

CODEX ALIMENTARIUS COMMISSION



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Agenda Item 7

CX/CF 18/12/7-Add.1
Original language only

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

12th Session

Utrecht, The Netherlands, 12 - 16 March 2018

PROPOSED DRAFT MAXIMUM LEVELS FOR METHYLMERCURY IN FISH INCLUDING ASSOCIATED SAMPLING PLANS

Comments submitted at Step 3 by Australia, Canada, Colombia, Cuba, EU, Japan, Kenya, Malaysia, Republic of Korea, Uganda, USA, AU, ICGMA and ISDI

AUSTRALIA

- As part of the background context for proposing to establish MLs for methyl mercury in fish, the benefits of fish consumption should feature more prominently along the lines of the previous Joint FAO/WHO Expert Consultation on the Risks and Benefits of Fish Consumption. In particular, a statement to the effect that "*risk managers need to consider the known benefits of fish consumption when developing national guidance for consumption of specific species of fish in parallel to applying these MLs*" could be a useful addition.
- In establishing MLs based on ALARA, Australia would support establishing MLs based on the application of a 2-3% rejection rate consistent with the previous approach to the establishment of MLs for lead and inorganic arsenic.
- Australia does not support the setting of an ML for Amberjack on the basis that the available scientific data shows that mean total mercury is 0.24 mg/kg (n=179) and mean methylmercury is 0.18 mg/kg (n=49). This is less than the 0.30 mg/kg methylmercury threshold used by the electronic working group in the identification of species for consideration of MLs
- Similar to Amberjack, Australia does not consider that an ML is necessary for Spanish mackerel as the average total mercury level from currently available data in the GEMS/FOOD Contaminants database is 0.24 mg/kg (n=101). This is less than the 0.30mg/kg methylmercury threshold used by the electronic working group in the identification of species for consideration of MLs.
- Australia re-iterates its position that the ML for fresh tuna should not be applied to canned tuna. On this basis the existing footnote attached to the current GL should be clarified.

Existing footnote:

"The guideline levels are intended for methylmercury in fresh or processed fish and fish products moving in international trade"

Suggested amendment:

"The maximum levels are intended for methylmercury in fresh or processed fish and fish products moving in international trade, excluding canned tuna"

- Australia supports a third footnote indicating the need for additional risk management measures to all proposed MLs. Australia would like to propose an amended footnote as the three proposal do not clearly articulate the benefits of frequent fish consumption.

"In some cases, the benefits associated with the frequent consumption of specific fish species may be outweighed by the risks from methyl mercury exposure. Countries should consider developing nationally relevant consumer advice for pregnant women and young children to supplement these MLs".

- Australia supports the proposal to send the sampling plan to CCMAS for endorsement with specific questions.

- The sampling plan should be representative, practical and not impose excessive compliance costs on industry. In particular, CCMAS should be asked if a more practical sampling plan is feasible in light of the high number of samples proposed to be required.
- In relation to the sampling of whole fish or specific fractions, it is unclear if the data present in the GEMS/Food Contaminant database is based on standard robust sampling methodology that is representative of the edible portion. Research on farmed Southern Bluefin Tuna has demonstrated that mercury concentrations can vary based on the edible tissue cut.

CANADA

Canada wishes to express its appreciation to the chair, the Netherlands, and co-chairs, New Zealand and Canada, for once again leading the electronic working group (eWG) on the Proposed Draft Maximum Levels for Methylmercury in Fish Including Associated Sampling Plans.

Canada supports the following recommendations of the eWG that are outlined in the discussion document (CX/CF 18/12/7):

- Additional analysis of Spanish mackerel to confirm methylmercury levels and ratio of total to methylmercury.
- ML development in other fish species should consider the ratio of total to methylmercury.
- Include a footnote indicating that countries or importers may analyse total mercury; if the total mercury concentration is above the ML for methylmercury, follow-up testing should be conducted to determine if the methylmercury concentration is above the ML.
- To consider sending the sampling plan to the Committee on Methods of Analysis and Sampling (CCMAS) for endorsement with specific questions.

Canada also supports inclusion of the current footnote to the GL to the proposed MLs: "*The guideline levels are intended for methylmercury in fresh or processed fish and fish products moving in international trade*". Although at CCCF11 it was determined that an ML was unnecessary for canned tuna, Canada supports the inclusion of this footnote as it would prevent fish non-compliant with the MLs from being processed into canned fish products.

Canada is in favour of attaching a footnote indicating the need for additional risk management measures (i.e. consumption advice) to all MLs for mercury in fish in the GSCTFF and supports the option presented in the paragraph 22(6)(a) of the CX/CF 18/12/7.

Canada also supports the following options presented in CX/CF 18/12/7 for further discussion at CCCF12:

- In general, MLs based on the P95 concentration. If MLs with a <5% rejection rate were to be considered, which would allow more fish with higher Hg levels on the market, an additional rationale would need to be developed (e.g. benefits for certain subgroups, effectiveness of consumption advisories).
- A single ML for all tuna species.
- An ML for all marlin, as that proposed based on blue marlin data would result in too high of exposure to inorganic mercury.
- Additional discussion by the CCCF as to if an ML is required for amberjack, noting that a number of tuna species would also fall into the category of having < 0.3 ppm total mercury but are not excluded from the ML for tuna.

COLOMBIA

Colombia tiene el agrado de presentar posición de acuerdo al ANTEPROYECTO DE NIVELES MÁXIMOS DE METILMERCURIO EN EL PESCADO INCLUIDOS LOS PLANES DE MUESTREO ASOCIADOS, en el sentido de manifestar lo siguiente:

APARTE:

1. Percentil apropiado para establecer NM.

11. Al igual que en el GTE anterior, se utilizó el valor P95 como valor por defecto para obtener NM propuestos, lo que generaría una tasa de rechazos del 5%. Tres miembros del GTE indicaron que serían apropiadas unas tasas de rechazos más bajas, como las utilizadas en el GTE del CCCF sobre el plomo; un miembro específico que la tasa de rechazos debería ser del 2-3%. Por tanto, además del enfoque basado en el P95 como el utilizado el año anterior en el documento de debate, el enfoque empleado por el GTE sobre el plomo se ha utilizado y se han obtenido NM propuestos adicionales.

APÉNDICE I-PARTE I

Tabla 1 “Proposed Draft MLs for Methylmercury in the Following Species of Fish”

APÉNDICE II

Cuadro 1: Resumen de datos de presencia del total de mercurio en mg/kg en muestras de atún, datos tomados de la base de datos sobre contaminantes del SIMUVIMA/Alimentos. Análisis estadísticos excluyendo datos sin LOD/LOQ.

Se considera que se requiere recopilar más datos actualizados para tener un panorama de los niveles de este metal en pescados crudos refrigerados y/o congelados, especialmente de países de Latinoamérica, resaltando la importancia en las diferentes tallas.

Adicionalmente es importante solicitar a los miembros que envíen datos actualizados de los niveles de mercurio total de sus planes de muestreos para actualizar la base de datos de contaminantes.

2. NM para todo el atún

13. En la CCCF11, se acordó que se debería desarrollar un NM para todo el atún, por lo que los NM propuestos se obtuvieron a partir de los datos combinados de las especies de atún. Sobre la base de los comentarios de la CCCF11 y del GTE acerca de que el anteproyecto de NM debería estar basado en el atún con mayor nivel, se realizaron análisis adicionales para dos categorías: el atún con mayor nivel (atún patudo y atún rojo) y el atún con menor nivel. Para estas categorías también se indicaron propuestas de NM

Colombia apoya la posición de establecer un valor máximo de metilmercurio para todos los atunes independientemente de la especie.

3. 17. La CCCF11 decidió no desarrollar un NM para el atún enlatado, ya que los niveles en estas muestras eran generalmente bajos. Esta decisión se basó exclusivamente en el análisis de datos para la CCCF11. El NR actual incluye una nota «Los niveles de referencia son para el metilmercurio en pescado fresco o elaborado y productos pesqueros destinados al comercio internacional», que incluye el pescado enlatado.

No se tomó ninguna decisión en la CCCF11 en relación con esta nota. La presidencia del GTE planteó la pregunta de si la nota actual sobre el NR se debería incorporar a los nuevos NM. No incluir la nota significaría que el NM para pescado fresco/congelado no se aplicaría al pescado enlatado, lo que podría abrir la posibilidad de aparición de pescado no conforme con el NM para pescado fresco/congelado procesado en latas. Cuatro miembros se opusieron a incorporar la nota existente a los NM, dada la decisión de la CCCF11 de no obtener un NM para el atún enlatado, e indicaron que podría tener como resultado una realización innecesaria de análisis. Tres miembros se mostraron a favor de incorporar la nota actual al NM.

Se requiere recopilar más datos actualizados para tener un panorama de los niveles de este metal en atún enlatado para lo cual Colombia tiene la posibilidad de presentar datos de monitoreo de mercurio total en atún enlatado, para evidenciar el estado actual de este contaminante.

4. Recomendaciones adicionales para su consideración por parte del CCCF 22

6. Considerar la siguiente opción de texto para esta tercera nota:

c. «Para las especies de pescado con alto contenido en metilmercurio, los países deberían considerar el desarrollo de consejos para los consumidores relevantes a nivel nacional para mujeres embarazadas y niños pequeños como complemento a estos NM.»

Colombia apoya la opción de Texto C.

5. 3 Notas sobre el NM:

37. Por tanto, la nota sobre el NM para el arsénico en el arroz se ha utilizado como ejemplo y adaptado para el metilmercurio:

«Los países o importadores pueden decidir utilizar su propia selección al aplicar el NM para metilmercurio en pescado analizando el total de mercurio en el pescado. Si la concentración del total de mercurio es inferior al NM de metilmercurio, no es necesario ningún ensayo ulterior y se determina que la muestra cumple el NM. Si la concentración del total de mercurio es superior al NM de metilmercurio, se realizarán ensayos de seguimiento para determinar si la concentración de metilmercurio es superior al NM.»

Se invita a los países a considerar establecer un factor de correlación entre mercurio total y metilmercurio, previa validación de estudios realizados en los países o bibliografía, dada la inestabilidad analítica del metilmercurio y por aspectos de seguridad para el analista (uso de solventes).

6. APÉNDICE I-PARTE II

PLAN DE MUESTREO

66. Los miembros del GTE tenían preguntas específicas acerca del plan de muestreo; lo mejor sería transmitir las al CCMAS. Por tanto, se invita a la CCCF12 a considerar el envío del plan de muestreo del Apéndice II al CCMAS para su ratificación con las siguientes preguntas específicas:

e. ¿Deberían analizarse crudas las muestras para mercurio en pescado (o sin ningún otro procesamiento o cocción para productos ya procesados, p. ej. pescado enlatado)?

Colombia apoya la propuesta de remitir el plan de muestreo para revisión del CCMAS, sin embargo se considera importante se realice diferenciación de muestreo por calidad en planta y de vigilancia ejercido por autoridad sanitaria, ya que cada uno tiene un propósito diferente.

e. ¿Deberían analizarse crudas las muestras para mercurio total y metilmercurio en pescado congelado y subproductos del pescado p. ej. Pescado enlatado)?

7. 41. Si la nota se adjunta a los nuevos NM, esto no significaría que el análisis de datos para la obtención de los NM debería incluir también los datos sobre pescado enlatado. Como ilustración, se ha proporcionado un análisis actualizado de los datos sobre el atún enlatado

Colombia puede presentar datos ante SIMUVIMA en relación a conservas. Para lo cual se invita al GTE revisar este tema para poder contar con un mayor número de resultados con características analíticas adecuadas.

8. Comentarios Generales:

8.1 *El pescado blanco de Gyunggi (Korea) ha sido reportada mediante cromatografía de gases con niveles de mercurio total de $0,042 \pm 0,011$ mg/kg y metilmercurio de $0,007 \pm 0,008$ mg/kg (Yang, Kim, Hwang, Park, & Kim, 2015).*

De igual forma, en Omán, la Sardina pilchardus mediante espectrometría de absorción atómica, reportó niveles de mercurio total de $0,034$ mg/kg (Al-Mughairi et al., 2013), así como la Sardinella longiceps reportó niveles de mercurio total de $0,02 \pm 0,02$ mg/kg (Al-Busaidi et al., 2011) por lo que se deja a consideración incluir esta especie en el grupo de peces.

8.2 *Se sugiere incluir pescados como Anchovy (Engraulis encrasicolus), Anglerfish (Lophius piscatorius), Blue shark (Micromesistius poutassou), Blue whiting (Micromesistius poutassou), Cat shark (Galeus melastomus), Cuttlefish (Sepia officinalis), entre otros, en los cuales se han encontrado niveles de mercurio total y metilmercurio según la importancia por el consumo y la región donde se encuentran (Al-Busaidi et al., 2011; Al-Mughairi et al., 2013; Blanco, González, & Vieites, 2008; Chung, Kwong, Tang, Xiao, & Ho, 2008; Olmedo et al., 2013; Yang et al., 2015)*

CUBA

En respuesta a la carta circular: CL 2018/3-CF, Cuba agradece la oportunidad de expresar su comentario respecto a esta carta circular, donde en principio se apoya el documento con lo descrito en el mismo.

EUROPEAN UNION (EU)

The European Union (EU) welcomes and appreciates the work on the revision of the maximum levels for mercury by the electronic Working Group led by The Netherlands and co-chaired by New Zealand and Canada.

In general, the EU considers that the MLs should be lowered wherever possible. The EU MLs are currently lower than the Codex MLs proposed in Appendix I – part I. In view of the public health concerns identified for the exposure to mercury, the EU can for the time being not support Codex MLs, which would result, when implemented in EU legislation, in an increase of the EU MLs for mercury in fish.

The EU supports adding a footnote to the MLs that they apply to fresh and processed fish and fish products, so that Codex MLs will also apply to canned fish. This should avoid that non-compliant fish will be processed in cans.

The EU supports the addition of a footnote on additional risk management measures to be added to all proposed MLs for fish. The EU would like to make the following re-phrasing suggestion:

*Adverse effects due to methylmercury exposure may outweigh the benefits **of consumption of certain fish species compliant with the MLs**, when frequently consuming this fish species, particularly by pregnant women, infants, **toddlers and children up to 12 years old**. The development of additional RM measures (e.g. consumption advice) may be necessary at a national level to restrict exposure in order to avoid unacceptably high levels of methylmercury.*

The EU would like to comment that for the proposed sampling plan in the definition of 'lot', it should be added that: 'In the case of fish, also the size of fish shall be comparable'. The EU agrees with the proposed sampling plan.

The EU would prefer only the setting of performance criteria for analytical methods, but can also agree on a listing of analytical methods.

JAPAN

Japan thanks the electronic working group, chaired by the Netherlands, and co-chaired by New Zealand and Canada, and appreciates the opportunity to comment on the above paper.

As we have stated previously, Japan is of the strong opinion that consumption advice for consumers, particularly for high-risk groups, is more effective and appropriate for reducing health risk associated with methylmercury intake from fish than maximum levels for methylmercury.

Nonetheless, as the CCCF agreed to consider MLs for fish, Japan wishes to provide the following comments to contribute in the discussion.

< The Proposed draft MLs >

First of all, Japan would like to remind the CCCF that in the past discussions on MLs for certain contaminants, such as Pb and inorganic As, there was a general agreement that a violation rate around 2-3% was appropriate while that of 5% was too high. CCCF should continue using a violation range of 2-3% unless there is a scientific reason to do otherwise.

Second of all, regarding the establishment of MLs for contaminants, the GSCTFF stipulates, "Numerical values for MLs should preferably be regular figures in a geometric scale (0.01, 0.02, 0.05, 0.1, 0.2, 0.5, 1, 2, 5 etc.), unless this may pose problems in the acceptability of the MLs." The draft MLs for methylmercury considered until the 9th Session were regular numerical values with one significant values (e.g. 1, 2, 3, 4, 5 mg/kg). As for the impact on dietary methylmercury intakes, the reduction rate of intakes from the six specified tuna species in different ML scenarios (1, 2, 3, 4, 5 mg/kg) estimated in the discussion paper prepared for the 9th Session (Table 5 of CX/CF 15/9/13) showed only small difference among the 5 different ML scenarios. It means that whichever ML value is used, the impact on dietary intakes by consumers would be insignificant. Furthermore, the nutritional and developmental importance of fish consumption should be considered. The FAO/WHO Expert Consultation report (2011)¹ concluded that fish is an important food source of energy, protein and a range of essential nutrients and the net neurodevelopmental benefit to offspring of fish consumption by women of childbearing age, particularly pregnant women and nursing mothers. And it also recommended member states to develop and evaluate risk management and communication strategies that both minimize risks and maximize benefits from fish consumption.

In the discussion paper (CX/CF 18/12/7), some ML values have two significant digits, one before the decimal point and the other after the decimal point (e.g., 1.2, 1.4, etc.). While Japan understands that for using a violation rate consistently, this is inevitable, enforcement of MLs with two significant values will have impact on regulatory analysis as the requirements for precision, accuracy and uncertainty will need to be stricter than those for values with one significant value. In addition, MLs used geometrical scales should be considered not only from the viewpoints shown in the discussion paper, but also from the contribution rate for PTWI by setting MLs and the benefits of fish consumption.

¹ FAO/WHO. 2011. Joint FAO/WHO Expert Consultation on the Risks and Benefits of Fish Consumption

① Tuna

Japan would like to remind the Committee that it already agreed at the previous session to set MLs for all tuna species. In addition, as Japan stated at the 11th Session of CCCF, if MLs are to be set for fish as a group, MLs should be established on a basis of the data on species with the highest methylmercury concentrations (Para. 130 of REP17/CF).

Table1 in AppendixII of the discussion paper indicates southern bluefin tuna as the tuna species with the highest methylmercury concentrations. An analysis by Japan of the dataset containing the results of both wild and farmed bluefin tuna samples shows that the wild contains methylmercury at much higher concentrations than the farmed (see the table below). Therefore, if one ML is to be established for all tuna species, it should be based on the methylmercury concentrations in southern bluefin tunas, especially the wild ones. Japan proposes that an ML for tuna should be 2 mg/kg.

Table. Analysis of Occurrence Data of Methylmercury in Southern Bluefin Tuna on Methylmercury
(Analysis by Japan)

Percentile	Methylmercury in southern bluefin tuna (mg/kg)		
	All * (n=240)	Wild** (n=120)	Farmed** (n=120)
P95	1.21	1.51	0.40
P97.5	1.5	1.71	0.41
P99	1.88	2.08	0.42
P100(max)	2.90	2.90	0.43

* Data from Table 1, Appendix II of the discussion paper

** Analysis of the GEMS/Food database. The data on southern Bluefin tuna in Table 1, Appendix II of the discussion paper is also based on this database. All farmed southern bluefin tuna samples analyzed were from imported products.

② Alfonsino

Following the above principle, Japan proposes that an ML for alfonsino should be 2mg/kg.

③ Amberjack

According to Table 19 in Appendix II of the discussion paper, the average and the median for total mercury concentrations in amberjack (*Seriola lalandi*, *Seriola dumenli*, *Seriola quinqueradiata*) are 0.24 mg/kg and 0.17 mg/kg, respectively. Both of them are lower than 0.3 mg/kg (average value or median), which was used as the selection criterion of fish species for MLs development at the 11th Session (Paragraph 27, Appendix 1 of CX/CF 17/11/12). This criterion was derived using the PTWI of methylmercury for the high-risk group (1.6 µg/kg, JECFA (2007)¹), the consumption of fish, and the Expert consultation report (FAO/WHO, 2011¹) (3.2, 1 and 5.2 of CX/CF 17/11/12). The report describes that adverse effects on the high-risk group associated with the intake of fish species containing methylmercury below 0.3 mg/kg are extremely limited, and the benefit is considered to exceed the risk if methylmercury concentration does not exceed 0.3 mg/kg. Therefore, for consistent application of the selection criterion and limited effects on the high-risk group, an ML does not seem necessary for amberjack.

④ Marlin

The same principle should be followed as above. If an ML is to be set for marlin as a group, ML should be based on the marlin species containing the highest methylmercury concentrations. Table 14 in Appendix II indicates that “blue marlin (unspecified)” may be the species with the highest methylmercury concentrations. We should keep this fact in mind in the development of an ML.

¹ JECFA. 2007. Evaluation of Certain Food Additives and Contaminants

⑤ Shark

The same principle should be followed as above. Japan proposes that an ML for shark should be 2 mg/kg.

⑥ Swordfish

The same principle should be followed as above. Japan proposes that an ML for swordfish should be 3 mg/kg.

Additional recommendations for consideration by CCCF (page 4)

- *Recommendation 1* (More analyses for Spanish Mackerel)

For Spanish mackerel, the average and the median for total mercury are 0.24 mg/kg and 0.17 mg/kg respectively, both lower than 0.3 mg/kg, the selection criterion of fish species as described above (Para. 27, Appendix 1 of CX/CF 17/11/12). It is not necessary to set an ML for Spanish mackerel as for amberjack. Therefore, no further data analysis is required.

- *Recommendation 2* (Ratio of total mercury and methylmercury)

Because the ratio between methylmercury and total mercury varies considerably for different fish species, it is necessary to consider the ratio for each fish species.

- *Recommendation 3* (To include the footnote to the MLs for methylmercury)

Japan supports attaching the footnote to MLs for methylmercury as proposed.

- *Recommendation 4* (To attach the footnote for canned tuna)

At the 11th Session, the Committee agreed not to establish MLs for canned tuna (Para. 135 of REP17/CF). Therefore, neither ML nor footnote is necessary for canned tuna.

- *Recommendation 5* (To attach the footnote for Additional risk management measure)

Japan supports attaching the footnote to all MLs as proposed for additional risk management measures.

- *Recommendation 6* (To consider the option for text for this third footnote)

Japan supports applying the proposed footnote a. because this footnote clarifies why additional risk management measures (e.g. consumption advice) aimed at pregnant women and infants may be necessary at the national level.

- 23.-6. (analysis parts)

For consistent conformity judgment in countries, it is necessary to more clearly describe the part of fish to which MLs apply (analysis parts) rather than the term "middle part" - for example, muscle of specific part. From an economic point of view, it is necessary to consider whether it is feasible to obtain the analysis parts from a carcass of large expensive fish. For example, as to large fish like tuna, muscle of tail part (see a photograph below) should be accepted as an analysis part for alleviating huge economic loss.



KENYA**GENERAL COMMENT**

Kenya would like to thank the EWG led by the Netherlands ,Canada and New Zealand for the good work done to come up with the recommendations regarding Methyl mercury in fish.

We know that methyl mercury is more toxic than inorganic mercury and it can accumulate in the body and impairs neurological development in infants ,foetuses and children. According to WHO, the level of Methylmercury is lower in canned tuna since smaller sized of tuna is used for canning .Other fish with lower methylmercury include fresh water fish such as salmon. Larger predators tend to have higher level of methylmercury since they are exposed to higher levels of this chemical

For these reasons we would propose that the safety levels of methylmercury be set case by case for larger predators such as shark, sword fish; canned tuna and mostly marine in origin fish.

MALAYSIA

Malaysia would like to congratulate members of the Electronic Working Group led by The Netherlands, Canada and New Zealand on the progression of the document.

For para 22(3):

Malaysia supports the inclusion of the footnote as in para 22(3) to the MLs for methylmercury.

For para 22(6):

Malaysia supports the text as in option (c) for the third footnote as follows:

“c. For fish species high in methylmercury, countries should consider developing nationally relevant consumer advice for pregnant women and young children to supplement these MLs.”

REPUBLIC OF KOREA

The Republic of Korea would like to submit the following comments on the proposed draft maximum levels for methylmercury in fish

- We support the EWG's approach to use the P95 value (5% rejection rate) for deriving proposals for MLs.
- We do not support the setting of separate MLs for "Bigeye and Bluefin tuna" and suggest having one ML for "All tuna". We also do not support the setting of a ML based on Blue marlin. The ML for 'Marlin' should be based on the data for all species included in marlin.
- We support the inclusion of the existing footnote attached to the current GLs so the MLs are applicable to canned fish.
- We support the inclusion of a footnote indicating the need for additional risk management measures to all proposed draft MLs, and we support the following proposed text for the footnote.

“There is a potential risk for specific consumers (particularly pregnant women and infants) from methyl mercury exposure and the proposed MLs are a risk management measure to control exposure to ALARA. Therefore, it is important for consumers to follow advice on consumption of specific species of fish in place at the national level, including advice on the known benefits of fish consumption.”

UGANDA

Uganda is not in favour of establishing MLs for methylmercury for fish species other than predatory fish. This is premised on the fact that the data we have for total mercury in Nile perch (*Lates niloticus*) products obtained between 2010 and 2017 as indicated in Table 2 is below the current MLs for methyl mercury (0.5 mg/kg) as established in the General Standard for Contaminants and Toxins in Food and Feed. We associate with the fact that if the total mercury concentration is below the ML for methylmercury, no further testing is required and the sample is determined to be compliant with the methylmercury requirements.

Table 2: Total mercury content of Nile perch (*Lates niloticus*) between 2010 and 2017

SN	Date of analysis	Results (mg/kg) ¹
1	07/07/2017	< 0.03
2	24/05/2017	< 0.01
3	11/05/2017	< 0.02
4	29/03/2017	< 0.01
5	15/03/2017	< 0.01
6	11/11/2016	< 0.01
7	01/11/2016	< 0.01
8	17/02/2016	0.04
9	11/11/2015	0.02
10	07/07/2015	0.03
11	19/03/2015	< 0.01
12	06/11/2014	< 0.01
13	24/01/2014	< 0.01
14	17/01/2013	< 0.10
15	17/10/2012	< 0.02
16	03/07/2012	< 0.01
17	31/03/2012	< 0.03
18	11/08/2011	< 0.02
19	06/07/2011	< 0.04
20	06/06/2011	< 0.01
21	03/05/2011	< 0.10
22	18/01/2011	< 0.04
23	25/11/2010	< 0.09
24	26/08/2010	< 0.04

¹ Obtained using the FIMS–food-Hg

UNITED STATES OF AMERICA (USA)

The U.S. appreciates the work that the Netherlands, Canada, and New Zealand have done in preparing the recommendations on maximum levels (MLs) for methylmercury in fish.

General Comments:

- As we have stated previously, the U.S. believes that consumption advice is more appropriate for addressing methylmercury in fish than MLs.
- Since the Committee agreed to establish MLs, the U.S. supports setting these MLs at a rejection rate of less than 5%, consistent with the approach taken by the electronic working group for revision of lead MLs in the GSCTFF.
- The U.S. supports establishing one ML for all tuna species, based on bigeye and bluefin tuna.
- The U.S. supports not establishing an ML for amberjack as the average and median mercury levels are below the selection criterion of 0.3 mg/kg to identify species of concern (CX/CF 17/11/12, paragraph 27).
- The U.S. does not support applying the following footnote: *“The guideline levels are intended for methylmercury in fresh or processed fish and fish products moving in international trade,”* as that would result in the MLs established in fresh/frozen fish (tuna) being applicable to canned fish (tuna). The 11th Session of CCCF agreed to not establish MLs for canned tuna.
- The U.S. supports the following footnote for application to higher MLs to indicate the need for additional risk management measures: *“For fish species high in methylmercury, countries should consider developing nationally relevant consumer advice for pregnant women and young children to supplement these MLs.”*
- The U.S. supports the addition of a footnote to the ML to clarify that the levels are being established for methylmercury, with screening for total mercury (similar to what was done for inorganic arsenic in rice).
 - The footnote reads as follows: *“Countries or importers may decide to use their own screening when applying the ML for methylmercury in fish by analyzing total mercury in fish. If the total mercury concentration is below the ML for methylmercury, no further testing is required and the sample is determined to be compliant with the ML. If the total mercury concentration is above the ML for methylmercury, follow-up testing shall be conducted to determine if the methylmercury concentration is above the ML.”*
- The U.S. does not support development of MLs for other fish species at this time given the workload of the Committee.

Sampling plan

- The U.S. recommends that the EWG address Questions 3 and 6 on methylmercury variation between individual fish in a lot and between tissue sites in individual fish, based on review of scientific literature.
- Regarding Questions 1 and 2 on performance criteria and methods, the U.S. recommends that when CCCF sends forward MLs at Steps 5/8 or 8, that CCCF also recommend methods so that CCMAS can calculate performance criteria from the MLs, using the guidelines in the *Procedural Manual*, and evaluate the methods against the performance criteria.
- Regarding Questions 4 and 5 on canned fish, the U.S. recommends that CCCF consider if these questions are relevant if the ML does not apply to canned tuna.

The final plan should not include references to EU-specific terms, such as “member states.” The U.S. also recommends that CCCF consider whether the sampling plan should include language, as it currently does, on sampling at retail.

AFRICAN UNION (AU)

Position 1: African Union supports setting of ML of 1.4mg/kg for tuna as a group of fish.

Issue and rationale: The 11th CCCF (2017) agreed to establish MLs based on the ALARA principle, which was in line with the criteria for establishing MLs in the GSCTFF (REP 17/CF, para 129). It was also agreed that an ML would be established for tuna as a group, and that the subspecies of tuna taken into account for this would be indicated (REP 17/CF, para 130). The eWG determined that Bigeye and Bluefin tuna have the highest contamination and proposed an ML of 1.3mg/kg (with 5% rejection) or 1.4m/kg (with less than 5% rejection). Setting an ML with less rejection is advisable. Information from South Africa and Ghana shows that tuna in those countries will be able to meet the proposed ML. This suggests that Tuna from other countries in Africa may comply with the limit as well.

Position 2: African Union recommends the need to do more work on the setting of MLs for the other fish species.

Rationale: The number of samples used in derivation of the MLs were too small and their geographical distribution limited.

Position 3: African Union further recommends that the CCCF should refer issues on sampling plan to the Committee on Methods of Analysis and Sampling (CCMAS) for endorsement with specific questions listed below:

1. Could CCMAS advise on the use of analytical methods or performance criteria?
2. Could CCMAS advise on the necessary performance criteria for the proposed draft MLs?. Draft performance criteria to the current proposals for MLs are included in Table 9 of Appendix II.
3. Is there evidence that methyl mercury can vary widely between individual fish sampled at the same time? How would this apply to large fish sold as individual units? Does the sampling plan provide enough basis to deal with this?
4. Is the following text relevant for methylmercury in fish: “If the result of the test for an aggregate sample of cans is less than but close to the maximum level of methylmercury and if it is suspected that individual cans might exceed the maximum level, then it might be necessary to conduct further investigations”?
5. Should the samples for mercury in fish be analyzed raw (or with no further processing or cooking for already processed products, e.g. canned fish)?
6. In addition – is the whole fish to be analyzed or only specific fractions edible portions? Now the only mention is that mid-section should be sampled for some large fish.

INTERNATIONAL COUNCIL OF GROCERY MANUFACTURERS ASSOCIATIONS (ICGMA)

ICGMA thanks the eWG chairs for their dedication to this work and drafting a thorough document.

Specific Comments

At CCCF11, the decision was made not to develop an ML for canned tuna as levels in samples were generally low. Therefore, ICGMA does not support the inclusion of canned tuna in the ML’s established for fresh/frozen tuna.

ICGMA does not support the following proposed footnote: “*The guideline levels are intended for methylmercury in fresh or processed fish and fish products moving in international trade,*” as this would result in the ML’s established in fresh/frozen fish (tuna) being applicable to canned tuna, and this contradicts the decision made at the 11th session of CCCF to not establish ML’s for canned tuna. Additionally, the idea that tuna with mercury levels higher than the ML will be diverted to the canned tuna industry to avoid detection is unfounded. Because the tuna supply chain for the canned industry is different from the fresh/frozen market, it is not likely that higher mercury tuna will be diverted for canning.

ICGMA is in support of applying the following footnote to higher MLs to indicate the need for additional risk management measures: “*For fish species high in methylmercury, countries should consider developing nationally relevant consumer advice for pregnant women and young children to supplement these MLs.*” ICGMA also recommends the inclusion of language that encourages pregnant women to eat seafood for optimal baby brain and eye development, per the communications recommendation from the FAO/WHO 2010 report.¹

Conclusion

ICGMA thanks the eWG chairs for their extensive work on preparing this draft discussion paper relative to proposed maximum levels for methylmercury in fish and associated sampling plans and looks forward to further discussion of this draft.

INTERNATIONAL SPECIAL DIETARY FOODS INDUSTRIES (ISDI)

ISDI thanks the Chairs of the four Working Groups of CCCF, together with the Netherlands as the host of CCCF for the Discussion Paper on “Proposed Draft Maximum Levels for Methylmercury in Fish Including Associated Sampling Plans (CX/CF 18/12/7).” ISDI is pleased to have the opportunity to provide the following brief comments on the Discussion Paper:

ISDI supports the proposed draft MLs. The proposed MLs are aligned with recent worldwide surveys of methyl mercury content in these different fish species, account for that methyl mercury distribution in a specific fish tissue is dependent of its predatory status, size, sex, age, diet and environmental conditions.

¹ FAO/WHO (2010). Report of the Joint FAO/WHO Expert Consultation on the Risks and Benefits of Fish Consumption. <<http://www.fao.org/docrep/014/ba0136e/ba0136e00.pdf>

Proposed Maximum Levels (MLs) – Appendix I	
Fish species	Proposed draft ML in mg/kg
Tuna	1.1
Alfonsino	1.5
Amberjack	0.7
Marlin	1.5
Shark	1.5
Swordfish	2.3

Footnote on fresh or processed fish and fish products (Para 17)

The current GL includes a footnote 'The guideline levels are intended for methylmercury in fresh or processed fish and fish products moving in international trade', which includes canned fish.

ISDI supports this footnote. These MLs can also be applied to canned fish as only potential contamination by processing can occur taking into account a global lower found content of methyl mercury in this kind of processed fish.

Data on Spanish mackerel (Para 14)

Data on Spanish mackerel have been analysed as these were encountered during the sorting of Jack mackerel data for the derivation of a proposed draft ML for Amberjack. As last year, data were lacking for these species, the data were analysed.

ISDI supports conducting more testing of Spanish mackerel.

Ratio of total mercury and methylmercury (Para 15)

The EWG recommends that if consideration may be given to development of MLs in for other fish species, any ML development would need to take into consideration the ration of total mercury and methylmercury as this can vary largely between species.

ISDI supports this recommendation. Even if methylmercury is generally the most important species of mercury (vs inorganic mercury) in the listed fish species, a better knowledge of its speciation in listed and new fish species will allow to better defining new MLs and adapt existing ones. Moreover, speciation data will allow to better understanding mercury uptake and storage in fish tissues.

Footnote on benefits (Para 19)

The following text for the footnote was proposed to the EWG: 'Adverse effects due to methylmercury exposure may outweigh the benefits of fish consumption at lower levels than the ML when frequently consuming this fish species, particularly by pregnant women and infants. The development of additional risk management measures (e.g. consumption advice) may be necessary on a national level to restrict exposure in order to avoid unacceptably high levels of methylmercury.'

ISDI supports this footnote.

Methods of analysis (Para 52)

In Codex standard CXS 234-1999 'Recommended methods of analysis and sampling', in part A it is recommended to use for the analysis of mercury in fish and fishery products the standard AOAC 977.15 Flameless atomic absorption spectrophotometry, type III, and for the GL for methylmercury in the fish the standard 988.11 Atomic absorption spectrophotometry, type II.

ISDI supports this paragraph with the following comments:

- Current Codex methods based on AAS are just acceptable for monitoring routinely with adequate trueness and precision methyl mercury at this level of concentration.
- As with advice on other metals (such as arsenic in rice), Codex could consider recommending in the official methods determination of total mercury in fish as a first step and proceeding to speciation to methylmercury only if total mercury is above the ML
- Methods with new technologies (ICP-MS with isotope dilution procedure (ID)), better separation (high resolution GC with specific column phase) and extraction techniques (soft microwave assisted alkaline or acid leaching) are available for accurately measuring total and methylmercury in fish.
- A new official CEN method using ID-GC-ICP-MS is available for methyl mercury determination in fish (EN 16801:2016 Foodstuffs. Determination of elements and their chemical species. Determination of methylmercury in foodstuffs of marine origin by isotope dilution GC-ICP-MS)

Sampling plan (Appendix I – Part II)

Endorsement of the sampling plan

ISDI supports endorsement of the sampling plan as presented in Appendix I – Part II