



Report of Informal meeting on Agenda item 12, 11 March 2018

Prepared by New Zealand and the Netherlands

1. This CRD covers the discussions and feedback from the informal consultation meeting convened by New Zealand and the Netherlands to consider Agenda Item 12 on the Draft Guidelines for risk analysis of chemicals inadvertently present in food at low levels. The informal consultation was attended by some 75 participants from member countries and observer organizations.
2. After a general discussion on the draft guidelines the meeting focussed on the following key points which were also the key questions highlighted in the introduction to agenda Item 12:
 - a. Scope and supporting narratives.
 - b. The incorporation of a cut off value and its implementation
 - c. Identification of any alternative methodologies to the TTC.
 - d. The need for guidelines that provide a pragmatic approach.
3. The consensus of views as expressed by participants are summarised as follows:
 - Support for revisiting the title to provide more clarity on the purpose of the guidelines;
 - Providing a more focused description of scope and supporting narrative;
 - Removal of definitions;
 - Inclusion of criteria for establishing a numerical cut-off value;
 - Striving for a numerical level for the cut-off; in doing so ensure transparency of input values;
 - Recognising that the TTC decision tree at this time provides the only validated methodology for rapid screening;
4. Based on the comments and feedback from the informal consultations New Zealand and the Netherlands have prepared a draft text which incorporates these views within the current agenda item. These are presented as Appendix 1 for the consideration of the Committee.
5. At the request of the informal meeting, the examples presented to the meeting on establishment of a cut-off values are included as Appendix II. These examples are intended to assist the committee when discussing the option for establishing a cut off value.
6. As a further request from the informal meeting, the criteria that might be used to establish a cut off value are included in the revised draft.
7. The informal meeting recognised that at this stage there was no intention to make any formal request for scientific input from JECFA to support the guidelines.
8. This CRD is intended to inform and support discussion on Agenda Item 12 and provides in Appendix 1, an alternative working document that the CCCF 12 may decide to use as a basis for further development of the guidelines.

**PROPOSED DRAFT GUIDELINES FOR RAPID RISK ANALYSIS
OF EMERGING CONTAMINANTS IN FOOD****[PROPOSED DRAFT GUIDELINES FOR RISK ANALYSIS OF INSTANCES OF CONTAMINANTS IN
FOOD WHERE THERE IS NO REGULATORY LEVEL OR RISK MANAGEMENT FRAMEWORK
ESTABLISHED]****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.

Simple alternative text to the first two paragraphs- [The detection of chemicals in foods that are not already 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 protective of public health but also takes account of the practicalities of initial detections.]

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 pragmatic*] ~~a fit for purpose risk~~ [*-based approach*] ~~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~~ [*decision tree*] 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~~ [*instances of contaminants in food where there is no regulatory level or risk management framework established*].

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 guidelines¹;*
- *Those where the detections are a novel or recently emerged occurrence, or have not been previously reported in the food;*
- *Those found within a specific lot or consignment of food ;*

Where there are continuing detections of a contaminant in food, targeted surveillance activities should be undertaken to determine the extent of potential human exposure and the source of contamination. In conjunction, exploration of risk management options, such as maximum levels, might be necessary, e.g. commissioning of a full risk assessment to characterise the potential hazard and risk]

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.

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

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

- ~~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.~~

4. PRINCIPLES

- ~~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~~
- Detection information acted upon by risk managers should satisfy the requirements of official food control programmes for sampling and validation
- 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 for application as a first step
- Where there is a detection of [the] ~~an emerging~~ contaminant in a traded consignment the competent authority in the exporting country should be notified and any relevant food safety information shared
- ~~The availability of toxicological data should be taken into account in the choice of a rapid evaluation method~~
- Risk assessors carrying out the rapid evaluation method should have appropriate competency and experience
- [The risk assessment and risk management decision should be documented in a transparent and systematic manner]*
- ~~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.~~
- ~~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~~
- ~~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~~

5. 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 ~~[the] an emerging~~ contaminant in food as soon as possible and evaluation methodologies are [is] 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 [the]~~ contaminant 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 [doing]~~ a risk [analysis] management response.

6. 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

7. [DERVIATION OF THE CUT-OFF VALUE

7.1 General considerations

A pragmatic step in the establishment of a rapid screening methodology is the derivation of a cut-off value for the test result or cluster of results below which the consignment or lot of food does not constitute a public health concern. Establishing this cut-off value should take into account the very limited exposure scenario and the need to apply any risk management measures proportional to risks to human health.

The cut-off value must be sufficiently conservative so that any chemical exposure that could be a food safety concern is flagged for further rapid evaluation, the TTC decision tree genotoxicity threshold provides a benchmark for this. A fit for purpose cut-off value should cater for foods for infant consumption as well as foods for the general population. Tests below the cut-off value should indicate to risk managers that no expert risk assessment is required and safe food is not unduly wasted.

7.2 Criteria for establishment of a cut-off value

The cut-off should represent a conservative estimate of negligible risk for all chemicals, excepting categories that are excluded from appropriate consideration within the TTC decision tree.

The cut-off should be based on a realistic estimate for dietary intake for the general population, for the consignment in question. Therefore the average daily portion size should be adjusted for the likely proportion of the total daily dietary intake resulting from the affected consignment or batch.

Where relevant to the contaminant finding, the cut-off value should account for infant body weight and consumption patterns.

The cut-off value should be easily applied by risk managers without recourse to specialist advice.

7.3 Example cut-off value

The application of the above criteria can be realised by cut-off values of [0.3 / 1 µg/kg] as presented in the example in Appendix 2.]

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

On confirmation of the presence of ~~an emerging~~ [the] 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~~ [decision tree] 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 possible².

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 [~~the~~ ~~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~~ [Application of the TTC decision tree], exposure assessment and risk characterisation (Steps 6-9 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 7)

~~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)~~

~~[In the absence of a health based guidance value, or sufficient toxicological data to establish one, the TTC decision tree should be applied to arrive at an appropriate threshold of no concern for the contaminant (Step 6).]~~

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 [~~threshold of no concern established through the TTC decision tree~~] ~~hazard characterisation outcome from the rapid evaluation method~~ (Steps 8 and 9). Any assumptions and uncertainties in the exposure assessment should be recorded.

8.8. ~~Application and Reporting of rapid evaluation~~ (Steps 10 and 11 of the decision tree)

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

~~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 [, *in an agreed time frame*].

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

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~~ [*the*] 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.

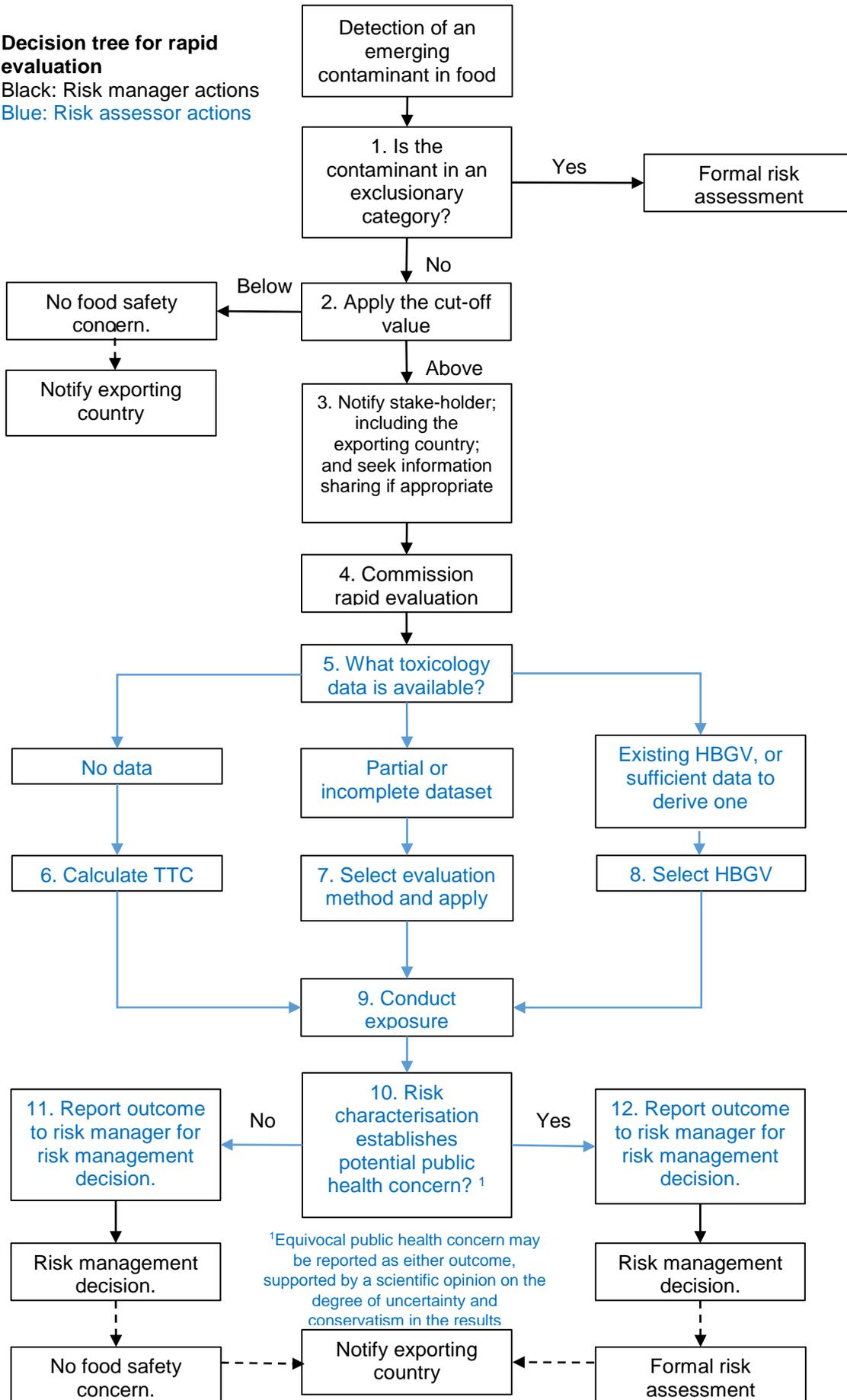
11. TRAINING

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

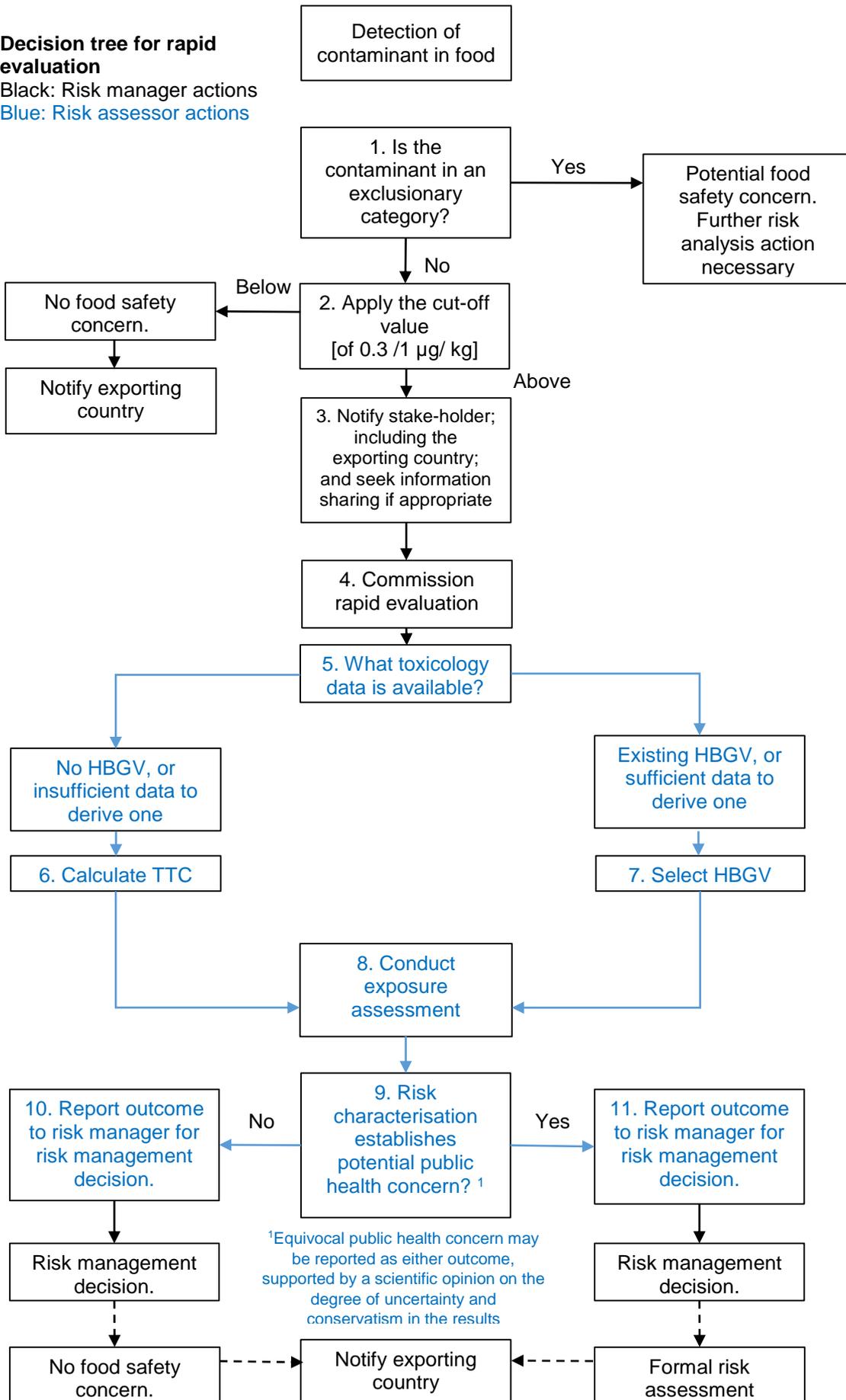


[Annex 1 of Appendix I: Decision tree

Decision tree for rapid evaluation

Black: Risk manager actions

Blue: Risk assessor actions



[Annex 2 of Appendix I: Example of derivation of cut-off value

A cut-off value can be calculated using the following formula:

$$\text{Cut-off value} = (TNC / (BWM * CAF)) * CF$$

Where:

TNC is the Threshold of No concern ($\mu\text{g}/\text{kg}$ bw/day)

BWM is the Body Weight adjusted mass of food consumed per day (g/ kg bodyweight /day)

CAF is the Consignment adjustment factor ¹ (dimensionless).

CF is the unit conversion factor (1000)

¹ The consignment adjustment factor (CAF) is defined as the ratio of the maximum mass of the daily diet that would be impacted through the instance of a detection of a contaminant in a consignment or lot to the total daily mass of foodstuffs consumed.

Example cut-off value calculations:

Foods for infant consumption

$$\text{Cut-off value} = 0.3 \mu\text{g}/\text{kg} = (0.0025 \mu\text{g}/\text{kg} \text{ bw}/\text{day} / (72 * 0.1)) * 1000$$

TNC = TTC decision tree genotoxicity threshold: 0.0025 $\mu\text{g}/\text{kg}$ bw/day

BWM = 72 g/kg bodyweight/ day = total daily diet intake: 550g/day* / bodyweight: 7.64 kg[#]

* A rounded daily intake value calculated from the annual mass of foodstuffs consumed by an infant in the first year of life, as reported in Annex 1 of the Radionuclide Guidelines in CXS 193-1995.

[#] Average of median bodyweights for male and female 5-6 month old infants, reported according to the Joint FAO/WHO/UNU expert report on human energy requirements (FAO/WHO/UNU, 2004).

CAF = 0.1

CF = 1000

Foods for consumption by the general population

$$\text{Cut-off value} = 1 \mu\text{g}/\text{kg} = (0.0025 \mu\text{g}/\text{kg} \text{ bw}/\text{day} / (25 * 0.1)) * 1000$$

TNC = TTC decision tree genotoxicity threshold: 0.0025 $\mu\text{g}/\text{kg}$ bw/day

BWM = 25 g/kg bodyweight/ day = total daily diet intake: 1500g/day* / bodyweight: 60 kg[#]

* A rounded daily intake value calculated from the annual mass of foodstuffs consumed by an adult, as reported in Annex 1 of the Radionuclide Guidelines in CXS 193-1995.

[#] Assumed average adult bodyweights (EHC 240, 2009).

CAF = 0.1

CF = 1000]

Annex [3] 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-occurrence-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