CODEX ALIMENTARIUS COMMISSION

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Agenda Item 12 **CX/CF 18/12/12**

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON CONTAMINANTS IN FOODS

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PROPOSED DRAFT GUIDELINES FOR RISK ANALYSIS OF CHEMICALS INADVERTENTLY PRESENT IN FOOD AT LOW LEVELS

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

Codex members and Observers wishing to submit comments at Step 3 on this proposed draft should do so as instructed in CL 2018/8-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 Committee on General Principles (CCGP), 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 (REP 16/GP, para 61).
2. At the 48th Session of Committee on Pesticides (CCPR), New Zealand introduced CRD16 that was presented at CCGP30 (April 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 (CCEXEC) and the 39th Session of the Codex Alimentarius Commission (CAC39) (REP 16/PR, para 195).
3. At CCEXEC71, 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. He indicated that the 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. It 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 (REP 16/EXEC, paras 49, 53 and 54).
4. At CAC39, the Commission agreed with the recommendation of CCEXEC to forward the document (CRD20) to CCCF for further examination (REP 16/CAC, para 207).
5. At CCCF11, New Zealand presented a revised version of the project document prepared following a workshop held prior to CCCF11. The Committee 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 the CAC for approval (Appendix XI); and agreed to establish an EWG chaired by New Zealand, co-chaired by the Netherlands, working in English, to advance this work (REP 17/CF, paras 152 and 153).
6. CCEXEC73 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*. CCEXEC73 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 (REP 17/EXEC2, paras 59 and 60).
7. CAC40 approved the new work, taking into account the critical review of CCEXEC73 (REP 17/CAC, para 83).
8. An EWG chaired by New Zealand and co-chaired by The Netherlands was established. The list of participants in the EWG is presented in Appendix II.

PURPOSE

9. Lowered detection limits for chemicals have led to the detection of residues in food for chemicals that have been present in that food for some time, but simply had not been detected before. Food imports are usually monitored for compliance with the importing country's residue requirements, and new analytical methodologies will detect residues that had been previously undetectable and not expected in the food being analysed. Often, these unexpected residues will not have been assessed for safety and will not be regulated.

10. The consequences of unexpected detections of unregulated chemicals in foods on import will often be that the food shipment is rejected at the border. This will often lead to the destruction of the food, and ongoing trade disruptions until the presence of the chemical can be eliminated. If the detected residue does not pose a consumer health risk, then the destruction of that shipment is an unnecessary waste.

11. The purpose of these guidelines is to give importing countries an internationally acceptable means of determining if the residue in imported food poses a consumer health risk and if there is no risk, enable a robust decision to allow the shipment to continue to market and enable appropriate subsequent action to be taken to avoid future disruption to trade.

Discussion and conclusions

12. In developing the proposed draft guidelines, the EWG considered the following key questions and came to the following conclusions:

13. Q1: How do we define inadvertent presence and non-regulated chemical?

Proposed text:

Non-regulated chemicals: A contaminant in the food under investigation, not subject to a quantitative level or guideline for risk management in Codex or National food standards

Inadvertent presence: A non-regulated chemical in any food for which there has been an initial or occasional detection at a low level in the food under investigation.

Summary Nine members and five observers provided responses to the question. The majority of the comments proposed refinements to the definitions, with one member noting a definition for inadvertent presence is not necessary given this is largely covered within the definition of contaminant. One member commented that certain national standards may be derived from arbitrary values, such as current analytical sensitivity, as a result a toxicological basis for the standard is required to ensure its relevance for risk assessment. One member commented that regional standards may also apply to an individual country and should be captured.

Conclusion The suggested definition made by one member for "non-regulated" seems useful, but with a change to the end to read "…established in Codex, or for an individual country, a national food standard informed by toxicological assessment". A National standard set in one country should not apply to other National authorities, and so needs to be separated from the Codex Standards in the definition. The proposed wording is:

Emerging food contaminant

A contaminant in the food under investigation, which is a novel or recently emerged occurrence, or has not previously reported or anticipated to be detected at the time of regulatory consideration of prior uses; and,

For which there is no quantitative level or guideline for risk management established in Codex, or for an individual country, a regional or national food standard informed by toxicological assessment.

The definition of inadvertent presence is deleted as it is inherent within the definition of a contaminant. Commentary on the long-term use of the guidelines to respond to a continuous presence of a chemical in food is already included in section 9 so it is not necessary to specify a temporal limit in the definition.

14. Q2: Is a cut-off level for a first risk management decision step appropriate

Summary: Nine members and four observers provided a response to the question. Seven members and four observers supported setting a cut-off level, while two members and one observer also noted this concept should be developed to provide guidance on how and when to apply cut-offs and potentially allow a range of cut-off levels for different end points. One member identified that additional considerations such as processing factors could be necessary in dealing with raw or semi-processed commodities. Two members and four observers specifically noted the cut-offs could be taken from the Threshold of Toxicological Concern (TTC) concept. One member noted that it is impracticable to establish one cut-off level which can universally apply to emerging food contaminant because there are various types of contaminants with quite different toxicity and exposure level.

Conclusion: There is broad agreement that retaining a cut off level in the guideline would be of value for risk management of emerging contaminants.

15. Q3: If a cut-off level is an agreed decision step how do we derive it? (possible request for advice from FAO/WHO).

    a. A cut-off level based on the TTC genotoxic threshold

    b. A cut-off level derive by other methodology?

    c. Are different cutoff levels appropriate for non-genotoxic/genotoxic substances?

Summary Nine members and four observers provided responses to this question. Four members and three observers supported having multiple cut-off levels for genotoxic and non-genotoxic classes, while two members noted other cut-off levels, either organophosphate and carbamates, or other effects such as teratogenicity and acute toxicity. Six members and three observers supported the cut-off values being derived from the TTC classifications. Three members noted the benefits of referring to the Joint FAO/WHO Committee on Food Additives (JECFA) for advice on establishing cut-off values and one country provided specific example calculations for how cut off values might be derived. Two observers noted that *de minimis* levels exist already in some members. One member and one observer reflected that specific guidance on the food intake scenario would be important. One member noted that work is being undertaken on expanding the TTC databases and that deferring the establishment of the cut off values until this is completed in 2018 may be beneficial.

Conclusion The setting of cut off values from the TTC classes is widely supported, however in support of this it is also proposed to request advice from JECFA on establishment criteria for a cut off value, noting that further work on the TTC databases is being undertaken in 2018.

16. Q4: Should these guidelines provide for a harmonized methodology(s) (TTC or other; or combination) to perform a rapid evaluation (e.g. by provision of appendices)? If a harmonized approach is desirable, should JECFA (or other risk assessment bodies) play a role in identifying and reviewing harmonized approaches?

Summary Eight members and four observers provided a response to the question. A harmonized approach is strongly supported, with two members and four observers specifically identifying the TTC as a good fit for this. One member noted a harmonized approach should be evaluated with a description on the applicability and limitation, especially regarding a cut-off levels and TTC. The recommendation to seek JECFA advice was also supported, with five members indicating a request for JECFA guidance would be beneficial in identifying and reviewing harmonized approaches. One member noted that if the TTC was selected than a request for advice may not be necessary given the WHO has already supported this tool. Two members and three observers noted that JECFA already uses the TTC in flavouring assessments. One member noted that elaborating a text on risk assessment methodologies might be out of terms of reference of CCCF. The guidance on choosing risk assessment methods could be separated from these guidelines (Codex recommendations) as a reference to a FAO/WHO document.

Conclusion A harmonized methodology is supported. It is proposed that JECFA be asked for advice as to their potential role in identifying and reviewing harmonized approaches.

17. Q5: To what extent do we include guidance on choosing alternative methods to the TTC (possible request for advice from FAO/WHO)? Do we need the description of these methods as an annex to the guidelines or as a reference to a possible publication by FAO/WHO?

Summary Eight members and three observers provided a response to this question. Eight members supported that information on alternative methods could be offered including applicability and limitations, with the common suggestion being an overview of the methods, or by reference to a separate publication. One member identified that the benefit of including an extensive range of methods, for which a high level of expertise may be required to choose between, may negate the intention that the guideline allows a rapid risk assessment. The three observers supported that the TTC is the optimum method and that guidance could be included to extrapolate from partial safety data sets. One member noted that elaborating a text on risk assessment methodologies might be out of terms of reference of CCCF. The guidance on choosing risk assessment methods could be separated from these guidelines (Codex recommendations) as a reference to a FAO/WHO document.

Conclusion Guidance on alternative methods to the TTC and how to select will be developed and included in an appendix in the guidelines.

Q6: Should feed be included within the scope of the guidelines?

Summary Nine members and four observers provided a response to this question. Two members believed feed should be included, a further two members suggested that it be included only if human food would be affected and three members and one observer recommended that it should not be included. One member commented on the difficulty that dual use crops/commodities could present whereby feed use may be prohibited while the commodity is deemed acceptable for entry into the food supply and that a cut-off value for feed whilst potentially conservative would be a better option than a zero tolerance. Two members and three observers supported the principle of feed being included but cautioned that the methodology would likely differ and may delay the development of the food guidelines, with one observer noting that two distinct approaches may be advantageous.

Conclusion As the identified risk assessment methodologies are essentially designed for human risk assessment, at this stage feed should not be included. At the point where risk assessment methodologies are demonstrated as appropriate to be extrapolated to livestock the guidelines could be expanded to allow application to feed. There may however be value in considering extrapolation of any cut-off values to feed and this can be included within the request for advice from JECFA.

Recommendations to CCCF:

18. The Committee should consider the proposed draft guidelines in Appendix I and in particular to decide upon the following issues:

    - Agree to the definition of an emerging contaminant,
    - Agree on the use of a cut-off value as an initial risk management step,
    - Agree that an internationally agreed rapid risk assessment methodology is used,
    - Agree that feed is excluded from the proposed draft guidelines.

19. The Committee should seek scientific advice from JECFA on the following:

    - The criteria for establishing appropriate cut-off values, with the specific questions developed and timeframes,
    - The role of JECFA in identifying and reviewing an internationally agreed rapid risk assessment methodology.

APPENDIX I

PROPOSED DRAFT GUIDELINES FOR RAPID RISK ANALYSIS OF EMERGING CONTAMINANTS IN FOOD

1. INTRODUCTION

When chemicals that are not regulated in any food are inadvertently found in a food commodity they are generally classed as emerging, or unexpected contaminants. With continued development of analytical methodology the increasing range and sensitivity of chemical screens will likely lead to a greater number of contaminant detections in food.

Detections may be of chemicals not anticipated in the past to eventuate in foods at detectable concentrations and thus any presence would be considered inadvertent. There may be chemicals that may contaminate food and that may not be subject to specific food safety regulation. Some of these chemicals may be of potential public health interest. In addition to those that may enter during primary production of foods, there are those that may inadvertently enter during food processing e.g. traces of cleaning agents.

Many such emerging contaminants will not be regulated at either a Codex or national level. There may be a number of reasons why an emerging, or unexpected, contaminant is not regulated, including a novel or recent emergence as a food contaminant, or lack of resources to support regulatory intervention on non-priority contaminants.

Where detection of an emerging contaminant in food necessitates a rapid risk management response, a fit for purpose risk analysis process should be applied. In situations where there is limited or no toxicological data available the risk analysis process must accommodate this limitation, and ensure protection of public health while any unjustified effects on trade are minimised. Further the risk analysis process should be able to be applied within the competence of most countries and within a restricted timeframe. Given this scenario under time constraints a full risk assessment is neither a practicable or feasible option. The Threshold of Toxicological Concern approach is a valid screening tool, based on scientific risk assessment principles, to assess low dose chemical exposures, and to distinguish those for which further data are required to assess the human health risk from those with no appreciable risk.

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

2. PURPOSE OF THIS GUIDELINES

These guidelines provide an approach to assist governments in the rapid risk analysis of emerging contaminants in food.

These guidelines should be read in conjunction with the following relevant texts:

1. Working Principles for Risk Analysis for Food Safety for Application by Governments (CXG 62-2007)
2. The WTO Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement);
3. Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius (Codex Alimentarius Commission Procedural Manual. Twenty-fifth edition);
4. Principle and Guidelines for National Food Control Systems (CXG 82-2013);
5. Principles for Food Import and Export Inspection and Certification (CXG 20-1995);
6. Guidelines for the Design, Operation, Assessment and Accreditation of Food Import and Export Inspection and Certification (CXG 26-1997);
7. Guidelines for Food Import Control Systems (CXG 47-2003);
8. Guidelines for the Exchange of Information between countries on rejections of imported foods (CXG 25-1997);
9. Principles and Guidelines for the Exchange of Information in Food Safety Emergency Situations (CXG 19-1995);
10. Guidelines for Setting Disputes over Analytical (Test) Results (CXG 70-2009);
11. Principles and guidelines for the exchange of information between importing and exporting countries to support the trade in food (CXG 89-2016); and
12. Principles for Traceability / Product Tracing as a Tool Within a Food Inspection and Certification System (CXG 60-2006)

3. SCOPE

Contaminants subject to these guidelines are those falling within the mandate of the Codex Committee on Contaminants in Foods and for which there are no specific Codex standards, recommendations or guidelines[1]; and a specific risk management context.

The following examples are groups of chemicals that would be considered emerging contaminants if present in food:

(i) 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

(ii) Emerging contaminants from materials used during processing of food e.g. non-regulated packaging materials and printing inks, oils/lubricants/resins used as manufacturing maintenance compounds

(iii) Emerging natural toxins e.g. newly characterised mycotoxins or food crop phytotoxins

(iv) Environmental contaminants e.g. corrosion inhibitors, flame retardants and musks/fragrances

Chemicals identified to have a role in economically motivated adulteration of food, and present at a level reflective of adulteration, are not covered by these guidelines.

4. DEFINITIONS

These definitions should be read in conjunction with the definitions for risk analysis in the "Codex Procedural Manual, latest edition".

For the purposes of this document, and falling within the broader definition for contaminants within the procedural manual:

Emerging contaminant

- A contaminant in the food under investigation, which is a novel or recently emerged occurrence, or has not previously reported or anticipated to be detected at the time of regulatory consideration of prior uses; and,
- For which there is no quantitative level or guideline for risk management established in Codex, or for an individual country, a regional or national food standard informed by toxicological assessment.

Rapid evaluation method

- A risk assessment methodology for provision of scientific advice within a limited time period, that informs a food safety risk management decision on a specific lot or consignment of food.

5. PRINCIPLES

a. A fit for purpose risk analysis process should be applied as rapidly as possible to the detection of low levels of emerging contaminants in food

b. Detection information acted upon by risk managers should satisfy the requirements of official food control programmes for sampling and validation

c. A cut-off value(s) of no public health concern should be established for emerging contaminants in food and applied early in the risk analysis process

d. Where there is a detection of an emerging contaminant in a traded consignment the competent authority in the exporting country should be notified and any relevant food safety information shared

e. The availability of toxicological data should be taken into account in the choice of a rapid evaluation method

f. Risk assessors carrying out the rapid evaluation method should have appropriate competency and experience

g. Decisions by risk managers on low levels of emerging contaminants in food should be proportional to the evaluated level of risk to public health these chemicals present.

[1] Note that some countries may have national standards in the absence of Codex standards

h. Where there are continuing detections of an emerging contaminant in food, targeted surveillance activities should be undertaken to determine the extent of potential human exposure and the source of exposure

i. Where there are continuing detections of emerging contaminants in food and risk management options such as maximum levels might be necessary, risk managers should consider the commissioning of a full risk assessment to characterise the potential hazard and risk, determine possible impacts on human health and to subsequently inform risk management actions e.g. address toxicological data gaps, obtain additional exposure information, development of a specific standard

6. ROLES

In most cases, it will be the competent authority that is the risk manager and decisions on the safety or otherwise of the food consignment in question will be taken under food safety legislation

When carrying out risk management activities, the competent authority should ensure that relevant stakeholders are notified of the detection of an emerging contaminant in food as soon as possible and evaluation methodologies are carried out in a timely manner. This is particularly important in the case of food in trade.

Stakeholders other than the competent authority may carry out non-regulatory monitoring activities for a range of reasons e.g. satisfying provisions of supplier contracts. If the detection in food of emerging contaminants is reported by other stakeholders, the competent authority should ensure that such results as reported are validated in an officially approved / recognised laboratory before mounting a risk management response.

7. REPORTING OF DETECTION(S)

Risk managers should be informed of detections of concentrations of emerging contaminants found in official / officially recognised food monitoring and surveillance programmes as a routine procedure. As such, the presence of the emerging contaminant will have been validated in an approved / recognised laboratory and the samples will have been subject to quality assurance provisions as required by an official regulatory programme. Sample provenance 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
- Test method and its analytical performance
- Number of detections and total number of samples tested
- Summary statistics of occurrence data
- Identification of chemical class / chemical type.

In supplying this information, the officially recognised laboratory may provide a scientific/technical opinion on the possible source(s) of the chemical substance detected

8. APPLICATION OF THE DECISION TREE FOR RISK MANAGEMENT DECISION MAKING

On confirmation of the presence of an emerging contaminant in food the risk manager should apply the decision tree to inform a risk management decision in a timely manner. See Appendix 1

8.1. Exclusionary categories (Step 1 of the Decision Tree)

As identified in the Threshold of Toxicological Concern (TTC) method certain chemical groupings may not be suitable for rapid evaluation given chemical or toxicological properties. Unless there is prior experience with rapid evaluation of the chemical grouping, a risk manager should exclude applying the decision tree to the following categories of emerging contaminants:

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

If a chemical is within an exclusionary category a formal risk assessment may be necessary.

8.2. Application of the cut-off value (Step 2 of the Decision Tree)

The risk manager should apply the cut-off value to the detected concentration of the emerging contaminants in the food under investigation.

If the detection of the emerging contaminant exceeds the cut-off value:

- then rapid evaluation should be sought.
- the risk manager should inform relevant stakeholders of the detections and their submission for rapid evaluation as soon as possible[2].

Where the detection does not exceed the cut-off value a risk management decision can be made that the consignment does not present a food safety concern. Informing the relevant stakeholders of the detection may still be of value

8.3. Country of origin information sharing (Step 3 of the Decision Tree)

In the case of food in trade, in addition to notifying of the detection of an emerging contaminant in food, the risk manager should request any relevant food safety information 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 and any history of use.

8.4. Request for rapid evaluation (Step 4 of the Decision Tree)

The risk manager should seek rapid evaluation of the detection in the first instance, for completion as soon as possible and practicable. The risk manager will provide any country of origin information obtained to the risk assessor

8.5. Toxicological data collection (Step 5 of the Decision Tree)

The risk assessor will access any readily available toxicology data on the emerging contaminant that will inform the choice of the rapid evaluation method.

8.6. Other relevant food safety information

The risk assessor will access any other readily available food safety data on the emerging contaminant that will inform the choice of the rapid evaluation method. This may include, but is not limited to, prior occurrence, exposure data and processing information.

8.7. Rapid evaluation: Selection of a hazard characterisation method, exposure assessment and risk characterisation (Steps 6-10 of the Decision Tree)

If there is no toxicological information available the TTC method should be used to obtain a hazard characterisation value. (Step 6)

If a health based guidance value for the emerging contaminant is available, or sufficient toxicological data is available to establish one, hazard characterisation should be undertaken using the health based guidance value. (Step 8)

If toxicology data is available, but it is insufficient to establish a health based guidance value, there are a range of options available to rapidly derive a hazard characterisation for a chemical. (Step 7; Example methodologies are summarised in appendix 3)

With the dataset available the risk assessor should undertake an exposure assessment of the emerging contaminant in the food of interest and characterise the risk in relation to the hazard characterisation outcome from the rapid evaluation method (Steps 9 and 10). Any assumptions and uncertainties in the exposure assessment should be recorded.

8.8. Application and reporting of rapid evaluation (Steps 11 and 12 of the decision tree)

Where a rapid evaluation methodology is available and applied, the risk assessor should report back to the risk manager within an agreed limited time frame.

The risk assessor should provide the results to the risk manager in a clear and standardised manner.

The risk assessor may provide a scientific opinion on the degree of uncertainty in the results of the rapid evaluation.

[2] In the case of food in trade, The Codex Committee on Food Import and Export Inspection and Certification systems (CCFICS) provides guidance on exchange of food safety information between Competent Authorities

8.9. Decision by the risk manager

The risk manager should take into account the scientific opinion provided by the risk assessor and decide on the risk management response. This includes:

(i) Judging the food consignment / lot as fit for human consumption on the basis of negligible risk to human health

(ii) Judging the food consignment / lot as unfit for human consumption on the basis of a potential risk to human health

(iii) Seeking further information on the possible level of the contamination in further consignments / lots so as to better establish whether there is a potential public health concern and a formal risk assessment may be required

The risk manager should communicate the option taken and any decision on fitness or otherwise of the consignment / lot as soon as possible and practicable. In the case of food in trade, The Codex Committee on Food Import and Export Inspection and Certification systems (CCFICS) provides guidance on exchange of food safety information between competent authorities (Principles and guidelines for the exchange of information between importing and exporting countries to support the trade in food (CXG 89-2016)).

9. FURTHER RISK MANAGEMENT ACTIVITIES

The risk management scenario may result in targeted surveillance to gain more information on the possibility of further events and more closely evaluate the level of dietary exposure over time.

Where a detection of an emerging contaminant becomes a frequent or consistent occurrence in food, new information becomes available on the toxicity of the contaminant, or there are indications that dietary exposure may be at a level that constitutes a potential risk to human health; consideration should be given to undertaking toxicological studies and/or planning for a formal risk assessment.

10. RISK COMMUNICATION

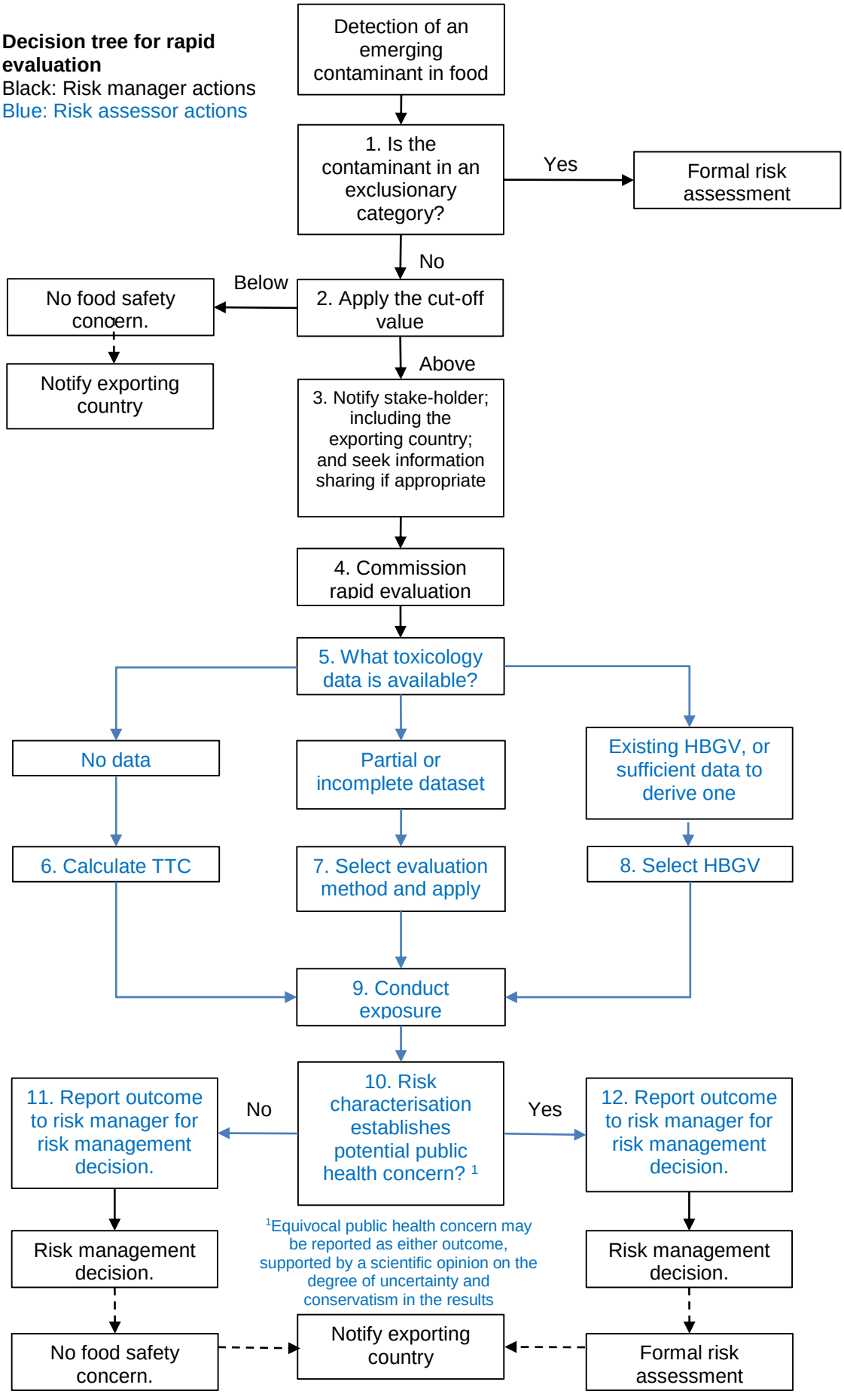
Consumers and other stakeholders have a high level of interest in the presence of chemicals in food and the outcomes of the risk assessment and risk management activities of competent authorities. Thus the communication of risk management decisions for emerging contaminants that might be found in foods should be appropriately addressed in broader risk communication plans.

11. TRAINING

The competency and experience of risk assessors applying the rapid evaluation methodology within the decision tree is a key input to consistent and transparent scientific advice being provided to risk managers. It is likely that the risk assessors will be employees of the competent authority but in the case that non-government personnel are contracted to provide risk assessment advice, they should be subject to competency and experience requirements as specified by the competent authority.

Annex 1 of Appendix I: Decision tree

Decision tree for rapid evaluation
Black: Risk manager actions
Blue: Risk assessor actions



[1]Equivocal public health concern may be reported as either outcome, supported by a scientific opinion on the degree of uncertainty and conservatism in the results

Annex 2 of Appendix I: Case studies

United Kingdom Food Standards Authority interim assessment for tetrodotoxin:

https://www.food.gov.uk/sites/default/files/uk-provisional-risk-assessment-july-2016.pdf

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 3 of Appendix I: Internationally-recognised rapid evaluation methodologies and their suitability in the context of these guidelines

To be developed

APPENDIX II

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