Proposal Subject: Deletions and Additions to Table 1 Action Levels, Tolerances and Guidance Levels for Poisonous or Deleterious Substances in Seafood

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

Text of Proposal/ Requested Action Delete arsenic, cadmium, chromium, lead, and nickel from Table 1 – Action Levels, Tolerances and Guidance Levels for Poisonous and Deleterious Substances in NSSP Section IV Guidance Documents Chapter II.04.

Add the following chemicals and chemotherapeutic drugs and the associated safety level to Table 1 – Action Levels, Tolerances and Guidance Levels for Poisonous and Deleterious Substances in NSSP Guidance Documents Chapter II.04:

Carbaryl in oysters – 0.25 ppm
Endothall and its monomethyl ester in all fish – 0.1 ppm
Chloramphenicol in all fish – no residue
Clenbuterol in all fish – no residue
Diethylstilbestrol (DES) in all fish – no residue
Demetridazole in all fish – no residue
Ipronidazole and other nitroimidazoles in all fish – no residue
Frazolidone and other nitrofurans in all fish – no residue
Fluoroquinilones in all fish – no residue
Glycopeptides in all fish – no residue

Delete the less than symbol in front of 20 MU/100 g for Neurotoxic Shellfish Poisoning (NSP) in Table 1 – Action Levels, Tolerances and Guidance Levels for Poisonous and Deleterious Substances in NSSP Guidance Documents Chapter II.-04.

Public Health Significance: Acceptable levels established in the FDA guidance documents for each of the five elements to be deleted were intended only as general guidance. Use of these Guidance Documents as a general formula for calculating levels of concern is somewhat subjective based on the particular circumstances under which they are applied, for example, the rate of consumption. Furthermore, in the 14 years since their publication, new scientific data and information has rendered them somewhat obsolete and in need of revision. Until such time as they can be updated with current information and science, FDA toxicologists have determined the safe levels set forth in them for molluscan shellfish are inappropriate.

Addition to the NSSP of the two named chemicals and the nine chemotherapeutic drugs is in keeping with establishment of FDA and EPA safety levels for their presence in shellfish meats and with their citation in the FDA Seafood HACCP Fish and Fisheries Products Hazards and Controls Guide.

Cost Information (if available): None

Action by 2007 Task Force I Recommended referral of Proposal 07-107 to an appropriate committee as determined by the Conference Chairman.

Action by 2007 General Assembly Adopted recommendation of 2007 Task Force I.

Action by USFDA December 20, 2007
Concurred with Conference action.

Action by 2009 Chemical Contamination Committee

(1) (a) Recommended the guidance levels for these heavy metals listed above should be removed from Table 1 as proposed by FDA. (b) The Conference should recommend that FDA work to expeditiously update the heavy metals guidance documents based on current science and set standards for national and international commerce.

(2) The Conference should reach out to FDA's National Shellfish Team for information on standards on heavy metals used by foreign countries to help assure consistency in our approach.

(3) The Chemical contaminants listed for addition in the FDA proposal should be added to Table 1 Action Levels, Tolerances and Guidance Levels for Poisonous or Deleterious Substances in Seafood.

(4) The less than symbol in front of 20 MU/100 g for Neurotoxic Shellfish Poisoning (NSP) in Table 1 should be removed as proposed by FDA in 07-107.

Action by 2009 Task Force I Recommended adoption of Chemical Contamination Committee recommendations (1) (a), (3), and (4) and recommended no action on recommendations (1) (b) and (2).

Action by 2009 General Assembly Adopted recommendation of 2009 Task Force I on Proposal 07-107.

Action by USFDA 02/16/2010 Concurred with Conference action on Proposal 07-107.