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CODEX ALIMENTARIUS COMMISSION

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World Health Organization

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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON CONTAMINANTS IN FOODS

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Bangkok, Thailand

MAXIMUM LEVELS FOR LEAD IN CERTAIN FOOD CATEGORIES

(Prepared by the Electronic Working Group chaired by Brazil)

Codex members and observers wishing to submit comments at Steps 6 and 3 on the proposed maximum levels for lead in certain food categories should do so as instructed in CL 2025/09-CF, available on the Codex webpage[1]

BACKGROUND

JECFA evaluations of lead

1. Lead exposure is associated with a wide range of toxic effects, including neurodevelopmental effects such as decreases in IQ and attention span in children, impaired renal function, hypertension, cardiovascular disease, impaired fertility, and adverse pregnancy outcomes. Foetuses, infants, and children are the subgroups that are most sensitive to lead. Based on the conclusions of the 73rd JECFA Meeting (JECFA73, 2010)[2] about dietary lead exposure in 2010, there is no safe level of lead. Therefore, measures should be taken to identify major contributing sources and, if appropriate, to identify methods for reducing dietary exposure.

2. Based on the conclusions of JECFA73, 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].

CCCF discussions on new MLs for lead in spices and culinary herbs

3. CCCF11 (2017) noted that the revision of MLs for lead was limited to those food categories listed in CXS193, and there was broad 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]

4. CCCF13 (2019) agreed to focus on ML proposals for lead in food for infants and young children (except those for which MLs had already been established in CXS193), spices and culinary herbs, eggs, sugars and confectionery, excluding cocoa. The EWG worked on lead data extracted from the GEMS/Food database, covering data analysed from 2008 to 2019. MLs were proposed for eggs, preserved eggs, fresh and dried culinary herbs and spices (including fruits and berries, fresh and dried rhizomes, bulbs and roots, bark, floral parts, and seeds). A call for data was issued by JECFA in July 2019, requesting lead data in food for infants and young children, as well as in spices, aromatic herbs, eggs, sugars, and confectionery (excluding cocoa).[5]

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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 https://www.who.int/publications/i/item/9789241209601

3 Reports of working documents of different sessions of CCCF can be found on the Codex/CCCF webpage:
https://www.fao.org/fao-who-codexalimentarius/committees/committee/en/?committee=CCCF

4 REP17/CF11, paras. 85-87, 89

5 REP19/CF13, paras. 88-96

5. Several new MLs for the foods mentioned above were established (and some discontinued) between CCCF14 (2021) and CCCF17 (2024). This summary focuses on the discussion on MLs for spices and culinary herbs.

6. Due to the COVID-19 pandemic, CCCF14 was postponed to 2021, and a call for data was issued in August 2020 to advance work on these MLs. CCCF14 agreed to continue working on MLs for lead in dried spices and culinary herbs, including dried bulbs, rhizomes and roots, and 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 database.

7. CCCF14 also concluded that there was no support for using concentration factors to derive an ML for dried culinary herbs; there was no support for applying the ML for fresh leafy vegetables to fresh culinary herbs; and noted that dried commodities are the main materials in international trade. The Committee thus agreed to postpone discussion on MLs for one year to allow for the submission of new data to the GEMS/Food database. If no new data were submitted, CCCF15 would make its decision based on the available dataset.[6]

8. Following CCCF14, a JECFA call for data was issued in July 2021, requesting lead data in cereal-based foods and ready-to-eat meals for infants and young children, as well as in dried spices and culinary herbs, eggs, sugars, and sugar-based candies.

9. CCCF15 (2022) agreed to continue discussing MLs for culinary herbs (fresh and dried) and spices (dried) following a JECFA call for data in 2022. The Committee also noted that sufficient data were available to set MLs for spices, fresh, and dried culinary herbs. If no new or few data are submitted for the call for data, CCCF should proceed to establish MLs using the available data. The Committee therefore agreed to return the MLs for spices and culinary herbs to Step 2/3 for further consideration by the EWG based on a JECFA call for data. The Committee encouraged interested Codex members to submit data, clearly identifying whether the samples were in a dried or fresh state, to the GEMS/Food database to consider proposals for MLs for fresh and dried culinary herbs at CCCF17. If no agreement is reached at CCCF17, the work on this category would be discontinued.[7]

10. CCCF16 (2023) recalled that the EWG, chaired by Brazil, would continue to work on MLs for lead in culinary herbs (fresh and dried) and spices (dried) for consideration by CCCF17, and that a JECFA call for data had already been issued.[8]

<u>Adoption of MLs for lead in spices</u>

11. CCCF17 (2024) agreed to forward to the 47th Session of the Codex Alimentarius Commission (CAC47, 2024), MLs for lead in the following spices: dried aril (0.9 mg/kg); dried seeds, excluding celery seed (0.9 mg/kg); dried celery seeds (1.5 mg/kg); dried rhizomes and roots (2.0 mg/kg); dried floral parts (2.5 mg/kg), dried fruit and berries, excluding Sichuan pepper, star anise, paprika and sumac (0.6 mg/kg); dried paprika and sumac (0.8 mg/kg) and dried Sichuan pepper and star anise (3.0 mg/kg) for final adoption at Step 5/8.[9]

12. CAC47 adopted these MLs at Step 5/8.[10]

<u>Continuation of work on MLs for lead in spices and culinary herbs</u>

<u>ML for dried bark</u>

13. CCCF17 considered different MLs for dried bark, ranging from 2.0 to 3.0 mg/kg, in relation to public health protection, trade facilitation (i.e., rejection rates), data availability, and data quality (i.e., data not based on good management practices).

14. Brazil, as EWG Chair, proposed advancing an ML of 2.5 mg/kg to Step 5 and further considering new data in the following year, should such data become available.

15. Members supporting the proposal of the EWG Chair requested that any new data that could reflect economic adulteration should be excluded and that the EWG could remove the outliers, as they may increase the high percentile samples.

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6 REP21/CF14, paras. 67-72; 101-102
7 REP22/CF15, paras. 85-92, 102-104
8 REP23/CF16, paras. 21, 29
9 REP24/CF17, paras. 21-36, 39-49, 61, Appendix II
10 REP24/CAC47, para. 63, Appendix II

16. CCCF17 agreed to advance an ML of 2.5 mg/kg to Step 5 for spices, dried bark, and to request the JECFA Secretariat to issue a call for data with a note that data which could be related to economic adulteration should not be submitted and that the EWG would consider the newly collected data in their review.[11]

17. CAC47 adopted the ML at Step 5 and advanced it to Step 6 for comments and further consideration by CCCF18.[12]

ML for dried culinary herbs

18. CCCF17 noted general support for an ML of 2.5 mg/kg for dried culinary herbs. However, it was pointed out that data were available to support the establishment of a lower ML for this commodity group, but these data were not accessible on the GEMS/Food database.

19. As the proposed ML was based on data available on the GEMS/Food database, Brazil, as EWG Chair, proposed advancing the ML of 2.5 mg/kg to Step 5 and further considering new data in the following year, should such data become available.

20. CCCF17 agreed to advance an ML of 2.5 mg/kg to Step 5 for dried culinary herbs, to change "humidity" with "moisture content" in the note to the ML, and to request the JECFA Secretariat to issue a call for data for lead in dried culinary herbs so that the EWG consider new available data in their review.[13]

21. CAC47 adopted the ML at Step 5 and advanced it to Step 6 for comments and further consideration by CCCF18.[12]

MLs for lead in dried bark and dried culinary herbs

22. The EWG continued to work on MLs for lead in dried bark and dried culinary herbs, to consider the relevance of the note on moisture content to the ML for fresh culinary herbs, for comments and consideration by CCCF18.

23. The JECFA Secretariat issued a call for data in June 2024 for lead in spices, dried bark, including a note not to submit data that could be related to economic adulteration, as well as for dried culinary herbs.

SUMMARY OF JECFA DATA CALLS TO SUPPORT WORK ON THE ESTABLISHMENT OF MLs FOR ADDITIONAL COMMODITIES

24. The following is the list of JECFA data calls issued by the JECFA Secretariat at the request of CCCF to support work on establishing new MLs for lead in commodities not included in CXS193, including spices and culinary herbs.

- JECFA call for data (2019)
  Issued in July 2019 with a deadline for submission of data of 15 November 15, 2020.
  https://www.who.int/news-room/articles-detail/lead-in-food-commodities.

- JECFA call for data (2020)
  Issue in August 2020 with a deadline for submission of data of November 21, 2020.
  https://openknowledge.fao.org/server/api/core/bitstreams/1cfa0a1b-cd2f-4045-a4c0-e5cdc393d4aa/content

- JECFA call for data (2021)
  Issued in July 2021 with a deadline for submission of data of October 15, 2021
  https://www.who.int/news-room/articles-detail/call-for-data-lead-in-food-commodities

- JECFA call for data (2022)
  Issued in July 2022 with a deadline for submission of data of October 10, 2022
  https://www.who.int/news-room/articles-detail/Call-for-data-lead-in-food-commodities-in-fresh-and-dried-culinary-herbs-and-dried-spices

- JECFA call for data (2024)
  Issued in June 2024, with a deadline for submission of data of October 31, 2024.
  https://www.who.int/news-room/articles-detail/lead-in-food-commoditiescall-for-data-on-lead-in-spices--dried-bark--and-dried-culinary-herbs

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11 REP24/CF17, paras. 37-38, 61, Appendix II
12 REP24/CAC47, para. 68, Appendix III
13 REP24/CF17, paras. 50-61, Appendix II

WORK PROCESS

25. Data on lead in dried bark and culinary herbs collected from 2014 to 2025 were extracted by the WHO administrator of the GEMS/Food database. They were analysed as detailed in Appendix II.

26. The EWG evaluated if the new data available could support the MLs' advancement to Step 5 or if other MLs were more appropriate based on the "as low as reasonably achievable" (ALARA) approach and considering a rejection rate of 5% or less.

27. ML proposals are available in Appendix I for comments, and the work process and the rationale for the ML recommendations are provided in Appendix II. A complementary table summarizing the lead levels in the commodities under discussion is provided in Appendix III, and the list of participants is available in Appendix IV.

28. The EWG had a short period to analyse data extracted from the GEMS/Food database and prepare the document; thus, only one draft was circulated, receiving comments from Canada, Japan, Mexico, Thailand, Uruguay, and the United States of America (USA).

SUMMARY OF KEY POINTS OF DISCUSSION

29. During the EWG discussion, it was requested to perform a sensitivity analysis considering the entire dataset and the dataset after removing samples with results reported on a dry weight basis. The analysis was done and included in Appendix II.

30. Based on the dataset available in the GEMS/Food database for lead in bark spices and considering CCCF17 discussions on the possibility that higher levels may be related to fraud, an analysis was conducted comparing the results obtained after the 2024 JECFA call for data. No reduction in the mean level was observed, and it was decided to propose an ML considering the entire dataset, as it is more globally representative.

31. One member pointed out that a Codex Standard for cinnamon is under development within the Codex Committee on Spices and Culinary Herbs (CCSH), as approved at CAC47. As no relevant Codex standard for bark spices exists, no information is added in the "Notes/Remarks" column at Appendix I for the moment.

32. One country requested an evaluation of samples with high limit of quantification (LOQ) values for dried herbs, as the first draft did not mention any analysis on this parameter. It was observed that a few samples (n = 23) were evaluated using methods with high LOQ values of 3 and 4 mg/kg. The results were all non-detected. Therefore, it was decided to remove these results from the analysis, as the methodology used is not appropriate for evaluating a possible ML of 2.5 mg/kg, which was advanced to Step 5 at CCCF17. The remaining samples were analysed using methods with an LOQ lower than 0.4 mg/kg.

33. It was requested to include 95th percentile (P95) values to decide on the need to exclude certain herbs from the ML. P95 values were included in Appendix III only for those herbs with 59 or more samples, as discussed in the "*Guidance on data analysis for the development of maximum levels and improved data collection*". P95 is at or below the ML; therefore, no specific herb is excluded from the ML of dried herbs.

34. Fourteen (14) data points of lead in Stevia were included in the first draft as they were reported in the food category "Herbs, spices and condiments". One country questioned if Stevia was used as a culinary herb. The EWG Chair then decided to exclude these data, as Stevia may not be used as a culinary herb in many countries.

35. Concern was raised regarding the fact that the majority of the data available on lead in culinary herbs originates from a single region (the WHO European Region). As Codex MLs serve as global standards, this disproportionate representation could not provide an appropriate basis for ML determination. P95 values were calculated by region and are presented in Appendix II, Table 5. P95 values by region based on data available in the GEMS/Food database are lower than the proposed ML of 2.0 mg/kg. Additionally, an analysis was performed of the impact of hypothetical MLs based on data from the region with the highest P95 value, confirming the applicability of the ML proposed.

36. The EWG members were asked to comment on whether the ML for dried culinary herbs should contain a note indicating that the ML for fresh culinary herbs could be extrapolated based on the moisture content of the dried versus the fresh one. Only one comment was received on this point, that if such information is considered, it should detail how the extrapolation is made. The Criteria for the Establishment of Maximum Levels in Food and Feed in Annex I of CXS193 address processing factors, such as drying, in the application of the MLs established for primary products to processed products and multi-ingredient products. It is suggested not to include any note on the possible extrapolation.

CONCLUSIONS

37. New MLs for lead in dried bark and in dried culinary herbs are proposed, based on the following considerations:

(i) The new MLs are based on the ALARA principle to ensure public health protection with minimal impact on trade, as rejection rates for the proposed MLs are less than 5%, the cut-off level agreed upon by CCCF.

(ii) The new MLs are based on data available in the GEMS/Food database, including a considerable amount of additional data submitted in response to the JECFA call for data issued in June 2024.

(iii) The new MLs take into consideration the discussions held at, and recommendations made by CCCF17, specially the inclusion of some missing data in CX/CF 24/17/5[3], exclusion of the outliers and the comparison between the data submitted after the last JECFA call for data on June 2024 and data submitted before that to assess the possibility to identify adulterated results, as well as broad discussions around MLs for lead in dried spices and culinary herbs.

(iv) The new MLs aim to reduce lead exposure in the diet and support fair trade practices.

38. CCCF should consider the new MLs proposed by the EWG based on the rationale provided in paragraph 39.

RECOMMENDATIONS

39. Based on the points raised in the conclusions, the additional data/information presented in Appendices II and III, and the assessment of such data/information as well as other considerations presented in the said Appendices, CCCF is invited to consider MLs for lead in dried bark and dried culinary herbs as presented in Appendix I as follows:

MLs for lead in dried bark and dried culinary herbs at Step 7

(i) Consider whether the MLs for spices, dried bark, and dried culinary herbs as proposed by CCCF17 (2024) and adopted by CAC47 (2024) should be discontinued.

MLs for lead in dried bark and dried culinary herbs at Step 4

(ii) Consider whether the new MLs for spices, dried bark, and dried culinary herbs as proposed by the EWG should be advanced in the Step Procedure for adoption by CAC48 (2025).

APPENDIX I

MAXIMUM LEVELS FOR LEAD FOR SELECTED FOOD CATEGORIES.

(For comments)

Commodity/Product Name	Maximum Level (ML) mg/kg (as adopted by CAC47 at Step 5) For comments at Step 6	Maximum Level (ML) mg/kg (new proposals by the EWG) For comments at Step 3	Portion of the Commodity/Product to which the ML applies	Notes/Remarks
Spices, dried bark	2.5	3.0	whole, ground, powder, crushed	-
Dried culinary herbs	2.5	2.0	whole, ground, powder, crushed	Relevant Codex commodity standards are CXS 328-2017, CXS 342-2021, CXS 345-2021.

APPENDIX II

SUMMARY REPORT
(For information)

LEAD OCCURRENCE IN FOODS

1. The EWG analysed data extracted in February 2025 by the WHO administrator of the GEMS/Food database, covering data from 2014 to 2024 of lead levels in spices, culinary herbs, and condiments. Data was categorized based on the names entered by the countries in the fields: Food Category, Food Name, Local Food Name, and Food State Name, removing data from fresh culinary herbs, condiments, and spices not from the group of consideration. The "Remarks" column was checked to evaluate if there was additional information that could support the classification. Based on the available data, food categories were grouped by food similarity, considering the classification[1] of spices and culinary herbs established by the Codex Committee on Spices and Culinary Herbs (CCSCH).

Table 1. Examples of foods in each subcategory of culinary herbs and spices.

Classification	Food examples
Culinary herbs	Apple mint, basil, bay leaves, celery, chervil, chives, cilantro, coriander, dill, dillweed, fennel, herbs NES, herb of grace, hyssop, kaffir lime leaves, lemon balm, lemongrass, lemon thyme, lovage leaves, mint, oregano, parsley, peppermint, pimpernel, rosemary, sage, savoury, stevia, tarragon, thyme, spearmint, wormwoods
Spices, dried, bark	Cinnamon, bark, canella bark, cassia bark

2. Data that did not meet basic criteria, such as incomplete information, analytical results from aggregated samples (i.e. samples reported as summary statistics rather than individually), duplicate data, targeted and unknown sampling, and results from samples collected before 2014 were not considered. Canada identified that some samples were reported as analysed following target sampling, but they should be considered as random sampling; hence, the data were included.

3. Ideally, data expressed on a different basis (i.e., results on a "dry weight" basis) should be converted to an "as is basis"; however, conversion information was not available in the GEMS/Food database. Therefore, it was decided not to consider results on a dry weight basis at this moment. It should be noted that this column on the GEMS/Food database is related to the basis for the analytical results. Thus, "dry weight basis" means that the result is reported considering the weight of the dehydrated sample. Data from Canada and Thailand, reported on a dry weight basis, were considered to be reported on an "as is" basis, as previously identified by these countries.

4. In the section on statistical analysis in the document "Guidance on data analysis for the development of maximum levels and improved data collection" (under discussion by CCCF), there was reference to three substitution methods to handle left-censored data: lower bound (LB), middle bound (MB) and upper bound (UB). The standard approach to deal with left-censored data is the use of the substitution approach. In this method, at the LB, results below the LOQ and LOD are replaced by zero; at the UB, the results below the limit of detection (LOD) are replaced by the numerical value of the LOD, and those below the limit of quantification (LOQ) are replaced by the value reported as LOQ. Since there is no indication on which method should be used in each case, the Electronic Working Group (EWG) decided to present the results using the LB and UB methods after converting all data to the same units (mg/kg).

[1] REP22/SCH06, Appendix VIII, Annex II

ANALYSIS OF FOOD CATEGORIES

DRIED BARK

5. A total of 854 individual results of lead in barks (cinnamon, cassia) are available in the GEMS/Food database from 5 regions (EMRO, EURO, PAHO, SEARO, WPRO), covering 15 countries and the European Union. Regions were grouped based on the information available in the GEMS/Food database, which categorizes the WHO Eastern Mediterranean Region as EMRO, the WHO European Region as EURO, the WHO/PAHO Region of the Americas as PAHO, the WHO South-East Asian Region as SEARO, and the WHO Western Pacific Region as WPRO. No data were submitted from the WHO African Region, AFRO. The data available is for both cinnamons, also referred to as Ceylon cinnamon or "true cinnamon", and Cassia, also referred to as "false cinnamon"[2]. Excluding results reported on a dry weight basis and those analysed following targeted sampling, 769 results were obtained from 13 countries and the European Union, representing 4 regions (EURO, PAHO, SEARO, WPRO).

6. Considering the raw dataset (N = 854), a mean level of 0.72 mg/kg was observed in the LB scenario and 0.73 mg/kg in the UB, with a 95th percentile (P95) of 2.46 in both cases. Excluding 42 data points with results reported on a dry weight basis, no significant difference in statistical parameters (mean and P95 value) was observed. The mean level of the cleaned dataset is 0.69 mg/kg in the LB scenario and 0.70 mg/kg in the UB scenario, and P95 is 2.33 (LB and UB).

7. One sample was considered an outlier, with a result (16.4 mg/kg) outside the data distribution of the other samples, as shown in Figure 1; hence, it was removed from the dataset. The final dataset comprised 768 remaining results, consisting of samples analysed from 2014 to 2024. Figure 1 illustrates the distribution of lead concentration data (mg/kg) in dried bark, while summary statistics by region are presented in Table 2. The orange line in Figure 1 was defined at 2.5 mg/kg, the ML under consideration.

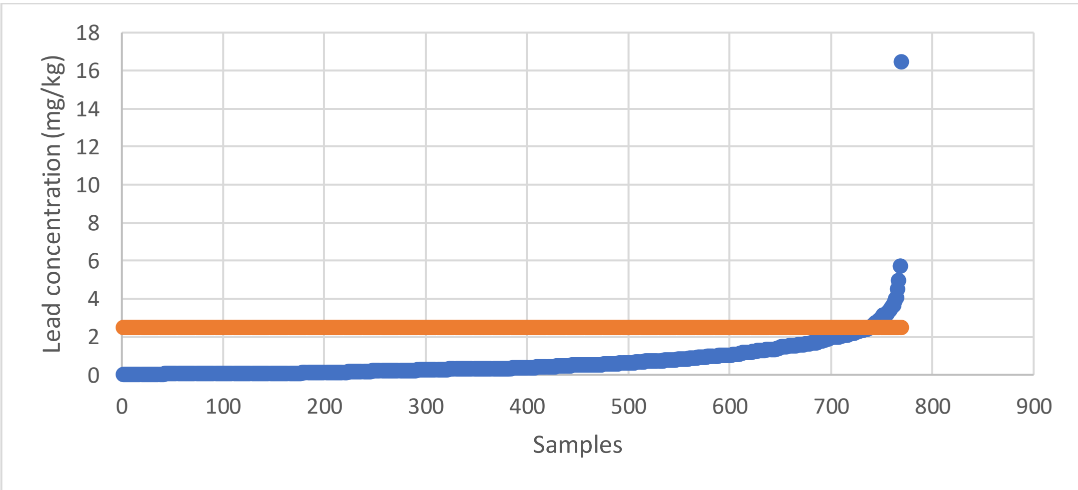

Figure 1: Lead data distribution (mg/kg) in dried bark.

2 CRD07, CCSCH7

Table 2. Summary statistics of lead concentration (mg/kg) in dried bark by region, showing the number of data (N), mean, and P95 levels in mg/kg.

Region (countries)	N	LB (mg/kg)		UB (mg/kg)	
		Mean	P95	Mean	P95
EURO (European Union)	84	0.72	1.97	0.75	1.97
PAHO (Brazil, Canada, Uruguay, USA)	301	0.89	2.88	0.89	2.88
SEARO (India, Indonesia, Sri Lanka, Thailand)	260	0.46	1.76	0.48	1.76
WPRO (China, Malaysia, New Zealand, Singapore, Vietnam)	123	0.52	2.15	0.52	2.15
Complete dataset	768	0.67	2.32	0.68	2.32

8. At the 17th Session of the Codex Committee on Contaminants in Foods (CCCF17, 2024), concerns were raised that bark could be adulterated and that high levels of lead could reflect economic adulteration. Besides the unique high level of 16.4 mg/kg in one sample, which was removed from the dataset, it was not possible to identify samples that could be considered adulterated. In the last JECFA call for data[3] on lead in spices, submission of new or additional data was requested, with a clear identification to exclude from the submission data that could be related to economic adulteration.

9. An analysis was made considering all data with 768 datapoints, ranging from 0.001 to 5.71 mg/kg, with a mean of 0.68 mg/kg and P95 of 2.32 mg/kg, as well as only data submitted in 2024 and 2025, with 284 datapoints ranging from 0.003 to 5.71 mg/kg, with a mean of 0.87 mg/kg and P95 of 2.3 mg/kg. Data were submitted by Canada (n = 11), the European Union (n = 80), Indonesia (n = 11), Singapore (n = 20), and the USA (n = 162), and were from samples analysed in 2016, 2020, 2022, 2023, and 2024.

10. In the 2024 call for data, it was requested that data that could be related to economic adulteration be excluded from the submission. Hence, it is considered that data submitted in 2024 and the beginning of 2025 reflect the natural occurrence of lead in bark spices. A slightly higher mean concentration was found in the data submitted following the call for data, showing that natural occurrence can be related to a few samples having high lead levels. As the entire dataset is more geographically representative, it was considered more appropriate to evaluate the impact of establishing hypothetical MLs based on all data available that meet the criteria (see paragraphs 2-4).

11. Summary statistics of lead data in bark for the entire dataset and data submitted in 2024 and 2025 are presented in Table 3. Hypothetical MLs are shown in Table 4 based on the entire dataset. The impact of establishing hypothetical maximum levels (MLs) for lead on dietary intake was evaluated for the GEMS/Food Cluster Diet with the highest consumption pattern (worst-case scenario – G12 = 0.4 g/person/day). LOQ values reported ranged from 0.001 mg/kg to 1.33 mg/kg; therefore, no sample was analysed with a method having a LOQ higher than the ML of 2.5 mg/kg.

[3] https://www.who.int/news-room/articles-detail/lead-in-food-commoditiescall-for-data-on-lead-in-spices--dried-bark--and-dried-culinary-herbs

Table 3. Number of samples and positive samples, minimum, maximum, mean, P95, and P97.5 values of lead levels (mg/kg) on dried bark.

	N/N+	Minimum (mg/kg)	Maximum (mg/kg)	LB (mg/kg)			UB (mg/kg)		
				Mean	P95	P97.5	Mean	P95	P97.5
Total	768/717	0.001	5.71	0.67	2.32	2.97	0.68	2.32	2.97
Data submitted in 2024 and 2025 (subset of Total)	284/276	0.024	5.71	0.85	2.32	2.98	0.86	2.32	2.98

N/N^{+}: Total samples/positive samples

Table 4. Effect of implementing hypothetical MLs for lead on dried bark (n = 768), based on the UB approach.

ML (mg/kg)	Mean levels (mg/kg)	Sample rejection (%)	Intake reduction* (%)
No ML	0.68	0.0	0.0
3.0	0.60	2.6	12
2.5	0.57	4.0	16
2.0	0.49	8.2	27
1.5	0.40	14.8	41
1.0	0.31	23.7	55

*Intake at the worst-case consumption scenario: Bark (0.4 g/day G12); theoretical body weight value = 70 kg.

12. P95 values are higher in the PAHO region, with a P95 of 2.88 mg/kg that is higher than the ML of 2.5 mg/kg. The effect of implementing hypothetical MLs for lead on dried bark in the PAHO region is shown in Table 5. An ML of 2.5 mg/kg could result in the rejection of almost 7% of samples from this region, and an ML of 3.0 mg/kg is more appropriate.

Table 5. Effect of implementing hypothetical MLs for lead on dried bark (n = 301) in the PAHO region, based on the UB approach.

ML (mg/kg)	Mean levels (mg/kg)	Sample rejection (%)	Intake reduction* (%)
No ML	0.89	0.0	0.0
3.0	0.76	4.98	15
2.5	0.71	6.98	23
2.0	0.61	12.96	39
1.5	0.48	22.59	67
1.0	0.38	32.23	107

*Intake at the worst-case consumption scenario: Bark (0.4 g/day G12); theoretical body weight value = 70 kg.

DRIED CULINARY HERBS

13. At CCCF17, concerns were raised about the exclusion of over 1,500 samples of dry culinary herbs from the European Union. After the meeting, the EWG chair met with delegates from the European Union, including EFSA personnel, and the GEMS/Food Administrator. The raw European database was sent for consideration.

14. The GEMS/Food Administrator made a great effort to upload the European data and extracted all available data from the database in February 2025. Nevertheless, it was observed that a huge amount of European data was still missing. With the aim of not hindering the progress of discussions and allowing the topic to be discussed at CCCF18, the EWG chair decided to eliminate all European data from the file sent by the GEMS/Food Administrator and instead consider the raw data sent by the European Union directly to the EWG.

15. Twenty-three (23) samples with non-detected results were analysed using LOQ values of 3.0 mg/kg (n = 22) or 4.0 mg/kg (n = 1). They were excluded from further analysis because the results did not allow for verifying the achievability of an ML of 2.5 mg/kg, which was advanced to Step 5 at CCCF17. One sample was considered an outlier (see Figure 2), with a concentration of 28.3 mg/kg, and hence, was removed from the dataset. Additionally, it was observed that the dataset included 14 results from lead in dried Stevia, which may not be used as culinary herbs in many countries, and the data was excluded. The exclusion of Stevia data did not affect the mean level of the 2,297 remaining results.

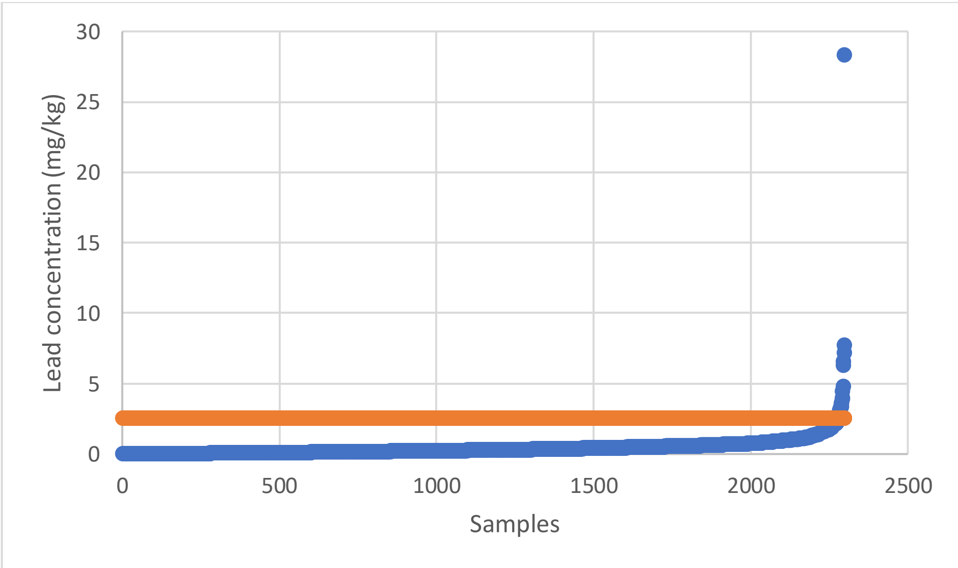

Figure 2: Distribution of lead concentration data (mg/kg) in dried culinary herbs.

16. Considering the dataset of 2,297 datapoints, the mean is 0.40 mg/kg (LB and UB) and P95 is 1.2 mg/kg (LB and UB), with results varying from 0.047 to 7.7 mg/kg and LOQ values ranging from 0.003 to 0.395 mg/kg. Removing 75 samples with results reported on a dry weight basis, there are 2,222 datapoints with quantified values ranging from 0.005 to 7.7 mg/kg, with a mean level of 0.40-0.41 mg/kg (LB-UB) and P95 of 1.20 (LB and UB). The removal of results reported on a dry weight basis didn't result in different values of mean or P95.

17. One hundred ninety-two (192) samples out of the 2,222 were neither identified as fresh nor as dried, with a mean level of 0.24 mg/kg, and results varied from 0.005 to 6.57 mg/kg.

18. The number of samples available, mean, and P95 values of lead data in dried and non-identified culinary herbs, either fresh or dried, by region, are presented in Table 6.

Table 6. Mean levels of lead (mg/kg) in dried and non-identified, either fresh or dried culinary herbs, by region.

Region (countries)	N	LB		UB	
		Mean (mg/kg)	P95 (mg/kg)	Mean (mg/kg)	P95 (mg/kg)
EMRO (Egypt, Morocco, Saudi Arabia)	34	0.16	0.51	0.16	0.51
EURO (Albania, EU, Switzerland, Turkey, United Kingdom)	1,826	0.38	1.10	0.39	1.10
PAHO (Brazil, Canada, Peru, Uruguay, USA)	274	0.58	1.83	0.58	1.83
SEARO (India, Indonesia, Thailand)	39	0.38	0.94	0.38	0.94
WPRO (New Zealand, Singapore)	49	0.36	0.61	0.36	0.61
Complete dataset	2,222	0.40	1.20	0.41	1.20

19. The mean, minimum, and MLs of lead concentration in specific dried culinary herbs were estimated and can be found in Appendix III. P95 values were calculated only for herbs with at least 59 results, considering the discussions on the "Guidance on data analysis for development of maximum levels (MLs) and for improved data collection.". Due to the diversity of samples, number, and types of herbs, it was proposed to consider all culinary herbs to establish a single ML for lead. Additionally, the P95 for specific herbs, as detailed in Appendix III, is 2.0 or below. Summary statistics, including the total number of samples (N), the number of positive samples (N+), the mean, the P95, and P97.5, as well as the minimum and maximum concentrations, are presented in Table 7.

Table 7. Summary statistics of lead levels in dried culinary herbs.

N/N+	Minimum	Maximum	LB (mg/kg)			UB (mg/kg)		
			Mean	P95	P97.5	Mean	P95	P97.5
2,222/2,109	0.005	7.70	0.40	1.20	1.68	0.41	1.20	1.68

N^+: number of positive samples

20. The impact of establishing hypothetical MLs for lead on dietary intake was evaluated for the GEMS/Food Cluster Diet with the highest consumption pattern (worst-case scenario - G09 = 8.89 g/person/day) (Table 8). As the highest P95 was seen in the PAHO region (Table 6), an analysis of the impact of the hypothetical MLs was also done for this region (Table 9). Although an ML of 2.5 mg/kg was advanced to Step 5 by CCCF17 and adopted at Step 5 by CAC47, a revised ML of 2.0 mg/kg is now proposed based on newly available data, to further reduce consumer exposure while maintaining the violation rate in international trade below 5%.

Table 8. Effect of implementing hypothetical MLs for lead in dried culinary herbs, based on the UB approach.

ML (mg/kg)	**Mean levels (mg/kg)**	**Sample rejection (%)**	**Intake reduction* (%)**
No ML	0.41	0.0	0.0
3.0	0.38	0.7	7
2.5	0.37	0.9	8
2.0	*0.36*	*1.7*	*12*
1.5	0.34	3.4	17
1.0	0.29	7.9	27

*Considering the highest consumption of raw culinary herbs (including dried and fresh) in cluster diets of 8.89 g/person/day in cluster diet G09, considering body weight of 70 kg.

Table 9. Effect of the implementation of hypothetical MLs for lead on dried culinary herbs, based on UB approach, for PAHO region.

ML (mg/kg)	**Mean levels (mg/kg)**	**Sample rejection (%)**	**Intake reduction* (%)**
No ML	0.58	0.0	0.0
3.0	0.50	1.8	13
2.5	0.48	2.5	16
2.0	*0.45*	*4.7*	*23*
1.5	0.42	6.9	28
1.0	0.34	15.0	41

Considering the highest consumption of raw culinary herbs (including dried and fresh) in cluster diet G09, at 8.89 g/person/day, given a body weight of 70 kg.

APPENDIX III

Table A: Summary statistics of lead concentration (mg/kg) in dried bark spices, using upper-level approach

Food	N/N+	Mean (mg/kg)	P95 (mg/kg)	Minimum (mg/kg)	Maximum (mg/kg)
Bark total	768/717	0.68	2.3	0.001	5.71
Cinnamon	589/565	0.78	2.4	0.001	4.98
Cassia	179/152	0.33	1.5	0.017	5.71

Table B: Summary statistics of lead concentration (mg/kg) in dried culinary herbs, using upper-level approach

Food name	N	Mean (mg/kg)	P95 (mg/kg)	Minimum (mg/kg)	Maximum (mg/kg)
Apple mint	1	0.350	-	0.350	0.350
Basil	93	0.359	0.95	0.004	1.27
Bay leaf	30	0.764	-	0.060	2.760
Celery	2	0.390	-	0.270	0.510
Chervil	2	0.580	-	0.250	0.910
Chives	9	0.057	-	0.016	0.095
Cilantro	1	1.701	-	1.701	1.701
Common Nettle	264	0.554	1.79	0.054	4.800
Coriander	19	0.226	-	0.023	1.13
Dill	17	0.113	-	0.005	0.360
Dillweed	3	0.148	-	0.116	0.176
Fennel	2	0.098	-	0.026	0.170
Herbs of grace	1	0.263	-	0.263	0.263
Herbs, NES	722	0.265	1.07	0.003	7.700
Hibiscus	1	0.023	-	0.023	0.023
Hyssop	1	0.190	-	0.190	0.190
Kaffir lime leaves	1	0.255	-	0.255	0.255
Lemon balm	43	0.401	-	0.050	1.850
Lemon thyme	2	0.342	-	0.073	0.610
Lemongrass	49	0.243	-	0.014	0.777
Lovage leaves	7	0.490	-	0.250	0.720
Marjoran	121	0.422	0.96	0.020	3.620
Mint	24	0.690	-	0.016	1.630
Oregano	96	0.427	1.31	0.001	3.970
Parsley	67	0.146	0.47	0.005	0.900
Peppermint	110	0.361	0.84	0.030	3.200
Pimpernel	2	0.080	-	0.080	0.080
Rosemary	162	0.443	0.78	0.015	2.135
Sage	85	0.714	2.04	0.043	3.320
Savory	30	0.314	-	0.010	0.764
Spearmint	37	0.264	-	0.026	1.010
Tarragon	23	0.189	-	0.022	0.980
Thyme	188	0.747	1.50	0.020	6.570
Wormwoods	7	0.983	-	0.120	3.900

APPENDIX IV
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