

Section IV. Guidance Documents**Chapter II. Growing Areas**

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.04 Action Levels, Tolerances and Guidance levels for Poisonous or Deleterious Substances in Seafood

Because shellfish are filter feeders, they can readily accumulate substances from the water column. The types of poisonous or deleterious substances that have been recovered from shellfish include heavy metals, pesticides, petroleum products, polychlorinated biphenyls, and naturally occurring marine biotoxins. The source of these contaminants may be industrial, agricultural, mining, spillage, sewage, dredging operations, sludge dumps, and naturally occurring toxigenic marine organisms.

The FDA has established action levels, tolerances and guidance levels for poisonous or deleterious substances to control the levels of contaminants in human food including seafood (FDA Federal Register, 1977; FDA, 1985). Action levels are established and revised according to criteria specified in the *Code of Federal Regulations* (21 CFR 109 and 509), and are revoked when a regulation establishing a tolerance for the same substance and use becomes effective. Action levels and tolerance represent limits at or above which FDA will take legal action to remove adulterated products, including shellfish, from the market. Action levels and tolerances, are established based on the unavoidability of the poisonous or deleterious substance and do not represent permissible levels of contamination where it is avoidable. Guidance levels are used to assess the public health impact of the specified contaminant.

Table 1 lists action levels, tolerances and guidance levels established by the FDA for poisonous or deleterious substances in seafood including shellfish. Notices are published in the *Federal Register* as new action levels are established or as existing action levels are revised or revoked. Should any of these notices affect Table 1, FDA will issue an interpretation advising NSSP participants of this revision or addition.

Class of Substance	Substance	Level	Food Commodity ^a	Reference
Deleterious Substance	Aldrin/Dieldrin ^c	0.3 ppm	All Fish	CPG sec 575.100b
	Chlordane	0.3 ppm	All Fish	CPG sec 575.100b
	Chlordecone ^d	0.3 ppm	All Fish	CPG sec 575.100b
		0.4 ppm	Crabmeat	CPG sec 575.100b
	DDT, DDE, TDE ^e	5.0 ppm	All Fish	CPG sec 575.100b
	Diquat ^g	2.0 ppm	All Fish	40 CFR 180.226
		20.0 ppm	Shellfish	40 CFR 180.226
	Glyphosate ^g	0.25 ppm	Fin Fish	40 CFR 180.364
		3.0 ppm	Shellfish	40 CFR 180.364
	Carbaryl	0.25 ppm	Oysters	40 CFR 180.169
	Endothall and its Monomethyl ester	0.1 ppm	All Fish	40 CFR 180.293
	Methyl Mercury	1.0 ppm	All Fish	CPG sec 540.600
	Heptachlor / Heptachlor Epoxide ^f	0.3 ppm	All Fish	CPG sec 575.100
	Mirex	0.1 ppm	All Fish	CPG sec 575.100
Polychlorinated Biphenyls (PCBs) ^g	2.0 ppm	All Fish	21 CFR 109.30	
	2,4-D ^g	1.0 ppm	All Fish	40 CFR 180.142
Chemotherapeutics	Chloramphenicol	No Residue	All Fish	21 CFR 530.41
	Clenbuterol	No Residue	All Fish	21 CFR 530.41
	Diethylstilbestrol (DES)	No Residue	All Fish	21 CFR 530.41

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	Demetridazole	No Residue	All Fish	21 CFR 530.41
	Ipronidazole and other nitroimidazoles	No Residue	All Fish	21 CFR 530.41
	Frazolidone and other nitrofurans	No Residue	All Fish	21 CFR 530.41
	Fluoroquinilones	No Residue	All Fish	21 CFR 530.41
	Glycopeptides	No Residue	All Fish	21 CFR 530.41
Natural Toxins	Paralytic Shellfish Poison (PSP)	80 µg/100g	All Fish	CPG sec 540.250
	Neurotoxic Shellfish Poison (NSP) ^e	20 MU	Clams, mussels, Oysters, fresh frozen or canned	NSSP MO
	Amnesic Shellfish Poison (ASP)	20 ppm	All Fish (except in the viscera of Dungeness crab where 30 ppm is permitted)	Compliance Program 7303.842

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)*.

Footnotes for Table 1

a) Unless otherwise specified, the action levels, tolerances and other values listed apply to both the raw and processed food commodity. Procedures for sample collection and analyses are specified in Sections 420 and 450 of the *FDA Investigations Operation Manual; FDA Pesticide Analytical Manual (PAM)* Volume I or II; *AOAC Official Methods of Analysis*; *APHA Recommended Procedures for the Examination of Sea Water and Shellfish*, Fourth Edition, 1970; or, peer reviewed literature for domoic acid (ASP) methodologies.

b) References designated as CPG represent the FDA Compliance Policy Guides and all associated numbers as they appear in appropriate sections of FDA's Compliance Policy Guides Manual.

c) The action level for aldrin and dieldrin are for residues of the pesticides individually or in combination. However, in adding amounts of aldrin and dieldrin do not count aldrin or dieldrin found at the level below 0.1 ppm for fish.

d) Previously listed as Kepone, the tradename for chlordecone.

e) The action level for DDT, TDE, and DDE are for residues of the pesticides individually or in combination. However, in adding amounts of DDT, TDE, and DDE do not count any of the three found below 0.2 ppm for fish.

f) The action level for heptachlor and heptachlor epoxide are for the pesticides individually or in combination. However, do not count heptachlor or heptachlor epoxide found below 0.1 ppm.

g) The levels published in 21 CFR and 40 CFR represent tolerances rather than guidance levels or action levels.

REFERENCES

1. Food and Drug Administration. 1977. Poisonous Or Deleterious Substances In Food. *Federal Register*. 42(190):52814-52819.
2. Food and Drug Administration. 1985. *Action Levels For Poisonous Or Deleterious Substances In Human Food And Animal Feed*. U.S. Department of Health and Human Services, Public Health Service, Washington, D.C. 13 pages.
3. Food and Drug Administration. 1993. *Guidance Document for Arsenic in Shellfish*. U.S. Department of Health and Human Services, Public Health Service, Office of Seafood (HFS-416), 200 C Street, SW, Washington, DC 20204. 44 pages.
4. Food and Drug Administration. 1993. *Guidance Document for Cadmium in Shellfish*. U.S. Department of Health and Human Services, Public Health Service, Office of Seafood (HFS-416), 200 C Street, SW, Washington, D.C. 20204. 44 pages.
5. Food and Drug Administration. 1993. *Guidance Document for Chromium in Shellfish*. U.S. Department of Health and Human Services, Public Health Service, Office of Seafood (HFS-416), 200 C Street, SW, Washington, D.C. 20204. 40 pages.
6. Food and Drug Administration. 1993. *Guidance Document for Lead in Shellfish*. U.S. Department of Health and Human Services, Public Health Service, Office of Seafood (HFS-416), 200 C Street, SW, Washington, D.C. 20204. 45 pages.
7. Food and Drug Administration. 1993. *Guidance Document for Nickel in Shellfish*. U.S. Department of Health and Human Services, Public Health Service, Office of Seafood (HFS-416), 200 C Street, SW, Washington, D.C. 20204. 39 pages.
8. Food and Drug Administration. 2001. *Fish and Fisheries Products Hazards & Controls Guidance*, Third Edition. U.S. Department of Health and Human Services, Public Health Service, Office of Seafood, 5100 Paint Branch Parkway, College Park, Maryland 20740-3835. 326 pages.