



**JOINT FAO/WHO FOOD STANDARDS PROGRAMME
CODEX COMMITTEE ON CONTAMINANTS IN FOODS**

Eleventh Session

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**Emerging Issues: A proposed risk management approach to address chemicals inadvertently present in food at very low levels
(Proposal from New Zealand)**

Introduction

1. One of the strategic objectives of the Codex Alimentarius Commission (CAC) is to proactively identify emerging issues and members' needs, and where appropriate, develop relevant food standards¹.
2. The 39th session of the CAC noted the recommendations of CCEXEC71 and acknowledged the importance of the above issue as raised in CAC/39 CRD20. The CAC agreed on the need to address this emerging issue and referred the document to the Codex Committee on Contaminants in Foods (CCCF) for further consideration.

Purpose

3. The purpose of this paper is to seek CCCF support for, and agreement to develop internationally harmonised risk management approach to address chemicals inadvertently present in food at very low levels².
4. Advanced analytical methods and testing technologies increasingly result in unexpected detections in food. Risk-based evaluation of such results often indicate no reason for public health concern and should not result in undue precaution in terms of food safety and/or food security, nor in an unnecessary negative impact on trade.

Background

5. The potential for very low levels of chemicals to inadvertently get into food at various stages of production and processing (e.g. cleaning agents) has long been recognised by regulatory authorities around the world. This potential is increasing as new technologies related to food production and processing are adopted and innovation in broader aspects of food systems expands e.g. dealing with climate change and protection of the environment.
6. Over recent years, regulatory authorities and scientific bodies, both at national and international levels have developed pragmatic approaches to responding to such detections in the absence of established international regulatory frameworks. However, risk management responses differ between countries and this can lead to undue consumer concern and trade difficulties.
7. The CAC is ideally placed to consider and promote an internationally harmonised approach for regulators to respond to unexpected detections of chemicals in food at very low levels in situations where there are no Codex standards and/or existing international regulatory frameworks for risk management decisions. A sound body of science can now be drawn upon to assist with developing a harmonised international regulatory approach.

¹ Codex Alimentarius Commission Strategic Plan 2014-2019, Strategic Goal 1, Objective 1.2

² See paragraph 11

Chemicals inadvertently present in food at very low levels: scientific issues

8. There are many chemicals that can be present in food following proper and legitimate use that can inadvertently enter the food chain. Established Codex standards and guidance for residues of pesticides, veterinary drugs and contaminants are essential to regulatory risk management³. There is, however, a growing imperative to look beyond those chemicals already dealt with by existing Codex standards and guidelines and address risk management issues arising from those chemicals that may be inadvertently present in food at very low levels and for which no regulatory recommendations exist. In many cases, the chemicals may have been in long term use without previously being able to be detected in foods or they may be “old” chemicals that are now used in new ways.
9. The scope of this proposal includes the following group of chemicals when they are inadvertently present in food and for which no international regulatory recommendations exist:
 - *chemicals* that inadvertently get into food during production and processing. Typically these chemicals could include cleaning agents, and surface coatings e.g. quaternary ammonium compounds;
 - *chemicals* that are currently in use in agriculture to address specific environmental and climate change related issues e.g. nitrification or urease inhibitors; and
 - *fertilisers* and other chemicals that are commonly used to promote plant growth and improve yields; very low levels of these chemicals and/or impurities within them might be detected in food.
10. Advances in analytical methods and testing technologies mean that compounds are now able to be detected at very low concentrations (parts per billion) with hundreds of compounds able to be screened simultaneously. At the levels detected, many of these chemicals are highly unlikely to represent any risk to public health but may lead to unjustified restrictions on food supply and trade. Against this background there is a clear imperative to promote internationally-agreed guidelines to address this risk management issue.
11. The issue of what constitutes “very low levels” will be developed during the work programme. There may be a range of views on this issue depending on the screening methodology used.

Contemporary approaches

12. As noted earlier in this paper, some regulatory authorities already have pragmatic processes for addressing detection of very low levels of chemicals in the absence of regulatory standards. Currently the Threshold of Toxicological Concern (TTC) approach has significant international attention as one possible approach. This can be used to assess potential human health concerns for chemicals (in the absence of specific toxicology data) based on their structures and potential human exposures.
13. The TTC approach has been recently reviewed by an expert consultation convened by the European Food Safety Authority (EFSA) and the World Health Organization (WHO), with the participation of the US Food and Drug Administration (FDA) to update and extend the TTC framework.⁴ The report of this consultation was released in March 2016, and recommends a globally harmonised decision tree framework for the application of the TTC in the risk assessment of chemicals.⁵
14. The TTC approach is not a substitute for the risk assessment and establishment of regulatory limits for regulated compounds such as pesticides and food/feed additives. In particular, it is not applicable when compound specific assessment and toxicity data are available or are required under existing international regulatory frameworks. However, the TTC approach offers a means of assessing potential human health risks that might be associated with the finding of inadvertent and very low levels of chemicals in foods.

³ Codex Committees on Pesticide Residues (CCPR), Residues of Veterinary Drugs in Food (CCRVDF), and Contaminants in Foods (CCCF) are the traditional bodies responsible for establishing maximum limits and establishing international guidelines for risk management. Pesticides in animal feed are managed by CCPR, CCRVDF has responsibility for veterinary drugs in feed and the feed additive ethoxyquin, an antioxidant. CCCF has responsibility for contaminants in feed if they lead to residues in food.

⁴ <http://www.efsa.europa.eu/en/supporting/pub/1006e>

⁵ It is also noted that the WHO/EFSA Expert Consultation suggests that the way forward for a broader consideration of this approach is for further discussions to now take place between risk assessors and risk managers to agree on the application of the TTC and its consequences.

15. It is emphasised that the TTC approach is one of several possible approaches. The proposed new work will provide the opportunity to review the range of risk assessment approaches currently available. Other known approaches include the following:
- The use of computer modelling such as the QSAR (quantitative structure activity relationships) toolbox;
 - Read-across; and
 - Margin of exposure approach.

Next Steps

16. Codex, as the pre-eminent international food standards body, has a clear interest and responsibility to address the issues raised in this paper and support the development of an internationally harmonised risk management approach.
17. As noted in para 2 above, the 39th session of the CAC recognised the importance of the issues raised in CRD 20 and the need for Codex to address the issues raised. It referred the paper and Project Document for further consideration by the 11th session of CCCF.
18. To help the process of consideration and advancement of the new work proposal by CCCF, New Zealand, as the initiator of the proposal, has prepared this revised document that takes account the subsequent informal comments and feedback on the proposal contained in CRD 20. It is recommended that this revised document be used for deliberations at the 11th session of CCCF.

Recommendation

19. **Noting** the decision of the 39th session of the CAC⁶ that the proposal in this paper is an important emerging issue, **it is recommended that the CCCF:**
- a. **Endorse** new work on the development of Risk Management Guidelines to address chemicals inadvertently present in food at very low levels; and
 - b. **Forward** the attached Project Document to the CAC for approval.

⁶<http://www.fao.org/fao-who-codexalimentarius/meetings-reports/detail/en/?meeting=CAC&session=39>

PROJECT DOCUMENT**GUIDELINES (BEST PRACTICE) FOR RISK ANALYSIS OF CHEMICALS⁷ INADVERTENTLY PRESENT IN FOOD AT LOW LEVELS**

(Prepared by New Zealand)

1. Purpose

The purpose of this work is to provide guidelines which will promote an internationally harmonised approach to addressing possible public health and trade issues arising from detections of low levels of chemicals inadvertently present in the food of interest.

The work will be based on a review of current regulatory approaches and global best practices taking into account risk analysis principles and frameworks. Case studies and examples that will inform development of the guidelines will be sought as appropriate.

2. Scope

Chemicals⁷ which are inadvertently present at low levels in the food of interest and are not subject to international recommendations or national legislation

3. Its relevance and timeliness

The potential for very low levels of chemicals to inadvertently get into food at various stages of production and processing (e.g. cleaning agents) has long been recognised by regulatory authorities around the world. Regulatory authorities and scientific bodies, at national levels have, over the years, developed sound, pragmatic approaches to responding to such detections. However, there is no internationally harmonised approach.

The Codex Alimentarius Commission (CAC) is ideally placed to consider and promote an internationally harmonised approach for regulators to address possible public health and trade issues when responding to inadvertent presence and detections in food of low levels of chemicals for which no international recommendations or national legislation exists. In almost all previous cases, such situations do not constitute a risk to public health. There is now a sound body of science that can be drawn upon to assist with developing a harmonised international regulatory approach.

4. The main aspects to be covered

The proposed work will review current regulatory approaches to risk analysis of chemicals that may inadvertently be present in the food of interest.

Regulatory authorities already have pragmatic and well established processes for addressing chemicals inadvertently present in food at low levels and for which no regulatory standards or guidelines exist. In respect of risk assessment currently the Threshold of Toxicological Concern (TTC) approach appears to have the most international attention. This can be used to assess potential human health concerns for chemicals (for which there is little if any toxicology data) based on their structures and potential human exposures. The TTC approach is not a substitute for the risk assessment and establishment of regulatory standards for regulated compounds such as pesticides and food/feed additives. In particular it is not applicable when compound-specific assessment and toxicity data are available or are required under existing international regulatory frameworks.

The TTC approach has been recently reviewed by an expert consultation convened by the European Food Safety Authority (EFSA) and the World Health Organization (WHO), with the participation of the US Food and Drug Administration (FDA) to update and extend the TTC framework⁸. The report of this consultation was released in March 2016, and recommends a globally harmonised decision tree framework for the application of the TTC in the risk assessment of chemicals.

The TTC approach is one of several approaches available for risk assessment of chemicals to determine if they are of any public health concern. The proposed new work will provide the opportunity to review the range of risk tools currently available. Other known approaches include the following:

⁷ Chemicals within the mandate of the CCCF and excluding chemicals fraudulently added to food

⁸ <http://www.efsa.europa.eu/en/supporting/pub/1006e>

- The use of computer modelling such as the QSAR (quantitative structure activity relationships) toolbox;
- Read-across; and
- Margin of exposure approach.

In respect of risk management considerable guidance can be developed on best practices on taking up scientific advice and making risk management decisions that take in to account public health, trade concerns and other factors such as food wastage. Risk management may also include other actions such as increased monitoring and traceability requirements.

Both risk assessment and risk management should be guided by predetermined risk assessment policy. For example, are the chemicals in the food of interest subject to regulation in other food types?

The guidelines will include a section on risk communication. This is a challenging area for risk managers communicating decisions in the absence of regulatory limits in the foods of interest.

5. **An assessment against the *criteria for the establishment of work priorities***

General Criterion

Relevance to the Codex Strategic Objectives

The proposed work would contribute to the Commission's ***Strategic Goal 1 to establish international food standards that address current and emerging food issues*** by promoting a harmonised approach to risk analysis.

Advanced analytical methods and testing technologies increasingly result in detections that are of very low exposure and very low potential health concern. An internationally harmonised risk analysis approach is important to avoid undue precaution in terms of food safety and/or food security and help minimise any unnecessary negative impact on trade. It will also help national authorities to make efficient use of limited national resources.

Criteria applicable to general subjects

a. *Diversification of national legislations and apparent or potential impediments to international trade*

As noted in the covering paper regulatory authorities in a number of countries have already in place sound science based approaches to address detection of very low levels of chemicals inadvertently found in food. A globally harmonised approach to address such detections is particularly relevant against the background of advances in analytical methods and testing technologies and the imperatives of climate change and sustainable agricultural practices and need to reduce food losses and wastage.

b. *Scope of work and establishment of priorities between the various sections of work*

See 1 above

c. *Work already undertaken by other international organizations in this field and/or suggested by the relevant international intergovernmental body (ies)*

See information presented in 3 above

d. *Amenability of the subject of the proposal to standardisation*

The proposed work would draw on the experience gained from current regulatory approaches. Members would benefit from an internationally harmonised risk analysis approach to address chemicals inadvertently present in food at very low levels.

e. *Consideration of the global magnitude of the problem or issue*

As noted in this paper, the issue of detection of very low levels of chemicals inadvertently present in food is of significant interest to the wider membership of Codex as advances in analytical methods lead to detection of ever decreasing levels in food of chemicals which may be of very low public health concern. An internationally harmonised approach will be helpful to:

- Promoting a science and risk based approach to responding to such inadvertent presence and detections in food;
- Promote efficient use of limited global and national risk analysis resources to addressing chemicals of greatest public health concern;

- Minimise any potential impediments to international trade;
- Support the global goal of reducing food losses and wastage through rejection of food without adequate technical justification; and
- Enhance risk communication to consumers and promote confidence in national regulatory approaches.

6. **Information on the relation between the proposal and other existing Codex documents**

The proposed work will be strongly linked to and guided by, but not limited to the:

- *Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius*; and
- *Working Principles for Risk Analysis for Food Safety for Application by Governments*.

7. **Identification of any requirement for and availability of expert scientific advice**

It is expected that the CCCF will, as part of its deliberations, review current approaches to risk assessment and risk management of chemicals inadvertently found in food at low levels and for which no international regulatory frameworks and/or standards exist.

8. **Identification of any need for technical input to the standard from external bodies so that this can be planned for the proposed timeline for completion of the new work**

None identified at this stage.

9. **Proposed timeline for completion of work**

Approval, in principle, of new work proposal by the CAC	July 2016
Consideration of new work proposal by the relevant Codex Committee (the Codex Committee on Contaminants) and commencement of new work by the Committee over two sessions	March 2017
Adoption of draft guidelines at step 5	July 2018
Proposed date for adoption of draft guidelines at step 8	July 2019