CODEX ALIMENTARIUS COMMISSION

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World Health Organization

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Agenda Item 6 **CX/CF 21/14/6**

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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON CONTAMINANTS IN FOODS

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MAXIMUM LEVELS FOR CADMIUM IN CHOCOLATES AND COCOA-DERIVED PRODUCTS (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 2021/11/OCS-CF available on the Codex webpage[1]

BACKGROUND

1. Background information on maximum levels (MLs) for chocolates and cocoa-derived products at different sessions of the Codex Committee on Contaminants in Foods (CCCF) is summarized in circular letter CL 2019/81-CF. For full details of the discussions on this matter between 2012 and 2019 please check the reports of the relevant sessions of CCCF in the footnotes of this CL. A summary of the discussion at the last session of the Committee is presented here below to aid consideration of the proposed maximum levels (MLs).

2. CCCF13 (2019) agreed to re-establish the Electronic Working Group (EWG) chaired by Ecuador and co-chaired by Ghana to continue work on MLs for the categories of chocolates containing or declaring ≥30% to <50% (total cocoa solids on a dry matter basis) and cocoa powder (100% total cocoa solids on a dry matter basis) for consideration by CCCF14 (2020) using a proportional approach. Furthermore, if no consensus were reached at CCCF14 for the remaining chocolate categories, the work would be discontinued until the Code of practice for the prevention and reduction of cadmium contamination in cocoa (COP) was finalized and implemented.[2]

3. CCCF14 was postponed from May 2020 to May 2021 due to the COVID-19 pandemic and in view of the additional time at the disposal of the Committee, an interim report of the EWG was published as CX/CF 20/14/6. This document included data/information from GEMS/Food that was available in reply to a call for data issued by the JECFA Secretariat in 2019. Comments on the proposals made in that document were requested through CL 2020/19/OCS-CF for further consideration by the EWG. The comments received in reply to this CL were compiled in CX/CF 20/14/6-Add.1. In addition, the JECFA Secretariat issued a preliminary assessment of the data submitted to GEMS/Food in reply to the call for data issued in 2019. The preliminary assessment and conclusions were presented in CX/CF 20/14/3-Add.1. Comments on the observations provided by the JECFA Secretariat were requested by means of CL 2020/50/OCS-CF and compiled in CX/CF 20/14/6-Add.2. Following the preliminary assessment presented in CX/CF 20/14/3-Add.1, a second call for data was issued by the JECFA Secretariat in 2020 requesting data/information on cadmium in all food commodities including chocolates and cocoa which has been considered in this document. A chronology of the work performed by the EWG is presented below to easy the reference:

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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 REP19/CF, paras 45-56

- CCCF13: May 2019
- JECFA Call for Data (July 2019): Part I – Request for data on cadmium in chocolates and cocoa-derived products.
- CX/CF 20/14/6 (February 2020): Report of the EWG, proposals for MLs for cadmium in chocolate and cocoa powder
- CL 2020/19/OCS-CF (February 2020): Request for comments on MLs for cadmium in chocolate and cocoa powder presented in CX/CF 20/14/6.
- CX/CF 20/14/6-Add.1 (July 2020): Comments in reply to CL 2020/19/OCS-CF
- CX/CF 20/14/3-Add.1 (July 2020): Preliminary assessment of data submitted on GEMS/Food in reply to the call for data issued in July 2019.
- CL 2020/50/OCS-CF (July 2020): Request for comments on the conclusions contained in CX/CF 20/14/3-Add.1.
- JECFA Call for Data (August 2020): Request for data on cadmium in all food commodities incuding chocolates and cocoa products.
- CX/CF 20/14/6-Add.2 (November 2020): Comments in reply to CL 2020/50/OCS-CF
- CX/CF 21/14/6: Report of the EWG, proosals for MLs for cadmium in chocolate and cocoa powder for consideration by CCCF14.
- CL 2021/11/OCS-CF (March 2021): Request for comments on MLs for cadmium in chocolate and cocoa powder presented in CX/CF 21/14/6.
- CX/CF 21/14/6-Add.1 (April 2021): Comments in reply to CL 2021/11/OCS-CF
- CCCF14: May 2021

4. This paper therefore addresses key points raised in response to CL 2020/19/OCS-CF and CL 2020/50/OCS-CF as well as new/additional data/information submitted to GEMS/Food in reply to JECFA data calls[3] issued in 2019[4] and 2020[5] and takes into account the outcomes of the JECFA73 (2010) and JECFA77 (2013) evaluations. In view that the full report and monographs of JECFA91 (2021) is not yet available, the EWG did not consider this report, however, the data that was available to JECFA91 on GEMS/Food in reply to the call for data issued in August 2020 were taken into considering in revising the MLs for consideration by CCCF14.

5. Working documents issued during 2020, which has been revised or updated in 2021 for consideration by CCCF14, can be found on the Codex website[6].Circular letters relevant to this item can also be found on the Codex website[1].

WORKING PROCEDURES

6. The EWG analyzed available data in GEMS/Food for the aforesaid categories. 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 2020. The analysis of such data/information can be found in AppendixII and constitute the basis for the revised proposals shown in Appendix I.

7. By means of CX/CF 20/14/3-Add.1, the JECFA Secretariat communicated that it would be important to update the exposure assessment for cadmium from all food sources, particularly chocolates and cocoa products and that it is making preparations for this. Given this, 14 countries, 1 organization and 2 observers expressed their comments. Eight countries expressed their concern on a new JECFA evaluation without input from CCCF and the request for comments on suspension of work in CL 2020/50/OCS-CF in view of the conclusions in CX/CF 20/14/3-Add.1, given the prior recommendations of CCCF13[7] and CAC42[8] on the paths forward for the remaining chocolate and cocoa powder product categories. In the same way, eight members supported the suspension of the work of the eWG until the update of the evaluation of exposure to cadmium.

CONCLUSIONS

Chocolates containing or declaring ≥30% to <50% total cocoa solids

8. The MLs proposed by the EWG for this category, which can be seen in the recommendations section, are evaluated based on two considerations: (i) the analysis of data shown in Appendix II and (ii) the proportionality based on MLs already adopted from categories of chocolates (1) between ≥50% and <70% of total cocoa solids (0.8 mg/kg), and (2) >70% of total cocoa solids (0.9 mg/kg). Based on the two considerations, this evaluation results in a range of MLs that both conclude in the same values.

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3 http://www.fao.org/food-safety/scientific-advice/calls-for-data-and-experts-expert-rosters/en/
4 http://www.fao.org/3/ca5650en/ca5650en.pdf
5 http://www.fao.org/3/cb0557en/cb0557en.pdf
6 http://www.fao.org/fao-who-codexalimentarius/meetings/extra/cccf14-2020/en/
7 REP19/CF, para. 56
8 REP19/CAC paras. 65-66

9. The range of MLs proposed by the EWG represents the lowest possible percentage of rejection worldwide (10.39% and 5.74%, respectively). At this level, the regions of Europe, Asia and North America and the Southwest Pacific would have 0% rejections, while the Latin American and Caribbean region, on the other hand, would have rejection percentages of 13.16% and 7.33%, respectively.

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

10. In 2020 (CX/CF 20/14/6), when analyzing the data uploaded to the GEMS/Food database for cocoa powder, the EWG was able to verify that only 115 of the 4245 samples of data submitted, for the preparation of the first draft, declared either in the "Remarks" and "Local Food Name" columns if the cocoa powder was: (1) 100% total cocoa solids, (2) natural cocoa powder or (3) pure cocoa powder. The rest of the samples did not provide any information that implied the sample had 100% cocoa solids. Furthermore, no data sent to the database offered information on the intended use of the product (e.g. final consumption).

11. The category of cocoa powders was agreed for those that contain 100% ready-to-eat cocoa solids, but when the available data was reviewed, there were composite products that incorporated sugars and other cocoa products (such as intermediate products that were suspended by CCCF11) which left the uncertainty as to whether these data fully met the content of 100% ready-to-eat cocoa solids).

12. Despite the lack of information on the declaration of cocoa solids, and intended use of the product, in the "Local Food Name" and "Remarks" columns, the EWG decided to consider all cocoa powder data, to propose an ML for the cocoa powder category, taking into account that all data for cocoa mixtures and sugars were discarded from the database, following the mandate of CCCF13 and the importance to propose an ML for such category.

13. For this category, two possible scenarios are presented, the first taking into account proportionality with reference to the MLs in the other categories to propose a level; and a second scenario, analyzing the data uploaded by countries in GEMS/Food as explained in paragraph 10.

14. The EWG, based on the data analysis detailed in Appendix I, presents two possible scenarios for consideration: (1) a proposed ML as a result of the analysis of the GEMS/Food data and (2) an ML resulting from the calculation of proportionality with the other categories that already have a ML. For the first scenario, an ML range of between 2.0 mg/kg to 3.0 mg/kg is proposed (with possible rejection percentages of 5.39% and 2.49% respectively). For the second scenario (ML = 1.3 mg/kg – 1.5 mg/kg) a potential rejection range of 8.26% to 11.48% is reached.

15. In the EWG, there were some positions on the analysis and subsequent determination of levels for this category. There were proposals to (1) continue with the determination of the maximum levels with the analysis carried out in this document, as well as the (2) consideration of performing the data analysis but taking into account all the data available in GEMS/Food for which should be reconsidered the name of the category

16. With the current data analysis detailed in Appendix II, the MLs that are being to be proposed for consideration by CCCF14, following the main objectives of Codex to protect consumers' health and ensure fair practices in trade are shown in Appendix I.

RECOMMENDATIONS

17. CCCF is invited to consider the proposed scenarios for the categories of chocolate and cocoa-derived products as presented in Appendix I namely: (i) chocolates containing or declaring ≥30% to <50% (total cocoa solids on a dry matter basis); (ii) cocoa powder (100% total cocoa solids on a dry matter basis); and (iii) the possibility of including all available data on powdered products for the establishment of ML(s) for cocoa powder since data available on GEMS/Food do not have the declared percentage of cocoa content in the samples analyzed.

18. In considering points (i) – (iii), CCCF is advised to take into account the recommendation of CCCF13 on the use of the proportional approach, the conclusions presented in this document, the data analysis presented in Appendix II, the background information presented in paragraphs 1-7 (in particular background information provided in CL 2019/81-CF) and comments submitted by Codex members and observers.

APPENDIX I

MAXIMUM LEVELS FOR CADMIUM IN CHOCOLATES AND COCOA-DERIVED PRODUCTS
(For comments at Step 3)

1. Chocolate:

Commodity/Product Name	Maximum Level (ML) (mg/kg)	Notes/ Remarks
SCENARIO 1 (analysis of the GEMS/Food data): Chocolate containing or declaring ≥30% to <50% total cocoa solids on a dry matter basis,	0.6 – 0.7	Including sweet chocolate, Gianduja chocolate, semi – bitter table chocolate, Vermicelli chocolate/chocolate flakes, bitter table chocolate, couverture chocolate
SCENARIO 2 (proportionality approached): Chocolate containing or declaring ≥30% to <50% total cocoa solids on a dry matter basis,	0.5 – 0.6	Including sweet chocolate, Gianduja chocolate, semi – bitter table chocolate, Vermicelli chocolate/chocolate flakes, bitter table chocolate, couverture chocolate

2. Cocoa powder:

Commodity/Product Name	Maximum Level (ML) (mg/kg)	Notes/ Remarks
SCENARIO 1 (analysis of the GEMS/Food data): Cocoa powder (100% total cocoa solids on a dry matter basis) ready for consumption	2.0 – 3.0	Product sold for final consumption
SCENARIO 2 (proportionality approached): Cocoa powder (100% total cocoa solids on a dry matter basis) ready for consumption	1.3 – 1.5	Product sold for final consumption

3. Reconsider the name of the category "cocoa powder (100% total cocoa solids based on dry matter) ready for consumption":

Taking into account that more than 80% of the data available in GEMS / Food does not show the declared percentage of cocoa content in the analyzed samples, nor is it detailed if they are intermediate or final products, it is recommended to change the name of the category so that all available data can be used to establish an ML.

APPENDIX II

DATA COLLECTION AND ANALYSIS

(For information)

DATA COLLECTION

1. The EWG took as a starting point the cadmium occurrence database in 2018, which was updated by the Call for Data issued by WHO the 10th July 2019 and according to the mandate of the CCCF13 and CAC42, took into account only the data from the chocolate categories containing or declaring ≥30% to 50% total cocoa solids on dry matter basis and cocoa powder (100% total cocoa solids on a dry matter basis ready for consumption). The EWG, as well, excluded cadmium occurrence data for the category of dry mixtures of cocoa and sugars.

2. The EWG again evaluated the database available on the GEMS/Food database, which was updated after the new data call made by JECFA on August 13, 2020 (which had a deadline to submit data until December 1 2020). This call requested new data on the incidence of cadmium in all food categories but with an emphasis on chocolates and cocoa products.

3. With the resulting database, the EWG, evaluated the information presented in the "Local Food Name" and "Remarks" columns, taking into account two main factors that relate to the mandate of the committee, 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 forconsumption").

4. Considering those two factors, the EWG categorized the samples according to the information provided, data categorization that can be shown in Table1. This table includes only the valid samples that are considered in the data analysis of the proposal (explained on paragraph 3).

Table 1. Cocoa products categories and provision of data in GEMS/Food for CCCF13 and CCCF14 proposals considering new call data (2020).

Categories	Number of samples with declaration of % solids used in the Proposal in CX/CF 20/14/6 (2020)	Number of samples that declared the intended use of the product in the JECFA data call (2020)	Countries that uploaded information in the JECFA data call (2020) with% solids
Chocolates that contain or declare ≥30% to <50% total cocoa solids	763	161	Canada, Ecuador, United States of America
Cocoa powder (100% cocoa solids, ready for consumption)	4245	1698	Brazil, Cameroon, Canada, Chile, Colombia, Czech Republic, Congo, Cote d'Ivore 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 matter as the EWGs proposal in 2017, 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 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 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 in the trade of cocoa products.

DATA ANALYSIS

6. 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 concentration below a certain level, then this level is deemed achievable and may be proposed as a ML (ALARA principle).

Chocolates containing or declaring ≥30% to <50% total cocoa solids.

7. Of 924 chocolate samples that met the criteria (Table 1), 14.6% (135 samples) are samples of domestic origin, 22% (203 samples) are imported, and 63% (585 samples) were of unknown origin. Since most of the data did not have information on the samples' origin; it was, therefore, decided to categorize the data according to the countries that submitted the information toGEMS/Food.

8. In Table 2 it can be observed that worldwide, the occurrence of cadmium in chocolates with ≥30% to <50% of total cocoa solids is 0.26 mg/kg; and when comparing the values from the different regions, it can be observed that mean concentrations range between 0.04 mg/kg and 0.31 mg/kg, where the values from the LAC region are the highest. Additionally, the influence of the data from the LAC region for the 95th percentile over the worldwide value can be observed; where the LAC value at P95 is 0.85 mg/kg, and the worldwide P95 value is 0.80 mg/kg, and the African, Asian and NASWP regions have P95 values between 0.12 mg/kg and 0.30 mg/kg. Additionally, average values from LAC (0.31 mg/kg) are above worldwide average, while the values from Africa (0.05 mg/kg), Asia (0.04 mg/kg) and NASWP (0.1 mg/kg) are below the worldwide average

9. 79% of the data used for the analysis of occurrence of cadmium in chocolates with ≥30% to <50% total cocoa solids come from the LAC region (737 samples), 12% (108 samples) from NASWP, and 6% (53 samples) from Africa; Asia (26 samples= 2.8%) submitted the least amount of data for this category.

Table 2: Occurrence data for cadmium worldwide and by data on origin region* in chocolates with ≥30% to <50% of total cocoa solids.

Origin of data	Number of samples	Values (mg/kg)			
		Average	Max	Min	P95
Worldwide	924	0.26	1.58	0	0.80
LAC	737	0.31	1.58	0	0.85
ASIA	26	0.04	0.18	0	0.13
AFRICA	53	0.05	0.15	0.01	0.12
NASWP	108	0.10	0.52	0.01	0.30

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 may not be the true origin of the chocolate.

Source: GEMS/Food

10. The per capita consumption of cocoa and its derivatives ranges from 0.2 g/day 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 the proposal for the MLs could help evaluate their impact in the international trade.

11. Table 3 shows the impact of different MLs on cadmium intake and the proportion of samples that would not meet the MLs in international trade. For each proposed ML for the category of chocolates with ≥30% to <50% of total cocoa solids, the average concentration 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% to <50% 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) (0.025 mg/kg bw) 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.

Table 3. Impact of different MLs for cadmium in the statistical distribution of cadmium for chocolates with ≥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 with Worldwide data					
Scenario ML (mg/kg)	**Number of samples**	**Average Cd concentration (mg/kg)**	**Cd intake (µg/kg bw/month)**	**% PTMI**	**Possible rejected samples (%)**
No ML	924	0.276	1.035	4.140%	0
0.9	889	0.230	0.863	3.450%	3.79
0.8	880	0.229	0.859	3.435%	4.76
0.7	871	0.223	0.836	3.345%	5.74
0.6	828	0.201	0.754	3.015%	10.39
0.5	774	0.176	0.660	2.640%	16.23
0.4	717	0.155	0.581	2.325%	22.40
0.3	559	0.099	0.371	1.485%	39.50
0.2	462	0.036	0.135	0.540%	50.00
0.1	339	0.036	0.135	0.540%	63.31

LAC					
Scenario ML (mg/kg)	**Number of samples**	**Average Cd concentration (mg/kg)**	**Cd intake (µg/kg bw/month)**	**% PTMI**	**Possible rejected samples (%)**
No ML	737	0.31	1.163	4.7%	0.00
0.9	702	0.277	1.039	4.2%	4.08
0.8	692	0.270	1.013	4.1%	6.11
0.7	683	0.263	0.986	3.9%	7.33
0.6	640	0.237	0.889	3.6%	13.16
0.5	587	0.208	0.780	3.1%	20.53
0.4	528	0.182	0.683	2.7%	28.36
0.3	384	0.118	0.443	1.8%	47.90
0.2	293	0.071	0.266	1.1%	60.24
0.1	207	0.038	0.143	0.6%	71.91

ASIA					
Scenario ML (mg/kg)	**Number of samples**	**Average Cd concentration (mg/kg)**	**Cd intake (µg/kg bw/month)**	**% PTMI**	**Possible rejected samples (%)**
No ML	26	0.037	0.14	0.56%	0
0.9	26	0.037	0.14	0.56%	0
0.8	26	0.037	0.14	0.56%	0
0.7	26	0.037	0.14	0.56%	0
0.6	26	0.037	0.14	0.56%	0
0.5	26	0.037	0.14	0.56%	0
0.4	26	0.037	0.14	0.56%	0
0.3	26	0.037	0.14	0.56%	0
0.2	26	0.037	0.14	0.56%	0
0.1	24	0.03	0.113	0.45%	7.692

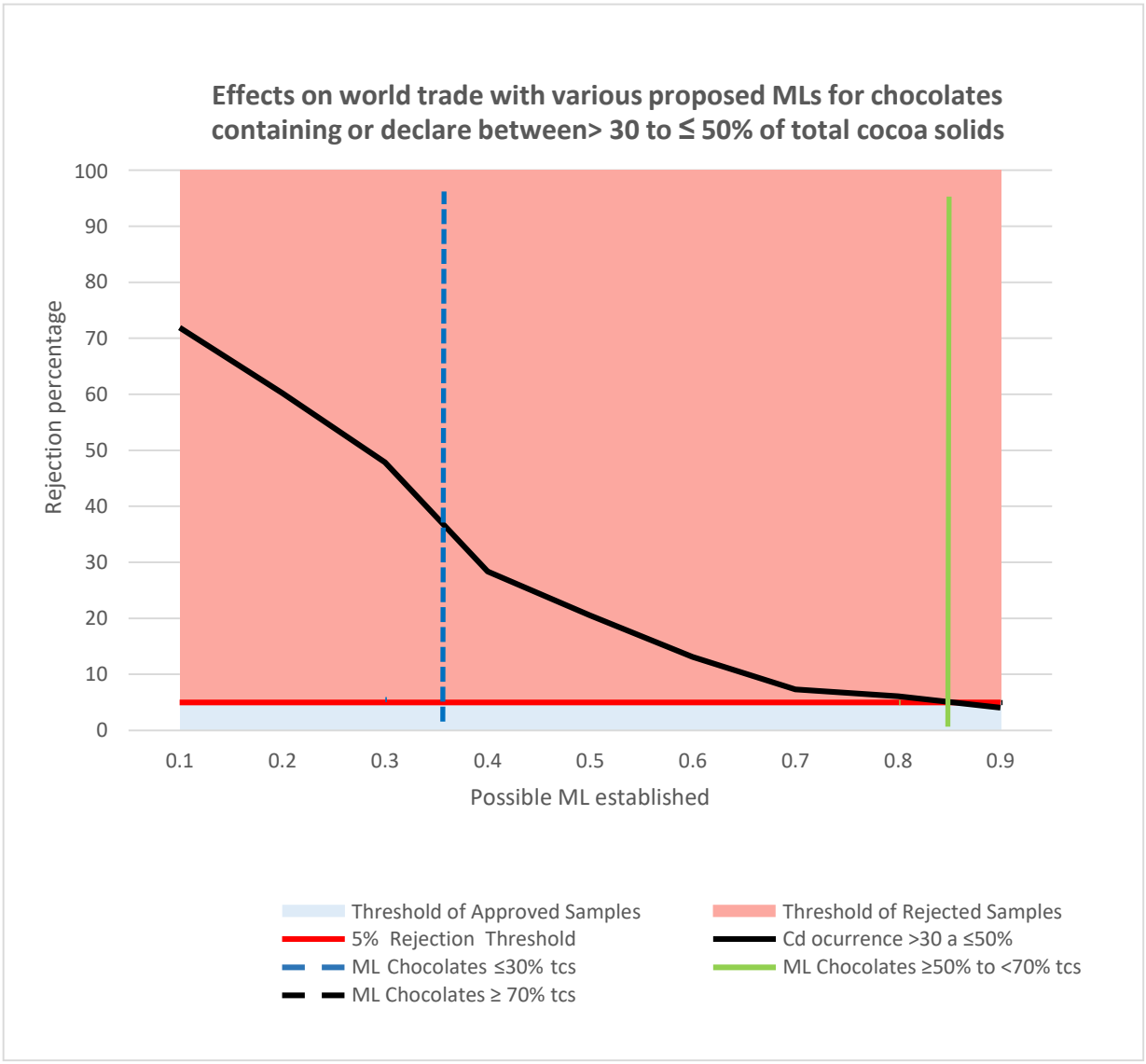
NASWP					
Scenario ML (mg/kg)	**Number of samples**	**Average Cd concentration (mg/kg)**	**Cd intake (µg/kg bw/month)**	**% PTMI**	**Possible rejected samples (%)**
No ML	108	0.099	0.371	0.0148%	0
0.9	108	0.099	0.371	0.0148%	0
0.8	108	0.099	0.371	0.0148%	0
0.7	108	0.099	0.371	0.0148%	0
0.6	108	0.099	0.371	0.0148%	0
0.5	107	0.099	0.371	0.0148%	0.9
0.4	104	0.086	0.323	0.0129%	3.7
0.3	102	0.081	0.304	0.0121%	5.5
0.2	98	0.074	0.278	0.0111%	9.2
0.1	69	0.043	0.161	0.0064%	36.1

AFRICA					
Scenario ML (mg/kg)	**Number of samples**	**Average Cd concentration (mg/kg)**	**Cd intake (µg/kg bw/month)**	**% PTMI**	**Possible rejected samples (%)**
No ML	53	0.049	0.185	0.742%	0
0.9	53	0.049	0.185	0.742%	0
0.8	53	0.049	0.185	0.742%	0
0.7	53	0.049	0.185	0.742%	0
0.6	53	0.049	0.185	0.742%	0
0.5	53	0.049	0.185	0.742%	0
0.4	53	0.049	0.185	0.742%	0
0.3	53	0.049	0.185	0.742%	0
0.2	53	0.049	0.185	0.742%	4
0.1	46	0.038	0.143	0.57%	13.20

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).

12. Considering Cluster Diet 7 as the one with greatest cocoa intake in their diet, according to "Cluster Diet 2012",from WHO ("Cocoa 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% to <50% of total cocoa solids, in a world-wide scenario, the intake would represent a maximum of 4.1% of the PTMI estimated by JECFA (0.025 mg/kg b.w). Also, on a worldwide basis with application of the proposed MLs of 0.1 mg/kg to 0.9 mg/kg, estimated cadmium intakes range between 0.54% to 3.45% of the PTMI. Additionally, it can be observed that the scenario with the data from the LAC region has the highest value for intake, if setting an ML of 0.9 mg/kg, representing 4.2% of the PTMI, but yet this value is below the 5 percent for a significant effect noted by JECFA.

Figure 1: Effects on world trade with several proposed ML for chocolates that contain or declare >30 to ≤50% total cocoa solids, in relation to the 5% cut off point for accepted rejections used by Codex Alimentarius, the MLs already adopted by the CAC41(for chocolates that contain or declare 1) ≥50% to < 70% and 2) ≥70% total cocoa solids) and in Step 5 (ML for chocolates that contain or declare ≤30% total cocoa solids, on dry matter basis)



13. By setting an ML of less than 0.8 mg/kg, it can be observed that, in the global context, 4.76% of the samples would fail and this is acceptable when comparing with the threshold of rejection of 5% (please corroborate this in Table 3).

14. Furthermore, Table 3 shows that 22.4% and 16.23% of the samples could be rejected if the proposed MLs of 0.4 mg/kg and 0.5 mg/kg respectively, would be applied in the context of the world data; considering that the ML of 0.3 mg/kg was accepted by the 13th CCCF Meeting for chocolates that contain or declar ≤ 30% total cocoa solids.

15. While performing the same analysis at the regional level, if applying the proposed MLs of 0.4 mg/kg and 0.5 mg/kg for Latin America and the Caribbean, it would generate rejection rates of 28.36% and 20.53% respectively. Regarding the regions of Asia, Africa and NASWP, there was an opposite result, with 0% to 0.9% rejections for the same ML. This leads to the conclusion that the data on the occurrence of cadmium from LAC significantly affects the world average.

16. While analyzing the results for both global, and regional rejection rates, according to Figure 1 and Table 3, it can be observed that the ML range from 0.7 mg/kg to 0.6 mg/kg would present 5.74% to 10.39% rejected samples worldwide with a PTMI of 3.345% to 3.015% respectively, which will mean 7.33% to 13.16% rejection rates for LAC.

Determination of ML by proportionality

17. The proportionality approach implies a reasonable ML based on the MLs already determined. If the principle of proportionality is considered with the other categories (0.8 mg/kg and 0.9 mg/kg for chocolates containing or declaring ≥50% to <70% and ≥70% of total cocoa solids) for this category an approximate value range of 0.5 – 0.6 mg/kg could be determined.

18. Noting the lack of consensus to postpone discussion on the remaining categories, CCCF19 considered the proposal of the CCCF Chair to consider the MLs on a proportional basis to the existing MLs as follows:

- chocolate and chocolate products containing or declaring =30% to <50% total cocoa solids on a dry matter basis: 0.5 mg/kg;

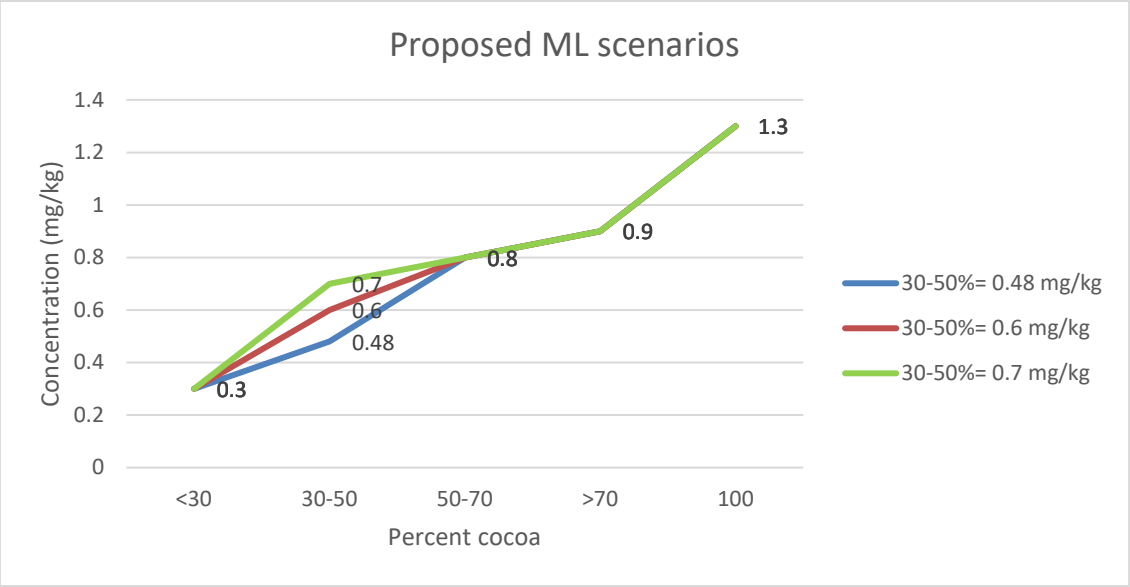


Figure 2: Proposed ML based on the middle of the ranges of TCS for the adopted MLs.

Table 4. Impact of different MLs for cadmium in the statistical distribution of cadmium for chocolates with ≥30% - <50% total cocoa solids of rejected samples in the world market with the proportionally approach.

Scenario with Worldwide data					
Scenario ML (mg/kg)	**Number of samples**	**Average Cd concentration (mg/kg)**	**Cd intake (µg/kg bw/month)**	**% PTMI**	**Possible rejected samples (%)**
No ML	924	0.276	1.035	4.140%	0
0.9	889	0.230	0.863	3.450%	3.79
0.8	880	0.229	0.859	3.435%	4.76
0.7	871	0.223	0.836	3.345%	5.74
0.6	828	0.201	0.754	3.015%	10.39
0.5	774	0.176	0.660	2.640%	16.23
0.4	717	0.155	0.581	2.325%	22.40
0.3	559	0.099	0.371	1.485%	39.50
0.2	462	0.036	0.135	0.540%	50.00
0.1	339	0.036	0.135	0.540%	63.31

LAC					
Scenario ML (mg/kg)	**Number of samples**	**Average Cd concentration (mg/kg)**	**Cd intake (µg/kg bw/month)**	**% PTMI**	**Possible rejected samples (%)**
No ML	737	0.31	1.163	4.7%	0.00
0.9	702	0.277	1.039	4.2%	4.08
0.7	683	0.263	0.986	3.9%	7.33
0.6	640	0.237	0.889	3.6%	13.16
0.5	587	0.208	0.780	3.1%	20.53
0.4	528	0.182	0.683	2.7%	28.36
0.3	384	0.118	0.443	1.8%	47.90
0.2	293	0.071	0.266	1.1%	60.24
0.1	207	0.038	0.143	0.6%	71.91

ASIA					
Scenario ML (mg/kg)	**Number of samples**	**Average Cd concentration (mg/kg)**	**Cd intake (µg/kg bw/month)**	**% PTMI**	**Possible rejected samples (%)**
No ML	26	0.037	0.14	0.56%	0
0.9	26	0.037	0.14	0.56%	0
0.8	26	0.037	0.14	0.56%	0
0.7	26	0.037	0.14	0.56%	0
0.6	26	0.037	0.14	0.56%	0
0.5	26	0.037	0.14	0.56%	0
0.4	26	0.037	0.14	0.56%	0
0.3	26	0.037	0.14	0.56%	0
0.2	26	0.037	0.14	0.56%	0
0.1	24	0.03	0.113	0.45%	7.692

NASWP					
Scenario ML (mg/kg)	**Number of samples**	**Average Cd concentration (mg/kg)**	**Cd intake (µg/kg bw/month)**	**% PTMI**	**Possible rejected samples (%)**
No ML	108	0.099	0.371	0.0148%	0
0.9	108	0.099	0.371	0.0148%	0
0.8	108	0.099	0.371	0.0148%	0
0.7	108	0.099	0.371	0.0148%	0
0.6	108	0.099	0.371	0.0148%	0
0.5	107	0.099	0.371	0.0148%	0.9
0.4	104	0.086	0.323	0.0129%	3.7
0.3	102	0.081	0.304	0.0121%	5.5
0.2	98	0.074	0.278	0.0111%	9.2
0.1	69	0.043	0.161	0.0064%	36.1

AFRICA					
Scenario ML (mg/kg)	**Number of samples**	**Average Cd concentration (mg/kg)**	**Cd intake (µg/kg bw/month)**	**% PTMI**	**Possible rejected samples (%)**
No ML	53	0.049	0.185	0.742%	0
0.9	53	0.049	0.185	0.742%	0
0.8	53	0.049	0.185	0.742%	0
0.7	53	0.049	0.185	0.742%	0
0.6	53	0.049	0.185	0.742%	0
0.5	53	0.049	0.185	0.742%	0
0.4	53	0.049	0.185	0.742%	0
0.3	53	0.049	0.185	0.742%	0
0.2	53	0.049	0.185	0.742%	4
0.1	46	0.038	0.143	0.57%	13.20

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).

19. In a world scenario with an ML range of 0.5 – 0.6 mg/kg, a monthly cadmium intake between 0.660 µg/kg bw and 0.754 µg/kg bw is observed, which represents 2.640-3.015% of the PMTI, which could generate a total of 10.23-16.23% of the samples possibly rejected in the world market. Considering these scenarios with regional data, for the LAC region, an ML of 0.5 mg/kg could generate at least, 20.53% of possibly rejected samples. For the Asia, Africa and NASWP regions, there would be a potential rejection rate of 0.0%, 0.0% and 0.9% respectively.

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

20. Following the mandate of the CCCF13, the EWG discarded data from cocoa powder samples that claimed to be mixtures of cocoa with sugars and other added ingredients having 1210 new samples in 2019; which, added to data from previous years, resulted in 4245 total samples.

21. The EWG then classified the data submitted, according to the samples' declaration of intended use of the product, and the percentage of cocoa solids. According to Table 1 in CX/CF 20/14/6, only 115 samples of the 4245 samples declared: 1) to have 100% cocoa solids, 2) to be "pure" cocoa powder or 3) to be "natural" cocoa powder; in the "Local Food name" and "Remarks" columns. None of the samples provided, declared their intended use.

22. Considering that the number of samples that provided information on the percentage of cocoa solids and intended use of the product, was not representative (Table 1), and despite the lack of such information would possibly affect the veracity of the ML proposed; the EWG decided to consider all cocoa powder data to propose ML for the cocoa powdercategory.

23. Although most of the data did not indicate the information on the origin of the samples, it was decided to categorize the data according to the countries that submit the information onto GEMS/Food.

24. 5943 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 0.712 and 95th percentile of 3.096. Calculating the standard deviation, the value of 1.16 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 ±3 σ (with "σ" the standard deviation) since this covers 99.7% of the data. In this new range (5781 data), the average is 0.566 with minimum and maximum values of 0 and 4.2 mg/kg respectively.

25. Table 5 shows that worldwide the presence of cadmium in cocoa powder has an average of 0.566 mg/kg, and the regional average values vary from 0.17 mg/kg to 1.095 mg/kg. This difference can also be observed in the 95th percentile values with variations from 0.54 mg/kg to 3.34 mg/kg between regions.

Table 5. 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	Max	Min	P95
Worldwide	5781	0.566	4.2	0	2.12
LAC	2272	1.095	4.2	0	3.34
ASIA	449	0.336	1.8	0	0.61
NASWP	218	0.496	3.0	0	1.35
AFRICA	267	0.171	1.3	0	0.54
EURO	2575	0.187	2.6	0	0.55

*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

26. Based on the occurrence data in Table 5, values from 0.20 mg/kg to 5 mg/kg were proposed to assess the impact of different MLs on cadmium intake and trade in cocoa powder (Table 6). The same considerations as the previous ones were used for the calculation of cadmium intake, except that the consumption data was specific for cocoa powder for the worst case scenario (cluster diet 7 = 2.78 µg/kg bw/day), the comparison with the reference value (PTMI) and the number of possible rejections in international trade.

Table 6. Summary of the impact of different ML for cadmium on the statistical distribution for cadmium in cocoa powder, including the estimated proportion of PTMI of cadmium intake for GEMS/ Food Diet 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 (µg/kg bw/month)**	**% PTMI**	**Possible rejected samples (%)**
No ML	5781	0.566	0.787	3.147	0.000
4.0	5762	0.600	0.834	3.336	0.329
3.8	5743	0.500	0.695	2.780	0.657
3.6	5704	0.500	0.695	2.780	1.332
3.4	5674	0.500	0.695	2.780	1.851
3.2	5656	0.500	0.695	2.780	2.162
3.0	5637	0.500	0.695	2.780	2.491
2.8	5594	0.500	0.695	2.780	3.235
2.6	5569	0.500	0.695	2.780	3.667
2.4	5534	0.400	0.556	2.224	4.273
2.2	5502	0.400	0.556	2.224	4.826
2.0	5469	0.400	0.556	2.224	5.397
1.6	5341	0.400	0.556	2.224	7.611

LAC					
Scenario ML (mg/kg)	**Number of samples**	**Average Cd concentration (mg/kg)**	**Cd intake (µg/kg bw/month)**	**% PTMI**	**Possible rejected samples (%)**
No ML	2272	1.095	1.522	6.086	0.000
5.0	2272	1.100	1.529	6.116	0.000
4.8	2272	1.095	1.522	6.088	0.000
4.2	2272	1.095	1.522	6.088	0.000
4.0	2253	1.069	1.486	5.944	0.836
3.8	2234	1.045	1.453	5.810	1.673
3.6	2195	0.998	1.387	5.549	3.389
3.4	2165	0.963	1.339	5.354	4.710
3.2	2147	0.943	1.311	5.243	5.502
3.0	2128	0.924	1.284	5.137	6.338
2.8	2087	0.885	1.230	4.921	8.143
2.6	2062	0.863	1.200	4.798	9.243
2.4	2030	0.837	1.163	4.654	10.651
2.2	2000	0.815	1.133	4.531	11.972
2.0	1967	0.794	1.104	4.415	13.424
1.6	1844	0.726	1.009	4.037	18.838
1.3	1644	0.600	0.834	3.336	27.641
1.2	1551	0.605	0.841	3.364	31.734

ASIA					
Scenario ML (mg/kg)	**Number of samples**	**Average Cd concentration (mg/kg)**	**Cd intake (µg/kg bw/month)**	**% PTMI**	**Possible rejected samples (%)**
No ML	449	0.336	0.467	1.868	0.000
1.6	448	0.333	0.463	1.851	0.891
1.3	445	0.325	0.452	1.807	0.891
1.2	445	0.325	0.452	1.807	0.891
1.0	445	0.325	0.452	1.807	0.891
0.8	437	0.317	0.441	1.763	2.673
0.6	426	0.307	0.427	1.707	5.122
0.4	308	0.245	0.341	1.362	31.403
0.2	89	0.076	0.106	0.423	80.178

NASWP					
Scenario ML (mg/kg)	**Number of samples**	**Average Cd concentration (mg/kg)**	**Cd intake (µg/kg bw/month)**	**% PTMI**	**Possible rejected samples (%)**
No ML	218	0.496	0.690	2.760	0.00
1.4	208	0.420	0.584	2.335	4.59
1.2	204	0.400	0.556	2.224	6.42
1.0	188	0.340	0.473	1.890	13.76
0.8	169	0.280	0.389	1.557	22.48
0.6	150	0.220	0.306	1.223	31.19
0.4	137	0.200	0.278	1.112	37.16

AFRICA					
Scenario ML (mg/kg)	**Number of samples**	**Average Cd concentration (mg/kg)**	**Cd intake (µg/kg bw/month)**	**% PTMI**	**Possible rejected samples (%)**
No ML	267	0.171	0.237	0.949	0.000
1.4	267	0.170	0.236	0.945	0.000
1.3	267	0.170	0.236	0.945	0.000
1.2	266	0.160	0.222	0.890	0.375
1.0	265	0.160	0.222	0.890	0.749
0.8	265	0.160	0.222	0.890	0.749
0.6	265	0.160	0.222	0.890	0.749
0.4	251	0.140	0.195	0.778	5.993
0.2	236	0.130	0.181	0.723	11.610

EURO					
Scenario ML (mg/kg)	**Number of samples**	**Average Cd concentration (mg/kg)**	**Cd intake (µg/kg bw/month)**	**% PTMI**	**Possible rejected samples (%)**
No ML	2575	0.187	0.261	1.042	0.000
1.4	2563	0.181	0.252	1.006	0.466
1.3	2555	0.177	0.246	0.984	0.777
1.2	2546	0.173	0.240	0.962	1.126
1.0	2524	0.167	0.232	0.929	1.981
0.8	2504	0.159	0.221	0.884	2.757
0.6	2463	0.151	0.210	0.840	4.350
0.4	2344	0.134	0.186	0.745	8.971
0.2	2066	0.115	0.160	0.639	19.767

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 µg/kg b.w. per day.

27. In a global scenario with an ML of 3.2 mg/kg, a cadmium intake of 0.695 µg/kg b.w. monthly, which represents 2.78% of PTMI, which could generate a total of 2.16% of the samples possibly rejected in the world market. Considering these scenarios with regional data, for LAC, an ML of 3.2 mg/kg could generate 5.5% 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 3.4 mg/kg, which is a level above the level considered in the CCCF13. For NASWP countries, Africa and Asia using the same scenario of a ML of 3.2 mg/kg could generate a rejection of 0% of the samples.

28. On the other hand, the ML worldwide that ensures a rejection percentage of less than 5% would be 2.2 mg/kg, however, said ML would still represent a rejection percentage for the Latin American and Caribbean Region of 11.97%

29. When analyzing the results for both global and regional rejection rates, according to Table 5, it can be seen that the ML range from 2.0 mg/kg to 3.0 mg/kg would present between 5.39% and a 2.49% of samples rejected worldwide with an PMTI of 2.78% to 2.22% for both cases, which will mean rejection rates of between 13.42% and 6.33% for the Latin American region and Caribbean.

Determination of ML by proportionality

30. The proportionality approach implies a reasonable ML based on the MLs already determined (Table 6). If the principle of proportionality is considered with the other categories (0.8 mg/kg and 0.9 mg/kg for chocolates containing or declaring ≥50% to <70% and ≥70% of total cocoa solids) for this category an approximate value range of 1.3 – 1.5 mg/kg could be determined.

31. Noting the lack of consensus to postpone discussion on the remaining categories, CCCF13 considered the proposal of the CCCF Chair to consider the MLs on a proportional basis to the existing MLs as follows:

- cocoa powder (100% total cocoa solids on a dry matter basis): 1.5 mg/kg

Table 7. Comparison between cadmium ML in categories of chocolates according to proportionality approached.

CATEGORIES	ML (mg/kg)
Chocolate and chocolate products containing or declaring <30% (*)	0.3
Chocolate and chocolate products containing or declaring ≥30% to <50% total cocoa solids on a dry matter basis (*)	[0.5 - 0.7]
Chocolate and chocolate products containing or declaring between ≥50% and <70%	0.8
Chocolate and chocolate products containing or declaring ≥70%	0.9
Cocoa powder (100% total cocoa solids on a dry matter basis) ready for consumption. (*)	[1.3-1.5]

(*) MLs not determined yet.

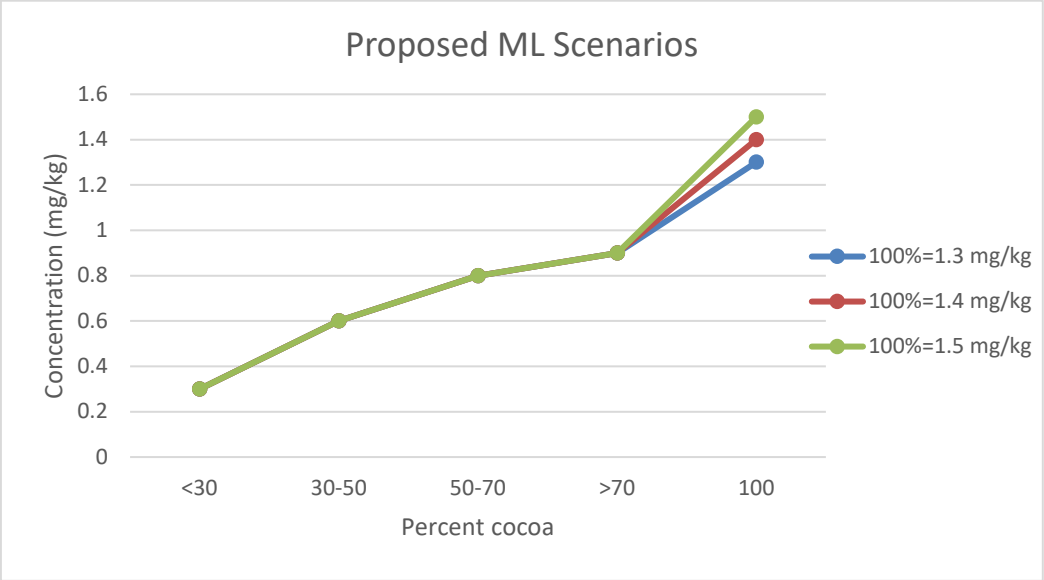


Figure 3: Proposed ML based on the middle of the ranges of TCS for the adopted MLs.

Table 8. Summary of the effects of an ML of 1.3 -1.5 mg/kg on the statistical distribution for cadmium in cocoa powder, including the estimated proportion of PMTI 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 (µg/kg bw/month)**	**% PTMI**	**Possible rejected samples (%)**
No ML	5781	0.566	0.787	3.147	0.00
1.6	5341	0.400	0.556	2.224	7.61
1.5	5303	0.400	0.556	2.224	8.26
1.4	5209	0.400	0.556	2.224	9.89
1.3	5117	0.300	0.417	1.668	11.48
1.2	5012	0.300	0.417	1.668	13.30
0.8	4356	0.200	0.278	1.112	24.65
0.4	3622	0.200	0.278	1.112	37.34

LAC					
Scenario ML (mg/kg)	**Number of samples**	**Average Cd concentration (mg/kg)**	**Cd intake (µg/kg bw/month)**	**% PTMI**	**Possible rejected samples (%)**
No ML	2272	1.095	1.522	6.086	0.000
1.6	1844	0.726	1.009	4.037	18.838
1.5	1809	0.700	0.973	3.892	20.379
1.4	1724	0700	0.973	3.892	24.120
1.3	1644	0.600	0.834	3.336	27.641
1.2	1551	0.605	0.841	3.364	31.734
0.8	979	0.362	0.503	2.013	56.910
0.4	582	0.299	0.416	1.662	74.384

ASIA					
Scenario ML (mg/kg)	**Number of samples**	**Average Cd concentration (mg/kg)**	**Cd intake (µg/kg bw/month)**	**% PTMI**	**Possible rejected samples (%)**
No ML	449	0.336	0.467	1.868	0.000
1.6	448	0.333	0.463	1.851	0.223
1.5	447	0.330	0.459	1.835	0.445
1.4	446	0.327	0.455	1.818	0.668
1.3	445	0.325	0.452	1.807	0.891
1.2	445	0.325	0.452	1.807	0.891
1.0	445	0.325	0.452	1.807	0.891
0.8	437	0.317	0.441	1.763	2.673
0.6	426	0.307	0.427	1.707	5.122
0.4	308	0.245	0.341	1.362	31.403
0.2	89	0.076	0.106	0.423	80.178

NASWP					
Scenario ML (mg/kg)	**Number of samples**	**Average Cd concentration (mg/kg)**	**Cd intake (µg/kg bw/month)**	**% PTMI**	**Possible rejected samples (%)**
No ML	218	0.496	0.690	2.760	0.00
1.5	211	0.430	0.598	2.391	3.21
1.4	208	0.420	0.584	2.335	4.59
1.3	206	0.400	0.556	2.224	5.50
1.2	204	0.400	0.556	2.224	6.42
1.0	188	0.340	0.473	1.890	13.76
0.8	169	0.280	0.389	1.557	22.48
0.6	150	0.220	0.306	1.223	31.19
0.4	137	0.200	0.278	1.112	37.16
0.2	82	0.140	0.195	0.778	62.39

AFRICA					
Scenario ML (mg/kg)	**Number of samples**	**Average Cd concentration (mg/kg)**	**Cd intake (µg/kg bw/month)**	**% PTMI**	**Possible rejected samples (%)**
No ML	267	0.171	0.237	0.949	0.000
1.5	267	0.170	0.237	0.949	0.000
1.4	267	0.170	0.236	0.945	0.000
1.3	267	0.170	0.236	0.945	0.000
1.2	266	0.160	0.222	0.890	0.375
1.0	265	0.160	0.222	0.890	0.749
0.8	265	0.160	0.222	0.890	0.749
0.6	265	0.160	0.222	0.890	0.749
0.4	251	0.140	0.195	0.778	5.993
0.2	236	0.130	0.181	0.723	11.610

EURO					
Scenario ML (mg/kg)	**Number of samples**	**Average Cd concentration (mg/kg)**	**Cd intake (µg/kg bw/month)**	**% PTMI**	**Possible rejected samples (%)**
No ML	2575	0.187	0.261	1.042	0.000
1.5	2568	0.187	0.260	1.040	0.272
1.4	2563	0.181	0.252	1.006	0.466
1.3	2555	0,177	0,246	0,984	0,777
1.2	2546	0,173	0,240	0,962	1,126
1.0	2524	0,167	0,232	0,929	1,981

32. In a world scenario with an ML range of 1.3 – 1.5 mg/kg, a monthly cadmium intake between 0.417 µg/kg bw and 0.556 µg/kg bw is observed, which represents 1.668-2.224% of the PMTI, which could generate a total of 8.26-11.48% of the samples possibly rejected in the world market. Considering these scenarios with regional data, for the LAC region, an ML of 1.3 mg/kg could generate at least, 27.64% of possibly rejected samples. For the Asia, Africa and NASWP regions, there would be a potential rejection rate of 0.9%, 0.0% and 5.5% respectively.

APPENDIX III

LIST OF PARTICIPANTS

Chair: Ecuador
Co-chair: Ghana

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