CODEX ALIMENTARIUS COMMISSION

Food and Agriculture Organization of the United Nations

World Health Organization

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Agenda Item 5 **CRD07**

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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON CONTAMINANTS IN FOODS

16th Session
18-21 April 2023 (physical plenary meeting)
26 April 2023 (virtual report adoption)

REPORT OF THE PRE-SESSION WORKING GROUP ON MAXIMUM LEVELS FOR LEAD IN CERTAIN FOOD CATEGORIES

(Prepared by Brazil as Chair of the Electronic Working Group)

INTRODUCTION

1. The virtual working group (VWG) was held on 12 April 2023 to consider recommendations and issues to the proposed maximum levels for lead in a) brown and raw cane sugars; and b) ready-to-eat meals for infants and young children (considering exclusion of certain foods).

2. The Chair of the EWG from Brazil provided an overview of the work done. 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). Two drafts were circulated in the EWG.

   a) Brown and raw cane sugars

3. The EWG decided to combine MLs for brown and raw sugar. Considering the low representativity specially of raw sugar, the difficulty in differentiating less processed sugars and the similarity of them, it was 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.

4. The Chair informed that there was general support for this ML (0,15 mg/Kg) in response to Circular Letter 2023/18-CF.

   b) Ready-to-eat meals for infants and young children (considering exclusion of certain foods).

5. Considering the difficulty in classifying products of this category as the products are in general multi-ingredients and that no percentage of cereals are available, it would be more appropriate to establish a ML for the whole category. Considering the responses to CL 2023/18-CF, the Chair noted that there was general support to consider a single ML for lead in the whole category with a ML of 0.02 mg/kg, and additional analyses of the data were carried out.

6. Depending on the MLs evaluated by the EWG, different LOQs would be required for the analytical methods. Brazil evaluated how many samples on GEMS/ Food would fit for purpose considering hypothetical MLs of 0.05, 0.04, 0.03 and 0.02 mg/kg considering the performance criteria of the Codex Manual Procedural. For instance, a ML of 0.02 mg/Kg would require a LOQ of 0.008 mg/Kg. If this ML were to be approved, only Canada, European Union and the United States of America currently have adequate methods based on data available on GEMS/FOOD (Table 1). The chair also informed that the mean lead occurrence for the different ML scenarios would not change very much (0.007 mg/Kg x 0.008 mg/Kg). So, if a restricted ML is chosen it may not impact much on exposure.

Table 1: Lead occurrence samples on ready-to-eat meals that would be fit for purpose considering data available on GEMS/FOOD, hypothetical Maximum Levels and LOQs derived from performance criteria required as established in Codex Procedural Manual.

		SCENARIOS			
Hypothetical ML (mg/kg)		0.05	0.04	0.03	0.02
LOQ (mg/kg)		< 0.020	< 0.016	< 0.012	< 0.008
Mean* (mg/kg)		0.008	0.007	0.007	0.007
Total N(% of Ntotal)	3738	2087 (56)	1864 (50)	1443 (39)	1202 (32)
Countries	Ntotal	% of Ntotal			
Australia	4	0	0	0	0
Brazil	7	100	100	100	0
Canada	741	100	100	61	58
China	18	100	100	100	0
Saudi Arabia	6	0	0	0	0
Singapore	38	0	0	0	0
Thailand	13	0	0	0	0
USA	546	59	55	55	53
WHO European Region	2365	42	50	39	21

7. The chair of the EWG also pointed out that few countries questioned the reason to exclude all values analysed with high LOQ values, even quantified ones. For this reason, Table 2 was presented adding impact on rejection rates for hypothetical MLs considering a third dataset in which only non-quantified results analysed with high LOQ values were excluded. It can be seen that removing only non-quantified increases the rejection rate comparing with the data that removes all data with high LOQ values.

Table 2: Effect of the implementation of hypothetical MLs for lead on RTE 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 – (Dataset with exclusion of values from method with high LOQ)* (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 (Dataset with exclusion of non-quantified values from method with high LOQ)* (n = 2,118)		
No ML	0.011	0.0
0.05	0.008	1.4
0.04	0.008	1.8
0.03	0.007	3.2
0.02	0.007	6.5

* LOQ >0.02 mg/kg

Based on the information provided, the Chair of EWG invited the VWG to evaluate the following proposals: a ML of 0.05 mg/Kg considering analytical capacities of countries (existing methods) and a rejection rate less than 5%; or a ML of 0.02 mg/Kg considering a vulnerable public but having rejection rate higher than 5%.

DISCUSSION

a) Brown and raw cane sugars

8. Thailand supported the ML provided (0.15 mg/Kg) considering the rejection rate of 1,6% and that ML is slightly higher than the ML of refined sugar.

9. USA also supported the ML provided but mentioned that wording non-centrifugal instead of non-centrifuged sugar would be more appropriate, as is the terminology used in FAO documents.

b) Ready-to-eat meals for infants and young children (considering exclusion of certain foods).

10. USA asked for clarification if the proposed ML applied to single ingredient RTE foods or multi-ingredients RTE foods. The Chair informed that the dataset included both single ingredient RTE foods and multi-ingredients RTE foods, but most of the samples were multi-ingredients products.

11. European Union (EU) is of the view that infants and young children are the population more vulnerable, so ingredients should be selected to ensure that the lead content of these products is as low as reasonably achieved. Since a ML of 0.02 mg/Kg was agreed for cereal based foods for infants and young children, believes that it is possible to achieve concentrations below 0.02 mg/Kg also for ready-to-eat meals for infants and young children. Additionally, understands that it would not be appropriate to establish a higher maximum level for ready to eat meals for infants and young children containing cereals, or for the whole category of ready to eat meals. Considers acceptable a rejection rate of 5.3% for this category.

12. Brazil informed the concern about fit for purpose methods of analysis, emphasizing that only 21% of the data from a well develop region, as Europe, would be considered as samples analyzed with adequate methods to quantify a ML of 0.02 mg/Kg (LOQ < 0.008 mg/kg). Brazil also noted the cost of the test, because to achieve a low LOQ as 0.008 mg/Kg, it may be necessary to use special reagents that can lead to higher costs. Brazil believes that CCCF would make a more assertive choice if a maximum level a little bit higher than 0.02 mg/kg were adopted. The mean lead occurrence for the different ML scenarios (0.02 mg/Kg versus 0.04 mg/Kg) is almost the same and the rejection rate will not be so high. Regarding rejection rate, Brazil pointed out that this product is RTE so they cannot be reprocessed o achieve a low ML. So, considering the analytical issues, geographical representations of methods and still a protective approach for a vulnerable population, Brazil supports a higher maximum level, such as 0.04 mg/kg.

13. Singapura and Japan agreed with a ML of 0.02 mg/kg since the same ML was achievable for cereal-based products for infants and young children.

14. USA also supported the ML of 0.02 mg/kg considering the fact of higher level of protection for infants and young children, and so a rejection rate slighter than 5 % is fair.

15. Indonesia supported a higher ML of 0.05 mg/kg because of the difficulties in reaching the maximum level of 0.02, as mentioned by Brazil´s delegation.

WORKING GROUP RECOMMENDATIONS TO CCCF16

16. The following recommendations are put forward to CCCF16 for consideration and adoption:
    - a ML of 0.15 mg/Kg for soft brown, raw and non-centrifugal sugars; and
    - a ML of 0.02 mg/kg for ready-to-eat meals for infants and young children.