



JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX ALIMENTARIUS COMMISSION

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Emerging Issues: A proposed Risk Management Approach to Address Detection in Food of Chemicals of Very Low Public Health Concern

(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.

Purpose

2. The purpose of this paper is to seek support for an internationally harmonised approach for regulators to address possible public health and trade issues when responding to detections of traces of chemicals presenting very low exposure and very low potential public health concern that may inadvertently be present in food.

3. Advanced analytical methods and testing technologies increasingly result in detections that are of very low exposure and very low potential public health concern but such detections can place unjustified strain on resources and cause unnecessarily negative impacts on trade.

Background

4. The potential for trace 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 potentiality is increasing as new technologies related to food production and processing are adopted and innovation in broader areas expands e.g. dealing with climate change and protection of the environment.

5. Regulatory authorities and scientific bodies, both at national and international levels have, over the years, developed pragmatic approaches to responding to detections in food, of trace levels of chemicals that constitute a very low exposure and very low public health concern.

6. The 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 detections in food of traces of chemicals of very low potential public health concern. In almost all situations, such traces do not constitute a risk to public health and there is now a sound body of science that can be drawn upon to assist with developing a harmonised international regulatory approach.

Chemicals of very low public health concern: scientific issues

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

7. There are many chemicals that can be present in food following proper and legitimate use that can inadvertently enter the food chain. The traditional focus on standards for residues of pesticides, veterinary drugs and contaminants remain essential for Codex and regulators². There is, however, a growing imperative to look beyond those chemicals already dealt with by existing Codex processes and address issues arising from the use and detection of chemicals of very low exposure and very low potential public health concern, that may be inadvertently present in food at trace levels.

8. Technological advances in food production, processing and residue detection mean that ever decreasing levels of many chemicals may be inadvertently present and detectable in food and drinking water. 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 and focus of the proposed new work is on the following groups of chemicals when they are present inadvertently in food:

- *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; traces of these chemicals and/or impurities within them might be detected in food.

10. The proposed new work will not include any chemicals that may fall into the above categories and which are subject prior regulatory approval requirements.

11. 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 these chemicals are highly unlikely to represent any risk to public health but may lead to unjustified restrictions on food supply and trade.

12. There is an important need to promote internationally-agreed guidelines to address this generic risk management issue.

Contemporary approaches

13. As noted earlier in this paper, regulatory authorities already have pragmatic and well established processes for addressing detections in food of traces of chemicals that are determined to be of very low public health concern. Currently the Threshold of Toxicological Concern (TTC) approach appears to have significant international attention as one possible approach. This approach 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.

14. 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.³ 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.⁴

15. 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 regulations. However, it does appear to offer an alternative means of assessing potential human health risks that might be associated with the finding of inadvertent traces of chemicals in foods.

16. Finally it should be emphasised that the TTC approach is but one of several possible approaches available for risk assessment of chemicals to determine if they are very low public health concern. The proposed new work will provide the opportunity to review the full range of risk assessment approaches.

² 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, CCRVDR 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.

³ <http://www.efsa.europa.eu/en/supporting/pub/1006e>

⁴ 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.

The Way Forward: Strategic options in Codex

17. 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.

18. As a way forward, it is proposed that this paper and the associated project document be endorsed, *in principle*, as new work by the 39th session of the CAC.

19. The CAC might discuss different options for progressing the work, including referral to one or more committee(s) such as the Codex Committee on Contaminants in Foods (CCCF), for further consideration and advancement as new work.

20. Noting the suggestion from the WHO/EFSA Expert Consultation (above), an important first step for the development of international risk management guidelines would be to convene an *ad hoc* expert consultation of risk assessors and risk managers to review current approaches to risk assessment and risk management of chemicals of very low exposure and very low potential public health concern and provide recommendations for consideration at the international level.

21. With this in mind, an *ad hoc* expert consultation (under the auspices of FAO/WHO and with possible funding from interested members) could be convened at an early stage. The expert consultation would be helpful to clarifying the nature and extent of the problems and issues raised in this paper and review current approaches to risk assessment and risk management of chemicals of very low exposure and very low public health concern and provide recommendations regarding possible harmonised approaches for consideration at the international level. The output of this consultation would provide valuable input to the Codex committee(s) undertaking the development of international guidance.

Recommendation

22. It is recommended that the Executive Committee:

- a. **Note** the issues raised in this paper and the potential problems in international food trade arising from the inadvertent presence and detection of traces of chemicals in food that are of very low public health concern;
- b. **Endorse**, *in principle*, new work by Codex to develop risk management guidelines to address detection in food of trace levels of chemicals of very low exposure and very low potential public health concern;
- c. **Decide** on an appropriate Codex process to pursue the new work, including the option of referral to the CCCF; and
- d. **Note** the proposal for an *ad hoc* expert consultation (with support from interested members) at an early stage to support the proposed new work.

PROJECT DOCUMENT

A PROPOSED RISK MANAGEMENT APPROACH TO ADDRESS DETECTION IN FOOD OF CHEMICALS OF VERY LOW PUBLIC HEALTH CONCERN

(Prepared by New Zealand)

1. The purposes and scope of the standard

The purpose and scope of this standard is to promote an internationally harmonised approach to addressing possible public health and trade issues arising from detections of traces of chemicals presenting very low exposure and very low potential public health concern that may inadvertently be present in food. The proposed new work:

- Excludes intentional and fraudulent addition of chemicals to foods; and
- does not cover any chemicals that are subject to prior regulatory approval requirements;

The scope of the work would primarily 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 would be sought as appropriate.

2. Its relevance and timeliness

The potential for trace 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 detections of trace levels of chemicals that constitute a very low exposure and very low public health concern. However, these are not internationally harmonised and accepted.

The Codex Alimentarius (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 detections in food of traces of chemicals of very low potential public health concern. In almost all situations, such traces do not constitute a risk to public health and there is now a sound body of science that can be drawn upon to assist with developing a harmonised international regulatory approach.

3. The main aspects to be covered

The proposed work will review current regulatory approaches to risk assessment and risk management of chemicals of very low potential public health concern that may inadvertently be present in food.

As noted earlier in this paper, regulatory authorities already have pragmatic and well established processes for addressing detections in food of traces of chemicals that are determined to be of very low human health concern. 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 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 regulations

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 framework⁵. 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 very low public health concern. The proposed new work and the related *ad hoc* expert consultation will provide the opportunity to review the full range of risk assessment approaches.

⁵ <http://www.efsa.europa.eu/en/supporting/pub/1006e>

4. 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 management of chemicals presenting very low exposure and very low potential public health concern, that may inadvertently be present in food.

Advanced analytical methods and testing technologies increasingly result in detections that are of very low exposure and very low potential health concern but such detections can place unjustified strain on resources and cause unnecessarily negative impacts on food supply and trade.

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 traces of chemicals of very low public health concern. A globally harmonised approach to address detection of traces of chemicals of very low public health concern 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 management approach to address detection of traces of chemicals of very low public health concern that may inadvertently be present in food.

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

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

- Promoting a science and risk based approach to responding to the detection in food of traces of chemicals that may be inadvertently present and are determined to be very low public health concern;
- 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
- Enhance risk communication to consumers and promote confidence in national regulatory approaches

5. 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*.

6. Identification of any requirement for and availability of expert scientific advice

It is proposed to convene, at an early stage in the process, an *ad hoc* expert consultation of risk assessors and risk managers under the auspices of the FAO and WHO (and funded by possible contributions from interested Codex member governments) to review current approaches to risk assessment and risk management of chemicals of very low exposure and very low potential public health concern and provide appropriate recommendations for consideration by relevant Codex committee(s)

7. 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

8. 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 (e.g. 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