

## **02 NCAC 09B .0116 ADOPTIONS BY REFERENCE**

(a) The Board incorporates by reference, including subsequent amendments and editions, "Official Methods of Analysis of AOAC," published by the Association of Official Analytical Chemists. Copies of this document may be obtained from the Association of Official Analytical Chemists International, Department 0742, 1970 Chain Bridge Road, McLean, VA 22109-0742, at a cost of seven hundred thirty dollars (\$730.00).

(b) The Board incorporates by reference, including subsequent amendments and editions, "U.S. Pharmacopeia National Formulary USP XXXIII-NFXXVIII" and supplements, published by the U.S. Pharmacopeial Convention, Inc. Copies of this document may be obtained from The United States Pharmacopeial Convention, Inc., Attention: Customer Service, 12601 Twinbrook Parkway, Rockville, MD 20852, at a cost of eight-hundred fifty dollars (\$850.00).

(c) The Board incorporates by reference, including subsequent amendments and editions, "ASTM Volume 15.05 Engine Coolants and Related Fluids; Halogenated Organic Solvents and Fire Extinguishing Agents," published by ASTM International. Copies of this document may be obtained from ASTM International, 100 Bar Harbor Drive, West Conshohocken, PA 19428-2959, or by visiting <https://www.astm.org/BOOKSTORE/BOS/1505.htm> at a cost of one hundred ninety dollars (\$190.00).

(d) The Board incorporates by reference, including subsequent amendments and editions, "EPA Manual of Chemical Methods for Pesticides and Devices" and supplements, published by AOAC. Copies of this document may be obtained online at no cost from the Environmental Protection Agency National Service Center for Environmental Publications at <http://nepis.epa.gov/EXE/ZyPURL.cgi?Dockey=2000YS3Y.txt>.

(e) The Board incorporates by reference, including subsequent amendments and editions, "Pesticide Analytical Manual," Volumes I and II, published by the United States Department of Health and Human Services, Food and Drug Administration. Copies of this document may be obtained online at no cost at <http://www.fda.gov/Food/ScienceResearch/LaboratoryMethods/PesticideAnalysisManualPAM/default.htm>.

(f) The Board incorporates by reference, including subsequent amendments and editions, "FDA Compliance Policy Guides," published by the United States Department of Health and Human Services, Food and Drug Administration. Copies of this document may be obtained online at no cost at [http://www.fda.gov/iceci/compliancemanuals/compliancepolicy\\_guidancemanual/default.htm](http://www.fda.gov/iceci/compliancemanuals/compliancepolicy_guidancemanual/default.htm) or from the State Information Branch (HFC-151), Division of Federal-State Relations, US Food and Drug Administration, 5600 Fishers Lane, Room 12-07, Rockville, MD 20857.

(g) The Board incorporates by reference, including subsequent amendments and editions, "Bergey's Manual of Determinative Bacteriology," Lippincott, Williams & Wilkins Company, Baltimore. Copies of this document may be obtained from the Lippincott, Williams & Wilkins Company, P.O. Box 1620, Hagerstown, MD 21741 at a cost one hundred forty five dollars and ninety nine cents (\$145.99).

(h) The Board incorporates by reference, including subsequent amendments and editions, "Microbiology Laboratory Guidebook," published by the United States Department of Agriculture, Food Safety and Inspection Service, Washington, DC. Copies of this document may be obtained online at no cost from <http://www.fsis.usda.gov>.

(i) The Board incorporates by reference, including subsequent amendments and editions, "FDA Bacteriological Analytical Manual," published by the United States Department of Health and Human Services, Food and Drug Administration. Copies of this document may be obtained online at <http://www.fda.gov/Food/FoodScienceResearch/LaboratoryMethods/ucm114664.htm> at no charge.

(j) The Board incorporates by reference, including subsequent amendments and editions, "Standard Methods for the Examination of Dairy Products," published by the American Public Health Association. Copies of this document may be obtained from the American Public Health Association Publication Sales, P.O. Box 933019, Atlanta, GA at a cost of eighty-five dollars and fifty cents (\$87.50) for members and one hundred twenty-five dollars (\$125.00) for non-members.

(k) The Board incorporates by reference, including subsequent amendments and editions, "Compendium of Methods for the Microbiological Examination of Foods," published by the American Public Health Association. Copies of this document may be obtained from the American Public Health Association Publication Sales, P.O. Box 933019, Atlanta, GA at a cost of one hundred forty seven dollars and fifty cents (\$147.50).

(l) The Board incorporates by reference, including subsequent amendments and editions, "Bergey's Manual of Systematic Bacteriology," Springer Publishing, New York, NY. Copies of this document may be obtained from Springer Publishing, 233 Spring Street, New York, NY, 10013 at a cost of one hundred fifty-nine dollars (\$159.00).

(m) The Board incorporates by reference, including subsequent amendments and editions, "Manual of Clinical Microbiology," published by the American Society for Microbiology. Copies of this document may be obtained

from the American Society for Microbiology Press, PO Box 605, Herndon, VA 22070, at a cost of two hundred sixty-nine dollars and ninety-five cents (\$269.95).

(n) The Board incorporates by reference, including subsequent amendments and editions, "Standard Methods for the Examination of Water and Waste Water," published by American Public Health Association, American Water Works Association, and Water Pollution Control Federation. Copies of this document may be obtained from the American Public Health Association Publication Sales, P.O. Box 933019, Atlanta, GA at a cost of two hundred ninety-five dollars (\$295.00).

(o) The Board incorporates by reference, including subsequent amendments and editions, the following parts or sections of the Code of Federal Regulations, Title 21, Chapter I, as promulgated by the Commissioner of the Food and Drug Administration under the authority of the Federal Food, Drug, and Cosmetic Act:

	Part or Section	Description of Part or Section
(1)	1.1	General
(2)	1.3	Definitions
(3)	1.20	Presence of Mandatory Label Information
(4)	1.21	Failure to Reveal Material Facts
(5)	1.24	Exemptions from Required Label Statements
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(7)	1.327	Who is Excluded from All or Part of the Regulations in this Subpart?
(8)	1.328	What Definitions Apply to this Subpart?
(9)	1.329	Do Other Statutory Provisions and Regulations Apply?
(10)	1.330	Can Existing Records Satisfy the Requirements of this Subpart?
(11)	1.337	What Information Must Nontransporters Establish and Maintain to Identify the Nontransporter and Transporter Immediate Previous Sources of Food?
(12)	1.345	What Information Must Nontransporter Establish and Maintain to Identify the Nontransporter and Transporter Immediate Subsequent Recipients of Food?
(13)	1.352	What Information Must Transporters Establish and Maintain?
(14)	1.360	What are the Record Retention Requirements?
(15)	1.361	What are the Record Availability Requirements?
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(17)	1.363	What are the Consequences of Failing to Establish, or Maintain Records or Make Them Available to FDA as Required by this Subpart?
(18)	1.368	What are the Compliance Dates for this Subpart?
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(20)	2.35	Use of Secondhand Containers for the Shipment or Storage of Food and Animal Feed
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(23)	7.12	Guaranty
(24)	7.13	Suggested Forms of Guaranty
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Copies of the Code of Federal Regulations may be obtained at no cost by accessing the website of the U.S. Government Printing Office at <http://www.gpoaccess.gov/cfr/index.html>.

(p) The Board incorporates by reference, including subsequent amendments and editions, "Tolerances and Exemptions for Pesticide Chemical Residues in Food," 40 C.F.R. Part 180. Copies of the Code of Federal Regulations may be obtained at no cost by accessing the website of the U.S. Government Printing Office at <http://www.gpoaccess.gov/cfr/index.html>.

(q) The Board incorporates by reference, including subsequent amendments and editions, "Definitions and Standards of Identity or Composition," 9 C.F.R. Part 319. Copies of the Code of Federal Regulations may be obtained at no cost by accessing the website of the U.S. Government Printing Office at <http://www.gpoaccess.gov/cfr/index.html>.

(r) The Board incorporates by reference, including subsequent amendments and editions, "Definitions and Standards of Identity or Composition," 9 C.F.R. Sections 381.155 through 381.170. Copies of the Code of Federal Regulations may be obtained at no cost by accessing the website of the U.S. Government Printing Office at <http://www.gpoaccess.gov/cfr/index.html>.

(s) The Board incorporates by reference, including subsequent amendments and editions, "Labels: Definitions; Required Features," 9 C.F.R. Section 317.2 of the Code of Federal Regulations. Copies of Title 9 of the Code of Federal Regulations may be obtained at no cost by accessing the website of the U.S. Government Printing Office at <http://www.gpoaccess.gov/cfr/index.html>.

(t) The Board incorporates by reference, including subsequent amendments and editions, "Special Handling Label Requirements," 9 C.F.R. Section 381.125 of the Code of Federal Regulations. Copies of the Code of Federal Regulations may be obtained at no cost by accessing the website of the U.S. Government Printing Office at <http://www.gpoaccess.gov/cfr/index.html>.

(u) The Board incorporates by reference, including subsequent amendments and editions, a document entitled, "Fresh Air '2000' - A Look At FDA's Medical Gas Requirements," published by the United States Department of Health and Human Services, Food and Drug Administration. A copy of this material may be obtained at no cost from the Food and Drug Protection Division of the North Carolina Department of Agriculture and Consumer Services.

(v) The Board incorporates by reference, including subsequent amendments and editions, the definition of "dietary supplement" found at 21 USC 321(ff).

(w) The Board incorporates by reference, including subsequent amendments and editions, the definition of "processed food" found at 21 USC 321(gg).

(x) The Board incorporates by reference, including subsequent amendments and editions, the definition of "major food allergen" found at 21 USC 321(qq).

(y) The Board incorporates by reference, including subsequent amendments and editions, the definition of "knowingly" or "knew" found at 21 USC 321(bb).

(z) The Board incorporates by reference, including subsequent amendments and editions, the definition of "animal feed" found at 21 USC 321(w).

*History Note:* Authority G.S. 106-139; 106-245.16; 106-245.22; 106-245.32; 106-267; 106-284.41; Eff. December 14, 1981; Amended Eff. May 1, 2013; January 1, 2011; June 1, 2004; April 1, 2003; June 1, 1995; April 1, 1992; June 1, 1988; October 1, 1987;

*Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. March 22, 2015;  
Amended Eff. February 1, 2019; May 1, 2018.*