CODEX ALIMENTARIUS COMMISSION \square



Food and Agriculture Organization of the United Nations



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

(Prepared by the Electronic Working Group led by Ecuador and co-chaired by Brazil and Ghana)

Codex members and Observers wishing to submit comments at Step 3 on this matter should do so as instructed in CL 2019/08-CF available on the Codex webpage/Circular Letters: http://www.fao.org/fao-who-codexalimentarius/resources/circular-letters/en/

BACKGROUND

- At the 6th Session of the Codex Committee on Contaminants in Foods (CCCF6, 2012) the Committee agreed to include the proposal for an exposure assessment of cadmium (Cd) from cocoa and cocoa products on the priority list of contaminants and naturally occurring toxicants 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. Following the request of CCCF07 (2013), the JECFA Secretariat informed CCCF that the forthcoming 77th Meeting of JECFA (2013) would carry out the requested assessment of the exposure to cadmium from cocoa and cocoa products, and insured that, if additional data became available in the near future, the assessment would be updated. At CCCF08 (2014), the JECFA Secretariat informed the Committee on the outcome of the JECFA77 evaluation regarding the exposure assessment to cadmium from cocoa and cocoa products. In summary, JECFA77 concluded that total cadmium exposure including for high consumers of cocoa and cocoa products was not considered to be of concern.
- 3. At CCCF08, it was agreed to establish an Electronic Working Group (EWG) led by Ecuador, co-chaired by Ghana and Brazil, to prepare new work on Maximum Levels (MLs) for cadmium in chocolate and cocoaderived products at Step 3, considering that although cadmium intake through consumption of chocolate and cocoa-derived products is not a health concern, the lack of a Maximum Level (ML) for cadmium in cocoa and its products could threaten the exports of some Member Countries.²
- 4. At CCCF09 (2015), it was identified that it would be difficult to reach agreement on MLs for cadmium in chocolate and cocoa-derived products and that the EWG should continue to develop the proposal for consideration at the next session. The Committee agreed to re-establish the EWG, led by Ecuador and co-chaired by Brazil and Ghana, working in English and Spanish, to reconsider the proposed draft MLs taking into account the comments submitted to that 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.

¹ REP 12/ CF, para. 161

² REP 14/CF, para. 142, Appendix XI

- 5. At CCCF10 (2016), it was noted that there was no consensus in the EWG 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 to which the MLs should apply, 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 to work on for the establishment of MLs for cadmium. CCCF10 considered the recommendations of the in-session WG and agreed on the following food categories for which MLs for cadmium would be set: 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.³
- 6. CCCF10 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.
- 7. At CCCF11 (2017) it was agreed to establish an EWG, chaired by Ecuador and co-chaired by Brazil and Ghana, working in English and Spanish, to prepare proposals for MLs for the identified categories for "chocolates" and "cocoa powder and dry mixtures of cocoa and sugars" sold for final consumption and to discontinue work on intermediate products.⁴
- At CCCF12 (2018) it was agreed to advance the MLs 0.8 mg/kg for chocolate containing or declaring ≥50% to <70% total cocoa solids on a dry matter basis, and the ML of 0.9 mg/kg for chocolate containing or declaring ≥70% total cocoa solids on a dry matter basis, for adoption at Step 5/8 by CAC41.⁵
- 9. Additionally, CCCF12 agreed to continue work on the category of chocolate and chocolate products containing or declaring: (1) <30%; and, (2) ≥30% to <50% total cocoa solids on a dry matter basis and to assess if it is feasible to merge these two categories to derive one ML for chocolate containing or declaring <50% total cocoa solids on a dry matter basis. Likewise, it agreed to continue the work on cocoa powder (100% total cocoa solids on a dry matter basis) taking into consideration MLs established for other product categories and discontinue work on dry mixtures of cocoa and sugars sold for final consumption.</p>
- 10. CCCF12 further agreed to re-establish an EWG chaired by Ecuador, co-chaired by Brazil and Ghana, working in English and Spanish reporting to CCCF13, to work on points detailed in paragraph 9.
- 11. At CAC41 (2018), the Commission adopted the proposed MLs for the chocolate categories that contain or declare ≥50% to <70%, and ≥70% total cocoa solids on a dry matter basis, proposed by the CCCF, noting the reservation expressed by Peru and that they applied to the final product (chocolate) as opposed to the raw material (cocoa beans) since the name of the product was "chocolate" and the relevant note stated that the MLs applied to the whole commodity as prepared for wholesale or retail distribution. ⁶
- 12. The EWG examined the available data in GEMS/Food according to the recommendations of the Committee. The work process is available in Appendix II.

CONCLUSIONS

Cadmium occurrence in chocolates with <30% total cocoa solids worldwide have an average concentration of 0.05 mg/kg, and when comparing the values of different regions, it can be observed that the average concentrations vary between 0.01 and 0.15 mg/kg. On the worst-case scenario, cadmium intake was 2.2% of the PTMI, although there were no studies for cadmium intake for children in this category. For this category of chocolates, a ML of 0.4 mg/kg (as considered by CCCF12), would see 1.4% of worldwide samples possibly rejected, and 4.7% of samples submitted by the Latin America and the Caribbean possibly rejected. Additional data was submitted for this category during the last GEMS/Food Call for Data in 2018.

⁴ REP 17/CF, para. 90-99

⁵ REP 18/CF, para. 47-68

⁶ REP 18/CAC, pg. 29-32

- Cadmium occurrence for chocolates with ≥30% to <50% total cocoa solids worldwide, has an average concentration of 0.32 mg/kg, and when comparing the values of different regions, it can be observed that the average concentrations vary between 0.04 and 0.35 mg/kg. On the worst-case scenario, cadmium intake was 5.4% of the PTMI, although there were no studies for cadmium intake for children in this category.
- While analyzing the category of chocolates that contain or declare ≥30% to <50% total cocoa solids, a 95th percentile worldwide cadmium occurrence of 0.9 mg/kg was observed. For this category of chocolates, a ML of 0.9 mg/kg would see 2.7% of samples possibly rejected worldwide and, as such, would be achievable with respect to the 5% 'cut-off' point for possible rejected samples. However, this level of 0.9 mg/kg is the same as/similar to the MLs already agreed during the 12th Session of the CCCF, as well as the 41st Session of the CAC, for the chocolates containing or declaring ≥50% to <70% (0.8 mg/kg); and ≥70% (0.9 mg/kg). This could be problematic because the expectation is that chocolate with lower percentages of total cocoa solids should also have lower MLs of cadmium. However, it should be noted that a large proportion of the additional data submitted for this category was provided by Latin America and the Caribbean region; this region is known to produce cocoa beans with naturally higher levels of cadmium than other regions, and this factor should be considered for its impact on the results of this analysis.</p>
- Cadmium occurrence in cocoa powder worldwide has an average concentration of 0.7 mg/kg, and when comparing the values of different regions, it can be observed that the average concentrations vary between 0.16 and 1.4 mg/kg. On the worst-case scenario, cadmium intake was 7.7% of the PTMI, although there were no studies for cadmium intake for children. For the worldwide scenario, a ML of 3.2 mg/kg would see a total of 4.7% of the samples in the world trade possibly being rejected. However, this same ML could see 11.9% of samples from the Latin America and the Caribbean possibly being rejected—being well above the 5% threshold level and having a significant impact for trade in this region. A level of 3.2 mg/kg is substantially greater than the one proposed at the 12th CCCF Meeting, which was 1.5 mg/kg.

RECOMMENDATIONS FOR COSIDERATION BY CCCF:

- 13. With the current data analysis, detailed in Appendix II, the MLs to be proposed to the CCCF, following the main objectives of Codex to ensure consumer health protection and fair practices in trade, should be the ones detailed in Appendix I.
- 14. Codex members and observers are encouraged to consult the data analysis and work process described in Appendix II in order to provide informed comments and advise CCCF13 on the best way forward to make progress on this matter including the conclusions above.

<u>APPENDIX I</u>

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

Commodity / Product Name	Maximum Level (ML) (mg/kg)	Notes/Remarks
Chocolate products containing or declaring <30% total cocoa solids on a dry matter basis	0.3 – 0.4	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 ≥30% to <50% total cocoa solids on a dry matter basis	0.9	Including sweet chocolate, Gianduja chocolate, semi – bitter table chocolate, Vermicelli chocolate / chocolate flakes, bitter table chocolate, couverture chocolate.
Cocoa powder (100% total cocoa solids on a dry matter basis)	3.0 - 4.0	Product sold for final consumption.

When commenting on the proposed MLs, Codex members and observers are invited to take into account the following additional considerations:

- Lack of clear consensus between EWG members;
- Current MLs calculated for the remaining categories can be inconsistent comparing to those approved by CAC41 for the categories of chocolates containing or declaring >50% total cocoa solids;
- From the previous point it can be stated that it would be impossible to propose a ML at the moment;
- Having a greater amount of data from one region, allowed to obtain a current reality, that can be evidenced in the results.
- The facts shown previously, could invite us to insist in the proposal to request a new evaluation to JECFA.

Consequently, Codex members and observers are invited to provide comments on alternative options to the establishment of MLs as indicated below for consideration by CCCF13:

- Continue enriching the GEMS/Food database and request a new Call for Data of cadmium occurrence for all the chocolate categories (those categories adopted by CAC41 and those remaining categories for consideration in CCCF), as well as data on cadmium occurrence in cocoa powder (100% cocoa solids ready for consumption), in order to reevaluate all MLs, given that the current data analysis shows a clear discrepancy of the results.
- 2) Request a new reevaluation to JECFA considering what was established at CCCF07 (2013)⁷.
- 3) Postpone the proposal for MLs in the table for the remaining chocolate categories and cocoa powder categories.
- 4) Establish ML for the remaining chocolate and cocoa powder categories with the current data and values presented in the conclusions.
- 5) Due to the high amount of data scattered in the analysis carried out by each of the categories of chocolates and powders, it is recommended to request the CCMAS to work on a standard methodology to determine Cd in chocolates.

⁷ REP 13/CF, pg. 2

INFORMATION FOR CODEX MEMBERS AND OBSERVERS WHEN CONSIDERING THE MAXIMUM LEVELS DATA COLLECTION

- 15. 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.
- 16. The EWG took as a starting point the cadmium occurrence database in 2017, already categorized and refined, and following the mandate of the 12th Session of the CCCF, took into account only the data from the chocolate categories containing or declaring < 30% and ≥ 30% to < 50% total cocoa solids on a dry matter basis and cocoa powder (100% total cocoa solids on a dry matter basis). Additionally, it excluded the cadmium occurrence data for the category dry mixtures of cocoa and sugars, having a total of 765 eliminated samples.</p>
- 17. During the second step in the data analysis, the EWG extracted all cadmium occurrence data from GEMS/Food database for cocoa and cocoa derived products, under the categories to be analyzed according to the mandate of the Committee.
- 18. Data categorization was done following the same procedure done in the last EWG proposal for the 12th CCCF⁸, using the information on percentage of total cocoa solids and denominations in "local food name" and "remarks" columns. Subsequently, the additional data submitted during the last GEMS/Food Call for Data in 2018, was added.
- 19. A summary of data with these considerations is shown in Table 1.

Categories	Number of Samples	Countries that submitted the data
Chocolates that contain or declare <30% cocoa solids	1176	Germany, Australia, Brazil, Colombia, Cuba, Ivory Coast, Denmark, Ecuador, Slovakia, United States of America, France, Ghana, Indonesia, Japan, Mexico, Peru, Singapore, Sweden, European Union*
Chocolates that contain or declare ≥ 30% to < 50% total cocoa solids	599	Australia, Brazil, Canada, Colombia, Ecuador, United States of America, Japan, Peru, Singapore
Cocoa powder (100% cocoa solids)	3035	Germany, Brazil, Cameron, 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

Table 1. Cocoa products categories and	d provision of data in GEMS/Food
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* For chocolates, the only samples considered were those that presented information on the percentage of total cocoa solids or the descriptors given in the REP17/CF, Appendix XIII.

20. As there is a difference by world regions in cadmium content in cocoa beans and, consequently, in cocoa products, all data was analyzed in the same matter as the EWGs proposal in 2017, which analyzed the data 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, which takes into account the data's origin, it is not necessarily indicative of the product's origin and, as such, the content of cadmium in cocoa produced in these regions. However, important differences were observed in the data from the various regions that could have consequences in the trade of cocoa products.

DATA ANALYSIS

21. The CCCF has previously used a figure of approximately 5% of samples as a 'cut-off' point for determining an achievable ML. 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 ML. This technique has been used as a starting point (notwithstanding other factors) to derive proposed MLs for the two categories of chocolate and cocoa powder, as described below.

⁸ CX/CF 18/12/6, para. 36-37

Cadmium in chocolates <30% of total cocoa solids

- 22. According to the origin of chocolates containing <30% total cocoa solids, that was reported in the GEMS/Food database, 22% (257 samples) of all the data evaluated (denoted as "worldwide" in table 2) are samples of domestic origin, 54% (635 samples) are imported, and 24% (284 samples) were of unknown origin. Despite this issue, most 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.
- 23. In Table 2 it can be observed that worldwide, the occurrence of cadmium in chocolates with <30% of total cocoa solids has an average concentration of 0.05 mg/kg, and when comparing the values from the different regions, it can be observed that mean concentrations range between 0.01 and 0.15 mg/kg, where the values from Latin America and the Caribbean (LAC) region are the highest. Additionally, the influence of the data from Latin America and the Caribbean for the 95th percentile, over the worldwide value can be observed; where the LAC concentration at P95 is 0.40 mg/kg, which increases the worldwide value to 0.3 mg/kg, while the African, Asian and European region have P95 values of between 0.0 and 0.1 mg/kg.
- 24. More than 70% 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, and 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, it is assumed that most of the European data are for products containing cocoa that originally came from Africa.

Table 2. Occurrence data for cadmium worldwide and by data origin region* in chocolates with <30% of total cocoa solids</th>

		Values expressed in mg/kg				
Origin of data	Number of samples	Average	Máx	Min	P95	
Worldwide	1176	0.05	0.67	0.00	0.34	
LAC	277	0.15	0.67	0.00	0.44	
AFRICA	18	0.01	0.02	0.01	0.02	
ASIA	53	0.04	0.49	0.00	0.11	
EURO	410	0.02	0.41	0.00	0.06	
NASWP	418	0.02	0.46	0.00	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. * 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

- 25. 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 MLs on cadmium intake and in the international trade.
- 26. Table 3 shows the impact of different MLs on cadmium intake and on international trade. For each proposed ML 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 ML. 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 ML, a percentage of possible rejected samples was calculated for total data available worldwide and by region.</p>

Table 3. Impact of different MLs 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	1176	0.051	0.190	0.8	0.0
0.5	1168	0.050	0.188	0.8	0.6
0.4	1159	0.040	0.150	0.6	1.4
0.3	1137	0.037	0.139	0.6	3.2
0.2	1074	0.020	0.075	0.3	8.6
0.1	1060	0.020	0.075 data from LAC	0.3	9.8
No ML	277	0.148	0.554	2.2	0.0
0.5	270	0.137	0.514	2.1	2.2
0.4	263	0.128	0.480	1.9	4.7
0.3	243	0.103	0.386	1.5	12.0
0.2	179	0.030	0.113	0.5	35.1
0.1	171	0.020	0.075	0.3	38.0
		Scenario with da	ata from AFRICA	N	
No ML	18	0.012	0.045	0.2	0.0
0.5	18	0.012	0.045	0.2	0.0
0.4	18	0.012	0.045	0.2	0.0
0.3	<u>18</u> 18	0.012	0.045	0.2	0.0
0.2	18	0.012	0.045	0.2	0.0
0.1	10		data from ASIA	0.2	0.0
No ML	53	0.040	0.150	0.6	0.0
0.5	52	0.030	0.113	0.5	1.9
0.4	52	0.030	0.113	0.5	1.9
0.3	52	0.030	0.113	0.5	1.9
0.2	52	0.030	0.113	0.5	1.9
0.1	50	0.030	0.113	0.5	5.7
		Scenario with da	ata from NASWF		
No ML	418	0.020	0.075	0.3	0.0
0.5	418	0.020	0.075	0.3	0.0
0.4	417	0.020	0.075	0.3	0.2
0.3	417	0.020	0.075	0.3	0.2
0.2	417	0.020	0.075	0.3	0.2
0.1	414	0.020	0.075	0.3	1.0
		Scenario with da	ta from EUROP	E	
No ML	410	0.020	0.075	0.3	0.0
0.5	410	0.020	0.075	0.3	0.0
0.4	410	0.020	0.075	0.3	0.0
0.3	409	0.020	0.075	0.3	0.2
0.2	408	0.020	0.075	0.3	0.5
0.1	407	0.020	0.075	0.3	0.7

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

- 27. Table 3 shows that 12% of the samples from the Latin America and the Caribbean region could be rejected proposing a ML of 0.3 mg/kg. However, only 4.7% of samples from that region could be rejected if proposing a ML of 0.4 mg/kg, as considered by CCCF 12.
- 28. 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 ML for cadmium for the chocolates with <30% of total cocoa solids, in a world-wide scenario, the intake would represent a maximum of 0.8% of the PTMI estimated by JECFA (0.025 mg/kg b.w). Also, on a worldwide basis with application of the proposed MLs of 0.10 to 0.50 mg/kg, estimated cadmium intakes range between 0.3 to 0.8% 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 2.2% of the PTMI, but yet this value is well below the 5⁹ percent for a significant effect noted by JECFA.
- 29. 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 a regular basis in greater quantities.
- 30. With respect to rejected samples, Table 3 shows that 8.6% and 9.8% of the samples could be rejected if proposed ML of 0.2 and 0.1 mg/kg are 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 ML of 0.1 would generate rejections of 38% of chocolate with <30% of total cocoa solids. For the scenario with data from Latin America and the Caribbean, a ML of 0.4 mg/kg would only affect 4.7% of the samples and could reduce intake of cadmium to 1.9% of the PTMI (from 2.2% of the PTMI with not having a ML).

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

- 31. According to data on the origin of chocolates containing ≥ 30% to < 50% total cocoa solids, 9% of all the data evaluated (53) are samples of domestic origin, 25% of the samples (149 samples) where imported, and 66% (397) was of unknown origin. Thus, data was classified according to the countries that submitted the information to GEMS/Food.
- 32. In Table 4 it can be observed that at the worldwide level, the occurrence of cadmium in chocolates with ≥30% to <50% total cocoa solids averages 0.32 mg/kg, and when comparing the values among the regions, they range from 0.04 to 0.35 mg/kg. Data from Latin America and the Caribbean is over the world average, and data from Asia and North America and the Southwest Pacific were below the worldwide average. No data from Africa and Europe were received.
- 33. Likewise, the 95th percentile value for the worldwide scenario and Latin America and the Caribbean is greater than that for North America and the Southwest Pacific and Asia.

		Values expressed in mg/kg				
Origin of data	Number of Samples	Average	Max	Min	P95	
Worldwide	599	0.32	1.58	0.00	0.92	
LAC	539	0.35	1.58	0.00	0.93	
ASIA	26	0.04	0.18	0.00	0.13	
NASWP	34	0.06	0.37	0.00	0.21	

Table 4: Occurrence data for cadmium worldwide and by data origin region* in chocolates with \geq 30% to <50% of total cocoa solids.

LAC: Latin America and the Caribbean; NASWP: North America and the Southwest Pacific; Min: Minimum; Max: Maximum; P95: 95% Percentile. * 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

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⁹ Codex Alimentarius Commission Procedural Manual pg. 125-127.

- 34. Tables 3 and 5 show the impact of different MLs on cadmium intake and on international trade, for chocolates with <30% total cocoa solids, and chocolates with ≥30% to <50% of total cocoa solids, respectively. The intake and % PTMI calculations are based on Cluster Diet 7.
- 35. Table 5 shows that on a worldwide scenario, a ML of 0.9 mg/kg, could cause the rejection of a total of 2.7% of the simples on the world market if applied; on the other hand, when applying any other ML, lower than 0.9 mg/kg would see a greater than 5% rejection rate for <u>all</u> the simples coming from Latin America and the Caribbean and North America and the Southwest Pacific, with the exception of the Asian region. It is worth noting that 21.7% of samples worldwide could be rejected based on the ML of 0.5 mg/kg proposed at CCCF12.

Table 5. Impact of different MLs for cadmium in the statistical distribution of cadmium for chocolates with \geq 30% - <50% 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	599	0.320	1.199	4.8	0.0		
0.9	583	0.320	1.200	4.8	2.7		
0.8	552	0.280	1.050	4.2	7.8		
0.7	540	0.270	1.013	4.1	9.8		
0.6	507	0.240	0.900	3.6	15.4		
0.5	469	0.200	0.750	3.0	21.7		
0.4	429	0.190	0.713	2.9	28.4		
0.3	340	0.130	0.488	2.0	43.2		
0.2	235	0.050	0.188	0.8	60.8		
0.1	213	0.040	0.150	0.6	64.4		
		Scenario with	data from LAC				
No ML	539	0.359	1.345	5.4	0.0		
0.9	534	0.340	1.275	5.1	0.9		
0.8	503	0.310	1.163	4.7	6.7		
0.7	491	0.290	1.088	4.4	8.9		
0.6	458	0.270	1.013	4.1	15.0		
0.5	420	0.240	0.900	3.6	22.1		
0.4	380	0.210	0.788	3.2	29.5		
0.3	292	0.150	0.563	2.3	45.8		
0.2	177	0.050	0.188	0.8	67.2		
0.1	158	0.040	0.150	0.6	70.7		
	Scenario with data from ASIA						
No ML	26	0.037	0.139	0.6	0.0		
0.6	26	0.037	0.139	0.6	0.0		
0.5	26	0.037	0.139	0.6	0.0		
0.4	26	0.037	0.139	0.6	0.0		
0.3	26	0.037	0.139	0.6	0.0		
0.2	26	0.037	0.139	0.6	0.0		
0.1	24	0.030	0.113	0.5	7.7		

Scenario	Number of samples	Average Cd content (mg.kg-1)	Cd intake (µg/kg b.w. month)	% PTMI	Possible rejected samples (%)
		Scenario with d	ata from NASW		
No ML	34	0.063	0.236	0.9	0.0
0.6	34	0.063	0.236	0.9	0.0
0.5	34	0.063	0.236	0.9	0.0
0.4	34	0.063	0.236	0.9	0.0
0.3	33	0.050	0.188	0.8	2.9
0.2	32	0.050	0.188	0.8	5.9
0.1	31	0.040	0.150	0.6	8.8

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

36. Table 4 indicates a cadmium concentration of 0.9 mg/kg for 95th Percentile for the world, meaning that a ML of 0.9 mg/kg would have to be established based on the analysis process, for the chocolates containing or declaring ≥ 30% to <50% total cocoa solids on dry matter basis. However, this level is higher than/equal to MLs approved during the 12th Session of the CCCF and 41st Session of the CAC, for the chocolate categories containing or declaring ≥ 50% to <70% (0.8 mg/kg) and ≥ 70% (09 mg/kg), respectively, which have a greater quantity of cocoa solids. It should be stressed, however, that the Latin America and the Caribbean region submitted a greater number of data to the GEMS/Food platform, having 400 more samples for this category.

Cocoa powder 100% total cocoa solids, ready for consumption

- 37. According to data on the origin of cocoa powder, 18% (548 samples) of samples are of domestic origin, 19% (576 samples) of samples are imported (unknown origin), and 63% (1912 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 sample's origin, it was decided to categorize the data according to the countries that submitted the information to GEMS/Food.
- 38. In Table 6 it can be observed that worldwide cadmium occurrence in cocoa powder averages 0.7 mg/kg, and regional average values, range from 0.17 to 1.39 mg/kg. This difference can also be observed in the 95th percentile values with variations of 0.24 to 4.95 mg/kg among regions.

	Values expressed in mg/kg				
Origin of data	Number of samples	Average	Máx	Min	P95
Worldwide	3035	0.70	9.90	0.00	3.08
LAC	1192	1.39	9.90	0.02	4.95
AFRICA	105	0.16	1.30	0.01	0.24
ASIA	404	0.36	1.80	0.02	0.61
EURO	1164	0.17	1.70	0.00	0.46
NASWP	170	0.51	2.99	0.00	1.42

Table 6. Occurrence data for cadmium at world level and by data origin region* in cocoa powder

LAC: Latin America and the Caribbean; NASWP: North America and the Southwest Pacific; Min: Minimum; Max: Maximum; P95: 95% Percentile. * 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

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39. From occurrence data in Table 6, values of 0.4 to 3.2 mg/kg were proposed to evaluate the impact of different MLs on cadmium intake and in cocoa trade (Table 7). The same considerations as the others were used for the calculation of cadmium intake, except that the consumption value was specific for cocoa powder for the worst-case scenario (Cluster Diet 7= 2.78 μg/kg b.w. day), the comparison with the safety reference value (PTMI) and the number of possible rejections on international trade.

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	3035	0.69	0.962	3.8	0.0		
3.2	2893	0.50	0.695	2.8	4.7		
2.8	2866	0.50	0.695	2.8	5.6		
2.4	2834	0.40	0.556	2.2	6.6		
2	2809	0.40	0.556	2.2	7.4		
1.6	2754	0.40	0.556	2.2	9.3		
1.2	2622	0.30	0.417	1.7	13.6		
0.8	2272	0.20	0.278	1.1	25.1		
0.4	1960	0.20	0.278	1.1	35.4		
	I	Scenario with da	ata from EUROPI				
No ML	1164	0.20	0.278	1.1	0.0		
2	1164	0.20	0.278	1.1	0.0		
1.6	1163	0.20	0.278	1.1	0.1		
1.2	1157	0.20	0.278	1.1	0.6		
0.8	1141	0.20	0.278	1.1	2.0		
0.4	1101	0.10	0.139	0.6	5.4		
			ata from NASWF				
No ML	170	0.50	0.695	2.8	0.0		
2	165	0.40	0.556	2.2	2.9		
1.6	164	0.40	0.556	2.2	3.5		
1.2	158	0.40	0.556	2.2	7.1		
0.8	129	0.30	0.417	1.7	24.1		
0.4	113	0.20	0.278	1.1	33.5		
0.1			data from LAC		0010		
	1100						
No ML	1192	1.39	1.932	7.7	0.0		
5	1135	1.10	1.529	6.1	4.8		
4.8	1131	1.10	1.529	6.1	5.1		
4.2	1109 1098	1.10 1.00	1.529 1.390	6.1 5.6	7.0 7.9		
3.8	1098	1.00	1.390	5.6	8.5		
3.2	1050	0.90	1.251	5.0	11.9		
2.8	1030	0.90	1.251	5.0	14.1		
2.4	995	0.80	1.112	4.4	16.5		
2	971	0.80	1.112	4.4	18.5		
1.6	919	0.70	0.973	3.9	22.9		
1.2	803	0.60	0.834	3.3	32.6		
0.8	503	0.30	0.417	1.7	57.8		
0.4	335	0.20	0.278	1.1	71.9		

0.4

Scenario	Number of samples	Average Cd content (mg.kg-1)	Cd intake (µg/kg b.w. month)	% PTMI	Possible rejected samples (%)
		Scenario with d	ata from AFRICA		
No ML	105	0.16	0.222	0.9	0.0
2	105	0.16	0.222	0.9	0.0
1.6	105	0.16	0.222	0.9	0.0
1.2	105	0.16	0.222	0.9	0.0
0.8	103	0.14	0.195	0.8	1.9
0.4	103	0.14	0.195	0.8	1.9
		Scenario with	data from ASIA		
No ML	404	0.36	0.500	2.0	0.0
2	404	0.36	0.500	2.0	0.0
1.6	403	0.35	0.487	1.9	0.2
1.2	400	0.35	0.487	1.9	1.0
0.8	396	0.34	0.473	1.9	2.0

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). Cocoa powder consumption in Cluster Diet 7= 2.78 µg/kg b.w. day.

0.403

1.6

0.29

307

On a world scenario with ML of 3.2 mg/kg, a cadmium intake of 0.695 µg/kg b.w. per month can be observed, which represents 2.8% of the PTMI, and which would see a total of 4.7% of the samples in the world trade possibly being rejected. Considering these scenarios with the regional data for Latin America and the Caribbean a ML of 3.2 mg/kg would see 11.9% of samples possibly being rejected. The lowest possible ML that could be derived for Latin America and the Caribbean, which ensures that rejected samples sit under the 5% threshold is 5 mg/kg which is a large departure from the level considered at CCCF12. For the countries of North America and the Southwest Pacific, using the same scenario of a ML of 3.2 mg/kg would see 0% of their samples being rejected. Considering the ML proposed at CCCF12 of 1.5 mg/kg, it is worth noting that with the additional GEMS/Food data, 9.3% of samples worldwide would now be rejected based on a similar ML (of 1.6 mg/kg).

Summary of positions of EWG Members for survey established during 1st round of observations.

Position	Country members and observers in favor
In favor that the EWG proposes ML for the remaining chocolate categories with current data.	3 countries and 2 observers.
In favor of proposing a reevaluation of the MLs already approved during the CAC41 meeting (chocolates that contain or declare \geq 50% to <70% total cocoa solids (0,8 mg/kg), and \geq 70% total cocoa solids (0,9 mg/kg).	1 country and 2 observers
In favor of postponing the proposal of ML, for the remaining chocolate categories.	2 countries
Requesting a new evaluation to JECFA	1 country and 0 observers
Merging the remaining chocolate categories (chocolates that contain or declare <30% total cocoa solids and \ge 30% to <50% total cocoa solids) into one category.	1 country
Cocoa powder: In favor of proposing ML / Proposed ML	2 countries and 2 observers

24.0

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