### CODEX ALIMENTARIUS COMMISSION





Viale delle Terme di Caracalla, 00153 Rome, Italy - Tel: (+39) 06 57051 - E-mail: codex@fao.org - www.codexalimentarius.org

Agenda item 13

CX/CF 25/18/14-Add.1 May 2025 ORIGINAL LANGUAGE ONLY

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

Eighteenth Session 23-27 June 2025 Bangkok, Thailand

## DEVELOPMENT OF A CODE OF PRACTICE FOR THE PREVENTION AND REDUCTION OF TROPANE ALKALOIDS IN FOOD AND FEED

(Comments in reply to CL 2025/41-CF)

submitted by
Canada, Cuba, Egypt, Ghana, Iraq, Iran, Japan, Kenya, Singapore,
the United States of America (USA),
FoodDrinkEurope and the Institute of Food Technologists (IFT)

#### **Background**

1. This document compiles comments received through the Codex Online Commenting System (OCS) in response to CL 2025/41-CF<sup>1</sup> issued in April 2025. Under the OCS, comments are compiled in the following order: general comments are listed first, followed by comments on specific sections.

#### Explanatory notes on the appendix

2. The comments submitted through the OCS are hereby annexed and presented in a tabulated format.

https://www.fao.org/fao-who-codexalimentarius/resources/circular-letters/en/
https://www.fao.org/fao-who-codexalimentarius/committees/committee/related-circular-letters/en/?committee=CCCF

#### **ANNEX**

#### Points to be addressed in reply to CL 2025/41-CF

CCCF is invited to consider if new work should be proposed on the development of a code of practice for the prevention and reduction of tropane alkaloids contamination in food and feed and, in the affirmative, to consider the points below based on the data/information provided in Appendix I of CX/CF 25/18/14:

- (i) Review the project document in Appendix II of CX/CF 25/18/14 and make any necessary adjustments to ensure it provides a robust rationale for the development of a CoP in order to forward the proposal to the 48<sup>th</sup> Session of the Codex Alimentarius Commission (CAC48, 2025) for approval as new work.
- (ii) Review the proposed revised CoP as presented in Appendix III of CX/CF 25/18/14 and provide general comments on the structure and overall content of the CoP to guide the EWG in further developing the CoP following approval of new work by CAC48, and specific comments as to whether:
  - (a) Improvements could be made, e.g., addition of new sections, further development of revised sections, etc.
  - (b) Data/information to support such revisions is available for consideration by the EWG in further developing the CoP.

#### **GENERAL COMMENTS**

COMMENT	MEMBER/OBSERVER
Canada is supportive of new work being undertaken on the development of a CoP for tropane alkaloids to expand on the work that has already taken place during CCCF17 and CCCF18.	Canada
Canada believes the discussion paper (CX/CF 25/18/14) presented this year for CCCF18 and that presented last year for CCCF17 (CX/CF 24/17/11) provide a beneficial summary of the current status of TA's. We do not believe that the discussion paper needs further development, but are open to doing so if that is the general consensus of the committee.	
(i) Canada finds the project document to be clear in its intentions and is supportive of the content of the document as it stands.	
(ii) Canada finds the structure and overall content of the CoP to be informative and fit for purpose. However, an additional Section discussing the disposal (e.g., burning) of weed seeds and other weed parts may be a beneficial addition to the CoP to prevent re-entry into the food or feed chain. In addition, in paragraph 13, it is recommended to implement cover crops (e.g., rye, clover, or mustard species) to suppress weeds. Mustard is a priority allergen, therefore care must be taken to prevent its occurrence in cereals.	
Cuba agradece la oportunidad de emitir sus observaciones sobre el documento CX/CF 25/18/14 DOCUMENTO DE DEBATE SOBRE LA ELABORACIÓN DE UN CÓDIGO DE PRÁCTICAS PARA PREVENIR Y REDUCIR LA PRESENCIA DE ALCALOIDES DEL TROPANO EN LOS ALIMENTOS Y LOS PIENSOS, confirmando que se debe proceder a desarrollar un nuevo trabajo sobre ello y además que deben tenerse en cuenta que las medidas de gestión de riesgos que se deben incluir en este Código de práctica del Codex deben ser fácilmente accesibles, aplicables en todo el mundo y con eficacia demostrada en diferentes escalas de producción, incluidas empresas pequeñas y medianas, por lo que proponemos que se realice este documento.	Cuba
Egypt appreciates the work done by EWG, and supports proceeding with the development of a code of practice for tropane alkaloids in food and feed, and the development of the project for final adoption by the Codex Alimentarius Commission (CAC48)	Egypt
Purpose and scope of the project	Ghana
i <u>Position</u>	
Ghana supports the proposed new Code of Practice to address Tropane Alkaloids (TAs) in food and feed.	
ii. <u>Rationale for Support</u>	
a) Public Health Concern:	
TAs such as atropine and scopolamine pose serious acute toxicity risks.	
Outbreaks linked to contaminated grains, legumes, teas, and herbs have occurred globally, including in Africa.	
The CCCF18 is respectfully recommended to consider the following actions:	Iran
1. Endorse the initiation of new work based on the existing scientific evidence and risk assessments.	
2. Reconstitute the Electronic Working Group (EWG) to prioritize the development of the Code of Practice (CoP), with a focus on resolving identified gaps (e.g., data limitations on processing impacts, inclusion of additional TA-producing plants such as Atropa belladonna).	
3. Request member states to submit granular data on TA contamination at specific processing stages (pre- and post-harvest) to refine mitigation strategies and validate control measures.	

	MEMBER/OBSERVE
Agree	Iraq
The discussion paper is well-organized, with data and information clearly presented, and reflects the comments within the EWG. Therefore, we support the proposal to initiate a new work on the development of a Code of Practice for the prevention and reduction of tropane alkaloids contamination in food and feed.	Japan
As shown in the table in the annex of the discussion paper, we are concerned about the significant contamination found in food for infants and young children. In this regard, Japan also supports including preventive practices for these products, as indicated under item 3) "Main aspects to be covered" in the project document in Appendix II.	
Although the current proposed draft Code of Practice in Appendix III does not include specific guidance for products for infants and young children, we propose that further information be collected on this issue and, if sufficient data are available, that a new section be added or relevant content be included in the main text of the Code. Furthermore, since foodborne illnesses caused by tropane alkaloids can also occur at the household level, we support including consumers within the scope of this Code of Practice.	
General Comments:	Kenya
Kenya supports the proposal for new work on the development of a Code of Practice for the Prevention and Reduction of Tropane Alkaloids Contamination in Food and Feed. As a country where smallholder and informal food production systems are predominant, the presence of toxic weeds such as Datura stramonium in crop fields presents a significant risk of unintentional TA contamination. There is an urgent need for internationally agreed-upon guidance to support national efforts in managing this risk across the food and feed chains.	
Kenya also supports the re-establishment of the Electronic Working Group (EWG) to develop the draft CoP further, as this will provide an inclusive platform to integrate feedback from diverse production contexts, particularly from developing countries.	
<u>Justification</u> : The development of this CoP aligns with Kenya's Food Safety Policy and National Feed Policy, both of which emphasize prevention-based approaches, the control of contaminants in feed and food, and capacity building for producers and processors. Moreover, strengthening preventive measures at the primary production level will reduce the risk of aflatoxins and other co-contaminants often associated with similar sources.	
Specific Comments:	
(i) Project Document (Appendix II)—Support with Minor Revisions	
Kenya supports the project document with the following refinements:	
• <u>Clarify risk profile for low- and middle-income countries</u> (LMICs): The rationale should highlight the heightened vulnerability of LMICs to TA contamination due to widespread hand harvesting, limited weed control technologies, and weak monitoring infrastructure.	
<u>Justification</u> : Contextualizing the risks in LMICs ensures that mitigation strategies developed in the CoP are inclusive, feasible, and responsive to on-the-ground challenges.	
(ii) <u>Draft CoP</u> (Appendix III)	
a. <u>Structure and Content</u> — <u>General Observations</u>	

COI	MMENT	MEMBER/OBSERVER
1.	Section on Identification and Mapping of High-Risk Crops and Areas: Guidance should be provided for countries to identify crops and regions most at risk for TA contamination, based on environmental conditions and known prevalence of TA-producing weeds.	
	<u>Justification</u> : Tailoring interventions requires targeted surveillance. This would support better resource allocation for mitigation and capacity building.	
2.	<u>Section on Analytical Methods and Laboratory Capacity Needs</u> : Include recommendations for tiered approaches to TA testing (e.g., basic screening and confirmatory testing), and reference international initiatives for laboratory support in developing countries.	
	<u>Justification</u> : Kenya, like many developing countries, faces challenges in TA detection due to limited access to specialized instrumentation. Including accessible methods and regional collaboration options will enhance implementation.	
3.	Section on Stakeholder Training and Public Awareness: Introduce a section focused on farmer education, extension services, and awareness for food and feed manufacturers about TA risks and mitigation techniques.	
	<u>Justification</u> : Raising awareness at the farm level and along the feed value chain is critical in achieving meaningful reduction in TA contamination. Kenya's experience with aflatoxin control shows that behavioral change is essential for risk mitigation.	
b. <u>C</u>	omments on Existing Sections	
	Good Agricultural Practices (GAP): Kenya recommends expanding guidance on integrated weed management, including culturally appropriate practices such as manual weeding and intercropping.	
	<u>Justification</u> : Many Kenyan farmers rely on non-chemical methods. Practical, low-cost interventions need to be explicitly recognized and supported in the CoP.	
	Post-Harvest Handling: Emphasize the importance of sorting and removal of weed seeds during threshing and storage, especially for small-scale operations.	
	Justification: Post-harvest contamination remains a concern in informal sectors where mechanized cleaning is limited.	
	port for Re-establishing the EWG: Kenya supports re-establishing the Electronic Working Group to further develop the CoP, with participation from a anced representation of developing and developed countries.	
Just	ification: This will ensure the final CoP is globally applicable and reflective of the practical realities of food and feed production in varied contexts.	
	gapore supports the commencement of new work to develop a CoP to prevent and reduce tropane alkaloid contamination in food and feed, ticularly in addressing the incidences of tropane alkaloid contamination in the United Nations World Food Programme supply chains.	Singapore
limi imp	gapore supports prioritising upstream good agricultural practices (GAP) to prevent Datura species weed contamination, particularly given the current tations in removing tropane alkaloids once food products are contaminated. While emphasizing prevention, Singapore also endorses the lementation of downstream verification measures, specifically referencing the intervention levels recommended by the Joint FAO/WHO expert eting on tropane alkaloids, to verify the effectiveness of upstream Good Agricultural Practices (GAP) implementation. These measures should be ended to food distributed through the UN World Food Programme.	
refe	gapore noted that previous outbreak incidents were attributed to undetected sporadic high-level contamination. Therefore, in addition to erencing the intervention levels recommended by FAO/WHO, Singapore recommends developing guidance on sampling and analysis to enhance the ection of these intermittent contamination events.	

COMMENT	MEMBER/OBSERVER
The United States appreciates the work of the electronic working group (EWG), chaired by China and co-chaired by Saudi Arabia, on the proposal for the development of a Code of practice for the prevention and reduction of tropane alkaloids contamination in food and feed.	USA
The United States supports forwarding the project document, with edits, to CAC48 (2025) for approval as new work, and re-establishing the EWG to develop the CoP further, based on the guidance provided by CCCF, for consideration by CCCF19. The United States has proposed edits directly in the project document below. The Project Document should also address:	
Whether an animal feed section will be included.	
2. Whether there is a need to coordinate the discussion of weed control measures with the pyrrolizidine alkaloids CoP.	
If the EWG is re-established, the United States makes the following recommendations for the development of the CoP:	
a. There should be consistency throughout the CoP regarding which plants will be covered by the CoP. There are references to TA-containing plants, Datura species, Datura stramonium, and Datura spp. While there are places in the draft CoP where it seems appropriate to specify specific plant types (e.g., Datura stramonium), it is not always clear when guidance is specific to one plant vs. Datura species vs. TA-containing plants.	
b. It should be made clear when the CoP is referring to contamination with whole plants vs. seeds.	
c. In the Introduction section, it would be beneficial and informative to provide a sentence or two on which crops grown for human foods naturally contain TAs, and at what levels, relative to levels of concern identified at the expert meeting.	
d. The discussion of various weeding techniques should be more concise. Many of the techniques discussed are general techniques for weed control.  The CoP should identify specific techniques, if available, for removing and controlling the growth of TA-containing plants.	
e. Table 1 should clearly identify TA-containing plants.	
f. Additional pictures of the TA-containing seeds and plants that are of concern for producers should be included in Table 1, whereas pictures of plants that are unlikely to be consumed (e.g., pumpkin flowers) could be excluded.	
g. The CoP should include material on outbreaks and prevention associated with leafy green vegetable (e.g., spinach) contamination.	
h. If more information on animal feed is included, a separate section would be appropriate.	
i. The consumer education section can be shortened to focus on particular foods of concern, rather than medical symptoms and medication.	
The CoP shall also cover feed. However, in the proposal for new work, animal health/criteria to also cover feed are not mentioned. This should be added. Replace by legume vegetables.	FoodDrinkEurope
IFT appreciates the opportunity to respond to the request for comments on the CoP for prevention and reduction of tropane alkaloids.	IFT
We reviewed the proposed revised CoP in Appendix III, but OCS did not allow comments to be made there. We suggest expansion of the section on GMP's for food producers / manufacturers to include recommendations on techniques for removal of Datura stramonium seeds. Also, with recent food safety events in the fresh or processed vegetable arena, we recommend inclusion of those in the list of food products of concern.	
See: Heslop DJ. Tropane alkaloids and the potential for accidental or non accidental mass outbreaks of anti-cholinergic toxidrome. Global Biosecurity. 2023; 5(1).	

#### SPECIFIC COMMENTS

COMMENT	MEMBER/OBSERVER	
PROPOSAL FOR NEW WORK ON THE DEVELOPMENT OF A CODE OF PRACTICE FOR THE PREVENTION AND REDUCTION OF TROPANE ALKALOIDS CONTAMINATION IN FOOD AND FEED		
1. Purpose and scope of the project		
IRAN comments on "Code of practice for the prevention and reduction of tropane alkaloids contamination in food and feed":	Iran	
The proposed document establishes a robust framework for managing the risks posed by tropane alkaloids (TAs) and, given the comprehensive data presented, warrants approval as new work at CAC48. However, its finalization necessitates supplementary efforts, particularly in addressing gaps related to processing-stage data, broadening the scope of plant species covered, and enhancing regulatory coordination.		
The purpose of the proposed new work is to develop a code of practice (CoP) to prevent and reduce tropane alkaloids contamination in food and feed. The scope of the work is to complete a CoP to prevent and reduce tropane alkaloids (TAs) contamination in food and feed, particularly derived from Datura, for various stakeholders including farmers, food and feed manufacturers, competent authorities, and consumers.	USA	
The United States suggests that the scope of the project should specify which foods will be covered by the CoP (e.g., cereal grains, dried legumes, and leafy green vegetables such as spinach).		
2. Relevance and timeliness		
Food aid contaminated with TAs was determined to cause food poisoning outbreaks in the Republic of Uganda and the Republic of South Sudan in 2019. These events affected more than 300 people and even resulted in deaths. The <i>Joint FAO/WHO expert meeting on tropane alkaloids</i> (FAO/WHO, 2020) provided expert scientific advice on TAs in processed and unprocessed food products. To develop appropriate risk management measures in the United Nations World Food Programme (WFP) supply chains, it was recognized that limits expressed as physical toxic <i>Datura stramonium</i> seed contamination of cereals and grains will be beneficial for screening purposes at the field level. An <i>FAO/WHO guidance document on physical Datura stramonium seed contamination</i> was developed and published in 2020 to address this. The 17th Session of the Codex Committee on Contaminants in Foods (CCCF17, 2024) agreed to follow up on the findings of these documents and consider the development of a code of practice and project document for consideration by CCCF18.	IFT	
Since that report, numerous additional reports of food contamination or food poisoning have occurred globally in plant-based food products, including cereals & grains, fresh fruits & vegetables, herbs & spices, baby foods, and teas. [3] Gravador, R. S., Haughey, S., Meneely, J., Greer, B., Nugent, A., Daniel, C. S., & Elliott, C. (2024). Reports of tropane alkaloid poisonings and analytical techniques for their determination in food crops and products from 2013 to 2023. Comprehensive Reviews in Food Science and Food Safety, 23, e70047. https://doi.org/10.1111/1541-4337.70047 TA contamination concerns have been noted across temperate growing regions across all six populated continents.		
3. Main aspects to be covered		
This work will address measures for preventing TA contamination in food, including <u>pre-harvest agricultural</u> mitigation strategies related to <u>preventing /handling the growth of plants that produce TAs, with special attention to Datura weed control. <i>Datura</i> weeds. It will also address post-harvest measures such as sorting <u>grains</u> and <u>seeds to remove Datura seeds, sorting Datura plants from leafy green vegetables, and extra precautions for processed cereal-based food for infants and young children.</u></u>	USA	

COMMENT	MEMBER/OBSERVER
This work will address measures for preventing TA contamination in food, including mitigation strategies related to preventing /handling the growth of plants that produce TAs, with special attention to <i>Datura</i> weeds. It will also address post-harvest measures such as sorting and extra precautions for processed cereal-based food for infants and young children.	IFT
Additionally, the work will recommend potential actions to be taken by other Codex Committees, such as the development of globally aligned methods of analysis (CCMAS) related to TA and potential further evaluation on TA health impacts and toxicity by JECFA.	
Ref: Modular Point-of-Need Tropane Alkaloid Detection at Regulatory Levels: Combining Solid–Liquid Extraction from Buckwheat with a Paper-Immobilized Liquid-Phase Microextraction and Immuno-Detection in Interconnectable 3D-Printed Devices	
Ids B. Lemmink, Linda Willemsen, Erik Beij, Toine F. H. Bovee, Han Zuilhof, and Gert IJ. Salentijn	
Analytical Chemistry 2024 96 (41), 16462-16468	
DOI: 10.1021/acs.analchem.4c04811	
4. Assessment against the criteria for the establishment of work priorities	
(d) Work already undertaken by other international organizations in this field. Several bodies and organizations, such as the Joint FAO/WHO Expert Committee on Food Additives (JECFA), the Food and Agriculture Organization (FAO), the World Health Organization (WHO), and the World Food Programme (WFP), have undertaken work on TAs and can be consulted in developing a CoP. These organizations have made recommendations but have not offered a CoP.	IFT
Additional recommendations to help develop a CoP should include an assessment of recent key food and agricultural research efforts conducted at universities and research institutes, along with their recommended mitigation actions.	
Refs: 1. de Nijs M, Crews C, Dorgelo F, MacDonald S, Mulder PPJ. Emerging Issues on Tropane Alkaloid Contamination of Food in Europe. Toxins	
(Basel). 2023 Jan 19;15(2):98. doi: 10.3390/toxins15020098. PMID: 36828413; PMCID: PMC9961018	
2. Marín-Sáez J, Lopez-Ruiz R, Ferreira IMPLVO, Cunha SC. Gastrointestinal bioaccessibility and fiber mitigation of tropane alkaloids assessed on tea and cookies by in vitro digestion. J Sci Food Agric. 2023 Aug 30;103(11):5539-5546. doi: 10.1002/jsfa.12627. Epub 2023 Apr 29.	
7. Identification of any requirement for any availability of expert scientific advice	
The Joint FAO/WHO Expert Meeting (FAO/WHO, 2020) and other risk assessment bodies, such as the European Food Safety Authority (EFSA) (EFSA CONTAM Panel, 2008, 2013, 2016, 2018, and 2022), have already provided expert scientific advice.	IFT
However, the EWG may consider requesting additional expert scientific advice to be conducted if determined to be necessary.	