

CODEX ALIMENTARIUS COMMISSION



Food and Agriculture
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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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PROPOSED DRAFT MAXIMUM LEVELS FOR LEAD IN SELECTED COMMODITIES IN THE GENERAL STANDARD FOR CONTAMINANTS AND TOXINS IN FOOD AND FEED (CXS 193-1995)

Comments submitted by Australia, Canada, Cuba, European Union, Japan, Kazakhstan, Kenya, Mexico, Peru, Republic of Korea, United States of America, FIVS, OIV

Australia

MLs for wine and fortified wine

1. Australia supports progression of an ML of 0.1 mg/kg for lead in wine and 0.15 mg/kg in fortified wine for grapes harvested after the establishment of MLs.
2. The additional option proposed of 0.1 mg/Kg is preferred given the reduced impact on trade (1% of wine in trade would be non-compliant rather than 3% with an ML of 0.05 mg/Kg).
3. The ML of 0.1 mg/Kg for lead in wine is consistent with the International Organisation of Vine and Wine's (OIV's) proposal to revise their current ML for lead in wine to 0.10 mg/L.
4. The proposed ML of 0.15 mg/kg for fortified or liqueur wines is consistent with the OIV's current ML of 0.15 mg/L for liqueur wines (includes fortified wine).

MLs for edible offal

5. Australia is unable to support the recommendations for the revised (lower) MLs in edible offal without considering data more representative of international production and trade. In addition, clearer justification for these reductions is needed as offal is a very minor and sporadic contributor to total lead exposure.
6. It is positive that the dataset contains some major exporters of cattle, pig and poultry offal but the data are not entirely representative of international production and trade.
 - Cattle - Includes Brazil, EU and USA comprising only 41.4% of the world's cattle production. It does not include India and China, which account for approximately 40% of the world's production.
 - Pig - includes Brazil, China, EU and USA which account for 76% of the world's pork production in 2011 - the dataset does not include additional key countries like Germany and Spain.
7. We suggests obtaining additional data from India, Africa, Asia, the Middle East, Canada, New Zealand as major producers of edible offal.
8. Australia seeks clarity on whether the analysis accounts for different sample numbers from different regions. Analysis of data does not appear to have been weighted to reflect different numbers of samples from different regions. For example, the dataset for cattle represented 41.4% of the world herd - Although the EU provided the most samples they were the smallest producer.

Canada

Canada supports the work of the eWG to ensure that the MLs for lead are as low as reasonably achievable (ALARA principle) and are harmonized, where possible, across food commodities for which MLs are being updated.

Canada supports the lower proposed ML for wine of 0.05 mg/kg given that the large majority of products in this category, which are those that are most widely consumed, can meet this ML.

Canada is also in agreement with establishing a separate ML for fortified or liqueur wine of 0.15 mg/kg.

Canada is in general agreement to the lower MLs being proposed for edible offal. However, in light of the previous recommendation from the CCCF Chair, as described in REP16/CF, that the Committee, when possible, should establish MLs for broad food categories as opposed to MLs for the individual food category or subset(s) of the broad categories, Canada recommends that a single ML for lead in all types of edible offal (i.e. cattle, pig, poultry) of 0.15 mg/kg could be proposed.

Cuba

Document CX/CF 19/13/5, displays, under each box No 3 for each food analysed, the explanatory note *Hypothetical MLs shown in italics, which is potentially confusing as all the results presented in the **Current and hypothetical MLs (mg/kg)** are in italics. This note should be more explicit, and indicate that the value marked by (*) is the hypothetical value recommended as the Maximum Level for this food

European Union

In general, the EU considers that the MLs for lead should be lowered wherever possible.

As regards the proposed actions for the individual commodities, the EU would like to present the following position:

For **wine**, the EU can support an ML of 0.1 mg/kg for wine, made from grapes harvested after the date of the establishment of the ML.

For **fortified or liqueur wine**, the EU can support an ML of 0.15 mg/kg for wine, made from grapes harvested after the date of the establishment of the ML.

For **edible offal cattle**, the EU can support an ML of 0.15 mg/kg.

For **edible offal pig**, the EU can support an ML of 0.15 mg/kg.

For **edible offal poultry**, the EU can support an ML of 0.1 mg/kg.

With a view of simplification of enforcement, the EU would also like to suggest to CCCF to consider a single ML of 0.15 mg/kg for all three species.

Japan

Wine:

Japan supports an ML of 0.1 mg/kg for lead in wine made from grapes for the following reasons:

- At a hypothetical ML of 0.05 mg/kg, violation rates will be 5-11% for subcategories of “desert wine” and “white wine”. The high violation rates will have significant impact on the availability of wine as well as on the economic interests of wine industry.
- As wines are not consumed by children of 6 years and younger, there is no need to establish for wine as strict ML as the one for grape juice which is consumed significantly by adults and children.

As for fortified or liqueur wine, Japan supports the ML of 0.15 mg/kg as recommended by the EWG.

Edible offal:

Japan supports the proposed MLs as recommended by the EWG.

Kazakhstan

Kazakhstan requests to establish a **transitional level** of the MLs for lead for wine and fortified wine. In compliance with our national technical regulations, ML for lead in wine and wine products is 0.3 mg / kg. So the transitional level will provide time needed for a smooth transition to the production of wine at reduced ML for lead.

Kenya

Kenya supports the following recommendations: -

1. Wine:

a. Revise the ML for lead in wine from 0.2 mg/kg to 0.05 mg/kg, with the ML applying to wine made from grapes harvested after the date of the establishment of the ML,

b. Establish an ML for lead in fortified or liqueur wines of 0.15 mg/kg, for products made from grapes harvested after the date of the establishment of the ML.

2. Edible offal:

- a. Cattle: Lower the ML for lead in edible offal of cattle from 0.5 mg/kg to 0.15 mg/kg.
- b. Pig: Lower the ML for lead in edible offal of pig from 0.5 mg/kg to 0.15 mg/kg.
- c. Poultry: Lower the ML for lead in edible offal of poultry from 0.5 mg/kg to 0.1 mg/kg.

JUSTIFICATION

Lead is a health hazard through accumulation in the body. The exposure to lead is increasing due to high consumption of wine and edible offal.

General comment: Kenya is requesting this committee that Edible offal should include intestines for cattle, pig and Poultry because intestines are consumed in large quantities in Kenya and if it is not part of edible offal then the committee should consider including it.

Mexico

Tipo de comentario/ Referencia	Categoría	Cambio propuesto	Comentario/ Justificación
<u>General</u>	<u>Técnico</u>	México no cuenta con datos analíticos recientes que nos permitan modificar los límites de plomo en grupos de alimentos de manera tan específica como se plantea en el documento de trabajo	En la Normativa Mexicana únicamente contempla la NOM-130-SSA1-1995, bienes y servicios. Alimentos envasados en recipientes de cierre hermético y sometido a tratamiento térmico. Disposiciones y especificaciones sanitarias, cuyo objetivo es establecer las disposiciones y especificaciones sanitarias que deben cumplir los alimentos envasados en recipientes de cierre hermético y sometidos a tratamiento térmico, con excepción de los productos que cuenten con Normas Oficiales Mexicanas específicas, se fijan los valores máximo de plomo para diversos productos, jugos, productos cárnicos, vegetales y productos lácteos”

Peru

In accordance with the revision of the proposed draft maximum levels for lead in products selected from the General Standard for Contaminants and Toxins in Food and Feed (CXS 193-1995), we would like to offer the following opinion with a view to safeguarding public health:

In respect of the limit for lead in wines (Codex Standard – CXS 193-1995):

The maximum proposed limit of 0.05 mg/kg is considerably lower than the limit established by the International Organisation of Vine and Wine (OIV) which sets a limit of 0.15 mg/kg and somewhat lower than that established by many wine-producing countries, and much lower than that currently established by the Codex Alimentarius of 0.2 mg/kg.

The World Health Organisation (WHO) does not establish a maximum level for lead in foods but it does say that “there is no known level of lead exposure that is considered safe”.

The Asia-Pacific Economic Cooperation (APEC) forum has deemed this product to be of low risk, and considers that its consumption in different countries is by specific age group and not general, and consequently its consumption is not intended for vulnerable groups, pregnant women, small children, etc.

Of the 21 APEC economies, only 6 require the analysis and monitoring of lead in wine, as reported at the Wine Regulatory Forum 2018 Honolulu – Hawaii.

It should be noted that to establish Levels of analysis (in this case for lead, the International Organisation of Vine and Wine (OIV) states that government should implement limits on the levels of analysis in the case of wine, and specify the method used to confirm observance of these limits, and to make these limits and methods publicly available. This is important when it comes to establishing new limits.

The General Directorate of Environmental Health and Food Safety (DIGESA – Peru), as part of its duties, has strengthened its checks and surveillance activities, and table N° 1 provides information about the results of analyses into lead in wine carried out during 2018. As can be seen, of the 24 samples analysed, 2 samples report 0.45 mg/l and 0.18 mg/l, and the remaining 22 samples report <0.11 mg/l.

Table N° 1: Results of the analysis of lead in wine

N°	Country	LAB Code	Lead Levels (mg/l) ¹
1	Peru	148	<0.11
2	Peru	152	<0.11
3	Peru	153	<0.11
4	Peru	159	<0.11
5	Peru	190	<0.11
6	Peru	191	<0.11
7	Peru	200	<0.11
8	Peru	231	<0.11
9	Peru	234	<0.11
10	Peru	236	<0.11
11	Peru	238	<0.11
12	Peru	232	<0.11
13	Peru	233	<0.11
14	Peru	239	<0.11
15	Peru	276	<0.11
16	Peru	277	<0.11
17	Peru	279	<0.11
18	Peru	280	<0.11
19	Peru	282	0.45
20	Peru	301	<0.11
21	Peru	455	0.18
22	Peru	458	<0.11
23	Peru	459	<0.11
24	Peru	414	<0.11

It should be noted that, in Peru, the national reference standard for safety in heavy metals, in the case of alcoholic beverages, is Law N° 29632 – “Law for the Eradication of Manufacture and Commercialization of Alcoholic Beverages Informal or Adulterated or not suitable for Human Consumption”, and its Regulation approved by means of Supreme Decree N° 005-2013-PRODUCE, which also, in Art. 42, replicates the existing national standard.

Article 42. – Alcoholic Beverages not suitable for Human Consumption

The criteria to determine alcoholic beverages not suitable for human consumption are as follows:

- a) *With the presence of particles foreign to the nature of the product.*
- b) *Those that contain heavy metals which exceed the following limits:*
 - + Copper (Cu) 2.0 mg/L
 - + Lead (Pb) 0.5 mg/L**
 - + Arsenic (As) 0.5 mg/L ; + Zinc (Zn) 1.5 mg/L

- c) *Those produced with industrial-grade or second-generation ethanol*
- d) *Those produced with methanol*
- e) *Those produced with additives not permitted.*
- f) *With oxide in the cap.*
- g) *Alcoholic beverages contained in used non-returnable containers or in non-food-grade containers.*
- h) *Those which do not have current and corresponding health registration.*
- i) *Those past their expiration date (when applicable)*
- j) *Those from manufacturing establishments which do not comply with compulsory health requirements.*

On these grounds, we express our observations on the maximum level for lead proposed in the draft maximum levels for lead in products selected from the General Standard for Contaminants and Toxins in Food and Feed (CXS 193-1995), which should be regarded as NOT modifying the current maximum level for lead established for wines of 0.2 mg/kg in the Codex Alimentarius standard.

Republic of Korea

Republic of Korea would like to express its agreement with the proposed revisions and new maximum levels (MLs) for lead in wine, fortified or liqueur wine suggested by eWG.

United States of America

The United States supports the recommendations in APPENDIX I on page 5 of the document.

The recommendations to revise the MLs for wine and edible offal are consistent with the recommendations of the JECFA73 evaluation of lead, and the overall goal of reducing lead exposure from foods by lowering recommended maximum levels in the General Standard for Contaminants and Toxins in Food and Feed (CXS 193-1995).

FIVS

This paper presents the consensus comments of the members of FIVS² regarding the proposed draft maximum levels (ML) of lead in selected commodities in the General Standard for Contaminants and Toxins in Food and Feed (CXS 193-1995).

FIVS is grateful for the opportunity to submit comments on this important proposal and would like to offer the following opinions:

FIVS welcomes the recognition that it is appropriate to establish a slightly higher ML (0.150 mg/kg) for lead in fortified or liqueur wines in the light of the GEMS dataset that was examined and the characteristics of these products. In its comments on the previous eWG report (CX/CF 19/13/5) FIVS had pointed out that a significant proportion of products in the marketplace (apparently as much as 24%) would be negatively affected by an immediate move to an ML of 0.05 mg/kg. This seemed disproportionate given that these products are generally consumed in smaller quantities than standard wines.

Likewise, FIVS welcomes the fact that the proposals recommend the application of new MLs for lead in wines and fortified wines to products made from grapes harvested after the date of the establishment of the ML. FIVS had pointed out in its previous comments that some form of grandfathering of products already in the marketplace is appropriate given the long shelf life of these categories of product.

FIVS notes that the eWG recommendations present two options for the revised ML applicable to non-fortified wine – either 0.05 mg/kg or 0.1 mg/kg. For the following reasons, FIVS favours the higher limit of 0.1 mg/kg:

- This represents a halving of the current ML (0.2 mg/kg) and sends a clear signal that the trend for this ML is very definitely downwards. The GEMS dataset indicates that producers have been exerting downward pressure on the levels of lead in their products and a new ML at this level should help to maintain that momentum.
- The limit also represents a decrease from the ML of 0.15 mg/kg that was established by the OIV in 2006, which was itself a lowering from the current ML of 0.2 mg/kg in the GSCTF.
- Both OIV and FIVS in their separate comments to the eWG noted the very significant impacts that an immediate reduction of the ML to 0.05 mg/kg would cause: approximately 7.5 million hectolitres of wine would be excluded from the international market (a little less than the annual production of Germany). The full economic consequences to the economies in which wine is produced are far greater (e.g. due to ancillary industries, hospitality and tourism). The recommendation of an ML of 0.1 mg/kg would mitigate these effects to a large degree.

² FIVS is an international federation serving trade associations and companies in the alcohol beverage industry from around the world. It provides a forum for its members to work collaboratively on legal and policy issues and communicates Federation views to national governments and international organisations. FIVS is an Observer to the Codex Alimentarius Commission.

Finally, OIV indicated in its comments to the eWG that its own recommended ML for lead in wine is under discussion at present. The recommended MLs of organisations such as Codex Alimentarius and OIV are incorporated not just in national regulations, but also in private standards established in the supply chain and elsewhere. Consequently, FIVS would urge a return to situation that prevailed before 2006, in which the same numerical ML for lead is recommended both by Codex Alimentarius and OIV in order to prevent unnecessary confusion in the marketplace, where some regulations are based on an OIV recommendation and others on the Codex Alimentarius standard.

Conclusions

FIVS is grateful for the opportunity to provide comments on this important proposal.

We welcome the fact that several of our previous comments have been taken into account in the new report from the eWG, and favour the establishment of lower, revised MLs for lead in wine at 0.1 mg/kg and in fortified or liqueur wines at 0.15 mg/kg, both to be applied to products made from grapes harvested after the date of the establishment of the ML.

We remain firmly committed to consumer safety, and thus to seeing a continuing reduction in the levels of lead in wine. We encourage the establishment of MLs based on representative data and sound science and that are harmonized globally to facilitate commerce.

OIV

GENERAL COMMENTS

During the last session, the 12th CCCF noted the view that when setting MLs for wine, the specific characteristics of certain types of wines should be considered, such as the fruit which was used and whether the wine was a fortified or liqueur wine. It was also noted that the ML should only be set for wine produced from grapes harvested after the date of the modification of the ML due to the aging period and shelf life of wine (e.g. old vintage with high added value). It was further noted that an ML of 0.05 mg/kg was too restrictive considering wines were not aimed at infants and young children.

The Observer of OIV indicated that OIV had set an ML of 0.15 mg/kg in 2012 and continued to work on the reduction of lead contamination in wines that might lead to the further reduction of the OIV ML in future. Collaboration between Codex and OIV was important to avoid duplication of work or inconsistent standards that may be trade disruptive. The Observer supported that any revised Codex ML should apply to wines from grapes harvested after the date of adoption of the ML.

The 12th CCCF (March 2018) agreed to re-establish the EWG, chaired by the USA, working in English only, to work on MLs for wine made from grapes and for fortified wines made from grapes, harvested after the date of the establishment of the ML, and on edible offal as previously agreed (edible offal of cattle, pig, and poultry).

The OIV would like to thank the United States of America for preparing the document CX/CF 19/13/5 on proposed revised MLs for lead in wines and fortified wines which compiles all outstanding approaches of members of the eWG including the views of the OIV.

The OIV is an intergovernmental organisation which currently has 47 Member States producer and consumer representing 85% of world wine production and 65% of consumption respectively.

Regarding lead in wines, The Member-states of the OIV are very concerned and they have adopted different recommendations on lead in wines since many years

- In 1996, the OIV has established a maximum limit at 0.20 mg/L which has been endorsed by the Codex in 2001
- And in 2006 the OIV has established a new maximum limit at 0.15 mg/L
- After the CCCF 12 meeting, the Member states of the OIV have decided to launch a revision of the current OIV lead limit and draft the following proposal based on the information available and provided by member states. This draft resolution is in step 3 of the procedure.

Update of the OIV limit of lead in wines

Lead:	0.10 mg/L for wine made, starting from the [date of adoption] harvest year
	0.15 mg/L for liqueur wines, starting from the [date of adoption] harvest year

SPECIFIC COMMENTS

In these circumstances, and taking into account the recommendations as presented in document CX/CF 19/13/5,

- The OIV strongly support the distinction on ML for lead between wine and fortified wines.
- The OIV support the approach to apply the ML to wine or fortified/liqueur wines made from grapes harvested after the date of the establishment of the ML

However, based on the recommendation of the document CX/CF 19/13/5, the OIV understand that the committee have to decide on the two options proposed.

Either revising the ML for lead in wine from 0.2 mg/Kg to 0.05 mg/Kg or from 0.2 mg/Kg to 0.1 mg/Kg.

The OIV would like to draw the attention of the committee that a limit too low, only based on a statistic analysis of samples could have an important consequence in the international trade by eliminating an non negligible part of the world wine production.

For example, data provided by some member states indicate that for export wines the total of still wines (white, red and rosé) with a lead content upper 0.05 mg/Kg represents approximately 5.5%.

In addition, in reference to paragraph 10 of the document CX/CF 19/13/5, the eWG recognizes that “*While most types of wine would meet the proposed ML of 0.05 mg/kg, some types of wine had a lead concentration that would approach 5 percent. Based on these observations, the EWG could recommend that the Committee consider lowering the ML for lead in wine to 0.1 mg/kg, for products made from grapes harvested after the date of the establishment of the ML.*”

➤ Therefore, in order to be consistent with the report of the eWG and with the OIV member states proposal for the new limits and in order to avoid a substantial amount of wines be excluded of the international wine trade

- **The OIV proposes to consider lowering the ML for lead in wine from 0.2 mg/kg to 0.1 mg/kg**, for products made from grapes harvested after the date of the establishment of the ML
- **We fully support** the proposal of the eWG to consider **establishing an ML for lead in fortified wine of 0.15 mg/kg**, for products made from grapes harvested after the date of the establishment of the ML

In addition, the OIV would like to draw the attention of the eWG on the classification and the definition of the different wine products. At the OIV level, “fortified wine” is not defined, these products are cover by the definition of “Liqueur wines”. **For clarification, it is recommended to make reference to the OIV definitions.**

The OIV will appreciate that the eWG will consider these comments