

APPENDIX 5: FDA and EPA Safety Levels in Regulations and Guidance

This guidance represents the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the telephone number listed on the title page of this guidance.

This appendix lists 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.

**TABLE A-5
FDA AND EPA SAFETY LEVELS IN REGULATIONS AND GUIDANCE**

PRODUCT	LEVEL
READY-TO-EAT FISHERY PRODUCTS (MINIMAL COOKING BY CONSUMER)	Listeria monocytogenes - presence of organism in 25 gram sample.
ALL FISH	Salmonella spp. - presence of organism in 25 gram sample.
ALL FISH	1. Staphylococcus aureus - positive for staphylococcal enterotoxin; or 2. Staphylococcus aureus - level equal to or greater than 10 ⁴ /g (MPN).
READY-TO-EAT FISHERY PRODUCTS (MINIMAL COOKING BY CONSUMER)	Vibrio cholerae - presence of toxigenic O1 or O139 or non-O1 and non-O139 in 25 gram sample.
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).
POST-HARVEST PROCESSED CLAMS, MUSSELS, OYSTERS, AND WHOLE AND ROE-ON SCALLOPS, FRESH OR FROZEN, THAT MAKE A LABEL CLAIM OF "PROCESSED TO REDUCE VIBRIO PARAHAEMOLYTICUS TO NON-DETECTABLE LEVELS"	Vibrio parahaemolyticus - levels less than 30/g (MPN).
COOKED READY-TO-EAT FISHERY PRODUCTS (MINIMAL COOKING BY CONSUMER)	Vibrio vulnificus - presence of organism.
POST-HARVEST PROCESSED CLAMS, MUSSELS, OYSTERS, AND WHOLE AND ROE-ON SCALLOPS, FRESH OR FROZEN, THAT MAKE A LABEL CLAIM OF "PROCESSED TO REDUCE VIBRIO VULNIFICUS TO NON-DETECTABLE LEVELS"	Vibrio vulnificus - levels less than 30/g (MPN).
ALL FISH	Clostridium botulinum - 1. Presence of viable spores or vegetative cells in products that will support their growth; or 2. Presence of toxin.
CLAMS, OYSTERS, MUSSELS, AND WHOLE AND ROE-ON SCALLOPS, FRESH OR FROZEN	Microbiological - 1. E. coli or fecal coliform - 1 or more of 5 subs exceeding MPN of 330/100 g or 2 or more exceeding 230/100 g; 2. APC - 1 or more of 5 subs exceeding 1,500,000/g or 2 or more exceeding 500,000/g.
TUNA, MAHI-MAHI, AND RELATED FISH	Histamine - 500 ppm based on toxicity; 50 ppm defect action level.
ALL FISH	Polychlorinated Biphenyls (PCBs) - 2.0 ppm (edible portion). ¹
FINFISH AND SHELLFISH	Aldrin and dieldrin - 0.3 ppm (edible portion).
FROG LEGS	Benzene Hexachloride (BHC) - 0.3 ppm (edible portion).
OYSTERS	Carbaryl ¹ - 0.25 ppm.
ALL FISH	Chlordane - 0.3 ppm (edible portion).
ALL FISH	Chlordecone - 0.4 ppm crabmeat and 0.3 ppm in other fish (edible portion).
ALL FISH	DDT, TDE, and DDE - 5.0 ppm (edible portion).
FARM-RAISED, FRESHWATER FISH	Diuron and its metabolites ¹ - 2.0 ppm.
ALL FISH	Endothall and its monomethyl ester - 0.1 ppm. ¹
ALL FISH	Heptachlor and heptachlor epoxide - 0.3 ppm (edible portion).
ALL FISH	Mirex - 0.1 ppm (edible portion).
ALL FISH	Diquat - 0.1 ppm. ¹

**TABLE A-5
FDA AND EPA SAFETY LEVELS IN REGULATIONS AND GUIDANCE**

PRODUCT	LEVEL
FINFISH AND CRAYFISH	Fluridone - 0.5 ppm. ¹
FINFISH	Glyphosate - 0.25 ppm. ¹
SHELLFISH	Glyphosate - 3.0 ppm. ¹
FINFISH	Simazine and its metabolites - 12 ppm. ¹
ALL FISH	2,4-D - 1.0 ppm. ¹
CHANNEL CATFISH AND FRESHWATER-REARED SALMONIDS	Florfenicol - 1.0 ppm (muscle tissue). ¹
FINFISH AND LOBSTER	Oxytetracycline - 2.0 ppm (muscle tissue). ¹
TROUT	Sulfamerazine - no residue permitted. ¹
SALMONIDS AND CATFISH	Sulfadimethoxine/ormetoprim combination - 0.1 ppm for each drug (edible tissue). ¹
ALL FISH	Drugs prohibited for extra-label use in animals - no residue permitted: Chloramphenicol; Clenbuterol; Diethylstilbestrol (DES); Dimetridazole, Iprnidazole, and other Nitroimidazoles; Furazolidone, Nitrofurazone, and other nitrofurans; Fluoroquinilones; Glycopeptides.
ALL FISH	Methylmercury - 1.0 ppm. ²
ALL FISH	Paralytic Shellfish Poisoning - 0.8 ppm (80µg/100g) saxitoxin equivalent.
CLAMS, MUSSELS, OYSTERS, AND WHOLE AND ROE-ON SCALLOPS, FRESH, FROZEN, OR CANNED	Neurotoxic Shellfish Poisoning - 0.8 ppm (20 mouse units/100 g) brevetoxin-2 equivalent.
CLAMS, MUSSELS, OYSTERS, AND WHOLE AND ROE-ON SCALLOPS, FRESH, FROZEN, OR CANNED	Diarrhetic Shellfish Poisoning - 0.2 ppm okadaic acid plus 35-methyl okadaic acid (DTX 1).
ALL FISH	Amnesic Shellfish Poisoning - 20 ppm domoic acid, except in the viscera of dungeness crab, where 30 ppm is permitted.
ALL FISH	Ciguatera Fish Poisoning - 0.01 ppb CTX equivalent for Pacific ciguatoxin and 0.1 ppb CTX equivalent for Caribbean ciguatoxin.
ALL FISH	Hard or sharp foreign object - generally 0.3 (7 mm) to 1.0 (25 mm) in length.

MPN = Most probable number. CTX = ciguatoxin.

1. These values are tolerances.

2. See Chapter 10, "Methylmercury," for additional information.

Note: The term "fish" refers to fresh or saltwater finfish, crustaceans, other forms of aquatic life other than birds or mammals, and all mollusks, where such animal life is intended for human consumption, as defined in the Fish and Fishery Products, "Definitions," 21 CFR 123.3(d).

NOTES: