CODEX ALIMENTARIUS COMMISSION

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Food and Agriculture Organization of the United Nations

World Health Organization

Viale delle Terme di Caracalla, 00153 Rome, Italy - Tel: (+39) 06 57051 - Fax: (+39) 06 5705 4593 - E-mail: codex@fao.org - www.codexalimentarius.org

Agenda Item 14 **CX/CF 15/9/13**

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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON CONTAMINANTS IN FOODS

9th Session

New Delhi, India, 16 – 20 March 2015

DISCUSSION PAPER ON MAXIMUM LEVELS FOR METHYLMERCURY IN FISH

(Prepared by the Electronic Working Group led by Japan)

BACKGROUND

1. The 7th Session of the Committee on Contaminants in Food (CCCF) (April 2013) reviewed the current Guideline Levels (GLs) for methylmercury in fish and predatory fish and considered other measures, including consumption advice, taking into consideration the outcome of the Joint FAO/WHO Expert Consultation on the Risks and Benefits of Fish Consumption (REP13/CF, para. 113-123)[1]. While there was support for setting GLs or Maximum Levels (MLs) for methylmercury in fish, it was recognized that further information was necessary to review the current GLs taking into account the benefits of fish consumption (REP13/CF, para.124).

2. At the 8th Session, the CCCF (March 2014) considered the current GLs based on the data on total mercury and methylmercury in those fish species important in international trade as contained in the CX/CF 14/8/16. The CCCF further discussed the compound for which MLs or GLs should apply, classification of fish and violation rates for the current GLs (REP14/CF, para.104-112).

3. Noting that there was wide, but not unanimous, support for establishing ML(s) for methylmercury, the 8th Session of the CCCF agreed that total mercury may be analyzed for screening purposes, but that further consideration was needed on an appropriate level or levels; and the identification of fish species would have to be further developed as proposed by the chair of the EWG. The Committee further noted that this decision did not preclude the usefulness of consumer advice and confirmed the decision of the 7th Session of the CCCF that consumer advice should be developed at the national or regional level as the advice would vary between countries because the risk of mercury exposure from the diet would depend on, amongst others, the patterns of consumption of fish and the types of fish consumed, and that no further work would be done at the international level (REP14/CF, para.113).

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[1] Report of the Joint FAO/WHO Expert Consultation on the Risks and Benefits of Fish Consumption, 25–29 January 2010, Rome, Italy (http://www.fao.org/docrep/014/ba0136e/ba0136e00.pdf).

4. As it was recognized that further consideration was necessary, the 8th Session of the CCCF agreed to re-establish an EWG, led by Japan and co-chaired by Norway to develop a discussion paper to provide proposals for ML(s) for methylmercury, to express to which fish species these should apply, and to include a project document for a new work proposal for consideration by the next session of the Committee (REP14/CF, para.114).

5. Codex members and observers are invited consider the conclusions and recommendations in paragraphs 46-48 while taking into account the information provided (including Appendices I and II). The list of participants is presented in Appendix III.

INTRODUCTION

6. The current GLs for methylmercury in fish (1 mg/kg for predatory fish and 0.5 mg/kg for other fish species[2]) were adopted in 1991. Those GLs were developed on the basis of occurrence data on total mercury in fish and fishery products, which indicated that approximately 97% of the mean levels of mercury reported in fish were at or below 0.5 mg/kg; and 99% of the values were at or below 1.0 mg/kg (ALINORM 87/12A, para.235).

7. In 2003, the Joint FAO/WHO Expert Committee on Food Additives (JECFA) revised the provisional tolerable weekly intake (PTWI) for methylmercury to 1.6 μg/kg body weight from the previous one of 3.3 μg/kg body weight, based on the most sensitive toxicological end-point (developmental neurotoxicity) in the most susceptible species (humans)[3].

8. The process for establishing the current GLs did not take into account net effects of fish consumption that include both adverse contributions from methylmercury exposure and beneficial contributions from nutrients in fish on the same health endpoints (CX/CF 13/7/16, para. 75; REP13/CF, para. 118).

9. In this context, the current GLs for methylmercury in predatory and non-predatory fish should be reviewed to take into consideration the results of discussion of the CCCF, risk assessments by the JECFA and the conclusions of the Joint FAO/WHO Expert Consultation on the Risks and Benefits of Fish Consumption.

10. The mandate of the current EWG is to address the following points in a discussion paper for consideration at the 9th Session of the CCCF:

- Identification of fish species to which ML(s) should apply
- ML(s) for methylmercury in identified fish species
- Analytical methods for enforcement
- A draft project document for a new work proposal

IDENTIFICATION OF FISH SPECIES TO WHICH ML(s) SHOULD APPLY

11. In identifying fish species to which ML(s) should apply, the following criteria were considered:

- The importance in international trade (volume);
- The representative value of methylmercury concentrations in fish species;
- Whether there are sufficient occurrence data on methymercury or total mercury concentrations; and
- The benefits of fish consumption.

It should be noted that the benefits of fish consumption was considered in the Joint FAO/WHO Expert Consultation on the Risks and Benefits of Fish Consumption, and no additional information has been provided.

[2] CODEX STAN 193-1995: General Standard for Contaminants and Toxins in Food and Feed (GSCTFF).
[3] Joint FAO/WHO Expert Committee on Food Additives (JECFA), report of the sixty-first meeting, Rome 10-19 June 2003 (ftp://ftp.fao.org/es/esn/jecfa/jecfa61sc.pdf).

Importance in international trade

12. At the 8th Session, the CCCF focused its consideration on the fish species important in international trade for the review of the current GLs (CX/CF 14/8/16). The subsection on the “Criteria for the Establishment of Work Priority” in Section II of the Procedural Manual (22nd ed. pp. 39-40) includes the volume of trade between countries as one of the criteria for setting priority to elaborate related text within its terms of reference.

13. Fish species important in international trade were selected using the data on trade quantity in 2011 contained in the “FAO Fisheries Commodities Production and Trade” database. There are about 70 fish species and fishery products with import or export volume of more than 100000 tons[4]. By excluding molluscs, crustaceans and other items without species identification (e.g. “Fish meals”, “Fish body oils”, “Fish fillets/frozen/nei”) from the list, the following 20 species remained: Albacore, Bigeye tuna, Brisling, Capelin, Catfish, Cod, Croaker, Haddock, Hairtail, Hake, Herring, Mackerel, Pilchard, Plaice, Pollock, Salmon, Sardine, Skipjack tuna, Tilapia and Yellowfin tuna.

Concentrations of methylmercury in the fish species

14. The Joint FAO/WHO Expert Consultation on the Risks and Benefits of Fish Consumption concluded that among women of childbearing age, pregnant women and nursing mothers, considering benefits of Docosahexaenoic acid (DHA) versus risks of methylmercury, fish consumption lowers the risk of suboptimal neurodevelopment in their offspring compared with not eating fish in most circumstances evaluated. More specifically, it concluded that with an upper estimate of methylmercury risk, neurodevelopmental risks of not eating fish exceed risks of eating fish for up to at least seven 100 g servings per week for all fish containing less than 0.5 µg/g (mg/kg) methylmercury. In that calculation, the following figures were used:

- median methylmercury concentration of 0.3 µg/g for fish species with the arithmetic means of methylmercury concentrations between 0.1 and 0.5 µg/g
- seven 100 g servings (i.e. 700 g) per week, which is larger than the world’s average of 362 g/week (“FAO Food Balance Sheet” in 2011) and even the largest consumption of 551.6 g/week (Cluster G17) in the Global Environment Monitoring System /Food (GEMS/Food) Cluster Diets data in 2012 (the smallest consumption is 61 g/week in Cluster G1) (Table 1).

15. Therefore, the EWG concluded that for fish species whose medians of methylmercury concentrations are lower than or equal to 0.3 mg/kg, the benefits of fish consumption would outweigh the risk at the mean consumption level based on the conclusions of the Expert Consultation.

[4] The 8th Session of the CCCF focused on the top 50 fish and fishery products listed in the “FAO Fisheries Commodities Production and Trade” database (CX/CF 14/8/16, para. 16).

Table 1: Seafood consumption of the world's average (2011) and of the 17 GEMS/Food Consumption Cluster Diets (2012) (g/person/week)

World's average	G01	G02	G03	G04	G05	G06	G07	G08	G09	G10	G11	G12	G13	G14	G15	G16	G17
362	61.4	157	165	220	117	172	317	253	428	393	255	240	86.9	338	204	153	551

16. However, considering the variability of methylmercury as well as long-chain n-3 polyunsaturated fatty acids (LCn3PUFAs) concentrations even within the same fish species, using 0.2 mg/kg of total mercury concentration as a threshold, instead of 0.3 mg/kg, would be preferable from the consumer health protection point of view.

17. In the discussion paper prepared for the 8th Session of the CCCF (CX/CF 14/8/16), the occurrence data on total mercury of a total of 17148 samples were provided by 13 countries and one observer. The summary table of the occurrence data on total mercury is shown again in Table 2. For this discussion paper, it was assumed that all of total mercury was present as methylmercury.

18. In Table 2, of 20 fish species identified as important species in international trade in para. 13 above, the summary of occurrence data of Albacore, Bigeye tuna, Catfish, Cod, Herring, Mackerel, Pollock, Salmon, Sardine, Skipjack tuna, Tilapia and Yellowfin tuna are presented. In the category of "Others" in Table 2, the occurrence data of various fish species such as Haddock or Hake were included. In this discussion paper, the occurrence data of Brisling, Capelin, Croaker, Haddock, Hairtail, Hake, Pilchard and Plaice, which had been included in the "Other" category, were separately analyzed: but either the medians of their total mercury were less than 0.2 mg/kg, or the occurrence data were not available. As a result, the fish species with their medians of total mercury concentrations higher than 0.2 mg/kg were identified as follows: Albacore, Alfonsino, Bigeye tuna, Bluefin tuna, Blue marlin, Shark, Southern Bluefin tuna, Striped marlin and Swordfish.

Table 2: Summary of the occurrence data on total mercury

Fish species	N	# of <LOQ (*)	Min (mg/kg) (*)	Max (mg/kg)	Average (mg/kg) (**)	Median (mg/kg)	90%ile (mg/kg)	95%ile (mg/kg)	97.5%ile (mg/kg)
Sardine	**258**	**199**	**< LOD**	**0.24**	**0.01**	**- (***)**	**0.03**	**0.06**	**0.07**
Salmon	**812**	**193**	**< LOD**	**0.29**	**0.02**	**0.02**	**0.04**	**0.05**	**0.06**
Tilapia	**375**	**268**	**< LOD**	**0.39**	**0.02**	**- (***)**	**0.07**	**0.11**	**0.13**
Mackerel	**2035**	**686**	**< LOD**	**17.9**	**0.05**	**0.03**	**0.07**	**0.1**	**0.13**
Herring	**1672**	**3**	**< LOQ**	**0.4**	**0.04**	**0.04**	**0.08**	**0.10**	**0.12**
Pollock	**1748**	**5**	**< LOD**	**0.66**	**0.05**	**0.04**	**0.1**	**0.12**	**0.15**
Cod	**2372**	**72**	**< LOQ**	**0.96**	**0.08**	**0.05**	**0.16**	**0.21**	**0.26**
Whiting	**25**	**2**	**< LOQ**	**0.23**	**0.11**	**0.1**	**0.15**	**- (****)**	**- (****)**
Others	2248	659	< LOD	1.91	0.10	0.05	0.24	0.34	0.48
Catfish	**152**	**89**	**< LOD**	**2**	**0.10**	**- (***)**	**0.26**	**0.38**	**0.68**
Skipjack tuna	**430**	**54**	**< LOD**	**0.49**	**0.14**	**0.13**	**0.26**	**0.31**	**0.34**
Yellowfin tuna	**1269**	**467**	**< LOD**	**1.4**	**0.14**	**0.08**	**0.35**	**0.52**	**0.68**
Halibut	1288	0	0.01	1.17	0.22	0.18	0.45	0.59	0.67
Albacore	**306**	**11**	**< LOQ**	**1.80**	**0.39**	**0.33**	**0.77**	**0.92**	**1**
Bluefin tuna	618	0	0.005	3.13	0.48	0.42	0.85	0.98	1.18
Striped marlin	121	0	0.07	1.4	0.40	0.35	0.88	0.97	1.06
Bigeye tuna	**243**	**8**	**< LOQ**	**2.30**	**0.56**	**0.43**	**1.2**	**1.3**	**1.4**
Southern Bluefin tuna	240	0	0.10	4.4	0.56	0.43	1.2	1.31	1.8
Alfonsino	123	0	0.10	2.8	0.78	0.7	1.3	1.4	1.70
Swordfish	227	2	< LOQ	3.9	1.22	1.11	2	2.41	2.71
Shark	286	0	< LOD	4.6	0.98	0.68	2.15	3.2	3.77
Blue marlin	125	0	0.01	24	2.04	0.85	4.8	6.96	11.32

(*) The values of LOQ and LOD depend on analytical methods.

(**)

For fish species whose proportion of <LOQ is less than 60%, the averages were calculated by replacing <LOQ with 1/2 LOQs.

For fish species whose proportion of <LOQ is more than 60%, the averages were calculated by replacing <LOQ with zero.

(***) Since the proportions of <LOQ are more than 50%, the medians are not available.

(****) Since the number of sample of Whiting was only twenty-five, 90%ile and 97.5%ile were not considered.

Notes:

- Fish species are listed in the ascending order of 90%ile values.
- The numbers of significant figures were various, and they are basically shown in the Table as provided by members.
- Fish species expressed by bold texts indicate those important in international trade.

Occurrence data availability

19. For the estimation of appropriate ML(s), it is necessary to draw a distribution curve of methylmercury concentration for each fish species. The number of samples for each species in Table 2, except for Whiting, was more than 119, the minimum number of samples required for determining 97.5th percentile with 95% confidence interval.

Conclusion

20. As a result of considering each of the 20 fish species against the first three criteria shown in para. 11, Albacore and Bigeye tuna are identified as fish species to which ML(s) should be established, as they met all three criteria.

21. Various views were expressed on potential visual distinction of Albacore and Bigeye tuna from other tunas. If it is difficult to distinguish Albacore or Bigeye tuna from other tunas in a form of fillets, it may be appropriate to establish ML(s) for tuna species in general, instead of establishing ML(s) only for Albacore and Bigeye tuna, to avoid any potential or unnecessary disputes in the international fish trade on the identification of fish species. For this discussion paper, the EWG tentatively considered ML(s) applicable to all tuna species.

Definition of tuna

22. If an ML is established for tuna species in general, it is necessary to clearly define the list of species which are included in the category. While the current GL for "Predatory fish" applies to tuna (WS 0132), as well as shark (WS 0131), swordfish, pike (WF 0865) and others[5], there is no clear list of species in the category of tuna (WS 0132) defined in the Codex Commodity Categories[6]. According to the FAO Fisheries Technical Paper[7], "tunas", which are sometimes referred to as "true tunas", refers to the 14 species of the tribe Thunnini, such as Albacore, Bigeye tuna, Bluefin tuna (Atlantic, Pacific), Bullet tuna, Little tunny, Skipjack tuna, Slender tuna, Southern Bluefin tuna and Yellowfin tuna, etc[8]. Among them, Skipjack tuna can be distinguished from other tunas even in a form of fillets, and thus can be excluded from the list in the "tunas" used in the FAO Technical paper. The discussion in the following sections is tentatively based on the definition of "tunas" by the FAO Fisheries Technical Paper, except for Skipjack tuna.

ML(s) FOR METHYLMERCURY IN IDENTIFIED FISH SPECIES

Distribution Curves and Estimation of appropriate ML for Methylmercury in Fish

23. In the discussion paper prepared for the 8th Session of the CCCF, the occurrence data on total mercury of a total of 17148 samples were provided while those on methylmercury were reported for only 2315 samples. As the occurrence data of methylmercury were limited, the EWG recalculated the distribution curves assuming that all of total mercury was present as methylmercury, and using those occurrence data of total mercury shown in Table 2. Among tunas, more than 119 occurrence data of total mercury, considered to be sufficient for drawing a distribution curve for estimating 97.5th percentile, were available for the following 6 species: Albacore, Bigeye tuna, Bluefin tuna, Southern Bluefin tuna, Yellowfin tuna and Skipjack tuna[9].

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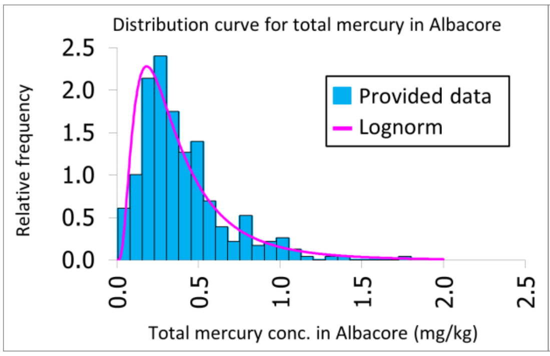
[5] CODEX STAN 193-1995: General Standard for Contaminants and Toxins in Food and Feed (GSCTFF).
[6] http://www.codexalimentarius.org/pestres/commodities (accessed at September 17, 2014)
[7] Majkowski J (2007), "Global fishery resources of tuna and tuna-like species", FAO Fisheries Technical Paper. No. 483.
[8] Other categories such as "tuna, billfish and bonitos" or "tuna and tuna-like species", are also used to describe "tunas" and other biologically close-related species, including Swordfish, Striped marlin or other species in the Family Scombridae.
[9] The occurrence data of total mercury in Skipjack tuna were also considered to show that their total mercury concentrations are lower than other tuna species.

24. The occurrence data of those 6 species were not merged as a single dataset, as the total mercury concentration of Yellowfin tuna was significantly different from those of all the other tuna species (i.e., Albacore, Bigeye tuna, Bluefin tuna and Southern Bluefin tuna) (CX/CF 14/8/16, para. 53). Furthermore, as a result of same statistical test which was used in the paragraph 53 of CX/CF 14/8/16, the total mercury concentration of Bigeye tuna was significantly different from those of Bluefin tuna and Southern Bluefin tuna. Similarly, the total mercury concentration of Bluefin tuna was found to be significantly different from that of Southern Bluefin tuna.

25. The EWG used the Lognormal distribution model by @RISK software for curve fitting to the dataset of each fish species (Fig. 1-6). The mean concentration of methylmercury, assuming that all of total mercury was present as methylmercury, was calculated for each model. The histogram of Bigeye tuna seems to be from multiple populations (Fig. 2), and fitting a single distribution model may not be appropriate. However, for the purpose of the following discussions, the Lognormal model was applied as others.



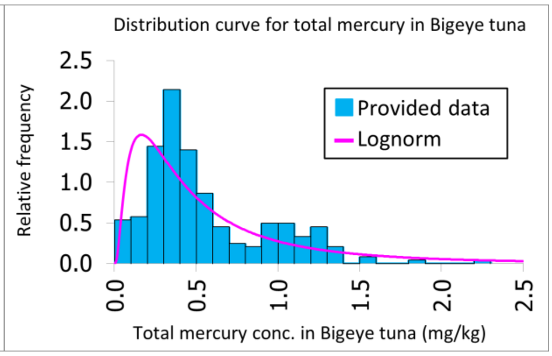
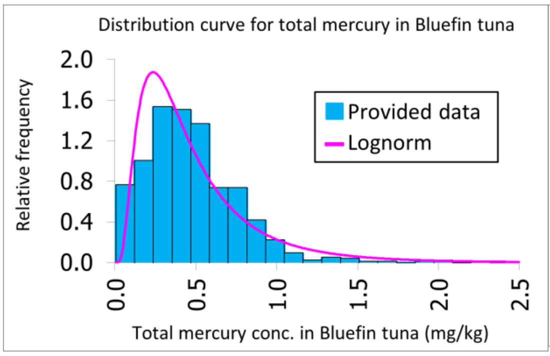


Fig. 1: Albacore Fig. 2: Bigeye tuna



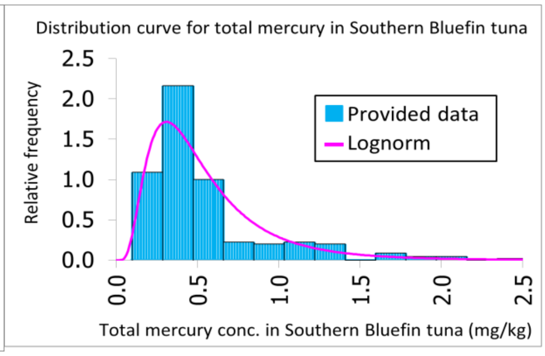
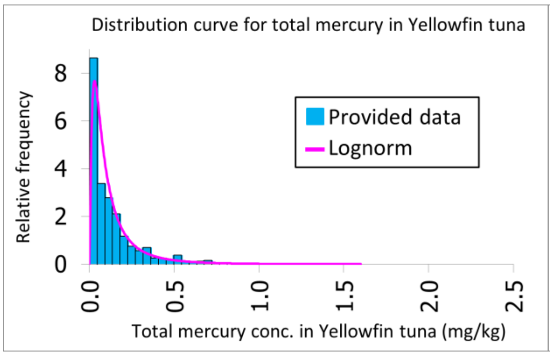


Fig. 3: Bluefin tuna Fig. 4: Southern Bluefin tuna



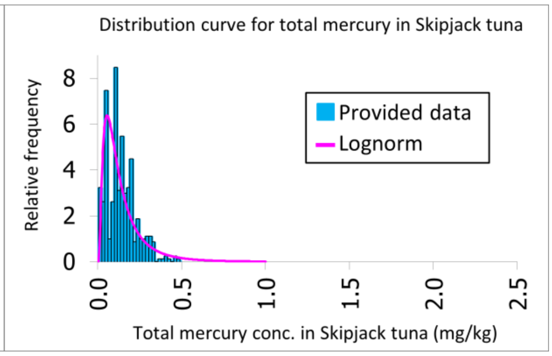


Fig. 5: Yellowfin tuna Fig. 6: Skipjack tuna

26. From the distribution models identified above, impacts on violation rate of different ML scenarios and mean concentration were estimated (Table 3). Under the scenario that tunas with methylmercury concentrations larger than each ML scenarios would be excluded from the market, the mean of methylmercury in samples hypothetically remaining in the market was determined. Each of the means was used for estimating methylmercury intake from the 6 tuna species in the next section.

Table 3: Impact of different ML scenario scenarios for methylmercury in tunas

ML scenario (mg/kg)	Albacore		Bigeye tuna		Bluefin tuna		Southern Bluefin tuna		Yellowfin tuna		Skipjack tuna	
	Violation rate (%)	Mean* (mg/kg)	Violation rate (%)	Mean* (mg/kg)	Violation rate (%)	Mean* (mg/kg)	Violation rate (%)	Mean* (mg/kg)	Violation rate (%)	Mean* (mg/kg)	Violation rate (%)	Mean* (mg/kg)
None	-	0.41	-	0.66	-	0.50	-	0.55	-	0.14	-	0.15
1	5.6	0.35	18	0.39	8.9	0.40	10	0.46	0.7	0.13	0.3	0.15
2	0.6	0.40	5.1	0.52	1.0	0.47	0.8	0.53	0.1	0.14	0	0.15
3	0.1	0.40	2.0	0.58	0.2	0.49	0.1	0.55	0	0.14	0	0.15
4	0	0.41	0.9	0.61	0	0.49	0	0.55	0	0.14	0	0.15
5	0	0.41	0.5	0.63	0	0.50	0	0.55	0	0.14	0	0.15

Impact of ML scenario on methylmercury intakes

27. In order to estimate methylmercury intakes from the 6 tuna species, the EWG used the world's average seafood consumption data in 2011 in the "FAO Food Balance Sheet" database and the consumption data in 2012 in the 17 GEMS/Food consumption Cluster Diets. The consumption pattern of the 6 tuna species would be largely different by regions; however, as the detailed consumption data of each fish species was not available, the EWG made the following assumptions:

- The proportion of consumption of each tuna species in total seafood consumption is the same for all Clusters.
- The proportion of consumption of each tuna species in total seafood consumption is equal to the proportion of its production in total fishery production, despite the fact that not all the fish caught will be consumed as food.

28. The production data of each of the 6 tuna species and total fishery production data in 2011 is presented in Table 4. For example, for Albacore, it was assumed that the percentage of its consumption in the total seafood consumption was 0.15% for all Clusters, which was equal to the percentage of its production in total fishery production. It was noted that this assumption might lead to the underestimation of methylmercury intake from the 6 tuna species, because some of other species are used also for non-food purposes such as fish oils, feeds or fertilizers, while most of those tunas are consumed as foods.

29. With regard to the proportion of food and non-food uses of caught fish, one member provided the data that the proportions of domestically caught fish used for non-food purposes were less than 0.1% (2010-2012). With regard to the data on the proportion of tunas to the total amount of fish consumed as fish, a member provided the national survey data from 2004 which indicated that of total 5191 eating occasions of all types of fish and seafood over a 24-hour period, 26% were tuna products, nearly all of which were comprised of canned tuna.

Table 4: Global production of tunas in 2011

	Production* (ton)	Percentage of total production
Total fishery production**	155813127	-
Albacore	228421	0.15
Bigeye tuna	402463	0.26
Bluefin tuna	40870	0.03
Skipjack tuna	2644767	1.70
Southern Bluefin tuna	10926	0.01
Yellowfin tuna	1239232	0.80

* Production is a sum of capture and aquaculture production.

** Productions of aquatic plants and aquatic mammals are excluded.

(Source: “FAO Global Production Statistics 1950-2012” database[10])

30. The EWG estimated methylmercury intakes from the 6 tuna species by multiplying means of methylmercury concentrations in each tuna species under each scenario (Table 3) by the consumption data calculated based on the assumption in para.27. Then, the estimated methylmercury intakes were compared to the PTWI of 1.6 µg/kg body weight per week, using a 60 kg of body weight (i.e., 96 µg/capita/week) (Table 5).

[10] Accessed on September 25, 2014.

Table 5: Estimated methylmercury intakes from tunas for the world's average and the 17 GEMS/Food Consumption Cluster Diets, taking into consideration the impact of ML scenarios (µg/capita/week)

ML scenario (mg/kg)	World's average	G01	G02	G03	G04	G05	G06	G07	G08	G09	G10	G11	G12	G13	G14	G15	G16	G17
None	2.2	0.4	1.0	1.0	1.3	0.7	1.1	1.9	1.6	2.6	2.4	1.6	1.5	0.5	2.1	1.3	0.9	3.4
(% of PTWI *)	2.3	0.4	1.0	1.1	1.4	0.7	1.1	2.0	1.6	2.7	2.5	1.6	1.5	0.6	2.2	1.3	1.0	3.5
1	1.9	0.3	0.8	0.9	1.1	0.6	0.9	1.6	1.3	2.2	2.0	1.3	1.2	0.4	1.7	1.1	0.8	2.9
(% of PTWI*)	2.0	0.3	0.8	0.9	1.2	0.6	0.9	1.7	1.4	2.3	2.1	1.4	1.3	0.5	1.8	1.1	0.8	3.0
2	2.1	0.4	0.9	0.9	1.3	0.7	1.0	1.8	1.4	2.4	2.2	1.5	1.4	0.5	1.9	1.2	0.9	3.2
(% of PTWI *)	2.2	0.4	0.9	1.0	1.3	0.7	1.0	1.9	1.5	2.6	2.3	1.5	1.4	0.5	2.0	1.2	0.9	3.3
3	2.1	0.4	0.9	1.0	1.3	0.7	1.0	1.9	1.5	2.5	2.3	1.5	1.4	0.5	2.0	1.2	0.9	3.3
(% of PTWI *)	2.2	0.4	1.0	1.0	1.4	0.7	1.1	2.0	1.6	2.6	2.4	1.6	1.5	0.5	2.1	1.3	0.9	3.4
4	2.2	0.4	0.9	1.0	1.3	0.7	1.0	1.9	1.5	2.6	2.4	1.5	1.4	0.5	2.0	1.2	0.9	3.3
(% of PTWI *)	2.3	0.4	1.0	1.0	1.4	0.7	1.1	2.0	1.6	2.7	2.5	1.6	1.5	0.5	2.1	1.3	1.0	3.4
5	2.2	0.4	0.9	1.0	1.3	0.7	1.0	1.9	1.5	2.6	2.4	1.5	1.5	0.5	2.0	1.2	0.9	3.3
(% of PTWI *)	2.3	0.4	1.0	1.0	1.4	0.7	1.1	2.0	1.6	2.7	2.5	1.6	1.5	0.5	2.1	1.3	1.0	3.5

* A 60 kg of body weight was assumed (96 µg/capita/week).

31. As a result, the estimated current methylmercury intake from the 6 tuna species is 2.2 µg/capita/week at the world's average. For each cluster, they are 0.4 – 3.4 µg/capita/week. The percentages of methylmercury intake to the PTWI are 2.3% as the world's average, and 0.4 – 3.5% for each Cluster. When the ML of 1 mg/kg, which is same as the current GL for predatory fish, is introduced, the estimated intake from 6 tuna species is 1.9 µg/capita/week (2.0% of PTWI) at the world's average, and 0.3 – 2.9 (0.3 – 3.0% of PTWI) for each Cluster. For an ML of 2 mg/kg, the estimated intake is 2.1 µg/capita/week (2.2% of PTWI) at the world's average, and 0.4 – 3.2 (0.4 – 3.3% of PTWI) for each Cluster. When the ML of 3 mg/kg is introduced, the estimated intake from the 6 tuna species does not change much from that for 2 mg/kg; it is 2.1 µg/capita/week (2.2% of PTWI) at the world's average, and 0.4 – 3.3 (0.4 – 3.4% of PTWI) for each Cluster.

32. Next, the EWG calculated the rates of reduction in methylmercury intakes from the 6 tuna species at the world's average for each ML scenario (Table 6). The rates of reduction are 15.6% for 1 mg/kg, 6.6% for 2 mg/kg of ML, 3.5% for 3 mg/kg, 2.1% for 4 mg/kg and 1.3% for 5 mg/kg. Those rates of reduction are also compared with the violation rate for each ML scenario calculated in para. 26.

33. The EWG noted that the discussion on the different ML scenarios above does not take into consideration the benefit of fish consumption. Also, since it was assumed that all of total mercury was present as methylmercury in this discussion paper, further consideration may be necessary on the proportion of methylmercury in total mercury. In most fish species, there was a strong correlation between total mercury and methylmercury concentrations with a slope of 0.837 as in CX/CF 14/8/16, Figure 2(b).

Table 6: Rate of decrease in methylmercury intake from tunas at the world's average and violation rate for each ML scenario

ML scenario (mg/kg)	Rate of reduction in methylmercury intake from tunas (%)	Violation rate (%)					
		Albacore	Bigeye tuna	Bluefin tuna	Southern Bluefin tuna	Yellowfin tuna	Skipjack tuna
1	16	5.6	18	8.9	10	0.7	0.3
2	6.6	0.6	5.1	1.0	0.8	0.1	0
3	3.5	0.1	2.0	0.2	0.1	0	0
4	2.1	0	0.9	0	0	0	0
5	1.3	0	0.5	0	0	0	0

Total mercury for screening purposes

34. At the 8th Session of the CCCF, while there was wide support for establishment of an ML for methylmercury, the Committee agreed that total mercury may be analyzed for screening purposes, but that further consideration was needed on an appropriate level(s).

35. There was a strong correlation between total mercury and methylmercury concentration in fish with a slope of 0.837 as presented in the discussion paper prepared for the 8th Session of the CCCF (CX/CF 14/8/16, Figure 2(b)). Thus, 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.

ANALYTICAL METHODS FOR ENFORCEMENT

36. The subsection "Principles for the Establishment of Codex Method of Analysis" in Section II of the Procedural Manual lays down the general criteria for the selection of appropriate methods of analysis and/or the set of criteria to which a method used for the determination must comply.

37. The Procedural Manual states that in the case of Codex Type II and III methods, method criteria may be identified and values quantified for incorporation into the appropriate Codex commodity standard. When a Codex Committee decides that a set of criteria should be developed, in some cases the Committee may find it easier to recommend a specific method and request the Codex Committee on Methods and Sampling (CCMAS) to "convert" that method into appropriate criteria.

38. In order for the method to be applicable, it first has to be applicable for the specified provision; specified commodity and the specified ML. Using the proposed MLs from Table 3, including the current Codex GL of 0.5 mg/kg for fish in general and Table 1: Guidelines for establishing numeric values for the criteria from the Procedural Manual, the numeric values for the method criteria shown in Table 7 are obtained.[11]

Table 7: Numeric values for method criteria for ML ≥ 0.1

ML ≥ 0.1 in mg/kg	LOD mg/kg	LOQ mg/kg	Minimum applicable range		Precision RSD_R[12] (%)	Recovery (%)
			From mg/kg	To mg/kg		
0.5	0.05	0.1	0.234	0.766	35.5 (HorRat[13] ≤ 2)	80-110
1	0.1	0.2	0.520	1.480	32.0 (HorRat ≤ 2)	80-110
2	0.2	0.4	1.135	2.865	28.8 (HorRat ≤ 2)	80-110
3	0.3	0.6	1.780	4.220	27.1 (HorRat ≤ 2)	80-110
4	0.4	0.8	2.442	5.558	26.0 (HorRat ≤ 2)	80-110
5	0.5	1	3.117	6.883	25.1 (HorRat ≤ 2)	80-110

Methods for the determination of total mercury

39. A number of collaboratively validated methods for the determination of mercury in foods in general, including fish in particular, are available from different standard developing organizations (SDOs). Codex STAN 234-1999 lists AOAC 977.15 as type III method for the determination of total mercury in fish and fishery products. An overview of standard methods, including the type III method, and their method characteristics regarding the determination of total mercury in fish are listed in Appendix I along with comments on the applicability of the different methods.

Methods for the determination of methylmercury

40. In the discussion paper prepared for the 7th Session of the CCCF (CX/CF 13/7/16) Table X lists collaboratively validated methods for the determination of methylmercury in fish. CODEX STAN 234-1999 lists AOAC 988.11 as type II method for determination with respect to the GL of methylmercury in fish. Since some of the method performance characteristics were missing from the Table X in CX/CF 13/7/16 an updated version can be found in Appendix II along with comments on the applicability of the different methods..

41. Methods of analysis for the determination of methylmercury in fish used by Codex members listed in the discussion paper prepared for the 7th Session of the CCCF (CX/CF 13/7/16) Table XX may also be applicable for selection by Codex provided they fulfill the General Criteria for the Selection of Single-Laboratory Validated Methods of Analysis in the Procedural Manual.

Summary on analytical methods for enforcement

42. More information on the method characteristics for the methods listed in Appendices I and II should be obtained from the relevant SDOs in order for a full proper evaluation to be done concerning the applicability of the methods listed.

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[11] The table was calculated using the "Excel Spread Sheet for Codex Method Criteria" downloaded from (http://www.nmkl.org/dokumenter/regneark/Method_criteriaML.xls)
[12] Relative standard deviations for reproducibility
[13] Horwitz ratio

43. Some of the older methods have problems complying with the method criteria concerning sufficient sensitivity (i.e. LOD/LOQ) for MLs of 0.5 and 1 mg/kg. Most methods seem to have difficulties complying with the criteria for applicable range when MLs are > 1 mg/kg. SDOs should therefore be encouraged to develop and validate methods with larger applicable range covering higher MLs.

44. For screening purposes using total mercury concentration, the correlation between total mercury and methylmercury, and also the expanded measurement uncertainty of the total mercury determination, should be taken into account for evaluation when the total mercury concentration is above the ML for methylmercury.

45. If MLs are agreed, a sampling plan would also be necessary. However, taking into consideration the small production amount of some specific fish species, statistical approach may be difficult.

CONCLUSIONS

46. The following conclusions are presented based on the information above:

- Albacore and Bigeye tuna were identified as fish species to which ML should be applied based on the volume of international trade, the medians of methylmercury concentrations and whether there were sufficient occurrence data.
- If it would be difficult to distinguish Albacore or Bigeye tuna from other tunas except for skipjack tuna in a form of fillets, it may be appropriate to establish ML applicable to all tuna species.
- From distribution curves of total mercury concentrations for Albacore, Bigeye tuna, Bluefin tuna, Southern Bluefin tuna, Yellowfin tuna and Skipjack tuna, the findings on the ML scenarios are summarized in Table 8.

Table 8: Summary of the rate of decrease in methylmercury intake from tunas and corresponding maximum violation rate for each ML scenario

ML scenario (mg/kg)	Rate of reduction in methylmercury intake from tuna (%)	Maximum violation rate (%)	Fish species with violation rate > 1%
1	16	18	Albacore, Bigeye tuna, Bluefin tuna, Southern Bluefin tuna
2	6.6	5.1	Bigeye tuna
3	3.5	2.0	Bigeye tuna
4	2.1	0.9	-
5	1.3	0.5	-

- The ML scenario of 1 mg/kg would reduce the intake of methylmercury significantly but would not be economically feasible as the maximum violation rate is 18%. The maximum violation rate under the ML scenario of 2 mg/kg is 5.1% and may result in some economic loss.
- Under the ML scenario of 5 mg/kg, while the maximum violation rate is 0.5%, the rate of the reduction in

methylmercury intake from tunas is 1.3%.

- Even if no ML is set, the methylmercury intake from tunas is 2.3% of PTWI. The subsection on the “Policy of the Codex Committee on Contaminants in Foods for Exposure Assessment of Contaminants and Toxins in Foods or Food Groups” in Section IV of the Procedural Manual (22nd ed. pp. 127) stipulates the criteria for selecting foods or food groups that contribute significantly to total dietary exposure of a contaminant; (a) 10% or more of the tolerable intake in one of the GEMS/Food Consumption Cluster Diets; (b) 5% or more of the tolerable intake in two or more of the GEMS/Food Consumption Cluster Diets; or (c) food that may have a significant impact on exposure for specific group of consumers, although exposure many not exceed 5% of the tolerable intake in any of the GEMS/Food Consumption Cluster Diets.
- While there was wide support for establishment of an ML in the 8th Session of CCCF, several EWG members were of the opinions that no MLs were necessary. Another EWG member questioned if an ML is the most appropriate risk management strategy for methylmercury in fish, based on the challenges relating to achievability at 1 mg/kg and low impact on exposure reduction at 2 mg/kg.
- For Skipjack tuna, the violation rate even under the lowest ML scenario (1 mg/kg) is 0.3%. If Skipjack tuna can be distinguished from other tunas, it can be excluded from the list for which MLs are applied.
- Total mercury can be used for screening purposes with the same level as ML for methylmercury.
- As the currently available collaboratively validated methods have limitations in terms of minimum applicable rages, standard developing organizations (SDOs) are encouraged to develop and validate methods with larger applicable ranges.

RECOMMENDATIONS

47. The CCCF should consider whether or not ML(s) should be established for methylmercury in fish taking into account the conclusions above.

48. If the CCCF agrees that ML(s) should be established, a project document is necessary. For developing ML(s), the following should be further considered:

- Appropriate ML(s) (e.g. 1, 2, 3, 4, 5 mg/kg) based on the conclusions above;
- Whether ML(s) should be applied to Bigeye tuna and Albacore only or to all tuna species except for Skipjack tuna;
- Proportion of methylmercury in total mercury by species;
- The analysis of total mercury for screening purposes; and
- Analytical methods used for enforcement purposes.

Appendix I

Comments to the applicability of the collaboratively validated methods listed in Appendix I for the determination of total mercury in fish

The following comments are based on the data presented in the table below compared to the numeric values for method criteria for MLs presented in Table 7 of the main document. Since the table below is not exhaustive with regards to the method characteristics, missing data in the table should be obtained from the relevant SDO so that a complete evaluation of the method's applicability may be performed.

AOAC 977.15:

- may not be applicable for any ML since applicable range is to small (0.275-0.944 mg/kg)
- may not be applicable since HorRat is up to 2.5 but it is unclear if this HorRat is relevant to fish

AOAC 2013.06:

- may be applicable but important method characteristics are missing

NMKL 186 (2007) (equivalent to EN 15763:2009):

- may not be applicable for any ML since applicable range is to small (0.047-0.57 mg/kg)

NMKL 170 (2002) (equivalent to EN 13806:2002):

- applicable to MLs ≤ 2. Minimum applicable range is 0.154-13.5 mg/kg in dry weight (dw) which is approximately 0.04-3.38 mg/kg in wet weight (ww) given a dry matter of 25%.

AOAC 974.14, AOAC 971.21, AOAC 952.14:

- method characteristics are missing

Table: Method characteristics of collaboratively validated methods for the determination of total mercury in fish

Method	Summary of method	Principle	Applicability	Minimum applicable range (mg/kg)	LOD/ LOQ (mg/kg)	Recovery (%)	RSDR (%)	Note	Comment
AOAC 977.15 Mercury in Fish	The sample is boiled with V_2O_5 and H_2SO_4–HNO_3 (1 + 1), cooled and diluted with water and Hg determined using FAAS	FAAS	Fish	0.275-0.944	LOD: 0.05		4 – 49 (HorRat 0.24-2.5)	Type III method for Hg in fish and fishery products	Ref (CX/MAS 08/29/7 table 1)
AOAC 2013.06 Arsenic, cadmium, mercury, and lead in foods	Pressure Digestion with HNO_3 and H2O2 and determination with ICP-MS	ICP-MS	Foods Fish/Fish Muscle Fish/Mussels		LOQ: 0.09*		17 (fish muscle) (HorRat 0.7)		Ref (AOAC 2013.06)
NMKL 186 (2007) TRACE ELEMENTS - As, Cd, Hg, Pb and other elements.	Pressure Digestion with HNO_3 and H_2O_2 and determination with ICP-MS	ICP-MS	All foods	0.047-0.57			16-32 (HorRat < 1.5)		Ref (CX/MAS 08/29/7 table 1) Equivalent to EN 15763:2009
NMKL 170 (2002) MERCURY. Determination in Seafood	Pressure Digestion with HNO_3 and H_2O_2 and determination with FI-CVAAS after divalent mercury is reduced to elemental mercury with sodium boron hydride.	FI-CVAAS	Fish and seafood products	0.154-13.5*	< 0.04		8-17 (HorRat < 2)		Ref (CX/MAS 08/29/7 table 1) Equivalent to EN 13806:2002

Method	Summary of method	Principle	Applicability	Minimum applicable range (mg/kg)	LOD/ LOQ (mg/kg)	Recovery (%)	RSDR (%)	Note	Comment
AOAC 974.14 Mercury in fish	Digestion with HNO3, dilution and determination with FAAS	FAAS	Foods/Fish						
AOAC 971.21 Mercury in food	The sample is boiled with H_2SO_4, HNO_3 and sodium molybdate, cooled and diluted with water and Hg determined using FAAS	FAAS	Foods						
AOAC 952.14 Mercury in food	Sample is digested with HNO_3 and H_2SO_4 under reflux and Hg is isolated by dithizone extraction, Cu is removed, and Hg is estimated by photometric measurement of Hg dithizonate	Dithizone Method Colorimeter	Foods						

* = Numbers in dry weight

Appendix II

Comments to the applicability of the collaboratively validated methods listed in Appendix II for the determination of methylmercury in fish

All the methods in Appendix II express results of methylmercury as mg Hg/kg. The following comments are based on the data presented in the table below compared to the numeric values for method criteria for MLs presented in Table 7 of the main document.

AOAC 988.11:

- may not be applicable for ML ≤ 1 since LOQ is to high (0.25 mg Hg/kg)
- may not be applicable for ML ≥ 2 since applicable range is to small (0.5-2.30 mg Hg/kg)

AOAC 990.04:

- may not be applicable for ML ≥ 2 since applicable range is to small (0.15-2.48 mg Hg/kg)

AOAC 983.20:

- may not be applicable for any ML since recovery is too high (99-120%) but it is unclear if the high recovery is relevant to fish since the method can also determine methylmercury in shellfish
- may otherwise be applicable to MLs < 2

IRMM-IMEP-115:

- may not be applicable for other MLs except 0.5 since the applicable range is too small (0.02-5.12 mg Hg/kg dw). MLs are in ww and a 5.12 mg Hg/kg dw is approximately 1.3 mg Hg/kg ww given a dry matter of 25%.
- recovery of 143% applies to NIST SRM 1566b (oyster tissue, i.e. not a fish sample) with a very low content of methylmercury (0.0132 mg Hg/kg dw)

prEN16801:

- may not be applicable for other MLs except 0.5 since the applicable range is too small (0.04-3.6 mg Hg/kg dw). MLs are in ww and 3.6 mg Hg/kg dw is approximately 0.9 mg Hg/kg ww given a dry matter of 25%.
- RSDR of 41% applies to a sample of mussel tissue with very low content of methylmercury (0.035 mg Hg/kg dw).

Table: Method characteristics of collaboratively validated methods for the determination of methylmercury in fish

Method	Summary of method	Principle	Applicability	Minimum applicable range (mg Hg/kg)	LOD/ LOQ (mg Hg/kg)	Recovery (%)	RSDR (%)	Note	Comment
AOAC 988.11 Mercury (Methyl) in Fish and Shellfish	Organic interferences are removed from homogenized seafood by acetone wash followed by toluene wash. Protein-bound methyl Hg is released by addition of HCl and extracted into toluene. Toluene extract is analyzed for CH_3HgCl by electron capture GC.	GC-ECD	Fish and shellfish	0.50-2.30	LOQ: 0.25	86-98	4-15	Type II method for GL of methyl-mercury	
AOAC 990.04 Mercury (Methyl) in seafood	LC effluent is heated to produce Hg vapor from organomercury compounds. Hg vapor, together with vaporized mobile phase, is directed into water-cooled condenser where mobile phase is liquefied. Hg vapor is swept with nitrogen into absorption cell in light path of atomic absorption spectrophotometer.	LC-AAS	Seafood	0.15-1.86	LOQ: 0.06	94.4-99.6	10.5-18.2		
AOAC 983.20 Mercury (Methyl) in Fish and Shellfish	Organic interferences are removed from homogenized material by acetone wash followed by benzene wash. Protein-bound methyl Hg is released by addition of HCl and extracted into benzene. Benzene extract is concentrated and analyzed for CH_3HgCl by GC.	GC-ECD	Fish and shellfish	0.15-2.48	LOQ: 0.05	99-120	3-13		

Method	Summary of method	Principle	Applicability	Minimum applicable range (mg Hg/kg)	LOD/ LOQ (mg Hg/kg)	Recovery (%)	RSDR (%)	Note	Comment
IRMM-IMEP-115 Methylmercury in seafood (EUR 25830 EN 2013)	The method is based on a double liquid-liquid extraction, first with an organic solvent and then with a cysteine solution. The final quantification is done with a direct mercury analyzer.	DMA or EMA	Seafood	0.02-5.12*	LOQ: 0.02*	85-143	8.4-24.8 (HorRat 0.5-1.2)		Proposal to become future CEN standard
prEN16801 Methylmercury in foodstuffs of marine origin	The sample is spiked with an appropriate amount of Hg-isotope enriched MMHg and extracted using tetramethylammonium hydroxide (TMAH). After pH adjustment, derivatisation and extraction, the organic phase is analysed using GC-ICP-MS.	GC-ICP-MS	Seafood	0.04-3.6*	LOQ: 0.04*	100 (see note)	5.8-41 (HorRat 1.6-0.3)	Recovery of NRCC DOLT 4	Formally adopted for CEN enquiry

* = Numbers in dry weight

Appendix III

LIST OF PARTICIPANTS

Australia

Leigh Henderson

Food Standards Australia New Zealand

Email: leigh.henderson@foodstandards.gov.au

codex.contact@agriculture.gov.au

Austria

Mag. Kristina Marchart

Austrian Agency for Health and Food Safety, Risk Assessment, Data and Statistics

Email: Kristina.marchart@ages.at

Belgium

Isabel De Boosere

Belgian Federal Public Service Health, Food Chain Safety and Environment

Email: Isabel.deboosere@health.belgium.be

Brazil

Lígia Lindner Schreiner

National Health Suveillance Agency- Anvisa

Email: ligia.schreiner@anvisa.gov.br

Fabio Silva

National Health Suveillance Agency- Anvisa

Email: fabio.silva@anvisa.gov.br

Canada

Elizabeth Elliott

Health Canada

Email: elizabeth.elliott@hc-sc.gc.ca

Robin Churchill

Health Canada

Email: robin.churchill@hc-sc.gc.ca

Steven Mavity

Bumble Bee Seafoods

Email: Steven.Mavity@bumblebee.com

Chile

Jaminton Ramírez

Institute of Public Health (ISP)

Email: jramirez@ispch.cl

China

Yongning Wu

China National Center for Food Safety Risk Assessment (CFSA)

Email: wuyongning@cfsa.net.cn

china_cdc@aliyun.com

Xiaowei Li

China National Center for Food Safety Risk Assessment (CFSA)

Email: lixw@cfsa.net.cn

Yi Shao

China National Center for Food Safety Risk Assessment (CFSA)

Email: shaoyi@cfsa.net.cn

Xiaohong Shang

China National Center of Food Safety Risk Assessment (CFSA)

Email: shangxh@cfsa.net.cn

Ghana

Lawrence D. Abbey

CSIR - Food Research Institute

Email: abbeyld@yahoo.com; codex@gsa.gov.gh

codexghana@gmail.com

India

Pramod PK

Export Inspection Council of India

Email:

tech6@eicindia.gov.in

codex-india@nic.in

Shri P. Karthikeyan

Food Safety and Standards Authority of India

Email: karthik@fssai.gov.in

Japan (chair)

Hirohide Matsushima

Ministry of Agriculture, Forestry and Fisheries

Email: hirohide_matsushima@nm.maff.go.jp

Yukiko Yamada

Ministry of Agriculture, Forestry and Fisheries

E-mail: codex_maff@nm.maff.go.jp

Hidetaka Kobayashi

Ministry of Agriculture, Forestry and Fisheries

Email: hidetaka_kobayashi@nm.maff.go.jp

Rei Nakagawa

Ministry of Health, Labour and Welfare

Email: codexj@mhlw.go.jp

Luxembourg

Danny Zust

Food safety department, Ministry of Health

Email: danny.zust@ms.etat.lu

Micronesia (Federated States of)

Moses E. Pretrick

Department of Health and Social Affairs

Email: mpretrick@fsmhealth.fm

New Zealand

John Reeve

Ministry for Primary Industries

Email: john.reeve@mpi.govt.nz

Norway (co-chair)

Anders Tharaldsen

Norwegian Food Safety Authority

Email: Anders.Tharaldsen@mattilsynet.no

An-Katrin Eikefjord

Norwegian Food Safety Authority

Email: An-Katrin.Eikefjord@mattilsynet.no

Kirstin Færden

Norwegian Food Safety Authority

Email: Kirstin.Faerden@mattilsynet.no

Republic of Korea

Moo-Hyeog Im

Ministry of Food and Drug Safety

Email: imh0119@hanmail.net

codexkorea@korea.kr

Hyungsoo Kim

Ministry of Food and Drug Safety

Email: jungin98@yahoo.com

Chon ho Jo

Ministry of Food and Drug Safety

Email: jch77@korea.kr

Ockjin Paek

Ministry of Food and Drug Safety

Email: ojpaek@naver.com

Hyunah Kim

Ministry of Food and Drug Safety

Email: kamjee94@korea.kr

Seychelles

Christopher Hoareau

Seychelles Bureau of Standards (SBS)

Email: vetfiqcu@seychelles.net

Spain

Ana López-Santacruz

Ministry of Health, Social Services and Equality

Email: contaminantes@msssi.es

Anouchka Biel Canedo

Ministry of Health, Social Services and Equality

Email: contaminantes@msssi.es

Mª Eugenia Cirugeda Delgado

Ministry of Health, Social Services and Equality

Email: mecirugeda@msssi.es

Mª Ignacia Martín de la Hinojosa de la Puerta

Ministry of Agriculture, Food and Environment.

Email: imhinojosa@magrama.es.

Carola González Kessler

Ministry of Agriculture, Food and Environment.

Email: cgonzalez@magrama.es

Julián García Baena

Ministry of Agriculture, Food and Environment.

Email: JGBaena@magrama.es

Argelia Castaño Calvo

National Center for Environment and Health (CNSA),

Institute of Health Carlos III (ISCIII)

Email: castano@isciii.es

Sweden

Carmina Ionescu

National Food Administration, Food Standards Division

Email: carmina.ionescu@slv.se

United Kingdom

Paul Jenkins

Food Standards Agency

Email: paul.jenkins@foodstandards.gsi.gov.uk

United States of America

Henry Kim

U.S. Food and Drug Administration Center for Food

Safety and Applied Nutrition

Email: Henry.kim@fda.hhs.gov

Nega Beru

U.S. Food and Drug Administration Center for Food

Safety and Applied Nutrition

Email: Nega.beru@fda.hhs.gov

Vietnam

Thach Thi Tu Cau

Vietnam Codex Office

Email: codexvn@vfa.gov.vn

Do Thi Yen

Hanoi University of Science and Technology

Email: yen.dothi@hust.edu.vn

Bui The Anh

Ministry of Agriculture and Rural Development

Email: anhbt.khcn@mard.gov.vn

Uruguay

María Salhi

Dirección Nacional de Recursos Acuáticos (MGAP)

Email: msalhi@dinara.gub.uy; codex@latu.org.uy

Raquel Huertas

Laboratorio Tecnológico del Uruguay

Email: rhuertas@latu.org.uy

FoodDrinkEurope

Patrick Fox

Email: p.fox@fooddrinkeurope.eu

International Frozen Food Association

Maia M. Jack

Email: mjack@aff