FDA & EPA Safety Levels in Regulations and Guidance

***Third Edition* June 2001**

This table contains a listing of FDA and EPA levels relating to safety attributes of fish and fishery products published in regulations and guidance. In many cases, these levels represent the point at or above which the agency will take legal action to remove products from the market. Consequently, the levels contained in this table may not always be suitable for critical limits.

FDA & EPA Safety Levels in Regulations and Guidance		
Product	***Level***	***Reference***
Ready to eat fishery products (minimal cooking by consumer)	Enterotoxigenic *Escherichia coli* (ETEC) - 1 x 10^3 ETEC/g, LT or ST positive.	Compliance Program 7303.842
Ready to eat fishery products (minimal cooking by consumer)	*Listeria monocytogenes*- presence of organism.	Compliance Program 7303.842
All fish	*Salmonella* species- presence of organism.	Sec 555.300 Compliance Policy Guide
All fish	1.*Staphylococcus aureus* - positive for staphylococcal enterotoxin, or 2. *Staphylococcus aureus* level is equal to or greater than 10^4/g (MPN).	Compliance Program 7303.842
Ready to eat fishery products (minimal cooking by consumer)	*Vibrio cholerae* - presence of toxigenic 01 or non-01.	Compliance Program 7303.842
Ready to eat fishery products (minimal cooking by consumer)	*Vibrio parahaemolyticus*- levels equal to or greater than 1 x 10^4/g (Kanagawa positive or negative).	Compliance Program 7303.842
Ready to eat fishery products (minimal cooking by consumer)	*Vibrio vulnificus* - presence of pathogenic organism.	Compliance Program 7303.842
All fish	*Clostridium botulinum* -	Compliance Program

	1. Presence of viable spores or vegetative cells in products that will support their growth; or, 2. Presence of toxin.	7303.842
Clams and oysters, fresh or frozen - imports	Microbiological - 1. *E. coli* - MPN of 230/100 grams (average of subs or 3 or more of 5 subs); 2. APC - 500,000/gram (average of subs or 3 or more of 5 subs).	Sec 560.600 Compliance Policy Guide
Clams, oysters, and mussels, fresh or frozen - domestic	Microbiological - 1. *E. coli* or fecal coliform - 1 or more of 5 subs exceeding MPN of 330/100 grams or 2 or more exceeding 230/100 grams; 2. APC - 1 or more of 5 subs exceeding 1,500,000/gram or 2 or more exceeding 500,000/gram.	Compliance Program 7303.842
Salt-cured, air-dried uneviscerated fish	Not permitted in commerce (Note: small fish exemption).	Sec 540.650 Compliance Policy Guide
Tuna, mahi mahi, and related fish	Histamine - 500 ppm based on toxicity. 50 ppm defect action level, because histamine is generally not uniformly distributed in a decomposed fish. Therefore, 50 ppm is found in one section, there is the possibility that other units may exceed 500 ppm.	Sec 540.525 Compliance Policy Guide
All fish	Polychlorinated Biphenyls (PCBs) - 2.0 ppm (edible portion)*.	21 CFR 109.30
Fin fish and shellfish	Aldrin and dieldrin - 0.3 ppm (edible portion).	Sec 575.100 Compliance Policy Guide
Frog legs	Benzene Hexachloride - 0.3 ppm (edible portion).	Sec 575.100 Compliance Policy Guide

All fish	Chlordane - 0.3 ppm (edible portion).	Sec 575.100 Compliance Policy Guide
All fish	Chlordecone - 0.4 ppm crabmeat and 0.3 ppm in other fish (edible portion).	Sec 575.100 Compliance Policy Guide
All fish	DDT, TDE and DDE - 5.0 ppm (edible portion).	Sec 575.100 Compliance Policy Guide
All fish	Heptachlor and heptachlor epoxide - 0.3 ppm (edible portion).	Sec 575.100 Compliance Policy Guide
All fish	Mirex - 0.1 ppm (edible portion).	Sec 575.100 Compliance Policy Guide
All fish	Diquat - 0.1 ppm*.	40 CFR 180.226
Fin fish and crayfish	Fluridone - 0.5 ppm*.	40 CFR 180.420
Fin fish	Glyphosate - 0.25 ppm*.	40 CFR 180.364
Shellfish	Glyphosate - 3.0 ppm*.	40 CFR 180.364
Fin fish	Simazine - 12 ppm*.	40 CFR 180.213a
All fish	2,4-D - 1.0 ppm*.	40 CFR 180.142
Salmonids, catfish and lobster	Oxytetracycline - 2.0 ppm.	21 CFR 556.500
All fish	Sulfamerazine - no residue permitted.	21 CFR 556.660
Salmonids and catfish	Sulfadimethoxine/ormetoprim combination - 0.1 ppm.	21 CFR 556.640
All fish	Unsanctioned drugs ** - no residue permitted	Sec 615.200 Compliance Policy Guide
Crustacea	Toxic elements: 76 ppm arsenic; 3 ppm cadmium; 12 ppm chromium; 1.5 ppm lead; 70 ppm nickel.	FDA Guidance Documents
Clams, oysters, and mussels	Toxic elements: 86 ppm arsenic; 4 ppm cadmium; 13 ppm chromium; 1.7 ppm lead; 80 ppm nickel.	FDA Guidance Documents

All fish	Methyl mercury - 1.0 ppm ***	Sec 540.600 Compliance Policy Guide
All fish	Paralytic shellfish poison - 0.8 ppm (80µg/100g) saxitoxin equivalent.	Sec 540.250 Compliance Policy Guide, and Compliance Program 7303.842
Clams, mussels and oysters, fresh, frozen or canned	Neurotoxic shellfish poison - 0.8 ppm (20 mouse units/100 gram) brevetoxin-2 equivalent.	National Shellfish Sanitation Program Manual of Operations
All fish	Amnesic shellfish poison - 20 ppm domoic acid, except in the viscera of dungeness crab, where 30 ppm is permitted.	Compliance Program 7303.842
All fish	Hard or sharp foreign object - generally 0.3 (7mm) to 1.0 (25mm) in length	Sec 555.425 Compliance Policy Guide

* These values are tolerances.

** Sanctioned drugs are approved drugs and drugs used under an INAD. For additional information.

Unregulated/unapproved drugs administered to aquacultured fish pose a potential human health hazard. These substances may be carcinogenic, allergenic, and/or may cause antibiotic resistance in man. To control this hazard in food animals, all drugs, whether for direct medication or for addition to feed, must be approved by FDA. Under certain conditions authorized by FDA, unapproved new animal drugs may be used in conformance with the terms of an Investigational New Animal Drug (INAD) application.

Incentives for the use of animal drugs in aquatic animal species include the need to: 1) treat and prevent disease; 2) control parasites; 3) affect reproduction and growth; and, 4) tranquilization (e.g. during transit). Relatively few drugs have been approved for aquaculture. As a result, aquaculture growers may use unapproved drugs, general purpose chemicals that are not labeled for drug use, and approved drugs in a manner that deviates from the labeled instructions.

When a drug is approved by FDA's Center for Veterinary Medicine, the conditions of the approval are listed on its label. These conditions include: the species for which the drug is approved; the approved dosage; the approved route of administration; the approved frequency of use; and the approved indications for use. Only a licensed

veterinarian may legally prescribe or use a drug under conditions that are not listed on the label. This restriction is more fully explained in 21 CFR 530.

Labels of approved drugs list mandatory withdrawal times, where applicable. These withdrawal times must be observed to ensure that the edible tissue is safe when it is offered for sale. Tissue residue tolerances have been established for some drugs.

*** For additional information.

The draft Fish and Fishery Products Hazards and Controls Guide (February 16, 1994) listed methyl mercury as a potential safety hazard for bonito, halibut, Spanish mackerel, king mackerel, marlin, shark, swordfish, and bluefin tuna. The selection of these species was based on historical data on levels of methyl mercury found in fish consumed in the U.S. The selection was also based on an FDA action level of 1.0 ppm in the edible portion of fish.

While FDA has not changed the 1.0 ppm action level, the agency is re-evaluating it in light of significant new data on the health effects of methyl mercury from consumption of fish. These data have become available since the action level was developed.

When the action level re-evaluation is completed, FDA will, among other things, update this Guide by including advice on how to assess the significance of a potential methyl mercury hazard in fish, and what controls, if any, are necessary to ensure the safety of fish in this regard.

The Food and Drug Administration (FDA) and the Environmental Protection Agency (EPA) announced on March 19 2004 their joint consumer advisory on methylmercury in fish and shellfish for reducing the exposure to high levels of mercury in women who may become pregnant, pregnant women, nursing mothers, and young children. This unifies advice from both FDA and EPA and supersedes FDA's and EPA's 2001 advisories.

The FDA and EPA want to emphasize the benefits of eating fish - consumers should know that fish and shellfish can be important parts of a healthy and balanced diet. They are good sources of high quality protein and other essential nutrients; however, as a matter of prudence, women might wish to modify the amount and type of fish they consume if they are planning to become pregnant, pregnant, nursing, or feeding a young child. By following these three recommendations for selecting and eating fish or shellfish, women will receive the benefits of eating fish and shellfish and be confident that they have reduced their exposure to the harmful effects of mercury.

1. Do not eat Shark, Swordfish, King Mackerel, or Tilefish because they contain high levels of mercury.

2. Eat up to 12 ounces (two average meals) a week of a variety of fish and shellfish that are lower in mercury.

- Five of the most commonly eaten fish that are low in mercury are shrimp, canned light tuna, salmon,pollock, and catfish.
- Another commonly eaten fish, albacore ("white") tuna has more mercury than canned light tuna. So, when choosing your two meals of fish and shellfish, you may eat up to six ounces (one average meal) of albacore tuna per week.

3. Check local advisories about the safety of fish caught by family and friends in your local lakes, rivers and coastal areas. If no advice is available, eat up to six ounces (one average meal) per week of fish you catch from local waters, but don't consume any other fish during that week.

Follow these same recommendations when feeding fish and shellfish to your young child, but serve smaller portions.

"This revised advisory is a culmination of months of hard work by both agencies," said FDA Deputy Commissioner Lester M. Crawford, D.V.M., Ph.D. "By following this advice, we're confident that women and young children can safely include fish as an important part of a healthy diet."

In July 2002, FDA's Food Advisory Committee met and made several recommendations to FDA on how to revise its 2001 consumer advisory on methylmercury in fish with special concern for pregnant women, nursing mothers, women who may become pregnant, and young children. One recommendation was for FDA and EPA to coordinate mercury advisories on commercial fish and recreational fish and say something specific about canned tuna.

In December 2003, FDA's Food Advisory Committee met again to be updated on the progress FDA had made in responding to their recommendations. At that time the committee recommended listing in the advisory fish that are low in mercury. Since the December 2003 meeting and the period of time between the two meetings, FDA and EPA have been working together toward the goal of providing an updated consumer advisory in response to the recommendations from the Food Advisory Committee. This work has included conducting ongoing interagency meetings, conducting field assignments which provided additional testing of mercury in fish for which there were low sample sizes, sampling over 3400 cans of tuna, undertaking exposure assessments using these new data and conducting focus group testing on the revised advisory.

"Our guidance allows consumers to make educated dietary choices for fish they catch or buy," said EPA's Acting Assistant Administrator for the Office of Water Benjamin Grumbles. "With a few simple adjustments, consumers can continue to enjoy these foods in a manner that is healthy and beneficial."

As part of announcing the revised consumer advisory, FDA and EPA plan to launch a comprehensive outreach and educational campaign. Additional information can be found at: www.cfsan.fda.gov or the EPA website at www.epa.gov/ost/fish.

Mercury Levels in Commercial Fish and Shellfish

Table 1. Fish and Shellfish With Highest Levels of Mercury

SPECIES	MERCURY CONCENTRATION (PPM)					NO. OF SAMPLES	SOURCE OF DATA
	MEAN	MEDIAN	STDEV	MIN	MAX		
MACKEREL KING	0.730	N/A	N/A	0.230	1.670	213	GULF OF MEXICO REPORT 2000
SHARK	0.988	0.830	0.631	ND	4.540	351	FDA 1990-02
SWORDFISH	0.976	0.860	0.510	ND	3.220	618	FDA 1990-04
TILEFISH (Gulf of Mexico)	1.450	N/A	N/A	0.650	3.730	60	NMFS REPORT 1978

Table 2. Fish and Shellfish With Lower Levels of Mercury†

SPECIES	MERCURY CONCENTRATION (PPM)					NO. OF SAMPLES	SOURCE OF DATA
	MEAN	MEDIAN	STDEV	MIN	MAX		
ANCHOVIES	0.043	N/A	N/A	ND	0.340	40	NMFS REPORT 1978
BUTTERFISH	0.058	N/A	N/A	ND	0.360	89	NMFS REPORT 1978
CATFISH	0.049	ND	0.084	ND	0.314	23	FDA 1990-04
CLAM *	ND	ND	ND	ND	ND	6	FDA 1990-02
COD	0.095	0.087	0.080	ND	0.420	39	FDA 1990-04
CRAB [1]	0.060	0.030	0.112	ND	0.610	63	FDA 1990-04
CRAWFISH	0.033	0.035	0.012	ND	0.051	44	FDA 2002-04
CROAKER ATLANTIC (Atlantic)	0.072	0.073	0.036	0.013	0.148	35	FDA 1990-03
FLATFISH [2]*	0.045	0.035	0.049	ND	0.180	23	FDA 1990-04
HADDOCK (Atlantic)	0.031	0.041	0.021	ND	0.041	4	FDA 1990-02
HAKE	0.014	ND	0.021	ND	0.048	9	FDA 1990-02
HERRING	0.044	N/A	N/A	ND	0.135	38	NMFS REPORT 1978
JACKSMELT	0.108	0.060	0.115	0.040	0.500	16	FDA 1990-02
LOBSTER (Spiny)	0.09	0.14	‡	ND	0.27	9	FDA SURVEY 1990-02
MACKEREL ATLANTIC (N.Atlantic)	0.050	N/A	N/A	0.020	0.160	80	NMFS REPORT 1978
MACKEREL CHUB (Pacific)	0.088	N/A	N/A	0.030	0.190	30	NMFS REPORT 1978
MULLET	0.046	N/A	N/A	ND	0.130	191	NMFS REPORT 1978
OYSTER	0.013	ND	0.042	ND	0.250	38	FDA 1990-04
PERCH OCEAN *	ND	ND	ND	ND	0.030	6	FDA 1990-02

POLLOCK	0.041	ND	0.106	ND	0.780	62	FDA 1990-04
SALMON (CANNED) *	ND	ND	ND	ND	ND	23	FDA 1990-02
SALMON (FRESH/FROZEN) *	0.014	ND	0.041	ND	0.190	34	FDA 1990-02
SARDINE	0.016	0.013	0.007	0.004	0.035	29	FDA 2002-04
SCALLOP	0.050	N/A	N/A	ND	0.220	66	NMFS REPORT 1978
SHAD AMERICAN	0.065	N/A	N/A	ND	0.220	59	NMFS REPORT 1978
SHRIMP *	ND	ND	ND	ND	0.050	24	FDA 1990-02
SQUID	0.070	N/A	N/A	ND	0.400	200	NMFS REPORT 1978
TILAPIA *	0.010	ND	0.023	ND	0.070	9	FDA 1990-02
TROUT (FRESHWATER)	0.072	0.025	0.143	ND	0.678	34	FDA 2002-04
TUNA (CANNED, LIGHT)	0.118	0.075	0.119	ND	0.852	347	FDA 2002-04
WHITEFISH	0.069	0.054	0.067	ND	0.310	28	FDA 2002-04
WHITING	ND	ND	‡	ND	ND	2	FDA SURVEY 1990-02

Table 3. Mercury Levels of Other Fish and Shellfish[†]

SPECIES	MERCURY CONCENTRATION (PPM)					NO. OF SAMPLES	SOURCE OF DATA
	MEAN	MEDIAN	STDEV	MIN	MAX		
BASS (SALTWATER, BLACK, STRIPED)[3]	0.219	0.130	0.227	ND	0.960	47	FDA 1990-04
BASS CHILEAN	0.386	0.303	0.364	0.085	2.180	40	FDA 1990-04
BLUEFISH	0.337	0.303	0.127	0.139	0.634	52	FDA 2002-04
BUFFALOFISH	0.19	0.14	‡	0.05	0.43	4	FDA SURVEY 1990-02
CARP	0.14	0.14	‡	0.01	0.27	2	FDA SURVEY 1990-02
CROAKER WHITE (Pacific)	0.287	0.280	0.069	0.180	0.410	15	FDA 1990-03
GROUPER (ALL SPECIES)	0.465	0.410	0.293	0.053	1.205	43	FDA 2002-04
HALIBUT	0.252	0.200	0.233	ND	1.520	46	FDA 1990-04
LOBSTER (NORTHERN/AMERICAN)	0.310	N/A	N/A	0.050	1.310	88	NMFS REPORT 1978
LOBSTER (Species Unknown)	0.169	0.182	0.089	ND	0.309	16	FDA 1991-2004
MACKEREL SPANISH (Gulf of Mexico)	0.454	N/A	N/A	0.070	1.560	66	NMFS REPORT 1978
MACKEREL SPANISH (S. Atlantic)	0.182	N/A	N/A	0.050	0.730	43	NMFS REPORT 1978
MARLIN *	0.485	0.390	0.237	0.100	0.920	16	FDA 1990-02
MONKFISH	0.180	N/A	N/A	0.020	1.020	81	NMFS REPORT 1978
ORANGE ROUGHY	0.554	0.563	0.148	0.296	0.855	49	FDA 1990-04
PERCH (Freshwater)	0.14	0.15	‡	ND	0.31	5	FDA SURVEY

							1990-02
SABLEFISH	0.220	N/A	N/A	ND	0.700	102	NMFS REPORT 1978
SCORPIONFISH	0.286	N/A	N/A	0.020	1.345	78	NMFS REPORT 1978
SHEEPSHEAD	0.128	N/A	N/A	0.020	0.625	59	NMFS REPORT 1978
SKATE	0.137	N/A	N/A	0.040	0.360	56	NMFS REPORT 1978
SNAPPER	0.189	0.114	0.274	ND	1.366	43	FDA 2002-04
TILEFISH (Atlantic)	0.144	0.099	0.122	0.042	0.533	32	FDA 2002-04
TUNA (CANNED, ALBACORE)	0.353	0.339	0.126	ND	0.853	399	FDA 2002-04
TUNA(FRESH/FROZEN, ALL)	0.383	0.322	0.269	ND	1.300	228	FDA 2002-04
TUNA (FRESH/FROZEN, ALBACORE)	0.357	0.355	0.152	ND	0.820	26	FDA 2002-04
TUNA (FRESH/FROZEN, BIGEYE)	0.639	0.560	0.184	0.410	1.040	13	FDA 2002-04
TUNA (FRESH/FROZEN, SKIPJACK)	0.205	N/A	0.078	0.205	0.260	2	FDA 1993
TUNA (FRESH/FROZEN, YELLOWFIN)	0.325	0.270	0.220	ND	1.079	87	FDA 2002-04
TUNA (FRESH/FROZEN, Species Unknown)	0.414	0.339	0.316	ND	1.300	100	FDA 1991-2004
WEAKFISH (SEA TROUT)	0.256	0.168	0.226	ND	0.744	39	FDA 2002-04

Source of data: FDA 1990-2004, "National Marine Fisheries Service Survey of Trace Elements in the Fishery Resource" Report 1978,
"The Occurrence of Mercury in the Fishery Resources of the Gulf of Mexico" Report 2000

Mercury was measured as Total Mercury except for species (*) when only Methylmercury was analyzed.

Note: the term "fish" refers to fresh or saltwater fin fish, crustaceans, other forms of aquatic animal life other than birds or mammals, and all mollusks, as defined in 21 CFR 123.3(d).