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SUBCHAPTER 9B - RULES AND STANDARDS ADOPTED BY REFERENCE

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History Note: Authority G.S. 150B-14;
Eff. February 1, 1976;
Repealed Eff. December 14, 1981.

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02 NCAC 09B .0115	TITLE 9: PART 381: CODE OF FEDERAL REGULATIONS

History Note: Authority G.S. 150B-14;
Eff. February 1, 1976;
Amended Eff. December 20, 1980;
Repealed Eff. December 1, 1981.

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 six hundred thirty dollars (\$630.00).

(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 dollars (\$800).

(c) The Board incorporates by reference, including subsequent amendments and editions, "ASTM Standards on Engine Coolants," published by the American Society for Testing Materials. Copies of this document may be obtained from the American Society for Testing Materials, 100 Bar Harbor Drive, West Conshohocken, PA 19428-2959, at a cost of one hundred eighty-six dollars (\$186.00).

(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 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 <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 <http://www.fda.gov/ICECI/ComplianceManuals/CompliancePolicyGuidanceManuals/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 of one hundred ten dollars (\$110.00).

(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 from http://www.fsis.usda.gov/science/microbiological_Lab_Guidebook/ at no charge.

(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/ScienceResearch/LaboratoryMethods/BacteriologicalAnalyticalManualBAM/default.htm>.

(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 (\$85.00).

(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 fifty dollars (\$150.00).

(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 thirty-nine dollars (\$139.00).

(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 nine dollars and ninety-five cents (\$209.95).

(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 fifty dollars (\$250.00).

(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	Subject of Part or Section
(1)	1.1	General
(2)	1.3	Labeling - 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
(6)	2.25	Grain Seed Treated with Poisonous Substances; Color Identification to Prevent Adulteration of Human and Animal Food
(7)	2.35	Use of Secondhand Containers for the Shipment or Storage of Food and Animal Feed
(8)	7.12	Guaranty
(9)	7.13	Suggested Forms of Guaranty
(10)	70	Color Additives
(11)	73	Listing of Color Additives Exempt from Certification
(12)	74	Listing of Color Additives Subject to Certification

(13)	81	General Specifications and General Restrictions for Provisioned Color Additives for Use in Foods, Drugs and Cosmetics
(14)	82	Listing of Certified Provisionally Listed Colors and Specifications
(15)	100	General
(16)	101	Food Labeling
(17)	102	Common or Usual Name for Nonstandardized Foods
(18)	104	Nutritional Quality Guidelines for Foods
(19)	105	Foods for Special Dietary Use
(20)	106	Infant Formula Quality Control Procedures
(21)	107	Infant Formula
(22)	108	Emergency Permit Control
(23)	109	Unavoidable Contaminants in Food for Human Consumption and Food-Packaging Material
(24)	110	Current Good Manufacturing Practice in Manufacturing, Processing, Packing, or Holding Human Food
(25)	113	Thermally Processed Low-Acid Foods Packaged in Hermetically Sealed Containers
(26)	114	Acidified Foods
(27)	120	Hazard Analysis and Critical Control Point (HACCP) Systems
(28)	123	Frozen Raw Breaded Shrimp
(29)	129	Processing and Bottling of Bottled Drinking Water (Except as amended by 02 NCAC 09C .0700 - Bottled Water)
(30)	130	Food Standards: General
(31)	131	Milk and Cream
(32)	133	Cheeses and Related Cheese Products
(33)	135	Frozen Desserts
(34)	136	Bakery Products
(35)	137	Cereal Flours and Related Products
(36)	139	Macaroni and Noodle Products
(37)	145	Canned Fruits
(38)	146	Canned Fruit Juices
(39)	150	Fruit Butters, Jellies, Preserves, and Related Products
(40)	152	Fruit Pies
(41)	155	Canned Vegetables
(42)	156	Vegetable Juices
(43)	158	Frozen Vegetables
(44)	160	Eggs and Egg Products
(45)	161	Fish and Shellfish (Except Section 161.30 and 161.130 through 161.145)
(46)	163	Cacao Products
(47)	164	Tree Nut and Peanut Products
(48)	165	Beverages
(49)	166	Margarine
(50)	168	Sweeteners and Table Syrups
(51)	169	Food Dressings and Flavorings
(52)	170	Food Additives
(53)	172	Food Additives Permitted for Direct Addition to Food for Human Consumption
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(55)	174	Indirect Food Additives: General
(56)	175	Indirect Food Additives: Adhesive Coatings and Components
(57)	176	Indirect Food Additives: Paper and Paperboard Components
(58)	177	Indirect Food Additives: Polymers
(59)	178	Indirect Food Additives: Adjuvants, Production Aids, and Sanitizers
(60)	179	Irradiation in the Production, Processing and Handling of Food
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(83)	331	Antacid Products for Over-the-Counter (OTC) Human Use
(84)	332	Antiflatulent Products for Over-the-Counter Human Use
(85)	361	Prescription Drugs for Human Use Generally Recognized as Safe and Effective and Not Misbranded: Drugs Used in Research
(86)	369	Interpretive Statements Re: Warnings on Drugs and Devices for Over-the-Counter Sale
(87)	809	In Vitro Diagnostic Products for Human Use
(88)	812	Investigational Device Exemptions
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(91)	861	Procedures for Performance Standards Development
(92)	870	Cardiovascular Devices
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(96)	500	General
(97)	501	Animal Food Labeling
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(101)	511	New Animal Drugs for Investigational Use
(102)	514	New Animal Drug Applications
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(104)	522	Implantation of Injectable Dosage Form New Animal Drugs Not Subject to Certification
(105)	524	Ophthalmic and Topical Dosage Form New Animal Drugs Not Subject to Certification
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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 from Tolerances for Pesticide Chemicals in or on Raw Agricultural Commodities," 40 C.F.R. Part 180. Copies of the Code of Federal Regulations may be obtained from the Superintendent of Documents, Government Printing Office, Washington, DC 20402, at a cost of fifty-six dollars (\$56.00).

(q) The Board incorporates by reference, including subsequent amendments and editions, "Definitions and Standards of Identity or Composition for Meats, Meat By-products, and Meat Food Products," 9 C.F.R. Part 319. Copies of the Code of Federal Regulations may be obtained from the Superintendent of Documents, Government Printing Office, Washington, DC 20402, at a cost of sixty-four dollars (\$64.00).

(r) The Board incorporates by reference, including subsequent amendments and editions, "Definitions and Standards of Identity or Composition for Poultry and Poultry Products," 9 C.F.R. Sections 381.155 through 381.170. Copies of the Code of Federal Regulations may be obtained from the Superintendent of Documents, Government Printing Office, Washington, DC 20402, at a cost of sixty-four dollars (\$64.00).

(s) The Board incorporates by reference, including subsequent amendments and editions, Title 9, Part 317.2(1) of the Code of Federal Regulations. Copies of Title 9 of the Code of Federal Regulations may be obtained from the Superintendent of Documents, Government Printing Office, Washington, DC 20402, at a cost of sixty-four dollars (\$64.00).

(t) The Board incorporates by reference, including subsequent amendments and editions, Title 9, Part 381.125(b) of the Code of Federal Regulations. Copies of Title 9 of the Code of Federal Regulations may be obtained from the Superintendent of Documents, Government Printing Office, Washington, DC 20402, at a cost of sixty-four dollars (\$64.00).

(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 the definition of "dietary supplement" found at 21 USC 321 (ff).

History Note: Authority G.S. 106-139; 106-267; 106-267.2;

Eff. December 14, 1981;

Amended Eff. January 1, 2011; June 1, 2004; April 1, 2003; June 1, 1995; April 1, 1992; June 1, 1988; October 1, 1987.

02 NCAC 09B .0117 NATIONAL FORMULARY

History Note: Authority G.S. 150B-14;

Eff. December 14, 1981;

Repealed Eff. January 1, 1985.

02 NCAC 09B .0118 U.S. PHARMACOPEIA NATIONAL FORMULARY

*History Note: Authority G.S. 106-139; 106-267; 106-267.2;
Eff. December 14, 1981;
Amended Eff. January 1, 1985;
Transferred to T02.09B .0016 Eff. April 1, 1987.*

02 NCAC 09B .0119 ASTM STANDARDS

*History Note: Authority G.S. 106-139; 106-267; 106-267.2;
Eff. December 14, 1981;
Amended Eff. January 1, 1985;
Transferred to T02.09B .0016 Eff. April 1, 1987.*

02 NCAC 09B .0120 REFERENCE MANUALS

*History Note: Authority G.S. 106-139; 106-267; 106-267.2;
Eff. December 14, 1981;
Amended Eff. January 1, 1985;
Transferred to T02.09B .0016 Eff. April 1, 1987.*

02 NCAC 09B .0121 GENERAL

*History Note: Authority G.S. 106-139; 150B-14;
Eff. December 1, 1981;
Transferred to T02.09B .0016 Eff. April 1, 1987.*

02 NCAC 09B .0122 FOOD FOR HUMAN CONSUMPTION

*History Note: Authority G.S. 106-139; 150B-14;
Eff. December 1, 1981;
Amended Eff. January 1, 1987; July 1, 1985; March 1, 1985; June 1, 1984;
Transferred to T02.09B .0016 Eff. April 1, 1987.*

02 NCAC 09B .0123 DRUGS

*History Note: Authority G.S. 106-139; 150B-14;
Eff. December 1, 1981;
Transferred to T02.09B .0016 Eff. April 1, 1987.*

02 NCAC 09B .0124 DRUGS FOR HUMAN USE

History Note: Authority G.S. 106-139; 150B-14;
 Eff. December 1, 1981;
 Transferred to T02.09B .0016 Eff. April 1, 1987.

02 NCAC 09B .0125 MEDICAL DEVICES

History Note: Authority G. S. 106-139; 150B-14;
 Eff. December 1, 1981;
 Transferred to T02.09B .0016 Eff. April 1, 1987.

02 NCAC 09B .0126 ANIMAL DRUGS: FEEDS: AND RELATED PRODUCTS

History Note: Authority G.S. 106-139; 150B-14;
 Eff. December 1, 1981;
 Transferred to T02.09B .0016 Eff. April 1, 1987.

02 NCAC 09B .0127 COSMETICS

History Note: Authority G.S. 106-139; 150B-14;
 Eff. December 1, 1981;
 Transferred to T02.09B .0016 Eff. April 1, 1987.

02 NCAC 09B .0128 TITLE 40: CODE OF FEDERAL REGULATIONS

History Note: Authority G.S. 106-139; 150B-14;
 Eff. December 1, 1981;
 Transferred to T02.09B .0016 Eff. April 1, 1987.

02 NCAC 09B .0129 TITLE 9: PART 319: CODE OF FEDERAL REGULATIONS

History Note: Authority G.S. 106-139; 150B-14;
 Eff. December 1, 1981;
 Transferred to T02.09B .0016 Eff. April 1, 1987.

02 NCAC 09B .0130 TITLE 9: PART 381: CODE OF FEDERAL REGULATIONS

History Note: Authority G.S. 106-139; 150B-14;
 Eff. December 1, 1981;
 Transferred to T02.09B .0016 Eff. April 1, 1987.

02 NCAC 09B .0131 ETHYLENE DIBROMIDE TOLERANCE

(a) The following tolerances are established for the organic bromide residues of the insecticide ethylene dibromide when used as a fumigant after harvest for grains:

- (1) 900 parts per billion in or on raw grains intended for human consumption;
- (2) 150 parts per billion in or on uncooked grain products; and
- (3) 30 parts per billion in or on ready-to-eat grain products.

(b) As used in this Regulation:

- (1) "Raw Grains" means whole kernels of wheat, corn, rice, rye, barley, oats and popcorn. This category also includes bran, shorts and middlings fractions (milling and grain processing by-products) from these grains.
- (2) "Uncooked Grain Products" means milled and otherwise processed grain products that must be cooked by the consumer prior to consumption. This category includes partially cooked products.
- (3) "Ready-to-Eat Grain Products" means grain products or foods containing grain products which require no cooking prior to consumption.

(c) This Regulation supersedes Title 40 Code of Federal Regulations 180.1006, which was adopted by reference in 2 NCAC 9B .0028.

*History Note: Filed as a Temporary Rule Eff. February 6, 1984, for a Period of 120 Days to Expire on June 4, 1984;
 Authority G.S. 106-139;
 Eff. June 1, 1984.*

02 NCAC 09B .0132 EFFECTIVE DATE FOR ADOPTIONS BY REFERENCE

*History Note: Authority G.S. 106-139; 150B-14;
 Eff. January 1, 1987;
 Transferred to T02.09B .0016 Eff. April 1, 1987.*

02 NCAC 09B .0133 DOCUMENT AVAILABILITY

Copies of documents adopted by reference in 2 NCAC 9B .0016 are available for inspection in the Office of the Director of the Food and Drug Protection Division and may be obtained at a cost as determined by the publisher by contacting the Superintendent of Documents, Government Printing Office, Washington, D.C. 20402.

*History Note: Authority G.S. 106-139; 150B-14;
 Eff. January 1, 1987;
 Amended Eff. June 1, 1988.*