CODEX ALIMENTARIUS COMMISSION

Food and Agriculture Organization of the United Nations

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

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DISCUSSION PAPER ON MAXIMUM LEVELS FOR METHYLMERCURY IN FISH

Background

1. The full history of the discussion on methylmercury dating back to 1992 is contained in Information document CF/11 INF/1. A summary for the current discussion paper is given below.

2. The 6th CCCF (2012) agreed to the development of a discussion paper on the review of the guideline level for methylmercury in fish and predatory fish through an EWG led by Norway and co-chaired by Japan for consideration and discussion at the 7th session with the view of identification of possible actions or new work on this issue (REP 12/CF, para. 174).

3. The 7th CCCF (2013) agreed that consumer advice should not be developed at the international level and that such guidance was more appropriate at the national level. It was agreed to review the GLs with a view to their revision or conversion to MLs. The Committee therefore re-established the EWG, led by Japan and co-chaired by Norway, to prepare a discussion paper; collect data on total mercury and methylmercury in fish species important in international trade in order to review the current GLs; and explore the possibility of revising the GLs or their conversion to MLs and to identify the fish for which the level or levels could apply (REP 13/CF, paras. 125,126).

4. The 8th CCCF (2014) noted that there was wide support for establishment of an ML for methylmercury, and agreed that this would be the approach with the use of total mercury for screening purposes, but that further consideration was needed on an appropriate level or levels; and the fish classification 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 last session of the Committee that consumer advice should be developed at the national or regional level as the advice would vary between countries because of 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.

5. The Committee agreed to re-establish the 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 9th session of the Committee (REP 14/CF, paras. 113-114).

6. The 9th CCCF (2015) noted the continued support for an ML for methylmercury and agreed that further work on this should continue through the development of another discussion paper to consider expanding the ML to fish species that can accumulate high methylmercury concentrations, other than tuna and that consideration should be given to narrowing down the ML ranges. It was recognized that development of this paper would require additional data and that an exposure assessment based on different MLs should be conducted. The Committee agreed to re-establish the EWG, chaired by Japan and co-chaired by New Zealand to prepare a discussion paper with proposals for ML for methylmercury, including a project document for consideration by the next session. (REP 15/CF, paras. 125-126)

7. The 10^{th} CCCF (2016) agreed that it would establish an ML for tuna, but that it was not ready at this point to submit a project document to the CAC through the CCEXEC for approval of new work, as it was necessary to determine whether it was possible to establish a single ML for tuna or whether it should be set for different species of tuna, and whether it was possible and appropriate to set MLs for canned tuna.

8. The Committee agreed to establish an electronic working group, chaired by The Netherlands, and co-chaired by New Zealand and Canada, working in English only to prepare a discussion paper presenting a proposal for:

- one ML for fresh and frozen tuna, or for MLs for different tuna species, if the need for differentiation is justified
- an ML for canned tuna, if possible and appropriate, and to determine whether it should be based on occurrence data or derived from the ML(s) for fresh tuna
- the need for MLs for other species of fish, based on the information in CCCF10/CRD18 and other relevant sources, together with a project document (REP 16/CF, paras 160-161).

9. The EWG was established, the participants list is included in Appendix III.

10. The recommendations of the EWG for consideration by CCCF are described in paragraphs 12 to 19 below. A project document on proposals for new work based on these recommendations is provided in Appendix II.

11. The full discussion paper is provided in Appendix I. The information contained therein are to inform CCCF of the key points of discussion in the EWG (paragraphs 66-74), the work process followed (paragraphs 8-11) as well as all the data and information considered by the EWG which altogether provide the basis for the recommendations in paragraphs 12 to 19 below.

Recommendations:

12. For the establishment of MLs in tuna, it is possible to distinguish in subspecies based on mercury levels. As there were different views in the EWG, the EWG recommends to CCCF to determine whether it prefers to establish MLs in tuna based on species or on subspecies.

13. Not to establish an ML for canned tuna as levels are generally low and canned tuna is consumed in smaller quantities than fresh or frozen fish

14. From the fish that were identified to be of possible concern by FAO/WHO in their expert consultation on risk/benefits of fish consumption or CCCF10/CRD18, the EWG recommends to:

    a. Consider establishing MLs for Alfonsino, Kingfish/Amberjack, Marlin (based on methylmercury data), Shark, Dogfish and Swordfish
    b. to gather data on Spanish or King mackerel, Orange roughy and Gulf tilefish, as recent data were lacking to determine the need for MLs in these species

15. From the other species that were represented in the GEMS database, to consider starting discussion on MLs for the species. Cardinal fish (*Epigonus telescopus*), Inshore hagfish (*Eptatretus burger*), Ribaldo (*Mora moro),* Selachoidae (*Pleurotremata*), Toothfish (*Dissostichus sp*.) and Tusk (*Brosme brosme*). Also: Barbel and Hapuku, and Anchovies, Bass, Bream, (Sea) catfish and Wolffish, Cod, Halibut, Ling, Monkfish, Mullet, Rays, Ribaldo, Sardines and Snapper.

16. The EWG recommends CCCF to decide to establish MLs based on ALARA or guided by risk/benefit, as both options have different consequences. There was no agreement in the EWG on which option is preferred.

Based on ALARA, the P95 values per subspecies which could be used as a starting point for establishing MLs are:

Species	**Proposed ML based on P95 (in mg/kg)**
Bigeye tuna, Atlantic Bluefin tuna and Southern Bluefin tuna:	1.2 or 1.3
Albacore tuna and other (than Atlantic and Southern) Bluefin tuna	0.9
Or: All tuna (based on worst case scenario)	 1,2
Alfonsino	1.2 or 1.3
Kingfish/Amberjack	0.8
Marlin (based on methylmercury data only)	0.8
Shark	1.4
Dogfish	2.3
Swordfish	2.0

Guided by the FAO/WHO quantitative risk/benefit assessment, the MLs would be

Species	**Proposed ML based on risk/benefit (in mg/kg)**
Albacore tuna and other (than Atlantic and Southern) Bluefin tuna, Bigeye tuna, Alfonsino, Dogfish, Marlin, Shark, and Swordfish	0.3
OR:	
Albacore tuna and other (than Atlantic and Southern) Bluefin tuna, Bigeye tuna, Alfonsino, Dogfish, Marlin, Shark, and Swordfish	0.75 (number of servings per week to be restricted, the amount depending on EPA + DHA levels)

17. The EWG recommends to add a footnote to the higher MLs, indicating the need for additional risk management measures to protect health (e.g. consumption advice). One option could also be to indicate the amount of servings of fish that could be consumed safely based on the FAO/WHO risk benefit evaluation.

18. There was no agreement in the EWG if an impact assessment of proposed MLs should be performed by JECFA. Several members commented that, as the FAO/WHO expert consultation on risk benefit of fish consumption was performed in 2010, CCCF could examine if new information on the benefits of (EHA + DHA in) fish give cause to verify the values used in 2010.

19. Other options that were suggested in the EWG:

    To consider setting MLs based on total mercury and not methylmercury. This because it would offer a conservative approach and the analytical methods for total mercury are widely available and low in cost.

APPENDIX I
(For information to CCCF)

DISCUSSION PAPER ON MAXIMUM LEVELS FOR METHYLMERCURY IN FISH

1 Introduction

1. The current guideline levels for methylmercury in the General Standard for Contaminants and Toxins in Food and Feed (GSCTFF) are 0.5 mg/kg for non-predatory fish and 1 mg/kg for predatory or piscivorous fish species. As indicated in the background, review of these guideline levels was the reason to start work on developing MLs for methylmercury. However, in the current paper, these guideline levels have not been further considered for the establishment of MLs for methylmercury in fish. A new analysis has been done on data available in GEMS, it should be noted that not all data used in the previous EWG were uploaded in GEMS at the time of analysis. Nevertheless, as indicated in the data analysis, there were thousands of data points available, which still provides a robust basis for discussion on possible MLs.

2. As for the toxicological effects, JECFA established a PTWI 1.6 µg/kg bw (2003; confirmed in 2006[1]) based on the most sensitive toxicological end-point (developmental neurotoxicity) in the most susceptible species (humans). However, the Committee noted that life-stages other than the embryo and fetus may be less sensitive to the adverse effects of methylmercury. The Committee considered that intakes of up to about two times higher than the existing PTWI would not pose any risk of neurotoxicity in adults, except for women of childbearing age in order to protect the embryo and fetus. Concerning infant and children up to about 17 years no firm conclusions could be drawn; it is clear that they are not more sensitive than the embryo or fetus, but may be more sensitive than adults because significant development of the brain continues in infancy and childhood.

3. The Joint FAO/WHO Expert Consultation on the Risks and Benefits of Fish Consumption[2], was convened in January 2010 in response to a request from CCFAC38. A quantitative risk/benefit assessment was performed, and the Consultation drew the following conclusions:

   1) The Expert Consultation finds the evidence convincing that maternal fish consumption contributes to optimal neurodevelopment in their offspring.
   2) With a central estimate[3] 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 and methylmercury levels up to at least 1 µg/g.
   3) 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 methylmercury and for up to at least two servings per week for fish with greater than 8 mg/g EPA plus DHA and up to 1 µg/g methylmercury.
   4) Neurodevelopmental benefits of fish consumption are reduced by methylmercury contamination, and reducing anthropogenic mercury contamination in fish would result in even greater neurodevelopmental benefits from fish consumption.

4. In short, the risks of consumption of fish species with highest mean content of methylmercury in the classes 0.5 ≤ 1 mg/kg and ≥ 1 mg/kg (tables 3 and 5 of the expert consultation) may outweigh the benefits of eating fish with higher EPA+DHA content. The fish species of concern would then be according to the expert meeting:

   o Alfonsino (*beryx splendens)*
   o Mackerel, king *(Scomberomorus cavalla)*
   o Marlin *(Makaira spp.)*
   o Orange roughy *(Hoplostethus atlanticus),*
   o Shark *(selachimorpha spp.)*
   o Swordfish *(Xiphias gladius)*
   o Tuna bigeye *(Thunnus obesus)*
   o Tuna, Pacific bluefin *(Thunnus orientalis)*

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[1] Joint FAO/WHO Expert Committee on Food Additives. Meeting (67th: 2006: Rome, Italy) Evaluation of certain food additives and contaminants: sixty-seventh report of the Joint FAO/WHO Expert Committee on Food Additives Accessed Oct., 13, 2016: http://apps.who.int/iris/bitstream/10665/43592/1/WHO_TRS_940_eng.pdf

[2] Report of the Joint FAO/WHO Expert Consultation on the Risks and Benefits of Fish Consumption, FAO Fisheries and Aquaculture Report No. 978. Rome, 25-92 January 2010. Accessed Feb 8, 2017: http://www.fao.org/docrep/014/ba0136e/ba0136e00.pdf

[3] After reviewing all the evidence presented in the publications, the Expert Consultation decided to use the following linear estimates of the dose–response relationship for the risk–benefit analysis: −0.18 IQ points per ug per gram of mercury in maternal hair as the central estimate (from the Axelrad et al., 2007 analysis) and −0.7 IQ points per ug per gram of mercury in maternal hair as the upper limit (from the Cohen, Bellinger and Shaywitz, 2005b analysis).

5. For CCCF10, the FAO and WHO suggested in CRD18[4] to add two species to this 'list of concern' based on mercury levels identified in the expert consultation, namely:

o Tuna, Atlantic bluefin *(Thunnus thynnus)*

o Tilefish, gulf *(caulolatilus microps)*

6. The species mentioned above in this 'list of concern' will in any case be the focus of the work of the EWG, while possible other relevant species will be identified also based on GEMS data.

7. It should be noted that the Expert consultation recommended 'to develop and evaluate risk management and communication strategies that both minimize risks and maximize benefits from eating fish', indicating that a combination of different management measures should be implemented. The current work only focuses on the development of MLs as one of these management measures, as CCCF decided that, as indicated in the background, no further work on consumption advice would be done at the international level.

2 Work process

2.1 Determine critical concentration methylmercury in fish

8. To be able to select species for ML development, critical methylmercury concentrations in fish were determined. For this, hypothetical methylmercury concentrations were used to determine the amount of fish containing these concentrations that could be consumed by specified women (i.e. women of childbearing age and those who are pregnant or breastfeeding) which would result in methylmercury exposures reaching the provisional tolerable weekly intake (PTWI). These consumption amounts were then compared to the fish consumption in the GEMS/Food diets, and the concentration of methylmercury in fish which could pose a risk (i.e. reaching the PTWI) in one of the GEMS clusters was taken as a selection criterion for species of possible concern and thus eligible for ML setting..

2.2 Selection of fish species for ML develoment

9. According to its mandate, the EWG focused on tuna species, both fresh/frozen and canned, and on other fish species which contain high mercury content. In order to determine which species could be of concern, all data on total mercury and methylmercury in fish species were extracted from GEMS/Food and statistically analyzed. Average levels and percentiles of total mercury and methylmercury were determined in tuna and the species on the FAO 'list of concern'. Using the selection criterion as determined in paragraph 2.1, fish species of concern which might be candidates for setting MLs (besides tuna) were selected. For this, it was assumed that all total mercury was present as methylmercury (as calculated in the previous EWG, total mercury in fish comprises on average 85% of methylmercury).To identify other possible candidate fish species, for all other fish species in the GEMS/Food database, the average and maximum mercury concentrations were determined. Using the same selection criterion from paragraph 2.1, fish species were selected that could be focus of future discussion on MLs.

2.3 Options for ML setting

10. The General Standard on Contaminants and Toxins in Food and Feed (GSCTFF) indicates the criteria for the establishment of MLs in food and feed, in which it states that 'MLs should be set as low as reasonably achievable (ALARA) and at levels necessary to protect the consumer'. In this section both approaches to setting MLs are discussed.

ALARA: There is no explicit guidance in the GSCTFF or the Procedural Manual on which percentile in the distribution curve to use as starting point for developing MLs based on ALARA, however it has been the practice previously in CCCF (e.g. in the work on MLs for Lead) to aim for a rejection rate of 5% of the food product. Therefore we used the P95 as a starting point for developing MLs based on ALARA.

Health protection: in addition to the selection criterion developed based on the PTWI in paragraph 2.1, we tried to determine 'health based' MLs in the context of the findings of the FAO/WHO risk/benefit evaluation (FAO, 2010).

2.4 Possible other options for risk management

11. The MLs as determined in the previous steps were evaluated for achievability, while additional risk management options that would supplement the setting of MLs were discussed for consideration by CCCF.

[4] http://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FMeetings%252FCX-735-10%252FCRD%252Fcf10_CRD18x%2BAgenda%2BItem%2B14.pdf

3 Determine critical concentration of methylmercury in fish

3.1 Gathering of consumption data

12. To determine a critical concentration of methylmercury in fish, a first attempt was made to use existing consumption data to calculate critical concentrations of methylmercury in fish using the PTWI. In advance of CCCF10 (2016), the EWG for methylmercury in fish requested that EWG members submit consumption data for shark, swordfish, marlin and any other fish species or group of similar fish species known to accumulate high levels of methylmercury by children (≥ 6 years old), women of childbearing age, and the general population. Data were submitted by New Zealand and the United States of America (USA) and are reported in Table 1 of CX/CF 16/10/15 for a limited number of fish species. For all of the predatory fish types for which consumption information from the United States and New Zealand was included in Table 1 of CX/CF/16/10/15, only a maximum of 5% of each population subgroup (general population, children, women of childbearing age) reported consuming a given fish type.

13. In addition to the submitted data, other sources of publicly available fish consumption data were discussed in CX/CF 16/10/15; however the only other source of information provided was the Comprehensive Food Consumption Database[5] maintained by the European Food Safety Authority (EFSA) (CX/CF 16/10/15, p. 19-21). Aside from a number of general fish and seafood categories, this EFSA database contains consumption data for a small number of individual fish species. No additional sources of species specific, national fish consumption data have been identified.

14. As this provided too little information on consumption of fish species, the consumption figures reported in the Global Environmental Monitoring System (GEMS)/Food Cluster Diets (2012) were employed. The GEMS/Food consumption cluster diet information presented herein was refined from those previously presented in CX 15/9/13 (Table 1) at CCCF9, which reported consumption of all types of seafood by each of the 17 GEMS/Food clusters. The GEMS/Food consumption cluster diets report mean per capita consumption on a grams per day basis. Although young children are considered to be more sensitive to the effects of methylmercury exposure compared to adults, because consumption data are not available for children, they are not specifically considered in this assessment.

15. The developing foetus is also identified as a sensitive subgroup for exposure to methylmercury. The GEMS/Food consumption cluster diets are considered to adequately reflect the consumption habits of women that are or may become pregnant. Therefore, the discussion herein focuses on women of childbearing age, and those who are pregnant or breastfeeding, hereafter referred to as 'specified women'.

3.1.1 Fresh and Frozen Marine Fish

16. Maximum levels for methylmercury in fresh and frozen tuna, and possibly other fresh and frozen fish species, are under consideration. The GEMS/Food consumption figures for all seafood categories of non-canned marine finfish were summed to yield overall weekly consumption amounts for each GEMS/Food cluster; these categories included fresh, frozen and cured marine fish. Freshwater finfish, molluscs, cephalopods, crustaceans and aquatic animals and all types of canned fish were excluded from this calculation. Overall world median, mean, and 95th percentile marine finfish consumption values were also calculated using the data for each individual GEMS/Food cluster (*Table **1***).

[5] The EFSA Comprehensive European Food Consumption Database. Accessed Oct. 17, 2016: http://www.efsa.europa.eu/en/food-consumption/comprehensive-database

Table 1: Fresh, frozen and cured marine finfish consumption of the 17 GEMS/Food Consumption Cluster Diets (2012); values exclude freshwater fish, molluscs, cephalopods, crustaceans, aquatic animals and canned seafood (g/person per week)

Median	Average	95th Percentile	G01	G02	G03	G04	G05	G06	G07	G08	G09	G10	G11	G12	G13	G14	G15	G16	G17
110	122	285	42	115	110	130	50	88	126	100	98	200	154	96	51	277	111	12	316

3.1.1.1 Contribution of tuna and other mercury accumulating fish species in marine finfish consumption

17. Little information is available regarding the proportion of marine finfish that may be comprised of tuna species for any of the GEMS/Food clusters. Some limited data on the frequency of fresh and frozen tuna consumption from dietary recall surveys in Canada and the United States (both in cluster G10) suggest that the proportion of overall non-canned marine finfish consumption that is comprised of fresh or frozen tuna in these countries is extremely low. The Canadian Community Health Survey, Cycle 2.2 on Nutrition[6] reports the number of times a certain type of food is consumed over the recall period. Over 30,000 individuals were included in the survey and there were 2711 reports of fresh, frozen or cured marine finfish consumption over the 24-hour recall period, 0.85% of which were fresh or frozen tuna. Information reported by the USA in Table 1 of CX/CF 16/10/15 indicates that of the over 30,000 people surveyed, approximately 0.2% of the general population consumed fresh tuna on the survey day.

18. Although Hawaii is included with the USA in GEMS/Food cluster G10, the Hawaiian population's consumption of fish that can contain high concentrations of mercury may provide insight into the consumption patterns of fish containing high concentrations of mercury in other GEMS/Food clusters. For example, GEMS/Food cluster G17 and G14 are comprised of remote island nations, which report the first and second highest consumption, respectively, of fresh, frozen and cured marine finfish (Table 1). In Hawaii between 2000 and 2009, the average per capita total consumption of all types of seafood (commercial and non-commercial catches) was reported as 322 g/person per week[7]. Consumption of fresh or frozen yellowfin, bigeye and 'other' species of tuna was reported at a rate of 111 g/person per week while, in comparison, tuna consumption in the entire United States is 3-fold lower and is specifically reported as canned tuna. Billfish (marlin, sailfish and swordfish) are consumed at a rate of 21 g/person per week while none of these species are reported in the top ten most widely consumed fish in the entire United States. The total average consumption of the above fish species (132 g/person per week) comprises about half of the total consumption amounts of reported in Table 1 for clusters G14 and G17. Both of these clusters are comprised primarily of Pacific island countries, in which tuna forms a substantial component of the commercial and the artisanal (subsistence and sale to local markets) fisheries[8].

19. In French Polynesia, which is included in GEMS/Food Cluster G04, tuna is the most commonly consumed type of pelagic fish, being consumed at 75% of all meals that comprise of some type of pelagic fish.[9]

20. Limited information on the frequency of other types of fresh and frozen marine fish that commonly contain elevated mercury concentrations are available for Canada and the USA (both in cluster G10) and European countries (predominantly in clusters G07, G08, G10 and G11). In the 2004 Canadian Community Health Survey, no survey respondents reported consuming shark, marlin, orange roughy or tilefish while swordfish was consumed in 0.18% of the 2711 reported eating events of fresh, frozen or cured marine finfish over the 24-hour recall period. Table 1 of CX/CF 16/10/15 indicates that of the over 30,000 American's surveyed, 0.3% or less of the general population consumed either school shark, unspecified shark species or swordfish on the survey day. The EFSA Comprehensive Food Consumption Database[10] reports only two countries where residents reported consuming swordfish or shark, and then only in less than approximately 1% of the surveyed populations.

[6] Statistics Canada, 2004. Canadian Community Health Survey – Nutrition (CCHS). Detailed information for 2004 (cycle 2.2). Ottawa (ON): Statistics Canada. Accessed Nov. 25, 2016: http://www23.statcan.gc.ca/imdb/p2SV.pl?Function=getSurvey&SDDS=5049&lang=en&db=imdb&adm=8&dis=2

[7] Loke, M. et al. 2012. An overview of seafood consumption and supply sources. College of Tropical Agriculture and Human Resources, University of Hawaii at Mãnoa. Economic Issues, March 2012, EI-22. Accessed Dec. 2. 2016: http://www.fpir.noaa.gov/SFD/pdfs/seafood/EI-22.pdf

[8] FAO, 2010. Building Resilience to Climate Change: Root Crop and Fishery Production. Module 5 - Pacific Fisheries. Accessed Dec. 6, 2016: http://www.fao.org/docrep/013/am014e/am014e05.pdf

[9]Dewailly, E. et al. 2008. High fish consumption in French Polynesia and prenatal exposure to metals and nutrients. Asia Pacific Journal of Clinical Nutrition 17:461-470.

[10] The EFSA Comprehensive European Food Consumption Database. Accessed Oct. 17, 2016: http://www.efsa.europa.eu/en/food-consumption/comprehensive-database

3.1.2 Canned Tuna

21. An ML for methylmercury in canned tuna is also under consideration, if possible and appropriate. Therefore, consumption data on canned marine finfish were examined. The GEMS/Food consumption figures for canned marine finfish were derived by summing all canned seafood categories except canned freshwater fish, molluscs, crustaceans and cephalopods for each GEMS/Food cluster to yield overall weekly consumption amounts for canned marine finfish for each cluster. Overall world median, mean, and 95th percentile consumption values for canned marine fish were also calculated based on the GEMS clusters (*Table **2***).

Table 2: Canned marine finfish consumption of the 17 GEMS/Food Consumption Cluster Diets (2012) (g/person per week)

Median	Average	95th Percentile	G01	G02	G03	G04	G05	G06	G07	G08	G09	G10	G11	G12	G13	G14	G15	G16	G17
22	29	78	3	18	4	30	5	9	49	56	1	30	40	31	1	22	34	2	165

3.1.2.1 Contribution of tuna and other mercury accumulating fish species in marine canned finfish consumption

22. Additional information is available on the per capita consumption of canned tuna in different countries. The European Union (EU) and the USA are the two highest consuming regions of canned tuna in the world[11]. The average annual per capita consumption of canned tuna in the EU was estimated to be 1.53 kg between approximately 2000 and 2005 (29 g/person per week) [5], which comprises the majority of the per capita canned marine finfish consumption amounts in Table 2 for clusters G07, G08, G10 and G11, which are the clusters that include the majority of European countries. In the United States, per capita canned tuna consumption is reported in various sources as 1.3 kg in 2007 (25 g/person per week)[5] and 1.04 kg in 2014[12] (20 g/person per week), which comprises the majority of per capita canned marine finfish consumption for cluster G10, which includes the USA. Information regarding the canned tuna consumption rates by other countries was not identified.

23. Data on canned tuna consumption from 24-hour recall dietary surveys conducted in the USA and Canada provide more detailed information on canned tuna consumption in the United States and Canada. Based on information from the United States that was provided in CX/CF 16/10/15, Table 1, average all persons (AP) consumption of canned tuna for the general population, assuming a 60 kg body weight, is 14 g/person per week; further, approximately 5% of the general population of over 30, 000 individuals surveyed consume canned tuna. The Canadian Community Health Survey, Cycle 2.2 on Nutrition[13] reported an annual AP consumption for the all population age-sex groups of almost 15 g/person per week. As well, 2.6% of the over 30,000 individual Canadians surveyed reported consuming canned tuna. These weekly consumption values are lower than per capita data amounts reported in the previous paragraph, which is expected as per capita consumption amounts do not typically account for losses from, for example, spoilage, cooking or waste. This information indicates that in the G10 cluster that includes the USA and Canada, approximately half of the canned marine finfish consumed is comprised of canned tuna.

3.1.3 Total fish consumption data

24. For completeness, total fish consumption data (fresh/frozen, cured and canned marine finfish) have been compiled in *Table **3***.

[11]FAO Fisheries and Aquaculture Technical Paper 543. 2010. Recent developments in the tuna industry. Accessed Dec. 1, 2016: http://www.fao.org/docrep/013/i1705e/i1705e00.htm
[12]National Marine Fisheries Service Office of Science and Technology, 2014. Fisheries of the United States. Accessed Nov. 25, 2016: https://www.st.nmfs.noaa.gov/Assets/commercial/fus/fus14/documents/FUS2014.pdf
[13]Statistics Canada, 2004. Canadian Community Health Survey – Nutrition (CCHS). Detailed information for 2004 (cycle 2.2). Ottawa (ON): Statistics Canada. Accessed Nov. 25, 2016: http://www23.statcan.gc.ca/imdb/p2SV.pl?Function=getSurvey&SDDS=5049&lang=en&db=imdb&adm=8&dis=2

Table 3: Fresh, frozen, cured and canned marine finfish consumption of the 17 GEMS/Food Consumption Cluster Diets (2012); values exclude freshwater fish, molluscs, cephalopods, crustaceans and aquatic animals (g/person per week)

Median	Average	95th Percentile	G01	G02	G03	G04	G05	G06	G07	G08	G09	G10	G11	G12	G13	G14	G15	G16	G17
132	151	363	45	133	114	160	55	97	175	156	99	230	194	127	52	299	145	14	481

3.2 Fish Consumption Rates to Reach the PTWI

3.2.1 Fresh and Frozen Marine Fish

25. The amount of fish containing various concentrations of methylmercury that could be consumed by specified women which would result in methylmercury exposures reaching the provisional tolerable weekly intake (PTWI) for methylmercury of 1.6 µg/kg body weight, which was established by the Joint FAO/WHO Expert Committee on Food Additives (JECFA, 2007) for the most sensitive toxicological endpoint of developmental neurotoxicity, are presented in *Table **4***. These consumption amounts were determined using the above-noted PTWI, a series of hypothetical methylmercury concentrations and a body weight of 60 kg.

Table 4: Weekly fish consumption amounts required to reach PTWI of 1.6 µg/kg bw at various methylmercury concentrations. The GEMS cluster diets are based on the consumption information for fresh, frozen and cured marine fish in Table 1.

Methylmercury Concentration (mg/kg)	**Fish consumption to reach PTWI (g/person per week)**	**GEMS Cluster Diets potentially exceeding PTWI (fresh/frozen fish)**
0.1	960	0
0.2	480	0
0.3	320	0
0.4	240	G14, G17
0.5	192	G10, G14, G17,
0.6	160	G10, G14, G17,
0.7	137	G10, G11, G14, G17,
0.8	120	G4, G7, G8, G10, G11, G14, G17,
0.9	107	G2, G3, G4, G7, G10, G11, G14, G15, G17
1.0	96	G2, G3, G4, G7, G8, G9, G10, G11, G12, G14, G15, G17

26. Based on the fish consumption amounts estimated to meet the PTWI at different hypothetical methylmercury concentrations (***Table 4*****),** and the median (110 g/week) and average (122 g/week) consumption rates of fresh, frozen and cured marine finfish (*Table **1***), specified women could consistently consume fish containing approximately 0.9 ppm and 0.8 ppm methylmercury, respectively, before exceeding the PTWI for methylmercury. However, at the 95th percentile consumption rate of marine finfish (285 g/person per week), specified women would have to restrict fish consumption to those species containing much lower methylmercury concentrations, approximately 0.3 to 0.4 ppm, in order to limit their methylmercury exposure such that it does not exceed the PTWI. The reported consumption rates of GEMS/Food clusters G14 and G17 both approximate this 95th percentile consumption rate, although no specific information is available for the countries in these clusters regarding the proportion of overall non-canned marine fish consumption that may be attributed to tuna or other types of marine finfish. Any additional methylmercury exposure from other types of fish (e.g. canned, freshwater) would result in exposure exceeding the PTWI.

27. Based on this, 0.3 mg//kg mercury (average or median concentration) in fresh/frozen fish was taken as a selection criterion to identify species of concern. For this, it was assumed that all total mercury was present as methylmercury (as calculated in the previous EWG, total mercury in fish comprises on average 85% of methylmercury[14]).

[14] In CX/CF 14/8/16, Figure 2(b), there was a strong correlation between total mercury and methylmercury concentrations with a slope of 0.837 in most fish species.

3.2.2 Canned fish

28. Based on the fish consumption amounts estimated to meet the PTWI at different hypothetical methylmercury concentrations (*Table **4***) and the worldwide 95th percentile consumption rate of canned marine fish (78 g/person per week; *Table **2***), specified women could consistently consume fish containing slightly more than 1.0 ppm methylmercury before exceeding the PTWI for methylmercury. There is only one cluster whose consumption rate of canned marine fish exceeds the world 95th percentile, which is cluster G17 (165 g/person per week); this cluster could consume fish containing approximately 0.6 ppm methylmercury consistently before reaching the PTWI.

29. Based on this, 0.6 mg//kg mercury (average or median concentration) in canned fish was taken as a selection criterion to identify necessity of ML setting.

4 Selection of fish species for ML development

30. The data analysis focused on total mercury and methylmercury data of all fish species in the GEMS/Food database. Concentrations of (total or methyl-)mercury were analyzed to see if the mean content exceeded 0.3 mg/kg total or methylmercury. For the development of MLs, it was assumed that all total mercury was present as methylmercury, but to avoid duplicate samples in one analysis, mercury and methylmercury were separately analyzed. No distinction was made between predatory or non-predatory fish.

31. Data were extracted from GEMS/Food for Total mercury and methylmercury in ‘Fish and other seafood (including amphibians, reptiles, snails and insects)’. This resulted in 44513 records. In the results, EFSA FoodEx codes were replaced by the descriptions of the corresponding food categories. After this, categories that were not fish species as well as aggregated data were excluded[15]. Also, data from before the year 2000 have been excluded as they would not be considered representative of current levels, this excluded 6919 records. This left a database of 25744 records. After this the fish were categorized by species. There were 325 records which could not be categorized, these data had less than 20 data points per species and levels were below 0.5 mg/kg, except for 4 records which were barracuda (0.93 and 1.46 mg/kg), smooth-hound (0.74 mg/kg), zeomorphi (0.62 mg/kg) and non-ictarulus fish (0.66 mg/kg).

32. All results were converted to mg/kg and non-detects were treated as zeros in the analysis, following the same strategy of the CCCF EWG reviewing the MLs for lead. Results of both total mercury and methylmercury were in the dataset. As mostly the methylmercury data resulted from samples that were also analyzed for total mercury, combining the data in one analysis would result in the same sample being taken into account twice. As this could influence the outcome, separate analyses were performed for total and methylmercury.

Cooking is not expected to have a significant impact on the (methyl)mercury level, therefore data for raw and cooked fish were taken together. Where ‘unknown’ was indicated for the food state, it was assumed that the analysis was done on raw fish.

4.1 Fresh/frozen tuna

33. For tuna, data were analyzed both for all tuna species together, as well as for separate tuna species, the results are shown in Table 5-8. It should be noted that a large part of the data was specified as ‘tuna’ without indicating specific species.

[15] These categories were ‘Fish and other seafood (including amphibians, reptiles, snails and insects)’, ‘fish meat’, ‘fish collagen’, ‘fish roe’, ‘other fish offal’, ‘crustaceans’, ‘crab’, ‘lobster’, ‘Norway lobster’, ‘rock lobster’, ‘prawns’, ‘shrimps’, ‘shrimps and prawns’, ‘crawfish’, ‘crayfish’, ‘water molluscs’, ‘squid’, ‘octopus’, ‘cuttlefish (incl crispy)’, ‘clam’, ‘cockle’, ‘mussel’, including green-lipped), ‘oyster’, ‘queen scallop’, ‘scallop’, ‘Razor clam (Solen margrinatus)’, ‘Whelk (Buccinum undatum, Fusus antiquus)’, ‘Winkle (Littorina littorea)’, and ‘Snail (Helix sp., escargots)’., Arrow squid (Nototodarus sloanii), belacan shrimp, chili cuttlefish and rolls, clams, Cooked Chilli Mussel, Cooked Sea Cucumber with Spinach, coquille st jacques, ‘crevette’, ‘cod liver’, ‘crocodile’, ‘dried fish’, ‘dried seaweed’, ‘fish balls/cakes’, ‘fish fillets’, ‘fish portions’, ‘fish stick’, ‘freshwater fish’, ‘fennel’, giant squid, ‘marine bivalve molluscs, ‘marine fish’, ‘poisson pané’, ‘seal’, ‘unknown’.

Table 5: Summary of occurrence data on total mercury in mg/kg in tuna samples, data taken from GEMS/Food

	WHO region	Years	Total records	Non-detects	Average	P50	P95	P97.5	P99	P100 (max)
Albacore tuna (Thunnus alalunga)	Europe (143), South-east Asia (12), Western Pacific (185)	2005-2013	355	7	0.37	0.31	0.89	1.00	1.15	1.80
Bigeye tuna (Thunnus thynnus)	African (3), Europe (81), South-east Asia (24), Western Pacific (135),	2004-2013	243	8	0.56	0.43	1.30	1.40	1.57	2.30
Atlantic bluefin tuna (Thunnus thynnus)	Europe (3), Western Pacific (136),	2006-2011	139	0	0.60	0.52	1.20	1.56	2.00	2.30
Bluefin tuna (unspecified)	Europe (358), South-east Asia (2), Western Pacific (125),	2006-2009 2011-2012	485	0	0.41	0.35	0.95	1.10	1.40	3.13
Pacific bluefin tuna (Thunnus orientalis)	Western Pacific (67)	2007-2008	67	0	0.50	0.35	0.89	0.96	1.35	1.90
Southern bluefin tuna (Thunnus maccoyii)	Western Pacific (240)	2006-2007, 2009	240	0	0.56	0.43	1.31	1.80	2.30	4.40
Bullet tuna (Auxis spp)	Europe (54)	2005-2008, 2010-2011	54	8	0.21	0.17	0.41	0.72	1.39	2.00
Skipjack tuna (Katsuwonus pelamis)	Africa (36), Europe (111), South-east Asia (48), Western Pacific (123)	2004-2013	318	40	0.13	0.13	0.31	0.33	0.36	0.49
Yellowfin tuna (Thunnus albacares)	Africa (74), Central America (912), Europe (305), South-east Asia (17), Western Pacific (120)	2003-2013	1428	706	0.24	0.17	0.71	0.85	1.02	1.40
Tuna (unspecified)	Africa (73), Americas (120), Europe (874), South-east Asia (49)	2000-2016	1136	86	0.25	0.16	0.79	1.00	1.52	3.37
All tuna	See above	See above	4465	855	0.33	0.25	0.96	1.20	1.57	4.40

Table 6: Summary of occurrence data on methylmercury in mg/kg in tuna samples, data taken from GEMS/Food.

	WHO region	Years	Total records	Non-detects	Average	P50	P95	P97.5	P99	P100 (max)
Albacore tuna (Thunnus alalunga)	Western Pacific (120)	2006, 2008	120	0	0.44	0.40	0.75	0.85	0.98	1.10
Bigeye tuna (Thunnus thynnus)	Western Pacific (175)	2007-2009, 2012	175	0	0.55	0.41	1.20	1.33	1.48	2.00
Atlantic bluefin tuna (Thunnus thynnus)	Western Pacific (136)	2006-2009	136	0	0.52	0.45	0.96	1.26	1.77	1.80
Bluefin tuna (unspecified)	Western Pacific (78)	2009, 2012	78	14	0.55	0.55	0.79	0.88	1.01	1.10
Pacific bluefin tuna (Thunnus orientalis)	Western Pacific (67)	2007-2008	67	0	0.46	0.30	0.79	0.88	1.01	1.60
Southern bluefin tuna	Western Pacific (240)	2006-2007, 2009	240	0	0.48	0.37	1.21	1.50	1.88	2.90
Skipjack tuna (Katsuwonus pelamis)	Western Pacific (123)	2007-2009	123	4	0.13	0.13	0.28	0.29	0.31	0.35
Yellowfin tuna (Thunnus albacares)	Western Pacific (120)	2007-2008	120	0	0.23	0.13	0.64	0.71	0.98	1.20
Tuna (unspecified)	Europe (125), Western Pacific (26)	2006-2010, 2012	151	2	0.21	0.13	0.73	0.84	1.07	1.73
All tuna	See above	See above	1188	20	0.40	0.34	1.00	1.20	1.60	2.90

34. As can be seen from the results, based on the total of tuna species the results on total- and methylmercury are lower than when looking at specific tuna species. Especially the Bluefin tuna species have higher levels of total mercury and methylmercury. Also, the average levels of methylmercury are in some species higher than the total mercury levels (albacore and yellowfin tuna), however it should be noted that the number of samples are different between the two mercury analyses.

35. Based on these results, only Skipjack and Yellowfin tuna have average levels below the selection criterion of 0.3 mg/kg and would therefore not be candidate for setting MLs. Also, as subspecies can be distinguished, it could be recommended that MLs are developed for separate tuna species and not for tuna in general.

4.2 <u>Canned tuna</u>

36. Due to the low number of specific canned tuna samples, all canned tuna data were analysed together for total mercury and methylmercury (*Table **7***, *Table **8***).

Table 7: Summary of occurrence data on total mercury in mg/kg in canned tuna samples, data taken from GEMS/Food. Canned samples with additional other ingredients (e.g. mayonnaise, curry, spices) than tuna were excluded.

	WHO region	Years	Total records	Non-detects	Average	P50	P95	P97.5	P99	P100 (max)
Canned tuna	Europe (4), Western Pacific (51)	2000-2002, 2007-2008, 2014-2015	55	8	0.12	0.10	0.29	0.31	0.38	0.47

Table 8: Summary of occurrence data on methylmercury in mg/kg in canned tuna samples, data taken from GEMS/Food.

	WHO region	Years	Total records	Non-detects	Average	P50	P95	P97.5	P99	P100 (max)
Canned tuna (Albacore, Skipjack, Yellowfin and unspecified)	Western Pacific (104)	2000, 2007-2008, 2012, 2015	104	27	0.06	0.03	0.22	0.22	0.34	0.43

37. The data show that levels are generally low, well below the 0.6 mg/kg selection criterion.

38. Generally, the species of tuna that are most commonly used for canning are skipjack, albacore and yellowfin[16]. Skipjack, yellowfin and, to a lesser degree, tongol are commonly marketed as 'light' tuna, and may be canned interchangeably, however, the species is also often denoted on the label.

Even if the weekly consumption amounts reported in *Table **2*** were comprised entirely of canned tuna, there would not be any safety concerns or need for risk management. It is recommended that no MLs are developed for canned tuna.

4.3 Species identified based on FAO/WHO expert consultation

39. The results for Alfonsino are given in Table 9 and 10.

4.3.1 Alfonsino

Table 9: Summary of occurrence data on total mercury in mg/kg in alfonsino samples, data taken from GEMS/Food.

	WHO region	Years	Total records	Non-detects	Average	P50	P95	P97.5	P99	P100 (max)
Alfonsino (Beryx splendens, Centroberyx affinis)	Europe (10), Western Pacific (163)	2007-2008, 2010-2012	173	3	0.65	0.58	1.40	1.56	2.08	2.80

Table 10: Summary of occurrence data on methylmercury in mg/kg in alfonsino samples, data taken from GEMS/Food.

	WHO region	Years	Total records	Non-detects	Average	P50	P95	P97.5	P99	P100 (max)
Alfonsino (Beryx splendens)	Western Pacific (123)	2007-2008	123	0	0.65	0.58	1.25	1.42	1.83	2.20

40. Both the average and median are above 0.3 mg/kg, indicating that alfonsino is a species of concern which could be eligible for ML setting.

[16] FAO Fisheries and Aquaculture Technical Paper 543. 2010. Recent developments in the tuna industry. Accessed Dec. 1, 2016: http://www.fao.org/docrep/013/i1705e/i1705e00.htm

4.3.2 Mackerel and Jack mackerel

Table 11: Summary of occurrence data on total mercury in mg/kg in mackerel samples, data taken from GEMS/Food.

	WHO region	Years	Total records	Non-detects	Average	P50	P95	P97.5	P99	P100 (max)
Blue mackerel (Scomber australicus)	Western Pacific (61)	2012	61	0	0.17	0.16	0.22	0.23	0.24	0.25
Indian mackerel	South-east Asia (312)	2006-2013	312	221	0.01	0.00	0.04	0.06	0.09	0.13
Spanish or King mackerel	Americas (7)	2011-2014	7	1	0.69	0.23	2.35	2.52	2.62	2.69
Chub mackerel (Scomber japonicus, 4), Narrow-based Spanish mackerel (Scomberomus commerson, 1), Indo-pacific king mackerel (Scomberomus guttatus, 5), Spotted mackerel (Scomberomorus munroi, 2)	Americas (1), South-east Asia (2), Western Pacific (9)	2007, 2012	12	0	0.13	0.23	0.24	0.25	0.26	0.26
Mackerel (unspecified)	Americas (24), European (1610), South-east Asia (620)	2000, 2002, 2004-2015	2254	542	0.08	0.03	0.39	0.57	0.80	1.56
All Scomber spp, including saba and scomberomorus spp	See above	See above	2646	764	0.07	0.03	0.35	0.53	0.79	2.69
Barracouta (Thyrsites atun)	Western Pacific (58)	2011-2013	58	32	0.09	0.11	0.45	0.65	0.67	0.68
Saury (Cololabis saira, cololabis adocetus)	South-east Asia (15)	2006-2007, 2009-2013	57	31	0.09	0.11	0.46	0.65	0.67	0.68
Wahoo (Acanthocybium solandri), Frigate mackerel (Auxis thazard), Okhotsk atka mackerel (Pleurogrammus azonus)	African (1), Europe (2), South-east Asia (3)	2009-2013	6	1	0.04	0.03	0.08	0.09	0.10	0.10
All mackerel	See above	See above	2725	766	0.07	0.03	0.36	0.54	0.78	2.69

Table 12: Summary of occurrence data on methylmercury in mg/kg in mackerel samples, data taken from GEMS/Food.

	WHO region	Years	Total records	Non-detects	Average	P50	P95	P97.5	P99	P100 (max)
Mackerel (Scomber spp., scomberomorus spp (6))	Western Pacific (131)	2007-2008	131	11	0.12	0.03	0.51	0.59	0.82	1.11

Table 13: Summary of occurrence data on total mercury in mg/kg in Jack mackerel samples, data taken from GEMS/Food.

	WHO region	Years	Total records	Non-detects	Average	P50	P95	P97.5	P99	P100 (max)
Jack mackerel (Trachurus declivis, Trachurus novaezelandiae, Trachurus trachurus, Trachurus japonicus)	Western Pacific (46), European (15)	2000, 2002, 2007, 2010-2013	61	1	0.15	0.16	0.25	0.27	0.28	0.30
Kingfish/Amberjack (Seriola lalandi, Seriola dumenli, 3)	Americas (8), South-east Asia (30), Western Pacific (58)	2005-2012	96	0	0.30	0.26	0.77	0.87	1.02	1.62
Trevally (Pseudocaranx dentex)	Western Pacific (60)	2007, 2010	60	0	0.14	0.06	0.41	0.42	0.53	0.67
Yellowstripe scad, pompano (trachinotus), black pomfret	Americas (1), South-east Asia (4), Western Pacific (3)	2006, 2007, 2009, 2014	8	0	0.05	0.04	0.12	0.13	0.14	0.15
All Jack mackerel	See above	See above	225	1	0.21	0.16	0.62	0.74	0.88	1.62

Table 14: Summary of occurrence data on methylmercury in mg/kg in Jack mackerel samples, data taken from GEMS/Food.

	WHO region	Years	Total records	Non-detects	Average	P50	P95	P97.5	P99	P100 (max)
Jack mackerel (Trachurus japonicus, 3), Kingfish/Amberjack (Seriola lalandi 6, Seriola dumenli 3), Trevally (Pseudocaranx dentex 3), Pompano (Trachinotus blochii 3)	Western Pacific (18)	2007	18	0	0.08	0.07	0.19	0.20	0.20	0.20

41. Based on the results of the analysis, Spanish or King mackerel has an average of over 0.3 mg/kg. However, this result is based on seven samples and can therefore only be taken as an indication that this species accumulates higher levels of mercury, and more data should be gathered to evaluate if an ML is warranted. Also, Kingfish or Amberjack just meets the criterion of 0.3 mg/kg. There are no other species with averages above 0.3 mg/kg, indicating that based on these data, there would be no need for an ML for other species mackerel or Jack mackerel.

4.3.3 Marlin

Table 15: Summary of occurrence data on total mercury in mg/kg in Marlin samples, data taken from GEMS/Food.

	WHO region	Years	Total records	Non-detects	Average	P50	P95	P97.5	P99	P100 (max)
Atlantic blue marlin (Makaira nigricans)	European (4), Western Pacific (50)	2009-2012	54	0	1.68	1.05	3.65	4.91	11.69	19.00
Blue marlin (unspecified)	Western Pacific (10)	2009	10	0	7.62	5.90	18.60	21.30	22.92	24.00
Indo-Pacific blue marlin (Makaira mazara)	Western Pacific (60)	2008-2009	60	0	1.40	0.63	5.96	8.41	10.37	11.36
Striped marlin (Kajikia audax)	Western Pacific (120)	2009	120	0	0.40	0.35	0.97	1.00	1.17	1.40
All marlin	See above	See above	244	0	1.22	0.54	4.80	6.99	11.72	24.00

Table 16: Summary of occurrence data on methylmercury in mg/kg in Marlin samples, data taken from GEMS/Food.

	WHO region	Years	Total records	Non-detects	Average	P50	P95	P97.5	P99	P100 (max)
Atlantic blue marlin (Makaira nigricans)	Western Pacific (50)	2009	50	0	0.16	0.14	0.36	0.37	0.39	0.41
Blue marlin (unspecified)	Western Pacific (10)	2009	10	0	0.49	0.38	0.92	1.01	1.06	1.10
Indo-Pacific blue marlin (Makaira mazara)	Western Pacific (60)	2008-2009	60	0	0.30	0.23	0.56	0.73	0.88	0.93
Striped marlin (Kajikia audax)	Western Pacific (120)	2009	120	0	0.33	0.29	0.81	0.86	1.06	1.15
Marlin (unspecified)	Western Pacific (28)	2012	28	3	0.55	0.39	1.44	1.51	1.52	1.52
All marlin	See above	See above	270	3	0.32	0.24	0.84	0.97	1.16	1.52

42. Based on total mercury, the levels are extremely high in marlin. However, when looking at the methylmercury levels, the levels are much lower. However, averages of methylmercury concentration in most marlin species are around 0.3 mg/kg, indication that Marlin could be candidate for ML setting.

4.3.4 Orange roughy

There were no data available for Orange roughy in GEMS/Food of samples taken after the year 2000.

Table 17: Summary of occurrence data on mercury in mg/kg in Orange Roughy samples, data taken from GEMS/Food.

	WHO region	Years	Total records	Non-detects	Average	P50	P95	P97.5	P99	P100 (max)
Orange roughy	Western Pacific (1125)	1980-1983, 1990	1125	0	0.41	0.40	0.82	0.89	1.04	1.42

43. The EWG recommends that more data is gathered on orange roughy to determine the need for MLs.

4.3.5 Shark and dogfish

Table 18: Summary of occurrence data on total mercury in mg/kg in shark and dogfish samples, data taken from GEMS/Food.

	WHO region	Years	Total records	Non-detects	Average	P50	P95	P97.5	P99	P100 (max)
Blue shark	Western Pacific (120)	2008-2009	120	0	0.74	0.62	1.40	1.77	2.04	2.50
Ghost shark (Hydrolagus spp.)	Western Pacific (102)	2002	102	0	0.32	0.29	0.57	0.64	0.67	0.70
Pale ghost shark (Hydrolagus bemisi)	Western Pacific (102)	2002, 2013	102	0	0.39	0.36	0.71	0.77	0.78	0.79
Porbeagle (Lamna nasus)	European (6)	2011-2012	6	0	0.92	0.93	1.32	1.34	1.35	1.36
Shark (unspecified)	Americas (16), European (13), Western Pacific (35)	2000, 2002, 2010-2014	64	0	0.89	0.67	2.13	3.18	4.77	6.34
Houndshark (Mustellus asterias, 2), Shortfin mako (Isurus oxyrinchus, 1), Thresher shark (Alopias vulpinus, 1), Sharp Nosed Shark (1), Cat Shark (4), Tope shark (Galeorhinus galeus, 1)	European (8), South-east Asia (2)	2009-2011	10	0	0.49	0.42	0.99	1.02	1.03	1.04
All Shark	See above	See above	404	0	0.57	0.47	1.23	1.70	2.14	6.34
Lesser spotted dogfish (Scyliorhinus canicula)	European (14)	2010-2012	14	0	0.37	0.36	0.72	0.73	0.74	0.74
Portuguese dogfish (Centroscymnus coelolepis)	European (3)	2010-2011	3	0	1.73	1.03	3.27	3.39	3.47	3.52
Smooth skin dogfish (Centroscymnus owstonii)	Western Pacific (1)	2013	1	0	-	-	-	-	-	
Dogfish (unspecified)	South-east Asia (30)	2005-2007, 2009-2013	30	1	0.49	0.14	2.34	2.98	3.28	3.48
All dogfish	See above	See above	48	1	0.55	0.21	2.44	3.35	3.50	3.52
All sharks and dogfish	See above	See above	452	1	0.56	0.45	1.28	1.79	2.74	6.34

Table 19: Summary of occurrence data on methylmercury in mg/kg in shark samples, data taken from GEMS/Food.

	WHO region	Years	Total records	Non-detects	Average	P50	P95	P97.5	P99	P100 (max)
Blue shark	Western Pacific (120)	2008-2009	120	0	0.66	0.57	1.20	1.59	1.77	2.20
Shark (unspecified)	Western Pacific (45)	2012	45	1	0.83	0.49	2.08	3.86	5.10	5.93
All shark	See above	See above	165	1	0.71	0.55	1.57	1.78	2.87	5.93

44. Based on the results of the analysis or total mercury and methylmercury, all shark and dogfish species have an average of over 0.3 mg/kg. Although there are only methylmercury data for one species, the results for ‘all shark’ indicate that the levels of total mercury and methylmercury do not differ much (in contrast to the levels in Marlin). According to the criterion following the FAO/WHO expert consultation, MLs for these species could be warranted for both shark and dogfish.

4.3.6 Swordfish

Table 20: Summary of occurrence data on total mercury in mg/kg in swordfish samples, data taken from GEMS/Food.

	WHO region	Years	Total records	Non-detects	Average	P50	P95	P97.5	P99	P100 (max)
Swordfish (Xyphias gladius)	African (86), Americas (18), European (279), South-east Asia (4), Western Pacific (185)	2006-2008, 2010-2012	572	14	1.13	1.00	2.70	3.23	4.64	6.76

Table 21: Summary of occurrence data on methylmercury in mg/kg in swordfish samples, data taken from GEMS/Food.

	WHO region	Years	Total records	Non-detects	Average	P50	P95	P97.5	P99	P100 (max)
Swordfish (Xyphias gladius)	European (25), Western Pacific (122)	2006-2008, 2010-2012	177	0	1.09	1.00	2.11	2.56	2.70	2.80

45. Levels of mercury in swordfish are very high and establishment of MLs in this species is recommended.

4.3.7 Gulf tilefish (Caulolatilus microps)

46. There were no data available for Gulf tilefish in GEMS/Food. In the report of the FAO/WHO expert meeting it was indicated in Appendix A that a mean concentration of mercury was found of 1.45 mg/kg. The EWG recommends that more data is gathered on this species to determine the need for MLs.

4.3.8 Conclusions on fish species of 'list of concern'

47. The information presented above suggests that maximum levels for methylmercury in tuna, alfonsino, kingfish/amberjack, shark, marlin and swordfish, may be required to help ensure that exposure to methylmercury remains below the PTWI in high-end consumers of these types of fish. More data on Spanish or king mackerel, orange roughy and gulf tilefish should be gathered to determine the need for setting MLs in these species.

4.4 <u>Other relevant species identified in GEMS/Food</u>

48. In order to identify other species that might have high levels of mercury, a preliminary analysis was done on all species in the prepared database. For this, the total and methylmercury data were kept combined. When averages show a concentration of above 0.3 mg/kg and/or a maximum of above 1.0 mg/kg, the current guideline level for predatory fish, a refined analysis as data of these species could be statistically examined further in the future as done in the previous paragraphs.

Table 22: Preliminary analysis of the sum of mercury and methylmercury in other fish species in the GEMS/Food database. Orange highlight = average concentration above 0.3 mg/kg, yellow highlight = maximum concentration above 1.0 mg/kg, red highlight = average concentration above 0.3 mg/kg and maximum concentration above 1.0 mg/kg.

Species	Samples	Average	Maximum
Anchovies	139	0.07	1.25
Barb	68	0.03	0.41
Barbel	17	0.37	0.79
Barramundi	49	0.09	0.33
Bass	210	0.14	1.00
Bluenose	47	0.14	0.62
Bonito	6	0.09	0.10
Bream	394	0.17	2.91
Butterfish	63	0.03	0.73
Cardinal fish	70	1.27	2.13
Carp	456	0.05	0.99
(Sea) Catfish and wolffish	306	0.08	2.00
Cod	4345	0.08	1.00
Croaker	58	0.04	0.19
Dorade dolphinfish	75	0.12	0.67
John Dory	5	0.08	0.27
Eel	546	0.17	1.88
Greater forkbeard	59	0.12	0.25
Gurnard	28	0.11	0.47
Haddock	250	0.07	0.41
Inshore hagfish	75	0.72	2.30
Hake	436	0.11	0.66
Halibut	2208	0.21	2.40
Hapuku	70	0.33	0.98
Herring	1333	0.04	0.40
Hoki	31	0.08	0.18
Ling	1025	0.22	2.00
Moki	35	0.12	0.64
Monkfish	128	0.14	2.90
Mullet	111	0.09	1.00
Pangasius	109	0.00	0.02
Perch	557	0.16	0.78
Pike	26	0.12	0.75
Plaice	259	0.06	0.55
Pollack	1074	0.07	0.49
Rays	99	0.21	1.91
Redbait	33	0.15	0.30
Ribaldo	60	0.49	1.24
Roach	38	0.15	0.33
Rockfish	25	0.15	0.28
Salmon, pacific	436	0.05	0.65
Sardines	888	0.03	2.00
Selachoidei	276	0.70	5.56
Snapper	230	0.15	1.21
Sole	116	0.06	0.50
Tilapia	396	0.02	0.43
Toothfish	118	0.44	2.35
Trout	2448	0.03	0.95
Turbot	102	0.05	0.24
Tusk	1449	0.33	2.70
Warehou	21	0.06	0.14
Whitefish	38	0.08	0.26
Whiting	140	0.16	0.48

49. Based on the results, further analysis could be done on the species indicated above to determine the need for developing MLs. These are (in red, highest priority): Cardinal fish (*Epigonus telescopus*), Inshore hagfish (*Eptatretus burger*), Ribaldo (*Mora moro)*, Selachoidae (*Pleurotremata*), Toothfish (*Dissostichus sp*.) and Tusk (*Brosme brosme*). In orange: Barbel and Hapuku, and in yellow: Anchovies, Bass, Bream, (Sea) catfish and Wolffish, Cod, Halibut, Ling, Monkfish, Mullet, Rays, Sardines and Snapper.

5 Options for MLs

5.1 Based on ALARA:

50. Based on the mandate of the EWG, MLs are proposed for tuna. Additionally, using the selection criterion of 0.3 mg/kg (methyl)mercury in fresh/frozen fish, the fish species Alfonsino, Kingfish/Amberjack, Marlin, Shark, Dogfish and swordfish were selected.

51. As indicated in the workplan, the proposals for start of the discussion on MLs were based on P95. This resulted in the following proposed values per species:

Table 23: Proposed MLs for selected fish species based on ALARA per species (P95)

Species	**Proposed ML based on P95 (in mg/kg)**
Bigeye tuna, Atlantic Bluefin tuna and Southern Bluefin tuna:	1.2 or 1.3
Albacore tuna and other (than Atlantic and Southern) Bluefin tuna	0.9
Or: All tuna (based on worst case scenario)	1,2
Alfonsino	1.2 or 1.3
Kingfish/Amberjack	0.8
Marlin (based on methylmercury data only)	0.8
Shark	1.4
Dogfish	2.3
Swordfish	2.0

52. When fish species are grouped based on methylmercury concentrations, the proposed MLs based could be as presented in ***Table 24***

Table 24: Proposed MLs for selected fish species based on ALARA grouped species (P95)

Species	**Proposed ML based on P95 (in mg/kg)**
Dogfish and Swordfish	2.1
Bigeye tuna, Atlantic Bluefin tuna and Southern Bluefin tuna, Alfonsino and Shark:	1.3
Albacore tuna and other (than Atlantic and Southern) Bluefin tuna, Kingfish/Amberjack, Marlin (based on methylmercury data only)	0.8

5.2 Levels based on health protection

53. In this section, MLs for methylmercury in fish species are determined taking into account the outcomes of the Joint FAO/WHO Expert Consultation on the Risks and Benefits of fish Consumption. The Expert Consultation based their conclusions for a 60 kg pregnant woman, on the assumption that methylmercury levels were the same as total mercury and that the portion of fish per serving was 100 g.

54. Table 3 of the Expert consultation report[17] classifies 96 species of fish based on their total concentrations of EPA + DHA as well as their total mercury, and Table 5 of that report details the estimated change in child IQ resulting from the child's mother having consumed fish with different methylmercury and EPA + DHA contents at one, two, four and seven servings per week. Based on these Tables, *Table **25*** below identifies the combinations of total mercury and EPA + DHA concentrations in fish that have similar risk/benefit ratios. This allows the determination of levels of mercury for which the risks of fish consumption outweigh the benefits for the different fish species once they have been classified based on their total mercury and EPA + DHA concentrations using the risk/benefit methodology detailed in the Expert consultation report (*Table **26***).

Table 25: Identification of parts of the matrix for fish species with a similar risk/benefit ratio

		Range EPA + DHA mg/g (median)			
		X ≤ 3 (2)	3 < x ≤ 8 (5.5)	8 < x ≤ 15 (11.5)	x > 15 (20)
Range me-Hg µg/g (median)	x≤ 0.1 (0.05)				
	0.1 < x ≤ 0.5 (0.3)				
	0.5 < x ≤ 1 (0.75)				
	x > 1 (1.5)				

Table 26: Identification of the risk/benefit outcome for consumers of fish classified in the appropriate parts of the matrix identified in Table 1

Up to 0.3 mg mercury/kg, risks outweighed by the benefits of consumption even at seven 100 g servings per week (includes all GEMS diets)
0.75 mg mercury/kg, risks outweighed by the benefits of consumption if fish not consumed more than four 100 g servings a week (includes all GEMS/Food diets except G17)
1.5 mg mercury/kg, risks outweighed by the benefits of consumption if fish not consumed more than two 100 g servings per week (includes all GEMS/Food diets except G10, G14, G17)
0.75 mg and 1.5 mg mercury/kg, benefits outweighed by the risks when fish not consumed more than two 100g servings per week (GEMS/Food diets G1, G5, G6, G9, G13, G16 consume less than 100 g serving per week)

55. The data from the 17 GEMS/Food cluster diets *(Table **3**)* indicates that no cluster consumes more than 400 grams of fish (four 100 g servings) per week except for diet cluster G17 that consumes 481 g fish per week. Only clusters G 17, G14 (consuming 299 g per week) and G10 (consuming 230 g per week) consume more than 200 g (two 100 g servings) per week. This indicates that an ML of 1.5 mg/kg for all but the species classified in the orange and red cells would be protective apart from the populations in GEMS/Food clusters G10, G14 and G17.

An ML of 1.5 mg/kg would also be protective for consumers of fish in cluster diets G10, G14 and G17 if they consumed no more than 200 g (two 100 g fish servings) per week.

56. At 1.5 ppm methylmercury, and fish consumption of up to two (100 g) fish servings per week, containing only fish with ≤ 8 mg/g EPA + DPA, the net risks outweigh the benefits. At higher EPA + DPA concentrations and 1.5 mg/kg mercury, the risks are outweighed by the benefits. This would potentially impact only GEMS cluster diets G10 (total fish consumption 230 g per week), G14 (total fish consumption 299 g per week) and G17 (total fish consumption 481 g per week), meaning that in these clusters, at a methylmercury concentration of 1.5 mg/kg in the fish, only eating fish with EPA+DHA levels lower than 8 mg/g would pose a net health risk.

[17] Report of the expert consultation available at http://www.fao.org/docrep/014/ba0136e/ba0136e00.pdf

57. At 0.75 mg/kg methylmercury (the median used by the expert consultation for the class 0.5 ≤ 1 mg/kg), and fish consumption of up to four (100 g) fish servings per week, containing only for fish with ≤ 3 mg/g EPA + DHA, the net risks outweigh the benefits. At higher EPA + DHA concentrations and 0.75 mg/kg total mercury, the risks are outweighed by the benefits. Only GEMS cluster diet G17 (total fish consumption of 481 g per week) would be potentially impacted, meaning that in this cluster, at a methylmercury concentration of 0.75 mg/kg in the fish, only eating fish with EPA+DHA levels lower than 3 mg/g would pose a net health risk.

58. At 0.3 ppm methylmercury (the median used by the expert consultation for the class 0.1 ≤ 0.5 mg/kg), fish consumption of up to seven (100 g) servings per week, regardless of EPA + DHA concentrations, the risks of fish consumption are outweighed by the benefits. As no GEMS cluster diets exceed 500 g per week total fish intake, no cluster diet would be impacted, meaning that at a maximum methylmercury concentration of 0.3 mg/kg fish, eating fish would not pose a net health risk.

59. Depending on the methylmercury level in the fish, for those GEMS cluster diets for which the risk outweigh the benefits, additional risk management measures such as consumption advice may be needed specifically for those fish species with higher concentrations of methylmercury.

60. Guided by the FAO/WHO quantitative risk/benefit assessment and the conclusions stated above, possible MLs for species identified in *Table **23*** (except for Atlantic Bluefin tuna, Southern Bluefin tuna and kingfish/amberjack) could be 0.3 mg/kg at the GEMS/Food consumption volumes or 0.75 mg/kg when number of servings per week are restricted, the amount depending on EPA + DHA levels. The three species identified as exceptions were not included in Table 3 of the expert consultation and so while the EWG has data on methyl mercury levels, it did not have data on EPA + DHA levels. If this data was available, then MLs could be proposed for these species.

Table 27: Proposed MLs for selected fish species based on FAO/WHO risk-benefit evaluation (2010)

Species	**Proposed ML based on risk/benefit (in mg/kg)**
Albacore tuna and other (than Atlantic and Southern) Bluefin tuna, Bigeye tuna, Alfonsino, Dogfish, Marlin, Shark, and Swordfish	0.3
OR:	
Albacore tuna and other (than Atlantic and Southern) Bluefin tuna, Bigeye tuna, Alfonsino, Dogfish, Marlin, Shark, and Swordfish	0.75 (number of servings per week to be restricted, depending on EPA + DHA levels in the individual species)

6 Possible other/additional options for risk management

61. The MLs proposed above do reduce exposure to methylmercury, but do have severe limitations. For the MLs based on ALARA, the resulting values are sometimes so high that consumption would need to be tightly limited to ensure protection of health. For example: setting an ML at 2.0 ppm for swordfish would allow for consumption of only 48 g/week of that species with no other mercury intake in order not to exceed the PTWI.

62. On the other hand, the levels identified from the risk/benefit expert consultation where the risks outweigh the benefits could be used as guidance for ‘health based’ MLs. However, the identified levels of 0.3 and 0.75 mg/kg for all fish are too low because it would result in a very high rejection rate. For example: based on Table 20 and 21, for swordfish an ML of 0.75 mg/kg would result in a rejection rate of more than 50%.

63. It is common in ML development in CCCF that JECFA performs an impact assessment of hypothetical MLs to determine how much exposure is decreased after implementation of these MLs. However, in the current discussion, a quantitative risk/benefit evaluation is available from which it can be deduced what the impact of ML development on exposure would be (paragraph 5.2). Therefore, a JECFA impact assessment would not be necessary. It should be noted however, that the FAO/WHO expert consultation has been performed in 2010, and possible new information which would change the balance of risk/benefit is therefore not taken into account in the current discussion.

64. Both options for MLs may not be feasible in practice. Additional measures to ML setting might include an option to enable effective risk management. CCCF has decided not to use the option of developing consumption advice, as this should be done on a national level where there is information on which species are on the local market and how much these are consumed. However, depending on the ML established, it might be an option to attach a footnote to the MLs for species which have very high methylmercury concentrations, in order to trigger consumption advice on a national level, Such a footnote could (as an example) read 'for this fish species, additional risk management measures may be necessary on a national level to restrict exposure to unacceptably high levels of methylmercury (e.g. consumption advice)'

65. Other options might be proposed by the CCCF

7 Discussion and conclusions

Selection of relevant fish species

66. The EWG used 0.3 mg/kg for average total mercury or methylmercury concentration as criterion for fresh/frozen fish to select fish species for setting MLs, as at a total mercury or methylmercury concentration of 0.4 mg/kg, reported fish intakes in 2 GEMS clusters (G14 and G17) could result in exceedance of the PTWI. At higher Hg concentrations, additional cluster diets would be impacted. This allowed the selection of species that are eligible for setting MLs. Species that were selected were Tuna (according to mandate), Alfonsino, Kingfish/Amberjack, Marlin, Shark, Dogfish and Swordfish. Recent data were lacking for Spanish or King mackerel, Orange roughy and Gulf tilefish, data is needed as to determine the need for MLs in these species.

Three EWG members agreed that these species would be eligible for setting MLs, one member agreed on these species but had reservations on setting MLs, and one member did not agree with setting MLs for methylmercury in fish.

67. Based on the fact that levels in canned tuna are far below the selection criterion as mentioned above, no ML is required for canned tuna.

All responding members of the EWG agreed with this conclusion.

68. Using this same criterion, with an additional criterion of 1.0 mg/kg (the current GL for predatory fish) for maximum total mercury or methylmercury concentration for fresh/frozen fish in the GEMS/Food data, the following species were selected for possible future data analysis to determine the need for MLs: Cardinal fish (*Epigonus telescopus*), Inshore hagfish (*Eptatretus burger*), Ribaldo (*Mora moro)*, Selachoidae (*Pleurotremata*), Toothfish (*Dissostichus sp*.) and Tusk (*Brosme brosme*). Also, with lesser priority: Barbel and Hapuku, and Anchovies, Bass, Bream, (Sea) catfish and Wolffish, Cod, Halibut, Ling, Monkfish, Mullet, Rays, Sardines and Snapper. Data on the levels of EPA + DHA would be required for these species if the EWG/CCCF decides that the risk/benefit approach is to be taken when determining MLs.

Four members agreed with this conclusion, one of which suggested a staged approach with selecting fish species per year, and one member did not agree with setting MLs for methylmercury in fish.

MLs for single species vs MLs for grouped fish species vs generic MLs for species

69. Using the data to determine MLs based on ALARA, specific tuna species with higher mercury levels can be singled out from the other tuna species. This also goes for Kingfish/Amberjack within the Jack Mackerels. This provides the option of setting specific MLs for these species, if giving targeted risk management advice. However, this may lead to a large diversity of MLs for fish species and control might not be feasible in practice as in some cases it might not be easy to distinguish between specific species. The second option is to group fish species based on mercury content, and determine an ML per group of fish species. This may lead to fewer MLs but still could provide difficulty in distinguishing between specific species. Another option is to determine one generic ML for the whole fish species, based on the subspecies with the highest levels. While this provides a clear situation with few MLs in total, this might lead to unnecessary control measures (some species always have low mercury levels). Also, an ML based on worst-case scenario might not enable enough reduction of methylmercury levels in other members of the fish species. Therefore, a choice on which way to regulate is needed.

One member preferred setting MLs for groups of species, one member preferred setting MLs at subspecies level, one member preferred one generic ML for species and one member considered that additional data were necessary before making this decision.

MLs based on ALARA versus risk/benefit

70. For the MLs based on ALARA, the resulting values are sometimes so high that consumption would need to be tightly limited to ensure protection of health. On the other hand, the 'health based' MLs of 0.3 or 0.75 mg/kg for all fish could be too low because it would result in a very high rejection rate. For both cases, it is still required that consumption is restricted when methylmercury levels exceed a certain level of ML.

Three members of the EWG preferred that if MLs are set, this is done based in principle on ALARA, as rejection rates may be more justifiable and MLs based on ALARA would be more compatible with the use of national consumption advice. One member that agreed in principle with MLs based on ALARA, suggested combining these with a health-based 'upper limit' for MLs. This member also indicated that MLs should not be raised above the current guideline levels. Two members preferred setting MLs based on risk/benefit, using the FAO/WHO expert consultation from 2010 as a basis as this would also take the positive effects of eating fish into account.

Use of a footnote

71. As indicated in the previous paragraph, for MLs with higher values, it is still required that consumption is restricted. CCCF has decided in previous sessions that it will not develop consumption advice, as this should be done on a national level.

72. However, it might be an option to attach a footnote to the MLs for species which have very high methylmercury concentrations, in order to trigger such options on a national level. Such a footnote could read (as an example and open for discussion) 'for this fish species, additional risk management measures may be necessary on a national level to restrict exposure to unacceptably high levels of methylmercury (e.g. consumption advice)'

All responding members of the EWG were in favor of using a footnote or accompanying text with the MLs. One of these members specified that MLs based on risk/benefit would be accompanied by a consumer advisory for sensitive consumers (i.e. pregnant women and young children) to restrict consumption of the most contaminated fish species, expressed as number of portions of 100 grams per unit of time as suggested by the FAO/WHO expert consultation on risk/benefit.

JECFA assessment

73. As described above, a JECFA impact assessment of proposed MLs would not be necessary. A quantitative risk/benefit evaluation has been performed by the FAO/WHO expert consultation in 2010 from which it can be deduced what the impact of ML development on exposure would be (paragraph 5.2). It should be noted however, that the FAO/WHO expert consultation has been performed in 2010, and possible new information which would change the balance of risk/benefit is therefore not taken into account in the current discussion.

Two members indicated that a JECFA impact assessment of proposed MLs would not be needed, one of which indicated that it would possibly be of greater benefit to see if the same benefit and risks associated with essential fatty acids and methylmercury used by the Expert consultation are still valid. One member indicated that in the case of MLs based on risk/benefit, the consequences of such MLs on trade and viability of fish industry should be clear. One member did support a JECFA impact assessment of proposed MLs, and indicated that more recent data (e.g., AHRQ report, 2016[18]), challenge some of the benefit estimates in the FAO/WHO expert consultation, and therefore sole reliance on EPA+DHA concentrations in fish to determine benefits of fish consumption may no longer be appropriate. One member suggested that countries which have performed a risk benefit evaluation since the FAO/WHO expert consultation could advise on the amount of new studies and whether these are likely to give cause for reanalysis.

[18] http://effectivehealthcare.ahrq.gov/index.cfm/search-for-guides-reviews-and-reports/?pageaction=displayproduct&productid=2321

Other species for future ML development

74. Based on a first analysis of the GEMS/Food data the following species were selected for possible future ML development: Cardinal fish (*Epigonus telescopus*), Inshore hagfish (*Eptatretus burger*), Selachoidae (*Pleurotremata*), Toothfish (*Dissostichus sp*.) and Tusk (*Brosme brosme*). Also: Barbel and Hapuku, and Anchovies, Bass, Bream, (Sea) catfish and Wolffish, Cod, Halibut, Ling, Monkfish, Mullet, Rays, Ribaldo, Sardines and Snapper.

This paragraph overlaps with the third discussion point, and therefore responses are combined there.

Other options

75. Other options that were suggested in the EWG:

One member, while recognizing that the CCCF already been agreed that MLs should be set for methylmercury with the use of total mercury for screening purposes, suggested to consider establishing MLs based on total mercury. This because it would offer a conservative approach and the analytical methods for total mercury are widely available and low in cost.

APPENDIX II
(For consideration by CCCF)

PROJECT DOCUMENT FOR NEW WORK ON MLS FOR METHYLMERCURY IN FISH

1- Purpose and Scope of the new work

This work aims to establish Maximum Levels (MLs) for methylmercury in 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 species2) were adopted in 1991[19]. 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)[20]. 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[21].

3- Main aspects to be covered

ML(s) for methylmercury in 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

d) Achievability of the MLs

- As a start of the discussion, the following MLs are proposed

Species	**Proposed ML based on P95 (in mg/kg)**
Bigeye tuna, Atlantic Bluefin tuna and Southern Bluefin tuna:	1.2 or 1.3
Albacore tuna and other (than Atlantic and Southern) Bluefin tuna	0.9
Or: All tuna (based on worst case scenario)	1,2
Alfonsino	1.2 or 1.3
Kingfish/Amberjack	0.8
Marlin (based on methylmercury data only)	0.8
Shark	1.4
Dogfish	2.3
Swordfish	2.0

OR

[19] CODEX STAN 193-1995: General Standard for Contaminants and Toxins in Food (GSCTFF).
[20] 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).
[21] the Joint FAO/WHO Expert Consultation on the Risks and Benefits of Fish Consumption, FAO Fisheries and Aquaculture Report No. 978. Rome, 25-92 January 2010. Accessed Feb 8, 2017: http://www.fao.org/docrep/014/ba0136e/ba0136e00.pdf)

Species	Proposed ML based on risk/benefit (in mg/kg)
Albacore tuna and other (than Atlantic and Southern) Bluefin tuna, Bigeye tuna, Alfonsino, Dogfish, Marlin, Shark, and Swordfish	0.3
OR:	
Albacore tuna and other (than Atlantic and Southern) Bluefin tuna, Bigeye tuna, Alfonsino, Dogfish, Marlin, Shark, and Swordfish	0.75 (number of servings per week to be restricted, the amount depending on EPA + DHA levels)

A call for data for methylmercury levels and EPA+DHA levels in fish would be needed to revisit the proposed MLs.

- 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 fish.

- *Diversification of national legislation and apparent resultant or potential impediments to international trade.*

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

- *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 fish and 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.

- *Strategic goal 5: Promoting maximum application of codex standards*

Due to the international nature of this problem, this work will support and embrace all aspects of this objective by requiring participation of both developed and developing countries to conduct the work

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

This new work is recommended following the General Standard for Contaminants and Toxins in Food and Feed (GSCTFF).

7- Identification of any requirement for and 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

Currently, there is no need for additional technical input from external bodies.

9- The proposed timeline for completion of the new work, including the starting date, proposed date of adoption at Step 5 and the proposed date for the adoption by the Commission, the timeframe for developing a standard should not normally exceed 5 years.

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 12th Session of the CCCF with a view to its finalization in 2020 at the latest. A staged approach based on dealing with few fish species a year could be considered, in that case, the work would take longer to finalize.

APPENDIX III:
PARTICIPANTS LIST

Chair
Astrid Bulder
Senior Risk Assessor
Centre for Nutrition, Prevention and Health Services (VPZ)
National Institute for Public Health and the Environment (RIVM)
P.O. Box 1, 3720 BA, Bilthoven, The Netherlands
Tel: +31 6 4686 0725
Email: Astrid.Bulder@rivm.nl

Co-chairs
John Reeve
Principal Adviser (Toxicology)
Biosecurity Science, Food Science and Risk Assessment Directorate
Regulation and Assurance Branch
Ministry for Primary Industries - Manatū Ahu Matua
Pastoral House 25, The Terrace
PO Box 2526, Wellington, New Zealand
Telephone: +6448942533
Mobile: +64298942533
Email: John.Reeve@mpi.govt.nz

Mark Feeley
Associate Director
Bureau of Chemical Safety
Food Directorate
Health Canada
Telephone: 613-957-1314
Email: mark.feeley@hc-sc.gc.ca

Australia
Ms Leigh Henderson
Section Manager
Food standards Australia New Zealand
Email: Leigh.Henderson@foodstandards.gov.au

Brazil
Mrs. Ligia Lindner Schreiner
Health Regulation Expert
Brazilian Health Regulatory Agency
Email: ligia.schreiner@anvisa.gov.br

Mr. Lucio Akio Kikuchi
Official Inspector
Ministry of Agriculture, Livestock and Supply
Email: lucio.kikuchi@agricultura.gov.br

Canada
Matthew Decan
Scientific Evaluator, Food Contaminants Section
Bureau of Chemical Safety, Health Products and Food Branch
Health Canada
Email: matthew.decan@hc-sc.gc.ca

Elizabeth Elliott
Head, Food Contaminants Section
Bureau of Chemical Safety, Health Products and Food Branch
Health Canada
Email: Elizabeth.Elliott@hc-sc.gc.ca

Chile
Ms. Lorena Delgado Rivera
Chilean Coordinator of CCCF
Institute of Public Health, Chile
Tel: +56225755493
Email: ldelgado@ispch.cl

China
Mr Yongning WU
Professor, Chief Scientist
China National Center of Food Safety Risk Assessment (CFSA)
Diretor of Key Lab of Food Safety Risk Assessment, National Health and
Family Planning Commission
Building 2, 37 Guangqulu, Chaoyang District, Beijing 100022
CHINA
Tel: 86-10-52165589
Fax: 86-10-52165489
E-mail: wuyongning@cfsa.net.cn, china_cdc@aliyun.com

Ms Xiaohong Shang
Researcher
China National Center for Food Safety Risk Assessment (CFSA)
Key Lab of Food Safety Risk Assessment, National Health and
Family Planning Commission
Building 2, 37 Guangqulu, Chaoyang District, Beijing 100022 CHINA
Tel: 86-10-52165434
e-mail: shangxh@cfsa.net.cn

Ms Yi SHAO
Research Associate
Divisoin II of Food Safety Standards
China National Center of Food Safety Risk Assessment (CFSA)
Building 2 No.37, Guangqulu, Chanoyang District, Beijing 100022
CHINA
Tel: 86-10-52165421
E-mail: shaoyi@cfsa.net.cn

Cuba

Mr. Orlando José Ruqué Martí
Especialista en Gestión de Calidad
Dirección de Calidad y Tecnología
Ministerio de la Industria Alimentaria
Email: orlando.ruque@minal.cu

European Union

Mr Frank Swartenbroux,
European Commission
DG Santé
F101 04/057
1049 Brussels, BELGIUM
Email: Frank.Swartenbroux@ec.europa.eu

France

Dr Laurent Noel
Adjoint au chef du Bureau de la Coordination en matière de Contaminants Chimiques et Physiques (B3CP)
DGAL - service de alimentation
Ministry of Agriculture
25, rue de Vaugirard 75762 Paris
Email: laurent.noel@agriculture.gouv.fr

Germany

Ms. Klara Jirzik
Food Chemist
Federal Office of Consumer Protection and Food Safety (BVL) Unit 101
Mauerstr. 39 - 42
D-10117 Berlin
Tel: +49 30 18444 10128
Fax: +49 30 18444 89999
E-Mail: klara.jirzik@bvl.bund.de

India

R.M. Mandlik
Deputy Director (T)
Export Inspection Council of India
E-mail: tech1@eicindia.gov.in

Indonesia

Mrs. Elin Herlina
Director of Food Product Standardization
National Agency of Drug and Food Control
Republic of Indonesia
Email: codexbpom@yahoo.com

Japan

Dr. Yukiko YAMADA
Guest Scholar
National Institute of Health Sciences,
E-mail: yyamada1201@gmail.com

Mr. Kazuhito IKAWA
Technical officer
Standards and Evaluation Division, Department of Environmental Health and Food Safety, Ministry of Health, Labour and Welfare
E-mail: codexj@mhlw.go.jp

Mr. Hirohide MATSUSHIMA
Assistant Director
Fisheries Management Division, Fisheries Agency of Japan, Ministry of Agriculture, Forestry and Fisheries
Email: hiro_matsushima500@maff.go.jp

Republic of Korea

Ministry of Food and Drug Safety(MFDS)
Email (MFDS contact point): codexkorea@korea.kr

Miok, Eom
Senior Scientific officer
Livestock Products Standard Division
Ministry of Food and Drug Safety(MFDS)
E-mail: miokeom@korea.kr

Seong-ju, Kim
Scientific officer
Livestock Products Standard Division
Ministry of Food and Drug Safety(MFDS)
Email: foodeng78@korea.kr

So-young, Yune
Scientific officer
Livestock Products Standard Division
Ministry of Food and Drug Safety(MFDS)
Email: biosyyune@korea.kr

Min, Yoo
Codex researcher
Food Standard Division
Ministry of Food and Drug Safety(MFDS)
Email: minyoo83@korea.kr

Malta

Hadrian Bonello
Secretary, Food Safety Commission
hadrian.bonello@gov.mt

John Attard Kingswell
Environmental Health Manager
john.attard-kingswell@gov.mt

Ann Marie Borg
Senior Policy Officer
Perm. Rep. Malta- CODEX
ann-marie.borg@gov.mt

Morocco

Dr Nabil Abouchouaib
Médecin vétérinaire
Directeur du Laboratoire Régional d’Analyse et de Recherche de Casablanca (Office National De La Sécurité Sanitaire Des Produits Alimentaires)
Email: nabilabouchoaib@gmail.com;

Dr Oleya EL HARIRI: Médecin vétérinaire, Direction régionale de Rabat (Office National De La Sécurité Sanitaire Des Produits Alimentaires)
Email: oleyafleur@yahoo.fr

Pr. Abdelaziz EL HRAIKI, DVM, PhD Département des Sciences Biologiques et Pharmaceutiques Vétérinaires à l'Institut Agronomique et Vétérinaire Hassan II
Email: a.elhraiki@iav.ac.ma

Dr Ali Benhra
Chef URD "Contaminants Chimiques "
INRH Institut National de Recherche Halieutique de Casablanca
Email: abenhra@hotmail.com

Mexico
Jessica Gutiérrez Zavala
Dirección Ejecutiva de Operación Internacional
Comisión Federal para la Protección Contra Riesgos Sanitarios (COFEPRIS)
MÉXICO
jgutierrezz@cofepris.gob.mx

Luis Atzin Rocha Lugo
Dirección Ejecutiva de Operación Internacional
Comisión Federal para la Protección Contra Riesgos Sanitarios (COFEPRIS)
MÉXICO
lrocha@cofepris.gob.mx
codex@cofepris.gob.mx

Norway
Mr Anders Tharaldsen
Senior Adviser
Norwegian Food Safety Authority
NORWAY
Email: antha@mattilsynet.no

Spain
Ms. Marta PEREZ
Technical expert
Contaminants Management Department
Subdirectorate-General for Food Safety Promotion
Spanish Agency for Consumer Affairs, Food Safety and Nutrition
E-mail: contaminantes@msssi.es

Manuela Mirat Temes
Departamento: Departamento de técnicas Espectroscópicas
Subdirección de Control y Laboratorios Alimentarios
MAGRAMA
Correo: mmiratte@magrama.es

Mr. Julian Garcia Baena
Jefe de Servicio Técnico
Subdireccion General de Economía Pesquera
MAGRAMA
Velázquez, 147. 2ª planta
28002 MADRID, SPAIN
Tel: + 34 91 3 47 62 80
Email: JGBaena@magrama.es

Thailand
Chutiwan Jatupornpong
Standards officer
Office of Standard Development
National Bureau of Agricultural Commodity and Food Standards
50 Phaholyothin Road, Ladyao, Chatuchak, Bangkok 10900 Thailand
Tel (+662) 561 2277
Fax (+662) 561 3357, (+662) 561 3373
E-mail: codex@acfs.go.th and chutiwan9@hotmail.com

Tunisia
Mr. Lassad CHOUBA
Laboratory manager Trace metals
National Institute of Science and Technology of the Sea
Ministry of Scientific Research, Technology and Competency Development
Email: lassaad.chouba@instm.rnrt.tn

United States of America
Henry Kim
On Behalf of Lauren Posnick Robin, U.S. Delegate to CCCF
U.S. Food and Drug Administration
Center for Food Safety and Applied Nutrition
5001 Campus Drive
College Park, MD 20740
Email: henry.kim@fda.hhs.gov

Eileen Abt
U.S. Food and Drug Administration
Center for Food Safety and Applied Nutrition
5001 Campus Drive
College Park, MD 20740
Email: eileen.abt@fda.hhs.gov

AIPCE-CEP
Mr. Carlos Ruiz Blanco
ANFACO
Carretera Colegio Universitario 16 (Campus Universitario de Vigo)
Apartado 258
E - 36310 Vigo (Pontevedra)
Tel: 34/98/646.93.01
Fax: 34/98/646.92.69
Email: cruiz@anfaco.es

ICGMA
René Viñas, MS, PhD
Delegate to CCCF
International Council of Grocery Manufacturers Associations
1350 I Street, NW, Suite 300,
Washington DC, 20005
Tel: 202-639-5972
Tel (cell): 830-352-5583
Fax: 202-639-5991
Email: RVinas@gmaonline.org

FoodDrinkEurope
Eoin Keane
Manager Food Policy, Science and R&D
Avenue des Nerviens 9-31
1040 Bruxelles, BELGIUM
Tel. +32 2 5008756
Email: e.keane@fooddrinkeurope.eu

FAO
Ms. Esther Garrido Gamarro
Food safety and quality officer
Products, Trade and Marketing Branch (FIAM)
Fisheries and Aquaculture Policy and Resources Division
The Fisheries and Aquaculture Department
Food and Agriculture Organization of the United Nations
Tel.: +39 06 570 56712
Email: Esther.GarridoGamarro@fao.org

Dr Vittorio Fattori
Food Safety Officer
Agriculture and Consumer Protection Department Food and Agriculture Organization of the UN
Viale delle Terme di Caracalla
Rome, Italy
Tel: +39 06 570 56951
Email: vittorio.fattori@fao.org

Dr Markus Lipp
Senior Officer
Agriculture and Consumer Protection Department
Food and Agriculture Organization of the UN
Viale delle Terme di Caracalla
Rome, Italy
Tel: +39 06 57053283
Email: markus.lipp@fao.org