CODEX ALIMENTARIUS COMMISSION E

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World Health Organization

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Agenda Item 16 **CX/CF 14/8/16**
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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON CONTAMINANTS IN FOODS

Eighth Session
The Hague, The Netherlands, 31 March – 4 April 2014

DISCUSSION PAPER ON THE REVIEW OF THE GUIDELINE LEVELS FOR METHYLMERCURY IN FISH AND PREDATORY FISH

(Prepared by the Electronic Working Group led by Japan)

BACKGROUND

1. The 7th Session of the Committee on Contaminants in Food (CCCF) (April 2013) reviewed the current Guideline Levels (GLs) for methylmercury in fish and predatory fish and considered other measures including consumption advice taking into consideration outcome of the joint FAO/WHO expert consultation on the risks and benefits of fish consumption. While there was support for setting GLs or Maximum Levels (MLs) for methylmercury in fish, it was recognized that further information was necessary to review the current GLs taking into account the benefits of fish consumption. The Committee thus agreed to re-establish the electronic working group (eWG), led by Japan and co-chaired by Norway, and requested the eWG to: (i) prepare a discussion paper; (ii) collect data on total mercury and methylmercury in fish species important in international trade in order to review the current GLs; (iii) explore the possibility of revising the GLs or their conversion to MLs; (iv) and identify the fish for which the level or levels could apply (REP13/CF para. 126).

2. Several members proposed that the eWG should consider consumption advice as an alternative approach in this discussion paper. However, the terms of reference of this eWG is limited to reviewing the current GLs based on the occurrence data on total mercury/methylmercury in fish. Therefore, the eWG did not consider the consumption advice, and it will be discussed at the 8th CCCF in the context of what the most appropriate risk management measure for methylmercury in fish is.

3. A summary of the discussion on this matter at sessions of the Codex Alimentarius Commission (CAC), Executive Committee (CCEXEC), Committee on Food Additives and Contaminants (CCFAC), Committee on Fish and Fishery Products (CCFFP) and the Committee on Contaminants in Foods (CCCF) is presented in Appendix III. The List of Participants is presented in Appendix IV.

4. The Committee is invited to consider the conclusions and recommendations in relation to the review of the guideline levels for methylmercury in fish and predatory fish (Appendix I) while paying due attention to the information, data and discussion provided in Appendix II.

APPENDIX I

REVIEW OF THE GUIDELINE LEVELS FOR METHYMERCURY IN FISH AND PREDATORY FISH

CONCLUSIONS

1. There are various views on the options. Majority of comments (6 out of 11 Members' comment) supported setting GLs for ToHg and analyzing only ToHg. Four members supported setting GLs for MeHg, and setting screening levels for ToHg if necessary. One member supported setting no GL as a new proposal.

2. Classification of fish species into two groups, "tunas, billfish and sharks" and "species except tunas, billfish or sharks," instead of "predatory" and "non-predatory" fish would be **statistically** possible with regard to concentration of MeHg. However, whether skipjack tuna and yellowfin tuna are included in "tunas" should be considered as the concentrations of total mercury in these two species are significantly lower than other tuna species. Availability of practical species identification of fish in a form of fillets should also be considered

3. The current GL for fish at 0.5 mg/kg may be unnecessary because violation rates of fish species except tunas and catfish are less than 1%. The GL for predatory fish at 1 mg/kg would need to be reviewed taking into account the higher violation rates of Albacore (5.6%) and Bigeye tuna (18%) which were calculated using a lognormal density model. A member requested to consider revocation of 0.5 mg/kg more carefully since the data set used for this analysis could be biased by the current GLs, and the revocation may allow distribution of a large number of fish containing higher levels of mercury in retail. Some members requested that benefits of fish consumption should be considered in reviewing GLs, and suggested discussing appropriateness of GLs as risk management tools.

4. While several members proposed to discuss consumption advice, the eWG did not because it was out of the ToR.

RECOMMENDATION

5. The CCCF should consider the following on the basis of the conclusions above

   1) Appropriate analyte and necessity of conversion factor;

   2) New classification of fish species instead of "Predatory" and "Non-predatory";

   3) Effectiveness of the GL for fish other than predatory fish at 0.5 mg/kg as a risk management tool;

   4) Revocation of the GL for predatory fish, 1 mg/kg and elaboration of new MLs for total mercury or methylmercury in new class such as a group covering tunas, billfish and sharks

   5) Whether GLs are an appropriate risk management tool for MeHg in fish by giving more consideration to health benefit from fish consumption.

6. If it is agreed that regulatory limits for mercury in fish are necessary, then the current GLs should be reviewed, and they should preferably be converted to MLs.

7. Although consumption advice was out of the ToR of this eWG, it should be discussed at the 8th CCCF.

APPENDIX II

REVIEW OF THE GUIDELINE LEVELS FOR METHYMERCURY IN FISH AND PREDATORY FISH

INTRODUCTION

1. At the 7th CCCF, members considered the effectiveness of consumption advice and the current GLs for methylmercury as risk management tools.

2. While the effectiveness of consumption advice was recognized, it was pointed out that consumption advice would be more appropriate at the national or regional level rather than international level. To help members to develop consumption advice at national or regional level, the joint UNEP/WHO publication, "Guidance of identifying populations at risk from mercury exposure, 2008" was introduced by the WHO representative at the 7th CCCF.

3. The committee agreed to develop a discussion paper to review the current GLs through the re-established eWG. Some delegations proposed that the current GLs are not consistent with the state of science because they do not take into account actual risk or the benefits of fish consumption, and therefore could cause harm by reducing fish consumption unnecessarily and losing net health benefits. Under this view, the better approach would be appropriate consumption advice at the national level based on a "net effects" analysis of risk, as reflected in the Report of the Joint FAO/WHO Expert Consultation on the Risks and Benefits of Fish Consumption (FAO Fisheries and Agriculture Report No. 978 FIPM/R978 (EN) (http://www.fao.org/docrep/014/ba0136e/ba0136e00.pdf).This Consultation was conducted at the request of the Codex Committee for Food Additives and Contaminants at its 38th meeting to seek scientific advice from FAO and WHO on the risks and benefits of fish consumption: specifically, advice on the nutritional health benefits compared to the risks of consuming fish that may be contaminated with methylmercury. Other delegations supported setting GLs (or MLs) in combination with consumption advice. It was also pointed out that the current GLs should be reviewed taking into consideration 1) the benefit of fish consumption, 2) appropriateness of setting GLs for total mercury, 3) appropriateness of maintaining two categories (i.e. "predatory fish" and "non-predatory fish"), and 4) conversion of GLs to MLs.

4. The eWG addressed the following points in this discussion paper for consideration at the 8th CCCF:

   A) Guidance on determining the appropriate risk management option in relation to the UNEP/WHO publication

   B) For what GLs/MLs should be recommended?

      - "Total mercury" or "Methylmercury"
      - "Predatory" or "not predatory"
      - GLs or MLs

   C) Preliminary estimation of GLs or MLs

5. Due to the time constraint, the eWG considered the possibility of revising the current GLs only from a statistical point of view based on the submitted data by eWG members.

GUIDANCE ON DETERMINING THE APPROPRIATE RISK MANAGEMENT OPTION IN RELATION TO THE UNEP/WHO PUBLICATION

6. At the 7th CCCF, the Committee agreed that consumption advice was more appropriate at the national level than at international level. The representative of WHO informed the Committee of the joint UNEP/WHO publication as a possible tool for national authorities when developing fish consumption advice. The publication, "Guidance of identifying populations at risk from mercury exposure, 2008" is available on the website:
http://www.unep.org/hazardoussubstances/LinkClick.aspx?fileticket=DUJZp8XnXq8%3d&tabid=3593&language=en-US

7. The publication provides guidance for conducting a risk assessment process to identify populations potentially at risk due to mercury exposure and for choosing risk management options. If estimated methylmercury intake exceeds a toxicological endpoint, such as Provisional Tolerable Weekly Intake (PTWI), two options are proposed: information approaches (i.e. Consumption advice) and regulatory approaches (Setting GL/ML). A Step by step approach, such as a risk manager's decision tree, is introduced for governments and appropriate organizations to conduct the risk assessment. The risk manager can introduce risk management tools based on the assessment.

8. The publication provides examples of information approaches. When national risk managers implement such information approaches, the publication suggests tailoring the examples to country's specific circumstances taking into account variations in amount and type of commonly consumed fish and levels of mercury in these species.

9. In order to evaluate the necessity of risk management measures, the publication recommends comparing methylmercury intake with the PTWI (1.6 μg/kg bw/week) for children up to about 17 years of age and women of child bearing age. A different value, 3.2 μg/kg bw/week, is recommended for other adults.

10. The eWG noted that the publication 1) provides useful guidance to conduct a risk assessment, 2) offers two options of risk management tools, and 3) uses different criterion between high risk group and general population for deciding the necessity of risk management tool and/or the appropriate risk management tool to use.

THE ANALYSIS OF OCCURRENCE DATA ON TOTAL MERCURY/METHYLMERCURY IN FISH

(1) Occurrence data submitted by members

11. Following the request by the 7th CCCF, Japan and Norway, as the chair and the co-chair of the eWG, asked the Codex members to provide occurrence data/information on total mercury and methylmercury in fish for development of the discussion paper on the review of the GLs for methylmercury in fish.

12. Data were submitted by the following 13 countries and one observer: Australia, Chile, China, France, Ghana, Ireland, Japan, Mexico, Norway, Poland, Spain, Seychelles, Thailand and FoodDrink Europe. The data provided by FoodDrink Europe were same as a part of those provided by Spain, and only one dataset was used.

13. The occurrence data on total mercury of total 17148 samples were provided for: Albacore, Alfonsino, Bigeye tuna, Bluefin tuna, Blue marlin, Catfish, Cod, Halibut, Herring, Mackerel, Pollock, Salmon, Sardine, Shark, Skipjack tuna, Southern bluefin tuna, Squid, Striped marlin, Swordfish, Tilapia, Whiting, Yellowfin tuna and others. The detailed information on species or genus level is described in each of the later sections.

14. Occurrence data on both total mercury and methylmercury were available only for 2315 samples which were provided by China and Japan. These fish species were: Albacore, Alfonsino, Bigeye tuna, Bluefin tuna, Blue marlin, Cod, Pollock, Shark, Skipjack tuna, Southern bluefin tuna, Striped marlin, Swordfish, Yellowfin tuna and others.

(2) Identification of fish species important in international trade

15. Fish species important in international trade were selected using information on trade quantity in 2009 shown in the "FAO Fisheries Commodities Production and Trade" database.

16. From the top 50 fish and fishery products listed in that database, eighteen fish species were identified as a result of exclusion of molluscs, crustaceans or items whose fish species were not specified (e.g. "Fish fillets/frozen/nei", "Marine fish nei/minced/prepared or preserved") from the 50 products. Those eighteen species selected are: Albacore, Atlantic cod, Atlantic salmon, Bigeye tuna, Catfish, Cuttlefish, European plaice, Herring, Mackerel, Pacific salmon, Pollock, Sardine, Skipjack tuna, Sprat, Squid, Tilapia, Yellowfin tuna and Whiting.

FOR WHAT GLs/MLs SHOULD BE RECOMMENDED?

(1) Total mercury or Methylmercury

17. The CCFAC26 in 1994 "noted that an analysis for total mercury would generally be adequate to ensure that the levels for methylmercury were not exceeded (i.e., total mercury content in fish is commonly about 90% methylmercury). An analysis of methylmercury would only be required in those cases where a measurement of total mercury exceeded the guideline level of 1 mg/kg (predatory) and 0.5 mg/kg (others). Therefore, it was decided that the establishment of a guideline levels for total mercury in fish was not necessary" (ALINORM 95/12, para. 15). At the 7th CCCF, some members proposed setting GLs (MLs) for total mercury rather than methylmercury because the analysis of total mercury is less costly and takes less time than for MeHg. Also, if the majority of total mercury in fish exists in the form of methylmercury, or if there is a correlation between total mercury and methylmercury concentration, setting GLs for total mercury will be equally effective.

18. On the premise that GLs should be set, in order to consider whether the GLs should be set for total mercury or methylmercury, the eWG analyzed the proportions of methylmercury in total mercury (MeHg/ToHg) using occurrence data provided by members.

19. As mentioned before, occurrence data on both total mercury and methylmercury were available for 2315 samples which were provided by China and Japan. The eWG carried out statistical evaluations of the ratios of MeHg/ToHg for 13 fish species with 120 or more samples, the sample size that is sufficient for determining 97.5%ile with a probability of 95% or higher. For other fish species, their sample sizes were less than 10, which were insufficient for statistical evaluation. Because it was unknown whether or not concentrations of MeHg or ToHg were adjusted by their molecular weights, their occurrence data were used as provided.

20. Out of 13 fish species analyzed, the following 6 fish species are important in international trade: Albacore (*T. alalunga*), Bigeye tuna (*T. obesus*), Cod (Pacific cod: *G. macrocephalus*), Skipjack tuna (*K. pelamis*), Pollock (Walleye pollock: *T. chalcogramma*) and Yellowfin tuna (*T. albacares*). The other 7 fish species analyzed were: Alfonsino (*B. splendens*), Bluefin tuna (*T. thynnus*, *T. orientalis*), Blue marlin (*M. mazara*, *M. nigricans*), Shark (Blue shark: *P. glauca*), Southern bluefin tuna (*T. maccoyii*), Striped marlin (*T. audax*) and Swordfish (*X. gladius*).

21. With regards to sampling sites for Albacore, Bigeye tuna, Bluefin tuna, Blue marlin, Southern bluefin tuna, Striped marlin, Swordfish and Yellowfin tuna, their samples were collected from all of their habitats (all or a part of the Atlantic Ocean, the Pacific Ocean and the Indian Ocean).

22. For Skipjack tuna and Shark, a portion of their samples was collected from the Pacific Ocean. The sampling sites of other samples were not provided, and it is unknown where those samples were collected across their habitats, which are the Atlantic Ocean, the Indian Ocean and the Pacific Ocean.

23. For Cod (Pacific cod) and Pollock (Walleye pollock), while their sampling sites were not provided, their habitats are limited to the North Pacific Ocean.

24. For Alfonsino, their sampling sites were not provided, and its habitat ranges across the Atlantic Ocean, the Pacific Ocean and the Indian Ocean.

25. The calculated MeHg/ToHg for the 13 fish species are shown in Fig. 1(a)-(m) and Table 1(a) and (b).

<u>Histograms on proportions of methylmercury in total mercury for fish species important in international trade</u>

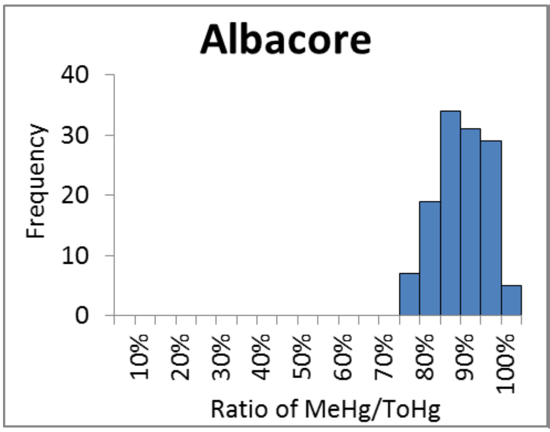

Fig. 1 (a): Albacore

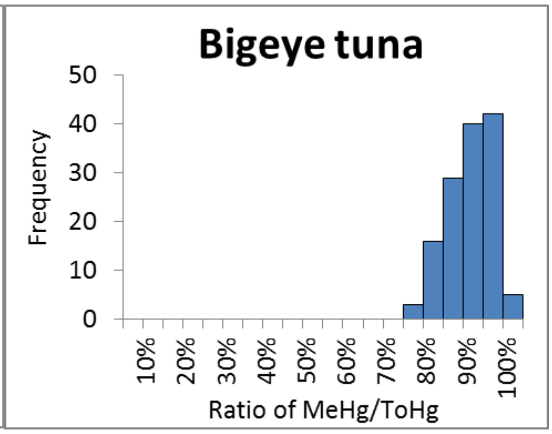

Fig. 1 (b): Bigeye tuna

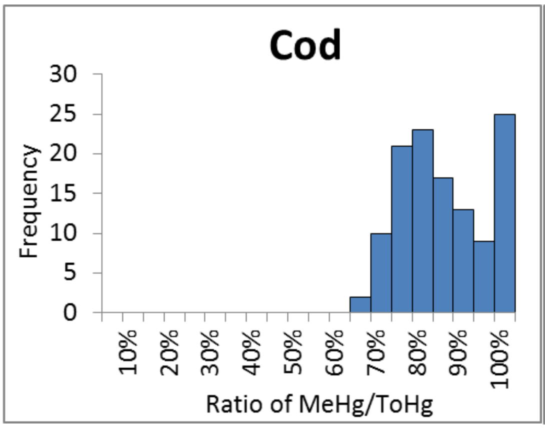

Fig. 1 (c): Cod

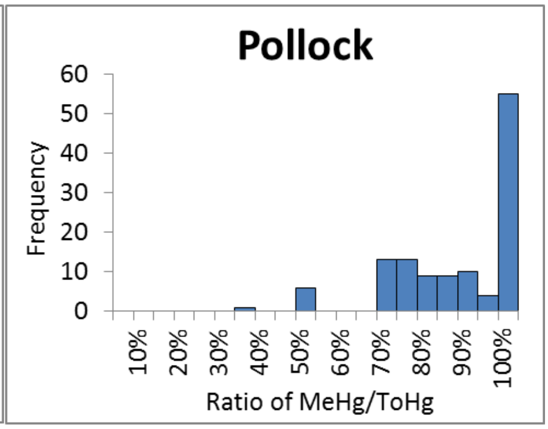

Fig. 1 (d): Pollock

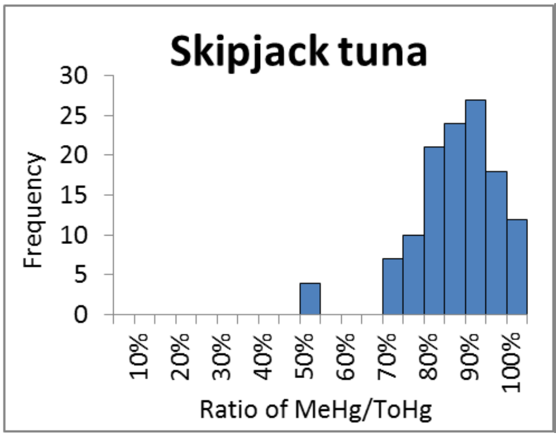

Fig. 1 (e): Skipjack tuna

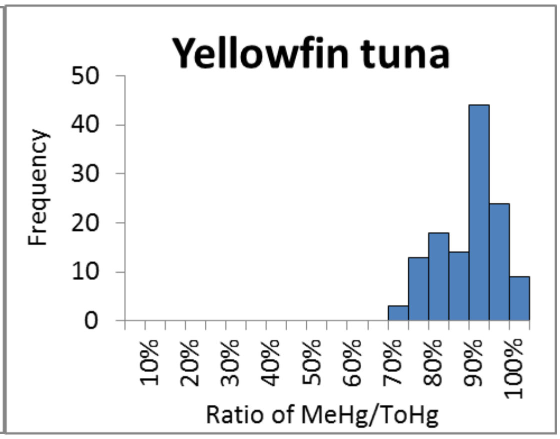

Fig. 1 (f): Yellowfin tuna

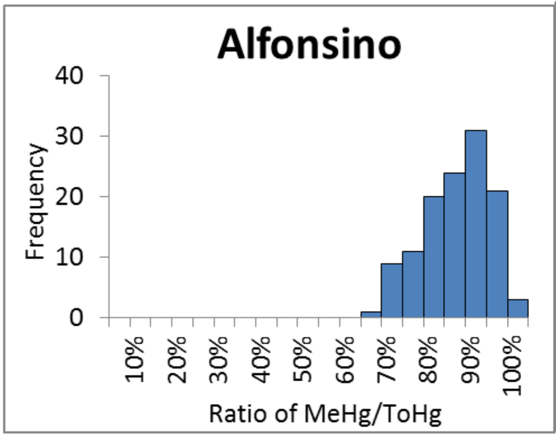

Fig. 1 (g): Alfonsino

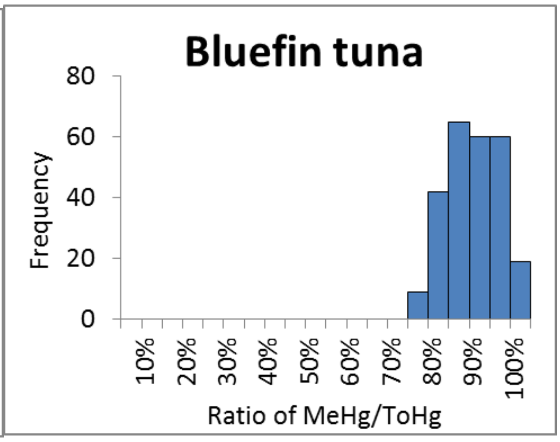

Fig. 1 (h): Bluefin tuna

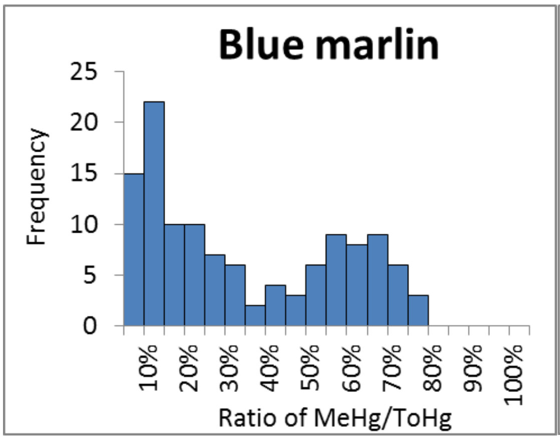

Fig. 1 (i): Blue marlin

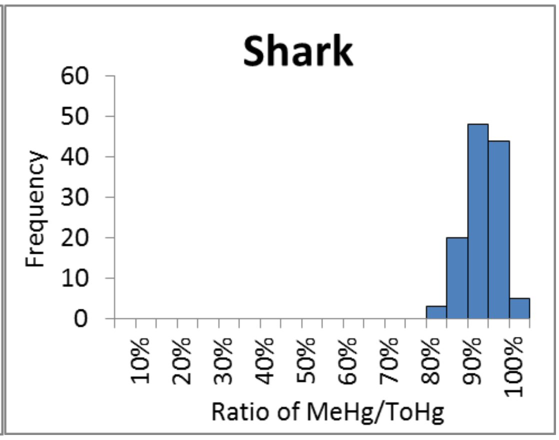

Fig. 1 (j): Shark

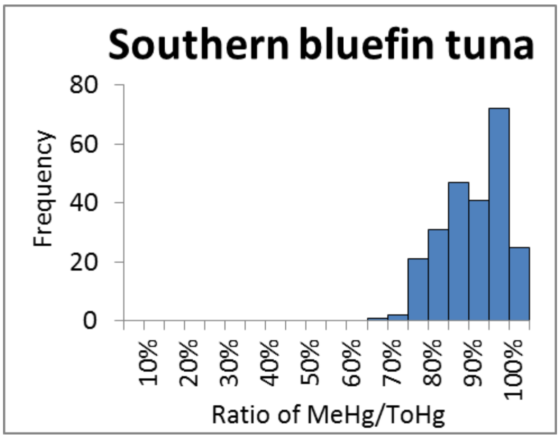

Fig. 1 (k): Southern bluefin tuna

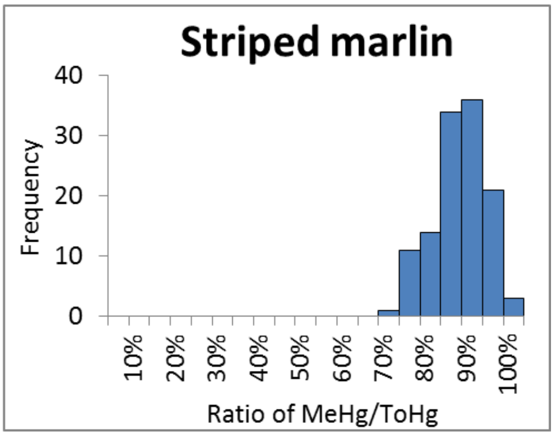

Fig. 1 (l): Striped marlin

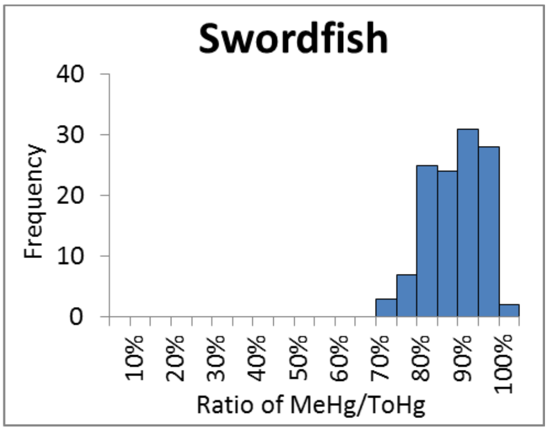

Fig. 1 (m): Sword fish

Table 1 (a): Proportions of methylmercury in total mercury for fish species important in international trade

	N	min (%)	Max (%)	Average (%)	Median (%)	SD
Albacore	125	70	100	85	85	6.4
Bigeye tuna	135	71	100	87	88	5.6
Cod	120	63	100	84	83	11
Pollock	120	33	100	86	89	15
Skipjack tuna	123	50	100	83	85	10
Yellowfin tuna	125	67	100	86	88	7.6

Table 1 (b): Proportions of methylmercury in total mercury for other fish species

	N	min (%)	Max (%)	Average (%)	Median (%)	SD
Alfonsino	120	63	98	83	84	7.5
Bluefin tuna	255	71	100	86	86	6.4
Blue marlin	*120*	*22*	*75*	*30*	*23*	*23*
Shark	120	79	100	89	89	4.5
Southern bluefin tuna	240	63	100	86	88	7.6
Striped marlin	120	70	100	85	85	6.3
Swordfish	120	67	98	85	85	6.7

26. For all species except Blue marlin and Pollock, the ratios of MeHg/ToHg are generally more than 70% with the modes around 90%. For Blue marlin, the ratios range between 2% and 75% with its mode in a range of 5-10%. For Pollock, the ratios range between 33% and 100% with its mode in a range of 95-100%.

27. Averages of the ratios of MeHg/ToHg in these fish species were between 83% and 89% except in blue marlin. For blue marlin, the proportion was remarkably lower compared to the other fish species.

28. In order to consider whether MeHg/ToHg were significantly different between fish species, a series of statistical evaluations were carried out in the following steps.

29. First of all, in order to assess the normality of MeHg/ToHg distributions, the Shapiro-Wilk test, a more powerful normality test for small size of dataset compared with other normality tests, e.g. the Kolmogorov-Smirnov test, was performed on each fish species. The distributions of most of fish species were non-normal at 5% level of significance.

30. The Bartlett's test, a statistical test for homogeneity of variances, was then performed to test if the variances of the ratios of MeHg/ToHg were equal across fish species. The variances were unequal at 5% level of significance.

31. Because the data set of 13 fish species were evaluated to be non-normally distributed, the Kruskal-Wallis test, the non-parametric method for testing whether samples originate from the same distribution by ranks, was used. The result showed the differences among those fish species at 5% level of significance.

32. Finally, in order to evaluate differences between each pair of 13 fish species, non-parametric all-pairs multiple comparison based on pairwise rankings was conducted using the Steel-Dwass test[1]. The statistical significance level was set at 5%. The ratio of MeHg/ToHg of Blue marlin was significantly lower than those of all the other 12 fish species. There was no other fish species whose ratio of MeHg/ToHg was significantly different from those of all the other 12 fish species.

33. Next, a correlation between the concentration of methylmercury and that of total mercury was evaluated by performing a single linear regression analysis. In this analysis, all of the occurrence data on total mercury and methlymercury of 2315 samples were used.

34. The results are shown in the Fig. 2 (a), (b) and (c). It seems that there is no significant correlation between the concentration of methylmercury and that of total mercury (Fig. 2 (a)) when all the datasets were analyzed. However, a strong positive correlation was found (R^2=0.985) when the dataset of Blue marlin was excluded (Fig. 2 (b)). The regression equation estimated for fish species except Blue marlin was approximately: (Methylmercury) = 0.837 × (Total mercury). This indicates that the concentration of methylmercury can be calculated by multiplying 0.837 to that of total mercury. For Blue marlin, there was no strong positive correlation between the concentrations of total mercury and methylmercury (R^2=0.397, Fig. 2 (c)).

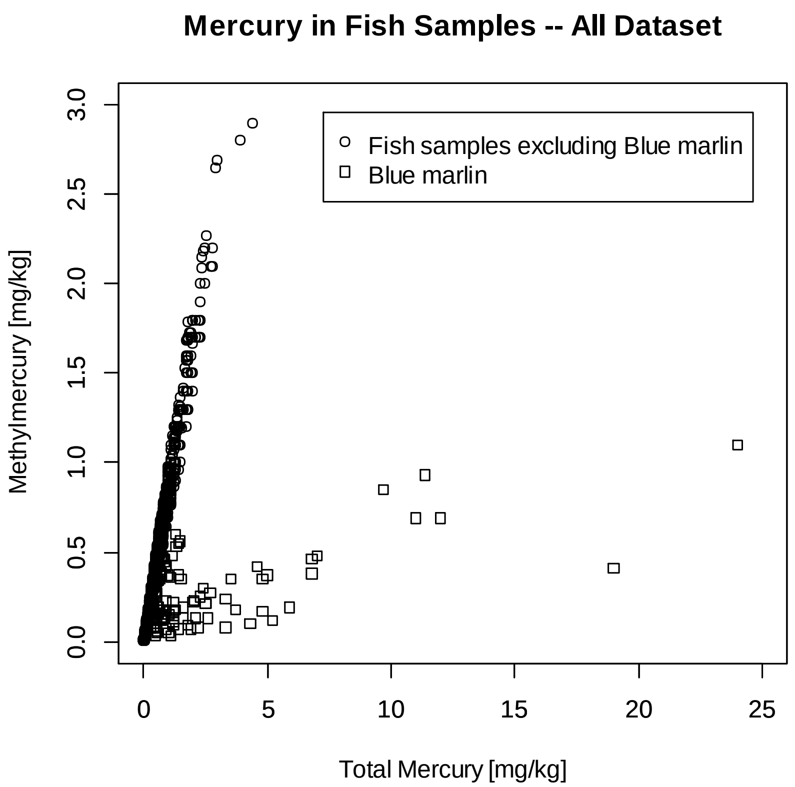

Fig. 2 (a): Concentrations of total mercury and methylmercury for all fish species

[1] This is the non-parametric counterpart to Turkey test.

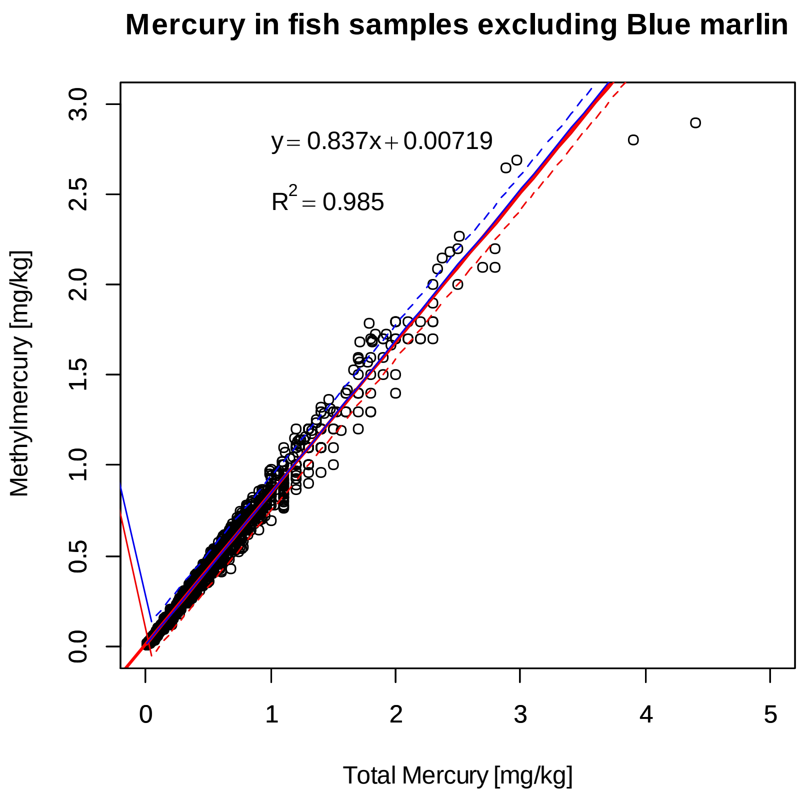

Fig. 2 (b): Concentrations of total mercury and methylmercury for all fish species excluding Blue marlin

Notes:

- The BOLD red line indicates the estimated regression line.
- The blue and red lines, which are overlapping with the bold red line, indicate the upper and lower limit of 95% confidence interval.
- The dotted blue and red lines indicate upper and lower limit of 95% prediction interval.

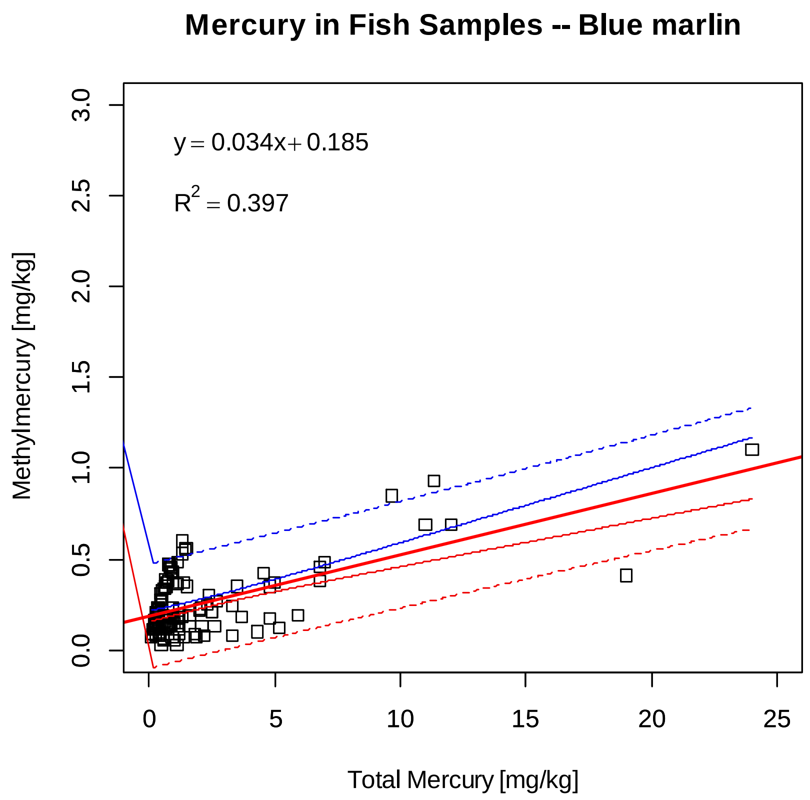

Fig. 2 (c): Concentrations of total mercury and methylmercury for Blue marlin

Notes:

- The BOLD red line indicates the estimated regression line.
- The blue and red lines indicate the upper and lower limit of 95% confidence interval.
- The dotted blue and red lines indicate upper and lower limit of 95% prediction interval.

35. According to Fig. 2 (b) and the estimated regression equation for 12 fish species except Blue marlin, the regression line can be considered to be crossing the origin. In this case, the slope of the equation represents the ratio of MeHg/ToHg. When the model is developed so that the ratio of MeHg/ToHg is maximized taking into account measurement uncertainties, the ratio can be higher than 0.837.

36. The correlations between the concentration of methylmercury and that of total mercury have also been estimated in two scientific studies (1, 2). The estimated regression coefficients in these studies were 0.922 and > 0.8 respectively. In other scientific studies, the proportions of methylmercury in total mercury have been reported to be in a range of 72% to 100% (3-7). Considering the results of analysis of occurrence data above and reports of existing scientific studies, the ratios of MeHg/ToHg might reach 100%.

37. Based on the discussion above, eWG considered the following three options on whether the GLs should be set for total mercury or methylmercury:

- **Option 1:** GLs should be set for methylmercury, and additionally, screening levels should be set for total mercury at the discretion of national authorities.

  Note: In this option, screening levels for total mercury should be set at the same level as GLs for methylmercury. If the concentration of total mercury exceeds the respective screening level, methylmercury in the sample needs to be analyzed for confirmation with the GL. For fish species with lower proportions of methylmercury in total mercury, such as Blue marlin, a different screening level may be established. However, as fillets of Blue marlin and other billfishes may be difficult to distinguish from each other, for example, it might be practical to use the same screening level.

- **Option 2:** GLs should be set for total mercury, and only total mercury should be analyzed.

Note: In this option, only GLs are necessary without need for setting screening levels. If the Committee agrees to convert the current or revised GLs for methylmercury into those for total mercury, it may be necessary to consider a more accurate conversion factor by, for example, collecting more occurrence data of both methylmercury and total mercury in each fish species including more fish species in the analysis. For fish species whose proportions of MeHg/ToHg are lower than other fish species, different conversion factors may be necessary since applying the same factor to these species would make GLs more stringent for them. It may be possible to set new GLs for total mercury using occurrence data on total mercury by applying the ALARA principle to them. In this case, however, the Committee needs to keep in mind that methylmercury is more toxic than metal mercury and that JECFA conducted the risk assessment on methylmercury. In addition, two members requested to take into account the benefits associated with fish consumption.

- **Option 3:** GLs should be set for methylmercury, and only methylmercury should be analyzed.

38. The comparison of those three options is summarized in Table 2.

39. A member requested to include Option 4 in which no GL needs to be set but consumption advice should be considered, taking into account of benefit from fish consumption. As the 7th CCCF noted that there was support for either GLs or MLs for methylmercury in fish (REP13/CF, para. 124) and therefore, proposed Option 4 is not included in this discussion paper.

Table 2: Comparison of three options for setting GLs

	Option 1	**Option 2**	**Option 3**
GLs are set for	Methylmercury	Total mercury	Methylmercury
Screening by	Total mercury	No need	No need
Simplicity of Analysis	Easy as long as the concentration of ToHg does not exceed the respective screening level	Easy	Difficult
Conversion factor to estimate MeHg concentration from that of ToHg	Necessary	Necessary if the GLs for MeHg are converted into those for ToHg	Not necessary

(2) Predatory or non-predatory

40. The current GLs do not provide a definition of predatory fish. As pointed out in the previous discussion paper (CX/CF 13/7/16 para. 55), classifying fish species into "predatory" and "non- predatory" does not necessarily reflect their methylmercury concentrations (e.g. certain non-predatory fish contain higher concentrations of methylmercury than predatory fish). A recent study shows that mercury accumulation in some marine fish could be linked not only with their positions in the food chain but also with the depth of the sea where they feed (8).

41. The eWG analyzed the occurrence data provided by members for verifying correlation between the two groups, "predatory" and "non-predatory", with the concentration of methylmercury.

42. For the purpose of this analysis, the eWG used the assumption that all of total mercury was present as methylmercury in order to use all the occurrence data of total mercury provided by members. This assumption closely reflects the real situation except in some fish species, such as Blue marlin.

43. Among the 23 species shown in para. 13, those important in international trade are 14 species: Albacore (*T. alalunga*), Bigeye tuna (*T. obesus*), Catfish (*A. felis, C. fuscus, C. fuerthii, Arius* spp.*, Hemibagrus* spp.*, Kryptoplems* spp.), Cod (*G. macrocephalus, G. morhua*), Herring (*C. harengus*), Mackerel (*S. japonicas, S. sierra, S. australasicus, S. scombrus, S. guttatus, Scomber* spp.*, Decapterus* spp.), Pollock (*T. chalcogramma, P. virens*), Salmon (*S. Salar, Oncorhynchus* spp.), Sardine (*S. bentincki, S. longiceps, S. gibbosa, S. longiceps, S. melanostictus, S. pilchardus, S. sagax, Opisthonema* spp.*, Centropomus* spp.), Skipjack tuna (*K. pelamis*), Squid (*D. gigas, I. argentines, L. gahi, Dosidicus* spp.*, Illex* spp.*, Loligo* spp.), Tilapia (*Tilapia* spp.), Whiting (*M. poutassou, M. merlangus*) and Yellowfin tuna (*T. albacares*).

44. Some of the data provided for salmon identified samples simply as salmon without reference to either Atlantic salmon or Pacific salmon. Thus, all of those data, including those specified Atlantic or Pacific, were classified as "Salmon" in this analysis. This is also the case for "Cod". For Cuttlefish, since data of Cuttlefish are limited, those data are combined with data on "Squid".

45. Besides fish species important in international trade, the eWG also analyzed additional 8 fish species with more than 120 samples analyzed: Alfonsino (*B. splendens*), Bluefin tuna (*T. thynnus*, *T. orientalis*), Blue marlin (*M. mazara*, *M. nigricans*), Halibut (*R. hippoglossoides*), Shark (*P. glauca, I. oxyrinchus, C. limbatus, P. glauca, C. leucas, M. albipinnis, R. longurio, S. lewini, A. pelagicus, D. licha, G. galeus, S. acanthias, Mustelus* spp.*, Sphyrna* spp.*, Carcharhinus* spp.), Southern bluefin tuna (*T. maccoyii*), Striped marlin (*T. audax*) and Swordfish (*X. gladius*).

46. Other fish species not listed in para. 43 or para. 45 were classified as "Others".

47. The eWG did not include European plaice and Sprat identified as being important in international trade in the analysis since the available data sets were limited.

48. The occurrence data on total mercury for each fish species are summarized in Table 3.

Table 3: Summary of the occurrence data on total mercury

Fish species	N	# of <LOQ (*)	Min (mg/kg) (*)	Max (mg/kg)	Average (mg/kg) (**)	Median (mg/kg)	90%ile (mg/kg)	95%ile (mg/kg)	97.5%ile (mg/kg)
Sardine	**258**	**199**	**< LOD**	**0.24**	**0.01**	**- (***)**	**0.03**	**0.06**	**0.07**
Salmon	**812**	**193**	**< LOD**	**0.29**	**0.02**	**0.02**	**0.04**	**0.05**	**0.06**
Squid	**175**	**113**	**< LOD**	**0.68**	**0.02**	**- (***)**	**0.07**	**0.09**	**0.12**
Tilapia	**375**	**268**	**< LOD**	**0.39**	**0.02**	**- (***)**	**0.07**	**0.11**	**0.13**
Mackerel	**2035**	**686**	**< LOD**	**17.9**	**0.05**	**0.03**	**0.07**	**0.1**	**0.13**
Herring	**1672**	**3**	**< LOQ**	**0.4**	**0.04**	**0.04**	**0.08**	**0.10**	**0.12**
Pollock	**1748**	**5**	**< LOD**	**0.66**	**0.05**	**0.04**	**0.1**	**0.12**	**0.15**
Cod	**2372**	**72**	**< LOQ**	**0.96**	**0.08**	**0.05**	**0.16**	**0.21**	**0.26**
Whiting	**25**	**2**	**< LOQ**	**0.23**	**0.11**	**0.1**	**0.15**	**- (****)**	**- (****)**
Others	2248	659	< LOD	1.91	0.10	0.05	0.24	0.34	0.48
Catfish	**152**	**89**	**< LOD**	**2**	**0.10**	**- (***)**	**0.26**	**0.38**	**0.68**
Skipjack tuna	**430**	**54**	**< LOD**	**0.49**	**0.14**	**0.13**	**0.26**	**0.31**	**0.34**
Yellowfin tuna	**1269**	**467**	**< LOD**	**1.4**	**0.14**	**0.08**	**0.35**	**0.52**	**0.68**
Halibut	1288	0	0.01	1.17	0.22	0.18	0.45	0.59	0.67
Albacore	**306**	**11**	**< LOQ**	**1.80**	**0.39**	**0.33**	**0.77**	**0.92**	**1**
Bluefin tuna	618	0	0.005	3.13	0.48	0.42	0.85	0.98	1.18
Striped marlin	121	0	0.07	1.4	0.40	0.35	0.88	0.97	1.06
Bigeye tuna	**243**	**8**	**< LOQ**	**2.30**	**0.56**	**0.43**	**1.2**	**1.3**	**1.4**
Southern Bluefin tuna	240	0	0.10	4.4	0.56	0.43	1.2	1.31	1.8
Alfonsino	123	0	0.10	2.8	0.78	0.7	1.3	1.4	1.70
Swordfish	227	2	< LOQ	3.9	1.22	1.11	2	2.41	2.71
Shark	286	0	< LOD	4.6	0.98	0.68	2.15	3.2	3.77
Blue marlin	125	0	0.01	24	2.04	0.85	4.8	6.96	11.32

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

(**)

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

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

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

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

Notes:

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

49. In order to consider whether the concentrations of total mercury are significantly different between fish species, a series of statistical analyses were conducted

50. In order to assess normality of the distributions, the Shapiro-Wilk test was performed on each fish species. All fish species data were non-normally distributed at 5% level of significance.

51. The Bartlett's test was performed to test if the variances of total mercury concentrations were equal across fish species. The variances were unequal at 5% level of significance.

52. Because the data sets of 23 species, including "Others", were evaluated to be non-normally distributed, the Kruskal-Wallis test was performed. The result showed the differences of total mercury concentrations among those fish species at 5% level of significance.

53. Finally, in order to evaluate differences between each pair of 23 fish species, a non-parametric all-pairs multiple comparison based on pairwise rankings was conducted using Steel-Dwass test. The statistical significance level was set at 5%. The following findings were obtained:

- For Sardine, Salmon, Squid, Tilapia, Mackerel, Herring, Pollock, Cod, Catfish and Others, their total mercury concentrations were significantly different from those of tuna, shark and billfish (i.e. Albacore, Bigeye tuna, Bluefin tuna, Blue marlin, Shark, Skipjack tuna, Southern bluefin tuna, Striped marlin, Swordfish and Yellowfin tuna), which are described as "Predatory fish" in the current GLs.
- For Whiting, their total mercury concentrations were not significantly different when compared with those of Yellowfin tuna and Skipjack tuna.
- For Halibut, its total mercury concentration was significantly different from those of tuna, shark and billfish.
- For Alfonsino, their total mercury concentrations were not significantly different when compared with those of Shark and Blue marlin.
- Among tuna, shark and billfish, the total mercury concentrations of Skipjack tuna and Yellowfin tuna were significantly different from those of all the other tunas, shark and billfish. Except Skipjack tuna and Yellowfin tuna, there was no other species that is significantly different from all the other tunas, shark and billfish.

54. From the findings above, assuming that all of ToHg is present as MeHg, it may be possible to classify species into "tuna, shark and billfish" and "species except tunas, billfish or sharks", as in the current GLs. For whiting, its classification should be further considered with more data. For Halibut, although its total mercury concentration was significantly different from those of "tuna, shark and billfish", it may be more appropriate to classify it together with "tuna, shark and billfish" rather than with "species except tunas, billfish orsharks", considering its ToHg concentration. For Alfonsino, it is appropriate to classify them together with "tuna, shark and billfish". Since the average of about 80% of total mercury was composed of methylmercury in most of fish species analyzed above (Table 1), the same conclusion is likely to be drawn from statistical analysis for methylmercury.

55. However, defining "tuna, shark and billfish" as "Predatory" and "species except tunas, billfish or sharks" as "Non-predatory" does not seem to be appropriate and requires further consideration. Furthermore, since total mercury concentrations of Skipjack tuna and Yellowfin tuna, whose body weights are smaller compared to other tunas, were significantly different from those of all other tuna, shark and billfish, it may be worthwhile to consider further classifying "tunas, billfish and sharks" group into two subgroups, "Skipjack tuna and Yellowfin tuna" and "other tunas, shark and billfish".

56. Another issue for consideration is whether farmed and wild-caught fish should be classified separately for the same fish species. A member pointed out that methylmercury concentrations of farmed fish are lower than those of wild-caught fish because methylmercury concentrations in farmed fish can be more easily reduced by controlling their feeds. In order to verify this, more occurrence data of MeHg and ToHg in both farmed and wild fish species are necessary. Another member suggested more consideration of setting different GLs between famed and wild-caught fish in terms of enforceability.

57. A member expressed its preference for current classification to new one. The member supports the implementation of a broad-based classification system where each country is able to develop its own list of species to which each GL could apply.

(3) GLs or MLs

58. The Codex General Standard for Contaminants and Toxins in Food and Feed (GSCTFF) defines the terms Maximum level and Guideline levels. While ML is the maximum concentration legally permitted in that commodity, GL gives government discretion; "When the GL is exceeded, governments should decide whether and under what circumstances the food should be distributed within their territory or jurisdiction." The GSCTFF also states that GL shall be reviewed with a view of conversion to ML after risk assessment by JECFA because the CAC decided that the preferred format of a Codex standard in food is an ML.

59. The 45th CCEXEC noted that the Agreement on Sanitary and Phytosanitary Measures of the World Trade Organization (WTO/SPS Agreement) does not differentiate between the terms "standards", "guidelines" or "recommendation" (ALINORM 99/3, para. 42). Therefore, there is no difference between MLs and GLs in terms of the SPS Agreement.

60. Thus, if it is agreed that regulatory limits for mercury in fish are necessary then the current GLs should be reviewed, and they should preferably be converted to MLs.

PRELIMINARY ESTIMATION OF GLs (MLs)

61. For the review of the current GLs, the eWG analyzed occurrence data on fish species important in international trade and calculated violation rates at the current GLs for each species. In this analysis, too, the eWG assumed that all of total mercury was present as methylmercury.

62. Fish species analyzed are: Albacore (*T. alalunga*), Bigeye tuna (*T. obesus*), Catfish (*A. felis, C. fuscus, C. fuerthii, Arius* spp., *Hemibagrus* spp., *Kryptoplems* spp.), Cod (*G. macrocephalus, G. morhua*), Herring (*C. harengus*), Mackerel (*S. japonicas, S. sierra, S. australasicus, S. scombrus, S. guttatus, Scomber* spp., *Decapterus* spp.), Pollock (*T. chalcogramma, P. virens*), Salmon (*S. Salar, Oncorhynchus* spp.), Sardine (*S. bentincki, S. longiceps, S. gibbosa, S. longiceps, S. melanostictus, S. pilchardus, S. sagax, Opisthonema* spp., *Centropomus* spp.), Skipjack tuna (*K. pelamis*), Squid (*D. gigas, I. argentines, L. gahi, Dosidicus* spp., *Illex* spp., *Loligo* spp.), Tilapia (*Tilapia* spp.), Whiting (*M. poutassou, M. merlangus*) and Yellowfin tuna (*T. albacares*).

63. First of all, histograms on total mercury concentrations were drawn for each fish species (Figure 3 (a)-(n)).

Histograms of total mercury concentrations in fish species important in international trade

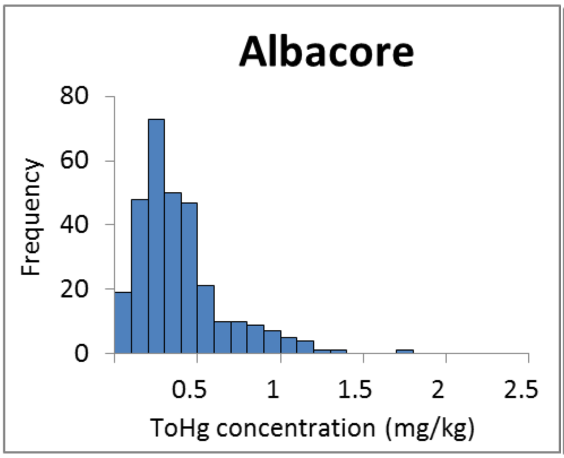

Fig. 3 (a): Albacore

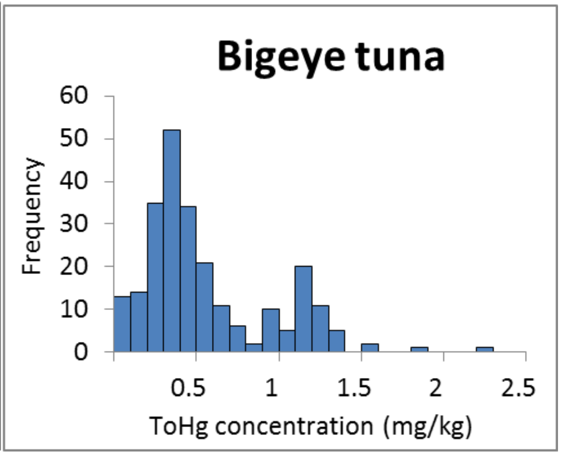

Fig. 3 (b): Bigeye tuna

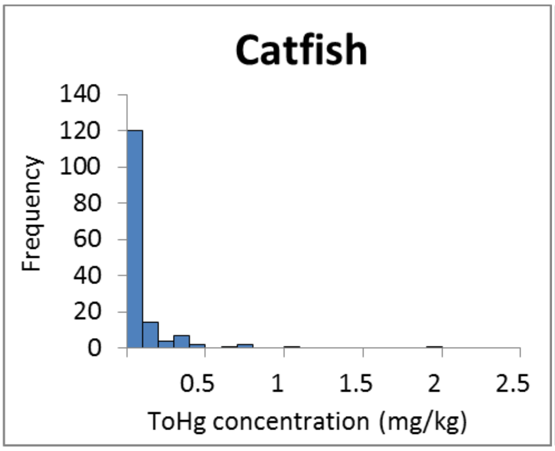

Fig. 3 (c): Catfish

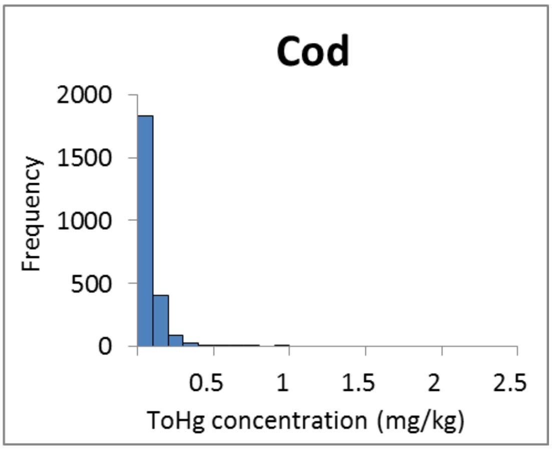

Fig. 1 (d): Cod

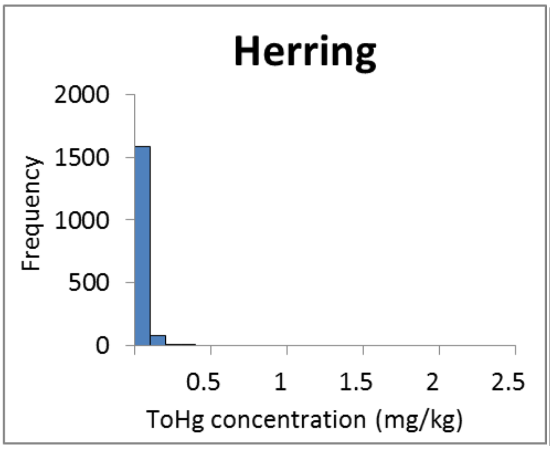

Fig. 3 (f): Herring

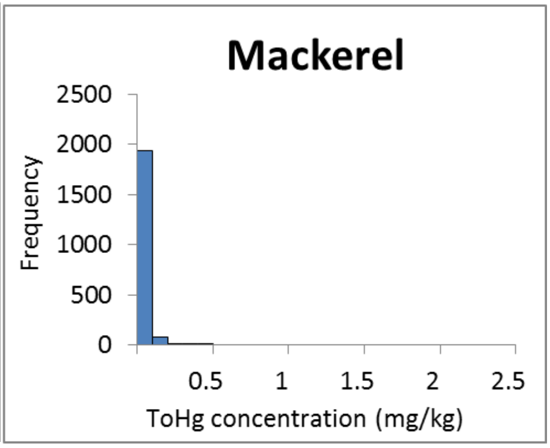

Fig. 3 (g): Mackerel

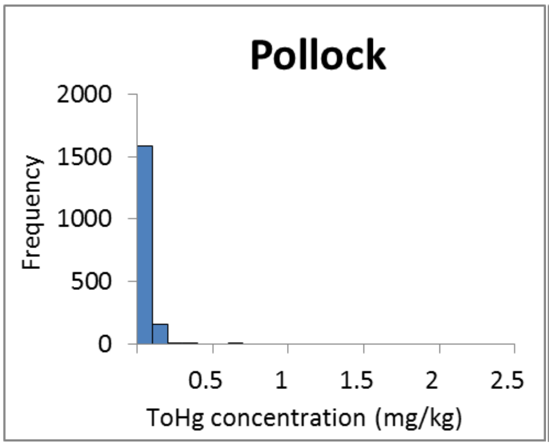

Fig. 3 (g): Pollock

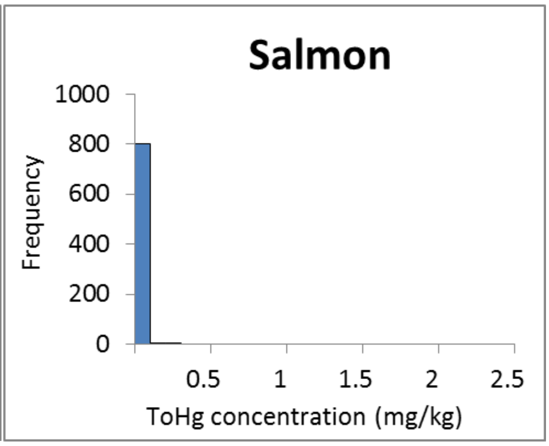

Fig. 3 (h): Salmon

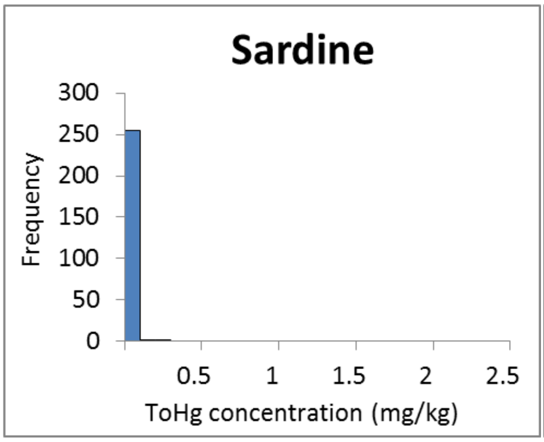

Fig. 3 (i): Sardine

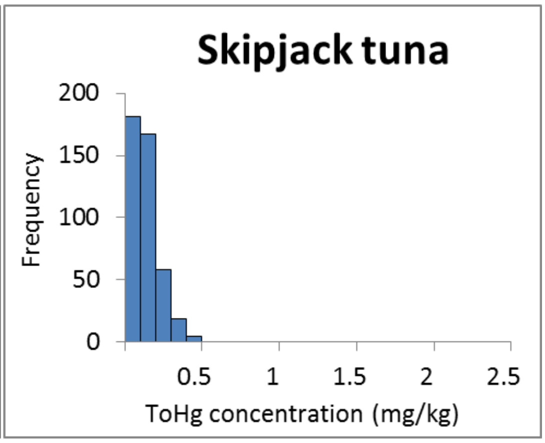

Fig. 3 (j): Skipjack tuna

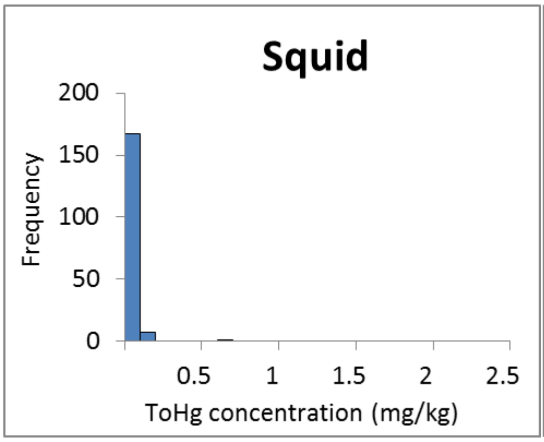

Fig. 3 (k): Squid

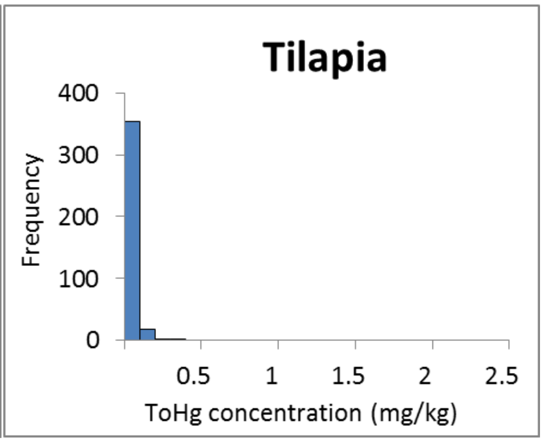

Fig. 3 (l): Tilapia

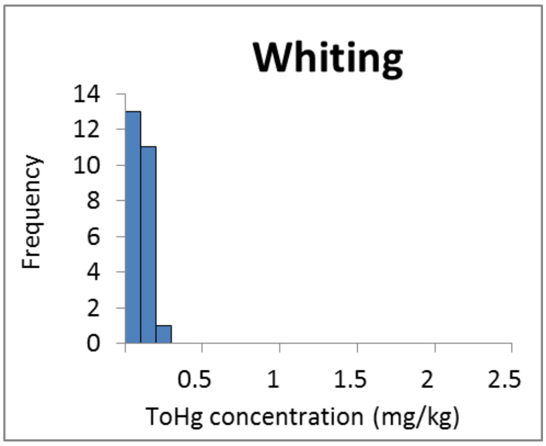

Fig. 3 (m): Whiting

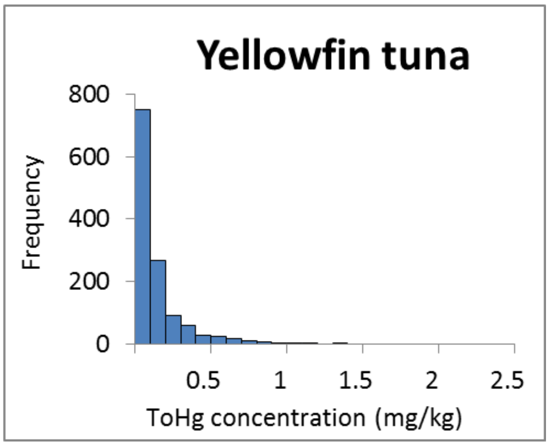

Fig. 3 (n): Yellowfin tuna

Notes:

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

64. For fish species except tuna species (i.e. Albacore, Bigeye tuna, Skipjack tuna and Yellowfin tuna), their total mercury concentrations are mostly less than 0.5 mg/kg, although a portion of Catfish samples exceeds 1 mg/kg as well as 0.5 mg/kg. Their modes are in a range of 0-0.1 mg/kg. Among tuna species, for Skipjack tuna, its total mercury concentrations were less than 0.5 mg/kg with its mode in a range of 0-0.1 mg/kg. For Yellowfin tuna, while a portion of samples exceed 1 mg/kg as well as 0.5 mg/kg, its mode was in a range of 0-0.1 mg/kg. For Albacore and Bigeye tuna, the ratios of samples that exceed 1 mg/kg are higher than those of other fish species, their modes of total mercury concentration are in ranges of 0.2-0.3 mg/kg and 0.3-0.4 mg/kg respectively.

65. For the calculation of violation rates at the current GLs, two types of probability density curves, lognormal and gamma probability density curves, were fitted using @RISK software[2]. Those two probability curves were selected as they fitted generally well to histograms of all fish species. A gamma probability density curve was fitted for all fish species except Catfish and Mackerel, and a lognormal probability density curve was fitted for all fish species except Sardine, Squid, and Tilapia (Figure 5 (a)-(k)). The histogram of Bigeye tuna shows a few different peaks (Fig. 4 (b)), which means that its samples seem to have come from multiple populations. In that case, fitting a single distribution model is not appropriate. For the purpose of the following discussions, however, the violation rates of the current GLs were obtained using the models mentioned above (Table 4 and 5).

Table 4: Violation rates of the current GLs and 97%iles calculated using gamma distribution modelling

Fish species	> 0.5 mg/kg (%)	> 1 mg/kg (%)	97%ile (mg/kg)
Albacore	27	2.8	0.98
Bigeye tuna	46	14	1.6
Cod	0	0	0.22
Pollock	0	0	0.13
Salmon	0	0	0.056
Sardine	0	0	0.12
Skipjack tuna	0.5	0	0.36
Squid	0	0	0.19
Tilapia	0	0	0.19
Whiting	0	0	0.20
Yellowfin tuna	2.8	0.1	0.49

Table 5: Violation rates of the current GLs and 97%iles calculated using lognormal distribution modelling

Fish species	> 0.5 mg/kg (%)	> 1 mg/kg (%)	97%ile (mg/kg)
Albacore	26	5.6	1.2
Bigeye tuna	42	18	2.5
Catfish	1.5	0.3	0.35
Cod	0.3	0	0.25
Herring	0	0	0.11
Mackerel	0.1	0	0.15
Pollock	0	0	0.14
Salmon	0	0	0.057
Skipjack tuna	2.8	0.3	0.49
Whiting	0	0	0.22
Yellowfin tuna	4.0	0.7	0.57

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66. The violation rates and 97%iles calculated using a lognormal distribution model are generally higher than those calculated using a gamma distribution model as expected. In this paper, the values calculated using a lognormal probability density curve were used for the following discussion.

67. Table 5 shows that for all tuna species (Albacore, Bigeye tuna, Skipjack tuna and Yellowfin tuna), a portion of their samples exceed the current GL of 1 mg/kg as well as that of 0.5 mg/kg though the violation rates differ largely among them. For other fish species, their violation rates are mostly less than 1% with respect to the GLs of both 1 and 0.5 mg/kg except Catfish. Even for Catfish, its 97.5%ile is below 0.5 mg/kg. Although the violation rate of Sardine, Squid and Tilapia were not calculated, considering their proportions of < LOQ are more than 60%, their violation rates should also be less than 1%. Consequently, based on the violation rates of the GLs, it is possible to classify fish species important in international trade into two categories, "tuna, shark and billfish" and "species except tuna, shark or billfish", as discussed in the Section (2) (paras. 43 – 69) on "Predatory or non-predatory".

68. The current GLs were then reviewed. With regards to the GL of 0.5 mg/kg, it should be noted that for fish species, except tuna species, their violation rates at 0.5 mg/kg are mostly less than 1% except for Catfish.

69. For the review of the GL of 1 mg/kg, violation rates of "tuna" were considered. Among the "tuna" species, the violation rates of Albacore and Bigeye are relatively high at 5.6% and 18% respectively. This shows that the GL needs to be reviewed against occurrence data.

70. For the **preliminary** estimation of the GL for Albacore and Bigeye by applying the ALARA principle, the values of 97%ile for the tunas were calculated as shown in Table5. For this discussion paper, a revised GL was tentatively proposed at 2 mg/kg. Assuming that samples of > 2 mg/kg are eliminated, the average of total mercury concentrations were calculated for those two species using a distribution model: 0.40 mg/kg for Albacore and 0.55 mg/kg for Bigeye tuna.

71. The world average of seafood consumption in 2009 is 18.5 kg/capita/year (0.354 kg/capita/week) ("FAO Food Balance Sheet" database). Using the calculated averages for Albacore and Bigeye tuna (see para. 70) and assuming that Albacore or Bigeye tuna is the only seafood consumed, the weekly intake of total mercury will be 140 µg/capita/week for Albacore and 190 µg/capita/week for Bigeye tuna. As the ratios of methylmercury in total mercury in those species are higher than 70% (Fig. 1 (a) and (b)), these intakes exceed the PTWI for methylmercury (96 µg/capita = 1.6 (µg/kg bw) x 60 (kg)).

72. However, it is unrealistic to assume that either Albacore or Bigeye tuna is the sole seafood consumed. The intake of methylmercury from other food categories should also be considered. For the risk management of methylmercury, detailed consumption data of not only seafood as a whole but of individual seafood and other food categories are indispensable. When considering appropriate consumption levels, and also for the setting of GLs, it is also important to take the benefit of fish consumption into consideration.

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APPENDIX III

Summary of discussion about establishment of the current guideline levels for methylmercury in fish in fish and predatory fish

Year	Committee	Summary of discussion
1984	CCFAC17	The committee noted that many countries had established different maximum permitted levels for mercury in fish. It was also pointed out that mercury in fish created problems in international trade and might also create a health problem.
1985	CCFAC18	The committee agreed that limits should refer to total mercury (ToHg rather than methylmercury (MeHg), especially since ToHg was easier to measure analytically. 0.5 mg/kg was considered as appropriate limit based on the available data. However, it was recognized that more data collection was necessary. The committee agreed that it was not yet appropriate to establish levels for mercury but first more data should be collected.
1987	CCFAC19	Reviewing mercury levels, exposure, methods of computing dietary intakes of mercury and a summary of data received from Codex Contact Points, the committee noted that approximately 97% of the mean level of mercury reported in a variety of fish and shellfish were at or below 0.5 mg/kg; and 99% of the values were at or below 1.0 mg/kg. The committee agreed to establish guideline level (GL) rather than mandatory maximum level (ML), noting that the CCFFP commented there was no need to set maximum levels. The committee adopted 0.5 mg/kg in fish as the guideline levels for ToHg except predatory fish, such as shark, swordfish, tuna, and pike. 1 mg/kg was applied to such predatory fish.
	CAC17	Upon request from the CCFAC, the Commission agreed that submission the proposed guideline levels at Step 3 be postponed until the new JECFA evaluation on mercury was available.
1988	CCFFP18	The Committee reaffirmed its earlier view that establishment of GLs for mercury in fish did not seem to be the most appropriate way to protect consumers and that current fisheries management was being applied in effective manner. However, if GLs for mercury were to be established, they should be for MeHg not for ToHg.
	CCEXEC35	The committee agreed that work on GLs should be continued, and that GLs should be elaborated for MeHg, rather than for ToHg in fish, noting that JECFA recommended that efforts should continue to minimize human exposure to MeHg.
1989	CCFAC21	The Committee proposed 0.5 mg/kg MeHg for fish in general and 1.0 mg/kg MeHg for predatory fish (i.e. same as proposed level for ToHg at CCFAC19) because most of mercury in fish was present in the organic form.
1990	CCFAC22	While it was pointed out that two different MLs for various fish species could lead to technical barriers to trade, the Committee decided that two GLs for MeHg in fish and predatory fish could be advanced for adoption by the CAC. The CCFFP's advice was sought in terms of practicability of the GLs.
	CCFFP19	The committee agreed to oppose the GLs because more work was necessary to determine those fish for which the different levels should be applied.
1991	CCFAC23	The Committee agreed on the 0.5 mg/kg MeHg for fish in general and 1.0 mg/kg MeHg for predatory fish (e.g. sharks, swordfish, tuna and pike), and seeking more information about another predatory fish which were creating problems in international trade.
	CAC19	The Committee adopted the two GLs for MeHg in fish with the understanding that the GL would be kept under review by the CCFAC and CCFFP, especially as to the identification of predatory species of fish to which the higher GL applied.

Year	Committee	Summary of discussion
1992	CCFAC24	The Committee agreed to inform the Commission and CCFFP that the GLs adopted at Step 8 referred to ToHg rather than MeHg, that is, 0.5 mg/kg (fish) and 1 mg/kg (predatory) for ToHg, not MeHg.
1993	CAC20	The Commission decided to maintain the current GLs for MeHg in fish as previously adopted, while recommending that the establishment of corresponding GLs for ToHg in fish be considered by the CCFAC26.
1994	CCFAC26	The Committee noted that an analysis for ToHg would generally be adequate to ensure that the levels for MeHg were not exceeded (i.e. total mercury is approximately 90% MeHg). An analysis of MeHg would only be required in those cases where a measurement of ToHg exceeded the MeHg GL level of 1 mg/kg (predatory) and 0.5 mg/kg (others). Therefore, it was decided that the establishment of guideline levels for ToHg in fish was not necessary.
1996	CCFFP22	The committee decided to compile a list of fish families containing naturally high level of MeHg for circulation at Step3. The Committee also agreed that the CCEXEC, the Commission and the CCFAC should be informed of its conclusion and of the difficulties identified in the development of a list.
	CCEXEC43	The Committee recommended that a new risk analysis be undertaken, including an evaluation of newly available safety information, with consideration being given to the establishment of new risk management options as part of the Codex Guideline, particularly action relevant to the current Guideline. The Committee asked the CCFAC to initiate the necessary work.
1997	CCFAC29	The Committee agreed to defer any decision on this matter until JECFA had performed the appropriate risk assessment.
2005	CCFAC37	The Committee agreed that the revision of the GLs requires more comprehensive consideration by CCFAC in order to take into account all factors related to the consumption of fish, in particular, risks and benefits.
2006	JECFA67	The Committee confirmed the PTWI of 1.6 µg/kg bw. However, the Committee considered that intakes of up to about two times higer 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. The Committee recommended that setting of GLs for MeHg in fish may not be an effective way of reducing exposure for the general population, however, advice to population subgroups that may be at risk may provide an effective method for lowering the number of individuals with exposures greater than the PTWI.
	CCFAC38	The Committee agreed to forward a request to the CAC for an FAO/WHO expert consultation on health risks associated with MeHg in fish and health benefits of fish consumption. The Committee also agreed to postpone consideration on the need to revise the GLs for MeHg in fish pending the outcome of the requested FAO/WHO consultation.
2007	CCCF1	The Committee was informed by WHO representative that JECFA's conclusion with respect to GLs must be considered in relation to the fact that GLs already place in some national jurisdictions had already influenced the range of observed mercury concentrations by eliminating fish containing high concentrations of mercury form the market.
2011	CCCF5	The Committee agreed to consider the need to review the existing GLs for MeHg in fish and predatory fish when the full report of the Joint FAO/WHO Expert consultation.

APPENDIX IV

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