CODEX ALIMENTARIUS COMMISSION

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World Health Organization

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Agenda Item 5 **CX/CF 23/16/5**

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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON CONTAMINANTS IN FOODS

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MAXIMUM LEVELS FOR LEAD IN CERTAIN FOOD CATEGORIES

(At Steps 4 and 7)

(Prepared by the Electronic Working Group chaired by Brazil)

Codex members and observers wishing to submit comments at Steps 3 and 6 on MLs for lead in certain food categories should do so as instructed in CL 2023/18-CF available on the Codex webpage[1]

BACKGROUND

1. Lead exposure is associated with a wide range of effects, including neurodevelopmental effects, impaired renal function, hypertension, impaired fertility and adverse pregnancy outcomes. Foetuses, infants and children are the subgroups that are most sensitive to lead due to neurodevelopmental effects. Since no safe level of lead could be identified, measures should be taken to identify major contributing sources and, if appropriate, to identify methods of reducing dietary exposure that are commensurate with the level of risk reduction.

2. Based on the conclusions of JECFA73 (2011) about dietary lead exposure, revision of Maximum Levels (MLs) for lead established in the *General Standard for Contaminants in Food and Feed* (CXS 193-1995) was undertaken between the 6th and 13th Sessions of the Codex Committee on Contaminants in Foods (CCCF06, 2012 to CCCF13, 2019).

3. CCCF11 (2017)[2] noted that the revision of MLs of lead was limited to those food categories listed in CXS 193 and there was wide support to continue working on new MLs for lead in other food categories. Since then, an Electronic Working Group (EWG) led by Brazil has been working on proposals for new MLs for lead in selected food commodities.

4. CCCF12 (2018)[3] and CCCF13 (2019)[4] discussed the criteria to select new food categories for ML elaboration[5], considering international trade and potential exposure. CCCF13 agreed to focus on MLs proposals for lead in food for infants and young children (except those for which MLs have already been established in CXS 193, spices and aromatic herbs; eggs and sugars and confectionery, excluding cocoa.

5. The EWG established at CCCF13 worked on lead data extracted from the Global Environment Monitoring System (GEMS/Food) from 2008 – 2019. MLs were proposed for eggs, preserved eggs, fresh and dried culinary herbs and spices (fruits and berries; fresh and dried rhizomes, bulbs and roots; bark; floral parts; seed).

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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 REP 17/CF11, paras. 85-86

3 REP 18/CF12, para. 131

4 REP 19/CF13, paras. 90-96

5 CX/CF 19/13/9, Appendix II, para.3 (selection) and CX/CF 19/13/9, paras. 8-16 (prioritization)

6. Due to the COVID19 pandemic, CCCF14 was postponed to 2021 and a new JECFA call for data[6] was issued in 2020. CCCF14 (2021)[7] agreed to clarify that the MLs for lead in fruit juices and grape juices in CXS 193 also apply to juices for infants and young children, and no further work was required. It was also decided to discontinue work on MLs for herbal teas, yoghurt, cheese and milk-based products for infants and young children at that time as these products were complex mixtures with limited dataset, information on international trade was unclear and there was a lack of consumption data.

7. An EWG chaired by Brazil was re-established to continue working on MLs for lead in dried spices and culinary herbs, including dried bulbs, rhizomes and roots; fresh culinary herbs; eggs; sugars and sugar-based candies; cereal-based products for infants and young children and ready-to-eat meals for infants and young children considering the written comments that were received, decisions made at the session and new data available in the GEMS/Food.

8. CCCF15 (2022) agreed to discontinue work on fresh eggs considering its low relevance for international trade and the low occurrence levels observed, dried garlic as there is already an ML of 0.1 mg/kg for fresh garlic on the GSTCFF and molasses as there was not sufficient data to establish a ML.

9. CCCF15 also agreed to forward the MLs for lead in cereal-based foods for infants and young children at 0.02 mg/kg; white and refined sugar, corn and maple syrups and honey at 0.1 mg/kg at step 5/8 and sugar-based candies at 0.1 mg/kg at Step 5/8, which were adopted by the Codex Alimentarius Commission (CAC45, 2022)[8]. CCCF15 further agreed to consider a separate ML for brown and raw sugar due to the high-value commodity in international trade and because it is likely to contain more lead than white or refined sugar

10. During discussions at CCCF15, a member noted that certain ready-to-eat meals for infants and young children may have slightly higher occurrence levels, e.g. products containg certain root vegetables, which might require a separate treatment. Therefore for ready-to-eat meals for infants and young children, CCCF15 agreed to forward the ML for lead at 0.02 mg/kg at Step 5 and further consideration by the EWG as per the possible exclusion of certain foods that may not be able to achieve this ML for consideration at CCCF16 (2023).

11. CCCF15 agreed to re-establish the EWG, led by Brazil, to consider MLs for ready-to-eat meals for infants and young children (exclusion of certain foods) and brown and raw cane sugars based on data currently available on GEMS/Food for consideration by CCCF16 (2023) and MLs for culinary herbs (fresh/dried) and spices (dried) following a JECFA call for data in 2022[9] for consideration by CCCF17 (2024).

12. CCCF15 recommended that the EWG work in close collaboration with the EWG on data analysis to ensure consistency in the methodology applied to derive the MLs, as information becomes available.[10]

WORK PROCESS

13. Data on brown sugar, raw sugar and ready-to-eat meals for infants and young children from 2011 to 2021, were extracted by the WHO administrator of GEMS/Food. The EWG used the approach “As Low As Reasonably Achievable” (ALARA) and evaluated rejection rates of samples to propose MLs since JECFA did not identify a safe level of lead exposure. There was a general support for a maximum cut-off at 5% and the acceptable rejection rates to be determined on a case-by-case basis at CCCF14[11].

14. Two drafts were circulated in the EWG. On the first one, MLs of 0.15 mg/kg were proposed for brown and raw sugars, of 0.02 mg/kg for ready-to-eat meals for infants and young children, excluding products with cereals, and of 0.05 mg/kg for ready-to-eat meals for infants and young children with cereals. Comments were received from Thailand, Netherlands, Canada, the United States, Japan, New Zealand and Iran.

15. Based on the comments received, a second draft was circulated for comments on MLs of 0.15 mg/kg for brown sugar, 0.10 mg/kg for raw sugar, 0.12 mg/kg for non-centrifuged sugar and 0.04 mg/kg for ready-to-eat meals for infants and young children. Comments were received from Netherlands, Canada, the United States and Japan.

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6 https://www.fao.org/3/cb0618en/cb0618en.pdf
7 REP21/CF14, paras. 98, 101
8 REP22/CAC45, para. 65, Appendix II
9 https://www.who.int/news-room/articles-detail/Call-for-data-lead-in-food-commodities-in-fresh-and-dried-culinary-herbs-and-dried-spices
10 REP22/CF15, paras. 69-104
11 REP21/CF14, paras. 62-63

16. Considering information available at GEMS/Food and definitions on the *Standard for Sugars* (CXS 212-1999), it was considered results reported as brown sugar as being "soft brown sugar" and the ones reported as "demerara" as being "raw sugar'. It was observed that the Database contains results of lead in "panela", a non-centrifuged sugar, that is not covered by CXS 212 according to circular letter CL 2019/34-CS, paragraph 8.

17. For ready-to-eat meals for infants and young children, data were extracted from GEMS/Food considering samples reported on the food name field as "Ready-to-eat meal for infants and young children" and comprises multi-ingredient products. Although a ML of 0.02 mg/kg was forward as step 5, it was observed that products containing cereals could have a higher contamination profile. Nevertheless, it is not possible to identify minimum percentage of cereals containing in these products and thus it could be difficult to differentiate products. For this reason, it is proposed to consider either a higher ML for the whole category or to exclude products containing cereals from the ML.

18. The detailed work process followed for the proposed MLs for lead in ready-to-eat meals for infants and young children (exclusion of certain foods) and brown and raw cane sugars is provided in Appendix II and the list of participants in Appendix III.

SUMMARY OF KEY POINTS OF DISCUSSION

Substitution method employed

19. It was questioned if the same substitution method was followed as the previous year. Both for sugars and ready-to-eat meals for infants and young children, CX/CF 22/15/7[12] considered the middle bound (MB) approach.

20. On the section of statistical analysis of the document "Guidance on data analysis for the development of maximum levels and improved data collection" (under discussion by CCCF), there is reference to three substitution methods to handle left-censored data: lower bound (LB), middle bound (MB) and upper bound (UB). There is no indication on which method should be used for each case.

21. Considering that more than 27% of lead in sugar and more than 60% of lead in ready-to-eat meals for infants and young children is left-censored (Appendix II, Annex I), it was considered more appropriate to discuss MLs for these food categories using the UB approach.

Obtaining the second dataset

22. During CCCF15, it was observed that many data were classified as non-detected (ND), but the results were obtained with methods with high level of quantification (LOQ) values. The EWG decided then to derive a second dataset removing results with methods with high LOQ values. The cut-off was decided to be the P95 values for sugars, as no ML was advanced for brown and raw sugars. For ready-to-eat meals for infants and young children, the second dataset was obtaining removing samples analysed with methods with LOQs higher than the ML that was at step 5.

23. It was also considered that removing only ND samples from methods with high LOQ values could introduce bias in the results and, for this reason, it was decided to remove all data (even quantified ones) that were obtained using methods with high LOQ values. The document "Guidance on data analysis for the development of maximum levels and improved data collection" (under discussion by CCCF) states that results from methods with LOQ values higher than the ML under discussion should be excluded from the analysis. However, there is no guidance on how to deal with this issue when there is no actual ML. It was then considered by this EWG that when no actual ML exists, the solution would be to exclude data from methods with LOQ values higher than the P95.

Sample rejection rates and P95 values

24. Few countries pointed some inconsistencies between the P95 values and the sample rejection percentages reported. The inconsistencies were verified and corrected if needed and were in general related to the method used to evaluated rejection rates that was considering also as rejected samples with results equal to the hypothetical ML under consideration. For instance, in the case of brown sugar, the P95 is 0,20 mg/kg when all data is being considered, but if this level is set as a ML, there won't be a rejection of 5% of the data as 8 samples (out of 90) had results ND, with a level of detection (LOD) of 0,20 mg/kg and thus the rejection rate is less than 5% (2,2%).

[12] CX/CF 22/15/7, Appendix II – para. 43 and tables C1 and D1 in Annex I

Soft brown and raw sugars definitions

25. The EWG raised some questions around the references of "brown sugar", "soft brown sugar", "demerara" and "raw sugars". Although CXS 212 defines soft brown sugar and raw sugar, GEMS/Food does not contain any results for lead in soft brown sugar. On the other hand, there are reports of lead in "brown sugar" and "demerara". The EWG considered that results reported as brown sugar were referred to soft brown sugar and as demerara were raw sugar.

26. Additionally, the first draft considered panela, mascavo and tapon sugar as raw sugars. One country mentioned that according to CXS 212, these were not considered raw cane sugar, but were instead non-centrifuged sugars. Further, GEMS/Food contains only results from lead in panela and does not have any reports in mascavo and tapon sugar. For instance, all Brazilian data (n = 73) were initially classified as raw sugar, but all the reports are referred as brown sugar - panela. In this document, all reports of panela were classified as non-centrifuged sugars.

Combining maximum levels for brown and raw sugars

27. Some members proposed to combine MLs for brown and raw sugars, considering also non-centrifuged sugars in the same ML given the similarities across products (i.e. less refined sugars) and difficulty of classification of these products. It was also mentioned that CAC42 (2019) agreed to discontinue the work on draft standard for panela and/or common or vernacular name as known in each country (non-centrifuged sugars). It is suggested then that a single ML be established that would cover brown, raw and non-centrifuged sugars as in Appendix I. Besides, the ML proposed is slightly higher than the ML established for white and refined sugar adopted by CAC45 (2022) at Step 5/8 of 0.1 mg/kg, which is consistent with the discussions held at CCCF15.

Geographical representative data

28. Few countries mentioned that there might be limited geographic representation with the current dataset for brown and raw sugars based on countries that submitted data. On 2021, producing countries were encouraged to submit data and the decisions on MLs for sugars were postponed for a year to allow more time for submission of data to GEMS/Food for analysis[13]. The decision was again postponed in 2022 as it was considered that a separate ML for brown and raw sugars could be established as it is a high-value commodity in international trade that is likely to contain more lead than white or refined sugar. CCCF15 decided to consider a ML for brown and raw sugars based on data available from GEMS/Food and to submit a proposal for consideration by CCCF16[14]. The Committee is invited to consider establishing a single ML for brown sugars, raw sugars and non-centrifuged sugars as in Appendix I, considering data analysis in Appendix II.

Ready-to-eat meals for infants and young children

29. Some countries questioned how ready-to-eat (RTE) meals containing roots vegetables or cereals were identified. It is worth noting that GEMS/Food does not have information on the whole composition of the products that were analysed. The EWG considered all data reported on the fields "food category" as "food for infants and small children" <u>and</u> "food name" as "Ready-to-eat meal for infants and young children". Results reported in other food categories or under other food names were not considered. Besides, ML for lead in cereal-based foods for infants and young children were adopted[15] at Step 5/8 by CAC 45, which includes "rice-based foods for infants and young children", for instance.

30. In this sense, the EWG considered that RTE containing cereals in this document refers to multi-ingredient products that contains other ingredients and the percentage of specified ingredients (such as cereals or root vegetables) in the product is unknown. The procedure used to identify and classify products containing roots vegetables or cereals was to verify if there was any mention to one or more roots vegetables or cereals in the fields "local food name" and "remarks". The RTE containing cereals reported one of the ingredients: rice, barley, corn, oat, granola and mixed cereal (examples of products: "RTE organic baby food with oats, carrot, bean, spinach and tomato" or "RTE multi-ingredient chicken, apple, corn"). The RTE containing roots vegetables reported one of the following ingredients: carrot, sweet potato or beet (examples of products "RTE apple, carrot, apricot and millet" and "banana, blueberry, sweet potato, carrot yogurt").

13 REP21/CF14, para. 94
14 REP22/CF15, para. 93-95
15 REP22/CAC45, paras. 65, 75, Appendix III

Maximum levels for ready-to-eat meals for infants and young children

31. In the first draft, it was proposed to establish a separate ML for ready-to-eat meals for infants and young children containing cereals as these products seem to contain higher levels of lead. The available dataset does not show that RTE products containing other ingredients could have a different contamination profile (such as products containing root vegetables).

32. Given that these products are multi-ingredients, and the percentage of cereals is unknown, having a separate ML could be difficult to enforce. One country also considered that the decision from CCCF15 was to exclude foods that could not conform to the ML of 0.02 mg/kg at step 5 and not to accommodate all foods in the category. It was also pointed out that CAC45 adopted the ML of 0.02 mg/kg for cereal-based food for infants and young children and a higher ML for ready-to-eat meals containing cereals may not be justified as cereals would be diluted in these products. On the other hand, cereal-based products are in general made of cereal flour and ready-to-eat meals containing cereal are in general made of whole grains, but this information cannot be checked considering data available from GEMS/Food. No further discussion on breakdown of other food categories (e.g. RTE containing meat, fruit, vegetable, fruit/vegetable) is done as CX/CF 22/15/7 showed that these products had a similar contamination profile and also since these products are multi-ingredients.

33. Taking these points under consideration and data analysis in Appendix II, the Committee is invited to consider setting a higher ML of 0.03 mg/kg for the entire food category or a ML of 0.02 mg/kg excluding products containing cereals as in Appendix I.

CONCLUSIONS

34. MLs for lead in sugars (brown, raw and non-centrifuged) and ready-to-eat meals for infants and young children are being proposed considering ALARA, with rejections rates less than 5%.

35. For soft brown sugar, raw sugar and non-centrifuged sugar, it was observed a slight difference in the levels of lead between these products. However, considering the low representativity specially of raw sugar, the difficulty in differentiating less processed sugars and the similarity of them, it is being proposed a single ML at 0.15 mg/kg, a slightly higher level than the ML adopted at step 5/8 by CAC 45 for lead in white and refined sugars of 0.01 mg/kg.

36. It was identified that establishing the ML of 0.02 mg/kg for ready-to-eat meals for infants and young children could exclude more than 5% of products containing cereals, which would not be applicable. On the other hand, it is difficult to identify percentage of cereals in these products (data not available at GEMS/Food) and given that they are multi-ingredients. A single ML of 0.03 mg/kg is being proposed for the entire food category, slightly higher than the one that was advanced at Step 5 by CCCF15, or to exclude products containing cereals from the ML of 0.02 mg/kg.

RECOMMENDATIONS

37. The EWG recommends CCCF to consider the proposals for the establishment of MLs for sugars (soft brown, raw and non-centrifuged), and for ready-to-eat meals for infants and young children, as presented in Appendix I, considering the data/information provided on paragraphs 13-36 and Appendix II.

APPENDIX I

PROPOSED MAXIMUM LEVELS FOR LEAD FOR CERTAIN FOOD CATEGORIES

SUGARS
(SOFT BROWN, RAW AND NON-CENTRIFUGED)

(For comments at Step 3)

Codex members and observers are kindly invited to consider the following proposals:

- Establish the following ML for sugar, excluding white and refined:

Commodity/ Product Name	Maximum Level (ML) mg/kg	Portion of the Commodity/Product to which the ML applies	Notes/Remarks
Soft brown, raw and non –centrifuged sugars	0.15	Whole commodity	The ML applies to soft brown sugar[1], raw sugar and non-centrifuged sugar. Relevant Codex commodity standard is CXS-212-1999. (Note non-centrifuged sugars includes panela and mascavo)

[1] While the *Standard for Sugars* (CXS 212-1999) defines "soft brown sugar" but not "brown sugar", the occurrence data were uploaded to "brown sugar" in the GEMS/Food.

READY-TO-EAT MEALS FOR INFANTS AND YOUNG CHILDREN

(For comments at Step 6)

- Consider to establish a single ML of 0.02 mg/kg for the whole category of ready-to-eat meals for infants and young children as proposed by CCCF15 and adopted at Step 5 by CAC44 in 2022

Commodity/ Product Name	**Maximum Level (ML) mg/kg**	**Portion of the Commodity/Product to which the ML applies**	**Notes/Remarks**
Ready-to-eat meals for infants and young children	0.02	Whole commodity	Relevant Codex commodity standard is CXS 73-1981. The ML applies to all ready-to-eat meals intended for infants (up to 12 months) and young children (12 to 36 months).

(For comments at Step 3)

- Consider either to establish a single ML of 0.03 mg/kg for the whole category of ready-to-eat meals for infants and young children or to establish a ML of 0.02 mg/kg for ready-to-eat meals for infants and young children, excluding products containing cereals as proposed by the EWG established by CCCF15.

Commodity/ Product Name	**Maximum Level (ML) mg/kg**	**Portion of the Commodity/Product to which the ML applies**	**Notes/Remarks**
Ready-to-eat meals for infants and young children	0.03	Whole commodity	Relevant Codex commodity standard is CXS 73-1981. The ML applies to all ready-to-eat meals intended for infants (up to 12 months) and young children (12 to 36 months).
or			
Ready-to-eat meals for infants and young children, excluding products containing cereals	0.02	Whole commodity	Relevant Codex commodity standard is CXS 73-1981. The ML applies to all ready-to-eat meals intended for infants except products containing cereals (up to 12 months) and young children (12 to 36 months).

APPENDIX II

SUMMARY DISCUSSION
INCLUDING ASSESSMENT OF DATA/INFORMATION
GATHERED THRUGH GEMS/Food AND FROM EWG MEMBERS

(For information)

LEAD OCCURRENCE IN FOODS

1. No new call for data was conducted to consider maximum levels (MLs) for ready-to-eat (RTE) meals for infants and young children (exclusion of certain foods) and brown and raw cane sugars for consideration by the 16th Session of the Codex Committee on Contaminants in Foods (CCCF16. 2023). The Electronic Working Group (EWG) analysed data extracted in 2021 by the WHO Administrator of GEMS/Food, covering data from 2011 to 2021 of lead levels in sugars and ready-to-eat meals for infants and young children.
2. Data was categorized based on the names entered by the countries on the fields: Food Category, Food Name, Local Food Name and Food State Name. The “Remarks” column was checked to evaluate if there was additional information that could support the classification.
3. Data were not considered if they did not meet basic criteria, such as incomplete information and results from samples collected before 2011. Analytical values available were expressed “as is” (as presented) or “as consumed”, and all of them were considered. All data were converted to the same unit (mg/kg).
4. It was observed that most results of lead in sugars and ready-to-eat meals for infants and young children are non-detected. In order to assure that the MLs are not established below the limit of quantification (LOQ) of most methods, the first step was to use the upper bound approach in which the results below level of detection (LOD) were replaced by the numerical value of the LOD and those below the LOQ were replaced by the value reported as LOQ.
5. The second step was to consider a second scenario, excluding results obtained with methods with a LOQ higher than the initial proposed ML. To avoid bias due to a distortion in distribution of data obtained from partial exclusion of data, the EWG proposed to exclude all data obtained with methods with a high LOQ. For brown sugar, raw cane sugar and non-centrifuged sugars that do not have ML proposed, it was considered that high LOQ values were those higher than the 95th percentile of the first dataset and all the samples having this high LOQ method were excluded, even if the results were quantified to avoid bias. For ready-to-eat meals for infants and young children, high LOQ values were considered on ML advanced at step 5 CCCF15 of 0.02 mg/kg. For ready-to-eat meals for infants and young children it was observed that P95 values in this second scenario were not modified if Middle-bound or Upper Bound (UB) approach were used, with P95 of 0.023 mg/kg in both cases (data not shown). The EWG decided then to use only the UB approach.
6. Summary statistics including total number of samples, mean, and 95th percentile concentrations were determined for this second dataset for each category **(Appendix II).** Finally, hypothetical MLs and the rate of sample rejection were analysed aiming to propose MLs, based on the second dataset.
7. The proposed MLs are based on the “As Low As Reasonably Achievable” (ALARA) Principle. The EWG considered a maximum cut-off at 5% taking into account a case-by-case basis approach as detailed by each food category as summarized in preliminary work by the EWG on “Guidance on data analysis for development of MLs and for improved data collection”.

ANALYSIS OF FOOD CATEGORIES

Brown and raw sugars

8. The *Standard for Sugars* (CXS 212-1999) was considered to classify the sugars intended for human consumption (sugars sold directly to the final consumer and sugar used as ingredient in foodstuffs). It was observed that the Global Environment Monitoring System (GEMS/Food) includes results of lead in brown sugar, raw cane sugar, demerara and panela. During the EWG discussions, demerara, mascavo and panela were initially considered as raw cane s/ugar. Nevertheless, CL 2019/34-CS, paragraph 8 describes panela and mascavo as non-centrifuged sugars, and thus are not covered in raw cane sugars as defined in CXS 212.
9. Although CXS 212 defines soft brown sugar, GEMS/Food contains only results for brown sugar. The EWG considered then that brown sugar refers to soft brown sugar. Raw cane sugar is defined by this standard as “partially purified sucrose, which is crystallized from partially purified cane juice, without further purification, but which does not preclude centrifugation or drying, and which is characterized by sucrose crystals covered with a film of cane molasses”. Considering this, demerara sugar was classified by the EWG as raw cane sugar as it is defined as a partially processed sugar that retains more molasses than naturally present[1].

[1] Light brown sugar, sometimes known as Demerara sugar or raw cane sugar, is a partially processed sugar that retains more of the molasses naturally present. (https://www.braziliansugar.com.br/en/icumsa-600-1200).

10. All results following removal of the data from methods with high LOQ are shown on **Appendix II – Table A1**. After first draft and considering all contributions received during the EWG discussions, data were re-classified as shown from Table 1 until Table 14 (see para 8). Data of brown sugar were submitted from one region (WHO European) and four countries: Brazil, Singapore, Thailand and United States of America (USA) (**Table 1**). From 90 results submitted, 9 results were excluded because they were obtained from methods with high LOQ values, i.e. >0.20 mg/kg (**Table 2**).

Table 1. Data contribution by country for brown sugar dataset for all data and data after the exclusion of samples with high LOQ.

Countries	n – All data	n – Data after high LOQs exclusion*
Brazil	1	1
Singapore	1	0
Thailand	28	20
USA	15	15
WHO European region	45	45
Total	90	81

*Data obtained with methods with LOQ values >0.20 mg/kg were excluded.

Table 2. Mean and 95th percentile for brown sugar datasets

Brown sugar	N	Mean (mg/kg)	95th percentile (mg/kg)
Brown sugar, all data	90	0.06	0.20
Brown sugar, data after high LOQs exclusion *	81	0.04	0.12

*Data obtained with methods with LOQ values >0.20 mg/kg were excluded.

11. The effect of hypothetical MLs on sample rejection rate for lead in brown sugar is shown in **Table 3**. Considering ALARA principles and rejection rates up to 5% from dataset with samples with high LOQs excluded, a ML of 0.15 mg/kg for lead in brown sugar could be established for brown sugar.

Table 3. Effect of the implementation of hypothetical MLs for lead in brown sugar

ML (mg/kg)	Mean lead occurrence (mg/kg)	Sample rejection (%)	Intake reduction (%)[a]
Brown sugar, all data (n = 90)			
No ML	0.059	0.0	-
0.25	0.059	0.0	0.0
0.20	0.055	2.2	6.2
0.15	*0.040*	*3.3*	*33.0*
0.10	0.035	15.6	38.7
Brown sugar, data after high LOQs exclusion[b] (n = 81)			
No ML	0.045	0.0	-
0.20	0.040	2.5	9.8
0.15	*0.039*	*3.7*	*13.1*
0.10	0.035	7.4	20.7

[a] Sugar consumption of 111.73 g/person (G11); [b] Data obtained with methods with LOQ values >0.20 mg/kg were excluded.

12. Data of raw cane sugar, including demerara, were submitted from four countries: Cuba, Singapore, Thailand and USA (**Table 4**). From 250 results submitted, 23 results were excluded because they were obtained from methods with higher LOQ values, i.e. >0.09 mg/kg (**Table 5**).

Table 4. Data contribution by country to raw cane sugar for all data and data after the exclusion of samples high LOQ

Countries	n – All data	n – Data after high LOQs exclusion *
Cuba	1	0
Singapore	8	0
Thailand	240	226
USA	1	1
Total	250	227

*Data obtained with methods with LOQ values >0.09 mg/kg were excluded.

Table 5. Mean and 95th percentile for raw cane sugar datasets

Raw cane sugar	N	Mean (mg/kg)	95th percentile (mg/kg)
All data	250	0.033	0.09
Raw cane sugar, data after high LOQs exclusion*	227	0.030	0.09

*Data obtained with methods with LOQ values >0.09 mg/kg were excluded.

13. The effect of hypothetical MLs for lead on sample rejection rate in raw cane sugar is shown in **Table 6**. Considering ALARA principles and rejection rates up to 5% from dataset with high LOQs excluded, a ML of 0.10 mg/kg for lead in raw cane sugar could be established. If considered a ML of 0.10 mg/kg, almost 2.6% of total samples from Thailand dataset would be rejected, the country that submitted the majority of data. It is important to consider that the samples are reported from practically one country and lead levels on raw cane sugar are expected to be slightly higher than on white and refined sugars, for which a ML of 0.10 mg/kg was established.

Table 6. Effect of the implementation of hypothetical MLs for lead on raw cane sugar

ML (mg/kg)	Mean lead occurrence (mg/kg)	Sample rejection (%)	Intake reduction (%)[a]
Raw cane sugar, all data (n = 250)			
No ML	0.033	0.0	-
0.15	*0.023*	*2.8*	*30.1*
0.10	0.021	4.0	34.2
Raw cane sugar, data after high LOQs exclusion[b] (n = 227)			
No ML	0.022	0.0	-
0.15	*0.019*	*1.3*	*10.9*
0.10	0.018	2.2	16.8

[a] Sugar consumption of 111.73 g/person (G11); [b] Data obtained with methods with LOQ values >0.09 mg/kg were excluded.

14. After the first draft of the document, comments received helped clarifying that some products classified initially as raw sugar were instead non-centrifuged sugars considering CL 2019/34-CS. Because of that, data of non-centrifuged sugars were re-organized and were analysed separately. Data of non-centrifuged sugars (*e.g*. panela) were submitted from three countries: Brazil, Singapore and USA (**Table 7**). From 76 results submitted, one result was excluded because it was obtained from method with high LOQ value, i.e. >0.11 mg/kg (**Table 8**).

Table 7. Data contribution by country to non-centrifuged sugars (*e.g*. panela) dataset for all data and data after the exclusion of samples with high LOQ

Countries	n – All data	n – Data after high LOQs exclusion *
Brazil	72	72
Singapore	1	0
USA	3	3
Total	76	75

*Data obtained with methods with LOQ values >0.11 mg/kg were excluded.

Table 8. Mean and 95th percentile for non-centrifuged sugars datasets

Non-centrifuged sugars	N	Mean (mg/kg)	95th percentile (mg/kg)
All data	76	0.082	0.11
Non-centrifuged sugars data after high LOQs exclusion*	75	0.081	0.11

*Data obtained with methods with LOQ values >0.11 mg/kg were excluded.

15. The effect of hypothetical MLs for lead in non-centrifuged sugars on sample rejection is shown in **Table 9**. Considering ALARA principles and rejection rates up to 5% from dataset with high LOQs excluded, a ML of 0.15 mg/kg for lead in non-centrifuged sugar could be established.

Table 9. Effect of the implementation of hypothetical MLs for lead on non-centrifuged, sugars

ML (mg/kg)	Mean lead occurrence (mg/kg)	Sample rejection (%)	Intake reduction (%)[a]
Non-centrifuged sugars, all data (n = 76)			
No ML	0.082	0.0	-
0.15	*0.082*	*0.0*	*0.0*
0.10	0.076	17.1	7.1
Non-centrifuged sugars, data after high LOQs exclusion[b] (n = 75)			
No ML	0.081	0.0	-
0.15	*0.081*	*0.0*	*0.0*
0.10	0.076	17.3	7.3

[a] Sugar consumption of 111.73 g/person (G11);
[b]Data obtained with methods with LOQ values >0.11 mg/kg were excluded.

16. Although CCCF recommended to evaluate sugars individually, one country suggested during the EWG discussions that a single ML for all 3 products (soft brown sugar, raw cane sugar and non-centrifuged sugars) be considered given the similarities across products and hence difficulty on classifying. So, the EWG recalculated the mean, median, 95 and 97.5 percentiles (**Appendix II).**

17. Data of all sugar (brown sugar, raw cane sugar and non-centrifuged sugars) submitted are shown in **Table 10**. From 416 results submitted, 47 results were excluded because they were obtained from methods with higher LOQ values, i.e. >0.12 mg/kg (P95 of all sugar) (**Table 11**).

Table 10. Data contribution by country to all sugars (brown sugar, raw cane sugar and non-centrifuged sugars) dataset for all data and data after the exclusion of samples with high LOQ

Countries	**n – All data**	**n – Data after high LOQs exclusion***
Brazil	73	73
Cuba	1	0
Singapore	10	0
Thailand	268	256
USA	19	19
WHO European region	45	21
Total	416	369

*Data obtained with methods with LOQ values >0.12 mg/kg were excluded

Table 11. Mean and 95th percentile for all sugar (brown sugar, raw cane sugar and non-centrifuged sugars) datasets

All sugar (brown sugar, raw cane sugar and non-centrifuged sugars)	**N**	**Mean (mg/kg)**	**95th percentile (mg/kg)**
All data	416	0.05	0.12
Data after high LOQs exclusion*	369	0.04	0.11

*Data obtained with methods with LOQ values >0.12 mg/kg were excluded.

18. The effect of hypothetical MLs for lead in all sugars (brown sugar, raw cane sugar and non-centrifuged sugars) on sample rejection is shown in **Table 12**. Considering ALARA principles and rejection rates up to 5% from dataset with high LOQs excluded, a ML of 0.15 mg/kg for lead in all sugars (brown sugar, raw cane sugar and non-centrifuged sugars) is suggested.

Table 12. Effect of the implementation of hypothetical MLs for lead on all sugar (brown sugar, raw cane sugar and non-centrifuged sugars)

ML (mg/kg)	**Mean lead occurrence (mg/kg)**	**Sample rejection (%)**	**Intake reduction (%)[a]**
All data (n = 416)			
No ML	0.048	0.0	-
0.15	*0.037*	*4.3*	*21.7*
0.10	0.033	8.9	29.6
Data after high LOQs exclusion[b] (n = 369)			
No ML	0.038	0.0	-
0.15	*0.035*	*1.6*	*7.1*
0.10	0.031	6.5	17.9

[a] Sugar consumption of 111.73 g/person (G11); [b]Data obtained with methods with LOQ values >0.12 mg/kg were excluded.

Ready-to-eat meals for infant and young children

19. A total of 3,738 data of ready-to-eat meals for infant and young children were submitted from one region (WHO European) and eight countries (**Table 13, Appendix II – Table B1**). Based on CCCF15 report that considered a ML of 0.02 mg/kg for this category at step 5, a second dataset was organized removing data from analytical methods with LOQ above 0.02 mg/kg, even quantified results (**Table 14**). The effect of hypothetical MLs for lead in ready-to-eat meals for infant and young children on sample rejection is shown in **Table 15.**

20. During CCCF15 discussions, it was noted that certain foods that are very nutritious but may have slightly higher occurrence levels, e.g., certain root vegetables, which might require a separate treatment. Because of that, information on the field's "remarks" and "local food name" were considered to evaluate products containing roots vegetables separately. Information available does not allow to identify all the ingredients containing in the products and the proportion of them, only if the product had a specific ingredient that was reported on one of the fields mentioned before.

21. Products with fruits and meats were analysed separately in 2021 as shown in CX/CF 22/15/7 and CF15/CRD26. It was not observed a different profile contamination and thus this categorization was not reconsidered.

22. It was noted that products containing cereals could have a higher occurrence level. Information on the field's "remarks" and "local food name" were considered to evaluate products containing cereals separately. Information available does not allow to identify all the ingredients containing in the products and the proportion of them.

23. Considering ALARA principles and rejection rates up to 5% from dataset with high LOQs excluded, a ML of 0.03 mg/kg for lead could be established for ready-to-eat meals for infant and young children. The difference in the ML proposed in CCCF15 is related to the approach undertaken to treat left censored data. CX/CF 22/15/7 considered middle-bound approach while the upper-bound approach was considered here (see para 4 Appendix I).

24. A ML of 0.02 mg/kg could reject more than 5% of ready-to-eat meals for infant and young children containing cereals. Considering the difficulty in classifying products within this category as the products are in general multi-ingredient and that no percentage of cereals are available, it may be more appropriate to establish a ML for the whole category. For this reason, a ML of 0.03 mg/kg is proposed for ready-to-eat meals for infants and young children or to establish a ML 0f 0.02 mg/kg for ready-to-eat meals for infants and young children, excluding products with cereals.

25. It can be observed from **Table 13** that almost 50% of the results were excluded. All the samples from Australia, Saudi Arabia, Singapore and Thailand and significant part of the samples from USA and WHO European region were excluded.

26. From **Tables 14** and **15**, it can be observed that P95 for ready-to-eat meals for infants and young children containing cereals drop from 0.10 mg/kg to 0.02 mg/kg when samples analysed with LOQs higher than 0.02 mg/kg were excluded. This could indicate that methods used to analyse these products may not be accurate to evaluate a hypothetical ML of 0.02 mg/kg.

Table 13. Data contribution by country to ready-to-eat meals for infant and young children dataset for all data and data after the exclusion of samples with high LOQ

Countries	**n – All data**	**n – Data after high LOQs exclusion***	**Range of LOQ >0.02 mg/kg**
Australia	4	0	0.025
Brazil	7	7	-
Canada	741	741	-
China	18	18	-
Saudi Arabia	6	0	0.023
Singapore	38	0	0.03-0.3
Thailand	13	0	0.04
USA	546	321	0.021-5.1
WHO European region	2,365	1,000	0.021-0.067
Total	3,738	2,087	0.021-5.1

*Data obtained from analytical methods with LOQ values >0.02 mg/kg were excluded.

Table 14. Mean and 95th percentile for ready-to-eat meals for infant and young children datasets

Ready-to-eat meals	n	Mean (mg/kg)	95th percentile (mg/kg)
All types			
All data	3,738	0.01	0.04
Data after high LOQs exclusion[a]	2,087	0.01	0.02
Ready-to-eat meals containing roots[b]			
All data	182	0.01	0.02
Data after high LOQs exclusion[a]	168	0.01	0.02
Ready-to-eat meals containing cereals[b]			
All data	380	0.02	0.10
Data after high LOQs exclusion[a]	145	0.01	0.02

a) Data obtained with methods with LOQ values >0.02 mg/kg were excluded. b) products containing specified ingredients, but their proportion in products is unknown

Table 15. Effect of the implementation of hypothetical MLs for lead on ready-to-eat meals for infant and young children

ML (mg/kg)	Mean lead occurrence (mg/kg)	Sample rejection (%)
Ready-to-eat meals – All data (n = 3,738)		
No ML	0.015	0.0
0.05	0.011	2.2
0.04	0.010	3.3
0.03	0.009	7.1
0.02	0.009	13.0
Ready-to-eat meals – Data after high LOQs exclusion[a] (n = 2,087)		
No ML	0.008	0.0
0.05	0.008	0.3
0.04	0.008	0.7
0.03	0.007	1.8
0.02	0.007	5.3
Ready-to-eat meals containing roots[b] – All data (n = 182)		
No ML	0.008	0.0
0.04	0.008	0.5
0.03	0.007	0.5
0.02	0.006	8.2

ML (mg/kg)	Mean lead occurrence (mg/kg)	Sample rejection (%)
Ready-to-eat meals containing roots[b] – Data after high LOQ exclusion* (n = 168)		
No ML	0.007	0.0
0.04	0.007	0.6
0.03	0.007	0.6
0.02	0.006	4.8
Ready-to-eat meals containing cereals[b] – All data (n = 380)		
No ML	0.019	0.0
0.15	0.018	2.6
0.1	0.017	2.6
0.05	0.013	7.4
0.04	0.013	8.4
0.03	0.013	9.5
0.02	0.012	13.9
Ready-to-eat meals containing cereals[b] – Data after high LOQ exclusion[a] (n = 145)		
No ML	0.008	0.0
0.15	0.008	4.1
0.10	0.008	4.1
0.05	0.007	4.8
0.04	0.007	4.8
0.03	0.007	5.5
0.02	0.006	11.7

a)Data with methods with LOQ values >0.02 mg/kg were excluded. b) Products containing specified ingredients, but their proportion in products is unknown

Annex I: Tables

Table A1. Lead concentrations in **sugar subcategories** (LOQs excluded).

Food Category	Countries	N + / N	Mean (mg/kg)	Median (mg/kg)	95th Percentile (mg/kg)	97.5th Percentile (mg/kg)	Min (mg/kg)	Max (mg/kg)
Total	Brazil, Thailand, USA, WHO European Region	101/369	0.038	0.017	0.110	0.120	0.001	0.230
Brown sugar	Brazil, Thailand, USA, WHO European Region	31/81	0.045	0.050	0.119	0.154	0.0006	0.229
Raw cane sugar	Thailand, USA	101/227	0.022	0.010	0.065	0.099	0.0005	0.230
Non-centrifuged sugars	Brazil, USA	75/75	0.081	0.082	0.110	0.119	0.007	0.122

N^+/N = positive samples/total samples. Total data obtained with methods with LOQ values >0.12 mg/kg were excluded. Brown sugar data obtained with methods with LOQ values >0.20 mg/kg were excluded; Raw cane sugar data obtained with LOQ values >0.09 mg/kg were excluded. Non-centrifuged sugars data obtained with LOQ values >0.11 mg/kg were excluded.

Table B1. Lead concentration in food for **ready-to-eat meal for infants and young children** (LOQs excluded)

Food category	Countries	N+ / N	Mean (mg/kg)	Median (mg/kg)	95th Percentile (mg/kg)	97.5th Percentile (mg/kg)	Min (mg/kg)	Max (mg/kg)
Total	Brazil, Canada, China, USA, WHO European Region	777/2,087	0.008	0.005	0.021	0.028	0.0003	0.140
Ready-to eat meal** (containing cereal)	Canada, USA, WHO European region	57/145	0.008	0.004	0.023	0.026	0.0004	0.079
Ready-to-eat meals** (containing root)	Canada, USA,	73/168	0.007	0.005	0.019	0.023	0.0004	0.056

N^+/N = positive samples/total samples. ** products containing specified ingredients, but their proportion in products is unknown. Data obtained from analytical methods with LOQ values >0.02 mg/kg were excluded.

APPENDIX III

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