CODEX ALIMENTARIUS COMMISSION E

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CODEX COMMITTEE ON CONTAMINANTS IN FOODS

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DISCUSSION PAPER ON THE ESTABLISHMENT OF NEW MAXIMUM LEVELS FOR LEAD IN COMMODITIES ACCORDING TO A PRIORITIZATION APPROACH

(Prepared by the Electronic Working Group led by Brazil)

BACKGROUND

1. At the 73rd JECFA meeting it was concluded that, in populations with prolonged dietary exposures to higher levels of lead, measures should be taken to identify major contributing sources and, if appropriate, to identify methods of reducing dietary exposure that are commensurate with the level of risk reduction.

2. Since no safe level of lead has been identified by JECFA, the 6th Session of the Codex Committee on Contaminants in Foods (CCCF06, 2012) agreed to establish an electronic Working Group (EWG) led by the United States of America (USA) to revise the maximum levels (MLs) for lead in foods in the *General Standard for Contaminants and Toxins in Food and Feed* (GSCTFF) (CXS 193-1995).[1]

3. CCCF11 (2017)[2] noted that current work on the revision of the MLs for lead is limited to those food categories listed in the GSCTFF. There was however wide support to continue working on new MLs for lead for a range of categories and an EWG led by Brazil was established to prepare a discussion paper on a structured approach to prioritize commodities not included in the GSCTFF.

4. CCCF12 (2018)[3] considered the discussion paper which used as prioritization criteria the occurrence level and the impact on international trade, besides the vulnerable population.

5. CCCF12 agreed to re-establish the EWG led by Brazil to prepare a revised discussion paper and project document which also took into consideration the importance of the lead reduction intake to human health, the importance of the commodities to international trade, the lead intake and the data availability in establishing the prioritization categories for MLs, and to propose MLs for the categories indicated with a focus on commodities identified as high in the priority list.

6. In order to support the discussion paper, a call for data on lead in cereal-based food for infants and young children; canned baby food and fruit juice and herbal tea for infants and young children; tea and herbal tea (herbs/fruits for infusions); cocoa and cocoa products; seafood (except fish); processed fishes; eggs; algae and seaweeds; nuts and oilseeds; sugar and confectionary (excluding cocoa) and spices and aromatic herbs was done. Data covering approximately the last 10 years for lead in the food categories listed was requested to be submitted no later than 1 October 2018.

7. The background information in support of the conclusions and recommendations is provided in Appendices II and III. The list of participants is presented in Appendix IV.

[1] REP12/CF. paras. 126-127
[2] REP17/CF. para. 85-86
[3] REP18/CF. para. 131

PRIORITIZATION CRITERIA

8. The EWG thanks all country members and organizations that submitted comments to improve this Discussion Paper. In 2018 more than 23166 new data were submitted, totaling 51.437 analytical data, used in this document. For this Discussion Paper the relationship between lead exposure and trade was considered as recommended by CCCF. To avoid using a different approach the EWG considered the principles established in Policy of the Committee on Contaminants in Foods for Exposure Assessment of Contaminants and Toxins in Foods or Food Groups (Codex Alimentarius Commission Procedural Manual) (hereafter referred to as the "policy of CCCF)to prioritize by food category and JECFA information (e.g. hazard endpoint, consumption data for children). Beyond that, the EWG considered the WHO recommendation to data analysis. All foods for children were considered as priority. Furthermore some members suggested it is necessary to submit information about food really consumed by children and its consumption. The priority food categories are listed in this document. If the prioritization criteria are approved, the members also considered, to start the new work for lead in food of the high priority list considering new occurrence data to be submitted and the food specificities (e.g. to evaluate differences of tea and herbal tea (dried or beverage), spices and aromatic herbs, cocoa products).

9. The Preamble of the GSCTFF recommends in Section 1.3.2 that "maximum levels (MLs) shall only be set for those foods in which the contaminant may be found in amounts that are significant for the total exposure of the consumer. They should be set in such a way that the consumer is adequately protected". In this point of view, it is important to highlight that lead is a contaminant widely distributed in food and it will rarely be found in a single food/food category. Although lead is found in a wide variety of foods, some foods may be a more significant source of exposure.

10. According to paragraph 10 of the Policy of the CCCF[4], "the criteria for selecting foods/food groups that contribute significantly to total dietary exposure of a contaminant or toxin should be based upon the percentage of the tolerable intake (or similar health hazard endpoint) that is contributed by a given food/food group and the number of geographic regions (as defined by the GEMS/Food Consumption Cluster Diets) for which dietary exposures exceed that percentage". Food and food groups that may have a significant impact on exposure for specific groups of consumers should also be considered. The criteria are established in paragraph 11 of the Policy of the CCCF.

11. It was defined by the Committee that the commodities prioritization list should take into consideration the relationship between the impact on lead intake or exposure and international trade (exportation or importation data). The first step was to classify the food categories in high, intermediate and low impact of lead exposure and high, intermediate and low impact on international trade.

12. Dietary lead intake was calculated based on mean lead occurrence in food categories obtained from the GEMS/Food database and mean consumption data obtained from the GEMS/Food Consumption Cluster Diets database. For food not listed in GEMS/Food Consumption Cluster Diets Database, we considered consumption data available in CIFOCOss (Chronic Individual Food Consumption Database summary statistics). Children consumption was assumed to be three times more than adult, in the same way established by JECFA (WHO, 2011).

13. To evaluate the impact of lead exposure, we considered dietary intake of lead for each food category (based on mean consumption from the cluster diet database and mean lead occurrence) and the percentage of the intake in relation to the following health hazard endpoints developed by JECFA: 0.6 µg/kg b.w./day which is associated with a 1 point decrease in IQ in children) and 1.2 µg/kg b.w./day which is associated with a population increase in systolic blood pressure of 1 mm Hg (JECFA 2011).

14. The two highest lead intakes among the 17 GEMS/Food Cluster Diets were compared to those toxicological endpoints and were used to estimate the impact of lead exposure of each food category (Table A3).

15. The eWG considered as high impact of lead exposure those food categories for which lead intake equalled 10% or more of the tolerable intake (or similar health hazard endpoint) in one of the GEMS/Food Consumption Cluster Diets or more than 5% of the tolerable intake in two or more of the GEMS/Food consumption cluster diets. For intermediate impact of lead exposure, the eWG considered the food categories for which lead intake equalled 5% to less than 10% of the tolerable intake (or similar health hazard endpoint) in one of the GEMS/Food Consumption Cluster Diets. Lead intake lower than 5% of the tolerable intake (or similar health hazard endpoint) in all of the GEMS/Food Consumption Cluster Diets was considered low impact of lead exposure. Food categories without consumption data in GEMS/Food Consumption Cluster Diets database were not considered in the list. The classification based on the impact of lead exposure using reference values for blood pressure increases in adults and reference values for IQ reduction in children are shown in Table 1.

[4] Policy of the Committee on Contaminants in Foods for Exposure Assessment of Contaminants and Toxins in Foods or Food Groups, Section 3. Codex Alimentarius Commission Procedural Manual.

16. International trade data were obtained from Trade Map (http://www.trademap.org) for imports and exports in 2017 (quantities in tons and value in thousand dollars). The total international trade of food categories listed (sum of commodities in the table A4) was used to convert data to percentages. International trade was empirically classified in three groups, considering the percentage contribution of each category in value of international trade: high impact (>10%), intermediate impact (1 ≤ x < 10%) and low impact (< 1%) on international trade (

17. Table).

18. The eWG considered food categories as priorities to work on new MLs for lead if the categories showed high impact of lead exposure for at least one of the two toxicological endpoints as well as a high or intermediate impact on international trade.

19. It is important to emphasize that infants and young children are the most susceptible groups to the toxic effects of lead and, therefore, food categories for infants and young children should be evaluated in more detail, even if they do not have consumption data to estimate lead intake or a high impact on international trade. Others food groups that can have a significant health impact for specific groups of consumers, although low exposure, must be considered important for establishing protective measures.

20. In addition, dried products and multi-ingredient products were also excluded, because it is possible to derive MLs based on raw commodities MLs using processing factors or from the composition of the food based on raw material ingredients, respectively.

Table 1: Classification of food categories based on lead intake estimated by the two highest clusters diet consumption and by mean lead occurrence.

High lead intake foods (Intake ≥ 10% of hazard endpoint in one Cluster Diet or 5 ≤ x < 10% in at least two Cluster Diet)	**Intermediate lead intake foods** (Intake 5 ≤ x < 10% of hazard endpoint in one Cluster Diet)	**Low lead intake foods** (Intake < 5% of hazard endpoint)
Point of departure for blood pressure = 1.2 µg/kg b.w. per day		
- Spices and aromatic herbs - Eggs and eggs products - Cereal flours and starch	- Sugar and confectionary excluding cocoa - Seafood - Alcoholic beverages excluding wine	- Teas and herbal teas - Stalk vegetables - Processed fish excluding frozen and sliced - Cocoa and cocoa products - Coffee and coffee-based products - Nuts and oilseed - Edible land snail
** Point of departure for decrease IQ = 0.6 µg/kg b.w. per day*		
- Spices and aromatic herbs - Eggs and eggs products - Cereal flours and starch - Sugar and confectionary excluding cocoa - Seafood - Teas and herbal teas - Cocoa and cocoa products - Stalk vegetables - Processed fishes	- Coffee and coffee-based products	- Nuts and oilseeds - Edible land snails

Algae and seaweeds, non-alcoholic beverages and vegetable juices were not listed because there is no consumption data in GEMS/Food Cluster Diet Consumption database.

* For IQ reference, consumption for children was derived from GEMS/Food Cluster Diets considering that children eat three times more than adults on a per kilogram body weight basis.

Table 2: Classification of food categories based on contribution on international trade, considering exportation and importing values.

Percentage of total international trade*		
High impact (≥10%)	**Intermediate impact (1 ≤ x < 10%)**	**Low impact (<1%)**
- Seafood - Sugar and confectionary excluding cocoa - Cocoa and cocoa products - Alcoholic beverages excluding wine - Coffee and coffee-based products	- Nuts and oilseeds - Processed fish excluding frozen and sliced - Non-alcoholic beverages - Spices and aromatic herbs - Teas and herbal teas - Cereal flours and starches - Eggs and egg products	- Stalk vegetables - Vegetable juice - Algae and seaweeds

Edible land snails were not listed since international trade data was not found.

* Percentage of total international trade refers to the rate of commodity trade and the sum of all commodities in the table A4.

CONCLUSIONS

21. To identify and prioritize commodities which are not included in the GSCTFF to work on new MLs for lead, the above mentioned approach for prioritization has been fulfilled, taking global data of lead occurrence available from 2008 to 2018 in these foods into consideration, lead intake, and the impact to international trade. Data about lead levels, lead intake and international trade are presented in tables A1 – A4 in Appendix I.

22. Based on the impact of exposure of lead and international trade impact, it is possible to identify the follow food categories, in descending order of % hazard endpoint, to work on new MLs for lead:

a. Spices and aromatic herbs
b. Eggs and eggs products
c. Cereal flours and starch
d. Sugars and confectionary, excluding cocoa
e. Seafood
f. Teas and herbal teas
g. Cocoa and cocoa products
h. Processed fish excluding frozen and sliced

23. Beside this, given the health impact of lead, particularly for infants and young children, as they constitute the most sensitive subpopulation in terms of neurodevelopmental effects, food for infants and young children identified in this work (see table A1) was considered critical for establishing work on new MLs for lead. In addition, the eWG considers it important to recommend CCCF members to identify other foods that are highly consumed by children and their consumption.

24. Hypothetical MLs for lead in priority food categories are described in Appendix I (tables A5 to A13). Food categories and the hypothetical limits shown in this document reflect data available in GEMS/Food database at this moment and were included to illustrate the importance of setting MLs for these products. Thus, when the discussion on the establishment of the ML starts, food categories and MLs should be revised according to available data.

RECOMMENDATIONS

25. Based on the above conclusions and the technical information provided in Appendices II and III, CCCF is invited:

- To agree on the prioritization criteria (paragraphs 8-16).
- To agree on the proposed prioritization list of foods (paragraph 21)
- To start new work to set MLs for lead in the priority food categories mentioned in paragraph 21, based on the impact of exposure of lead and international trade impact and considering the available data in the GEMS/Food database based on a project document provided in Appendix I.
- To agree on a call of data for food categories identified as priorities.
- To consider if it is necessary to identify other foods that are highly consumed by children and their respective consumption. Such information could be requested by a Circular Letter.
- To discuss if it is important to consider individual countries' consumption data for food categories that have high occurrence levels or significant international trade impact (e.g. algae and seaweed, non-alcoholic beverages) and do not have consumption data in the GEMS/Food Cluster Diets database.

APPENDIX I

PROJECT DOCUMENT
(For consideration by CCCF)

MAXIMUM LEVELS FOR LEAD FOR INCLUSION IN THE GENERAL STANDARD FOR CONTAMINANTS AND TOXINS IN FOOD AND FEED (CXS 193-1995)

1. Purpose and scope

The purpose of this work is to protect public health by harmonizing the level of lead in food categories not included in the General Standard for Contaminants and Toxins in Food and Feed (CXS 193-1995) (GSCTFF) and ensure fair practices in international food trade.

2. Its relevance and timeliness

Lead was evaluated by the JECFA at its 16th, 22nd, 30th, 41st, 53rd and 73rd meetings. At the 73rd JECFA meeting a new toxicological evaluation of lead in food was conducted, at the request of Codex Committee on Contaminants in Food (CCCF). In the evaluation[1] JECFA73 stated that exposure to lead is associated with a wide range of effects, including various neurodevelopmental effects, impaired renal function, hypertension, impaired fertility and adverse pregnancy outcomes. Because of the neurodevelopmental effects, fetuses, infants and children are the subgroups that are most sensitive to lead. JECFA withdrew the previously established provisional tolerable weekly intake (PTWI) of 25 µg/kg bw and concluded that since there is no indication for a threshold of effect it was not able to establish a new tolerable intake level. JECFA also concluded that, in populations with prolonged dietary exposures to higher levels of lead, measures should be taken to identify major contributing sources and, if appropriate, to identify methods of reducing dietary exposure that are commensurate with the level of risk reduction.

Food is the major source of exposure to lead. The GSCTFF does not have MLs for lead established for several food categories that impact more in the dietary expose than several current ML for categories such as mango chutney, pickled cucumbers, etc. Nevertheless, some food categories are broadly consumed and/or may contain high levels of lead and can significantly contribute to the intake of lead.

In this context, a new work for MLs for lead in different food categories which are not covered by the GSCTFF should be developed aiming lower lead exposure.

3. The main aspects to be covered

MLs for lead in several food categories, taking into account the following:

a) Results of discussions of the CCCF
b) Risk assessments conducted by JECFA
c) Achievability of the MLs
d) Occurrence in the food category
e) Availability of data
f) Impact on the exposure
g) Rejection rates

4. An assessment against the criteria for the establishment of work priorities

a) Consumer protection from the point of view of health, food safety, ensuring fair practice in the food trade and taking into account the identified needs of the developing countries.

The new work will establish Maximum Level(s) for lead in several categories.

b) Diversification of national legislations and apparent resultant or potential impediments to international trade.

The new work will provide harmonized international maximum levels.

c) Work already undertaken by other organizations in this field

The risk assessment has already been done for lead by JECFA.

5. Relevance to the Codex Strategic Objectives

The work proposed falls under the following Codex Strategic Goals of the Codex Strategic Plan 2014-2019:

[1] JECFA. Evaluation of Certain Food Additives and Contaminants. Seventy-third report of the joint FAO/WHO Ex-pert Committee on Food Additives. WHO Technical Report Series 960.

Strategic goal 1 Establish international food standards that address current and emerging food issues

This work was proposed in response to needs identified by JECFA to decrease lead dietary exposure.

Strategic goal 2 Ensure the application of risk analysis principles in the development of Codex standards

The establishment of MLs shall take into account the exposure assessment proposed by JECFA.

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

This work follows-up on the ongoing work on the revision of existing MLs for lead in the GSCTFF.

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

Expert scientific advice has been already provided by JECFA.

8. Identification of any need for technical input to the standard from external bodies so that this can be planned for the proposed timeline for completion of the new work

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

9. Proposed timeline for completion of work

Subject to the approval by the 42nd Session of the Codex Alimentarius Commission in 2019, the following working plan is proposed:

i. Work package 1, depending on the availability of occurrence data:

- Food for infants and young children
- Spices and aromatic herbs
- Eggs
- Cereal flours and starch

The proposed draft ML(s) for lead in different food categories will be considered at CCCF14 and CCCF15 with a view to its finalization in 2021.

j. Work package 2, depending on the availability of occurrence data:

- Sugars and confectionary, excluding cocoa
- Seafood
- Teas and herbal teas

The proposed draft ML(s) for lead in different food categories will be considered at CCCF15 and CCCF16 with a view to its finalization in 2022.

k. Work package 3, depending on the availability of occurrence data:

- Cocoa and cocoa products
- Other categories identified by the CCCF

The proposed draft ML(s) for lead in different food categories will be considered at CCCF17 with a view to its finalization in 2024.

APPENDIX I

BACKGROUND DOCUMENT
(For information)

INTRODUCTION

1. This document aims to provide recommendations on a prioritization list of foods that do not have Codex MLs for lead to initiate a new work for relevant categories.

2. The prioritization criteria proposed to elaborate a food categories list took into consideration the importance of reduction of lead intake to human health and the importance of the commodities to international trade.

3. The collection and initial categorization of data were presented at the 12th Session of CCCF and were performed based on food categories which are currently not listed in the GSCTFF with an ML for lead and followed one of these criteria:

- It was designated as important for working on new ML for lead by the 11th Session of CCCF;
- There was a Codex Standard, considering that commodities standards are, also, the reference used to identify foods for establishment of MLs;
- There were available data in GEMS/Food.
- There were international trade data available.

4. CXS 193-1995 () recommends “the possible application of MLs established for primary products to processed products and multi-ingredient products. When products are concentrated, dried or diluted, use of the concentration or dilution factor from raw commodity is generally appropriate in order to obtain a primary judgement of the contaminant levels in these processed products. The maximum contaminant concentration in a multi-ingredient food and feed can likewise be calculated from the composition of the food and feed. Information regarding the behaviour of the contaminant during processing (e.g. washing, peeling, extraction, cooking, drying etc.) is ho desirable to give more adequate guidance.”

5. Based on CXS 193-1995, dried fruits and vegetables were not included in the analysis for prioritization since maximum levels can be calculated using concentration factors. Multi-ingredients products, such as some confectionary, ice and desserts, were also not included since the maximum contaminant concentration can likewise be calculated from the composition of the food and quality control in raw materials is more efficient.

LEAD OCCURRENCE IN FOODS

6. Since the *Code of Practice for the Prevention and Reduction of Lead Contamination in Foods* (CXC 56-2004) was adopted in 2004, the eWG recommended using working data from the past 10 years. The collection of data was performed by the JECFA Secretariat based on the GEMS/Food database and the initial categorization of data was performed by the eWG. Analysis of results and decisions about which data were excluded, how data should be presented, and what recommendations should be included were made by the eWG.

7. Data were categorized based on the names entered by the countries in the field: FoodCategory, FoodName, LocalFoodName and FoodStateName. The “Remarks” column was also checked to see if there was some information that complemented the classification.

8. Data that did not comply with basic criteria were removed, such as incomplete information, aggregated data, results on dry matter basis and data without LOD and LOQ reported. The eWG considered the WHO recommendation to data analysis.

9. Data were converted on a unique unit (mg/kg). The eWG adopted for non-detects (ND) results values half of LOD in the analysis and values between LOD and LOQ were treated as (LOD + LOQ)/2 as recommended by WHO (1995)[2].

10. Food categories analysed are shown in Table A1. The summary statistics including N+/N (number of positive results/number of total samples), mean, median, 95th and 97.5th percentile concentrations (abbreviated as P95TH and P97.5TH), minimum and maximum concentrations are presented in Table A2.

[2] Joint FAO/WHO Food Contamination Monitoring Programme, Global Environment Monitoring System & World Health Organization. (1985(.Guidelines for the study of dietary intakes of chemical contaminants . http://www.who.int/iris/handle/10665/39255

11. After a call for data a total of 51,437 results from 13 countries (Australia, Brazil, Canada, China, Cuba, France, Japan, New Zealand, Republic of Korea, Singapore, Thailand, USA and Uruguay) and one region (European Region) were analysed (Table A1). Alcoholic beverages excluding wine represented 20.4% of the samples, followed by seafood (14.0%), nuts and oilseeds (7.5%), teas and herbal teas (7.4%), cocoa and cocoa products (5.9%), sugar and confectionary excluding cocoa (5.6%), spices and aromatic herbs (5.6%), processed fish products excluding frozen and sliced (4.8%), cereal flours and starches (4.7%), egg and eggs products (4.2%), stalk vegetables (3.5%), algae and seaweeds (2.9%), and non-alcoholic beverages (2.6%).

12. Lead concentrations were not detected (<LOD) in 53.3% of samples. The LOD and LOQ of the methods of analysis varied by category, with LODs from 0.00002 mg/kg to 5.0 mg/kg and LOQ values from 0.00005 mg/kg to 16.7 mg/kg. Even the maximum LOD and LOQ values were quite high, at first no exclusion was done for establish the prioritization list. To establish MLs, a refinement may be necessary. Food categories with the highest proportion of positive samples were teas and herbal teas (80.4%), edible land snails (72.8%), algae and seaweeds (65.8%), seafood (61.2%), spices and aromatic herbs (57.2%) and alcoholic beverages excluding wine (50.6%). Food categories with the lowest proportion of positive samples were non-alcoholic beverages (13.5%), processed fishes excluding frozen and sliced (19.5%), vegetable juices (20.9%) and food for infants and young children (24.6%).

13. The overall mean concentration for the food categories varied between 0.01 and 0.63 mg/kg (Table A2). Higher mean results were recorded for teas and herbal teas (0.63 mg/kg), spices and aromatic herbs (0.28 mg/kg), algae and seaweeds (0.25 mg/kg), eggs and egg products (0.19 mg/kg), cocoa and cocoa products (0.17 mg/kg), edible land snails (0.16 mg/kg) and seafood (0.09 mg/kg).

Table A1. Description of food categories analysed and countries submitting data

Food Category	Food included	Countries submitting data
Teas and herbal tea	Herbal tea (dried and infusion), tea (dried and infusion), mate	Australia, Brazil, Canada, China, France, New Zealand, Singapore, USA, WHO European Region
Spices and aromatic herbs	Anis seed, spices, peppers (chilli, black, white), basil, cinnamon bark, cardamom seed, herbs, aromatic herbs, cloves buds, coriander seeds, cumin seed, fennel bulb and seed, garlic, ginger root, rosemary, mace, thyme, turmeric root	Brazil, Canada, China, Cuba, Japan, Republic of Korea, Singapore, Thailand, USA, WHO European Region
Algae and seaweeds	e.g. (dried, prepared, roasted, fresh, preserved, salted)	Singapore, USA, WHO European Region
Eggs and eggs products	Chicken, ducks, quail eggs; eggs NES, eggs products (salted, boiled, preserved, lime, yolk, scrambled with oil, cooked, powder)	Australia, Canada, China, France, New Zealand, USA, Singapore, WHO European Region
Cocoa and cocoa products	Beans, powder, mass, butter, chocolate	Australia, Canada, China, France, New Zealand, Singapore, WHO European Region
Edible land snails	Fresh and processed (e.g. frozen, canned, in chilli)	Canada, China, Singapore, WHO European Region
Seafood	Crustaceans (shrimps, lobsters, crabs), molluscs (oysters, mussels, scallops), cephalopods (squids)	Australia, Brazil, Canada, China, France, Europe, New Zealand, Norway, Singapore, USA
Non-alcoholic beverages	Soft drink (fruit drink, carbonated beverage), non-alcoholic beverage NES, (e.g. cereal drink, caffeinated beverage, energy drink, ion supply drink, isotonic drink)	Australia, Canada, China, France, Japan, New Zealand, Singapore, USA, WHO European Region
Sugar and confectionary excluding cocoa	Sugar (cane, beet, white, brown), honey, syrup, confectionary (e.g. chewing gum, icings and frostings, hard and soft candy, marzipan and nougats)	Australia, Brazil, Canada, China, France, New Zealand, Singapore, USA, WHO European Region

Food Category	Food included	Countries submitting data
Nuts and oilseeds	Almonds, Brazil nuts, cashew nuts, chestnut, coconut, macadamia, walnut, pistachio nut, peanut, pecan, pine nut, tree nut, oilseed, cotton seed, sunflower seed, sesame, oilseeds, rape, poppy seed, linseed	Australia, Brazil, Canada, China, France, New Zealand, Singapore, Thailand, USA, Uruguay, WHO European Region
Processed fishes excluding frozen and sliced	Canned, boneless, roasted, smoked, sticks, crispy, breaded, in oil, in sauce	Australia, Brazil, Canada, France, New Zealand, Singapore, Thailand, USA, WHO European Region
Cereal flours and starch	Cereal flours, bran and starch	Brazil, Canada, Singapore, USA, New Zealand, WHO European Region
Stalk vegetables	Celery, asparagus, artichoke, cardoon, rhubarb, bamboo shoots, palm hearts, excluding canned products	Australia, Canada, China, France, Japan, New Zealand, Singapore, Thailand, USA, WHO European Region
Coffee and coffee-based products	Coffee beans (ground, roasted, decaffeinated), soluble, instant, canned, iced, coffee beverage and coffee imitate beverages	Australia, Brazil, Canada, China, France, USA, New Zealand, Singapore, WHO European Region
Food for infants and young children except infant formula, formula for special medical purposes intended for infants and follow-up formula	Cereal-based food for infants and young children, food for infant or children NES, fruit juice and herbal tea for infants and young children, ready-to-eat meal for infants and young children, yoghurt, cheese and milk-based dessert for infants and young children	Australia, Canada, Cuba, Japan, New Zealand, Singapore, Thailand, USA, WHO European Region
Vegetables juices	Beetroot, carrot, vegetable mix, Aloe vera, tomato.	Canada, Japan, Singapore, Thailand, USA, WHO European Region
Alcoholic beverages excluding wine	Beer and beer-like beverage, liqueur and spirits, wine-like drinks, alcoholic beverage NES	Australia, Canada, China, France, New Zealand, Singapore, USA, WHO European Region

Table A2. Lead concentrations in different food commodities

Food Category	N + / N	Lead concentration (mg/kg)					
		Mean	Median	P95TH	P97.5TH	Min	Max
Teas and herbal tea	3,053/3,797	0.63	0.32	1.74	2.30	0.00002	325.6
Spices and Aromatic Herbs	1,646/2,880	0.28	0.02	0.59	1.09	0.0001	350
Algae and seaweeds	966/1,468	0.25	0.20	0.87	1.11	0.001	4.10
Eggs and eggs products	790/2,143	0.19	0.02	0,58	1.24	0.0001	27.7
Cocoa and cocoa products	1,763/3,049	0.17	0.05	0.31	0.37	0.00001	45.4
Edible land snails	110/151	0.16	0.07	0.58	0.91	0.001	2.38
Seafood	4,400/7,194	0.09	0.03	0.32	0.47	0.000002	17.0
Non-alcoholic beverages	181/1,344	0.05	0.003	0.25	0.25	0.00007	2.00
Sugar and confectionary excluding cocoa	984/2,888	0.03	0.01	0.05	0.12	0.0001	16.5
Nuts and oilseeds	1129/3,857	0.02	0.01	0.06	0.10	0.0001	1.41
Processed fishes excluding frozen and sliced	484/2,476	0.02	0.01	0.11	0.14	0.00008	1.47
Cereal flours and starch	1,030/2,406	0.02	0.01	0.05	0.06	0.0004	0.30
Stalk vegetables	1,017/1,733	0.02	0.003	0.07	0.13	0.0002	1.44
Coffee and coffee-based products	301/877	0.03	0.01	0.06	0.09	0.0004	0.58
Food for infants and young children except infant formula, formula for special medical purposes intended for infants and follow-up formula	1,115/4,524	0.01	0.005	0.04	0.05	0.00001	1.20
Vegetables juices	23/110	0.01	0.005	0.03	0.04	0.0005	0.06
Alcoholic beverages excluding wine	5,302/10,470	0.01	0.002	0.02	0.05	0.00001	0.78

N^+/N = positive samples/total samples; P95TH = 95th percentile concentrations; P97.5TH = 97.5th percentile concentrations; Min = minimum; Max = maximum.

LEAD DIETARY EXPOSURE

14. Dietary lead intake (Tables X2 and X3) was calculated through mean lead occurrence in food categories obtained from the GEMS/Food database (Table A2) and mean consumption data obtained from the GEMS/Food Consumption Cluster Diets database (Table X1). For algae and seaweeds, non-alcoholic beverages and vegetable juices, which are not listed in GEMS/Food Consumption Cluster Diets Database, consumption data was obtained from report of countries available in CIFOCOss (Chronic Individual Food Consumption Database summary statistics). In the case of mean consumption data from different countries from the same cluster a weighted arithmetic mean was calculated considering the sample size of the consumption survey. For children, consumption was estimated as three times of consumption Cluster Diets since children eat two to three times more than adults on a body weight basis.[3]

15. In the 73rd JECFA Meeting it was defined a point of departure for the toxicological study that lead intake of 1.2 µg/kg b.w./day is associated with a 1 mmHg increase in blood pressure in adults and lead intake of 0.6 µg/kg b.w./day is associated with a 1 IQ point decrease in children. The two highest lead intakes among the 17 Cluster Diets were compared to those toxicological endpoints and were used to estimate the impact of lead exposure of each food category (Table A3).

16. According to the Codex Procedural Manual, maximum levels should be established for food categories for which the exposure contributes approximately 10% or more of the tolerable intake (or similar health hazard endpoint) in one of the GEMS/Food consumption clusters diets or more than 5% in two or more of the GEMS/Food consumption cluster diets. Besides that, the maximum level could be established for foods or food groups that may have a significant impact on exposure for specific groups of consumers, although exposure may not exceed 5% of the tolerable intake (or similar health hazard endpoint) in any of the GEMS/Food Consumption Cluster Diets (example: infant or young children).

17. Lead intake estimated from mean consumption and mean occurrence showed three food categories (non-alcoholic beverages, spices and aromatic herbs, eggs and egg products) with values that represented 10% or more of the reference value for blood pressure (1.2 µg/kg b.w. per day) in at least one cluster diet and one category (cereal flours and starches) with values that represented more than 5% of the reference value for blood pressure in at least two cluster diets.

18. Lead intake estimated from mean consumption for children and mean occurrence showed ten food categories (non-alcoholic beverages, spices and aromatic herbs, cereal flours and starches, sugar and confectionary, eggs and egg products, seafood, teas and herbal teas, algae and seaweeds, stalk vegetables and cocoa and cocoa products) with values that represented 10% or more of the reference value for IQ decrease (0.6 µg/kg b.w. per day) in at least one cluster diet and one category (processed fishes) with values that represented more than 5% of the reference value for decreased IQ in at least two cluster diets.

[3] Evaluation of certain food additives and contaminants (Seventy-third report of the Joint FAO/WHO Expert Committee on Food Additives). WHO Technical Report Series, No. 960, 2011.

Table A3. Highest estimated lead intakes (µg/kg b.w. day) for food categories and percentage of the contribution of each food category to the reference values for blood pressure increase (1.2 µg/kg b.w. day) in adults and decrease of IQ point in children (0.6 µg/kg b.w. day[a]).

Food Category	Cluster diet	Adults		Children	
		Estimated lead intake (µg/kg b.w. day)	% hazard endpoint for blood pressure	Estimated lead intake (µg/kg b.w. day)[b]	% hazard endpoint for decrease in IQ point
Teas and herbal teas	G14 G07	0.056 0.040	4.7 3.4	0.169 0.121	28.1 20.1
Spices and aromatic herbs	G15 G09	0.171 0.157	14.3 13.1	0.513 0.470	85.5 78.4
Algae and seaweeds*	G10 G09	0.038 0.004	3.19 0.35	0.115 0.013	19.1 2.1
Eggs and eggs products	G11 G10	0.116 0.106	9.7 8.8	0.318 0.269	58.2 53.0
Cocoa and cocoa products	G13 G15	0.021 0.016	1.8 1.3	0.064 0.048	10.7 8.0
Edible land snails	G08 G07	0.0005 0.0001	0.04 0.01	0.0014 0.0003	0.24 0.05
Seafood	G10 G17	0.068 0.055	5.7 4.6	0.205 0.168	34.1 27.9
Non-alcoholic beverages*	G11 G06	0.261 0.144	21.8 12.0	0.783 0.432	130.5 72.1
Sugar and confectionary excluding cocoa	G06 G11	0.072 0.045	6.0 3.7	0.215 0.135	35.9 22.5
Nuts and oilseeds	G01 G09	0.0017 0.0013	0.14 0.11	0.005 0.004	0.9 0.7
Processed fishes excluding frozen and sliced	G17 G10	0.019 0.012	1.6 1.0	0.056 0.037	9.4 6.1
Cereal flours and starch	G06 G01	0.103 0.086	8.6 7.2	0.308 0.258	51.4 43.0
Stalk vegetables	G09 G11	0.021 0.009	1.8 0.7	0.064 0.026	10.6 4.3
Coffee and coffee-based products	G11 G17	0.009 0.006	0.8 0.5	0.028 0.019	4.7 3.2
Vegetable juice*	G10 G08	0.0005 0.0001	0.04 0.01	0.002 0.0003	0.27 0.05
Alcoholic beverages excluding wine	G16 G08	0.065 0.050	5.4 4.2	NC	NC

b.w.: body weight; NC: not calculated since alcoholic beverages are not recommended for children.
[a]Reference values for increase in blood pressure and decrease in IQ were developed by JECFA (2011).
[b]Estimated lead intake for children was calculated considering that children's consumption is three times more than adults on a body weight basis.
*Consumption data from CIFOCOss

INTERNATIONAL TRADE

19. International trade data were obtained mainly from Trade Map (http://www.trademap.org) that covers 220 countries and territories and 5300 products of the Harmonized System. Global data were included for imports and exports in 2017 (quantities in tons and value in thousand dollars).

20. Trade data for food for infants and young children and for edible land snails were not found. However, infant and young children are the group most susceptible to the toxic effects of lead and, therefore, these food categories, even if they do not have a high impact on international trade, should be evaluated in more detail.

21. Food categories with the highest percentage of total import and export quantity were sugar and confectionary, seafood, cocoa and cocoa products and flours and starches representing together more than 70% of tons of foods in international trade among the food categories evaluated (Table A4).

22. Food categories with the highest percentage of total import and export value were seafood, cocoa and cocoa products, alcoholic beverages excluding wine, coffee and coffee-based products and sugar and confectionary, representing together more than 60% of the values of international trade among the food categories evaluated (Table A4). To identify the impact of food categories on international trade, total import and export value (in thousand dollars) were used as these data were more complete.

Table A4. Estimated quantity (in tons) and value (in thousand dollars) of imports and exports of food categories and percentage of the contribution of each category in total categories trade

Food Category	Exported				Imported			
	Quantity (tons)	% total trade	**Value (US$ thousand)**	% total trade	**Quantity (tons)**	% total trade	**Value (US$ thousand)**	% total trade
Seafood	25371120	15.7	54795355	15.6	5209979	4.7	51736899	14.7
Sugar and confectionary excluding cocoa	78004303	48.3	50060006	14.3	41109890	37.2	52864288	15.1
Cocoa and cocoa products	12564299	7.8	47781271	13.6	12493652	11.3	47919395	13.6
Alcoholic beverages excluding wine	0	0.0	46638683	13.3	0	0.0	48334880	13.8
Coffee and coffee-based products	9601184	5.9	39789945	11.3	9423335	8.5	39738460	11.3
Nuts and oilseeds	7310776	4.5	30422929	8.7	7986730	7.2	30101412	8.6
Processed fishes excluding frozen and sliced	5093527	3.2	21866498	6.2	4402264	4.0	20986434	6.0
Non-alcoholic beverages	0	0.0	19955345	5.7	0	0.0	19459443	5.5
Spices and Aromatic herbs	2863148	1.8	11153313	3.2	1625372	1.5	10988992	3.1
Teas and herbal teas	2505547	1.6	9232710	2.6	2138743	1.9	8474708	2.4
Cereal flours and starches	16702524	10.3	9507592	2.7	24608956	22.3	10396734	3.0
Eggs and eggs products	430664	0.3	5031442	1.4	448915	0.4	4985746	1.4
Vegetables juices	0	0.0	2589334	0.7	16021	0.0	2377318	0.7
Stalk vegetables	810850	0.5	1716944	0.5	835499	0.8	1906040	0.5
Algae and seaweeds	201746	0.1	570806	0.2	251613	0.2	807274	0.2
Edible land snails	NF	-	NF	-	NF	-	NF	-
Food for infants and young children	NF	-	NF	-	NF	-	NF	-

NF = not found. Source: Trade Map data (2017)

RISK MANAGEMENT CONSIDERATIONS FOR LEAD IN PRIORITY FOOD CATEGORIES

23. JECFA revoked the previously established provisional tolerable weekly intake (PTWI) of 25 µg/kg bw for lead and concluded that since there is no indication of a threshold of effect it was not able to establish a new tolerable intake level. JECFA also concluded that measures should be taken to reduce dietary exposure that is commensurate with the level of risk reduction. In this scenario lead exposure should be as low as reasonably achievable (ALARA).

24. The impact of the establishment of hypothetical MLs for lead on its dietary intake and sample rejection rate were analysed for those food categories considered priority categories. Hypothetical MLs were chosen according to the contamination distribution profile of each group. Tables A5 to A13 show the impact of hypothetical MLs for lead in each food category for the Cluster Diet with the highest consumption pattern for that group (worst case scenario).

25. During the discussion on the establishment of MLs, food categories should be evaluated to identify for which subcategories ML will be established, considering also the availability of data in GEMS/Food database and data quality.

Spices and aromatic herbs

26. Table A5 shows the impact of different MLs on lead intake and sample rejection for spices and aromatic herbs. Considering a rejection of less than 5%, a ML of 0.7 mg/kg is proposed. However, it should be noted that this ML considers spices and aromatic herbs as a general category and it does not consider the different profiles of sub-categories. Some spices contain more lead than others, and the amount of lead in spices may vary by geographical region. Spices and aromatic herbs may also be classified, for example, into rhizomes, roots, leaves, fruits, that may have different occurrence profiles. This may be look upon once the work to establish MLs starts and considering the data available at that time.

Table A5. Effect of the implementation of hypothetical MLs on lead intake through the consumption of spices and aromatic herbs for cluster G01 (highest consumption pattern).

Spices and aromatic herbs (n = 2,773)				
ML (mg/kg)	**Mean lead (mg/kg)**	**Intake (µg/kg b.w. day)**	**Intake reduction (%)**	**Sample rejection (%)[a]**
No ML	0.28	1.844	0	0
1.5	0.10	0.654	64.6	1.8
1.0	0.09	0.577	68.7	2.7
0.7	0.08	0.500	72.9	4.2
0.5	0.07	0.440	76.2	5.9

Consumption data used: sum of spices and herbs; G01=12.36 g/person (mean consumption). [a]Percentage of samples above proposed MLs for lead.

Eggs and eggs products

27. Table A6 shows the impact of different MLs on lead intake and sample rejection for eggs and eggs products category and subcategories. Setting MLs of 0.7 and 0.5 mg/kg would reject 4.4% and 5.6% of samples, respectively. Eggs products showed lower mean and median results, but the number of samples was small compared to egg samples. Taking this matter into consideration, it is recommended to establish a ML of 0.7 mg/kg for eggs and to evaluate more egg products data.

Table A6. Effect of the implementation of hypothetical MLs on lead intake through the consumption of eggs and eggs products for cluster G11 (highest consumption pattern).

Eggs and eggs products (n = 2,143)				
ML (mg/kg)	**Mean lead (mg/kg)**	**Intake (µg/kg b.w. day)**	**Intake reduction (%)**	**Sample rejection (%)[a]**
No ML	0.19	0.116	0	0
1.5	0.08	0.046	60.3	2.1
1.0	0.07	0.040	65.5	2.9
0.7	0.05	0.032	72.4	4.4
0.5	0.05	0.028	75.9	5.6
Eggs (n = 2,006)				
ML (mg/kg)	**Mean lead (mg/kg)**	**Intake (µg/kg b.w. day)**	**Intake reduction (%)**	**Sample rejection (%)a**
No ML	0.20	0.124	0	0
1.5	0.08	0.049	60.5	2.3
1.0	0.07	0.042	66.1	3.1
0.7	0.06	0.034	72.6	4.7
0.5	0.05	0.030	75.8	6.0
Processed eggs (n = 137)				
ML (mg/kg)	**Mean lead (mg/kg)**	**Intake (µg/kg b.w. day)**	**Intake reduction (%)**	**Sample rejection (%)a**
No ML	0.01	0.006	0	0
0.5	0.01	0.006	0	0
0.4	0.007	0.004	33.3	6.6
0.3	0.006	0.004	33.3	8.0
0.2	0.006	0.004	33.3	8.0
0.1	0.004	0.003	50.0	17.5

Consumption data used: Eggs, raw, (incl dried); G11=36.44 g/person (mean consumption). [a]Percentage of samples above proposed MLs for lead.

Cereal flours and starch

28. Table A7 shows the impact of different MLs on lead intake and sample rejection for cereal flours and starches category and subcategories. Setting an ML of 0.05 or 0.06 mg/kg, 5.5% or 2.3% of cereal flours and starches samples would possibly be rejected. Cereal flours showed higher occurrence levels than others products and can have a different ML established.

29. There is an ML for cereal grain (ML = 0.2 mg/kg) but according to the impact of cereal flours and starch on lead intake, it is recommended to evaluate if an ML can be derived from raw commodity or if it should be established based on cereal flours and starch data.

Table A7. Effect of the implementation of hypothetical MLs on lead intake through the consumption of cereal flours and starches for cluster G06 (highest consumption pattern).

Cereal flours and starches (n = 2,406)				
ML (mg/kg)	**Mean lead (mg/kg)**	**Intake (µg/kg b.w. day)**	**Intake reduction (%)**	**Sample rejection (%)[a]**
No ML	0.015	0.103	0	0
0.10	0.014	0.093	9.7	1.0
0.06	0.013	0.087	15.5	2.3
0.05	0.012	0.077	25.2	5.5
0.04	0.010	0.069	33.0	8.6
Bran (n = 272)				
ML (mg/kg)	**Mean lead (mg/kg)**	**Intake (µg/kg b.w. day)**	**Intake reduction (%)**	**Sample rejection (%)[a]**
No ML	0.016	0.108	0	0
0.10	0.014	0.094	7.0	0.7
0.06	0.013	0.088	12.8	2.2
0.05	0.013	0.086	14.9	2.9
0.04	0.011	0.072	28.4	8.5
Starch (n = 195)				
ML (mg/kg)	**Mean lead (mg/kg)**	**Intake (µg/kg b.w. day)**	**Intake reduction (%)**	**Sample rejection (%)[a]**
No ML	0.010	0.066	0	0
0.10	0.010	0.066	0	0
0.05	0.010	0.065	1.6	0.5
0.04	0.010	0.065	1.6	0.5
0.02	0.010	0.063	4.2	2.1
0.01	0.009	0.062	5.6	5.1
Flours (n = 1,810)				
ML (mg/kg)	**Mean lead (mg/kg)**	**Intake (µg/kg b.w. day)**	**Intake reduction (%)**	**Sample rejection (%)[a]**
No ML	0.016	0.108	0	0
0.10	0.015	0.097	9.7	1.2
0.06	0.014	0.090	16.3	2.7
0.05	0.012	0.078	28.2	6.7
0.04	0.010	0.070	35.6	10.0
Dextrin (n = 126)				
ML (mg/kg)	**Mean lead (mg/kg)**	**Intake (µg/kg b.w. day)**	**Intake reduction (%)**	**Sample rejection (%)[a]**
No ML	0.012	0.079	0	0
0.10	0.011	0.072	9.0	0.8
0.05	0.010	0.070	12.0	1.6
0.04	0.010	0.070	12.0	1.6
0.02	0.010	0.067	15.8	4.8
0.01	0.010	0.066	16.2	6.3

Consumption data used: sum of cereal flour and starch; G06=397.43 g/person (mean consumption).
[a]Percentage of samples above proposed MLs for lead.

Sugar and confectionary, excluding cocoa

30. Table A8 shows the impact of different MLs on lead intake and sample rejection for sugar and confectionary excluding cocoa and subcategories. If a ML of 0.05 mg/kg was set, 4.8% of samples would possibly be rejected. All subcategories have significant intake reduction and acceptable rejection with a proposed ML of 0.05 mg/kg.

Table A8. Effect of the implementation of hypothetical MLs on lead intake through the consumption of sugar and confectionary excluding cocoa for cluster G06 (highest consumption pattern).

Sugar and confectionary excluding cocoa (n = 2,888)				
ML (mg/kg)	**Mean lead (mg/kg)**	**Intake (µg/kg b.w. day)**	**Intake reduction (%)**	**Sample rejection (%)[a]**
No ML	0.02	0.072	0	0
0.1	0.02	0.050	30.6	2.6
0.05	0.01	0.045	36.9	4.8
0.04	0.01	0.036	50.4	13.4
Sugars (n = 2,416)				
ML (mg/kg)	**Mean lead (mg/kg)**	**Intake (µg/kg b.w. day)**	**Intake reduction (%)**	**Sample rejection (%)[a]**
No ML	0.02	0.057	0	0
0.1	0.02	0.050	13.5	1.7
0.05	0.01	0.045	22.0	4.2
0.04	0.01	0.036	36.9	11.7
Confectionary excluding cocoa (n = 439)				
ML (mg/kg)	**Mean lead (mg/kg)**	**Intake (µg/kg b.w. day)**	**Intake reduction (%)**	**Sample rejection (%)[a]**
No ML	0.03	0.078	0	0
0.1	0.02	0.047	39.5	3.4
0.05	0.01	0.045	42.8	4.8
0.04	0.01	0.032	59.8	16.2

Consumption data used: sum of grasses for sugar or syrup; G06=188.04 g/person (mean consumption).
[a]Percentage of samples above proposed MLs for lead.

Seafood

31. Table A9 shows the impact of different MLs on lead intake and sample rejection for seafood category and subcategories. A proposed ML of 0.3 mg/kg would result in 5.5% of seafood samples being rejected. However, for aquatic molluscs the rejection can be higher. Taking this matter into consideration, it is recommended to establish a ML of 0.4 mg/kg for seafood or 0.3 mg/kg excluding molluscs. Sea cucumber and sea urchins were not included in any subcategories as they are echinoderms.

Table A9. Effect of the implementation of hypothetical MLs on lead intake through the consumption of seafood for cluster G10 (highest consumption pattern).

Seafood (n = 7,194)				
ML (mg/kg)	**Mean lead (mg/kg)**	**Intake (µg/kg b.w. day)**	**Intake reduction (%)**	**Sample rejection (%)[a]**
No ML	0.09	0.068	0	0
1.0	0.08	0.059	13.8	0.5
0.5	0.07	0.050	26.6	2.3
0.3	0.06	0.042	38.1	5.5
0.2	0.04	0.033	50.8	10.8
Crustaceans (n = 2,897)				
ML (mg/kg)	**Mean lead (mg/kg)**	**Intake (µg/kg b.w. day)**	**Intake reduction (%)**	**Sample rejection (%)[a]**
No ML	0.05	0.037	0	0
1.0	0.04	0.028	23.7	0.6
0.5	0.03	0.023	37.6	1.5
0.3	0.03	0.020	45.9	2.6
0.2	0.02	0.018	52.7	4.0
0.1	0.02	0.013	64.5	8.6
Aquatic molluscs including cephalopods (n = 4,269)				
ML (mg/kg)	**Mean lead (mg/kg)**	**Intake (µg/kg b.w. day)**	**Intake reduction (%)**	**Sample rejection (%)[a]**
No ML	0.12	0.090	0	0
1.0	0.11	0.079	11.8	0.5
0.5	0.09	0.069	23.9	2.9
0.4	0.09	0.065	27.6	4.1
0.3	0.08	0.058	35.7	7.6
0.2	0.06	0.046	49.1	15.5

Consumption data used: sum of seafood; G10=45.22 g/person (mean consumption). [a]Percentage of samples above proposed MLs for lead.

Teas and herbal teas

32. Table A10 shows the impact of different MLs on lead intake and sample rejection for teas and herbal teas (beverage and dried). Setting MLs of 2.0 and 1.5 mg/kg, 3.5 and 6.7%, respectively, of samples would possibly be rejected. As for other categories, subcategories may have different contamination profiles. It has also to be considered that some teas in particular herbal and fruit teas are usually blends of quite a lot of different ingredients. All of this may be taken into consideration when the work to establish MLs starts.

Table A10. Effect of the implementation of hypothetical MLs on lead intake through the consumption of teas and herbal teas for cluster G14 (highest consumption pattern).

Teas and herbal teas (n = 3,797)				
ML (mg/kg)	**Mean lead (mg/kg)**	**Intake (µg/kg b.w. day)**	**Intake reduction (%)**	**Sample rejection (%)[a]**
No ML	0.63	0.056	0	0
2.5	0.45	0.040	28.6	2.0
2.0	0.42	0.038	32.1	3.5
1.5	0.38	0.034	39.3	6.7
1.0	0.30	0.026	53.6	14.7

Consumption data used: sum of teas, herbal teas and mate; G14=5.35 g/person (mean consumption). [a]Percentage of samples above proposed MLs for lead.

Cocoa and cocoa products

33. Table A11 shows the impact of different MLs on lead intake and sample rejection for cocoa and cocoa products. Setting MLs of 0.5 and 0.3 mg/kg, 1.0 and 5.4% of samples may possibly be rejected. All subcategories showed lower mean, except cocoa powder. Lead seems to have the same behaviour as cadmium in cocoa products, i.e., it is concentrated in cocoa powder and there are low residue levels in cocoa butter. Although the mean levels of lead in chocolates were low.

Table A11. Effect of the implementation of hypothetical MLs on lead intake through the consumption of cocoa and cocoa products for cluster G13 (highest consumption pattern).

Cocoa and cocoa products (n = 3,049)				
ML (mg/kg)	**Mean lead (mg/kg)**	**Intake (µg/kg b.w. day)**	**Intake reduction (%)**	**Sample rejection (%)[a]**
No ML	0.17	0.021	0	0
1.0	0.10	0.013	39.9	0.3
0.5	0.10	0.012	41.9	1.0
0.3	0.08	0.011	49.4	5.4
0.2	0.07	0.009	55.2	10.2
Cocoa beans (n = 19)				
ML (mg/kg)	**Mean lead (mg/kg)**	**Intake (µg/kg b.w. day)**	**Intake reduction (%)**	**Sample rejection (%)[a]**
No ML	0.05	0.007	0	0
0.5	0.05	0.007	0	0
0.3	0.05	0.007	0	0
0.2	0.05	0.007	0	0
0.1	0.02	0.003	55.5	26.3
Cocoa mass (n = 70)				
ML (mg/kg)	**Mean lead (mg/kg)**	**Intake (µg/kg b.w. day)**	**Intake reduction (%)**	**Sample rejection (%)[a]**
No ML	0.11	0.014	0	0
0.5	0.11	0.014	0	0
0.3	0.11	0.013	3.4	1.4
0.2	0.11	0.013	4.9	2.9
0.1	0.05	0.006	58.7	42.9
Cocoa powder (n = 1,407)				
ML (mg/kg)	**Mean lead (mg/kg)**	**Intake (µg/kg b.w. day)**	**Intake reduction (%)**	**Sample rejection (%)[a]**
No ML	0.32	0.040	0	0
1.0	0.17	0.021	47.5	0.6
0.5	0.16	0.020	49.5	2.1
0.4	0.16	0.020	51.3	4.1
0.3	0.14	0.018	55.9	11.2
Cocoa butter (n = 390)				
ML (mg/kg)	**Mean lead (mg/kg)**	**Intake (µg/kg b.w. day)**	**Intake reduction (%)**	**Sample rejection (%)[a]**
No ML	0.04	0.006	0	0
0.5	0.04	0.006	0	0
0.3	0.04	0.006	1.6	0.3
0.1	0.04	0.005	2.5	0.5
0.05	0.04	0.005	3.0	1.0

Chocolates (n = 1,161)				
ML (mg/kg)	**Mean lead (mg/kg)**	**Intake (µg/kg b.w. day)**	**Intake reduction (%)**	**Sample rejection (%)[a]**
No ML	0.04	0.005	0	0
0.5	0.04	0.005	0	0
0.3	0.04	0.005	3.4	0.3
0.1	0.03	0.004	16.3	4.0
0.05	0.03	0.003	31.2	16.3

Consumption data used: cocoa and cocoa products; G13=7.54 g/person (mean consumption). [a]Percentage of samples above proposed MLs for lead.

Processed fish excluding sliced and frozen fish

34. Table A12 shows the impact of different MLs on lead intake and sample rejection for processed fish. It is recommended to establish a ML of 0.1 mg/kg with a reduction of 48.5% of lead intake from processed fish.

Table A12. Effect of the implementation of hypothetical MLs on lead intake through the consumption of processed fish excluding sliced and frozen fish for cluster G17 (highest consumption pattern).

Processed fish (n = 2,476)				
ML (mg/kg)	**Mean lead (mg/kg)**	**Intake (µg/kg b.w. day)**	**Intake reduction (%)**	**Sample rejection (%)[a]**
No ML	0.02	0.019	0	0
0.2	0.02	0.017	9.4	0.4
0.1	0.01	0.010	48.5	5.1
0.05	0.01	0.007	63.1	8.3

Consumption data used: processed fish; G17=68.69 g/person (mean consumption). [a]Percentage of samples above proposed MLs for lead.

Food for infants and young children

35. Foods for infants and young children were not included in the lead exposure estimates since this food category is intended for consumption by a specific population group and worldwide consumption data for this group is not available. However, infants and young children are of great concern regarding lead exposure and, therefore, the effect of establishing an ML on sample rejection was also evaluated for this food category (Table A13). Sample rejection rate was obtained considering the percentage of samples above the proposed MLs.

36. Considering a rejection of less than 5%, it is proposed a ML of 0.05 mg/kg for cereal-based food for infants and young children, an ML of 0.02 mg/kg for fruit juice and herbal tea for infants and young children and an ML of 0.03 for Yoghurt, cheese and milk-based dessert for infants and young children and an ML of 0.03 mg/kg for Ready-to-eat meal for infants and young children.

Table A13. Effect of the implementation of hypothetical MLs for lead in foods for infant and young children

All food for infant and young children, except infant formula (n = 4,524)		
ML (mg/kg)	**Mean lead (mg/kg)**	**Sample rejection (%)[a]**
No ML	0.012	0
0.05	0.008	1.8
0.04	0.007	5.0
0.03	0.007	6.2
0.02	0.006	10.0
0.01	0.004	22.1
Cereal-based food for infants and young children (n = 1,642)		
ML (mg/kg)	**Mean lead (mg/kg)**	**Sample rejection (%)[a]**
No ML	0.014	0
0.05	0.010	2.5
0.04	0.008	9.0
0.03	0.007	11.7
0.02	0.006	17.6
0.01	0.005	25.6
Fruit juice and herbal tea for infants and young children (n = 240)		
ML (mg/kg)	**Mean lead (mg/kg)**	**Sample rejection (%)a**
No ML	0.013	0
0.05	0.007	1.3
0.04	0.007	2.1
0.03	0.007	2.1
0.02	0.007	3.3
0.01	0.004	31.7
Yoghurt, cheese and milk-based dessert for infants and young children (n = 115)		
ML (mg/kg)	**Mean lead (mg/kg)**	**Sample rejection (%)a**
No ML	0.006	0
0.05	0.006	0.9
0.04	0.006	0.9
0.03	0.005	1.7
0.02	0.004	6.1
0.01	0.003	14.8
Ready to eat meal for infants and young children (n = 1,990)		
ML (mg/kg)	**Mean lead (mg/kg)**	**Sample rejection (%)a**
No ML	0.010	0
0.05	0.007	1.1
0.04	0.006	2.6
0.03	0.006	3.3
0.02	0.006	5.4
0.01	0.003	20.6

[a]Percentage of samples above proposed MLs for lead.

APPENDIX III

For information

Table X1. Mean consumption (g/day) of food categories for the 17 GEMS/Food Cluster Diets

Food category	Food consumption (g/day)																
	G01	G02	G03	G04	G05	G06	G07	G08	G09	G10	G11	G12	G13	G14	G15	G16	G17
Teas and herbal teas	2.50	2.19	2.48	2.56	3.43	3.16	3.83	1.85	1.22	1.96	2.40	0.85	2.81	5.35	0.97	0.66	0.88
Spices and aromatic herbs	12.58	19.83	10.97	22.66	10.87	27.19	11.18	20.69	33.68	17.03	18.51	10.25	12.07	21.13	36.73	3.01	5.25
Algae and seaweeds [a]	*	*	*	*	*	*	*	*	1.00	9.09	*	*	*	*	*	*	*
Eggs and egg products	7.84	23.08	2.88	14.89	9.81	14.83	25.84	29.53	28.05	33.19	36.44	8.89	3.84	4.41	27.25	1.13	7.39
Cocoa and cocoa products	0.72	0.00	4.20	0.00	0.60	0.00	4.21	0.00	0.42	0.00	0.78	0.00	7.54	0.00	5.59	0.00	0.29
Edible land snails	0.02	0.00	0.00	0.00	0.00	0.02	0.04	0.18	0.00	0.01	0.02	0.00	0.00	0.00	0.01	0.00	0.00
Seafood	1.71	14.98	10.14	16.07	4.76	6.65	36.30	29.99	25.61	45.22	23.63	20.41	5.78	13.77	23.54	2.45	36.99
Non-alcoholic beverages [a]	*	*	*	*	34.24	173.91	122.63	142.70	17.30	52.46	314.98	*	21.34	*	137.67	*	*
Sugar and confectionary excluding cocoa	162.63	175.26	51.20	164.30	151.75	245.26	189.45	193.94	53.58	194.91	236.51	207.40	66.30	163.98	160.70	47.53	133.29
Nuts and oilseeds	4.47	0.00	0.00	0.00	0.00	0.00	0.00	0.00	3.42	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
Processed fish excluding frozen and sliced	5.92	18.26	14.20	23.57	6.91	14.01	32.28	32.31	15.26	44.94	33.49	19.96	8.31	39.23	25.20	3.29	68.69
Cereal flours and starches	332.89	327.29	135.22	276.31	208.77	397.74	218.04	242.99	130.79	213.09	177.72	184.97	270.81	98.51	258.07	122.75	132.62
Stalk vegetables	5.96	9.30	5.75	14.64	2.67	8.49	14.07	16.53	72.50	8.41	29.43	10.06	8.98	6.47	7.59	6.06	12.10
Coffee and based-coffee products	1.36	3.59	1.44	5.18	2.02	1.70	10.90	12.44	0.77	9.48	22.07	8.15	0.95	1.32	11.64	2.96	14.73
Vegetable juices [a]	*	*	*	*	0.25	*	0.18	0.80	0.0002	4.18	0.62	*	*	*	0.37	*	*
Alcoholic beverages excluding wine	5.69	106.55	73.64	14.28	42.95	22.31	289.24	332.55	55.25	207.28	296.09	73.01	145.78	11.61	287.62	430.31	84.08

* Not found. [a] Consumption data reported by countries in CIFOCOss database.

Table X2. Estimated lead intake (µg/kg b.w. day) from food for the 17 GEMS/Food Cluster Diets consumption data and mean occurrence data

Food category	Lead intake (µg/kg b.w. day)																
	G01	G02	G03	G04	G05	G06	G07	G08	G09	G10	G11	G12	G13	G14	G15	G16	G17
Teas and herbal teas	0.026	0.023	0.026	0.027	0.036	0.033	0.040	0.019	0.013	0.021	0.025	0.009	0.030	0.056	0.010	0.007	0.009
Spices and aromatic herbs	0.059	0.092	0.051	0.105	0.051	0.127	0.052	0.096	0.157	0.079	0.086	0.048	0.056	0.098	0.171	0.014	0.024
Algae and seaweeds [a]	*	*	*	*	*	*	*	*	0.004	0.038	*	*	*	*	*	*	*
Eggs and egg products	0.025	0.074	0.009	0.048	0.031	0.047	0.083	0.094	0.090	0.106	0.116	0.028	0.012	0.014	0.087	0.004	0.024
Cocoa and cocoa products	0.002	0.000	0.012	0.000	0.001	0.000	0.002	0.000	0.021	0.000	0.016	0.000	0.001	0.002	0.000	0.012	0.000
Edible land snails	0.00005	0.00000	0.00000	0.00000	0.00000	0.00006	0.0001	0.0005	0.00001	0.00001	0.00004	0.00000	0.00000	0.00000	0.00002	0.00000	0.00000
Seafood	0.003	0.023	0.015	0.024	0.007	0.010	0.055	0.045	0.039	0.068	0.036	0.031	0.009	0.021	0.036	0.004	0.056
Non-alcoholic beverages [a]	*	*	*	*	0.028	0.144	0.102	0.118	0.014	0.043	0.261	*	0.018	*	0.114	*	*
Sugar and confectionary excluding cocoa	0.062	0.067	0.020	0.063	0.058	0.094	0.072	0.074	0.020	0.074	0.090	0.079	0.025	0.063	0.061	0.018	0.051
Nuts and oilseeds	0.0017	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0013	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000
Processed fish excluding frozen and sliced	0.002	0.005	0.004	0.006	0.002	0.004	0.009	0.009	0.004	0.012	0.009	0.005	0.002	0.011	0.007	0.001	0.019
Cereal flours and starches	0.086	0.085	0.035	0.071	0.054	0.103	0.056	0.063	0.034	0.055	0.046	0.048	0.070	0.025	0.067	0.032	0.034
Stalk vegetables	0.002	0.003	0.002	0.004	0.001	0.002	0.004	0.005	0.021	0.002	0.009	0.003	0.003	0.002	0.002	0.002	0.004
Coffee and coffee-based products	0.001	0.002	0.001	0.002	0.001	0.001	0.005	0.005	0.000	0.004	0.009	0.003	0.000	0.001	0.005	0.001	0.006
Vegetable juices [a]	*	*	*	*	0.00003	*	0.00002	0.0001	0.00000002	0.0005	0.0001	*	*	*	0.00005	*	*
Alcoholic beverages excluding wine	0.001	0.016	0.011	0.002	0.006	0.003	0.044	0.050	0.008	0.031	0.045	0.011	0.022	0.002	0.043	0.065	0.013

* Not found. [a] Estimated intake calculated by consumption data reported by countries in CIFOCOss database.

Table X3. Estimated lead intake (µg/kg b.w. day) for children based on the 17 GEMS/Food Cluster Diets consumption data plus three times (children eat three times more than adults on a per kg bw basis) and mean occurrence data

Food category	Lead intake (µg/kg b.w. day)																
	G01	G02	G03	G04	G05	G06	G07	G08	G09	G10	G11	G12	G13	G14	G15	G16	G17
Teas and herbal teas	0.079	0.069	0.078	0.081	0.108	0.100	0.121	0.058	0.038	0.062	0.076	0.027	0.089	0.169	0.031	0.021	0.028
Spices and aromatic herbs	0.176	0.277	0.153	0.316	0.152	0.380	0.156	0.289	0.470	0.238	0.258	0.143	0.168	0.295	0.513	0.042	0.073
Algae and seaweeds [a]	*	*	*	*	*	*	*	*	0.044	0.115	*	*	*	*	*	*	*
Eggs and egg products	0.075	0.221	0.028	0.143	0.094	0.142	0.248	0.283	0.269	0.318	0.349	0.085	0.037	0.042	0.261	0.011	0.071
Cocoa and cocoa products	0.006	0.000	0.036	0.000	0.005	0.000	0.036	0.000	0.004	0.000	0.007	0.000	0.064	0.000	0.048	0.000	0.002
Edible land snails	0.0001	0.0000	0.0000	0.0000	0.0000	0.0002	0.0003	0.0014	0.0000	0.0000	0.0001	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000
Seafood	0.008	0.068	0.046	0.073	0.022	0.030	0.164	0.136	0.116	0.205	0.107	0.092	0.026	0.062	0.107	0.011	0.168
Non-alcoholic beverages [a]	*	*	*	*	0.085	0.432	0.305	0.355	0.043	0.130	0.783	*	0.053	*	0.342	*	*
Sugar and confectionary excluding cocoa	0.186	0.201	0.059	0.188	0.174	0.281	0.217	0.222	0.061	0.223	0.271	0.237	0.076	0.188	0.184	0.054	0.153
Nuts and oilseeds	0.005	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.004	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000
Processed fish excluding frozen and sliced	0.005	0.015	0.012	0.019	0.006	0.011	0.026	0.026	0.012	0.037	0.027	0.016	0.007	0.032	0.021	0.003	0.056
Cereal flours and starches	0.258	0.254	0.105	0.214	0.162	0.308	0.169	0.188	0.101	0.165	0.138	0.143	0.210	0.076	0.200	0.095	0.103
Stalk vegetables	0.005	0.008	0.005	0.013	0.002	0.007	0.012	0.015	0.064	0.007	0.026	0.009	0.008	0.006	0.007	0.005	0.011
Coffee and coffee-based products	0.002	0.005	0.002	0.007	0.003	0.002	0.014	0.016	0.001	0.012	0.028	0.010	0.001	0.002	0.015	0.004	0.019
Vegetable juices [a]	*	*	*	*	0.0001	*	0.0001	0.0003	0.0000001	0.002	0.0002	*	*	*	0.0001	*	*

* Not found. [a] Estimated intake calculated by consumption data reported by countries in GEMS/Food database plus three time relative a children consumption.

APPENDIX IV

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