codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

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Agenda Item 17 (a)

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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON FOOD ADDITIVES AND CONTAMINANTS

Thirty-seventh Session

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DRAFT MAXIMUM LEVEL FOR LEAD IN FISH (AT STEP 7) PROVISIONAL LIST OF MAIN INTERNATIONALLY TRADED FISH SPECIES(INCLUDING PROPOSAL FOR MAXIMUM LEVELS FOR LEAD IN DIFFERENT FISH SPECIES)

(IN RESPONSE TO CL 2004/9-FAC)

The following comments have been received from Cuba, Egypt, European Community , Philippines, South Africa and WHO

Cuba:

En el documento preparado por Dinamarca, se propone un nivel máximo de 0.2 mg/kg de Pb para la inmensa mayoría de las especies relacionadas como por ejemplo Salmón (*Salmo salar)*, Merluza (*Merluccius spp),* Anchoa (*Engraulida)*, Macarela (*Scomber spp.) yTúnidos (Tunnidae)* y 0.4 mg/kg para Jurel (Trachurus spp.) y Sardina (*Sardina pilchardus*

Estamos de acuerdo con el MN de 0.4 mg/kg de Pb para jurel (Trachurus spp.) por considerar que el mismo no ofrece riesgo a los consumidores. En el resto de las especies relacionadas Cuba está de acuerdo con las propuestas*, con excepción de los túnidos (Tunnidae) y el pez espada (Xiphias gladius) para los que Cuba propone 0.4 mg/kg de* Pb,

Consideramos que con un NM de 0.4 mg/kg de Pb, por el consumo de pescado la contribución de Pb a la ISTP (0.025 mg de Pb semanales por kg de peso corporal) no es significativa.

(ENGLISH TRANSLATION)

The document prepared by Denmark proposes a maximum level for lead of 0.2 mg/kg for the huge majority of related species, for instance Salmon (*Salmo salar),* Hake (*Merluccius spp),* Anchovy (*Engraulida),* Mackerel (*Scomber spp.)* and Tuna *(Tunnidae),* and 0.4 mg/kg for Horse mackerel (Trachurus spp.) and Sardine (*Sardina pilchardus)*

We agree to the maximum level for lead of 0.4 mg/kg for Horse mackerel (Trachurus spp.) because we think it does not pose a consumer risk. As for the rest of the related species Cuba agrees with the proposals, except for tuna (Tunnidae) and swordfish (Xiphias gladius) for which Cuba proposes 0.4 mg/kg for lead.

In our view, with an ML for lead of 0.4 mg/kg, the lead contribution to the PTWI (weekly 0.025 mg/kg b.w.) due to fish consumption is not significant.

Egypt:

The proposed level for Lead (0.2 mg/kg) is considered high particularly in case of populations whose consumption of fish are high.

The level suggested by Egypt (0.1 mg/kg), which is actually adopted in Egypt, can be considered an accepted level.

European Community:

The European Community has examined the discussion document on the provisional list of main internationally traded fish species and the proposals for draft maximum levels for lead in different fish species.

1. The European Community in principle supports the approach being taken to list the main traded species of fish and to assign maximum levels which are as low as reasonably achievable. However, as highlighted in the paper, it has been difficult to provide a sufficiently accurate list using information from limited regional and national investigations. It would seem that the FAO may be best placed to use its databases to help clarify details on the main internationally traded fish for food use.
2. Ideally, setting maximum levels for lead in all fish species is preferred, although we acknowledge that this is difficult in view of the information already exchanged in the extended discussions at CCFAC. As previously discussed, the European Community supports a maximum level of 0.2 mg/kg as reasonably achievable in most of the main traded fish species, with a separate higher maximum level of 0.4 mg/kg in certain species.
3. In view of the difficulties experienced on trying to reach agreement on this issue, and subject to further possible progress by FAO, we welcome the alternative approach proposed in the discussion paper, to consider limiting the list to those fish species most eaten by children. This approach would help to protect this vulnerable group of the population, this being important in view of the effects of lead on cognitive development and intellectual performance in children.
4. The discussion paper proposes a limited list of fish consumed by children, including tuna, salmon, mackerel, sardines and herring. More precise listing by scientific/ latin names would be helpful. In addition, we would propose to add white fish species used in fish products aimed at children (such as fish fingers/ fish sticks, fish nuggets, fish burgers). For example, this could include cod, haddock, hoki, coley, whiting, sand eel, anglerfish. Of the proposed varieties of fish, the European Community could support a maximum level of 0.2 mg/kg, with the exception of sardines (we propose this covers *Sardina pilchardus* and also *Sardinops* species) for which we would propose 0.4 mg/kg (0.2 mg/kg has been found to be lower than reasonably achievable in these species). Also, the basis for including each species would need to be considered.
5. In conclusion, the European Community would support two approaches for listing fish:
    a) the need for the FAO to investigate its available data on international trade of fish, to help identify those species that are most traded;
    b) as an alternative, the need to identify and list the species of fish that are most eaten by children and also internationally traded.

Philippines

The 36th CCFAC stressed the need to take into account the results of the JECFA evaluation (53rd meeting, June 1999) in future consideration of the ML for Lead in fish. The risk assessment information from this JECFA meeting has not been considered in the setting of the currently proposed draft ML for Lead in fish of 0.2 ppm. The decision of the 36th CCFAC to discuss the results of the 53rd JECFA meeting is noteworthy.

The emotional situation of people is very negative about lead. However CCFAC has also not made an attempt to discuss the findings and so to get people to read and understand the 53rd JECFA Report. This gives us the impression that standards are sometimes now being set at levels that are as low as can be measured rather than as low as necessary to protect public health. This has placed us in a difficult position.

In accordance with the above decision of the 36th CCFAC, we are providing information from the 53rd JECFA to show that ML's of 0.2 ppm or 0.5ppm provide identical protection against the effects of lead on the intellectual performance of children. On this basis and following CCFAC principles for the establishment of ML's for contaminants, an increase in the current proposed draft ML for Lead in fish from 0.2 ppm to 0.5 ppm should be considered to avoid problems in trade and analytical difficulties for countries.

The Philippine government is grateful to Dr Manfred Luetzow formerly of the Joint FAO-WHO Secretariat of JECFA for giving us guidance in understanding the toxicological monograph of the 53rd JECFA when he was in the Philippines in 2003. He has brought to us this useful way of discussing this problem at CCFAC.

A. Information from the 53rd JECFA Meeting,

Ref: WHO Food Additive Series :44 Prepared by the 53rd JECFA :

1. The 53rd JECFA evaluated the effects of Codex ML's on the total dietary intake from lead and on the PTWI.

Using proposed Codex ML's for all food categories, including 0.2 ppm for fish, and combining these with the FAO – WHO regional diets, the Meeting showed that the resulting total dietary intake from Lead was below its PTWI. Using the same process but substituting the Codex ML for fish with 0.5 ppm, we can show that the resulting total dietary intake will only be slightly increased and will remain below the PTWI (see enclosed Table 1). This indicates that an ML of 0.5 ppm will provide the same level of health protection as an ML of 0. 2ppm.

The Meeting also showed that when actual maximum residue data for the food category from the United States is used, rather than the proposed Codex ML's, the resulting total dietary intake is much lower (Table 1). MLs are thus exaggerated assumptions.

2. The 53rd JECFA also presented simulation models which can be used to evaluate the effects of any proposed ML to reduce exposure to lead. The assumption derived the blood level of Lead from the dietary level. This allows us to assess scenarios on how children could be damaged by different levels of Lead in the diet because from the blood level we have the relation to the IQ reduction.

The important relationship derived by the 53rd JECFA is that a dietary intake of 1 ug/kg bw per day of Lead, will result in an increase in the Lead concentration of blood of 1 ug/dL, the upper estimate for infants. This relationship is valid during the long term exposure period (in utero + 10 years). A dietary intake of 1 ug/kg bw per week of Lead would correspond to an intake of 0.14 ug/kg bw per day and to an increase in blood Lead concentration of 0.14 ug/.dL. The toxicological monograph also gives (in Table 14 of page 32), the Net decrease in IQ associated with blood lead concentration.

Using the relationships derived above, it can be shown that increasing the proposed draft ML for Lead in fish from 0.2 ppm to 0.5 ppm, will have negligible effects on the intellectual performance of children (see enclosed Table 2). Thus while setting an ML is a useful intervention measure, a level of 0.2 ppm or 0.5 ppm, will make little difference in protecting children against the effects on intellectual performance of dietary exposure to Lead.

B. The Philippine Position and CCFAC Principles

In the absence of health effects at a proposed ML (the ML of 0.5 ppm), CCFAC principles for establishing ML's for contaminants dictate that higher ML's should be considered when this is necessary to avoid problems in trade and in methods of analysis.

These principles are contained in ALINORM 97/12 entitled CCFAC Criteria for the Establishment of ML's in Foods and in ALINORM 01/12 entitled CCFAC General Procedure for Establishing ML's for Contaminants. The conditions prescribed in these documents should be respected. In particular, we call attention to the following:

- ALINORM 01/12, which states that ..”provided it is acceptable from the toxicological point of view, the value of a draft ML should be set at the upper end of the range of contaminant concentrations normally found in food. “

  The level of 0.2 ppm does not represent the upper end of the range of contaminant concentrations found in fish and fish products. It represents the most frequently found level of lead by countries which recently submitted data to CCFAC for Lead in fish.

  The level of 0. 2ppm however will create problems in trade due to the naturally higher levels of Lead in some species of tuna. Last October 2003, two shipments of tuna from Indonesia were rejected in the EU due to Lead. (RASFF)

- ALINORM 97/12 states that… "In all cases, (provided that it is toxicologically acceptable) ML's should not be lower than a level that can be analyzed with methods of analysis that can be readily applied in normal product control laboratories".

  The level of 0.2 ppm is lower than the detectable limit of the internationally validated AOAC method for Lead in fish. Analysis of Lead at 0.2 ppm will require new equipment and in so doing, reduce available funds for this purpose for the analysis of other contaminants in the food chain. These outcomes are not in accordance with CCFAC principles.

  Several countries have expressed their concern over the difficulty of analyzing Lead at 0.2 ppm. Japan in 1996 had recommended that before advancing the steps, CCMAS should discuss whether present methods can practically detect Lead.

In the absence of a health concern with an ML for Lead in fish of 0.5 ppm, the current proposed draft ML of 0.2 ppm should be increased to 0.5 ppm in view of problems in trade and analytical difficulties for countries.

We have shown that this increase is supported by risk assessment information from the 53rd JECFA and is in accordance with Codex principles for establishing ML's for contaminants. Said principles were developed and agreed to by CCFAC. It is incumbent upon us to respect these.

Table 1 Dietary Intake Of Lead Based On WHO Regional Diets And Different Maximum Limits For The Food Category

TYPE OF DIET (1)	Using Codex ML's for the food category including fish at 0.2 ppm (2)		Using Codex ML's for the food category substituting fish with 0.5 ppm (3)		Using Maximum US residue levels for the food category (4)	
	Dietary Intake (ug/kg-bw/week)	% PTWI (5)	Dietary Intake (ug/kg-bw/week)	% PTWI (5)	Dietary Intake (ug/kg-bw/week)	% PTWI (5)
Middle Eastern	17	68	17	68	3	12
Far Eastern	15	60	16	64	2	8
African	13	52	15	60	2	8
Latin America	13	52	15	60	2	8
European	20	80	21	84	4	16

(1) From: WHO Regional Diets
(2) Data in this column is from Table 2. Estimated intake of lead based on WHO regional diets and proposed Codex maximum limits, p 14-15. WHO Food Additive Series : 44 Prepared by the 53rd JECFA
(3) Data in this column is calculated based on the WHO regional diets and proposed codex maximum limits for the food category, as in (2), substituting the proposed codex limit for fish of 0.2 ppm with 0.5 ppm.
(4) Data in this column is from Table 4. Estimated intake of lead based on WHO regional diets and the maximum residue for the food category from the United States Total Diet Study, p 16. Same reference as (2)PTWI (Provisional Tolerable Weekly Intake) for Lead is 25 ug/kg-bw/week

Table 2. Effect Of Dietary Intake Of Lead On IQ

TYPE OF DIET (1)	CODEX ML Used for Fish 0.2 ppm			CODEX ML Used for Fish 0.5 ppm		
DIET (1)	Dietary Intake ug/kg-bw/week (2)	Blood Levels of Lead ug/dL (3)	Median IQ Decrement (4)	Dietary Intake ug/kg-bw/week (5)	Blood Levels of Lead ug/dL (3)	Median IQ Decrement (4)
Middle Eastern	17	2.38	0.4	17	2.38	0.4
Far Eastern	15	2.10	0.4	16	2.24	0.4
African	13	1.82	0.4	15	2.10	0.4
Latin America	13	1.82	0.4	15	2.10	0.4
European	20	2.80	0.4	21	2.94	0.4

(1) From: WHO Regional Diets
(2) Data in this column is from Table 2. Estimated intake of lead based on WHO regional diet and proposed codex maximum limits, p 14-15, in the WHO Food Additive Series : 44, Prepared by 53rd JECFA
(3) Data in this column is calculated from the relationship : 1 ug lead/kg-bw/week = 0.14 ug lead/ dL blood, p 32 in the WHO Food Additive Series : 44, Prepared by the 53rd JECFA
(4) Data in this column is based on Table 14. Net decrease in IQ associated with blood lead, p 32 in the WHO Food Additive Series : 44, Prepared by 53rd JECFA
(3) Data in this column is calculated based on the WHO regional diets and proposed codex maximum limits for the food category, substituting the proposed codex limit for fish of 0.2 ppm with 0.5 ppm.

<u>South Africa:</u>

Provisional List of Main Internationally Traded Fish Species – including proposals for maximum levels for lead in different species

Background

The 36th Session decided to maintain at **Step 7** a level of 0.2 mg/kg for **lead in fish** for further discussion at the next CCFAC meeting. This was after the Committee was requested to consider the findings of the 53rd JECFA meeting, elaborated list of main fish species traded internationally, and the difficulty experienced by developing countries in analyzing lower levels.

Comments

South Africa is of the opinion that developing a list of species would be unnecessary because it would be difficult to include all species, and once developed, it would act as a trade barrier for species not included in the list. Also, as the 35th CCFAC meeting pointed out that the list was not meant to be comprehensive, the reason for developing such a list is therefore not clear.

South Africa, therefore, believes that the 53rd JECFA findings would provide clear guide and direction for the discussions on maximum levels, not the list of species.

Thailand:

Data from Thailand on Maximum Level of Lead in Fish

The provisional list of main internationally traded fish species that we would like to propose the maximum level at 0.4 mg/kg are summarized in Table 1 as follows:

Table 1 Provisional List of Main Internationally Traded Fish Species

Entry Number	Common Name	Latin Name/ Species	Maximum Level Proposed (mg / kg)
1	Mackerels, Jack and Horse Mackerel	*Scomber spp, Pneumatophorus spp., Tranchurus spp., Decapterus spp.* ***Rastrelliger kanagurta*** ***Rastrelliger brachysoma*** ***Rastrelliger kfeaughni (matsui)*** ***Rastrelliger neglectus*** ***Rastrelliger spp.*** ***Scomber australasicus*** ***Scomberomorus commerson*** ***Scomberomorus guttatus*** ***Scomberomorus koreanus*** ***Scomberomorus lineolatus*** ***Decapterus dayi*** ***Decapterus killiche*** ***Decapterus kurroides*** ***Decapterus maruadsi*** ***Decapterus macrosoma***	0.4
	Mackerels, Jack and Horse Mackerel (Continue)	***Decapterus russelli*** ***Decapterus sp.*** ***Decapterus jacobeus*** ***Decapterus pinnulatus*** ***Selar crumenophthalmus*** ***Selar boops*** ***Atule mate*** ***Alepes melnopterus*** ***Selaroides leptolepis*** ***Caranx sexfasciatus*** ***Caranx praeustus / Carangoides prawustus*** ***Carangoides armatus*** ***Carangoides caeruleopinnatus*** ***Carangoides chrysophrys*** ***Carangoides equula*** ***Carangoides fuloguttatus*** ***Carangoides gymostethus*** ***Carangoides hedlandensis*** ***Carangoides malabaricus*** ***Carangoides oblongus*** ***Carangoides talamparoides***	0.4

Entry Number	Common Name	Latin Name/ Species	Maximum Level Proposed (mg / kg)
2	Sadine, Sardinella, Brisling, Sprat	*Sardina pilchardus, Sardinops spp., Sardinalla spp., Sprattus sprattus* ***Sardinelia clupeodies / Amblygaster clupeoides*** ***Sardinella leiogaster / Amblygaster leiogaster*** ***Sadinella sirm / Amblygaster sirm*** ***Sadinella brachysoma*** ***Sadinella fimbriata*** ***Sadinella gibbosa*** ***Sardinella longiceps***	0.4
3	Tuna, Skipjack tuna, Yellow fin tuna, Bonit, **Albacore, Blackfin tuna, Southern bluefin tuna, Bigeye tuna, Northern bluefin tuna, Longtail tuna, Skipjack tuna, Kawakawa, Little tunny, Black skipjack, Bullet tuna, Frigate tuna, Slender tuna, Dogtooth tuna, Australian bonito, Eastern Pacific bonito, Striped bonito, Atlantic bonito, Leaping bonito, Plain bonito**	*Tunnidae, Euthynnus pelamis, Katsuwonus pelamis, Thunnus albacares, Neothunnus albacares, Sarda spp.* ***Thunnus alalunga*** ***Thunnus albacares*** ***Thunnus atlanticus*** ***Thunnus maccoyii*** ***Thunnus obesus*** ***Thunnus thynnus*** ***Thunnus tonggol*** ***Katsuwonus pelamis*** ***Euthynnus affinis*** ***Euthynnus alltteratus*** ***Euthynnus lineatus***	0.4
	Tuna, Skipjack tuna, Yellow fin tuna, Bonit, **Albacore, Blackfin tuna, Southern bluefin tuna, Bigeye tuna, Northern bluefin tuna, Longtail tuna, Skipjack tuna, Kawakawa, Little tunny, Black skipjack, Bullet tuna, Frigate tuna, Slender tuna, Dogtooth tuna, Australian bonito, Eastern Pacific bonito, Striped bonito, Atlantic bonito, Leaping bonito, Plain bonito** (Continue)	***Auxis rochei*** ***Auxis thazard*** ***Allothunnus fallai*** ***Gymnosarda unicolor*** ***Sarda australis*** ***Sarda chiliensis*** ***Sarda oreintalis*** ***Sarda sarda*** ***Cybiosarda elegans*** ***Orcynosis unicolor***	0.4

WHO:

In reference to Agenda Item 17 (a) concerning the Draft Maximum Level of lead in fish, WHO GEMS/Food has queried its database of aggregate records for lead in fish and has found a total of 453 aggregate records representing 8820 individual measurements on lead contamination in fish. These records may be accessed through the Summary of Information on Global Health Trends Website (http://sight.who.int/newsearch.asp?cid=131&user=GEMSuser&pass=GEMSu).

The data were evaluated based on the percent of records that would exceed the one of the three Maximum Levels (ML) of 0.2, 0.4 and 0.5 parts per million (See Table 1 below). Therefore, this assessment provides an evaluation of the potential "violation rates" for the various MLs being considered by the CCFAC. Note that in the case of the reported mean values, results below the limit of determination (LOD) are based on assigning values of LOD/2 for those results. Consequently, the median values might be more reliable in predicting distributions. If regulatory sampling is not likely to establish a reliable mean or median, the values provided for the 90th percentile may be useful in assessing the likelihood of a high sample exceeding a proposed ML. At the extreme end, i.e. 100th percentile, the large number of data sets with reported values over even the highest proposed ML suggests that a sampling plan would be useful in reducing the number of false positives in enforcement monitoring.

Table 1. Evaluation of Draft Maximum Levels of Lead in Fish with GEMS/Food Database

Proposed MLs	0.2 ppm	0.4 ppm	0.5 ppm
Mean	14%	2%	.7%
Median	7%	3.8%	2%
90th Percentile	21%	11%	7.7%
Maximum Reported	38%	24%	17%

Note that no attempt was made to separate fish into various species although this information is included as part of the aggregate record. GEMS/Food records use the Codex Classification of Foods and Animal Feeds (1993) which is available from the Codex website (CAC/MISC 4): http://www.codexalimentarius.net/web/standard_list.do?lang=en This includes extensive categories for fish and other seafood, both in English and Latin, and provided in a hierarchal system that simplifies consolidation of subcategories.