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CODEX ALIMENTARIUS COMMISSION

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World Health Organization

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Agenda Item 5 **CX/CF 13/7/5 Add.1**
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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON CONTAMINANTS IN FOODS

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PROPOSED DRAFT REVISION OF THE MAXIMUM LEVELS FOR LEAD IN SELECTED COMMODITIES IN THE GENERAL STANDARD FOR CONTAMINANTS AND TOXINS IN FOOD AND FEED (CODEX STAN 193-1995): Fruit juices, milk, infant formula, canned fruits and vegetables, and cereal grains (except buckwheat, cañihua and quinoa)

Comments at Step 3 submitted by Argentina, Brazil, Costa Rica, European Union, India, Kenya, Republic of Korea, Russian Federation, Uruguay, African Union, FoodDrinkEurope and ISDI

ARGENTINA

- Paragraph 10 - *Both the raw and the LOQ limited data sets contained NDs, which were treated as zeros in the analysis. NDs may be replaced by such values as zero, or a value between zero and the limit of detection (LOD), to provide a more conservative indicator of exposure. In this project we are not considering an exposure analysis, but determining what percentage of samples can meet the current or proposed new MLs. In this case, replacing NDs are replaced by a value between zero and the LOD would underestimate the ability of foods to meet the proposed MLs. Therefore, we replaced NDs with zeros.*

Argentina thinks that treating the informed NDs (non detectable) as zero would underestimate the results. They should be directly replaced by the LOD (limit of detection)

- Paragraph 22 refers to the fact that ICP-MS methods can obtain limits of quantification of 0.003 to 0.01 mg/kg in infant formulas, however in paragraph 21 lower values are reported (0.0014 mg/kg)

Argentina would appreciate an explanation of how the lower limits to the LOQ were obtained, the ones referred to in paragraph 22.

- Paragraph 19 - With regard to infant formulas, only the data provided by two countries are taken into consideration (138 data), and of these, only 11 are quantifiable data, so we believe it would be convenient to have more data, and especially with a wider geographical representation in order to revise the MLs.

Argentina noted in the analysis of data that have been discarded, that they are always data that show limits of quantification over the Codex MLs (maximum levels). We request clarification with regard to those cases in which the LOQ (limit of quantification) falls within the interval between the Codex current ML and the proposed ML.

BRAZIL

Brazil supports the position to consider a future work in more than one ML for different fruit juices and agree with the recommendation of the WG to keep the ML in 0.02 mg/Kg in milk.

Considering the infant formulas, Brazil points out the need of to take into consideration the occurrence in a higher amount of quantified samples (more than 11 out of 138) before setting new MLs. It is important highlight that basic ingredient to infant formula is milk and was not proposed to revise due to the variation in results between samples.

In general, Brazil agrees with the proposed ML to canned fruits and vegetables, but it is important to consider if it is necessary different MLs for those canned fruits and vegetables which the original raw material has higher ML.

COSTA RICA

Costa Rica welcomes the opportunity to provide comments on document CX/CF 13/7/5 Proposed Draft Maximum Levels for Lead in Selected Commodities in the General Standard for Contaminants and Toxins in Food and Feed

Comment:

Costa Rica does not have data on lead levels in these food groups; nor do we have comments to the proposed modifications to the MLs for lead in the proposed foods.

EUROPEAN UNION

The European Union (EU) would like to thank the United States for their role in the drafting of the proposed draft revision for lead in selected commodities.

The EU would like to submit comments related to the recommendation proposed to fruit juice, infant formula and canned fruit and vegetables.

For fruit juice, the recommended revision of the maximum level to 0.03 mg/kg is acceptable. However, maximum levels for fruit juices could possibly reflect the higher maximum levels for berries and small fruit. Hence, in addition to the proposed maximum level of 0.030 mg/kg for fruit juices, it should be considered to establish a higher maximum level for fruit juices from berries and small fruits, e.g. at 0.050 mg/kg.

For infant formula, the EU can agree to the proposed revision of the maximum level to 0.01 mg/kg and to the addition of a note in the GSCTFF specifying that the maximum level for infant formula also applies to powdered formula with a dilution factor. As the Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants (CODEX STAN 72–1981) specifies that the maximum level for lead in "Formula for Special Medical Purposes Intended for Infants" is identical to the maximum level for lead in "Infant Formula", the EU considers that this proposed revision automatically applies to both categories.

For canned fruits and vegetables, the EU agrees to the recommendation to consolidate the maximum levels to 0.1 mg/kg. However, the scope should be limited to the canned fruits and vegetables for which there are currently maximum levels in CODEX STAN 193-1995. A statement confirming that the standards apply to the canned products as consumed should be included in the GSCTFF.

For cereals, the EU can agree to the recommendation to maintain the current maximum levels of 0.2 mg/kg. In case more than one maximum level would be considered in the future, the EU considers that specific stricter levels could be applicable to certain cereal species in light of available data.

The EU has no comments on the recommended maximum level for milk, but proposes that this level is reviewed together with the review of the milk products foreseen for next year.

INDIA

General Comment

India would be in favour that wherever lower MLs are proposed, the MLs should be referred to CCMAS to verify the feasibility of the current methodology to support the proposed MLs, otherwise wherever it does not support, the analysis results would be 'Not Detected'.

Specific Comments

1. Paragraph 35

- **Point 2):** The recommendation to maintain the current maximum level of 0.02 mg/kg of lead in milk is acceptable.
- **Point 3):** The recommendation to revise the maximum level to 0.01 mg/kg of lead in infant formula is acceptable. It would be appropriate if the level is also made applicable to the powdered infant formula through use of dilution factor.
- **Point 7):** It would be useful if the milk products can be identified for the purpose of generating data. For example, milk powders, butter, butteroil etc., which are important milk products in international trade may be identified so that the countries can focus for data generation in respect of these identified products.

2. Paragraph 36:

The recommendations in the three bullets are useful and acceptable.

KENYA

General Comment

Kenya would like to thank the Electronic Working Group led by United States of America on the work mentioned above. We accept the other products maximum limits **except fruit juices and infant formula**, therefore our comments on the maximum limits on fruits juices and infant formula are as follows:

Comment:

Kenya would like to maintain 0.05mg/kg for fruit juices and 0.01 for infant formula together with powder formula with a dilution factor as indicated in GSCTFF since no safe level of lead has been identified by JECFA. The focus of the paper/report was to review occurrence data to determine what percentage of samples can meet proposed new MLs.

Justification:

The report did not propose MRL levels based on consumption and exposure.

REPUBLIC OF KOREA

The Republic of Korea supports the proposed draft maximum levels for lead.

RUSSIAN FEDERATION

Position:

Sharing the concern of the toxic effect of lead on the population (especially for children), we suggest it is necessary to continue work to obtain more complete data of the lead content in these foods taking into account the data from Russian Federation.

Rational:

We consider the revised data for ML of lead content in some foods are more strict and their adoption is to be premature.

URUGUAY

Uruguay is grateful to have the opportunity to present these comments on document CX/CF 13/7/5: Proposed Draft Revision of the Maximum Levels for Lead in selected Commodities in the General Standard for Contaminants and Toxins in Food and Feed (CODEX STAN 193-1995): fruit juices, milk, infant formula, canned fruits and vegetables and cereal grains (except buckwheat, cañihua and quinoa) (at Step 3).

Paragraph 35.

Concerning the recommendations in the document, Uruguay has the following comments-

Recommendation 1 - Although our ruling establishes 0.05 mg/kg, according to data collected from local products and by the methodology used, we have no problem with lowering the value to 0.03 mg/kg.

Recommendation 4 - We have no objections to this recommendation.

Recommendations 2, 3 & 5 - We have no comments on these.

AFRICAN UNION

African Union DOES NOT support the proposed lowering of MLS for lead by two folds in fruits juice (from 0.05mg/kg to 0.025mg/kg) and infant formula 0.02mg/kg to 0.01mg/kg) and by ten folds for canned fruits (1.0mg/kg to 0.1mg/kg) and vegetables (1.0mg/kg to 0.1mg/kg). However, we AGREE that the current MLs for milk (0.02mg/kg) and cereals (0.2mg/kg) be maintained. Although **African Union** DOES NOT support the proposed lowering of the ML for infant formula, we do support the recommendation to add a note in the note/remarks column in the GSCTFF that the ML of 0.02mg/kg also applies to powdered formula with a dilution factor.	The reason for establishing MLs is to protect the health of the consumer worldwide, in this case from lead which has been associated with a wide range of adverse health effects including various neurodevelopmental effects, impaired renal function, hypertension, impaired fertility and adverse pregnancy outcomes. Due to the neurodevelopmental effects, foetuses, infants and children are the most vulnerable to lead. However, when data used to revise MLs have narrow geographical representation then the objective of setting world standards is defected. The MLs for fruits juice, infant formula, and canned fruits and vegetable were revised without consideration of lead contamination status in Africa. Mali was the only African country that contributed 99 of the 9080 results analysed to reach the decision to uphold the current MLs for cereals. This makes the decision credible with regards to geographical representation and so gains our support. The absolute lack of data from the continent on levels of lead in milk, fruits juice, canned fruits and vegetables underscores the need for Africa to support researches at regional laboratories that would generate valid data that will meet world standards. The footnote is necessary to address situation where infant formula is marketed in liquid form (ready-to-eat)

FOODDRINKEUROPE

FRUIT JUICE (§12-15)[1]

There is a general concern with lead maximum limits set below 0.05 mg/kg for fruit juices. Using methods of analysis with a lower LOQ of 0.01 mg/kg is achievable globally but not always current practice. Many existing standard laboratory methods have an LOQ of 0.05 mg/kg for commodities such as fruit juice, concentrate and purees due to EU limits for fruit juices being set to 0.05 mg/kg. Applying another method with a lower LOQ (down to 0.01 mg/kg) would result in a financial impact where there are no safety concerns with the current higher 0.05 mg/kg maximum limit.

[1] It is our understanding the current proposal applies not only to fruit juices and nectars but also to reconstituted juices, purees and concentrated purees.

There is further concern over berry fruit juices. Generalising all juices together is not a scientific approach as there are differences in lead levels present among the various juices. The assumption is that one would be able to apply concentration factors for concentrated juices. However, a concern regarding the limit of 0.03 mg/kg for berry juices still exists. A higher limit should be proposed for these. In EC reg. 1881/2006 there is a higher limit for lead in berries and small fruit (0,20 mg/kg), by comparison to fruit in general (0,10 mg/kg), recognising that the former types of fruits are more prone to present higher concentrations of lead (larger surface compared to fruit weight). A more reliable update from a relevant sector group (more data on concentration factors) could be made.'

It is also worth noting that the fruit juices ML appears to have had limited geographic sampling as many South American markets have not been incorporated into the assessment.

§ 15: We believe that, in addition to cherry juices, that the scope of this point be extended to include all small fruit and berry juices, which need a higher ML, or of at least.05 mg/kg. The European producers of fruit juices and nectars are in favour of maintaining the current ML of 0.05 mg/kg, and would like to put forward the following arguments:

- § 14: The suggested reductions in the document prepared by the eWG are not consistent for all the food groups assessed: the basis to decide that eliminating 4% of the international trade of fruit juices could be acceptable for producers is not clear;
- § 12: It is arguable whether decreasing maximum levels simply considering what is achievable according to the GEMS database and disregarding which foods contribute most to lead exposure is the best approach;
- § 4: The per capita consumption of fruit juices in Europe is set at ca 21 litres (58 ml/day). Surveys show that dietary lead exposure has been decreasing over the years. Fruit juices contribute a small percentage to lead exposure.

§ 15: In the event that the current ML of 0.05 mg/kg cannot be maintained, we would like to suggest a split level between:

- Big fruits – for which <0.030 mg/kg is potentially manageable
- Small fruits and berries – ML < 0.05 mg/kg is not manageable:
  - This type of fruits presents higher levels of lead
  - Are not used to make 100% juices (taste and economic reasons)
  - Are used in juice/nectars recipes in a concentration up to 25% max.
  - Consumption data shows that consumption of small fruits and berries' juices is very little and in general these contribute ≤ 1% to the overall juices and nectars consumption.

Data on lead in fruit juices, collected during 2011, highlights the need for a higher than 0,030 mg/kg level;

- 22% of 32 samples of black currant fruit juice was higher than 0,030 mg/kg
- 6% of 33 samples of Grape fruit juice tested above 0,030 mg/kg
- 10% of 19 samples of Strawberry fruit juice tested above 0,050 mg/kg

The following chart is part of a certificate of analysis. The result for Lead (which is for concentrate), once taken back to single strength juice would be 0,047 mg/kg.

Test	Campden BRI Test Reference	Result
Lead (ICP-MS)	Tes-AC-686 UKAS	0.24 mg/kg

§ 15: FoodDrinkEurope supports the recommendation of Codex as future work considering whether fruit juices should have more than one ML.

INFANT (§ 19-23)

§ 21: A wider geographical representation and a higher amount of quantifiable results (11 out of 138 in this document) should be taken into consideration for setting new MLs for infant formulae.

§ 21 & 34: We agree that currently there is a lack of scientific results to lower the current safety and limit and therefore suggest maintaining the current ML of 0.02 mg/kg. The data presented from the GEMS/Food database provides evidence of what the lead levels are in infant formula. The fact that the infant formula samples tested contained a lower lead level than the current Codex ML is not a scientific justification for lowering this safety limit.

§ 23: In terms of consideration of a separate category for follow-on formulas which has been discussed, because of the variation in the definition of this product category between countries it would be extremely challenging to develop a single limit for the product category that would fit a risk assessment for all of the individuals that fall within this category globally. Therefore, we would recommend against creating a separate limit for this product category.

§ 32: While JECFA has not been able to establish a safe limit for lead, the proposed revision of the lead limit for infant formula does not provide any evidence that the current ML for lead in infant formula is unsafe, nor does it provide evidence that the proposed ML increases safety of infant formula.

Furthermore JECFA withdrew its previous provisional tolerable weekly intake (see JECFA evaluation, WHO technical report series 960) due to a wide range of effects linked to the exposure to lead. We are aware of the wide range of effects, including various neurodevelopmental effects, which make fetuses, infants and children the most sensitive subgroups to lead. Due to the above, we would agree with revisiting the MLs for lead in various food stuffs.

According to a survey conducted by the World Health Organization in 1989, human breast milk concentrations of lead range from less than 0.001 ppm to 0.219 ppm, and more recent publications have also demonstrated that the concentrations of lead in breast milk have regional differences which often exceed the existing limit. Due to these large regional differences in lead concentrations in human breast milk, it is likely that regional variations in lead concentrations in the environment produce a much larger difference in risk than the proposed change in the ML for lead in infant formula (0.02 to 0.01 ppm) would create.

CANNED FRUIT AND VEGETABLE (§ 25 - 29)

§ 25-28: The level of 0.1mg/kg proposed by Codex for canned fruit and vegetables is appropriate. We however do find that further data collection is necessary

CEREALS (§ 30 - 31)

§ 31: We agree that the current ML 0.2mg/kg for all cereals is appropriate

ALL

Although FoodDrinkEurope data was not taken into account, results would not have been noticeable altered. FoodDrinkEurope appreciates a possible opportunity to contribute data, which has been collected, on lead in fruit juices, next year.

When defining new MLs for lead in various foodstuffs,

> § 9: An exposure analysis should also be carried out (which is not the case in this document).
>
> § 14 & 27 respectively. A consistent approach should be followed in defining which% of samples should be eliminated from international trade (e.g. why 4% for fruit juices and 2% for canned fruits?)
>
> § 31. Agreed. A need to update the proposed revised MLs for re-consideration next year.

ISDI

The International Special Dietary Foods Industries (ISDI) represents at Codex Alimentarius the associations of manufacturers of special dietary foods and hence is highly involved and interested in contributing to any work that will relate to nutrition products.

ISDI supports keeping the current Codex ML of 0.02 mg/kg for lead in infant formula. We do not support lowering the ML to 0.01 mg/kg because there is no scientific justification for making this change.

The eWG recommendation to lower the ML for lead in infant formula from 0.02 mg/kg to 0.01 mg/kg was based on data from the Joint FAO/WHO Joint Expert Committee on Food Additive's (JECFA) Global Environment Monitoring System – Food Contamination Monitoring and Assessment Programme (GEMS/Food). The GEMS/Food database provides evidence of what the lead levels are in infant formula, but does not assess the health or safety aspects of these levels. JECFA has not established a safe level for lead, and the CCCF document does not provide any evidence that the current ML for lead in infant formula is unsafe. Lowering the Codex ML because the infant formula samples in the GEMS database contained lower levels is not a scientific justification for such action, Further, the document provides no evidence that the proposed lower ML would increase the safety of infant formula.

According to a 1989 World Health Organization survey, lead concentrations in human breast milk ranged from 0.001 to 0.219 mg/kg, and more recent publications have demonstrated that lead concentrations vary by region and many exceed the current Codex ML. Due to this broad range of lead concentrations among regions, it is likely that regional variations in lead concentrations in the environment produce a larger difference in risk than the proposed change in the ML for lead in infant formula (e.g., 0.02 to 0.01 mg/kg) would create. In addition, the dataset that this recommendation is based on is very narrow, with nearly all samples tested coming from a couple different regions, so there may be some countries where the lower ML does cause an issue.

It has been discussed that a separate ML for lead in follow-up formula (FUF) may be explored. However, due to the variation in the definition for FUF between countries, it would be challenging to develop a single ML for the entire product category that would fit a risk assessment that covers the global population for this category. Therefore, we recommend against establishing a separate ML for lead in FUF.

Finally, the GEMS/Food database contained data only on ready-to-feed liquid infant formulas. If the ML for lead in infant formula is lowered, we recommend language be added to indicate the ML is intended for infant formula "as consumed."