CODEX ALIMENTARIUS COMMISSION

Food and Agriculture Organization of the United Nations

World Health Organization

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CODEX COMMITTEE ON CONTAMINANTS IN FOODS

Tenth Session

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DISCUSSION PAPER ON MAXIMUM LEVELS FOR METHYLMERCURY IN FISH

(Prepared by the Electronic Working Group chaired by Japan and co-chaired by New Zealand)

Codex Members and Observers are kindly invited to consider the conclusions and recommendations in paragraphs 34-37 while taking into account the data and information provided in the discussion paper in order to assist the Committee on how to proceed further with the consideration of maximum levels for methylmercury in fish.

BACKGROUND

1. The 7th Session of the Committee on Contaminants in Food (April 2013) reviewed the current Guideline Levels (GLs)[1] 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)[2]. While there was support for setting GLs or Maximum Levels (MLs)[3] 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 (March 2014), the CCCF 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 (methylmercury or total mercury) for which MLs or GLs should apply, classification of fish and the percentage of samples with methylmercury levels exceeding the current GLs (REP14/CF, para.104-112). 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.

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[1] A Codex guideline level (GL) is the maximum level of a substance in a food or feed commodity which is recommended by the CAC to be acceptable for commodities moving in international trade. When the GL is exceeded, governments should decide whether and under what circumstances the food should be distributed within their territory or jurisdiction (CODEX STAN 193-1995: General Standard for Contaminants and Toxins in Food and Feed (GSCTFF)).

[2] 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).

[3] The Codex maximum level (ML) for a contaminant in a food or feed commodity is the maximum concentration of that substance recommended by the Codex Alimentarius Commission (CAC) to be legally permitted in that commodity (CODEX STAN 193-1995).

3. The 9th Session of the CCCF (March 2015) considered Maximum Levels (MLs) for methymercury in fish with particular regard for the following points (REP 15/CF, para. 118):

- Fish species to which ML(s) apply and the criteria for identifying those species (e.g. the importance in international trade, the representative value of methylmercury concentrations, etc.)
- ML(s) for methylmercury in identified fish species
- Analytical methods for enforcement

4. The 9th Session of CCCF, noting the continued support for and some views against establishing an ML, agreed that further work on this should continue by re-establishing the electronic working group (EWG), chaired by Japan and co-chaired by New Zealand, to prepare another discussion paper (REP 15/CF, para. 121, 125 and 126).

5. The mandate of the current EWG is to address the following points in a discussion paper for the consideration at the 10th Session of the CCCF (REP 15/CF, para. 125 and 126);

- To consider expanding the ML to fish species that can accumulate high methylmercury concentrations, other than tuna, while narrowing down the ML ranges;
- To conduct an exposure assessment based on different MLs; and
- To include a project document.

6. The list of participants is presented in Appendix II.

INTRODUCTION

7. The current Guideline Levels (GLs) for methylmercury in fish (1 mg/kg for predatory fish and 0.5 mg/kg for other fish species[4]) 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).

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

9. In 2003, the Joint FAO/WHO Expert Committee on Food Additives (JECFA) revised the provisional tolerable weekly intake (PTWI) for methylmercury from 3.3 to 1.6 µg/kg body weight, based on the most sensitive toxicological end-point in the most susceptible species (humans)[5].

10. For adults, JECFA considered that intakes of up to two times higher than the PTWI would not pose any risk of neurotoxicity, although in the case of women of childbearing age, intake should not exceed the PTWI in order to protect the embryo and fetus. Concerning infants and children up to 17 years, no firm conclusions were drawn regarding their sensitivity compared to that of adults.

[4] CODEX STAN 193-1995

[5] 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).

11. JECFA further concluded that the setting of guideline levels for methylmercury in fish might not be an effective way of reducing exposure for the general population. JECFA noted that advice targeted at population subgroups that might be at risk from methylmercury exposure could provide an effective method for lowering the number of individuals with exposures greater than the PTWI.

12. After the JECFA assessment, the Joint FAO/WHO Expert Consultation on the Risks and Benefits of Fish Consumption also carried out risk-benefit assessments of fish consumption in 2010, associated with risk of methylmercury exposure and beneficial contributions from nutrients in fish.

13. In this context, the current GLs should be reviewed to develop ML(s) taking into consideration the results of discussions of the CCCF, risk assessments by JECFA and the conclusions of the Joint FAO/WHO Expert Consultation on the Risks and Benefits of Fish Consumption.

CONSUMPTION DATA FOR FISH THAT CAN ACCUMULATE HIGH METHYLMERCURY CONCENTRATIONS

Consumption data provided by members

14. At its 9th Session, the CCCF recognized that in order to estimate methylmercury intake from fish species that contain high concentrations of methylmercury, other than tuna, such as shark, sword fish or blue marlin, additional consumption data for those species was necessary (REP 15/CF, para 120).

15. Consumption data available in the GEMS/Food database and the Global Food Consumption Database by FAO and WHO were not sufficiently detailed for dietary exposure assessment taking account of different sources of methylmercury, except for tuna.

16. The EWG therefore requested the submission of consumption data for shark, swordfish and blue marlin or any other fish species or groups of similar fish species known to accumulate high levels of methylmercury for the following three population groups: general population[6], children (≥ 6 years old) and women of child-bearing age. In the absence of consumption data, production/import/export data for individual fish species or specific groups of fish species with high levels of methylmercury were also requested to provide as possible alternative means of estimating dietary exposure.

17. Data were submitted by the following three countries: Chile, New Zealand and the United States of America (USA), on different kinds of fish species. Among them, the consumption data provided by Chile were of a sum of fish and seafood consumption without data at the species level; therefore they were not suitable for calculating methylmercury intake from specific fish species that could potentially accumulate high methylmercury concentrations. The summary of data provided by the other two countries is shown in Table 1. The consumption data provided by the USA was from a 2-day survey, while that provided by NZ was single-day data that was weighted to take into account the proportion of different ethnic groups in the population. Consumption data over a week or an even longer period of time were not available.

[6] Whole population of the cluster including children and women of childbearing age.

18. In addition to the consumption data, the occurrence data of total mercury for 7720 and 476 samples were provided by NZ and the USA, respectively. They were incorporated into the dataset[7] which had been used for the analyses in the previous discussion papers for the 8th and 9th Session of CCCF, and the revised dataset was used for calculating methylmercury intake from Swordfish, Shark, Southern Bluefin tuna, Tuna-canned and Tuna-fresh (Table 2). Among the dataset provided by NZ, the occurrence data of total mercury for School Shark, Cardinal fish, Ribaldo and Ling, whose data were not available in the dataset which had been used for the analyses in the previous discussion papers, were also included.

Consumption data publicly available

19. The European Food Safety Authority (EFSA) released on its website "The Comprehensive Food Consumption Database", in which consumption data for a number of EU countries are available (http://www.efsa.europa.eu/en/food-consumption/comprehensive-database[8]).

20. In this EFSA database, individuals are categorized into seven age groups covering infants (< 1 year), toddlers (1 - < 3 years), other children (3 - < 10 years), adolescents (10 - < 18 years), adults (18 - < 65 years), elderly (65 - < 75 years) and the very elderly (≥ 75 years)[9]. Also, food consumption data are presented by classifying into three layers: Level 1 (including 20 food categories), Level 2 (including around 160 food categories) and Level 3[10]. The Level 1 food category 'Fish and other seafood' is split in six subcategories at Level 2, including 'Fish meat', 'Fish products', 'Fish offal', 'Crustaceans', 'Molluscs' and 'Amphibians, reptiles, snails, insects'. The 'Fish meat' category is further split into 32 fish species[11] in the Level 3.

21. Among shark, swordfish and blue marlin, only the category of Swordfish is contained in the Level 3. Furthermore, the category of Swordfish was recently established; before that, it had been classified into "fish meat". According to Chronic food consumption statistics in the Comprehensive Food Consumption Database which contains the consumption data obtained from 44 surveys across the EU countries, only two individuals' consumption data are currently reported for Swordfish; therefore, the data were not used in this paper.

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[7] The occurrence data of total mercury were used by assuming that all of total mercury was present as methylmercury.
[8] Accessed on October 10, 2015.
[9] "Use of the EFSA Comprehensive European Food Consumption Database in exposure assessment" EFSA Journal, 2011; 9(3):2097
[10] "Scientific Opinion on the risk for public health related to the presence of mercury and methylmercury in fish", EFSA Journal, 2012; 10(12):2985
[11] Fish meat, Herring (Clupea), Sprat (Sprattus sprattus), Sardine and pilchard (Sardina), Anchovy (Engraulis), Shad (Alosa), Salmon and trout (Salmo spp.), Char (Salvelinus), Smelt (Osmerus), Whitefish (Coregonus), Perch (Perca), Bass (Marone), Mackeral (Scomber), Tuna (Thunnus), Sea catfish and wolf-fish (Anarhichas), Grey mullet (Mugil), Cod and whiting (Gadus spp.), Hake (Merluccius), Flounder (Platichthys flesus), Halibut (Hippoglossus spp.), Plaice (Pleuronectes), Sole (Limanda; Solea), Carp (Cyprinus), Babel (Barbus), Bream (Charax), Eels (Apodes), Lophiiformes (Pediculati), Selachoidei (Pleurotremata), Rays (Hypotremata), Bonito (Sarda Sarda), Sardinops (Sardinops sagax), Swordfish (Xiphidae spp.).

Other studies

22. In 2003, JECFA compiled dietary intake assessments for methylmercury provided by some countries in its report of the sixty-first meeting[12]. However, the consumption data for specific fish species were not available, and therefore, the information about dietary intake was not included in this paper.

DIETARY EXPOSURE TO METHYLMERCURY FROM FISH THAT CAN ACCUMULATE HIGH METHYLMERCURY CONCENTRATIONS

The dietary exposure to methylmercury were calculated for specific fish species for which the occurrence data and consumption data were available. Due to the developmental neurotoxicity profile of methylmercury, the dietary exposure not only for general population but also for children and women of child-bearing age were calculated on the basis of consumption data of the whole population (eaters and non-eaters) and "eaters only".

Whole populations (i.e., eaters and non-eaters)

23. In Table 3, the methylmercury dietary exposure were calculated for fish species that had more than 100 eaters (identified in Table 1): Tuna-canned, Cardinal fish (only for general population) and Ribaldo (only for general population).

24. The weekly dietary exposures of methylmercury (μg/kg bw/week) were calculated by using the average of consumption data (g/kg bw/day) and the average and maximum of occurrence data (mg/kg); calculated daily dietary exposures were multiplied by "7" in order to express intake on a weekly basis. Consumption values derived from single-day or two-day survey data, expressed as one-day consumption. As not everyone eat fishery products every day, this calculation might result in overestimation of actual weekly dietary exposures. For Tuna-canned, as the species was not specified, the occurrence data of three species, Albacore, Yellowfin tuna and Skipjack tuna, which could be generally used for canned tuna, were used[13].

25. The calculated weekly dietary exposures (μg/kg bw/week) are shown in Table 3. All of them were ＜ PTWI of 1.6 μg/kg bw.

Eaters only

26. As methylmercury has a potential to show toxicity among susceptible population after a relatively short period of exposure (in utero exposure is the most sensitive exposure period for the most sensitive toxic outcome of neurodevelopment effects), dietary exposure to methylmercury by "eaters only" were also calculated in Table 4 for specific fish species with ＞50 eaters (identified in Table 1): Tuna-canned, Tuna-fresh (only for general population), Cardinal fish (only for general population), and Ribaldo (only for general population).

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[12] Safety evaluation of certain food additives and contaminants. WHO Food Additives Series No. 52, 2004.

[13] The occurrence data can include those of samples that were not canned products.

27. The weekly dietary exposures to methylmercury (µg/kg bw/week) were calculated by using the average and 90th percentile of consumption data (g/kg bw/day) and the average and maximum of occurrence data (mg/kg). For Tuna-fresh, as the species was not specified, the occurrence data of three species, Albacore, Yellowfin tuna and Bigeye tuna, which could be generally consumed as fresh tuna, were used[14].

28. The calculated weekly dietary exposures (µg/kg bw/week) are shown in Table 4. Except for several cases for Tuna-canned and Tuna-fresh, the calculated dietary exposures to methylmercury, which might be overestimates (see para. 24) were ＞PTWI of 1.6 µg/kg bw.

29. With regard to Swordfish, School shark, Shark, Southern bluefin tuna and Ling, the numbers of eaters were 0 – 13 persons and the proportions of eaters among whole populations were less than 0.3% for all of three groups. Accordingly, their average and 90%ile consumption data were not used for calculating the weekly dietary exposures from them for whole populations as well as eaters; thus, the results of preliminary exposure assessments were not provided.

Evaluation of preliminary exposure assessment

30. As provided in paragraph 17, two member countries provided consumption data of fish species that can accumulate high methylmercury concentrations; however, in order to represent the consumption pattern across the world, more data would be necessary. Despite the limitations, the data provided suggests that the numbers of eaters of Swordfish, Shark and Southern bluefin tuna were generally small, but in some countries, fish species are often not identified in fast food meals at the point of sale and shark is commonly used and consumption may be more significant but not able to be quantified.

31. As for Cardinal fish and Ribaldo, whose proportions of eaters were relatively large, which were about 3%, the categories of those species were not established in “FAO Fishery Commodities Global Production and Trade” database[15] and it could be considered that their international trade volumes were not large. It should be noted that in the discussion paper prepared for the 9th Session of CCCF, the threshold of 100000 tons was used to identify fish species important in international trade[16].

32. It should also be noted that the preliminary dietary exposure assessment did not take into account the benefits of fish consumption or the outcome of the Joint FAO/WHO Expert Consultation on the Risks and Benefits of Fish Consumption.

33. This Consultation found the evidence convincing that maternal fish consumption contributes to optimal neurodevelopment in their offspring. The report of the Consultation identified the species of fish, frequency of consumption, and the level of methylmercury such that the risks outweighed the benefits of fish consumption for those species of fish for which the level of LCn3PUFAs[17] were known.

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[14] The occurrence data can include those of samples that were not canned or fresh products.
[15] Accessed on October 10, 2015.
[16] The 8th Session of CCCF focused on the top fish and fishery products listed in the “FAO Fisheries Commodities Production and Trade” data base. Fish and fishery products with more than import or export values of 100000 tons corresponded approximately to those top 50 products.
[17] Long chain n-3 polyunsaturated fatty acid

CONCLUSIONS

34. The provisional dietary exposure assessment of methylmercury for whole populations and/or "eaters only", using the consumption data provided by the EWG members, was conducted for Tuna-canned (Thunnus *spp.*), Tuna-fresh (Thunnus *spp*.), Cardinalfish and Ribaldo. While the calculated dietary exposures for whole population were less than the PTWI of 1.6 µg/kg bw, those for "eaters only" exceeded the PTWI in most of the cases.

35. In evaluating the outcomes of those preliminary assessments, however, the following points should be taken into account;

- The consumption data were provided by only two member countries and there was only one dataset for each fish species;
- Despite the limitation, the numbers of eaters for Swordfish, Shark and Southern bluefin tuna were small; and,
- For Cardinal fish and Ribaldo, whose proportions of eaters were relatively large, their international trade volumes would not be large.
- It did not take into account the benefits of fish consumption or the outcome of the Joint FAO/WHO Expert Consultation on the Risks and Benefits of Fish Consumption.
- The calculated dietary exposures were conservative and possibly overestimated the exposure.

RECOMMENDATIONS

36. The Committee is invited to consider the followings:

- Confirming the decision of the 9th Session of CCCF to develop ML(s)
- For which species ML(s) should be developed
  - Tuna[18]
  - Fish species which can accumulate high methylmercury concentrations other than tuna
  - Predatory fishes including/excluding tuna, etc.
- Whether or not additional occurrence and/or consumption data should be collected.

37. A project document has been prepared and attached as Appendix I.

[18] Tuna was identified by the EWG for the 9th Session of CCCF that ML(s) should be applied (CX/CF 15/9/13, para. 46)

Table 1: Summary of consumption data provided by EWG members

Fish species or category name (*1)		Member of data source	Population	No. of people surveyed	No. of eaters	% of eaters	Consumption (g/kg bw/day) – Whole population				Consumption (g/kg bw/day) – Eaters only			
							Ave.	Median	90%ile	Max	Ave.	Median	90%ile	Max
Swordfish	*Xiphias Gladius*	USA	General	33027	13	0.04	0	0	0	1.124	0.614	0.472	1.058	1.124
			Children	5442	0	0	-	-	-	-	-	-	-	-
			Women of CB	6405	4	0.06	0.001	0	0	0.739	0.606	-	-	0.739
School shark	*Galeorhinus Galeus*	NZ	General	4721	13	0.3	0.0095	0	0	17	2.84	2.6	3.94	17
			Children	692	1	0.1	0.0065	-	-	-	7.75	-	-	-
			Women of CB	1553	3	0.2	0.002	0	0	1.11	2.22	2.07	-	2.63
Shark	*(Unspecified)*	USA	General	33027	2	0.01	-	-	-	1.037	0.932	-	-	1.037
			Children	5442	0	0	-	-	-	-	-	-	-	-
			Women of CB	6405	0	0	-	-	-	-	-	-	-	-
Southern bluefin tuna	*Thunnus Maccoyii*	NZ	General	4721	2	0.04	0.001	-	-	3.44	5.86	-	-	8.68
			Children	692	1	0.1	0.0013	-	-	-	3.34	-	-	-
			Women of CB	1553	1	0.06	0.002	-	-	-	3.03	-	-	-
Tuna-canned	*Thunnus spp.*	USA	General	33027	1721	5	0.036	0	0	6.308	0.572	0.439	1.145	6.308
			Children	5442	163	3	0.037	0	0	6.308	1.099	0.783	2.44	6.308
			Women of CB	6405	338	5	0.03	0	0	2.593	0.488	0.419	0.946	2.593
Tuna-fresh	*Thunnus spp.*	USA	General	33027	62	0.2	0.002	0	0	3.348	0.703	0.603	1.399	3.348
			Children	5442	1	0.02	-	-	-	-	1.049	-	-	1.049
			Women of CB	6405	15	0.2	0.003	0	0	3.048	0.65	0.414	1.614	3.048

Fish species or category name (*1)		Member of data source	Population	No. of people surveyed	No. of eaters	% of eaters	Consumption (g/kg bw/day) – **Whole population**				Consumption (g/kg bw/day) – **Eaters only**			
							Ave.	Median	90%ile	Max	Ave.	Median	90%ile	Max
Cardinal fish	*Epigonus Telescopus*	NZ (*2)	General	4721	135	3	0.05	0	0	43.77	1.71	0.88	3.82	43.77
			Children	692	6	0.9	0.04	0	0	37.53	5.85	2.61	11.92	11.92
			Women of CB	1553	37	2	0.031	0	0	18.24	1.32	0.94	2.11	18.24
Ling	*Genypterus Blacodes*	NZ	General	4721	1	0.02	0.00008	-	-	-	1.35	-	-	-
			Children	692	0	0	-	-	-	-	-	-	-	-
			Women of CB	1553	0	0	-	-	-	-	-	-	-	-
Ribaldo	*Gadiformes Mora-moro*	NZ (*2)	General	4721	135	3	0.05	0	0	43.77	1.71	0.88	3.82	43.77
			Children	692	6	0.9	0.04	0	0	37.53	5.85	2.61	11.92	11.92
			Women of CB	1553	37	2	0.031	0	0	18.24	1.32	0.94	2.11	18.24

(*1) The information on fish species and category names are shown as provided.

(*2) The New Zealand consumption data for Cardinal fish and Ribaldo was not specific and the figure used was that for “Fish not elsewhere specified” and hence the consumption figures are potentially an overestimate as this category includes some fish that are popular such as gurnard (*Chelidonichthys kumu*).

Notes:

The numbers of significant figures are various, and they are basically shown in the Table as provided by members.

Table 2: Summary of occurrence data total mercury provided by EWG members

Fish species or category name (*1)		Data Source		Number of samples	Average (mg/kg)	Median (mg/kg)	Maximum (mg/kg)
Swordfish	*Xiphias Gladius*	EWG (*2)		308	1.1	0.96	3.9
School shark	*Galeorhinus Galeus*	NZ		58	0.56	0.44	3.0
Shark	*(Unspecified)*	EWG		301	0.98	0.69	4.6
Southern bluefin tuna	*Thunnus Maccoyii*	EWG (*2)		252	0.61	0.44	4.4
Tuna-canned	*Thunnus spp.*	EWG (*2, 3)	Albacore tuna	385	0.36	0.30	1.8
			Yellowfin tuna	1343	0.15	0.080	1.4
			Skipjack tuna	523	0.14	0.14	0.49
Tuna-fresh	*Thunnus spp.*	EWG (*2, 4)	Bigeye tuna	243	0.56	0.43	2.3
			Albacore tuna	385	0.36	0.30	1.8
			Yellowfin tuna	1343	0.15	0.080	1.4
Cardinal fish	*Epigonus Telescopus*	NZ		70	1.3	1.2	2.1
Ling	*Genypterus Blacodes*	NZ		627	0.52	0.44	2.4
Ribaldo	*Gadiformes Mora-moro*	NZ		101	0.49	0.46	1.2

(*1) The information on fish species and category names are shown as provided.

(*2) The dataset which had been used for the analyses in the previous discussion papers for the 8th and 9th Session of CCCF. The occurrence data were provided the following 13 countries and one observer: Australia, Chile, China, France, Ghana, Ireland, Japan, Mexico, Norway, Poland, Spain, Seychelles, Thailand and FoodDrink Europe

(*3) As species was not specified, the occurrence data of three species which could be generally used for canned tuna are shown.

(*4) As species was not specified, the occurrence data of three species which could be generally consumed as fresh tuna are shown.

Table 3: The estimated weekly dietary exposures to methylmercury for whole populations (eaters and non-eaters) (µg/kg bw/week) (PTWI: 1.6 µg/kg bw/week)

	Tuna-canned			Cardinal fish	Ribaldo
	Albacore	Yellowfin tuna	Skipjack tuna		
Concentration					
Average (mg/kg)	0.36	0.15	0.14	1.3	0.49
Max (mg/kg)	1.8	1.4	0.49	2.1	1.2
Consumption - Average (g/kg bw/day)					
General population	0.036			0.050	0.05
Children	0.037			-	-
Women of child-bearing age	0.030			-	-
Weekly dietary exposure (µg/kg bw/week) (Average concentration x Average consumption x 7)					
General population	0.091	0.038	0.035	0.46	0.17
Children	0.093	0.039	0.036	-	-
Women of child-bearing age	0.076	0.031	0.029	-	-
Weekly dietary exposre (µg/kg bw/week) (Max concentration x Average consumption x 7)					
General population	0.45	0.35	0.12	0.74	0.42
Children	0.47	0.36	0.13	-	-
Women of child-bearing age	0.38	0.29	0.10	-	-

Table 4: Estimated weekly dietary exposure to methylmercury for eaters only (µg/kg bw/week) (PTWI: 1.6 µg/kg bw/week)

	Tuna-canned			Tuna-fresh			Cardinal fish	Ribaldo
	Albacore	Yellowfin tuna	Skipjack tuna	Albacore	Yellowfin tuna	Bigeye tuna		
Concentration								
Average (mg/kg)	0.36	0.15	0.14	0.36	0.15	0.56	1.3	0.49
Max (mg/kg)	1.8	1.4	0.49	1.8	1.4	2.3	2.1	1.2
Consumption - Average (g/kg bw/day)								
General population			0.57			0.70	1.7	1.7
Children			1.1			-	-	-
Women of child-bearing age			0.49			-	-	-
Consumption - 90th percentile (g/kg bw/day)								
General population			1.1			1.4	3.8	3.8
Children			2.4			-	-	-
Women of child-bearing age			0.95			-	-	-
Weekly dietary exposure (µg/kg bw/week)(Average concentration x Average consumption x 7)								
General population	1.4	0.60	0.56	1.8	0.74	2.7	16	5.8
Children	2.8	1.2	1.1	-	-	-	-	-
Women of child-bearing age	1.2	0.51	0.48	-	-	-	-	-

Weekly dietary exposure (µg/kg bw/week)(Average concentration x 90th percentile consumption x 7)								
General population	2.8	1.2	1.1	3.5	1.5	5.5	35	13
Children	6.1	2.5	2.4	-	-	-	-	-
Women of child-bearing age	2.4	1.0	0.93	-	-	-	-	-
Weekly dietary exposure (µg/kg bw/week)(Max concentration x Average consumption x 7)								
General population	7.2	5.6	2.0	8.9	6.9	11	25	14
Children	14	11	3.8	-	-	-	-	-
Women of child-bearing age	6.2	4.8	1.7	-	-	-	-	-
Weekly dietary exposure (µg/kg bw/week)(Max concentration x 90th percentile consumption x 7)								
General population	14	11	3.8	18	14	23	56	32
Children	30	24	8.2	-	-	-	-	-
Women of child-bearing age	12	9.3	3.3	-	-	-	-	-

APPENDIX I

PROJECT DOCUMENT

PROPOSAL FOR NEW WORK ON MAXIMUM LEVEL(S) FOR METHYLMERCURY IN [TUNA][FISH][1]

1. The purpose and scope of the project

This project aims to establish Maximum Level(s) (ML(s)) for methylmercury in [tuna] [fish].

2. Relevance and timeliness

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. 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 3.3 µg/kg body weight, based on the most sensitive toxicological end-point (developmental neurotoxicity) in the most susceptible species (humans)[3]. Also, the current Guideline Levels (GLs) did not take into account net effects that include both adverse contributions from methylmercury and beneficial contributions from nutrients in fish on the same health endpoints (CX/CF 13/7/16, para. 75; REP13/CF, para. 118).

In this context, the current GLs for methylmercury in fish should be reviewed to establish appropriate ML(s) taking into consideration the results of discussion of the Codex Committee on Contaminants in Food (CCCF), risk assessments by the JECFA and the conclusions of the Joint FAO/WHO Expert Consultation on the Risks and Benefits of Fish Consumption.

3. The main aspects to be covered

- ML(s) for methylmercury in [tuna] [fish], taking into account the following:
  a) Results of discussions of the CCCF
  b) Risk assessments by JECFA
  c) Conclusions of the Joint FAO/WHO Expert Consultation on the Risks and Benefits of Fish Consumption
- Fish species to which ML(s) should apply
- An associated sampling plan

4. Assessment against the criteria for the establishment of work priorities

- *Consumer protection from the point of view of health, food safety, ensuring fair practices in the food trade and taking into account the identified needs of developing countries.*

  The new work will establish Maximum Level(s) for methylmercury in [tuna] [fish].
- *Diversification of national legislation and apparent resultant or potential impediments to international trade.*

  The international trade of [tuna] [fish] and [tuna] [fishery] products is increasing, and the new work will provide an internationally-harmonized standard.

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[1] In accordance with the recommendations of the Discussion Paper on Maximum Levels for methylmercury in fish, the 10th Session of the Codex Committee on Contaminants in Food (CCCF) will consider whether ML(s) should be established for tuna only, other fish species that can accumulate high methylmercury concentrations, predatory fishes including/excluding tuna, or others.

[2] CODEX STAN 193-1995: General Standard for Contaminants and Toxins in Food (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).

- *Work already undertaken by other international organizations in this field and/or suggested by the relevant international intergovernmental body(ies).*

  While the analyses on benefit and risk of fish consumption have been conducted by several Codex members, the proposed work to establish ML(s) for methylmercury in fish globally has not been undertaken by any other international organizations in this field nor suggested by any relevant international intergovernmental bodies.

- *Consideration of the global magnitude of the problem or issue*

  The consumption and international trade of [tuna] [fish] and [tuna] [fishery] products are increasing globally, and thus this work is of worldwide interest and becoming increasingly significant.

5. Relevance to Codex Strategic Goals

The proposed work falls under the following Codex Strategic Goals of the Codex Strategic Plan 2014-2019:

- *Strategic goal 1: Establish international food standards that address current and emerging food issues*

  This work was proposed in response to needs identified by Members in relation to food safety, nutrition and fair practices in the food trade. There is already significant trade in fish species which have methylmercury levels which exceed the current GLs.

- *Strategic goal 2: Ensure the application of risk analysis principles in the development of Codex standards*

  This work will use the scientific advice of the joint FAO/WHO expert bodies to the fullest extent possible. Also, all relevant factors will be fully considered in exploring risk management options.

6. Information on the relationship between the proposal and other existing Codex documents

This new work is recommended in the Discussion paper on Maximum Levels for methylmercury in fish that will be discussed at the 10th Session of Codex Committee on Contaminants in Foods.

7. Identification of any requirement for any availability of expert scientific advice

Expert scientific advice has been already provided by JECFA and the Joint FAO/WHO Expert Consultation on the Risks and Benefits of Fish Consumption.

8. Identification of any need for technical input to the standard from external bodies

Additional technical input from external bodies may not be necessary.

9. The proposed time-line for completion of the new work, including the starting date, proposed date for adoption at Step 5 and the proposed date for adoption by the Commission

Subject to the approval by the Codex Alimentarius Commission in 2016, the proposed draft ML(s) for methylmercury in fish will be considered at the 11th Session of the CCCF with a view to its finalization in 2018 at the earliest.

APPENDIX II

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