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CODEX COMMITTEE ON CONTAMINANTS IN FOODS

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MAXIMUM LEVELS FOR LEAD IN CERTAIN FOOD CATEGORIES

(At Step 4)

(Prepared by the Electronic Working Group chaired by Brazil)

Codex members and observers wishing to submit comments at Step 3 on MLs for lead in certain food categories should do so as instructed in CL 2024/02-CF available on the Codex webpage[1]

BACKGROUND

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 about dietary lead exposure in 2011, there is no safe level of lead. So, measures should be taken to identify major contributing sources and, if appropriate, to identify methods of reducing dietary exposure.

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, 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. 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 several food categories including culinary herbs (fresh and dried) 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. 87, 89

3 REP 18/CF12, para. 131

4 REP 19/CF13, paras. 90-96

5. Due to the COVID19 pandemic, CCCF14 was postponed to 2021 and a new JECFA call for data[5] was issued in 2020. 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, amongst others, considering the written comments that were received, decisions made at the session and new data available in the GEMS/Food database.

6. CCCF14 considered spices and culinary herbs and concluded that there was no support for the use of concentration factors to derive an ML for dried culinary herbs; there was no support to apply the ML for fresh leafy vegetables to fresh culinary herbs; and it noted that the dried commodities are the main materials in international trade. The Committee agreed to postpone discussion on MLs for one year to allow submission of new data to GEMS/Food database and if no new data were submitted, that CCCF15 would take a decision based on the available dataset.[6]

7. CCCF15 (2022) noted that there was sufficient data available to set MLs for spices, fresh and dried culinary herbs and in case that no new or few data are submitted for the call for data, CCCF should proceed to establish MLs with the available data. Consequently, CCCF agreed to return the MLs for spices and culinary herbs to the EWG for further consideration based on a new JECFA call for data in 2022. It was agreed to discontinue work on an ML for lead in dried garlic.

8. 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[7] for consideration by CCCF17 (2024). CCCF 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 became available. CCCF also encouraged interested Codex members to submit data with clear identification of the dried/fresh state of the samples to GEMS/Food database to consider proposals for MLs for fresh and dried culinary herbs at CCCF17 (2024) and if no agreement is reached at CCCF17, to discontinue work on this category.[8]

WORK PROCESS

9. Data on lead in spices and culinary herbs collected from 2011 to 2022 were extracted by the WHO administrator of GEMS/Food database and were analysed as detailed in APPENDIX II.

10. 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 general support at CCCF14 for a maximum cut-off at 5% but with the acceptable rejection rates to be determined on a case-by-case basis in CCCF14[9].

11. MLs proposals also considered the availability and amount of occurrence and consumption data.

12. MLs proposals are available in Appendix I for comments and the working process and the rationale for the ML recommendations is provided in Appendix II. Complementary table with the mean level of the commodities under discussion is provided in Appendix III and the list of participants is available in Appendix IV.

13. This document circulated twice, and comments were received from Canada, Chile, China, Indonesia, Iran, Japan, Mexico, the Netherlands, Thailand, Türkiye, the United States of America and IOSTA (International Organization of Spice Trade Associations).

14. Based on the comments received, the following modifications were made:

    a. editorial amendments;

    b. the inclusion of occurrence data submitted as “dry weight basis” from country members that informed that their data should have been submitted as “as is” basis instead (China, Canada, Japan, Thailand);

    c. the inclusion of occurrence data of culinary herbs submitted without clear identification if they were dried or fresh from one country member that informed that their data should have been submitted as “fresh culinary herbs” instead (Thailand);

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5 https://www.fao.org/3/cb0618en/cb0618en.pdf

6 REP21/CF14, paras. 67-72, 101

7 https://www.who.int/news-room/articles-detail/Call-for-data-lead-in-food-commodities-in-fresh-and-dried-culinary-herbs-and-dried-spices

8 REP22/CF15, para. 85-92, 102

9 REP21/CF14, para. 62

d. reclassification of subcategories proposed for spices and culinary herbs based on the classification established by the Committee on Spices and Culinary Herbs (CCSCH) in REP22/SCH06, Appendix VIII; and

e. datasets with and without samples with limit of quantification (LOQs) higher than the initial proposed ML were analysed.

SUMMARY OF KEY POINTS OF DISCUSSION

Data

15. One country questioned if some herbs such as chamomile would be considered as infusion. Only samples submitted as being Herbs, spices and condiments were extracted by the GEMS/Food database administrator and were thus considered by the EWG as being destined for use as culinary herbs and not for infusions.

16. It was raised that spices are in general traded dried, so it was decided to exclude samples identified clearly as being fresh. Additionally, samples of spices that were not identified as "fresh" or "dried" were retained. For culinary herbs, it was considered only samples clearly identified as being fresh or dried, not considering data that do not have a clear identification.

17. In the second draft one country asked about the food name mentioned on the document (as example: Anise). The EWG informs that the food names were obtained from the GEMS/Food database as described by each country. So, only Anise seed was considered as being Spices, dried seeds.

Geographical representative data

18. It is a recurrent issue that there is limited geographical representation in establishing MLs. In 2022, CCCF15 encouraged interested Codex members to submit data to GEMS/Food database with clear identification if the samples were dried or fresh to allow the discussion of ML proposals for lead in fresh and dried culinary herbs at CCCF17 session (2024).

19. The EWG clarifies that after the JECFA call for data in 2022, a total of 4,063 new data from Canada, China, European Union, United Kingdom, New Zealand, United States were submitted (GEMS/Food database Submission Date column) and 3,097 were sampled after 2011 year.

20. Considering all data available and after applying the criteria as detailed in APPENDIX II, the EWG worked with 7,519 data in total that were indicated as appropriated using the "Guidance on data analysis for development of maximum levels and for improved data collection" as reference.

Obtaining the second dataset

21. One country mentioned that the specific treatment of left-censored data in the upper bound (UB) scenario and the lower bound (LB) scenario is unknown because the "Guidance on data analysis for the development of maximum levels and improved data collection" are being developed. Until the aforementioned discussion is finalized, the EWG advises that the standard approach to dealing with left-censored data is to use the substitution methodology, in which results below the LOQ and below the limit of detection (LOD) are replaced by zero at the LB and results below the LOD are replaced by the numerical value of the LOD and those below the LOQ are replaced by the value reported as LOQ at the UB.

22. It was observed that 20% of results of lead were non-detectable (ND). Although during the discussion of the "Guidance on data analysis for the development of maximum levels and improved data collection" there were requests to conduct an impact assessment to compare datasets with and without samples with LOQs higher than the initial proposed ML, no approach was recommended by the EWG, especially in cases where few data are ND. Given that, the EWG excluded results obtained with methods with a LOQ higher than the initial proposed ML (Tables 4 and 8 in Appendix II), and no relevant impact were observed.

MLs proposals

23. There was a general support to establish MLs for the whole categories. One country questioned about the difference between rejection rate for the whole category and specific commodities if applied the same MLs. When different contamination profile is seen for specific commodities, individual MLs are proposed. However, due to the low sample number of different commodities in the same (sub)category, establishing individual MLs may not be possible. So, the EWG considered to be feasible to establish MLs for the whole category as proposed in Appendix I, with the exceptions identified.

24. In general, the MLs proposed for spices and culinary herbs presented by the EWG are similar to MLs reported in some national/regional regulations as mentioned for some country members.

25. Countries mentioned that MLs for culinary herbs should be set only for dried culinary herbs, considering this is the main form presented in international trade for this commodity. Furthermore, it was raised that the ML for fresh leafy vegetables should not be applied to fresh culinary herbs, as already discussed by CCCF14. However, one country is of the view that the most culinary herb trade is in the form of fresh herbs. For the reasons explained, the EWG suggests that MLs be set for both (fresh and dried).

26. One country mentioned that since occurrence levels of lead in the subcategories of fruit and berries spices were not different, pepper (black, green and white) should be included in the ML for fruit and berries spices. Another country asked to exclude Sichuan Pepper from the ML considering that their own data showed different profiles. The EWG, after re-analysing Sichuan pepper data, recommend excluding this commodity from the ML for the category fruit and berries spices, as data were mainly from only one country and the levels were higher than the remaining commodities in the category. The Committee should discuss if a ML of 3 mg/kg could be set for Sichuan pepper based on data from only one country or if no ML should be set for this spice and it is excluded from ML for fruit and berries spices.

27. In general, there was agreement with the MLs proposed for all categories and (sub)categories. Countries agreed with the proposal of ML of 2.5 mg/kg for lead in Spices, dried rhizomes, bulbs, and roots with the exclusions notes for galangal and garlic, considering the occurrence data of "Ginger, only reported dried" and that the impact on the intake is similar for hypothetical MLs of 2.0 and 2.5 mg/kg.

28. In general, country members supported that the MLs in each spice group should be set for the whole category without adding the list of spices that were included in the discussion, which was made considering the information available on GEMS/Food database. However some contries reported it could be important to keep this information in notes/remarks for understanding the range of each category.

CONCLUSIONS

29. MLs for lead in dried spices and in culinary herbs (dried/fresh) are being proposed considering ALARA, with rejections rates less than 5%.

30. Based on data available on GEMS/Food database, including a considerable amount of new data submitted, and considering the discussions held in CCCF15 and broad discussions around MLs for lead in dried spices and culinary herbs, the impact on health and the already identified need to reduce lead dietary exposure, it is appropriate to establish MLs.

RECOMMENDATIONS

31. CCCF is invited to consider the ML proposals for spices and culinary herbs as presented in Appendix I, considering data/information provided under the key points of discussion and Appendices II and III.

APPENDIX I

PROPOSED MAXIMUM LEVELS FOR LEAD FOR CERTAIN FOOD CATEGORIES

(For comments at Step 3)

Codex members and observers are kindly invited to consider to:

1. SPICES

1.1 Consider the following MLs for spices

Commodity/ Product Name	Maximum Level (ML) mg/kg	Portion of the Commodity/Product to which the ML applies	Notes/Remarks
Spices, dried bark[a]	2.5	whole, ground, powder, crushed	
Spices, dried flowers[b]	0.4	whole, ground, powder, crushed	
Spices, dried floral parts[c]	2.5	whole, ground, powder, crushed	Relevant Codex commodity standard is CXS 344-2021.
Spices, dried fruits and berries[d]	0.6	whole, ground, powder, crushed	The ML does not apply to Sichuan pepper. Relevant Codex commodity standards are CXS 326-2017 and CXS 353-2022.
Sichuan pepper	3.0	whole, ground, powder, crushed	
Spices, dried rhizomes, bulbs and roots[e]	2.0	whole, ground, powder, crushed	The ML does not apply to dried galangal and garlic. Relevant Codex commodity standard is CXS 343-2021.
Spices, dried seeds[f]	0.8	whole, ground, powder, crushed	Relevant Codex commodity standards are CXS 327-2017 and CXS 352-2022.
Spices, dried aril[g]	0.9	whole, ground, powder, crushed	

a: Cinnamon, canella, cassia.

b: Chamomile flower.

c: Saffron, Cloves, Capers.

d: Star Anise, Cardamom, Cayenne, Black pepper, Green pepper, White pepper, Pink pepper, Red pepper, Paprika, Peppers chilli, Pimento, Tamarind, Sumac, Vanilla.

e: Ginger, Turmeric.

f: Anise seed, Coriander seed, Cumin seed, Dill seed, Fenugreek seed, Fennel seeds, Mustard, Nutmeg.

g: Mace.

1.2 Evaluate if the MLs should consider the whole category or only the specific spices for which there are data available on GEMS/Food database be considered.

2. CULINARY HERBS

2.1 Consider the following MLs for culinary herbs

Commodity/ Product Name	Maximum Level (ML) mg/kg	Portion of the Commodity/Product to which the ML applies	Notes/Remarks
Fresh culinary herbs	0.2	Whole commodity	
Dried culinary herbs	2.5	Whole commodity	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 Electronic Working Group (EWG) analysed data extracted in February 2023 by the WHO administrator of GEMS/Food database, covering data from 2011 to 2022 of lead levels in spices and culinary herbs. 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. Based on the data available, food categories were grouped by food similarity considering the classification provided in the template for Codex standards for spices and culinary herbs as shown in REP22/SCH06, Appendix VIII, Annexes I and II.

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

Classification	Food examples
Culinary herbs	Mixed herbs, anise, basil, celery, cilantro, chamomile, chives, coriander, dill, fennel leaves, holy basil, kaffir lime leaves, lemon grass, lemon basil, mint, oregano, parsley, thyme, sage, rosemary
Spices, dried, seed	Anise seed, coriander seed, cumin seed, dill seed, fenugreek seed, fennel seeds, mustard, nutmeg
Spices, dried, fruits and Berries	Anise, cardamom, cayenne, chilli, paprika, ground chili, pimento, tamarind, star anise, sumac, vanilla, pepper (black ,white, green), Sichuan pepper
Spices, dried, bark	Cinnamon, bark, canella bark, cassia bark
Spices, dried, rhizomes, bulbs, and roots	Asafoetida roots, coriander root, ginger (galangal), turmeric (curcuma)
Spices, dried, floral parts	Saffron, cloves cassia, capers
Spices, dried, flower	Chamomile flower
Spices, dried, aril	Mace

2. A total of 19,264 data were extracted covering spices, herbs, and condiments. 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), duplicates data, targeted and unknown sampling and results from samples collected before 2011 were not considered.

3. The 15th Session of the Codex Committee on Contaminants in Foods (CCCF15, 2021) had encouraged interested Codex members to submit data with clear identification of the dried/fresh state of the samples to GEMS/Food database to consider proposals for maximum levels (MLs) for fresh and dried culinary herbs and dried spices at CCCF17 (2024). 4,063 results were submitted in 2022 from Canada, China, European Union (EU), United Kingdom, New Zealand, United States of America (USA) and thus many data submitted before did not comply if this criterion and were excluded as detailed in paragraphs 5-6.

4. Data which do not clearly identify the species of spices or culinary herbs were considered as incomplete information. Data from garlic, onion, sauce, condiment, savoury, summer, winter, salt, essence, yeast, mayonnaise, ketchup, pectin, pasta, seaweeds, belachan, curry, masala, miso, tea, vinegar, stock cubes and fresh spices were excluded. Ideally data expressed on different basis (*i.e.,* results on a "dry weight" basis) should be converted to an "as is basis", however, the conversion information was not available in GEMS/Food database. Therefore, it was decided to not consider results on a dry weight basis at this moment. It should be noted that this column on GEMS/Food database is related to the basis for the analytical results and thus "dry weight basis" means that the result is reported considering the weight of the dehydrated sample.

5. Fresh spices samples were excluded because only dry spices were being used to establish MLs. The EWG also identified inconsistencies in the "food state name" column, such as, dried ginger or ginger; paprika, paprika pods or paprika powder being described at the same time as raw and unknown. Even so, the EWG decided to consider all samples as dried, except those clearly described as being fresh. [1]

[1] REP22/CF15, paras 71-104

6. For culinary herbs, the EWG divided the data in order to differentiate between fresh and dried culinary herbs. Firstly, all data available were considered and were presented to demonstrate the inconsistences in GEMS/Food database. After comments received on the first draft of the document, the EWG decided to analyse only culinary herbs data clearly described as dried and fresh, excluding those that did not identify the state of the herb.

7. 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 was the use of the substitution. In this method, at the LB, results below the limit of quantification (LOQ) and limit of detection (LOD) are replaced by zero; at the UB the results below the LOD are replaced by the numerical value of the LOD and those below the LOQ are replaced by the value reported as LOQ. Since there is no indication on which method should be used in each case, the EWG decided to present the results using LB and UB methods after converting all data to the same units (mg/kg) (Summary Tables).

8. Summary statistics including total number of samples, mean, and 95th percentile (P95) concentrations were determined also for this second dataset for each category. Finally, hypothetical MLs and the rate of sample rejection were analysed aiming to propose MLs. Data were organized using Microsoft® Excel version Office 365. The statistical analysis was performed by using statistic program SAS® (Statistical Analyses System) *OnDemand for Academics*, with Microsoft® Excel version Office 365, was also used to validate the SAS information.

ANALYSIS OF FOOD CATEGORIES

DRIED SPICES

9. After applying the exclusion criteria (see paragraphs 2-4), the EWG considered then a total of 7,624 data (dried and non-identified as fresh spices), from 6 regions (AFRO, EMRO, EURO, PAHO, SEARO, WPRO) and 35 countries (Table 2). Due to the absence of a clear description about the name in the GEMS/Food database, some spices could not be identified and classified into the groups. A total of 1,092 data points that corresponded to non-classified spices were excluded, leaving 6,532 samples (Table 3). The global mean level of lead in dried spices ranged from 0.34 mg/kg (LB) to 0.35 mg/kg (UB).

10. The distribution by region, as described in the GEMS/Food database is presented in Table 2. The lowest levels of lead were observed in the EMRO region (corresponding to the countries Afghanistan, Egypt, Iran, and Syria), that together submitted 35 samples that met the inclusion criteria.

Table 2. Distribution and mean and P95 levels of lead in all spices (mg/kg) by region.

Region (countries)	N	LB (mg/kg)		UB (mg/kg)	
		Mean	P95	Mean	P95
AFRO (Comoros, Zambia, South Africa, Nigeria, Kenya)	24	0.19	0.71	0.19	0.71
EMRO (Syrian, Iran, Egypt, Afghanistan)	35	0.10	0.21	0.10	0.21
EU	6	0.11	0.23	0.19	0.23
EURO (Ukraine, Spain, European Union, Türkiye, Yugoslavia)	1,318	0.18	0.56	0.20	0.57
PAHO (Brazil, Canada, Ecuador, Guatemala, Honduras, Jamaica, Mexico, Peru, Uruguay, USA)	1,898	0.53	1.19	0.53	1.19
SEARO (India, Indonesia, Sri Lanka, Thailand)	2,982	0.27	1.09	0.34	1.09
WPRO (China, Japan, Malasia, New Zealand Singapore, Vietnam)	1,361	0.65	2.19	0.67	2.19

11. Dried spices, when categorized by similarity (7 groups), have mean levels of lead ranging from 0.05 mg/kg to 0.70 mg/kg (LB) and from 0.06 mg/kg to 0.70 mg/kg (UB) (Table 3).

Table 3. Number of samples and positive samples, minimum, maximum, mean, Percentiles 95th and 97.5th values of lead levels (mg/kg) on dried and spices not identified as fresh spices.

Group	N/N+	Minimum (mg/kg)	Maximum (mg/kg)	LB (mg/kg)			UB (mg/kg)		
				Mean	P95	P97.5	Mean	P95	P97.5
Spice, dried, aril	64/63	0.04	1.23	0.24	0.83	0.98	0.24	0.83	0.99
Spice, dried, bark	549/495	0.001	23.8	0.60	2.32	3.12	0.60	2.32	3.12
Spice, dried, floral	105/92	0.001	6.70	0.37	2.19	2.96	0.38	2.19	2.96
Spice, dried, flower	126/76	0.000	0.77	0.05	0.40	0.47	0.06	0.40	0.47
Spice, dried, fruits and berries	3,208/2,852	0.000	33.3	0.37	1.40	2.14	0.38	1.44	2.20
Spice, rhizomes, bulbs and roots	1,422/1,363	0.000	135.6	0.69	1.75	3.15	0.70	1.75	3.15
Spice, dried, seeds	1,058/898	0.001	11.7	0.20	0.75	1.03	0.21	0.75	1.03
Total	6,532/5,868	0.000	135.6	0.43	1.50	2.28	0.44	1.50	2.28

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

12. To avoid bias due to a distortion in distribution of data obtained from partial exclusion of data, the EWG proposes to remove all data from methods with LOQ higher than MLs proposal (Table 4). It was observed differences only for some dried spices: bark; fruits and berries, flowers, rhizomes, bulbs and roots and seed.

Table 4 Mean, Percentiles 95th and 97.5th values of lead levels (mg/kg) on dried spices not identified as fresh spices from dataset after the exclusion of samples with high LOQ.

Group	N/N+	LB (mg/kg)			UB (mg/kg)		
		Mean	P95	P97.5	Mean	P95	P97.5
Spice, dried, aril[a]	64/63	0.24	0.83	0.98	0.24	0.83	0.99
Spice, dried, bark [b]	549/495	0.61	2.39	3.13	0.62	2.39	3.13
Spice, dried, floral[c]	105/105	0.37	2.19	2.96	0.38	2.19	2.96
Spice, dried, flower [d]	124/76	0.06	0.40	0.47	0.06	0.40	0.47
Spice, dried, fruits and berries[e]	3,203/2,851	0.37	1.40	2.14	0.38	1.44	2.20
Spice, rhizomes, bulbs and roots[f]	1,418/1,359	0.57	1.69	2.87	0.57	1.69	2.87
Spice, dried, seeds[g]	1,056/898	0.20	0.73	1.02	0.21	0.73	1.02

Data obtained with methods with high LOQ values were excluded: a: LOQ > 0.9 mg/kg; b,c,f: LOQ > 2.5 mg/kg; d: LOQ > 0.4 mg/kg; e: LOQ > 0.6 mg/kg and g: LOQ > 0.8 mg/kg

13. The impact of sample rejection and lead intake on proposed hypothetical MLs for each spice subgroup is shown in Table 5. It is important to note that it was assumed that all spice samples were dried spices.

14. CCCF15 noted that there was general support to establish a single ML for dried rhizomes, bulbs, and roots, but there were divergent views as to the ML equal to or lower than 2.0 mg/kg. Due to the views expressed for the group dried rhizomes, bulbs, and roots in CCCF15, the EWG highlighted that targeted[2] and fresh samples were excluded. Also, the EWG analysed separately turmeric and ginger samples.

15. Based on Table 5, the EWG proposes a MLs of 2.5 mg/kg for lead in Spice, dried, bark, 2.5mg/kg Spice, dried, floral parts, 0.9 mg/kg for Aril, 0.8 mg/kg in Spice, dried seeds, 0.6 mg/kg in Spice, dried fruits & berries, excluding Sichuan pepper, 3.0 mg/kg in Sichuan pepper, 0.4 mg/kg in Spice, dried, flower and 2.0 in Spices, dried rhizomes, bulbs and roots, excluding galangal and garlic, with sample rejections of less than 5%.

16. The proposed ML of 0.6 mg/kg for Spice, dried, fruits & berries would reject 51% of Sichuan pepper samples. Therefore, the EWG recommends establishing MLs for the category Spice, dried, fruits & berries excluding Sichuan pepper and establish a ML of 3 mg/kg for Sichuan pepper.

17. Hypothetical MLs obtained from datasets with samples results reported as dried and not identified as fresh spices for rhizomes, bulbs, and roots; galangal; ginger and turmeric were 2.0 mg/kg, 10 mg/kg, 2.0 mg/kg, and 1.0 mg/kg respectively. Considering only samples results reported as dried, the 95th percentile value estimated for spices for rhizomes, bulbs, and roots; galangal; ginger and turmeric were 2.5 mg/kg, 10 mg/kg, 2.5 mg/kg, and 1.5 mg/kg respectively. For Dried rhizomes, bulbs, and roots, excluding galangal, it was observed that a ML of 2.0 mg/kg would correspond to a rejection rate of less than 5%. If a ML of 2.0 mg/kg for Spice dried rhizomes, bulbs and roots is considered, the rejection of ginger dried samples would be greater than 5% (11.7%).

[2] Targeted samples are collected in analytical surveys for enforcement purposes in response to specific problems (e.g., heavy metal contamination from a known source). Concentration data from such samples would not normally be used in dietary exposure assessments, as they are not likely to be representative of all the food available for sale or may not represent the concentration in foods consumed over a lifetime in the context of a chronic risk assessment. Chapter 6: Dietary Exposure Assessment of Chemicals in Food Principles and methods for the risk assessment of chemicals in food Environmental health criteria, 240

Table 5. Effect of the implementation of hypothetical MLs for lead on dried spices, based on UB approach.

ML (mg/kg)	Mean levels (mg/kg)	Sample rejection (%)	Intake reduction (%)
Spice, dried, aril (n=64)			
No ML	0.24	0.0	0.0
0.9	0.21	3.1	12.5
0.8	0.18	6.3	21.5
0.7	0.18	6.3	21.5
0.5	0.18	7,8	21.5
Spice, dried, bark (n=549)			
No ML	0.60	0.0	0.0
3.5	0.47	2.0	21.8
3.0	0.45	2.7	25.3
2.5	0.41	4.2	30.9
2.0	0.35	7.3	41.2
Spice, dried, floral parts (n= 105)			
No ML	0.38	0.0	0.0
3.0	0.26	2.8	31.8
2.5	0.21	4.8	45.2
2.0	0.17	6.7	55.7
Spice, dried, flowers (n= 126)			
No ML	0.06	0.0	0.0
0.5	0.05	1.6	18.1
0.4	0.03	4.8	51.8
0.3	0,02	9.5	72.2
Spice, dried, fruits & berries (n=3,203)			
No ML	0.38	0.0	0.0
2	0.28	3.3	30.2
1.5	0.25	5.1	37.1
1	0.21	8.9	46.9
0.6	0.16	16.1	58.9

ML (mg/kg)	Mean levels (mg/kg)	Sample rejection (%)	Intake reduction (%)
Spice, dried, Sichuan pepper (n=825)			
No ML	0.95	0.0	0.0
3	0.75	3.8	20.5
2.5	0.70	6.2	26.1
2	0.63	10.2	33.2
0.6	0.27	51.4	71.1
Spice, dried, fruits & berries excluding Sichuan pepper (n=2,383)			
No ML	0.21	0.0	0.0
2	0.16	0.9	19.8
1	0.15	1.6	23.7
0.6	0.14	3.8	30.6
0.5	0.13	6.4	35.9
Spice, dried, fruits & berries excluding Sichuan pepper and star anise (n=2,315)			
No ML	0.19	0.0	0.0
2	0.16	0.7	16.5
1	0.15	1.6	20.7
0.6	0.14	3.0	26.2
0.5	0.13	5.5	31.8
Spice, rhizomes, bulbs, and roots, dried and not identified as fresh (n= 1,422)a			
No ML	0.70	0.0	0.0
2.5	0.28	3.4	58.8
2.0	0.26	4.3	61.5
1.5	0.22	6.3	66.5
Spice, rhizomes, bulbs, and roots (excluding galangal), dried and not identified as fresh , (n= 1,387)a			
No ML	0.62	0.0	0.0
2.5	0.28	1.8	54.8
2.0	0.26	2.8	57.9
1.5	0.23	4.8	63.4

ML (mg/kg)	Mean levels (mg/kg)	Sample rejection (%)	Intake reduction (%)
Spice, galangal, dried and not identified as fresh spices (n= 23)			
No ML	2.68	0.0	0.0
10.0	2.30	4.34	14.3
2.5	0.24	43.5	91.3
2.0	0.24	43.5	91.3
1.5	0.09	47.8	96.3
Spice, ginger, dried and not identified as fresh spices (n= 420)			
No ML	0.44	0.0	0.0
2.5	0.39	1.4	8.8
2.0	0.36	3.6	17.6
1.5	0.39	7.8	32.1
Spice, turmeric, dried and not identified as fresh spices (n= 818)			
No ML	0.75	0.0	0.0
2.0	0.20	1.9	72.9
1.5	0.19	2.8	74.6
1.0	0.17	4.4	76.9
Spice, rhizomes, bulbs, and roots, only reported as dried (n= 669)[b]			
No ML	1.18	0.0	0.0
2.5	0.41	4.3	65.2
2.0	0.37	6.4	68.5
1.5	0.31	10.4	73.6
Spice, rhizomes, bulbs, and roots, only reported as dried, excluding galangal (n= 657)[b]			
No ML	1.09	0.0	0.0
2.5	0.41	2.7	62.5
2.0	0.37	4.8	66.1
1.5	0.31	8.9	71.7
Spice, galangal, only reported as dried (n= 12)			
No ML	5.14	0.0	0.0
10	4.59	5.0	10.7
2.0	1.49	83.3	71.1
1.5	1.10	91.7	78.6

ML (mg/kg)	Mean levels (mg/kg)	Sample rejection (%)	Intake reduction (%)
Spice, ginger, only reported as dried (n=179)			
No ML	0.97	0.0	0.0
2.5	0.87	4.5	10.1
2.0	0.77	11.7	20.9
1.5	0.62	23.5	35.7
Spice, turmeric, only reported as dried (n=462)			
No ML	1.16	0.0	0.0
2.5	0.23	2.2	79.7
2.0	0.21	2.4	80.1
1.5	0.19	3.7	81.7
1.0	0.192	5.6	83.5
Spice, rhizomes, bulbs and roots, only reported as dried, excluding galangal, asafoetida, ganthoda and haldi (n= 641)b			
No ML	1.11	0.0	0.0
2.5	0.41	2.8	62.9
2.0	0.37	4.9	66.5
1.5	0.31	9.2	72.1
Spice, dried, seeds (n= 1,072)			
No ML	0.21	0.0	0.0
1.0	0.16	2.7	22.1
0.8	0.15	4.5	28.7
0.5	0.14	8.9	32.0

Intake at the worst case consumption scenario: Bark (0.4 g/day G12); Bud (0.32 g/day G04); Flower & stigma (1.0 g/day based on saffron consumption – G10); Fruits & berries (1.12 g/day G14); Mace (0.004 g/day G15); Peppers (1.12 g/day G14); Roots & rhizomes (1.16 g/day G04); Seeds (1.82 g/day G04), Theoretical body weight value: 70 kg, a: All samples = dried and non-identified as fresh. b: Only dried sample.

CULINARY HERBS

18. After excluding samples collected before 2011 and applying the exclusion criteria (see paragraphs 3-4), a total of 3,866 data of lead in culinary herbs (fresh, dried, and non-identified either as fresh or dried), were identified from 5 regions (Table 6). A total of 978 data samples in dried (dried, ground, powder) and fresh culinary herbs were considered.

19. In general, lead levels (mg/kg) for fresh herbs were lower than dried herbs. Usually, herbs are commercialized in dried form, but the incomplete information in GEMS/Food database made it impossible to recognize the real condition of samples. Therefore, only samples clearly identified as dried and fresh were considered. Thailand informed that its data of culinary herbs not specified as dried or fresh were checked and all data were of fresh culinary herbs. In this way, these data were included as fresh culinary herbs.

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

Region (countries)	Sub-group	N	Mean (mg/kg)	
			LB	UB
EMRO (Marocco, Egypt)	Non-identified as fresh or dried	33	0.15	0.15
EURO (Albania, Poland, Spain, United Kingdon, Türkiye, EU)	Non-identified as fresh or dried	2,586	0.44	0.48
PAHO (Brazil, Canada, Mexico, Peru, Uruguay, USA)	Dried herbs	136	0.81	0.81
	Non-identified as fresh or dried	268	0.59	0.59
	Fresh herbs	260	0.04	0.04
SEARO (India, Thailand)	Dried herbs	9	1.32	1.32
	Fresh herbs	523	0.03	0.04
WPRO (New Zealand, Singapore)	Dried herbs	49	0.35	0.36
	Non-identified as fresh or dried	1	0.20	0.20

20. Mean, 95th percentile, minimum and maximum levels for lead in dried and fresh culinary herbs were estimated (APENDIX III). Due to the diversity of samples, number, and type of herbs, it was proposed to consider all culinary herbs to establish a single ML for lead.

21. The classification of herbs in GEMS/Food database is the responsibility of each country. Mean levels of lead (UB) were higher in dried culinary herbs (0.72 mg/kg) than fresh culinary herbs (0.04mg/kg).

22. Summary statistics including only dried and fresh samples information as total number of samples, mean, 95th and 97.5th percentile, minimum and maximum concentrations are presented in Table 7.

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

Group	N/N+	Minimum	Maximum	LB (mg/kg)			UB (mg/kg)		
				Mean	P95	P97.5	Mean	P95	P97,5
Culinary herbs	978/433	0.001	9.99	0.17	0.78	1.08	0.17	0.78	1.08
Dried	194/193	0.01	9.99	0.72	2.11	2.25	0.72	2.11	2.25
Fresh	784/240	0.001	0.35	0.04	0.12	0.15	0.04	0.12	0.15

N^{+}: number of positive samples

23. To avoid bias due to a distortion in distribution of data obtained from partial exclusion of data, the EWG analysed the impact of the removal of all data from methods with high LOQ, and no differences were seen between the two datasets (Table 8).

Table 8. Mean, Percentiles 95th and 97.5th values of lead levels (mg/kg) on dried spices not identified as fresh spices from dataset after the exclusion of samples with high LOQ.

Culinary herbs	N/N+	LB (mg/kg)			UB (mg/kg)		
		Mean	P95	P97.5	Mean	P95	P97.5
Dried[a]	194/192	0.72	2.11	2.67	0.72	2.11	2.67
Fresh[b]	805/558	0.04	0.14	0.18	0.04	0.14	0.18

Data obtained with methods with high LOQ values were excluded: a: LOQ > 2.5mg/kg; b: LOQ > 0.2 mg/kg.

24. The impact of sample rejection and lead intake in hypothetical MLs for each culinary herbs' subgroup is shown in Table 9. The impact of the establishment of 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). MLs of 0.2 mg/kg for fresh culinary herbs and 2.5 mg/kg for dried culinary herbs are proposed with rejection rates both less than 5%.

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

ML (mg/kg)	Mean levels (mg/kg)	Sample rejection (%)	Intake reduction (%)
Dried culinary herbs (n=194)			
No ML	0.722	0.0	0.0
2.5	*0.588*	*3.1*	*18.6*
2.0	0.537	6.2	25.7
1.5	0.511	8.2	29.2
Fresh culinary herbs (n= 784)			
No ML	0.043	0.0	0.0
0.2	*0.037*	*2.2*	*12.8*
0. 15	0.035	4.0	18.4
0.1	0.030	9.3	30.2

*Culinary herbs raw (included dried) consumption = 8.89 g/person/day; theoretical body weight value = 70 kg.

APPENDIX III

MEAN LEVELS FOR SPICES AND CULINARY HERBS

(For information)

Table A: Mean levels of lead (mg/kg) in dried and non-identified as fresh spices, using upper-level approach

Food categories	Food	N	Mean (mg/kg)	P95 (mg/kg)
Aril	Mace	64	0.24	0.83
Bark	Bark	1	0.03	0.03
	Cinnamon bark	548	0.60	2.32
Floral parts	Caper	3	0.07	0.09
	Clove	87	0.43	2.40
	Saffron	15	0.14	0.25
Flowers	Camomile or chamomile	126	0.06	0.40
Fruits and Berries	Allspice (P. dioica)	40	0.05	0.12
	Cardamom	84	0.31	0.62
	Paprika non-identified as fresh	24	0.17	0.37
	Paprika (dried)	315	0.35	0.73
	Pepper (black, white)	732	0.14	0.43
	Peppers Chili (dried)	1102	0.17	0.39
	Sichuan Peper	825	0.95	2.80
	Star Anise	68	0.79	3.23
	Sumac	12	0.37	0.80
	Vanilla	2	0.31	0.52
Roots and rhizomes	Asafoetida (dried)	13	0.31	0.58
	Ganthoda (dried)	1	0.50	0.50
	Haldi (dried)	2	0.18	0.28
	Ginger (dried)	179	0.98	2.30
	Turmeric (dried)	462	1.16	1.83
	Ginger non-identified as fresh	249	0.15	0.74
	Turmeric non-identified as fresh	481	0.22	0.71
SPICES	Annatto non-identified as fresh	1	0.04	0.04
	Berbere (dried)	2	0.18	0.25
	Jaifal (dried)	1	0.09	0.09
	Carob (dried)	1	0.02	0.02
	SPICES[a]	1085	0.30	0.50

Food categories	Food	N	Mean (mg/kg)	P95 (mg/kg)
Seeds	Anise seed	48	0.18	0.53
	Caraway seed	37	0.03	0.14
	Carom seed	2	0.11	0.12
	Celery seed	60	0.74	1.47
	Chives seed	1	0.05	0.05
	Coriander seed	202	0.11	0.30
	Cumin seed	454	0.24	0.67
	Dill seed	1	0.30	0.30
	Fennel seed	62	0.10	0.27
	Fenugreek seed	61	0.28	0.49
	Mahllab	1	0.02	0.02
	Mustard seed	50	0.06	0.15
	Nutmeg	89	0.10	0.33
	Poppy seed	2	0.01	0.01
Spice peel	Dried bergamot peel	1	0.09	0.09

a) Results reported as “spices”, without information on the specific spice.

Table B: Mean levels of lead (mg/kg) in culinary herbs, using upper-level approach

Food name	N	Mean (mg/kg)	P95 (mg/kg)
Dried culinary herbs			
Bay leaf	8	2.28	7.01
Dillweed	2	0.15	0.17
Marjoran	9	0.66	0.89
Parsley	2	0.16	0.16
Rosemary	10	0.69	1.19
Basil	15	0.38	0.56
Coriander	16	0.18	0.59
Lemongrass	8	0.31	0.72
Mint	3	0.17	0.31
Oregano	30	0.55	1.73
Sage	33	1.00	2.14
Thyme	58	0.81	1.90
Fresh culinary herbs			
Aneth	2	0.01	0.01
Basil	284	0.03	0.08
Bay leaves	1	0.15	0.15
Chives	5	0.01	0.04
Cilantro	50	0.05	0.22
Coriander	1	0.12	0.12
Dill	17	0.01	0.03
Fennel	6	0.01	0.01
Fine herbs	17	0.04	0.16
Celery	16	0.02	0.04
Kaffir lime leaves	66	0.03	0.07
Pandan leaves	6	0.02	0.04
Pennywort	44	0.04	0.08
Phak-kha-yeang	28	0.04	0.08
Phak-paew	34	0.07	0.18
Stink weed	54	0.04	0.08
Marjoram	1	0.03	0.03
Mint	53	0.04	0.13
Oregano	1	0.06	0.06
Parsley	71	0.04	0.12
Rosemary	7	0.09	0.23
Sage	4	0.05	0.09
Thyme	16	0.07	0.18

APPENDIX IV

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