CODEX ALIMENTARIUS COMMISSION E

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World Health Organization

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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON CONTAMINANTS IN FOODS

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

Codex members and Observers are invited to consider the discussion (paragraphs 74-83) and in particular the recommendations (paragraphs 81-83) in order to assist the Committee on how to proceed further with the review of the Guideline Levels for Methylmercury in Fish and Predatory Fish in the General Standard for Contaminants and Toxins in Food and Feed (GSCTFF).

BACKGROUND

1. The 38th session of the Committee on Food Additives and Contaminants (CCFAC)[1] requested the 29th session of the Codex Alimentarius Commission (CAC)[2] in 2006 to seek scientific advice from the Food and Agriculture Organization of the United Nations (FAO) and the World Health Organization (WHO) on the risks and benefits of fish consumption (1): specifically, advice on the nutritional health benefits compared to the risks of consuming fish that may be contaminated with methylmercury and dioxins[3]. The report from the Joint FAO/WHO Expert Consultation on the Risks and Benefits of Fish Consumption was published in 2011 and is available at the following URL: http://www.who.int/foodsafety/chem/meetings/jan2010/en/index.html.

2. As a follow up to the Expert Consultation, the 6th session of the Committee on Contaminants in Food (CCCF) agreed to the development of a discussion paper on the review of the guideline levels (GLs) for methylmercury in fish and predatory fish through an electronic Working Group led by Norway and co-chaired by Japan for consideration and discussion at the 7th session of the CCCF in 2013 with a view to identifying possible actions or new work on this issue.[4]

3. The electronic Working Group addressed the following issues in the discussion paper for consideration at the 7th CCCF Session:

- Whether a review of the guideline levels for methylmercury in fish and predatory fish is required;
- Appropriate analytical methods for checking compliance with Codex GLs (GLs for methylmercury vs for total mercury);
- Definition of predatory fish;
- What other risk management options have been implemented by Codex members to address the risk and benefits from fish consumption (including regulatory and non-regulatory options).

4. The electronic Working Group members have been the following: Argentina, Australia, Brazil, Canada, China, Colombia, IACFO, Japan, Norway, Oman, Spain, United Kingdom and the United States of America (See Appendix).

INTRODUCTION

5. Fish is an integral component of a balanced diet, providing a healthy source of dietary protein and nutrients such as LCn3PUFAs. There is evidence of beneficial effects of fish consumption. In contrast, fish can also contribute significantly to the dietary exposure to certain chemical contaminants under some circumstances. The health benefits and risks are likely to vary according to the fish species, fish size, harvesting, and cultivation practices, as well as the amount consumed and the way in which it is served. There are a number of potential contaminants of concern in fish; methylmercury is the subject of this discussion paper.

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[1] ALINORM 06/29/12, paras. 191-193.
[2] ALINORM 06/29/41, para. 195.
[3] Dioxins include polychlorinated dibenzo-p-dioxins [PCDDs] and polychlorinated dibenzofurans [PCDFs] as well as dioxin-like polychlorinated biphenyls [PCBs]).
[4] REP12/CF, paras. 45, 174.

6. In January 2010, the FAO and WHO held an Expert Consultation on the Risks and Benefits of Fish Consumption on the background of growing public concern regarding the presence of specific chemical contaminants in fish, while at the same time multiple nutritional benefits of including fish in the diet have become increasingly apparent. This situation has led to confusion and questions about how much fish should be consumed, and by what populations, in order to minimize the health risks of contaminants that may be present in fish, yet maximize the health benefits of fish consumption. National authorities have been faced with the challenge of communicating the risks and benefits of fish to consumers and also with questions on whether maximum levels are the appropriate risk management tools for specific chemical contaminants in fish and other foods.

7. Seventeen experts in nutrition, toxicology, epidemiology, dietary exposure and risk-benefit assessment attended the Expert Consultation. Their tasks were to review data on levels of nutrients (long-chain omega-3 fatty acids) and specific chemical contaminants (methylmercury and dioxins) in a range of fish species, as well as recent scientific literature covering the risks and benefits of fish consumption. The review was used to consider risk-benefit assessments for specific end-points.

8. Based on the strength of the evidence, the Expert Consultation examined the benefits of fish consumption for optimal neurodevelopment and prevention of cardiovascular disease. The Expert Consultation also examined the risks to fish consumers of ingesting methylmercury and dioxins.

9. Codex GLs for methylmercury are set at 1 mg/kg for predatory fish and 0.5 mg/kg for all other fish. In view of the recommendations from the Expert Consultation, it seems necessary to review these levels and other risk management measures and options available to the Codex Alimentarius.

TOXICOLOGY METHYLMERCURY

10. Methylmercury is toxic, particularly to the nervous system. The Joint FAO/WHO Committee on Food Additives (JECFA) (2) concluded that methylmercury can induce toxic effects in several organ systems and that neurotoxicity is the most sensitive endpoint. The developing brain is thought to be the most sensitive target organ. High methylmercury intake by pregnant women has been linked to adverse effects in neurological developmental in children. In utero exposure is believed to be the critical period for methylmercury neurodevelopmental toxicity. However, the duration of increased susceptibility may extend into postnatal development (3), for example during the first few years of life when the brain is developing and growing rapidly.

11. The 67th JECFA meeting in 2006 confirmed the provisional tolerable weekly intake (PTWI) of 1.6 µg/kg bw, set in 2003, based on the most sensitive toxicological end-point (developmental neurotoxicity) in the most susceptible species (humans) (4). However, the Committee noted that life-stages other than the embryo and fetus may be less sensitive to the adverse effects of methylmercury.

12. The Joint FAO/WHO Expert Consultation on the risks and benefits of fish consumption concluded that:

- There is convincing evidence of adverse neurological/neurodevelopmental outcomes in infants and young children associated with methylmercury exposure during fetal development due to maternal fish consumption during pregnancy;
- In addition, there is possible evidence for cardiovascular harm and for other adverse effects (e.g. immunological and reproductive effects) associated with methylmercury exposure.

13. In addition to the JECFA risk assessment, it is prudent also to consider the conclusions of relevant risk assessments conducted elsewhere. For example, a previous evaluation by the United States (US) National Research Council (NRC) in 2000 recommended an upper intake limit of 0.7 µg/kg bw per week (5), which is lower than that of JECFA.

14. In the European Union, the European Food Safety Authority (EFSA) very recently (December 2012) considered new developments regarding inorganic mercury and methylmercury toxicity and evaluated whether the JECFA provisional tolerable weekly intakes for methylmercury of 1.6 µg/kg bw and of 4 µg/kg bw for inorganic mercury were still appropriate (6). In line with JECFA, the CONTAM Panel established a tolerable weekly intake (TWI) for inorganic mercury of 4 µg/kg bw, expressed as mercury. For methylmercury, new developments in epidemiological studies from the Seychelles Child Developmental Study Nutrition Cohort have indicated that n-3 long-chain polyunsaturated fatty acids in fish may counteract negative effects from methylmercury exposure. Together with the information that beneficial nutrients in fish may have confounded previous adverse outcomes in child cohort studies from the Faroe Islands, the Panel established a TWI for methylmercury of 1.3 µg/kg bw, expressed as mercury.

OCCURRENCE IN FISH

15. Mercury occurs in the environment from natural sources, but also as a result of atmospheric deposition and pollution from man's activities. It accumulates in the aquatic food chain, including in fish and seafood, largely as methylmercury, which is the form of toxicological concern. Methylmercury accumulates more in some types of fish than others. Key factors include the age, size, natural environment and food sources. Fish that are more likely to accumulate higher levels of methylmercury are larger, longer living and predatory species.

16. Examples of varieties found to contain high levels include shark (all species), swordfish/broadbill (*Xiphias gladus*), marlin (*Makaira* species, *Tetrapturus* species) and orange roughy (*Hoplostethus atlanticus*). Some species of tuna can also contain high levels, such as big eye (*Thunnus obesus*), blue fin (*Thunnus thynnus*) and albacore tuna (*Thunnus alalunga*), although the average concentrations tend to be significantly lower than in the fish varieties listed above. Pike (*Esox lucius*), tilefish (*Caulolatilus princes*) and king mackerel (*Scomberomous cavalla*) from certain geographic locations can also contain relatively high levels of mercury. Mercury levels in canned tuna are often lower than in fresh tuna, largely due to the species or because smaller-sized fish are used. Skipjack tuna (*Katsuwonus pelamis*) is often canned and this variety tends to contain lower levels of mercury. However, species with higher levels may also be canned, such as albacore tuna (*Thunnus alalunga*) known as canned 'white' tuna in some countries including the US).

17. Available data collected on mercury in fish are largely for total mercury rather than methylmercury. In most fish, methylmercury can contribute more than 90% of the total mercury content; hence total mercury is generally a good indicator of methylmercury exposure. In this paper unless otherwise defined a reference to mercury means total mercury.

18. Using available data the Expert Consultation analyzed the composition of fish by developing a matrix comparing the levels of the LCn3PUFAs DHA and EPA with levels of total mercury.

19. A significant correlation was found between the fat and EPA plus DHA concentrations.

20. No significant correlation was found between the mercury content and content of another compound.

21. A compiled data set created by the Expert Consultation in 2010, including the arithmetic mean content of total fat, EPA plus DHA and total mercury for 103 fish species, can be found in Appendix A of the report of the Expert Consultation[5], while it should be noted that, as the Expert Consultation pointed out, evaluation of the analytical quality of the samples is not possible in terms of analytical methods.

EXPOSURE

22. The 67th JECFA reported intake estimates close to and sometimes exceeding the PTWI of 1.6 µg/kg body weight (4). Values ranged from 0.3 to 1.5 µg/kg body weight per week for the five regional GEMS/Food diets and from 0.1 to 2.0 µg/kg body weight per week for numerous nationally-reported diets.

23. In general, consumers who eat average amounts of varied fishery products are not likely to be exposed to unsafe levels of methylmercury. However, people who eat appreciably more than average amounts of certain types of fish are more likely to exceed the recommended safety thresholds. Mercury toxicity in high consumers has been reported (7). In particular, based upon monitoring data, population groups who frequently consume top predatory fish, such as shark, swordfish and some species of tuna, may have a considerably higher intake of methylmercury and exceed the PTWI.

24. The Expert Consultation in its risk-benefit estimations uses one, two, three or seven servings of fish per week, typical concentrations of EPA plus DHA in different fish species and existing health based guideline levels for methylmercury, and assumes a serving size of 100 grams.

25. The recent EFSA opinion concluded that the mean dietary exposure across age groups in Europe does not exceed the (new) TWI for methylmercury, with the exception of toddlers and other children in some surveys. The 95th percentile dietary exposure is close to or above the TWI for all age groups. High fish consumers, which might include pregnant women, may exceed the TWI by up to approximately six-fold. Unborn children constitute the most vulnerable group. Biomonitoring data from blood and hair indicate that methylmercury exposure is generally below the TWI in Europe, but higher levels are also observed. Exposure to methylmercury above the TWI is of concern. If measures to reduce methylmercury exposure are considered, the potential beneficial effects of fish consumption should also be taken into account.

26. In Australia, in 2011, the most recent dietary exposure estimates indicate that dietary exposures to methylmercury are below the PTWI of 1.6 µg/kg bw for all age groups at the 90th percentile, and consequently within acceptable safety standards. The highest level of exposure was for 2-5 year olds at 80% of the PTWI, because of their high food consumption relative to body weight. Due to the potential adverse effects of methylmercury on vulnerable population groups, such as pregnant women and young children, methylmercury will continue to be monitored in future studies.S eafoods were major sources of methylmercury exposure for all age groups. Fish (uncrumbed/unbattered or canned) contributed 42-53% of total methylmercury exposure in children 12 years and younger. Battered seafood contributed 41-44% of total methylmercury exposure for those aged 13 years and over.

27. In Japan, the results of a total diet study for mercury under the normal dietary conditions showed an estimated average daily intake of total mercury to be 8.17 µg/person from 1999 to 2008. This value is below the re-evaluated PTWI of JECFA.

28. In China, the results from 2007 total diet study for total mercury and methylmercury under the normal dietary conditions showed an estimated average of 0.068 µg/kg bw weekly and 0.041 µg/kg bw weekly, respectively, which are far below the corresponding provisional tolerable weekly intake (PTWI).

[5] See http://www.who.int/foodsafety/chem/meetings/jan2010/en/index.html

ANALYTICAL METHODS

29. The review of the GLs for methylmercury in fish should be based on scientifically sound occurrence data obtained using analytical methods validated in accordance with the internationally harmonized protocols[6].

30. In determining total mercury in fish, cold vapor flameless atomic absorption spectrophotometery (CV-AAS) methods and rapid methods with direct mercury analyzers (an automated AAS which can determine total mercury in a test portion without any chemical pretreatment) are usually used. In CV-AAS methods, all chemical forms of mercury are converted into mercury(II) ion by digestion of a test portion (fish sample) with such mineral acid as nitric acid or sulfuric acid, and sometimes with additional oxidizing reagent. Mercury(II) ion is then reduced to elemental mercury by addition of reducing reagent such as tin(II) chloride. The elemental mercury vapor at room temperature is introduced into an absorption cell and the absorption at 253.7 nm is measured for determination. In Codex, AOAC 977.15, CV-AAS method, has been endorsed as a Type III method for the determination of total mercury in fish and fishery products (CODEX STAN 234-1999). Other CV-AAS methods, such as AOAC 971.21, and AOAC 974.14, are available.

40. Analytical methods for methylmercury in fish involve the extraction of methylmercury. Two types of extraction, hydrochloric acid leaching extraction and dithizone (diphenylthiocarbazone) extraction, have been widely used. In the hydrochloric acid leaching extraction, methylmercury in a test portion is extracted with organic solvent such as benzene or toluene, followed by acidification to its halide, back-extraction into an aqueous solution of cysteine or glutathione, and re-extraction into an organic solvent. If necessary, the organic extract is dehydrated by addition of disodium sulfonate anhydride. In the dithizone extraction, a test portion is decomposed under alkaline conditions and methylmercury is extracted with a dithizone-toluene solution as its dithizonate, followed by back-extraction into alkaline sodium sulfide and dithizone re-extraction. Recently, extraction without using benzene or toluene is also used: methylmercury in a test portion is extracted with an aqueous solution of cysteine and HCl, or of cysteine, HCl and mercaptoethanol, without subsequent extraction with organic solvents. The aqueous extract is then injected into a gas chromatograph (GC) or liquid chromatograph (LC) for separation and methylmercury is detected by electron capture detector (ECD), atomic fluorescence spectrophotometers (AFS), inductively coupled plasma-mass spectrometry (ICP-MS), or any other appropriate detector. The methylmercury concentration in a test portion is determined by comparing the average peak heights of test solution to those of standard solutions.

41. Analytical methods available for determining methylmercury in biological and environmental samples have been extensively reviewed in several articles (8, 9). In 2005, more than ten analytical methods, which were state-of-the-art at that time, were compared within the framework of the International Committee for Weights and Measures (CIPM) Pilot Study organized by the Institute for Reference Materials and Measurements (IRMM) (10). Additionally, the IRMM is currently undertaking the inter-laboratory comparison for the validation (collaborative trial) of a method for the determination of methylmercury in seafood[7]. This method employs a double liquid-liquid extraction, first with an organic solvent and second with a cysteine solution, and the quantification with a direct mercury analyzer. The National Institute of Nutrition and Seafood Research of Norway is also undertaking a collaborative trial of a method for the determination of methylmercury in seafood using GC-ICP-MS, joined by 11 laboratories in Europe. The trial is expected to complete by the end of 2012, and the result would be available in 2013.

42. In Codex, AOAC 988.11 has been endorsed as the Type II method for the determination of methylmercury in fish (CODEX STAN 234-1999). Other internationally validated analytical methods, such as AOAC 990.04, are also applicable to fish and fishery products. Table X provides the summary of the principles and performance characteristics of these methods.

43. At the national level, various analytical methods are also used for routine food control or monitoring purposes (See Table XX).

44. In reviewing the guideline levels for methylmercury in fish and predatory fish, appropriate analytical methods for regulatory purposes should also be considered. As seen above, there are currently many, potentially newer, analytical methods used by Codex Members for the determination of methylmercury in fish, in addition to internationally validated methods. As science develops rapidly in the area of analytical methods including those for the determination of methylmercury in fish, an established list of specific methods may become out of date in the near future. Under these circumstances, using the criteria approach is recommended for consideration in accordance with the Codex general method principles and performance criteria (General Criteria)[8] rather than prescribing specific analytical methods.

SUMMARY OF OUTCOME OF THE JOINT FAO/WHO EXPERT CONSULTATION ON THE RISKS AND BENEFITS OF FISH CONSUMPTION

45. The Joint FAO/WHO Expert Consultation on the Risks and Benefits of Fish Consumption (25 to 29 January 2010) was convened to review data on levels of nutrients, methylmercury and dioxin in fish, and epidemiological data, and to carry out risk-benefit assessments on fish consumption.

46. The Expert Consultation reached several conclusions on risks associated with exposure to methylmercury in fish, such as:

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[6] CAC/GL 28-1995 recommends to use the following Protocol for quality assurance of food control laboratories: "Protocol for the Design, Conduct and Interpretation of Method Performance Studies", *Pure & Appl. Chem.*, 65 (1995) 2132-2144 and *J. AOAC International*, 76 (1993) 926-940.

[7] The IRMM website: http://irmm.jrc.ec.europa.eu/EURLs/EURL_heavy_metals/interlaboratory_comparisons/Pages/IMEP-115Determinationofmethylmercuryinseafood.aspx

[8] The Principles for the Establishment of Codex Methods of Analysis section in the Codex Alimentarius Commission PROCEDURAL MANUAL, 20th ed. Document.

- there is convincing evidence of adverse neurological/neurodevelopmental outcomes in infants and young children associated with exposure during fetal development due to maternal fish consumption during pregnancy; and there is possible evidence for cardiovascular harm and for other adverse effects (e.g. immunological and reproductive effects).

47. The Expert Consultation pointed out, as for benefit of fish consumption, that:

- it leads to valuable health benefits such as the reduction of mortality from cardiovascular diseases and the improvement of neurodevelopment in infants and young children if a mother eats fish before and during pregnancy (convincing evidence);
- long-chain n-3 polyunsaturated fatty acids (LCn3PUFA) are most likely to be a main contributor for the health benefits:
- there is convincing evidence for the benefits of LCn3PUFA intake on reduction of coronary heart disease mortality;
- there is convincing evidence for the benefits of maternal DHA (as a representative LCn3PUFA) consumption during gestation on neurodevelopment in their children: a maximum IQ increase of 5.8 IQ point was observed;
- other nutrients, such as protein, selenium, iodine, vitamin D, choline and taurine, may also contribute to health benefits; and
- fish is a very important protein source in some countries, and eating fish is cultural tradition for many people.

48. In summary, the Expert Consultation concluded that:

- Consumption of fish provides energy, protein and a range of essential nutrients;
- Eating fish is part of the cultural traditions of many peoples. In some populations, fish is a major source of food and essential nutrients;
- Among the general adult population, consumption of fish, particularly fatty fish, lowers the risk of coronary heart disease mortality. There is an absence of probable or convincing evidence of coronary heart disease risks of methylmercury. Potential cancer risks of dioxins are well below established coronary heart disease benefits;
- Among women of childbearing age, pregnant women and nursing mothers, considering benefits of DHA versus risks of methylmercury, fish consumption lowers the risk of suboptimal neurodevelopment in their offspring compared with not eating fish in most circumstances evaluated;
- At levels of maternal dioxin exposure (from fish and other dietary sources) that do not exceed the PTMI, neurodevelopmental risk is negligible. At levels of maternal dioxin exposure (from fish and other dietary sources) that exceed the PTMI, neurodevelopmental risk may no longer be negligible;
- Among infants, young children and adolescents, evidence is insufficient to derive a quantitative framework of health risks and benefits. However, healthy dietary patterns that include fish consumption and are established early in life influence dietary habits and health during adult life.

49. Based on the conclusions above, the Consultation recommended that the members should:

- acknowledge fish as an important food source of energy, protein and a range of essential nutrients and fish consumption as part of the cultural traditions of many people;
- emphasize the benefits of fish consumption on reducing coronary heart disease mortality (and the risks of mortality from coronary heart disease associated with not eating fish) for the general adult population;
- emphasize the net neurodevelopmental benefits to offspring of fish consumption by women of childbearing age, particularly pregnant women and nursing mothers, and the neurodevelopmental risks of not consuming fish to offspring of such women;
- develop, maintain and improve existing databases on specific nutrients and contaminants, particularly methylmercury and dioxins, in fish consumed in their region; and
- develop and evaluate risk management and communication strategies that both minimize risks and maximize benefits from eating fish.

RISK MANAGEMENT OPTIONS TO LOWER THE RISK AND MAXIMIZE THE BENEFIT FROM FISH CONSUMPTION

50. The Joint FAO/WHO Expert Consultation on the Risks and Benefits of Fish Consumption concluded that there are both risks and benefits in consuming fish. In order to lower the risk and maximize the benefit from fish consumption, Members of Codex have implemented risk management measures of setting maximum levels for methylmercury or total mercury and/or giving advice on fish consumption to consumers (See Table Y).

A) Maximum levels/Guideline levels

51. The current GLs for methylmercury are 1 mg/kg for predatory fish and 0.5 mg/kg for other fish species (CODEX STAN 193-1995: GSCTFF). The purpose of the GSCTFF is to provide guidance about possible approaches to eliminate or reduce the contamination problem and to promote international harmonization through recommendations which in turn may prevent trade barriers and disputes. In line with this, the current GLs for methylmercury were developed. There has been no clear definition for predatory fish although some attempts have been made.[9]

52. On the other hand, the 67th JECFA concluded that setting of GLs for methylmercury in fish may not be an effective way of reducing exposure for the general population. Rather, it noted that consumer advice targeted to specific populations vulnerable to methylmercury may be a more effective way to lower dietary exposures that may be exceeding the PTWI.

53. Also the following two issues need to be considered by the CCCF: definition of predatory fish and appropriate analyte (methylmercury vs. total mercury). These issues have been discussed at the past CCFAC and CCFFP (Committee on Fish and Fishery Products).

Definition of predatory fish

54. Although Codex has established different GLs for predatory and other fish species, there has not been any definition of "predatory fish." Shark, swordfish, tuna, and pike are listed as examples. One may say that in order to avoid possible trade conflicts among Members, it is desirable to develop a clear definition for "predatory fish".

55. However, Members need to reconsider whether dividing fish species into "predatory" and "not predatory" with different GLs is really meaningful and scientifically valid. According to Table 3 developed by the Expert Consultation, fish with high levels of methylmercury, such as orange roughy and alfonsino, are not necessarily located at the higher level of the food chain. Classifying fish species into the "predatory" and "not predatory" does not necessarily provide proper indication of their methylmercury levels and may be misleading in some cases. In reviewing the GLs for the two different categories, consideration should be given to the distribution of actual concentrations of methylmercury in these species rather than whether a fish species is predatory or not. In this sense, the first step to proceed is to compile detailed data of methylmercury for each fish species or group important in trade and diet in each region. This will allow the CCCF to understand if a clear differentiation between predatory and non-predatory can be determined based on the distribution of methylmercury in various species.

56. Alternatively, each exporting Member's competent authority decides whether a fish is predatory or not because huge number of species can be considered as predatory fish in each region, and it is impossible to create one general list. In this case, objective criteria are necessary for classifying fish species into "predatory" or "not predatory".

Methylmercury vs. total mercury

57. Members should also be aware that while the current GLs were set for methylmercury, MLs or GLs for total mercury have been set in a number of countries. This is because analysis of total mercury is easier than that of methylmercury.

58. In Codex, MLs are set for methylmercury in line with the criteria in the GSCTFF based on the risk assessments by the JECFA, that is, methylmercury is more of a toxicological concern than total mercury. However, considering that the analysis of methylmercury requires higher expertise and sophisticated equipment than that of total mercury, it may be reasonable to utilize the analysis of total mercury for screening purpose. If the total mercury levels surpass a certain level, such as GLs for methyl mercury, analysis should then be conducted on methylmercury. Total mercury may be used as a surrogate of methylmercuy in monitoring. Nonetheless, to confirm compliance of samples with the MLs, analysis on methylmercury is necessary. While, as Canada reported in a section on the Occurrence in Food, the methylmercury/total mercury ratio was 30% - 94% in highly migratory fish species, it was about 16% in pacific blue marlin (total mercury: 1.19 mg/kg, methylmercury: 0.19 mg/kg) as Japan reported. For this purpose, sufficient amount of data for both methylmercury and total mercury should be collected for the main fish species concerned in order to know the relationship between the concentrations of these two analytes.

B) Consumer advice

59. Information and guidance on methylmercury and fish consumption has been developed by some Members (See Table YY).

60. Advice to consumers on the benefits of fish consumption has also been developed at the national level. For instance, in Canada, website advice is provided on the health benefit of eating fish; namely that LCn3PUFA (EPA and DHA) from fish can help maintain healthy heart function. Consumption of fish has also been associated with reduced risk of sudden cardiac death. The website additionally explains that regular consumption of fish by pregnant women and women who may become pregnant plays a role in normal fetal brain and eye development (11).

61. In the United Kingdom, people have been encouraged to eat at least two portions of fish a week, including one of oily fish for healthy diet (12).

62. In Spain, in terms of risk-benefit, fish is considered, within a healthy nutrition, an important part of the diet. This is basically due to the quality of its protein and fat, with essential amino acids in amounts more than adequate, low saturated fat and a significant proportion of omega 3 fatty acids and vitamins A, D, E, B6 and B12 (13).

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[9] For example, ALINORM 93/12 (para. 105) and ALINORM 93/18 (paras. 153-156).

63. In Australia, the Australian Dietary Guidelines advise eating one or two fish meals per week for good health. Australia (FSANZ) has found that it is safe for all population groups to eat 2-3 servings per week of most types of fish. There are only a few types of fish which FSANZ recommends limiting in the diet – these are billfish (swordfish / broadbill and marlin), shark/flake, orange roughy and catfish. Therefore, FSANZ advises that pregnant women, women planning pregnancy and young children continue to consume a variety of fish as part of a healthy diet but limit their consumption of certain species (14).

64. In Norway the population is encouraged to eat more fish and seafood; fish as a main meal 2-3 times per week, and also as part of a lighter meal several times weekly is recommended. The consumers are advised to choose between different types of fish, and that half of the fish consumed should be oily fish which contains high levels of beneficial n-3 fatty acids. Pregnant women, the most vulnerable group of the population, are advised to avoid certain fish species, extra-large, old specimens of fish and fresh water fish such as pike, because of potentially high accumulated levels of contaminants, including methylmercury (15).

65. In Japan, the Ministry of Health, labour and Welfare advises the general population to eat a variety of fish and shellfish as good suppliers of protein and fatty acids (such as EPA and DHA) while the Ministry recommends pregnant women limit consumption of certain species. (16).

C) International consumer advice

66. As different species of fish are available for consumption in different parts of the world, it may be appropriate to develop specific regional or national consumer advice on consumption to accommodate the different dietary exposure scenarios for various populations. However, general international advice could form a helpful background in developing specific regional or national consumer advice.

67. The report of the 38th session of the CCFAC listed the following points to be considered when developing a general guideline on fish consumption, such as:

1) advice would need to be sufficiently general to avoid conflict with national provision;
2) the risks of adverse effects, e.g. limiting health and nutritional benefits, would need to be carefully considered; and
3) defining fish species containing high levels of methylmercury would be difficult because similar common names are used to describe different fish species in different regions of the world.

68. The Expert Consultation considered that the utilization of tables displaying the risks and benefits as a matrix, such as Table 3 in their report displaying the methylmercury (risk) and LCn3PUFA (benefits) may be useful as a risk-benefit communication tool.

69. However, it could also lead consumers to either over- or under-consume certain fish species, which is not desirable for a balanced diet. Thus, risk management authorities should keep in mind the following issues in utilizing the table as a risk-benefit communication tool:

- This table is not appropriate for national or regional level risk-benefit communication because levels of LCn3PUFA and methylmercury may differ seasonally and regionally, even in the same species. Farmed fish may also have different levels of LCn3PUFA and methylmercury from wild one as the concentration of these substances reflect what fish feed on.
- To avoid unbalanced fish consumption among the general population, both risk (high level of methylmercury) and benefit (high levels of LCn3PUFA) should be communicated.

70. Risk management authorities also should bear in mind the following matters in developing tables similar to Table 3 of the Expert Consultation's report:

- Data collection on levels of LCn3PUFA and methylmercury is essential for each region/state; and
- Satisfactorily validated analytical methods should be used for data collection.

71. The Expert Consultation also developed Table 5, according to which the benefit of consuming fish exceeds the risk in many cases. This table may also help consumers to understand the relationship between the risk and benefit of fish consumption. However, in order to help consumers understand the content of the table, if this table is to be used as risk-benefit communication tool, an easy and useful explanation on its use is necessary, commensurate with Table 3.

72. In summary, consumer advice using such tables that show risk and benefit may be very effective risk management options. In order to encourage Members to introduce those options, the CCCF may wish to develop a general guidance for their utilization. In addition, each country itself should be committed to collecting data on mercury or methylmercury and LCn3PUFA composition in fish, taking into account the dominant fish species in their countries.

D) Other risk management options implemented by Members

73. In order to disseminate information about maximum level of fish consumption and consumer advice relating to risk and benefit of fish consumption, Members publicize such information through brochures and websites. For instance, some Members, such as Australia, Canada, Spain, Norway, Japan and United Kingdom, provide information relating to benefit and risk of fish consumption through their websites as described in the previous section.

DISCUSSION

74. The GLs for methylmercury in fish were developed and adopted in 1995 (for the purpose of protecting consumers from adverse neurological effects and promoting international harmonization through preventing trade barriers and disputes. However, the 67th JECFA concluded that setting of GLs for methylmercury in fish may not be an effective way of reducing exposure for the general population. Rather, it noted that, consumer advice targeting specific generations vulnerable to methylmercury may be a more effective way to lower dietary exposures that may be exceeding the PTWI.

75. As studies associating fish consumption during pregnancy with neurodevelopmental benefits to the fetus did not start appearing in the scientific literature until 2004, the current 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. Enforcement of the GLs could, therefore, unduly limit or even eliminate consumption of fish that are, in fact, net beneficial. In that respect, the potential neurodevelopmental deficits that must be accounted for are not solely from methylmercury. That potential is demonstrated in the report of the Expert Consultation in which all fish that exceed the current GLs are estimated to be net beneficial through 7 servings per week (central estimates) and most fish that exceed the GLs are still estimated to be net beneficial at some levels of consumption when an upper bound estimate for methylmercury is applied.

76. As the Expert Consultation demonstrates, the data may now be adequate to assess risk through quantitative assessment, as contemplated in the discussion on how different risk assessment outputs can be considered in the choice of risk management (Guidance for Risk Management Options in Light of Different Risk Assessment Outcomes, Report of the 6th session of the Committee on Contaminants in Foods, REP12/CF, para. 27, Appendix XIII). It is a quantitative health impact assessment in that it assesses the overall neurodevelopmental consequences of eating fish during pregnancy from both methylmercury and nutrients in fish, assumed in this case to be from LCn3PUFA.

77. As mercury occurs naturally in fish and its level in fish is highly variable depending on the species, age, size and geographical location in which the fish has lived, it is not possible to ‘control’ the level of mercury that may be present in a particular fish. Furthermore, the nature of fish and fish marketing means it may not be practical or realistic to ‘control’ levels of mercury in fish by setting MLs/GLs. Similarly, the current Codex GLs may therefore not be practical to manage the risk from high dietary exposure to mercury from fish for sensitive populations.

78. However, the combination of GLs/MLs and consumer advice may still be considered the best way to protect vulnerable groups. Such levels could prevent exposure to fish with unacceptably high levels of MeHg and promote international trade harmonization.

79. Considering all of the above, consumer advice may seem to be a more appropriate risk management measure than MLs/GLs.

80. The details of the consumer advice may vary between countries because the risk of mercury exposure from the diet depends on the environment in that country, the type of fish commonly caught and eaten, the patterns of the consumption of fish and other foods that may also contain mercury. Hence, it is important for optimal management of the risk and benefits of mercury in fish, that an approach be used with a greater focus on regionally or nationally-based information for consumers.

RECOMMENDATION

81. The CCCF should further discuss the appropriateness of GLs as a risk management measure.

82. If the CCCF concludes that the GLs are necessary to manage the risk of methylmercury exposure, it should consider the following:

- Whether it is necessary to compile detailed data of methylmercury for each of fish species or group?
- Whether it is useful to develop clear distinction between predatory and non-predatory on a basis of the distribution of methylmercury in various species?
- Whether the combination of GLs and consumer advice is necessary?

83. If the CCCF concludes that the GLs are not practical to manage the risk of methylmercury exposure and may limit the consumption of fish, it should consider the following:

- Whether the current GLs are maintained or revoked?
- Whether consumer advice is appropriate to manage the risk of methylmercury?
- Whether it is necessary to compile detailed data of methylmercury and LCn3PUFA for each of fish species or group

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Table X: Inter-laboratory validated methods for the determination of methylmercury in fish

Method	Summary of method	Principle	Applicability	Minimum applicable range (mg/kg)	LOD/LOQ (mg/kg)	Recovery (%)	RSD_R (%)	Note
AOAC 988.11 Mercury (Methyl) in Fish and Shellfish	Organic interferences are removed from homogenized seafood by acetone wash followed by toluene wash. Protein-bound methyl Hg is released by addition of HCl and extracted into toluene. Toluene extract is analyzed for CH3HgCl by electron capture GC.	GC-ECD	Fish and shellfish	0.50-2.30 Hg	LOQ: 0.25 Hg	86-98	4-15	Type II
AOAC 990.04 Mercury (Methyl) in Seafood	LC effluent is heated to produce HG vaper from organomercury compouds. Hg vapor, together with vaporized mobile phase, is directed into water-cooled condenser where mobile phase is liquefied. Hg vapor is swept with nitrogen into absorption cell in light path of atomic absorbtion spectrophotometer.	LC-AAS	Seafood	0.15-1.86 Hg	LOQ： 0.06 Hg	94.4-99.6	10.5-18.2	
AOAC 983.20 Mercury (Methyl) in Fish and Shellfish	Organic interferences are removed from homogenized material by acetone wash followed by benzene wash. Protein-bound methyl Hg is released by addition of HCl and extracted into benzene. Benzene extract is concentrated and analyzed for CH3HgCl by GC.	GC-ECD	Fish and shellfish	0.15-2.48 Hg	LOQ: 0.05 Hg	99-120	3-13	

Method	**Summary of method**	**Principle**	**Applicability**	**Minimum applicable range (mg/kg)**	**LOD/LOQ (mg/kg)**	**Recovery (%)**	**RSD_R (%)**	**Note**
IRMM-IMEP-115 Methylmercury in seafood (validation process currently ongoing in the EU)	The method is based on a double liquid-liquid extraction, first with an organic solvent and then with a cysteine solution. The final quantification is done with a direct mercury analyzer.		Seafood					
CEN/TC 275 WG 10 (validation process currently ongoing in the EU)	Digestion with TMAH.	ID-GC-ICP-MS						

Table XX: Analytical methods for the determination of methylmercury in fish used by Codex members

Country	Method	Summary of method	Principle	Validation study	Applicability	Minimum applicable range (mg/kg)	LOD,LOQ (mg/kg)	Recovery (%)	RSD_R
Canada	HPLC-ICP-MS method for mercury and methylmercury speciation analysis in fish	Fish samples extracted with 0.75% Hcl L-Cysteine and analyzed on an Agilent ICP/MS 7500 equipped with a Micromist nebulizer and a Scott type nebulisation chamber cooled at 2◦C followed by separation on HPLC	HPLC-ICP-MS	Two laboratory comparison using two different HPLC systems	Fish		LOD: Hg: 0.002 MeHg: 0.005 LOQ: Hg: 0.006 MeHg: 0.015 (3X LOD)	Hg: 103±2.1% MeHg:99±2.1%	Hg: 2.1% MeHg: 2.1%
China	Determination of Methylmercury and Total Mercury in Seafood	Methylmercury in the samples is extracted by HCl and cysteine-aqueous solution. Then it is separated by LC and detected by Atomic Fluorescence Spectrometer (AFS)	LC-AFS		Seafood		LOD: 0.002 LOQ: 0.008		
Japan	Acid leaching-benzene extraction with GC-ECD	Methylmercury in the samples is extracted into benzene after acidification by HCl(cysteine-aqueous solution is used for back-extraction). Methylmercury is separated by GC and detected by ECD	GC-ECD	Single-laboratory	Seafood	0.01-5.0 MeHg	LOQ: 0.01 MeHg	70-120	-

Country	Method	Summary of method	Principle	Validation study	Applicability	Minimum applicable range (mg/kg)	LOD,LOQ (mg/kg)	Recovery (%)	RSD_R
USA	Determination of Methylmercury and Total Mercury in Seafood	Hg species are isolated from samples by extracting with cysteine-aqueous solution. Hg species are separated by HPLC and detected by ICP-MS	HPLC ICP-MS	Single-laboratory	Seafood	0.055-2.78 MeHg	LOD: MeHg: 0.0038 Hg: 0.0065 LOQ: MeHg: 0.028 Hg: 0.047	87-104	

Note: Methods that are not internationally validated are also included.

Table Y: Maximum level or guideline levels for methylmercury or total mercury in fish established in the territories of Codex members

Country	Year	type (Maximum level, guideline level, or any other level)	Level (mg/kg)	Chemical substance regulated (total mercury or methylmercury)	fish species regulated	remarks
Australia		Maximum level	mean level of 0.5	Total mercury	Crustacea	
			mean level of 0.5		Fish and fish products, excluding gemfish, billfish (including marlin), southern bluefin tuna, barramundi, ling, orange roughy, rays and all species of shark	
			mean level of 1.0		Gemfish, billfish (including marlin), southern bluefin tuna, barramundi, ling, orange roughy, rays and all species of shark	
			mean level of 0.5		Molluscs	
Canada	2007	Maximum limit (guideline standard)	0.5 mg/kg	Total mercury	In the edible portion of all retail fish, with six exceptions (see the 1 ppm standard below)	ML applies to commercial fish that are sold at the retail level
			1 mg/kg		The edible portion of escolar, orange roughy, marlin, fresh and frozen tuna, shark, and swordfish	
China	2005	Maximum level	1.0 mg/kg	Methylmercury	Predatory fish (shark, tuna and other predatory fishes)	
			0.5 mg/kg		Fish and other aquatic products (except predatory fishes)	

Country	**Year**	**type (Maximum level, guideline level, or any other level)**	**Level (mg/kg)**	**Chemical substance regulated (total mercury or methylmercury)**	**fish species regulated**	**remarks**
Colombia	2008	Maximum level	1.0 mg/kg	Total mercury	Bonito (Sarda sarda) Tuna (Thunnus species, Euthynnus species, Katsuwonus pelamis)	
			0.5 mg/kg		For other species of fish	
Japan	1973	Provisional regulation value	0.4 mg/kg	Total mercury	All fish except tunas (including marline, swordfish and skipjack), deep-sea fish (including rockfishes, alfonsino, sablefish and sharks), and fresh water fish (except lake fish)	The level was established in response to the outbreak of Minamata disease
Norway and UK (same levels as in EU)		Maximum level	0.5 mg/kg		Fishery products and muscle meat of fish, excluding certain species. The maximum level for crustaceans applies to muscle meat from appendages and abdomen. In case of crabs and crab-like crustaceans (Brachyura and Anomura) it applies to muscle meat from appendages	
			1.0 mg/kg		Muscle meat of the following fish: anglerfish (Lophius species) Atlantic catfish (Anarhichas lupus) bonito (Sarda sarda) eel (Anguilla species) emperor, orange roughy, rosy soldierfish (Hoplostethus species) grenadier (Coryphaenoides rupestris) halibut (Hippoglossus hippoglossus) kingklip (Genypterus capensis) marlin (Makaira species) megrim (Lepidorhombus species) mullet (Mullus species)	

Country	Year	type (Maximum level, guideline level, or any other level)	Level (mg/kg)	Chemical substance regulated (total mercury or methylmercury)	fish species regulated	remarks
					pink cusk eel (Genypterus blacodes) pike (Esox lucius) plain bonito (Orcynopsis unicolor) poor cod (Tricopterus minutes) Portuguese dogfish (Centroscymnus coelolepis) rays (Raja species) redfish (Sebastes marinus, S. mentella, S. viviparus) sail fish (Istiophorus platypterus) scabbard fish (Lepidopus caudatus, Aphanopus carbo) seabream, pandora (Pagellus species) shark (all species) snake mackerel or butterfish (Lepidocybium flavobrunneum, Ruvettus pretiosus, Gempylus serpens) sturgeon (Acipenser species) swordfish (Xiphias gladius) tuna (Thunnus species, Euthynnus species, Katsuwonus pelamis)	

Table YY: Each member's consumer advice

Country	Year	Target group	Species	Recommended amounts for consumption	Scientific basis (TDI, methylmercury level for each fish species, exposure to methylmercury from fishery products and other etc.
Australia		Pregnant women and women planning pregnancy (1 serve equals 150 g) and children up to 6 years (1 serve equals 75 g)	Any fish and seafood not listed below:	2 – 3 serves per week	PTWI for methyl mercury
			Or Orange Roughy (Sea Perch) or Catfish and no other fish that week	1 serve per week	
			Or Shark (Flake) or Billfish (Swordfish / Broadbill and Marlin) and no other fish that fortnight	1 serve/fortnight	
		Rest of the population (1 serve equals 150 g)	Any fish and seafood not listed below:	2 – 3 serves per week	
			Shark (Flake) or Billfish (Swordfish / Broadbill and Marlin) and no other fish that week	1 serve per week	
Canada	2007	•Women who are or who may become pregnant, or who are breastfeeding	Canned albacore tuna (other types of canned tuna specifically excluded from this guidance)	Up to four 75 g servings of canned albacore tuna each week. One Food Guide Serving is 75 g, 2 ½ oz, 125 mL, or ½ cup.	TDI
		Children between 1 and 4 years of age	Canned albacore tuna	One 75 g serving of albacore tuna each week.	
		•Children between five and eleven years old	Canned albacore tuna	two 75 g servings of albacore tuna each week.	
	2008	General Population	fresh/frozen tuna, shark, swordfish, marlin, orange roughy and escolar	- 150 g per week	
		Specified Women - those who are or may become pregnant or are breastfeeding	fresh/frozen tuna, shark, swordfish, marlin, orange roughy and escolar	- 150 g per month	

Country	Year	Target group	Species	Recommended amounts for consumption	Scientific basis (TDI, methylmercury level for each fish species, exposure to methylmercury from fishery products and other etc.
		Children 5-11 years old	resh/frozen tuna, shark, swordfish, marlin, orange roughy and escolar	- 125 g per month	
		Children 1-4 years old	fresh/frozen tuna, shark, swordfish, marlin, orange roughy and escolar	75 g per month	
		General population	Any species, except those mentioned above as potentially containing higher levels of mercury; the Guide specifcally mentions choosing fish such as char, herring, mackerel, salmon, sardines and trout	Recommended to eat at least two Food Guide Servings of 75 g (1/2 cup) each a week of fish	Eating Well with Canada's Food Guide – dietary recommendations
		General Population	Any species of concern	Specific provinces publish specific guidance for particular sport fish species that may contain levels of mercury that may represent a health risk	Provincial websites – generally based on Health Canada's TDI

Country	Year	Target group	Species	Recommended amounts for consumption	Scientific basis (TDI, methylmercury level for each fish species, exposure to methylmercury from fishery products and other etc.
Japan	2 November 2005 (revised 1 June)	Pregnant women	Group 1: Bottlenose dolphin (*Tursiops truncates*) Gropu 2: Short-finned pilot whale (*Globicephala macrorhynchus*) Group 3:Alfonsino (*Beryx splendens*), Swordfish (*Xiphias gladus*), Bluefin tuna (*Thunnus thynnus*), Bigeye tuna (*Thunnus obesus*), Finely-striate Buccinum (*Buccinum striatissimum*), Baird's beaked whale (*Berardius bairdii*) and Sperm whale (*Physeter macrocephalus*); Group 4:Yellowback Seabream (*Dentex tumifrons*), Marlin (*Makaira spp, Tetrapturus spp*), Hilgendorf saucord, (*Helicolenus hilgendorfii*) Southern bluefin tuna (*Thunnus maccoyii*), Blue shark (*Prionace glauca*), Dall's porpoise (*Phocoenoides dalli*) and Japanese bluefish (*Scombrops gilbert*)	Group 1: up to 80 g per 2 months Group 2: up to 80 g per 2 weeks Group 3: up to 80 g per week Group 4:- up to 160 g per week	TWI for methylmercury in pregnant women
Norway		Pregnant and breastfeeding women	Do not eat pike (*Esox lucius*), perch (*Perca fluviatilis*) above 25 cm, trout (*Salmo trutta*) above 1 kg or Arctic char above 1 kg (*Salvelinus alpinus*)		
		All	Do not eat pike (*Esox lucius*), perch (*Perca fluviatilis*) above 25 cm, trout (*Salmo trutta*) above 1 kg or Arctic char (*Salvelinus alpinus*) above 1 kg more than once a month		
Spain	April 2011	Pregnant women, breastfeeding women, women of childbearing age and children	Do not eat swordfish, shark, bluefin tuna (Thunnus thynnus) and pike	Avoid	JECFA PTWI, national occurrence data on Hg in fish and national consumption data on fish

Country	Year	Target group	Species	Recommended amounts for consumption	Scientific basis (TDI, methylmercury level for each fish species, exposure to methylmercury from fishery products and other etc.
		Children under 3 years old	Do not eat swordfish, shark, bluefin tuna (Thunnus thynnus) and pike	Avoid	
		Children from 3 up to 12 years old	Limit consumption of swordfish, shark, bluefin tuna (Thunnus thynnus) and pike	Up to 50 g/week or 100 g/2 weeks (do not eat any other fish of this group within the same week)	
United Kingdom		Pregnant women and women intending to become pregnant Children (under 16)	Shark, Marlin and Swordfish Tuna (Only for Pregnant women and women intending to become pregnant)	Avoid to eat Avoid to eat more than four medium-sized cans or two fresh tuna steaks per week	
United States	2004	Women who may become pregnant, pregnant women, and nursing mothers Young Children	1. Shark, Swordfish, King Mackerel, Tilefish 2. Variety of fish and shellfish 3. Fish caught by family and friends in local lakes, rivers and coastal areas	1. Do not eat 2. Eat up to 12 ounces (two average meals) a week 3. If no local advisories are available, eat up to 6 ounces (one average meal) per week of fish caught from local waters, but do not eat any other fish during that week Follow above recommendation but serve smaller portions	Combination of national occurrence data in fish and national fish consumption data

APPENDIX

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