Proposal Subject: Action Levels, Tolerances and Guidance Levels for Poisonous or Deleterious Substances in Seafood

Specific NSSP Guide Reference: NSSP Section IV Guidance Documents Section IV. Chapter II. Growing Areas .05 Action Levels, Tolerances and Guidance Levels for Poisonous or Deleterious Substances in Seafood

Text of Proposal/ Requested Action

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~~2002). 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 tolerances 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.

Table 1

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

Class of Substance	Substance	Level	Food Commodity	Reference
Deleterious Substance	Aldrin/Dieldrin c	0.3 ppm	All Fish	CPG sec 575.100b
Deleterious Substance	Chlordane	0.3 ppm	All Fish	CPG sec 575.100b
Deleterious Substance	Chlordecone d	0.3 ppm	All Fish	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
	Diquat g	20.0 ppm	Shellfish	40 CFR 180.226
	Glyphosate g	0.25 ppm	Fin Fish	40 CFR 180.364
	Glyphosate g	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 /	0.3 ppm	All Fish	CPG sec

	Heptachlor Epoxide f			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	0.1 ppm	Fish	40 CFR 180.142
	2,4-D g	1.0 ppm	All Fish Shellfish	40 CFR 180.142
Chemotherapeutics	Chloramphenicol	No Residue	All Fish	21 CFR 530.41
Chemotherapeutics	Clenbuterol	No Residue	All Fish	21 CFR 530.41
Chemotherapeutics	Diethylstilbesterol (DES)	No Residue	All Fish	21 CFR 530.41
	Demetridazole	No Residue	All Fish	21 CFR 530.41
	Ipronidazole and other nitroimidazoles	No Residue	All Fish	21 CFR 530.41
	Furazolidine and other nitrofurans	No Residue	All Fish	21 CFR 530.41
	Fluoroquinolones	No Residue	All Fish	21 CFR 530.41
	Glycopeptides	No Residue	All Fish	21 CFR 530.41
Natural Toxins	Paralytic Shellfish Poisoning (PSP) toxins	80 µg/100g	All Fish	CPG sec 540.250
Natural Toxins	Neurotoxic Shellfish Poisoning (NSP) toxins	20 MU/100g	Clams, mussels, oysters, fresh frozen or canned	NSSP MO
Natural Toxins	Azaspiracid Shellfish Poisoning (AZP) toxins	0.16 mg/kg	Clams, mussels, oysters, fresh frozen or canned	NSSP MO
Natural Toxins	Diarrhetic Shellfish Poisoning (DSP) toxins	0.16 mg/kg	Clams, mussels, oysters, fresh frozen or canned	NSSP MO
Natural Toxins	Amnesic Shellfish Poisoning (ASP) toxins	20 mg/kg	All Fish (except in the viscera of Dungeness crab where 30 mg/kg 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 trade name 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.

Public Health Significance:

"Table 1" within this guidance has been updated to be consistent with current FDA action levels, tolerances and guidance levels for poisonous or deleterious substances in seafood.

Cost Information (if available):

N/A – no cost

Action by 2013 Task Force I

Recommended adoption of Proposal 13-108 as amended:

Table 1

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Action by 2013 General Assembly Adopted recommendation of 2013 Task Force I on Proposal 13-108.

Action by FDA May 5, 2014 Concurred with Conference action on Proposal 13-108.