

REQUEST FOR TECHNICAL CHANGE

AGENCY: Board of Agriculture

RULE CITATION: 02 NCAC 09B .0116

DEADLINE FOR RECEIPT: Friday, January 11, 2019

The Rules Review Commission staff has completed its review of this Rule prior to the Commission's next meeting. The Commission has not yet reviewed this Rule and therefore there has not been a determination as to whether the Rule will be approved. You may call our office to inquire concerning the staff recommendation.

In reviewing this Rule, the staff recommends the following technical changes be made:

In (o)(11), Page 3, line 8, you have "Non-transporter" but the phrase is not hyphenated on lines 9, 10, or 11. Please remove the hyphen here.

In the History Note, please change the Amended Effective date to February 1, 2019.

Please retype the rule accordingly and resubmit it to our office at 1711 New Hope Church Road, Raleigh, North Carolina 27609.

Amanda J. Reeder
Commission Counsel
Date submitted to agency: January 3, 2019

02 NCAC 09B .0116 is amended as published in 33:02 NCR 84-88 as follows:

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 ~~sixseventy~~ hundred thirty dollars ~~(\$630.00)-(\$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 Standards on Engine Coolants,"~~ "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 ~~two hundred eleven dollars (\$211.00)-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 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 thirty seven dollars and ninety nine cents (\$137.99)-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/science/microbiological_Lab_Guidebook/~~ at no charge ~~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 (\$85.00)~~ 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 fifty dollars (\$150.00)~~ 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	Labeling Definitions
(3)	1.20	Presence of Mandatory Label Information

1	(4)	1.21	Failure to Reveal Material Facts
2	(5)	1.24	Exemptions from Required Label Statements
3	(6)	1.326	Who is Subject to this Subpart?
4	(7)	1.327	Who is Excluded from All or Part of the Regulations in this Subpart?
5	(8)	1.328	What Definitions Apply to this Subpart?
6	(9)	1.329	Do Other Statutory Provisions and Regulations Apply?
7	(10)	1.330	Can Existing Records Satisfy the Requirements of this Subpart?
8	(11)	1.337	What Information Must Non-transporters Establish and Maintain to Identify the
9			Nontransporter and Transporter Immediate Previous Sources of Food?
10	(12)	1.345	What Information Must Non-transporters <u>Nontransporter</u> Establish and Maintain to Identify
11			the Nontransporter and Transporter Immediate Subsequent Recipients of Food?
12	(13)	1.352	What Information Must Transporters Establish and Maintain?
13	(14)	1.360	What are the Record Retention Requirements?
14	(15)	1.361	What are the Record Availability Requirements?
15	(16)	1.362	What Records are Excluded from this Subpart?
16	(17)	1.363	What are the Consequences of Failing to Establish, or Maintain Records or Make Them
17			Available to FDA as Required by this Subpart?
18	(18)	1.368	What are the Compliance Dates for this Subpart?
19	(19)	2.25	Grain Seed Treated with Poisonous Substances; Color Identification to Prevent
20			Adulteration of Human and Animal Food
21	(20)	2.35	Use of Secondhand Containers for the Shipment or Storage of Food and Animal Feed
22	(21)	7.1	Scope
23	(22)	7.3	Definitions
24	(23)	7.12	Guaranty
25	(24)	7.13	Suggested Forms of Guaranty
26	(25)	7.40	Recall Policy
27	(26)	7.41	Health Hazard Evaluation and Recall Classification
28	(27)	7.42	Recall Strategy
29	(28)	7.45	Food and Drug Administration - Requested Recall
30	(29)	7.46	Firm-initiated Recall
31	(30)	7.49	Recall Communications
32	(31)	7.50	Public Notification of Recall
33	(32)	7.53	Recall Status Reports
34	(33)	7.55	Termination of a Recall
35	(34)	7.59	General Industry Guidance
36	(35)	70	Color Additives
37	(36)	73	Listing of Color Additives Exempt from Certification

1	(37)	74	Listing of Color Additives Subject to Certification
2	(38)	81	General Specifications and General Restrictions for Provisioned <u>Provisional</u> Color
3			Additives for Use in Foods, Drugs <u>Drugs</u> , and Cosmetics
4	(39)	82	Listing of Certified Provisionally Listed Colors and Specifications
5	(40)	100	General
6	(41)	101	Food Labeling
7	(42)	102	Common or Usual Name for Nonstandardized Foods
8	(43)	104	Nutritional Quality Guidelines for Foods
9	(44)	105	Foods for Special Dietary Use
10	(45)	106	Infant Formula Quality Control Procedures <u>Requirements Pertaining to Current Good</u>
11			<u>Manufacturing Practice, Quality Control Procedures, Quality Factors, Records and</u>
12			<u>Reports, and Notifications</u>
13	(46)	107	Infant Formula
14	(47)	108	Emergency Permit Control
15	(48)	109	Unavoidable Contaminants in Food for Human Consumption and Food-Packaging
16			Material
17	(49)	110	Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Human Food
18	(50)	111	Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding
19			Operations for Dietary Supplements
20	(51)	112	Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human
21			Consumption
22	(52)	113	Thermally Processed Low-Acid Foods Packaged in Hermetically Sealed Containers
23	(53)	114	Acidified Foods
24	(54)	115	Shell Eggs
25	(55)	117	Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive
26			Controls for Human Food
27	(56)	118	Production, Storage, and Transportation of Shell Eggs
28	(57)	120	Hazard Analysis and Critical Control Point (HACCP) Systems
29	(58)	123	Fish and Fishery Products
30	(59)	129	Processing and Bottling of Bottled Drinking Water (Except as amended by 02 NCAC 09C
31			.0700 - Bottled Water)
32	(60)	130	Food Standards: General
33	(61)	131	Milk and Cream
34	(62)	133	Cheeses and Related Cheese Products
35	(63)	135	Frozen Desserts
36	(64)	136	Bakery Products
37	(65)	137	Cereal Flours and Related Products

1	(66)	139	Macaroni and Noodle Products
2	(67)	145	Canned Fruits
3	(68)	146	Canned Fruit Juices
4	(69)	150	Fruit Butters, Jellies, Preserves, and Related Products
5	(70)	152	Fruit Pies
6	(71)	155	Canned Vegetables
7	(72)	156	Vegetable Juices
8	(73)	158	Frozen Vegetables
9	(74)	160	Eggs and Egg Products
10	(75)	161	Fish and Shellfish (Except Section 161.30 and 161.130 through 161.145)
11	(76)	163	Cacao Products
12	(77)	164	Tree Nut and Peanut Products
13	(78)	165	Beverages
14	(79)	166	Margarine
15	(80)	168	Sweeteners and Table Syrups
16	(81)	169	Food Dressings and Flavorings
17	(82)	170	Food Additives
18	(83)	172	Food Additives Permitted for Direct Addition to Food for Human Consumption
19	(84)	173	Secondary Direct Food Additives Permitted in Food for Human Consumption
20	(85)	174	Indirect Food Additives: General
21	(86)	175	Indirect Food Additives: Adhesives and Components of Coatings
22	(87)	176	Indirect Food Additives: Paper and Paperboard Components
23	(88)	177	Indirect Food Additives: Indirect Food Additives: Polymers
24	(89)	178	Indirect Food Additives: Adjuvants, Production Aids, and Sanitizers
25	(90)	179	Irradiation in the Production, Processing and Handling of Food
26	(91)	180	Food Additives Permitted in Food or in Contact with Food on an Interim Basis Pending
27			Additional Study
28	(92)	181	Prior-Sanctioned Food Ingredients
29	(93)	182	Substances Generally Recognized as Safe
30	(94)	184	Direct Food Substances Affirmed as Generally Recognized as Safe
31	(95)	186	Indirect Food Substances Affirmed as Generally Recognized as Safe
32	(96)	189	Substances Prohibited from Use in Human Food
33	(97)	190	Dietary Supplements
34	(98)	200	General
35	(99)	201	Labeling
36	(100)	202	Prescription Drug Advertising
37	(101)	210	Current Good Manufacturing Practice in Manufacturing, Processing, Packing or Holding

1			of Drugs; General
2	(102)	211	Current Good Manufacturing Practice for Finished Pharmaceuticals
3	(103)	225	Current Good Manufacturing Practice for Medicated Feeds
4	(104)	226	Current Good Manufacturing Practice for Type A Medicated Articles
5	(105)	250	Special Requirements for Specific Human Drugs
6	(106)	290	Controlled Drugs
7	(107)	299	Drugs; Official Names and Established Names
8	(108)	300	General
9	(109)	310	New Drugs
10	(110)	312	Investigational New Drug Application
11	(111)	314	Applications for FDA Approval to Market New Drug
12	(112)	320	Bioavailability and Bioequivalence Requirements
13	(113)	330	Over-the-Counter (OTC) Human Drugs Which Are Generally Recognized as Safe and
14			Effective and Not Misbranded
15	(114)	331	Antacid Products for Over-the-Counter (OTC) Human Use
16	(115)	332	Antiflatulent Products for Over-the-Counter Human Use
17	(116)	361	Prescription Drugs for Human Use Generally Recognized as Safe and Effective and Not
18			Misbranded: Drugs Used in Research
19	(117)	369	Interpretive Statements Re: Warnings on Drugs and Devices for Over-the-Counter Sale
20	(118)	809	In Vitro Diagnostic Products for Human Use
21	(119)	812	Investigational Device Exemptions
22	(120)	820	Quality System Regulation
23	(121)	860	Medical Device Classification Procedures
24	(122)	861	Procedures for Performance Standards Development
25	(123)	870	Cardiovascular Devices
26	(124)	882	Neurological Devices
27	(125)	884	Obstetrical and Gynecological Devices
28	(126)	895	Banned Devices
29	(127)	500	General
30	(128)	501	Animal Food Labeling
31	(129)	502	Common or Usual Names for Nonstandardized Animal Foods
32	(130)	<u>507</u>	<u>Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive</u>
33			<u>Controls for Food for Animals</u>
34	(130) <u>(131)</u>	509	Unavoidable Contaminants in Animal Food and Food-Packaging Material
35	(131) <u>(132)</u>	510	New Animal Drugs
36	(132) <u>(133)</u>	511	New Animal Drugs for Investigational Use
37	(133) <u>(134)</u>	514	New Animal Drug Applications

1	(134) (135)	520	Oral Dosage Form New Animal Drugs
2	(135) (136)	522	Implantation or Injectable Dosage Form New Animal Drugs
3	(136) (137)	524	Ophthalmic and Topical Dosage Form New Animal Drugs
4	(137) (138)	526	Intramammary Dosage Form New Animal Drugs
5	(138) (139)	529	Certain Other Dosage Form New Animal Drugs
6	(139) (140)	556	Tolerances for Residues of New Animal Drugs in Food
7	(140) (141)	558	New Animal Drugs for Use in Animal Feeds
8	(141) (142)	570	Food Additives
9	(142) (143)	573	Food Additives Permitted in Feed and Drinking Water of Animals
10	(143) (144)	582	Substances Generally Recognized as Safe
11	(144) (145)	584	Food Substances Affirmed as Generally Recognized as Safe in Feed and Drinking
12			Water of Animals
13	(145) (146)	589	Substances Prohibited from Use in Animal Food or Feed
14	(146) (147)	700	General
15	(147) (148)	701	Cosmetic Labeling
16	(148) (149)	720	Voluntary Filing of Cosmetic Product Ingredient Composition Statements
17	(149) (150)	740	Cosmetic Product Warning Statements

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19 Copies of the Code of Federal Regulations may be obtained at no cost by accessing the website of the U.S. Government
20 Printing Office at <http://www.gpoaccess.gov/cfr/index.html>.

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

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

29 (r) The Board incorporates by reference, including subsequent amendments and editions, "Definitions and Standards
30 of Identity or ~~Composition for Poultry and Poultry Products,~~" Composition," 9 C.F.R. Sections 381.155 through
31 381.170. Copies of the Code of Federal Regulations may be obtained at no cost by accessing the website of the U.S.
32 Government Printing Office at <http://www.gpoaccess.gov/cfr/index.html>.

33 (s) The Board incorporates by reference, including subsequent amendments and editions, "Labels: Definitions;
34 Required Features," Title 9, 9 C.F.R. Part 317.2(1)Section 317.2 of the Code of Federal Regulations. Copies of Title
35 9 of the Code of Federal Regulations may be obtained ~~from the Superintendent of Documents, Government Printing~~
36 ~~Office, Washington, DC 20402, at a cost of sixty four dollars (\$64.00),~~ at no cost by accessing the website of the U.S.
37 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,” Title 9, 9 C.F.R. Part 381.125(b) 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~~reference, including subsequent amendments and editions, the definition of "dietary supplement" found at 21 USC 321(ff).

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

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

(y) The Board incorporates by ~~reference~~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, 2018; May 1, 2018.

02 NCAC 09B .0135 is adopted as published in 33:02 NCR 88 as follows:

**02 NCAC 09B .0135 CURRENT GOOD MANUFACTURING PRACTICES FOR RETAIL FOOD
ESTABLISHMENTS**

Subpart B of 21 C.F.R. Part 117, as incorporated by reference pursuant to Rule .0116(o)(55) of this Subchapter, shall apply to “retail food establishments” as defined by 21 C.F.R. 1.227, and shall include bakeries, retail food outlets, and seafood markets.

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

Eff. February 1, 2019.