

Appendix 5: FDA & EPA Guidance Levels

This appendix contains a listing of published FDA and EPA tolerances, action levels, and guidance levels relating to safety attributes of fish and fishery products. 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-3

FDA & EPA Guidance Levels

<i>Product</i>	<i>Guideline/Tolerance</i>	<i>Reference</i>
Ready to eat fishery products (minimal cooking by consumer)	Enterotoxigenic <i>Escherichia coli</i> (ETEC) - 1×10^5 ETEC/g, LT or ST positive.	Compliance Program 7303.842
Ready to eat fishery products (minimal cooking by consumer)	<i>Listeria monocytogenes</i> - presence of organism.	Compliance Program 7303.842
All fish	<i>Salmonella</i> species- presence of organism.	Sec 555.300 Compliance Policy Guide
All fish	<i>Staphylococcus aureus</i> - 1. positive for staphylococcal enterotoxin, or 2. <i>Staphylococcus aureus</i> level is equal to or greater than 10^4 /g (MPN).	Compliance Program 7303.842
Ready to eat fishery products (minimal cooking by consumer)	<i>Vibrio cholerae</i> - presence of toxigenic 01 or non-01.	Compliance Program 7303.842
Ready to eat fishery products (minimal cooking by consumer)	<i>Vibrio parahaemolyticus</i> - levels equal to or greater than 1×10^4 /g (Kanagawa positive or negative).	Compliance Program 7303.842
Ready to eat fishery products (minimal cooking by consumer)	<i>Vibrio vulnificus</i> - presence of pathogenic organism.	Compliance Program 7303.842
All fish	<i>Clostridium botulinum</i> - 1. Presence of viable spores or vegetative cells in products that will support their growth; or 2. Presence of toxin.	Compliance Program 7303.842
Clams and oysters, and mussels fresh or frozen - imports	Microbiological - 1. <i>E. coli</i> - MPN of 230/100 grams (average of subs or 3 or more of 5 subs); or 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. <i>E. coli</i> or fecal coliform - 1 or more of 5 subs exceeding MPN of 330/100 grams or 2 or more exceeding 230/100 grams; or 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 unviscerated fish	Not permitted in commerce (Note: small fish exemption).	Sec 540.650 Compliance Policy Guide
Tuna, mahi mahi, and related fish	Histamine - 500 ppm set based on toxicity. 50 ppm set as defect action level, because histamine is generally not uniformly distributed in a decomposed fish. Therefore, if 50 ppm is found in one section, there is the possibility that other units may exceed 500 ppm.	Sec 540.525 Compliance Policy Guide

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).

<i>Product</i>	<i>Guideline/Tolerance</i>	<i>Reference</i>
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 in 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 Document

* These values are tolerances.

** Sanctioned drugs are approved drugs, low regulatory priority drugs, and drugs used under an INAD. See Chapter 11 for additional information.

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).

<i>Product</i>	<i>Guideline/Tolerance</i>	<i>Reference</i>
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 (80ug/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

*** See Chapter 10 for additional information

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).