

CODEX ALIMENTARIUS

INTERNATIONAL FOOD STANDARDS



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

CXG 92-2019

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1. INTRODUCTION

The detection of chemical contaminants in foods where there is no regulatory level is increasing due to both the diversity of the food supply and the continuing advancement of analytical capabilities. Risk managers must respond to such detections in a manner that is adequately protective of public health but that at the same time also takes account of the practicalities of import admissibility processes.

Where detection of a chemical contaminant in food where there is no regulatory level necessitates a rapid risk management response, e.g. to consider import admissibility a pragmatic risk-based approach should be applied. This approach:

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

The guidelines incorporate a rapid risk analysis approach using a cut-off value¹ and the Threshold of Toxicological Concern (TTC), to assess low levels of chemical exposures, and to identify if further data are required to assess human health risk.^{2,3}

2. PURPOSE

The guidelines provide an approach to assist governments in the rapid risk analysis of instances of detection of chemical contaminants in food where there is no regulatory level.

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 Agreement on the Application of Sanitary and Phytosanitary Measures of the World Trade Organization* (WTO/SPS Agreement);
- *Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius* (Codex Alimentarius Commission Procedural Manual.);
- *Principles 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 Settling 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);
- *Guidelines on the Application of Risk Assessment to Feed* (CXG 80-2013);
- *Guidance for Governments on Prioritizing Hazards in Feed* (CXG 81-2013);
- *General Guidelines on Sampling* (CXG 50-2004)

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

² Principles and methods for the risk assessment of chemicals in food. Environmental Health Criteria 240. Chapter 9.

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

3. SCOPE

Contaminants subject to these guidelines are:

- Those detected in food where there is no regulatory level; and,
- 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 and are unexpected (i.e. not a recurring or an intermittent occurrence); and,
- Those found within a specific lot or consignment of food or food ingredient,

Contaminants detected in situations where the risk manager is investigating the possibility of intentional adulteration of food are excluded.

Examples of (groups of) contaminants included in the scope of these guidelines

- Contaminants that may occur in materials used or created during processing of food and that may be inadvertently present in the food (e.g. printing inks, oils/lubricants/resins used as manufacturing maintenance compounds, cleaning compounds, traces of chemicals used in the manufacturing facility);
- Chemicals used to mitigate specific environmental, sustainability and climate change issues, (e.g. nitrification and urease inhibitors), which have not been anticipated to be present in food;

4. PRINCIPLES

The following principles apply:

- These guidelines apply to food for human consumption that is currently in trade;
- Contaminant detection information used in this scheme should satisfy the requirements of the relevant official food control programs for sampling and analysis;
- Where there is an instance of the detection of a contaminant in a traded consignment of food where there is no regulatory level the competent authority in the exporting country can be notified and any relevant food safety information shared;
- The risk assessment and risk management decisions, including data and information used to support the decision, should be documented in a transparent and systematic manner and made available upon request;
- Where there are continuing or frequent detections of a contaminant in food where there is no regulatory level, targeted surveillance activities should be undertaken to determine the extent of potential human exposure and the source(s) of contamination.

5. ROLES

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

In many cases the risk manager will be the competent authority performing the official control/ surveillance programs 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 contaminant in food where there is no regulatory level 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 programs for a range of reasons e.g. satisfying provisions of supplier contracts. If the detection of the contaminant in food is reported by other stakeholders, the competent authority can consider such results in a preliminary assessment but should ensure that the reported results are confirmed in an accredited or equivalent level laboratory before doing a final assessment.

6. REPORTING OF DETECTION(S)

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

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

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

7. APPLICATION OF THE DECISION TREE FOR RAPID RISK ANALYSIS

On confirmation of an instance of the detection of a contaminant in food where there is no regulatory level the risk manager should, in a timely manner, apply the rapid risk analysis approach in the accompanying decision tree (see Annex). The rapid risk analysis approach allows for prioritization of only those instances where further in-depth investigations are warranted.

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

Contaminants for which there are established health-based guidance values (HBGVs), toxicological points of departure (POD) or benchmark dose levels (BMDLs) can progress directly to rapid exposure assessment (Step 9)⁴ as these values enable risk characterization.

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

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

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

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

⁴ Taking note of the appropriate assessment factors

7.3. Application of the cut-off-value (Step 3 of the Decision Tree for Rapid Risk Analysis)

If quantitative measurement of the contaminant in food where there is no regulatory level exceeds the cut-off value of 1 µg/kg, the risk manager should inform relevant stakeholders of such measurements and request that all available information be shared for rapid risk assessment as soon as possible.

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

Where measured levels do not exceed the cut-off value of 1 µg/kg a risk management decision can be made that the consignment does not require a specific risk management response. The cut-off value does not necessitate the analytical laboratory achieving a limit of detection of 1 µg/kg.

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

Beyond notifying relevant stakeholders about the instance of detection of the contaminant in food where there is no regulatory level, the risk manager should request any relevant food safety information, if available, from the competent authorities of the exporting country. Relevant food safety information may include, but is not limited to, toxicological datasets, prior occurrence in food, food processing information and any history of use.

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

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

7.6. Toxicological data collection (Step 6 of the Decision Tree for Rapid Risk Analysis)

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

7.7. Selection of the TTC value / Establishment of a HBGV/POD/BMDL, exposure assessment and risk characterization (Steps 7-10 of the Decision Tree for Rapid Risk Analysis)

If sufficient toxicological data are available for the contaminant in food where there is no regulatory level, it should be determined if establishment of an ad-hoc HBGV/POD/BMDL is feasible in the agreed timeframe⁵. If a HBGV/POD/BMDL can be established the risk characterization should be undertaken using this value.

In the absence of sufficient toxicological data to establish a HBGV/POD/BMDL for the contaminant in food where there is no regulatory level, dietary intake against an appropriate threshold of no concern or reference value for any outcome whether genotoxic or non-genotoxic, should be selected for the contaminant based on its structural properties (Step 7).⁶

With the available dataset the risk assessor should undertake an exposure assessment⁷ of the contaminant in the food of interest, possibly considering exposure from other foods if data are available and characterize the risk in relation to the TTC or HBGV/POD/BMDL selected through the Decision Tree for Rapid Risk Analysis (Steps 9 and 10). Any assumptions and uncertainties in the rapid risk assessment should be recorded.

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

⁶ Evaluation of certain food additives. 82nd report of the Joint FAO/WHO Expert Committee on Food Additives. <https://apps.who.int/iris/handle/10665/250277>

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

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

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

7.9. Decision by the risk manager

The risk manager should consider the results of the rapid risk assessment provided by the risk assessor and decide whether a risk management response is warranted. This includes for example:

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

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

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

8. FURTHER RISK MANAGEMENT ACTIVITIES

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

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

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

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

9. RISK COMMUNICATION

Consumers and other stakeholders have a high level of interest in information on the presence of 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 contaminants in food where there are no regulatory levels.

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

DECISION TREE FOR RAPID RISK ANALYSIS

