



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

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**PROPOSED DRAFT MAXIMUM LEVELS FOR
CADMIUM IN CHOCOLATES AND COCOA-DERIVED PRODUCTS**

(Prepared by the Electronic Working Group led by Ecuador, Brazil and Ghana)

Codex members and Observers wishing to submit comments at Step 3 on this proposed draft should do so as instructed in CL 2018/2-CF available on the Codex webpage/Circular Letters: <http://www.fao.org/fao-who-codexalimentarius/resources/circular-letters/en/>.

BACKGROUND

1. The 6th Session of the Committee on Contaminants in Foods (2012) agreed to include the proposal for an exposure assessment of cadmium (Cd) from cocoa and cocoa products in the priority list of contaminants and naturally occurring toxicants for evaluation by the Joint FAO/WHO Expert Committee on Food Additives (JECFA). The Committee also noted that relevant data would be needed to undertake the assessment.¹
2. The 77th Meeting of JECFA (2013) carried out the exposure assessment to cadmium from consumption of cocoa and cocoa-derived products which concluded that total cadmium exposure including for high consumers of cocoa and cocoa products was not considered to be of concern.
3. Based on the JECFA77 Meeting, CCCF08 (2014) considered that, although cadmium intake through consumption of chocolate and cocoa-derived products was not a health concern, the lack of MLs for cadmium in cocoa and its products could threaten the exports of some member countries. The Committee therefore agreed to establish an Electronic Working Group (EWG) led by Ecuador, co-chaired by Ghana and Brazil, to prepare maximum levels (MLs) for cadmium in chocolate and cocoa-derived products for consideration at its next session.²
4. CCCF09 (2015) identified difficulties in reaching an agreement on MLs for cadmium in chocolate and cocoa-derived products and agreed to re-establish the EWG, led by Ecuador and co-chaired by Brazil and Ghana, to reconsider the MLs taking into account the comments submitted to the session. It was noted that the EWG should clearly identify the products for which the MLs were being established and provide the rationale for the MLs.³
5. CCCF10 (2016) noted that there was no consensus as to the food categories to which the MLs should apply i.e. raw material (cocoa beans, cocoa nibs), intermediate products (cocoa liquor, cocoa powder for further processing) or finished products (cocoa-containing products e.g. chocolate, cocoa powder ready-for-consumption). In view of the difficulty to agree on the food categories, the Committee agreed to establish an in-session WG chaired by Ecuador and co-chaired by Brazil and Ghana to discuss with those interested member countries and observer organizations an agreement on the food categories in order to proceed with work on the establishment of MLs. The Committee considered the recommendations of the in-session WG and agreed on the following food categories: intermediate products i.e. cocoa liquor and cocoa powder and finished products based on total cocoa solids content (%) i.e. chocolate and cocoa powder ready for consumption.
6. The Committee further agreed that the Codex Secretariat would issue a circular letter (CL) requesting information on: (1) occurrence data on cadmium and designation of origin in the following intermediate products: cocoa liquor and cocoa in powder from cake; (2) occurrence data of cadmium linked with total cocoa solids content (%) or chocolate classification (e.g. bitter, with milk) in the following final products: chocolates and cocoa powder ready-for-consumption; and to provide the geographic origin of the cocoa raw materials as well as information on the manufacturing country, when available.⁴

¹ REP 12/CF, paras. 159, 161, 162

² REP 14/CF, paras. 6, 7, 141, 142, Appendix XI

³ REP 15/CF, paras. 52-55

⁴ REP16/CF, paras. 101-119

7. CCCF11 (2017) agreed to re-establish an EWG, chaired by Ecuador and co-chaired by Brazil and Ghana, to prepare proposals for MLs for the identified categories i.e. “chocolates” and “cocoa powder and dry mixtures of cocoa and sugars” sold for final consumption and to discontinue work on intermediate products.⁵
8. The EWG reviewed the available data in GEMS/Food in accordance with the recommendation of the Committee. The work process followed for the analysis of the food categories and conclusion are provided in Appendix II. The list of participants is contained in Appendix III.
9. The proposed draft MLs are presented in Appendix I for comments and consideration by CCCF.

⁵ REP 17/CF, para. 90-99

APPENDIX I**PROPOSED DRAFT MAXIMUM LEVELS FOR CADMIUM
IN CHOCOLATES AND COCOA-DERIVED PRODUCTS****Table 1.** Proposal for maximum levels for cadmium in chocolates

Commodity / Product Name	Maximum Level (ML) $\mu\text{g}/\text{kg}$	Portion of the Commodity / Product to which the ML applies	Notes / Remarks
Chocolate products containing or declaring < 30% total cocoa solids on a dry matter basis	0.40		Including milk chocolate, family milk chocolate, milk chocolate couverture, Gianduja milk chocolate, table chocolate, milk chocolate Vermicelli/milk chocolate flakes
Chocolate and chocolate products containing or declaring $\geq 30\%$ to < 50% total cocoa solids on a dry matter basis	0.50		Including sweet chocolate, Gianduja chocolate, semi – bitter table chocolate, Vermicelli chocolate / chocolate flakes, and bitter table chocolate.
Chocolate containing or declaring $\geq 50\%$ to < 70% total cocoa solids on a dry matter basis	0.80		
Chocolate containing or declaring $\geq 70\%$ total cocoa solids on a dry matter basis	1.00		

Table 2. Proposal for maximum levels for cadmium in dry mixtures of cocoa and sugars sold for final consumption.

Commodity / Product Name	Maximum Level (ML) $\mu\text{g}/\text{kg}$	Portion of the Commodity / Product to which the ML applies	Notes / Remarks
Dry mixtures of cocoa and sugars containing <29% total cocoa solids on a dry matter basis.	0.4		
Dry mixtures of cocoa and sugars containing $\geq 29\%$ to <50% total cocoa solids on a dry matter basis.	0.6		Including chocolate powder.
Dry mixtures of cocoa and sugars containing $\geq 50\%$ total cocoa solids on a dry matter basis.	1.2		Including chocolate powder.

Table 3. Proposal for maximum levels for cadmium in cocoa powder

Commodity / Product Name	Maximum Level (ML) $\mu\text{g}/\text{kg}$	Portion of the Commodity / Product to which the ML applies	Notes / Remarks
Cocoa powder (100% total cocoa solids on a dry matter basis).	1.5		Product sold for final consumption.

APPENDIX II

**INFORMATION FOR CODEX MEMBERS AND OBSERVERS
WHEN CONSIDERING THE MAXIMUM LEVELS**

INTRODUCTION

10. Trace metals in food have become a topic of concern in many countries around the world as dietary exposure to elevated concentrations may cause health problems in humans.
11. Cadmium content in chocolate and cocoa powder is related to its occurrence in cocoa beans. The addition of ingredients such as milk and sugar does not contribute significantly to cadmium concentrations (Lee & Low, 1985).
12. Cadmium is associated with nonfat cocoa solids, therefore during the processing of cocoa liquor, over 95% of cadmium is accumulated in cocoa powder. Cadmium levels in chocolates may be correlated with the percentage of nonfat cocoa solids in the final products.
13. Cadmium levels in cocoa beans largely depend on the world region where they are grown. Cadmium can be released into the environment in a number of ways, including natural activities, such as volcanic activity (WHO, 2010). In regions with intermittent deposition of volcanic ash, each addition of new material affects the soil (Ugolini & Dahlgren, 2002), and the kind of soil has an important influence on cadmium absorption by the plant (Benavides et al., 2005; Rodríguez-Serrano et al., 2008, HuamanI-Yupanqui et al., 2012).
14. A summary of the cadmium content in cocoa beans classified by origin is shown in Table 3 using data from the last 17 years (1998-2017). Differences among the main cocoa producers in the world were observed. Africa presented the lowest cadmium levels in cocoa beans, while cocoa beans from other origins have inherently higher cadmium content.

Table 3. Occurrence data for cadmium cocoa beans by declared region of origin, based on GEMS/Food data

World region	Number of samples	Mean (mg/kg)	Minimum (mg/kg)	Maximum (mg/kg)	95th Percentile (mg/kg)
Africa	748	0.12	0.01	1.40	0.32
South West Pacific	46	0.20	0.05	0.67	0.31
Asia	68	0.44	0.06	1.40	0.81
Latin America and Caribbean	432	0.62	0.01	6.00	2.00
Total	1294	0.30	0.01	6.00	1.14

Source: GEMS/Food

15. The exposure assessment to cadmium from cocoa and cocoa products considered by the 77th Meeting of the JECFA (2013) concluded that total exposure of cadmium in diets with high levels of consumption of cocoa and cocoa derived products was likely overestimated and it was not considered to be a health concern.
16. However, the lack of a maximum level for cadmium in chocolate and cocoa derived products could compromise fair trade for these products. As mentioned in paragraph 14, the occurrence of cadmium in cocoa beans is influenced by the region in which the cocoa bean is grown, and this could have consequences for the commerce of cocoa products from different regions of the world. Therefore, this work is undertaken primarily to facilitate fair trade through the establishment of maximum levels for cadmium in chocolate and cocoa derived products.

DEFINITIONS

17. In this document the following concepts are defined:

- **Cocoa:** Fruit of the trees of the species *Theobroma cacao* L.
- **Chocolate:** Chocolate (in some regions also named bittersweet chocolate, semi-sweet chocolate, dark chocolate or “chocolat fondant”) shall contain, on a dry matter basis, not less than 35% total cocoa solids, of which not less than 18% shall be cocoa butter and not less than 14% fat-free cocoa solids.
- **Cocoa bean:** The seed of the cacao fruit (*Theobroma cacao* L.); commercially, and for the purpose of this document, the term refers to the whole seed which has been fermented and dried.
- **Cocoa butter:** Fat obtained from cocoa beans with the following characteristics: Free fatty acids (expressed as oleic acid): not greater than 1.75% m/m (percentage by mass); unsaponifiable matter: not greater than 0.7% m/m, except in the case of press cocoa butter that should not exceed 0.35% m/m.
- **Cocoa (Cacao) mass (cocoa/chocolate liquor):** Product obtained from the cocoa nib, which is obtained from cocoa beans of merchantable quality which have been cleaned and freed from shells as thoroughly as is technically possible with/without roasting, and with/without removal or addition of any of its constituents.
- **Cocoa powder:** Product obtained from cocoa cake transformed into powder.
- **Dry mixtures of cocoa and sugars:** The name of the products defined in CODEX STAN 105 – 1981, section 3.1.2 will be used
- **Nibs:** Small fragments of cocoa beans roasted at different temperatures according to the formula established by the manufacturer.
- **Non-fat dry cocoa solids:** Remaining cocoa components (carbohydrates, fiber, protein and minerals), after removal of the fat and moisture.
- **Total cocoa solids:** All cocoa components, therefore, the sum of cocoa butter plus the non-fat cocoa solids.
- **Total cocoa solids, percentage:** Total percentage of ingredients by weight in a chocolate product that comes from the cocoa bean, including liquor and cocoa butter

ACRONYMS

18. The following acronyms are mentioned:

- **bw:** Body weight
- **CAC:** Codex Alimentarius Committee
- **CCCF:** Codex Committee on Contaminants in Foods
- **Cd:** Cadmium
- **CL:** Circular Letter
- **EWG:** Electronic Working Group
- **FAO:** Food and Agriculture Organization
- **F-AAS:** Flame Atomic Absorption Spectrometry
- **GF-AAS:** Graphite Furnace with Atomic Absorption Spectrometry
- **ICCO:** International Cocoa Organization
- **ICP_MS:** Inductively Coupled Plasma Mass Spectrometry
- **ICP-OES:** Inductively Coupled Plasma Optical Emission Spectrometry
- **JECFA:** Joint FAO/WHO Expert Committee on Food Additives
- **LAC:** Latin America and the Caribbean
- **LOD:** Limit of Detection
- **LOQ:** Limit of Quantification
- **ML:** Maximum Level
- **NASWP: North America and Southwest Pacific**
- **ND:** Not detected
- **PTMI:** Provisional Tolerable Monthly Intake
- **WHO:** World Health Organization

ECONOMIC IMPORTANCE OF CHOCOLATE AND COCOA DERIVED PRODUCTS

19. Cocoa is a vitamin, fiber and mineral-rich food, and a valuable non-perishable commercial crop, generally produced by small-scale farmers, who contribute to the economies of developing countries. According to ICCO (2012) the main regions of production of this crop, rated by importance are West Africa, Latin America and Southeast Asia.
20. Europe comprises nearly 40% of the global cocoa processing market. European cocoa grindings accounted for 1.3 million tons in 2014 (CBI, 2016). These grindings are transformed to cocoa products (ICCO, 2007). The majority of the cocoa imports to Europe come from West Africa (93%); the imports coming from Latin America and Southeast Asia are the second and third in importance respectively (ICCO, 2012).
21. According to Trade Map data (2017) in 2016 chocolate and other food preparations containing cocoa represented 55.71% of global value exported for cocoa and cocoa preparations; followed by cocoa beans, whole or broken, raw or roasted (21.49%), cocoa butter, fat and oil (10.89%), cocoa paste, whether or not defatted (6.71%), cocoa powder, not containing added sugar or other sweetening matter (5.11%), and cocoa husks, skins and other cocoa waste (0.09%).
22. The world cocoa market recognizes two main categories of cocoa beans: “fine or flavor cocoa” and the “bulk” or “common” cacao. According to the ICCO, the global proportion of fine or flavor cocoa is 5 to 7%, which represents 100 to 170 thousand tons of cocoa coming from: Ecuador, Indonesia, Papua New Guinea, Colombia, Venezuela, Trinidad and Tobago, amongst others. On the other hand, the “bulk cacao” or “common cacao” that comes from Africa, Asia, Central America and South America represents around 93 to 95% of the global cocoa production (ICCO, 2012).
23. The “fine or flavor” cocoa is characterized by its superior aroma and flavor, traits that are highly sought after by the producers of fine chocolates. Typical consumers of this type of cocoa are located in countries in Western Europe (Belgium, Luxemburg, Netherlands, France, Germany, Italy, Switzerland, and the United Kingdom), and, as such, these represent the largest consumer markets. Thereby in recent years, chocolate manufacturers are more frequently identifying the origin of the cocoa beans used in their products (Quingaísa & Riveros, 2007).

METHODS OF ANALYSIS

24. Methods of analysis to determine cadmium in cocoa include Flame Atomic Absorption Spectrometry (F-AAS), Graphite Furnace with Atomic Absorption Spectrometry (GF-AAS), Inductively Coupled Plasma Optical Emission Spectrometry (ICP-OES) and Inductively Coupled Plasma Mass Spectrometry (ICP-MS). The general sample preparation can be conducted by digestion in an open system (dry incineration [Lee & Low, 1985] or wet digestion [Yanus et al., 2014]) or in a closed system (microwave - Nardi et al., 2009, Jalbani et al., 2009). Sample preparation depends on the detection methods chosen and the use of hydrogen peroxide may be beneficial for high fat samples and certain analytical detection methods, however, sample preparation should be performed according to the method procedures. For example, an open system like dry incineration may affect the results in low limit of detection techniques since contamination in these procedures is very common (Nardi et al., 2009; Villa et al., 2014).
25. General Methods of Analysis for Contaminants (CODEX STAN 228-2001) suggests some cadmium analytical methods such as atomic absorption spectrometry (AAS) after incineration or microwave digestion and Anodic stripping voltammetry.
26. Table 4 presents the LOD (detection limit) for cadmium by the different analytical methods mentioned above. A member country mentioned that these detection limits are overly optimistic since they are much lower than the proposed MLs.

Table 4. Detection limits with different methods.

Technique	Detection limit (µg/L)
F-AAS	0.8 – 1.5
ICP-OES	0.1 – 1.0
GF-AAS	0.002 – 0.02
ICP-MS	0.00001 – 0.001

Source: EFSA, 2009*

27. Taking into account the performance criteria for analysis, set out in the Procedural Manual of the Codex Alimentarius Commission, several methods not included in the CXS 228/2001 could be used for analysis of cadmium. Laboratories may select any valid method of analysis; however, the method selected should meet the criteria described in the Procedural Manual of the Codex Alimentarius Commission (Table 5).
28. Performance criteria required for maximum levels over 0.1 mg.kg⁻¹ established in the Procedural Manual of the Codex Alimentarius Commission are the same as those established in the EU regulation for the limit of detection (LOD), limit of quantification (LOQ) and precision. The recovery should range from 80% to 110%.

Table 5. Performance criteria for methods of analysis.

Parameters	ML for $\geq 0.1 \text{ mg.kg}^{-1}$
Minimum Applicable Range	[ML - 3 SR, ML + 3 SR] SR = reproducibility standard deviation
LOD	$\leq \text{ML } 1/10$
LOQ	$\leq \text{ML } 1/5$
Precision	HorRat Value ≤ 2
Recovery (%)	80 - 110 (from 0.1 to 10 mg.kg ⁻¹)
Trueness	Other guidelines are available for expected recovery ranges in specific areas of analysis. In cases where recoveries have been shown to be a function of the matrix other specified requirements may be applied. For the evaluation of trueness preferably certified reference material should be used. For the evaluation of the conformity, preferably the certified reference material should be used.

Source: CAC, 2015.

RISK ASSESSMENT OF CADMIUM

29. Cadmium accumulates primarily in the kidneys and liver, and its biological half-life in humans is estimated to be 10-35 years. Cadmium accumulation may eventually lead to renal tubular dysfunction, which manifests in an increase of the excretion of low molecular weight proteins in urine. When this low molecular weight proteinuria exceeds a specific value (greater than 1000 $\mu\text{g/g}$ creatinine of beta-2-microglobulin), the kidney damage is generally considered to be irreversible. A high intake of cadmium can also lead to distortions in calcium metabolism and the formation of kidney stones. Cadmium also affects the skeletal and respiratory systems (WHO, 2010).
30. Diet is the most important source of non-occupational exposure to cadmium. The absorption of cadmium from the gastrointestinal tract is approximately 50% (Ramirez, 2002). Vegetables and cereals are the main sources of background cadmium exposure in the typical diet, although cadmium is found in meat and fish to a lesser extent, while crustaceans and molluscs can accumulate large amounts from the aquatic environment (Satarug et al., 2010).
31. Cadmium was evaluated in Sessions 16, 33, 41, 55, 61, 64, 73 and 77 of JECFA. In 2010, JECFA decided to express the tolerable intake as a monthly value, establishing a Provisional Tolerable Monthly Intake (PTMI) of 25 μg Cd/kg b.w.
32. JECFA estimated exposure to cadmium from consumption of products containing cocoa and its derivatives for the average population diet in the 17 GEMS / Food Cluster Diets. These estimates ranged from 0.005 to 0.39 $\mu\text{g} / \text{kg bw} / \text{month}$, which is equivalent to 0.02 to 1.6% of the PTMI. This represents an estimate of the average cadmium dietary exposure of cocoa and its derivatives for the entire population. Similar dietary exposures to cadmium in the population for individual cocoa products were estimated from national data, which ranged from 0.001 to 0.46 $\mu\text{g/kg bw/month}$ (0.004 to 1.8% PTMI).
33. Since 5% of the PTMI of cadmium from cocoa-derived products for the general population was not exceeded, relative to total cadmium dietary intake in any of GEMS/Food Cluster Diets, according to the Codex Alimentarius Commission Procedural Manual (21st ed.)⁶, cadmium consumption from cocoa-derived products does not significantly contribute to the total cadmium exposure of the consumer. Thus maximum levels established for cocoa-derived products should be based primarily on practical achievability worldwide.

⁶ Codex Alimentarius Commission Procedural Manual pg. 125-127.

34. The potential dietary exposure to cadmium for high consumers of products containing cocoa and its derivatives, in addition to cadmium derived from other foods, was estimated to be 30-69% of the PTMI for adults and 96% of the PTMI for children from 0.5 to 12 years old. The Committee noted that this cadmium total dietary exposure for high consumers of cocoa and its products was likely to be overestimated and did not consider it cause for concern (JECFA, 2013).

DATA COLLECTION

35. Analysis of results and decisions about which data should be excluded, how data should be presented, and what recommendations should be included were made by the EWG.
36. EWG extracted all cadmium occurrence data from GEMS/Food database for cocoa and cocoa products. The first step in data analysis was to classify the chocolates following the mandate of the 11th Session of the CCCF using the information on percentage of total cocoa solids and denominations in “local food name” and “remarks” columns. For cocoa powder and dry mixtures of cocoa and sugars there were only two samples with total cocoa solids information (one cocoa powder 100% and one cocoa powder 85% of total cocoa solids). Therefore it was not possible to classify dry mixtures of cocoa and sugars data based on a percentage of total cocoa solids as to the Committee’s mandate. These products were classified initially as: cocoa powder (including bitter, dark, premium cocoa powders; containing 100% cocoa solids); and dry mixtures of cocoa and sugars (including cocoa powder preparations for beverages, mixtures with sugars and milk, chocolate powder and cocoa powder 85% of total cocoa solids).
37. During the second step in the data analysis, the data for aggregated samples, as well as two outliers for the cocoa powder samples were excluded, in order to reduce bias for all data to be analyzed. The third step was to treat the censored values and prepare a dataset based on the limit of detection (LOD) of the analytical method associated with each sample. The EWG adopted values of half of LOD for not detected (ND) results. Several data did not have LOD and LOQ information: in the groups, chocolates with <30% total cocoa solids there were 501 data points without LOD/LOQ; in the group, chocolates with ≥30 – 50% total cocoa solids, there were 24 data points without LOD/LOQ; in the group, chocolates ≥50 – 70% total cocoa solids there were 56 data without LOD and 46 data without LOQ; in the group chocolates ≥70% total cocoa solids, there were 201 data without LOD and 186 data without LOQ; in cocoa powders there were 906 data without LOD/LOQ and in dry mixtures of cocoa and sugars there were 199 data without LOD/LOQ. Data were not excluded on the basis of missing LOD and LOQ information.
38. A summary of data with these considerations is showed in Table 6.

Table 6. Cocoa products categories and provision of data in GEMS/Food

Categories	Number of samples	Countries that submitted the data
Chocolates that contain <30% cocoa solids	1063	Germany, Australia, Brazil, Colombia, Ivory Coast, Denmark, Ecuador, Slovakia, United States of America, France, Ghana, Indonesia, Japan, México, Peru, Singapore, Sweden, European Union*
Chocolates and chocolate products that contain or declare ≥ 30% to < 50% total cocoa solids.	182	Australia, Brazil, Canada, Ecuador, United States of America, Japan, Singapore
Chocolates and chocolate products that contain or declare ≥ 50% to < 70% total cocoa solids.	211	Australia, Brazil, Ecuador, United States of America, France, Japan, Singapore
Chocolates that contain or declare ≥ 70% total cocoa solids.	453	Australia, Brazil, Canada, Ecuador, United States of America, France, Japan, Singapore
Dry mixtures of cocoa and sugars.	765	Germany, Canada, Cuba, Denmark, Ecuador, Japan, Singapore, Slovakia, United States of America, European Union

Categories	Number of samples	Countries that submitted the data
Cocoa powder (100% cocoa solids)	2335	Germany, Brazil, Cameroon, Canada, Chile, Colombia, Cuba, Ivory Coast, Ecuador, Slovakia, United States of America, France, Ghana, Indonesia, Japan, Malaysia, México, Peru, Singapore, Spain, Sweden, Thailand, Czech Republic, Dominican Republic, United Republic of Tanzania, European Union, Vanuatu

* For chocolates, the only samples considered were those that presented information of the percentage of total cocoa solids or the descriptors given in the REP17/CF, Appendix XIII.

39. As there is a difference by world regions of cadmium content in cocoa beans and for consequence in cocoa products, all data should also be analyzed by five regions: Latin America and Caribbean, Africa, Asia, Europe, North America and South West Pacific. For the analysis of the samples only the origin of data was considered, and this is recognized as being a limitation with the available data. Despite the regionalization of the data, taking into account the data's origin, is not directly indicative of the content of cadmium in the cocoa produced in these regions, important differences were observed among the regions that could have consequences in the trade of cocoa products.

DATA ANALYSIS FOR THE PROPOSAL OF MAXIMUM LEVELS

40. The CCCF has previously used a figure of approximately 5% of samples as a 'cut-off' point for determining an achievable maximum level. That is, if 95% of samples have a cadmium content below a certain level, then this level is deemed achievable and may be proposed as a maximum level. This technique has been used as a starting point (notwithstanding other factors) to derive proposed maximum levels for all of the categories of chocolate, dry mixtures of cocoa and sugars, and cocoa powder, as described below.

Cadmium in chocolates <30% of total cocoa solids

41. According to the origin of chocolates containing <30% total cocoa solids, that was reported in the GEMS/Food database 22% (235 samples) of all of the data evaluated (denoted as "worldwide" in table 7) are samples of domestic origin, 57% (609 samples) are imported, and 21% (219 samples) are of unknown origin. Despite this issue, the majority of the data did not have the information of the samples origin, therefore it was decided to categorize the data according to the countries that submitted the information to GEMS/Food.

42. In Table 7 it can be observed that worldwide, the occurrence of cadmium in chocolates with <30% of total cocoa solids has an average concentration of 0.03 mg/kg; and when comparing the values from the different regions it can be observed that mean concentrations range between 0.01 and 0.08 mg/kg, and values from Latin America and the Caribbean (LAC) region are highest. This difference can also be observed at the 95th percentile concentration, where LAC region presents a value of 0.40 mg/kg, which is approximately 3 times greater than the world mean (0.12 mg/kg), and the African region presents a value approximately 5 times lower (0.02 mg/kg) than the world mean.

43. More than 50% of the data used for the analysis of occurrence of cadmium in chocolates <30% of total cocoa solids, is from the regions of the European Union, North America and the Southwest Pacific, where the region of Africa was the one with the least number of reported samples for this study (18 data samples). However, Africa is the largest cocoa producing region (production of "bulk cacao" or "common cacao") and the majority of cocoa imports to Europe come from West Africa (93%). In this way most of European data are from Africa.

Table 7. Occurrence data for cadmium worldwide and by data origin region* in chocolates with <30% of total cocoa solids.

Origin of data	Number of Samples	Values expressed in mg/kg							
		Average	Min	Max	P95	LOD		LOQ	
						Min	Max	Min	Max
Worldwide	1063	0.03	ND	0.49	0.12	0.00002	0.05	0.001	0.17
LAC	190	0.08	ND	0.49	0.40	0.001	0.03	0.002	0.05
AFRICA	18	0.01	0.01	0.02	0.02	0.002	0.01	0.005	0.01
ASIA	53	0.04	ND	0.49	0.11	0.00002	0.04	0.005	0.14
EURO	410	0.02	ND	0.41	0.06	0.001	0.05	0.003	0.17
NASWP	392	0.02	ND	0.46	0.04	0.0002	0.05	0.001	0.10

LAC: Latin America and the Caribbean; EURO: European Union; NASWP: North America and the Southwest Pacific; Min: Minimum; Max: Maximum; P95: 95% Percentile; LOD: Limit of Detection; LOQ: Limit of Quantification; ND: not detected. * The origin of data in the table was determined by the country that submitted data to GEMS/Food, and not by the true origin of the chocolate.

Source: GEMS/Food

44. The per capita consumption of cocoa and its derivatives ranges from 0.2 to 7.5 g/day in the 17 Cluster Diets in the GEMS/Food database. The Cluster Diet 7 has the greatest consumption of cocoa products in their diet and is comprised of the following countries: Australia, Bermuda, Finland, France, Iceland, Luxemburg, Norway, Switzerland, United Kingdom and Uruguay (WHO, 2012) Therefore, the estimated cadmium intake of Cluster Diet 7 will serve as the worst-case scenario for the evaluation of the impact of maximum levels on cadmium intake and in the international trade.
45. Table 8 shows the impact of different maximum levels on cadmium intake and on international trade. For each proposed maximum level for the category of chocolates with <30% of total cocoa solids, the average content of cadmium was calculated from the available data per scenario, excluding data higher than the proposed maximum level. Cadmium intake was calculated considering the average of each scenario (assuming chocolates with <30% of total cocoa solids is the only source of cocoa products in the diet), the Cluster Diet 7 per-capita consumption (7.5 g/day), 30 days in the month and the average body weight (b.w.) of 60 kg. Subsequently, the relationship with the provisional tolerable monthly intake (PTMI) was considered. From data that were excluded for each proposed maximum level, a percentage of possible rejected samples was calculated for total data available worldwide and by region. Additionally it can be observed that the scenario with the data of the Latin America and the Caribbean (LAC) region has the highest intake value, representing 1.3% of the IMTP, but this value is still too low, as observed by JECFA.

Table 8. Impact of different maximum levels for cadmium in the statistical distribution of cadmium for chocolates with <30% total cocoa solids, including the expected proportion of PTMI for the intake of cadmium for the Cluster Diet 7 and the projected proportion of rejected samples in the world market.

Scenario	Number of samples	Average content of Cd (mg.kg-1)	Cd intake (µg/kg b.w. monthly)	% PTMI	Possible rejected samples (%)
Scenario with worldwide data					
No ML	1063	0.031	0.116	0.5	0.0
ML: 0.4 mg/kg	1051	0.026	0.099	0.4	1.1
ML: 0.35 mg/kg	1043	0.024	0.089	0.4	1.9
ML: 0.30 mg/kg	1031	0.020	0.075	0.3	3.0
ML: 0.20 mg/kg	1020	0.018	0.066	0.3	4.0
ML: 0.10 mg/kg	1007	0.016	0.060	0.2	5.3

Scenario	Number of samples	Average content of Cd (mg.kg ⁻¹)	Cd intake (µg/kg b.w. monthly)	% PTMI	Possible rejected samples (%)
Scenario with data from LAC					
No ML	190	0.08	0.31	1.3	0.0
ML: 0.4 mg/kg	181	0.066	0.25	1.0	4.7
ML: 0.35 mg/kg	174	0.054	0.20	0.8	8.4
ML: 0.30 mg/kg	162	0.033	0.12	0.5	14.7
ML: 0.20 mg/kg	152	0.019	0.07	0.3	20.0
ML: 0.10 mg/kg	150	0.017	0.06	0.3	21.1
Scenario with data from AFRICA					
No ML	18	0.01	0.05	0.2	0.00
ML: 0.4 mg/kg	18	0.01	0.05	0.2	0.00
ML: 0.35 mg/kg	18	0.01	0.05	0.2	0.00
ML: 0.30 mg/kg	18	0.01	0.05	0.2	0.00
ML: 0.20 mg/kg	18	0.01	0.05	0.2	0.00
ML: 0.10 mg/kg	18	0.01	0.05	0.2	0.00
Scenario with data from ASIA					
No ML	53	0.04	0.16	0.6	0.0
ML: 0.4 mg/kg	52	0.03	0.13	0.5	1.9
ML: 0.35 mg/kg	52	0.03	0.13	0.5	1.9
ML: 0.30 mg/kg	52	0.03	0.13	0.5	1.9
ML: 0.20 mg/kg	52	0.03	0.13	0.5	1.9
ML: 0.10 mg/kg	50	0.03	0.11	0.4	5.7
Scenario with data from EURO					
No ML	410	0.0212	0.0795	0.3	0.0
ML: 0.4 mg/kg	409	0.202	0.7575	0.3	0.2
ML: 0.35 mg/kg	408	0.0193	0.072375	0.3	0.5
ML: 0.30 mg/kg	408	0.0193	0.072375	0.3	0.5
ML: 0.20 mg/kg	408	0.0193	0.072375	0.3	0.5
ML: 0.10 mg/kg	402	0.0176	0.066	0.3	2.0
Scenario with data from NASWP					
No ML	392	0.017	0.06375	0.3	0.0
ML: 0.4 mg/kg	391	0.016	0.06	0.2	0.3
ML: 0.35 mg/kg	391	0.016	0.06	0.2	0.3
ML: 0.30 mg/kg	391	0.016	0.06	0.2	0.3
ML: 0.20 mg/kg	390	0.016	0.06	0.2	0.5
ML: 0.10 mg/kg	387	0.015	0.05625	0.2	1.3

LAC: Latin America and the Caribbean; EURO: European Union; NASWP: North America and the Southwest Pacific; PTMI: Provisional Tolerable Monthly Intake; ML: maximum level; b.w.: body weight (60 kg).

46. In Table 8, 8.4% of samples from the Latin America and Caribbean region would be possible rejections if, a maximum level of 0.35 mg/kg was observed. Taking this matter into consideration, as well as the observations of various countries and observers, it is recommended to establish a maximum level of 0.4 mg/kg for the group of chocolates with <30% total cocoa solids.

47. Considering Cluster Diet 7 as the one with greatest cocoa intake in their diet, according to “Cluster Diet 2012”, from WHO (“Cocoa, cola and their non-liquid derivatives”) and after developing all mentioned calculations, it can be observed that without a maximum level for cadmium for the chocolates with <30% of total cocoa solids, in a world- wide scenario, the intake would represent a maximum of 0.5% of the PTMI estimated by JECFA (0.025 mg/kg b.w). Also on a worldwide basis with application of the proposed maximum levels of 0.10 to 0.40 mg/kg, estimated cadmium intakes range between 0.2 to 0.4% of the PTMI. Additionally it can be observed that the scenario with the data from Latin America and the Caribbean region has the highest value for intake, representing 1.3% of the PTMI, but yet this value is well below the 5⁷ percent for a significant effect noted by JECFA.
48. It should be stressed that the intake mentioned above was calculated considering the chocolates with <30% of total cocoa solids, as the only source of cocoa products in the diet. However, it is important to emphasize that cadmium is also present in other food products that are consumed on regular basis in greater quantities.
49. With respect to rejected samples, Table 8 shows that 4.0% and 5.3% of the samples could be rejected if proposed maximum level of 0.2 and 0.1 mg/kg applied, respectively, in the context of the worldwide data. This scenario is different if data from the Latin American and the Caribbean region are used, where a maximum level of 0.1 would generate rejections of 21.1% of chocolate with <30% of total cocoa solids. For the scenario with data from Latin America and the Caribbean, a maximum level of 0.4 mg/kg would only affect 4.7% of the samples and rejections of percentage of the PTMI would be reduced to 1% (in comparison to 1.3% with not having a maximum level).

Cadmium in chocolates ≥30% to- <50% total cocoa solids.

50. According to data on the origin of chocolates containing ≥ 30% to < 50% total cocoa solids, 100% of the samples were imported (182 samples), and their origin was unknown. Thus, the only alternative available was to classify the data according to the countries that submitted the information to GEMS/Food.
51. In Table 9 it can be observed that at the world wide level, the occurrence of cadmium in chocolates with ≥30% to - <50% total cocoa solids averages 0.05 mg/kg, and when comparing the values among the regions, they range from 0.04 to 0.06 mg/kg. Data from Latin America and the Caribbean, and North America and the Southwest Pacific are over the world average, and data from Asia were below the world wide average. No data from Africa and Europe were received.
52. Likewise, the 95th percentile value is greater for Latin America and the Caribbean and North America and the Southwest Pacific regions compared to the 95th percentile worldwide. However, data from Asia reflect a 95th percentile concentration that is about half of that of the 95th percentile estimate for Latin American and the Caribbean region.
53. The LOD values for this dataset ranged between 0.00002 and 0.04 mg/kg and LOQ values from 0.002 to 0.14 mg/kg.

Table 9: Occurrence data for cadmium worldwide and by data origin region* in chocolates with ≥30% to- <50% of total cocoa solids.

Origin of data	Number of samples	Values expressed in mg/kg							
		Average	Min	Max	P95	LOD		LOQ	
						Min	Max	Min	Max
Worldwide	182	0.05	ND	0.71	0.18	0.00002	0.04	0.002	0.14
LAC	122	0.06	ND	0.71	0.25	0.001	0.001	0.002	0.002
ASIA	26	0.04	ND	0.18	0.13	0.00002	0.04	0.005	0.14
NASWP	34	0.06	ND	0.37	0.21	0.000408	0.025	0.0034	0.05

LAC: Latin America and the Caribbean; NASWP: North America and the Southwest Pacific; Min: Minimum; Max: Maximum; P95: 95% Percentile; LOD: Limit of Detection; LOQ: Limit of Quantification; ND: not detected.
 * The origin of data in the table was determined by the country that submitted data to GEMS/Food, and not by the true origin of the chocolate.

Source: GEMS/Food

⁷ Codex Alimentarius Commission Procedural Manual pg. 125-127.

54. As in Table 8, Table 10 shows the impact of different maximum level on cadmium intake and on international trade. The intake and % PTMI calculations, are based on Cluster Diet 7.
55. On a worldwide scenario with maximum levels of 0.2 mg/kg to 0.25 mg/kg, a cadmium intake of 0.14 µg/kg b.w. per month was observed, which represents 0.6% of the PTMI. These proposed maximum levels would also cause the rejection of a total of 4.9% of the samples in world trade, if applied. These same maximum levels would see 5.7% of samples submitted by Latin America and the Caribbean region rejected, and North America and the Southwest Pacific would have 5.9% of their samples rejected. However, for the Asian region, none of its samples would be rejected in all the established scenarios for chocolates with ≥30% - <50% of total cocoa solids.

Table 10. Impact of different maximum level for cadmium in the statistical distribution of cadmium for chocolates with ≥30% - <50% of total cocoa solids, including the expected proportion of PTMI for the intake of cadmium for the Diet Cluster 7 and the projected proportion of rejected samples in the world market.

Scenario	Number of samples	Average Cd content (mg.kg-1)	Cd intake (µg/kg b.w. month)	% PTMI	Possible rejected samples (%)
Scenario with worldwide data					
No ML	182	0.05	0.20	0.81	0.00
ML: 0.5 mg/kg	181	0.05	0.20	0.81	0.55
ML: 0.45 mg/kg	181	0.05	0.20	0.81	0.55
ML: 0.4 mg/kg	180	0.05	0.19	0.76	1.10
ML: 0.35 mg/kg	179	0.05	0.18	0.70	1.65
ML: 0.3 mg/kg	175	0.04	0.15	0.61	3.85
ML: 0.25 mg/kg	173	0.04	0.14	0.57	4.95
ML: 0.2 mg/kg	173	0.04	0.14	0.57	4.95
Scenario with data from LAC					
No ML	122	0.06	0.21	0.83	0
ML: 0.5 mg/kg	121	0.05	0.18	0.71	0.82
ML: 0.45 mg/kg	121	0.05	0.18	0.71	0.82
ML: 0.4 mg/kg	120	0.05	0.18	0.71	1.64
ML: 0.35 mg/kg	120	0.05	0.18	0.71	1.64
ML: 0.3 mg/kg	117	0.04	0.15	0.59	4.10
ML: 0.25 mg/kg	115	0.04	0.13	0.53	5.74
ML: 0.2 mg/kg	115	0.04	0.13	0.53	5.74
Scenario with data from ASIA					
No ML	26	0.04	0.14	0.56	0
ML: 0.5 mg/kg	26	0.04	0.14	0.56	0.00
ML: 0.45 mg/kg	26	0.04	0.14	0.56	0.00
ML: 0.4 mg/kg	26	0.04	0.14	0.56	0.00
ML: 0.35 mg/kg	26	0.04	0.14	0.56	0.00
ML: 0.3 mg/kg	26	0.04	0.14	0.56	0.00
ML: 0.25 mg/kg	26	0.04	0.14	0.56	0.00
ML: 0.2 mg/kg	26	0.04	0.14	0.56	0.00

Scenario	Number of samples	Average Cd content (mg.kg-1)	Cd intake ($\mu\text{g/kg}$ b.w. month)	% PTMI	Possible rejected samples (%)
Scenario with data from NASWP					
No ML	34	0.06	0.24	0.95	0
ML: 0.5 mg/kg	34	0.06	0.24	0.95	0.00
ML: 0.45 mg/kg	34	0.06	0.24	0.95	0.00
ML: 0.4 mg/kg	34	0.06	0.24	0.95	0.00
ML: 0.35 mg/kg	33	0.05	0.20	0.81	2.94
ML: 0.3 mg/kg	32	0.05	0.17	0.69	5.88
ML: 0.25 mg/kg	32	0.05	0.17	0.69	5.88
ML: 0.2 mg/kg	32	0.05	0.17	0.69	5.88

LAC: Latin America and the Caribbean; NASWP: North America and the Southwest Pacific; PTMI: Provisional Tolerable Monthly Intake; ML: maximum level; b.w.: body weight (60 kg).

56. Table 9 indicates a value of 0.25 mg/kg for 95th percentile for Latin American and the Caribbean region, which was the highest for this category of chocolate. This category of chocolate contains a higher percentage of total cocoa solids than the <30% total cocoa solids category analyzed above and, as such, higher cadmium levels would also be expected here, because, as the percentage cocoa solids increases, it would be expected that the cadmium level increases as well. However, this is not the case (0.25 mg/kg compared with 0.40 mg/kg) This may largely be due to the fact that the data presented was not representative of all the regions, and the few reported samples were from Brazil, and these had no confirmed origin from Latin America and the Caribbean. In addition, the total number of worldwide samples for this category was only 182, and this may have an impact on the representativeness of the data and results of the analysis. Taking into account these considerations, it is recommended to establish a maximum level of 0.5 mg/kg for the group of chocolates with $\geq 30\%$ to <50% total cocoa solids.

Cadmium in chocolates with ≥ 50 – to <70% of total cocoa solids

57. According to the origin of chocolates containing $\geq 50\%$ to < 70% total cocoa solids, the 25% (53 samples) worldwide corresponds to samples of domestic origin, 49% (104 samples) for imported samples, and 26% (54 samples) of unknown origin. Despite this issue, the majority of the data did not have the information of the samples origin, therefore it was decided to categorize the data according to the countries that submitted the information to GEMS/Food.

58. In Table 11 it can be observed that at the worldwide level the occurrence of cadmium in chocolates with ≥ 50 – to <70% of total cocoa solids has an average of 0.19 mg/kg; and average values for the different regions range from 0.14 and 0.21 mg/kg. This difference can also be observed in the 95th percentile values, with variations of 0.21 to 0.61 mg/kg among the regions. There are no data from Africa in this group of chocolates and there are only 5 samples from the European Union; these were excluded from further analysis.

59. In Table 11 great variation can also be observed in the LODs (0.00002 to 0.04 mg/kg) and LOQs (0.002 to 0.14 mg/kg) that can impact on the final average of cadmium occurrence.

Table 11. Occurrence data for cadmium at world level and by origin data region* of chocolates with ≥ 50 – <70% of total cocoa solids.

Origin of data	Number of samples	Values expressed in mg/kg							
		Average	Min	Max	P95	LOD		LOQ	
						Min	Max	Min	Max
Worldwide	211	0.19	0.02	1.50	0.57	0.00002	0.04	0.002	0.14
LAC	129	0.21	0.02	1.50	0.61	0.001	0.03	0.002	0.1
ASIA	42	0.17	0.02	0.74	0.58	0.00002	0.04	0.005	0.14
EURO	5	0.15	0.11	0.22	0.21	-	-	-	-
NASWP	35	0.14	0.02	0.58	0.51	0.0004	0.003	0.004	0.02

LAC: Latin America and the Caribbean y; EURO: European Union; NASWP: North America and the Southwest Pacific; Min: Minimum; Max: Maximum; P95: 95th Percentile; LOD: Limit of Detection; LOQ: Limit of Quantification. * The origin of data in the following table was determined by the country that submitted data to GEMS/Food, and not by the true origin of the chocolate

Source: GEMS/Food

60. From occurrence data in Table 11, values between 0.5 to 0.6 mg/kg can be used to evaluate the impact of the different maximum levels on cadmium intake and in chocolate trade (Table 12). The same analyses were used for the calculation of cadmium intake, the comparison with the safety reference value (PTMI) and the number of rejections in international trade.

Table 12. Impact of different maximum levels for cadmium on the statistical distribution of cadmium in chocolates with ≥ 50 to $<70\%$ of total cocoa solids, including the predicted proportion of PTMI of cadmium intake for GEMS/Food Cluster Diet 7 and the predicted proportion of rejected samples from the world market.

Scenario	Number of samples	Average Cd content (mg.kg-1)	Cd intake ($\mu\text{g}/\text{kg}$ b.w. month)	% PTMI	Possible rejected samples (%)
Scenario with worldwide data					
No ML	211	0.19	0.71	2.8	0.0
ML: 0.9 mg/kg	209	0.18	0.66	2.7	0.9
ML: 0.8 mg/kg	206	0.17	0.63	2.5	2.4
ML: 0.7 mg/kg	203	0.16	0.60	2.4	3.8
ML: 0.6 mg/kg	202	0.16	0.59	2.4	4.3
ML: 0.5 mg/kg	198	0.15	0.56	2.2	6.2
Scenario with data from LAC					
No ML	129	0.21	0.79	3.2	0.0
ML: 0.9 mg/kg	127	0.19	0.71	2.9	1.6
ML: 0.8 mg/kg	124	0.17	0.66	2.6	3.9
ML: 0.7 mg/kg	122	0.17	0.62	2.5	5.4
ML: 0.6 mg/kg	122	0.17	0.62	2.5	5.4
ML: 0.5 mg/kg	122	0.17	0.62	2.5	5.4
Scenario with data from ASIA					
No ML	42	0.17	0.64	2.6	0.0
ML: 0.9 mg/kg	42	0.17	0.64	2.6	0.0
ML: 0.8 mg/kg	42	0.17	0.64	2.6	0.0
ML: 0.7 mg/kg	41	0.16	0.59	2.4	2.4
ML: 0.6 mg/kg	40	0.15	0.54	2.2	4.8
ML: 0.5 mg/kg	38	0.12	0.46	1.8	9.5
Scenario with data from NASWP					
No ML	35	0.14	0.53	2.1	0.0
ML: 0.9 mg/kg	35	0.14	0.53	2.1	0.0
ML: 0.8 mg/kg	35	0.14	0.53	2.1	0.0
ML: 0.7 mg/kg	35	0.14	0.53	2.1	0.0
ML: 0.6 mg/kg	35	0.14	0.53	2.1	0.0
ML: 0.5 mg/kg	33	0.11	0.43	1.7	5.7

LAC: Latin America and the Caribbean; NASWP: North America and the Southwest Pacific; PTMI: Provisional Tolerable Monthly Intake; ML: maximum level; b.w.: body weight (60 kg).

61. Considering Cluster Diet 7 as the worst-case scenario globally relative to dietary cadmium intake from consumption of only chocolates with ≥ 50 to $< 70\%$ of total cocoa solids and evaluating regional data for cadmium in chocolates, it is observed that even without a maximum level cadmium intake from chocolate in this category represents only approximately a maximum of 3% of PTMI (25 $\mu\text{g}/\text{kg}$ b.w.) On a worldwide basis with application of the proposed maximum level of 0.5 to 0.9 mg/kg, estimated cadmium intakes ranged between 2.2 and 2.8% of the PTMI. It can be observed that the scenario with the data from Latin America and the Caribbean region reports the highest value for intake, representing 3.2% of the PTMI, but yet this value is below the 5% for a significant effect noted by JECFA.
62. Considering the impact of a maximum level of 0.8, mg/kg such a maximum level could reduce the cadmium intake from 2.8% (no ML) to 2.5% of the PTMI worldwide and the percentage of possible rejected samples would be approximately 2.4% worldwide.
63. In Table 12, 5.4% of samples from the Latin America and Caribbean region could be rejected if, a maximum level of 0.7 mg/kg or lower was observed. Taking this into consideration, as well as the observations of various countries and observers, it is recommended to establish a maximum level of 0.8 mg/kg for the group of chocolates with ≥ 50 – to $< 70\%$ total cocoa solids. This would see the reduction of possible rejected samples worldwide to 2.4%.

Cadmium in chocolates $\geq 70\%$ of total cocoa solids

64. According to the origin of chocolates containing $\geq 70\%$ total cocoa solids, 20% of worldwide data corresponds to samples of domestic origin with 93 samples, 37% for imported samples (166 samples), and 43% (194 samples) of unknown origin. Despite this issue, the majority of data did not have the information of the samples origin, therefore it was decided to categorize the data according to the countries that submitted the information in GEMS/Food.
65. In Table 13 it can be observed that at the worldwide level, the occurrence of cadmium in chocolates with $\geq 70\%$ of total cocoa solids averages concentration 0.31 mg/kg, and the average values among the regions range from 0.20 to 0.34 mg/kg. This difference can also be observed in the 95th percentile estimates with values ranging between 0.46 to 0.77 mg/kg among regions. There were no data from Africa in this group of chocolates, however it is important to remember that the majority of cocoa imports to Europe come from West Africa (93%).
66. In Table 13 great variation can be observed in the LODs (0.00002 to 0.04 mg/kg) and LOQs (0.002 to 0.14 mg/kg) that can impact on the final average cadmium occurrence.

Table 13. Occurrence data for cadmium at world level and by origin data region* of data submitted for chocolates with $\geq 70\%$ of total cocoa solids

Origin of data	Number of samples	Values expressed in mg/kg							
		Average	Min	Max	P95	LOD		LOQ	
						Min	Max	Min	Max
Worldwide	453	0.31	ND	2.30	0.74	0.00002	0.04	0.002	0.14
LAC	272	0.34	ND	1.76	0.77	0.001	0.01	0.002	0.06
ASIA	80	0.30	0,05	2.30	0.76	0.00002	0.04	0.005	0.14
EURO	14	0.20	0,07	0.60	0.46	-	-	-	-
NASWP	87	0.23	ND	1.29	0.65	0.00032	0.025	0.002	0.05

LAC: Latin America and the Caribbean; EURO: European Union; NASWP: North America and the Southwest Pacific; Min: Minimum; Max: Maximum; P95: 95th Percentile; LOD: Limit of Detection; LOQ: Limit of Quantification; ND: not detected. * The origin of data in the following table was determined by the country that submitted data to GEMS/Food, and not by the true origin of the chocolate.

Source: GEMS/Food

67. From occurrence data in Table 13, values of 0.7 to 1.5 mg/kg were proposed to evaluate the impact of different maximum levels on cadmium intake and in the chocolate trade with $\geq 70\%$ of total cocoa solids (Table 14). The same considerations as for the other chocolate categories were used for the calculation of cadmium intake, the comparison with the safety reference value (PTMI) and the number of rejections based in international trade.

Table 14. Impact of different maximum levels for cadmium on the statistical distribution of cadmium in chocolates with $\geq 70\%$ of total cocoa solids, including the predicted proportion of PTMI of cadmium intake for GEMS/Food Cluster Diet 7 and the predicted proportion of rejected samples from the world market.

Scenario	Number of samples	Average Cd content (mg.kg-1)	Cd intake ($\mu\text{g}/\text{kg}$ b.w. month)	% PTMI	Possible rejected samples (%)
Scenario with worldwide data					
No ML	453	0.31	1.16	4.7	0.0
ML: 1.5 mg/kg	447	0.29	1.07	4.3	1.3
ML: 1.0 mg/kg	445	0.28	1.06	4.2	1.8
ML: 0.9 mg/kg	442	0.28	1.04	4.2	2.4
ML: 0.8 mg/kg	433	0.27	1.00	4.0	4.4
ML: 0.7 mg/kg	425	0.26	0.96	3.9	6.2
Scenario with data from LAC					
No ML	272	0.34	1.27	5.1	0.0
ML: 1.5 mg/kg	268	0.32	1.19	4.8	1.5
ML: 1.0 mg/kg	267	0.32	1.18	4.7	1.8
ML: 0.9 mg/kg	266	0.31	1.17	4.7	2.2
ML: 0.8 mg/kg	260	0.30	1.13	4.5	4.4
ML: 0.7 mg/kg	254	0.29	1.09	4.3	6.6
Scenario with data from ASIA					
No ML	80	0.30	1.13	4.5	0.0
ML: 1.5 mg/kg	78	0.25	0.95	3.8	2.5
ML: 1.0 mg/kg	78	0.25	0.95	3.8	2.5
ML: 0.9 mg/kg	76	0.23	0.88	3.5	5.0
ML: 0.8 mg/kg	76	0.23	0.88	3.5	5.0
ML: 0.7 mg/kg	74	0.22	0.83	3.3	7.5
Scenario with data from EURO					
No ML	14	0.20	0.76	3.0	0.0
ML: 1.5 mg/kg	14	0.20	0.76	3.0	0.0
ML: 1.0 mg/kg	14	0.20	0.76	3.0	0.0
ML: 0.9 mg/kg	14	0.20	0.76	3.0	0.0
ML: 0.8 mg/kg	14	0.20	0.76	3.0	0.0
ML: 0.7 mg/kg	14	0.20	0.76	3.0	0.0
Scenario with data from NASWP					
No ML	87	0.23	0.86	3.5	0.0
ML: 1.5 mg/kg	87	0.23	0.86	3.5	0.0
ML: 1.0 mg/kg	86	0.22	0.82	3.3	1.1
ML: 0.9 mg/kg	86	0.22	0.82	3.3	1.1
ML: 0.8 mg/kg	83	0.20	0.74	2.9	4.6
ML: 0.7 mg/kg	83	0.20	0.74	2.9	4.6

LAC: Latin America and the Caribbean; EURO: European Union; NASWP: North America and the Southwest Pacific; PTMI: Provisional Tolerable Monthly Intake; ML: maximum level; b.w.: body weight (60 kg).

68. According to Table 14, if a maximum level of 0.8mg/kg or 0.9 mg/kg is established, the Asian region would be affected by a 5% rejection of products available in this region, but with a maximum level of 1.0 mg/kg, only 2.5% could potentially be rejected. As such, several country members recommended increasing the maximum level to 1.0 mg/kg, in order to reduce the percentage of possible rejections worldwide.
69. Considering Cluster Diet 7 as the worst-case scenario globally relative to dietary cadmium intake from consumption of only chocolates containing >70% total cocoa solids and evaluating regional data for cadmium in chocolates, it is observed that without a maximum level, cadmium intake represents approximately 5% of the PTMI. With the most restrictive maximum level assessed (0.7 mg/kg) it would be reduced to approximately 4% of the PTMI, considering worldwide data. Additionally it can be observed that the scenario with the data from Latin America and the Caribbean region has the highest value for intake, as a percentage of the PTMI, this being 4.8% of the PTMI (with a proposed maximum level of 1.5 mg/kg); this value is very close to the 5% value. Scenarios using worldwide data and proposed maximum level of 0.9 and 1.0 mg/kg showed less than 5% of samples being possibly rejected and a reduction in intake from 47% (no ML) to 4.2% of the PTMI.

Cocoa powder

70. According to the origin of cocoa powder, 17% (405 samples) of samples are of domestic origin, 23% (529 samples) of samples are imported (unknown origin), and 60% (1401 samples) are of unknown origin. Since there was no description of further processing or direct commercialization for final consumption for cocoa powder, all submitted data for cocoa powder was considered. Despite the major data did not have the information of the samples origin, it was decided to categorize the data according to the countries that submitted the information to GEMS/Food.
71. In Table 15 it can be observed that worldwide cadmium occurrence in cocoa powder averages 0.29 mg/kg, and regional average values, range from 0.17 to 0.53 mg/kg. This difference can also be observed in the 95th percentile values with variations of 0.25 to 1.46 mg/kg among regions.
72. In Table 15 there is great variation among the LODs (0.00002 to 0.05 mg/kg) and LOQs (0.0004 to 0.167 mg/kg) that can create an impact in the final average of cadmium concentration

Table 15. Occurrence data for cadmium at world level and by data origin region* in cocoa powder

Origin of data	Number of samples	Values expressed in mg/kg							
		Average	Min	Max	P95	LOD		LOQ	
						Min	Max	Min	Max
Worldwide	2335	0.29	ND	3.64	0.94	0.00002	0.05	0.0004	0.1666
LAC	515	0.45	0.02	3.64	1.22	0.0001	0.05	0.001	0.1
AFRICA	88	0.17	0.01	1.30	0.25	0.0001	0.025	0.001	0.05
ASIA	410	0.36	0.02	1.80	0.61	0.00002	0.05	0,001	0.14
EURO	1164	0.17	ND	1.70	0.46	0.000133	0.05	0.00013	0.1666
NASWP	158	0.53	0.01	2.99	1.46	0,00048	0.0064	0.0021	0.04

LAC: Latin America and the Caribbean; EURO: European Union; NASWP: North America and the Southwest Pacific; Min: Minimum; Max: Maximum; P95: 95th Percentile; LOD: Limit of Detection; LOQ: Limit of Quantification; ND: not detected. * The origin of data in the following table was determined by the country that submitted data to GEMS/Food, and not by the true origin of the cocoa powder.

Source: GEMS/Food

73. From occurrence data in Table 15, values of 0.8 to 1.5 mg/kg were proposed to evaluate the impact of different maximum levels on cadmium intake and in cocoa trade (Table 16). The same considerations as the others were used for the calculation of cadmium intake, the comparison with the safety reference value (PTMI) and the number of possible rejections on international trade.

Table 16. Impact of different maximum levels for cadmium on the statistical distribution of cadmium in cocoa powder, including the predicted proportion of PTMI of cadmium intake for GEMS/Food Cluster Diet 7 and the predicted proportion of rejected samples from the world market.

Scenario	Number of samples	Average Cd content (mg.kg-1)	Cd intake ($\mu\text{g}/\text{kg}$ b.w. month)	% PTMI	Possible rejected samples (%)
Scenario with worldwide data					
No ML	2335	0.29	1.09	4.4	0.0
ML: 1.5 mg/kg	2313	0.27	1.01	4.1	0.9
ML: 1.3 mg/kg	2295	0.26	0.98	3.9	1.7
ML: 1.1 mg/kg	2268	0.25	0.94	3.8	2.9
ML: 1 mg/kg	2244	0.24	0.90	3.6	3.9
ML: 0.9 mg/kg	2207	0.23	0.86	3.5	5.5
ML: 0.8 mg/kg	2176	0.22	0.83	3.3	6.8
Scenario with data from LAC					
No ML	515	0.45	1.69	6.8	0.0
ML: 1.5 mg/kg	503	0.4	1.50	6.0	2.3
ML: 1.3 mg/kg	497	0.39	1.46	5.9	3.5
ML: 1.1 mg/kg	480	0.36	1.35	5.4	6.8
ML: 1 mg/kg	470	0.34	1.28	5.1	8.7
ML: 0.9 mg/kg	449	0.32	1.20	4.8	12.8
ML: 0.8 mg/kg	434	0.3	1.13	4.5	15.7
Scenario with data from AFRICA					
No ML	88	0.17	0.64	2.6	0.0
ML: 1.5 mg/kg	88	0.17	0.64	2.6	0.0
ML: 1.3 mg/kg	88	0.17	0.64	2.6	0.0
ML: 1.1 mg/kg	87	0.16	0.60	2.4	1.1
ML: 1 mg/kg	87	0.16	0.60	2.4	1.1
ML: 0.9 mg/kg	86	0.14	0.53	2.1	2.3
ML: 0.8 mg/kg	86	0.14	0.53	2.1	2.3
Scenario with data from ASIA					
No ML	410	0.36	1.35	5.4	0.0
ML: 1.5 mg/kg	408	0.35	1.31	5.3	0.5
ML: 1.3 mg/kg	406	0.34	1.28	5.1	1.0
ML: 1.1 mg/kg	406	0.34	1.28	5.1	1.0
ML: 1 mg/kg	406	0.34	1.28	5.1	1.0
ML: 0.9 mg/kg	403	0.34	1.28	5.1	1.7
ML: 0.8 mg/kg	400	0.34	1.28	5.1	2.4
Scenario with data from EURO					
No ML	1164	0.17	0.64	2.6	0.0
ML: 1.5 mg/kg	1162	0.17	0.64	2.6	0.2
ML: 1.3 mg/kg	1157	0.16	0.60	2.4	0.6
ML: 1.1 mg/kg	1153	0.16	0.60	2.4	0.9
ML: 1 mg/kg	1150	0.16	0.60	2.4	1.2
ML: 0.9 mg/kg	1146	0.15	0.56	2.3	1.5
ML: 0.8 mg/kg	1140	0.15	0.56	2.3	2.1

Scenario	Number of samples	Average Cd content (mg.kg-1)	Cd intake ($\mu\text{g}/\text{kg}$ b.w. month)	% PTMI	Possible rejected samples (%)
Scenario with data from NASWP					
No ML	158	0.53	1.99	8.0	0.0
ML: 1.5 mg/kg	152	0.45	1.69	6.8	3.8
ML: 1.3 mg/kg	147	0.42	1.58	6.3	7.0
ML: 1.1 mg/kg	142	0.39	1.46	5.9	10.1
ML: 1 mg/kg	132	0.34	1.28	5.1	16.5
ML: 0.9 mg/kg	123	0.3	1.13	4.5	22.2
ML: 0.8 mg/kg	116	0.26	0.98	3.9	26.6

LAC: Latin America and the Caribbean; EURO: European Union; NASWP: North America and the Southwest Pacific; PTMI: Provisional Tolerable Monthly Intake; ML: maximum level; b.w.: body weight (60 kg).

Source: GEMS/Food

74. On a world scenario with maximum level of 1.5 mg/kg, a cadmium intake of 0.98 $\mu\text{g}/\text{kg}$ b.w. per month can be observed, which represents 3.9% of the PTMI, and which would see a total of 1.7% of the samples in the world trade possibly being rejected. However, considering these scenarios with the regional data for Latin America and the Caribbean a maximum level of 1.3 mg/kg would see 3.5% of samples possibly being rejected; a maximum level that was any more restrictive would see over 5% of products in this region possibly being rejected. For the countries of North America and the Southwest Pacific, using the same scenario of a maximum level of 1.3 mg/kg would see 7% of their samples being rejected. Therefore, when also taking into consideration the regions of Latin America and the Caribbean, and North America and the Southwest Pacific a maximum levels of 1.3 mg/kg should be considered. This maximum level would also result in the reduction of cadmium intake to 6.0 % (LAC) and 6.8% (NASWP) of the PTMI from approximately 7% and 8 % respectively, if no maximum level applied.

Cadmium in dry mixtures of cocoa and sugars

75. According to the origin of mixtures of cocoa and sugars, 17% of the worldwide samples (n=128) are of domestic origin, 22% are imported samples (168 samples), and 61% (469 samples) of unknown origin. Despite this issue, the majority of the data did not have the information of the samples origin, therefore it was decided to categorize the data according to the countries that submitted the information to GEMS/Food.
76. In Table 17 it can be observed that worldwide, cadmium occurrence in dry mixtures of cocoa and sugars averages 0.12 mg/kg; and with average estimates for the regions ranging between 0.08 and 0.45 mg/kg, with Latin America and the Caribbean showing the highest average concentration. This difference can also be observed at the 95th percentile, where the LAC region presents a value of 0.97 mg/kg, which is approximately two times greater than the worldwide mean (0.47 mg/kg) and the European region presents the lowest P95 value (0.19 mg/kg nearly 2.5 times lower than the worldwide mean).
77. Over 90% of data used for the evaluation of cadmium occurrence in dry mixtures of cocoa and sugars were from Europe and Asia, with Latin America and the Caribbean having few data (18 samples). The African region did not have data for this category of dry mixtures of cocoa and sugars for analysis, but again it is necessary to remember that the majority of cocoa imports to Europe come from West Africa, therefore African Region is indirectly represented.

Table 17. Occurrence data for cadmium worldwide and by origin data region* in dry mixtures of cocoa and sugars.

Origin of data	Number of Samples	Values expressed in mg/kg							
		Average	Min	Max	P95	LOD		LOQ	
						Min	Max	Min	Máx
Worldwide	765	0.12	ND	1.91	0.47	0.00002	0.04	0.0004	0.14
LAC	18	0.45	0.13	1.32	0.97	0.001	0.04	0.004	0.089
ASIA	294	0.14	ND	1.60	0.69	0.00002	0.04	0.005	0.14
EURO	413	0.08	ND	1.91	0.19	0.00013	0.03	0.0004	0.10
NASWP	40	0.18	ND	1.09	0.43	0.00016	0.008	0.001	0.05

LAC: Latin America and the Caribbean y; EURO: European Union; NASWP: North America and the Southwest Pacific; Min: Minimum; Max: Maximum; P95: 95th Percentile; LOD: Limit of Detection; LOQ: Limit of Quantification; ND: not detected. * The origin of data in the following table was determined by the country that submitted data to GEMS/Food, and not by the true origin of the dry mixtures of cocoa and sugars

Source: GEMS/Food

Table 18. Impact of different maximum levels for cadmium in the statistical distribution of cadmium for dry mixtures of cocoa and sugar, including the expected proportion of PTMI for the intake of cadmium for the Cluster Diet 7 and the projected proportion of rejected samples in the world market.

Scenario	Number of samples	Average Cd content (mg.kg-1)	Cd intake ($\mu\text{g}/\text{kg}$ b.w. month)	% PTMI	Possible rejected samples (%)
Scenario with worldwide data					
No ML	765	0.12	0.45	1.8	0.0
ML: 1.1 mg/kg	755	0.1	0.38	1.5	1.3
ML: 1.0 mg/kg	754	0.1	0.38	1.5	1.4
ML: 0.9 mg/kg	750	0.09	0.34	1.4	2.0
ML: 0.7 mg/kg	742	0.08	0.30	1.2	3.0
ML: 0.5 mg/kg	731	0.08	0.30	1.2	4.4
ML: 0.4 mg/kg	719	0.07	0.26	1.1	6.0
Scenario with data from LAC					
No ML	18	0.45	1.69	6.8	0.0
ML: 1.1 mg/kg	17	0.4	1.50	6.0	5.6
ML: 1.0 mg/kg	17	0.4	1.50	6.0	5.6
ML: 0.9 mg/kg	15	0.33	1.24	5.0	16.7
ML: 0.7 mg/kg	15	0.33	1.24	5.0	16.7
ML: 0.5 mg/kg	13	0.29	1.09	4.4	27.8
ML: 0.4 mg/kg	10	0.24	0.90	3.6	44.4
Scenario with data from ASIA					
No ML	294	0.14	0.53	2.1	0.0
ML: 1.1 mg/kg	288	0.12	0.45	1.8	2.0
ML: 1.0 mg/kg	288	0.12	0.45	1.8	2.0
ML: 0.9 mg/kg	286	0.11	0.41	1.7	2.7
ML: 0.7 mg/kg	279	0.1	0.38	1.5	5.1
ML: 0.5 mg/kg	271	0.08	0.30	1.2	7.8
ML: 0.4 mg/kg	265	0.07	0.26	1.1	9.9
Scenario with data from EURO					
No ML	413	0.08	0.30	1.2	0.0
ML: 1.1 mg/kg	410	0.06	0.23	0.9	0.7
ML: 1.0 mg/kg	410	0.06	0.23	0.9	0.7
ML: 0.9 mg/kg	410	0.06	0.23	0.9	0.7
ML: 0.7 mg/kg	410	0.06	0.23	0.9	0.7
ML: 0.5 mg/kg	409	0.06	0.23	0.9	1.0
ML: 0.4 mg/kg	407	0.06	0.23	0.9	1.5

Scenario	Number of samples	Average Cd content (mg.kg-1)	Cd intake ($\mu\text{g}/\text{kg}$ b.w. month)	% PTMI	Possible rejected samples (%)
Scenario with data from NASWP					
No ML	40	0.18	0.68	2.7	0.0
ML: 1.1 mg/kg	40	0.18	0.68	2.7	0.0
ML: 1.0 mg/kg	39	0.16	0.60	2.4	2.5
ML: 0.9 mg/kg	39	0.16	0.60	2.4	2.5
ML: 0.7 mg/kg	38	0.14	0.53	2.1	5.0
ML: 0.5 mg/kg	38	0.14	0.53	2.1	5.0
ML: 0.4 mg/kg	37	0.13	0.49	2.0	7.5

LAC: Latin America and the Caribbean; EURO: European Union; NASWP: North America and the Southwest Pacific; PTMI: Provisional Tolerable Monthly Intake; ML: maximum level; b.w.: body weight (60 kg).

78. Considering Cluster Diet 7 as the one with greatest consumption of cocoa products in their diet, according to "Cluster Diet 2012" from WHO (Cocoa, cola and their non-liquid derivatives), and after developing the estimates in Table 18, it can be observed that with no maximum level for cadmium in dry mixtures of cocoa and sugars, in a worldwide scenario, the intake will be 1.8% of the PTMI. With the application of the proposed maximum levels of 0.4 to 1.1 mg/kg, intakes will range from 1.1 to 1.5% of the PTMI. Additionally it can be observed that the scenario with the data from Latin America and the Caribbean region has the highest value for intake, representing 6.8% of the PTMI, if no maximum level applied, but it is necessary to emphasize that this is overestimated, since the worst case scenario was considered.
79. It can be observed that with the proposed maximum levels of between 0.40 to 1.10 mg/kg for the dry mixtures of cocoa and sugars worldwide, the calculated intake for the available data ranges between 1.10 to 1.50% of the PTMI (Table 18). It should be stressed that the intake mentioned was calculated considering the dry mixtures of cocoa and sugars, as the only source of cocoa products in diet. However, it is important to emphasize that cocoa products are not a significant source of cadmium, in the context of the overall diet.
80. Regarding the percentage of possible rejected samples, 4.4% and 6% of the samples would be considered non-compliant with the proposed maximum levels of 0.5 mg/kg and 0.4 mg/kg respectively in the worldwide scenario. This is not the case for the Latin American and Caribbean region which, if the proposed lower maximum level of 0.4 mg/kg was applied, it would result in the possible rejection of 44.4% of dry mixtures of cocoa and sugars. For the scenario with data from Latin America and the Caribbean, a maximum level of 1.0 mg/kg would affect 5.6% of the samples and could reduce the intake to 6.0% of the PTMI compared to 6.8% of the PTMI, if no maximum level was applied.
81. To fulfill the Committee's mandate about the classification of dry mixtures of cocoa and sugars, estimates were done using the maximum level for cocoa powder category with 100% total cocoa solids, as a reference value, that corresponds to the maximum level of 1.2 mg/kg. Such estimations can be observed in Table 19. It should be emphasized that defining only one maximum level for all mixtures, does not guarantee fair trade; and this is the reason why many submitted comments pointed out the need to establish maximum levels for specific categories of dry mixtures of cocoa and sugars according to CCCF11.

Table 19. Estimated maximum levels for cadmium in dry mixtures of cocoa and sugars category, based on the maximum level of 1.2 mg/kg for cocoa powder category with 100% total cocoa solids, as a reference value

Name of the product	Maximum Level (ML) (mg/kg)	Notes/Remarks
Dry mixtures of cocoa and sugars containing <29% total cocoa solids on a dry matter basis	0.4	
Dry mixtures of cocoa and sugars containing ≥29 to <50% total cocoa solids on a dry matter basis	0.4 - 0.6	Includes chocolate powder, and such ranges are established according to the amount of cocoa solids the mixes could have.
Dry mixtures of cocoa and sugars containing ≥50% total cocoa solids on a dry matter basis	0.6 -1.2	Includes chocolate powder, and such ranges are established according to the amount of solids the mixes could have.

CONCLUSIONS

- The 77th JECFA evaluation noted that the total exposure to cadmium in diets of consumers with high levels of consumption of cocoa and cocoa products was likely to be overestimated and JECFA did not consider it was a matter of concern. There were only minimal variations in cadmium intake from cocoa products by setting the maximum levels since cocoa products are not a significant source of this contaminant.
- An analysis of cadmium intake, including as a percentage of the PTMI, has been provided. However, according to the 77th Joint WHO/FAO Expert Committee on Food Additives (JECFA), there is no health concern with regards to cadmium exposure due to consumption of cocoa and cocoa-derived products, and maximum levels established for cocoa-derived products should be based primarily on practical achievability worldwide. In addition, generally, cadmium intake does not approach 5% of the PTMI⁸ and a more restrictive maximum level did not reduce significantly the % PTMI.
- Cadmium levels in cocoa products can vary considerably among regions and countries. A review of cadmium occurrence data in cocoa beans (by region of origin), as shown in Table 3, indicates that the region with the lowest concentrations of cadmium in cocoa is Africa; while cocoa beans from other regions such as Latin America and the Caribbean have inherently higher cadmium contents.
- The Committee generally considers that a 5% rejection rate in worldwide trade is acceptable in the establishment of maximum levels when the impact on health is reduced. However it was observed that the establishment of maximum levels for chocolate and cocoa derived products based on worldwide cadmium data could possibly result in maximum levels that do not reflect the reality of all cocoa producing countries - in particular Latin America and the Caribbean that have naturally high cadmium content in cocoa and derived cocoa products.

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⁸ Codex Alimentarius Commission Procedural Manual pg. 125-127.

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ANNEX 1

DATA ANALYSIS EXCLUDING SAMPLES WITHOUT LOD / LOQ

Cadmium in chocolates <30% of total cocoa solids**Table 1.** Occurrence data for cadmium worldwide and by data origin region in chocolates with <30% of total cocoa solids.

Origin of data	Number of samples	Values expressed in mg/kg							
		Average	Min	Max	P95	LOD		LOQ	
						Min	Max	Min	Max
Worldwide	562	0.03	ND	0.49	0.31	0.00002	0.05	0.001	0.17
LAC	189	0.08	ND	0.49	0.40	0.001	0.03	0.002	0.05
AFRICA	18	0.01	0.01	0.02	0.02	0.002	0.01	0.005	0.01
ASIA	53	0.03	ND	0.49	0.11	0.00002	0.04	0.005	0.14
EURO	114	0.00	ND	ND	0.00	0.001	0.05	0.003	0.17
NASWP	188	0.00	ND	0.10	0.02	0.0002	0.05	0.001	0.10

Table 2. Impact of different maximum levels for cadmium in the statistical distribution of cadmium for chocolates with <30% total cocoa solids, including the expected proportion of PTMI for the intake of cadmium for the Cluster Diet 7 and the projected proportion of rejected samples in the world market

Scenario	Number of samples	Average Cd content (mg.kg-1)	Cd intake (µg/kg b.w. month)	% PTMI	Possible rejected samples (%)
Scenario with worldwide data					
NO ML	562	0.030	0.113	0.5	0.0
ML: 0.4 mg/kg	552	0.034	0.129	0.5	1.8
ML: 0.35 mg/kg	545	0.034	0.129	0.5	3.0
ML: 0.30 mg/kg	533	0.034	0.129	0.5	5.2
ML: 0.20 mg/kg	523	0.034	0.129	0.5	6.9
ML: 0.10 mg/kg	518	0.034	0.129	0.5	7.8
Scenario with data from LAC					
NO ML	189	0.08	0.32	1.3	0.0
ML: 0.4 mg/kg	180	0.084	0.32	1.3	4.8
ML: 0.35 mg/kg	173	0.084	0.32	1.3	8.5
ML: 0.30 mg/kg	161	0.084	0.32	1.3	14.8
ML: 0.20 mg/kg	151	0.084	0.32	1.3	20.1
ML: 0.10 mg/kg	149	0.084	0.32	1.3	21.2

Scenario with data from AFRICA					
NO ML	18	0.01	0.05	0.2	0.00
ML: 0.4 mg/kg	18	0.01	0.05	0.2	0.00
ML: 0.35 mg/kg	18	0.01	0.05	0.2	0.00
ML: 0.30 mg/kg	18	0.01	0.05	0.2	0.00
ML: 0.20 mg/kg	18	0.01	0.05	0.2	0.00
ML: 0.10 mg/kg	18	0.01	0.05	0.2	0.00
Scenario with data from ASIA					
NO ML	53	0.03	0.12	0.47	0
ML: 0.4 mg/kg	52	0.03	0.11	0.45	1.89
ML: 0.35 mg/kg	52	0.03	0.11	0.45	1.89
ML: 0.30 mg/kg	52	0.03	0.12	0.47	1.89
ML: 0.20 mg/kg	52	0.03	0.12	0.47	1.89
ML: 0.10 mg/kg	50	0.03	0.12	0.47	5.66
Scenario with data from EURO					
NO ML	114	0.02	0.075	0.3	0
ML: 0.4 mg/kg	114	0.02	0.075	0.3	0.00
ML: 0.35 mg/kg	114	0.02	0.075	0.3	0.00
ML: 0.30 mg/kg	114	0.02	0.075	0.3	0.00
ML: 0.20 mg/kg	114	0.02	0.075	0.3	0.00
ML: 0.10 mg/kg	114	0.00	0	0	0.00
Scenario with data from NASWP					
NO ML	188	0.00	0.012	0.050	0.00
ML: 0.4 mg/kg	188	0.00	0.013	0.051	0.00
ML: 0.35 mg/kg	188	0.00	0.014	0.056	0.00
ML: 0.30 mg/kg	188	0.00	0.015	0.058	0.00
ML: 0.20 mg/kg	188	0.00	0.015	0.059	0.00
ML: 0.10 mg/kg	188	0.00	0.015	0.060	0.00

Cadmium in chocolates $\geq 30\%$ to- $< 50\%$ total cocoa solids.**Table 3:** Occurrence data for cadmium worldwide and by data origin region in chocolates with $\geq 30\%$ to- $< 50\%$ of total cocoa solids.

Origin of data	Number of samples	Values expressed in mg/kg							
		Average	Min	Max	P95	LOD		LOQ	
						Min	Máx	Min	Máx
Worldwide	158	0.05	ND	0.71	0.19	0.00002	0.04	0.002	0.14
LAC	104	0.06	ND	0.71	0.28	0.001	0.001	0.002	0.002
ASIA	26	0.04	ND	0.18	0.13	0.00002	0.04	0.005	0.14
NASWP	28	0.06	ND	0.31	0.14	0.000408	0.025	0.0034	0.05

Table 4. Impact of different maximum level for cadmium in the statistical distribution of cadmium for chocolates with $\geq 30\%$ - $< 50\%$ of total cocoa solids, including the expected proportion of PTMI for the intake of cadmium for the Diet Cluster 7 and the projected proportion of rejected samples in the world market.

Scenario	Number of samples	Average Cd content (mg.kg-1)	Cd intake ($\mu\text{g/kg}$ b.w. month)	% PTMI	Possible rejected samples (%)
Scenario with worldwide data					
No ML	158	0.05	0.20	0.81	0
ML: 0.5 mg/kg	157	0.05	0.20	0.79	0.63
ML: 0.45 mg/kg	156	0.05	0.20	0.79	1.27
ML: 0.4 mg/kg	155	0.05	0.20	0.79	1.90
ML: 0.35 mg/kg	152	0.05	0.20	0.79	3.80
ML: 0.3 mg/kg	151	0.05	0.20	0.79	4.43
ML: 0.25 mg/kg	150	0.05	0.20	0.79	5.06
ML: 0.2 mg/kg	158	0.05	0.20	0.81	0
Scenario with data from LAC					
No ML	104	0.06	0.21	0.84	0
ML: 0.5 mg/kg	103	0.06	0.21	0.84	15.57
ML: 0.45 mg/kg	102	0.06	0.21	0.84	16.39
ML: 0.4 mg/kg	102	0.06	0.21	0.84	16.39
ML: 0.35 mg/kg	99	0.06	0.21	0.84	18.85
ML: 0.3 mg/kg	98	0.00	0.00	0.00	19.67
ML: 0.25 mg/kg	97	0.06	0.21	0.84	20.49
ML: 0.2 mg/kg	122	0.06	0.21	0.83	0

Scenario	Number of samples	Average Cd content (mg.kg-1)	Cd intake ($\mu\text{g/kg}$ b.w. month)	% PTMI	Possible rejected samples (%)
Scenario with data from ASIA					
No ML	26	0.04	0.15	0.60	0
ML: 0.5 mg/kg	26	0.04	0.15	0.60	0.00
ML: 0.45 mg/kg	26	0.04	0.14	0.55	0.00
ML: 0.4 mg/kg	26	0.04	0.14	0.55	0.00
ML: 0.35 mg/kg	26	0.04	0.14	0.55	0.00
ML: 0.3 mg/kg	26	0.04	0.14	0.55	0.00
ML: 0.25 mg/kg	26	0.04	0.14	0.56	0.00
ML: 0.2 mg/kg	26	0.04	0.15	0.60	0
Scenario with data from NASWP					
No ML	28	0.05	0.19	0.75	0
ML: 0.5 mg/kg	28	0.05	0.19	0.75	0.00
ML: 0.45 mg/kg	28	0.05	0.19	0.75	0.00
ML: 0.4 mg/kg	28	0.05	0.19	0.75	0.00
ML: 0.35 mg/kg	28	0.05	0.20	0.81	0.00
ML: 0.3 mg/kg	27	0.05	0.20	0.81	3.57
ML: 0.25 mg/kg	27	0.05	0.20	0.81	3.57
ML: 0.2 mg/kg	28	0.05	0.19	0.75	0

Cadmium in chocolates with ≥ 50 – to $< 70\%$ of total cocoa solids

Table 5. Occurrence data for cadmium at world level and by origin data region of chocolates with ≥ 50 – $< 70\%$ of total cocoa solids.

Origin of data	Number of samples	Values expressed in mg/kg							
		Average	Min	Max	P95	LOD		LOQ	
						Min	Máx	Min	Máx
Worldwide	155	0.16	0.02	1.50	0.45	0.00002	0.04	0.002	0.14
LAC	83	0.16	0.02	0.45	0.32	0.001	0.03	0.002	0.1
ASIA	42	0.17	0.02	0.74	0.58	0.00002	0.04	0.005	0.14
NASWP	30	0.15	0.02	0.58	0.52	0.0004	0.003	0.004	0.02

Table 6. Impact of different maximum levels for cadmium on the statistical distribution of cadmium in chocolates with ≥ 50 – to $< 70\%$ of total cocoa solids, including the predicted proportion of PTMI of cadmium intake for GEMS/Food Cluster Diet 7 and the predicted proportion of rejected samples from the world market.

Scenario	Number of samples	Average Cd content (mg.kg ⁻¹)	Cd intake ($\mu\text{g}/\text{kg}$ b.w. month)	% PTMI	Possible rejected samples (%)
Scenario with worldwide data					
NO ML	155	0.16	0.60	2.40	0.00
ML: 0.9 mg/kg	155	0.16	0.60	2.40	0.00
ML: 0.8 mg/kg	155	0.16	0.61	2.45	0.00
ML: 0.7 mg/kg	154	0.16	0.61	2.45	0.65
ML: 0.6 mg/kg	153	0.16	0.61	2.45	1.29
ML: 0.5 mg/kg	149	0.16	0.61	2.45	3.87
Scenario with data from LAC					
NO ML	83	0.16	0.60	2.40	0.00
ML: 0.9 mg/kg	83	0.16	0.60	2.40	0.00
ML: 0.8 mg/kg	83	0.16	0.60	2.40	0.00
ML: 0.7 mg/kg	83	0.16	0.60	2.40	0.00
ML: 0.6 mg/kg	83	0.16	0.60	2.40	0.00
ML: 0.5 mg/kg	83	0.16	0.61	2.45	0.00
Scenario with data from ASIA					
NO ML	42	0.16	0.60	2.40	0.00
ML: 0.9 mg/kg	42	0.16	0.60	2.40	0.00
ML: 0.8 mg/kg	42	0.16	0.60	2.41	0.00
ML: 0.7 mg/kg	41	0.16	0.59	2.35	2.38
ML: 0.6 mg/kg	40	0.16	0.59	2.35	4.76
ML: 0.5 mg/kg	38	0.16	0.59	2.35	9.52
Scenario with data from NASWP					
NO ML	30	0.16	0.60	2.40	0.00
ML: 0.9 mg/kg	30	0.16	0.60	2.40	0.00
ML: 0.8 mg/kg	30	0.16	0.60	2.41	0.00
ML: 0.7 mg/kg	30	0.16	0.60	2.41	0.00
ML: 0.6 mg/kg	29	0.16	0.60	2.41	3.33
ML: 0.5 mg/kg	28	0.16	0.60	2.41	6.67

Cadmium in chocolates $\geq 70\%$ of total cocoa solids**Table 7.** Occurrence data for cadmium at world level and by origin data region of data submitted for chocolates with $\geq 70\%$ of total cocoa solids

Origin of data	Number of samples	Values expressed in mg/kg							
		Average	Min	Max	P95	LOD		LOQ	
						Min	Máx	Min	Máx
Worldwide	252	0.33	ND	2.30	0.73	0.00002	0.04	0.002	0.14
LAC	106	0.40	ND	1.76	0.71	0.001	0.01	0.002	0.06
ASIA	80	0.30	0.05	2.30	0.76	0.00002	0.04	0.005	0.14
NASWP	66	0.26	0.003	1.29	0.77	0.00032	0.025	0.002	0.05

Table 8. Impact of different maximum levels for cadmium on the statistical distribution of cadmium in chocolates with $\geq 70\%$ of total cocoa solids, including the predicted proportion of PTMI of cadmium intake for GEMS/Food Cluster Diet 7 and the predicted proportion of rejected samples from the world market.

Scenario	Number of samples	Average Cd content (mg.kg-1)	Cd intake ($\mu\text{g/kg}$ b.w. month)	% PTMI	Possible rejected samples (%)
Scenario with worldwide data					
NO ML	251	0.332	1.25	4.676	0.00
ML: 1.5 mg/kg	247	0.332	1.25	4.676	1.59
ML: 1.0 mg/kg	245	0.332	1.25	4.676	2.39
ML: 0.9 mg/kg	243	0.332	1.25	4.676	3.19
ML: 0.8 mg/kg	240	0.332	1.25	4.676	4.38
ML: 0.7 mg/kg	236	0.332	1.25	4.676	5.98
Scenario with data from LAC					
NO ML	104	0.335	1.25	4.706	0.00
ML: 1.5 mg/kg	103	0.335	1.25	4.706	0.96
ML: 1.0 mg/kg	103	0.335	1.26	4.711	0.96
ML: 0.9 mg/kg	102	0.335	1.25	4.706	1.92
ML: 0.8 mg/kg	102	0.335	1.25	4.706	1.92
ML: 0.7 mg/kg	100	0.335	1.25	4.706	3.85
Scenario with data from ASIA					
NO ML	80	0.312	1.17	4.389	0.00
ML: 1.5 mg/kg	78	0.312	1.17	4.389	2.50
ML: 1.0 mg/kg	78	0.312	1.17	4.389	2.50
ML: 0.9 mg/kg	76	0.312	1.17	4.389	5.00
ML: 0.8 mg/kg	76	0.312	1.17	4.389	5.00
ML: 0.7 mg/kg	74	0.312	1.17	4.389	7.50

Scenario	Number of samples	Average Cd content (mg.kg-1)	Cd intake ($\mu\text{g}/\text{kg}$ b.w. month)	% PTMI	Possible rejected samples (%)
Scenario with data from NASWP					
NO ML	66	0.323	1.21	4.541	0.00
ML: 1.5 mg/kg	66	0.323	1.21	4.541	0.00
ML: 1.0 mg/kg	65	0.323	1.21	4.541	1.52
ML: 0.9 mg/kg	65	0.323	1.21	4.541	1.52
ML: 0.8 mg/kg	62	0.323	1.21	4.541	6.06
ML: 0.7 mg/kg	62	0.323	1.21	4.541	6.06

Cocoa powder

Table 9. Occurrence data for cadmium at world level and by data origin region in cocoa powder

Origin of data	Number of samples	Values expressed in mg/kg							
		Average	Min	Max	P95	LOD		LOQ	
						Min	Máx	Min	Máx
Worldwide	1429	0.33	3.64	0.00	0.97	0.00002	0.05	0.0004	0.1666
LAC	486	0.46	3.64	0.02	1.24	0.0001	0.05	0.001	0.1
AFRICA	88	0.17	1.30	0.01	0.25	0.0001	0.025	0.001	0.05
ASIA	410	0.36	1.80	0.02	0.61	0.00002	0.05	0.001	0.14
EURO	340	0.12	1.35	0.00	0.25	0.000133	0.05	0.00013	0.1666
CCNASWP	105	0.37	2.46	0.01	1.06	0.00048	0.0064	0.0021	0.04

Table 10. Impact of different maximum levels for cadmium on the statistical distribution of cadmium in cocoa powder, including the predicted proportion of PTMI of cadmium intake for GEMS/Food Cluster Diet 7 and the predicted proportion of rejected samples from the world market.

Scenario	Number of samples	Average Cd content (mg.kg-1)	Cd intake ($\mu\text{g}/\text{kg}$ b.w. month)	% PTMI	Possible rejected samples (%)
Scenario with worldwide data					
NO ML	1429	0.33	1.24	5.0	0.00
ML: 1.5 mg/kg	1414	0.31	1.16	4.7	1.05
ML: 1.3 mg/kg	1404	0.3	1.13	4.5	1.75
ML: 1.1 mg/kg	1385	0.29	1.09	4.4	3.08
ML: 1 mg/kg	1367	0.27	1.01	4.1	4.34
ML: 0.9 mg/kg	1339	0.26	0.98	3.9	6.30
ML: 0.8 mg/kg	1317	0.25	0.94	3.8	7.84

Scenario with data from LAC					
NO ML	486	0.46	1.73	6.9	0.00
ML: 1.5 mg/kg	474	0.42	1.58	6.3	0.84
ML: 1.3 mg/kg	468	0.4	1.50	6.0	1.26
ML: 1.1 mg/kg	451	0.37	1.39	5.6	2.45
ML: 1 mg/kg	441	0.36	1.35	5.4	3.15
ML: 0.9 mg/kg	420	0.33	1.24	5.0	4.62
ML: 0.8 mg/kg	405	0.31	1.16	4.7	5.67
Scenario with data from AFRICA					
NO ML	88	0.17	0.63	2.5	0.00
ML: 1.5 mg/kg	88	0.17	0.63	2.5	0.00
ML: 1.3 mg/kg	88	0.17	0.63	2.5	0.00
ML: 1.1 mg/kg	87	0.16	0.60	2.4	0.07
ML: 1 mg/kg	86	0.14	0.53	2.1	0.14
ML: 0.9 mg/kg	86	0.14	0.53	2.1	0.14
ML: 0.8 mg/kg	86	0.14	0.53	2.1	0.14
Scenario with data from ASIA					
NO ML	410	0.36	1.34	5.4	0.00
ML: 1.5 mg/kg	408	0.35	1.31	5.3	0.14
ML: 1.3 mg/kg	406	0.34	1.28	5.1	0.28
ML: 1.1 mg/kg	406	0.34	1.28	5.1	0.28
ML: 1 mg/kg	406	0.34	1.28	5.1	0.28
ML: 0.9 mg/kg	403	0.34	1.28	5.1	0.49
ML: 0.8 mg/kg	400	0.34	1.28	5.1	0.70
Scenario with data from EURO					
NO ML	340	0.12	0.45	1.8	0.00
ML: 1.5 mg/kg	340	0.12	0.45	1.8	0.00
ML: 1.3 mg/kg	339	0.11	0.41	1.7	0.07
ML: 1.1 mg/kg	339	0.11	0.41	1.7	0.07
ML: 1 mg/kg	339	0.11	0.41	1.7	0.07
ML: 0.9 mg/kg	339	0.11	0.41	1.7	0.07
ML: 0.8 mg/kg	339	0.11	0.41	1.7	0.07

Scenario with data from NASWP					
NO ML	105	0.37	1.40	5.6	0.00
ML: 1.5 mg/kg	104	0.35	1.31	5.3	0.07
ML: 1.3 mg/kg	103	0.34	1.28	5.1	0.14
ML: 1.1 mg/kg	102	0.33	1.24	5.0	0.21
ML: 1 mg/kg	95	0.28	1.05	4.2	0.70
ML: 0.9 mg/kg	91	0.25	0.94	3.8	0.98
ML: 0.8 mg/kg	87	0.22	0.83	3.3	1.26

Cadmium in dry mixtures of cocoa and sugars

Table 11. Occurrence data for cadmium worldwide and by origin data region in dry mixtures of cocoa and sugars.

Origin of data	Number of samples	Values expressed in mg/kg							
		Average	Min	Max	P95	LOD		LOQ	
						Min	Max	Min	Max
Worldwide	566	0.12	1.60	0.00	0.56	0.00002	0.04	0.0004	0.14
LAC	18	0.45	1.32	0.13	0.97	0.001	0.04	0.004	0.089
ASIA	0	-	-	-	-	0.00002	0.04	0.005	0.14
EURO	294	0.14	1.60	0.00	0.69	0.00013	0.03	0.0004	0.10
NASWP	214	0.04	0.38	0.00	0.15	0.00016	0.008	0.001	0.05

Table 12. Impact of different maximum levels for cadmium in the statistical distribution of cadmium for dry mixtures of cocoa and sugar, including the expected proportion of PTMI for the intake of cadmium for the Cluster Diet 7 and the projected proportion of rejected samples in the world market.

Scenario	Number of samples	Average Cd content (mg.kg-1)	Cd intake ($\mu\text{g}/\text{kg}$ b.w. month)	% PTMI	Possible rejected samples (%)
Scenario with worldwide data					
NO ML	566	0.12	0.44	1.8	0.00
ML: 1.1 mg/kg	561	0.11	0.41	1.7	0.88
ML: 1.0 mg/kg	559	0.1	0.38	1.5	1.24
ML: 0.9 mg/kg	558	0.1	0.38	1.5	1.41
ML: 0.7 mg/kg	554	0.09	0.34	1.4	2.12
ML: 0.5 mg/kg	546	0.08	0.30	1.2	3.53
ML: 0.4 mg/kg	536	0.08	0.30	1.2	5.30

Scenario	Number of samples	Average Cd content (mg.kg-1)	Cd intake ($\mu\text{g}/\text{kg}$ b.w. month)	% PTMI	Possible rejected samples (%)
Scenario with data from LAC					
NO ML	18	0.45	1.69	6.8	0.00
ML: 1.1 mg/kg	15	0.33	1.24	5.0	16.67
ML: 1.0 mg/kg	15	0.33	1.24	5.0	16.67
ML: 0.9 mg/kg	15	0.33	1.24	5.0	16.67
ML: 0.7 mg/kg	15	0.33	1.24	5.0	16.7
ML: 0.5 mg/kg	15	0.33	1.24	5.0	16.7
ML: 0.4 mg/kg	13	0.29	1.09	4.4	27.8
Scenario with data from ASIA					
NO ML	0	0	0.00	0.0	0.0
ML: 1.1 mg/kg	0	0	0.00	0.0	0.0
ML: 1.0 mg/kg	0	0	0.00	0.0	0.0
ML: 0.9 mg/kg	0	0	0.00	0.0	0.0
ML: 0.7 mg/kg	0	0	0.00	0.0	0.0
ML: 0.5 mg/kg	0	0	0.00	0.0	0.0
ML: 0.4 mg/kg	0	0	0.00	0.0	0.0
Scenario with data from EURO					
NO ML	294	0.14	0.53	2.1	0.00
ML: 1.1 mg/kg	290	0.13	0.49	2.0	1.36
ML: 1.0 mg/kg	288	0.12	0.45	1.8	2.04
ML: 0.9 mg/kg	288	0.12	0.45	1.8	2.04
ML: 0.7 mg/kg	286	0.11	0.41	1.7	2.72
ML: 0.5 mg/kg	279	0.09	0.34	1.4	5.10
ML: 0.4 mg/kg	271	0.08	0.30	1.2	7.82
Scenario with data from NASWP					
NO ML	214	0.04	0.15	0.6	0.00
ML: 1.1 mg/kg	214	0.04	0.15	0.6	0.00
ML: 1.0 mg/kg	214	0.04	0.15	0.6	0.00
ML: 0.9 mg/kg	214	0.04	0.15	0.6	0.00
ML: 0.7 mg/kg	214	0.04	0.15	0.6	0.00
ML: 0.5 mg/kg	214	0.04	0.15	0.6	0.00
ML: 0.4 mg/kg	214	0.04	0.15	0.6	0.00

LIST OF PARTICIPANTS**CHAIR
ECUADOR**

MsC. Israel Vaca
Coordinador General de Inocuidad de Alimentos
Agencia de Regulación y Control Fito y Zoonosológico– AGROCALIDAD
Ministerio de Agricultura y Ganadería Acuacultura – MAG
Av. Eloy Alfaro N30-350 y Av. Amazonas
israel.vaca@agrocalidad.gob.ec

CO-CHAIRS**BRAZIL**

Mrs. Ligia Schreiner
Regulation National Health Surveillance Specialist
Brazilian Health Surveillance Agency - ANVISA
Brasília
ligia.schreiner@anvisa.gov.br

GHANA

Mr. Ebenezer Kofi Essel
Head Food and Drugs Authority
Food Inspector P.O. Box CT 2783 Cantonments,
Accra - Ghana
kooduntu@yahoo.co.uk

Member countries

Country	Name	Organisation	Position	email
Argentina	Lic. Silvana Ruarte	Dirección de Fiscalización, Vigilancia y Gestión de Riesgo - Instituto Nacional de Alimentos	Jefe de Servicio Analítica de Alimentos	sruarte@anmat.gov.ar
Australia	Ms Matthew O'Mullane	Food Standards Australia New Zealand	Section Manager	matthew.o'mullane@foodstandards.gov
Canada	Stephanie Glanville	Bureau of Chemical Safety, Health Canada	Scientific Evaluator, Food Contaminants Section	stephanie.glanville@hc-sc.gc.ca
Canada	Elizabeth Elliott	Bureau of Chemical Safety, Health Canada	Head, Food Contaminants Section	elizabeth.elliott@hc-sc.gc.ca
Chile	Lorena Delgado		Coordinadora Nacional del Comité del CCCF	ldelgado@ispch.cl
Colombia	Wilmer Humberto Fajardo Jimenez	Instituto Nacional de Vigilancia y Control de Medicamentos y Alimentos – Invima	Coordinador Grupo del Sistema de Análisis de Riesgos Químicos en Alimentos y Bebidas	wfajardoj@invima.gov.co

Country	Name	Organisation	Position	email
Costa Rica	Maria Elena Aguilar Solano	Ministerio de Salud	Dirección de Regulación de Productos de Interés Sanitario, Unidad de Normalización y Control	maguilar@ministeriodesaludgo.cr
Costa Rica	Lic. Amanda Lasso Cruz	Ministry of Economy, Trade and Industry	Licensed Food Technologist	alasso@meic.go.cr
Ecuador	Ana Gabriela Escobar	AGROCALIDAD	Responsable de la Unidad de Vigilancia y Control de Contaminantes	Ana.escobar@agrocalidad.gob.ec
Egypt	Noha Mohammed Atyia	Egyptian Organization for Standardization & Quality (EOS)	Food Standards Specialist	nonaaatia@yahoo.com
El Salvador	Claudia Guzmán	Organismo Salvadoreño de Reglamentación Técnica	Especialista CODEX ALIMENTARIUS	cguzman@osartec.gob.sv
Germany	Dr. Annette Rexroth	Federal Ministry for Nutrition and Agriculture	Senior Officer	Annette.Rexroth@bmel.bund.de
Greece	Eleni Papavasileiou	General Chemical State Laboratory (GCSL)	Chemist PhD and Contact Person of the National Reference Laboratory on Heavy Metals of the Department of "Chemical Hazards in foods and special analyses" of the GCSL	e.papavasileiou@gcsl.gr
Japan	Tsuyoshi ARAI	Ministry of Health, Labour and Welfare	Food Standards and Evaluation Division	codexj@mhlw.go.jp
Japan	Mao YANAGISAWA	Ministry of Health, Labour and Welfare	Office of International Food Safety	mao.yanagisawa.0522@gmail.com
Perú	Carlos Leyva Fernandez	SENASA		cleyva@senasa.gob.pe
República Dominicana	Dra. Fátima del Rosario Cabrera		Dirección General de Medicamentos, Alimentos y Productos Sanitarios (DIGEMAPS) en el Ministerio de Salud Pública y Asistencia Social (MISPAS)	Codex.pccdor@msp.gob.do
Spain	Marta Perez Gonzalez	Spanish Agency for Consumer Affairs, Food Safety and Nutrition	Technical expert - Contaminants Management Department	contaminantes@msssi.es
Trinidad y Tobago	Farz Khan	Ministry of Health	Chief Chemist and Director Food and Drugs	farz.khan@health.gov.tt; cfdd@health.gov.tt

Country	Name	Organisation	Position	email
United States	Henry Kim	U.S. Food and Drug Administration	On behalf of Lauren Posnick Robin, U.S. Delegate to CCCF	henry.kim@fda.hhs.gov
United States	Eileen Abt	U.S. Food and Drug Administration		eileen.abt@fda.hhs.gov
Uganda	Hakim Baligeza Mufumbiro	Ag. Manager, Standards Department	Uganda National Bureau of Standards	hakimmufumbiro@yahoo.com
Uruguay	Claudia Boullosa			cboullosa@msp.gub.uy

Member organizations

Name	Organisation	Position	email
Eoin Keane	Manager of Food Policy	Food Drink Europe	e.keane@fooddrinkeurope.eu
Catherine ENTZMINGER	EUROPEAN COCOA ASSOCIATION	General Secretary	Catherine.entzminher@eurococoa.com
Laura Shumow	Candy USA	International Confectionery Association	Laura.shumow@candyusa.com
Amy Tatelbaum	Candy USA	International Confectionery Association	Amy.tatelbaum@candyusa.com
Alice Costa	CAOBISCO ICA/IOCCC	International Confectionery Association	Alice.Costa@caobisco.eu
Dr. James R. Coughlin	Institute of Food Technologists (IFT)	President & Founder	jrcoughlin@cox.net
Markus Lipp	FAO	JECFA Secretariat, Scientific Advice	markus.lipp@fao.org
Angelika Tritscher	WHO	Coordinator - Risk Assessment and Management	tritschera@who.int