

# CODEX ALIMENTARIUS COMMISSION



Food and Agriculture  
Organization of the  
United Nations



World Health  
Organization

E

Viale delle Terme di Caracalla, 00153 Rome, Italy - Tel: (+39) 06 57051 - E-mail: [codex@fao.org](mailto:codex@fao.org) - [www.codexalimentarius.org](http://www.codexalimentarius.org)

**Agenda Item 5**

**CX/CF 18/12/5-Add.1**

## JOINT FAO/WHO FOOD STANDARDS PROGRAMME CODEX COMMITTEE ON CONTAMINANTS IN FOODS

12<sup>th</sup> Session

Utrecht, The Netherlands, 12 - 16 March 2018

### PROPOSED DRAFT AND DRAFT MAXIMUM LEVELS OF LEAD IN SELECTED COMMODITIES IN THE GENERAL STANDARD FOR CONTAMINANTS AND TOXINS IN FOOD AND FEED (CXS 193-1995) (AT STEPS 7 AND 4)

Comments submitted at Steps 6 and 3 by Argentina, Australia, Canada, Colombia, Costa Rica, Egypt, India, Japan, Kenya, Republic of Korea, Turkey, Uruguay, FIVS, OIV and WPTC

#### ARGENTINA

##### General comment:

Argentina is grateful for the work done by the EWG on revising and setting new maximum limits for contaminants, and for the support provided by JECFA in evaluating risks.

Argentina shares the concerns of JECFA on whether exposure to lead is associated with a significant range of human health problems. Despite this fact, Argentina would like to set out some individual concerns.

##### Specific comments:

- 1) Regarding the proposed limit for wines, Argentina wishes to point out that – taking into account that a Worldwide Standard is being established – the collected data do not include any contributions from the Africa and South America region. Argentina is an important, traditional wine producer and it undertakes to pass on information about its statistical survey, so the data can be taken into account and so data from our region is considered.
- 2) With regard to the data, we note with concern that the limit to be modified would not only apply to wines; we note that the data taken into account also cover wine-based products (e.g. fortified wines, wines based on grapes and other fruit, mead, ice wine, etc.). We do not know which criterion has been used in defining this grouping. It could skew the results of the statistical study. We would therefore prefer to differentiate this type of samples in the study and set the limit only for grape-based wine.
- 3) As regards the proposed maximum limit of 0.05% [*sic*] mg/kg, this figure is substantially less than that set by the International Organisation of Vine and Wine (OIV) – which is 0.15 mg/kg – and considerably less than that set by many countries, thereby overly penalising this product; what is more, it is not consumed in all countries, nor is it consumed by all age groups nor generally by many vulnerable groups, pregnant women, young children, etc.
- 4) Furthermore, we have noted the correlations drawn between the current Maximum Limit for lead and the hypothetical limits, as well as the restrictions that each of these limits would impose on trade. We do not understand the reason for the recommended limit of 0.05 mg/kg, which we believe will be an undue restraint on trade, since 3% of the samples would be outside the market. We would actually like to see a quantification of the substantial change that would occur between each of the suggested hypothetical values for consumer health, given that – to take account of the Codex standard subsequently at the national level – we are obliged by WTO agreements to lay down measures that are proportional to the assessed risk and that we therefore need to know the level of proportionality of each of the hypothetical limits.
- 5) We therefore believe that it would be very important not to make a decision just now, but to urge countries – especially wine producers – to provide information on their methods for sampling lead in wine. Although no information has been provided to date in the case of Argentina, the world's fifth-largest wine producer, this provision could be done in the near future.

**AUSTRALIA**

1. Australia's comments relate to the proposed reduction in the ML of wine from 0.20 to 0.05 mg/kg.
2. Australia requests that Codex consider harmonising with the current OIV limit of 0.15 mg/kg as an interim measure to allow contemporary evidence to be sought before any additional reduction in the ML is proposed.
3. Australia requests that any new ML is not applied to fortified wine, which generally has a higher level of lead and a different consumption pattern than table wine. Preliminary estimates are that a significant proportion of fortified wine would be impacted by the proposed ML of 0.05 mg/kg. Additionally, consideration should be given to distinguishing between table, fortified and sparkling wines given the different consumption patterns for each.
4. In relation to fortified wine, consideration should be given to grandfathering provisions as there may be instances of higher lead concentrations from wine stored long-term in barrels due to the historically-higher prevalence of lead-based contaminants.

**CANADA**

Canada wishes to express its appreciation to the United States for once again leading the electronic Working Group (eWG) on the *Proposed Draft and Draft Maximum Levels (ML) of Lead in Selected Commodities in the General Standard for Contaminants and Toxins in Food and Feed*. Canada would like to convey its agreement with the proposed MLs for lead in various foods.

Canada is supportive of the proposed draft and draft MLs presented in Appendix I for lead in various foods.

Canada has a comment relating to the work process outlined in paragraph 5 of Appendix II. A large number of results submitted for food categories evaluated as part of this year's work did not report a limit of quantification (LOQ) and were initially excluded from analysis. Subsequently, the eWG requested re-entry of datasets with large numbers of non-reported LOQs and samples with no reported LOQ but with results reporting positive detections of lead were retained. When the retained samples affected the eWG's recommended MLs for a given food commodity, MLs were proposed based on sample sets that included the retained samples (i.e. positive concentrations with no reported LOQ).

While the approach described above is reasonable, it is unclear whether the same approach was consistently applied in past years when other lead MLs in the GSTCFF were updated. Canada suggests that a single, consistent approach to the treatment of samples with no reported LOQ be taken when both updating the existing Codex MLs for lead in the GSTFF and when proposing new MLs for lead in additional food commodities. The existing Codex MLs for lead that have previously been updated could be verified using the chosen assessment method.

With respect to Appendix II, paragraph 39 outlining 'additional topics' brought to the attention of the eWG, several countries commented that because wines are not produced with the intention of being consumed by infants and young children and are not as frequently consumed as non-alcoholic drinks, an ML as low as that proposed by the eWG (0.05 mg/kg) may not be necessary. Canada is of the opinion that lead concentrations in all foods should be as low as reasonable achievable (ALARA principle) and supports the proposed ML of 0.05 mg/kg lead in wine.

**COLOMBIA**

Colombia is pleased to state that it is in agreement with the PROPOSED DRAFT REVISION OF MAXIMUM LEVELS FOR LEAD IN SELECTED FRUITS AND VEGETABLES (FRESH AND PROCESSED) FOR THE GENERAL STANDARD FOR CONTAMINANTS AND TOXINS IN FOOD AND FEED (CXS193-1995) and that, taking into account the geographical representativeness and the number of samples shown in Table GJ-1 of the Annex for Pb levels in grape juice, more data need to be gathered in order to gain an overall picture of lead levels and in particular a clearer distribution of these levels in the regions.

The above is the consensus reached in the Food Contaminants Subcommittee of Colombia.

**COSTA RICA**

Costa Rica is grateful to the working group for the work that it has done and for the opportunity to make comments. In this connection, it wishes to express its support for the proposals made by the working group.

## EGYPT

Egypt supports the following recommendations:

- 1- 0.04 mg/kg for grape juice.
- 2- 0.3 mg/kg for lead in Mango chutney.
- 3- 0.1 mg/kg for lead in Canned brassica vegetables.
- 4- 0.2 mg/kg for lead in fresh farmed mushrooms [common mushrooms (*Agaricus bisporous*), shiitake mushrooms (*Lentinula edodes*), and oyster mushrooms (*Pleurotus*)]
- 5- 0.05 mg/kg for Wine.
- 6- 1 mg/kg for salt, food grade.
- 7- 0.04 mg/kg for fat spreads and blended spreads.
- 8- 0.07 mg/kg for Edible fats and oils.

## INDIA

**General Comment:** India appreciates the work of Electronic Working Group chaired by USA and comments of India are as under:

Lead is present naturally in the environment and its levels may vary due to diverse geographical locations and agro climatic conditions. As a result, lead comes in agri produces. In addition, there is no concrete solution/technology available with the industries for removal of these heavy metals at processing levels as these are imbibed in the agri produce. Further, as per the available studies, the minimum time required for reducing these heavy metals by phytoremediation techniques of soil and water, is not less than 6-7 years. [Source: Technology Evaluation Report TE-98-01, Mandal et al., International Journal of Bio-resource and Stress Management 2014, 5(4):553-560, International Journal of Environmental Bioremediation & Biodegradation, 2014, Vol. 2, No. 4, 178-191]. A drastic reduction of MLs of lead in various food commodities might not be reflective to a large extent of the occurrence levels of lead in foods and therefore may impact international food trade.

**Specific Comment:** In case of mango chutney, India proposes an ML of 0.5mg/kg for lead considering the data submitted by India.

**Rationale:** The revision of MLs of lead in foods by the Committee is largely based on the occurrence data of lead and possible impact on trade, since there is no safe level of lead in foods as PTWI was withdrawn by JECFA. However, the proposed level of 0.3 mg/kg does not appear to be reflective of actual occurrence data considered by the EWG, which includes large proportion of data provided by India (major producer of mango chutney).

## JAPAN

Japan expresses its appreciation for the efforts of the United States of America, Chair of the EWG in preparing the "Proposed Draft and Draft Revised Maximum Levels for Lead in Selected Commodities in the GSCTFF (CXS 193-1995)" (CX/CF 18/12/5). We would like to provide the following comments in response to CL2018/1-CF.

Japan supports the revised maximum levels for lead in all commodities proposed, except those for fresh farmed mushrooms and wine. We are pleased that the number of samples and geographical distribution of data became sufficient for setting MLs.

### Fresh farmed mushrooms

Japan proposes an ML of 0.3 mg/kg rather than 0.2 mg/kg recommended by the EWG for following reasons:

- ✓ While setting an ML at the hypothetical level of 0.2 mg/kg would eliminate 4 percent of the products in international trade, setting an ML of 0.3 mg/kg would eliminate 2 percent. The latter is consistent with the violation rate of 2-3 % used by the current CCCF for setting new MLs based on occurrence data such as MLs for inorganic arsenic in rice.
- ✓ Introducing a new ML for fresh farmed mushrooms of 0.3 mg/kg has full effect on removing highly contaminated mushrooms from the international trade and reducing lead exposure of consumer from the current situations without a Codex ML.

## **Wine**

With regards to paragraph 39 of Appendix II on additional topics, Japan also recognizes that alcohol beverages are not produced with the intention for consumed by infants and young children, the most vulnerable populations to lead toxicity. Therefore, it is not necessary to set an ML for wine as low as that for fruit juices (0.04 mg/kg for fruit juices, or 0.05 mg/kg for fruit juice exclusively from berries and other small fruit).

In addition, Japan thinks it necessary to minimize economic impact when lowering the ML in wine because alcohol beverages are subject to taxation for national income of Japan.

From these points of view, Japan proposes setting an ML of 0.07 or 0.08 mg/kg for wine which would eliminate 2 percent of the products in the international trade although Japan prefers an ML of 0.1 mg/kg at the violation rate of 1 percent.

## **KENYA**

### **GENERAL COMMENT**

*Kenya would like to thank the EWG led by United States of America for the good work done to come up with the recommendations for revised and new maximum levels for lead in several commodities in the GSCTFF.*

### **APPENDIX I**

### **RECOMMENDATIONS FOR REVISED AND NEW MAXIMUM LEVELS FOR LEAD IN SEVERAL COMMODITIES IN THE GSCTFF**

#### **SPECIFIC COMMENT**

Considering the damages that can be done to consumer health it is important to scientifically lower the level of lead in these products. For this reason we have no objection for lowering the MLs as proposed by the EWG for the products mentioned below from 1-9.

Rationale: since studies revealed that exposure to lead is associated with various neurodevelopment effects making fetuses, infants and children most sensitive to lead poisoning we are obliged to protect these susceptible groups.

1. **Grape juice:** Consider lowering the ML for grape juice from 0.05 mg/kg to 0.04 mg/kg.
2. **Processed tomato concentrates:** Consider lowering the ML for lead in processed tomato concentrates from 1.5 mg/kg (currently 0.05 mg/kg at Step 5) to 0.08 mg/kg.
3. **Mango chutney:** Consider lowering the ML for lead in mango chutney from 1 mg/kg to 0.3 mg/kg.
4. **Canned brassica vegetables:** Consider including canned brassica vegetables in the canned vegetables category with an ML of 0.1 mg/kg.
5. **Fresh farmed mushrooms:** Consider establishing an ML for fresh farmed mushrooms [common mushrooms (*Agaricus bisporus*), shiitake mushrooms (*Lentinula edodes*), and oyster mushrooms (*Pleurotus*)] of 0.2 mg/kg.
6. **Wine:** Consider lowering the ML for lead in wine from 0.2 mg/kg to 0.05 mg/kg.
7. **Salt:** Consider lowering the ML for lead in salt from 2 mg/kg to 1 mg/kg.
8. **Fat spreads and blended spreads:** Consider lowering the ML for lead in fat spreads and blended spreads from 0.1 mg/kg to 0.04 mg/kg.
9. **Edible fats and oils:** Consider lowering the ML for lead in edible fats and oils from 0.1 mg/kg to 0.07 mg/kg.

## **REPUBLIC OF KOREA**

The Republic of Korea supports the maximum levels of lead proposed by the Electronic Working Group.

## **TURKEY**

Turkey welcomes and appreciates the work on the revision of the maximum levels for lead by the eWG led by the United States of America.

The eWG presented in the document CX/CF 18/12/5 several recommendation for lowering the MLs for lead for various foods and establishing an ML for certain other foods.

Turkey would like to provide the following comments:

Lead is a natural environmental contaminant. Although it seems that food is the major source of human exposure to lead, we should also take into consideration water, air, soil and dust. There is no recommended tolerable intake level as there is no evidence of thresholds for a number of critical health effects. Therefore, ML should be compatible with the ALARA principle.

For **grape juice**, Turkey support that ML should remain at **0.05 mg/kg**.

Turkey would like to submit the data for grape (Table 1), and grape juice concentrate as follows. In general, fruit juices are traded in concentrated form. Therefore, during the international trade, the product that is concentrated not to being ready-to-drink, is faced with some difficulties. Thus, setting an ML at the hypothetical level of 0.04 mg/kg would eliminate 15 percent of the grape juice concentrated (Table 2) in international trade. Although, last year, the Committee agreed to delete the note in the GSCTFF on the adjustment of the ML to take into account the concentration of the product, it would be a problem during border inspection.

**Table 1. Grape**

Lead (mg/kg)	2011-2017					
	Number of Samples	%	>LOD		>0,04	
Not detected (LOD)	394	83,30				
<LOQ	5	1,06				
>LOQ	74	15,64	mean	max	Number of samples	% (Total 473)
			0,04	0,19	30	<b>6,34</b>
<b>Total Number of samples</b>	<b>473</b>	<b>100</b>				

Current and hypothetical MLs (mg/kg)	Samples < MLs	
	Number	%
0,05	455	96
0,04	443	94
0,03	431	91

**Table 2. Grape juice concentrate**

Lead (mg/kg)	2011-2017					
	Number of Samples	%	>LOD		>0,04	
Not detected (LOD)	30	65,22				
<LOQ	4	8,69				
>LOQ	12	26,09	mean	max	Number of samples	% (Total 46)
			0,04	0,13	7	<b>15</b>
<b>Total Number of samples</b>	<b>46</b>	<b>100</b>				

Current and hypothetical MLs (mg/kg)	Samples < MLs	
	Number	%
0,05	44	96
0,04	39	85
0,03	39	85

In accordance with the 73rd Meeting of the Joint FAO/WHO Expert Committee on Food Additives (JECFA), it should be taken into consideration that **mean value for fruit juices is 0.058 mg/kg**.

For processed tomato concentrates, Turkey support ML should not be lower than 0.9 mg/kg.

In the proposed draft, it is considered lowering the ML for lead in processed tomato (PT) concentrates from 1.5 mg/kg (currently 0.05 mg/kg at Step 5) to 0.08 mg/kg. The reduction amount for ML would be 95 percent. And it would be a big revision taking into consideration environmental changes all around the World. ML would be reduced gradually.

**Table 3. Tomatoes**

Lead (mg/kg)	2011-2017					
	Number of Samples	%				
Not dedected (LOD)	24	66,67				
<LOQ	3	8,33	>LOD		>0,08	
>LOQ	9	25,00	mean	max	Number of samples	% (Total 36)
			0,04	0,08	19	3
<b>Total Number of samples</b>	<b>36</b>	<b>100</b>				

Current and hypothetical MLs (mg/kg)	Samples < MLs	
	Number	%
0,08	35	97
0,06	33	92
0,05	30	83

In accordance with the Codex stan 57-1981, natural total soluble solids should not less than 24%. In Turkey, natural total soluble solids for double PT is 28-30% (produced from 6-6.5 kg tomatoes/ 1 kg PT) and for triple PT, it is 36-38% (produced from 7.8-8.2 kg tomatoes/1 kg PT).

**Table 4. Processed tomato concentrate**

Lead (mg/kg)	2011-2017					
	Number of Samples	%				
Not dedected (LOD)	34	46,58				
<LOQ	1	1,40	>LOD		>0,08	
>LOQ	38	52,02	mean	max	Number of samples	% (Total 73)
			0,066	0,86	19	11
<b>Total Number of samples</b>	<b>73</b>	<b>100</b>				

Current and hypothetical MLs (mg/kg)	Samples < MLs	
	Number	%
0,09	70	96
0,08	65	89
0,07	62	85
0,05	54	74

Turkey exports nearly 120 to 160 thousand tons of PT annually. Setting an ML at the hypothetical level of 0.08 mg/kg for PT would eliminate 11 percent of samples and nearly 12 to 16 thousand tons of PT (Table 4) in international trade. In accordance with the occurrence data in Table 4, max level for PT is 0.86 mg/kg. Taking into consideration occurrence data (max 0.08 mg/kg) for tomatoes (Table 3), and triple PT (8 times bigger), Turkey suggest that ML would not lower than 0.9 mg/kg.

For wine, Turkey support ML should be not less than 0.07 mg/kg.

In Tukey the mean value of production and export between years 2011-2016 are 57.500.000 Liter ve 3.000.000 Liter, respectively. Setting an ML at the hypothetical level of 0.05 mg/kg for wine would eliminate 8 percent of samples in international trade. It is bigger than the 5 percent.

**Table 5. Wine**

Lead (mg/kg)	2011-2017					
	Number of Samples	%				
Not dedected (LOD)	63	57,80				
<LOQ	0	0	>LOD		>0,05	
>LOQ	46	42,20	mean	max	Number of samples	% (Total 109)
			0,03	0,15	9	8
<b>Total Number of samples</b>	<b>109</b>	<b>100</b>				

Current and hypothetical MLs (mg/kg)	Samples < MLs	
	Number	%
0,07	104	95
0,06	101	93
0,05	100	92
0,04	98	90

**Method of analysis and performance criteria for lead as below:**

Method: NMKL-186 (ICP-MS)

LOD: 0,001 mg/kg

LOQ: 0,01 mg/kg

**URUGUAY**

We are grateful for the opportunity to comment.

The comment relates to point 8 of document CX/CF 18/12/5), which states as follows:

“RECOMMENDATIONS FOR REVISED AND NEW MAXIMUM LEVELS FOR LEAD IN SEVERAL COMMODITIES IN THE GSCTFF”.

“8. Fat spreads and blended spreads: Consider lowering the ML for lead in fat spreads and blended spreads from 0.1 mg/kg to 0.04 mg/kg.

Uruguay reckons that since the EWG study considers 542 items of data, of which 388 are from the EU, the data may come from very similar samples and may not reflect the diversity that could be covered by a category called “blended fat spreads according to CXS 256-2007”. We suggest that, if possible, the request for data from the member countries is reissued to obtain variability of more data.

**FÉDÉRATION INTERNATIONALE DES VINS ET SPIRITUEUX (FIVS)**

This paper presents the consensus comments of the members of FIVS<sup>1</sup> regarding the proposed draft and draft maximum levels 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;

- 1) A new limit for lead in wine (0.05 mg/L) is proposed in paragraphs 28-29 of the Working Group report, based on analysis of almost 9500 data points from the GEMS database.
- 2) The OIV recommended limit for lead in wine is currently 0.150 mg/L - lower than the current limit recommended in the GSCTFF (0.200 mg/L). Over the years, OIV (where FIVS also functions as an official observer) has repeatedly reduced its recommended limit so that it is among the lowest currently appearing in regulations for wine around the world. OIV is also committed to making further reductions as appropriate – a stance that FIVS wholeheartedly endorses. This represents clear evidence of the seriousness accorded to these issues. Producers have responded accordingly, as is very clear from the GEMS dataset.
- 3) FIVS notes that the introduction of a limit of 0.05 mg/L is anticipated, based on the data analysed, to result in the elimination of 3% of products in international trade (paragraph 29 of the Working Group report). For 2016, global production of wine was provisionally estimated at 270 million hectolitres in volume with an average value per litre (for exported wine) of 2.78 Euros/L (OIV data). On this approximation, a 3% elimination of product would amount to some 2.25 billion Euros of production value and much more in terms of the full impact to national economies. In addition, it seems clear from the dataset that a limit of 0.05 mg/L has a more significant impact on fortified wines than on other product categories, eliminating as much as 24% of products in international trade.
- 4) Looking at the data from which the new limit is derived, although there are many data points, it seems very difficult if not impossible to establish exactly how representative the data are of products circulating in international trade. Clearly, when a global limit is being considered, it is most important to establish it based on a dataset that is clearly as comprehensive and as representative as possible of the prevailing situation, in order to avoid possible unintended consequences. Accordingly, FIVS urges CCCF to ensure that the dataset being used as the basis for any proposal is in fact representative of the product in trade at this time.
- 5) FIVS recalls that Codex Alimentarius adopted a Code of Practice for the Prevention and Reduction of Ochratoxin A Contamination in Wine (CAC/RCP 63-2007, supplied in draft by OIV). FIVS suggests that a similar code in respect of lead would be a useful means by which to continue the downward trend of lead levels in wine, and FIVS would be happy to contribute to the effort should such a project be considered appropriate.
- 6) Finally, it is well known that wines tend to have long shelf lives. Most wines are made to be consumed within 2-5 years of production, so they can remain in the market place for longer periods of time than many food products. Some are even made to be consumed up to 50 years after the harvest year of the grapes from which they are produced. Such products are, of course, highly specialized and highly prized. For some they are even regarded as financial investments. They represent a negligible proportion of the population of wines available for public consumption. The OIV, in recommending lower limits for lead in wine, has taken account of such factors by proposing that application should begin with products made from grapes harvested in a specified year, and should not apply to products made from grapes harvested earlier. Some government authorities have followed this recommendation when introducing these measures into regulation. In a relatively short period of time with such an approach, the vast majority of products in the market place become compliant with the lower limit proposed. FIVS respectfully suggests that in recommending any lower limit for lead in wine, the CCCF gives consideration in addition to recommending implementation provisions along these lines to members of Codex Alimentarius.

---

<sup>1</sup> 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.

- 7) In the light of all these considerations, FIVS proposes the following as elements of a measured but effective approach on this issue:
- a. A more modest reduction in the limit for lead in wine at this time (to 0.150 mg/L to mirror the limit recommended by OIV).
  - b. A recommendation that the new limits be implemented by Codex Alimentarius members in a way that takes account of the longevity of some products in the market (for example, by applying the limits to products of a given grape harvest year and later).
  - c. The development of a code of practice covering the means by which lead content of wines may be further decreased.
  - d. An undertaking to revisit the limit value perhaps 5 years after the code of practice is adopted.

## Conclusions

FIVS is grateful for the opportunity to provide comments on this important proposal. We are committed to seeing a continuing reduction in the levels of lead in wine as rapidly as appropriate, and provided that any recommendations are based on representative data and take account of the longevity of wine in the market place.

## ORGANISATION INTERNATIONALE DE LA VIGNE ET DU VIN (OIV)

### Comments from International Organisation of Vine and Wine (OIV)<sup>1</sup>

This document does not commit Member States of the OIV in the comments and views that they might provide or express separately

#### General comments

The 11<sup>th</sup> session of the CCCF agreed to re-establish the EWG, chaired by USA, working in English only, to continue to work on outstanding issues related to the review of MLs for lead in fruits and vegetables (fresh and processed) and other selected food categories in the GSCTFF, and in particular to review the following new categories, i.e., salt, **wine**, fat spreads and blended spreads,

The United States of America, as Chair of the EWG, prepared the paper on proposed revised MLs for lead in grape juice; processed tomato concentrates; mango chutney; canned brassica vegetables; fresh farmed mushrooms; **wine**; salt; fat spreads and blended spreads; and edible fats and oils.

The electronic working group presented in the document CX/CF 18/12/5 several recommendation for lowering the MLs for lead for various foods and establishing an ML for certain other foods. In particular the EWG recommends lowering the ML for lead in wine from 0.2 mg/kg to 0.05 mg/kg

The International Organisation of Vine and Wine (OIV) welcomes and appreciates the work on the discussion paper (CX/CF 18/12/5) on lead performed by the electronic Working Group under the lead of the United States.

The OIV would like to provide the following comments:

By the Agreement of 3 April 2001<sup>2</sup>, the OIV is established as “*intergovernmental organisation of a scientific and technical nature of recognised competence for its work concerning vines, wine, wine-based beverages, grapes, raisins and other vine products.*” Its activities concern notably “*conditions for grape production and the oenological practices*”.

The OIV has taken note of the conclusion of the 73rd Meeting of the Joint FAO/WHO Expert Committee on Food Additives (JECFA) which has conducted a new toxicological evaluation of lead in food, at the request of Committee on Contaminants in Food (CCCF). In the evaluation JECFA stated that exposure to lead is associated with a wide range of effects, including various neurodevelopmental effects, impaired renal function, hypertension, impaired fertility and adverse pregnancy outcomes.

<sup>1</sup> Members-states: Algeria, Argentina, Armenia, Australia, Austria, Azerbaijan, Belgium, Bosnia-Herzegovina, Brazil, Bulgaria, Chile, Croatia, Cyprus, Czech Republic, France, Georgia, Germany, Greece, Hungary, India, Israel, Italy, Lebanon, Luxemburg, FYROM, Malta, Mexico, Moldavia, Montenegro, Morocco, Netherlands, New Zealand, Norway, Peru, Portugal, Romania, Russia, Serbia, Slovakia, Slovenia, South Africa, Spain, Sweden, Switzerland, Turkey, Uruguay

Observers: Municipality of Yantai (China); Ningxia Hui Autonomous region (China)

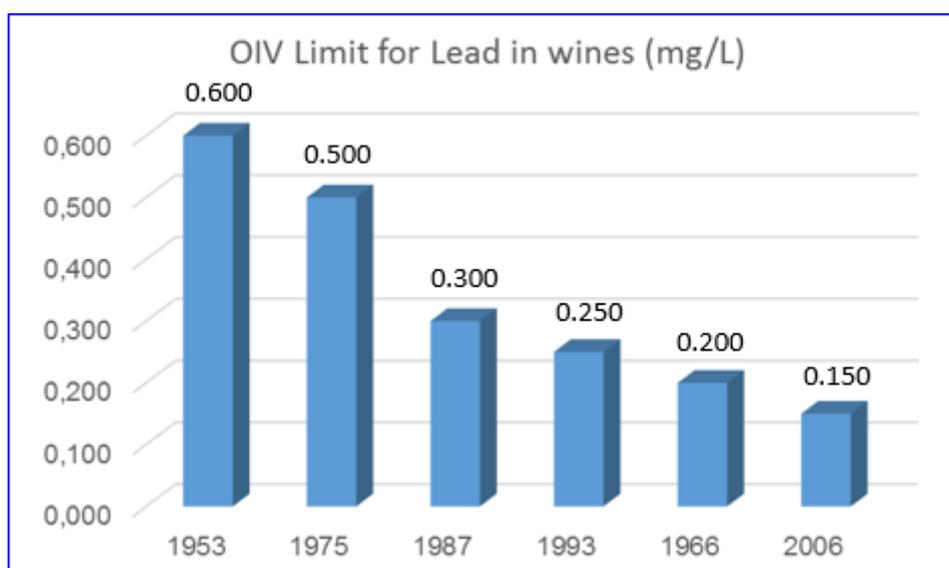
<sup>2</sup> Agreement of 3 April 2001 establishing the International Organisation of Vine and Wine  
<http://www.oiv.int/oiv/info/entextesfondamentaux>

Because of the neurodevelopmental effects, fetuses, infants and children are the subgroups that are most sensitive to lead. JECFA withdrew the previously established provisional tolerable weekly intake (PTWI) of 25 µg/kg bw and concluded that since there is no indication for a threshold of effect it was not able to establish a new tolerable intake level. JECFA also concluded that, in populations with prolonged dietary exposures to higher levels of lead, measures should be taken to identify major contributing sources and, if appropriate, to identify methods of reducing dietary exposure that are commensurate with the level of risk reduction.

### OIV works and OIV limits for lead

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

- Since 1953, the Member states of the OIV have reduced the lead levels in wines as the figures below shows.



- In addition, in 1990, the OIV has adopted a recommendation to stop the use of lead « capsules » in wine sector. This recommendation has been included in the Code of practice for the prevention and reduction of lead contamination in foods (CAC/RCP 56-2004) adopted by the Codex in 2004.
- However, three main sources of lead contamination have been identified
  - The environmental source (, industry, mining, (lead in gasoline -no longer considered))
  - The lead level in soil potential contamination
  - The metal material in the wine making process for which stainless is more and more used.
- It has been shown that a grape pectic polysaccharide rhamnogalacturonan-II (dRGII) that is not degraded during vinification is able to form complexes with lead<sup>1</sup>. In addition, it has been demonstrated that Rhamnogalacturonan-II Dimer decreases Intestinal absorption and tissue accumulation of lead in rats<sup>2</sup>. If the results showed that with dRGII residual Pb was not available for absorption. However, the added dRGII failed to induce any significant increase in faecal or urinary Pb excretion. Study shows that dRGII administration was not effective in decreasing tibia or kidney Pb levels in rats. In conclusion, Pb complexed by dRGII in fruits and vegetables and fruit juice is thus mostly unavailable for intestinal absorption. However, the addition of dRGII after chronic Pb exposure does not help Pb detoxification<sup>3</sup>.
- As reminder, in 2012, at the sixth session of the CCCF, the OIV has participated to the discussion paper on maximum levels for lead in various foods and the OIV has suggested that the Codex ML for lead in wine be lowered to 0.150 mg/kg, in order to be consistent with the OIV standard adopted in 2006. Therefore, the WG recommended reevaluating the ML for wine.

<sup>1</sup> J. Int. Sci. Vigne Vin, 1997,31, n°1, 33-41

<sup>2</sup> J. Nutr. 130: 249–253, 2000

<sup>3</sup> British Journal of Nutrition 2002, 87, 47–54. DOI: 10.1079/BJN2001476

## Recommendations of the EWG

Based on the data available from the GEMS/Food database and the analysis process, the EWG recommends that the Committee consider lowering the ML for lead in wine from 0.2 mg/kg to 0.05 mg/kg, considering that 100 percent of samples in the 2018 LOQ-limited dataset met the current ML of 0.2 mg/kg, 99 percent of samples in the 2018 LOQ-limited dataset may meet a hypothetical ML of 0.1 mg/kg; 97 percent of samples may meet a hypothetical ML of 0.05 mg/kg; and 95 percent of samples may meet a hypothetical ML of 0.04 mg/kg.

Thus, setting an ML at the hypothetical level of 0.1 mg/kg would eliminate 1 percent of the samples in international trade, setting an ML at the hypothetical level of 0.05 mg/kg would eliminate 3 percent of the samples in international trade, and setting an ML at the hypothetical level of 0.04 mg/kg would eliminate 5 percent of the samples in international trade.

In par.39 Annexe II of the document CX/CF 18/12/5 it is noted that « *On the issue of wine, several countries noted that because wines are not produced with the intention of being consumed by infants and young children, and are not as frequently consumed as non-alcoholic drinks, a low ML (e.g., 0.05 mg/kg) may be unnecessary* »

## Specific comments

The OIV agrees that wines are not produced with the intention of being consumed by infants and young children and should not be an important source of exposure for young children. However, even if JECFA did not identify exposure levels specifically from grape wines in its evaluation, the data available from the GEMS/Food database suggest that a lower ML for lead in wine may be achievable.

Moreover, the OIV would like to draw the attention of the committee that a limit too low, only based on a statistic analysis of samples and which is not specifically justified from a strictly health point of view, could have an important consequence in the international trade by eliminating an important part of the world wine production.

- **The wine production in the world is estimated at 247 Million hectoliters. Therefore the estimation of the working group that 97% of samples may meet an hypothetical ML of 0.05 mg/kg leads to consider that approximately 7.5 million hectoliter of wine will be excluded of the international wine trade.**

This corresponds to a little bit less than total wine production of Germany (8.1 MioHl) or a little bit more than that of Portugal (6.6 MioHl) in 2017 (Table 1).

- **Therefore the Committee should take into account the Article 5 §6 of the SPS agreement which states that, « *when establishing or maintaining sanitary or phytosanitary measures to achieve the appropriate level of sanitary or phytosanitary protection, Members shall ensure that such measures are not more trade-restrictive than required to achieve their appropriate level of sanitary or phytosanitary protection, taking into account technical and economic feasibility.* »**

**Table 1: Wine production (excluding juice and musts) (1)**

Unit: mhl	2013	2014	2015	2016 Provisional	2017 Forecast	2017/2016 Variation in volume	2017/2016 Variation in %	Ranking
Italy	54.0	44.2	50.0	50.9	39.3	-11.6	-23%	1
France	42.1	46.5	47.0	45.2	36.7	-8.5	-19%	2
Spain	45.3	39.5	37.7	39.3	33.5	-5.8	-15%	3
United States (2)	24.4	23.1	21.7	23.6	23.3	-0.3	-1%	4
Australia	12.3	11.9	11.9	13.1	13.9	0.8	6%	5
Argentina	15.0	15.2	13.4	9.4	11.8	2.4	25%	6
China*	11.8	11.6	11.5	11.4	11.4	0.0	0%	7
South Africa	11.0	11.5	11.2	10.5	10.8	0.3	2%	8
Chile	12.8	9.9	12.9	10.1	9.5	-0.7	-6%	9
Germany	8.4	9.2	8.9	9.0	8.1	-0.9	-10%	10
Portugal	6.2	6.2	7.0	6.0	6.6	0.6	10%	11
Russia*	5.3	4.9	5.6	5.6	5.6	0.0	0%	12
Romania	5.1	3.7	3.6	3.3	5.3	2.1	64%	13
Brazil	2.7	2.6	2.7	1.3	3.4	2.1	169%	14
Hungary	2.6	2.4	2.8	2.8	2.9	0.1	3%	15
New Zealand	2.5	3.2	2.3	3.1	2.9	-0.3	-9%	16
Greece	3.3	2.8	2.5	2.6	2.5	-0.1	-5%	17
Serbia*	2.3	2.3	2.3	2.3	2.3	0.0	0%	18
Austria	2.4	2.0	2.3	2.0	2.4	0.4	23%	19
Moldova	2.6	1.6	1.6	1.5	1.8	0.3	20%	20
Bulgaria	1.7	0.7	1.3	1.2	1.2	0.0	-2%	21
Georgia*	1.0	1.1	1.3	1.1	1.1	0.0	0%	22
<b>OIV World Total(3)</b>	<b>290.1</b>	<b>269.5</b>	<b>274.7</b>	<b>268.8</b>	<b>246.7</b>	<b>-22.1</b>	<b>-8%</b>	

(1): Countries for which information has been provided with a wine production of more than 1 mhl

(2): OIV estimate based on UDSA info

(3): OIV estimate: mid-range estimate. Range for evaluation of 2017 world production: from 243.3 mhl to 250.1 mhl

\* Report for the year 2016 – 2017 figures not yet available

Considering the data and taking into account the GEMS/Food database, it seems important to analyse the data according to the different type of wines.

Based on the data and information available on the database, the OIV Secretariat has roughly categorised the samples according to the type of wines by excluding beverages other than grape wines.

Among the 9322 samples, the global results according to the type of wines indicated roughly

	Number	samples > 0.05 mg/L		samples > 0.100 mg/L		samples > 0.150 mg/L (OIV limit)	
		N°	% rejection	N°	% rejection	N°	% rejection
<b>All wines *</b>	<b>8772</b>	<b>281</b>	<b>3,2</b>	<b>84</b>	<b>1,0</b>	<b>27</b>	<b>0,3</b>
<i>Red wines</i>	3808	114	3,0	32	0,8	8	0,2
<i>White wines</i>	2773	138	5,0	41	1,5	12	0,4
<i>Rosé wines</i>	112	1	0,9	0	0,0	0	0,0
<i>Sparkling wines</i>	1566	14	0,9	3	0,2	0	0,0
<i>Dessert/Ice wines</i>	513	14	2,7	8	1,6	6	1,2
<b>Fortified wines *</b>	<b>550</b>	<b>131</b>	<b>23,8</b>	<b>35</b>	<b>6,4</b>	<b>10</b>	<b>1,8</b>

- The OIV would like to point out that an hypothetical ML of 0.05 mg/kg also lead to reject an important part of the fortified wine.

In addition, based on the information above-mentioned, the OIV would like to recommend to the Committee:

\* Numeric filter is applied on the column "ResultText"

- As already indicated, the OIV has adopted different resolutions about lead and continue to work on this issue.

In particular, based on the evaluation of JECFA, the concerned OIV group of experts have already engaged a discussion on the potential reduction of the current OIV limit (0.150 mg/L).

At this time the OIV is receiving data and information on lead in wines and is in the process of preparing a proposal that could allow to adopt an international standard for ML of lead in wines.

**Therefore there is already considerable work on lead in wines being undertaken at the OIV in particular, and Codex work should therefore take into account the new OIV works on this issue, in order to avoid any duplication or inconsistency in potential limit in the future. The OIV is willing to provide scientific expertise and additional information for the next CCCF meeting.**

- when setting a limit for wine, CCCF could envisage the possibility to distinguish different wine categories especially fortified wines but also differentiate the grape wines category from wines other than grapes as does the Codex in its General Standard for Food Additives.
- Whatever the modification of the lead limit for wines, the OIV recommends to establish a limit with a footnote indicating that this new limit is established for products produced from « *the date of adoption* » fruit harvest onwards.

In fact, it is important to consider wines already bottled and marketed as well as the old vintage for which there is an important international trade with a high added value.

#### **WORLD PROCESSING TOMATO COUNCIL (WPTC)**

As the trade association representing more than 95% of the volume of tomatoes processed in the world, WPTC has been taking part as a “Codex Official Observer” within the eWG lead by USA for the revision of the Maximum Levels of Lead in selected Commodities and in particular in CXS 57 – 1981 Tomato Concentrates.

We have the following comments to make in reference to document CX/CF\_18/12/5.:

##### **- On data collection:**

- The revision has been organized exclusively with the aim to review occurrence data to assess what percentage of samples can meet proposed new MLs only partially take into account the most important global production and trade of tomato processed products (i.e. USA, China, Italy, Spain that are major players and Brazil is not, as we demonstrated in the figures we sent in February 2017).
- *“At the same time, Brazil indicated they could provide data on tomato concentrates at different ratio of concentrations because of the possibility that the proposed lower ML did not take into account the effect of the different concentration ratios on the achievability of the ML and therefore some tomato concentrates may not comply with the proposed ML. This year’s dataset includes 112 tomato puree results (“extract” and “pulp”) that Brazil supplied to GEMS/Food in 2017.” ...).*
- We strongly recommend considering collecting more sample analysis in order to better represent the effective international production and trade; the results should be carried out and expanded before a final decision is made
- What about the others processing tomato products excluded (sauces, ketchup, tomato powder, etc)

##### **- On product concentration:**

- We would like to remind also the necessity of an amendment that considers the effect of the different concentrations ratios in case of particular set of products (i.e. dried tomato powder or semi-dried or sun-dried tomatoes...).
- In the current relevant Codex commodity standards CODEX STAN 57-1981 (Processed tomato concentrates) and CODEX STAN 13-1981 (Preserved tomatoes), there is the following text: *“In order to consider the concentration of the product, the determination of the maximum levels for contaminants shall take into account the natural total soluble solids, the reference value being 4.5 for fresh fruit.”*

The reference to 4.5 corresponds to the average/reference brix in fresh tomatoes. The lead content should be calculated relative to this to take into account the concentration effect: i.e. if the ML is 0.1 ppm in fresh tomatoes it should be  $0.1 \times 28/4.5$  in 28/30 tomato paste = 0.62 or  $0.1 \times 38/4.5$  in 36/38 tomato paste = 0.84. (not 0,8 for all the tomato concentrates).

The new proposal does not make reference to the concentration.

- Example of the EU legislation:

The European Legislation (Reg. CE 1881/2006 – Reg. CE 629/2008 – Reg. CE 420/2011) sets the limits of Lead at 0,1 mg/kg wet weight ... But referring at drying, processing etc. we must follow what has been declared at *Article 2* of regulation CE 1881/2006:

*“Dried, diluted, **processed** and compound foodstuffs*

*1. When applying the maximum levels set out in the Annex to foodstuffs, which are dried, diluted, processed or composed of more than one ingredient, **the following shall be taken into account:***

*(a) **changes of the concentration of the contaminant caused by drying or dilution processes;***

*(b) **changes of the concentration of the contaminant caused by processing;**”*

- This issue has further relevance as tomato concentrates are never consumed as such but always diluted, either through second stage processing to produce sauces, ketchup, ... or by the final user at home or in a restaurant.

- **On natural conditions:**

- Despite the fact that all the analysed samples are very low in lead concentration, we would like to advise and hence to take into account the accidental high levels of lead coming from soils particularly naturally rich in metals, as shown by the following scientific articles:  
<https://doi.org/10.1016/j.envint.2015.12.017> &  
<https://www.sciencedirect.com/science/article/pii/S0048969716310452>
- Some high levels are found naturally in some of the regions where tomato concentrates are traditionally produced and setting a low ML could affect the industry in these regions, while not having any beneficial effects on human health