CODEX ALIMENTARIUS COMMISSION

Food and Agriculture Organization of the United Nations

World Health Organization

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Agenda Items 2, 6, 12, 13 and 16

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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON CONTAMINANTS IN FOODS

16th Session
18-21 April 2023 (physical plenary meeting)
26 April 2023 (virtual report adoption)

Comments submitted by Unites States of America (USA)

Agenda Item 2: Matters referred to the Committee by the Codex Alimentarius Commission and/or its subsidiary bodies

U.S. Comments:

- The United States agrees with the CAC and CCEXEC recommendations.
- The United States notes that proposals for evaluation of arsenic by JECFA can be considered under Agenda Item 16 (JECFA Priority List), but proposals for new MLs would be considered under other agenda items.

Agenda Item 6: Code of Practice for prevention and reduction of mycotoxin contamination in cassava and cassava-based products (at Step 7)

U.S. Comments:

- The United States appreciates the work done by Nigeria, as Chair of the EWG, to finalize the COP. The United States supports final adoption by CAC46 (2023) and provides the following editorial comments.

Para	Suggested edits
1	*Aspergillus ochraceus* as well as *A. carbonarius* and *A. niger*, ~~The aflatoxins are among the most potent carcinogenic, teratogenic, and mutagenic compounds known.~~ Depending on the ~~host~~ affected species, these mycotoxins can act as nephrotoxins, hepatotoxins, immunotoxins, neurotoxins, teratogens, or carcinogens, however, the liver is the primary target for toxicity. The major aflatoxins commonly found in agricultural commodities are aflatoxin B1, B2, G1, and G2, of which aflatoxin B1 is the most potent. Ochratoxin A may cause nephrotoxic, teratogenic, immunosuppressive and carcinogenic effects, depending on the affected species. It also causes porcine nephropathy and has been implicated in the etiology of Balkan endemic nephropathy (BEN) in
3	or by rodents, insects and other organisms also influences the severity of contamination. Good agricultural practices (GAP) and good manufacturing practices (GMP) could play a major role in reducing the severity of contamination. Storage duration may play a role in mycotoxin production, as it is known that the risk of postharvest fungal infection and production of mycotoxins in stored grain increases with the storage duration as indicated in the *Code of practice for the prevention and reduction of mycotoxin contamination in cereals* (CXC 51-2003).
4	*of HCN in cassava and cassava products* (CXC 73-2013). Cassava roots are ~~usually~~ processed and consumed in various forms, which may differ across countries. However, the primary reason for processing cassava root is to reduce the cyanogenic glycoside content. The presence of certain mycotoxins in cassava and cassava-based products destined for human food and animal feed use is not unexpected. Therefore, it is important to diligently monitor products and processes for ~~indications of the various~~ conditions that promote fungal contamination and mycotoxin accumulation. ~~as indicated in the *Code of Ppractice for the Pprevention and Rreduction of Mmycotoxin Ccontamination in Ccereals* (CXC 51-2003).~~
5-6	This Code of Practice provides science-based information for all countries to contemplate in their efforts to prevent and reduce mycotoxin contamination in cassava and cassava-based products. In addition, it provides a basis for training and education of farmers, agricultural workers, processors, manufacturers, and distributors.

5-6	The effectiveness of this Code of Practice will be determined by regulatory authorities, extension educators, farmers, producers, processors, distributors, and food business owners in each country by considering the general principles and examples of GAP and GMP provided in the Code. Additionally, other local crops, climate, and agronomic practices should be examined to facilitate implementation of these practices where applicable. ~~This Code of Practice is expected to apply to all cassava and cassava-based products relevant to human dietary intake and health, as well as international trade.~~ ~~This Code of Practice provides information on general principles for the reduction of various mycotoxins in cassava and cassava- based products. In addition, it provides a basis for training and education of farmers, agricultural workers, processors, manufacturers, and distributors.~~
7	with information and guidance to aid in the prevention and reduction of mycotoxin contamination in cassava and cassava-based products. This guidance covers: Good Agricultural Practices (GAP), Good Manufacturing Practices (GMP), Good Storage Practices (GSP) and Good Distribution Practices (GDP).
8	The farmer should avoid planting in valley bottoms, to avoid pooling water and flooding. Water can transport fungal innoculums. Where possible, ensure proper planning for crop rotation in successive seasons. This will help in reducing innoculums in the farm which may be present from post-harvest waste that can harbour toxigenic fungal spores. Particular crops (e.g. groundnuts, maize and sugarcane) have been found to be susceptible to certain
9	After selecting appropriate sites for planting, the land should be cleared, and waste properly disposed of to avoid contamination of the cassava roots with innocula from infected weed or other crops. The soil should be loosened by tilling, using clean (sanitized) and suitable farm tools and equipment to reduce stress to cassava roots. This is particularly critical during the root growth and maturation period ~~and also~~ to promote healthy root development. Farmers are encouraged to adopt good agricultural practices.
2.2/3	Selection and use of ~~healthy,~~ pest- and disease- ~~free~~ resistant cassava stems are important for good planting. ~~3. The ability to resist fungi and other plant pathogens should be considered when selecting cassava varieties. Cassava cuttings that are free of fungi should be planted.~~
10	To prevent fungal growth, no dead stems, diseased cuttings, or cuttings with visible fungi and pests should be planted. ~~Planting practices that have been reported to prevent rot could be adopted including~~ Vvertical planting, which involves placing the cassava cuttings vertically, may help to avoid rot, especially during the rainy season.
11	Avoid planting cassava on land where groundnut, maize, sugarcane, or other ~~highly susceptible~~ crops susceptible to *Aspergillus* were cultivated the previous year because such soils are more likely to be contaminated with toxigenic *Aspergillus* ~~*flavus, Aspergillus parasitic us* and related~~ species.
20	~~Prior to the processing step and~~ Wwhile being held on a short-term basis before processing~~for use~~, cassava roots should not be exposed to the sun, high temperatures, mechanical damage, or other conditions that could promote fungal contamination, since the roots still have a high water activity suitable for microbial development. Water activity (a_w), ~~is~~ commonly defined in foods as the water that is not bound to food molecules that can support the growth of bacteria, yeasts, and fungi. A continuous progression from harvest through processing to final product should be planned~~, in order~~ so that the roots will not be stored for a prolonged period of time. The ideal time is 2 to 3 days without enhanced storage methods
22	Cassava roots can be processed into various fermented or unfermented cassava-based products. These products, which may be specific to certain regions, have a wide range of applications including food for humans. The processing steps by which these various products are obtained differs and can be found in the *Code of practice for the reduction of HCN in cassava and cassava products* (CXC 73-2013). The approach here is to mention some of the various steps that may potentially influence fungal contamination but not for any specific product type. ~~For some product types see~~Refer to Figure 1 for different types of cassava products. Processing of cassava should be initiated within ~~within~~ 8-12 hours of receiving cassava roots as a raw material to avoid spoilage.
22	Comment: 8-12 hours seems to contradict the last sentence in paragraph 20/22. The previous section states that the ideal time to store product before processing is 2-3 days.
24	Immediately after washing, peeled cassava roots should be processed and should not be stored unprocessed. Peeling is ~~either~~ done either manually using a knife or ~~is done~~ mechanically. It is done to remove the outer inedible portion of the cassava roots. Peeling should be carried out in a clean environment~~, and~~ not in one where other crops have been stored, ~~otherwise, it~~which may serve as a source of contamination for the cassava.
25	~~Where~~ If further processing, including size reduction of washed cassava roots is needed, ~~includes size reduction activities, regardless of the size of the roots to be further processed, cassava variety, or type of available equipment~~, adequate care must be taken to ensure such ~~unit~~ processing does not lead to fungal contamination.

27	~~Where~~ If cassava chips or slices are dried at the farm level or in a processing facility, the chips or slices should be dried on a clean~~ed~~, dry, raised platform~~s~~ or on elevated drying mats such as raffia palm, bamboo, oil palm ~~mat~~, or banana leaves, among others, that would ensure good hygienic practice and reduce contamination potential~~and at an appropriate distance away from probable sources of contamination, (such as e.g., refuse dumps). Where If sun-drying is carried out, it should be done on elevated drying mats such as raffia palm, bamboo, oil palm mat, banana leaves, among others, that would ensure good hygienic practice~~.
30	The fermentation of cassava roots is primarily used for further cyanide elimination, flavor development and product stability. The sack and the container in which the grated pulp and the peeled root will be kept for fermentation ~~process,~~ should remain clean at all times, ~~and~~ especially before use~~,~~ to ensure it does not become a natural source of innoculums. Fermentation typically takes ~~place,~~ 2 to 5 days ~~fermentation~~.
32/33	Drying grated product, as with chips and slices, should ~~thereby~~ be done in a controlled environment and monitored. Drying cassava under the sun should be done only when the intensity of the sun light is sufficient. Drying should be properly done to avoid moisture. High microbial loads may be caused by use of unclean drying surfaces and materials such as sheets on raised platforms, so care must be taken to clean surfaces. Granules or chips should be properly spread out per square meter of drying surface and should not be overloaded to allow for air circulation. Platforms for drying should be raised to prevent contamination ~~(such as~~ e.g., dust, animals, and pests~~)~~. Batches of granules not adequately dried should be spread out in a ventilated room until the products are dried. ~~Drying surfaces and materials should be clean.~~
33	Comment: Is washing mills typical? Flour mills are typically not cleaned with water.
35	Comment: Is “monitoring” heating needed and what does that entail? Gari frying may decrease proliferation relative to the other processes, which don’t involve heating.
43	Specific storage instructions for the cassava and cassava-based products should be provided on the packaging to ensure protection from unfavourable conditions, which may promote fungal~~i~~ growth and contamination. The instructions for storage before ~~(e.g. store in a cool, dry, well-ventilated area)~~ and after the product is opened should be legible and in clear language, in order to maintain product quality. For example, instructions could say store in a cool, dry, well-ventilated area. Educators should create awareness on product stacking in storage areas to avoid increased humidity and temperature, which could encourage fungal growth.

Agenda Item 12: Guidance on data analysis for development of maximum levels and for improved data collection

U.S. Comments:

- The United States appreciates the work done by the Chair (European Union) and Co-Chairs (Netherlands, Japan, United States) and supports this work moving forward to provide assistance to EWGs developing documents for CCCF.
- The United States, as co-chair, chaired a virtual workgroup on data upload, data collection, data submission and extraction from GEMS Food database and prepared draft Section One. The United States also provided comments on draft Sections Two and Three.
- Comments from the United States include the need to provide practical advice in the guidelines such as advice on the minimum number of samples needed to develop MLs and possible updates to the GEMS/Food database.

Agenda Item 13: Forward work-plan for CCCF: Review of staple food-contaminant combinations for future work of CCCF

U.S. Comments:

- The United States appreciates the work by the Host Country, JECFA, and Codex Secretariats on the discussion paper and pilot project, which has initiated an important conversation about staple food-contaminant combinations.
- The United States believes that any further work should occur in an EWG or ISWG. If a member is willing to chair the work, we would not object to Option 2; however, CCCF should also consider the overall workload of the committee before starting new work.
- The United States also does not object to Option 3 or Option 4, given that the Codex standards review trial process is also addressing staple foods.

Agenda Item 16: Priority list of contaminants for evaluation by JECFA

1.1 Proposal for inclusion submitted by: **USA**

1.2 Name of compound; chemical name(s): **Thallium**

1.3 Identification of (additional) data (toxicology, metabolism, occurrence, food consumption) which could be provided to JECFA:

Toxicology: U.S. National Toxicology Program (NTP) is currently conducting studies of thallium (I) sulfate, including dose range-finding studies and a 90-day study in rats and mice exposed via drinking water, as well as 14-day cardiovascular toxicity studies in rats. FDA is conducting a systematic review of thallium toxicology data to identify research gaps.

Occurrence: FDA is planning analyses for thallium in brassica-containing foods, in baby foods and in Total Diet Study collections.

1.4 List of countries where surveillance data are likely to be available, and if possible, name of contact person who could provide such data, including quality assurance information on the data:

USA: Eileen Abt

Canada: John Fields

European Union:

Adding thallium to the pulldown menu in GEMS/Food will support additional data collection.

1.5 Timeline for data availability:

Occurrence data and NTP data are expected in 2024.

2.1 Whether or not the occurrence of the compound in commodities will have potential to cause public health and/or trade problems

Thallium is both an acute and chronic toxicant, and thus a potential concern for public health. As testing increases, there may be trade problems if there is no international health-based guidance value.

2.2 Whether or not commodities containing the compound are in international trade and represent a significant portion of the diet

Thallium is known to be present in brassica vegetables, but the extent of contamination in the food supply is not known.

2.3 Commitment that a dossier (as complete as possible) will be available for evaluation by the JECFA.

Yes

2.4.1 Consumer protection from the point of view of health, food safety, ensuring fair practices in the food trade

Understanding the extent of occurrence, exposure, and risk from dietary exposure to thallium addresses an important data gap regarding food safety and public health concerns.

2.4.2 The needs and concerns of developing countries

Exposures to thallium may occur in developing and developed countries due to environmental presence.

2.4.3 The diversity of national legislations and any apparent impediments to international trade

There are no known national legislations or apparent impediments to international trade from this work.

2.4.4 Work already undertaken by other international organisations

EFSA. 2020. Review of potentially toxic rare earth elements, thallium and tellurium in plant-based foods. EFSA journal.

EFSA. 2022. Risk assessment of rare earth elements, antimony, barium, boron, lithium, tellurium, thallium and vanadium in teas. EFSA journal.

2.4.5 The prospect of completing the work in a reasonable period of time

It is anticipated that the risk assessment can be completed in a reasonable time period.

2.4.6 The impact on international trade (i.e. magnitude of the problem in international trade)

The extent of thallium contamination in foods in international trade is not known. Adding thallium to the priority list will increase our understanding of thallium occurrence in foods worldwide. Submission of information on sources of thallium could also help address, in the future, any mitigation measures to reduce barriers to trade.

2.4.7 Compliance with the Codex Alimentarius Commission's Strategic Plan1 and its relevant plans of work

The addition of thallium to the JECFA priority list supports Goal 1 of the strategic plan to "establish international food standards that address current and emerging food issues."

2.4.8 The quality, quantity, adequacy, and availability of data pertinent to performing a risk assessment, including data from developing countries

Although sufficient data are not yet available, adding thallium to the priority list may lead to collection of additional occurrence data and development of toxicology studies.

2.4.9 Compliance with CCCF's Terms of Reference1

Yes

2.4.10 Compliance with JECFA's Terms of Reference2

Yes

2.5 Additional data/information to complement what is provided in this template: Note that this point does not replace the submission of the template through the OCS. This point is complementary to the data/information provided in points 1 – 2.4.

Thallium (I) sulfate 16019 (nih.gov)

Thallium | Toxicological Profile | ATSDR (cdc.gov)

EPA (2009) Toxicology Review of Thallium Compounds

EPA (2012) Provisional Peer-Reviewed Toxicity Values (PPRTV)