of the 10th bullet of the 2nd sentence should be fixed.

> Guidelines for Settling Disputes over Analytical (Test) Results (CXG 70-2009)

3. Scope

To avoid duplication and clarify the scope, Japan proposes changing the 1st paragraph as follows:

> Unregulated contaminants subject to these guidelines are **meeting all the following criteria** ~~contaminants meeting the definitions within the General Standard for Contaminants and Toxins in Food and Feed (CXS 193-1995) for which there are no specific Codex, regional or national standards, recommendations or guidelines. Unregulated contaminants may include~~:

Japan proposes changing 3.1 as follows:

> Examples of groups of contaminants that would fall under the scope of this document if present in food may include, but are not limited to:
>
> - **Contaminants from substances used for** Greenhouse gas mitigation ~~technology,~~ e.g., chemicals used to address specific environmental and climate change-related issues, including ~~within agriculture,~~ nitrification and urease inhibitors, which have not been anticipated to be present in food;
> - Contaminants from materials used during processing of food, e.g., printing inks, oils/lubricants/resins used as manufacturing maintenance compounds, cleaning compounds, traces of chemicals used in the manufacturing facility;
> - Natural toxins, e.g., mycotoxins or phytotoxins;
> - Environmental contaminants, e.g., flame retardants and musks/fragrances;
> - Processing-induced, e.g., heat-processing, contaminants.

Principle

“**Principle**” should be amended to “**4. Principle**” as the section number seems to be missing. This will require consequential re-numbering for subsequent sections.

Japan proposes replacing the 1st sentence with following text:

> The following principles should be considered as part of these guidelines:

5. Reporting of detection(s)

Japan proposes adding “or equivalent level” after “accredited” in the 2nd sentence of the 1st paragraph for consistency with the 1st sentence.

Japan proposes changing the word “analyst” in the 1st sentence of the 2nd paragraph to “analytical laboratory”.

Japan proposes changing the 5th bullet of the 2nd paragraph as follows:

> - Identification of chemical class / chemical type **of the analyte**;

6. Application of the decision tree for rapid risk assessment

Japan proposes replacing the term “groupings” with “categories” in the 1st paragraph of 6.1 to keep consistency with the title of 6.1, unless these terms mean the same.

Japan proposes changing the 2nd paragraph of 6.1 as follows:

> In cases when contaminants **falling into** ~~listed in~~ the exclusionary categories are detected, risk managers need to follow existing regulatory frameworks, standards, recommendations and guidance where these are available.

Japan agrees to the concept of using (a) cut-off values, but proposes replacing “the cut-off value of 1 µg/kg” with “(a) cut-off values derived from the following formula using TTC values or approach other than TTC taking into account the country-specific situation” in the 1st sentence, inserting the equation after the text and deleting “of 1 µg/kg” in the 2nd sentence in section 6.2 for following reasons:

(A) cut-off values should be non-exclusive and determined by the risk manager on a case-by case basis taking into account the difference in food consumption, body weight and food self-sufficiency rate among countries, toxicity of the contaminants, and LOD/LOQ of the available analytical method.

- ✓ At the last Session of the CCCF, Chair of the EWG explained that the example for derivation of cut-off value was there for illustrative purposes for the development of the document only, but would not be included in the final document.
- ✓ There is a concern that the cut-off value of 1 µg/kg might be regarded as a Codex maximum level for the unregulated contaminant in food.

Our proposal for 6.2 is as follows:

> If quantitative measurement of the unregulated contaminant exceeds **(a) cut-off values derived from the following formula using TTC values or approach other than TTC taking into account the country-specific situation** ~~the cut-off value of 1 µg/kg~~, the risk manager should inform relevant stakeholders of such measurements and request that all available information be shared for rapid risk assessment as soon as possible.
>
> ***Cut-off value = (TTC/ (BWM x CAF)) x CF***
>
> ***TTC*** is the TTC value (µg/kg bw/day)
>
> ***BWM*** is the Body Weight adjusted mass of food consumed per day (g/ kg bodyweight /day)
>
> ***CAF*** is the Consignment Adjustment Factor, the ratio of the maximum mass of the daily diet predicted to be impacted upon the detection of an unregulated contaminant in a consignment
>
> ***CF*** is the unit conversion factor (1000), this value converts the derived cut-off value from µg/g into µg/kg.
>
> Where measured levels do not exceed the cut-off value ~~of 1 µg/kg~~ a risk management decision can be made that the consignment does not present a food safety concern.
>
> The cut off values are derived from the consideration that within a population **an amount of daily food intake on a per kg body weight basis is almost the same** and the consignment will form **certain rates** ~~only a tenth~~ of the standard daily diet, based on access to a varied diet that may contain the same food from other sources and a range of other food groups. For certain sub-populations where a**n amount of daily food intake is significantly different, or** consignment could represent **different rates** ~~more than a tenth~~ of the daily diet intake, for example with foods for infants or sole source nutrition products, the cut-off values may not be appropriate. Such instances should be considered on a case-by-case basis and progressed for full risk assessment when there is uncertainty over the proportion of the diet for which a food consignment may represent for these sub-populations.

Japan proposes changing “necessary timeframe” to “agreed timeframe between the risk manager and the risk assessor” in the 1st sentence of section 6.6 to keep consistency with the provision of 6.7.

Japan proposes changing the last sentence in section 6.8 with following:

> Ultimately, when **dietary exposure in comparison with HBGV or other hazard characterization would pose a public health concern and possible risk management measures that would result in meaningful reductions to the dietary exposure are identified** ~~all the following three criteria are met (i.e. toxicity, occurrence levels that pose a public health concern, and identification of possible risk management measures that would result in meaningful reductions to adverse impact to public health)~~, then steps should be taken to implement ~~propose~~ appropriate ~~and meaningful~~ risk management measures.

7. Future risk management activities

Japan proposes changing the 2nd sentence of section 6.4 as follows:

> The risk manager should provide any toxicological and occurrence data obtained from the **relevant stakeholders including** exporting country to the risk assessor.

Annex 2 Derivation of the cut-off value

Japan supports the comments of Chair of the EWG that “the example for derivation of cut-off value was there for illustrative purposes for the development of the document only, but would not be included in the final document” at the last session of CCCF (REP18/CF, para.121).

As cut-off values should be non-exclusive, these guidelines should allow cut-off values derived from other risk assessment methodologies other than TTC.

Kenya

COMMENTS

Kenya endorses the work done by the EWG on the subject matter and believe that it will be advanced to the next step. The work will be very helpful especially for the development countries.

Republic of Korea

Republic of Korea supports the work of eWG, and would like to provide following comments on the proposed draft Guidelines:

6.2 Application of the cut-off value(Step 2 of the Decision Tree for Rapid Risk Assessment)

- Supports adding paragraph 'Where measured levels do not exceed the cut-off value of 1 µg/kg a risk management decision can be made that the consignment does not present a food safety concern.'.

Annex 1 Decision Tree for Rapid Risk Assessment

- Supports the **Decision Tree for Rapid Risk Assessment** since quick assessment in unregulated contaminant is possible although there is no sufficient toxicological data available for the unregulated contaminant.

Switzerland

Comments:

The remarks made by CCCF12 have properly been addressed by the EWG, as the scope has been defined clearly and it has been indicated that consignments for which a high consumption is expected (more than 10 % of the daily diet intake) have to be considered on a case-by-case basis.

To appendix I:

 Chapter 3. Scope:

In practice, it could be a challenge to figure out whether a regional or national standard, recommendation or guideline exists or the detections have been previously reported. If possible, a suggestion about how to implement these premises should be made.

 Chapter 3.2. Exclusions form the scope of these guidelines:

o Point 1: we suggest including the non-observance of good manufacturing practices writing "Contaminants detected in situations where the risk manager is investigating the possibility of intentional adulteration of food or non-observance of good manufacturing practices".

o Point 2 is a partial repetition of point 1 of the scope (chapter 3). We suggest indicating the exclusionary criteria only in chapter 3.2.

o The steps of this chapter should be added in the decision tree, as "are premises fulfilled?" and in the description in chapter 6.1.

Chapter 6.2. Application of the cut-off value:

We suggest to include a paragraph indicating that for any consignment with a contaminant (that fulfills the scope of the guidelines) in concentrations exceeding the cut-off values, a risk management decision has to be taken before the rapid risk assessment will be finalized. In some cases, it might not be possible to block the consignment at the border and another appropriate decision should be taken.

United States of America

Request for comments at Step 6 on the Draft Guidelines for Risk Analysis of Contaminants in Food Where There is no Regulatory Level or Risk Management Framework Established (CX/CF 19/13/8)

The United States would prefer that the following general comments be addressed before the draft guidelines are finalized. We will also share a tracked changes draft containing more specific comments with the Chairs of the EWG prior to the physical working group meeting that will precede the CCCF13 plenary session.

- The United States notes that it is important to strengthen the language throughout the document, including the title, to indicate clearly that the guidelines apply to unique or one-off situations, such as findings of unexpected contaminants during screening of imported shipments of food.
- The United States prefers not to use the term “unregulated” to describe these contaminants, because even in the absence of explicit regulation for a contaminant, there may be a regulatory framework for taking action on a contaminant finding. The United States recommends the use of an alternative term such as “unexpected contaminants.”
- The United States recommends avoiding terminology such as “proportional” in “Application of any risk management measures should be proportional to the anticipated human health risk . . .” and “meaningful” in “. . . meaningful reductions to adverse impact in public health. . .” in Section 6.8 of the guidelines as these terms are vague and subjective.
- The United States recommends more effective means to cite information about the Threshold of Toxicological Concern (TTC) to make the guidelines more useful, such as discussing the need to use the guidelines in conjunction with currently available scientific literature.
- The United States recommends text changes to refer more directly to possible use of non-TTC approaches, such as read-across safety assessment.
- The United States considers the Scope section of the guidelines to be unclear for the following reasons:
    - The inclusions section of the scope is both very specific (greenhouse gas mitigation technology) and very broad (natural toxins and environmental contaminants).
    - Contaminants with health-based guidance values (HBGVs) are in the decision tree, but also listed under the exclusions section of the scope.
    - The list of contaminants in the exclusions section does not appear to be complete based on currently available TTC databases.

The International Council of Beverages Associations (ICBA)

. Appendix I

3. SCOPE

Unregulated contaminants subject to these guidelines are contaminants meeting the definitions within the General Standard for Contaminants and Toxins in Food and Feed (CXS 193-1995) for which there are no specific Codex, regional or national standards, recommendations or guidelines. Unregulated contaminants may include:

- ~~Those meeting the definitions within the General Standard for Contaminants and Toxins in Food and Feed (CXS 193-1995) for which there are no specific Codex, regional or national standards, recommendations or guidelines; and,~~
- Those where the detections have not been previously reported in the food on a one-off basis, not an intermittent occurrence; and,
- Those found within a specific lot or consignment of food or food ingredient.

3.1 Inclusions in the scope of these guidelines

Examples of groups of contaminants that would fall under the scope of this document if present in food may include, but are not limited to:

- Greenhouse gas mitigation technology e.g. chemicals used to address specific environmental and climate change-related issues, including within agriculture, nitrification and urease inhibitors, which have not been anticipated to be present in food;
- Contaminants from materials used during processing of food e.g. printing inks, oils/lubricants/resins used as manufacturing maintenance compounds, cleaning compounds, traces of chemicals used in the manufacturing facility;
- Natural toxins e.g. mycotoxins or phytotoxins;
- Environmental contaminants e.g. flame retardants and musks/fragrances;
- Processing-induced, e.g. heat-processing contaminants.

3.2. Exclusions from the scope of these guidelines

Groups of contaminants that would be excluded from the scope of this document if present in food would include:

- Contaminants detected in situations where the risk manager is investigating the possibility of intentional adulteration of food; and,
- Contaminants for which there are regulatory requirements or an existing regulatory framework;
- ~~Contaminants for which there are health-based guidance values (HBGV) such as a tolerable daily intake established[2].~~

4. → PRINCIPLES

As part of these guidelines, countries should consider the following principles:

- These guidelines apply to food for human consumption that is currently in trade;
- Unregulated contaminant detection information used in this scheme should satisfy the requirements of official food control programmes for sampling and analysis;
- Where there is a detection of an unregulated contaminant in a traded consignment the competent authority in the exporting country should be notified and any relevant food safety information shared;
- Risk assessors carrying out the rapid risk assessment should have appropriate competency and experience;

Maia Jack
This first bullet can be deleted as the same language is included in the preamble to these bullets. Too repetitive otherwise.

Maia Jack
Suggest deletion.

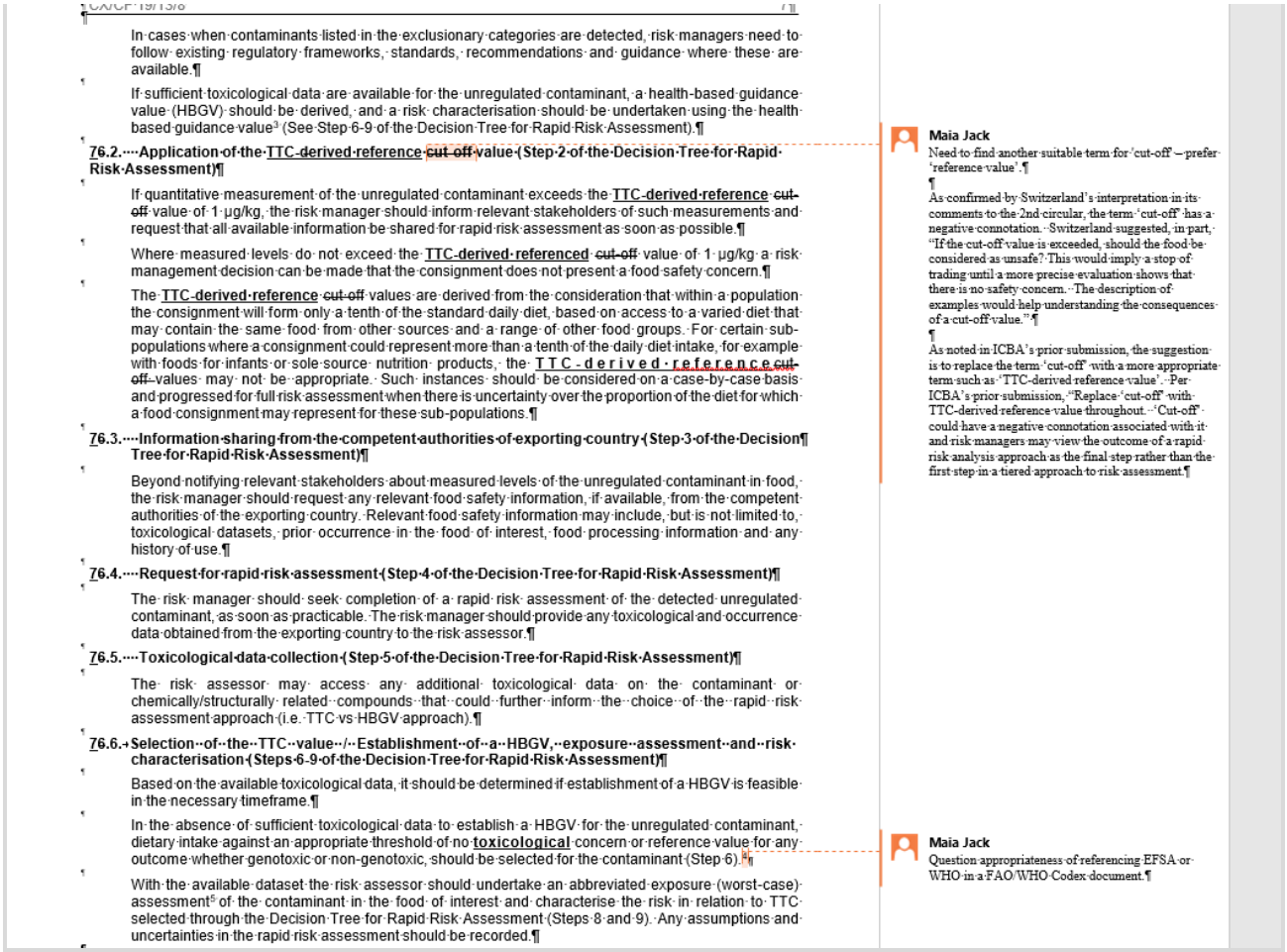
It is not the case that if an HBGV exists for a contaminant that the contaminants are then always regulated?

The threshold question should be whether the contaminant is already regulated or not independent of whether the HBGV has been established.

Deletion is likewise supported by the fact that the HBGV concept is referenced in the decision tree approach for unregulated contaminants.

Would suggest deleting this bullet to avoid confusion.

Maia Jack
Numerical was missing for this section. Corresponding changes to below sections required.



In cases when contaminants listed in the exclusionary categories are detected, risk managers need to follow existing regulatory frameworks, standards, recommendations and guidance where these are available.

If sufficient toxicological data are available for the unregulated contaminant, a health-based guidance value (HBGV) should be derived, and a risk characterisation should be undertaken using the health based guidance value[3] (See Step 6-9 of the Decision Tree for Rapid Risk Assessment).

76.2. Application of the TTC-derived reference ~~cut-off~~ value (Step 2 of the Decision Tree for Rapid Risk Assessment)

If quantitative measurement of the unregulated contaminant exceeds the TTC-derived reference ~~cut-off~~ value of 1 µg/kg, the risk manager should inform relevant stakeholders of such measurements and request that all available information be shared for rapid risk assessment as soon as possible.

Where measured levels do not exceed the TTC-derived referenced ~~cut-off~~ value of 1 µg/kg a risk management decision can be made that the consignment does not present a food safety concern.

The TTC-derived reference ~~cut-off~~ values are derived from the consideration that within a population the consignment will form only a tenth of the standard daily diet, based on access to a varied diet that may contain the same food from other sources and a range of other food groups. For certain sub-populations where a consignment could represent more than a tenth of the daily diet intake, for example with foods for infants or sole source nutrition products, the TTC-derived reference ~~cut-off~~ values may not be appropriate. Such instances should be considered on a case-by-case basis and progressed for full risk assessment when there is uncertainty over the proportion of the diet for which a food consignment may represent for these sub-populations.

76.3. Information sharing from the competent authorities of exporting country (Step 3 of the Decision Tree for Rapid Risk Assessment)

Beyond notifying relevant stakeholders about measured levels of the unregulated contaminant in food, the risk manager should request any relevant food safety information, if available, from the competent authorities of the exporting country. Relevant food safety information may include, but is not limited to, toxicological datasets, prior occurrence in the food of interest, food processing information and any history of use.

76.4. Request for rapid risk assessment (Step 4 of the Decision Tree for Rapid Risk Assessment)

The risk manager should seek completion of a rapid risk assessment of the detected unregulated contaminant, as soon as practicable. The risk manager should provide any toxicological and occurrence data obtained from the exporting country to the risk assessor.

76.5. Toxicological data collection (Step 5 of the Decision Tree for Rapid Risk Assessment)

The risk assessor may access any additional toxicological data on the contaminant or chemically/structurally related compounds that could further inform the choice of the rapid risk assessment approach (i.e. TTC vs HBGV approach).

76.6. Selection of the TTC value / Establishment of a HBGV, exposure assessment and risk characterisation (Steps 6-9 of the Decision Tree for Rapid Risk Assessment)

Based on the available toxicological data, it should be determined if establishment of a HBGV is feasible in the necessary timeframe.

In the absence of sufficient toxicological data to establish a HBGV for the unregulated contaminant, dietary intake against an appropriate threshold of no toxicological concern or reference value for any outcome whether genotoxic or non-genotoxic, should be selected for the contaminant (Step 6).

With the available dataset the risk assessor should undertake an abbreviated exposure (worst-case) assessment[5] of the contaminant in the food of interest and characterise the risk in relation to TTC selected through the Decision Tree for Rapid Risk Assessment (Steps 8 and 9). Any assumptions and uncertainties in the rapid risk assessment should be recorded.

Maia Jack
Need to find another suitable term for 'cut-off' – prefer 'reference value'.

As confirmed by Switzerland's interpretation in its comments to the 2nd circular, the term 'cut-off' has a negative connotation. Switzerland suggested, in part, "If the cut-off value is exceeded, should the food be considered as unsafe? This would imply a stop of trading until a more precise evaluation shows that there is no safety concern. The description of examples would help understanding the consequences of a cut-off value."

As noted in ICBA's prior submission, the suggestion is to replace the term 'cut-off' with a more appropriate term such as 'TTC-derived reference value'. Per ICBA's prior submission, "Replace 'cut-off' with TTC-derived reference value throughout. 'Cut-off' could have a negative connotation associated with it and risk managers may view the outcome of a rapid risk analysis approach as the final step rather than the first step in a tiered approach to risk assessment.

Maia Jack
Question appropriateness of referencing EFSA or WHO in a FAO/WHO Codex document.

The International Dairy Federation (IDF)

General comments

IDF has provided specific comments below. In addition, we would like to make the following general comments:

1. A rapid dietary exposure method is required to complement the rapid evaluation of the toxicity of an unregulated chemical. Currently the paper only provides a footnote to the EHC240 publication. This is unsatisfactory because the dietary exposure assessment methodologies outlined in that publication are comprehensive, and frequently require more underpinning data than may be available in the case of the initial detection of an unregulated chemical. For countries and regions which have detailed consumption patterns for their populations e.g. from total diet studies, then a rapid exposure assessment can be applied fairly simply. In cases where there are no national data available then international estimates could be applied using a conservative consumption point. In order to provide more guidance on the application of rapid dietary exposure methodologies, especially when required in a country with a paucity of population survey data, advice should be sought from JECFA on appropriate guidance.

2. IDF remains of the view that it seems unnecessarily restrictive to exclude unregulated contaminants with a health-based guidance value (HBGV) from the Scope. At least 35 contaminants have a JECFA HBGV but maximum limits have not yet been agreed or only determined for specific food categories. Where the unregulated contaminant is reported in a new food category, we believe that using the process described in this guidance document together with the JECFA HBGV for the unregulated contaminant may rapidly determine the appropriate risk management response. For example:

   If zearalenone or one of its metabolites was detected in milk powder at a level of 12.5 µg/kg. JECFA has established HBGV of PMTDI: 0.5 µg/kg body weight for total intake of zearalenone and its metabolites. Codex has not set MLs for this contaminant in any food category. Thus, in this example if zearalenone or one of its metabolites was found in milk powder, it may be appropriate to apply this guidance. Applying the Decision Tree in Annex 1:

   - Step 1: Zearalenone is not in a TTC exclusionary category (proceed to step 2)
   - Step 2: Zearalenone is detected above the cut-off value of 1 µg/kg (proceed to step 3-5)
   - Step 5: Sufficient toxicology data are available to establish a HBGV (proceed to step 8)

- Step 8: Conduct a rapid exposure assessment
- Step 9: Based on a comparison of exposure to the zearalenone HBGV of 0.5 µg/kg body weight, it can be determined whether or not this zearalenone detection of 12.5 µg/kg in milk powder would indicate a public health concern

In cases where a JECFA HBGV is established for an unregulated contaminant, the proposed process continues to have value since the risk assessment principles remain the same as those described in this document.

Specific comments

3. SCOPE. 2nd bullet:

- "Those where the detections have not been previously reported in the food on a one-off basis, not an intermittent occurrence; and, "

IDF comment: IDF understands that these guidelines are not intended to replace existing Codex procedures. However, IDF would seek reassurance that the application of these guidelines would not be limited to a single use for each unregulated chemical. Instead that it could, for example, be used in a subsequent detection in a different food group or different population should specific toxicological data not be available.

3.2. Exclusions from the scope of these guidelines

Groups of contaminants that would be excluded from the scope of this document if present in food would include:

- Contaminants detected in situations where the risk manager is investigating the possibility of intentional adulteration of food; and,
- Contaminants for which there are regulatory requirements or an existing regulatory framework;
- ~~Contaminants for which there are health-based guidance values (HBGV) such as a tolerable daily intake established~~.

IDF comments: These chemicals should not be excluded – even when detected in food a rapid exposure assessment is needed in order to determine the appropriate risk management to apply.

Note 1: Health-based guidance values (HBGV) established by JECFA ~~and/or endorsed by Codex~~

The 'endorsed by Codex' in the note may be unnecessary, if retained. In all cases where CCCF has set an ML they have used JECFA values so this additional requirement is unnecessary. Melamine is the only exception and would be excluded from consideration under these current guidelines as its presence arose from adulteration.

4. PRINCIPLES

- Risk assessors **and risk managers** carrying out the rapid risk assessment **and risk management** should have appropriate competency and experience;

IDF comment: The proposed changes acknowledge that risk management is an expertise involved the weighing up of impacts, uncertainties and options

7. APPLICATION OF THE DECISION TREE FOR RAPID RISK ASSESSMENT

On confirmation of the presence of the unregulated contaminant in food the risk manager should, in a timely manner, apply the rapid risk assessment approach in the accompanying decision tree. (see Annex 1). ~~The TTC framework – which is one element of the rapid risk assessment approach – is a science-based screening tool that enables rapid risk characterization when low levels of unregulated contaminants in food are found.~~ The rapid risk assessment approach allows for prioritization of only those instances where further in-depth investigations are warranted.

IDF comment: IDF suggests deletion as this has been described previously in the introduction. Also, the TTC is not the only risk assessment approach endorsed by the proposed Annex 1, as use of an HBGV (if sufficient information is available) is provided as an option

7.1 Exclusionary contaminant categories (Step 1 of the Decision Tree for Rapid Risk Assessment)

~~If sufficient toxicological data are available for the unregulated contaminant, a health-based guidance value (HBGV) should be derived, and a risk characterisation should be undertaken using the health based guidance value (See Step 6-9 of the Decision Tree for Rapid Risk Assessment).~~

IDF comments: IDF suggests that this paragraph is incorporated into Section 7.6 which also sets out when is appropriate to derive a HBGV.

7.3 Information sharing from the competent authorities of exporting country (Step 3 of the Decision Tree for Rapid Risk Assessment)

Beyond notifying relevant stakeholders about measured levels of the unregulated contaminant in food, the risk manager should request any relevant food safety information, if available, from the competent authorities of the exporting country. Relevant food safety information may include, but is not limited to, toxicological datasets, prior occurrence in ~~the~~ food ~~of interest~~, food processing information and any history of use.

IDF comment: IDF notes that relevant data may be broader than prior occurrence in the specific food of interest

7.6 Selection of the TTC / Establishment of a HBGV, exposure assessment and risk characterisation (Steps 6-9 of the Decision Tree for Rapid Risk Assessment)

~~Based on the available~~ **If sufficient** toxicological data **are available for the unregulated contaminant**, it should be determined if establishment of a HBGV is feasible in the necessary timeframe. **In the case where a JECFA HBGV for the unregulated contaminant exists, then the established HBGV can be used for the subsequent steps.**

IDF comment: IDF would recommend including the ability to rely on an established JECFA HBGV where it has been established, but when no regulatory limit exists.

In the absence of sufficient toxicological data to establish a HBGV for the unregulated contaminant, dietary intake against an appropriate threshold of no concern or reference value for any outcome whether genotoxic or non-genotoxic, should be selected for the contaminant **based on its structural properties** (Step 6).

IDF comment: For clarity.

With the available dataset the risk assessor should undertake an abbreviated exposure (worst-case) assessment of the contaminant in the food of interest and characterise the risk in relation to **either the TTC selected in Step 6 or the HBGV determined in Step 7 per** the Decision Tree for Rapid Risk Assessment (Steps 8 and 9). Any assumptions and uncertainties in the rapid risk assessment should be recorded.

IDF comment: The reference to the whole of the EHC does not assist, as that does not give specific advice on rapid dietary exposure methodologies. There is a need to address how this is done in countries which have no total diet survey. Alternative estimations based on global data may be useful. Guidance on considering population groups and high consumers may be useful.

Annex 1 Decision Tree for Rapid Risk Assessment

IDF comments: For consistency with Section 7.2, IDF suggests that Annex 1 Step 2 should include a footnote referencing exclusion of consignments for certain sub-populations

ISDI

Section 1: Introduction

ISDI proposes the following modification:

The Threshold of Toxicological Concern (TTC) is a well-recognised~~, hazard-based~~ tool, based on scientific risk assessment principles, to assess ~~low levels of~~ chemical exposures **in situations where compound-specific information is not available in order**~~, and to identify if further data are required~~ to assess human health risk.

Justification: The TTC considers both hazards (using chemical structure) to define an exposure that would be considered to have negligible risk. Therefore, while based on hazard, it is meant to be a risk management tool (as indicated in the rest of the language). Proposed edits we believe clarify the use of the TTC, in the context of these guidelines.

Substances with an existing Health-Based Guidance Value (HBGV)

ISDI notes an inconsistency in the draft guidelines in relation to substances with an existing HBGV. While Section 6.1 indicates that "If sufficient toxicological data are available for the unregulated contaminant, a health-based guidance value should be derived, and a risk characterisation should be undertaken using the health based guidance value", Section 3.2 excludes contaminants for which there are health-based guidance values from the scope of this guidance.

We believe it is important to differentiate the assessment of substances that have a previously established HBGV from those without. However, ISDI believes that this inconsistency in the guideline should be resolved.

ISDI's proposal to alleviate this inconsistency is to update the guidance document to remove the exclusion in Section 3.2 and also update the language in Section 6.1 to clearly distinguish the process for those substances that have an existing HBGV:

- *Section 3.2: Exclusions from the scope of these guidelines*

  Removal of third bullet, the exemption for substances for which there are established Health-Based Guidance Values (HBGVs)

- *Section 6.1 Exclusionary contaminant categories*

Addition of following section to make it clear that contaminants with an HBGV should not have the TTC or cut-off value applied. Proposed language (prior to paragraph starting "As identified"):

> **Contaminants for which there are health-based guidance values (HBGV) such as a tolerable daily intake established should rely on those HBGVs for risk assessment and risk management purposes. These contaminants can rely on the established HBGV for the purposes of a rapid risk assessment, rather than relying on process described in Steps 2-7 of the decision tree. In cases where a chemical contaminant with a HBGV is detected in a food that is not the subject to a regulatory framework, the rapid risk assessment of these contaminants can proceed from Step 1 to Step 8 in the process.**

- *Annex 1 Decision Tree for Rapid Risk Assessment*

  Removal of the reference to TTC in Step 1:

Is the contaminant in a~~n TTC~~ exclusionary category?

- *Annex 1 Decision Tree for Rapid Risk Assessment*

  Modification of the box to the right of Step 1

Contaminants with an established HBGV, proceed to Step 8. Other contaminants, ~~Potential food safety concern.~~ further risk analysis action necessary.

For the purposes of illustrating this point on HBGV, ISDI would like to describe an example of how the Annex 1 Decision Tree could be applied in a case where a contaminant, with an established HBGV is detected in a food that is not subject to a regulatory framework.

Deoxynivalenol (DON) is detected in chili powder at a level of 20 mcg/kg. JECFA has established HBGV for DON of 1 mcg/kg body weight, and Codex has set MLs for DON in three food categories dealing with cereals and cereal-based foods. In this example, DON (which has a HBGV) is detected in a food (chili powder) for which there is no regulatory framework that defines a regulatory limit. Applying the Decision Tree in Annex 1, with the proposed edits:

- Box 1: DON is in the exclusionary category because it has a HBGV. Since it has a HBGV, it proceeds to Step 8
- Box 8: Conduct a rapid exposure assessment
- Box 9: Based on a comparison of exposure to the DON HBGV of 1 mcg/kg body weight, it can be determined whether or not this DON detection of 20 mcg/kg in chili powder would indicate a public health concern

Footnote 2: HBGV established by JECFA and/or endorsed by Codex

ISDI proposes the following modification to the footnote:

Health-based guidance values (HBGV) established by **an authoritative risk assessment body such as** JECFA ~~and/or endorsed by Codex~~

Justification:

- HBGVs are established by JECFA, therefore we do not believe that the reference to endorsement by Codex is necessary
- The scope (Section 3) defines that this guidance would apply to contaminants for which there are no specific "Codex, regional or national standards, recommendations or guidelines". We believe that if scope includes reference to regional or national standards, and not only Codex standards, that it would be consistent to broaden this statement to also allow reference to other authoritative risk assessment bodies. This would allow application of this guidance in cases where a HBGV has been established locally, but not by JECFA, thus enhancing the value of this guidance.

Section X: Principles

ISDI recommends adding the following bullet after the second bullet:

This document focuses on risk management once the detection of a contaminant has been confirmed. Detection of a contaminant, especially at very low levels where analytical measurements have a greater degree of uncertainty, should be confirmed in order to avoid issues due to analytical methodology.

Justification:

Analytical methods, especially at very low concentrations, can produce spurious results. While challenges with analytical methods should not be part of the scope of this document, ISDI believes that this point is worth mentioning as a reminder to risk managers that analytical uncertainties are something that should also be considered

Section 6: Application of the decision tree for rapid risk assessment

ISDI recommends deleting the sentence describing the TTC framework, as this is redundant with the explanation in Section 1:

> On confirmation of the presence of the unregulated contaminant in food the risk manager should, in a timely manner, apply the rapid risk assessment approach in the accompanying decision tree. (see Annex 1). ~~The TTC framework – which is one element of the rapid risk assessment approach – is a cience-based screening tool that enables rapid risk characterization when low levels of unregulated contaminants in food are found.~~ The rapid risk assessment approach allows for prioritization of only those instances where further in-depth investigations are warranted.

Additionally, the TTC is used for generating the cut-off value in box 2, but it is not the only risk assessment approach endorsed by the proposed Decision Tree, as use of an HBGV (if sufficient information is available) is also provided as an option. Therefore, it does not make sense to talk about TTC in isolation here, and it is better suited in Section 6.1.

IFT

IFT values the opportunity to provide comments on CL 2019/10-CF and commends this Codex effort to address these important issues relating to risk analysis challenges. IFT has participated during the past two years in the Codex Committee on Contaminants in Foods' (CCCF) electronic working group (EWG) on "Risk Analysis of Contaminants in Food where there is no Regulatory Level or Risk Management Framework Established." I would like to submit for information purposes an important publication on this topic that was produced by IFT more than a decade ago (IFT, 2009). This publication, an effort by a distinguished Expert Panel of toxicologists and regulatory experts, was previously shared with the New Zealand Codex Contact Points following the CCCF12 workshop held in Utrecht in March 2018. As IFT's Codex Subject Expert to the CCCF, I participated in the workshop and will again be participating in Yogyakarta. IFT undertook this major effort, funded by the IFT Foundation, in 2007-2008, engaging the expert panelists who were struggling with many of the same issues that have been discussed and debated in CCCF, which are ably captured in the current draft Guidelines.

Reference

IFT. 2009. Making Decisions about the Risk of Chemicals in Foods with Limited Scientific Information. An Expert Report of the Institute of Food Technologists, Chicago, Ill. By Bidlack WR, Birt D, Borzelleca J, Clemens R, Coutrelis N, Coughlin JR, Dunaif GE, Ebert A, Hall R, Heimbach JT, Helferich W, Magnuson B, McColl DB, McQuate RS, Munro I, Petersen B, Roberts A, Scimeca J, Slayne M, Trautman T. C*omprehensive Reviews in Food Science and Food Safety* 8: 269-303.