

CODEX ALIMENTARIUS COMMISSION



Food and Agriculture
Organization of the
United Nations



World Health
Organization

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Agenda Item 12

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

18th Session

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REPORT OF THE PRE-SESSION WORKING GROUP ON THE REVIEW OF THE CODE OF PRACTICE FOR THE REDUCTION OF AFLATOXIN B1 IN RAW MATERIALS AND SUPPLEMENTAL FEEDINGSTUFFS FOR MILK-PRODUCING ANIMALS (CXC 45-1997)

(Prepared by the Chair of the WG on the review of Code of Practice CXC 45-1997, Canada)

BACKGROUND

1. CCCF17¹ agreed to re-established the EWG chaired by Canada, co-chaired by Saudi Arabia, to revise the discussion paper, propose revisions to the *Code of Practice for the Reduction of Aflatoxin B1 in Raw Materials and Supplemental Feedingstuffs for Milk-producing Animals* (CXC 45-1997), prepare a project document for new work and consider how different Codex CoPs for aflatoxins could be integrated or merged to avoid overlap, inconsistencies and redundancies.
2. This document summarizes comments received in response to the circular letter (CL) CL 2025/23–CF and the discussions of the virtual working group (VWG) which met the week before CCCF18.

COMMENTS IN RESPONSE TO CIRCULAR LETTER (CL 2025/23-CF)

3. The CL issued in advance of CCCF18 requested input on whether new work should be proposed to revise the CXC 45-1997. Specifically, it requested comments on the project document², the approach taken for the proposed revisions to the CoP to integrate related Codex CoPs to avoid inconsistencies, overlaps, and redundancies, whether the proposed revisions are reasonable and if improvements could be made (i.e. addition of new sections to the CoP, further development of revised sections, availability of data/information to support such revisions).³ It also asked if there is support for issuing a CL following CCCF18 requesting risk management practices and other data/information and for re-establishing the electronic working group (EWG) to further develop the CoP for consideration by CCCF19.
4. Ten (10) member countries provided comments in reply to CL 2025/23-CF: Argentina, Brazil, Canada, Chile, Ecuador, Egypt, Ghana, Thailand, Uruguay, the United States of America (USA) as well as two organizations: International Commission for Uniform Methods of Sugar Analysis (ICUMSA) and the International Dairy Federation (IDF/FIL). These comments are available on the CCCF18 website.⁴ Key comments are summarized below along with WG chair responses to the comments, when required.
5. There was overall support to move forward with revisions to the CoP, the approach taken to integrate related Codex CoPs, the new sub-sections proposed for inclusion and how the content in each section is being developed.
6. Some new information that would support further revisions was cited and revisions to text on control measures were suggested by several member countries and an observer organization. These suggestions will be addressed by next year's EWG, pending approval of new work by the CAC.
7. One (1) member suggested providing expanded information in 'Section 5.7.2-Decontamination Measures' and to include aflatoxin M1 removal techniques in milk, as these complement feed control practices and reduce the toxin in dairy products. This suggestion will also be considered for inclusion by next year's EWG, pending approval of new work by the CAC.

¹ REP24/CF17

² CX/CF 25/18/13, Appendix I – Project document

³ CX/CF 25/18/13, Appendix II – Proposed revisions to CXC 45-1997

⁴ CX/CF 25/18/13-Add.1

8. Two (2) member countries suggested streamlining and generalizing the information presented in certain sections of the CoP in order to be less prescriptive and also ensure information is within the scope of measures to reduce mycotoxin production. The WG chair notes that the CoP is 28 years old, the proposed updates to it include a significant amount of expanded and new information and is shorter than other Codex CoPs. Nonetheless, it will revise the CoP, pending approval of new work by the CAC, with the aim to include general and overarching control measures relevant to mycotoxin control in a level of detail that facilitates their widespread application, as advised by the Codex Secretariat.
9. Member countries suggested the following new topics be included in the CoP:
 - a. One (1) member suggested a new section on aflatoxin M1 detection methods in milk, highlighting specific, suitable methods
 - b. One (1) member suggested adding information on risk assessment and management guidelines, training and capacity-building programs and monitoring and compliance mechanisms
10. The chair also sought guidance from the Codex Secretariat to respond to these comments. The Secretariat indicated that CoPs are compilations of good management practices across the food chain (e.g. GAPs, GMPs) and that types of information in paragraph 9, above, can be briefly mentioned in the appropriate context and complementary information cross-referenced to relevant Codex texts to avoid duplication. Further, capacity building is a matter for the parent organizations (i.e. FAO, WHO), not for Codex, a standard-setting organization. Manuals or explanatory materials to support understanding or implementation of provisions in the CoP is outside the scope of Codex itself. The chair notes that the proposed revisions to the CoP include a recommendation to contact extension services, who are involved in training and capacity building at the regional level.
11. The WG chair also notes including detailed information about analytical methods is out of scope in a CoP; although there is no Codex sampling plan for aflatoxin M1 in milk, if one were developed this type of information could be included in it.
12. There was overall support for the project document presented in Appendix I of CX/CF 25/18/13, with the following revisions being suggested to the sub-sections below (bold text). The project document, with the itemized changes below recorded using the 'track changes' function, is included as Appendix I.
 - a. **Purpose and scope:** Add that the purpose of the new work is to serve dairy farmers in addition to member countries and the feed industry. The chair suggests striking "member countries and the food industry" and replacing it with text that mirrors the CoP, in addition to adding farmers to the list: "...competent authorities, producers, marketers, processors and farmers..."
 - b. **Relevance and timeline:** Change "Aflatoxin M1 is formed in milk" to "Aflatoxin M1 can be found in milk". Add "Updates will broaden the scope of the document to recognize its application to milk from animals in addition to bovine species" and "milk is used as a main ingredient of dairy-based infant formula."
 - c. **Main aspects to be covered:** Add "Conditions that are required for aflatoxin B1 formation will be explained to help ensure that control and mitigation measures are understood in the context of different geographic regions, feedstuffs, etc. in order to be adequately applied." Strike "figs" from the list of aflatoxin CoPs that could be leveraged, because information on figs is not included in the draft CoP.
 - d. **Relevance of the Codex strategic goals, (d) Goal 4:** Strike "and humid" for consistency with wording in 5 (c).
 - e. **Information on the relationship between the proposal and other existing Codex documents:** Strike "and figs" from the sentence immediately above the bullets. Strike "CoP for the prevention and reduction of aflatoxin contamination in dried figs (CXC 65-2008)" from the bulleted list.
 - f. **Proposed timeline for completion of the work:** Replace the last sentence on timelines with the simplified text: "The CoP is expected to be finalized for adoption by 2027."
13. Member countries also supported issuing a CL requesting risk management practices and other data/information that can support the further development of the CoP and re-establishing the EWG to further develop the CoP for consideration by CCCF19.

CONFERENCE ROOM DOCUMENTS

14. Following the deadline for CL comments, comments were also received, and posted as conference room documents (CRDs) on the CCCF18 website from one (1) member country (Singapore). This member country supported this new work and the approach taken thus far to update it.

DISCUSSION OF THE VIRTUAL PRE-SESSION WORKING GROUP

15. The VWG met on-line the week before CCCF18, on 16 June 2025. It was jointly chaired by Rosalie Awad (Canada) and Elizabeth Elliott (Canada), who also jointly served as rapporteurs. The key objectives of the VWG were to:

- a. Seek agreement the project document in order to present it to CCCF18
 - b. Address key points raised in the EWG and CL 2025/23-CF
 - c. Establish terms of reference for next year's EWG
16. The proposed edits to the project document (paragraph 12, above and Appendix I) were presented using the 'track changes' function. No concerns with the proposed changes were raised and no additional edits were suggested.
17. The information in paragraphs 8 to 12, above, was shared during a slide show presentation. No concerns or questions were raised on any of these items. One (1) observer organization shared links in the chat to three (3) ISO certified analytical methods for aflatoxin M1 in milk and milk products.⁵ The VWG chair asked if the organization also had materials on sampling; the member organization indicated that they did not.

RECOMMENDATIONS

18. Based on EWG comments and VWG discussion, the following recommendations are made to CCCF18:
- a. Proceed with new work to revise the *Code of Practice for the Reduction of Aflatoxin B1 in Raw Materials and Supplemental Feedingstuffs for Milk-producing Animals* (CXC 45-1997) focusing on good management practices along the food chain (e.g. GAP, GMP)
 - b. Forward the revised project document to CAC for approval
 - c. Issue a CL requesting risk management practices and other data/information that can support the further development of the CoP
 - d. Re-establish the EWG chaired by Canada and co-chaired by Saudi Arabia to further develop CXC 45-1997 for consideration by CCCF19

⁵ <https://shop.fil-idf.org/products/iso-14501-idf-171-2021-milk-and-milk-powder-determination-of-aflatoxin-m1-content-clean-up-by-immunoaffinity-chromatography-and-determination-by-high-performance-liquid-chroma>
<https://shop.fil-idf.org/products/milk-and-milk-powder-determin-of-aflatoxin-m1-content-clean-up-by-immunoaffinity-chromatography-and-determination-by-thin-layer-chromatography>
<https://shop.fil-idf.org/products/milk-and-milk-powder-determin-of-aflatoxin-m1-content-clean-up-by-immunoaffinity-chromatography-and-determination-by-thin-layer-chromatography>

APPENDIX I
PROJECT DOCUMENT
PROPOSAL FOR NEW WORK ON THE REVISION OF THE
CODE OF PRACTICE FOR THE REDUCTION OF AFLATOXIN B₁ IN RAW MATERIALS AND SUPPLEMENTAL
FEEDINGSTUFFS FOR MILK-PRODUCING ANIMALS (CXC 45-1997)

(For consideration by CCCF)

Note: Revisions are indicated in tracked changes.

1. Purpose and scope

The purpose of the proposed new work is to provide competent authorities, producers, marketers, processors and farmers member countries and the feed industry with updated guidance to prevent and reduce aflatoxin contamination in animal feeds intended for milk-producing animals.

The scope of the new work will focus on reviewing and updating the *Code of practice for the reduction of aflatoxin B₁ in raw materials and supplemental feedingstuffs for milk-producing animals (CXC 45-1997)*.

2. Relevance and timeline

Aflatoxin M₁ can be found is formed in milk as a result of aflatoxin B₁ contamination in animal feed. The *Code of practice for the reduction of aflatoxin B₁ in raw materials and supplemental feedingstuffs for milk-producing animals (CXC 45-1997)* has not been revised or amended since it was first elaborated in 1997. New information has become available since 1997 on aflatoxin management in the feedingstuffs of milk-producing animals. Updates will broaden the scope of the document to recognize its application to milk from animals in addition to bovine species. It is important to update this CoP as milk⁶ and milk products⁷ continue to be staple foods worldwide, including in developing countries, and milk is used as a main ingredient of dairy-based infant formula. Furthermore, JECFA concluded at its 56th meeting in 2002 that aflatoxin M₁ is a genotoxic carcinogen.

3. Main aspects to be covered

This work will address measures to prevent or reduce aflatoxin B₁ contamination in animal feed and feed ingredients in order to mitigate aflatoxin M₁ contamination of milk. All revisions will be supported by scientific data that have become available since CXC 45-1997 was elaborated in 1997.

Updates will expand upon or add new information about aflatoxin management approaches in feed and feed ingredients. It will also include current information on the use of preservatives, mycotoxin detoxifying agents and other emerging physical, biological and chemical control strategies for aflatoxins in feed. Conditions that are required for aflatoxin B₁ formation will be explained to help ensure that control and mitigation measures are understood in the context of different geographic regions, feedstuffs, etc. in order to be adequately applied.

As well, updates to CXC 45-1997 will consider how information in the Codex CoPs on aflatoxin prevention and control in cereals and, to a lesser extent, nuts, and figs, can be leveraged in order to limit redundancies between Codex texts, if possible (refer to Section 6 for more information).

4. Assessment against the criteria for the establishment of work priorities

General criterion

a) *Consumer protection from the point of view of health, food safety, ensuring fair practices in the food trade and taking into account the identified needs of developing countries.* Milk and milk products are staple foods in many countries worldwide, including developing countries. The updated CoP will provide additional guidance for member countries and the feed industry to reduce or prevent aflatoxin contamination in feed intended for milk-producing animals, thus minimizing dietary exposure to aflatoxin M₁.

A revised CoP will facilitate fair trade by making updated information on recommended practices to reduce aflatoxin contamination in the feedingstuffs of milk-producing animals available to all member countries and the feed industry. This, in turn, will support efforts to meet the Codex maximum level for aflatoxin M₁ in milks which will also facilitate trade.

Specific criteria

a) *Diversification of national legislations and apparent resultant or potential impediments to international trade.* The CoP would provide internationally available and recognized scientific and technical guidance that will assist in ensuring compliance with Codex and national maximum levels for aflatoxin M₁ in milk.

b) *Work already undertaken by other organisations in this field.* JECFA completed a risk assessment for aflatoxin M1 in 2002 at its 56th meeting.

5. Relevance of the Codex strategic goals

a) *Goal 1: Address current, emerging and critical issues in a timely manner.* Updating the CoP on the reduction of aflatoxin contamination in feeds intended for milk-producing animals will address the need for up-to-date guidance that will help ensure the health of consumers, particularly for globally relevant staple foods such as milk and milk products.

b) *Goal 2: Develop standards based on science and Codex risk-analysis principles.* This work will involve reviewing peer-reviewed scientific data and information that supports reducing aflatoxins in animal feed. Recommended strategies will help reduce consumer exposure to and risks posed by aflatoxin M1 in milk to meet the Codex ML for aflatoxin M1 in milks, which was supported by JECFA56's 2002 assessment of aflatoxin M₁.

c) *Goal 3: Increase impact through the recognition and use of Codex standards.* The proposed CoP will present a variety of recommended and scientifically proven strategies to control aflatoxin contamination in the feed of milk-producing animals that are based on current best practices and are globally available. The warm climate of many geographic regions worldwide and high humidity during storage lends itself to aflatoxin formation in feedingstuffs, making the updates to this CoP relevant to many member countries.

(d) *Goal 4: Facilitate the participation of all Codex Members throughout the standard-setting process.* Updates to the CoP would be conducted by an electronic working group in which all member countries will be invited to participate in. Updating an existing CoP through the Codex Step procedure will make the information on the best practices included in the CoP available to all members at each step of the process. The warm ~~and humid~~ climates of many regions worldwide lend itself to aflatoxin formation in feedingstuffs. As such, this work will benefit from the participation and expertise of both developed and developing countries.

(e) *Goal 5: Enhance work management systems and practices that support the efficient and effective achievement of all strategic plan goals.* An updated CoP will support the development and implementation of effective and efficient work management systems and practices by providing basic guidance for member countries and feed producers to reduce aflatoxin contamination in the feeds for milk-producing animals.

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

The Codex ML for aflatoxin M₁ in milks was adopted in 2001. Revisions to CXC 45-1997 will support the achievement of the Codex ML for aflatoxin M₁ in milks.

In 2003, the CAC approved the adoption of the *Code of practice for the prevention and reduction of mycotoxin contamination in cereals* (CXC 51-2003; amended 2014, 2017; revised 2016); this CoP includes aflatoxins and clearly indicates that it applies to mycotoxin prevention and reduction measures for cereal grains intended for both human and animal consumption. When first elaborated, CXC 51-2003 largely mirrored CXC 45-1997, although CXC 51-2003 has since been amended (2014, 2017) and revised (2016).

There are also Codex CoPs for aflatoxins in nuts ~~and figs~~, which could be used as feed:

- *Code of practice for the prevention and reduction of aflatoxin contamination in tree nuts* (CXC 59-2005)
- *Code of practice for the prevention and reduction of aflatoxin contamination in peanuts* (CXC 55-2004)
- ~~*Code of practice for the prevention and reduction of aflatoxin contamination in dried figs* (CXC 65-2008)~~

Any future updates to CXC 45-1997 will consider if and how the other Codex CoPs for aflatoxins in other agricultural commodities could be leveraged, with a view to reducing redundancy between Codex texts, when possible.

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

JECFA56 completed a risk assessment for aflatoxin M1 in 2002. Additional expert scientific advice is not required.

8. Identification of any need for technical input to the standard from external bodies

Currently, there is no need for additional technical input from external bodies.

9. Proposed timeline for completion of the work

Subject to approval by the CAC, work would commence in 2025, and proposed revisions to CXC 45-1997 would be presented to CCCF19 in 2026. The CoP is expected to be finalized for adoption by 2027.

~~Given that electronic working groups were established in advance of both CCCF17 and CCCF18, and that the potential updates to this CoP were discussed at both of those meetings, it is anticipated that the final adoption of CXC 45-1997 will be in 2027.~~