

## Fish and Fishery Products Hazards and Controls Guidance

Fourth Edition – April 2011

### Chapter 3

Page 73

Delete checks on Table 3-4 for allergens/additives for Raw oysters, clams and mussels (2 rows).

Please add the following:

#### ***BIBLIOGRAPHY.***

We have placed the following references on display in the Division of Dockets Management, Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. You may see them at that location between 9 a.m. and 4 p.m., Monday through Friday. As of March 29, 2011, FDA had verified the website address for the references it makes available as hyperlinks from the Internet copy of this guidance, but FDA is not responsible for any subsequent changes to non-FDA website references after March 29, 2011.

- Froese, R., and D. Pauly (ed.). Monthly. FishBase version April 2007. <http://www.fishbase.org>.
- Integrated Taxonomic Information System. April 2007. White House Subcommittee on Biodiversity and Ecosystem Dynamic. <http://www.itis.gov>.
- Krane, W. 1986. FISH five-language dictionary of fish crustaceans and molluscs. Van Nostrand Reinhold, New York, NY.
- McClane, A. J., and I. M. Krench (ed.), 1977. The encyclopedia of fish cookery. Holt, Rinehart and Winston. New York, NY.
- Nelson, J. S., E. J. Crossman, H. E. Pérez, L. T. Findley, C. R. Gilbert, R. N. Lea, and J. D. Williams. 2004. Common and scientific names of fishes from the United States, Canada and Mexico, 6th ed. American Fisheries Society, Spec. Publ. No. 29. Bethesda, MD.
- Organization for Economic Co-operation and Development. 1995. Multilingual dictionary of fish and fish products, 4th ed. Fishing News Books, Cambridge, MD.
- Robins, C. R., R. M. Bailey, C. E. Bond, J. R. Brooker, E. A. Lachner, R. N. Lea, and W. B. Scott. 1991. World fishes important to North Americans exclusive of species from the continental waters of the United States and Canada. American Fisheries Society, Spec. Publ. No. 21. Bethesda, MD.
- Turgeon, D. D., J. F. Quinn, Jr., A. E. Bogan, E. V. Coan, F. G. Hochberg, W. G. Lyons, P. M. Mikkelsen, R. J. Neves, C. F. E. Roper, G. Rosenberg, B. Roth, A. Scheltema, F. G. Thompson, M. Vecchione, and J. D. Williams. 1998. Common and scientific names of aquatic invertebrates from the United States and Canada: mollusks, 2nd ed. American Fisheries Society, Bethesda, MD.
- U.S. Food and Drug Administration. 2004. Federal Food, Drug, and Cosmetic Act. DHHS/PHS/U.S. Section 403(t). Department of Health and Human Services, Public Health Service, Food and Drug Administration, Center for Food Safety and Applied Nutrition, College Park, MD. <http://www.fda.gov/opacom/laws/fdcaact/fdctoc.htm>.
- U.S. Food and Drug Administration. 2009. Guidance for the industry: the seafood list - FDA's guidance to acceptable market names for seafood sold in interstate commerce. Department of Health and Human Services, Public Health Service, Food and Drug Administration, Center for Food Safety and Applied Nutrition. College Park, MD. <http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/Seafood/ucm113260.htm>
- Williams, A. B. 1988. Lobsters of the world - an illustrated guide, lobsters of the world in U.S. trade, Osprey Books, Huntington, NY.
- Williams, A. B., et al. 1989. Common and scientific names of aquatic invertebrates from the United States and Canada: decapod crustaceans. American Fisheries Society, Spec. Publ. No. 17, Bethesda, MD.

## Chapter 12

Page 211 (first column):

*S. aureus* and *B. cereus* toxin do not normally produce sufficient toxin to cause illness until numbers of the pathogen reach 100,000 to 1,000,000/gram.

Change to:

*S. aureus* does not produce sufficient toxin to produce illness until numbers of the pathogen reach 100,000/g of food. In the case of *B. cereus*, the number of organisms most often associated with illness is 100,000 to 100,000,000/g of food.

Page 230 (first column):

**CONTROL STRATEGY EXAMPLE 3 - COOLING AFTER COOKING CONTROL** It may be necessary to select more than one control strategy in order to fully control the hazard, depending upon the nature of your operation.

***Set Critical Limits.***

- The product is cooled from 135°F (57.2°C) to 70°F (21.1°C) within 2 hours;  
AND
- The product is further cooled from 135°F (57.2°C) to 40°F (4.4°C) within an additional 4 hours;

Change to :

**CONTROL STRATEGY EXAMPLE 3 - COOLING AFTER COOKING CONTROL** It may be necessary to select more than one control strategy in order to fully control the hazard, depending upon the nature of your operation.

***Set Critical Limits.***

- The product is cooled from 135°F (57.2°C) to 70°F (21.1°C) within 2 hours;  
AND
- The product is further cooled from 70°F (21.1°C) to 40°F (4.4°C) within an additional 4 hours;

## Chapter 14

Page 298 (first column)

- For shelf-stable products:
  - Maximum finished product water activity of 0.85 or above;

OR

- For refrigerated (not frozen), reduced oxygen packaged products:
  - Maximum finished product water activity of less than 0.97.

Change to:

- For shelf-stable products:
  - Maximum finished product water activity of 0.85;

OR

- For refrigerated (not frozen), reduced oxygen packaged products:
  - Finished product water activity of less than 0.97.

## Chapter 15

Page 309 (bottom of first column):

*S. aureus* toxin does not normally reach levels that will cause food poisoning until the numbers of the pathogen reach 500,000 to 1,000,000 per gram.

Change to:

*S. aureus* does not produce sufficient toxin to produce illness until numbers of the pathogen reach 100,000/g of food.

Page 314

Delete:

Potter, L., and L. Leistner. 1978. Minimal water activity for enterotoxin A production and growth of *Staphylococcus aureus*. *Appl. Environ. Microbiol.* 36:377-380.

#### Appendix 4

Page 420 Table A-1 (table heading)

MIN.  $A_w$

Change to:

MIN.  $a_w$

Page 426

Christiansen, L. N., J. Deffner, E. M. Foster, and H. Sugiyama. 1968. Survival and outgrowth of *Clostridium botulinum* type E spores in smoked fish. *Appl. Microbiol.* 16:553-557.

Change to:

Christiansen, L. N., J. Deffner, E. M. Foster, and H. Sugiyama. 1968. Survival and outgrowth of *Clostridium botulinum* type E spores in smoked fish. *Appl. Microbiol.* 16:133-137.

Page 433

Delete:

Potter, L., and L. Leistner. 1978. Minimal water activity for enterotoxin A production and growth of *Staphylococcus aureus*. *Appl. Environ. Microbiol.* 36:377-380.

Page 435

Tatani, S. R. 1973. Influence of food environments on growth of *Staphylococcus aureus* and production of various enterotoxins. *J. Milk Food Technol.* 36:559.

Change to:

Tatani, S. R. 1973. Influence of food environments on growth of *Staphylococcus aureus* and production of various enterotoxins. *J. Milk Food Technol.* 36:559.