CODEX ALIMENTARIUS COMMISSION

Food and Agriculture Organization of the United Nations

World Health Organization

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Agenda item 6

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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON CONTAMINANTS IN FOODS

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SAMPLING PLANS FOR METHYLMERCURY IN FISH

Comments at Step 3 in reply to CL 2024/3-CF
submitted by
Brazil, Canada, Egypt, European Union, Iraq, Japan, Peru, Suriname, USA and Venezuela

Background

1. This document compiles comments received through the Codex Online Commenting System (OCS) in response to CL 2024/3-CF[1] issued in January 2024. Under the OCS, comments are compiled in the following order: general comments are listed first, followed by comments on specific sections.

Explanatory notes on the appendix

2. The comments submitted through the OCS are hereby annexed and presented in tabulated format.

[1] https://www.fao.org/fao-who-codexalimentarius/resources/circular-letters/en/
https://www.fao.org/fao-who-codexalimentarius/committees/committee/related-circular-letters/en/?committee=CCCF

ANNEX

GENERAL COMMENTS

COMMENT	MEMBER / OBSERVER
Comment: There are no paragraphs 55 and 56. In Appendix II, Example 1, Brazil is suggesting or proposing to maintain consistency.	**Brazil**
Question 2 (i): Canada considers it a priority to progress the sampling plan for methylmercury in fish for the following reasons: i) It has been in development for many years; and ii) The remaining key data gap (tissue mercury distribution in species for which there are MLs, other than tuna) will not be addressed by member country data submission in the near future; and iii) Questions about execution and practicality of the sampling plan, namely the subdivision or reconditioning of lots of fish with significant size variability, may not be fully known by member countries until it is put into practice, which adoption of the sampling plan would facilitate.	**Canada**
Egypt thanks the work done by chair and co-chair of the Electronic Working Group. Egypt agrees to advance this draft Code of Practice for the next step.	**Egypt**
Japan would like to thank the EWG Chairs, New Zealand and Canada, for their efforts in developing this ambitious and challenging draft sampling plan and for the opportunity to submit comments. Japan considers that proceeding to final adoption of the proposed draft sampling plan is not feasible, given the many data gaps, outstanding issues and concerns regarding its practicability. Therefore, Japan supports proposal (ii) and suggests either holding the draft sampling plan at Step 4 or proceeding only to Step 5 after CCCF17 make the necessary amendments to the draft in Annex I. This would allow Members to verify its feasibility over a period of a few years before final adoption. Regarding this page, 2.(ii),(iii), there is no description of the relevant section. 44 and 45?	**Japan**
El Perú agradece a la Secretaría de la Comisión del Codex Alimentarius por el esfuerzo emprendido a la fecha y al trabajo realizado electrónicamente que se encuentran plasmados en el Apéndice I del documento CX/CF 24/17/6 que figura en la página web de la 17.ª reunión del Comité del Codex sobre Contaminantes de los Alimentos (CCCF), y en atención y respuesta al documento CL 2024/03-CF Perú establece que debe continuar desarrollándose para seguir considerando los aspectos planteados en el párrafo 32 (Apéndice III).	**Peru**
Regarding the definition of sampling plan: "If the total mercury concentration is below or equal to 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." Question: Is the measurement uncertainty included in the total mercury concentration?	**Suriname**

United Arab Emirates, UAE advises that the sampling plan should follow: (iii) other approach(es) that could facilitate completion of work at CCCF17 such as to consider the usefulness of having a preliminary sampling plan that can facilitate implementation of maximum levels. The sampling plan could be further developed or completed in future when more data/information become available based on the points raised in paragraphs 32, 55 and 56 of CX/CF 24/17/6, Appendix III. • United Arab Emirates, UAE believe that due to the differing weights among various fish species, additional information is necessary to determine the appropriate size classifications for each type of fish.	**United Arab Emirates**
The United States supports the need for a sampling plan given the established MLs for methylmercury in various fish species. The United States can support interim adoption of the recommendations in the working document at Step 5, which would allow for further consideration and comment by the Committee, allow time to address outstanding data gaps on the methylmercury distribution in fish tissues for the species/groupings of fish which have established MLs, and enable consideration of data to confirm the practicality of the sampling plan. However, if no significant technical challenges to implementation of the sampling plan are raised at CCCF17, the United States can support final adoption at Step 5/8. The United States suggests renaming Table 3 as "Number of incremental samples to be taken depending on the weight of the lot or sublot."	**USA**

SPECIFIC COMMENTS

G	**PROPOSED SAMPLING PLAN FORMAT FOR METHYLMERCURY CONTAMINATION IN FISH** Further develop of sampling plan when more data/information become available based on the points raised in paragraphs 32, 55 and 56 of CX/CF 24/17/6, Appendix III.	**Iraq**
G	**PROPOSED SAMPLING PLAN FORMAT FOR METHYLMERCURY CONTAMINATION IN FISH** Even though the majority of the Codex Member are not in favour of establishing sampling plans for mercury in fish at a retail stage, the EU would still like to emphasize that established MLs should be applied to fish throughout the whole chain regardless the stage of food chain where the samples were taken (i.e. MLs should be applied also to fish and fish products placed on the market for final consumer). Therefore the EU is of the opinion that it might be appropriate to also provide specific sampling provisions for fish products. The EU is of the opinion that the draft sampling plan can be recommended for final adoption at step 5/8 based on the data/ information provided in Appendices II and III. Specific comments on Appendix II: • Appendix II, example 1 o 40 incremental samples of 100 grams, result in an aggregate sample of 4 kilograms instead of 1 kilogram. Following the suggestion of the EU to delete the 4 rows at the bottom of table 3, it is proposed to re-phrase as follows: A first aggregate sample is taken of the smaller sized (lot relative) fishes, which weigh about 2-2.75 kg: 10 incremental samples	**European Union**

	(fishes) are taken. A second aggregate sample is taken of the larger sized (lot relative) fishes, which weigh about 2.75-3.5 kg: 10 incremental samples (fishes) are taken. • Appendix II, example 2. o 40 incremental samples of 100 grams, result in an aggregate sample of 4 kilograms instead of 1 kilogram. Following the suggestion of the EU to delete the 4 rows at the bottom of table 3, it is proposed to re-phrase as follows: A first aggregate sample is taken of the smaller sized (lot relative) fishes, which weigh about 2-4 kg: 10 incremental samples (fishes) are taken… A second aggregate sample is taken of the fishes of the medium size (lot relative) of about 4-6 kg: 10 incremental samples (fishes) are taken…. o In line with the EU suggestion that for lots of 10 tons 10 incremental samples need to be taken, it is proposed to adjust the example for the third aggregate accordingly: A third aggregate sample is taken of the larger size (lot relative fishes) of about 6-8 kg: 10 incremental samples (fishes) are taken, each incremental sample is • Constituted of the right side dorso-lateral muscle meat in the middle part of the fish (symmetrically around line B in Figure 1) and weighs about 100 grams. This results in an aggregate sample of about 1 kg to be homogenised and analysed separately. This results in one aggregate sample of about 1 kg to be homogenised and analysed separately. OR • Constituted of equal parts of 50 grams of the muscle meat close to the tail part (the regions around line C in Figure 1) and the muscle meat close to the head part of one fish (the region of line A in Figure 1) which are combined to form an incremental sample of about 100 grams per fish. This results in one aggregate sample of about 1 kg to be homogenised and analysed separately.	
DEFINITION		
~~Countries or importers may decide to use their own screening when applying the ML~~ A procedure for ~~methylmercury in fish by analysing total mercury in fish. If~~ the ~~total mercury concentration is below or equal to the ML for methylmercury~~sampling of food from a certain lot with a view of a specific chemical analysis of that lot, ~~no further testing is required, and~~ in order to ensure that the sample that is ~~determined to be compliant with the ML. If the total mercury concentration~~ taken, is ~~above the ML~~ representative for ~~methylmercury, follow-up testing shall be conducted to determine if~~ the ~~methylmercury~~ concentration ~~is above~~ of the ~~ML~~concerned chemical within the lot. The definition of sampling plan: the proposed definition is rather a definition of a methylmercury test procedure, which can be included as a separate entry. The second paragraph on screening methods should be deleted from the definition, as it not strictly needed for the definition and it is a repetition of paragraph 20. It is proposed to add the following definition a sampling plan: 'A procedure for the sampling of food from a certain	**European Union**

	lot with a view of a specific chemical analysis of that lot, in order to ensure that the sample that is taken, is representative for the concentration of the concerned chemical within the lot.’	
	The combined total of all the incremental samples that is taken from the lot or sub-lot. The aggregate sample has to be at least as large as the laboratory sample or samples combined. The entire aggregate sample should be comminuted in a mill. The EU agrees with the provisions of paragraph 14 that the entire aggregate sample should be homogenised, in order to allow the preparation of a representative laboratory sample. The definition of ‘test portion’ seems to suggest that it is sufficient to comminute only the laboratory sample. Therefore it is proposed to add the following sentence to the definition of ‘aggregate sample’: ‘The entire aggregate sample should be comminuted in a mill.’	
	~~The smallest~~ A sample intended for the laboratory, which consists out of a comminuted quantity of fish muscle, or whole fish. The laboratory sample may be a portion of or the entire aggregate sample. The aggregate sample should be comminuted in a mill. If the aggregate sample is larger than the laboratory sample(s), the laboratory sample(s) should be removed in a random manner from the homogenised aggregate sample.	
	A randomly removed portion of the comminuted laboratory ~~sample. The entire laboratory~~ sample ~~should be comminuted in a mill. A portion of the comminuted laboratory sample is randomly removed~~ for the extraction of the methylmercury for chemical analysis.	
INCREMENTAL SAMPLE		
Para. 5	The recommended minimum number of incremental samples taken from the lot or sub-lot is dependent on the size of the lot or sub-lot as specified in Table 3. If there is scientific evidence that a smaller number of incremental samples is sufficient to determine representative concentration of methyl mercury in fish species subject to Codex ML, the number of incremental samples can be reduced from the recommended number in Table 3. Japan is of the view that there is insufficient information in Appendix II and III on whether it is feasible to take and aggregate such a large number of incremental samples and whether such a number is needed to statistically determine the average concentration on methyl mercury in fish in a lot/sub-lot. If Members have scientific evidence that a smaller number of incremental samples is sufficient to determine the representative concentration of Me-Hg in fish in a lot, we suggest adding a provision that the number of incremental samples can be reduced in the interests of flexibility and practicality of the sampling plan. CXG 50 specified that it is important to ensure that any sampling plan chosen will be practical to apply in terms of cost of sampling and testing and ease of use.	**Japan**
Para. 6	The ~~suggested~~ aggregate sample should contain a quantity of sample of at least 1 kilogram. The minimum weight of the incremental sample should be ~~an approximate division of~~ determined by dividing 1 kilogram by the ~~minimum aggregate sample based on the~~ required number of incremental ~~samples taken from the lot~~ samples, as ~~specified~~ listed in Table ~~2 (100 g) resulting in an aggregate sample of at least 1kg~~3. Incremental samples taken from a lot or sub-lot should be of comparable weight. It is proposed to begin with provision that the minimum weigh of the aggregate sample should be 1 kilogram and then to explain how the size of the incremental sample should be calculated.	**European Union**

	The EU proposes to limit the number of incremental samples to maximum 10 incremental samples of 100 grams. More incremental samples of a lower weight seem impractical and are not considered to contribute to a higher representativeness of the sample for the lot. For example taking 100 incremental samples of 10 grams of fish from a specific part of the fish would be extremely laborious. On the other hand, taking more than 20 to 100 incremental samples of 100g would lead to an aggregate sample size, which will be difficult to homogenise.	
Para. 6	The suggested minimum weight of the incremental sample should be an approximate division of the minimum aggregate sample based on the number of incremental samples taken from the lot as specified in Table 2 ~~(100 g)~~ resulting in an aggregate sample of at least 1kg. Incremental samples taken from a lot or sub-lot should be of comparable weight.	**Japan**
Para. 6	**El peso mínimo sugerido de la muestra incremental deberá ser una división aproximada de la muestra total mínima, partiendo del número de muestras incrementales tomadas del lote, tal y como se especifica en el Cuadro 2 (100 g), lo que tendrá como resultado una muestra global de como mínimo 1 kg. Las muestras incrementales extraídas de un lote o sublote deberán tener un peso similar.** No se comprende que la muestra global a obtener sea de aproximadamente 1 kg, a partir de muestras totales de 100 g tomadas de 40 peces, considerando que la definición de muestra global es que constituye el total combinado de todas las muestras elementales del lote o sublote.	**Venezuela**
Table 3	**Table 3. Number of incremental samples to be taken depending on the weight of the lot** In line with the previous comment, the EU proposes to remove the 4 rows at the bottom of the table. On the fourth row the lot weight range could be modified from '>0.5 - ≤ 1' to '> 0.5'. This way for large lots of more than 1 ton 10 incremental samples of 100 grams will need to be taken.	**European Union**
Table 4	**Table 4. Tissue area the incremental sample is taken from for whole fish based on weight classes** For lots of 0.05MT or greater where the aggregate sample would exceed 3 kg the midline (halfway between the gill opening and the anus) strip from backbone to belly ~~should~~ can be sampled Japan suggests that the word "can" rather than "should" be used here, to allow inspectors flexibility in choosing which part to use, depending on situation. The same applies to the next weight class, 1-10 kg.	**Japan**
Table 4	For lots of 0.05 MT or greater where the aggregate sample would exceed 3kg, the muscle close to the ~~tail~~tail can be sampled	**Japan**
Table 4	For ~~lots~~ very large fish 6-10 kilograms and in case the sampling in the middle of ~~0.05 MT or greater where~~ the ~~aggregate sample~~ fish would ~~exceed 3kg~~cause a significant economic damage, incremental samples can also be taken as equal parts of the muscle from behind the head and close to the tail Table 4 for the category 1-10 kg: the draft sampling plan foresees that the aggregate sample should be at least 1 kg, by calculating the size of the required incremental samples, so normally the aggregate sample size should not exceed 3 kilograms. This is scenario that can only occur for the category < 1 kg, where whole fishes are sampled. Therefore the EU is of the opinion that the option of sampling at the tail of the fish, should rather be related to the size of the fish and	**European Union**

	not to the size of the lot. Because only for tuna studies are available on the distribution of mercury in the different parts of the fish, because for fishes of 1-10 kilograms no significant economical damage is expected for the sampling at the head and the tail and in order to be consistent with the provisions for the category of > 10 kilograms, it is proposed to re-phrase as follows: 'Midline (halfway between the gill opening and the anus) strip from backbone to belly. For lots of 0.05 MT or greater where the aggregate sample would exceed 3kg, the muscle close to the tail. For very large fish 6-10 kilograms and in case the sampling in the middle of the fish would cause a significant economic damage, incremental samples can also be taken as equal parts of the muscle from behind the head and close to the tail. ' This approach is also consistent with example 2 in Appendix II.	
Table 4	~~For lots of 0.05 MT or greater where the aggregate sample would exceed 3kg, the muscle close to the tail~~The Brazil proposes to remove this topic.	**Brazil**
Table 4	**Equal composite of muscle from behind the head and close to the tail** Brazil proposes the inclusion of the topic: For lots of 0.05 MT or greater where the aggregate sample would exceed 3kg, the muscle close to the tail. Comment: To maintain consistency the possibility of using muscle close to tail should also be an option for individuals weighing over 10 kg regardless commercial value (the same as the option for 1-10kg)	**Brazil**
Table 4	> 10 kg ~~(significant commercial value)~~(tuna) The commercial value of fish is not an objective indicator, unlike length and weight, and it is undesirable that there should be discrepancies in its interpretation between Codex Members. Japan proposes here to explicitly identify the fish as tuna. The scientific information provided by Japan to the EWG also relates to tuna (see para.15 in Appendix III) and there may be no scientific basis for applying the same concept to larger fish such as sharks and marlin.	**Japan**
SAMPLE PREPARATION PRECAUTIONS		
Para 13	Wherever possible, apparatus and equipment coming into contact with the sample should not contain mercury and should 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~~edges to take increment samples and make comminuted/mixed samples. Japan proposes to specify what the cutting edge is used for.	**Japan**

ANALYTICAL METHODS		
Para 20	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 or equal to 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 (CXS 193-1995; REP18/CF). The criteria-based approach is also recommended for analysis of total mercury in fish. Japan proposes to specify that the criteria approach should also be adopted for the analysis of total mercury.	**Japan**
Para 20	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 or equal to 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 (CXS 193-1995; REP18/CF)~~ML.	**Japan**
Para 22	A lot or sub-lot where fish ~~that~~ are not of comparable length and/or weight ~~and~~ can be considered in compliance with the ~~aggregate~~ ML if the methylmercury concentration of the aggregated sample ~~is~~ taken from the highest length and/or weight class ~~can be considered in compliance if the methylmercury concentration~~ is below the ML. However, export or trade requirements (e.g. certificates of analysis) may require testing lots or sub-lots of smaller length and/or weight classes. It is generally known that larger fish have higher concentrations of methylmercury, and it is reasonable to assume that if the sub-lot with the largest length/weight in the same lot complies with ML, then the whole lot complies with ML. It is not considered necessary to analyse all sublots.	**Japan**
Para 23	Where the methylmercury concentration in the aggregate sample taken from a length and/or weight class is above the ML then the next largest length/weight class should also be analysed. If the methylmercury concentration in this sample is below the ML the lot or sub-lot can be reconditioned to remove length and/or weight classes that exceed the ML to ensure the remaining fish are in ~~compliance~~compliance with the ML.	**Japan**
Para 24	For a lot or sub-lot separated into three length or weight ~~classes~~ classes, paragraph 23 should be repeated for the smallest length/weight classes if the methylmercury concentration in the aggregate sample taken from the middle length/weight class is also above the ML.	**Japan**
ANNEX I		
ANNEX I	**Corrected the accuracy of Orange Rafi to 33 for the table below.ANNEX I: Method criteria for methylmercury in fish with MLs.** Japan proposes to revise the figure to be correct base on the Procedural Manual as below; regarding the table below, amend Precision (%) of Orange roughy to "≤ 33", amend LOD (mg/kg) of Pink cusk-eel to ≤0.10 and amend LOQ (mg/kg) of Pink cusk-eel to ≤ 0.20.	**Japan**