



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

**Eleventh Session**

**Rio de Janeiro, Brazil, 3 – 7 April 2017**

**MATTERS REFERRED TO THE COMMITTEE BY THE CODEX ALIMENTARIUS COMMISSION  
AND/OR ITS SUBSIDIARY BODIES**

**A. MATTERS ARISING FROM THE CODEX ALIMENTARIUS COMMISSION**

**MATTERS FOR INFORMATION**

**Standards and related texts adopted at Steps 8, 5/8 (with omission of Steps 6/7) and 5 of the Procedure**

1. CAC39 (July 2016) adopted the following maximum levels and related texts:

- Draft maximum level for inorganic arsenic in husked rice (at Step 8) on the understanding that the ML would be reviewed three years after the implementation of the Code of Practice for the Prevention and Reduction of Arsenic Contamination in Rice (under development) as agreed by CCCF and would take into account all available data from all regions. Reservation to this decision were expressed by Egypt, European Union, Norway, India, Philippines and Sri Lanka. Consumers International and the National Health Federation expressed their strong concern on this decision<sup>1</sup>;
- Draft revised Code of Practice for the Prevention and Reduction of Mycotoxin Contamination in Cereals (CAC/RCP 51-2003) (general provisions) and the proposed draft Annexes on Zearalenone, Fumonisin, Ochratoxin A, Trichothecenes and Aflatoxins (specific provisions) at Steps 8 and 5/8 respectively<sup>2</sup>;
- Proposed draft revised maximum levels for lead in fruit juices and nectars, ready-to-drink (inclusion of passion fruit); canned fruits (inclusion of canned berries and other small fruits); canned vegetables (inclusion of canned leafy vegetables and canned legume vegetables); jams, jellies and marmalades; pickled cucumbers (lower ML) and table olives (lower ML) (at Step 5/8)<sup>3</sup>; and
- Proposed draft maximum levels for preserved tomatoes (lower ML and deletion of the note on the adjustment of the ML to take into account the concentration of the product) and jams, jellies and marmalades (lower ML and inclusion of marmalades) (at Step 5) on the understanding that countries concerned would submit relevant data in reply to a call for data in order to finalize these MLs at the 11<sup>th</sup> Session of the Committee on Contaminants in Foods (April 2017)<sup>4</sup>.

2. The Committee is invited to note the information above. Proposed draft MLs for preserved tomatoes and jams, jellies and marmalades will be considered under Agenda Item 5.

**Revocation of standards and related texts**

3. The Commission revoked the MLs for lead in the General Standard for Contaminants and Toxins in Food and Feed (CODEX STAN 193-1995) in view of the adoption of revised MLs at Step 8 and 5/8 (see paragraph 1)<sup>5</sup>.

4. The Committee is invited to note the information above.

**Consistency of the risk analysis texts across the relevant committees**

Committee on General Principles

5. CCGP30 (April 2016) agreed to recommend to CAC39 that the Secretariat should address minor numbering issues in the texts for the Committees on Contaminants in Foods, Residues of Veterinary Drugs in Foods and Pesticide Residues with the relevant committees.<sup>6</sup>

<sup>1</sup> [REP16/CF](#), paras. 30 – 45, Appendix II; [REP16/CAC](#), paras. 58 – 66, Appendix III

<sup>2</sup> [REP16/CF](#), paras. 120 – 128, Appendix IV; [REP16/CAC](#), Appendix III

<sup>3</sup> [REP16/CF](#), paras. 46 – 90, Appendix III; [REP16/CAC](#), paras. 67 - 74, Appendix III

<sup>4</sup> [REP16/CF](#), paras. 46 – 90, Appendix III; [REP16/CAC](#), paras. 67 – 74, Appendix IV

<sup>5</sup> [REP16/CF](#), paras. 46 – 90, Appendix III; [REP16/CAC](#), para. 94, Appendix V

<sup>6</sup> [REP16/GP](#), paras. 40 - 58

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6. The Commission endorsed the recommendations of CCGP that the Secretariat should address minor numbering issues in the texts for CCCF, CCRVDF and CCPR with the relevant committees.

7. The Commission further noted that CCGP had completed work on the consistency of the risk analysis principles within Codex.<sup>7</sup>

8. The Committee is invited to note the information above.

**MATTERS FOR ACTION*****Emerging issues: A proposed risk management approach to address detection in food of chemicals of very low public health concern***Executive Committee

9. The Member for South-West Pacific presented the matter noting that many of the chemicals that constitute a very low exposure and very low public health concern were currently not covered by Codex. He indicated that CCCF would be an appropriate starting point for work on this matter.

10. The Representative of FAO agreed that it was very timely and appropriate for Codex to consider, among others the TTC (threshold of toxicological concern) approach. The Representative further noted that while CCCF was one of the main committees concerned with this over-arching issue, other committees may have some interest in such work including the Committees on Pesticide Residues, Food Additives and Residues of Veterinary Drugs in Foods. He underlined the need to better hone the question and supported the approach of holding an FAO/WHO expert meeting of risk managers and risk assessors for this purpose.

11. The Representative of WHO reiterated the timeliness and importance of the matter. New technologies now allowed for screening for low level presence of chemicals and often there was zero tolerance in place for compounds that did not fall into any of the existing categories of chemicals for which the approaches to assessing and managing risks had been established, though they might not actually constitute appreciable risk. The suggested consultation would bring together risk assessors and risk managers to further analyse what a project proposal could contain. In this sense, CCCF could be the first point of reference.

12. CCEXEC71 (July 2016) 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.<sup>8</sup>

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13. CAC39 noted the recommendation of CCEXEC71 on the importance of the issue; the need for Codex to address it; and that the issue should be further examined by CCCF based on a conference room document (CRD20) prepared by New Zealand.

14. Japan noted the following:

- (i) Chemicals discussed in the paper present very low exposure and were of very low toxicity;
- (ii) Such chemicals were present inadvertently in food and were consumed without any public health implications;
- (iii) A problem might arise from different regulatory systems between exporting and importing countries rather from a strict safety concern;
- (iv) The matter raised in CRD20 was more of a trade than a safety issue and could be better handled by the Committee on Food Import and Export Inspection and Certification Systems whose mandate included the development of principles and guidelines for food import and export inspection and certification systems with a view to harmonizing methods and procedures to protect consumer health, ensure fair trade practices, and facilitate international food trade;
- (v) CCFICS had also developed *Guidelines for the exchange of information between countries on rejection of imported food* (CAC/GL 25-1997) which might be relevant to the issue raised in CRD20;
- (vi) A FAO/WHO expert meeting should be convened to better hone the question, which will provide more information for Codex to decide on the scope of this work and on the best forum to handle this issue due to its broader and complex nature rather than putting the question to CCCF.

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<sup>7</sup> [REP16/CAC](#), paras. 169 - 181

<sup>8</sup> [REP16/EXEC](#), paras. 49 - 54

15. The Commission agreed with the recommendation of CCEXEC to forward [CRD20](#) to CCCF for further examination.<sup>9</sup>

16. For easy of reference, an extract of CRD20 is presented in the Annex to this document.

17. The Committee is invited to consider this matter.

## **B. MATTERS ARISING FROM SUBSIDIARY BODIES OF THE COMMISSION**

### **MATTERS FOR ACTION**

#### **FAO/WHO Coordinating Committee for Africa**

##### ***Proposed draft Regional Standard for Fermented Cooked Cassava Based Products***

18. CCAFRICA22 (January 2017) considered contaminants in fermented cooked cassava-based products and put the following questions to CCCF for consideration:

Section 4 – Contaminants: The Coordinating Committee:

##### *Hydrocyanic acid*

- (i) considered whether the existing provision for maximum levels of hydrocyanic acid content for gari in the GSCTFF (i.e. 2 mg/kg as hydrocyanic acid in the free-state) was applicable to fermented cooked cassava based products.
- (ii) was explained that while both gari and fermented cassava-based products are derived from cassava, their production processes were different. Fermented cassava-based products were foodstuffs obtained from fresh cassava roots which are peeled, cut, dipped in water for fermentation for 3 to 5 days, then pressed prior to packaging into natural leaves and finally cooked. Sometimes, for commercial reasons, the fresh packaged products are stored at freezing or deep-freezing temperature before cooking which would extend the shelf life (from 3 to 6 months).
- (iii) agreed to request the CCCF to consider if the existing maximum levels for hydrocyanic acid in gari (less than or equal to 2 mg/kg as hydrocyanic acid in the free state) could be extended to fermented cassava based products and if so, to consider extending this ML to cover also fermented cassava-based products or to consider whether another ML could be developed for these products.

##### *Mycotoxins*

- (i) noted that there were no established maximum levels for mycotoxins for this product in the GSCTFF. Some delegations expressed the view that there was no need to establish the MLs for this product as fermented cooked cassava based products were not susceptible to mycotoxin contamination, and that fermentation was one of the ways to reduce mycotoxins. It was further noted that mycotoxin contamination normally occurred at household level after the product has been opened.
- (ii) further noted that there was a gap in this regard and agreed to request CCCF to consider if these products were susceptible to mycotoxin contamination; and if so, to consider if an ML could be developed for this product.<sup>10</sup>

19. The Committee is invited to consider the matters raised in points (iii) (hydrocyanic acid) and (ii) (mycotoxins).

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<sup>9</sup> [REP16/CAC](#), paras. 204 – 207

<sup>10</sup> [REP16/AFRICA](#), paras. 71 – 74, Appendix II.

**ANNEX**  
**EXERCPT FROM CRD20**  
**JOINT FAO/WHO FOOD STANDARDS PROGRAMME**  
**CODEX ALIMENTARIUS COMMISSION**

**39<sup>th</sup> Session**  
**FAO Headquarters, Rome, Italy, 27 June – 1 July 2016**

**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 standards<sup>1</sup>.

**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**

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 regulators<sup>2</sup>. 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.

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<sup>1</sup> Codex Alimentarius Commission Strategic Plan 2014-2019, Strategic Goal 1, Objective 1.2

<sup>2</sup> 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.

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.<sup>3</sup> 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.<sup>4</sup>
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.

### 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 39<sup>th</sup> 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

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

<sup>4</sup> 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.

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.