



ANALYSIS OF AGENDA ITEMS IN PREPARATION FOR THE 15th SESSION OF THE CODEX COMMITTEE ON CONTAMINANTS IN FOOD

9th – 13th and 24th MAY 2022 Virtual Meeting

AGENDA ITEM 7

Maximum levels for lead in certain food categories (at Step 4)

OBJECTIVES

This document offers a review and analysis of the agenda items planned for discussion at the 15th session of the Codex Committee on Contaminants in Food (CCCF), scheduled to take place virtually from May 9th – 13th and 24th, 2022.

The document is intended for possible use by the Codex communities of practice promoted by [GForSS](#) and [PARERA](#), as part of their contribution to enhancing awareness and supporting effective participation in international food standard setting meetings (Codex meetings) by representatives from members and observers.

The analysis provided in this document offers a factual review of agenda items, their background and a discussion of some considerations. This analysis is indicative in nature and does not represent an official position of the organizations mentioned above ([PARERA](#) and [GForSS](#)), their membership or their management. It provides a synthesis and analysis of the work currently under discussion in the CCCF committee, which may be useful for delegations from Arab countries to prepare their positions taking into account the needs and specificity of the region and potential impact of the proposed food standards.

This document is prepared as part [of the Arab Codex Initiative](#) implemented by [PARERA](#) and [GForSS](#), hosted and coordinated by the Arab Industrial Development, Standardization and Mining Organization (AIDSMO) and funded by the US Codex Office, US Department of Agriculture.

The focus of the analysis, of agenda item 7 of CCCF15, relates to lead in food commodities aim to establish maximum levels for lead in certain food categories.

**It is important to note that experts – members of the Expert Working Group (EWG) – do not represent the organizations and / or jurisdictions to which they are affiliated. The selection and participation in the EWG proceedings is based on each expert's own credentials and experience which should not be misconstrued as the country's / delegation's / organization's position to which they belong.*

Agenda Item 7: Maximum levels for lead in certain food categories (at Step 4)

Documents

- ❖ CX/CF 21/14/7
- ❖ CX/CF 21/14/7-Add.1
- ❖ CX/CF 22/15/7

CCCF 15 is invited to consider the MLs proposed by the EWG chaired by Brazil for lead in dried spices and culinary herbs, including dried bulbs, rhizomes and roots; fresh culinary herbs; eggs; sugars and sugar-based candies; cereal-based products for infants and young children and ready-to-eat meals for infants and young children.

Background of work

In their previous sessions, CCCF has established MLs for lead for certain food commodities contributing in lead exposure and also developed code of practice for the prevention and reduction of lead contamination in foods (COP) which the updated version is adopted at CCCF14 at step 5/8, offering additional mitigation measures to limit the presence of lead in food production across the supply chain.

The main areas of work and decisions made by the committee are presented below:

At the CCCF11 (April 2017), The Committee agreed to expand the work on Lead beyond the current food categories listed in the General Standard for Contaminants and Toxins in Food and Feed (GSCTFF), with the consideration of new Maximum Levels (MLs) for a range of food commodities

An Electronic Working Group (EWG) chaired by Brazil was established to prepare a discussion paper on a structured approach to prioritize this work (commodities that would be covered by MLs in the GSCTFF).

At the CCCF12 (March 2018), the Committee re-established the EWG chaired by Brazil, to prepare a revised discussion paper and a project document for consideration by CCCF13. Prioritization criteria considered availability of exposure data as well as other factors, in selecting commodities requiring interventions in the form of MLs.

At the CCCF13 (April 2019), the committee agreed to start new work depending on the availability of further occurrence data. This work was approved by CAC42 (2019).

The EWG established at CCCF13 worked on lead data extracted from the GEMS/Food Database considering results from 2008 – 2019. MLs were proposed for eggs, preserved eggs, fresh and dried culinary herbs and spices (fruits and berries; fresh and dried rhizomes, bulbs and roots; bark; floral parts; seed) in CX/CF 20/14/8.

Due to inconsistencies in the database, such as divergence between uploaded data by countries and downloaded data by the GEMS/Food Database administrator, it was not possible to propose at that time MLs for lead in foods for infants and young children and sugar and confectionery.

Due to the COVID19 pandemic, CCCF14 was postponed to 2021 and a new call for data was issued. After analyzing data extracted from the GEMS/Food Database, the EWG proposed to CCCF14 to include culinary herbs (fresh leaves) in the ML for lead in leafy vegetables in CXS193 and to establish the following MLs:



Food commodities	ML (mg/kg)
Eggs	0,1
Culinary Herbs (dried leaves or mixed herbs)	2.0
Dried bulbs, rhizomes, roots spices	2.0
Bark	2.0
Dried fruits and berries spices	0.6
Dried seeds spices	0.6
Dried floral parts spices	0.7
White and refined sugar	0.1
Raw and brown sugar	0.2
Syrup and molasses	0.1
Honey	0.1 or 0.05
fruit juices for infants and young children	the same MLs for lead in fruit juices in CXS193
Cereal-based products for infants and young children, expressed as consumed	0.04
Ready-to-eat meals for infants and young children	0.03
Herbal tea for infants and young children	0.6

At the CCCF14 (May 2021), CCCF agreed to:

i) clarify the MLs for fruit juices and grape juices in the GSCFF also apply to infants and young children and to advance this ML to CAC44 for adoption noting the reservations of the European Union and Norway;

ii) Discontinue work on an ML for herbal teas, yoghurt, cheese and milk-based products for infants and young children at this time;

iii) Re-establish the EWG, chaired by Brazil to:

a. continue working on MLs for lead in dried spices and culinary herbs, including dried bulbs, rhizomes and roots; fresh culinary herbs; eggs; sugars and sugar-based candies; cereal-based products for infants and young children and ready-to-eat meals for infants and young children taking into account the written comments submitted, comments and decisions made at the session and new data from GEMS/Food; and to describe in more detail the data analysis and present a broader range of MLs and rejections rates and,

b. work in close collaboration with the EWG on data management “Guidance on data analysis for development of MLs and for improved data collection”.

iv) Request JECFA to issue a call for data to get more (geographically representative) data available to the EWG, with the aim to finalize the MLs following year.

At the CCCF15, MLs established by EWG for the selected food categories will be discussed and submitted for adoption.

The following **table 1** summarizes all discussions, comments and decisions reached by the EWG:



Table 1: Proposal MLs for food commodities selected and corresponding commentary and decisions

Food	ML (mg/kg)	Commentary and decision
Fresh eggs (chicken and ducks)	0.25 mg/kg or to not establish a maximum level (ML)	- The Data were submitted from two regions (African Union and European Union) and seven countries; -The sample rejection for chicken and duck eggs would be 0.1% with the application of the LM, -One-member country commented about the relevance of fresh eggs for international trade compared to processed eggs. Considering the low relevance for international trade, the low levels of lead in eggs and the analytical methods available for lead in eggs, a ML may not be necessary.
Culinary herbs (fresh) (except Rosemary)	0.25	-Data were submitted from one region (European Union) and 42 countries. -The impact of the establishment of hypothetical MLs for lead on dietary intake was evaluated for each subcategory using the GEMS/Food Cluster Diet with the highest consumption pattern for each group (worst case scenario). -The sample rejection would be 4.5 % with the application of the ML,
Rosemary (fresh)	0.5	The sample rejection would be 3 % with the application of the ML,
Culinary herbs (dried)	2.0	The sample rejection would be 3.8-5.1 % with the application of the LM,
Dried spices Floral parts (cloves, excluding saffron)	2.5	-Since there are limited numbers of occurrence data for saffron, the EWG suggests establishing ML for spices of floral parts (cloves) and to not establish ML for saffron. -The sample rejection would be 5 % with the application of the ML,
Fruits and berries spices (excluding star anise and sumac)	0.8	-The EWG propose to establish ML for all spices of fruit and berries excluding sumac and star anise which the number of samples was less than 15. -The sample rejection would be 2.5-4.8 % with the application of the ML,
Rhizomes, bulbs and roots spice (excluding garlic)	3.5	-The EWG evaluated hypothetical MLs considering rhizomes, bulbs and roots with and without turmeric. Considering that the 95th percentile value was 2.82 mg/kg for turmeric alone, it is expected that adulterated samples would be excluded when a ML is established. -The sample rejection would be 4% with the application of the ML,

Garlic	0.4	Although available data are limited, levels of lead might be lower in garlic samples, suggesting the possibility to establish a separate ML. The sample rejection would be 2.8% with the application of the ML,
Bark	2.5	The sample rejection would be 4.7% with the application of the ML,
Seeds spices (excluding, carom, celery, dill, mahlab, mustard and poppy)	0.8	-The EWG identified few (less than 20) data of carom, dill, mahlab, mustard and poppy. -The LMs are based on all occurrence data and the removal of samples up to the 95th percentile.
Celery seeds	1.5	-The sample rejection would be 2% with the application of the ML for spices dried seeds and 4.2% for celery seeds,
Sugar, white and refined	0.1	-The data were submitted from two regions (Africa and EU) and ten countries including Saudi Arabia; -The EWG do not propose a ML for all syrups neither for glucose and beet syrups , because glucose and beet syrups had less than 20 samples and were all from one region; - With the application of the ML, The sample rejection would be 4.4 % for honey, 0-3.2 % for sugar, 5% for molasses, 0-2.99 % syrups
Sugar, brown and raw	0.1	
Honey	0.06	
Corn and maple syrups	0.1	
Molasses	0.3	
Hard candies, Gummy and jellies	0.05	
Soft candies	0.07	
Candy powder	0.2	
Ready-to-eat meals for infants and young children	0.05	-Data were submitted from one region (European Union) and ten countries: Australia, Brazil, Canada, China, Cuba, Japan, Saudi Arabia, Singapore, Thailand and USA. -The sample rejection would be 0.9- 1.9% with the application of the ML,
Cereal-based products for infants and young children, expressed "as is"	0.05	The sample rejection would be 0-3.33% with the application of the ML,

Analysis

Considering the decisions of CCCF14, a call for data was issued on lead levels in several products. Data from 2011 to 2021 were extracted by the WHO administrator of the GEMS/Food Database.

The dataset was analyzed by the EWG and MLs for 21 food commodities were proposed by the EWG and submitted for comments except for the following products: star, anise sumac, glucose, beet syrups, saffron, carom, celery, dill, mahlab, mustard and poppy for lack of occurrence data (less than 20).

For the establishment of MLs, the EWG considered the As-Low-As-Reasonably-Possible (ALARA) principle and a maximum rejection rate of 5% taking into account a case-by-case basis approach for each food category and considered only the categories for which there were more than 20 samples as recommended by the EWG of "Guidance on data analysis for development of MLs and for improved data collection".



In case of availability of consumption data, the EWG calculated the intake and the impact of hypothetical MLs to complement the decisions.

Taking the dataset for spices as example, EWG observed that the rejection rate could be above 5% with the exclusion of outliers/extreme values, which is against the CCCF14 decision to consider up to 5% of rejection rate.

As CCCF still have not reached consensus about identification and exclusion of outlier's data, the rationale used by EWG to propose the various MLs was based on the previous approach adopted by CCCF, in recent years to accept a maximum rejection rate of 5% (i.e. rejection rates of 5% or less may offer room for reduction of exposure to be implemented), with the caveat that such rate, may lead to higher rejecting rates for some producing countries.

Impact of MLs in Arab Region

In order to strengthen the capacities of the region in the field of health risk analysis, the expert working group affiliated to the Arab Codex Initiative conducted a research to identify studies carried out in the Arab countries in order to collect occurrence data for contaminants.

A systematic scanning of the published scientific literature was performed between 2005 and 2022. Over 200 articles were retrieved, representing the 22 Arab countries and their activities on monitoring metallic trace elements in food. For article retrieval, major scientific databases (ScienceDirect, Wiley, Springer, Taylor & Francis, MDPI, etc.) and search engines (Google Scholar, PubMed, etc.) were independently searched. Keywords including trace elements, heavy metals, food, and the names of the different Arab countries were used in the formulation of the search queries.

Concerning lead contamination, the data collected shows that various levels can be found depending of the products investigated, some of them exceed the MLs proposed by the EWG.

Of consideration, for the region the following uncertainties:

- ❖ Levels of honey from the region (from data not provided to GEMS Food) were consistently found above 0.06 ppm, leading to consider that this value may not be achievable for the vast majority of producing countries in the region,
- ❖ Levels proposed for spices and aromatic herbs may represent a challenge for the region. Data (not provided to GEMS Food) indicates much higher occurrence levels for products found in the region. It will be important to consider the possible root causes for such contamination and whether measures amongst those proposed in the Code of Practice for the reduction of Lead (previously adopted) would contribute to mitigate such occurrence.

Conclusion and Considerations for the Region

It would be important to document the possible impacts and in particular the achievability of several MLs on the designated food products from the region by conducting exposure assessment based on real consumption data generated by Arab countries reflecting the consumption habit in the country.

For the vast majority of levels proposed, it may be beneficial to return the proposed standards (MLs) at step 2, with further investment from the region to characterize impacts of the proposed MLs or their alternatives.

Some MLs offer sufficient rationale to be adopted such as:

Corn and maple syrups, 0.1 mg/kg

Molasses, 0.3 mg/kg.

Candy, 0.1 mg/kg; powder candy, 0.2 mg/kg.

Cereal-based products for infants and young children, expressed “as is” at 0.05 mg/kg (ppm).

It would also be important to document the feed-back from representatives of the Food industry in the region, on the feasibility of these MLs, in particular for importers and processors of the region.

In general, it may be recommended that the Arab region consider:

- ❖ Examining monitoring data related to lead in food products sold and produced in the region;
- ❖ Reviewing current risk management measures, in particular regulatory measures related to lead in food ingredients and food products in the Arab region;
- ❖ Developing proposed approaches for MLs in lead for possible consideration in the Region, based on data collected from the region, while Codex is in the process of establishing these new MLs and aim for regional harmonization and alignment with international standards;
- ❖ A regional (Arab region) Expert Working Group could be created to examine the above proposal and develop a risk analysis for Lead in food, in the Arab region.

