codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS | WORLD HEALTH ORGANIZATION

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Agenda Item 16 A **CX/FAC 02/23**

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON FOOD ADDITIVES AND CONTAMINANTS
Thirty-fourth Session
Rotterdam, The Netherlands, 11-15 March 2002

DRAFT MAXIMUM LEVELS FOR LEAD IN FISH, CRUSTACEANS AND BIVALVE MOLLUSCS AND BUTTER

The following comments have been received from Australia, Canada, Malaysia, Brazil, Spain, Philippine, USA and European Community

AUSTRALIA

BACKGROUND

The 33rd CCFAC decided to return the draft Maximum Levels for Lead in Crustaceans (0.5 mg/kg) and draft Maximum Levels for Lead in Molluscs (1.0 mg/kg), for additional comments at Step 6 (Appendix XIV).

AUSTRALIAN LEVELS FOR LEAD IN CRUSTACEA AND MOLLUSCS

Crustacea
The joint Australia New Zealand Food Standards Code does not set an ML for lead in crustacea. The levels for this food commodity were not set in Australia because the exposure of consumers to lead from this commodity is not significant in Australia in terms of the total dietary exposure (less than 5% of the exposure to lead from food) either for the general population or for children. The proposed Codex ML for lead in crustacea is 0.5 mg/kg.

Australian lead levels in crustacea, based on 3,166 samples comprising different taxonomic and ecological groupings as well as different feeding habits, indicates that only 0.13% of the 19 commercial species of lobsters, crabs, prawns and freshwater crayfish caught in Australian waters have lead levels above 0.5 mg/kg.

Molluscs:
The joint Australia New Zealand Food Standards Code sets a ML of 2 mg/kg for lead in molluscs. The proposed draft Codex ML for lead in molluscs is 1 mg/kg.

Current data from 785 samples of Australian molluscs, including 450 samples of bivalves, indicates that none of the samples would exceed the proposed draft Codex MLs of 1.0 mg/kg.

COMMENT ON THE PROPOSED DRAFT MAXIMUM LEVELS

Australia did not agree to the proposal to develop draft ML for lead in crustacea at the 33rd CCFAC, on the basis that this proposal was not supported by a scientific risk assessment that demonstrated that this food group contributes significantly to exposure to lead from food.

The proposal by CCFAC to establish a ML for lead in crustacea and molluscs does not appear to meet the second Principle set out in the Principles in a preamble to the General Standard for Contaminants and Toxins. These state that MLs shall be set:

a. Only for those contaminants that present both a significant risk to public health and a known or expected problem in international trade;

b. Only for those foods that are significant for the total exposure of the consumer to the contaminant;

c. As low as reasonably achievable. Providing it is acceptable from the toxicological point of view, MLs shall be set at a level which is (slightly) higher than the normal range of variation in levels in foods that are produced with current adequate technological methods, in order to avoid undue disruptions of food production and trade.

CCFAC needs to develop criteria for what constitutes a significant contribution to the total exposure from food and to support any proposal for a draft ML by a scientific risk assessment that demonstrates that such criteria have been met.

In reference to CL 2001/13 – FAC, Part B, para 162 – Draft Maximum Levels for Lead in Fish, Crustaceans and Bivalve Molluscs at Step 6, Australia wishes to provide the following comments in relation to fish.

BACKGROUND

The 33rd CCFAC decided to return the draft Maximum Levels for Lead in Fish (0.2 mg/kg), for additional comments at Step 6 (ALINORM 01/12A Appendix XIV). The Committee agreed that comments would be requested on lead levels in specific subspecies of fish by Latin name and/or by habitat or behaviour and that Denmark would make a compilation of the data forwarded on fish. It was also agreed that information would be requested from FAO and WHO in this regard.

A number of Member States, including Australia, did not agree to the proposed ML for fish on the basis that the proposed level was not achievable, as based on the available data at the time of the proposal.

The joint Australia New Zealand Food Standards Code sets a ML of 0.5 mg/kg for lead in fish. The proposed Codex ML for lead in fish is 0.2 mg/kg.

Australia is aware of the need to maintain the levels of lead in food at the lowest achievable levels, in particular to protect children, the most vulnerable target group, from the adverse consequences of lead exposure. The development of MLs for lead in food commodities must be based on the principles set out in the General Standard for Contaminants and Toxins in Food. These state that MLs shall be set:

d. Only for those contaminants that present both a significant risk to public health and a known or expected problem in international trade;
e. Only for those foods that are significant for the total exposure of the consumer to the contaminant;
f. As low as reasonably achievable. Providing it is acceptable from the toxicological point of view, MLs shall be set at a level which is (slightly) higher than the normal range of variation in levels in foods that are produced with current adequate technological methods, in order to avoid undue disruptions of food production and trade.

AUSTRALIAN DATA ON LEAD IN FINFISH

Australia has now re-assessed existing and new data on lead in fish to address the issue of achievable levels and whether the database could identify differential levels of lead in various fish species. The data is attached in Appendix 1. The data provided is from 6 groups of commercially-harvested finfish, each representing a broad category of habitat (eg estuaries, deep ocean), feeding behaviour (eg predator) and other biological characteristics (eg longevity). It comprises 966 samples taken from unprocessed product collected Australia-wide from major fishing areas.

PROPOSED CODEX MLS FOR FINFISH

Species differences in lead levels

The data indicates that of the groups sampled, only long-lived predatory fish high in the food-chain (shark, and occasionally orange roughy) and detritus-feeders (eg sea mullet) contain lead at levels above 0.2mg/kg.

Appropriate Codex ML

The above data, from 966 samples from 15 commercial species of fish caught in Australian waters, indicate that only about 0.1% have levels of lead above 0.2 mg/kg. Of these, 3.8% of sharks and 1.5% of sea mullet exceeded 0.2 mg/kg.

Australia therefore maintains its position that if a single ML is set for lead in fish, it should be set at 0.5mg/kg. However, recognising the importance of setting the ML as low as reasonably achievable, Australia could support a Codex ML of 0.2mg/kg for fish, with a higher level set for particular species likely to contain higher levels of lead. That level could be 0.5mg/kg or an alternative level calculated from information provided by member countries on lead levels in fish throughout the world and their contribution to dietary exposure.

Product definition

Australia considers it important that Codex clearly identify the product to which the proposed ML will apply (eg fresh fish, edible portion only, dried, canned etc).

APPENDIX 1 Australian data for lead levels in finfish, comprising both predatory fish and other species lower in the food chain.

Fish Species	Habitat, trophic position	Geographic distribution	Samples tested	No of samples above 0.2 mg/kg	No of samples above 0.5 mg/kg
Sharks *(Furgaleus macki, Galeorhinus galeus, Mustelus antarticus, Carcarhinus obscurus, C brachyurus, C sorrah, C.tilsonii)*	Continental shelf and slope. Top level pelagic or demersal predator. Feed on fish and benthic organisms.	**Some are endemic to Australian waters (***F. macki, M antarticus, C obscurus, C brachyurus, C. tilsoni***), some spp have a wide Australian distribution, but are also found in NZ, Europe, and west coasts of South America and Africa (***G. galeus, C. sorrah).*	138	5	0
Orange roughy *(Haplostethus atlanticus)*	Waters from 700m to 1500m, on continental shelf slopes. Preys upon fish and squids. Demersal	North Atlantic, NW Africa, South Atlantic, Southern Indian and SW Pacific Ocean to NZ .	231	1	0
Bluefin tuna (*Thunnus maccoyii*)	Opportunistic predators, chiefly of cephalopods, crustaceans and fish. Pelagic	Circumglobal distribution between 30^0 S and 50^0 S.	33	0	0
Patagonian toothfish (*Dissostichus eleginoides*)	Top of food chain demersal predator, feeds on other fish, molluscs and crustaceans**.**	Distributed within Antarctic waters	148	0	0
Sea mullet *(Mugil cephalus)*	Coastal water, estuaries and fresh water (rivers, river-mouths). Feed on detritus, diatoms, algae and small invertebrates. Sand is ingested to assist digestion. Demersal	Tropical and temperate waters world-wide.	266	4	1
School whiting *(Silago flindersi, S. bassensis)*	Live in close to sea bed over sandy substrate, waters up to 80m. Bento-demersal. Feed on amphipods, prawns and	Endemic to southern regions of the Australian continental shelf	150	0	0

	polychaete worms.				

CANADA

Draft Maximum Level for Lead in Butter (Paragraph 159)

Based on data available from studies conducted in Canada, lead levels in butter have been found to be low. In a study by Dabeka *et al.* (*J.A.O.A.C. Intl.*, **78**(4): 897-909), the mean level of lead in butter was found to be 16.4 ng/g. This is calculated to represent 0.001% of the JECFA PDTI for Pb of 3.57 ÿg/kg b.w./day for adults or 0.04% the JECFA PTDI for Pb of 3.57 ÿg/kg b.w./day for children. In this regard, Canada agrees with comments made by the Delegation of India that a maximum limit for lead in butter is not necessary.

Canada would also indicate that sources of lead in butter would most likely be packaging materials or handling procedures. Therefore, good manufacturing practices would be the preventative measure for lead contamination of butter.

Draft Maximum Levels for Lead in Fish, Crustaceans and Bivalve Molluscs (Paragraph 162 and Appendix XIV)

In general, the proposed MLs of 0.2, 0.5 and 1.0 mg/kg in fish, crustaceans and bivalve molluscs, respectively, are acceptable to Canada. Although, based on available data, the lead levels in fish and mussels may occasionally exceed these MLs (0.2 and 1.0 mg/kg, respectively), it is expected that the lead levels in the majority of these two commodities will be lower than these proposed MLs.

MALAYSIA

Draft Maximum Level for Lead in Butter At Step 6 (ALINORM 01/12A: para. 159)

Malaysia is of the opinion that the maximum level of lead in butter should be 0.05mg/kg in line with the Codex Standard for Butter (Codex Stand A-1-1971, Rev1-1999).

US A

Proposed Draft Maximum Levels for Lead in Fish, Crustaceans and Bivalve Molluscs (ALINORM 12A/01, para. 162 and Appendix XIV).

At the 33rd Session of the CCFAC, the Committee returned the proposed draft Maximum Levels (MLs) for lead in Fish (0.2 mg/kg), Crustaceans (0.5 mg/kg) and Bivalve Molluscs (1.0 mg/kg) to Step 6 for additional comments. The Committee agreed that comments would be requested on lead levels in specific subspecies of fish by Latin name and/or by habitat or behavior and on lead levels in crustaceans and bivalve molluscs.

Based on available occurrence data from the U.S. Food and Drug Administration's (FDA's) 1991-1998 Compliance Monitoring Program and recent FDA Total Diet Study Survey (TDS)[1] (Tables 1-6), we offer the following comments on the proposed MLs for lead in fish, crustaceans, and bivalve molluscs.

Proposed ML for Fish

As requested by the Committee, Table 1 presents lead levels in various species (both the market and Latin names provided) of finfish. We note that although more than one Latin name appears under the market names (e.g., bass, flounder, tuna), breakout of data points for each Latin name species are not available. Based on FDA's Compliance Monitoring Program and TDS Survey data (Tables 1, 4, and 5), with the exception of canned mackerel and canned sardines, the U.S. believes that lead levels below the proposed ML of 0.2 mg/kg are achievable for those species of finfish presented in Table 1.

Considering the plausible high consumption of tuna by children, the U.S. believes that a ML lower than 0.2 mg/kg for lead in tuna is appropriate and recommends that a separate category for tuna be established with a lead ML of 0.1 mg/kg. The USDA 1989-1992 Continuous Survey of Food Intakes by Individuals data show a 90th percentile daily consumption of canned tuna of 26 g for 1-2 year old children and 46 g for 3-5 year old children. Based on this information, consumption of tuna containing lead at the proposed ML of 0.2 mg/kg results in lead intake of 5 ?g/day for 1-2 year old children and 9 ?g/day for 3-5 year old children at the 90 th percentile. Consequently, 1-2 year old and 3-5 year old children could consume 15 and 26 percent of JECFA's tolerable daily intake for lead at the 90th percentile, respectively, solely from consumption of tuna. Based on FDA's Compliance Monitoring Program and TDS Survey data (Table 1 and 4), we believe that a lead level of 0.1 mg/kg in tuna is feasible to reduce unnecessary lead exposure for the susceptible population of children.

Proposed ML for Crustaceans

Based on FDA's Compliance Monitoring Program and TDS Survey data (Table 2 and 6), the U.S. believes that lead levels below the proposed ML of 0.5 mg/kg are achievable in crab, shrimp, and lobster.

Proposed ML for Bivalve Molluscs

Based on FDA's compliance monitoring data for lead in bivalve molluscs (Tables 3), the U.S. believes that lead levels below the proposed ML of 1.0 mg/kg are achievable in clams, oysters, mussels, and scallops.

Summary

The U.S. continues to emphasize that, because infants and small children are the most sensitive to the adverse health effects of lead, establishing maximum limits (ML's) for lead needs to be focused on those foods consumed by this population group. Further, to reduce exposure to lead to as low as possible, particularly children, the U.S. position is that lead in foods should be reduced to the lowest level feasible using good agricultural and good manufacturing practices.

The U.S. believes that CCFAC should continue to exercise a transparent, consistent, and reproducible risk management framework for proposing ML's to the Codex Alimentarius Commission for adoption. We believe that JECFA's evaluation (53rd meeting of the Joint FAO/WHO Expert Committee on Food Additives,

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[1] TDS is FDA's annual survey of market baskets representing 265 core foods (ready-to-eat) in the U.S. food supply to assess the levels of contaminants and nutrients in those foods. Each data point for a contaminant or a nutrient represents composite of 3 samples of a food type.

June 1999) of exposure and the resulting risk for lead provides the necessary tools to develop an initial framework for assessing potential risk of dietary lead.

The U.S. appreciates the opportunity to comment on the proposed draft MLs for lead in fish, crustaceans and bivalve molluscs.

Enclosures

FSIS:USCodex:E.Matten:ym:205-7760:11/8/01:[2001 – Response to CL 2001/13-FAC]

TABLE 1 – Lead Levels in Fish (FDA Compliance Monitoring Program)

A. Bass

Bass; Micropterus spp. or Ambloplites spp.
SeaBass, Black; Centropristis striata
Bass, Black; Micropterus dolomieui
Bass, Spotted; Micropterus punctulatus
Bass, Largemouth; Micropterus salmoides
Bass, Striped; Morone saxatilis

YR-MIN	1989	
YR-MAX	1999	
MEAN	0.032	mg/kg
STDDEV	0.027	mg/kg
COUNT	9	
MIN	0.000	mg/kg
MAX	0.064	mg/kg
MEDIAN	0.035	mg/kg
PROPOSED ML	0.200	mg/kg

LEAD (mg/kg)	# SAMPLES	CUMULATIVE%
0.000	3	33.3%
0.025	0	33.3%
0.050	4	77.8%
0.075	2	100.0%
0.100	0	100.0%
0.125	0	100.0%
0.150	0	100.0%
0.175	0	100.0%
0.200	0	100.0%
> 0.200	0	100.0%

TABLE 1 – Lead Levels in Fish (FDA Compliance Monitoring Program) (cont.)

B. Catfish

Catfish; Ictalurus spp.
Catfish, Channel; Ictalurus punctatus

YR-MIN	1989	
YR-MAX	1999	
MEAN	0.026	mg/kg
STDDEV	0.047	mg/kg
COUNT	49	
MIN	0.000	mg/kg
MAX	0.214	mg/kg
MEDIAN	0.010	mg/kg
PROPOSED ML	0.200	mg/kg

LEAD (mg/kg)	# SAMPLES	CUMULATIVE%
0.000	11	22.4%
0.025	26	75.5%
0.050	7	89.8%
0.075	2	93.9%
0.100	0	93.9%
0.125	0	93.9%
0.150	0	93.9%
0.175	1	95.9%
0.200	0	95.9%
0.225	2	100.0%
> 0.225	0	100.0%

TABLE 1 – Lead Levels in Fish (FDA Compliance Monitoring Program) (cont.)

C. Cod
Cod, Rock; Lotella rhacina
Cod, Black; Paranotothenia microlepidota
Cod, Pacific; Gadus macrocepholus
Cod, Atlantic; Gadus morhua

YR-MIN	1989	
YR-MAX	1999	
MEAN	0.022	mg/kg
STDDEV	0.072	mg/kg
COUNT	198	
MIN	0.000	mg/kg
MAX	0.600	mg/kg
MEDIAN	0.000	mg/kg
PROPOSED ML	0.200	mg/kg

LEAD (mg/kg)	# SAMPLES	CUMULATIVE %
0.000	103	52.0%
0.025	62	83.3%
0.050	20	93.4%
0.075	3	94.9%
0.100	3	96.5%
0.125	2	97.5%
0.150	0	97.5%
0.175	0	97.5%
0.200	0	97.5%
0.225	0	97.5%
0.250	1	98.0%
0.275	1	98.5%
0.300	0	98.5%
0.325	0	98.5%
0.350	0	98.5%
0.375	0	98.5%
0.400	0	98.5%
0.425	1	99.0%
0.450	0	99.0%
0.475	0	99.0%
0.500	0	99.0%
0.525	0	99.0%
0.550	0	99.0%
0.575	0	99.0%
0.600	2	100.0%
> 0.600	0	100.0%

TABLE 1 – Lead Levels in Fish (FDA Compliance Monitoring Program) (cont.)

D. Drum
Drum nsp.; Family: Sciaenidae
Drum, Black; Pogonias cromis

YR-MIN	1989	
YR-MAX	1999	
MEAN	0.041	mg/kg
STDDEV	0.011	mg/kg
COUNT	6	
MIN	0.020	mg/kg
MAX	0.051	mg/kg
MEDIAN	0.043	mg/kg
PROPOSED ML	0.200	mg/kg

LEAD (mg/kg)	# SAMPLES	CUMULATIVE %
0.000	0	.0%
0.025	1	16.7%
0.050	4	83.3%
0.075	1	100.0%
0.100	0	100.0%
0.125	0	100.0%
0.150	0	100.0%
0.175	0	100.0%
0.200	0	100.0%
> 0.200	0	100.0%

TABLE 1 – Lead Levels in Fish (FDA Compliance Monitoring Program) (cont.)

E. Flounder (Flounder, Dab, Sole)

Flounder; *Paralichthys spp.*
Flounder, Yellowtail; *Limanda ferruginea*
Flounder, Winter; *Pseudopleuronectes americanus*
Dab; *Pleuronectes limanda*
Dab, Sand; *Pleuronectes punctatissimus*
Sanddab, Pacific; *Citharichthys sordidus*
Sole, Dover; *Microstomus pacificus*
Sole, European Dove; *Solea vulgaris*
Sole, Petrale; *Eopsetta jordani*
Sole, Grey; *Glyptocephalus cynoglossus*
Sole, English; *Parophrys vetula*
Sole, Rex; *Glyptocephalus zachirus*

YR-MIN	1989	
YR-MAX	1999	
MEAN	0.024	mg/kg
STDDEV	0.027	mg/kg
COUNT	47	
MIN	0.000	mg/kg
MAX	0.111	mg/kg
MEDIAN	0.016	mg/kg
PROPOSED ML	0.200	mg/kg

LEAD (mg/kg)	# SAMPLES	CUMULATIVE %
0.000	14	29.79%
0.025	16	63.83%
0.050	10	85.11%
0.075	4	93.62%
0.100	1	95.74%
0.125	2	100.00%
0.150	0	100.00%
0.175	0	100.00%
0.200	0	100.00%
> 0.200	0	100.00%

TABLE 1 – Lead Levels in Fish (FDA Compliance Monitoring Program) (cont.)

F. Mackerel, Canned

Mackerel nsp.; Scomberomorus spp./Scomber spp.
Mackerel, Jack; Trachurus symmetricus

YR-MIN	1989	
YR-MAX	1999	
MEAN	0.134	mg/kg
STDDEV	0.305	mg/kg
COUNT	35	
MIN	0.000	mg/kg
MAX	1.650	mg/kg
MEDIAN	0.042	mg/kg
PROPOSED ML	0.200	mg/kg

LEAD (mg/kg)	# SAMPLES	CUMULATIVE %
0.000	11	31.4%
0.025	4	42.9%
0.050	3	51.4%
0.075	4	62.9%
0.100	2	68.6%
0.125	5	82.9%
0.150	0	82.9%
0.175	0	82.9%
0.200	1	85.7%
0.225	1	88.6%
0.250	1	91.4%
0.275	0	91.4%
0.300	0	91.4%
0.325	0	91.4%
0.350	0	91.4%
0.375	0	91.4%
0.400	0	91.4%
0.425	0	91.4%
0.450	1	94.3%
0.475	0	94.3%
0.500	0	94.3%
0.525	0	94.3%
0.550	0	94.3%
0.575	0	94.3%
0.600	0	94.3%
0.625	0	94.3%
0.650	0	94.3%

F. Mackerel, Canned (cont.)

LEAD (mg/kg)	# SAMPLES	CUMULATIVE %
0.675	0	94.3%
0.700	0	94.3%
0.725	0	94.3%
0.750	0	94.3%
0.775	0	94.3%
0.800	1	97.1%
0.825	0	97.1%
0.850	0	97.1%
0.875	0	97.1%
0.900	0	97.1%
0.925	0	97.1%
0.950	0	97.1%
0.975	0	97.1%
1.000	0	97.1%
>1.000	1	100.0%

TABLE 1 – Lead Levels in Fish (FDA Compliance Monitoring Program) (cont.)

G. Milkfish

Milkfish; Chanos chanos

YR-MIN	1989	
YR-MAX	1999	
MEAN	0.115	mg/kg
STDDEV	0.059	mg/kg
COUNT	6	
MIN	0.053	mg/kg
MAX	0.208	mg/kg
MEDIAN	0.101	mg/kg
PROPOSED ML	0.200	mg/kg

LEAD (mg/kg)	# SAMPLES	CUMULATIVE %
0.000	0	.0%
0.025	0	.0%
0.050	0	.0%
0.075	2	33.3%
0.100	1	50.0%
0.125	1	66.7%
0.150	0	66.7%
0.175	1	83.3%
0.200	0	83.3%
0.225	1	100.0%
> 0.225	0	100.0%

TABLE 1 – Lead Levels in Fish (FDA Compliance Monitoring Program) (cont.)

H. Perch, Ocean

Perch, Ocean Pacific; Sebastes alutus
Perch, Ocean Redfish; Sebastes marinus

YR-MIN	1989	
YR-MAX	1999	
MEAN	0.015	mg/kg
STDDEV	0.036	mg/kg
COUNT	10	
MIN	0.000	mg/kg
MAX	0.109	mg/kg
MEDIAN	0.000	mg/kg
PROPOSED ML	0.200	mg/kg

LEAD (mg/kg)	# SAMPLES	CUMULATIVE %
0.000	8	80.0%
0.025	0	80.0%
0.050	1	90.0%
0.075	0	90.0%
0.100	0	90.0%
0.125	1	100.0%
0.150	0	100.0%
0.175	0	100.0%
0.200	0	100.0%
> 0.200	0	100.0%

TABLE 1 – Lead Levels in Fish (FDA Compliance Monitoring Program) (cont.)

I. Perch, Lake

Perch, Yellow (Lake); Perca flavescens
Perch, White; Morone Americana

YR-MIN	1989	
YR-MAX	1999	
MEAN	0.018	mg/kg
STDDEV	0.022	mg/kg
COUNT	16	
MIN	0.000	mg/kg
MAX	0.069	mg/kg
MEDIAN	0.014	mg/kg
PROPOSED ML	0.200	mg/kg

LEAD (mg/kg)	# SAMPLES	CUMULATIVE %
0.000	7	43.8%
0.025	5	75.0%
0.050	1	81.3%
0.075	3	100.0%
0.100	0	100.0%
0.125	0	100.0%
0.150	0	100.0%
0.175	0	100.0%
0.200	0	100.0%
> 0.200	0	100.0%

TABLE 1 – Lead Levels in Fish (FDA Compliance Monitoring Program) (cont.)

J. Pickerel

Pickerel; Esox spp.

YR-MIN	1989	
YR-MAX	1999	
MEAN	0.022	mg/kg
STDDEV	0.013	mg/kg
COUNT	7	
MIN	0.007	mg/kg
MAX	0.042	mg/kg
MEDIAN	0.019	mg/kg
PROPOSED ML	0.200	mg/kg

LEAD (mg/kg)	# SAMPLES	CUMULATIVE %
0.000	0	.0%
0.025	5	71.4%
0.050	2	100.0%
0.075	0	100.0%
0.100	0	100.0%
0.125	0	100.0%
0.150	0	100.0%
0.175	0	100.0%
0.200	0	100.0%
> 0.200	0	100.0%

TABLE 1 – Lead Levels in Fish (FDA Compliance Monitoring Program) (cont.)

K. Pollock

Pollock; Pollachius virens
Pollock, Alaska; Theragra chalcogramma

YR-MIN	1989	
YR-MAX	1999	
MEAN	0.009	mg/kg
STDDEV	0.016	mg/kg
COUNT	126	
MIN	0.000	mg/kg
MAX	0.096	mg/kg
MEDIAN	0.000	mg/kg
PROPOSED ML	0.200	mg/kg

LEAD (mg/kg)	# SAMPLES	CUMULATIVE %
0.000	78	61.9%
0.025	33	88.1%
0.050	10	96.0%
0.075	4	99.2%
0.100	1	100.0%
0.125	0	100.0%
0.150	0	100.0%
0.175	0	100.0%
0.200	0	100.0%
> 0.200	0	100.0%

TABLE 1 – Lead Levels in Fish (FDA Compliance Monitoring Program) (cont.)

L. Salmon

Salmon, Chinook/ King; Oncorhynchus tshawytscha
Salmon, Chum; Oncorhynchus keta
Salmon, Coho/ Silver; Oncorhynchus kisutch
Salmon, Pink/ Humpback; Oncorhynchus gorbuscha
Salmon, Sockeye/ Red; Oncorhynchus nerka
Salmon, Atlantic; Salmo salar

YR-MIN	1989	
YR-MAX	1999	
MEAN	0.018	mg/kg
STDDEV	0.032	mg/kg
COUNT	187	
MIN	0.000	mg/kg
MAX	0.209	mg/kg
MEDIAN	0.000	mg/kg
PROPOSED ML	0.200	mg/kg

LEAD (mg/kg)	# SAMPLES	CUMULATIVE %
0.000	106	56.7%
0.025	39	77.5%
0.050	20	88.2%
0.075	10	93.6%
0.100	6	96.8%
0.125	1	97.3%
0.150	3	98.9%
0.175	1	99.5%
0.200	0	99.5%
0.225	1	100.0%
> 0.225	0	100.0%

TABLE 1 – Lead Levels in Fish (FDA Compliance Monitoring Program) (cont.)

M. Sardines, Canned

Sardine nsp.; Sardinella spp.

YR-MIN	1989	
YR-MAX	1999	
MEAN	0.339	mg/kg
STDDEV	0.922	mg/kg
COUNT	31	
MIN	0.000	mg/kg
MAX	4.498	mg/kg
MEDIAN	0.051	mg/kg
PROPOSED ML	0.200	mg/kg

LEAD (mg/kg)	# SAMPLES	CUMULATIVE %
0.000	2	6.5%
0.025	10	38.7%
0.050	3	48.4%
0.075	1	51.6%
0.100	3	61.3%
0.125	2	67.7%
0.150	1	71.0%
0.175	1	74.2%
0.200	0	74.2%
0.225	2	80.6%
0.250	0	80.6%
0.275	1	83.9%
0.300	0	83.9%
0.325	0	83.9%
0.350	0	83.9%
0.375	0	83.9%
0.400	0	83.9%
0.425	1	87.1%
0.450	0	87.1%
0.475	1	90.3%
0.500	0	90.3%
0.525	1	93.5%
0.550	0	93.5%
0.575	0	93.5%
0.600	0	93.5%
0.625	0	93.5%
0.650	0	93.5%
0.675	0	93.5%

M. Sardines, Canned (cont.)

LEAD (mg/kg)	# SAMPLES	CUMULATIVE %
0.700	0	93.5%
0.725	0	93.5%
0.750	0	93.5%
0.775	0	93.5%
0.800	0	93.5%
0.825	0	93.5%
0.850	0	93.5%
0.875	0	93.5%
0.900	0	93.5%
0.925	0	93.5%
0.950	0	93.5%
0.975	0	93.5%
1.000	0	93.5%
>1.000	2	100.0%

TABLE 1 – Lead Levels in Fish (FDA Compliance Monitoring Program) (cont.)

N. Snapper

Snapper; Lutjanus spp.
Snapper, Pacific Red; Lutjanus peru
Snapper, Red; Lutjanus campechanus

YR-MIN	1989	
YR-MAX	1999	
MEAN	0.003	mg/kg
STDDEV	0.014	mg/kg
COUNT	17	
MIN	0.000	mg/kg
MAX	0.058	mg/kg
MEDIAN	0.000	mg/kg
PROPOSED ML	0.200	mg/kg

LEAD (mg/kg)	# SAMPLES	CUMULATIVE %
0.000	16	94.1%
0.025	0	94.1%
0.050	0	94.1%
0.075	1	100.0%
0.100	0	100.0%
0.125	0	100.0%
0.150	0	100.0%
0.175	0	100.0%
0.200	0	100.0%
> 0.200	0	100.0%

TABLE 1 – Lead Levels in Fish (FDA Compliance Monitoring Program) (cont.)

O. Swordfish

Swordfish; Xiphias gladius

YR-MIN	1989	
YR-MAX	1999	
MEAN	0.026	mg/kg
STDDEV	0.070	mg/kg
COUNT	11	
MIN	0.000	mg/kg
MAX	0.234	mg/kg
MEDIAN	0.000	mg/kg
PROPOSED ML	0.200	mg/kg

LEAD (mg/kg)	# SAMPLES	CUMULATIVE %
0.000	7	63.6%
0.025	3	90.9%
0.050	0	90.9%
0.075	0	90.9%
0.100	0	90.9%
0.125	0	90.9%
0.150	0	90.9%
0.175	0	90.9%
0.200	0	90.9%
0.225	0	90.9%
0.250	1	100.0%
> 0.250	0	100.0%

TABLE 1 – Lead Levels in Fish (FDA Compliance Monitoring Program) (cont.)

P. Tilapia

Tilapia; Tilapia spp.

YR-MIN	1989	
YR-MAX	1999	
MEAN	0.008	mg/kg
STDDEV	0.015	mg/kg
COUNT	5	
MIN	0.000	mg/kg
MAX	0.035	mg/kg
MEDIAN	0.000	mg/kg
PROPOSED ML	0.200	mg/kg

LEAD (mg/kg)	# SAMPLES	CUMULATIVE %
0.000	3	60.0%
0.025	1	80.0%
0.050	1	100.0%
0.075	0	100.0%
0.100	0	100.0%
0.125	0	100.0%
0.150	0	100.0%
0.175	0	100.0%
0.200	0	100.0%
> 0.200	0	100.0%

TABLE 1 – Lead Levels in Fish (FDA Compliance Monitoring Program) (cont.)

Q. Trout

Trout, Rainbow; Oncorhynchus mykiss
Trout, Lake; Salvelinus namaycush
Trout, Speckled; Salvelinus fontinalis
Seatrout; Cynoscion spp.

YR-MIN	1989	
YR-MAX	1999	
MEAN	0.032	mg/kg
STDDEV	0.061	mg/kg
COUNT	31	
MIN	0.000	mg/kg
MAX	0.320	mg/kg
MEDIAN	0.014	mg/kg
PROPOSED ML	0.200	mg/kg

LEAD (mg/kg)	# SAMPLES	CUMULATIVE %
0.000	12	38.7%
0.025	9	67.7%
0.050	4	80.6%
0.075	2	87.1%
0.100	2	93.5%
0.125	1	96.8%
0.150	0	96.8%
0.175	0	96.8%
0.200	0	96.8%
0.225	0	96.8%
0.250	0	96.8%
0.275	0	96.8%
0.300	0	96.8%
0.325	1	100.0%
> 0.325	0	100.0%

TABLE 1 – Lead Levels in Fish (FDA Compliance Monitoring Program) (cont.)

R. Tuna, Fresh

Tuna nsp.; Thunnus spp.
Tuna, Albacore; Thunnus alalunga
Tuna, Yellowfin; Thunnus albacares
Tuna, Bigeye; Thunnus obsesus
Tuna, Skipjack; Katsuwonus pelamis

YR-MIN	1989	
YR-MAX	1999	
MEAN	0.013	mg/kg
STDDEV	0.020	mg/kg
COUNT	40	
MIN	0.000	mg/kg
MAX	0.070	mg/kg
MEDIAN	0.000	mg/kg
PROPOSED ML	0.200	mg/kg

LEAD (mg/kg)	# SAMPLES	CUMULATIVE %
0.000	24	60.0%
0.025	8	80.0%
0.050	4	90.0%
0.075	4	100.0%
0.100	0	100.0%
0.125	0	100.0%
0.150	0	100.0%
0.175	0	100.0%
0.200	0	100.0%
> 0.200	0	100.0%

TABLE 1 – Lead Levels in Fish (FDA Compliance Monitoring Program) (cont.)

S. Tuna, Canned

Tuna nsp.; Thunnus spp.
Tuna, Albacore; Thunnus alalunga
Tuna, Yellowfin; Thunnus albacares
Tuna, Bigeye; Thunnus obsesus
Tuna, Skipjack; Katsuwonus pelamis

YR-MIN	1989	
YR-MAX	1999	
MEAN	0.016	mg/kg
STDDEV	0.030	mg/kg
COUNT	256	
MIN	0.000	mg/kg
MAX	0.320	mg/kg
MEDIAN	0.000	mg/kg
PROPOSED ML	0.200	mg/kg

LEAD (mg/kg)	# SAMPLES	CUMULATIVE %
0.000	136	53.1%
0.025	64	78.1%
0.050	35	91.8%
0.075	15	97.7%
0.100	2	98.4%
0.125	2	99.2%
0.150	0	99.2%
0.175	1	99.6%
0.200	0	99.6%
0.225	0	99.6%
0.250	0	99.6%
0.275	0	99.6%
0.300	0	99.6%
0.325	1	100.0%
> 0.325	0	100.0%

TABLE 2 – Lead Levels in Crustaceans (FDA Compliance Monitoring Program)

A. Crab

YR-MIN	1989	
YR-MAX	1999	
MEAN	0.048	mg/kg
STDDEV	0.156	mg/kg
COUNT	147	
MIN	0.000	mg/kg
MAX	1.690	mg/kg
MEDIAN	0.010	mg/kg
PROPOSED ML	0.500	mg/kg

LEAD (mg/kg)	# SAMPLES	CUMULATIVE%
0.000	54	36.7%
0.025	41	64.6%
0.050	25	81.6%
0.075	8	87.1%
0.100	5	90.5%
0.125	3	92.5%
0.150	1	93.2%
0.175	1	93.9%
0.200	1	94.6%
0.225	0	94.6%
0.250	0	94.6%
0.275	1	95.2%
0.300	2	96.6%
0.325	0	96.6%
0.350	1	97.3%
0.375	2	98.6%
0.400	0	98.6%
0.425	0	98.6%
0.450	1	99.3%
0.475	0	99.3%
0.500	0	99.3%
0.525	0	99.3%
0.550	0	99.3%
0.575	0	99.3%
0.600	0	99.3%
0.625	0	99.3%
0.650	0	99.3%
0.675	0	99.3%
0.700	0	99.3%

A. Crab (cont.)

LEAD (mg/kg)	# SAMPLES	CUMULATIVE%
0.725	0	99.3%
0.750	0	99.3%
0.775	0	99.3%
0.800	0	99.3%
0.825	0	99.3%
0.850	0	99.3%
0.875	0	99.3%
0.900	0	99.3%
0.925	0	99.3%
0.950	0	99.3%
0.975	0	99.3%
1.000	0	99.3%
>1.000	1	100.0%

TABLE 2 – Lead Levels in Crustaceans (FDA Compliance Monitoring Program) (cont.)

B. Lobster

YR-MIN	1989	
YR-MAX	1999	
MEAN	0.089	mg/kg
STDDEV	0.198	mg/kg
COUNT	57	
MIN	0.000	mg/kg
MAX	1.030	mg/kg
MEDIAN	0.022	mg/kg
PROPOSED ML	0.500	mg/kg

LEAD (mg/kg)	# SAMPLES	CUMULATIVE%
0.000	14	24.6%
0.025	17	54.4%
0.050	9	70.2%
0.075	5	78.9%
0.100	1	80.7%
0.125	4	87.7%
0.150	0	87.7%
0.175	1	89.5%
0.200	1	91.2%
0.225	0	91.2%
0.250	0	91.2%
0.275	0	91.2%
0.300	0	91.2%
0.325	0	91.2%
0.350	0	91.2%
0.375	0	91.2%
0.400	0	91.2%
0.425	0	91.2%
0.450	0	91.2%
0.475	1	93.0%
0.500	0	93.0%
0.525	1	94.7%
0.550	0	94.7%
0.575	0	94.7%
0.600	0	94.7%
0.625	0	94.7%
0.650	1	96.5%
0.675	0	96.5%
0.700	0	96.5%
0.725	0	96.5%

B. Lobster (cont.)

LEAD (mg/kg)	# SAMPLES	CUMULATIVE%
0.750	0	96.5%
0.775	1	98.2%
0.800	0	98.2%
0.825	0	98.2%
0.850	0	98.2%
0.875	0	98.2%
0.900	0	98.2%
0.925	0	98.2%
0.950	0	98.2%
0.975	0	98.2%
1.000	0	98.2%
>1.000	1	100.0%

TABLE 2 – Lead Levels in Crustaceans (FDA Compliance Monitoring Program) (cont.)

C. Shrimp

YR-MIN	1989	
YR-MAX	1999	
MEAN	0.029	mg/kg
STDDEV	0.047	mg/kg
COUNT	188	
MIN	0.000	mg/kg
MAX	0.321	mg/kg
MEDIAN	0.015	mg/kg
PROPOSED ML	0.500	mg/kg

LEAD (mg/kg)	# SAMPLES	CUMULATIVE%
0.000	65	34.6%
0.025	50	61.2%
0.050	35	79.8%
0.075	24	92.6%
0.100	7	96.3%
0.125	2	97.3%
0.150	1	97.9%
0.175	0	97.9%
0.200	0	97.9%
0.225	1	98.4%
0.250	0	98.4%
0.275	0	98.4%
0.300	1	98.9%
0.325	2	100.0%
0.350	0	100.0%
0.375	0	100.0%
0.400	0	100.0%
0.425	0	100.0%
0.450	0	100.0%
0.475	0	100.0%
0.500	0	100.0%
> 0.500	0	100.0%

TABLE 3 – Lead Levels in Bivalve Molluscs (FDA Compliance Monitoring Program)

A. Clams

YR-MIN	1989	
YR-MAX	1999	
MEAN	0.300	mg/kg
STDDEV	0.241	mg/kg
COUNT	44	
MIN	0.000	mg/kg
MAX	1.040	mg/kg
MEDIAN	0.225	mg/kg
PROPOSED ML	1.000	mg/kg

LEAD (mg/kg)	# SAMPLES	CUMULATIVE%
0.000	3	6.5%
0.025	1	8.7%
0.050	1	10.9%
0.075	1	13.0%
0.100	3	19.6%
0.125	1	21.7%
0.150	3	28.3%
0.175	0	28.3%
0.200	5	39.1%
0.225	5	50.0%
0.250	2	54.3%
0.275	3	60.9%
0.300	1	63.0%
0.325	2	67.4%
0.350	1	69.6%
0.375	0	69.6%
0.400	1	71.7%
0.425	0	71.7%
0.450	3	78.3%
0.475	2	82.6%
0.500	2	87.0%
0.525	0	87.0%
0.550	1	89.1%
0.575	0	89.1%
0.600	1	91.3%
0.625	0	91.3%
0.650	1	93.5%
0.675	0	93.5%
0.700	0	93.5%
0.725	0	93.5%

A. Clams (cont.)

LEAD (mg/kg)	# SAMPLES	CUMULATIVE%
0.750	0	93.5%
0.775	0	93.5%
0.800	0	93.5%
0.825	0	93.5%
0.850	1	95.7%
0.875	0	95.7%
0.900	0	95.7%
0.925	0	95.7%
0.950	0	95.7%
0.975	0	95.7%
1.000	0	95.7%
>1.000	2	100.0%

TABLE 3 – Lead Levels in Bivalve Molluscs (FDA Compliance Monitoring Program) (cont.)

B. Mussels

YR-MIN	1989	
YR-MAX	1999	
MEAN	0.000	mg/kg
STDDEV	0.000	mg/kg
COUNT	7	
MIN	0.000	mg/kg
MAX	0.000	mg/kg
MEDIAN	0.000	mg/kg
PROPOSED ML	1.000	mg/kg

LEAD (mg/kg)	# SAMPLES	CUMULATIVE%
0.000	7	100.0%
> 0.000	0	100.0%

TABLE 3 – Lead Levels in Bivalve Molluscs (FDA Compliance Monitoring Program) (cont.)

C. Oysters

YR-MIN	1989	
YR-MAX	1999	
MEAN	0.145	mg/kg
STDDEV	0.245	mg/kg
COUNT	74	
MIN	0.000	mg/kg
MAX	1.501	mg/kg
MEDIAN	0.062	mg/kg
PROPOSED ML	1.000	mg/kg

LEAD (mg/kg)	# SAMPLES	CUMULATIVE%
0.000	22	29.7%
0.025	2	32.4%
0.050	12	48.6%
0.075	7	58.1%
0.100	9	70.3%
0.125	3	74.3%
0.150	1	75.7%
0.175	0	75.7%
0.200	3	79.7%
0.225	1	81.1%
0.250	0	81.1%
0.275	1	82.4%
0.300	0	82.4%
0.325	1	83.8%
0.350	1	85.1%
0.375	2	87.8%
0.400	1	89.2%
0.425	0	89.2%
0.450	1	90.5%
0.475	1	91.9%
0.500	0	91.9%
0.525	0	91.9%
0.550	0	91.9%
0.575	1	93.2%
0.600	1	94.6%
0.625	1	95.9%
0.650	0	95.9%
0.675	0	95.9%
0.700	0	95.9%

C. Oysters (cont.)

LEAD (mg/kg)	# SAMPLES	CUMULATIVE%
0.725	0	95.9%
0.750	1	97.3%
0.775	0	97.3%
0.800	0	97.3%
0.825	0	97.3%
0.850	1	98.6%
0.875	0	98.6%
0.900	0	98.6%
0.925	0	98.6%
0.950	0	98.6%
0.975	0	98.6%
1.000	0	98.6%
>1.000	1	100.0%

TABLE 3 – Lead Levels in Bivalve Molluscs (FDA Compliance Monitoring Program) (cont.)

D. Scallops

YR-MIN	1989	
YR-MAX	1999	
MEAN	0.025	mg/kg
STDDEV	0.015	mg/kg
COUNT	7	
MIN	0.001	mg/kg
MAX	0.051	mg/kg
MEDIAN	0.026	mg/kg
PROPOSED ML	1.000	mg/kg

LEAD (mg/kg)	# SAMPLES	CUMULATIVE%
0.000	0	.0%
0.025	3	42.9%
0.050	3	85.7%
0.075	1	100.0%
> 0.075	0	100.0%

TABLE 4 – Lead Levels in Canned Tuna (FDA Total Diet Study)[2]

YR-MIN	1991	
YR-MAX	1999	
MEAN	0.001	mg/kg
STDDEV	0.004	mg/kg
COUNT	26	
MIN	0.000	mg/kg
MAX	0.013	mg/kg
MEDIAN	0.000	mg/kg

LEAD (mg/kg)	# SAMPLES	CUMULATIVE%
0.000	23	88.5%
0.025	3	100.0%
0.050	0	100.0%
0.075	0	100.0%
0.100	0	100.0%
0.125	0	100.0%
0.150	0	100.0%
0.175	0	100.0%
0.200	0	100.0%
> 0.200	0	100.0%

[2] Each data point represents a composite of 3 samples.

TABLE 5 – Lead Levels in Haddock (FDA Total Diet Study)[3]

YR-MIN	1991	
YR-MAX	1997	
MEAN	0.003	mg/kg
STDDEV	0.007	mg/kg
COUNT	20	
MIN	0.000	mg/kg
MAX	0.022	mg/kg
MEDIAN	0.000	mg/kg

LEAD (mg/kg)	# SAMPLES	CUMULATIVE%
0.000	16	80.0%
0.025	4	100.0%
0.050	0	100.0%
0.075	0	100.0%
0.100	0	100.0%
0.125	0	100.0%
0.150	0	100.0%
0.175	0	100.0%
0.200	0	100.0%
> 0.200	0	100.0%

[3] Each data point represents a composite of 3 samples.

TABLE 6 – Lead Levels in Shrimp (FDA Total Diet Study)[4]

YR-MIN	1991	
YR-MAX	1999	
MEAN	0.032	mg/kg
STDDEV	0.048	mg/kg
COUNT	26	
MIN	0.000	mg/kg
MAX	0.210	mg/kg
MEDIAN	0.015	mg/kg

LEAD (mg/kg)	# SAMPLES	CUMULATIVE%
0.000	7	26.9%
0.025	11	69.2%
0.050	3	80.8%
0.075	2	88.5%
0.100	1	92.3%
0.125	0	92.3%
0.150	1	96.2%
0.175	0	96.2%
0.200	0	96.2%
0.225	1	100.0%
0.250	0	100.0%
0.275	0	100.0%
0.300	0	100.0%
0.325	0	100.0%
0.350	0	100.0%
0.375	0	100.0%
0.400	0	100.0%
0.425	0	100.0%
0.450	0	100.0%
0.475	0	100.0%
0.500	0	100.0%
> 0.500	0	100.0%

[4] Each data point represents a composite of 3 samples.

EUROPEAN COMMUNITY

Draft maximum level for Lead in Butter (point 5.)

The Codex Alimentarius Commission has adopted at its 24th Session, Geneva, 2-7 July 2001 the level of 0.02 mg/kg for lead in milk with the footnote « that for dairy products, an appropriate concentration factor should apply » and the level of 0.1 mg/kg for lead in milk fat (ALINORM 01/41, para.121).

Therefore, the European Community is of the opinion that there is no need for a separate maximum level for butter.

BRAZIL

Draft Maximum Level for Lead in Butter (para. 159). The Committee agreed to request comments on the necessity of a maximum level for lead in butter.
Brazilian Position: No Comments

Draft Maximum Levels for Lead in Fish, Crustaceans and Bivalve Molluscs (para. 162 and Appendix XIV).
The Committee agreed to return the draft maximum levels for lead in fish, crustaceans and bivalve molluscs for additional comments at Step 6.

Brazilian Position:
We also provide recent data on the lead content of selected foods:

Food	N	Lead (mg/kg)*	Analytical Method
Fish	52	0.05-0.06	ICP/AES
Bivalve molluscs	69	0.05- 0.30	ICP/AES
Oyster	70	0.05-0.17	ICP/AES
Liver of horse	6	0.11-3.7	AAS
Lettuce	60	Not detected -0.06 **	ICP/AES

* LOQ = 0.05 mg/kg
* *LOQ = 0.02 mg/kg
Nota: Dados disponíneis sobre monitoramento de metais em alimentos comercializados na região de São Paulo (LANARA/IAL)

SPAIN

Draft Maximum Levels for Lead in Fish, Crustaceans and Bivalve Molluscs (Appendix XIV)

The Spanish Kingdom reiterates the proposal made last year to establish two levels for lead in fish, namely 0.2 mg/kg for the majority of species of fish and 0.5 mg/kg for the species listed in table 1.1 attached.

For bivalve molluscs we also proposed two limits, 1 mg/kg for the majority of species of bivalve molluscs and 2 mg/kg for the species of bivalve molluscs listed in table 1.2 attached.

We attach the proposal we sent last year. **Codex Pb Cd peces.doc and lead peces.xls**
Draft Maximum Levels for Lead in Fish, Crustaceans and Bivalve Molluscs.

During the years 1990 to 2000 samples were taken and analyses carried out of fish and bivalve molluscs in the Autonomous Communities of Valencia, Andalucia and Galicia, as well as by the Laboratories of the National Association of Manufacturers of Preserved Foods and the Laboratory ‘Laboratorio Agroalimentario de la Coruña’ of the Ministry of Agriculture, Fisheries and Nutrition, in order to analyse the lead in specific species of fish and bivalve molluscs.

The results obtained show that the majority of the species would satisfy the draft maximum level for lead of 0.2 mg/kg (in fish) and 1 mg/kg (in bivalve molluscs), except for some species which would exceed the level of 0.2 mg/kg for fish and 1 mg/kg for bivalve moluscs.

The attached tables 1.1 and 1.2 include the results of the samples that have been analysed in the groups of fish species which exceed the limit of 0.2 mg/kg (fish) and 1 mg/kg (bivalve molluscs). The last two columns show the reject percentages under two assumptions: when the limit of 0.2 mg/kg is taken into account and when the limit of 0.5 mg/kg in fish is applied, and when the limits of 1 and 2 mg/kg in bivalve molluscs are taken into account.

As regards the tunny group, all related species could be classified under this group; this would be: bonito, tuna and listado.

In conclusion, Spain proposes that in addition a lead level of 0.5 mg/kg be fixed for the group of fish species included in table 1.1 and a lead level of 2 mg/kg for the group of bivalve molluscs included in table 1.2.

TABLE 1.1 LEAD CONTENT IN SPECIES OF FISH. SPAIN

SPECIES OF FISH	Year	Source	N	< 0.2 mg/Kg	0
Acedía (*Dicologoglossa cuneata)*	1994-1999	Valencia/Galicia/Andalucia	132	90	
Anguila (*Anguilla anguilla)*	1994-1999	Valencia/Galicia/Andalucia	20	10	
Bacaladilla (*Micromesistius poutassou)*	1994-1999	Valencia/Galicia/Andalucia	9	4	
Baila (*Dicentrarchus punctatus)*	1994-1999	Valencia/Galicia/Andalucia	24	15	
Bonito (Sarda sarda)	1998/2000	LA/Galicia	35	5	
Escualos *	1990	LAC	32	17	
Jurel *(Trachurus trachurus)*	1994-1999	Valencia/Galicia/Andalucia	45	27	
Lenguado *(Solea vulgaris)*	1995	IEO	25	17	
Lisa (*Mugil labrosus labrosus)*	1994-1999	Valencia/Galicia/Andalucia	22	15	
Listado *(Euthynus=Katsuwonus pelamys)*	1998	Anfaco	30	29	
Mojarra *(Diplodus vulgaris)*	1994-1999	Valencia/Galicia/Andalucia	90	62	
Pez espada (*Xiphias gladius)*	1994-1999	Valencia/Galicia/Andalucia	6	2	
Roncador (*Pomadasys benneti)*	1994-1999	Valencia/Galicia/Andalucia	40	26	
Sardina (Sardina pilchardus)	1994-1999	Valencia/Galicia/Andalucia	56	31	
Túnidos (*Thunnus spp*)	1998-2000	Anfaco/Galicia	73	41	

TABLE 1.2. LEAD CONTENT IN BIVALVE MOLLUSCS. SPAIN

SPECIES OF BIVALVE MOLLUSCS	Year	Source	N	< 1
Almejón *(Callista chione)*	1997-1999	IEO	13	
Coquina *(Donax trunculus)*	1997-199	IEO	23	
Mejillón *(Mytilus edulis)*	1997-1999	IEO	12	9

IEO- OCEANOGRAPHIC INSTITUTE OF SPAIN (Pb LOD 15 ug/kg, Cd LOD 2
LA - FOOD AND AGRICULTURE ARBITRAL LABORATORY (Pb LOD 4 ug/kg, Cd LOD 1 u
LAC- FOOD AND AGRICULTURE LABORATORY OF LA CORUÑA (Pb LOD 15 ug/kg, Cd LOD 2
ANFACO - NATIONAL ASSOCIATION OF PRESERVED FOOD MANUFACTURERS (Pb LOD 100 ug/kg Cd LOD 1
VALENCIA/GALICIA/ANDALUCÍA- REGIONAL HEALTH SERVICES OF VALENCIA/GALICIA/ANDALUSIA (Pb LOQ 0,01 mg/kg, Cd LOQ

METHOD OF ANALYSIS ALL REFERENCES ATOMIC ABSORPTION SPECTROPHOTOMETRY WITH G AND ZEEMAN EFFECT

* Escualos.
Isurus oxyrinchus
Galeorhinus galeus
Mustelus mustelus
Raja clavata
Scyliorhinus canicula
Squalus acanthias
Squalus blainvillei

PHILIPPINE

Fifty samples of tuna primarily of the specie yellow fin and skipjack, were collected and analyzed in the Philippines and were mostly found to have levels of lead that were less than the proposed Codex ML of 0.2 mg/kg (see Table 1). However as the proposed Codex ML as well as all positive values for lead found in the tuna samples were less than the Limit of Quantification (LOQ) of the method of analysis of 0.33 mg/kg, problems in establishing compliance from the results of testing laboratories can occur in the trade, because values less than the LOQ cannot be quantified with accuracy and precision.

The method of analysis used was the official method published by the Association of Official Analytical Chemists (AOAC) method 972.23 (1). Although as shown in Table 2, the method was found to have acceptable accuracy, recovery and precision with current instrumentation and laboratory capabilities, its sensitivity as measured by a Limit of Quantification of 0.33 mg/kg, would be inadequate for establishing compliance of samples in the trade with a proposed ML as low as 0.2 mg/kg.

In view of the above, the Philippines recommends an increase in the proposed ML for lead in fish from the current 0.2 mg/kg to 0.5 mg/kg and offers the following findings to support this recommendation:

1. Increasing the proposed ML for lead from 0.2 mg/kg to 0.5 mg/kg will bring the ML to a value greater than the Limit of Quantification of the AOAC method for lead in fish of 0.33 mg/kg and in a region where quantitative measurements can be made with accuracy and precision. This will make an unequivocal interpretation of the compliance of test results with the ML, possible.

2. The AOAC method 972.23 is practical for use in developing countries where atomic absorption spectrophotometers could already be existing for the general analysis of metals in foods including lead. Its development and application for the measurement of lead in fish could take place with greater ease as trained manpower and laboratory facilities required for the analysis will for the most part already be existing. The method when validated in 1972, was recommended for the analysis of lead in fish at levels of 1-11 ppm (4). The in-house validation work carried out in this study indicates that current instrumentation and laboratory skills have markedly improved the achievable detection limits but remains inadequate for a proposed ML as low as 0.2 mg/kg.

3. Carbon graphite AAS can increase the sensitivity of the method of analysis to levels adequate to measure the current ML of 0.2 mg/kg. However attachment of a carbon graphite furnace to an Atomic Absorption Spectrophotometer (AAS) will entail increased capital and operating costs and require further training of manpower currently used for AAS analysis.

A carbon graphite furnace is priced in the Philippines at 80% of the cost of an AAS to which it will be attached. Its need for an automatic sample introduction system will further increase instrument cost. Some otherwise satisfactory older AAS instruments can no longer be fitted with an automatic sample introduction system and such units therefore will not find use in monitoring lead unless replaced by a new more recent model. More meticulous maintenance requirements to prevent corrosion of the furnace electrodes due to the concentrated acids used in sample preparation is also required. A decision to adopt this method of analysis for monitoring lead in fish should await an evaluation by Codex of whether greater method sensitivity or much lower limits for lead in fish are necessary.

4. The contribution of an ML of 0.5 mg/kg to the Provisional Tolerable Weekly Intake (PTWI) of lead by an adult shown in Table 3, was estimated to be approximately 3% to 10%. This appears low and indicates that no compelling food safety reason exists to bring the ML for lead in fish to levels lower than 0.5 mg/kg. The estimate was made assuming that all fish consumed contains 0.5 mg/kg lead and levels of consumption are based on the GEMS FOOD regional diets of the WHO (13). More detailed consumption data especially of vulnerable groups as children worldwide is not available and prevents a more detailed assessment of lead intake.

5. An increase in the proposed ML of 0.5 mg/kg will be in line with higher maximum levels of lead reported in other ASEAN countries (8) as 0.410 mg/kg, 0.590 mg/kg and 0.417 mg/kg for canned tuna and a range of 0.02 to 1.28 ppm and of 0.05 and 0.29 ppm for marine and fresh water fish respectively. It is also in line with the regulatory limits for lead in fishes of 0.5 ppm in Singapore and Vietnam (8). The factors that determine the levels of lead in fishes is currently not well understood. Reviews indicate that the fate of metals in an aqueous environment is complex and the mechanism of its bioaccumulation and regulation by fishes is not well understood (6). Thus if public health considerations will allow it, maximum levels of lead reported in other studies should be carefully considered in the establishment of an ML to prevent problems in the trade.

METHODS USED IN THE COLLECTION OF DATA ON LEAD IN TUNA:

The tuna samples analyzed in this work and presented in Table 1 came from processing plants, fish markets and fish landing sites nationwide. Figure 1 shows the traditional tuna fishing areas where the tuna samples originated. A sample consisted of 1-2 kilograms of loins collected from large sized fishes 100 cm in length or the same weight of whole pieces of small fish 20-50 cm in length. Duplicate analysis were made on 25 gram portions of the sample. The method of sample collection preparation and analysis is described in a report on Survey of Levels of Lead in Philippine Seafoods, Part I Tuna.(14).

The in-house validation of the AOAC method for the analysis of lead in fish, Method 972.23, was carried out by making the following measurements
a) Limit of Detection from US-EPA, 1985 (12)
b) Limit of Quantification, from Lauren, 1999 (7)
c) Accuracy, from Garfield , 1991 (5)
d) Recovery, from AOAC (2)
e) Precision from Garfield, 1991 (5)
The procedures used for the in-house validation of the method are described in a report on Survey of Levels of Lead in Philippine Seafoods, Part I Tuna (14).

A flame atomic absorption spectrophotometer model SHIMADZU Model 6601 F was used. The instrument was set to the following operating condition: air acetylene oxidizing flame; warm up time of 20 minutes; Lead lamp wavelength of 283.3 nm; lamp current of 10 mA; lighting mode and background corrector, Deuterium lamp as described in the Report on Survey of Lead Levels in Philippine Seafoods. Part I Tuna (14).

The analysis was carried out by the chemistry laboratory of the Food Development Center, National Food Authority, FTI Complex Taguig, Metro Manila. The laboratory implements a quality assurance system and regularly participates in the international proficiency testing program of the Food Analysis Performance Assessment Scheme, Central Science Laboratory, United Kingdom (3). For this survey, the laboratory participated in Series 7. Metallic Contaminants, Round 33, July 2001.

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Table 1. LEVELS OF LEAD IN PHILIPPINE TUNA

Collected in July 2001 and analyzed from September to October 2001

Sample No.	Code	Water Source	Sampling Site	Specie	Size	Lead Content (ppm)
1	CEB-T1	Bohol Sea [b]	Pasil Fish Port Complex	YF	S	**0.23<LOQ***
2	GEN-T7	Foreign Water Pacific Ocean (Indonesia) [b]	Pacific Seas	YF	B	**0.23<LOQ**
3	GEN-T11	Palawan Sea [b]	Phil. Kingford, Inc.	YF	B	**0.20<LOQ**
4	SAN-T2	Moro Gulf [b]	Sanggali Fish Port Complex	SJ	S	0.16<LOQ
5	ZAM-T13	Sulu Sea [b]	Zamboanga Public Market	SJ	B	0.15<LOQ
6	ZAM-T14	Sulu Sea [b]	Zamboanga Public Market	YF	B	0.14<LOQ
7	GEN-T6	Sarangani Bay [b]	GenSan Public Market	YF	B	0.14<LOQ
8	GEN-T15	Sulu Sea [b]	Sapiens International	YF	B	0.13<LOQ
9	DAG-T1	Lingayen Gulf [a]	Dagupan Wet Market	YF	S	0.13<LOQ
10	ZAM-T5	Sulu Sea	Zamboanga Public Market	SJ	B	0.13<LOQ
11	ZAM-T7	Sulu Sea [b]	Recodo Public Market	SJ	B	0.13<LOQ
12	ZAM-T15	Foreign Water (Papua New Guina) [b]	Marfishing	SJ	B	0.12<LOQ
13	ZAM-T12	Basilan Strait [b]	Zamboanga Public Market	YF	B	0.12<LOQ
14	GEN-T2	Celebes Sea [b]	Fish Port Toril (East Asia)	YF	B	0.11<LOQ
15	ZAM-T11	Sulu Sea [b]	Guiwan Flea Market	YF	B	0.11<LOQ
16	DAL-T1	Pacific Ocean [b]	Dalahican Fish Landing Port, Quezon	YF	S	0.11<LOQ
17	GUI-T1	Leyte Gulf [b]	Guian Public Market	YF	S	0.11<LOQ
18	GUI-T2	Leyte Gulf [b]	Guian Public Market	SJ	S	0.11<LOQ
19	GEN-T5	Foreign Water Celebes Sea (Int'l. Water) [b]	Pescarich	YF	B	0.10<LOQ
20	GUI-T4	Sulu Sea [b]	Guiwan Flea Market	YF	B	0.10<LOQ
21	ZAM-T6	Sulu Sea [b]	Zamboanga Public Market	YF	B	0.10<LOQ
22	ZAM-T10	Pacific Ocean [b]	Tumaga Flea Market	YF	B	0.10<LOQ
23	MAS-T2	South China Sea [b]	Masinloc Market	YF	B	0.10<LOQ
24	SAN-T1	Moro Gulf [b]	Sanggali Fish Port Complex	Bonito	S	0.10<LOQ
25	GUI-T3	Pacific Ocean [b]	Sanggali Fish Port Complex	SJ	B	0.094<LOD**
26	DAV-T3	Davao Gulf [a]	Matina Market (Sta. Cruz, Davao)	YF	B	0.094<LOD
27	PAL-T2	South China Sea [b]	Poblacion Market, Puerto Princesa	SJ	B	0.091<LOD
28	ORA-T4	South China Sea [b]	Orani, Bataan Market	YF	S	0.091<LOD
29	GEN-T8	Zamboanga Sea [b]	Phil. Kingford Inc. (Tawi-Tawi)	YF	B	0.090<LOD
30	ZAM-T16	Foreign Water (Indonesia) [b]	Marfishing	SJ	B	0.088<LOD
Sample No.	**Code**	**Water Source**	**Sampling Site**	**Specie**	**Size**	**Lead Content (ppm)**

31	CEB-T3	Mindanao Sea [b]	Pasil, Fish Port	SJ	S	0.088<LOD
32	PAL-T3	Sulu Sea [b]	AA Export	SJ	B	0.083<LOD
33	GEN-T9	Surigao Sea [b]	Phil. Kingford, Inc.	YF	B	0.078<LOD
34	BAL-T3(4)	Pacific Ocean (Quezon) [b]	Baler, Quezon Province	SJ	S	0.074<LOD
35	GEN-T13	Foreign Water, Pacific Ocean (Indonesia) [b]	Mommy Gina Tuna Resources	YF	B	0.074<LOD
36	PAL-T4	Sulu Sea [b]	Poblacion Market, Puerto Princesa	YF	B	0.072<LOD
37	BAL-T3	South China Sea [b]	Balanga, Bataan Market	YF	S	0.071<LOD
38	ZAM-T8	Sulu Sea [b]	Recodo Public Market	SJ	B	0.070<LOD
39	CAT-T3	Philippine Sea [b]	Guian Public Market, Samar	SJ	S	0.069<LOD
40	IBA-T1	South China Sea [b]	Iba, Zambales Market	YF	S	0.069<LOD
41	ZAM-T9	Sulu Sea [b]	CVV Hai Flea Market	YF	B	0.063<LOD
42	PAL-T1	South China Sea [b]	Poblacion Market, Puerto Princesa	YF	B	0.062<LOD
43	TAC-T4	Philippine Sea [b]	Tacloban Market	SJ	S	0.060<LOD
44	GEN-T12	Foreign Water, Celebes Sea (Indonesia) [b]	Phil. Kingford	YF	B	0.058<LOD
45	GEN-T1	Moro Gulf [b]	Fish Port Toril (East Asia)	YF	B	0.057<LOD
46	DAV-T4	Davao Gulf [a]	Matina Market (Samal)	SJ	S	0.048<LOD
47	CEB-T2	Tañon Strait [a]	Pasil Fish Port Complex	YF	S	0.044<LOD
48	DAL-T2	Pacific Ocean [b]	Dalahican Fish Landing Port, Quezon	YF	S	0.042<LOD
49	GEN-T10	Sulu Sea [b]	Phil. Kingford Inc. (near Palawan)	YF	B	0.040<LOD
50	GEN-T14	Moro Gulf [b]	Angel Seafoods	YF	B	0.037<LOD

Legend: [a] - Identified as near mining areas
[b] - Identified as traditional source of exported seafood
YF - Yellowfin tuna
SJ - Skipjack tuna
S - Small fish (approx. weight: 250g-150g/piece, approx length: 20 cm – 50 cm)
B - Big fish (approx. length: 100 cm)
* - < LOQ means value is less than the Limit of Quantification (LOQ) of the Method of Analysis
** - < LOD means value is less than the Limit of Detection (LOD) of the Method of Analysis
All data <LOD should be considered as “not detected”.

LOD = 0.10 ppm
LOQ = 0.33 ppm

Table 2. RESULTS OF THE IN-HOUSE VALIDATION OF THE AOAC METHOD 972.23 FOR THE ANALYSIS OF LEAD IN FISH

Performance Characteristic Measured	Results
1. Limit of Detection (LOD)	0.10 mg/kg TUNA
2. Limit of Quantification (LOQ)	0.33 mg/kg TUNA
3. Accuracy	
3.1 Standard Addition	*The amount of added Lead recovered in the range of 0.1, 0.5, 1.0, 2.0 and 5.0 mg/kg TUNA was a linear function of the concentration of analyte added, r = 0.9998.*
3.2 Comparison with FAPAS* Test Material	Lead in the FAPAS test material of canned fish had an assigned value of 0.062 mg/kg. Lead found by the laboratory was 0.058 and 0.060 mg/kg which *is within* the acceptable range of 0.035-0.090 mg/kg. (3)
4. Recovery	The percent recovery obtained was 90-110% at 0.1 mg/kg TUNA, 90-95% at 0.2 mg/kg TUNA and 90-100% at 0.5 mg/kg TUNA. The percent recovery of added Lead *is within* the 80-110% range expected of an acceptable method of analysis, USDA, 1985 (vol II C17).
5. Precision using repeatability	The %Relative Standard Deviation (%RSD) for the analysis of 10 samples of tuna = 5.0% The %RSD should be $\leq$ 12% for a method to be considered precise, USDA, 1985 (vol II C17).

* FAPAS (Food Analysis Performance Assessment Scheme, Central Science Laboratory, Sand Hutton, York, YO41 1LZ, United Kingdom)

TABLE 3

ESTIMATED LEAD INTAKE IF ALL FISH CONTAINED 0.5 MG/KG LEAD AND CONSUMPTION LEVELS ARE THOSE OF THE GEMS FOOD REGIONAL DIETS

Code	Commodity	Fish intake (g/person per day)				
		Middle Eastern	Far Eastern	African	Latin American	European
	Fish and Seafood					
MD 180	Dried fish	0.3	2.8	4.4	4.8	0.8
WS 125	Demersal, frozen whole	0.0	0.0	0.9	0.5	3.8
WS 125	Demersal, frozen fillets	0.0	0.0	0.0	1.3	5.0
WS 125	Demersal, cured	0.0	0.3	0.6	4.5	0.5
WS 125	Demersal	2.0	3.0	2.4	0.0	9.0
WF 115	Freshwater, tinned	0.0	0.0	0.0	0.0	0.8
WF 115	Freshwater, frozen whole	0.0	0.0	0.0	0.0	0.3
WF 115	Fresh water, cured	0.3	0.5	1.4	0.0	0.0
WS 125	Marine fish (not otherwise specified), Fresh frozen	2.8	5.2	5.1	18.3	2.8
WS 125	Marine fish (not otherwise specified), Cured	0.0	1.0	0.0	0.3	0.0
WS 125	Pelagic, tinned	1.8	0.8	0.5	4.8	4.8
WS 125	Pelagic, frozen whole	0.3	2.0	0.7	0.3	1.3
WS 125	Pelagic, cured	0.0	1.0	2.4	0.0	0.3
WS 125	Pelagic marine fish, fresh	4.3	5.8	13	7.0	3.8
Total fish intake per day (g/person)		11.8	22.4	31.4	41.8	33.2
Total fish intake per week (g/person)		82.6	156.8	219.8	292.6	232.4
Estimated intake of lead						
Total (µg/person per day)		5.90	11.2	15.7	20.9	16.6
Total (µg/person per week)		41.3	78.4	109.9	146.3	116.2
Total (µg/kg bw per week) (for 60-kg adult)		0.69	1.31	1.83	2.44	1.94
% of PTWI (25 µg/kg bw per week) for 60-kg adult		2.76	5.24	7.32	9.76	7.76

FIGURE 1. CATCH AREAS OF TUNA USED IN THE SURVEY

OF LEAD IN PHILIPPINE SEAFOODS

JULY 2001

B - DENR identified sites