

orders otherwise, to the Director of Market Oversight or his designee, in consultation with the General Counsel or his designee, the authority reserved to the Commission under paragraph (m) of this section. The Director of the Division of Market Oversight may submit to the Commission for its consideration any matter which has been delegated pursuant to this paragraph (o).

■ 3. Appendix D to Part 30 is revised to read as follows:

Appendix D to Part 30—Commission Certification With Respect to Foreign Futures and Options Contracts on a Non-Narrow-Based Security Index

In its analysis of a request for certification by a foreign board of trade relating to a security index futures contract traded on that foreign board of trade pursuant to § 30.13, the Commission will evaluate the contract to ensure that it complies with the three criteria of section 2(a)(1)(C)(ii) of the Act.

(1) Because security index futures contracts are cash settled, the Commission also evaluates the contract terms and conditions relating to cash settlement. In that regard, the Commission examines, among other things, whether the cash price series is reliable, acceptable, publicly available and timely; that the cash settlement price is reflective of the underlying cash market; and that the cash settlement price is not readily susceptible to manipulation. In making its determination, the Commission considers the design and maintenance of the index, the method of index calculation, the nature of the component security prices used to calculate the index, the breadth and frequency of index dissemination, and any other relevant factors.

(2) In considering the susceptibility of an index to manipulation, the Commission examines several factors, including the structure of the primary and secondary markets for the component equities, the liquidity of the component stocks, the method of index calculation, the total capitalization of stocks underlying the index, the number, weighting and capitalization of individual stocks in the index, and the existence of surveillance sharing agreements between the board of trade and the securities exchange(s) on which the underlying securities are traded.

(3) To verify that the index is not narrow-based, the Commission considers the number and weighting of the component securities and the aggregate value of average daily trading volume of the lowest weighted quartile of securities. Under the Act, a security index is narrow-based if it meets any one of the following criteria:

- (i) The index is composed of fewer than 10 securities;
- (ii) Any single security comprises more than 30% of the total index weight;
- (iii) The five largest securities comprise more than 60% of the total index weight; or
- (iv) The lowest-weighted securities that together account for 25% of the total weight of the index have an aggregate dollar value of average daily trading volume of less than

US\$30 million (or US\$50 million if the index includes fewer than 15 securities).

Issued in Washington, DC, on September 16, 2011 by the Commission.

David A. Stawick,

Secretary of the Commission.

[FR Doc. 2011-24609 Filed 9-23-11; 8:45 am]

BILLING CODE P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 25, 173, 175, 177, 178, 182, and 184

[Docket No. FDA-2011-N-0011]

Environmental Impact Considerations, Food Additives, and Generally Recognized As Safe Substances; Technical Amendments

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendments.

SUMMARY: The Food and Drug Administration (FDA) is amending certain regulations regarding environmental impact considerations, food additives, and generally recognized as safe (GRAS) substances to correct minor errors in the Code of Federal Regulations (CFR). This action is editorial in nature and is intended to provide accuracy and clarity to the Agency's regulations.

DATES: This rule is effective October 3, 2011.

FOR FURTHER INFORMATION CONTACT: Ellen M. Waldron, Center for Food Safety and Applied Nutrition (HFS-206), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740-3835, 240-402-1256.

SUPPLEMENTARY INFORMATION: FDA is amending certain regulations in parts 25, 173, 175, 177, 178, 182, and 184 (21 CFR parts 25, 173, 175, 177, 178, 182, and 184). Minor errors were inadvertently published in the CFR affecting certain regulations regarding environmental impact considerations (part 25), food additives (parts 173, 175, 177, and 178), and GRAS substances (parts 182 and 184). This action makes the needed corrections.

The final rule contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

Publication of this document constitutes final action of these changes under the Administrative Procedure Act

(5 U.S.C. 553). These amendments are merely correcting nonsubstantive errors. FDA therefore, for good cause, finds under 5 U.S.C. 553(b)(3)(B) and (d)(3) that notice and public comment are unnecessary. The changes addressed in this document are as follows:

1. The Agency is correcting typographical errors. Two chemical names are corrected: Polytetrafluoroethylene in § 175.105 and dialkyl (C₈-C₁₈) dimethylammonium chloride in § 177.2600. Two chemical formulas are corrected: *N,N*-B-is(2-hydroxyethyl) alkylamine, where the alkyl groups (C₁₄-C₁₈) are derived from tallow in § 178.3130, and MnCl₂ in § 184.1446.

2. The Agency is also correcting five Chemical Abstract Service registry numbers (CAS Reg. Nos.) that are incorrectly listed: 123-93-5 in § 173.375, 1302-78-9 in § 184.1155, 7758-99-8 in § 184.1261, 10024-66-5 in § 184.1449, and 10025-69-1 in § 184.1845.

3. The Agency is updating citations. The two citations in 21 CFR 182.99 are updated to 40 CFR 180.910 and 40 CFR 180.920 due to a recent U.S. Environmental Protection Agency regulation. A citation in § 25.32 is updated. Section 25.32(p) refers to a petition pertaining to the label declaration of ingredients as described in § 101.103 (21 CFR 101.103). However, FDA revoked § 101.103 on June 3, 1996 (61 FR 27771 at 27779) because it duplicated the procedures in 21 CFR 10.30 for citizen petitions.

4. The Agency is amending tables in §§ 175.300 and 177.1210.

5. Finally, the Agency is updating § 184.1165. Under § 184.1165(a), both *n*-butane and iso-butane are described as odorless. However, the *Food Chemicals Codex*, 7th Edition (2010)¹ does not use the word "odorless" to describe the gases. Therefore, the Agency is amending its description by removing the word "odorless."

List of Subjects

21 CFR Part 25

Environmental impact statements, Foreign relations, Reporting and recordkeeping requirements.

21 CFR Part 173

Food additives.

21 CFR Part 175

Adhesives, Food additives, Food packaging.

¹ *Food Chemicals Codex*, 7th Edition, pp. 115 and 529, Rockville, MD: United States Pharmacopeial Convention, 2010.

21 CFR Part 177

Food additives, Food packaging.

21 CFR Part 178

Food additives, Food packaging.

21 CFR Part 182

Food ingredients, Food packaging, Spices and flavorings.

21 CFR Part 184

Food additives.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR parts 25, 173, 175, 177, 178, 182, and 184 are amended as follows:

PART 25—ENVIRONMENTAL IMPACT CONSIDERATIONS

■ 1. The authority citation for 21 CFR part 25 continues to read as follows:

Authority: 21 U.S.C. 321–393; 42 U.S.C. 262, 263b–264; 42 U.S.C. 4321, 4332; 40 CFR parts 1500–1508; E.O. 11514, 35 FR 4247, 3 CFR, 1971 Comp., p. 531–533 as amended by E.O. 11991, 42 FR 26967, 3 CFR, 1978 Comp., p. 123–124 and E.O. 12114, 44 FR 1957, 3 CFR, 1980 Comp., p. 356–360.

■ 2. Section 25.32 is amended by revising paragraph (p) to read as follows:

§ 25.32 Foods, food additives, and color additives.

* * * * *

(p) Issuance, amendment, or revocation of a regulation in response to a reference amount petition as described in § 101.12(h) of this chapter, a nutrient content claim petition as described in § 101.69 of this chapter, a health claim petition as described in § 101.70 of this chapter, or a petition pertaining to the label declaration of ingredients as described in § 10.30 of this chapter.

* * * * *

PART 173—SECONDARY DIRECT FOOD ADDITIVES PERMITTED IN FOOD FOR HUMAN CONSUMPTION

■ 3. The authority citation for 21 CFR part 173 continues to read as follows:

Authority: 21 U.S.C. 321, 342, 348.

■ 4. Section 173.375 is amended by revising the introductory text to read as follows:

§ 173.375 Cetylpyridinium chloride.

Cetylpyridinium chloride (CAS Reg. No. 123–93–5) may be safely used in food in accordance with the following conditions:

* * * * *

PART 175—INDIRECT FOOD ADDITIVES: ADHESIVES AND COMPONENTS OF COATINGS

■ 5. The authority citation for 21 CFR part 175 continues to read as follows:

Authority: 21 U.S.C. 321, 342, 348, 379e.

§ 175.105 [Amended]

■ 6. Section 175.105 is amended in the table in paragraph (c)(5), in the “Substances” column, by removing the entry for “Polytetrafluoroethylene” and by adding in its place the entry for “Polytetrafluoroethylene.”

■ 7. Section 175.300 is amended by revising Table 2 in paragraph (d) to read as follows:

§ 175.300 Resinous and polymeric coatings.

* * * * *

(d) * * *

TABLE 2—TEST PROCEDURES FOR DETERMINING AMOUNT OF EXTRACTIVES FROM RESINOUS OR POLYMERIC COATINGS, USING SOLVENTS SIMULATING TYPES OF FOODS AND BEVERAGES

Condition of use	Types of food (see Table 1)	Extractant		
		Water (time and temperature)	Heptane ^{1,2} (time and temperature)	8% alcohol (time and temperature)
A. High temperature heat-sterilized (e.g., over 212 °F).	I, IV–B	250 °F, 2 hr	
	III, IV–A, VII	do	150 °F, 2 hr	
B. Boiling water-sterilized	II	212 °F, 30 min	
	III, VII	do	120 °F, 30 min.	
C. Hot filled or pasteurized above 150 °F	II, IV–B	Fill boiling, cool to 100 °F.	
	III, IV–A	do	120 °F, 15 min	
	V	do	do	
D. Hot filled or pasteurized below 150 °F	II, IV–B, VI–B	150 °F, 2 hr	150 °F, 2 hr.
	III, IV–A	do	100 °F, 30 min	
	V	do	do	
	VI–A	do	do	
E. Room temperature filled and stored (no thermal treatment in the container).	II, IV–B, VI–B	120 °F, 24 hr	120 °F, 24 hr.
	III, IV–A	do	70 °F, 30 min	
	V, VII	do	do	
F. Refrigerated storage (no thermal treatment in the container).	VI–A	do	70 °F, 48 hr.
	I, II, III, IV–A, IV–B, VI–B, VII	70 °F, 48 hr	
G. Frozen storage (no thermal treatment in the container).	VI–A	do	
	I, II, III, IV–B, VII	70 °F, 24 hr	
H. Frozen storage: Ready-prepared foods intended to be reheated in container at time of use:				
	1. Aqueous or oil in water emulsion of high or low fat.	I, II, IV–B	212 °F, 30 min	
	2. Aqueous, high or low free oil or fat	III, IV–A, VII	do	

¹ Heptane extractant not to be used on wax-lined containers.

² Heptane extractivity results must be divided by a factor of five in arriving at the extractivity for a food product.

* * * * *

Authority: 21 U.S.C. 321, 342, 348, 379e.

§ 177.1210 Closures with sealing gaskets for food containers.

* * * * *

(c) * * *

PART 177—INDIRECT FOOD ADDITIVES: POLYMERS

■ 8. The authority citation for 21 CFR part 177 continues to read as follows:

■ 9. Section 177.1210 is amended by revising Table 4 of paragraph (c) to read as follows:

TABLE 4—TEST PROCEDURES WITH TIME-TEMPERATURE CONDITIONS FOR DETERMINING AMOUNT OF EXTRACTIVES FROM CLOSURE-SEALING GASKETS, USING SOLVENTS SIMULATING TYPES OF FOODS AND BEVERAGES

Conditions of use	Types of food (see Table 3)	Extractant		
		Water (time and temperature)	Heptane ¹ (time and temperature)	8% alcohol (time and temperature)
A. High temperature heat-sterilized (e.g., over 212 °F).	I, IV-B	250 °F, 2 hr	
	III, IV-A, VII	do	150 °F, 2 hr	
B. Boiling water-sterilized	II	212 °F, 30 min	
	III, VII	do	120 °F, 30 min	
C. Hot filled or pasteurized above 150 °F	II, IV-B	Fill boiling, cool to 100 °F.	
	III, IV-A	do	120 °F, 15 min	
	V	do	do	
D. Hot filled or pasteurized below 150 °F	II, IV-B, VI-B	150 °F, 2 hr	150 °F, 2 hr.
	III, IV-A	do	100 °F, 30 min	
	V	do	
	VI-A	
E. Room temperature filled and stored (no thermal treatment in the container).	II, IV-B, VI-B	120 °F, 24 hr	120 °F, 24 hr.
	III, IV-A	do	70 °F, 30 min	
	V	do	
F. Refrigerated storage (no thermal treatment).	VI-A	70 °F, 24 hr.
	I, II, III, IV-A, IV-B, VI-B, VII	70 °F, 48 hr	70 °F, 30 min	
G. Frozen storage (no thermal treatment in the container).	VI-A	70 °F, 48 hr.
	I, II, III, IV-B, VII	70 °F, 24 hr	

¹Heptane extractant not applicable to closure-sealing gaskets overcoated with wax.

§ 177.2600 [Amended]

■ 10. Section 177.2600 is amended in paragraph (c)(4)(ix) by removing the entry for “Dialkyl (C₈–C₁₈)” and by adding in its place the entry for “Dialkyl (C₈–C₁₈) dimethylammonium chloride for use only as a flocculating agent in the manufacture of silica.”

PART 178—INDIRECT FOOD ADDITIVES: ADJUVANTS, PRODUCTION AIDS, AND SANITIZERS

■ 11. The authority citation for 21 CFR part 178 continues to read as follows:

Authority: 21 U.S.C. 321, 342, 348, 379e.

§ 178.3130 [Amended]

■ 12. Section 178.3130 is amended in the table in paragraph (b), in the “List of Substances” column, by removing the entry for “N,N-Bis(2-hydroxyethyl) alkylamine, where the alkyl groups (C₁–C₁₈) are derived from tallow.” and by adding in its place the entry for “N,N-Bis(2-hydroxyethyl) alkylamine, where the alkyl groups (C₁₄–C₁₈) are derived from tallow.”

PART 182—SUBSTANCES GENERALLY RECOGNIZED AS SAFE

■ 13. The authority citation for 21 CFR part 182 continues to read as follows:

Authority: 21 U.S.C. 321, 342, 348, 371.

■ 14. Section 182.99 is revised to read as follows:

§ 182.99 Adjuvants for pesticide chemicals.

Adjuvants, identified and used in accordance with 40 CFR 180.910 and 40 CFR 180.920, which are added to pesticide use dilutions by a grower or applicator prior to application to the raw agricultural commodity, are exempt from the requirement of tolerances under section 409 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 348).

PART 184—DIRECT FOOD SUBSTANCES AFFIRMED AS GENERALLY RECOGNIZED AS SAFE

■ 15. The authority citation for 21 CFR part 184 continues to read as follows:

Authority: 21 U.S.C. 321, 342, 348, 371.

■ 16. Section 184.1155 is amended by revising the first sentence of paragraph (a) to read as follows:

§ 184.1155 Bentonite.

(a) Bentonite (Al₂O₃·4SiO₂·nH₂O, CAS Reg. No. 1302–78–9) is principally a colloidal hydrated aluminum silicate.

* * *

■ 17. Section 184.1165 is amended by revising the first sentence of paragraph (a) to read as follows:

§ 184.1165 n-Butane and iso-butane.

(a) n-Butane and iso-butane (empirical formula C₄H₁₀, CAS Reg. Nos. 106–97–8 and 75–28–5, respectively) are colorless, flammable gases at normal temperatures and pressures. * * *

* * *

■ 18. Section 184.1261 is amended by revising the first sentence of paragraph (a) to read as follows:

§ 184.1261 Copper sulfate.

(a) Copper sulfate (cupric sulfate, CuSO₄·5 H₂O, CAS Reg. No. 7758–99–8)

usually is used in the pentahydrate form. * * *

* * * * *

■ 19. Section 184.1446 is amended by revising the first sentence of paragraph (a) to read as follows:

§ 184.1446 Manganese chloride.

(a) Manganese chloride (MnCl₂, CAS Reg. No. 7773-01-5) is a pink, translucent, crystalline product. * * *

* * * * *

■ 20. Section 184.1449 is amended by revising the first sentence of paragraph (a) to read as follows:

§ 184.1449 Manganese citrate.

(a) Manganese citrate (Mn₃(C₆H₅O₇)₂, CAS Reg. No. 10024-66-5) is a pale orange or pinkish white powder. * * *

* * * * *

■ 21. Section 184.1845 is amended by revising the fourth sentence of paragraph (a) to read as follows:

§ 184.1845 Stannous chloride (anhydrous and dehydrated).

(a) * * * Dihydrated stannous chloride (SnCl₂·2H₂O, CAS Reg. No. 10025-69-1) is the chloride salt of metallic tin that contains two molecules of water. * * *

* * * * *

Dated: September 19, 2011.

Susan Bernard,

Acting Director, Office of Regulations, Policy and Social Sciences, Center for Food Safety and Applied Nutrition.

[FR Doc. 2011-24455 Filed 9-23-11; 8:45 am]

BILLING CODE 4160-01-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA-R04-OAR-2011-0386-201151; FRL-9471-1]

Approval and Promulgation of Air Quality Implementation Plans; North Carolina: Clean Smokestacks Act

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: EPA is approving a State Implementation Plan (SIP) revision submitted by the State of North Carolina for the purpose of establishing system-wide emission limitations from the North Carolina Clean Smokestacks Act (CSA) into the North Carolina SIP. On August 21, 2009, the State of North Carolina, through the North Carolina Department of Environment and Natural Resources (NC DENR), Division of Air

Quality (DAQ), submitted an attainment demonstration for the Hickory-Morganton-Lenoir and Greensboro-Winston Salem-High Point 1997 fine particulate matter (PM_{2.5}) nonattainment area. That submittal included a request that the system-wide emission limitations from the North Carolina CSA be incorporated into the State's federally approved SIP. EPA has determined that the CSA portion of this SIP revision is approvable pursuant to the Clean Air Act (CAA or Act).

DATES: This rule will be effective October 26, 2011.

ADDRESSES: EPA has established a docket for this action under Docket Identification No. EPA-R04-OAR-2011-0386. All documents in the docket are listed on the <http://www.regulations.gov> Web site. Although listed in the index, some information is not publicly available, *i.e.*, Confidential Business Information or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically through <http://www.regulations.gov> or in hard copy at the Regulatory Development Section, Air Planning Branch, Air, Pesticides and Toxics Management Division, U.S. Environmental Protection Agency, Region 4, 61 Forsyth Street, SW., Atlanta, Georgia 30303-8960. EPA requests that if at all possible, you contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section to schedule your inspection. The Regional Office's official hours of business are Monday through Friday, 8:30 to 4:30 excluding federal holidays.

FOR FURTHER INFORMATION CONTACT: Joel Huey or Nacosta C. Ward, Regulatory Development Section, Air Planning Branch, Air, Pesticides and Toxics Management Division, U.S. Environmental Protection Agency, Region 4, 61 Forsyth Street, SW., Atlanta, Georgia 30303-8960. Mr. Huey may be reached by phone at (404) 562-9104. Mr. Huey can also be reached via electronic mail at huey.joel@epa.gov. Ms. Ward may be reached by phone at (404) 562-9140 or via electronic mail at ward.nacosta@epa.gov.

SUPPLEMENTARY INFORMATION:

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- I. What is the background of North Carolina's CSA?
- II. This Action
- III. Final Action
- IV. Statutory and Executive Order Reviews

V. Statutory and Executive Order Reviews

I. What is the background of North Carolina's CSA?

In June 2002, the General Assembly of North Carolina, Session 2001, passed Session Law 2002-4, also known as Senate Bill 1078. This legislation, entitled "*An Act to Improve Air Quality in the State by Imposing Limits on the Emission of Certain Pollutants from Certain Facilities that Burn Coal to Generate Electricity and to Provide for Recovery by Electric Utilities of the Costs of Achieving Compliance with Those Limits*," requires significant actual emission reductions from coal-fired power plants in North Carolina. The State expected that emission reductions from the CSA would have significant health benefits for the citizens of North Carolina and other states.

North Carolina's CSA includes a schedule of system-wide limitations (or caps) on emissions of nitrogen oxides (NO_x) and sulfur dioxide (SO₂) from coal-fired power plants in the State, the first of which became effective in 2007. The State expects the resulting emission reductions will serve as a significant step towards meeting the 1997 PM_{2.5} and 8-hour ozone national ambient air quality standards (NAAQS), among other NAAQS, improving visibility in the mountains and other scenic vistas, and reducing acid rain. EPA notes that all areas in the State that were designated nonattainment for the 1997 PM_{2.5} and 8-hour ozone NAAQS are currently attaining the standards. Although the Hickory-Morganton-Lenoir and Greensboro-Winston Salem-High Point nonattainment areas for the 1997 PM_{2.5} NAAQS have not yet been redesignated to attainment, EPA determined that these areas had attaining data based on the three-year period 2006-2008.¹ Also, although the Charlotte 1997 8-hour ozone nonattainment area is still designated nonattainment, EPA has issued a proposed determination that the Area has attaining data based on the 2008-2010 design value period. *See* 76 FR 20293 (April 12, 2011). North Carolina has identified the CSA as part of its plan to attain and maintain the NAAQS. Because North Carolina is relying on

¹ EPA's determination that the Hickory-Morganton-Lenoir and Greensboro-Winston Salem-High Point PM_{2.5} nonattainment areas have attained the 1997 PM_{2.5} NAAQS is not equivalent to the redesignation of the areas to attainment. The designation status of the areas remains nonattainment for the 1997 PM_{2.5} NAAQS until such time as EPA determines that the areas meet all of the CAA requirements for redesignation to attainment. *See* 75 FR 54 (January 4, 2010) and 75 FR 230 (January 5, 2010), respectively.