

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration
21 CFR Part 177
[Docket No. 84F-0211]
Indirect Food Additives; Polymers
AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the food additive regulations to expand the use of hexamethylene bis(3,5-di-*tert*-butyl-4-hydroxyhydrocinnamate) as an antioxidant/stabilizer in polyoxymethylene copolymers that contact foods containing more than 8 percent alcohol. This action responds to a petition filed by Ciba-Geigy Corp.

DATES: Effective May 17, 1985; objections by June 17, 1985.

ADDRESS: Written objections to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

Thomas C. Brown, Center for Food Safety and Applied Nutrition (HFF-334), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-472-5690.

SUPPLEMENTARY INFORMATION: In a notice published in the *Federal Register* of July 30, 1984 (49 FR 30370), FDA announced that a food additive petition (FAP 4B3805) had been filed by Ciba-Geigy Corp., Hawthorne, NY 10532, proposing that § 177.2470

Polyoxymethylene copolymer (21 CFR 177.2470) be amended to expand the use of hexamethylene bis(3,5-di-*tert*-butyl-4-hydroxyhydrocinnamate) as an antioxidant/stabilizer in polyoxymethylene copolymers that contact foods containing more than 8 percent alcohol.

FDA has evaluated the data in the petition and other relevant material and concludes that the proposed food additive uses are safe and that the regulations should be amended as set forth below.

In accordance with § 171.1(h) (21 CFR 171.1(h)), the petition and the documents that FDA considered and relied upon in reaching its decision to approve the petition are available for inspection at the Center for Food Safety and Applied Nutrition (address above) by appointment with the information contact person listed above. As provided in 21 CFR 171.1(h), the agency will delete from the documents any

materials that are not available for public disclosure before making the documents available for inspection.

The agency has carefully considered the potential environmental effects of this action and has concluded that the action will not have a significant impact on the human environment and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding may be seen in the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857, between 9 a.m. and 4 p.m., Monday through Friday.

Any person who will be adversely affected by this regulation may at any time on or before June 17, 1985 submit to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857, written objections thereto and may make a written request for a public hearing on the stated objections. Each objection shall be separately numbered and each numbered objection shall specify with particularity the provision of the regulation to which objection is made. Each numbered objection on which a hearing is requested shall specifically so state; failure to request a hearing for any particular objection shall constitute a waiver of the right to a hearing on that objection. Each numbered objection for which a hearing is requested shall include a detailed description and analysis of the specific factual information intended to be presented in support of the objection in the event that a hearing is held; failure to include such a description and analysis for any particular objection shall constitute a waiver of the right to a hearing on the objection. Three copies of all documents shall be submitted and shall be identified with the docket number found in brackets in the heading of this regulation. Received objections may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 177

Food additives, Polymeric food packaging.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Food Safety and Applied Nutrition, Part 177 is amended as follows:

PART 177—INDIRECT FOOD ADDITIVES: POLYMERS

1. The authority citation for Part 177 is revised to read as follows:

Authority: Secs. 201(s), 409, 72 Stat. 1784-1788 as amended (21 U.S.C. 321(s), 348); 21 CFR 5.10 and 5.61.

§ 177.2470 [Amended]

2. Section 177.2470 *Polyoxymethylene copolymer* is amended in paragraph (b)(1) by revising the entry "Hexamethylene bis(3,5-di-*tert*-butyl-4-hydroxyhydrocinnamate) (CAS Reg. No. 35074-77-2) (for use in contact with foods containing no more than 8 percent alcohol)" to read "Hexamethylene bis(3,5-di-*tert*-butyl-4-hydroxyhydrocinnamate) (CAS Reg. No. 35074-77-2)."

Effective date. This regulation is effective May 17, 1985.

Dated: May 8, 1985.

Richard J. Ronk,

Acting Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 85-11922 Filed 5-16-85; 8:45 am]

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DEPARTMENT OF THE TREASURY
Bureau of Alcohol, Tobacco and Firearms
27 CFR Part 9
[T.D. ATF-204; Re: Notice No. 472]
Establishment of the Northern Sonoma Viticultural Area

AGENCY: Bureau of Alcohol, Tobacco and Firearms (ATF), Treasury.

ACTION: Final rule, Treasury decision.

SUMMARY: This final rule establishes a viticultural area in California known as "Northern Sonoma." The establishment of viticultural areas and the subsequent use of viticultural area names as appellations of origin in wine labeling and advertising will help consumers better identify wines they purchase. The use of this viticultural area as an appellation of origin will also help winemakers distinguish their products from wines made in other areas.

EFFECTIVE DATE: June 17, 1985.

FOR FURTHER INFORMATION CONTACT: John A. Linthicum, FAA, Wine and Beer Branch, Bureau of Alcohol, Tobacco and Firearms, 1200 Pennsylvania Avenue, NW, Washington, DC 20226 (202-566-7626).

SUPPLEMENTARY INFORMATION:**Background**

On August 23, 1978, ATF published Treasury Decision ATF-53 (43 FR 37672, 54624) revising regulations in 27 CFR Part 4. These regulations allow the establishment of definitive viticultural areas. The regulations also allow the name of an approved viticultural area to be used as an appellation of origin on wine labels and in wine advertisements.

On October 2, 1979, ATF published Treasury Decision ATF-60 (44 FR 56692) which added a new Part 9 to 27 CFR, providing for the listing of approved American viticultural areas, the names of which may be used as appellations of origin.

Section 4.25(e)(1), Title 27, CFR, defines an American viticultural area as a delimited grape-growing region distinguishable by geographical features. Section 4.25(e)(2) outlines the procedure for proposing an American viticultural area. Any interested person may petition ATF to establish a grape-growing region as a viticultural area.

E. & J. Gallo Winery on behalf of its subsidiary Frei Brothers, a winery located in Healdsburg, California, petitioned ATF for the establishment of a viticultural area in California to be known as "Northern Sonoma." In response to this petition, ATF published a notice of proposed rulemaking (Notice No. 472) in the *Federal Register* on June 27, 1983 (48 FR 29539) proposing the establishment of this viticultural area.

General Description

The Northern Sonoma viticultural area consists of approximately 329,000 acres encompassing 26,000 acres of grapevines and 72 wineries.

The Northern Sonoma viticultural area is located entirely within the North Coast viticultural area. Six approved viticultural areas are located entirely within the Northern Sonoma viticultural area as follows: Chalk Hill, Alexander Valley, Sonoma County Green Valley, Dry Creek Valley, Russian River Valley, and Knights Valley.

The Sonoma County Green Valley and Chalk Hill areas are each entirely within the Russian River Valley area. The boundaries of the Alexander Valley, Dry Creek Valley, Russian River Valley, and Knights Valley areas all fit perfectly together dividing northern Sonoma County into four large areas. The Northern Sonoma area uses all of the outer boundaries of these four areas with the exception of an area southwest of the Dry Creek Valley area and west of the Russian River Valley area. This area has nearly 300 acres of grapevines and possesses the same geographical

features as the rest of the Northern Sonoma area.

Name

The name "Northern Sonoma" was used as a community name by the *Healdsburg Enterprise*, a local newspaper, beginning in 1887. A winery was established in Geyserville in 1890 named "North Sonoma Winery"; the winery was destroyed by fire three years later. In 1910, *The Pacific Wine and Spirits Review*, reported that Sonoma County would soon become the leading grape producing county in the state, attributing the growth partly to the construction of three new wineries in Northern Sonoma. In January 1920, the *Healdsburg Enterprise* and the *Santa Rosa Press Democrat* both reported on a movement to divide northern and southern Sonoma County into two counties. These reports support the concept of "Northern Sonoma" as a distinct community. A winery was established in Geyserville at the end of prohibition named "Northern Sonoma Wines, Inc." By the mid-1940's, this winery was producing approximately one million gallons annually, most of which was sold in bulk to bottlers. This winery was phased out of existence in 1953. Beginning in 1950, tourism publications of the county government and local chambers of commerce have divided the county into "Northern Sonoma" and other regions. A series of articles published in 1973 and 1974 in *Wines & Vines*, a wine industry trade magazine, describe the "northern district" of Sonoma County. This "northern district" is approximately the same as the approved viticultural area. In the spring of 1980, another effort was initiated to establish a separate county comprising the northern part of Sonoma County. This also supports the idea that "Northern Sonoma" may be identified as a separate community.

Geographical Features Which Affect Viticultural Features

The approved area is separated from the Sonoma Valley viticultural area in southern Sonoma County by the city of Santa Rosa and Cotati Valley which are urban or undergoing urbanization. These and other urban areas distinguish the proposed area from areas located south of the proposed boundary.

The area west of the approved western boundary is mountainous and relatively inaccessible. A small part of the western portion of the approved area is also mountainous and inaccessible. However, for convenience the boundary was drawn as a series of straight lines connecting features which can be found conveniently on the map.

North and east of the approved area are mountain ridges which distinguish the microclimates of Northern Sonoma from the microclimates on the opposite sides of the mountain ridges. The northern part of the area is cooler than the Guenoc Valley viticultural area to the north. The eastern part of the area receives significantly more rainfall than the Napa Valley viticultural area to the east.

Public Comments

ATF received 2 comments in response to Notice No. 472, from ISC of California, Inc. and Heublein Wines. Both commenters were in favor of establishment of the Northern Sonoma viticultural area as proposed. Both commenters were specifically in favor of establishment of large areas which include smaller approved areas. Both commenters believe that the name "Northern Sonoma" applies to the proposed area and that the name would not be confusing to consumers.

Boundary Adopted as Proposed

Based on the foregoing, the boundary of the Northern Sonoma viticultural area, as proposed in Notice No. 472, is established unchanged. However, the proposed § 9.70(c)(20) erroneously referred to "Big Oak Mountain" where the correct name of the geographical feature is "Big Oat Mountain." This error is corrected in the final rule. The boundary of the approved viticultural area is described in § 9.70.

Miscellaneous

ATF does not wish to give the impression by approving Northern Sonoma as a viticultural area that it is approving or endorsing the quality of the wine from the area. ATF is approving this area as being distinct and not better than other areas. By approving the area, wine producers are allowed to claim a distinction on labels and advertisements as to origin of the grapes. Any commercial advantage gained can only come from consumer acceptance of Northern Sonoma wines.

Regulatory Flexibility Act

The provisions of the Regulatory Flexibility Act relating to a final regulatory flexibility analysis (5 U.S.C. 604) are not applicable to this final rule because it will not have a significant economic impact on a substantial number of small entities. The final rule will not impose, or otherwise cause, a significant increase in the reporting, recordkeeping, or other compliance burdens on a substantial number of small entities. The final rule is not

expected to have significant secondary or incidental effects on a substantial number of small entities.

Accordingly, it is hereby certified under the provisions of Section 3 of the Regulatory Flexibility Act (5 U.S.C. 605(b)) that this final rule will not have a significant economic impact on a substantial number of small entities.

Compliance With E.O. 12291

In compliance with Executive Order 12291 the Bureau has determined that this final rule is not a major rule since it will not result in:

(a) An annual effect on the economy of \$100 million or more;

(b) A major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; or

(c) Significant adverse effects on competition, employment, investment, productivity, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets.

Paperwork Reduction Act

The provisions of the Paperwork Reduction Act of 1980, Pub. L. 96-511, 44 U.S.C. Chapter 35, and its implementing regulations, 5 CFR Part 1320, do not apply to this final rule because no requirement to collect information is imposed.

List of Subjects in 27 CFR Part 9

Administrative practice and procedure, Consumer protection, Viticultural areas, Wine.

Drafting Information

The principal author of this document is John A. Linthicum, FAA, Wine and Beer Branch, Bureau of Alcohol, Tobacco and Firearms.

Authority and Issuance

27 CFR Part 9—American Viticultural Areas is amended as follows:

Paragraph 1. The authority citation for Part 9 continues to read as follows:

Authority: August 29, 1935, Chapter 814, sec. 5, 49 Stat. 981, as amended (27 U.S.C. 205), unless otherwise noted.

Par. 2. The table of sections in 27 CFR Part 9, Subpart C, is amended by adding the heading of § 9.70 to read as follows:

Subpart C—Approved American Viticultural Areas

Sec.

* * * * *

9.70 Northern Sonoma.

Par. 3. Subpart C is amended by adding § 9.70 to read as follows:

§ 9.70 Northern Sonoma.

(a) *Name.* The name of the viticultural area described in this section is "Northern Sonoma."

(b) *Approved map.* The approved map for determining the boundary of the Northern Sonoma viticultural area is the U.S.G.S. Topographic Map of Sonoma County, California, scale 1:100,000, dated 1970.

(c) *Boundary.* The Northern Sonoma Viticultural area is located in Sonoma County, California. The boundary description in paragraphs (c)(1)–(c)(23) of this section includes (in parentheses) the local names of roads which are not identified by name on the map.

(1) The beginning point is the point, in the town of Monte Rio, at which a secondary highway (Bohemian Highway) crosses the Russian River.

(2) The boundary follows this secondary highway (Bohemian Highway) southeasterly across the Russian River, along Dutch Bill Creek, through the towns of Camp Meeker, Occidental, and Freestone, then northeasterly to the point at which it is joined by State Highway 12.

(3) The boundary follows State Highway 12 through the town of Sebastopol to the point, near a bench mark at elevation 96 feet, at which it intersects a northbound secondary highway (Fulton Road) leading toward the town of Fulton.

(4) The boundary follows this secondary highway (Fulton Road) north to the town of Fulton where it intersects an east-west secondary highway (River Road).

(5) The boundary follows this secondary highway (River Road)—

(i) East past U.S. Highway 101 (where the name of this secondary highway changes to Mark West Springs Road),

(ii) Easterly, then northerly to the town of Mark West Springs (where the name of this secondary highway changes to Porter Road),

(iii) Easterly to the town of Petrified Forest (where the name of this secondary highway changes to Petrified Forest Road), and

(iv) Northeasterly to the Sonoma County-Napa County line.

(6) The boundary follows the Sonoma County-Napa County line northerly to the Sonoma County-Lake County line.

(7) The boundary follows the Sonoma County-Lake County line northwesterly to the section line on the north side of Section 11, Township 10 North, Range 8 West.

(8) The boundary follows this section line west to the northwest corner of Section 9, Township 10 North, Range 8, West.

(9) The boundary follows the section line south to the southwest corner of Section 4, Township 9 North, Range 8, West.

(10) The boundary proceeds in a straight line northwest to the northeast corner of Section 36, Township 10 North, Range 9, West.

(11) The boundary follows the section line north to the northeast corner of Section 13, Township 10 North, Range 9, West.

(12) The boundary proceeds in a straight line northwesterly to the intersection of 38° 45' North latitude parallel and 122° 52' 30" West longitude meridian.

(13) The boundary proceeds in a straight line northwesterly to the southeast corner of Section 4, Township 11 North, Range 10 West.

(14) The boundary follows the section line north to the Sonoma County-Mendocino County line.

(15) The boundary follows the Sonoma County-Mendocino County line west then south to the southwest corner of Section 34, Township 12 North, Range 11 West.

(16) The boundary proceeds in a straight line southeasterly to the southeast corner of Section 3, Township 11 North, Range 11 West.

(17) The boundary follows the section line and its extension south to 38° 45' North latitude parallel.

(18) The boundary follows this latitude parallel west to the west line of Section 5, Township 10 North, Range 11 West.

(19) The boundary follows the section line south to the southeast corner of Section 18, Township 9 North, Range 11 West.

(20) The boundary proceeds in a straight line southwesterly approximately 5 miles to the peak of Big Oat Mountain, elevation 1404 feet.

(21) The boundary proceeds in a straight line southeasterly approximately 2¾ miles to the peak of Pole Mountain, elevation 2204 feet.

(22) The boundary proceeds in a straight line southerly approximately 2¾ miles to the confluence of Austin Creek and the Russian River.

(23) The boundary follows the Russian River northeasterly, then southeasterly to the beginning point.

Signed: March 4, 1985.

Stephen E. Higgins,
Director.

Approved: April 24, 1985.

Edward T. Stevenson,
Deputy Assistant Secretary (Operations).

[FR Doc. 85-11879 Filed 5-16-85; 8:45 am]

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