



**JOINT FAO/WHO FOOD STANDARDS PROGRAMME
CODEX COMMITTEE ON CONTAMINANTS IN FOODS**

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**PROPOSED DRAFT MAXIMUM LEVELS FOR METHYLMERCURY IN FISH
INCLUDING ASSOCIATED SAMPLING PLANS**

(Prepared by the Electronic Working Group led by the Netherlands, Canada and New Zealand)

Background

1. The full history of the discussion on methylmercury dating back to 1992 is contained in Information document CF/11 INF/1. A summary for the current discussion paper is given below.
2. The 6th Session of the Codex Committee on Contaminants in Foods (CCCF06) (2012) agreed to the development of a discussion paper on the review of the guideline level (GL) for methylmercury in fish and predatory fish through an electronic working group (EWG) led by Norway and co-chaired by Japan for consideration and discussion at CCCF07 with the view of identification of possible actions or new work on this issue (REP 12/CF, para. 174).
3. CCCF07 (2013) agreed that consumer advice should not be developed at the international level and that such guidance was more appropriate at the national level. It was agreed to review the GLs with a view to their revision or conversion to maximum levels (MLs). The Committee therefore re-established the EWG, led by Japan and co-chaired by Norway, to prepare a discussion paper; collect data on total mercury and methylmercury in fish species important in international trade in order to review the current GLs; and explore the possibility of revising the GLs or their conversion to MLs and to identify the fish for which the level or levels could apply (REP 13/CF, paras. 125,126).
4. CCCF08 (2014) noted that there was wide support for establishment of an ML for methylmercury, and agreed that this would be the approach with the use of total mercury for screening purposes, but that further consideration was needed on an appropriate level or levels; and the fish classification would have to be further developed as proposed by the chair of the EWG. The Committee further noted that this decision did not preclude the usefulness of consumer advice and confirmed the decision of the last session of the Committee that consumer advice should be developed at the national or regional level as the advice would vary between countries because of the risk of mercury exposure from the diet would depend on, amongst others, the patterns of consumption of fish and the types of fish consumed; and that no further work would be done at the international level.
5. The Committee agreed to re-establish the EWG, led by Japan and co-chaired by Norway to develop a discussion paper and propose ML(s) for methylmercury for specific species of fish and to include a project document for a new work proposal for consideration by the 9th session of the Committee (REP 14/CF, paras. 113-114).
6. CCCF09 (2015) noted the continued support for an ML for methylmercury and agreed that further work on this should continue through the development of another discussion paper to consider expanding the ML to fish species that can accumulate high methylmercury concentrations, other than tuna, and that consideration should be given to narrowing down the ML ranges. It was recognized that development of this paper would require additional data and that an exposure assessment based on different MLs should be conducted. The Committee agreed to re-establish the EWG, chaired by Japan and co-chaired by New Zealand to prepare a discussion paper with proposals for ML for methylmercury, including a project document for consideration by the next session. (REP 15/CF, paras. 125-126)
7. CCCF10 (2016) agreed that it would establish an ML for tuna, but that it was not ready at this point to submit a project document to the Codex Alimentarius Commission (CAC) through the Executive Committee (CCEXEC) for approval of new work, as it was necessary to determine whether it was possible to establish a single ML for tuna or whether it should be set for different species of tuna, and whether it was possible and appropriate to set MLs for canned tuna.

8. The Committee agreed to establish an EWG, chaired by The Netherlands, and co-chaired by New Zealand and Canada to prepare a discussion paper presenting a proposal for:
 - one ML for fresh and frozen tuna, or for MLs for different tuna species, if the need for differentiation is justified;
 - an ML for canned tuna, if possible and appropriate, and to determine whether it should be based on occurrence data or derived from the ML(s) for fresh tuna;
 - the need for MLs for other species of fish, based on the information in CRD18 and other relevant sources, together with a project document (REP 16/CF, paras 160-161).
9. CCCF11 (2017) discussed the recommendations of the EWG contained in CX/CF 17/11/12 and agreed:
 - to establish MLs based on the ALARA principle, which was in line with the criteria for establishing MLs in the GSCTFF (REP 17/CF, para 129);
 - that an ML would be established for tuna as a group, and that the subspecies of tuna taken into account for this would be indicated (REP 17/CF, para 130);
 - to establish MLs for the species alfonsino, kingfish/amberjack, marlin, shark, dogfish and swordfish (REP 17/CF, para 134);
 - not to establish MLs for canned tuna (REP 17/CF, para 135);
 - to continue with the approach to establish MLs for methylmercury, while screening for total mercury (REP 17/CF, para 138);
 - to develop a footnote to the higher MLs to indicate the need for additional risk management measures, namely consumer advice, to protect health (REP 17/CF, para 139);
 - that MLs should be accompanied by sampling plans and to make this clear in the project document (REP 17/CF, para 140);
 - to establish an EWG, chaired by the Netherlands, and co-chaired by Canada and New Zealand, working in English, subject to approval of new work, to prepare proposals for MLs and associated sampling plans for circulation for comments and consideration by CCCF12 (REP 17/CF, para 142);
 - that the Codex Secretariat would request further data on total mercury and methylmercury in fish through a CL (REP 17/CF, para 143).
10. Following CCCF11, an EWG was established, and the participants are listed in Appendix III. The proposed draft MLs and sampling plan are provided in Appendix I. The background and approach used to formulate the recommendations of the EWG is included in Appendix II.

Discussion and conclusions

Appropriate percentile for setting MLs.

11. As for the previous EWG, the P95 value was used as default value for deriving proposals for MLs, this would give 5% rejection rate. Three members of the EWG indicated that lower rejection rates would be appropriate such as used in the CCCF EWG on lead, one member specified that the rejection rate should be 2-3%. Therefore, in addition to the approach based on P95 as used last year in the discussion paper, the approach taken by the EWG on lead has been used and additional proposed draft MLs have been derived.

Use of one decimal for the proposed draft MLs

12. One member suggested that no decimals should be used, and that the proposed draft MLs should consist of one rounded figure. In the Preamble of the General Standard for Contaminants and Toxins (GSCTFF, CXS 193-1995) it is stated that 'Numerical values for MLs should preferably be regular figures in a geometric scale (0.01, 0.02, 0.05, 0.1, 0.2, 0.5, 1, 2, 5 etc.), unless this may pose problems in the acceptability of the MLs'. In the case of methylmercury in fish, to consistently apply the same rejection rates, one decimal is needed in the proposed draft MLs. In addition, these decimals are not regular figures in a geometric scale. The use of one decimal does not pose problems for the analytical methods, most results are reported in two or sometimes three decimals in mg/kg.

ML for all tuna

13. At CCCF11, it was agreed that one ML should be developed for all tuna, therefore the MLs proposed were derived from the combined data for tuna species. Based on the comments in CCCF11 and the EWG that proposed draft MLs should be based on the higher level tuna, additional analyses were performed for two categories: the higher level tuna (Bigeye and Bluefin) and the lower level tuna. For these categories, proposals for MLs were also given.

Additional findings from the data analysis

14. Data on Spanish mackerel have been analysed as these were encountered during the sorting of Jack mackerel data for the derivation of a proposed draft ML for Amberjack. As last year, data were lacking for these species, the data were analysed. One member indicated that new work on this species would not be part of the current work for CCCF, as it was not agreed last year.
15. Analysis in a previous EWG has shown that in general the ratio of methylmercury to total mercury was 0.85, therefore total mercury was used in the data analysis for derivation of MLs, assuming that all total mercury is present as methylmercury. However, the analyses show that care is needed in doing this as there are at least two species (Marlin and Spanish mackerel) in which the ratio is much less than this. The EWG recommends that if consideration may be given to development of MLs in for other fish species, any ML development would need to take into consideration the ratio of total mercury and methylmercury as this can vary largely between species. One member also indicated that data should also have a good geographical distribution.

Footnotes to the MLs

16. CCCF11 decided to continue with the approach to establish MLs for methylmercury, while screening for total mercury (REP 17/CF, para 138). Therefore, a footnote to the ML indicating this option could be considered. Some members of the EWG indicated that this could be more clearly stated for the current proposed draft MLs. Therefore, the footnote to the ML for inorganic arsenic in rice has been used as an example and adapted for methylmercury, and as such included in the recommendations.
17. CCCF11 decided not to develop an ML for canned tuna as levels in these samples were generally low. This decision was solely based on the data analysis for CCCF11. The current GL includes a footnote 'The guideline levels are intended for methylmercury in fresh or processed fish and fish products moving in international trade', which includes canned fish. No decision was made at CCCF11 in relation to this footnote. The chairs of the EWG put forward the question whether the current footnote to the GL should be attached to the new MLs. Not including the footnote would mean that the ML for fresh/frozen fish would not apply to canned fish, which could possibly open the possibility of non-compliant fish for the ML for fresh/frozen fish being processed into cans. Four members were opposed to attaching the existing footnote to the MLs, because of the decision of CCCF11 not to derive an ML for canned tuna and they indicated it might result in unnecessary testing. Three members were in favor of attaching the current footnote to the ML.
18. CCCF11 agreed to develop a footnote to the higher MLs to indicate the need for additional risk management measures. In the discussion paper for CCCF11, fish consumption data from the GEMS/Food Cluster diets were gathered to determine a critical concentration for selecting fish species eligible for MLs development. That analysis was used again for deriving a threshold ML for attaching a footnote, and it was concluded that additional risk management measures could be considered for fish species with equal to or greater than 0.3 mg/kg methylmercury. Any additional form of risk management implemented should take into consideration the known nutritional benefits of fish consumption. One member questioned if only higher MLs should have the footnote, most responding members of the EWG agreed to propose to attach a footnote indicating the need for additional risk management measures to all proposed draft MLs.
19. The following text for the footnote was proposed to the EWG: "Adverse effects due to methylmercury exposure may outweigh the benefits of fish consumption at lower levels than the ML when frequently consuming this fish species, particularly by pregnant women and infants. The development of additional risk management measures (e.g. consumption advice) may be necessary on a national level to restrict exposure in order to avoid unacceptably high levels of methylmercury". One member indicated that the footnote could delete the reference to other risk management measures as only consumption advice would be an option in practice. Two members provided alternative proposals for text of the footnote. These proposals are included in the recommendations.
20. A sampling plan based on EU Regulation 333/2007 was proposed to the EWG. Only elements relevant for the sampling for methylmercury in fish have been included from the Regulation. The discussion points in the EWG include the specification of (updated) methods of analysis or including (only) the use of performance criteria; the scope of the sampling plan to also include provisions other than sampling, specific questions on homogeneity of distribution of methylmercury between and within fish, and the relevant part of the fish for methylmercury analysis. One member suggested that CCMAS endorse the sampling plan, which is taken up in the recommendations.

Recommendations

21. The proposed draft MLs and the proposed draft sampling plan are presented in Appendix I for comments and consideration by CCCF.

Additional recommendations for consideration by CCCF

22. The Committee is invited to consider the following additional matters in relation to the proposed MLs:
1. More analyses be done for Spanish mackerel to confirm the methylmercury levels and the ratio between total mercury and methylmercury;
 2. ML development in other fish species, would need to take into consideration the ratio of total mercury and methylmercury as this can vary largely between species;
 3. To include the following footnote to the MLs for methylmercury: *“Countries or importers may decide to use their own screening when applying the ML for methylmercury in fish by analysing total mercury in fish. If the total mercury concentration is below the ML for methylmercury, no further testing is required and the sample is determined to be compliant with the ML. If the total mercury concentration is above the ML for methylmercury, follow-up testing shall be conducted to determine if the methylmercury concentration is above the ML.”*;
 4. To discuss whether the existing footnote attached to the current GLs should also be applied to the above proposed draft MLs: *“The guideline levels are intended for methylmercury in fresh or processed fish and fish products moving in international trade”*. The effect of this footnote would result in the MLs established in fresh/frozen fish, being applicable to canned fish;
 5. To consider applying attach a third footnote indicating the need for additional risk management measures to all proposed draft MLs;
 6. To consider the following option for text for this third footnote:
 - a. *“Adverse effects due to methylmercury exposure may outweigh the benefits of fish consumption at lower levels than the ML when frequently consuming this fish species, particularly by pregnant women and infants. The development of additional risk management measures (e.g. consumption advice) may be necessary on a national level to restrict exposure in order to avoid unacceptably high levels of methylmercury.”*
 - b. *“There is a potential risk for specific consumers (particularly pregnant women and infants) from methyl mercury exposure and the proposed MLs are a risk management measure to control exposure to ALARA. Therefore, it is important for consumers to follow advice on consumption of specific species of fish in place at the national level, including advice on the known benefits of fish consumption.”*
 - c. *“For fish species high in methylmercury, countries should consider developing nationally relevant consumer advice for pregnant women and young children to supplement these MLs.”*
23. The Committee is invited to consider sending the sampling plan to the Committee on Methods of Analysis and Sampling (CCMAS) for endorsement with the following specific questions:
1. Could CCMAS advise on the use of analytical methods or performance criteria?
 2. Could CCMAS advise on the necessary performance criteria for the proposed draft MLs? Draft performance criteria to the current proposals for MLs are included in Table 9 of Appendix II.
 3. Is there evidence that methyl mercury can vary widely between individual fish sampled at the same time? How would this apply to large fish sold as individual units? Does the sampling plan provide enough basis to deal with this?
 4. Is the following text relevant for methylmercury in fish: *“If the result of the test for an aggregate sample of cans is less than but close to the maximum level of methylmercury and if it is suspected that individual cans might exceed the maximum level, then it might be necessary to conduct further investigations”*?
 5. Should the samples for mercury in fish be analyzed raw (or with no further processing or cooking for already processed products, e.g. canned fish)?
 6. In addition – is the whole fish to be analyzed or only specific fractions edible portions? Now the only mention is that mid-section should be sampled for some large fish.

APPENDIX I-PART I**PROPOSED DRAFT MLs FOR METHYLMERCURY IN THE FOLLOWING SPECIES OF FISH**

Fish species	Proposed draft ML in mg/kg based on P95	Proposed draft ML in mg/kg based on next higher ML that provides <5% rejection
All tuna Or Bigeye and Bluefin tuna	1.1	1.2
Tuna other than Bigeye and Bluefin	0.7	0.8
Alfonsino	1.5	1.5
Marlin Or Marlin (based on Blue marlin, unspecified)	1.6 4.5	1.7 4.6
Amberjack Or Amberjack	0.7 No ML	0.8 No ML
Shark	1.5	1.6
Swordfish	2.3	2.4

APPENDIX I-PART II**PROPOSED DRAFT SAMPLING PLAN FOR METHYLMERCURY CONTAMINATION IN FISH****DEFINITIONS**

The following definitions should apply:

Lot	An identifiable quantity of a food commodity delivered at one time and determined by the official to have common characteristics, such as origin, variety, type of packing, packer, consignor, or markings.
Sublot	Designated part of a larger lot in order to apply the sampling method on that designated part. Each sublot must be physically separate and identifiable.
Incremental sample	The quantity of material taken from a single random place in the lot or sublot.
Aggregate sample	The combined total of all the incremental samples that is taken from the lot or sublot. The aggregate sample has to be at least as large as the laboratory sample or samples combined.
Laboratory sample	A sample intended for a laboratory.

SAMPLING METHODS**GENERAL PROVISIONS****Personnel**

Sampling should be performed by an authorised person as designated by the national authority.

Material to be sampled

Each lot or sublot which is to be examined should be sampled separately.

Precautions to be taken

In the course of sampling, precautions should be taken to avoid any changes which would affect the levels of contaminants, adversely affect the analytical determination or make the aggregate samples unrepresentative.

Incremental samples

As far as possible, incremental samples should be taken at various places distributed throughout the lot or sublot.

Preparation of the aggregate sample

The aggregate sample should be made up by combining the incremental samples.

Samples for enforcement, defence and referee purposes

The samples for enforcement, defence and referee purposes should be taken from the homogenised aggregate sample unless this conflicts with the rules of the national authority as regards the rights of the food business operator.

Packaging and transmission of samples

Each sample should be placed in a clean, inert container offering adequate protection from contamination, from loss of analytes by adsorption to the internal wall of the container and against damage in transit. All necessary precautions should be taken to avoid any change in composition of the sample which might arise during transportation or storage.

Sealing and labelling of samples

Each sample taken for official use should be sealed at the place of sampling and identified following the locally applicable rules.

A record should be kept of each sampling, permitting each lot or sublot to be identified unambiguously (reference to the lot number should be given) and giving the date and place of sampling together with any additional information likely to be of assistance to the analyst.

SAMPLING PLAN**Division of lots into sublots**

Large lots should be divided into sublots on condition that the sublot may be separated physically. For products traded in bulk consignments Table 1 should apply. For other products Table 2 should apply. Taking into account that the weight of the lot is not always an exact multiple of the weight of the sublots, the weight of the sublot may exceed the mentioned weight by a maximum of 20%.

Number of incremental samples

The aggregate sample should be at least 1 kg except where it is not possible, e.g. when the sample consists of 1 package or unit.

The minimum number of incremental samples to be taken from the lot or subplot should be as given in Table 3.

The incremental samples should be of similar weight/volume. The weight/ volume of an incremental sample should be at least 100 grams, resulting in an aggregate sample of at least about 1 kg. Departure from this method should be recorded.

Table 1 Subdivision of lots into sublots for products traded in bulk consignments

Lot weight (ton)	Weight or number of sublots
≥ 1 500	500 tonnes
> 300 and < 1 500	3 sublots
≥ 100 and ≤ 300	100 tonnes
< 100	—

Table 2 Subdivision of lots into sublots for other products

Lot weight (ton)	Weight or number of sublots
≥ 15	15-30 tonnes
< 15	—

Table 3 Minimum number of incremental samples to be taken from the lot or subplot

Weight or volume of lot/sublot (in kg)	Minimum number of incremental samples to be taken
< 50	3
≥ 50 and ≤ 500	5
> 500	10

If the lot or subplot consists of individual packages or units, then the number of packages or units which should be taken to form the aggregate sample is given in Table 4.

Table 4 Number of packages or units (incremental samples) which should be taken to form the aggregate sample if the lot or subplot consists of individual packages or units

Number of packages or units in the lot/ subplot	Number of packages or units to be taken
≤ 25	at least 1 package or unit
26-100	about 5%, at least 2 packages or units
> 100	about 5%, at maximum 10 packages or units

If the result of the test for an aggregate sample of cans is less than but close to the maximum level of methylmercury and if it is suspected that individual cans might exceed the maximum level, then it might be necessary to conduct further investigations.

Where it is not possible to carry out the method of sampling set out in this chapter because of the unacceptable commercial consequences (e.g. because of packaging forms, damage to the lot, etc.) or where it is practically impossible to apply the abovementioned method of sampling, an alternative method of sampling may be applied provided that it is sufficiently representative for the sampled lot or subplot and is fully documented.

Specific provisions for the sampling of large fish arriving in large lots

In case the lot or subplot to be sampled contains large fish (individual fish weighing more than about 1 kg) and the lot or subplot weighs more than 500 kg, the incremental sample should consist of the middle part of the fish. Each incremental sample should weigh at least 100 g.

SAMPLING AT RETAIL STAGE

Sampling of foodstuffs at retail stage should be done where possible in accordance with the sampling provisions set out in this sampling plan.

Where it is not possible to carry out the method of sampling set out above because of the unacceptable commercial consequences (e.g. because of packaging forms, damage to the lot, etc.) or where it is practically impossible to apply the abovementioned method of sampling, an alternative method of sampling may be applied provided that it is sufficiently representative for the sampled lot or subplot and is fully documented.

SAMPLE PREPARATION AND ANALYSIS

LABORATORY QUALITY STANDARDS

Laboratories should be able to demonstrate that they have internal quality control procedures in place. Examples of these are the 'ISO/ AOAC/IUPAC Guidelines on Internal Quality Control in Analytical Chemistry Laboratories'¹.

Wherever possible the trueness of analysis should be estimated by including suitable certified reference materials in the analysis.

Precautions and general considerations

The basic requirement is to obtain a representative and homogeneous laboratory sample without introducing secondary contamination.

All of the sample material received by the laboratory should be used for the preparation of the laboratory sample.

Compliance with maximum levels laid down in the General Standard for Contaminants and toxins in Food and Feed should be established on the basis of the levels determined in the laboratory samples.

Specific sample preparation procedures

The analyst should ensure that samples do not become contaminated during sample preparation. Wherever possible, apparatus and equipment coming into contact with the sample should not contain mercury and be made of inert materials, e.g. plastics such as polypropylene, polytetrafluoroethylene (PTFE) etc. These should be acid cleaned to minimise the risk of contamination. High quality stainless steel may be used for cutting edges.

There are many satisfactory specific sample preparation procedures which may be used for the products under consideration. For those aspects not specifically covered by this sampling plan, the CEN Standard 'Foodstuffs. Determination of elements and their chemical species. General considerations and specific requirements'² has been found to be satisfactory but other sample preparation methods may be equally valid.

Treatment of the sample as received in the laboratory

The complete aggregate sample should be finely ground (where relevant) and thoroughly mixed using a process that has been demonstrated to achieve complete homogenisation.

Samples for enforcement, defence and referee purposes

The samples for enforcement, defence and referee purposes should be taken from the homogenised material unless this conflicts with the rules of the Member States on sampling as regards the rights of the food business operator.

¹ Edited by M. Thompson and R. Wood, Pure Appl. Chem., 1995, 67, 649-666.

² Standard EN 13804:2013, 'Foodstuffs. Determination of elements and their chemical species. General considerations and specific requirements', CEN, Rue de Stassart 36, B-1050 Brussels.

METHODS OF ANALYSIS

Definitions

r	Repeatability the value below which the absolute difference between single test results obtained under repeatability conditions (i.e., same sample, same operator, same apparatus, same laboratory, and short interval of time) may be expected to lie within a specific probability (typically 95%) and hence $r = 2,8 \times s r$.
s r	Standard deviation calculated from results generated under repeatability conditions.
RSD r	Relative standard deviation calculated from results generated under repeatability conditions $[(s r /) \times 100]$.
R	Reproducibility the value below which the absolute difference between single test results obtained under reproducibility conditions (i.e., on identical material obtained by operators in different laboratories, using the standardised test method), may be expected to lie within a certain probability (typically 95%); $R = 2,8 \times s R$.
s R	Standard deviation, calculated from results under reproducibility conditions. 'RSD R' = Relative standard deviation calculated from results generated under reproducibility conditions $[(s R /) \times 100]$.
LOD	Limit of detection, smallest measured content, from which it is possible to deduce the presence of the analyte with reasonable statistical certainty. The limit of detection is numerically equal to three times the standard deviation of the mean of blank determinations ($n > 20$).
LOQ	Limit of quantification, lowest content of the analyte which can be measured with reasonable statistical certainty. If both accuracy and precision are constant over a concentration range around the limit of detection, then the limit of quantification is numerically equal to 10 times the standard deviation of the mean of blank matrix determinations ($n \geq 20$).
HORRAT³ r	The observed RSD r divided by the RSD r value estimated from the (modified) Horwitz equation (2) (cf. point C.3.3.1 ('Notes to the performance criteria')) using the assumption $r = 0,66 R$.
HORRAT⁴ R	The observed RSD R divided by the RSD R value estimated from the (modified) Horwitz equation ⁵ (cf. point 'Notes to the performance criteria').
u	Combined standard measurement uncertainty obtained using the individual standard measurement uncertainties associated with the input quantities in a measurement model ⁶
U	The expanded measurement uncertainty, using a coverage factor of 2 which gives a level of confidence of approximately 95% ($U = 2u$).
Uf	Maximum standard measurement uncertainty.

General requirements

Methods of analysis used for food control purposes should comply with the provisions of the Standard on for recommended methods of analysis and sampling (CXS 234-1999).

Methods for analysis for total mercury are appropriate for screening purpose for control on methylmercury levels. If the total mercury concentration is below the maximum level for methylmercury, no further testing is required and the sample is considered to be compliant with the maximum level for methylmercury. If the total mercury concentration is at or above the maximum level for methylmercury, follow-up testing should be conducted to determine if the methylmercury concentration is above the maximum level for methylmercury.

³ Horwitz W. and Albert, R., 2006, The Horwitz Ratio (HorRat): A useful Index of Method Performance with respect to Precision, Journal of AOAC International, Vol. 89, 1095-1109. (2) M. Thompson, Analyst, 2000, p. 125 and 385-386.

⁴ Horwitz W. and Albert, R., 2006, The Horwitz Ratio (HorRat): A useful Index of Method Performance with respect to Precision, Journal of AOAC International, Vol. 89, 1095-1109.

⁶ International vocabulary of metrology – Basic and general concepts and associated terms (VIM), JCGM 200:2008.

Specific requirements

Performance criteria

Where no specific methods for the determination of contaminants in foodstuffs are prescribed at the Codex level, laboratories may select any validated method of analysis for the respective matrix provided that the selected method meets the specific performance criteria set out in Table 5.

It is recommended that fully validated methods (i.e. methods validated by collaborative trial for the respective matrix) are used where appropriate and available. Other suitable validated methods (e.g. in-house validated methods for the respective matrix) may also be used provided that they fulfil the performance criteria set out in Tables 5.

Where possible, the validation of in-house validated methods should include a certified reference material.

Table 5 Performance criteria for methods of analysis of mercury and methylmercury

Parameter	Criterion		
Applicability	Fish specified in the General Standard for Contaminants and Toxins in Food and Feed (GSCTFF, CXS 193-1995)		
Specificity	Free from matrix or spectral interferences		
Repeatability (RSD _r)	HORRAT _r less than 2		
Reproducibility (RSD _R)	HORRAT _R less than 2		
Recovery	The provisions of 'Recovery calculations' apply		
LOD	= three tenths of LOQ		
LOQ	Methylmercury	ML is < 0,100mg/kg ≤ two fifths of the ML	ML is ≥ 0,100 mg/kg ≤ one fifth of the ML

Notes to the performance criteria:

The Horwitz equation⁷ (for concentrations $1,2 \times 10^{-7} \leq C \leq 0,138$) and the modified Horwitz equation⁸ (for concentrations $C < 1,2 \times 10^{-7}$) are generalised precision equations which are independent of analyte and matrix but solely dependent on concentration for most routine methods of analysis.

Modified Horwitz equation for concentrations $C < 1,2 \times 10^{-7}$:

$$\text{RSD R} = 22\%$$

where:

- RSD R is the relative standard deviation calculated from results generated under reproducibility conditions $[(s R /) \times 100]$
- C is the concentration ratio (i.e. 1 = 100 g/100 g, 0,001 = 1 000 mg/kg). The modified Horwitz equation applies to concentrations $C < 1,2 \times 10^{-7}$.

Horwitz equation for concentrations $1,2 \times 10^{-7} \leq C \leq 0,138$:

$$\text{RSD R} = 2C^{(-0,15)}$$

where:

- RSD R is the relative standard deviation calculated from results generated under reproducibility conditions $[(s R /) \times 100]$
- C is the concentration ratio (i.e. 1 = 100 g/100 g, 0,001 = 1 000 mg/kg). The Horwitz equation applies to concentrations $1,2 \times 10^{-7} \leq C \leq 0,138$.

⁷ W. Horwitz, L.R. Kamps, K.W. Boyer, J.Assoc.Off.Analy.Chem.,1980, 63, 1344.

⁸ M. Thompson, Analyst, 2000, p. 125 and 385-386.

'Fitness-for-purpose' approach

For in-house validated methods, as an alternative a 'fitness-for-purpose' approach⁹ may be used to assess their suitability for official control. Methods suitable for official control must produce results with a combined standard measurement uncertainty (u) less than the maximum standard measurement uncertainty calculated using the formula below:

$$Uf = \sqrt{(\text{LOD}/2)^2 + (\alpha C)^2}$$

where:

- Uf is the maximum standard measurement uncertainty (µg/kg).
- LOD is the limit of detection of the method (µg/kg). The LOD must meet the performance criteria set in point C.3.3.1 for the concentration of interest.
- C is the concentration of interest (µg/kg);
- α is a numeric factor to be used depending on the value of C. The values to be used are given in Table 8.

Table 8 Numeric values to be used for α as constant in formula set out in this point, depending on the concentration of interest

C (µg/kg)	α
≤ 50	0,2
51-500	0,18
501-1 000	0,15
1 001-10 000	0,12
> 10 000	0,1

In Table 9, performance criteria to the proposed draft MLs have been calculated.

Table 9: Calculated performance criteria for ML ≥ 0.1 mg/kg

ML mg/kg	LOD mg/kg	LOQ mg/kg	Min. applicable range		Precision RSDR (%)
			From mg/kg	To mg/kg	
0.7	0.07	0.14	0.346	1.054	33.8
1.0	0.1	0.2	0.520	1.480	32.0
1.1	0.11	0.22	0.580	1.620	31.5
1.3	0.13	0.26	0.700	1.900	30.8
1.5	0.15	0.3	0.823	2.177	30.1
2.3	0.23	0.46	1.326	3.274	28.2

REPORTING AND INTERPRETATION OF RESULTS

Expression of results

The results should be expressed in the same units and with the same number of significant figures as the maximum levels laid down in the General Standard for Contaminants and Toxins in Food and Feed (GSCTFF, CXS 193-1995).

⁹ M. Thompson and R. Wood, Accred. Qual. Assur., 2006, p. 10 and 471-478.

Recovery calculations

If an extraction step is applied in the analytical method, the analytical result should be corrected for recovery. In this case the level of recovery must be reported.

In case no extraction step is applied in the analytical method, the result may be reported uncorrected for recovery if evidence is provided by ideally making use of suitable certified reference material that the certified concentration allowing for the measurement uncertainty is achieved (i.e. high accuracy of the measurement), and thus that the method is not biased. In case the result is reported uncorrected for recovery this should be mentioned.

Measurement uncertainty

The analytical result should be reported as $x \pm U$ whereby x is the analytical result and U is the expanded measurement uncertainty, using a coverage factor of 2 which gives a level of confidence of approximately 95% ($U = 2u$).

INTERPRETATION OF RESULTS**Acceptance of a lot/sublot**

The lot or subplot is accepted if the analytical result of the laboratory sample does not exceed the respective maximum level as laid down in the General Standard for Contaminants and Toxins in Food and Feed (GSCTFF, CXS 193-1995), taking into account the expanded measurement uncertainty and correction of the result for recovery if an extraction step has been applied in the analytical method used.

Rejection of a lot/sublot

The lot or subplot is rejected if the analytical result of the laboratory sample exceeds beyond reasonable doubt the respective maximum level as laid down in the General Standard for Contaminants and Toxins in Food and Feed (GSCTFF, CXS 193-1995), taking into account the expanded measurement uncertainty and correction of the result for recovery if an extraction step has been applied in the analytical method used.

Applicability

The present interpretation rules should apply for the analytical result obtained on the sample for enforcement. In case of analysis for defence or reference purposes, the locally applicable rules should apply.

APPENDIX II**BACKGROUND TO THE RECOMMENDATIONS OF THE EWG
(Information for Codex members and observers when considering
the MLs and the sampling plan)****1 Approach used by the EWG**

1. For CCCF11, 0.3 mg/kg for average total mercury or methylmercury concentration was used as criterion for fresh/frozen fish to select fish species for setting MLs, as at a total mercury or methylmercury concentration of 0.4 mg/kg, reported fish intakes in 2 GEMS clusters (G14 and G17) could result in exceedance of the PTWI. At higher Hg concentrations, additional cluster diets would be impacted. This allowed the selection of species that are eligible for setting MLs. Species that were selected were Tuna (according to mandate), Alfonsino, Kingfish/Amberjack, Marlin, Shark, Dogfish and Swordfish. CCCF11 agreed to develop MLs for these species.
2. The data analysis for the discussion paper CX/CF 17/11/12 was used as a basis for the current derivation of the proposed draft MLs. In week 49 of 2017, data that were submitted after the CCCF11 analysis were extracted from the GEMS/Food contaminants database for total mercury and methylmercury in 'Fish and other seafood (including amphibians, reptiles, snails and insects)'. This resulted in 10,242 records for total mercury and 2,765 for methylmercury. From this file, data related to the fish species under discussion were extracted. This resulted in 2,455 relevant data points for total mercury and 1,489 data points for methylmercury.
3. The data analysis was undertaken using the same approach as that used by the EWG for CCCF11 as follows:
 - It was assumed that total mercury was present as methylmercury;
 - To avoid duplicate samples in one analysis, mercury and methylmercury were separately analyzed;
 - No distinction was made between predatory or non-predatory fish;
 - All results were converted to mg/kg and non-detects were treated as zeros;
 - While various cooking processes have been shown to make only minor changes in the relative concentration of mercury in fish, depending on the extent of water loss, for transparency the 'cooked' samples were removed from the dataset;
 - Canned fish were excluded from the analysis. Fish packaged in plastic were considered canned and thus also excluded from the analysis;
 - Where 'unknown' was indicated for the food state, it was assumed that the analysis was done on raw fish.
4. For some fish species, many individual data points lacked information on LOD/LOQ (limit of detection/limit of quantification). Although the lowest quantified results were generally very low (<0.1 mg/kg), the lack of LOD/LOQ precluded quality check of the individual data, and for a consistent approach across all data, the data without information on LOD/LOQ were excluded. As this concerned thousands of data points, the impact of removal of these data was evaluated by doing statistical analysis on the dataset with and without these data, to see if extra effort in supplementing the missing information would be of use for the analysis. The results are presented in section 2 below.
5. In addition, from the CCCF11 dataset, data on Bonito were included in the dataset for tuna and Selachoidae (Pleurotremata) were included in the dataset for sharks, as these are considered to be tuna and sharks, respectively. The total dataset comprised data of the years 2000-2017.
6. The dataset was statistically analyzed for each fish species under investigation, percentiles were calculated and the P95 was used as a default value for derivation of the proposed MLs, as done for CCCF11. Based on the comments in the EWG, an additional proposal for the next lower ML that was <5% rejection rate was included, following the approach taken in the CCCF work on revision of the lead MLs.
7. In the Preamble of the General Standard for Contaminants and Toxins (GSCTFF, CXS 193-1995) it is stated that 'Numerical values for MLs should preferably be regular figures in a geometric scale (0.01, 0.02, 0.05, 0.1, 0.2, 0.5, 1, 2, 5 etc.), unless this may pose problems in the acceptability of the MLs'. In the case of methylmercury in fish, to consistently apply the same rejection rates, one decimal is needed in the proposed draft MLs. In addition, these decimals are because of the consistent approach for the same rejection rates, not regular figures in a geometric scale.

8. Subsequently, the number and percentage of samples meeting hypothetical MLs around the P95 were calculated.

2 Proposed draft MLs

2.1 Tuna

9. At CCCF11, it was agreed that one ML should be developed for all tuna, therefore the MLs proposed were derived from the combined data for tuna species. In order to have more insight into the variation of methyl and total mercury for various tuna species, data are specified per tuna species as done for CCCF11. Based on the comments in CCCF11 and the EWG that MLs should be based on the higher level tuna, additional analyses were performed for two categories: the higher level tuna (Bigeye and Bluefin) and the lower level tuna. For these categories, proposals for MLs were also derived.
10. After CCCF11, 1,328 new individual samples on total mercury and 356 for methylmercury in tuna were submitted to GEMS/Food. These new results were combined with the previous CCCF11 data and statistically analyzed. In addition, rejection rates at hypothetical MLs around the P95 percentile were calculated.
11. The results are presented in the tables below.

Table 1: Summary of occurrence data on total mercury in mg/kg in tuna samples, data taken from the GEMS/Food contaminants database. Statistical analysis excluding data without LOD/LOQ.

	GEMS Cluster	Years	Total records	Non-detects	Min LOQ	Max LOQ	Average	P50	P95	P97.5	P99	P100 (max)
Bigeye tuna (<i>Thunnus thynnus</i>)	G5 (10), G8 (81), G9 (24), G10 (182)	2004-2016	297	8	0	0.11	0.57	0.45	1.30	1.40	1.70	2.60
Atlantic bluefin tuna (<i>Thunnus thynnus</i>)	G5 (3), G7 (3), G10 (136)	2006-2011, 2013, 2015, 2016	142	0	0.01	0.11	0.60	0.52	1.20	1.54	2.00	2.30
Bluefin tuna (unspecified)	G9 (2), G10 (72)	2006-2009, 2011-2012, 2014	74	0	0	0.01	0.68	0.67	0.99	1.14	1.32	1.38
Pacific bluefin tuna (<i>Thunnus orientalis</i>)	G10 (83)	2007-2009, 2011, 2013-2016	83	0	0.01	0.05	0.49	0.37	0.86	0.91	1.21	1.90
Southern bluefin tuna (<i>Thunnus maccoyii</i>)	G10 (242)	2006-2007, 2009, 2011, 2013	242	0	0.01	0.05	0.56	0.43	1.30	1.80	2.30	4.40
Albacore tuna (<i>Thunnus alalunga</i>)	G5 (1), G8 (143), G9 (12), G10 (564)	2005-2017	736	7	0	0.11	0.33	0.29	0.73	0.90	1.07	1.80
Bullet tuna (<i>Auxis</i> spp)	G8 (48)	2005-2008, 2010-2011	48	8	0.05	0.1	0.17	0.15	0.37	0.45	0.66	0.84
Skipjack tuna (<i>Katsuwonus pelamis</i>)	G5 (49), G8 (111), G9 (51), G10 (257)	2004-2016	368	40	0.01	0.11	0.14	0.13	0.32	0.34	0.40	0.49
Yellowfin tuna (<i>Thunnus albacares</i>)	G5 (83), G7 (15), G8 (289), G9 (17), G10 (267)	2003-2017	671	47	0	0.2	0.28	0.21	0.74	0.87	1.03	1.40
Bonito (<i>Sarda sarda</i> , <i>Sarda chiliensis</i>)	G9 (3), G10 (21)	2007-2017	24	0	0.01	0.05	0.23	0.13	0.40	1.12	1.69	2.07
Little tuna (<i>Euthynnus alletteratus</i> , <i>Euthynnus lineatus</i>)	G5 (6), G10 (10)	2010-2017	16	0	0.01	0.13	0.27	0.19	0.71	0.75	0.78	0.80
Tongol tuna (<i>Thunnus tongol</i>)	G10 (2)	2016	2	0	0.05	0.05	0.07	-	-	-	-	0.09
Tuna (unspecified)	G3 (58), G5 (150), G9 (49), G10 (100)	2000-2017	357	35	0.01	0.2	0.28	0.15	0.83	1.11	2.11	4.74
Bigeye + Bluefin tuna	See above	See above	838	8	0	0.11	0.58	0.48	1.30	1.54	2.00	4.40
Other tuna than Bigeye and Bluefin	See above	See above	2222	137	0	0.2	0.27	0.22	0.72	0.87	1.10	4.74
All tuna	See above	See above	3060	145	0	0.2	0.35	0.28	0.93	1.20	1.40	4.74

Table 2: Summary of occurrence data on total mercury in mg/kg in tuna samples, data taken from the GEMS/Food contaminants database. Statistical analysis including data without LOD/LOQ.

	GEMS cluster	Years	Total records	Non-detects	Min LOQ	Max LOQ	Average	P50	P95	P97.5	P99	P100 (max)
Bigeye tuna (<i>Thunnus thynnus</i>)	G5 (7), G8 (81), G9 (24), G10 (182)	2004-2016	297	8	0	0.107	0.57	0.45	1.30	1.40	1.70	2.60
Atlantic bluefin tuna (<i>Thunnus thynnus</i>)	G5 (3), G7 (3), G10 (136)	2006-2011, 2013, 2015, 2016	142	0	0.01	0.107	0.60	0.52	1.20	1.54	2.00	2.30
Bluefin tuna (unspecified)	G8 (358), G9 (2), G10 (145)	2006-2009, 2011-2012, 2014	505	0	0	0.012	0.42	0.36	0.96	1.11	1.40	3.13
Pacific bluefin tuna (<i>Thunnus orientalis</i>)	G10 (83)	2007-2009, 2011, 2013-2016	83	0	0.01	0.051	0.49	0.37	0.86	0.91	1.21	1.90
Southern bluefin tuna (<i>Thunnus maccoyii</i>)	G10 (242)	2006-2007, 2009, 2011, 2013	242	0	0.01	0.051	0.56	0.43	1.30	1.80	2.30	4.40
Albacore tuna (<i>Thunnus alalunga</i>)	G5 (1), G8 (143), G9 (12), G10 (564)	2005-2017	736	7	0	0.107	0.33	0.29	0.73	0.90	1.07	1.80
Bullet tuna (<i>Auxis</i> spp)	G8 (53), G10 (1)	2005-2008, 2010-2011	54	8	0.05	0.1	0.21	0.17	0.41	0.72	1.39	2.00
Skipjack tuna (<i>Katsuwonus pelamis</i>)	G5 (49), G8 (111), G10 (157)	2004-2016	368	40	0.01	0.107	0.14	0.13	0.32	0.34	0.40	0.49
Yellowfin tuna (<i>Thunnus albacares</i>)	G5 (834), G7 (16), G8 (289), G9 (17), G10 (267)	2003-2017	1523	673	0	0.2	0.28	0.21	0.75	0.87	1.05	1.40
Bonito (<i>Sarda sarda</i> , <i>Sarda chiliensis</i>)	G10 (21)	2007-2017	21	0	0.01	0.051	0.25	0.14	0.41	1.24	1.74	2.07
Little tuna (<i>Euthynnus alletteratus</i> , <i>Euthynnus lineatus</i>)	G5 (6), G10 (10)	2010-2017	16	0	0.01	0.13	0.27	0.19	0.71	0.75	0.78	0.80
Tongol tuna (<i>Thunnus tongol</i>)	G10 (2)	2016	2	0	0.05	0.051	0.07	-	-	-	-	0.09
Tuna (unspecified)	G3 (58), G5 (150), G7 (65), G8 (577), G9 (49), G10 (132), G11 (20), G15 (179)	2000-2017	1230	80	0.01	0.2	0.29	0.18	0.85	1.13	1.62	4.74
Bigeye + Bluefin tuna	See above	See above	1269	8	0	0.107	0.51	0.42	1.20	1.40	1.90	4.40
Other tuna than Bigeye and Bluefin	See above	See above	3953	808	0	0.2	0.28	0.22	0.76	0.94	1.23	4.74
All tuna	See above	See above	5219	816	0	0.2	0.34	0.27	0.92	1.20	1.56	4.74

Table 3: Summary of occurrence data on methylmercury in mg/kg in tuna samples, data taken from the GEMS/Food contaminants database. Statistical analysis excluding data without LOD/LOQ.

	GEMS Cluster	Years	Total records	Non-detects	Min LOQ	Max LOQ	Average	P50	P95	P97.5	P99	P100 (max)
Bigeye tuna (Thunnus thynnus)	G10 (145)	2007-2009, 2014	145	0	0.01	0.01	0.60	0.45	1.20	1.24	1.57	2.00
Atlantic bluefin tuna (Thunnus thynnus)	G10 (136)	2006-2009	136	0	0.01	0.01	0.52	0.45	0.96	1.26	1.77	1.80
Bluefin tuna (unspecified)	G10 (72)	2009, 2014	72	0	0.01	0.01	0.57	0.55	0.80	0.95	1.07	1.10
Pacific bluefin tuna (Thunnus orientalis)	G10 (67)	2007-2008	67	0	0.01	0.01	0.46	0.30	0.82	0.89	1.18	1.60
Southern bluefin tuna	G10 (240)	2006-2007, 2009	240	0	0.01	0.01	0.48	0.37	1.21	1.50	1.88	2.90
Albacore tuna (Thunnus alalunga)	G10 (130)	2006, 2008, 2014	130	0	0.01	0.01	0.43	0.39	0.75	0.83	0.97	1.10
Bullet tuna (Auxis spp)			-	-	-	-	-	-	-	-	-	-
Skipjack tuna (Katsuwonus pelamis)	G9 (3), G10 (120)	2007-2009	123	4	0.006	0.006	0.13	0.13	0.28	0.29	0.31	0.35
Yellowfin tuna (Thunnus albacares)	G10 (130)	2007-2008, 2014	130	0	0.01	0.01	0.24	0.14	0.65	0.70	0.96	1.20
Bonito (Sarda sarda, Sarda orientalis)	WHO European region (2)	2014	3	0	0.006	0.006	0.08	-	-	-	-	0.08
Tuna (unspecified)			0	-	-	-	-	-	-	-	-	-
Bigeye + Bluefin tuna	See above	See above	660	0	0.01	0.01	0.52	0.43	1.20	1.30	1.70	2.90
Other tuna than Bigeye and Bluefin	See above	See above	386	4	0.006	0.006	0.26	0.22	0.67	0.74	0.91	1.20
All tuna	See above	See above	1046	4	0.006	0.006	0.43	0.36	1.05	1.20	1.60	2.90

Table 4: Summary of occurrence data on methylmercury in mg/kg in tuna samples, data taken from the GEMS/Food contaminants database. Statistical analysis including data without LOD/LOQ.

	GEMS Cluster	Years	Total records	Non-detects	Min LOQ	Max LOQ	Average	P50	P95	P97.5	P99	P100 (max)
Bigeye tuna (Thunnus thynnus)	G10 (185)	2007-2009, 2012, 2014	185	0	0.01	0.012	0.55	0.42	1.20	1.32	1.45	2.00
Atlantic bluefin tuna (Thunnus thynnus)	G10 (136)	2006-2009	136	0	0.01	0.01	0.52	0.45	0.96	1.26	1.77	1.80
Bluefin tuna (unspecified)	G10 (98)	2009, 2012, 2014	98	14	0.01	0.012	0.54	0.54	0.82	0.96	1.07	1.10
Pacific bluefin tuna (Thunnus orientalis)	G10 (67)	2007-2008	67	0	0.01	0.01	0.46	0.30	0.82	0.89	1.18	1.60
Southern bluefin tuna	G10 (240)	2006-2007, 2009	240	0	0.01	0.01	0.48	0.37	1.21	1.50	1.88	2.90
Albacore tuna (Thunnus alalunga)	G10 (130)	2006, 2008, 2014	130	0	0.01	0.01	0.43	0.39	0.75	0.83	0.97	1.10
Bullet tuna (Auxis spp)	WHO European region (2)	2014	2	0	0	0	0.05	-	-	-	-	0.05
Skipjack tuna (Katsuwonus pelamis)	G9 (3), G10 (120)	2007-2009	123	4	0.006	0.006	0.13	0.13	0.28	0.29	0.31	0.35
Yellowfin tuna (Thunnus albacares)	G10 (130)	2007-2008, 2014	130	0	0.01	0.01	0.24	0.14	0.65	0.70	0.96	1.20
Bonito (Sarda sarda, Sarda orientalis)	WHO European region (2)	2014	5	0	0.006	0.006	0.14	-	-	-	-	0.39
Tuna (unspecified)	G8 (125), G10 (22)	2006-2010, 2012-2015	298	10	0	0	0.26	0.16	0.84	0.97	1.24	1.99
Bigeye + Bluefin tuna	See above	See above	726	14	0.01	0.012	0.51	0.42	1.20	1.30	1.70	2.90
Other tuna than Bigeye and Bluefin	See above	See above	688	14	0.006	0.006	0.26	0.18	0.75	0.88	1.08	1.99
All tuna	See above	See above	1414	28	0.006	0.006	0.39	0.32	1.00	1.20	1.60	2.90

Table 5: Number and percentage of tuna samples meeting hypothetical MLs (compliance rate) based on total mercury data. Statistical analysis excluding data without LOD/LOQ.

Table 5a: all tuna; Table 5b: Bigeye and Bluefin tuna; Table 5c: Other tuna than Bigeye and Bluefin.

Total mercury All tuna Excluding data without LOD/LOQ			Total mercury Bigeye and bluefin tuna Excluding data without LOD/LOQ			Total mercury Tuna other than bigeye and bluefin Excluding data without LOD/LOQ		
Hypothetical MLs	Samples =< ML		Hypothetical MLs	Samples =< ML		Hypothetical MLs	Samples =< ML	
	Number	%		Number	%		Number	%
0.9	2883	94	1.1	768	89	0.4	1823	81
1.0	2941	95	1.2	785	91	0.5	1973	88
1.1	2967	96	1.3	807	93	0.6	2049	92
1.2	2988	97	1.4	815	96	0.7	2100	94
1.3	3013	97	1.5	816	97	0.8	2151	96
1.4	3027	98	1.6	821	97	0.9	2173	97
1.5	3028	99	1.7	824	98	1.0	2193	98
1.6	3033	99	1.8	826	98	1.1	2199	98
1.7	3036	99	1.9	828	98	1.2	2203	99
1.8	3039	99	2.0	832	98	1.3	2206	99
1.9	3042	99	2.1	832	99	1.4	2212	99
2.0	3046	99	2.2	832	99			

Table 6: Number and percentage of tuna samples meeting hypothetical MLs (compliance rate) based on total mercury data. Statistical analysis including data without LOD/LOQ.

Table 6a: All tuna; Table 6b: Bigeye and bluefin tuna; Table 6c: Other tuna than bigeye and bluefin.

Total mercury All tuna Including data without LOD/LOQ			Total mercury Bigeye and bluefin tuna Including data without LOD/LOQ			Total mercury Tuna other than bigeye and bluefin Including data without LOD/LOQ		
Hypothetical MLs	Samples =< ML		Hypothetical MLs	Samples =< ML		Samples =< ML		
	Number	%		Number	%	Hypothetical MLs	Number	%
0.9	4126	94	1.1	1188	92	0.4	2505	80
1.0	4210	95	1.2	1208	93	0.5	2709	86
1.1	4243	96	1.3	1231	95	0.6	2824	90
1.2	4271	97	1.4	1242	97	0.7	2909	93
1.3	4302	97	1.5	1243	97	0.8	2978	95
1.4	4320	98	1.6	1249	98	0.9	3013	97
1.5	4322	98	1.7	1252	98	1.0	3045	97
1.6	4331	98	1.8	1254	98	1.1	3055	98
1.7	4336	99	1.9	1257	98	1.2	3063	98
1.8	4340	99	2.0	1261	99	1.3	3071	99
1.9	4344	99	2.1	1261	99	1.4	3078	99
2.0	4350	99	2.2	1261	99			

Table 7: Number and percentage of tuna samples meeting hypothetical MLs (compliance rate) based on methylmercury data. Statistical analysis excluding data without LOD/LOQ

Table 7a: All tuna; Table 7b: Bigeye and Bluefin tuna; Table 7c: Other tuna than Bigeye and Bluefin..

Methylmercury All tuna Excluding data without LOD/LOQ			Methylmercury Bigeye and bluefin tuna Excluding data without LOD/LOQ			Methylmercury Tuna other than bigeye and bluefin Excluding data without LOD/LOQ		
Hypothetical MLs	Samples =< ML		Hypothetical MLs	Samples =< ML		Hypothetical MLs	Samples =< ML	
	Number	%		Number	%		Number	%
1.0	992	94	1.0	609	91	0.5	336	86
1.1	1007	95	1.1	622	92	0.6	352	91
1.2	1025	96	1.2	639	94	0.7	370	95
1.3	1031	97	1.3	645	96	0.8	379	98
1.4	1032	98	1.4	646	97	0.9	382	98
1.5	1034	98	1.5	648	97	1.0	383	98
1.6	1036	98	1.6	650	98	1.1	385	99
1.7	1040	99	1.7	654	98	1.2	386	99
1.8	1042	99	1.8	656	99			
1.9	1042	99	1.9	656	99			
2.0	1044	99	2.0	658	99			

Table 8: Number and percentage of tuna samples meeting hypothetical MLs (compliance rate) based on methylmercury data. Statistical analysis including data without LOD/LOQ.

Table 8a: All tuna; Table 8b: Bigeye and Bluefin tuna; Table 8c: Other tuna than Bigeye and Bluefin.

Methylmercury All tuna Including data without LOD/LOQ			Methylmercury Bigeye and bluefin tuna Including data without LOD/LOQ			Methylmercury Tuna other than bigeye and bluefin Including data without LOD/LOQ		
Hypothetical MLs	Samples =< ML		Hypothetical MLs	Samples =< ML		Hypothetical MLs	Samples =< ML	
	Number	%		Number	%		Number	%
1.0	1336	94	1.0	658	91	0.5	588	85
1.1	1353	95	1.1	671	92	0.6	614	89
1.2	1373	96	1.2	689	94	0.7	642	93
1.3	1380	98	1.3	695	96	0.8	661	96
1.4	1383	98	1.4	698	97	0.9	672	97
1.5	1385	98	1.5	700	98	1.0	678	98
1.6	1387	98	1.6	702	98	1.1	682	98
1.7	1391	99	1.7	706	98	1.2	684	99
1.8	1395	99	1.8	708	99	1.3	685	99
1.9	1395	99	1.9	708	99			
2.0	1398	99	2.0	710	99			

Proposed draft ML tuna

- The results of the analysis show that there is a consistent distribution of total mercury and methylmercury concentrations, both when ex- or including data without information on LOD/LOQ.

Based on the analysis and using the P95 as default principle for setting MLs or alternatively the next higher ML that provides <5% rejection rate, an ML of 1.1 mg/kg or 1.2 mg/kg for all tuna is proposed.

As alternative tuna categories, the following MLs are proposed: 1.3 mg/kg or 1.4 mg/kg for bigeye and bluefin tuna, and 0.7 mg/kg or 0.8 mg/kg for tuna other than Bigeye or Bluefin tuna.

2.2 Alfonsino

- After CCCF11, 240 new individual samples on methylmercury in alfonsino were submitted to GEMS/Food. No new individual data were submitted on total mercury in Alfonsino and all data had information on LOD/LOQ. These results were combined with the CCCF11 data and analyzed. The results are presented in the tables below.

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

	GEMS Cluster	Years	Total records	Non-detects	Min LOQ	Max LOQ	Average	P50	P95	P97.5	P99	P100 (max)
Alfonsino (Beryx splendens, Centroberyx affinis)	G08 (10), G09 (3), G10 (160)	2007-2008, 2010-2012	173	3	0.006	0.01	0.65	0.58	1.40	1.56	2.08	2.80

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

	GEMS Cluster	Years	Total records	Non-detects	Min LOQ	Max LOQ	Average	P50	P95	P97.5	P99	P100 (max)
Alfonsino (Beryx splendens)	G09 (3), G10(360)	2007-2008	363	0	0.006	0.01	0.69	0.64	1.40	1.60	2.08	2.80

Table 11: Number and percentage of Alfonsino samples meeting hypothetical MLs (compliance rate) based on total mercury data

Total mercury Alfonsino		
	Samples ≤ ML	
Hypothetical MLs	Number	Percentage
1.0	142	77
1.2	158	88
1.3	162	91
1.4	167	94
1.5	168	96
1.6	168	97
1.7	170	97
2.0	171	98

Table 12: Number and percentage of Alfonsino samples meeting hypothetical MLs (compliance rate) based on methylmercury data

Methylmercury Alfonsino		
	Samples ≤ ML	
Hypothetical MLs	Number	Percentage
1.0	305	78
1.2	335	90
1.3	343	93
1.4	349	94
1.5	352	96
1.6	354	96
1.7	356	97
2.0	359	98

Proposed draft ML for Alfonsino

14. The results of the analysis show that there is a consistent distribution of total mercury and methylmercury concentrations in Alfonsino. Using the P95 as default principle for setting MLs and alternatively the next higher ML that provides <5% rejection rate result in the same ML proposal, therefore an ML of 1.5 mg/kg for Alfonsino is proposed by the EWG.

2.3 Marlin

15. After CCCF11, 36 new individual samples on total mercury in Marlin were submitted to GEMS/Food. 480 new individual data were submitted on methylmercury in Marlin. The new results were combined with the CCCF11 data and analyzed. There were many data points without reported LOD/LOQ, thus the dataset was analyzed with and without these data points to evaluate the impact on the analysis.

16. As the levels of total mercury are very high in Marlin and are not similar to methylmercury as in other fish species (as calculated in the EWG for CCCF8, total mercury in fish comprises on average 85% of methylmercury), the analysis for rejection rates at hypothetical MLs is only performed on the methylmercury data.

17. One member of the EWG indicated that MLs for this category could be based on the category highest in methylmercury, being Blue marlin (unspecified). Although this would result in very high ML proposals, which could be unacceptable from a health point of view, an analysis of rejection rates at hypothetical MLs is also performed for this category.

18. The results are presented in the tables below.

Table 13: Summary of occurrence data on total mercury in mg/kg in Marlin samples, data taken from the GEMS/Food contaminants database.

	GEMS Cluster	Years	Total records	Non-detects	Min LOQ	Max LOQ	Average	P50	P95	P97.5	P99	P100 (max)
Atlantic blue marlin (<i>Makaira nigricans</i>)	G07 (4), G10 (50)	2009-2012	54	0	0.01	0.025	1.68	1.05	3.65	4.91	11.69	19.00
Blue marlin (unspecified and <i>Makaira nigricans</i>)	G10 (27)	2007-2011, 2014-2016	27	0	0.01	0.051	3.39	1.25	11.70	16.20	20.88	24.00
Indo-Pacific blue marlin (<i>Makaira mazara</i>)	G10 (60)	2008-2009	60	0	0.01	0.01	1.40	0.63	5.96	8.41	10.37	11.36
Striped marlin (<i>Kajikia audax</i>)	G10 (120)	2009	120	0	0.01	0.01	0.40	0.35	0.97	1.00	1.17	1.40
Marlin (<i>Tetrapturus</i> spp.)	G10 (10), G05 (2)	2007, 2009, 2011, 2013-2017	12	1	0.011	0.2	0.96	0.75	2.30	2.42	2.48	2.53
All marlin	See above	See above	273	1	0.01	0.2	1.19	0.56	4.66	6.84	11.54	24.00

Table 14: Summary of occurrence data on methylmercury in mg/kg in Marlin samples, data taken from the GEMS/Food contaminants database. Statistical analysis excluding data without LOD/LOQ.

	GEMS Cluster	Years	Total records	Non-detects	Min LOQ	Max LOQ	Average	P50	P95	P97.5	P99	P100 (max)
Atlantic blue marlin (<i>Makaira nigricans</i>)	G10 (50)	2009	50	0	0.01	0.01	0.16	0.14	0.36	0.37	0.39	0.41
Blue marlin (unspecified)	G10 (360)	2009	250	0	0.01	0.01	0.92	0.41	3.42	5.11	8.37	19.00
Indo-Pacific blue marlin (<i>Makaira mazara</i>)	G10 (60)	2008-2009	60	0	0.01	0.01	0.30	0.23	0.56	0.73	0.88	0.93
Striped marlin (<i>Kajikia audax</i>)	G10 (360)	2009	360	0	0.01	0.01	0.36	0.30	0.87	0.97	1.12	1.40
All marlin	See above	See above	720	0	0.01	0.01	0.53	0.31	1.40	2.31	4.80	19.00

Table 15: Summary of occurrence data on methylmercury in mg/kg in Marlin samples, data taken from the GEMS/Food contaminants database. Statistical analysis including data without LOD/LOQ.

	GEMS Cluster	Years	Total records	Non-detects	Min LOQ	Max LOQ	Average	P50	P95	P97.5	P99	P100 (max)
All marlin	G10 (748)	2008-2009, 2012	748	3	0.01	0.01	0.53	0.31	1.40	2.24	4.80	19.00

Table 16: Number and percentage of all Marlin samples meeting hypothetical MLs (compliance rate) based on methylmercury data. Statistical analysis excluding data without LOD/LOQ.

Methylmercury Marlin		
Excluding data without LOD/LOQ		
Hypothetical MLs	Samples =< ML	
	Number	Percentage
1.4	686	94
1.5	689	95
1.6	692	95
1.7	693	96
1.8	695	96
1.9	696	96
2.0	697	96
2.5	703	97
3.0	705	97

Table 17: Number and percentage of all Marlin samples meeting hypothetical MLs (compliance rate) based on methylmercury data. Statistical analysis including data without LOD/LOQ.

Methylmercury Marlin		
Including data without LOD/LOQ		
Hypothetical MLs	Samples =< ML	
	Number	Percentage
1.4	709	94
1.5	712	95
1.6	717	95
1.7	718	96
1.8	720	96
1.9	721	96
2.0	722	96
2.5	728	97
3.0	730	97

Table 18: Number and percentage of Blue marlin (unspecified) samples meeting hypothetical MLs (compliance rate) based on methylmercury data. All data had LOD/LOQ reported.

Methylmercury unspecified blue marlin		
Hypothetical MLs	Samples =< ML	
	Number	Percentage
1.6	222	87
1.7	223	88
1.8	225	89
1.9	226	90
2.0	227	90
2.5	233	92
3.0	235	93
4.0	238	95
4.5	239	95
4.6	240	96
5.0	242	97
6.0	245	98

Proposed draft ML for Marlin

- As compared to CCCF11, methylmercury concentrations in Blue marlin (unspecified) are much higher. The P95 during CCCF11 was 0.92 mg/kg, while with the new data points, the P95 is 3.41 mg/kg. CCCF should decide whether the new ML should be based on this category.

20. Based on the methylmercury data above, and using the P95 as default principle for setting MLs or alternatively the next higher ML that provides <5% rejection rate, an ML of 1.6 mg/kg or 1.7 mg/kg for marlin is proposed by the EWG. Should the ML be based on the category with the highest concentrations (Blue marlin, unspecified), the proposed MLs would be 4.5 mg/kg or 4.6 mg/kg.

2.4 Kingfish/Amberjack

21. Based on the decision of CCCF11 to develop MLs for Kingfish/Amberjack, only data on *Seriola* species have been considered, and no other jack mackerel species. 61 data on 'Yellowtail' (unspecified) were submitted, these were assumed to be Yellowtail amberjack (*Seriola lalandi*).

22. After CCCF11, 84 new individual samples on total mercury in amberjack were submitted to GEMS/Food. 40 new individual data points were submitted on methylmercury in Amberjack. There were no data without information on LOD/LOQ. One data point was excluded because of a very high reported LOQ (1.07 mg/kg). The new results were combined with the CCCF11 data and analyzed. The results are presented in the tables below.

Table 19: Summary of occurrence data on total mercury in mg/kg in Amberjack samples, data taken from the GEMS/Food contaminants database.

	GEMS Cluster	Years	Total records	Non-detects	Min LOQ	Max LOQ	Average	P50	P95	P97.5	P99	P100 (max)
Kingfish/Amberjack/Yellowtail (<i>Seriola lalandi</i> , <i>Seriola dumenli</i> , <i>Seriola quinqueradiata</i>)	G09 (39), G10 (109)	2005-2017	179	0	0.002	0.077	0.24	0.17	0.65	0.86	0.94	1.62

Table 20: Summary of occurrence data on methylmercury in mg/kg in Amberjack samples, data taken from the GEMS/Food contaminants database.

	GEMS Cluster	Years	Total records	Non-detects	Min LOQ	Max LOQ	Average	P50	P95	P97.5	P99	P100 (max)
Kingfish/Amberjack/Yellowtail (<i>Seriola lalandi</i> , <i>Seriola dumenli</i>)	G09 (9), G10 (40)	2007	49	0	0.006	0.01	0.18	0.13	0.48	0.68	0.77	0.81

Table 21: Number and percentage of Amberjack samples meeting hypothetical MLs (compliance rate) based on total mercury data

Total mercury amberjack		
	Samples ≤ ML	
Hypothetical MLs	Number	Percentage
0.5	157	87
0.6	166	92
0.7	171	95
0.8	172	95
0.9	175	97
1.0	178	98

Table 22: Number and percentage of Amberjack samples meeting hypothetical MLs (compliance rate) based on methylmercury data

Methylmercury amberjack		
		Samples ≤ ML
Hypothetical MLs	Number	Percentage
0.5	47	94
0.6	47	94
0.7	47	95
0.8	48	97
0.9	49	100
1.0	49	100

Proposed draft ML for Amberjack

23. The results show that, in contrast to the results for CCCF11, the average and P50 for Amberjack (*Seriola spp.*) are below the selection criterion of 0.3 mg/kg for both methylmercury and total mercury. CCCF12 should decide is work on MLs for this subspecies of Jack mackerel should be continued or not.
24. Should CCCF12 decide to continue work, using the P95 as default principle for setting MLs or alternatively the next higher ML that provides <5% rejection rate, an ML of 0.7 mg/kg or 0.8 mg/kg for Amberjack (*Seriola spp.*) is proposed.

Spanish mackerel

25. During the sorting of data for Amberjack, new data for Spanish or King mackerel were discovered; 98 data points were submitted after CCCF11. For CCCF11, only 7 samples on King or Spanish mackerel were available, of which the average was around the threshold level for selecting fish species for ML development, therefore an analysis of this subspecies of Jack mackerel was performed.
26. Two data points were excluded from the analysis because of very high reported LOQs (0.5 mg/kg and 1.182 mg/kg). The data were analyzed together with all *Scomberomorus spp.* data from CCCF11 to evaluate the MLs and are presented in the tables below.

Table 23: Summary of occurrence data on total mercury in mg/kg in King or Spanish mackerel samples, data taken from the GEMS/Food contaminants database.

	GEMS Cluster	Years	Total records	Non-detects	Min LOQ	Max LOQ	Average	P50	P95	P97.5	P99	P100 (max)
Spanish or King mackerel (<i>Scomberomorus cavalla</i>), Narrow-based Spanish mackerel (<i>Scomberomus commerson</i> , 1), Indo-pacific king mackerel (<i>Scomberomus guttatus</i> , 5), Spotted mackerel (<i>Scomberomorus munroi</i> , 2)	G09 (8), G10 (93)	2007-2017	101	0	0.002	0.087	0.24	0.17	0.61	0.83	1.38	2.69

Table 24: Summary of occurrence data on methylmercury in mg/kg in King or Spanish mackerel samples, data taken from the GEMS/Food contaminants database.

	GEMS Cluster	Years	Total records	Non-detects	Min LOQ	Max LOQ	Average	P50	P95	P97.5	P99	P100 (max)
Spanish mackerel (<i>Scomberomorus cavalla</i> , <i>Scomberomorus guttatus</i> , <i>Scomberomorus commerson</i>)	G09 (6), G10 (10)	2007, 2014	16	0	0.006	0.01	0.05	0.05	0.10	0.11	0.11	0.11

Conclusion for Spanish mackerel

- 27. As for marlin, the concentrations of total mercury and methylmercury differ significantly. The average for total mercury is only just below the selection criterion for ML elaboration of 0.3 mg/kg used in the analysis for CCCF11, the average for methylmercury is far below that value, but still only 16 data points were available. The EWG recommends that more methylmercury analyses be done in Spanish mackerel to confirm the methylmercury levels and the ratio between total mercury and methylmercury.
- 28. This finding also indicates that if consideration is given to development of MLs for other fish species, any ML development would need to take into consideration the ratio of total mercury and methylmercury as this can vary largely between species and it cannot always be assumed that total mercury is predominantly present as methylmercury.

2.5 Shark (including dogfish)

- 29. After CCCF11, 115 new individual samples on total mercury in shark and dogfish were submitted to GEMS/Food. 2 new individual data points were submitted on methylmercury in shark and dogfish. The new results were combined with the CCCF11 data and analyzed. There were many data points without LOD/LOQ, the dataset was analyzed with and without these data points to evaluate the impact on the analysis. The results are presented in the tables below.

Table 25: Summary of occurrence data on total mercury in mg/kg in shark samples, data taken from the GEMS/Food contaminants database. Statistical analysis excluding data without LOD/LOQ.

	GEMS Cluster	Years	Total records	Non-detects	Min LOQ	Max LOQ	Average	P50	P95	P97.5	P99	P100 (max)
Blue shark (<i>Prionace glauca</i>)	G05 (6), G10 (132)	2007-2014, 2017	138	0	0.01	0.13	0.75	0.61	1.58	1.92	2.35	3.40
Ghost shark (<i>Hydrolagus spp.</i>)	G10 (102)	2002	102	0	0.006	0.006	0.32	0.29	0.57	0.64	0.67	0.70
Pale ghost shark (<i>Hydrolagus bemisi</i>)	G10 (102)	2002, 2013	102	0	0.006	0.006	0.39	0.36	0.71	0.77	0.78	0.79
Porbeagle shark (<i>Lamna nasus</i>)	G07 (6), G10 (1)	2011-2012	7	0	0.01	0.03	0.92	-	-	-	-	1.36
Shortfin Mako shark (<i>Isurus oxyrinchus</i>)	G10 (5)	2007, 2010, 2011, 2015	5	0	0.011	0.051	0.82	-	-	-	-	1.18
Shark (unspecified)	G05 (1), G07 (97), G08 (128), G10 (86), G11 (1),	2000, 2002, 2007-2014, 2017	23	0	0	0.13	1.12	1.00	2.43	2.58	2.66	2.71
Houndshark (<i>Mustellus asterias</i> , 2), Shortfin mako (<i>Isurus oxyrinchus</i> , 1), Thresher shark (<i>Alopias vulpinus</i> , 3), Sharp Nosed Shark (1), Cat Shark (4), Tope shark (<i>Galeorhinus galeus</i> , 1), Tiger shark (<i>Galeocerdo cuvier</i> , 1), Freshwater shark	G07 (5), G09 (2), G10 (6)	2007-2013	13	0	0.01	0.025	0.48	0.25	1.42	1.71	1.88	1.99
Lesser spotted dogfish (<i>Scyliorhinus canicula</i>)	G07 (14)	2010-2012	14	0	0.01	0.03	0.37	0.36	0.72	0.73	0.74	0.74
Portuguese dogfish (<i>Centroscymnus coelolepis</i>)	G07 (3)	2010-2011	3	0	0.01	0.03	-	-	-	-	-	3.52
Smooth skin dogfish (<i>Centroscymnus owstonii</i>)	G10 (1)	2013	1	0	0.01	0.03	-	-	-	-	-	1.33
Spiny dogfish, Northern shark (<i>Squalus acanthias</i>)	G10 (74)	2007-2009, 2015	74	0	0.011	0.051	0.75	0.75	1.10	1.20	1.27	1.45
Dogfish (unspecified)	G09 (30)	2005-2007, 2009-2013	30	1	0.012	0.012	0.49	0.14	2.34	2.98	3.28	3.48
All sharks and dogfish	See above	See above	512	1	0.006	0.13	0.59	0.49	1.37	1.79	2.50	3.52

Table 26: Summary of occurrence data on total mercury in mg/kg in shark samples, data taken from the GEMS/Food contaminants database. Statistical analysis including data without LOD/LOQ.

	GEMS Cluster	Years	Total records	Non-detects	Min LOQ	Max LOQ	Average	P50	P95	P97.5	P99	P100 (max)
Blue shark (Prionace glauca)	G05 (7), G10 (132)	2007-2014, 2017	139	0	0.01	0.13	0.75	0.61	1.57	1.92	2.35	3.40
Ghost shark (Hydrolagus spp.)	G10 (102)	2002	102	0	0.006	0.006	0.32	0.29	0.57	0.64	0.67	0.70
Pale ghost shark (Hydrolagus bemisi)	G10 (102)	2002, 2013	102	0	0.006	0.006	0.39	0.36	0.71	0.77	0.78	0.79
Porbeagle shark (Lamna nasus)	G07 (6), G10 (1)	2011-2012	7	0	0.01	0.03	0.92	-	-	-	-	1.36
Shortfin Mako shark (Isurus oxyrinchus)	G10 (5)	2007, 2010, 2011, 2015	5	0	0.011	0.051	0.82	-	-	-	-	1.18
Shark (unspecified)	G05 (1), G07 (97), G08 (128), G10 (86), G11 (1), G15 (32)	2000, 2002, 2007-2014, 2017	345	29	0.008	0.33	0.74	0.57	2.17	2.71	3.61	6.34
Houndshark (Mustellus asterias, 2), Shortfin mako (Isurus oxyrinchus, 1), Thresher shark (Alopias vulpinus, 3), Sharp Nosed Shark (1), Cat Shark (4), Tope shark (Galeorhinus galeus, 1), Tiger shark (Galeocerdo cuvier, 1), Freshwater shark (boal,	G07 (8), G09 (2), G10 (6)	2007-2013	16	0	0.01	0.025	0.51	0.35	1.28	1.64	1.85	0.50
Lesser spotted dogfish (Scyliorhinus canicula)	G07 (14)	2010-2012	14	0	0.01	0.03	0.37	0.36	0.72	0.73	0.74	0.74
Portuguese dogfish (Centroscymnus coelolepis)	G07 (3)	2010-2011	3	0	0.01	0.03	-	-	-	-	-	3.52
Smooth skin dogfish (Centroscymnus owstonii)	G10 (1)	2013	1	29	0.01	0.03	-	-	-	-	-	1.33
Spiary dogfish, Northern shark (Squalus acanthias)	G10 (74)	2007-2009, 2015	74	0	0.011	0.051	0.75	0.75	1.10	1.20	1.27	1.45
Dogfish (unspecified)	G09 (30)	2005-2007, 2009-2013	30	1	0.012	0.012	0.49	0.14	2.34	2.98	3.28	3.48
All sharks and dogfish	See above	See above	838	30	0.006	0.33	0.64	0.50	1.68	2.30	3.08	6.34

Table 27: Summary of occurrence data on methylmercury in mg/kg in shark samples, data taken from the GEMS/Food contaminants database. Statistical analysis excluding data without LOD/LOQ.

	GEMS Cluster	Years	Total records	Non-detects	Min LOQ	Max LOQ	Average	P50	P95	P97.5	P99	P100 (max)
Blue shark	G10 (120)	2008-2009	120	0	0	0	0.66	0.57	1.20	1.59	1.77	2.20
Shark (unspecified)	-	-	0	-	-	-	-	-	-	-	-	-
All shark	See above	See above	120	0	0.01	0.01	0.66	0.57	1.20	1.59	1.77	2.20

Table 28: Summary of occurrence data on methylmercury in mg/kg in shark samples, data taken from GEMS/Food. Statistical analysis including data without LOD/LOQ.

	GEMS Cluster	Years	Total records	Non-detects	Min LOQ	Max LOQ	Average	P50	P95	P97.5	P99	P100 (max)
Blue shark (Prionace glauca)	G10 (120)	2008-2009	120	0	0	0	0.66	0.57	1.20	1.59	1.77	2.20
Shark (unspecified)	G08 (2) G10 (45), WHO European region (2)	2008 2012 2014	49	1	0	0	0.83	0.49	1.97	3.68	5.03	5.93
All shark	See above	See above	169	1	0.01	0.01	0.71	0.55	1.57	1.77	2.79	5.93

Table 29: Number and percentage of shark samples meeting hypothetical MLs (compliance rate) based on total mercury data. Statistical analysis excluding data without LOD/LOQ.

Total mercury shark		
Excluding data without LOD/LOQ		
Samples \leq ML		
Hypothetical MLs	Number	Percentage
1.0	448	87
1.1	464	89
1.2	477	92
1.3	484	94
1.4	490	95
1.5	491	95
1.6	495	96
1.7	502	97
2.0	507	98

Table 30: Number and percentage of shark samples meeting hypothetical MLs (compliance rate) based on total mercury data. Statistical analysis including data without LOD/LOQ.

Total mercury shark		
Including data without LOD/LOQ		
Samples \leq ML		
Hypothetical MLs	Number	Percentage
1.0	704	82
1.1	732	86
1.2	754	88
1.3	768	91
1.4	776	92
1.5	783	92
1.6	791	94
1.7	810	96
2.0	821	97

Table 31: Number and percentage of shark samples meeting hypothetical MLs (compliance rate) based on methylmercury data. Statistical analysis excluding data without LOD/LOQ.

Methylmercury shark		
Excluding data without LOD/LOQ		
Samples \leq ML		
Hypothetical MLs	Number	Percentage
1.0	103	83
1.1	108	88
1.2	114	94
1.3	115	95
1.4	115	95
1.5	115	95
1.6	117	96
1.7	119	98
2.0	120	-

Table 32: Number and percentage of shark samples meeting hypothetical MLs (compliance rate) based on methylmercury data. Statistical analysis including data without LOD/LOQ.

Methylmercury shark		
Including data without LOD/LOQ		
Samples \leq ML		
Hypothetical MLs	Number	Percentage
1.0	140	81
1.1	145	85
1.2	152	89
1.3	154	91
1.4	156	92
1.5	157	93
1.6	161	95
1.7	164	97
2.0	166	98

Proposed draft ML for shark

30. The results indicate difference between the analyses when including or excluding data without a LOQ. Efforts could be made to supplement the excluded data with information on LOD/LOQ to strengthen the analysis. Based on the current data, using the P95 as default principle for setting MLs or alternatively the next higher ML that provides <5% rejection rate, an ML of 1.5 mg/kg or 1.6 mg/kg for shark seems to be the most appropriate, giving 5% or 4% rejection based on methylmercury and total mercury when excluding the data without LOD/LOQ.

2.6 Swordfish

31. After CCCF11, 642 new individual samples on total mercury in Swordfish were submitted to GEMS/Food. 291 new individual data were submitted on methylmercury in Swordfish. The new results were combined with the CCCF11 data and analyzed. There were many data points without LOD/LOQ values, 34 data point on methylmercury were supplemented during the course of the EWG; based on reported LOQ, five data points were suspected to be falsely reported in ug/kg, these were converted to mg/kg. The dataset was analyzed with and without these data points to evaluate the impact on the analysis. The results are presented in the tables below.

Table 33: Summary of occurrence data on total mercury in mg/kg in Swordfish samples, data taken from the GEMS/Food contaminants database. Statistical analysis excluding data without LOD/LOQ.

	GEMS Cluster	Years	Total records	Non-detects	Min LOQ	Max LOQ	Average	P50	P95	P97.5	P99	P100 (max)
Swordfish (<i>Xyphias gladius</i>)	G05 (634), G07 (17), G09 (4), G10 (295)	2004-2017	950	3	0.00032	0.002	0.85	0.86	1.90	2.32	2.69	3.90

Table 34: Summary of occurrence data on total mercury in mg/kg in Swordfish samples, data taken from the GEMS/Food contaminants database. Statistical analysis including data without LOD/LOQ.

	GEMS Cluster	Years	Total records	Non-detects	Min LOQ	Max LOQ	Average	P50	P95	P97.5	P99	P100 (max)
Swordfish (<i>Xyphias gladius</i>)	G05 (635), G07 (18), G08 (183), G09 (4), G10 (353), G15 (21)	2004-2017	1214	15	0.00032	0.002	0.93	0.90	2.28	2.71	3.50	6.76

Table 35: Summary of occurrence data on methylmercury in mg/kg in Swordfish samples, data taken from the GEMS/Food contaminants database. Statistical analysis excluding data without LOD/LOQ.

	GEMS Cluster	Years	Total records	Non-detects	Min LOQ	Max LOQ	Average	P50	P95	P97.5	P99	P100 (max)
Swordfish (<i>Xyphias gladius</i>)	G07 (15), G10 (370), WHO European region (34)	2006-2008, 2010-2015	404	0	0.01	0.1	1.15	1.10	2.20	2.50	2.80	3.90

Table 36: Summary of occurrence data on methylmercury in mg/kg in Swordfish samples, data taken from the GEMS/Food contaminants database. Statistical analysis including data without LOD/LOQ.

	GEMS Cluster	Years	Total records	Non-detects	Min LOQ	Max LOQ	Average	P50	P95	P97.5	P99	P100 (max)
Swordfish (<i>Xyphias gladius</i>)	G07 (15), G08 (10), G10 (402), WHO EU region (41)	2006-2008, 2010-2012, 2014-2015	468	0	0.003	0.01	1.12	1.08	2.20	2.56	2.76	3.90

Table 37: Number and percentage of Swordfish samples meeting hypothetical MLs (compliance rate) based on total mercury data. Statistical analysis excluding data without LOD/LOQ.

Total mercury swordfish		
Excluding data without LOD/LOQ		
	Samples ≤ ML	
Hypothetical MLs	Number	Percentage
1.5	826	85
2.0	911	95
2.2	920	96
2.3	925	97
2.4	930	97
2.5	934	98
2.6	937	98
3.0	946	99
3.5	949	99

Table 38: Number and percentage of Swordfish samples meeting hypothetical MLs (compliance rate) based on total mercury data. Statistical analysis including data without LOD/LOQ.

Total mercury swordfish		
Including data without LOD/LOQ		
	Samples ≤ ML	
Hypothetical MLs	Number	Percentage
1.5	1014	82
2.0	1139	93
2.2	1150	94
2.3	1158	95
2.4	1165	95
2.5	1171	96
2.6	1178	96
3.0	1196	98
3.5	1201	98

Table 39: Number and percentage of Swordfish samples meeting hypothetical MLs (compliance rate) based on methylmercury data. Statistical analysis excluding data without LOD/LOQ.

Methylmercury swordfish		
Excluding data without LOD/LOQ		
	Samples =< ML	
Hypothetical MLs	Number	Percentage
1.5	308	73
2	371	91
2.2	384	94
2.3	390	96
2.4	392	96
2.5	393	97
2.6	394	97
3	403	99
3.5	403	99

Table 40: Number and percentage of Swordfish samples meeting hypothetical MLs (compliance rate) based on methylmercury data. Statistical analysis including data without LOD/LOQ.

Methylmercury swordfish		
Including data without LOD/LOQ		
	Samples ≤ ML	
Hypothetical MLs	Number	Percentage
1.5	364	75
2	432	91
2.2	445	94
2.3	451	95
2.4	453	96
2.5	455	96
2.6	456	96
3	467	99
3.5	467	99

Proposed draft ML for Swordfish

32. Excluding data without LOD/LOQ values for total mercury results in a lower P95 than including those data. However, for methylmercury the P95 for both analyses is only slightly different. Based on the data above, using the P95 as default principle for setting MLs or alternatively the next higher ML that provides <5% rejection rate, an ML of 2.3 mg/kg or 2.4 mg/kg for Swordfish is proposed by the EWG.

2.7 Conclusions

33. The following MLs for methylmercury are proposed.

Fish species	Proposed draft ML in mg/kg based on P95	Proposed draft ML in mg/kg based on next higher ML that provides <5% rejection
All tuna Or Bigeye and Bluefin tuna Tuna other than Bigeye and Bluefin	1.1 1.3 0.7	1.2 1.4 0.8
Alfonsino	1.5	1.5
Marlin Or Marlin (based on Blue marlin, unspecified)	1.6 4.5	1.7 4.6
Amberjack Or Amberjack	0.7 No ML	0.8 No ML
Shark	1.5	1.6
Swordfish	2.3	2.4

Additional recommendations resulting from the analysis

34. The EWG recommends that more methylmercury analyses be done in Spanish mackerel to confirm the methylmercury levels and the ratio between total mercury and methylmercury.
35. Earlier analysis has shown that in general the ratio of methylmercury to total mercury was 0.85, therefore total mercury was used in the data analysis for derivation of MLs, assuming that all total mercury is present as methylmercury. However, the analyses show that care is needed in doing this as there are at least two species (Marlin and Spanish mackerel) in which the ratio is much lower than this. The EWG recommends that if consideration may be given to development of MLs in for other fish species, any ML development would need to take into consideration the ratio of total mercury and methylmercury as this can vary largely between species. One member also indicated that data should also have a good geographical distribution.

3 Footnotes to the ML

3.1 Footnote on analysis of total mercury as a screening tool for methylmercury

36. CCCF11 decided to continue with the approach to establish MLs for methylmercury, while screening for total mercury (REP 17/CF, para 138). Therefore, a footnote to the ML indicating this option could be considered. Some members of the EWG indicated that this could be more clearly stated for the current proposed draft MLs, and not only in the sampling plan.
37. Therefore, the footnote to the ML for inorganic arsenic in rice has been used as an example and adapted for methylmercury:

“Countries or importers may decide to use their own screening when applying the ML for methylmercury in fish by analysing total mercury in fish. If the total mercury concentration is below the ML for methylmercury, no further testing is required and the sample is determined to be compliant with the ML. If the total mercury concentration is above the ML for methylmercury, follow-up testing shall be conducted to determine if the methylmercury concentration is above the ML.”

38. CCCF12 is invited to consider this proposal.

3.2 Existing footnote to the GL for processed fish and fish products

39. CCCF11 decided not to develop an ML for canned tuna as levels in these samples were generally low. This decision was solely based on the data analysis for canned tuna for CCCF11. The current GL includes a footnote ‘*The guideline levels are intended for methylmercury in fresh or processed fish and fish products moving in international trade*’, which includes canned fish. No decision was made at CCCF11 in relation to this footnote.
40. The chairs of the EWG put forward the question whether the current footnote to the GL should be attached to the new MLs. Not including the footnote would mean that the ML for fresh/frozen fish would not apply to canned fish, which could possibly open the possibility of non-compliant fish for the ML for fresh/frozen fish being processed into cans.
41. If the footnote is attached to the new MLs, this would not mean that the data analysis for derivation of the MLs should also include the data on canned fish. As illustration, an updated analysis of data on canned tuna has been provided in *Table 41*, to confirm the findings of CCCF11 that levels are generally low in canned tuna, and that including these data in the analysis would skew the distribution curve towards lower levels and thus result in lower MLs being proposed. It also shows that canned tuna meets the proposed MLs for fresh/frozen tuna.
42. In the EWG, four members were opposed to attaching the existing footnote to the MLs, because of the decision of CCCF11 not to derive an ML for canned tuna and one member indicated it might result in unnecessary testing. Three members were in favor of attaching the current footnote to the ML.
43. CCCF12 is invited to discuss the application of the existing footnote ‘*The guideline levels are intended for methylmercury in fresh or processed fish and fish products moving in international trade*’ to the proposed draft MLs.

Table 41: Summary of occurrence data on total mercury in mg/kg in canned tuna samples, data taken from the GEMS/Food contaminants database. Canned samples with additional other ingredients (e.g. mayonnaise, curry, spices) than tuna were excluded.

	Origin data	Years	Total records	Non-detects	Min LOQ	Max LOQ	Average	P50	P95	P97.5	P99	P100 (max)
Canned Albacore tuna (Thunnus alalunga)	G9 (5), G10 (176)	2007-2014, 2016-2017	181	0	0.01	0.05	0.44	0.43	0.69	0.75	0.85	0.98
Canned Skipjack tuna (Katsuwonus pelamis)	G9 (4), WHO Western Pacific (2), G10 (74)	2007-2017	78	0	0	0.10	0.10	0.06	0.31	0.39	0.43	0.47
Canned yellowfin tuna (Thunnus albacares)	G9 (5), G10 (99)	2007-2016	99	0	0	0.30	0.23	0.14	0.74	0.85	1.30	1.43
Canned mixed tuna (Thunnus obesus (3), Thunnus orientalis (2), Thunnus macoyii (2), Thunnus tongol (5), Euthynnus lineatus (2), Sarda chiliensis (5), Sarda sarda (2))	G10 (22)	2007-2010, 2012-2017	22	0	0.01	0.05	0.22	0.09	1.21	1.35	1.40	1.44
Canned tuna (unknown)	WHO Western Pacific (26), G5 (2), G7 (21), G10 (96)	2000-2002, 2007-2016,	129	4	0	0.22	0.13	0.08	0.32	0.49	0.77	1.58

3.3 Additional risk management measures (consumption advice)

3.3.1 *Selection of threshold ML for footnote*

44. CCCF11 agreed to develop a footnote to the higher MLs to indicate the need for additional risk management measures. In the discussion paper for CCCF11, fish consumption data from the GEMS/Food Cluster diets were gathered to determine a critical concentration for selecting fish species eligible for MLs development. That analysis was used again for deriving a threshold ML for attaching a footnote.
45. Based on the average (122 g/week) consumption rate from all GEMS cluster diets of fresh, frozen and cured marine finfish fish, women of childbearing age could consistently consume fish containing approximately 0.8 mg/kg methylmercury before exceeding the JECFA methylmercury PTWI. However, at the 95th percentile consumption rate of 285 g/person per week, specified women would have to restrict fish consumption to those species containing approximately no greater than 0.3 mg/kg methylmercury in order to limit their exposure such that it does not exceed the PTWI.

The reported consumption rates of GEMS/Food clusters G14 and G17 both approximate this 95th percentile consumption rate, although no specific information is available for the countries in these clusters regarding the proportion of overall non-canned marine fish consumption that may be attributed to tuna or other types of marine finfish. Any additional methylmercury exposure from other types of fish (e.g. canned, freshwater) could result in exposure exceeding the PTWI.

For countries where consumption of fish species with MLs equal to or greater than 0.8 mg/kg methylmercury is known to occur, some additional form of risk management, such as consumption advice, may be required. In addition, for countries with very high fish intake rates equivalent to the previously stated 95th percentile, additional risk management measures could be considered for fish species with equal to or greater than 0.3 mg/kg methylmercury. Any additional form of risk management implemented should take into consideration the known nutritional benefits of fish consumption.

46. Considering the above, and the fact that all proposed draft MLs exceed the 0.3 mg/kg, the EWG proposes to attach a footnote indicating the need for additional risk management measures to all proposed draft MLs.

3.3.2 *Proposed text for footnote*

47. In the discussion paper CX/CF 17/11/12 the following text was proposed and well received by the EWG: *'For this fish species, additional risk management measures may be necessary on a national level to restrict exposure to unacceptably high levels of methylmercury (e.g. consumption advice)'*
48. To give some more context to the need for additional risk management measures, the following text for the footnote was proposed to the EWG:

“Adverse effects due to methylmercury exposure may outweigh the benefits of fish consumption at lower levels than the ML when frequently consuming this fish species, particularly by pregnant women and infants. The development of additional risk management measures (e.g. consumption advice) may be necessary on a national level to restrict exposure in order to avoid unacceptably high levels of methylmercury.”

49. One member indicated that the footnote could delete the reference to other risk management measures as only consumption advice would be an option in practice. This member provided an alternative proposal for text of the footnote:

“There is a potential risk for specific consumers (particularly pregnant women and infants) from methylmercury exposure and the proposed MLs are a risk management measure to control exposure to ALARA. Therefore, it is important for consumers to follow advice on consumption of specific species of fish in place at the national level, including advice on the known benefits of fish consumption.”

50. A second member provided another alternative proposal for text of the footnote:

“For fish species high in methylmercury, countries should consider developing nationally relevant consumer advice for pregnant women and young children to supplement these MLs.”

51. CCCF is invited to consider these proposals for text for the footnote.

4 Methods of analysis and sampling

4.1 Methods of analysis

52. In Codex standard CXS 234-1999 ‘Recommended methods of analysis and sampling’, in part A it is recommended to use for the analysis of mercury in fish and fishery products the standard AOAC 977.15 Flameless atomic absorption spectrophotometry, type III, and for the GL for methylmercury in fish the standard 988.11 Atomic absorption spectrophotometry, type II.
53. Other methods have been suggested by the EWG, such as for total mercury, ICP-OES or ICP-MS based methods. For total mercury, AOAC 977.15 will work, but newer methods, such as AOAC 2013.06, are available. For methylmercury, ICP-MS hyphenated with HPLC or IC were suggested by the EWG. For methylmercury AOAC 983.20 and 990.04 also were mentioned to use relatively simple instrumentation. There are also very new HPLC-ICP-MS methods but require more sophisticated instrumentation.
54. It should be noted that, based on the proposed MLs, the analytical methods should be capable of accurately quantifying total mercury and methylmercury down to the 0.01 mg/kg.
55. One member suggested to forward the question on analytical methods to CCMAS for endorsement. Because there are a number of analytical methods available, the approach taken in other sampling plans, not to specify analytical methods but describe method performance criteria, (also described in Appendix II), could be followed.
56. CCCF12 is recommended to request CCMAS to advise if analytical methods should be included in the sampling plan for determining total mercury and methylmercury in fish and if so, which methods.

4.2 Methods of sampling

57. No sampling plan for methylmercury in fish is recommended in Codex standard CXS 234-1999 ‘Recommended methods of analysis and sampling’. No other suitable sampling plans exist in Codex. A new sampling plan to accompany the future Codex MLs should therefore be developed. It is in the mandate of CCCF to develop such a plan, however advice from CCMAS may be requested if necessary.
58. The following sampling plans for mercury in fish were available to the EWG:
- European Union: Commission Regulation (EC) No 333/2007 of 28 March 2007 laying down the methods of sampling and analysis for the control of the levels of trace elements and processing contaminants in foodstuffs.
 - Australia New Zealand Food Standards Code – Schedule 19 – Maximum levels of contaminants and natural toxicants, section 7 Mean and maximum levels of mercury in fish, crustacea and molluscs.
59. As EU Regulation 333/2007 was the most elaborate of the two plans, this was used as the basis for the proposed sampling plan. Only elements relevant for the sampling for methylmercury in fish have been included.
60. Because of the discussion point on applicability of the MLs to canned fish (see 3.2), provisions for packaged foods have been kept in the sampling plan for now.

61. Depending the decision of the EWG on the appropriateness of the existing Codex provisions on analytical methods (see 4.1), both the reference to the Codex standard as well as to performance criteria have been kept in the proposed sampling plan.
62. The proposed draft sampling plan is included in Appendix II.
63. One EWG member questioned whether the Sampling plan was too elaborate, as in addition to sampling provisions, it also included provisions on analytical requirements including method validation, reporting and interpretation of results. CCCF12 is requested to determine the scope of the sampling plan.
64. The EWG members had specific questions on the sampling plan which could best be referred to CCMAS. Therefore CCCF12 is invited to consider sending the sampling plan in Appendix II to CCMAS for endorsement with the following specific questions:
 - a. Could CCMAS advise on the use of analytical methods or performance criteria?
 - b. Could CCMAS advise on the necessary performance criteria for the proposed draft MLs? Proposed performance criteria are included in Table 9 of Appendix II.
 - c. Is there evidence that methyl mercury can vary widely between individual fish sampled at the same time? How would this apply to large fish sold as individual units? Does the sampling plan provide enough basis to deal with this?
 - d. Is the text "If the result of the test for an aggregate sample of cans is less than but close to the maximum level of methylmercury and if it is suspected that individual cans might exceed the maximum level, then it might be necessary to conduct further investigations." relevant for methylmercury in fish?
 - e. Should the samples for mercury in fish be analysed raw (or with no further processing or cooking for already processed products, e.g. canned fish)?
 - f. In addition – is the whole fish to be analyzed or only specific fractions edible portions? Now the only mention is that mid-section should be sampled for some large fish.

PARTICIPANTS LIST**Chair**

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

Co-chairs

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

Jeane Nicolas
Senior Adviser Toxicology
Biosecurity Science, Food Science and Risk Assessment Directorate
Regulation and Assurance Branch
Ministry for Primary Industries - Manatū Ahu Matua
Pastoral House 25, The Terrace
PO Box 2526, Wellington, New Zealand
Telephone: + 64 4 831 3024
Mobile: +64 27 5972058
Email: Jeane.Nicolas@mpi.govt.nz

Mark Feeley
Associate Director
Bureau of Chemical Safety
Food Directorate
Health Canada
Telephone: +1-613-957-1314
Email: mark.feeley@canada.ca

Argentina

Ms. Silvana Ruarte
Head of analytical food service
National Food Institute
Email: sruarte@anmat.gov.ar

Gabriela Catalani
Codex contact point
Email: codex@magyp.gob.ar

Australia

Dr. Matthew O'Mullane
Section Manager Product Safety Standards,
Risk Management & Intelligence Branch
Food standards Australia New Zealand
Email: matthew.o'mullane@foodstandards.gov.au

Dr. Glenn Stanley
Section Manager Monitoring & Surveillance
Risk Management & Intelligence Branch
Food standards Australia New Zealand
Glenn.Stanley@foodstandards.gov.au

Kate Slater
Codex contact point
Department of Agriculture and Water Resources
Email: codex.contact@agriculture.gov.au

Austria

Kristina Marchart
Email: Kristina.marchart@ages.at

Brazil

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

Ms. Carolina Araújo Vieira
Health Regulation Expert
Brazilian Health Regulatory Agency
Email: Carolina.vieira@anvisa.gov.br
Ms. Larissa Bertollo Gomes Porto
Health Regulation Expert
Brazilian Health Regulatory Agency
Email: larissa.porto@anvisa.gov.br

Bulgaria

Svetlana Tcherkezova
Chief Expert
Risk Assessment Center on Food Chain
Ministry of Agriculture, Food and Forestry
136 Tzar Boris III, bulv.
1618 Sofia, Bulgaria
Email: stcherkezova@mzh.government.bg

Burkina Faso

Alain Gustave Yaguibou
Agence Burkinabé de Normalisation (ABNORM)
Ouagadougou, Burkina Faso

Canada

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

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

Chile

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

China

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

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

Ms Yi SHAO

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

Mr Guoliang LI
Professor
School of Food and Biological Engineering
Shaanxi University of Science and Technology
CHINA
Email: 61254368@163.com

Colombia

Mr Wilmer Humberto Fajardo Jimenez
National institute for surveillance and control of
medicines and food
Tel: +57 1 2948700 ext 3906
Email: wfajardooj@invima.gov.co

Mr. Giovanni Cifuentes Rodriguez
Ministry of health and social protection
Tel: +57 1 3305000 ext 1255
Email: gcifuentes@minsalud.gov.co

Dominican Republic

Dr Fátima del Rosario CABRERA T.
Food Department of the Dominican Republic's
Ministry of Health,
Ave. Héctor H. Hernández esquina Ave.
Tirandentes, Ensanche La Fe, Santo Domingo,
D.N., Código Postal 10514
Dominican Republic
Tel: +1 809 541-3121, ext
E-mail: codex.pccdor@mhp.gob.do

Egypt

Noha Mohammed Atyia
Food standards specialist
Egyptian Organisation for Standardisation and
Quality (EOS)
16 Tadreeb AlMutadrbeen St
AlAmeriah
Cairo, Egypt
Email: nonaaatia@yahoo.com

European Union

Ms Veerle van Heusden
European Commission
Health and Food Safety Directorate-General
Brussels, BELGIUM
Tel: +32 229 90612
Email: veerle.vanheusden@ec.europa.eu

EU codex contact point
Email: sante-codex@ec.europa.eu

France

Ms Estelle Bitan-Crespi
Ministry of agriculture
Paris, France
Email: estelle.bitan-crespi@agriculture.gouv.fr

Ms Solene Guillotteau
Ministry of agriculture
Paris, France
Email: solene.guillotteau@agriculture.gouv.fr

Germany

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

Michael Jud
Federal Office of Consumer Protection and Food
Safety (BVL), Unit 101
Postfach 11 02 60
D-10832 Berlin
Tel.: +49 (0)30 18444-10110
Fax: +49 (0)30 18444-89999
E-Mail: michael.jud@bvl.bund.de

Codex contact point
Email: 313@bmel.bund.de

India

Satyen Kumar Panda
Senior Scientist QAM division
Central Institute of Fisheries Technology
Email: satyenpanda@gmail.com

Sunil Bakshi
Food Safety Standards Authority of India
Email: sbakshi@fssai.gov.in

Codex contact point
Email: codex-india@nic.in

Iran

Mansooreh Mazaheri
Standard Research Institute, Food Department
Karaj, Iran
Email: man2r2001@yahoo.com

Japan

Naoki YOSHIHARA
Food standards and Evaluation Division
Pharmaceutical Safety and Environmental Health
Bureau
Ministry of health, Labour and Welfare of Japan
Email: Codexj@mhlw.go.jp

Mako IIOKA
Food Safety and Consumer Affairs Bureau
Ministry of Agriculture, Forestry and Fisheries
Email: Mako_iioaka540@maff.go.jp

Kazakhstan

Zhanar Tolysbayeva
Email: tolyzhan@gmail.com

Gauhar Amirova
Expert for standartization and technical
regulation for veterinary and phytosanitary
Email: amirova.gauhar@gmail.com

Republic of Korea

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

Codex contact point
Email: codexkorea@korea.kr

Mexico

Codex contact point
Email: codexmex@economia.gob.mx

New Zealand

Andrew Pearson
Specialist Adviser (Environmental Chemistry &
Toxicology)
Biosecurity Science, Food Science and Risk
Assessment Directorate
Regulation and Assurance Branch
Ministry for Primary Industries - Manatū Ahu Matua
Pastoral House 25, The Terrace
PO Box 2526, Wellington, New Zealand
Telephone: +64-4-894 2535
Mobile: +64 22 0447054
Email: Andrew.Pearson@mpi.govt.nz

Norway

Oda Walle Almeland
Adviser
Norwegian Food Safety Authority
Email: oda.walle.almeland@mattilsynet.no

Codex contact point
Email: codex@mattilsynet.no

Peru

Carlos Alfonso Leyva Fernández
Especialista de la Subdirección de Inocuidad
Agroalimentaria
Dirección de Insumos Agropecuarios e Inocuidad
Agroalimentaria
Av. La Molina 1915
Lima, Peru
Email: cleyva@senasa.gob.pe

Poland

Magdalena Kowalska
Codex contact point
Email: kodeks@ijhars.gov.pl

South Africa

Deon Jacobs
Principal Inspector Food and Associated Industries
National Regulator for Compulsory Specifications
Email: dean.jacobs@nrccs.org.za

Malose Matlala
Codex contact point
Email: cacpsa@health.gov.za

Spain

Ana Lopez Santacruz
Technical Expert
Contaminants Management Department
Spanish Agency for Consumer Affairs, Food Safety
and Nutrition
Email: contaminantes@msssi.es

Thailand

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

United States of America

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

ECOWAS

Gbemenou Joselin Benoit Gnonlonfin

ICGMA

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

FoodDrinkEurope

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

FAO

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

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

Esther Garrido Gamarro
Food safety and quality officer
Fisheries and Aquaculture Department
Food and Agriculture Organization of the UN
Viale delle Terme di Caracalla
Rome, Italy
Tel.: +39 06 570 56712
Email: Esther.GarridoGamarro@fao.org

WHO

Ms Angelika Tritscher
Coordinator Risk Assessment and Management
Department of Food Safety and Zoonoses
World Health Organisation
20, Avenue Appia
CH-1211
Geneva, Switzerland
Tel: +41 22 791 3569
Email: tritschera@who.int