

- 1. UNITED STATES CODE AND CODE OF FEDERAL REGULATIONS**
- 2. BIBLIOGRAPHY**
- 3. SUPPORTING DOCUMENTS**
- 4. FOOD DEFENSE GUIDANCE FROM FARM TO TABLE**

**1. UNITED STATES CODE AND CODE OF FEDERAL REGULATIONS**

The *Food Code* makes frequent reference to federal statutes contained in the United States Code (USC) and the *Code of Federal Regulations* (CFR). Copies of the USC and CFR can be viewed and copied at government depository libraries or may be purchased as follows.

*(A) Viewing and Copying the USC or CFR*

(1) Federal Depository Library

The USC and CFR are widely available for reference and viewing in some 1300 "depository libraries" located throughout the United States. *A Directory of U.S. Government Depository Libraries* is published by the Joint Committee on Printing of the United States Congress and is available through the Superintendent of Documents, U.S. Government Printing Office. This publication lists all depository libraries by state, city, and congressional district.

Persons may also obtain information about the location of the depository library nearest to them by contacting:

GPO Customer Contact Center, IDCC  
U.S. Government Printing Office  
732 North Capitol Street, NW  
Washington, DC 20401-0001  
(866) 512-1800, Fax (202) 512-2104

(2) Internet World Wide Web Information System

The CFR are available on-line in downloadable form through the Internet World Wide Web information system. The source is:

The National Archives and Records Administration  
Copies of Federal Regulations - Retrieve CFR by Citation  
Provided through the Government Printing Office Web Site - GPO Inet Services

<http://www.access.gpo.gov/nara/cfr/cfr-table-search.html#page1>

*(B) Purchasing Portions of the USC or CFR*

Persons wishing to purchase relevant portions of the USC or CFR may do so by  
writing: or by calling:

Superintendent of Documents (New Orders) U.S. Government Printing Office P.O. Box 371954 Pittsburgh, PA 15250-7954;	(202) 512-1800 from 7:30 a.m. to 9:00 p.m. eastern time, Monday-Friday (except holidays. Orders may be charged to American Express, Discover, MasterCard, or Visa.
--	---

*(C) USC as it Relates to the Code Definition of "Adulterated"*

This language has been retyped as accurately as possible and inserted in the Food Code Annex for informational purposes. For legal purposes, use only language taken directly from the United States Code (USC).

21 USC Sec. 342  
Title 21 - Food and Drugs  
Chapter 9 - Federal Food, Drug and Cosmetic Act  
Subchapter IV - Food

## ADULTERATED FOOD

Sec. 402 [342]

A food shall be deemed to be adulterated -

(a) Poisonous, insanitary, etc., ingredients

A food shall be deemed to be adulterated—

### **(a) Poisonous, insanitary, etc., ingredients**

**(1)** If it bears or contains any poisonous or deleterious substance which may render it injurious to health; but in case the substance is not an added substance such food shall not be considered adulterated under this clause if the quantity of such substance in such food does not ordinarily render it injurious to health.<sup>11</sup>

**(2)**

**(A)** if it bears or contains any added poisonous or added deleterious substance (other than a substance that is a pesticide chemical residue in or on a raw agricultural commodity or processed food, a food additive, a color additive, or a new animal drug) that is unsafe within the meaning of section [346](#) of this title; or

**(B)** if it bears or contains a pesticide chemical residue that is unsafe within the meaning of section [346a \(a\)](#) of this title; or

**(C)** if it is or if it bears or contains

**(i)** any food additive that is unsafe within the meaning of section [348](#) of this title; or

**(ii)** a new animal drug (or conversion product thereof) that is unsafe within the meaning of section [360b](#) of this title; or

**(3)** if it consists in whole or in part of any filthy, putrid, or decomposed substance, or if it is otherwise unfit for food; or

**(4)** if it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health; or

**(5)** if it is, in whole or in part, the product of a diseased animal or of an animal which has died otherwise than by slaughter; or

(6) if its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health; or

(7) if it has been intentionally subjected to radiation, unless the use of the radiation was in conformity with a regulation or exemption in effect pursuant to section [348](#) of this title.

**(b) Absence, substitution, or addition of constituents**

(1) If any valuable constituent has been in whole or in part omitted or abstracted therefrom; or

(2) if any substance has been substituted wholly or in part therefor; or

(3) if damage or inferiority has been concealed in any manner; or

(4) if any substance has been added thereto or mixed or packed therewith so as to increase its bulk or weight, or reduce its quality or strength, or make it appear better or of greater value than it is.

**(c) Color additives**

If it is, or it bears or contains, a color additive which is unsafe within the meaning of section [379e \(a\)](#) of this title.

**(d) Confectionery containing alcohol or nonnutritive substance**

If it is confectionery, and—

(1) has partially or completely imbedded therein any nonnutritive object, except that this subparagraph shall not apply in the case of any nonnutritive object if, in the judgment of the Secretary as provided by regulations, such object is of practical functional value to the confectionery product and would not render the product injurious or hazardous to health;

(2) bears or contains any alcohol other than alcohol not in excess of one-half of 1 per centum by volume derived solely from the use of flavoring extracts, except that this clause shall not apply to confectionery which is introduced or delivered for introduction into, or received or held for sale in, interstate commerce if the sale of such confectionery is permitted under the laws of the State in which such confectionery is intended to be offered for sale;

**(3)** bears or contains any nonnutritive substance, except that this subparagraph shall not apply to a safe nonnutritive substance which is in or on confectionery by reason of its use for some practical functional purpose in the manufacture, packaging, or storage of such confectionery if the use of the substance does not promote deception of the consumer or otherwise result in adulteration or misbranding in violation of any provision of this chapter, except that the Secretary may, for the purpose of avoiding or resolving uncertainty as to the application of this subparagraph, issue regulations allowing or prohibiting the use of particular nonnutritive substances.

**(e) Oleomargarine containing filthy, putrid, etc., matter**

If it is oleomargarine or margarine or butter and any of the raw material used therein consisted in whole or in part of any filthy, putrid, or decomposed substance, or such oleomargarine or margarine or butter is otherwise unfit for food.

**(f) Dietary supplement or ingredient: safety**

**(1)** If it is a dietary supplement or contains a dietary ingredient that—

**(A)** presents a significant or unreasonable risk of illness or injury under—

**(i)** conditions of use recommended or suggested in labeling, or

**(ii)** if no conditions of use are suggested or recommended in the labeling, under ordinary conditions of use;

**(B)** is a new dietary ingredient for which there is inadequate information to provide reasonable assurance that such ingredient does not present a significant or unreasonable risk of illness or injury;

**(C)** the Secretary declares to pose an imminent hazard to public health or safety, except that the authority to make such declaration shall not be delegated and the Secretary shall promptly after such a declaration initiate a proceeding in accordance with sections [554](#) and [556](#) of title [5](#) to affirm or withdraw the declaration; or

**(D)** is or contains a dietary ingredient that renders it adulterated under paragraph (a)(1) under the conditions of use recommended or suggested in the labeling of such dietary supplement.

In any proceeding under this subparagraph, the United States shall bear the burden of proof on each element to show that a dietary supplement is

adulterated. The court shall decide any issue under this paragraph on a de novo basis.

(2) Before the Secretary may report to a United States attorney a violation of paragraph [\[2\]](#) (1)(A) for a civil proceeding, the person against whom such proceeding would be initiated shall be given appropriate notice and the opportunity to present views, orally and in writing, at least 10 days before such notice, with regard to such proceeding.

**(g) Dietary supplement: manufacturing practices**

(1) If it is a dietary supplement and it has been prepared, packed, or held under conditions that do not meet current good manufacturing practice regulations, including regulations requiring, when necessary, expiration date labeling, issued by the Secretary under subparagraph (2).

(2) The Secretary may by regulation prescribe good manufacturing practices for dietary supplements. Such regulations shall be modeled after current good manufacturing practice regulations for food and may not impose standards for which there is no current and generally available analytical methodology. No standard of current good manufacturing practice may be imposed unless such standard is included in a regulation promulgated after notice and opportunity for comment in accordance with chapter [5](#) of title [5](#).

**(h) Reoffer of food previously denied admission**

If it is an article of food imported or offered for import into the United States and the article of food has previously been refused admission under section [381 \(a\)](#) of this title, unless the person reoffering the article affirmatively establishes, at the expense of the owner or consignee of the article, that the article complies with the applicable requirements of this chapter, as determined by the Secretary.

---

[\[1\]](#) So in or". original. The period probably should be “;

[\[2\]](#) So in original. Probably should be “subparagraph”.

(As amended by Congress, 2002 – Subsec. (h). Pub. L. 107-188 added subsec. (h).)

## 2. BIBLIOGRAPHY

The following bibliography is a compilation of documents that were taken into consideration in developing the Food Code.

<b>Preface</b>
----------------

1. Archer, D.L. and J.E. Kvenberg, 1985. Incidence and cost of foodborne diarrheal disease in the United States. *J. Food Prot.* 48:887-894.
2. Committee on Salmonella, 1969. An Evaluation of the Salmonella Problem. NRC Pub. 1683, National Academy of Sciences, Washington, DC. 207 pp.
3. Council for Agricultural Science and Technology, 1994. Foodborne Pathogens: Risks and Consequences. Task Force Report No. 122, CAST, Ames, IA., 87 pp.
4. Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 374. Inspection.
5. Food and Drug Administration, January 24, 1994. Preliminary Regulatory Impact Analysis of the Proposed Regulations to Establish Procedures for the Safe Processing and Importing of Fish and Fishery Products.
6. Food and Drug Administration, 2004. Directory of State and Local Officials 2004 Edition. FDA/ORR Division of Federal-State Relations, Rockville, MD. [http://www.fda.gov/ora/fed\\_state/directorytable.htm](http://www.fda.gov/ora/fed_state/directorytable.htm).
7. Garthright, W.E., D.L. Archer and J.E. Kvenberg, 1988. Estimates of incidence and costs of intestinal infectious disease in the United States. *Public Health Rep.* 103:107-115.
8. Hirsch, D., 1989. Drafting Federal Law, 2nd Ed., Office of the Legislative Counsel, U. S. House of Representatives, Washington, DC. 122 pp.
9. Kvenberg, J.E. and D.L. Archer, 1987. Economic impact of colonization control on foodborne disease. *Food Technol.* 41:77-98.
10. Martineau, R.J., 1991. Drafting Legislation and Rules in Plain English, University of Cincinnati, Cincinnati, OH. 155 pp.
11. Maryland Office of the Secretary of State, 1991. Style Manual for Maryland Regulations, Div. of State Documents, Annapolis, MD. 58 pp.

12. McCracken, J.B. and G.P Carver, 1992. Recommended Agency Procedures for Implementing Federal Metric Policy. NISTIR 4855, U.S. Department of Commerce, National Institute of Standards and Technology, Technology Administration, Metric Program, Technology Services, Gaithersburg MD. 17 pp.
13. Mead, P.S., Slutsker, L., Dietz, V., McCraig, L.F., Bresee, J.S., Shapiro, C., Griffin, P.M., Tauxe, R.V., 1999. Food-related Illness and Death in the United States. *Emerg. Infect. Dis.* Vol. 5, No. 5, in: <http://www.cdc.gov/ncidod/EID/vol5no5/mead.htm>.
14. Metric Conversion Act of 1975, P.L. 94-168 Amended, 89 Stat. 1007; 15 U.S.C. § 205a et seq.
15. Omnibus Trade and Competitiveness Act of 1988, P.L. 100-418.
16. Research Triangle Institute, 1988. Estimating the Value of Consumer's Loss from Foods Violating the FD&C Act, FDA Contract No. 233-86-2098.
17. The Public Health Service Act, 42 U.S.C. Section 243. General Grant of Authority for Cooperation.
18. Metric Systems of Measurement; Interpretation of the International System of Units for the United States. Notice published July 28, 1998, 63 FR 40334-40340. This Federal Register notice supercedes the previous interpretation published on December 20, 1990, 55 FR 52242-52245.

## Chapter 1 Purpose and Definitions

### **1-201.10 Statement of Application and Listing of Terms**

1. Americans with Disabilities Act of 1990, as Amended. 42 U.S.C. 12111 et seq.
2. Code of Federal Regulations, Title 9, Section 362.1 Voluntary Poultry Inspection Regulations, Definitions.
3. Code of Federal Regulations, Title 9, Section 354.1 Voluntary Inspection of Rabbits and Edible Products Thereof, Definitions.
4. Code of Federal Regulations, Title 9, Part 301-2 Terminology; Adulteration and Misbranding Standards Definitions, Livestock.
5. Code of Federal Regulations, Title 9, Section 590.5 Egg Products Inspection Act, Terms Defined.



6. Code of Federal Regulations, Title 50, Part 17 Endangered and Threatened Wildlife and Plants.
7. Code of Federal Regulations, Title 9, Part 381 Poultry Products Inspection Regulations.
8. Code of Federal Regulations, Title 40, Part 141 National Primary Drinking Water Regulations.
9. Code of Federal Regulations, Title 40, Part 152.175 Pesticides classified for restricted use.
10. Doerry, W.T., 1996. Shelf-Stable Pumpkin Pies. A research report, American Institute of Baking, Manhattan, KS.
11. Federal Food, Drug and Cosmetic Act, 21 U.S.C. 321 Definitions (s) Food Additive, and Code of Federal Regulations, and Title 21 Part 170 Food Additives.
12. Federal Food, Drug and Cosmetic Act, 21 U.S.C. 321 Definitions (t) Color Additive, and Code of Federal Regulations, and Title 21 Part 70 Color Additives.
13. Federal Food, Drug and Cosmetic Act, 21 U.S.C. 342 Adulterated Food.
14. Federal Food, Drug and Cosmetic Act, 21 U.S.C. 379e (a) Unsafe Color Additives.
15. Federal Register: May 7, 2001 (Volume 66, Number 88), Rules and Regulations, Pages 22899-22907, DEPARTMENT OF AGRICULTURE, Food Safety and Inspection Service, 9 CFR Parts 362 and 381, Docket No. 01-045IF, RIN 0583-AC84, Mandatory Inspection Ratites and Squabs. [http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=2001\\_register&docid=R1-10679-filed.pdf](http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=2001_register&docid=R1-10679-filed.pdf).
16. Food Allergen Labeling and Consumer Protection Act of 2004. Public Law 108-282. <http://www.cfsan.fda.gov/~dms/algact.html>.
17. Food and Drug Administration/U. S. Public Health Service, 2003. National Shellfish Sanitation Program Guide for the Control of Molluscan Shellfish. <http://www.cfsan.fda.gov/~ear/nss2orpd.html>.
18. Food and Drug Administration/U. S. Public Health Service Publication No. 229, 2003 revision. Grade "A" Pasteurized Milk Ordinance. March 2, 2004. <http://www.cfsan.fda.gov/~ear/pmo03toc.html>.

19. Institute of Food Technologists (IFT) Report, Evaluation and Definition of Potentially Hazardous Foods, Food and Drug Administration Contract No. 223-98-2333, Task Order No. 4, December 31, 2001 <http://www.cfsan.fda.gov/~comm/ift4-toc.html>.

20. National Advisory Committee on Microbiological Criteria for Foods, 1992. Hazard Analysis and Critical Control Point System. *Int. J. Food Microbiol.* 16:1-23.

## Chapter 2 Management and Personnel

### 2-102.11 Demonstration.\*

1. Bean, N.H. and P.M. Griffin, 1990. Foodborne disease outbreaks in the United States, 1973-1987: pathogens, vehicles, and trends. *J. Food Prot.* 53:804-817.
2. Bryan, F.L., 1979. Prevention of foodborne diseases in food service establishments. *J. Environ. Health* 41:198-206.
3. Bryan, F.L., 1988a. Risks associated with vehicles of foodborne pathogens and toxins. *J. Food Prot.* 51(6):498-508.
4. Bryan, F.L., 1988b. Risks of practices, procedures and processes that lead to outbreaks of foodborne diseases. *J. Food Prot.* 51(8): 663-673.
5. Doyle, M.P., 1991. *Escherichia coli* O157:H7 and its significance in foods. *Int. J. Food Microbiol.* 12:289-302.
6. Liston, J., 1990. Microbial hazards of seafood consumption. *Food Technol.* 44(12):56, 58-62.
7. World Health Organization, 1989. Health Surveillance and Management Procedures for Food-handling Personnel, Technical Report Series 785, WHO, Geneva, Switzerland. 50 pp.

### 2-201.11 Responsibility of the Person in Charge, Food Employees, and Conditional Employees.\*

### 2-201.12 Exclusions and Restrictions.\*

1. Americans with Disabilities Act of 1990, as Amended. 42 U.S.C. 12111 et seq.

2. Anderson, A., V. Garrett, et al., 2001. Multistate Outbreak of Norwalk-Like Virus Gastroenteritis Associated with a Common Caterer. *American Journal of Epidemiology*. 154: 1013-1019.
3. Ando, et al., 2000. Genetic classification of "Norwalk-like viruses". *J. Infect. Dis.* 181 2 (2000), pp. S336-S348.
4. Atmar, R.L., M.K. Estes, 2001. Diagnosis of Noncultivable Gastroenteritis Viruses, the Human Caliciviruses. *Clinical Microbiology Reviews*. Vol. 14, No. 1, p. 15-37.
5. Black, R.E., G.F. Graun and P.A. Blake, 1978. Epidemiology of common-source outbreaks of shigellosis in the United States, 1961-1975. *Am. J. Epidemiol.* 108:47-52.
6. Brown, et al., 2003. Norovirus activity---United States, 2002. *Annals of Emergency Medicine*. Vol. 42, Issue 3, pp. 417-420.
7. Caul, E.O., 1994. Small round structured viruses: airborne transmission and hospital control. *The Lancet*. Vol. 343 (8908) pp. 1240-1242.
8. Caul, E.O., 1996a. Viral gastroenteritis: small round structured viruses, caliciviruses and astroviruses. Part 1. The clinical and diagnostic perspective. *J. Clin. Pathol.* 49: 874-880.
9. Caul, E.O., 1996b. Viral gastroenteritis: small round structured viruses, caliciviruses and astroviruses. Part II. The epidemiological perspective. *J. Clin. Pathol.* 49: 959- 964.
10. Centers for Disease Control and Prevention, October 4, 2004, Annual Update of List of Infectious and Communicable Diseases, Federal Register (Volume 69, Number 191), found at <http://a257.g.akamaitech.net/7/257/2422/06jun20041800/edocket.access.gpo.gov/2004/pdf/04-22260.pdf>.
11. Centers for Disease Control and Prevention, 2005. Health Information for International Travel (The "Yellow Book"). CDC Division of Global Migration and Quarantine, National Center for Infectious Diseases, Atlanta, GA. <http://www.cdc.gov/travel/yb/index.html>.
12. Chadwick, P.R. and R. McCann, 1994. Transmission of a small round structured virus by vomiting during a hospital outbreak of gastroenteritis. *Journal of Hospital Infection*. 26: 251-259.

13. Code of Federal Regulations, Title 29, Part 1630 Regulations to Implement the Equal Employment Provisions of the Americans with Disabilities Act.
14. Colorado Department of Health, 1993. Public Health Handbook For Management Of Acute Hepatitis A. Division of Disease Control and Environmental Epidemiology, 4300 Cherry Creek Drive South, Denver, CO 80222-1530, 27 pp.
15. de Wit, MAS, et al., 2003. Risk Factors for Norovirus, Sapporo-like Virus, and Group A Rotavirus Gastroenteritis. Emerging Infectious Diseases. Vol.9, No.12. pp.1563-1570.
16. Doyle, M.P. (Ed.), 1989. Foodborne Bacterial Pathogens, Marcel Dekker, Inc., New York. 796 pp.
17. Doyle, M.P., T. Zhao, J. Meng, S. Zhao, 1997. *Escherichia coli* O157:H7. In Food Microbiology Fundamentals and Frontiers, M.P. Doyle, L.R. Beuchat, and T.J. Montville, eds. pp. 183-186. ASM Press, Wash., D.C.
18. Equal Employment Opportunity Commission, 2004. *How to Comply with the Americans with Disabilities Act: A Guide for Restaurants and Other Food Service Employers*, found at [http://www.eeoc.gov/facts/restaurant\\_guide.html](http://www.eeoc.gov/facts/restaurant_guide.html) or [http://www.eeoc.gov/facts/restaurant\\_guide\\_summary.html](http://www.eeoc.gov/facts/restaurant_guide_summary.html).
19. Fankhauser, R.L., J.S. Noel, S.S. Monroe, T. Ando and R.I. Glass, 1998. Molecular epidemiology of “Norwalk-like viruses” in outbreaks of gastroenteritis in the United States. J. Infect. Dis. 178:1571-15788.
20. Food & Drug Administration, Center for Food Safety & Applied Nutrition, 2003. Foodborne Pathogenic Microorganisms and Natural Toxins Handbook (The Bad Bug Book) found at: <http://www.cfsan.fda.gov/~mow/intro.html>.
21. Grahm, D.Y., X. Jiang, et al., 1994. Norwalk virus infection of volunteers: new insights based on improved assays. J. of Infect. Diseases, Vol.170, Issue 1, p. 34.
22. Greenberg, H.B., R.G. Wyatt and A.Z. Kapikian, 1979. Norwalk virus in vomitus. Lancet. i: 55.
23. Griffin, P.M. and R.V. Tauxe, 1991. The epidemiology of infections caused by *Escherichia coli* O157:H7, other enterohemorrhagic *E. coli*, and the associated hemolytic uremic syndrome. Epidemiol. Rev. 13:60-98.
24. Heymann, David L. MD, (Ed.), 2004. Control of Communicable Diseases Manual, 18th Ed., American Public Health Association, Washington D.C.

25. Lopman, B., et al., 2003. Viral Gastroenteritis Outbreaks in Europe, 1995-2000. *Emerging Infectious Diseases*. Vol. 9, No.1.
26. Lopman, B.A., et. al., 2002. Human caliciviruses in Europe. *Journal of Clinical Virology*. Vol. 24, Issue 3, pp. 137-160.
27. Matsui, S.M., and H.B. Greenberg, 2000. Immunity to calicivirus infection. *The Journal of Infectious Diseases*. 181(Suppl 2): S331.
28. Meade, P.S., P.M. Griffin, 1998. *Escherichia coli* O157:H7. *Lancet* 1998; 352: 1207-12.
29. Mead, P.S., L. Slutsker, V. Dietz, L.F. McCraig, J.S. Bresee, C. Shapiro, P.M. Griffin, R.V. Tauxe, 1999. Food-related Illness and Death in the United States. *Emerg. Infect. Dis.* Vol. 5, No. 5, found at <http://www.cdc.gov/ncidod/EID/vol5no5/mead.htm>.
30. Monroe, S.S., T. Ando, and R.I. Glass, 2000. Introduction: human enteric caliciviruses—an emerging pathogen whose time has come. *The Journal of Infectious Diseases*. 181 (Suppl 2): S249.
31. Reid, J.A., 1988. Role of infected food handler in hotel outbreak of Norwalk-like viral gastroenteritis: implications for control. *Lancet*. Aug 6., 2(8606): 321-3.
32. Ryder, R.W. and P.A. Blake, 1979. Typhoid fever in the United States, 1975 and 1976. *J. Infect. Dis.* 139(1):124-126.
33. Shapiro, C.N., F.E. Shaw, E.J. Mandel, et al., 1991. Epidemiology of hepatitis A in the United States. In: *Viral Hepatitis and Liver Disease*, Hollinger, F.B., S.M. Lemon and H. Margolis (Eds.), Williams & Wilkins, Baltimore MD, pp. 71-76.
34. Soper, G.A., 1939. The curious career of Typhoid Mary. *Bull. N.Y. Acad Med.* 15:698-712.
35. Tauxe, R.V., K.E. Johnson, J.C. Boase, S.D. Helgerson and P.A. Blake, 1986. Control of day care shigellosis: A trial of convalescent day care in isolation. *Am. J. Public Health* 76(6):627-630.
36. Tauxe, R.V., N.D. Puhr, J.G. Wells, N. Hargrett-Bean and P.A. Blake, 1990. Antimicrobial resistance of *Shigella* isolates in the USA: The importance of international travelers. *J. Infect. Dis.* 162:1107-1111.
37. U.S. Department of Health and Human Services. *Healthy People 2010: Understanding and Improving Health*. 2nd ed. Washington, DC: U.S. Government

Printing Office, November 2000, found at <http://www.healthypeople.gov/Document/Word/Volume1/10Food.doc>.

38. Widdowson, Marc-Alain, et al. Jan. 2005. Norovirus and Foodborne Disease, United States, 1991-2000. *Emerging Infectious Diseases*. Vol. 11, No. 1. pp. 95-102, found at <http://www.cdc.gov/ed>.

## **2-201.13 Removal, Adjustment, or Retention of Exclusions and Restrictions.**

1. Code of Federal Regulations, Title 21, Section 110.10 Personnel. (a) Disease Control. " Any person who, by medical examination or supervisory observation is shown to have, or appears to have, an illness, ... shall be excluded from any operations which may be expected to result in contamination, ... Personnel shall be instructed to report such health conditions to their supervisors."

2. Equal Employment Opportunity Commission, 2004. *How to Comply with the Americans with Disabilities Act: A Guide for Restaurants and Other Food Service Employers*, found at [http://www.eeoc.gov/facts/restaurant\\_guide.html](http://www.eeoc.gov/facts/restaurant_guide.html) or [http://www.eeoc.gov/facts/restaurant\\_guide\\_summary.html](http://www.eeoc.gov/facts/restaurant_guide_summary.html).

3. Heymann, David L. MD, (Ed.), 2004. *Control of Communicable Diseases Manual*, 18th Ed., American Public Health Association, Washington D.C.

4. Lee, L.A., C.N. Shapiro, N. Hargrett-Bean and R.V. Tauxe, 1991. Hyperendemic Shigellosis in the United States: A review of surveillance data for 1967-1988. *J. Infect. Dis.* 164:894-900.

5. Ryder, R.W. and P.A. Blake, 1979. Typhoid fever in the United States, 1975 and 1976. *J. Infect. Dis.* 139:124-126.

## **2-301.12 Cleaning Procedure. (Handwashing)\***

1. Ansari, S. A., Springthorpe, V. S., Sattar, S. A., Tostowaryk, W., and Wells, G. A., 1991. Comparison of cloth, paper, and warm air drying in eliminating viruses and bacteria from washed hands. *Am. J. Infect. Cont.*, Vol.19. No. 5. pp. 243-249.

2. Ansari, S. A, Sattar, S. A., S., V. S., Wells, G. A. and Tostowaryk, W., 1989. In Vivo Protocol for Testing Efficacy of Hand-Washing Agents against Viruses and Bacteria: Experiments with Rotavirus and *Escherichia coli*. *Appl. Environ. Microbiol.*, Vol. 55, No. 12. pp. 3113-3118.

3. Ansari, S. A., Sattar, S. A., Springthorpe, V. S., Wells, G. A., and Tostowaryk, W., 1988. Rotavirus Survival on Human Hands and Transfer of Infectious Virus to Animate and Nonpourous Inanimate Surfaces, *J. Clin. Microbiol.*, Vol. 26, No. 8. pp.1513-1518.
4. Ayliffe, G.A.J., Babb, J.R., Davies, J.G., and Lilly, H.A., 1988. Hand disinfection: a comparison of various agents in laboratory and ward studies. *J. Hosp. Infect.*, Vol. 11, pp. 226-243.
5. Ayliffe, G.A.J., Babb, J.R., and Quoraishi, A.H., 1978. A test for 'hygienic' hand disinfection. *J. Clin. Path.*, Vol. 31, pp. 923-928.
6. Bellamy, K., Alcock, R., Babb, J.R., Davies, J.G., and Ayliffe, G.A.J. 1993. A test for the assessment of 'hygienic' hand disinfection using rotavirus. *J. Hosp. Infect.*, Vol. 24, pp. 201-210.
7. Casewell, M., Phillips, I., 1977. Hands as route of transmission for Klebsiella species. *Brit. Med. J.* Vol. 2, No.19. pp.1315-1317.
8. Cliver, D. O., and Kostenbader, K. D., 1984. Disinfection of virus on hands for prevention of food-borne disease. *Intern. J. Food Microbiol.*, Vol. 1, pp. 75-87.
9. De Witt, J.C. 1985. The importance of hand hygiene in contamination of foods. Netherlands Society for Microbiology, section for food microbiology meeting at Ede on 24 May, 1984. *Antonie von Leeuwenhoek*, Vol. 51, pp. 523-527.
10. Eckert, D.G., Ehrenkranz, N.J., Alfonso, B.C. 1989. Indications for alcohol or bland soap in removal of aerobic gram-negative skin bacteria: assessment by a novel method. *Infect. Control Hosp. Epidemiol.*, Vol. 10, pp. 306-311.
11. The National Restaurant Association Educational Foundation (NRAEF), 2004. The Safe Foodhandler, in *ServSafe Essentials*, 3<sup>rd</sup> Ed., NRAEF, Chicago, IL pages 4-1 – 4-25.
12. Eggers, H. J. 1990. Experiments on Antiviral Activity of Hand Disinfectants. Some Theoretical and Practical Considerations. *Zbl. Bakt.* Vol.273, pp.36-51.
13. Ehrenkranz, N.J., 1992. Bland soap handwash or hand antisepsis? The pressing need for clarity. *Infect. Control Hosp. Epidemiol.*, Vol. 13, No. 5, pp. 299-301.
14. Ehrenkranz, N.J., Alfonso, B., 1991. Failure of bland soap handwash to prevent hand transfer of patient bacteria to urethral catheters. *Infect. Control Hosp. Epidemiol.* Vol. 12, No. 11, pp. 654-662.

15. Garner, J.S. and M.S. Favero, 1985. Guidelines for Handwashing and Hospital Environmental Control. Hospital Infections Program, Center for Infectious Diseases, CDC, Atlanta, GA. pp. 7-9.
16. Kjolen H., and Andersen, B. M., 1992. Handwashing and disinfection of heavily contaminated hands – effective or ineffective? J. Hosp. Infect., Vol. 21, pp. 61-71.
17. Lane, C.G., and Blank, I.H., 1942. Cutaneous Detergents. J.A.M.A. 118 (10): 804-816.
18. Larson, E.L., 1995. APIC Guideline for handwashing and hand antisepsis in health care settings, American J. Infect. Control, Vol. 23, No. 4, pp. 251-269.
19. Lilly, H.A, Lowbury, E.J.L. 1978. Transient skin flora. Their removal by cleansing or disinfection in relation to their mode of deposition. J. Clin. Path. Vol. 31, pp. 919-922.
20. Mbithi, J.N., Springthorpe, S., and Sattar, S., 1993. Comparative in vivo efficiencies of hand-washing agents against Hepatitis A virus (HM-175) and Poliovirus Type 1 (Sabin). Applied Environ Microbiol. Vol.59, No.10, pp. 3463-3469.
21. McGinley, K.J., Larson, E.L., and Leyden, J.J. 1988. Composition and Density of Microflora in the Subungual Space of the Hand. J. of Clin. Micro. 26(5): 950-953.
22. Minnesota Department of Health, 1990. Guidelines for the Prevention of the Transmission of Viral Hepatitis, Type A in the Food Service Area. Minnesota Department of Health, Div. Environ. Health, Minneapolis, MN. 2 pp.
23. Paulson, D.S., 1992. Evaluation of three handwashing modalities commonly employed in the food processing industry. Dairy Food Environ. Sanit. 12(10):615-618.
24. Pether, J.V.S., and Gilbert, R.J., 1971. The survival of salmonellas on finger-tips and transfer of the organism to foods. J. Hyg. Vol. 69, pp. 673-681.
25. Price, P.B., 1938. The Bacteriology of Normal Skin; A New Quantitative Test Applied to a Study of the Bacterial Flora and the Disinfectant Action of Mechanical Cleansing, J. Infect. Dis. 63: 301-318.
26. Restaino, L. and Wind, C.E., 1990. Antimicrobial effectiveness of hand washing for food establishments. Dairy, Food and Environ. San. Vol.10, No. 3, pp.136-141.
27. Reybrouck, G., 1986. Handwashing and hand disinfection. J. Hosp. Infect. 8: 5-23.



28. Rotter, M.L., G.A.J. Ayliffe, 1991. Practical Guide on Rationale and Testing Procedures for Disinfection of Hands. World Health Organization. 57 pp.
29. Rotter, M.L., Koller, W., 1991. An European test for the evaluation of the efficacy of procedures for the antiseptic handwash? *Hyg. Med.*, Vol. 16, pp.4-12.
30. Rose, J.B., and Slifko, T.R., 1999. Giardia, Cryptosporidium, and Cyclospora and their impact on foods: a review. *J. Food Protect.* Vol. 62., No. 9, pp. 1059-1070.
31. Sattar, S.A., and Springthorpe, V.S. 1996. Environmental spread and germicide control of viruses in hospitals. *Infect Control & Steril.Tech*, Vol. 2, no.7, pp. 30-36.
32. Schurmann, W., and Eggers, H.J. 1985. An experimental study on the epidemiology of enteroviruses: water and soap washing of poliovirus 1 – contaminated hands, its effectiveness and kinetics. *Med. Microbiol. Immunol.* Vol. 174, pp. 221-236.
33. Smith, G.A., Jr, 1991. Handwashing et cetera, Lexington Board of Health, Personal Hygiene Sanitation Programs, Lexington, KY. 2 pp.
34. Stiles, M.E., and Sheena, A.Z. 1987. Efficacy of Germicidal Hand Wash Agents in Use in a Meat Processing Plant. *J. Food Protect.* 50 (4):289-295.
35. Sprunt, Katherine, Redman, Winifred, and Leidy, Grace, 1973. Antibacterial Effectiveness of Routine Hand Washing. *Pediatrics*, Vol. 52, No. 2, pp. 264-271.
36. Williams, R.E.O., 1963. Healthy carriage of ***Staphylococcus aureus***: Its prevalence and importance. *Bacteriol. Rev.* 27:56-71.

### **2-301.13 Special Handwashing Procedures.\***

Reserved.

### **2-301.14 When to Wash.\***

1. Ojarvi, J., 1980. Effectiveness of handwashing and disinfection methods in removing transient bacteria after patient nursing. *J. Hyg. Camb.* 85:193-203.

### **2-301.16 Hand Antiseptics.**

1. Code of Federal Regulations, Title 21, Part 178.1010 Sanitizing Solutions.

2. Code of Federal Regulations, Title 21, Part 170.39 Threshold of Regulation for Substances Used in Food-Contact Articles.
3. Code of Federal Regulations, Title 21, Part 182 Substances Generally Recognized as Safe.
4. Code of Federal Regulations, Title 21, Part 184 Direct Food Substances Affirmed as Generally Recognized as Safe.
5. Code of Federal Regulations, Title 21, Part 186 Indirect Food Substances Affirmed as Generally Recognized as Safe for Use in Contact with Food.
6. Federal Register (59) No. 116, June 17, 1994, Tentative Final Monograph (TFM) for Health Care Antiseptic Drug Products; Proposed Rule. Page 31440.  
[http://www.fda.gov/cder/otcmonographs/Antimicrobial/new\\_antimicrobial.htm](http://www.fda.gov/cder/otcmonographs/Antimicrobial/new_antimicrobial.htm)
7. Food and Drug Administration, Center for Drug Evaluation and Research, Office of Pharmaceutical Science, Office of Generic Drugs, 2005. Approved Drug Products with Therapeutic Equivalence Evaluations (the Orange Book).  
<http://www.fda.gov/cder/ob/default.htm>.
8. Food and Drug Administration. FDA Inventory of Effective Premarket Notifications for Food Contact Substances. Found at <http://www.cfsan.fda.gov/~dms/opa-fcn.html>.
9. Food and Drug Administration. FDA's Inventory of GRAS Notices. Found at <http://www.cfsan.fda.gov/~rdb/opa-gras.html>.
10. Food and Drug Administration, January, 2005. Investigations Operations Manual, Chapter 5, Establishment Inspection, Subchapter 530, Food Section 534, Equipment and Utensils.
11. Stiles, M.E. and A.Z. Sheena, 1987. Efficacy of germicidal hand wash agents in use in a meat processing plant. J. Food Prot. 50(4): 289-294.

### **2-302.11 Maintenance. (Fingernails)**

1. Pether, J.V.S. and R.J. Gilbert, 1971. The survival of salmonellas on finger-tips and transfer of the organisms to foods. J. Hyg. Camb. 69:673-681.
2. Pottinger, J., S. Burns, and C. Manake, 1989. Bacterial carriage by artificial versus natural nails. Am. J. Infect. Control, 17(6):340-344.

- 2-303.11 Prohibition. (Jewelry)
- 2-304.11 Clean Condition. (Outer Clothing)
- 2-401.11 Eating, Drinking, or Using Tobacco.\*
- 2-402.11 Effectiveness. (Hair Restraints)

1. Code of Federal Regulations, Title 21, Sections 110.10 Personnel. (b) (1) "Wearing outer garments suitable to the operation ...." (4) "Removing all unsecured jewelry ...." (6) "Wearing, where appropriate, in an effective manner, hair nets, head bands, caps, beard covers, or other effective hair restraints." (8) "Confining...eating food, chewing gum, drinking beverages or using tobacco...." and (9) "Taking other necessary precautions ...."

#### 2-403.11 Handling Prohibition. (Animals)\*

1. Bond, R., L.E.M. Saijonmaa-Koulumies, and D.H. Lloyd, 1995. Population sizes and frequency of *Malassezia pachydermatis* at skin and mucosal sites on healthy dogs. J. Small Animal Pract. 36: 147-150.
2. Code of Federal Regulations, Title 21, Section 110.35(c).
3. Food and Drug Administration, 1985. Premises - Acceptability of pets in common dining areas of group residences (5/17/85). Retail Food Protection Program Information Manual.
4. Hirooka, Elisa Y., Ernest E. Muller, Julio C. Freitas, Eduardo Vicente, Yuko Yoshimoto, and Merlin S. Bergdoll. 1988. Enterotoxigenicity of *Staphylococcus intermedius* of canine origin. Int. J. Food Micro. 7: 185-191.
5. Khambaty, F.M., R.W. Bennett, and D.B. Shah. 1994. Application of pulsed-field gel electrophoresis to the epidemiological characterization of *Staphylococcus intermedius* implicated in a food-related outbreak. Epidemiol. Infect. 133: 75-81.

<b>Chapter 3 Food</b>
-----------------------

#### 3-201.11 Compliance with Food Law.\*

1. Centers for Disease Control, 1987. International outbreak associated with ungutted, salted whitefish. Morb. Mortal. Wkly. Rep. 36:812-813.

2. Code of Federal Regulations, Title 21, Part 16, Regulatory Hearing Before the Food and Drug Administration.
3. Code of Federal Regulations, Title 21, Part 101, Food Labeling.
4. Code of Federal Regulations, Title 21, Part 115, Shell Eggs.
5. Federal Register: (Volume 65, Number 234), Pages 76091-76114.
6. Goverd, K.A., F.W. Beech, R.P. Hobbs and R. Shannon, 1979. The occurrence and survival of coliforms and salmonellas in apple juice and cider. J. Appl. Bacteriol. 46:521-530.
7. Zhao, T., M.P. Doyle and R.E. Besser, 1993. Fate of enterohemorrhagic *Escherichia coli* O157:H7 in apple cider with and without preservatives. Appl. Environ. Microbiol. 59(8): 2526-2530.

### **3-201.12 Food in a Hermetically Sealed Container.\***

1. Code of Federal Regulations, Title 21, Parts 108 - Emergency Permit Control, 113 - Thermally Processed Low-acid Foods Packaged in Hermetically Sealed Containers, and 114 - Acidified Foods.

### **3-201.13 Fluid Milk and Milk Products.\***

1. Black, R.E., R.J. Jackson, T. Tsai, M. Medvesky, M. Shaygani, J.C. Feely, K.I.E. MacLeod and A.M. Wakelee, 1978. Epidemic *Yersinia enterocolitica* infection due to contaminated chocolate milk. N. Engl. J. Med. 298:76-79.
2. Food and Drug Administration/U.S. Public Health Service Publication No. 229, 2003 revision. Grade "A" Pasteurized Milk Ordinance. March 2, 2004.  
<http://www.cfsan.fda.gov/~ear/pmo03toc.html>
3. Potter, M.E., A.F. Kauffmann, P.A. Blake and R.A. Feldman, 1984. Unpasteurized milk: The hazards of a health fetish. J. Am. Med. Assoc. 252:2048-2052.

### **3-201.14 Fish.\***

1. Code of Federal Regulations, Title 21, Part 123 Fish and Fishery Products.

2. Code of Federal Regulations, Title 21, Part 101.17(h) Food labeling warning notice, and safe handling statement.
3. Code of Federal Regulations, Title 9, Part 317.2(l) Labels: definition; required features.
4. Code of Federal Regulations, Title 9, Part 381.125(b) Special handling label requirements.
5. Engleberg, N.C., J.G. Morris, Jr., J. Lewis, J.P. McMillan, R.A. Pollard and P.A. Blake. 1983. Ciguatera fish poisoning: a major common source outbreak in the U.S. Virgin Islands. *Ann. Intern. Med.* 98:336-337.
6. EPA Annual National Listing of Fish Advisories and Press Release, March 2004, EPA-823-R-04-005, August 24, 2004, EPA Releases 12<sup>th</sup> Annual National Listing of Advisories at <http://www.epa.gov/waterscience/fish/advisories/index.html>
7. EPA Press Release, March 2004, EPA-823-R-04-005, What You Need to Know About Mercury in Fish and Shellfish, 2004 EPA and FDA Advice For: Women Who Might Become Pregnant, Women Who are Pregnant, Nursing Mothers, Young Children at <http://www.epa.gov/waterscience/fish/MethylmercuryBrochure.pdf> or <http://www.epa.gov/waterscience/fishadvice/advice.html>
8. EPA Technical Fact Sheet, EPA-823-F-04-016, August 2004. National Listing of Fish Advisories. <http://www.epa.gov/waterscience/fish/advisories/factsheet.pdf>
9. Liston, J. 1990. Microbial hazards of seafood consumption. *Food Technol.* 44(12):56, 58-62.
10. Morris, J.G., Jr. 1988. *Vibrio vulnificus*: A new monster of the deep? *Ann. Intern. Med.* 109:261-263.
11. Taylor, S.L. 1986. Histamine food poisoning: Toxicology and clinical aspects. *C.R.C. Crit. Rev. Toxicol.* 17:91-128.

### **3-201.15 Molluscan Shellfish.\***

1. Food and Drug Administration/U.S. Public Health Service, 2003. National Shellfish Sanitation Program Guide for the Control of Molluscan Shellfish. <http://www.cfsan.fda.gov/~ear/nss2-toc.html>
2. Guzewich, J.J. and D.L. Morse, 1986. Sources of shellfish in outbreaks of probable viral gastroenteritis: Implications for control. *J. Food Prot.* 49:389-394.

3. Sobsey, M.D., C.R. Hackney, R.J. Carrick, B. Ray and M.C. Speck, 1980. Occurrence of enteric bacteria and viruses in oysters. *J. Food Prot.* 43:111-128.

### **3-201.16 Wild Mushrooms.\***

1. Ammirati, J.F. et al., 1985. Poisonous Mushrooms of the Northern United States and Canada, University of Minnesota Press, Minneapolis, MN.
2. Associated Press, 1997 Cable News Network, Inc. CNN report: poisonous mushrooms kill Sebastiani wine family member, January 16, 1997.
3. Baltimore Sun Newspaper via Associated Press, February 9, 1996 report on girl who picked deadly mushrooms with family gets liver transplant.
4. Chang, S.T. and W.A. Hayes, 1978. The Biology and Cultivation of Edible Mushrooms, Academic Press, New York. 819 pp.
5. Food and Drug Administration, 1987. Food Supplies - Wild mushrooms (6/11/87). Retail Food Protection Program Information Manual.
6. Gecan, J.S., and S.M. Cichowicz. 1993. Toxic mushroom contamination of wild mushrooms in commercial distribution. *J. Food Prot.* 56(8):730-734.
7. Hoard, R. and K. Hoard, 1980. Poisonous Hallucinogenic Mushrooms, 2nd Ed., Homestead Books, Brookfield, NY. 164 pp.
8. Lincoff, G. and D. Mitchel, 1977. Toxic and Hallucinogenic Mushroom Poisoning, Van Nostrand Reinhold Company, New York, 267 pp.

### **3-201.17 Game Animals.\***

1. Code of Federal Regulations, Title 50, Part 17 Endangered and Threatened Wildlife and Plants.
2. Code of Federal Regulations, Title 9, Part 352 Exotic animals; voluntary inspection of rabbits.
3. Code of Federal Regulations, Title 9, Part 354 Voluntary inspection of rabbits and edible products thereof.

4. Codex Alimentarius Commission, 1993. Draft Revised Code of Hygienic Practice for Game (April 1993). Alinorm 93/16A, Appendix IV, pp. 119-149.
5. Federal Food, Drug, and Cosmetic Act, as Amended. 21 U.S.C. 201 et seq.
6. Federal Meat Inspection Act. 21 U.S.C. 601 et seq.
7. Hogue, A.T., D.W. Dreesen, S.S. Greene, A.D. Ragland, W.O. James, E.A. Bereron, L.V. Cook, M.D. Pratt, and D.R. Martin, 1993. Bacteria on beef briskets and ground beef: correlation with slaughter volume and antemortem condemnation. J. Food Prot. 56(2): 110-113, 119.
8. Poultry Products Inspection Act. 21 U.S.C. 451 et seq.

### **3-202.11 Temperature.\***

1. Code of Federal Regulations, Title 9, Part 590 Egg Products Inspection Act, Temperature and labeling requirements.
2. Humphrey, T.J., 1994. Contamination of egg shell and contents with **Salmonella enteritidis**: a review. International Journal of Food Microbiology, 21(1994) 31-40.
3. Mishu, B., J. Koehler, L. Lee, D. Rodrigue, F. Hickman Brenner, P. Blake, and R. Tauxe, 1994. Outbreaks of **Salmonella enteritidis** infections in the United States, 1985-1991. J. Infect. Dis. 169:547-552.
4. Rosenow, E.M. and E.H. Marth, 1987. Growth of **Listeria monocytogenes** in skim, whole and chocolate milk, and in whipping cream during incubation at 4,8,13,21 and 35° C. J. Food Prot. 50:452-259.
5. St. Louis, M.E., D.L. Morse, M.E. Potter, et al., 1988. The emergence of Grade A eggs as a major source of **Salmonella enteritidis** infections: New implications for the control of salmonellosis. J. Am. Med. Assoc. 259:2103-2107.

### **3-202.12 Additives.\***

1. Barlett, P.A., J.G. Morrie, Jr., and J. Spengler, 1982. Foodborne illness associated with niacin: Report of an outbreak linked to excessive niacin in enriched cornmeal. Public Health Rep. 97:258-260.

2. Code of Federal Regulations, Title 40, Part 180 Tolerances for pesticides chemicals in food, and exceptions.
3. Food and Drug Administration, 1987. Food Supplies - Sulfiting agents on food in retail food establishments (9/10/87). Retail Food Protection Program Information Manual.
4. Food and Drug Administration, 2003. Color Additives: FDA's Regulatory Process and Historical Perspectives. Reprinted from *Food Safety Magazine* October/November 2003 issue, CFSAN/Office of Cosmetics and Colors.  
<http://www.cfsan.fda.gov/~dms/col-regu.html>.
5. Food and Drug Administration, 2004. Summary of Color Additives Listed for Use in the United States in Foods, Drugs, Cosmetics, and Medical Devices. CFSAN/Office of Food Additive Safety. <http://www.cfsan.fda.gov/~dms/opa-col2.html>.
6. Food and Drug Administration, 2004. Food Contact Substance Notification Program. CFSAN/Office of Food Additive Safety. <http://www.cfsan.fda.gov/~dms/opa-notf.html>.

### 3-202.13 Eggs.\*

1. Bradshaw, J.G., D.B. Shah, E. Forney, and J.M. Madden, 1990. Growth of ***Salmonella enteritidis*** in yolk of shell eggs from normal and seropositive hens. *J. Food Prot.* 53 (12):1033-1036.
2. Centers for Disease Control, 1988. Update: ***Salmonella enteritidis*** infections and Grade A shell eggs - United States. *Morb. Mortal. Wkly. Rep.* 37:490-496.
3. Gast, R.K. and C.W. Beard, 1990. Production of ***Salmonella enteritidis*** - contaminated eggs by experimentally infected hens. *Avian Dis.* 34:438-446.
4. Kim, C.J., D.A. Emery, H. Rinkle, K.V. Nagaraja, and D.A. Halvorson. 1989. Effect of time and temperature on growth of ***Salmonella enteritidis*** in experimentally inoculated eggs. *Avian Dis.* 33:735-742.
5. St. Louis, M.E., D.L. Morse, E. Potter, T.M. DeMelfi, J.J. Guzewich, R.V. Tauxe, and P.A. Blake. 1988. The emergence of Grade A eggs as a major source of ***Salmonella enteritidis*** infections. *J. Am. Med. Assoc.* 259:2103-2107.
6. United States Standards, Grades, and Weight Classes for Shell Eggs, AMS 56.200 *et seq.*, administered by the Agricultural Marketing Services of USDA.



### 3-202.14 Eggs and Milk Products, Pasteurized.\*

1. Baker, R.C., S. Hogarty, W. Poon et al., 1983. Survival of **Salmonella typhimurium** and **Staphylococcus aureus** in eggs cooked by different methods. Poultry Sci. 62:1211-1216.
2. Code of Federal Regulations, Title 21, Part 133, Cheeses and related cheese products.
3. Code of Federal Regulations, Title 21, Part 135, Frozen desserts.
4. Code of Federal Regulations, Title 9, Part 590, Inspection of Eggs and Egg Products (Egg Products Inspection Act).
5. Cunningham, F.E., 1977. Egg pasteurization, in Egg Science and Technology, 2nd Ed., J. Stadelman, and O.J. Cotterill (Eds.), AVI Publishing Company, Inc., Westport, CT. pp. 161-186.
6. Doyle, M.P., L.M. Meske and E.H. Marth, 1985. Survival of **Listeria monocytogenes** during the manufacture and storage of nonfat dry milk. J. Food Prot. 48(9):740.
7. Food and Drug Administration/U.S. Public Health Service Publication No. 229, 2003 revision. Grade "A" Pasteurized Milk Ordinance. March 2, 2004. <http://www.cfsan.fda.gov/~ear/pmo03toc.html>.
8. Tacket, C.O., L.B. Dominguez, H.J. Fisher and M.L. Cohen, 1985. An outbreak of multiple-drug-resistant **Salmonella Enteritidis** from raw milk. J. Am. Med. Assoc. 253:2058-2060.

### 3-202.16 Ice.\*

1. Cliver, D.O., 1988. Virus transmission via foods; A scientific status summary by the Institute of Food Technologists' Expert Panel on Food Safety and Nutrition. Food Technol. 42(10):241-248.
2. Jackson, G.L., 1990. Parasitic protozoa and worms relevant to the U.S. Food Technol. 44(5):106-112.

### **3-202.17 Shucked Shellfish, Packaging and Identification.**

1. Code of Federal Regulations, Title 21, Subpart D – Specific Administrative Decisions Regarding Interstate Shipments, Section 1124.60(d) Molluscan shellfish.
2. Food and Drug Administration/U.S. Public Health Service, 2003. National Shellfish Sanitation Program Guide for the Control of Molluscan Shellfish, found at <http://www.cfsan.fda.gov/~ear/nss2orpd.html>.

### **3-202.18 Shellstock Identification.\***

#### **3-202.19 Shellstock, Condition.**

1. Code of Federal Regulations, Title 21, Part 1240, Control of Communicable Disease, Molluscan Shellfish.
2. Food and Drug Administration/U.S. Public Health Service, 2003. National Shellfish Sanitation Program Guide for the Control of Molluscan Shellfish, found at <http://www.cfsan.fda.gov/~ear/nss2orpd.html>.
3. Freudenthal, A.R. and J.L. Jijina. 1988. Potential hazards of *Dinophysis* to consumers and shellfisheries. J. Shellfish Res. 7:695-701.
4. Klontz, K.C., S. Lieb, M. Schreider, H.T. Janowski, L.M. Baldy and R.A. Gunn. 1988. Syndromes of *Vibrio vulnificus* infections: clinical and epidemiological features in Florida cases 1981-1987. Ann. Intern. Med. 109:318-323.
5. Morse, D.L., J.J. Guzewich, J.P. Hanrahan, R. Stricot, M. Shayegani, R. Deible, J.C. Grabau, N.A. Nowak, J.E. Herrman, G. Cukor and N.R. Blacklow. 1986. Widespread outbreaks of clam and oyster associated gastroenteritis: Role of Norwalk virus. N. Engl. J. Med. 314:678-681.
6. Nishitani, L. and K. Chew. 1988. PSP toxins in Pacific Coast states: monitoring programs and effects on bivalve industries. J. Shellfish Res. 1:653-669.
7. Rippey, S.R., 1994. Seafood Borne Disease Outbreaks. U.S. Department of Health & Human Services, Public Health Service, Food and Drug Administration, Office of Seafood, 82 pp.

### **3-202.110 Juice Treated.**

1. Code of Federal Regulations, Title 21, Part 120 Hazard Analysis and Critical Control (HACCP) Systems.

2. Code of Federal Regulations, Title 21, Part 101.17(g) Juices that have not been specifically processed to prevent, reduce, or eliminate the presence of pathogens.
3. Code of Federal Regulations, Title 21, Part 120.4 Process Controls.

### **3-203.11 Molluscan Shellfish, Original Container.**

1. Food and Drug Administration, 1983. Food Supplies - Special requirements for retaining shell-stock "tags". (3/29/83), Retail Food Protection Program Information Manual.
2. Food and Drug Administration, Center for Food Safety and Applied Nutrition, 2003. National Shellfish Sanitation Program Guide for the Control of Molluscan Shellfish, found at <http://www.cfsan.fda.gov/~ear/nss2-toc.html>.

### **3-203.12 Shellstock, Maintaining Identification.\***

1. Colburn, K.G., C.A. Kaysner, M.M. Wekell, J.R. Matches, C. Abeyta, Jr. and R.F. Stott, 1989. Microbiological quality of oysters (*Crassostrea gigas*) and water of live holding tanks in Seattle, WA markets. J. Food Prot. 52(2):100-104.
2. Food and Drug Administration/U.S. Public Health Service, 2003. National Shellfish Sanitation Program Guide for the Control of Molluscan Shellfish, found at <http://www.cfsan.fda.gov/~ear/nss2orpd.html>.

### **3-301.11 Preventing Contamination from Hands.\***

1. Bidawid, S., Farber, J.M., and Sattar, S.A. 2000. Contamination of Foods by Food Handlers: Experiments on Hepatitis A Virus Transfer to Food and Its Interruption. Applied Env. Micro. 66(7): 2759-2763.
2. Black, R.E., A.C. Dykes, K.E. Anderson et al., 1981. Hand washing to prevent diarrhea in day care centers. Am. J. Epidemiol. 113:445-451.
3. Cliver, D. O., and Kostenbader, K. D., 1984. Disinfection of virus on hands for prevention of food-borne disease. Intern. J. Food Microbiol., Vol. 1, pp.75-87.
4. Crisley, F.D. and M.J. Foter. 1965. The use of antimicrobial soaps and detergents for hand washing in food service establishments. J. Milk Food Technol. 28:278-284.

5. Food and Drug Administration, Center for Food Safety and Applied Nutrition, 2000. Hepatitis A virus, in Bad Bug Book, Foodborne Pathogenic Microorganisms and Natural Toxins Handbook, found at <http://www.cfsan.fda.gov/~mow/intro.html>.
6. Goldmann, D.A., 1991. The role of barrier precautions in infection control. *J. Hosp. Infect.*, Vol. 18, (Supplement A), pp. 515-523.
7. Goldmann, D.A., and Larson, E. 1992. Handwashing and nosocomial infections. *New Eng. J. Med.*, Vol. 327, No.2. pp. 120-122.
8. Horwood, M.P. and V.A. Minch, 1951. The numbers and types of bacteria found on the hands of food handlers. *Food Res.* 16:133-136.
9. Humphrey, T.J., K.W. Martin, and A. Whitehead. 1994. Contamination of hands and work surfaces with ***Salmonella enteritidis*** PT4 during the preparation of egg dishes. *Epidemiol. Infect.* 113: 403-409.
10. Kaferstein, F.K., Motarjemi, Y., and Bettcher, D.W. 1997. Foodborne disease control: A transnational challenge, *Emerg. Infect. Dis.*, Vol. 3, No. 4, pp. 503-511.
11. Lowbury, E.J.L., H.A. Lilly and J.P. Bull, 1964. Disinfection of hands: Removal of transient organisms. *Brit. Med. J.* 2:230-233.
12. Mead, P.S., Slutsker, L., Dietz, V., McCraig, L.F., Bresee, J.S., Shapiro, C., Griffin, P.M., Tauxe, R.V., 1999. Food-related illness and death in the United States. *Emerg. Infect. Dis.* Vol. 5, No.5, pp.38, found at <http://www.cdc.gov/ncidod/EID/vol5no5/mead.htm>.
13. Paulson, D.S., 1992. Evaluation of three handwashing modalities commonly employed in the food processing industry. *Dairy Food Environ. Sanit.* 12(10):615-618.
14. Pether, J.V.S. and R.J. Gilbert, 1971. The survival of salmonellas on finger-tips and transfer of the organisms to foods. *J. Hyg. Camb.* 69:673-681.
15. Rose, J.B., and Slifko, T.R., 1999. Giardia, Cryptosporidium, and Cyclospora and their impact on foods: a review. *J. Food Protect.* Vol. 62., No. 9, pp. 1059-1070.
16. Ross, M., and Guzewich, J., 1999. Evaluation of risks related to microbiological contamination of ready-to-eat food by food preparation workers and the effectiveness of interventions to minimize those risks. FDA White Paper, FDA, CFSAN, found at <http://www.cfsan.fda.gov/~ear/rterisk.html>.
17. Smith, J.L., 1993. Cryptosporidium and Giardia as agents of foodborne disease. *J. Food Protection.* Vol. 56: 451-461.

18. Williams, R.E.O., 1963. Healthy carriage of *Staphylococcus aureus*: Its prevalence and importance. *Bacteriol. Rev.* 27:56-71.

**3-302.11 Packaged and Unpackaged Food - Separation, Packaging, and Segregation.\***

1. Code of Federal Regulations, Title 21, Part 109, Unavoidable Contaminants in Food for Human Consumption and Food-Packaging Material.

2. Dickson, J.S., 1990. Survival and growth of *Listeria monocytogenes* on beef tissue surfaces as affected by simulated processing conditions. *J. Food Safety* 10:165-174.

3. Doyle, M.P. and J.L. Schoeni, 1987. Isolation of *Escherichia coli* O157:H7 from retail fresh meats and poultry. *Appl. Environ. Microbiol.* 53:2394-2396.

4. Stern, N.J., M.P. Hernandez, L. Blankenship, K.E. Deibel, S. Doors, M.P. Doyle, H. Ng, M.D. Pierson, J.N. Sofos, H. Sveum and D.C. Westhoff, 1985. Prevalence and distribution of *Campylobacter jejuni* and *Campylobacter coli* in retail meats. *J. Food Prot.* 48(7):595-599.

**3-302.12 Food Storage Containers, Identified with Common Name of Food.**

**3-302.13 Pasteurized Eggs, Substitute for Raw Shell Eggs for Certain Recipes.\***

1. Cunningham, F.E., 1977. Egg pasteurization, in Egg Science and Technology, 2nd Ed., J. Stadelman, and O.J. Cotterill (Eds.), AVI Publishing Company, Inc., Westport, CT. pp 161-186.

2. USDA/ARS. 1969. Egg Pasteurization Manual (ARS 74-48), USDA/ARS Albany, CA 94710. 47 pp.

**3-302.15 Washing Fruits and Vegetables.**

1. Beuchat, L. 1998. Food Safety Issues. Surface Decontamination of Fruits and Vegetables Eaten Raw: A Review. World Health Organization. 42 pp.

2. Chia-Min, Lin, Cheng-I Wei\*, 1997. Transfer of *Salmonella montevideo* onto the Interior Surfaces of Tomatoes by Cutting. *J. Food Prot.* 60(7): 858-863.

3. Geldreich, E.E. and R.H. Bordner, 1971. Fecal contamination of fruits and vegetables during cultivation and processing for market. *J. Milk Food Technol.* 34:184-195.
4. Heisick, J.E., D.E. Wagner, M.L. Nierman and J.T. Peeler, 1989. *Listeria* spp. found in fresh market produce. *Appl. Environ. Microbiol.* 55(8):1925-1927.
5. Madden, J.M., 1992. Microbial pathogens in fresh produce - the regulatory perspective. *J. Food Prot.* 55(10):821-823.
6. Satchell, F.B., P. Stevenson, W.H. Andrews, L. Estela and G. Allen, 1990. The survival of *Shigella sonnei* in shredded cabbage. *J. Food Prot.* 53:558-562.
7. Steinbrugge, E.S., R.B. Maxcy and M.B. Liewen, 1988. Fate of *Listeria monocytogenes* on ready-to-serve lettuce. *J. Food Prot.* 51:596-599.

**3-303.11 Ice Used as Exterior Coolant, Prohibited as Ingredient.**

**3-303.12 Storage or Display of Food in Contact with Water or Ice.**

1. Andrews, W.H., C.R. Wilson, P.L. Poelma and A. Romero, 1977. Bacteriological survey of channel catfish *Ictalurus punctatus* at the retail level. *J. Food Sci.* 42:359-364.

**3-304.11 Food Contact with Equipment and Utensils.\***

1. Chia-Min, Lin, Cheng-I Wei\*, 1997. Transfer of *Salmonella montevideo* onto the Interior Surfaces of Tomatoes by Cutting, *J. Food Prot.* 60(7): 858-863.
2. Escartin, E.F., A.C. Ayala and J.S. Lozano, 1989. Survival and growth of *Salmonella* and *Shigella* on sliced fresh fruit. *J. Food Prot.* 52(7):471-472.
3. Golden, G.A., E.J. Rhodehamel and D.A. Kautter, 1993. Growth of *Salmonella* spp. in cantaloupe, watermelon, and honeydew melons. *J. Food Prot.* 56(3):194-196.
4. Humphrey, T.J., K.W. Martin, and A. Whitehead. 1994. Contamination of hands and work surfaces with *Salmonella enteritidis* PT4 during the preparation of egg dishes. *Epidemiol. Infect.* 113: 403-409.
5. Kim, H.U. and J.M. Goepfert, 1971. Occurrence of *Bacillus cereus* in selected dry food products. *J. Milk Food Technol.* 34:12-15.

6. Lopes, J.A., 1986. Evaluation of dairy and food plant sanitizers against ***Salmonella typhimurium and Listeria monocytogenes***. J. Dairy Sci. 69:2791-2796.
7. Reida, P., M. Wolff, H.W. Pohls, W. Kuhlmann, A. Legnacher, S. Aleksic, H. Karch, J. Bockemuh. 1994. An Outbreak Due to Enterohemorrhagic ***Escherichia coli*** O157/H7 in a Children Day-Care-Center Characterized by Person-to-Person Transmission and Environmental Contamination. Zentralblatt Fur Bakteriologie-International, Int. J. Med. Micro. Vir. Para. Infect. Dis. 28(4): 534-543.
8. Scott, Elizabeth and Sally F. Bloomfield. 1990. The Survival and Transfer of Microbial Contamination via Cloths, Hands, and Utensils. J. Appl. Bacteriol. 68: 271-278.

### **3-304.12 In-Use Utensils, Between-Use Storage.**

1. Food and Drug Administration, 1984. Food Preparation - Between-use storage of food preparation utensils (5/14/84). Retail Food Protection Program Information Manual.

### **3-304.14 Wiping Cloths, Limitation.**

1. Scott, Elizabeth and Sally F. Bloomfield. 1990. Investigations of the effectiveness of detergent washing, drying and chemical disinfection on contamination of cleaning cloths. J. Appl. Bacteriol. 68: 279-283.
2. Scott, Elizabeth and Sally F. Bloomfield. 1990. The Survival and Transfer of Microbial Contamination via Cloths, Hands and Utensils. J. Appl. Bacteriol. 68: 271-278.

### **3-304.15 Gloves, Use Limitation.**

1. Beezhold, Donald H., David A. Kostyal, and Jeffrey Wiseman. March 1994. The Transfer of Protein Allergens From Latex Gloves. AORN J. 59(3): 605-613.
2. Reddy, Sumana, M.D. January 1, 1998. Latex Allergy. Am. Fam. Phys. 57(1): 93-100.
3. Schwartz, Howard J., 1995, Latex: A potential hidden "food" allergen in fast food restaurants, J. Allergy Clin. Immunol. 95: 139-140.

4. Tomazic, Vesna J., Eric L. Shampaine, Anthony Lamanna, Thomas J. Withrow, Franklin N. Adkinson, Jr., and Robert G. Hamilton. April, 1994. Cornstarch Powder on Latex Products is an Allergen Carrier, *J. Allergy Clin. Immunol.* 93(4): 751-758.

### **3-304.17 Refilling Returnables.**

1. Food and Drug Administration, 1985. Food Protection - Refilling of take-home beverage containers (8/29/85). Retail Food Protection Program Information Manual.

### **3-306.13 Consumer Self-Service Operations.\***

1. Food and Drug Administration, 1984. Food Protection - Customer self-service of bulk food (4/16/84). Retail Food Protection Program Information Manual.

### **3-401.11 Raw Animal Foods.\***

1. Baker, R.C., 1990. Survival of *Salmonella enteritidis* on and in shelled eggs, liquid eggs, and cooked egg products. *Dairy Food Environ. Sanit.* 10(5):273-275.

2. Blankenship, L.E. and S.E. Craven, 1982. *Campylobacter jejuni* survival in chicken meat as a function of temperature. *Appl. Environ. Microbiol.* 44(1):88-92.

3. Bryan, F.L. and T.W. McKinley, 1979. Hazard analysis and control of roast beef preparation in foodservice establishments. *J. Food Prot.* 42(1):4-18.

4. Castellani, A.G., R.R. Clark, M.I. Gibson and D. F. Meisner, 1952. Roasting time and temperature required to kill food poisoning microorganisms introduced experimentally into stuffing in turkeys, *Food Res.* 18:131-138.

5. Centers for Disease Control, 1993. Update: Multistate outbreak of *Escherichia coli* O157:H7 infections from hamburgers - western United States, 1992, 1993. *Morb. Mortal. Wkly. Rep.* 42 (14):258-263.

6. Code of Federal Regulations, Title 9, Part 318.10, Prescribed Treatment of Pork and Products Containing Pork to Destroy Trichinae.

7. Doyle, M.P. and J.L. Schoeni, 1984. Survival and growth characteristics of *Escherichia coli* associated with hemorrhagic colitis. *Appl. Environ. Microbiol.* 48 (4):855-856.



8. Dubey, J.P., A.W. Kotula, A. Sharar, C.D. Andrews, and D.S. Lindsay, 1990. Effect of high temperature on infectivity of *Toxoplasma gondii* tissue cysts in pork. J. Parasitol., 76 (2):201-204.
9. Dubey, J.P., 1998. *Toxoplasma gondii* Oocysts Survival under Defined Temperatures. J. Parasitol. 84(4):862-865.
10. Goodfellow, S.J. and W.L. Brown, 1978. Fate of Salmonella inoculated into beef for cooking. J. Food Prot. 41(8):598-605.
11. Hague, M.A., K.E. Warren, M.C. Hunt, D.H. Kropf, C.L. Kastner, S.L. Stroda, and D.E. Johnson, 1994. Endpoint Temperature, Internal Cooked Color, and Expressible Juice Color Relationships in Ground Beef Patties, J. Food Sci. 59(3):465-470.
12. Kotula, A.W., K.D. Murell, L. Acosta-Stein and L. Lamb, 1983. *Trichinella spiralis*: Effect of high temperature on infectivity in pork. Exp. Parasitol. 56:15-19.
13. Line, J.E., A.R. Fain, Jr., A.B. Moran, L.M. Martin, R.V. Lechowich, J.M. Carosella and W.L. Brown, 1991. Lethality of heat to *Escherichia coli* O157:H7: D-value and Z-value determinations in ground beef. J. Food Prot. 54 (10):62-766.
14. Shah, D.B., J.G. Bradshaw and J.T. Peeler. 1991. Thermal resistance of egg-associated epidemic strains of *Salmonella enteritidis*. J. Food Sci. 56:391-393.
15. Smith, J.L., 1994. *Taenia solium* neurocysticercosis. J. Food Prot. 57(9): 831-844.
16. Smith, J.L., 1992. *Toxoplasma gondii* in meats - a matter of concern? Dairy Food Environ. Sanit. 12(6):341-345.
17. Ward, D.R. and C.R. Hackney, 1991. Microbiology of Marine Food Products. Van Nostrand Reinhold, New York. 212 pp.
18. Webster, R.C. and W.B. Esselen, 1956. Thermal resistance of food poisoning microorganisms in poultry stuffing. J. Milk Food Technol. 19:209-212.

### 3-401.12 Microwave Cooking.\*

1. Aleixa, J.A.G., B. Swaminathan, K.S. Jamesen and D.E. Pratt, 1985. Destruction of pathogenic bacteria in turkeys roasted in microwave ovens. *J. Food Sci.* 50:873-875, 880.
2. Czechowicz, S.M. 1996. Destruction of *Escherichia coli* O157:H7 in food and Non-Food Systems by Microwaves. Ph.D. Thesis. University of Minnesota. 241 pages.
3. Craven, S.E. and H.S. Lillard, 1974. Effect of microwave heating of precooked chicken on *Clostridium perfringens*. *J. Food Sci.* 39:211-212.
4. Dahl, C.A., M.E. Matthews and E.H. Marth, 1980. Fate of *Staphylococcus aureus* in beef loaf, potatoes and frozen and canned green beans after microwave heating in a simulated cook/chill hospital food service system. *J. Food Prot.* 43:916-923.
5. Heddleson, R.A. and S. Doores, 1993. Factors Affecting Microwave Heating of Foods and Microwave Induced Destruction of Food Pathogens - A Review. *J. Food Prot.* 57(11)1025-1037.
6. Heddleson, R.A., S. Doores, R.C. Anantheswaran, and G.D. Kuhn, 1993. Viability Loss of *Salmonella* Species, *Staphylococcus aureus*, and *Listeria monocytogenes* in Complex Foods Heated by Microwave Energy. *J. Food Prot.* 59(8)813-818.
7. Sawyer, C.A., S.A. Biglari, and S.S. Thompson, 1984. Internal end temperature and survival of bacteria on meats with and without a polyvinylidene chloride wrap during microwave cooking. *J. Food Sci.* 49(3):972-973.
8. Sawyer, C.A., 1985. Post-processing temperature rise in foods: Hot air and microwave ovens. *J. Food Prot.* 48(5):429-434.

### 3-402.11 Parasite Destruction.\*

1. Bier, J.W. 1976. Experimental Anisakiasis: Cultivation and Temperature Tolerance Determinations. *J. Milk Food Technol.* 39:132-137.
2. Deardorff, T.L., R.B. Raybourne, R.S. Desowitz, 1986. Behavior and viability of third stage larvae of *Terranova* (HA) and *Anisakis simplex* (Type 1) under coolant conditions. *J. Food Prot.* 47:49-52.

3. Deardorff, T.L. and R. Throm, 1988. Commercial blast-freezing kills third stage larvae of *Anisakis simplex* encapsulated in salmon and rockfish. J. Parasitol. 74:233-250.
4. Food and Drug Administration, 1987. Food Preparation - Raw, marinated or partially cooked fishery products. Retail Food Protection Program Information Manual (8/21/87).
5. Food and Drug Administration, 1998. Fish and Fishery Products Hazards and Controls Guide, Office of Seafood. 276 pp.
6. Gustafson, P.V. 1953. The effect of freezing on encysted Anisakis larvae. J. Parasitol. 39:585-588.
7. Haigashi, G.I., 1985. Foodborne parasites transmitted to man from fish and other aquatic foods. Food Technol. 39(3):69-74.
8. Jackson, G.L., 1990. Parasitic protozoa and worms relevant to the U.S. Food Technol. 44(5):106-112.
9. Kaneko, J., and P. Bartram, 1994. A position paper dated May 25, 1994 submitted to Dockets Management Branch, U.S. Food and Drug Administration in response to the proposed FDA HACCP program for seafood. See Part 4: Critical Review of FDA Position on Parasite Hazards in Tuna.
10. Ronald, K., 1960. The effects of physical stimuli on larval stages of *Terranova decipiens*. Can. J. Zool. 38:623-642.
11. Ruitenbergh, E.J., 1970. Anisakiasis: Pathogenesis, Serodiagnosis and Control. University of Utrecht, Netherlands. 138 pp.

**3-402.12 Records, Creation, and Retention.**

**3-403.11 Reheating for Hot Holding.\***

1. Bennett, R.W. and M.R. Berry, 1987. Serological activity and *in vitro* toxicity of *Staphylococcus aureus* enterotoxins A and D in selected canned foods. J. Food Sci. 52:416-418.
2. Bradshaw, J.G., J.T. Peeler and R.M. Twedt, 1979. Thermal inactivation of *Clostridium botulinum* toxins types A and B in buffer, and beef and mushroom patties. J. Food Sci. 44(6):1653-1657.

3. Craven, S.E., 1980. Growth and sporulation of ***Clostridium perfringens*** in foods. *Food Technol.* 34(4):80-87.
4. Food Refrigeration & Process Engineering Research Centre, reporting period 1 March 95 to 1 August 96. Determination of unsatisfactory temperature distributions within foods heated in microwave ovens. Measurement and Testing Programme (MTP), Framework 3, Part 2, contract number MATI-CT 940014, University of Bristol, UK.
5. Heddleson, R.A., S. Doores, R.C. Anantheswaran, and G.D. Kuhn, 1993. Viability Loss of ***Salmonella*** Species, ***Staphylococcus aureus***, and ***Listeria monocytogenes*** in Complex Foods Heated by Microwave Energy. *J. Food Prot.* 59(8):813-818.
6. Johnson, K.M., C.L. Nelson and F.F. Busta, 1983. Influence of temperature on germination and growth of spores of emetic and diarrheal strains of ***Bacillus cereus*** in growth medium and in rice. *J. Food Sci.* 48:286-287.
7. Licciardello, J.J., C.A. Ribich, J.T.R. Nickerson and S.A. Goldblith, 1967. Kinetics of the thermal inactivation of type E ***Clostridium botulinum*** toxin. *Appl. Microbiol.* 15(2):344-349.
8. Roy, R.J., F.F. Busta and D.R. Thompson, 1981. Thermal inactivation of ***Clostridium perfringens*** after growth at several constant and linearly rising temperatures. *J. Food Sci.* 46:1586-1591.
9. Woodburn, M.J., E. Somers, J. Rodriguez and E.J. Schantz, 1979. Heat inactivation rates of botulism toxin A, B, E, and F in some foods and buffers. *J. Food Sci.* 44:1658-1661.

**3-501.11 Frozen Food.**

**3-501.12 Potentially Hazardous Food (Time/Temperature Control for Safety Food), Slacking.**

**3-501.13 Thawing.**

1. Bryan, F.L. and T.W. McKinley, 1974. Prevention of foodborne illness by time-temperature control of thawing, cooking, chilling and reheating of turkeys in school lunch kitchens. *J. Milk Food Technol.* 37:420-429.

### **3-501.14 Cooling.\***

1. Blankenship, L.C., S.E. Craven, R.G. Leffler and C. Custer, 1988. Growth of *Clostridium perfringens* in cooked chili during cooling. *Appl. Environ. Microbiol.* 54(5):1104-1108.
2. Bryan, F.L., 1974. Identifying Foodborne Disease Hazards in Food Service Establishments. *J. Environ. Health* 36(6):537-540.
3. Bryan, F.L., 1979. Prevention of Foodborne Diseases in Food Service Establishments. *J. Environ. Health* 41(4):198-206.
4. Dickerson, R.W., Jr. and R.B. Read, Jr., 1973. Cooling rates of foods. *J. Milk Food Technol.* 36(3):167-171.
5. Juneja, V.K., O.P. Snyder, Jr., and M. Cygnarowicz-Provost. 1994. Influence of cooling rate on outgrowth of *Clostridium perfringens* spores in cooked ground beef. *J. Food Prot.* 57:(12):1063-1067.
6. Lewis, M.N., H.H. Weisner and A.R. Winter, 1953. Bacterial growth in chicken salad. *J. Am. Diet. Assoc.* 29:1094-1099.
7. Longrée, K. and J.C. White, 1955. Cooling rates and bacterial growth in food prepared and stored in quantity. I. Broth and white sauce. *J. Am. Diet. Assoc.* 31:124-132.
8. USDA/FSIS. 1999. Final Rule-Performance Standards for the Production of Certain Meat and Poultry Products. *Federal Register*, 64:(3):732-749.\*

### **3-501.15 Cooling Methods.**

1. Bryan, F.L., 1990. Application of HACCP to ready-to-eat chilled foods. *Food Technol.* 45(7):7077.
2. Rollin, J.L. and M.E. Matthews, 1977. Cook-chill foodservice systems: Temperature histories of a cooked beef product during the chilling process. *J. Food Prot.* 40:782-784.

**3-501.16 Potentially Hazardous Food (Time/Temperature Control for Safety Food), Hot and Cold Holding.\***

1. Abdul-Raouf, U.M., L.R. Beauchat and M.S. Ammar, 1993. Survival and growth of *Escherichia coli*:O157:H7 in ground roasted beef as affected by pH, acidulants, and temperature. *Appl. Environ. Microbiol.* 59(8):2364-2368.
2. Ahmed, A. A., M.K. Moustafa and E.H. Marth. 1983. Incidence of *Bacillus cereus* in milk and some milk products. *J. Food Prot.* 46:126-128.
3. Angelotti, R., M.J. Foter and K.L. Lewis, 1961. Time-temperature effects on Salmonellae and Staphylococci in foods. II. Behavior in warm holding temperatures. *Am. J. Public Health* 51:76-88.
4. Baxter R. and W.H. Holzappel. 1982. A microbial investigation of selected spices, herbs, and additives in South Africa. *J. Food Sci.* 47: 570-578.
5. Blankenship, L.C. Craven, S.C., Leffler, R. G. and C. Custer. 1988. Growth of *Clostridium perfringens* in cooked chilli during cooling. *Appl. Environ. Microbiol.* 54: 1104-1108.
6. Brown, D.F. and R.M. Twedt, 1972. Assessment of the sanitary effectiveness of holding temperatures on beef cooked at low temperature. *Appl. Microbiol.* 24: 599-603.
7. Bryan, F.L., C.A. Bartleson, and N. Christopherson. 1981. Hazard analyses, in reference to *Bacillus cereus*, of boiled and fried rice in Cantonese-style restaurants. *J. Food Prot.* 44:500-512.
8. Collee, J.G., Knolden, J.A. and B.C. Hobbs. 1961. Studies on the growth, sporulation and carriage of *Clostridium welchii* with special reference to food poisoning strains. *J. Appl. Bacteriol.* 24:326-329.
9. Craven, S.E. Blankenship, L.C. and J.L. McDonel. 1981. Relationship of sporulation, enterotoxin formation and spoilage during growth of *Clostridium perfringens* type A in cooked chicken. *Appl. Environ. Microbiol.* 41: 1184-1191.
10. Doyle, M.P., N.J. Bains, J.L. Schoeni and E.M. Foster, 1982. Fate of *Salmonella typhimurium* and *Staphylococcus aureus* in meat salads prepared with mayonnaise. *J. Food Prot.* 45:152-156.

---

\* Federal Register volume 64, number 3, January 6, 1999 Rules and Regulations, pp 732-749.

11. El-Sherbeeney, M.R., M.F. Saddik, H.E-L. Aly, and F.L. Bryan. 1985. Microbiological profile and storage temperatures of Egyptian rice dishes. *J. Food Prot.* 48: 39-43.
12. Fermanian, C., Fremy, M. and M. Claisse. 1994. Effect of temperature on the vegetative growth of type and field strains of *Bacillus cereus*. *Let. Appl. Microbiol.* 19: 414-418.
13. Hall, H.E. and R. Angelotti. 1965. *Clostridium perfringens* in meat and meat product. *Applied Microbiology.* 13: 352-354.
14. Johnson, K. M., Nelson, C. L. and F. F. Busta. 1983. Influence of temperature on germination and growth of spores of emetic and diarrheal strains of *Bacillus cereus* in a broth model and in rice. *J. Food Sci.* 48: 286-287.
15. Kim, H.U. and J.M. Goepfert. 1971. Occurrence of *Bacillus cereus* in selected dry food products. *J. Milk Food Technol.* 34:12-15.
16. Ladiges, W.C., J.F. Foster and W.M. Ganz. 1974. Incidence and viability of *Clostridium perfringens* in ground beef. *J.Milk Food Technol.* 37(12) 622-623.
17. Lillard, H.S. 1971. Occurance of *Clostridium perfringens* in boiler processing and further processing operations. *J. Food Science.* 36: 1008-1010.
18. Makukutu, C.A. and R.K. Guthrie, 1986. Survival of *Escherichia coli* in food at hot-holding temperatures. *J. Food Prot.* 49(7):496-499.
19. Mead, G.C. 1969. Growth and sporulation of *Clostridium welchii* in breast and leg muscle of poultry. *J. Appl Bacteriol.* 32:86-95.
20. Mead, P., L. Slutsker, V. Dietz, L. F. McCaig, J. S. Bresee, C. Shapiro, P. M. Griffin, and R. V. Tauxe. 1999. Food related illness and death in the United States. *Emerging Infect Dis* 5:607-625.
21. Mikolajcik, E. M., Kearney, J.W. and T. Kristofferson. 1973. Fate of *Bacillus cereus* in cultured and direct acidified skim milk and cheddar cheese. *J Milk Food Technol.* 36: 317-320.
22. Morita, T.N. and M.J. Woodburn. 1977. Stimulation of *Bacillus cereus* growth by protein in cooked rice combinations. *J. Food Sci.* 42 (5) 1232-1235.
23. Nakamura, M. and K.D. Kelly. 1968. *Clostridium perfringens* in dehydrated soups and sauces. *J. Food Science* 33:424-426.

24. Park, Y. and E.M. Mikolaicik. 1979. Effect of temperature on growth and alpha toxin production by ***Clostridium perfringens***. J Food Protect. 42:848-851.
25. Rusul, G. and N. H. Yaacob. 1995. Prevalence of ***Bacillus cereus*** in selected foods and detection of enterotoxin using TECRA-VIA and BCET-RPLA. Int. J. Food Microbiol. 25: 131-139.
26. Seals, J.E., J.D. Snyder, T.A. Edell et al., 1981. Restaurant associated botulism: transmission by potato salad. Am. J. Epidemiol. 113:436-444.
27. Shoemaker, S. P., and M. D. Pierson. 1976. "Phoenix phenomenon" in the growth of ***Clostridium perfringens***. Appl. Environ. Micro. 32(6): 803-807.
28. Smart, J.L., T.A. Roberts, M.F. Stringer, and N. Shah. 1979. The incidence and serotypes of ***Clostridium perfringens*** on beef, pork and lamb carcasses. J. Applied Bacteriology. 46:377-383.
29. Solomon, H.M. and D.A. Kautter, 1988. Outgrowth and toxin production by ***Clostridium botulinum*** in bottles of chopped garlic. J. Food Prot. 51(11):862-865.
30. Strong, D., J.C. Canada and B. Griffiths. 1962. Incidence of ***Clostridium perfringens*** in American foods. Appl. Microbiol. 11:42-44.
31. Strong, D.H. and N.M. Ripp, 1967. Effect of cooking and holding on hams and turkey rolls contaminated with ***Clostridium perfringens***. Appl. Microbiol. 15:1172-1177.
32. Willardsen, R.R., F.F. Busta, C.E. Allen and L.B. Smith, 1978. Growth and survival of ***Clostridium perfringens*** during constantly rising temperatures. J. Food Sci. 43:470-475.
33. Willardsen, R.R., Busta, F.F., Allen, C.E. 1979. Growth of ***Clostridium perfringens*** in three different beef media and fluid thioglycollate medium at static and constantly rising temperatures. J. Food Protect. 42: 144-148.
- 3-501.17 Ready-to-Eat, Potentially Hazardous Food (Time/Temperature Control for Safety Food), Date Marking.\***
- 3-501.18 Ready-to-Eat, Potentially Hazardous Food (Time/Temperature Control for Safety Food), Disposition.\***
1. Chen, Y., W.H. Ross, V.N. Scott, V.N. and D.E. Gombas, 2003. ***Listeria monocytogenes***: Low Levels Equal Low Risk. J. Food Prot. 66(4):570-577.



2. Code of Federal Regulations, Title 21, Part 114 Acidified foods.
3. Code of Federal Regulations, Title 21, Part 133 Cheeses and related cheese products.
4. Code of Federal Regulations, Title 9, Part 430. 2003. Control of ***Listeria monocytogenes*** in Ready-to-Eat Meat and Poultry Products.
5. Code of Federal Regulations, Title 21, Part 110 Current good manufacturing practice in manufacturing, packing, or holding human food.
6. Code of Federal Regulations, Title 9, Part 317 Labeling, marking devices, and containers.
7. Code of Federal Regulations, Title 21, Part 131 Milk and cream.
8. Food and Drug Administration/CDC, 2003. Reducing the Risk of *Listeria monocytogenes*, 2003 Update of the Listeria Action Plan, found at <http://www.cfsan.fda.gov/~dms/lmr2plan.html>.
9. Food and Drug Administration/USDA/CDC, 2003. Quantitative Assessment of the Relative Risk to Public Health from Foodborne ***Listeria monocytogenes*** Among Selected Categories of Ready-to-Eat Foods, found at <http://www.foodsafety.gov/~dms/lmr2-toc.html>.
10. Food and Drug Administration Docket No. 99N-1168 and FSIS Docket No. 00-048N, 2001. Draft Assessment of the Relative Risk to Public Health from Foodborne ***Listeria monocytogenes*** Among Selected Categories of Ready-to-Eat Foods, found at <http://www.foodsafety.gov/~dms/lmrisk.html>.
11. Food and Drug Administration, 1999. Date Marking of Cheese. Retail Food Protection Team Program Information Manual (12/15/99), found at <http://www.cfsan.fda.gov/~ear/ret-chdt.html>.
12. Genigeorgis, C., M. Carniciu, D. Dutulescu and T.B. Farver, 1991. Growth and Survival of ***Listeria monocytogenes*** in Market Cheeses Stored at 4 to 30°C. J. Food Prot. 54(9):662-668.
13. Gombas, D.E., Y. Chen, R. Clavero, R. and V.N. Scott, V.N, 2003. Survey of ***Listeria monocytogenes*** in Ready-to-Eat Foods. J. Food Prot. 66(4):559-569.
14. Palumbo, S.A., 1986. Is refrigeration enough to restrain foodborne pathogens? J. Food Prot. 49(12):1003-1009.

15. Rosso, L., S. Bajard, J.P. Flandrois, C. Lahellec, J. Fournaud and P. Veit, 1996. Differential Growth of *Listeria monocytogenes* at 4 and 8°C: Consequences for the Shelf Life of Chilled Products, *J. Food Prot.* 59:944-949.
16. Ryser, E.T., E.H. Marth, 1987. Behavior of *Listeria monocytogenes* during the Manufacture and Ripening of Cheddar Cheese. *J. Food Prot.* 50(1):7-13.
17. Steinbruegge, E.D., R.B. Maxcy and M.B. Liewen, 1988. Fate of *Listeria monocytogenes* on ready to serve lettuce. *J. Food Prot.* 51:596-599.
18. USDA Agricultural Research Service. Pathogen Modeling Program Version 7.0. Microbial Food Safety Research Unit, Wyndmoor, PA., found at <http://www.arserrc.gov/mfs/pathogen.htm>.
19. USDA/FSIS, Directive 10.240.4. 2003. Verification Procedures for the *Listeria monocytogenes* Regulation and Microbial Sampling of Ready-to-Eat (RTE) Products for the FSIS Verification Testing Program, found at [http://www.fsis.usda.gov/OPPDE/rdad/FSISDirectives/10240.4/10240\\_4Int.pdf](http://www.fsis.usda.gov/OPPDE/rdad/FSISDirectives/10240.4/10240_4Int.pdf).
20. Wallace, F.M., J.E. Call, A.C.S. Porto, G.J. Cocoma, ERRC Special Project Team, and J.B. Luchansky, 2003. Recovery Rate of *Listeria monocytogenes* from Commercially Prepared Frankfurters during Extended Refrigerated Storage. *J. Food Prot.* 66(4):584-591.
21. Yousef, A.E. and E.H. Marth, 1988. Behavior of *Listeria monocytogenes* during the Manufacture and Storage of Colby Cheese. *J. Food Prot.* 51(1):12-15.

### **3-501.19 Using Time as a Public Health Control.\***

1. Bryan, F. L. and E. G. Kilpatrick, 1971. *Clostridium perfringens* related to roast beef cooking, storage and contamination in a fast food service restaurant. *Am. J. of Public Health.* 61 (9): 1869-1885.
2. Conference for Food Protection, Council III Committee Report, 2004. Time as a Public Health Control, Conference for Food Protection, Gilroy, CA., found at [http://www.foodprotect.org/2004\\_attachments.html](http://www.foodprotect.org/2004_attachments.html).
3. Doan, C. H. and P. M. Davidson, 1999. Growth of *Bacillus cereus* on Oil-Blanched Potato Strips for “Home-Style” French Fries. *J. Food Sci.* 64:909-912.
4. Doan, C. H. and P. M. Davidson, 1999. Growth and Production of Enterotoxin A by *Staphylococcus aureus* on “Home-Style” French Fries. *J. Food Sci.* 64:913-917.

5. Ferguson, R. D. and L.A. Shelef, 1990. Growth of *Listeria monocytogenes* in soy milk. *Food Micro.* 7: 49-52.
6. ICMSF, 1996. *Microorganisms in Foods 5. Characteristics of Microbial Pathogens.* Chapter 2 *Bacillus Cereus*. P20-35. Blackie Academic & Professional, London.
7. ICMSF, 1996. *Microorganisms in Foods 5. Characteristics of Microbial Pathogens.* Chapter 6 *Clostridium perfringens*. P112-125. Blackie Academic & Professional, London.
8. Johnson, K.M., C.L. Nelson and F.F. Busta, 1983. Influence of temperature on germination and growth of spores of emetic and diarrheal strains of ***Bacillus cereus*** in growth medium and in rice. *J. Food Sci.* 48:286-287.
9. Mead, P.S., L. Slutsker, V. Dietz, L.F. McCaig, J.S. Bresee, C. Shapiro, P. Griffen, and R.V. Tauxe, 1999. Food related illness and death in the United States. *Emerging Infectious Disease.* 5 (5): 607-625.
10. Melling, J. and B.J. Capel, 1978. Characteristics of *Bacillus cereus* toxin. *FEMS Micro Letters.* 4:133-135.
11. Sionkowski, P.J. and L.A. Shelef, 1990. Viability of *Listeria monocytogenes* strain Brie-1 in the avian egg. *J. Food Prot.* 53 (1): 15-17.
12. Solomon, H.M. and D.A. Kautter, 1986. Growth and toxin production by ***Clostridium botulinum*** in sauteed onions. *J. Food Prot.* 49(10):618-620.
13. Solomon, H.M. and D.A. Kautter, 1988. Outgrowth and toxin production by ***Clostridium botulinum*** in bottled chopped garlic. *J. Food Prot.* 51(11):862-865.
14. Tatini, S.R., 1973. Influence of food environments on growth of ***Staphylococcus aureus*** and production of various enterotoxins. *J. Milk Food Technol.* 36(11):559-563.
15. USDA Agriculture Agricultural Research Service. Pathogen Modeling Program Version 7.0. Microbial Food Safety Research Unit, Wyndmoor, PA., found at [www.arserrc.gov/mfs/](http://www.arserrc.gov/mfs/).

### **3-502.11 Variance Requirement.\***

1. Barber, F.E. and R.H. Deibel, 1972. Effect of pH and oxygen tension on Staphylococcal growth and enterotoxin formation in fermented sausage. *Appl. Microbiol.* 24:891-898.

2. Dickerson, R.W. and R.B. Read. 1968. Calculations and measurement of heat transfer in foods. *Food Technol.* 22:1533.
3. Dickerson, R.W. and R.B. Read, 1973. Cooling rates in foods. *J. Milk Food Technol.* 36(3):167-171.
4. Food and Drug Administration, 1999. Guidance for Industry: Reducing Microbial Food Safety Hazards for Sprouted Seeds, Washington, D.C., found at <http://www.cfsan.fda.gov/~dms/sprougd1.html>.
5. Food and Drug Administration, 1999. Guidance for Industry: Sampling and Microbial Testing of Spent Irrigation Water During Sprout Production, Washington, D.C., found at <http://www.cfsan.fda.gov/~dms/sprougd2.html>.
6. Montville, R. and D.W. Schaffner, 2004. Analysis of Published Sprout Seed Sanitation Studies Shows Treatments Are Highly Variable. *J. Food Prot.* 67(4): 758-765.
7. National Advisory Committee on Microbiological Criteria for Foods, 1992. Hazard analysis and critical control point system. *Int. J. Food Microbiol.* 16:1-23.
8. Pierson, M.D. and D. A. Corlett Jr. (Eds.) 1992. HACCP Principles and Applications. Van Nostrand Reinhold, New York. 212 pp.
9. Shigehisa, T., T. Nakagami and S. Taji, 1985. Influence of heating and cooling rates on spore germination and growth of *Clostridium perfringens* in media and in roast beef. *Jpn. J. Vet. Sci.* 47(2):259.
10. Snyder, O.P., Jr., 1986. Applying the Hazard Analysis and Critical Control Points system in foodservice and foodborne illness prevention. *J. Foodservice Systems* 4:125-131.
11. Sperber, W.H., 1982. Requirements of *Clostridium botulinum* for growth and toxin production. *Food Technol.* 36(12):89-94.
12. Tanaka, N., 1982. Challenge of pasteurized process cheese spreads with *Clostridium botulinum* using in-process and post-process inoculation, *J. Food Prot.* 45:1044-1050.
13. Troller, J.A., 1972. Effect of water activity on enterotoxin A production and growth of *Staphylococcus aureus*. *Appl. Microbiol.* 24(3):440-443.

### 3-502.12 Reduced Oxygen Packaging, Criteria.\*

1. Association of Food and Drug Officials, 1990. Retail guidelines - Refrigerated foods in reduced oxygen packages. *J. Assoc. Food Drug Offic.* 54(5):80-84.
2. Aureli, P., M. Di Cunto, A. Maffei, G. De Chiara, G. Fransiosa, L. Accorinti, A.M. Gambardella, and D. Greco. 2000. An outbreak in Italy of botulism associated with a dessert made with mascarpone cream cheese. *Europ. J. Epidemiol.* 16:913-918.
3. Bennett, R.W. and W.T. Amos, 1982. ***Staphylococcus aureus*** growth and toxin production in nitrogen packed sandwiches. *J. Food Prot.* 45(2):157-161.
4. Berrang, M.E., R.E. Brackett and L.R. Beuchat, 1989. Growth of ***Listeria monocytogenes*** on fresh vegetables under controlled atmosphere. *J. Food Prot.* 52:702-705.
5. Briozzo, J., E.A. de Lagarde, J. Chirife, and J.L. Parada. 1983. ***Clostridium botulinum*** Type A growth and toxin Production in media and process cheese spread. *Appl. and Env. Microbiol.* 45:1150-1152.
6. Code of Federal Regulations, Title 21, Part 133 Cheeses and Related Cheese Products.
7. Code of Federal Regulations, Title 9, Part 424 Preparation and Processing Operations, Use of food ingredients and sources of radiation.
8. Conner, D.E., V.N. Scott, D.T. Bernard and D.A. Kautter, 1989. Potential ***Clostridium botulinum*** hazards associated with extended shelf-life refrigerated foods: A review. *J. Food Safety* 10:131-153.
9. Davis, H., J.P. Taylor, J.N. Perdue, G.N. Stelma, Jr., J.M. Humphreys, Jr., R. Roundtree III, and K.D. Greene, 1988. A shigellosis outbreak traced to commercially distributed shredded lettuce. *Am. J. Epidemiol.* 128(6):1312-1321.
10. Doyle, M. P. 1991. Evaluating the potential risk from extended shelf-life refrigerated foods by ***Clostridium botulinum*** inoculation studies. *Food Tech.* 154-156.
11. Farber, J.M. and K.L. Dodd's (Eds.). 1995. Principles of Modified – Atmosphere and Sous Vide Product Packaging. Technomic Publishing Company, Inc., Lancaster, PA 17604.
12. Gill, C.O. and K.M. Delacy, 1991. Growth of ***Escherichia coli*** and ***Salmonella typhimurium*** on high-pH beef packaged under vacuum or carbon dioxide. *Int. J. Food Microbiol.* 13:21-30.

13. Glass, K.A. and E.A. Johnson. 2004. Factors that contribute to the botulinal safety of reduced-fat and fat-free process cheese products. *J. Food Prot.* 67:1687-1693.
14. Gould, G.W. 1999. Sous vide foods: Conclusions of an ECFF botulinum working party. *Food Control* 10. 47-51.
15. Grau, F.H. and P.B. Vanderline, 1990. Growth of ***Listeria monocytogenes*** on vacuum packaged beef. *J. Food Prot.* 53:739-741, 746.
16. Johnson, E.A., J.H. Nelson, and M. Johnson. 1990. Microbiology safety cheese made from heat-treated milk, Part 1 Executive summary, introduction and history. *J. Food Prot.* 53:441-452.
17. Juneja, Vijay, Stefan T. Martin and Gerald M. Sapers, 1998. Control of ***Listeria monocytogenes*** in Vacuum-Packaged Pre-Peeled Potatoes. *J. Food Science* 63(5):911-914.
18. Kautter, D.A., 1964. ***Clostridium botulinum*** type E in smoked fish. *J. Food Sci.* 29:843-849.
19. Marth, Elmer H., 1998. Extended Shelf Life Refrigerated Foods: Microbiological Quality and Safety. *Food Technology* 5(2):57-62.
20. National Advisory Committee on Microbiological Criteria for Foods. 1990. Refrigerated foods containing cooked, uncured meat or poultry products that are packaged for extended refrigerated shelf life and that are ready-to-eat or prepared with little or no additional heat treatment. Washington, DC, found at [http://www.fsis.usda.gov/OPHS/nacmcf/past/rec\\_rte1990.pdf](http://www.fsis.usda.gov/OPHS/nacmcf/past/rec_rte1990.pdf).
21. New York Department of Agriculture and Markets, 1993. Guidelines for Reduced Oxygen Packaging at Retail. Division of Food Safety and Inspection, 1 Winners Circle, Albany, NY 12235, 2 pp.
22. Nolan, D.A., D.C. Chamblin, and J.A. Troller, 1992. Minimal water activity for growth and survival of ***Listeria monocytogenes*** and ***Listeria innocua***. *Int. J. Food Microbiol.* 16:323-335.
23. Olarte, C., E. González-Fandos, M.Giménez, S. Sanz and J. Portu. 2002. The growth of *Listeria monocytogenes* in fresh goat cheese (Cameros cheese) packaged under modified atmospheres. *Food Microbiol.* 19, 75-82.
24. Pourshafie, M.R., M. Saifie, A. Shafiee, P. Vahdani, M. Aslani, and J.Salemian. 1998. An outbreak of food-borne Botulism associated with contaminated locally made cheese in Iran. *Scand. J. Infect.* 30:92-94.

25. Refrigerated Foods and Microbiological Criteria Committee of the National Food Processors Association, 1988. Factors to be Considered in Establishing Good Manufacturing Practices for the Production of Refrigerated Foods. *Dairy and Food Sanitation*, 8(6):288-291.
26. Refrigerated Foods and Microbiological Criteria Committee of the National Food Processors Association, 1988. Safety Considerations for New Generation Refrigerated Foods. *Dairy and Food Sanitation*, 8(1):5-7.
27. Smelt, J.P.P., G.J.M. Raatjes, J.S. Crowther, and C.T. Verrips. 1981. Growth and toxin formation by ***Clostridium botulism*** at low pH values. *J. Appl. Bact.* 52:75-82.
28. Townes, J. M., P. R. Cieslak, MD., C. L. Hatheway, PhD., H.M. Solomon, MS., J. T. Holloway, MD., M. P. Baker, MD., C. F. Keller, BS., L. M. McCrosky, BS., and P.M. Griffin, MD. 1996. An outbreak of Type A Botulism associated with a commercial cheese sauce. *Ann. Int. Med.* 125:558-563.
29. Whitley, E., D. Muir and W.M. Waites. 2000. The growth of ***Listeria monocytogenes*** in cheese packed under a modified atmosphere. *J. of Appl. Microbiol.* 88, 52-57.

- 3-601.11 Standards of Identity.**  
**3-601.12 Honestly Presented.**  
**3-602.11 Food Labels.**  
**3-602.12 Other Forms of Information.**  
**3-603.11 Consumption of Raw or Undercooked Animal Foods.\***

1. Centers for Disease Control, 1993. Update: Multistate outbreak of ***Escherichia coli*** O157:H7 infections from hamburgers - western United States, 1992,1993. *Morb. Mortal. Wkly. Rep.* 42(14):258-263.
2. Code of Federal Regulations, Title 9, Part 319 Definitions and standards of identity or composition.
3. Code of Federal Regulations, Title 21, Part 101 – Food labeling.
4. Code of Federal Regulations, Title 9, Part 317 Labeling, marking devices, and containers.
5. Federal Food, Drug, and Cosmetic Act, Sec. 403(q)(3)-(5), nutrition labeling.

6. Morris, J.G., Jr. 1988. ***Vibrio vulnificus***: A new monster of the deep? Ann. Intern. Med. 109:261-263.
7. Potter, M.E., A.F. Kauffmann, P.A. Blake and R.A. Feldman, 1984. Unpasteurized milk: The hazards of a health fetish. J. Am. Med. Assoc. 252:2048-2052.
8. St. Louis, M., et al. 1988. The emergence of Grade A eggs as a major source of ***Salmonella enteritidis*** infections. J. Am. Med. Assoc. 259:2103-2107.
9. Tacket, C.O., L.B. Dominguez, H.J. Fisher, and M.L. Cohen, 1985. An outbreak of multiple-drug-resistant ***Salmonella enteritidis*** from raw milk. J. Am. Med. Assoc. 253:2058-2060.

### 3-801.11 Pasteurized Foods, Prohibited Reservice, and Prohibited Food.\*

1. Besser, R.E., S.M. Lett, J.T. Webber, M.P. Doyle, T.J. Barrett, J.G. Wells, and P.M. Griffin, 1993. An Outbreak of Diarrhea and Hemolytic Uremic Syndrome From ***Escherichia coli*** O157H:7 in Fresh-Pressed Apple Cider. J. Am. Med. Assoc., 269(17):2217-2220.
2. Code of Federal Regulations, Title 21, Part 120 Hazard Analysis and Critical Control Point (HACCP): Procedures for the Safe and Sanitary Processing and Importing of Juice, found at <http://www.cfsan.fda.gov/~lrd/fr01119a.html>.
3. Conner, D.E., and J.S. Kotrola. Growth and Survival of ***Escherichia coli*** O157H:7 under Acidic Conditions. Applied and Environmental Microbiology, January, 1995, pp. 382-385.
4. Goverd, K.A., F.W. Beech, R.P. Hobbs and R. Shannon, 1979. The occurrence and survival of coliforms and salmonellas in apple juice and cider. J. Appl. Bacteriol. 46:521-530.
5. Humphrey, T.J., K.W. Martin, and A. Whitehead. 1994. Contamination of hands and work surfaces with ***Salmonella enteritidis*** PT4 during the preparation of egg dishes. Epidemiol. Infect. 113: 403-409.
6. Miller, L.G., and C.W. Kaspar, 1994. ***Escherichia coli*** O157:H7 Acid Tolerance and Survival in Apple Cider. J. Food Pro. 57(6):460-464.
7. Zhao, T., M.P. Doyle and R.E. Besser, 1993. Fate of enterohemorrhagic ***Escherichia coli*** O157:H7 in apple cider with and without preservatives. Appl. Environ. Microbiol. 59(8): 2526-2530.



## Chapter 4 Equipment, Utensils, and Linens

### 4-101.13 Lead, Use Limitation.

1. Food and Drug Administration, 2003. COMPLIANCE PROGRAM GUIDANCE MANUAL, PROGRAM 7304.019, Toxic Elements in Food and Foodware, and Radionuclides in Food – Import and Domestic, CHAPTER 04 – PESTICIDE AND CHEMICAL CONTAMINANTS, found at <http://www.cfsan.fda.gov/~comm/cp04019.html>.
2. Food and Drug Administration, 1995. Compliance Policy Guide Section 545.450 Pottery (Ceramics); Imported and Domestic – Lead Contamination (CPG 7117.07), found at [http://www.fda.gov/ora/compliance\\_ref/cpg/cpgfod/cpg545-450.html](http://www.fda.gov/ora/compliance_ref/cpg/cpgfod/cpg545-450.html).
3. Food and Drug Administration, 1998. Dangers of Lead Still Linger. FDA Consumer, January-February 1998, found at <http://www.cfsan.fda.gov/~dms/fdalead.html>.

### 4-101.14 Copper, Use Limitation.\*

1. Low, B.A., J.M. Donahue, and C.B. Bartley, 1996. FINAL REPORT - A STUDY ON BACKFLOW PREVENTION ASSOCIATED WITH CARBONATORS. NSF, International, Ann Arbor, MI. pp. 18-20.
2. Peterson, C.S., 1979. Microbiology of Food Fermentation, 2nd Ed. AVI Publishing Co., Inc., Westport, Connecticut, pp. 288-293.

### 4-101.16 Sponges, Use Limitation.

1. Enriquez, C.E., R. Enriquez-Gordillo, D.I. Kennedy, and C.P. Gerba, January, 1997. Bacteriological Survey of Used Cellulose Sponges and Cotton Dishcloths from Domestic Kitchens. Dairy, Food and Environmental Sanitation, Vol. 17, No. 1, pp. 20-24.

#### **4-101.17 Wood, Use Limitation.**

1. Abrishami, S.H., B.D. Tall, T.J. Bruursema, P.S. Epstein and D.B. Shah. Bacterial Adherence and Viability on Cutting Board Surfaces. Department of Microbiology, NSF International, Ann Arbor, MI and Division of Microbiological Studies, Center for Food Safety and Applied Nutrition, U.S. Food and Drug Administration, Washington, D.C. *Journal of Food Safety* 14 (1994) 153-172.
2. Agricultural Research Service, U.S. Department of Agriculture. ARS Affirms Plastic Cutting Board Policies. *Food Chemical News*, December 6, 1993, pp. 56-57.
3. Code of Federal Regulations, Title 21, Part 178.3800 Preservatives for wood.

#### **4-501.13 Microwave Ovens.**

1. Code of Federal Regulations, Title 21, Part 1030.10 Microwave ovens.

#### **4-501.114 Manual and Mechanical Warewashing Equipment, Chemical Sanitization - Temperature, pH, Concentration, and Hardness.\***

1. Code of Federal Regulations, Title 21, Part 1030.10 Microwave ovens.
2. Code of Federal Regulations, Title 40, Part 180.940 Tolerance exemptions for active and inert ingredients for use in antimicrobial formulations (food-contact surface sanitizing solutions), found at [http://www.access.gpo.gov/nara/cfr/waisiox\\_04/40cfr180\\_04.html](http://www.access.gpo.gov/nara/cfr/waisiox_04/40cfr180_04.html).
3. Miller, M.P., Principal Investigator, 1984. Relationship of Factors Affecting Bactericidal Effectiveness of Chlorine Sanitizing Solutions. Final Report. National Sanitation Foundation, Ann Arbor, MI., subcontract No. 9013-092-108-H0620-101; Booz, Allen & Hamilton, Inc. contract No. 223-80-2295.
4. Miller, M.P., Principal Investigator, 1985. Relationship of Factors Affecting Bactericidal Effectiveness of Chlorine Sanitizing Solutions. Addendum to Final Report. National Sanitation Foundation, Ann Arbor, MI., subcontract No. 9013-092-108-H0620-101; Booz, Allen & Hamilton, Inc. contract No. 223-80-2295.
5. National Sanitation Foundation, Ann Arbor, MI. November, 1990. Report on the Bacterial Effectiveness of a Chlorine Sanitizing Solution at Contact Times of Less than Ten Seconds. Purchase Order #FDA 665531-00-90-RB.

#### **4-602.11 Equipment Food-Contact Surfaces and Utensils.\***

1. Tauxe, R.V., M.D., Chief, Foodborne and Diarrheal Diseases Branch, Division of Bacterial and Mycotic Diseases, National Center for Infectious Disease and M.L. Cohen, M.D., Director, Division of Bacterial and Mycotic Diseases, National Center for Infectious Diseases, memo dated January 10, 1996 re: "Bacterial Contamination of Iced Tea," to State and Territorial Epidemiologists and State and Territorial Public Health Laboratory Directors. Memo includes two fact sheets by the Tea Association of the U.S.A., Inc.

#### **4-603.17 Returnables, Cleaning for Refilling.\***

1. Food and Drug Administration, 1985. Food Protection - Refilling of take-home beverage containers (8/29/85). Retail Food Protection Program Information Manual.

#### **4-703.11 Hot Water and Chemical.\***

1. Miller, M.P., Principal Investigator, 1984. Relationship of Factors Affecting Bactericidal Effectiveness of Chlorine Sanitizing Solutions. Final Report. National Sanitation Foundation, Ann Arbor, MI., subcontract No. 9013-092-108-H0620-101; Booz, Allen & Hamilton, Inc. contract No. 223-80-2295.

2. Miller, M.P., Principal Investigator, 1985. Relationship of Factors Affecting Bactericidal Effectiveness of Chlorine Sanitizing Solutions. Addendum to Final Report. National Sanitation Foundation, Ann Arbor, MI., subcontract No. 9013-092-108-H0620-101; Booz, Allen & Hamilton, Inc. contract no. 223-80-2295.

3. National Sanitation Foundation, Ann Arbor, MI. November, 1990. Report on the Bacterial Effectiveness of a Chlorine Sanitizing Solution at Contact Times of Less than Ten Seconds. Purchase Order #FDA 665531-00-90-RB.

#### **4-901.11 Equipment and Utensils, Air-Drying Required.**

1. Code of Federal Regulations, Title 40, Part 180.940 Tolerance Exemptions for Active and Inert Ingredients for Use in Antimicrobial Formulations (food-contact surface sanitizing solutions), before contact with food.

## Chapter 5 Water, Plumbing, and Waste

1. Code of Federal Regulations, Title 40, Part 180.940 Tolerance Exemptions for Active and Inert Ingredients for Use in Antimicrobial Formulations (food-contact surface sanitizing solutions), before contact with food.
2. Code of Federal Regulations, Title 21, Part 129 – Processing and Bottling of Bottled Drinking Water.
3. International Association of Plumbing and Mechanical Officials, 2003 Uniform Plumbing Code, Walnut, CA. Available for sale at <http://publications.iapmo.org/categories.asp?id=1>.
4. International Code Council. 2003 International Plumbing Code, Falls Church, VA. Available for sale at <http://www.iccsafe.org/e/prodcat.html?catid=C-P&pcats=ICCSafe.MP&stateInfo=nTMTVilbdXdaLjAa6624I4>.

### **5-202.12 Handwashing Facility, Installation.**

1. American Society for Testing and Materials, Designation: E 1838-02, Standard Test Method for Determining the Virus-Eliminating Effectiveness of Liquid Hygienic Handwash and Handrub Agents Using the Fingerpads of Adult Volunteers. ASTM, Philadelphia, PA.
2. American Society for Testing and Materials, Designation: E 2011-99, Standard Test Method for Evaluation of Handwashing Formulations for Virus-Eliminating Activity Using the Entire Hand. ASTM, Philadelphia, PA.
3. American Society for Testing and Materials, Designation: E 1327-90 (reapproved 2000), Standard Test Method for Evaluation of Health Care Personnel Handwash Formulations by Utilizing Fingernail Regions. ASTM, Philadelphia, PA.
4. American Society for Testing and Materials, Designation: E 1174-00, Standard Test Method for Evaluation of Health Care Personnel or Consumer Handwash Formulations. ASTM, Philadelphia, PA.
5. Code of Federal Regulations, Title 21, Part 129 Processing and Bottling of Drinking Water.

## Chapter 6 Physical Facilities

### 6-202.15 Outer Openings, Protected.

1. National Fire Protection Association, NFPA 101 Life Safety Code, 2003 Edition, Quincy, MA. Available for sale at <http://www.nfpa.org/Catalog/category.asp?%5Fname=codes+and+standards&page=2&src=catalog>.

2. National Fire Protection Association, NFPA 101 Life Safety Code Handbook, 2003 Edition, Quincy, MA.

### 6-303.11 Intensity.

1. Illuminating Engineering Society of North America, 2000. Lighting Handbook, 9th Ed., IESNA Publications Dept., New York, NY. 900+ pp.

## Chapter 7 Poisonous or Toxic Materials

### 7-202.12 Conditions of Use.\*

1. Federal Insecticide, Fungicide, and Rodenticide Act, 7 USC 136 Definitions, (e) Certified Applicator, of the Federal Insecticide, Fungicide, and Rodenticide Act found at <http://www.epa.gov/opp00001/regulating/fifra.pdf>.

### 7-204.11 Sanitizers, Criteria.\*

1. Code of Federal Regulations, Title 40, Part 180.940 Tolerance exemptions for active and inert ingredients for use in antimicrobial formulations (food-contact surface sanitizing solutions).

### 7-204.12 Chemicals for Washing Fruits and Vegetables, Criteria.\*

1. Code of Federal Regulations, Title 21, Part 173.315, Chemicals used in washing or to assist in the peeling of fruits and vegetables.

**7-204.13 Boiler Water Additives, Criteria.\***

2. Code of Federal Regulations, Title 21, Part 173.310, Boiler water additives.

**7-204.14 Drying Agents, Criteria.\***

1. Code of Federal Regulations, Title 21, Part 184, Direct Food Substances Affirmed as Generally Recognized as Safe.
2. Code of Federal Regulations, Title 21, Parts 175, Indirect Food Additives: Adhesives and Components of Coatings.
3. Code of Federal Regulations, Title 21, Parts 178, Indirect Food Additives: Adjuvants, Production Aids, and Sanitizers.
4. Code of Federal Regulations, Title 21, Parts 176, Indirect Food Additives: Paper and Paperboard Components.
5. Code of Federal Regulations, Title 21, Parts 177, Indirect Food Additives: Polymers.
6. Code of Federal Regulations, Title 21, Part 186, Indirect Food Substances Affirmed as Generally Recognized as Safe.
7. Code of Federal Regulations, Title 21, Part 181, Prior-Sanctioned Food Ingredients.
8. Code of Federal Regulations, Title 21, Part 182, Substances Generally Recognized as Safe.
9. Code of Federal Regulations, Title 21, Part 170.39, Threshold of regulation for substances used in food-contact articles.

**7-205.11 Incidental Food Contact, Criteria.\***

1. Code of Federal Regulations, Title 21, Part 178.3570, Lubricants with incidental food contact.

## **7-206.11 Restricted use Pesticides, Criteria.\***

1. Code of Federal Regulations, Title 40, Part 152 Subpart I, Classification of Pesticides.

### **3. SUPPORTING DOCUMENTS**

FDA is providing the following guidance documents for reference. A brief summary for each document is provided.

- A. (Draft) Recommended National Retail Food Regulatory Program Standards
- B. FDA Procedures for Standardization and Certification of Retail food Inspection/Training Officers
- C. Managing Food Safety: A Manual for the Voluntary Use of HACCP Principles for Operators of Food Service and Retail Establishments
- D. Managing Food Safety: A Regulator's Manual for Applying HACCP Principles to Risk-based Retail and Food Service Inspections and Evaluating Voluntary Food Safety Management Systems
- E. Food Establishment Plan Review Guide
- F. FDA Report on the Occurrence of Foodborne Illness Risk Factors in Selected Institutional Foodservice, Restaurant, and Retail Food Store Facility Types (2004)
- G. Growing Sprouts in a Retail Food Establishment
- H. Advisories for Retail Processing with Proper Controls and Variances for Product Safety
- I. Evaluation and Definition of Potentially Hazardous Foods
- J. The U.S. Equal Employment Opportunity Commission (EEOC) Guide, "How to Comply with the Americans with Disabilities Act: A Guide for Restaurants and Other Food Service Employers"
- K. Guidance for Retail Facilities Regarding Beef Grinding Logs Tracking Supplier Information
- L. Recommended Guidelines for Permanent Outdoor Cooking Establishments, 2003
- M. Comprehensive Guidelines for Food Recovery Programs

A. (Draft) Recommended National Retail Food Regulatory Program Standards

This document can be found at the web site <http://www.cfsan.fda.gov/~dms/ret-toc.html> and was formulated from ideas and input by Federal, State, and local regulatory officials, industry, trade and professional associations, academia, and consumers. The purposes of these standards are:

- To serve as a bench mark to retail food regulatory program managers in the design and management of a retail food program;

- To provide a means of recognition of programs meeting these standards;
- To promote uniformity in retail food programs to reduce the risk factors known to cause foodborne illness;
- To provide a foundation for the food regulatory program that is focused on the risk factors and other factors that may contribute to foodborne illness; and
- To promote, through the management of a retail food regulatory program, the active managerial control in the retail establishment of all the factors that may cause foodborne illness.

Further purposes of these standards are to serve as a guide to regulatory retail food program managers in the design and management of a retail food program and to provide a means of recognition for those programs that meet these standards.

The intent in the development of these standards is to establish a basic foundation in design and management of a retail food program. Program management may add additional requirements to meet individual program needs.

The standards apply to the operation and management of a regulatory retail food program focused on the reduction of risk factors known to cause foodborne illness as well as other factors that may contribute to foodborne illness and on the promotion of active managerial control of all factors that may cause foodborne illness.

#### B. FDA Procedures for Standardization and Certification of Retail Food Inspection/Training Officers

This document can be found at the web site <http://www.cfsan.fda.gov/~ear/rfi-toc.html>. This is a procedure that integrates the assessment of an individual's knowledge, skills, and abilities in a manageable number of inspections while preserving the quality and integrity of the process. At the same time, we continue to learn from our experiences in applying it and remain open to improving these Procedures based on your experiences and feedback.

As they are written, the Procedures address the situation wherein an FDA Standard is assessing a CANDIDATE who is not employed by FDA. For example, Paragraph 3-301(C) mentions but does not require recording citations (i.e., identifying the codified provision that relates to each observed violation). Since jurisdiction's codification systems (numeric or alphanumeric) are usually different from the system in the FDA Food Code, the utility of that practice would be minimal in an FDA-to-jurisdiction field exercise. However, within a jurisdiction where the same Code is in use, the practice could be useful in reinforcing diligence in ensuring that violations listed during inspections are, in fact, soundly based in regulation.



FDA invites and encourages jurisdictions to use these Procedures in their internal Standardization and Certifications and to add dimensions that promote uniformity such as citing codified provisions, as discussed above. With a few language changes, the document can be custom-tailored to fit individual jurisdictions and serve as their procedures. As with other documents provided as guidance for applying regulatory requirements in the retail sector, these Procedures are in the "public domain" and we encourage their duplication and use.

### C. Managing Food Safety: A Manual for the Voluntary Use of HACCP Principles for Operators of Food Service and Retail Establishments

The Operator's Manual can be found by accessing the following web site:

<http://www.cfsan.fda.gov/~dms/hret2toc.html>. FDA has issued guidance to industry in voluntarily applying HACCP principles in food establishments. It recognizes that there are differences between using HACCP at retail and in food manufacturing. By incorporating the seven principles of HACCP, a good set of Standard Operating Procedures, and using a process approach, this Guide sets up a framework for the retail food industry to develop and implement a sound food safety management system. This document is intended to serve as a guide in the writing of a simple plan based on HACCP principles that can be used to manage food safety. It is very important to understand that this Guide is intended to assist industry's voluntary implementation of HACCP principles. It is not meant to stand alone, but instead should be used together with advice from and in consultation with your Federal, State, local, or tribal food safety regulatory authority. The regulatory authority is an important resource for reviewing your food safety management system. Regulatory food safety professionals can provide important information for the public health rationale for controlling a particular hazard. Users of this document also need to consult and use the latest edition of the FDA Food Code since many of its requirements are not reproduced here but constitute a fundamental program that is prerequisite to implementing a HACCP program.

Hazard Analysis Critical Control Point (HACCP) is a common sense technique to control food safety hazards. It is a preventive system of hazard control rather than a reactive one. Food establishments can use it to ensure safer food products for consumers. It is not a zero risk system, but is designed to minimize the risk of food safety hazards. HACCP is not a stand alone program but is one part of a larger system of control procedures that must be in place in order for HACCP to function effectively. These control procedures are prerequisite programs and are discussed more in Annex 4.

The success of a HACCP program is dependent upon both people and facilities. Management and employees must be properly motivated and trained if a HACCP program is to successfully reduce the risk of foodborne illness. Education and training in the principles of food safety and management commitment to the implementation of a HACCP system are critical and must be continuously reinforced. Instilling food worker commitment and dealing with problems such as high employee

turnover and communication barriers must be considered when designing a HACCP plan.

Successful implementation of a HACCP plan is also dependent upon the design and performance of facilities and equipment. The likelihood of the occurrence of a hazard in a finished product is definitely influenced by facility and equipment design, construction, and installation that play a key role in any preventive strategy.

The Agency recognizes that this document has areas that need to be further clarified and developed with broader input and based on industry's experiences with the practicalities of integrating the HACCP approach in their operations. This Guide will continue to evolve and improve.

D. Managing Food Safety: A Regulator's Manual for Applying HACCP Principles to Risk-based Retail and Food Service Inspections and Evaluating Voluntary Food Safety Management Systems

The Regulator's Manual can be found by accessing the following website: <http://www.cfsan.fda.gov/~dms/hret3toc.html>. This document provides State, local, and tribal regulatory authorities with a step-by-step scheme for conducting risk-based inspections based on HACCP principles to assist them with identifying and assessing control of foodborne illness risk factors. In addition, the manual details intervention strategies that can be developed with retail and food service operators to reduce the occurrence of foodborne illness risk factors. It also provides recommendations for evaluating voluntarily-implemented food safety management systems if invited to do so by industry.

The utilization of voluntary food safety management systems by industry and the incorporation of risk-based methodology into regulatory inspection programs are important elements in reaching the goals established by the Healthy People 2010 health improvement strategy and FDA retail program goals.

In 2004, the Conference for Food Protection (CFP) endorsed both documents with a recommendation that both industry and regulatory entities consider implementing the principles of the documents into their respective food safety programs. The CFP is composed of regulators, industry, academia, professional organizations, and consumers whose purpose is to identify problems, formulate recommendations, and develop and implement practices that relate to food safety.

A Federal Register notice announcing the availability of these documents was published July 21, 2005 (Docket No. 2005D-0274).

## E. Food Establishment Plan Review Guide

This document can be found at the web site <http://www.cfsan.fda.gov/~dms/previntr.html>. This Food Establishment Plan Review document has been developed for the purpose of assisting both regulatory and industry personnel in achieving greater uniformity in the plan review process. It is the result of a joint effort by FDA and the Conference for Food Protection.

Plan review of food service establishments, retail food stores, and all other food operations, must be maintained as a high priority by all regulatory food agencies for both new and existing facilities.

This document has been developed to serve as a guide in facilitating greater uniformity and ease in conducting plan review whether your position is a regulator or an industry person wishing to build or to expand. You need not be an expert to effectively complete this process.

A good review of plans helps to avoid future problems. By listing and locating equipment on floor plans and diagramming specifications for electrical, mechanical and plumbing systems, potential problems can be spotted while still on paper and modifications made BEFORE costly purchases, installation and construction.

Food establishment plan review is recognized as an important food program component that allows:

- Regulatory agencies to ensure that food establishments are built or renovated according to current regulations or rules.
- Industry to establish an organized and efficient flow of food.
- Regulatory agencies to eliminate code violations prior to construction.

## F. FDA Report on the Occurrence of Foodborne Illness Risk Factors in Selected Institutional Foodservice, Restaurant, and Retail Food Store Facility Types (2004)

In 1998, FDA initiated a project designed to determine the incidence of foodborne illness risk factors in retail and food service establishments. Inspections focusing on the occurrence of foodborne illness risk factors were conducted in establishments throughout the United States. The results of this project are published in the 2000 *Report of the FDA Retail Food Program Database of Foodborne Illness Risk Factors*, commonly referred to as the "FDA Baseline Report." The Baseline Report is available from FDA through the following website: <http://www.cfsan.fda.gov/~dms/retrsk.html>. The data collection project was repeated in 2003 and the results are published in the *FDA Report on the Occurrence of Foodborne Illness Risk Factors in Selected Institutional Foodservice, Restaurant, and Retail Food Store Facility Types (2004)*. This

second report is available from FDA through the following website: <http://www.cfsan.fda.gov/~dms/retrsk2.html> . An additional data collection project is planned for 2008.

#### G. Growing Sprouts in a Retail Food Establishment

This document, Growing Sprouts in a Retail Food Establishment, can be found at the web site <http://www.cfsan.fda.gov/~dms/sprouret.html>. There were 25 reported outbreaks associated with raw and lightly cooked seed sprouts in the United States between January 1996 and December 2003. No single treatment so far has been shown to completely eliminate pathogens on seeds or sprouts without affecting germination or yield; therefore a combination of factors is used to eliminate and control potential pathogens and assure a safe, ready-to-eat food product. Seeds or beans grown using Good Agricultural Practices (GAPs) and conditioned, transported, and stored according to GMPs reduce the potential for seed to serve as a source of contamination. Retail Sprouting Industry Best Practices help ensure that no further contamination occurs and precautionary measures are taken to prevent high levels of bacteria from growing on the seeds or sprouts. Seeds for sprouting or sprouts should receive a chemical disinfection treatment that has been approved by EPA for reduction of pathogens. Other treatments such as irradiation of seeds [21 CFR 179.26(b)(10)] have been approved. Because no treatments are known to completely eliminate pathogens without adversely affecting germination or yield, microbial testing of spent irrigation water from the sprouting process is also necessary to verify that no pathogens are present. Raw sprouts are considered potentially hazardous food (PHF)/time/temperature control for safety food (TCS) and therefore, require refrigeration.

#### H. Advisories for Retail Processing with Proper Controls and Variances for Product Safety

These documents are available for purchase at minimum cost from the Association of Food and Drug Officials (AFDO) at the website <http://www.afdo.org/afdo/publication/index.cfm>. These guides were funded by USDA through the University of Florida in cooperation with Florida A&M University and the Association of Food and Drug Officials and developed by experts from academic, regulatory, and industry areas. Nine guides help retailers and regulatory personnel understand the food safety controls to implement in retail food and food service operations in order to process and sell safe food products. They can also be used as a reference in applying for or reviewing a variance and HACCP Plan, where required, for retail processing of beef jerky, cured and hot smoked sausage, cured and smoked ham, fermented and dried sausage, fresh-cut produce, fresh juice, reduced oxygen packaging (ROP), smoked seafood, and sushi.

Each guide provides a definition of terms, a flow diagram, and a detailed check list for operations including receiving, food storage, preparation, and display. Information in the Appendices helps identify specific food safety hazards associated with that product, necessary equipment calibrations, product labeling, recommended record keeping with sample log sheets, and a daily SOP check list. Authoritative sources are also referenced such as FDA's "Fish and Fisheries Products Hazards & Controls Guidance" and 21 CFR 101 for labeling requirements.

These guides are not intended to replace or duplicate existing regulations within the jurisdictions of the regulatory authority or food establishment but they offer information and references for more uniform practices.

#### I. Evaluation and Definition of Potentially Hazardous Foods

This document can be found at the web site <http://www.cfsan.fda.gov/~comm/ift4-toc.html>. The Institute of Food Technologists (IFT) prepared and submitted this report as part of a contract with FDA. It contains responses to various questions posed by FDA about potentially hazardous food (PHF)/time/temperature control for safety food (TCS food). The IFT reviewed the evolution of the term PHF and recommended a change to time/temperature control for safety (TCS) food as well as a science-based framework for determining the effectiveness of processing technologies that formulate a food so that it is nonpotentially hazardous/non-TCS.

The IFT Science and Technology Expert Panel reviewed the two protocols used by NSF International and the American Baking Association for determining if a food is a PHF and proposed an alternate approach. The report examines intrinsic factors such as  $a_w$ , pH, redox potential, natural and added antimicrobials and competitive microorganisms, and extrinsic factors such as packaging, atmospheres, storage conditions, processing steps, and new preservation technologies that influence microbial growth. The report also analyzes microbial hazards related to time/temperature control of foods for safety.

The IFT developed a framework that could be used to determine whether a food is a PHF (TCS food) or not. Part of the framework includes two tables that consider the interaction of pH and  $a_w$  in a food, whether the food is raw or heat-treated, and whether it is packaged. When further product assessment is required, the application of microbiological challenge testing (inoculation studies) is discussed along with pathogen modeling programs and reformulation of the food. An extensive reference list is included in the report.

- J. The U.S. Equal Employment Opportunity Commission (EEOC) Guide, “How to Comply with the Americans with Disabilities Act: A Guide for Restaurants and Other Food Service Employers” October 28, 2004

The guide is designed to assist restaurants and other food service employers in complying with the employment provisions of the Americans with Disabilities Act (ADA). The EEOC worked extensively with the Food and Drug Administration in developing this new publication.

Available online at [http://www.eeoc.gov/facts/restaurant\\_guide.html](http://www.eeoc.gov/facts/restaurant_guide.html), [http://www.eeoc.gov/facts/restaurant\\_guide\\_summary.html](http://www.eeoc.gov/facts/restaurant_guide_summary.html), and [www.fda.gov](http://www.fda.gov), the guide covers such topics as how the FDA Food Code provisions about restricting and excluding sick employees interact with the ADA’s requirements; types of reasonable accommodations, including the use of service animals; and what an employer should do if a charge of discrimination is filed against the employer’s business.

Title I of the ADA, which prohibits employment discrimination against people with disabilities in the private sector and State and local governments, and the Rehabilitation Act’s prohibitions against disability discrimination in the federal government. The EEOC enforces Title VII of the Civil Rights Act of 1964, which prohibits employment discrimination based on race, color, religion, sex, and national origin; the Age Discrimination in Employment Act, which prohibits discrimination against individuals 40 years of age or older; the Equal Pay Act; and sections of the Civil Rights Act of 1991.

- K. Guidance for Retail Facilities Regarding Beef Grinding Logs Tracking Supplier Information

This document may be found at the web site for “Compliance Guidelines for Establishments on the FSIS Microbiological Testing Program and Other Verification Activities for *Escherichia coli* O157:H7” at <http://www.fsis.usda.gov/oppde/rdad/fsisdirectives/10.010.1.pdf>. On October 7, 2002, USDA/FSIS published a Federal Register Notice (67 FR 62332) entitled, *E. coli* O157:H7 Contamination of Beef Products, available at [http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=2002\\_register&docid=02-25504-filed.pdf](http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=2002_register&docid=02-25504-filed.pdf), in which the Agency discussed its views on the application of the Hazard Analysis and Critical Control Point (HACCP) system regulations with respect to *Escherichia coli* (*E. coli*) O157:H7 contamination.

USDA/FSIS announced that there is sufficient new scientific data on the increased prevalence of *E. coli* O157:H7 in live cattle coming to slaughter and on its impact on public health to require that all establishments producing raw beef products reassess their HACCP plans, in light of these data.

Of particular concern to the USDA/FSIS is its ability to quickly and adequately traceback *E. coli* O157:H7 contaminated product that is in commerce to its source and to remove it from commerce. In March 2004, the agency issued "FSIS Directive 10,010.1; revision 1, Microbiological Testing Program and Other Verification Activities for *Escherichia coli* O157:H7 in Raw Ground Beef Products and Raw Ground Beef Components and Beef Patty Components" available at [http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=2002\\_register&docid=02-25504-filed.pdf](http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=2002_register&docid=02-25504-filed.pdf). In this Directive, the Agency stated that, effective May 17, 2004, it would conduct sampling and microbiological verification testing for *E. coli* O157:H7 in raw ground beef products at federally inspected establishments, retail facilities, as well as at import facilities. Some of the products most likely to be sampled and tested at retail facilities are:

- Ground beef products produced from retail steaks and roasts.
- Manufacturing trimmings derived at retail.
- Ground beef that is formulated at retail by co-mingling in-store trim and trim from federally inspected establishments.
- Irradiated ground beef co-mingled with non-irradiated meat or poultry.

To facilitate product traceback and to meet regulatory requirements, USDA/FSIS expects retail facilities as well as federally inspected establishments to maintain and provide FSIS with access to all applicable records associated with the source material used for ground beef products. In cases where USDA/FSIS identifies *E. coli* O157:H7 ground beef in a product, and a product recall is necessary, grinding logs will facilitate identifying the source of the product and narrowing the scope of the recall.

The following information would be adequate for meeting federal transaction requirements:

- The name or description of the purchased or received article(s).
- The name, address, and establishment number of the seller of the articles purchased or received.
- The supplier lot numbers and production dates of the articles purchased or received.
- Any other information that would be useful in the quick removal of adulterated product from the market or commerce.

In addition to the references cited above, the following references also provide information:

1. Federal Meat Inspection Act (21 USC Sec. 642).
2. Title 9 of the Code of Federal Regulations, section 320.1 Records required to be kept.

3. U.S. Department of Agriculture, Food Safety and Inspection Service, April 13, 2004, Compliance Guidelines For Establishments On The FSIS Microbiological Testing Program and Other Verification Activities For *Escherchia coli* O157:H7  
[http://www.fsis.usda.gov/OPPDE/rdad/fsisdirectives/10010\\_1/ecolio157h7dirguid4-13-04.pdf](http://www.fsis.usda.gov/OPPDE/rdad/fsisdirectives/10010_1/ecolio157h7dirguid4-13-04.pdf).

L. Recommended Guidelines for Permanent Outdoor Cooking Establishments, 2003

This document can be found at <http://www.foodprotect.org/documents.html>. Permanent Outdoor Cooking Establishments (POCE) include a wide range of facilities from barbecue pits at beach resorts to campfire meals at dude ranches, pig roasts and clam bakes, and multi-menu food service sites in amusement and theme parks. It is essential that the equipment and physical facility requirements be based upon a menu review of the items to be prepared, cooked, held, and served. Many of these POCEs are high risk operations engaging in extensive preparation of raw ingredients: processes that include the cooking, hot and cold holding, and reheating of potentially hazardous foods (time/temperature control for safety foods). These guidelines provide the basis on which regulatory authorities can evaluate and permit permanent outdoor cooking establishments.

M. Comprehensive Guidelines for Food Recovery Programs

Food recovery programs collect foods from commercial production and distribution channels and redistribute them to people in need. There are food recovery efforts carried out by public, private, and nonprofit organizations across the country. The primary goal of food recovery programs is to collect safe and wholesome food donated from commercial sources to meet the nutritional needs of the hungry.

With bipartisan support, Congress passed the Bill Emerson Good Samaritan Food Donation Act in 1996. The Act is designed to encourage the donation of food and grocery products to nonprofit organizations such as homeless shelters, soup kitchens, and churches for distribution to hungry individuals. The Bill Emerson Good Samaritan Food Donation Act promotes food recovery by limiting the liability of donors to instances of gross negligence or intentional misconduct.

The *Guidelines* are intended to provide guidance to those who want to participate in food recovery programs as donors and receiving operations as well as to those who oversee standards compliance as regulators or peer inspectors.

The *Guidelines* also give advice on implementing a food recovery program, various ways to contribute to food recovery programs, choosing suitable partners, and laying the foundation for a successful program. This includes food safety provisions in alignment with the FDA Food Code, guidelines for monitoring food recovery programs, and handling of donations of game animals. For simple recordkeeping, the *Guidelines*



contain sample forms designed to facilitate the management of a variety of aspects of food recovery programs.

For in-depth information, see the *Comprehensive Guidelines for Food Recovery Programs* available via the Conference for Food Protection web page at <http://www.foodprotect.org/documents.html>.

#### 4. FOOD DEFENSE GUIDANCE FROM FARM TO TABLE

The following is a summary of available resources on food defense that is of interest to the retail and food service food community. This listing is provided below and is not all-inclusive. It contains links to publications from federal regulatory agencies (primarily FDA, CDC, and USDA) and industry groups with information of interest to regulators, industry, and consumers. Responsibility for updating the web pages lies with the listed organization and those listed are up-to-date as of the printing of the 2005 Food Code.

##### **FDA Publications:**

These guidance documents identify the kinds of preventive measures that food establishment and food processing operators may take to minimize risks to food under their control, from tampering or other malicious, criminal, or terrorist actions:

- **Retail Food Stores and Food Service Establishments: Food Security Preventive Measures Guidance** at <http://www.cfsan.fda.gov/~dms/secqui11.html>.
- **Food Producers, Processors, and Transporters: Food Security Preventive Measures Guidance** at <http://www.cfsan.fda.gov/~dms/secguid6.html>.
- **Dairy Farms, Bulk Milk Transporters, Bulk Milk Transfer Stations and Fluid Milk Processors Food Security Preventive Measures Guidance** at <http://www.cfsan.fda.gov/~dms/secguid8.html>.
- **Importers and Filers: Food Security Preventive Measures Guidance** at <http://www.cfsan.fda.gov/~dms/secguid7.html>.
- The **Bioterrorism Act of 2002** at <http://www.fda.gov/oc/bioterrorism/bioact.html>

Additional information on FDA food security guidance publications is available over the Internet at <http://www.cfsan.fda.gov>; individual copies are available by mail from CFSAN (1-888-SAFE-FOOD).

Further information on Countering Bioterrorism and Other Threats to the Food Supply can be found at <http://www.foodsafety.gov/~fsg/bioterr.html>.

## USDA Publications:

- **Food Safety and Inspection Service (FSIS) Security Guidelines for Food Processors** at <http://www.fsis.usda.gov/oa/topics/securityguide.htm>.
- **FSIS Guidelines “Keep America’s Food Safe”** at [http://www.fsis.usda.gov/Food\\_Security\\_&\\_Emergency\\_Preparedness/Keep\\_America\\_as\\_Food\\_Safe/index.asp](http://www.fsis.usda.gov/Food_Security_&_Emergency_Preparedness/Keep_America_as_Food_Safe/index.asp). This guidance is designed to assist transporters, warehouses, distributors, retailers, and restaurants with enhancing their security programs to further protect the food supply from contamination due to criminal or terrorist acts.
- **FSIS Safety and Security Guidelines for the Transportation and Distribution of Meat, Poultry and Egg Products** at <http://www.fsis.usda.gov/oa/topics/transportguide.htm>. This guidance contains recommendations to ensure the security of food products through all phases of the distribution process.

Additional information on FSIS food security guidance publications is available over the Internet at <http://www.fsis.usda.gov>.

---

## Industry Publications:

- **National Restaurant Association**. Information for restaurants can be found on the National Restaurant Association’s web page at <http://www.restaurant.org>.
- **Food Marketing Institute (FMI) Security Information and Resources** web page at [http://www.fmi.org/foodsafety/bio\\_security.htm](http://www.fmi.org/foodsafety/bio_security.htm), provides access to security information and guidelines targeted specifically to food retailers.
- **Food and Agriculture ISAC** – Information Sharing and Analysis Center web page at <http://www.fmi.org/isac/>.

The Food and Agriculture ISAC is a partnership of food industry associations coordinated by the Food Marketing Institute (FMI). The primary purpose of the partnership is the rapid and confidential dissemination of information gathered by

the government's intelligence community to the food industry regarding any actual or potential threats arising from deliberately malicious or terrorist activity.

---

### **Guidance on Responding to Food Emergencies:**

- Centers for Disease Control and Prevention (CDC) Emergency Preparedness and Response information can be found at <http://www.bt.cdc.gov/>.
- USDA – Food and Nutrition Service food emergency publication, **Responding to a Food Recall** at <http://www.nfsmi.org/Information/recallmanual.pdf>.

FDA's Office of Emergency Operations at 301-443-1240 for FDA regulated products and FSIS Technical Service Center at 1-800-233-3935 for USDA regulated products.

---

### **Food Defense and Emergency Guidance of Interest to Schools:**

- **A Biosecurity Checklist for School Foodservice: Developing a Biosecurity Management Plan**

The document is from the USDA – Food and Nutrition Service and provides information for school food service managers. It can be found on the Healthy School Meals Resource System website at <http://schoolmeals.nal.usda.gov/Safety/FNSFoodSafety.htm>. The exact link to the checklist is <http://schoolmeals.nal.usda.gov/Safety/biosecurity.pdf>. Currently the checklist is only available in an electronic format.

- USDA – Food and Nutrition Service food emergency publication, **Emergency Readiness Plan: A Guide for the School Foodservice Operation** at <http://www.nfsmi.org/Information/e-readinessguide.pdf>.
- 

### **Defense Guidance of Interest to Consumers:**

- **Food Safety and Security: What Consumers Need to Know**, at [http://www.fsis.usda.gov/OA/topics/foodsec\\_cons.htm](http://www.fsis.usda.gov/OA/topics/foodsec_cons.htm).

- **Frequently Asked Consumer Questions About Food Safety and Terrorism.** An FDA /CFSAN publication to assist consumers in understanding the FDA role in protecting the food supply and the consumer role protecting their own food at <http://www.cfsan.fda.gov/~dms/fsterrqa.html>.
- **Food Tampering: An Extra Ounce of Caution,** at <http://www.cfsan.fda.gov/~dms/fstamper.html>.