CODEX ALIMENTARIUS COMMISSION



Food and Agriculture Organization of the United Nations



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#### Agenda item 15

CX/CF 24/17/15 March 2024

# JOINT FAO/WHO FOOD STANDARDS PROGRAMME

# CODEX COMMITTEE ON CONTAMINANTS IN FOODS

Seventeenth Session 15-19 April 2024 Panama City, Panama

# DISCUSSION PAPER ON 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 Electronic Working Group chaired by Canada and co-chaired by Japan and the United States of America)

# BACKGROUND

- The 13th session of the Codex Committee on Contaminants in Foods (CCCF13, 2019) agreed to establish an electronic working group (EWG) chaired by Canada and co-chaired by Japan and the United States of America to develop an approach for reviewing existing Codex standards developed by the CCCF<sup>1</sup>, for consideration at CCCF14.<sup>2</sup>
- 2. CCCF14 (2021) agreed to establish tracking lists of Codex standards<sup>3</sup>, an approach and prioritization criteria for recommending existing Codex contaminant standards for review, and to implement this approach for a three-year trial period (2022-24).<sup>4</sup>
- 3. CCCF15 (2022) agreed to maintain, without further prioritization, tracking Lists A and B and to create an *Overall Highest Priority List of Codex Standards and Related Texts for Contaminants in Food and Feed* (the "OHPL"), with nominations being made to the OHPL using the prioritization criteria or other clear, reasonable rationale. No new work to review an existing Codex standard was taken up by CCCF15.<sup>5</sup>
- 4. CCCF16 (2023) agreed to establish an electronic working group (EWG) chaired by Canada to develop a discussion paper 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).<sup>6</sup> A number of member countries or organizations recommended this code of practice (CoP) for inclusion in the OHPL and cited supporting prioritization criteria,<sup>7</sup> which are reported in Table 1 along with additional details regarding how CXC 45-1997 specifically meets each criterion.

<sup>&</sup>lt;sup>1</sup> maximum levels, guideline levels and codes of practice

<sup>&</sup>lt;sup>2</sup> REP19/CF, para. 178

<sup>&</sup>lt;sup>3</sup> Established or reviewed ≥25 years ago (List A.1) or ≥15 and <25 years ago (List A.2); Recommended for Re-Evaluation (List B)

<sup>&</sup>lt;sup>4</sup> CX/CF 21/14/16; REP21/CF, para. 218

<sup>&</sup>lt;sup>5</sup> REP22/CF15, para. 218

<sup>&</sup>lt;sup>6</sup> REP23/CF16, para. 102 (iv) (b)

<sup>&</sup>lt;sup>7</sup> CF16/CRD02(Rev), Annex II & Annex III

**Table 1.** Prioritization criteria cited by member countries or organizations in the OHPL in support of the possible 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)<sup>8</sup>

No.	<b>Prioritization criteria cited in OHPL<sup>1</sup></b> (likelihood of indicating a potential safety concern)	Details in support of the potential review of CXC 45-1997 <sup>2</sup>
1	List A.1: Established or reviewed ≥25 years ago. (moderate to high)	CoP initially established in 1997 and has not been reviewed or modified in any way since
2	<b>Health-based guidance value (HBGV) cannot be established:</b> Either JECFA, upon request by CCCF, or other relevant joint FAO/WHO expert consultations recognized by CCCF cannot establish a HBGV due to genotoxicity and carcinogenicity or other rationale that does not support establishment of a threshold for the critical effect (moderate to high)	Aflatoxin M1 is a genotoxic carcinogen; no tolerable daily intake established ( <u>JECFA, 2002</u> )
3	<b>Staple food:</b> The food commodity that the standard applies to is a staple food <i>(moderate to high)</i>	Animal-derived milk is a staple food on many countries worldwide
4	<b>Developing countries:</b> Standards relevant to the needs of developing countries ( <i>moderate to high</i> )	Animal-derived milk is a staple food on many countries worldwide, including developing countries
5	<b>Efficiencies with other work:</b> Standard review involving the same or similar commodity, or the same contaminant is underway or commencing (n/a)	Maximum level for aflatoxin M1 in milks is in List A.2
6	<b>Comparable CoP updated:</b> Updates to a CoP for a similar food or feed and contaminant combination may be transferable to another CoP or make an existing CoP redundant (n/a)	Code of Practice for the prevention and reduction of mycotoxin contamination in cereals (CXC 51-2003) (amended (2014, 2017) and revised (2016)), without a parallel review of CXC 45-1997
7	<b>Member country volunteer:</b> A Codex member country volunteers to take on the work to draft a discussion paper outlining any proposed changes to the Codex standard (n/a)	Canada volunteered to lead this work

OHPL – Overall Highest Priority List

<sup>1</sup> Refer to the most recent version of the prioritization criteria

<sup>2</sup> Refer to the most recent version of the OHPL for member countries or organizations citing each prioritization criteria and references to Codex documents n/a – not applicable

8 CF16/CRD02(Rev)

5. Aflatoxins are produced by three species of *Aspergillus* moulds that can contaminate plants. *A. flavus* produces aflatoxins B1 and B2. Aflatoxin B1 is hydroxylated in the liver of milk-producing animals to form aflatoxin M1, a metabolite that is excreted into the milk and can therefore be found in milk and milk products consumed by humans.

### WORK PROCESS

- 6. An EWG was convened using the Codex online forum. As a first step, EWG members were invited to contribute information on control measures for aflatoxins in feeds intended for milk-producing animals. Subsequently, the EWG was engaged in two rounds of comments, as described below.
- 7. Six (6) EWG members submitted comments on the first discussion paper (Brazil, Canada, Costa Rica, Denmark, Japan, United States). The first draft discussion paper outlined the new information available on aflatoxin reduction strategies and other possible updates that could be made to the background information. The EWG Chair also noted that the primary informational text in CXC 45-1997 is included in, and expanded upon, in CXC 51-2003, the *Code of practice for the prevention and reduction of mycotoxin contamination in cereals* (amended 2014, 2017; revised 2016). As CXC 51-2003 clearly states that it applies to cereal grains intended as food for both humans and animals, input was requested from the EWG on if they agreed that the contents of CXC 51-2003 would also apply to non-cereal feedingstuffs of agricultural origin used as animal feed. The EWG Chair also requested input on possible options for merging CXC 45-1997 with CXC 51-2003 or continuing to maintain these two CoPs as separate texts.
- 8. In response to three charge questions in the first draft discussion paper, the EWG:
  - i. agreed that there is sufficient new information to propose that the Committee start new work on the revision of CXC 45-1997;
  - ii. agreed that the majority of CXC 51-2003 could apply to non-cereal animal feedingstuffs of agricultural origin; and
  - iii. shared varying responses with respect to maintaining CXC 45-1997 as a separate document or revising CXC 51-2003 to include provisions from CXC 45-1997 and therefore merge the two CoPs into a single text. One EWG member suggested that such a decision could be made if and when the new work is approved by the Committee and that during preparation of the updated draft the best approach may become evident.
- 9. Two (2) EWG members commented on the second discussion paper and the project document to forward to the Codex Alimentarius Commission (CAC), if the new work is approved by CCCF17. No substantial comments were received; the member countries that commented supported the proposed recommendations of the EWG to make to CCCF17.
- 10. This discussion paper aims to:
  - summarize the additional information available on practices for reducing aflatoxins in the feedingstuffs of milk-producing animals that have become available since CXC 45-1997 was elaborated in 1997;
  - ii. identify other revisions that would improve CXC 45-1997, if updated; and
  - iii. highlight areas of redundancy with other Codex CoPs on aflatoxin prevention and control.
- 11. Key references are included at the end of the discussion paper for information but will not be included in the final CoP.
- 12. Annex A houses voluntary information about nationally approved aflatoxin control strategies. Compiling such information was suggested by some EWG members to provide context on the extent of the current global use of regulated aflatoxin control strategies and as a tool for information sharing between EWG members. These lists are provided for information will not be included in the final CoP.
- 13. Appendix I includes the draft project document for the proposal for new work to the CAC, pending approval by CCCF17, and Appendix II includes the list of participants in the EWG.

#### SCOPE OF CXC 45-1997

14. The title of CXC 45-1997 is "Code of practice for the reduction of aflatoxin B1 in raw materials and supplemental feedingstuffs for milk-producing animals." This CoP does not define 'raw materials' or 'supplemental feedingstuffs' and uses the general words 'feed' or 'feedingstuff(s)' throughout. It does not discuss specific types of animal feed of agricultural (e.g. cereals, hay, silage, soybeans) or non-agricultural (e.g. animal by-products, vitamin or mineral

supplements) origins. Past Codex records reviewed by the EWG Chair did not identify any discussions about the scope of CXC 45-1997 at the time it was developed.

15. Updates to CXC 45-1997 will include a statement on scope that outlines the types of feedingstuffs the CoP applies to. Updates will also include a review of existing key terms in the CoP to ensure their continued relevance. Key words in the updated draft will be defined using Codex, FAO or WHO definitions, as available, or definitions from other sources agreed upon by the EWG.

### AVAILABILITY OF NEW OR UPDATED INFORMATION

- 16. Aflatoxin contamination in animal feedingstuffs other than cereals has historically not been considered a significant problem in terms of frequency or magnitude of contamination. However, aflatoxins have been detected in feedingstuffs such as hay, forage, soybeans, alfalfa, clover, and various types of silage.
- 17. New information on mycotoxin prevention and reduction in animal feed, including feedingstuffs others than cereals, has become available since CXC 45-1997 was elaborated in 1997. The following paragraphs highlight the types of new or updated information that could be included in updates to this CoP. The information in paragraphs 18 to 24, below, is considered comprehensive but may not be exhaustive.
- 18. The section on 'Storage' presently only indicates to "aerate commodities stored in bulk" (para. 2.3.7). This section could be updated to include information on silage, which requires anaerobic conditions to mitigate aflatoxin formation.
- 19. New information is available pertaining to mould inhibitors and preservatives, some proven, others emerging, that can be applied to agricultural products post-harvest (e.g. various organic acids and their salts, copper sulphate, essential oils, nanoparticles). These products can generally be applied to agricultural commodities intended for both human and animal consumption if consistent with national regulations. The 'Storage' section of CXC 45-1997 mentions the use of one preservative, "organic acid such as propionic acid" (para. 2.3.8).
- 20. Emerging and novel mycotoxin mitigation strategies based on physical, biological, and chemical technologies are also being explored for use in human food and animal feed along their entire value chains. Examples of these technologies include both pre-harvest (e.g. nanotechnology (nano-fungicides, nano-fertilizers)), biotechnology including biopesticides, biostimulants) and post-harvest (e.g. ozone, cold plasma technology, electromagnetic radiation, metal nanoparticles) mitigation methods. These emerging strategies could be mentioned in CXC 45-1997 in the context of raising awareness and recommending that only strategies which are nationally approved/registered be used.
- 21. CXC 45-1997 briefly mentions decontamination treatments for animal feeds in the 'Background' section, noting that: "To date there has been no widespread government acceptance of any decontamination treatment intended to reduce aflatoxin B1 levels in contaminated animal feedingstuffs" (para. 1.5). The same paragraph mentions one potential feed treatment (i.e. ammoniation) and one binding agent (i.e. hydrated sodium calcium aluminosilicate). Such decontamination treatments are now more commonly referred to and regulated as "mycotoxin detoxifying agents", which are substances added to animal feed to reduce mycotoxin contamination through adsorbing/binding or degrading/biotransforming the toxin. Updates could include defining these agents, discussing currently available agents and the animals for which they are useful, and considerations surrounding their proper use.
- 22. Information about animal feed and feed ingredient sourcing considerations is not included in CXC 45-1997. New information on sourcing could draw attention to the potential for aflatoxin contamination of food industry by-products that may be used in animal feeds. How to handle products intentionally diverted from the human, to the animal, food chain due to elevated aflatoxin levels could also be included in the revised COP.
- 23. Additional, high-level background information that could be added in revisions to CXC 45-1997 includes, but may not be limited to:
  - i. the main animals that produce milk for human consumption and that transform aflatoxin B1 to M1, as CXC 45-1997 presently only mentions dairy cattle (paras. 1.3, 1.4);
  - ii. common types of feedingstuffs consumed by milk-producing animals and information about whether they may be prone to aflatoxin contamination;
  - iii. mechanism of aflatoxin M1 formation; and

- iv. reference to relevant information from the *Code of Practice on Good Animal Feeding* (CXC 54-2004; amended in 2008)<sup>9</sup> regarding the definitions in Section 3<sup>10</sup>, complying with mycotoxin standards, and best practices relating to feed additive use.
- 24. If deemed necessary, other possible, high-level updates to existing background information in CXC 45-1997 include, but may not be limited to:
  - i. determining if reference to the "FAO recommendations for sampling plans" is still relevant (para. 2.5.2);
  - ii. investigating whether there is new information on the transformation and transfer rates of aflatoxin B1 in feed to aflatoxin M1 in milk; and
  - iii. determining if any updates are required to how the relative toxicity of aflatoxin M1 relative to aflatoxin B1 is described.

# LEVERAGING RELATED CODEX CODES OF PRACTICE

- 25. Updates to CXC 45-1997 should be done in consideration of redundancy with the Codex CoPs on aflatoxins in foods that are also used as animal feedingstuffs; these specific CoPs are discussed further below.
- 26. A prioritization criterion agreed upon by CCCF for the review of existing Codex standards notes that an existing CoP may become redundant when a comparable CoP is updated (refer to Table 1, item 6, above). Furthermore, the Codex Secretariat communicated to the EWG Chair in July 2023 that it has no reservations about merging Codex texts and that it would be consistent with the recommendation of the CAC to move towards overarching and simplified texts, when possible.
- 27. Possibilities for updating CXC 45-1997 include maintaining it as a single, separate document or revising other, related Codex CoPs to include provisions from CXC 45-1997, thereby not maintaining it as a separate Codex text.

### Code of Practice For Mycotoxins In Cereals (CXC 51-2003)

- 28. The *Code of practice for the prevention and reduction of mycotoxin contamination in cereals* (CXC 51-2003), was amended in 2014 and 2017 and revised in 2016 (Table 1, item 6). The body of this CoP outlines prevention and reduction measures appropriate for mycotoxins in cereal grains that are intended for both human and animal consumption<sup>11</sup> and includes additional details pertaining to certain toxins in mycotoxin--specific annexes.<sup>12</sup>
- 29. A CoP that applies to cereals intended for both human and animal consumers is reasonable given that: i) prevention and control measures for mycotoxins are based on good agricultural and manufacturing practices (GAP, GMP) that are consistent with Hazard Analysis Critical Control Points (HACCP) along the cereal value chain are applicable to grains that enter either the human or animal food streams, and ii) the final consumer (i.e. human or animal) can change based on factors relating to, for example, supply, demand, pricing and market access.
- 30. Past Codex records and a comparison of the main informational text in CXC 45-1997 and CXC 51-2003 demonstrate that CXC 51-2003 mirrored CXC 45-1997 when it was first elaborated. CXC 51-2003 was amended (2014, 2017) and revised (2016) and, at present, is notably expanded upon relative to CXC 45-1997.
- 31. The EWG agreed that the majority of prevention and reduction measures for cereals in CXC 51-2003 would also apply to many other animal feedingstuffs of agricultural origin (e.g. hay and grasses, alfalfa, soybeans), although there are certain types of animal feed (e.g. silage) for which different aflatoxin prevention strategies are effective (e.g. anaerobic versus aerobic conditions).
- 32. CXC 45-1997 includes some topics that are not included in CXC 51-2003: information on the transformation, transfer and relative toxicity of aflatoxin B1 to M1, decontamination treatments applicable to animal feeds and considerations specific to aflatoxin-contaminated feed (national guidelines, appropriate uses etc.).

Codes of Practice for Aflatoxins in Peanuts (CXC 55-2004) and Tree Nuts (CXC 59-2005)

<sup>&</sup>lt;sup>9</sup> The CoP was developed by an Ad Hoc Intergovernmental Task Force on Animal Feeding; the task force is now dissolved as per the <u>Codex website</u>. The CoP's focus is to help ensure the safety of food for human consumption through good animal feeding and good manufacturing practices along the value chain for feed and feed ingredients for food-producing animals.

<sup>&</sup>lt;sup>10</sup> The following terms, which are relevant to CXC 45-1997, are defined: Feed (Feedingstuff), Feed Ingredient, Feed Additive and Undesirable Substances.

<sup>&</sup>lt;sup>11</sup> CXC 51-2003 para. 6 states that the CoP applies to "cereal grains, grain-derived foods and animal feeds"; para. 42 discusses control measures specific to animal feed.

<sup>&</sup>lt;sup>12</sup> Mycotoxin-specific annexes include: zearalenone, fumonisins, ochratoxin, trichothecenes, aflatoxins, and ergot alkaloids.]

- 33. Animal feedingstuffs may include nuts or nut meals, in addition to nut by-products such as shells, screenings or hay.
- 34. There are two Codex CoPs that focus on the prevention and reduction of aflatoxin contamination in nuts: the Code of Practice for the Prevention and Reduction of Aflatoxin Contamination in Tree Nuts (CXC 59-2005) and the Code of Practice for the Prevention and Reduction of Aflatoxin Contamination in Peanuts (CXC 55-2004).<sup>13</sup> The scopes of both of these CoPs indicate that they apply to "tree nuts/peanuts for entry into international trade for human consumption" and do not indicate that they would apply to nuts intended for use in animal feed.
- 35. The good agricultural, manufacturing and storage practices (GAP, GMP and GSP) aimed at preventing and reducing aflatoxin contamination in tree nuts and peanuts that are outlined in these two CoPs are also expected to be largely applicable to nuts that enter the animal food stream.

### **RECOMMENDATIONS TO CCCF17**

- 36. CCCF is invited to:
  - i. agree to review and update the *Code of practice for the reduction of aflatoxin B1 in raw materials and supplemental feedingstuffs for milk-producing animals* (CXC 45-1997) and to forward the project document (Appendix I) to the CAC for approval;
  - ii. agree that the information summarized in paragraphs 14 to 35, above, should be considered in the review and update of the CoP; and
  - iii. agree that the EWG may continue to explore various possibilities for updating CXC 45-1997 in order to consider if and how information in CXC 51-2003, CXC 59-2005 and CXC 55-2004 could be leveraged with a view to limit redundancies in Codex texts.

<sup>&</sup>lt;sup>13</sup> CCCF16 (2023) agreed to establish an EWG chaired by Brazil, working in English, to develop a discussion paper to explore if there is new information to support a revision of the *Code of practice for the prevention and reduction of aflatoxin contamination in peanuts* (CXC 55-2004) (REP16/CF, para. 105 (iv) (a)).

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# ANNEX

# Nationally Approved Aflatoxin Control or Detoxification Agents and Technologies for Animal Feed

(non-exhaustive - populated based on voluntarily information from member countries or organizations)

# (For information)

### **Post-Harvest Mould Inhibitors/Preservatives**

Country	ountry Active Ingredient General Registra Use Informat		Directions for Use		
	Methylparaben	Mould inhibitor products (mixed feeds) containing listed active ingredients require registration in Canada	Methylparaben is for use as a mould inhibitor in feeds in an amount not to exceed 0.1 percent of the total diet		
	(or Methyl p- hydroxybenzoate)				
	Propylparaben (or Propyl p- hydroxybenzoate)		Propylparaben is for use as a mould inhibitor in feeds in an amount not to exceed 0.1 percent of the total diet		
Canada	Sodium benzoate		Sodium benzoate is for use as a mould inhibitor in feeds in an amount not to exceed 0.1 percent of the total diet		
	Formaldehyde 37%		Formaldehvde 37% solution shall not be used in an		
	solution (or Formalin)		amount to exceed 0.25% of the total diet		
	Propionic acid		Propionic acid use varies according to mould inhibitor product		
	Various products approved, most using propionic acid as the active ingredient				
United States	None approved to date				

### Aflatoxin Detoxification Agents\*

Country	Product Name	Registrant Name	Active Ingredient	Year of First Registration	Directions for Use
Canada	NovasilPlus Mycotoxin Binder	BASF	Calcium bentonite	2022	-ruminant feeds not exceeding 20 ppb aflatoxins, as laid out in the <u>Canadian</u> <u>Feeds Regulations</u> , Standards and General Requirements, 19(1)(i) -0.5-2% of total diet (dry matter basis)
United States	None approved to date				

\*Substances added to animal feed to reduce mycotoxin contamination through adsorbing/binding or degrading/biotransforming the toxin

### Novel or Emerging Physical, Biological or Chemical Technologies\*

Country	Product Name	Registrant Name	Active Ingredient	Year of First Registration	Directions for Use
Canada Non approved to date					
United States	None approve	d to date			

\*Examples include field-level strategies (e.g. nanotechnology, biotechnology including biopesticides, biostimulants) and decontamination using ozone, cold plasma technology or electromagnetic radiation

# APPENDIX I

### **PROJECT DOCUMENT**

# PROPOSAL FOR NEW WORK ON 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)

# 1. Purpose and Scope

The purpose of the proposed new work is to provide to 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 timelines

The Code of practice for the reduction of aflatoxin B1 in raw materials and supplemental feedingstuffs for milkproducing 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. It is important to update this CoP as animal-derived milk and milk products continue to be staple foods worldwide, including in developing countries. Furthermore, JECFA concluded at its 56<sup>th</sup> 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 animal feeds and feed ingredients with specific aflatoxin management approaches (e.g. silage) or mycotoxin-related considerations (e.g. food industry by-products). 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.

As well, updates to CXC 45-1997 will consider how information in the Codex CoPs on aflatoxin prevention and control in cereals (CXC 51-2003), tree nuts (CXC 59-2005) and peanuts (CXC 55-2004) 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. Animal-derived 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. A risk assessment for aflatoxin M1 was completed by JECFA 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 a globally relevant staple food such as animal-derived milk and milk products.

*b)* Goal 2: Develop standards based on science and Codex risk-analysis principles. This work will involve the review of peer-reviewed scientific data and information that supports a reduction in aflatoxins in animal feed. Recommended strategies will help reduce consumer exposure to, and risks posed by, aflatoxin M1 in milk in order to meet the Codex ML for aflatoxin M1 in milks, which is a ML that was supported by JECFA'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 prevent 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 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 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 climate of many regions worldwide lends itself to aflatoxin formation in feedingstuffs. As such, this work will benefit from 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 maximum level 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 expanded upon.

There are also two Codex CoPs for aflatoxins in different types of nuts:

- 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)

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

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

A risk assessment for aflatoxin M1 was completed by JECFA in 2002 at its 56th meeting. There is no requirement for additional expert scientific advice.

# 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 time-line for completion of the work

Subject to approval by the CAC in 2024, work would commence in 2024 and a first draft presented to CCCF18 in 2025. Given the need to address linkages and possible redundancies between the subject CoP and CXC 51-2003, CXC 59-2005 and CXC 55-2004, it is estimated that this work will take at least three years to complete. Therefore, final adoption of the updated CoP by the CAC is foreseen by no earlier than 2027.

# APPENDIX II List of Participants Chair – Canada Elizabeth Elliott Scientific Evaluator Health Canada

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