CODEX ALIMENTARIUS COMMISSION

Food and Agriculture Organization of the United Nations

World Health Organization

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

Agenda Items 10 **CRD3**

ORIGINAL LANGUAGE

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON CONTAMINANTS IN FOODS

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

Report of Physical Working group on Agenda item 10, 28th April 2019

Prepared by New Zealand and the Netherlands

1. This CRD covers the discussions and feedback from the Physical Working Group convened by New Zealand and the Netherlands to consider Agenda Item 10 on the Draft Guidelines for risk analysis of chemicals inadvertently present in food at low levels. The meeting was attended by some 100 participants from member countries and observer organizations. New Zealand and the Netherlands thank members for their enthusiastic participation and sound technical advice throughout the development of the draft guidelines.

2. The Physical Working Group were presented the draft guidelines circulated as in agenda item 10 with additional tracked changes reflecting comments received since circulation of the circular letter (CX/CF 19/13/8-Add.1 –circulated in April 2019) . This document is attached for reference in appendix 2.

3. Given that there were no overarching concerns with the principles and objectives of the draft guidelines the Physical Working Group discussed four technical themes that had been commented on:

   a. Title

   b. Scope of contaminants with established HBGVs

   c. The terminology and characteristics of the cut-off value

   d. Ordering of process steps in the decision tree

Where comments were received throughout the document in relation to these themes they have been addressed collectively under each theme.

4. Minor editorial comments presented to and accepted by the Physical Working Group were transcribed in to the draft presented in appendix 1. Some additional wording suggested at the Physical Working Group has been tracked as changes on the draft guidelines.

5. Theme 1: Title.

A wide ranging discussion was held on the title, which reflected a number of formulations that had been explored throughout the development of the document. There was considerable concern about the use of the term “unregulated” and there were some proposals to replace this with “unexpected”. However, use of the term “unexpected” was problematic to several delegations and the consensus was that this should not be used. Most delegations felt strongly that the term “unregulated” was insufficient to describe the context of the guidelines because any risk management decision would have a regulatory context. Members felt the main issue was absence of a reference to levels that may or may not occur in regulation. The new draft title for consideration by the plenary is as follows

Draft guidelines for rapid risk analysis following instances of detection of contaminants in food where there is no regulatory level

The Physical Working Group recognised that there would be a number of consequential editorial changes to the draft once the title was finalised.

6. Theme 2: Scope of contaminants with established HBGVs.

The application of the guidelines to contaminants where a HGBV was already established was an area highlighted for discussion from the comments received at Step 7. In the Section 3.2 members raised two option:

a. excluding contaminants with an established HBGV, from being within the scope ; or
b. for contaminants with a HBGV, having an additional step to allow them to utilise, and have the benefit of, the rapid risk analysis process.

Drafting changes subsequent to the Physical Working Group, as expressed in this CRD reflect option b as this does not detract from the application of the decision tree but provides the additional benefit of utilising an established HBGV within a rapid risk analysis process. This is of particular advantage in that it can facilitate a rapid risk assessment. This also supports the change within the title as there will be instances of contaminants that have no regulatory levels but may have a HBGV in place.

Option b would result in the deletion of the third bullet point in section 3.2 and add an additional step in section 7 (Section 7.1) and a new step in the decision tree (step 1).

7. Theme 3: The terminology and characteristics of the cut-off value.

The concept of a cut-off value of 1 µg/kg received broad support from members during the second EWG. However some members raised concerns that the term “cut-off” had a negative connotation and that there was a possibility that this could be regarded as a regulatory value rather than a guideline for rapid risk analysis. The Physical Working Group discussed the terminology and agreed “cut-off” was an appropriate term, a footnote to describe its meaning would be beneficial as below:

[1]The cut-off value is a guideline indicating whether or not a specific risk management action might be taken on the basis of the concentration of the contaminant in the consignment tested. For values above the cut-off, application of these guidelines would result in the risk manager deciding to progress with a rapid risk analysis

Further discussion was held regarding the section of the guideline describing the application of the cut-off value (7.2). There was broad acceptance for the addition of a clause relating to considering diets for sub-populations on a case by case basis, although the position of this paragraph within the section was requested to be moved to improve the clarity. One member suggested that rather than a single value of 1 µg/kg an equation could be applied by each country tailored to their national circumstance. This was not generally supported because it would move away from the intent of the document to provide harmonised guidelines for consistent application by all countries.

8. Key theme 4: Ordering of process steps in the decision tree.

One Observer was of the view that the ordering of risk management and communication steps should be changed. Consequentially a large decision box has been created to merge both risk management and communication actions to indicate that they are likely to occur at the same time.

9. Other specific points raised by members and that have resulted in editorial change include:
   a. Revision of the title of the decision tree to Rapid Risk Analysis
   b. Addition of Codex texts relating to feed risk assessment into Section 2.
   c. The descriptions of the illustrative examples noted in section 3.1 were broadened.
   d. Adjustment of principles so as not to repeat content implicit within general Codex texts
   e. Addition of other toxicological reference values in addition to the HBGV, such as points of departure and benchmark doses.
   f. Addition of a paragraph within Section 5 stating that the text is without prejudice to national and regional frameworks.

g. Addition of a sentence in Section 7.3 to clarify that there is no obligation for laboratories to achieve a method sensitivity of 1 µg/kg.
h. Clarification that accreditation of laboratories applied to food contaminant testing, rather than for the specific contaminant detected.
i. Editorial changes in the document to replace “no food safety concern” with a reference to specific risk management measures being necessary.
j. Revision of the decision tree to refer back to relevant sections with the guideline text.

10. Several members commented on the placement of references and footnotes currently includes in the draft. There was a general consensus that the plenary with the guidance of the Codex secretariat should decide on this technical detail remaining within the final guidelines or being placed elsewhere within the FAO system for ready access.

APPENDIX I

DRAFT GUIDELINES FOR RAPID RISK ANALYSIS ~~OF UNREGULATED~~FOLLOWING INSTANCES OF DETECTION OF CONTAMINANTS IN FOOD WHERE THERE IS NO REGULATORY LEVEL ~~IN FOOD~~

1. INTRODUCTION

The detection in foods of chemical contaminants ~~that are not subject to a regulatory framework~~where there is no regulatory level established is increasing due to both the diversity of the food supply and the continuing advancement of analytical capabilities. Risk managers must respond to such detections in a manner that is adequately protective of public health but that at the same time also takes account of the practicalities of import admissibility processes.

Where detection of an unregulated chemical contaminant in food necessitates a rapid risk management response, e.g. to consider import admissibility a pragmatic risk-based approach should be applied. This approach:

- Should accommodate situations where there is limited or no toxicological data available;
- Should be able to be applied within the competence of the importing country;
- Should be rapid, where rapid means that it is able to be applied within a restricted timeframe in scenarios where a full risk assessment is neither a practicable, nor feasible, option.

The draft guideline incorporate a rapid risk analysis approach using a cut-off value[1] and the Threshold of Toxicological Concern (TTC), to assess low levels of chemical exposures, and to identify if further data are required to assess human health risk.[2,3]

A rapid risk analysis approach will adequately protect public health while supporting food security and minimising food wastage.

2. PURPOSE

The guidelines provide an approach to assist governments in the rapid risk analysis of instances of detection of ~~unregulated~~ chemical contaminants where there is no regulatory level established in the food~~; hereafter referred to as "unregulated contaminants"~~.

The guidelines should be read in conjunction with the following relevant texts: {add feed reference texts}

- Working Principles for Risk Analysis for Food Safety for Application by Governments (CAC GL 62-2007);
- The WTO Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement);
- Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius (Codex Alimentarius Commission Procedural Manual.);
- Principle and Guidelines for National Food Control Systems (CAC GL 82-2013);
- Principles for Food Import and Export Inspection and Certification (CAC GL 20-1995);
- Guidelines for the Design, Operation, Assessment and Accreditation of Food Import and Export Inspection and Certification (CAC GL 26-1997);
- Guidelines for Food Import Control Systems (CAC GL 47-2003);
- Guidelines for the Exchange of Information between countries on rejections of imported foods (CAC GL 25-1997);
- Principles and Guidelines for the Exchange of Information in Food Safety Emergency Situations (CAC GL 19-1995);

[1] The cut-off value is a guideline indicating where the concentration of the contaminant in the consignment tested indicates whether or not a specific risk management action might be taken. For values above the cut-off application of these guidelines would result in the risk manager deciding to progress with a rapid risk analysis

[2] Kroes. R., J. Kleiner, A. Renwick. 2005. The Threshold of Toxicological Concern Concept in Risk Assessment. Toxicological Sciences, 86 (2): 226–230. (https://doi.org/10.1093/toxsci/kfi169)

[3] These guidelines do not preclude other methods which may be considered in the future

- Guidelines for Settling Disputes over Analytical (Test) Results (CAC GL 70-2009);
- Principles and guidelines for the exchange of information between importing and exporting countries to support the trade in food (CAC GL 89-2016);
- Principles for Traceability / Product Tracing as a Tool Within a Food Inspection and Certification System (CAC GL 60-2006);
- Guidelines on the Application of Risk Assessment to Feed (CAC/GL 80-2013)
- Guidance for Governments on Prioritizing Hazards in Feed (CAC/GL 81-2013)

3. SCOPE

~~Unregulated c~~Contaminants subject to these guidelines are:

- Those detected where there is no regulatory level established for the food; and,
- Those meeting the definitions within the General Standard for Contaminants and Toxins in Food and Feed (CAC STAN 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 and are unexpected [(i.e. not a recurring or 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

The following (non-exhaustive) list of groups of contaminants would ~~fall under~~be within the scope of this document if ~~present~~ detected in a food:

- Contaminants that may occur in approved materials used during processing of food or contaminants from unapproved materials and that may be inadvertantl y present in teh food (e.g. printing inks, oils/lubricants/resins used as manufacturing maintenance compounds, cleaning compounds, traces of chemicals used in the manufacturing facility);
- ~~[Substances used for] gGreenhouse gas mitigation technology e.g. c~~Chemicals used to ~~address~~ mitigate specific environmental, sustainability and climate change~~-related~~ issues~~,~~ ~~including~~ (e.g. ~~within agriculture,~~ nitrification and urease inhibitors), which have not been anticipated to be present in food;

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;

~~4. Contaminants for which there are established health-based guidance values (HBGV)[4].~~

~~5.~~4. PRINCIPLES

The following principles apply:

- 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 the relevant official food control programmes for sampling and analysis;
- Where there is an instance of the detection of a~~n unregulated~~ contaminant for which no regulatory level is established in a traded consignment the competent authority in the exporting country ~~should~~ can be notified and any relevant food safety information shared;
- ~~Risk assessors [and risk managers] carrying out the rapid risk assessment [and risk management] should have appropriate competency and experience;~~

~~[4] Health-based guidance values (HBGV) established by JECFA and/or endorsed by Codex~~

- The risk assessment and risk management decisions, including data and information used to support the decision, should be documented in a transparent and systematic manner and made available upon request;
- Where there are continuing or frequent detections of a~~n unregulated~~ contaminant for which no regulatory level is established in food, targeted surveillance activities should be undertaken to determine the extent of potential human exposure and the source(s) of contamination.

~~6.~~5. ROLES

The provisions in this section are without prejudice to existing national or regional provisions already in place.

In many cases the risk manager will be the competent authority performing the official control/surveillance programmes or import controls, including sampling, and who subsequently will receive the results from the accredited or equivalent level laboratory. Decisions on the safety or otherwise of the food consignment in question will be made under national food safety legislation.

When carrying out the risk assessment, the competent authority should ensure that relevant stakeholders are notified of the detection of the ~~unregulated~~ contaminant for which no regulatory level is established in food as soon as possible and that a risk assessment is carried out in a timely manner. This is particularly important in the case of food in international trade.

Stakeholders other than the competent authority may also carry out non-regulatory monitoring programmes for a range of reasons e.g. satisfying provisions of supplier contracts. If the detection of the unregulated contaminant in food is reported by other stakeholders, the competent authority can consider such results in a preliminary assessment but should ensure that the reported results are confirmed in an accredited or equivalent level laboratory before doing a final assessment.

~~7.~~6. REPORTING OF DETECTION(S)

The ~~accredited or equivalent level~~ laboratory, with accreditation or equivalent level recognition for food contaminant analysis, should report all detections and measured contaminant levels from official / officially recognised food monitoring and surveillance programmes as prescribed by risk managers, including those contaminants for which no regulatory ~~framework~~ level is established. As such, the presence of the ~~unregulated~~ contaminant should have been confirmed by the accredited or equivalent level laboratory and the samples should have been subject to quality assurance provisions as required by an official regulatory programme. Sample source for reported detections should be unambiguous.

Information provided by the analytical laboratory to the risk manager should include:

- Type of sampling programme e.g. cross-sectional, longitudinal, random surveillance, targeted surveillance and sampling procedures;
- Sample preparation protocol;
- Test method, its analytical performance, mode of quantification and standards used for quantification and whether it is a confirmatory method that provides identifying information regarding the chemical structure of the analyte;
- Total number of samples tested, type of samples and number of detections, type of samples and;
- If available, summary statistics of occurrence data;
- Quantified uncertainty with sampling and analysis;
- Identification of chemical class / chemical type of the analyte;
- If available, assessment of the homogeneity of distribution for the contaminant in the ~~food~~lot.

~~8.~~7. APPLICATION OF THE DECISION TREE FOR RAPID RISK ~~ASSESSMENT~~ANALYSIS

On confirmation of an instance of the detection~~the presence of the unregulated~~ in food of a contaminant where no regulatory level is established ~~in food~~ the risk manager should, in a timely manner, apply the rapid risk ~~assessment~~ analysis approach in the accompanying decision tree. (see Annex 1). The rapid

risk ~~assessment~~ analysis approach allows for prioritization of only those instances where further in-depth investigations are warranted.

7.1. Contaminants with established HBGVs, PODs or BMDs (Step 1 of the Decision Tree for Rapid Risk Analysis)

Contaminants for which there are established health-based guidance values (HBGVs), toxicological points of departure (POD) or benchmark doses (BMDs) can progress directly to rapid exposure assessment (Step 9) as these values enable risk characterisation.

~~8.1.~~7.2. Exclusionary contaminant categories (Step ~~1~~2 of the Decision Tree for Rapid Risk ~~Assessment~~Analysis)

As identified in the TTC approach certain contaminant categories may not be suitable for rapid risk assessment given their chemical or toxicological properties. Unless there is prior experience with rapid risk ~~assessment~~ analysis of these groupings, a risk manager, seeking expert advice where required, should not apply the decision tree to the following categories of contaminants:

- High potency carcinogens (i.e. aflatoxin-like, azoxy- or N-nitroso-compounds, benzidines),
- Chemicals of unknown or unique structure,
- ~~[Polychlorinated dibenzo dioxins and furans,]~~
- Inorganic chemicals,
- Metals and organometallics,
- Proteins,
- Steroids,
- Nanomaterials,
- Radioactive substances
- Organo-silicon compounds, and
- Chemicals that are known or predicted to be persistent and bioaccumulate.

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

~~8.2.~~7.3. Application of the cut-off ~~—~~value (Step ~~2~~3 of the Decision Tree for Rapid Risk ~~Assessment~~Analysis)

If quantitative measurement of the ~~unregulated~~ contaminant for which there is no regulatory level established exceeds 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.

A premise for the application of the cut-off value is that within a population the consignment will form only a tenth of the standard adult 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 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.

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 require a specific risk management response. The cut-off value does not necessitate the analytical laboratory achieving a method sensitivity of 1 µg/kg.

~~8.3. The cut off values are derived from the consideration that within a population the consignment will form only a tenth of the standard [adult] 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 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.~~

~~8.4.~~7.4. Information sharing from the competent authorities of exporting country (Step ~~3~~ 4 of the Decision Tree for Rapid Risk ~~Assessment~~Analysis)

Beyond notifying relevant stakeholders about ~~measured levels~~the instance of detection in food ~~of the unregulated~~ contaminant ~~in food~~where there is no regulatory level established, 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 food, food processing information and any history of use.

~~8.5.~~7.5. Request for rapid risk assessment (Step ~~4~~ 5 of the Decision Tree for Rapid Risk ~~Assessment~~Analysis)

The risk manager should seek completion of a rapid risk assessment of the detected ~~unregulated~~ contaminant for which there is no regulatory level, as soon as practicable. The risk manager should provide any toxicological and occurrence data obtained from the exporting country to the risk assessor.

~~8.6.~~7.6. Toxicological data collection (Step ~~5~~6 of the Decision Tree for Rapid Risk Anal~~ysis~~~~ssessment~~)

The risk assessor ~~may~~ should 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/POD/BMD approach).

~~8.7.~~7.7. Selection of the TTC value / Establishment of a HBGV/POD/BMD, exposure assessment and risk characterisation (Steps ~~6~~ ~~9~~ 7-10 of the Decision Tree for Rapid Risk ~~Assessment~~Analysis)

If sufficient toxicological data are available for the ~~unregulated~~ contaminant for which there is no regulatory level, it should be determined if establishment of an ad-hoc HBGV/POD/BMD is feasible in the agreed timeframe[5]. If a HBGV/POD/BMD can be established the risk characterisation should be undertaken using this value.

In the absence of sufficient toxicological data to establish a HBGV/POD/BMD for the ~~unregulated~~ contaminant for which there is no regulatory level, 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~~7).[6]

With the available dataset the risk assessor should undertake an exposure assessment [7] of the contaminant in the food of interest and characterise the risk in relation to the TTC or HBGV/POD/BMD selected through the Decision Tree for Rapid Risk ~~Assessment~~ Analysis (Steps ~~8~~9 and ~~9~~10). Any assumptions and uncertainties in the rapid risk assessment should be recorded.

~~8.8.~~7.8. Reporting (Steps ~~10~~ 11 and ~~11~~12 of the Decision Tree for Rapid Risk ~~Assessment~~Analysis)

The risk assessor should provide the results, including information on assumption and uncertainties to the risk manager in a clear, consistent and standardised manner, within an agreed upon time frame.[8]

~~8.9.~~7.9. Decision by the risk manager

The risk manager should take into account the results of the rapid risk assessment provided by the risk assessor and decide whether a risk management response is warranted. ~~Application of any risk management measure should be proportional to the anticipated human health risk.~~ This includes:

- Judging the food consignment / lot as fit for human consumption on the basis of negligible risk to human health,

[5] HBGVs are the quantitative expression of an oral exposure (either acute or chronic) in the form of a dose that would be expected to be without appreciable health risk. (Principles and methods for the risk assessment of chemicals in food (EHC 240, 2009))

[6] EFSA and WHO, Review of the Threshold of Toxicological Concern (TTC) approach and development of new TTC decision tree. EFSA supporting publication 2016: EN-1006, https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/sp.efsa.2016.EN-1006

[7] Principles and methods for the risk assessment of chemicals in food (EHC 240, 2009). In the absence of domestic consumption data for the food of interest an exposure assessment could refer to alternative data sources such as the relevant, or alternatively highest overall, consumption value in the WHO Global Environment Monitoring System (GEMS) food cluster diets. A further approach could be to assess whether the intakes of the food of interest for the exposure to match the selected TTC value are sufficiently exaggerated over normal patterns (e.g. > 1 kg/day) to make such an exposure scenario unrealistic.

[8] The risk assessor should provide a scientific opinion on any assumptions and the degree of uncertainty in the results of the rapid risk assessment.

- Judging the food consignment / lot as unfit for human consumption on the basis of a potential risk to human health,
- Placing the food consignment on hold while seeking further information on the possible levels of the contaminant in other lots and consignments to better understand the potential public health concern and whether a full risk assessment may be required.

The risk manager should communicate the risk management option taken and any decision on safety or otherwise of the consignment / lot as soon as practicable. In the case of food in trade, *The Principles and Guidelines for the Exchange of Information between Importing and Exporting Countries to Support the Trade in Food* (CAC GL 89-2016) provides guidance on exchange of food safety information between competent authorities.

Ultimately, when dietary exposure in comparison with a HBGV or other hazard characterization value would pose a public health concern and possible risk management measures that would result in reductions to the dietary exposure are identified then steps should be taken to implement appropriate risk management measures.

~~9.~~8. FURTHER RISK MANAGEMENT ACTIVITIES

One risk management option may be targeted surveillance to gain more information on recurrence of ~~the~~ instances of detection of the ~~ed unregulated~~ contaminant~~s~~ in food and to more closely evaluate the level of dietary exposure over time.

Where the ~~unregulated contaminant~~ detection of the contaminant for which there is no established regulatory level occurs on one or more occasions but its presence is below a level of toxicological concern, subsequent surveillance or undertaking toxicological studies is unlikely to be required.

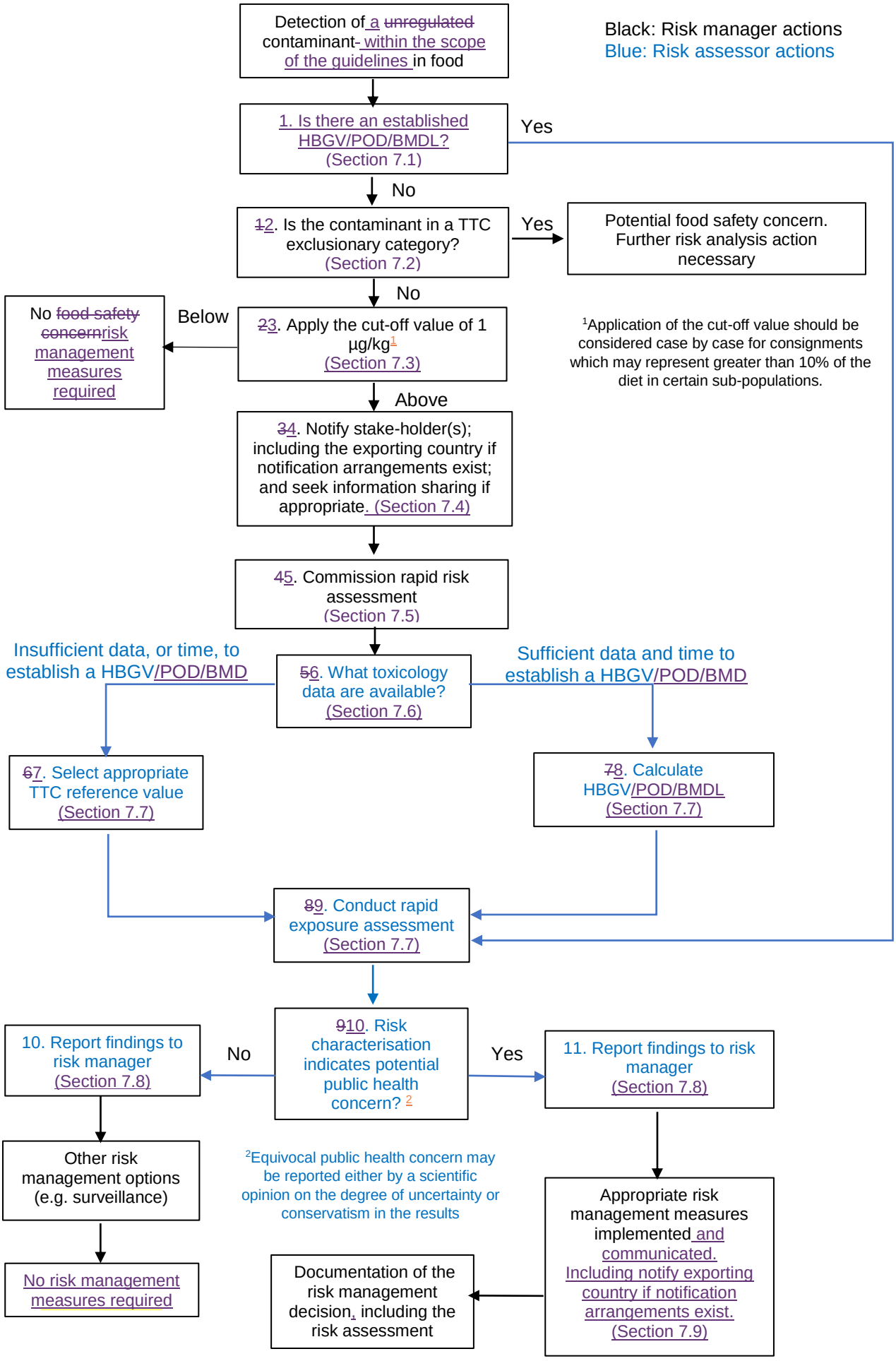
Where the ~~unregulated~~ detection of the contaminant for which there is no regulatory level becomes a repeated occurrence in food, and new information may become available on the toxicity of the contaminant, or when there are indications that dietary exposure may be at a level that constitutes a potential risk to human health, then consideration should be given to undertaking toxicological studies and/or initiating a full risk assessment.

Gathering and sharing data through the WHO Global Environmental Monitoring System Food Consumption Database would support any international consideration for development of standards.

~~10.~~9. RISK COMMUNICATION

Consumers and other stakeholders have a high level of interest in information on the presence of ~~unregulated~~ contaminants in food and the outcomes of the risk assessment and risk management activities of competent authorities. Thus, appropriate risk communication is recommended when risk management measures are implemented for ~~unregulated~~ contaminants found in food where there are no established regulatory levels ~~found in food~~.

Annex 1 Decision Tree for Rapid Risk ~~Assessment~~Analysis



APPENDIX II- DRAFT GUIDELINE PRESENTED TO THE PHYSICAL WORKING GROUP

DRAFT GUIDELINES FOR RISK ANALYSIS OF UNREGULATED CONTAMINANTS IN FOOD

(COMMENTS REQUESTED THROUGH CL 2019/10-CF)

1. INTRODUCTION

The detection in foods of chemical contaminants that are not subject to a regulatory framework is increasing due to both the diversity of the food supply and the continuing advancement of analytical capabilities. Risk managers must respond to such detections in a manner that is adequately protective of public health but that [at the same time] also takes account of the practicalities [of import admissibility processes].

Where detection of an unregulated chemical contaminant in food necessitates a rapid risk management response,[e.g. to consider import admissibility] a pragmatic risk-based approach should be applied. This approach:

- Should accommodate situations where there is limited or no toxicological data available;
- Should be able to be applied within the competence of the importing country;
- Should be [rapid, where rapid means that it is] able to be applied within a restricted timeframe in scenarios where a full risk assessment is neither a practicable, nor feasible, option.

[The draft guidelines incorporate a rapid risk analysis approach using a cut-off value and the] Threshold of Toxicological Concern (TTC), to assess low levels of chemical exposures, and to identify if further data are required to assess human health risk.[1,2]

A rapid risk analysis approach will adequately protect public health while supporting food security and minimising food wastage.

2. PURPOSE

The guidelines provide an approach to assist governments in the rapid risk analysis of unregulated chemical contaminants in food; hereafter referred to as “unregulated contaminants”.

The guidelines should be read in conjunction with the following relevant [Codex] texts:

- Working Principles for Risk Analysis for Food Safety for Application by Governments (CAC GL 62-2007);
- The WTO Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement);
- Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius (Codex Alimentarius Commission Procedural Manual.);
- Principle and Guidelines for National Food Control Systems (CAC GL 82-2013);
- Principles for Food Import and Export Inspection and Certification (CAC GL 20-1995);
- Guidelines for the Design, Operation, Assessment and Accreditation of Food Import and Export Inspection and Certification (CAC GL 26-1997);
- Guidelines for Food Import Control Systems (CAC GL 47-2003);
- Guidelines for the Exchange of Information between countries on rejections of imported foods (CAC GL 25-1997);
- Principles and Guidelines for the Exchange of Information in Food Safety Emergency Situations (CAC GL 19-1995);
- Guidelines for Settling Disputes over Analytical (Test) Results (CAC GL 70-2009);
- Principles and guidelines for the exchange of information between importing and exporting countries to support the trade in food (CAC GL 89-2016);

[1] Kroes. R., J. Kleiner, A. Renwick. 2005. The Threshold of Toxicological Concern Concept in Risk Assessment. Toxicological Sciences, 86 (2): 226–230. (https://doi.org/10.1093/toxsci/kfi169)

[2] These guidelines do not preclude other methods which may be considered in the future]

- Principles for Traceability / Product Tracing as a Tool Within a Food Inspection and Certification System (CAC GL 60-2006)

3. SCOPE

Unregulated contaminants subject to these guidelines are:

- Those meeting the definitions within the General Standard for Contaminants and Toxins in Food and Feed (CAC STAN 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 and are unexpected [(i.e., not a recurring or ~~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

[The following non-exhaustive list] of groups of contaminants would fall under the scope of this document if present in food:

- [Substances used for] greenhouse gas mitigation e.g. chemicals used to address specific environmental and climate change-related issues, including nitrification and urease inhibitors, which have not been anticipated to be present in food;
- Contaminants [that may occur in approved] materials used during processing of food [or contaminants from unapproved materials] e.g. [contaminants found in approved] printing inks, oils/lubricants/resins used as manufacturing maintenance compounds, cleaning compounds, traces of chemicals used in the manufacturing facility;

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[3].

4. PRINCIPLES

[The following principles apply]:

- 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 [the relevant] 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 [can] be notified and any relevant food safety information shared;
- Risk assessors [and risk managers] carrying out the rapid risk assessment [and risk management] should have appropriate competency and experience;
- The risk assessment and risk management decisions, including data and information used to support the decision, should be documented in a transparent and systematic manner and made available upon request;
- Where there are continuing [or frequent] detections of an unregulated contaminant in food, targeted surveillance activities should be undertaken to determine the extent of potential human exposure and the source(s) of contamination.

[3] Health-based guidance values (HBGV) established by JECFA

5. ROLES

In many cases the risk manager will be the competent authority performing the official control/surveillance programmes or import controls, including sampling, and who subsequently will receive the results from the accredited or equivalent level laboratory. Decisions on the safety or otherwise of the food consignment in question will be made under national food safety legislation.

When carrying out the risk assessment, the competent authority should ensure that relevant stakeholders are notified of the detection of the unregulated contaminant in food as soon as possible and that a risk assessment is carried out in a timely manner. This is particularly important in the case of food in international trade.

Stakeholders other than the competent authority may also carry out non-regulatory monitoring programmes for a range of reasons e.g. satisfying provisions of supplier contracts. If the detection of the unregulated contaminant in food is reported by other stakeholders, the competent authority can consider such results in a preliminary assessment but should ensure that the reported results are confirmed in an accredited or equivalent level laboratory before doing a final assessment.

6. REPORTING OF DETECTION(S)

The accredited or equivalent level laboratory should report all detections and measured contaminant levels from official / officially recognised food monitoring and surveillance programmes as prescribed by risk managers, including those [contaminants] for which no regulatory framework is established. As such, the presence of the unregulated contaminant should have been confirmed by the accredited [or equivalent level] laboratory and the samples should have been subject to quality assurance provisions as required by an official regulatory programme. Sample source for reported detections should be unambiguous.

Information provided by the - [analytical laboratory] to the risk manager should include:

- Type of sampling programme e.g. cross-sectional, longitudinal, [random surveillance,] targeted surveillance and sampling procedures;
- [Sample preparation protocol]
- Test method, its analytical performance, mode of quantification and standards used for quantification and whether it is a confirmatory method that provides identifying information regarding the chemical structure of the analyte;
- Total number of samples tested, type of samples and number of detections, type of samples and;
- [If available,] summary statistics of occurrence data;
- [Quantified uncertainty with sampling and analysis]
- Identification of chemical class / chemical type [of the analyte];
- [If available,] assessment of the homogeneity of distribution for the contaminant in the food.

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 rapid risk assessment approach allows for prioritization of only those instances where further in-depth investigations are warranted.

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

As identified in the TTC approach certain contaminant [categories] may not be suitable for rapid risk assessment given their chemical or toxicological properties. Unless there is prior experience with rapid risk assessment of these groupings, a risk manager, seeking expert advice where required, should [not] apply the decision tree to the following categories of contaminants:

- High potency carcinogens (i.e. aflatoxin-like, azoxy- or N-nitroso-compounds, benzidines),
- [Chemicals of unknown or unique structure,]
- [Polychlorinated dibenzo dioxins and furans,]

- Inorganic chemicals,
- Metals[and organometallics],
- Proteins,
- Steroids,
- Nanomaterials,
- Radioactive substances
- Organo-silicon compounds, and
- Chemicals that are known or predicted to be persistent and bioaccumulate.

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

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

If quantitative measurement of the unregulated contaminant exceeds 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.

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 the consignment will form only a tenth of the standard [adult] 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 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.

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 food, food processing information and any history of use.

7.4. 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.

7.5. 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).

7.6. 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)

[If sufficient toxicological data are available for the unregulated contaminant,] it should be determined if establishment of a HBGV is feasible in the [agreed] timeframe[4]. [If a HGBV can be established the risk characterisation should be undertaken using this value].

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

[4] HBGVs are the quantitative expression of an oral exposure (either acute or chronic) in the form of a dose that would be expected to be without appreciable health risk. (Principles and methods for the risk assessment of chemicals in food (EHC 240, 2009))

whether genotoxic or non-genotoxic, should be selected for the contaminant [based on its structural properties] (Step 6).[5]

With the available dataset the risk assessor should undertake an exposure assessment~~(worst-case)~~ [6] of the contaminant in the food of interest and characterise the risk in relation to [the] TTC [or HBGV] 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.

7.7. Reporting (Steps 10 and 11 of the Decision Tree for Rapid Risk Assessment)

The risk assessor should provide the results[, including information on assumption and uncertainties] to the risk manager in a clear, consistent and standardised manner, within an agreed upon time frame.[7]

7.8. Decision by the risk manager

The risk manager should take into account the results of the rapid risk assessment provided by the risk assessor and decide ~~on~~ whether a risk management response is warranted. Application of any risk management measure should be proportional to the anticipated human health risk. This includes:

- Judging the food consignment / lot as fit for human consumption on the basis of negligible risk to human health,
- Judging the food consignment / lot as unfit for human consumption on the basis of a potential risk to human health,
- Placing the food consignment on hold while seeking further information on the possible levels of the contaminant in [other] lots and consignments to better understand the potential public health concern and whether a full risk assessment may be required.

The risk manager should communicate the risk management option taken and any decision on safety or otherwise of the consignment / lot as soon as practicable. In the case of food in trade, *The Principles and Guidelines for the Exchange of Information between Importing and Exporting Countries to Support the Trade in Food* (CAC GL 89-2016) provides guidance on exchange of food safety information between competent authorities.

Ultimately, when [dietary exposure in comparison with a HBGV or other hazard characterization would pose a public health concern and possible risk management measures that would result in reductions to the dietary exposure are identified] then steps should be taken to [implement] appropriate risk management measures.

8. FURTHER RISK MANAGEMENT ACTIVITIES

One risk management option may be targeted surveillance to gain more information on recurrence of the detected unregulated contaminants in food and to more closely evaluate the level of dietary exposure over time.

Where the unregulated contaminant detection occurs on one or more occasions but its presence is below a level of toxicological concern, subsequent surveillance or undertaking toxicological studies is unlikely to be required.

Where the unregulated contaminant becomes a [repeated] occurrence in food, and new information may become available on the toxicity of the contaminant, or when there are indications that dietary exposure may be at a level that constitutes a potential risk to human health, then consideration should be given to undertaking toxicological studies and/or initiating a full risk assessment.

Gathering and sharing data through the WHO Global Environmental Monitoring System Food Consumption Database would support any international consideration for development of standards.

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[5] EFSA and WHO, Review of the Threshold of Toxicological Concern (TTC) approach and development of new TTC decision tree. EFSA supporting publication 2016: EN-1006, https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/sp.efsa.2016.EN-1006

[6] Principles and methods for the risk assessment of chemicals in food (EHC 240, 2009). [In the absence of domestic consumption data for the food of interest an exposure assessment could refer to alternative data sources such as the relevant, or alternatively highest overall, consumption value in the WHO Global Environment Monitoring System (GEMS) food cluster diets. A further approach could be to assess whether the intakes of food of interest for the exposure to match the selected TTC value are sufficiently exaggerated over normal patterns (e.g. > 1 kg/day) to make such an exposure scenario unrealistic]

[7] The risk assessor should provide a scientific opinion on any assumptions and the degree of uncertainty in the results of the rapid risk assessment.

9. RISK COMMUNICATION

Consumers and other stakeholders have a high level of interest in information on the presence of unregulated contaminants in food and the outcomes of the risk assessment and risk management activities of competent authorities. Thus[,] appropriate risk communication is recommended when risk management measures are implemented for unregulated contaminants found in food.

Annex 1 Decision Tree for Rapid Risk Assessment