CODEX ALIMENTARIUS COMMISSION

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World Health Organization

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Agenda Item 10 **CX/CF 19/13/8**

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

(Prepared by the electronic working group led by New Zealand and the Netherlands)

Codex members and Observers wishing to submit comments at Step 6 on this draft should do so as instructed in CL 2019/10-CF available on the Codex webpage/Circular Letters: http://www.fao.org/fao-who-codexalimentarius/resources/circular-letters/en/.

BACKGROUND

1. At the 30th Session of Codex Committee on General Principles (CCGP30), New Zealand introduced Conference Room Document 7 (CRD7), noting that the matter of detection of chemicals not anticipated previously to be present in food but likely of very low public health concern was a significant emerging issue for reasons highlighted in the paper, and had potential to impact on international trade. New Zealand announced its intention to submit a more detailed proposal and bring this matter to the attention of the Commission.[1]

2. At the 48th Session of Codex Committee on Pesticide Residues (CCPR48) (2016), New Zealand introduced CRD16 that was presented at CCGP30 (2016). The Delegation expressed that Codex has a clear interest and responsibility to take a proactive approach to address the issues in the New Zealand information paper and to support the development of an internationally harmonised risk management approach. Therefore, New Zealand would be presenting a new work proposal for consideration at 71st Session of the Executive Committee (CCEXEC71) and the 39th Session of the Codex Alimentarius Commission (CAC39).[2]

3. At CCEXEC71 (2016), the Member for South-West Pacific presented CRD8, noting that many of the chemicals that were unlikely to constitute a concern to public health were currently not covered by Codex. The Member indicated that the Codex Committee on Contaminants in Foods (CCCF) would be an appropriate starting point for work on this matter. CCEXEC agreed that the matter was relevant to several committees, but mainly to CCCF and noted that a decision on new work could only be taken after the proposal had been examined by CCCF taking into account its mandate and workload. CCEXEC acknowledged the importance of the issue and the need for Codex to address it and recommended to forward the document (CRD8) to CCCF for further examination.[3]

4. CAC39 (2016) agreed with the recommendation of CCEXEC71 to forward the document (CRD20) to CCCF for further examination.[4]

5. At CCCF11 (2017), New Zealand presented a revised version of the project document prepared following a workshop held prior to the plenary session. CCCF agreed to endorse new work on the development of risk analysis guidelines to address chemicals inadvertently present in food at low levels; forward the project document to CAC40 (2017) for approval; and agreed to establish an Electronic Working Group (EWG) chaired by New Zealand, co-chaired by the Netherlands, working in English, to advance this work.[5]

[1] REP 16/GP, para. 61
[2] REP 16/PR, para. 195
[3] REP 16/EXEC, paras. 49, 53 and 54
[4] REP 16/CAC, para 207
[5] REP 17/CF, paras 152 - 153, Appendix XI

6. CCEXEC73 (2017) noted that the project document on new work did not respond to the question on availability of scientific advice and that it was important to ensure that the work was consistent with the principles of risk analysis. CCEXEC recommended that FAO and WHO participate actively in the work on the development of the guidelines on risk analysis of chemicals inadvertently present in foods at low levels, with a view to ensuring consistency with the principles of risk analysis, in particular risk assessment.[6]

7. CAC40 approved the new work, taking into account the critical review of CCEXEC73.[7]

8. CCCF12 (2018) reviewed the proposed draft Guidelines for risk analysis of chemicals inadvertently present in food at low levels. The following comments and decisions were made:

   - the scope needed further refining to clearly indicate that the contaminants under discussion fall outside the scope of contaminants for which a regulatory framework already existed, i.e. for which there was a Codex standard and if not, a national standard. Compounds for which there are regulatory requirements, e.g. food additives, pesticides, veterinary drugs, etc. will be excluded from the Guidelines as well as compounds for which there may be health-based guidance value (such as tolerable daily intake (TDI)) established, and that this should be clearly indicated in the scope.
   - the entry for a cut-off value(s) in Section 4 Principles was kept in square brackets as further discussion was needed on the feasibility of establishing a single cut-off value or whether more than one cut-off value would be needed taking into account that different contaminants may have different toxicity levels and foods containing the contaminant may be consumed at significantly different levels in different countries or regions. Also the issue of acute toxicity would need to be considered as the threshold of toxicological concern (TTC) classes were based on chronic toxicity studies. A proposal was also made to consider whether a cut-off value should be mandatory.
   - the categories listed in Section 7.1 Exclusion Categories are excluded from the TTC approach since they are not covered in the databases from which the exposure class thresholds, the TTC values, were derived.
   - As the Guidelines are intended for application by governments, reference to relevant Codex texts, rather than specific Codex committees (e.g. contaminants in foods, inspection and certification systems) would be more appropriate. In this regard, the reference to the mandate of CCCF was not appropriate and text should rather be developed to explain the meaning of contaminants excluded from these Guidelines (Section 3 Scope). Along the same lines, texts developed by Codex Committee on Food Import and Export Inspection and Certification Systems (CCFICS) should be included as references instead of the current formulation of the text in Section 7.8 decision by the risk manager.

9. CCCF12 agreed to advance the proposed draft Guidelines to Step 5 for adoption by CAC41 (2018). CCCF12 also agreed to re-establish the EWG chaired by New Zealand and the Netherlands to further develop the guidelines especially those parts remaining in square brackets for consideration at the next session of the committee. CCCF12 also agreed to keep open the possibility of convening a physical working group meeting immediately prior to the next session of CCCF to consider written comments submitted and prepare a revised for consideration at CCCF13 (2019).[8]

10. CAC41 (2018) adopted the proposed draft Guidelines at Step 5 and advanced it for comments at Step 6.[9]

11. New Zealand and the Netherlands reconvened the EWG to continue work on revision and further development of the draft guidelines. The EWG comprised of representatives from 25 member countries, 2 international organizations and 9 non-governmental organizations. The EWG worked in English only. The list of participants is presented in Appendix II.

References and examples in the draft Guidelines

12. Technical references that provide the scientific basis for the development of the Guidelines such as those shown in footnotes 1 and 4 of the draft Guidelines (Appendix I) will not remain in the final document. Likewise, the reference to working documents (footnote 4), the case studies (Annex 3) and worked examples (Annex 4) are a source of information to assist CCCF with the development of the guidelines, but will not remain in the final document. References and examples such as case studies remain publicly available through the relevant working document (i.e. CX/CF 19/13/8) posted on the Codex website.

[6] REP 17/EXEC2, paras 59 - 60
[7] REP 17/CAC, para 83
[8] REP18/CF, paras. 123-124
[9] REP18/CAC, Appendix IV

Discussion and conclusions

13. In developing the proposed draft guidelines, the EWG considered amendments to the following sections to address specific points raised at CCCF12:

- Refinement of the scope to clearly indicate contaminants falling outside of the scope.
- Cut-off value(s)
- Reference to specific Codex texts, rather than Codex committees
- Other matters

Scope

14. Members of the EWG provided a number of comments regarding the refinement of the scope, largely supporting expansion of the contaminant types deemed within scope. As the contaminants listed are illustrative examples it was not deemed appropriate to include a prescriptive listing of contaminants as doing so may hinder the flexibility of a risk manager to apply the guidelines.

Cut-off value(s)

15. The EWG also considered the approach undertaken to establish the "cut-off" value, in view of ensuring the selected value was sufficiently protective for human health but also would be of utility given current analytical capabilities.

16. Members of the EWG submitted supporting both retention of the cut-off value and the removal of a specific value. As a consequence Annex 4 was included in the guidelines to illustrate the level of conservatism inherent to the proposed cut-off approach by comparing how the Genotoxic TTC classification compares to the published JECFA[10] health based guidance values or points of departure. This supported that the chosen value would provide more than adequate protection for the general population. However, it was acknowledged that applying the cut-off value to sub-populations where a consignment may make up greater than 10% of the diet would not necessarily provide an appropriate level of protection; as such an infant cut-off value was removed with a paragraph included in the general text to recommend applying a case by case approach for these occurrences.

Codex references

17. The EWG considered amendments to the draft guidelines to replace references to specific Codex committees with relevant Codex texts. Members of the EWG raised no concerns with the amendments.

Other matters

18. Members of the EWG submitted on other aspects of the guidelines additional to the specific points raised for consideration by CCCF 12. A summary of the outcomes of these is provided below:

- Submissions were made both to shorten and to expand the title; it was concluded that brevity in the title was preferable and the title of the guidelines was amended to: *DRAFT GUIDELINES FOR RISK ANALYSIS OF UNREGULATED CONTAMINANTS IN FOO*D
- Submissions were also made by members to shorten the introductory section; these were accepted and this section made more succinct;
- A range of other minor consistency and terminology amendments were made throughout the document to address points raised in the submissions.

Recommendations:

19. CCCF:

- note the revisions to the draft Guidelines based on the discussion held and comments submitted at CCCF12 as well as the submissions made to the EWG as summarized in paragraphs 5 to 11; and
- consider the draft guidelines as set out in Appendix I together with comments submitted in reply to CL 2019/10-CF and the findings of the meeting of the physical working group.

[10] Joint Expert Committee on Food Additives

APPENDIX I

DRAFT GUIDELINES FOR RISK ANALYSIS OF UNREGULATED CONTAMINANTS IN FOOD

(COMMENTS REQUESTED THROUGH CL 2019/10-CF)

1. INTRODUCTION

The detection of chemical contaminants in foods 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 also takes account of the practicalities of initial detections and trade equity.

Where detection of an unregulated chemical contaminant in food necessitates a rapid risk management response, 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 able to be applied within a restricted timeframe in scenarios where a full risk assessment is neither a practicable, nor feasible, option.

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, and to identify if further data are required to assess human health risk.[1]

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 texts:

- Working Principles for Risk Analysis for Food Safety for Application by Governments (CXG 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 (CXG 82-2013);
- Principles for Food Import and Export Inspection and Certification (CXG 20-1995);
- Guidelines for the Design, Operation, Assessment and Accreditation of Food Import and Export Inspection and Certification (CXG 26-1997);
- Guidelines for Food Import Control Systems (CXG 47-2003);
- Guidelines for the Exchange of Information between countries on rejections of imported foods (CXG 25-1997);
- Principles and Guidelines for the Exchange of Information in Food Safety Emergency Situations (CXG 19-1995);
- Guidelines for Setting Disputes over Analytical (Test) Results (CXG 70-2009);
- Principles and guidelines for the exchange of information between importing and exporting countries to support the trade in food (CXG 89-2016);
- Principles for Traceability / Product Tracing as a Tool Within a Food Inspection and Certification System (CXG 60-2006)

[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)

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].

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;
- 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 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.

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

4. 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.

5. 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 for which no regulatory framework is established. As such, the presence of the unregulated contaminant should have been confirmed by the accredited 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 analyst to the risk manager should include:

- Type of sampling programme e.g. cross-sectional, longitudinal, targeted surveillance and sampling procedures;
- 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;
- Number of detections, type of samples and total number of samples tested;
- Summary statistics of occurrence data;
- Identification of chemical class / chemical type;
- Assessment of the homogeneity of distribution for the contaminant in the food.

6. 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.

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

As identified in the Threshold of Toxicological Concern (TTC) approach certain contaminant groupings 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 should exclude applying the decision tree to the following categories of contaminants:

- High potency carcinogens (i.e. aflatoxin-like, azoxy- or N-nitroso-compounds, benzidines),
- Inorganic chemicals,
- Metals,
- Proteins,
- Steroids,
- Nanomaterials,
- Radioactive substances
- Organo-silicon compounds, and
- Chemicals that are known or predicted to be persistent and bioaccumulate.

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).

6.2. 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 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.

6.3. 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.

6.4. 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.

6.5. 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).

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)

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 concern or reference value for any outcome whether genotoxic or non-genotoxic, should be selected for the contaminant (Step 6).[4]

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.

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[3] 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))

[4] 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

[5] Principles and methods for the risk assessment of chemicals in food (EHC 240, 2009)

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

The risk assessor should provide the results to the risk manager in a clear, consistent and standardised manner, within an agreed upon time frame.[6]

6.8. 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 future 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* CXG 89-2016) provides guidance on exchange of food safety information between competent authorities.

Ultimately, when 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 propose appropriate and meaningful risk management measures.

7. 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 frequent 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 ~~to~~ support any international consideration for development of standards.

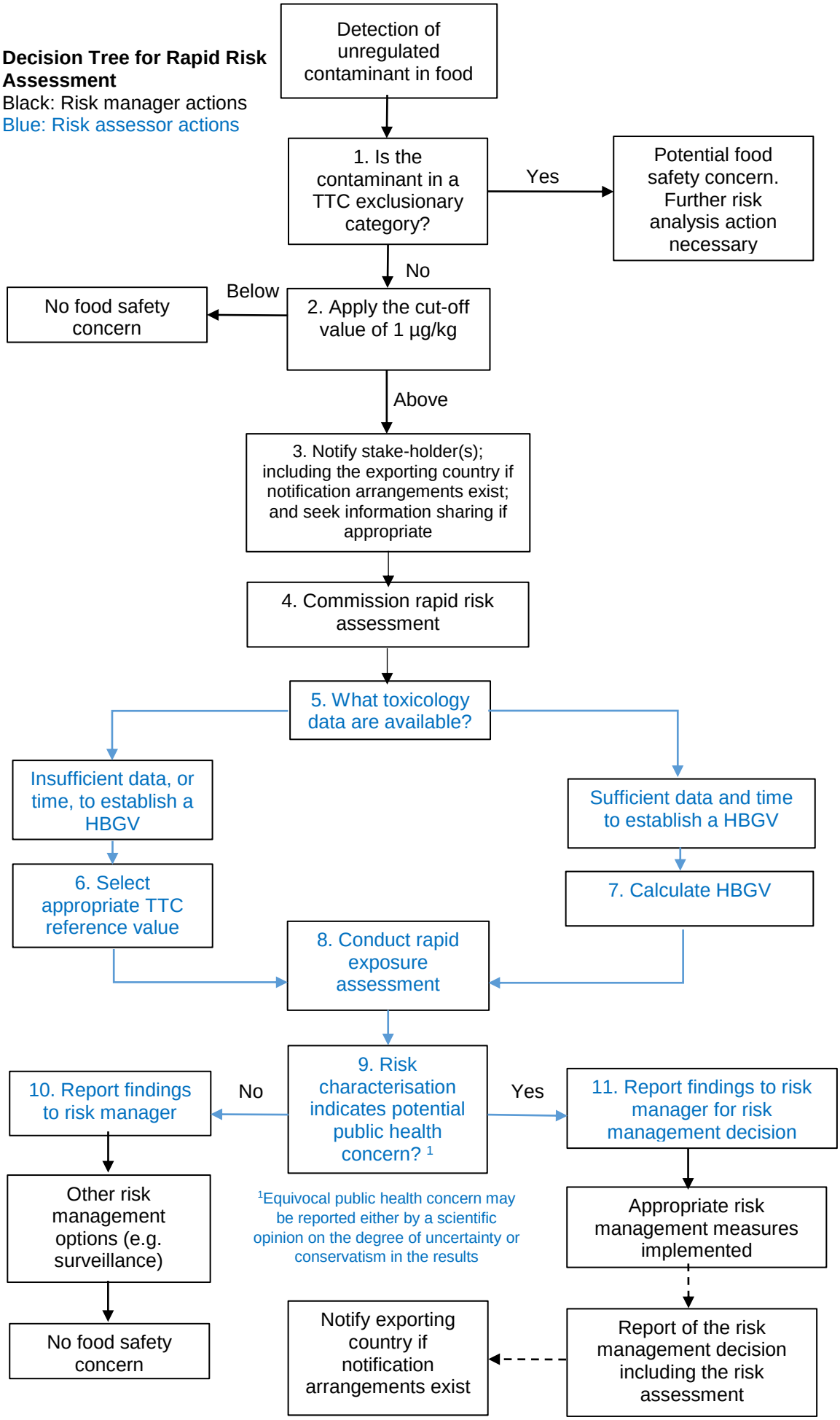
8. RISK COMMUNICATION

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.

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

Annex 1 Decision Tree for Rapid Risk Assessment

Decision Tree for Rapid Risk Assessment
Black: Risk manager actions
Blue: Risk assessor actions



Annex 2 Derivation of the cut-off value

A cut-off value is the concentration below which the vast majority of contaminants detected in a consignment at low levels are considered to not represent a health concern. The underlying premise of the cut-off value is that the contaminant is at the time of detection only observed in a single or limited number of consignments. Thus the unregulated contaminant would only be present in a small fraction of a typical varied diet. The cut-off value provides a practical approach for the application of risk management for contaminants in foods where limited information is available and a rapid assessment is required. As analytical methodology increases in sensitivity the practicality of the cut-off value is expected to increase.

The formula used to derive the cut-off value is adapted from the calculation in Annex 2 of the scientific justification for the guideline levels for radionuclides in foods contaminated following a nuclear on radiological emergency within General Standard for Contaminants and Toxins in Food and Feed (CXS 193-1995). The scenarios in which the Guidelines for Risk Analysis of Unregulated Contaminants in Food will be applied share similarities to those of the radionuclide guidelines, namely dealing with a contaminant exposure through a proportion of the diet, over ~~a~~ less than a lifetime timeframe.

The cut-off value would thus be calculated using the following formula:

Cut-off value = (TTC/ (BWM x CAF)) x CF

Cut-off value = 1 µg/kg = (0.0025 µg/kg bw/day / (25 g/kg bw/day x 0.1)) x 1000

Where:

TTC is the TTC value for DNA-reactive mutagenic or carcinogenic substances (0.0025 µg/kg bw/day). This value is selected as being the most protective for toxicity in the diet, with any exposures below this having a low probability of adverse health effects. Annex 4 identifies that for all the contaminants reviewed by JECFA, which are not within exclusionary categories, that a value of 0.0025 µg/kg bw/day is protective compared to acute and chronic health based guidance values, and was 10^4-10^6 fold below points of departure for contaminants without HBGVs.

BWM is the Body Weight adjusted mass of food consumed per day (g/ kg bodyweight /day). A value of 25 g/kg bw/day is calculated for this variable based on a 550 kg annual mass of foodstuffs consumed by an adult (as reported in Annex 1 of the Radionuclide Guidelines in CXS 193-1995) converted to a rounded daily intake of 1.5 kg, and then adjusted to a body weight basis for a 60 kg adult using the assumed average adult body weight in EHC 240.

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. Consistent with the calculation for the radionuclide guidelines a value of 0.1 (10%) is used on the basis that in a varied diet a single consignment is unlikely to constitute more than 10% of the total daily intake by an individual. Consistent with the radionuclide guideline, advice on the application of the cut-off value, is made in general text, with recommendations to consider foods that may make up a larger proportion of the diet for certain sub-populations on a case-by-case basis.

CF is the unit conversion factor (1000), this value converts the derived cut-off value from µg/g into µg/kg.

Annex 3 Case studies

EFSA Panel on Contaminants in the Food Chain (CONTAM), Scientific Opinion on the risks for animal and public health related to the presence of Alternaria toxins in feed and food, EFSA J. 2011, 9(10), 2407–2504, https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2011.2407

EFSA Panel on Contaminants in the Food Chain (CONTAM), Scientific Opinion on the risks to human and animal health related to the presence of beauvericin and enniatins in food and feed, EFSA J. 2014, 12(8), 3802–3976, https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2014.3802]

New Zealand Ministry for Primary Industries occurrence and risk characterisation of migration of packaging chemicals in New Zealand Foods:

http://www.mpi.govt.nz/dmsdocument/21871-occurence-and-risk-characterisation-of-migration-of-packaging-chemicals-in-new-zealand-foods

Annex 4 Worked examples using JECFA assessed contaminants

The conservative nature of the TTC Genotoxic/DNA reactive class (0.0025 µg/kg bw/day) is compared to JECFA established HBGV, or in their absence the identified toxicological point of departure (POD). Contaminants within exclusionary categories (metals, aflatoxin and dioxins) have not been considered.

Contaminant	JECFA HBGV	Magnitude of protection from TTC Genotoxic/DNA reactive class (0.0025 µg/kg bw/day)
1,3-DCP	No HBGV - Genotoxic carcinogen; POD: $BMDL_{10}$ 3.3 mg/kg bw/day	Margin of 10^6 to POD
3-MCPD/3-MCPD esters	4 µg/kg bw/day	1600x lower than HBGV
Acrylamide	No HBGV - Genotoxic carcinogen; POD: $BMDL_{10}$ 0.18/0.31 mg/kg bw.day	Margin of 10^4-10^5 to POD
Cyanogenic glycosides	ARfD: 0.09 mg/kg bw HCN eqv. PMTDI: 20 µg/kg bw/day HCN eqv.	36000x lower than ARfD 8000x lower than PMTDI
DON	ARfD: 8 µg/kg bw PMTDI: 1 µg/kg bw/day	3200x lower than ARfD 400x lower than PMTDI
Ethyl carbamate	No HBGV - Genotoxic carcinogen; POD: $BMDL_{10}$ 0.3 mg/kg bw/day	Margin of 10^5 to POD
Fumonisins	PMTDI: 2 µg/kg bw/day	800x lower than PMTDI
Furan	No HBGV - Genotoxic carcinogen; POD: $BMDL_{10}$ 0.96 mg/kg bw/day	Margin of 10^5 to POD
Glycidyl esters	No HBGV - Genotoxic carcinogen; POD: $BMDL_{10}$ 2.4 mg/kg bw/day	Margin of 10^5 to POD
Ochratoxin A	PTWI: 0.112 µg/kg bw/week (0.016 µg/kg bw/day)	6x lower than PTWI
PAHs	No HBGV - Genotoxic carcinogen; POD: 100 µg B[a]P/kg bw/day	Margin of 10^4 to POD
Patulin	PMTDI: 0.4 µg/kg bw/day	160x lower than PTWI
Sterigmatocystin	No HBGV - Genotoxic carcinogen; POD: $BMDL_{10}$ 0.16 mg/kg bw/day	Margin of 10^5 to POD
Styrene	PMTDI: 40 µg/kg bw/day	16000x lower than PMTDI
T-2, HT-2, DAS	PMTDI: 0.06 µg/kg bw/day	24x lower than PMTDI
Zearalenone	PMTDI: 0.5 µg/kg bw/day	200x lower than PMTDI

APPENDIX II

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