

CODEX ALIMENTARIUS COMMISSION



Food and Agriculture
Organization of the
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World Health
Organization

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Agenda Item 5

CX/CF 22/15/5

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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON CONTAMINANTS IN FOODS

15th Session

Virtual

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MAXIMUM LEVELS FOR CADMIUM IN COCOA POWDER

(100% Total cocoa solids on a dry matter basis)

(At Step 4)

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

Codex members and observers wishing to submit comments at Step 3 on this document should do so as instructed in CL 2022/14-CF available on the Codex webpage¹

BACKGROUND

1. Background information on the establishment of maximum levels (MLs) for chocolates and cocoa-derived products at different sessions of the Codex Committee on Contaminants in Foods (CCCF) is summarized in document CX/CF 21/14/6². Full details of the discussions on this matter between 2012 and 2021 are available in the reports³ of the relevant sessions of CCCF as referenced in the footnotes of this document.
2. At CCCF14 (2021), the Chair of the Electronic Working Group (EWG) reminded CCCF on the outcomes of the Joint FAO/WHO Expert Meeting on Food Additives (JECFA) evaluations on cadmium in chocolates and cocoa-derived products as stated in previous sessions of CCCF, and noted that the range of MLs proposed were all protective of consumers' health on a global basis, and therefore, the focus of the discussion should remain on considering an ML with a minimum negative impact on trade that could best accommodate all regions concerned.⁴
3. Maximum levels have already been set for four categories of cocoa-derived products. The 41st Session of the Codex Alimentarius Commission (CAC41, 2018) approved MLs for cadmium in chocolate containing or declaring $\geq 50\%$ to $< 70\%$ total cocoa solids on a dry matter basis -0.8 mg/kg-; and chocolate containing or declaring $\geq 70\%$ total cocoa solids on a dry matter basis -0.9 mg/kg) ⁵. CAC44 (2021) approved MLs for cadmium in chocolates containing or declaring $< 30\%$ total cocoa solids on a dry matter basis -0.3 mg/kg- and MLs for cadmium in chocolates containing or declaring $\geq 30\%$ to $< 50\%$ total cocoa solid on a dry matter basis -0.7 mg/kg-⁶. These MLs were developed resulting from the analysis of the data available in GEMS/Food and proposed by the EWG taking into account the importance of consumer health protection and that this does not generate, in turn, high potential rates of rejection worldwide.

¹ Codex webpage/Circular Letters:

<http://www.fao.org/fao-who-codexalimentarius/resources/circular-letters/en/>.

Codex webpage/CCCF/Circular Letters:

<http://www.fao.org/fao-who-codexalimentarius/committees/committee/related-circular-letters/en/?committee=CCCF>

² Working documents, including CX/CF 21/14/6, for CCCF14 are available at:

Working documents, including the reports, of sessions of CCCF are available at:

<https://www.fao.org/fao-who-codexalimentarius/meetings/detail/jp/?meeting=CCCF&session=14>

³ <https://www.fao.org/fao-who-codexalimentarius/committees/committee/related-meetings/jp/?committee=CCCF>

⁴ REP21/CF14, para. 31

⁵ REP18/CAC41, Appendix III

⁶ REP21/CAC44, Appendix III

4. Taking in consideration the category **“Cocoa powder containing or declaring 100% total cocoa solids on a dry matter basis ready for consumption”** the EWG Chair explained that the category had been previously agreed by CCCF, but when analyzing the data in the GEMS/Food database it was not always clear if the cocoa powder was (i) 100% total cocoa solids, (ii) natural cocoa powder, or (iii) pure cocoa powder and no information was provided on the intended use of the product (e.g. final consumption). The EWG had therefore decided to use all data to propose an ML,⁷ and most delegations agreed that it was appropriate to incorporate all GEMS/Food data for cocoa powder into the analysis irrespective of whether or not the declared percentage of total cocoa solids was given, or whether or not they were intermediate or final products.⁸
5. At CCCF14, two scenarios were presented taking a similar approach as for chocolates containing or declaring $\geq 30\%$ to $< 50\%$ total cocoa solids on a dry matter basis, namely:⁹
 - Scenario (1) – GEMS/Food data: A range between 2.0 – 3.0 mg/kg, for which the ML of 2.0 mg/kg accounts for rejection rates of 5.39% (worldwide basis) and 13.42% (regional basis, Latin America and the Caribbean) and the ML of 3.0 mg/kg accounts for rejection rates of 2.49% (worldwide basis) and 6.33% (regional basis, Latin America and the Caribbean).
 - Scenario (2) – Proportional approach: A range between 1.3 – 1.5 mg/kg, for which the ML of 1.3 mg/kg accounts for rejection rates of 11.48% (worldwide basis) and 27.64% (regional basis, Latin America and the Caribbean) and the ML of 1.5 mg/kg accounts for rejection rates of 8.26% (worldwide basis) and 20.37% (regional basis, Latin America and the Caribbean).
6. In consideration of MLs for cocoa powder, CCCF14 proceeded to consider the two scenarios and noted that a number of delegations expressed support of either Scenario 1 or Scenario 2 for the same reasons expressed for the category of chocolates containing or declaring less than 30% and $\geq 30\%$ to $< 50\%$ total cocoa solids on a dry matter basis. In addition, it was noted that this category was not usually consumed directly as food but as an ingredient.¹⁰
7. An observer highlighted a technical issue regarding Scenario 2 -proportionality approach. They explained that there was a big difference between chocolates and 100% cocoa powder. The non-fat component was the key component that could contain cadmium and this should be used for the proportional calculation. Chocolate would typically have about 45% non-fat solids, which is where the cadmium could be present, whereas in 100% cocoa powder, typically there would be about 90% non-fat solids. This tended to be twice the amount of non-fat solids in 100% cocoa powder compared to chocolate. Therefore, it was necessary to double a proposed ML derived using the proportionality approach for 100% cocoa powder. The proportional approach calculated in Scenario 2 did not take this into account, so if the proportional calculation were done appropriately, it would align with the GEMS/Food data scenario.¹¹
8. There are certain questions that the proportionality approach raises with respect to how the non-fat component of cocoa powder was accounted for, as described in para. 50 of REP21/CF. According to the observer's comment, had this been accounted for, the MLs proposed under this scenario would align with those under the GEMS/Food data scenario.
9. CCCF14 (2021) agreed to:
 - i) to postpone discussion on the MLs by one year to allow for more data submission and proposals for MLs;
 - ii) to re-establish the EWG chaired by Ecuador, and co-chaired by Ghana, working in English and Spanish to:
 - a. Continue working on the ML for cocoa powder containing or declaring 100% total cocoa solids on a dry matter basis ready for consumption taking into consideration submitted written comments and comments made at this session; and to present the analysis in more detail at the next session and
 - b. Collaborate closely with the EWG on data analysis (see Agenda Item 17).
 - iii) to request JECFA to issue a call for data specific to cocoa powder containing or declaring 100% total cocoa solids ready for consumption;
 - iv) to encourage Members to submit data and actively participate in the EWG and
 - v) that if no new data were submitted, the current data set would be used to derive the ML.¹²

⁷ REP21/CF14, para. 41

⁸ REP21/CF14, para. 44

⁹ REP21/CF14, para. 43

¹⁰ REP21/CF14, para. 45

¹¹ REP21/CF14, para. 50

¹² REP21/CF14, para. 52

10. Work on the **Guidance on Data Analysis for the Development of Maximum Levels and for Improved Data Collection** -agenda item 17- is currently in progress, so if there are any important observations to consider, these could be applied to the work of the cocoa powder, if they are available before the ML progresses further through the step procedure.

WORKING PROCEDURES

11. The EWG analyzed available data in GEMS/Food for the aforesaid category. This database already includes the contributions of new data/information provided by Member countries as a result of the data call issued by the JECFA Secretariat in 2021¹³; countries from the CCAFRICA, CCEURO, CCNASWP regions uploaded additional data (407 data). The analysis of such data/information can be found in Appendix II and constitutes the basis for the revised proposals shown in Appendix I.
12. The category of cocoa powders was agreed for those that contain 100% ready-to-eat cocoa solids, but when the available data is reviewed, there are composite products that incorporate sugars and also other cocoa products (such as intermediate products that were suspended in CCCF11), which leaves the uncertainty as to whether these data fully meet the content of 100% ready-to-eat cocoa solids.
13. For the CCCF15 proposal, the EWG decided to review all the information provided in the GEMS/Food Database fields "food name" and "remarks". Every single sample was reviewed to discard those that provided information that declared other percentages less than 100% cocoa or listed ingredients other than cocoa powder, for example: "Cocoa 12% L: 091209", "CHOCOLATE - ROASTED ALMOND", "Chocolate de mesa con Azúcar", etc.
14. Using this process, the EWG conducted a new review of the available dataset, with a total of 5 345 samples of the 6 737 samples originally submitted to the GEMS/Food database.
15. As with the work carried out to elaborate MLs in other categories of cocoa-derived products, the 95th percentile and analysis of the rejection rates for the different proposed MLs have been considered for this category.

CONCLUSIONS

Cocoa Powder containing or declaring 100% total cocoa solids ready for consumption

16. For the potential ML for this category, it took into account the analysis of the data uploaded by the countries in GEMS/Food as explained in paragraphs 11 to 15 including the new data upload in the last call for data. The JECFA Secretariat indicated that at a global level, there was no health benefit (i.e. a reduction in dietary exposure to cadmium) gained from putting up an ML on any cocoa containing products¹⁴, therefore the focus of these MLs is trade harmonization.
17. Since there are differences by regions of the world in the cadmium content in cocoa beans, and, consequently, in cocoa-based products, all data were analyzed in the same way as in the 2020 proposal¹⁵, performing the analysis by five regions: Latin America and the Caribbean (LAC), Africa, Asia, Europe, North America and the Southwest Pacific (NASWP). For the analysis of the samples, only the country submitting the data were considered, and this is recognized as being a limitation with the available data. Despite the regionalization of the data, which takes into account that the submitting country it is not necessarily indicative of the product's origin and, as such, the concentration of cadmium in cocoa produced in these regions. Nonetheless, significant differences were observed between regions that could have an impact on trade in these products.
18. The EWG, based on the data analysis detailed in Appendix II, presents one proposal for consideration: a proposed ML as a result of the analysis of the GEMS/Food data with the new data available.
19. MLs between 2.0 mg/kg and 3.0 mg/kg are proposed with possible global rejection rates of 4.39% and 1.87% respectively. The Latin American region would have potential rejection rates between 13.02% and 5.08%, respectively.¹⁶

¹³ Available in: <https://www.who.int/news-room/articles-detail/call-for-data-cocoa-powder-containing-or-declaring-100-total-cocoa-solids-ready-for-consumption>

¹⁴ REP21/CF14, para. 51

¹⁵ CX/CF 21/14/6-Add.1

¹⁶ Appendix II, table 3

RECOMMENDATIONS

20. CCCF is invited to consider:
- a. the proposed MLs for the cocoa powder category (100% total cocoa solids on a dry matter basis) ready for consumption as shown in Appendix I, based on the background information relevant to cocoa powder described in paragraphs 1-15, the conclusions presented in paragraphs 16-19 and the data analysis contained in Appendix II, the recommendation of CCCF14¹⁷; and
 - b. the advancement of the ML to final adoption by CAC45 (2022).

¹⁷ REP21/CF14, para. 52

APPENDIX I
PROPOSED MAXIMUM LEVELS FOR CADMIUM IN COCOA POWDER
(100% Total cocoa solids on a dry matter basis)
(For comments)

Commodity/Product Name	Maximum Level (ML) (mg/kg)	Notes/ Remarks
Analysis of the GEMS/Food data available: Cocoa powder (100% total cocoa solids on a dry matter basis) ready for consumption	2.0 – 3.0	Product sold for final consumption

APPENDIX II
DATA COLLECTION AND ANALYSIS
(For information)

DATA COLLECTION

1. The EWG again evaluated the database available on the GEMS/Food database, which was updated after the new data call made by JECFA on December 9, 2021 (which had a deadline to submit data February 15, 2022). This call requested new data on the incidence of cadmium in all food categories but with an emphasis on cocoa powder containing or declaring 100% total cocoa solids ready for consumption.
2. With the resulting database -6737 samples-, the EWG evaluated the information presented in the “Local Food Name” and “Remarks” columns, taking into account two main factors, which are the declaration of percentage of cocoa solids (“total cocoa solids on a dry matter basis”) and the intended use of the product (“ready for consumption”).
3. The EWG decided to review all the information provided in the GEMS/Food Database fields on the columns “food name” and “remarks”; every single sample was reviewed to discard anyone that provides information that declares other percentage different to the 100%, for example, “Cocoa 12% L: 091209”, “CHOCOLATE - ROASTED ALMOND”, “Chocolate de mesa con Azúcar”, etc. This selection results on 5,345 samples that were used in this proposal.
4. Considering those two factors, the EWG categorized the samples according to the information provided; data categorization that can be shown in Table 1. This table includes only the valid samples that are considered in the data analysis of the proposal (explained on paragraph 3).

Table 1. Provision of data in GEMS/Food and considering the 2021 call for data.

Categories	Number of samples containing or declaring 100% total cocoa solids from before 2021	Number of samples containing or declaring 100% total cocoa solids from the last JECFA data call (Dec-2021)	Countries that uploaded samples containing or declaring 100% total cocoa solids
Cocoa powder (100% cocoa solids, ready for consumption)	4938	407	Brazil, Cameroon, Canada, Chile, Colombia, Czech Republic, Denmark, Congo, Cote d'Ivoire, Cuba, Dominican Republic, European Union, Ecuador, Germany, France, Ghana, Indonesia, Japan, Malaysia, Mexico, Peru, Sierra Leone, Singapore, Spain, Switzerland, Thailand, United Republic of Tanzania, United States of America, Slovakia, Vanuatu, Venezuela.

5. As there is a difference by world regions in cadmium concentration in cocoa beans and, consequently, in cocoa products, all data was analyzed in the same manner as the EWGs proposal in 2021¹ - which analyzed the data by five regions: Latin America and the Caribbean (LAC), Africa, Asia, Europe, North America and South West Pacific (NASWP). For the analysis of the samples only the country submitting the data was available, and this is recognized as being a limitation with the available data. Despite the regionalization of the data, which takes into account the country that submitted the data to GEMS/Food, it is not necessarily indicative of the product’s origin and, as such, the concentration of cadmium in cocoa produced in these regions. However, important differences were observed in the data from the various regions that could have consequences on the trade of cocoa products.

¹ CX/CF 21/14/6-Add.1

DATA ANALYSIS**Cocoa Powder containing or declaring 100% total cocoa solids ready for consumption.**

6. The EWG used all the available data from cocoa powder samples that did not claim to be mixtures of cocoa with sugars and other added ingredients, as explained on paragraph 3, which, resulted in 5345 total samples including the new data from last data call -deadline February 15, 2022-.
7. Although in Appendix II, para. 24 of CX/CF 21/14/6, indicates that 5943 data were analyzed, this is because, for that proposal, all available data were used as indicated in paragraph 22². The current proposal, as explained in paragraph 3, resulted in a total of 5076 samples with which the analysis began.
8. Although most of the data did not indicate the information on the country of origin of the samples, it was decided to categorize the data according to the countries that submitted the information to GEMS/Food.
9. 5076 data were analyzed that ranged from minimum to maximum value of 0 to 9.9 mg/kg respectively. This data set had a mean of 0.629 mg/kg and 95th percentile of 2.867 mg/kg. Calculating the standard deviation, the value of 1.08 was found; when the deviation is greater than the average this is due to the wide variability of the data. We proceeded to select only the data that were within the range determined by the mean $\pm 3\sigma$ (with " σ " the standard deviation) since this covers 99.7% of the data. In this new range (4938 data), the average is 0.495 with minimum and maximum values of 0 and 3.9 mg/kg respectively. After this analysis, the new data -407 samples- was added to the 4938 samples resulting in a total of 5345.
10. This methodology to reduce the outliers was presented at CCCF14 for the analysis of this category.³
11. Table 2 shows that worldwide the presence of cadmium in cocoa powder has an average of 0.473 mg/kg, and the regional average values vary from 0.167 mg/kg to 1.135 mg/kg. This difference can also be observed in the 95th percentile values with variations from 0.47 mg/kg to 3.21 mg/kg between regions.

Table 2. Data on the occurrence of cadmium worldwide and data on region * of origin of cocoa powder.

Origin of data	Number of samples	Values (mg/kg)			
		Average	Min	Max	P95
Worldwide	5345	0.473	0.0	3.9	1.90
LAC	1535	1.135	0.0	3.9	3.21
ASIA	478	0.336	0.0	1.8	0.61
NASWP	277	0.453	0.0	2.9	1.27
AFRICA	252	0.175	0.01	1.3	0.51
EURO	2803	0.167	0.0	2.6	0.47

*LAC: Latin America and the Caribbean; NASWP: North America and the Southwest Pacific; EURO: Europe 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

12. Values ranging from 0.20 mg/kg up to 5 mg/kg, depending on the geographic scenario, were presented to assess the impact of different MLs on cadmium intake and trade in cocoa powder. The same considerations as the previous works to set NM in chocolate products were used for the calculation of cadmium intake, measuring the Cd intake and % of the provisional tolerable monthly intake (PTMI), except that the consumption data were specific for cocoa powder for the worst-case scenario (cluster diet 7 = 2.78 $\mu\text{g}/\text{kg}$ bw/day)⁴, the comparison with the reference value (PTMI: 25 $\mu\text{g}/\text{kg}$ bw/month) and the number of possible rejections in international trade.

² CX/CF 21/14/6-Add.1, para. 22.

³ CX/CF 21/14/6-Add.1

⁴ Australia, Bermuda, Finland, France, Iceland, Luxembourg, Norway, Switzerland, United Kingdom, Uruguay

Table 3. Summary of the effects of various hypothetical MLs on the estimated percentage of PTMI of cadmium for GEMS/Food Consumption Group 7 and the estimated proportion of samples rejected in the world market.

Scenario with worldwide data					
Scenario ML (mg/kg)	Number of samples	Average Cd concentration (mg/kg)	Cd intake ($\mu\text{g}/\text{kg}$ b.w./month)	% PTMI	Possible rejected samples (%)
No ML	5345	0.473	0.657	2.630	0.000
5.0	5345	0.473	0.657	2.630	0.000
4.8	5345	0.473	0.657	2.630	0.000
4.2	5345	0.473	0.657	2.630	0.000
3.8	5337	0.468	0.651	2.602	0.150
3.6	5303	0.447	0.621	2.485	0.786
3.4	5282	0.435	0.605	2.419	1.179
3.2	5267	0.427	0.594	2.374	1.459
3.0	5245	0.416	0.578	2.313	1.871
2.8	5215	0.401	0.557	2.230	2.432
2.6	5196	0.393	0.546	2.185	2.788
2.4	5161	0.370	0.514	2.057	3.442
2.2	5136	0.369	0.513	2.052	3.910
2.0	5110	0.360	0.500	2.002	4.397
1.8	5052	0.343	0.477	1.907	5.482
1.6	5001	0.329	0.457	1.829	6.436
1.5	4976	0.323	0.449	1.796	6.904
1.4	4915	0.309	0.430	1.718	8.045
1.3	4850	0.295	0.410	1.640	9.261
1.2	4767	0.279	0.388	1.551	10.814
0.8	4287	0.197	0.274	1.095	19.794
0.4	3714	0.144	0.200	0.801	30.514

LAC					
Scenario ML (mg/kg)	Number of samples	Average Cd concentration (mg/kg)	Cd intake ($\mu\text{g}/\text{kg b.w./month}$)	% PTMI	Possible rejected samples (%)
No ML	1535	1.135	1.578	6.310	0.000
5.0	1535	1.135	1.578	6.311	0.000
4.8	1535	1.135	1.578	6.311	0.000
4.2	1535	1.135	1.578	6.311	0.000
4.0	1534	1.135	1.578	6.311	0.000
3.8	1526	1.121	1.558	6.233	0.065
3.2	1457	1.005	1.397	5.588	0.586
3.0	1434	0.972	1.351	5.404	5.081
2.8	1407	0.934	1.298	5.193	6.580
2.6	1388	0.910	1.265	5.060	8.339
2.4	1356	0.873	1.213	4.854	9.577
2.2	1335	0.850	1.182	4.726	11.661
2.0	1307	0.823	1.144	4.576	13.029
1.8	1253	0.776	1.079	4.315	14.853
1.6	1208	0.742	1.031	4.126	18.371
1.5	1187	0.728	1.012	4.048	21.303
1.4	1136	0.695	0.966	3.864	22.671
1.3	1083	0.663	0.922	3.686	25.993
1.2	1015	0.684	0.951	3.803	21.303
0.8	606	0.359	0.499	1.996	33.876
0.4	359	0.207	0.288	1.151	60.521

ASIA					
Scenario ML (mg/kg)	Number of samples	Average Cd concentration (mg/kg)	Cd intake ($\mu\text{g}/\text{kg b.w./month}$)	% PTMI	Possible rejected samples (%)
No ML	478	0.319	0.443	1.772	0.000
3.0	478	0.319	0.443	1.772	0.000
2.8	478	0.319	0.443	1.772	0.000
2.6	478	0.319	0.443	1.772	0.000
2.4	478	0.319	0.443	1.772	0.000
2.2	478	0.319	0.443	1.772	0.000
2.0	478	0.319	0.443	1.772	0.000
1.8	478	0.318	0.442	1.768	0.000
1.6	477	0.315	0.438	1.751	0.209
1.2	474	0.308	0.428	1.712	0.837
0.8	467	0.298	0.414	1.657	2.301
0.4	337	0.226	0.314	1.257	29.498
0.2	117	0.060	0.083	0.334	75.523

NASWP					
Scenario ML (mg/kg)	Number of samples	Average Cd concentration (mg/kg)	Cd intake ($\mu\text{g}/\text{kg}$ b.w./month)	% PTMI	Possible rejected samples (%)
No ML	277	0.453	0.630	2.520	0.000
3.0	277	0.453	0.630	2.520	0.000
2.8	277	0.453	0.630	2.520	0.000
2.6	277	0.453	0.630	2.520	0.000
2.4	277	0.453	0.630	2.520	0.000
2.2	277	0.453	0.630	2.520	0.000
2.0	277	0.453	0.630	2.520	0.000
1.8	271	0.402	0.559	2.235	2.166
1.6	270	0.397	0.552	2.207	2.527
1.2	261	0.363	0.505	2.018	5.776
0.8	223	0.258	0.359	1.434	19.495
0.4	188	0.192	0.267	1.068	32.130
0.2	116	0.139	0.193	0.773	58.123

AFRICA					
Scenario ML (mg/kg)	Number of samples	Average Cd concentration (mg/kg)	Cd intake ($\mu\text{g}/\text{kg}$ b.w./month)	% PTMI	Possible rejected samples (%)
No ML	252	0.175	0.243	0.974	0.000
3.0	252	0.175	0.243	0.974	0.000
2.8	252	0.175	0.243	0.974	0.000
2.6	252	0.175	0.243	0.974	0.000
2.4	252	0.175	0.243	0.974	0.000
2.2	252	0.175	0.243	0.974	0.000
2.0	252	0.175	0.243	0.974	0.000
1.8	252	0.175	0.243	0.973	0.000
1.6	252	0.175	0.243	0.973	0.000
1.5	252	0.175	0.243	0.973	0.000
1.4	252	0.175	0.243	0.973	0.000
1.3	252	0.175	0.243	0.973	0.000
1.2	251	0.171	0.238	0.951	0.397
0.8	249	0.164	0.228	0.912	1.190
0.4	237	0.143	0.199	0.795	5.952
0.2	217	0.131	0.182	0.728	13.889

EURO					
Scenario ML (mg/kg)	Number of samples	Average Cd concentration (mg/kg)	Cd intake ($\mu\text{g}/\text{kg}$ b.w./month)	% PTMI	Possible rejected samples (%)
No ML	2803	0.167	0.231	0.926	0.000
3.0	2803	0.167	0.231	0.926	0.000
2.4	2803	0.167	0.231	0.926	0.000
2.2	2803	0.167	0.231	0.926	0.000
2.0	2803	0.167	0.231	0.926	0.000
1.6	2796	0.167	0.232	0.929	0.250
1.5	2792	0.159	0.221	0.884	0.392
1.4	2789	0.158	0.220	0.878	0.499
1.3	2782	0.155	0.215	0.862	0.749
1.2	2771	0.151	0.210	0.840	1.142
1.0	2759	0.147	0.204	0.817	1.570
0.8	2747	0.144	0.200	0.801	1.998
0.6	2712	0.137	0.190	0.762	3.247
0.4	2598	0.122	0.170	0.678	7.314
0.2	2290	0.104	0.145	0.578	18.302

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). Consumption of cocoa powder in Cluster Diet 7 = 2.78 $\mu\text{g}/\text{kg}$ b.w. per day.

13. In a global scenario with an ML of 3.0 mg/kg, a cadmium intake of 0.578 $\mu\text{g}/\text{kg}$ b.w. monthly, which represents 2.313% of PTMI, which could result in a total of 1.87% of the samples possibly rejected in the world market. Considering these scenarios with regional data, for LAC, an ML of 3.0 mg/kg could generate 5.081% of possibly rejected samples. The lowest possible ML that could be derived for LAC, which ensures that the rejected samples are under the "cut-off point" of 5%, is 3.0 mg/kg. For NASWP, Europe, Africa and Asia using the same scenario of an ML of 3.0 mg/kg could generate a rejection of 0% of the samples.
14. On the other hand, the worldwide ML that ensures a rejection percentage that approaches, but is still less than 5%, would be 2.0 mg/kg. However, this ML would represent a rejection percentage for the Latin American and Caribbean Region of 13.029%
15. When analyzing the results for both global and regional rejection rates, according to Table 3, the ML range from 2.0 mg/kg to 3.0 mg/kg would present between 4.39% and a 1.87% of samples rejected worldwide with a PMTI of 2.31% to 2.0%, respectively, which will mean rejection rates of between 13.02% and 5.08% for the Latin American region and the Caribbean.

APPENDIX II**LIST OF PARTICIPANTS**

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