codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

JOINT OFFICE: Viale delle Terme di Caracalla 00100 ROME Tel: 39 06 57051 www.codexalimentarius.net Email: codex@fao.org Facsimile: 39 06 5705 4593

Agenda Item 15 (a)

CX/FAC 04/36/26 -- Add. 1
March 2004
[Original language only]

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON FOOD ADDITIVES AND CONTAMINANTS

Thirty-sixth Session

Rotterdam, The Netherlands, 22 -26 March 2004

DRAFT MAXIMUM LEVEL FOR LEAD IN FISH:

STATISTICAL ANALYSIS OF DATA ON LEAD CONTENT FOR SIGNIFICANTLY TRADED FISH SPECIES THAT MIGHT CAUSE PROBLEMS IN INTERNATIONAL TRADE

- COMMENTS AT STEP 6

The following comments have been received from: Japan, Philippines, South Africa, Spain, and International Food Additives Council (ICFA).

JAPAN:

We would first like to express our gratitude to the Government of Denmark for preparing a statistical analysis of data on lead in fish species which have significant trade volumes and may have trade problems. At the last session, the Japanese delegation expressed its willingness to submit results of surveillance. Although we recognize that the dead line has already passed, we would be grateful if you could accept our comments.

A survey was conducted in Japan from 1995 through 1997 to quantify lead in fish species harvested in seas around Japan. Ash of a fish sample obtained by dry ashing was dissolved in a diluted hydrochloric acid solution with heating. Resulting solution was neutralized with ammoniacal solution and lead was extracted with methyl isobutyl ketone. Lead concentration in the methyl isobutyl ketone solution was determined using atomic absorption spectrophotometer.

Attached Table 1 shows the summary of analytical results of lead in those fish species contained in Table 4 of CX/FAC 04/36/26 which proposed fish species for ML discussions by the 36th Session of the CCFAC. All the results are below the limit of quantification. Attached Table 2 shows the summary of analytical results of lead in other fish species than those contained in Table 1.All the results, except those of pond smelt, are below the limit of quantification.

Table1. Distribution of lead concentration in fish (Proposed fish speices for ML discussions)

No	Species	English name	No of samples	%<0.05 mg/kg	%<0.1 mg/kg	%<0.2 mg/kg	%<0.3 mg/kg	%<0.4 mg/kg	%<0.5 mg/kg	Country
8	*Anguilla japonica*	Japanese eel	15	15						Japan
15	*Istiophorus orientails*	Pacific sailfish	5	5						Japan
15	*Makaira mazara*	Pacific blue marlin	5	5						Japan
15	*Xiphias gladius*	Swordfish	5	5						Japan
18	*Theragra chalcogramma*	Alaska pollack	15	15						Japan
19	*Oncorhynchus keta*	Chum salmon	15	15						Japan
19	*Salmo gairdnerii irideus*	Rainbow trout	15	15						Japan
20	*Sardinops melanosticta*	Spotlined sardine	15	15						Japan
24	*Katsuwonus pelamis*	Skipjack tuna	15	15						Japan
24	*Thunnus albacares*	Yellowfin tuna	5	5						Japan
24	*Thunnus alalunga*	Albacore	5	5						Japan
24	*Thunnus thynnus thynnus*	Bluefin tuna	5	5						Japan
24	*Thunus obesus*	Bigeye tuna	5	5						Japan
24	*Tyunnus maccoyi*	Southern bluefin tuna	5	5						Japan

Table2. Distribution of lead concentration in other fish species

No	Species	English name	No of samples	%<0.05 mg/kg	%<0.1 mg/kg	%<0.2 mg/kg	%<0.3 mg/kg	%<0.4 mg/kg	%<0.5 mg/kg	Country
	Astroconger myriaster	Conger eel	15	15						Japan
	Chrysophrys major	Red sea-bream	15	15						Japan
	Cololabis saira	Pacific saury	15	15						Japan
	Lateolabrax japonicus	Japanese seabass	15	15						Japan
	Limanda yokohamae	Flounder	15	15						Japan
	Paralichthys olivaceus	Flatfish	15	15						Japan
	Prionace glauca	Great blue shark	5	5						Japan
	Scomber japonicus	Chub-mackerel	15	15						Japan
	Seriola quinqueradiata	Yellowtail	15	15						Japan
	Trachurus japonicus	Horse-mackerel	15	15						Japan
	Cyprinus carpio	Common carp	15	15						Japan
	Plecoglossus altivelis	Ayu	15	15						Japan
	Hypomesus olidus	Pond smelt	15	8	6	1				Japan

PHILIPPINES:

The Philippines has opposed the proposed Maximum Level of lead in fish of 0.2 ppm and proposes a level of 0.5 ppm based on risk assessment information provided by the 53rd JECFA.

The 35th CCFAC suggested to adopt a tiered approach in the establishment of an ML. Although no consensus was reached on this issue, it was agreed to carry out a statistical analysis based on the comments submitted and additional data available using different levels of concern (0.2, 0.4 and 0.5 mg/kg) as a basis for making a decision on whether or not to adopt a tiered approach.

This document provides further comment on the tiered approach. It also provides information on the risk due to dietary exposure to lead from fish using the dose response simulation developed by the 53rd JECFA which CCFAC has not considered in the development of the proposed ML.

Comments

1. The Philippines does not support a tiered approach to establishing an ML (Maximum Level) for lead in fish, based on fish species. This approach will create a trade barrier because of its great potential to discriminate against species important to the economy of small industries of developing countries for which an ML cannot be established due to the absence of analytical data. Annex 1 shows the variety and number of species of fish that are exported from the Philippines. Of these, only tuna has analytical data to support a lead level. Exclusion of the other fish species from the list of ML's will create problems in trade.
2. The Philippines recommends that the proposed ML for lead in fish be increased from 0.2 ppm to 0.5 ppm for the following reasons:

2.1 Using information from the 53rd Meeting of JECFA, on the relationship between the levels of lead in the diet and corresponding levels in the blood; and the relationship of blood levels of lead and intellectual impairment, it can be shown that an increase in ML for lead in fish of from 0.2 ppm to 0.5 ppm will have a negligible effect in the reduction in IQ of children. The estimation carried out applied the dose response simulation developed by the 53rd JECFA on all of the GEMS/WHO regional diets for fish consumption.

2.2 The 53rd JECFA has in fact concluded that the overall concentration of lead found currently in food would have negligible effects on the neurobehavioral development of infants and children. In proposing an ML of 0.2 ppm for lead in fish, CCFAC did not consider the extensive risk assessment information provided by the 53rd JECFA. This is not in accordance with Codex procedures for contaminants.

2.3 Based on data gathered in the Philippines and from other ASEAN countries as well as other data submitted to CCFAC, there can be levels of lead in tuna and other fresh and marine water fishes higher than the proposed draft ML of 0.2 ppm. For tuna, it can be as high as 0.4 ppm. Unlike mercury, fishes do not biomagnify lead. Applying an ML of 0.2 ppm which is lower than background levels for fish species as tuna, is equivalent to removing an important source of protein from the food supply without basis from a public health standpoint.

2.4 It is not possible to accurately measure lead at a level of 0.2 ppm without providing expensive accessories to current AAS instruments routinely used for the analysis of metals. This can create trade problems for countries unable to afford the cost involved. It will also increase the burden of control for developing countries. This will not be consistent with the Codex principle for the *Establishment of maximum levels for contaminants* which states that "*providing it is acceptable from the toxicological point of view, MLs shall be set at levels that can be analyzed in routine quality control laboratories"*

ANNEX 1. COMMERCIAL SPECIES OF FISH EXPORTED BY THE PHILIPPINES

	Common Names	*Scientific Names*
1.	Yellowfin tuna	**Thunnus albacares**
2.	Skipjack tuna	*Euthynnus (Katsuwonus) pelamis*
3.	Atlantic bonito	*Sarda sarda*
4.	Eastern little tuna	*Euthynnus affinis*
5.	Eels	*Anguilla spp.*
6.	Carp	*Cyprinus carpio*
7.	Tilapia	*Tilapia niloticus*
8.	Grouper	*Cephalopholis spp/*
9.	Mackerel	*Rastrelliger spp./ Scomberomurus spp.*
10.	Milkfish	*Chanos chanos*
11.	Roundscad	*Decapterus spp.*
12.	Catfish	*Arius spp.*
13.	Fusilier	*Caesio spp.*
14.	Anchovies	*Stolephorus spp.*
15.	Herring	*Herklotsichthys spp.*
16.	Sardines	*Sardinella spp.*
17.	Rabbit fish	*Siganus spp.*
18.	Breams	*Nemipterus spp.*
19.	Mullet	***Mugil cephalus***
20.	Slipmouth	*Leiognathus spp.*

Source: National Statistics Office (NSO), Jan. – Dec. 2002

SOUTH AFRICA:

Request for data: Lead in fish (ALINORM 03/12A, paras 140 –142)

SN:	0103----	
CD:	10-Sep-2003	
CC:	SOA	
FD:	-	
OF:	SOA	
SP:	04/2003-07/2003	
REP:	SW	
NOL:	2	
AQA:	SP	
CON:	011	
DIM:	1	
LOD min:	0.02 (lab 1)	0.1 (lab 2)
LOQ max:	0.05 (lab1)	-
BASE: A		
N:	-	
STATUS:	0	

REM: The table below shows the results of different species of fish consignments analyzed by 2 South African accredited laboratories. Each sample is an average of ten cutlets taken randomly and submitted to the laboratories where samples were composited and analyzed. Consignments were selected at random and where there is one test result, either there was one exporter or one consignment.

Fish Species	**FD**	**N**	**MAX**	**MIN**	**MED**
Lophius spp (Monk)	WS125	1	-	-	0.500
Genypterus (Kingklip)	WS125	5	0.36	1.26	0.706
Merlucclus (Hake)	WS126	9	0.19	0.50	0.339
Albacore Tuna	WS132	9	0.40	1.22	0.656
Blgeye Tuna	WS132	2	1.40	1.80	1.600
Raja spp (Skates)	WS131	4	0.29	0.82	0.505
Escola (Butterfish)	WS125	1	-	-	0.170
Lepidopus (Ribbon fish)	WS125	1	-	-	0.560
Zeus (John Dory)	WS125	1	-	-	0.230
Sardinops (Pilchards)	WS130	9	0.80	1.16	0.98
Canned Pilchards	WS130	1	-	-	1.3
Loligo (Squids)	IM1002	7	0.47	0.77	0.590

SPAIN:

Please find enclosed Spanish data on lead in fish related with a study carried out by Instituto Español de Oceanografía (IEO) joint to Secretaría General de Pesca Marítima of Spain from 2001 to 2002. This study include fish samples taken by trained samplers in seas and oceans around the world.

They are 1.829 samples of 51 fish species. These data follow the model of the Annex 2 of the Codex CX/FAC 04/36/26 "Draft maximum level for lead in fish"

We would like these data substitute the Spain data just included in the Annex 2 of the Codex CX/FAC 04/36/26 "Draft maximum level for lead in fish".

The old data sent by Spain some years ago to the Codex Committee on Food Additives and Contaminants (CCFAC) were collected from different sources and laboratories and they did not include all the fish species marketed in Spain

Pb in fishes SPAIN (2001-2002) 3 March 2004

Order	Family	Species	English name	Nº of samples	%<0,05 mg/kg	%<0,1 mg/kg	%<0,2 mg/kg	%<0,3 mg/kg	%<0,4 mg/kg	%<0,5 mg/kg	Country	Habitat
Anguiliformes	Congridae	*Conger conger*	European conger	8	100						Spain	Atlántico
Beryciformes	Berycidae	*Beryx splendens*	Splendid alfonsino	14	93	100					Spain	Atlántico
Carcharhiniformes	Carcharhinidae	*Prionace glauca*	Blue shark	25	100						Spain	Atlántico Norte
		Prionace glauca	Blue shark	27	96	100					Spain	Atlántico Sur
		Prionace glauca	Blue shark	49	100						Spain	Índico
		Prionace glauca	Blue shark	13	69	100					Spain	Pacífico
Clupeiformes	Clupeidae	*Sardina pilchardus*	Pilchard	20	100						Spain	Atlántico Norte
		Sardina pilchardus	Pilchard	20	100						Spain	Atlántico Norte
	Engraulidae	*Engraulis encrasicholus*	Anchovy	25	100						Spain	Atlántico
		Engraulis encrasicholus	Anchovy	7	71	100					Spain	Mediterráneo
Gadiformes	Gadidae	*Gadus macrocephalus* y *Gadus ogac*	Cod	5	100						Spain	Pacífico y Groenlandia
		Micromesistius poutassou	Blue whiting	32	25	59	100				Spain	Atlántico Norte
		Micromesistius poutassou	Blue whiting	23	100						Spain	Mediterráneo
		Trisopterus minutus	Poor cod	24	100						Spain	Mediterráneo
	Lotidae	*Molva dypterigia*	Ling	9	100						Spain	Atlántico
	Merluciidae	*Macruronus magellanicus*	Patagonian grenadier	14	100						Spain	Alántico Sur
		Merluccius australis	Southern hake	15	100						Spain	Atlántico Sur
		Merluccius capensis	Shallow-water Cape hake	12	100						Spain	Sudáfrica
		Merluccius hubbsi	Argentine hake	17	100						Spain	Atlántico Sur
		Merluccius merluccius	European hake	42	45	48	100				Spain	Atlántico Norte

		Merluccius merluccius	European hake	22	100						Spain	Mediterráneo
	Moridae	*Mora moro*	Morid cod	13	100						Spain	Atlántico Norte
	Phycidae	*Phycis blennoides*	Greater forkbeard	27	85	100					Spain	Mediterráneo
Lamniformes	Lamnidae	*Isurus oxyrinchus*	Shortfin mako	26	92	100					Spain	Atlántico Norte
		Isurus oxyrinchus	Shortfin mako	30	97	100					Spain	Atlántico Sur
		Isurus oxyrinchus	Shortfin mako	51	100						Spain	Indico
		Isurus oxyrinchus	Shortfin mako	20	75	100					Spain	Pacífico
Lophiiformes	Lophiidae	*Lophius budegassa*	Black-bellied angler	15	100						Spain	Atlántico
		Lophius piscatorius	Anglerfish	51	100						Spain	Atlántico
Ophidiformes	Ophidiidae	*Brotula barbata*	Bearded brotula	13	100						Spain	Atlántico Sur
		Genypterus capensis	Kingklip	14	100						Spain	Atlántico Sur
Perciformes	Bramidae	*Brama brama*	Atlantic pomfret	8	100						Spain	Atlántico
	Carangidae	*Trachurus mediterraneus*	Mediterranean horse mackerel	8	100						Spain	Mediterráneo
		Trachurus trachurus	Horse mackerel	16	100						Spain	Atlántico
		Trachurus trachurus	Horse mackerel	8	100						Spain	Mediterráneo
	Macrouridae	*Coryphaenoides rupestris*	Roundnose grenadier	5	100						Spain	Atlántico
		Macrourus berglax	Onion-eye grenadier	24	100						Spain	Atlántico
	Moronidae	*Dicentrarchus labrax*	European seabass	9	100						Spain	Piscifactoria
	Mullidae	*Mullus barbatus*	Red mullet	24	58	83	96	100			Spain	Mediterráneo
		Mullus surmuletus	Striped red mullet	105	94	99	100				Spain	Atlántico Norte
		Mullus surmuletus	Striped red mullet	23	83	100					Spain	Mediterráneo

Perciformes (cont.)	Sparidae	*Pagellus acarne*	Axilary seabream	23	22	65	95	100			Spain	Mediterráneo
		Pagellus bogarabeo	Blackspot seabream	5	100						Spain	Atlántico Norte
		Pagellus erythrinus	Pandora	25	44	100					Spain	Atlántico Norte
		Pagellus erythrinus	Pandora	23	91	100					Spain	Mediterráneo
		Sparus aurata	Gilthead seabream	20	100						Spain	Piscifactoría
	Trachichthyidae	*Hoplostethus*	Rosy soldier fish	7	100						Spain	Atlántico

		mediterraneus										
Pleuronectiformes	Pleuronectidae	*Hippoglossoides platessoides*	European flounder	28	100						Spain	Atlántico
		Limanda ferruginea	Yellowtail flounder	25	96	100					Spain	Atlántico
		Reinhardtius hippoglossoides	Greenlad halibut	20	100						Spain	Atlántico
	Scophthalmidae	*Lepidorhombus boscii*	Fourspotted megrim	25	100						Spain	Atlántico
		Lepidorhombus boscii	Fourspotted megrim	19	100						Spain	Mediteráneo
		Lepidorhombus whiffiagonis	Megrim	22	100						Spain	Atlántico
		Lepidorhombus whiffiagonis	Megrim	14	100						Spain	Mediterráneo
	Soleidae	*Solea solea*	Common sole	29	59	86	100				Spain	Atlántico Norte
Rajiformes	Rajidae	*Amblyraia radiata*	Thorny skate	26	96	100					Spain	Atlántico
Salmoniformes	Salmonidae	*Salmo salar*	Atlantic salmon	5	100						Spain	Atlántico Norte
		Salmo trutta fario	Trout	6	100						Spain	Piscifactoría
Scombriformes	Scombridae	*Katsuwonus pelamis*	Skipjack	50	100						Spain	Atlántico Norte
		Katsuwonus pelamis	Skipjack	10	100						Spain	Indico
		Katsuwonus pelamis	Skipjack	10	100						Spain	Pacífico
		Scomber scombrus	Mackerel	15	100						Spain	Atlántico
		Scomber scombrus	Mackerel	23	96	100					Spain	Mediterráneo
		Thunnus alalunga	Albacore	29	100						Spain	Atlántico
		Thunnus alalunga	Albacore	31	94	100					Spain	Indico
		Thunnus albacares	Yellowfin tuna	33	100						Spain	Atlántico
		Thunnus albacares	Yellowfin tuna	24	100						Spain	Indico
		Thunnus albacares	Yellowfin tuna	9	100						Spain	Pacífico
		Thunnus obesus	Bigeye tuna	63	92	97	100				Spain	Atlántico
		Thunnus obesus	Bigeye tuna	50	100						Spain	Indico
		Thunnus thynnus	Bluefin tuna	55	78	84	97	97	97	97	Spain	Atlántico Norte
		Thunnus thynnus	Bluefin tuna	17	100						Spain	Mediterráneo/Jaul
	Xiphiidae	*Xiphias gladius*	Swordfish	25	100						Spain	Atlántico Norte

		Xiphias gladius	Swordfish	31	94	100					Spain	Atlántico Sur
		Xiphias gladius	Swordfish	54	100						Spain	Índico
		Xiphias gladius	Swordfish	7	100						Spain	Mediterráneo
		Xiphias gladius	Swordfish	23	100						Spain	Pacífico
Scorpeniformes	Scorpenidae	*Sebastes mentella*	Deepwater redfish	25	100						Spain	Atlántico

INTERNATIONAL COALITION OF FISHERIES ASSOCIATIONS (ICFA):

The ICFA is an international coalition of the major fishing industry associations around the world. The ICFA and its members are committed to providing the world's consumers with safe, wholesome, diverse, and abundant seafood choices and to ensuring that seafood contributes in a meaningful way to global food security.

The ICFA greatly appreciates the work of CODEX Alimentarius. The ICFA believes that international food safety standards should be based on sound science. We hope that the attached resolution regarding lead, adopted at our 2003 Annual Meeting, will be helpful to the CODEX Alimentarius and its Committees and Task Forces.

ICFA Resolution

2003 Annual Meeting

Auckland, New Zealand

Lead

Whereas:

- The establishment of maximum residue levels for contaminants should be based on sound science;
- The proposed establishment of a 0.2ppm maximum residue level for lead in seafood is arbitrary;
- The establishment of arbitrary or overly precautionary maximum residue levels will negatively impact international trade in seafood, particularly for developing countries, and may unnecessarily deny consumers access to wholesome and nutritious seafood products;
- The establishment of maximum residue levels must take into consideration the existence of affordable and readily available analytical capabilities;
- All nations should use the same sampling and analysis methodologies;
- There are no known adverse health affects related to dietary exposure to low levels of lead via seafood;

ICFA therefore:

- Questions whether a Maximum Residue Level for lead in seafood is necessary and, ICFA calls on the CODEX Alimentarius and the Joint FAO/WHO Expert Committee on Food Additives and Contaminant to postpone the development of a Maximum Level of lead in fish until adequate scientific research has been conducted on any potential health affects of exposure to low levels of lead in seafood, particularly with regard to the dose-response relationship and an estimate of risk in the context of dietary exposure.