as RC may be deviated from using accepted methods in accordance with the operator's maintenance or inspection program without obtaining approval of an AMOC, provided the procedures and tests identified as RC can be done and the airplane can be put back in an airworthy condition. Any substitutions or changes to procedures or tests identified as RC require approval of an AMOC.

(k) Additional Information

For more information about this AD, contact Dat Le, Aviation Safety Engineer, FAA, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; phone: (516) 228–7300; email: *9-avs-nyaco-cos@faa.gov*.

(l) Material Incorporated by Reference

(1) The Director of the Federal Register approved the incorporation by reference (IBR) of the service information listed in this paragraph under 5 U.S.C. 552(a) and 1 CFR part 51.

(2) You must use this service information as applicable to do the actions required by this AD, unless this AD specifies otherwise.

(i) European Union Aviation Safety Agency (EASA) AD 2023–0102, dated May 17, 2023.

(ii) [Reserved]

(3) For EASA AD 2023–0102, contact EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; telephone +49 221 8999 000; email *ADs@easa.europa.eu;* website *easa.europa.eu.* You may find this EASA AD on the EASA website at *ad.easa.europa.eu.*

(4) You may view this material at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195.

(5) You may view this material at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, visit *www.archives.gov/federal-register/cfr/ibr-locations* or email *fr.inspection@nara.gov*.

Issued on October 27, 2023.

Caitlin Locke,

Director, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2023–24166 Filed 11–2–23; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 180

[Docket No. FDA–2023–N–0937]

RIN 0910–AI81

Revocation of Authorization for Use of Brominated Vegetable Oil in Food

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA or we) is proposing to amend our regulations to revoke the authorization for the use of brominated vegetable oil (BVO) in food. This action is being taken because there is no longer a reasonable certainty of no harm from the continued use of BVO in food. Specifically, the proposed rule would revoke the authorization for the use of BVO as a food ingredient intended to stabilize flavoring oils in fruit-flavored beverages. There are no authorizations for other uses of BVO in food.

DATES: Either electronic or written comments on the proposed rule must be submitted by January 17, 2024.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of January 17, 2024. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov*.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2023–N–0937 for ''Revocation of Authorization for Use of Brominated Vegetable Oil in Food.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' We will review this copy, including the claimed confidential information, in our consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

FOR FURTHER INFORMATION CONTACT: Jason Downey, Center for Food Safety and Applied Nutrition (HFS–255), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–9241; or Philip L. Chao, Center for Food Safety and Applied Nutrition, Office of Regulations and Policy (HFS–024), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–2378.

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Executive Summary

A. Purpose of the Proposed Rule

The proposed rule would amend our regulations to revoke the authorization for the use of brominated vegetable oil (BVO) in food. We are taking this action because there is no longer a basis to conclude that this use is safe.

BVO is a complex mixture of plant-derived triglycerides that have been reacted to contain atoms of the element bromine bonded to the molecules. BVO is used primarily to help emulsify citrus-flavored soft drinks, preventing them from separating during distribution.

B. Summary of the Major Provisions of the Proposed Rule

The proposed rule would revoke the authorization for the use of BVO as an ingredient in food. Specifically, the proposed rule would remove § 180.30 (21 CFR 180.30).

C. Legal Authority

We are proposing this rule consistent with our authority under the Federal Food, Drug, and Cosmetic Act (FD&C Act). We discuss our legal authority in greater detail in part V.

D. Costs and Benefits

The costs of this proposed rule come from reformulating products currently manufactured with BVO, relabeling products currently manufactured with BVO, ingredient substitutes for BVO, and possible changes to sensory product properties (which could lead to decreased consumption). The benefits of this proposed rule come in the form of public health gains from reduced exposure to BVO. The annualized costs of this rulemaking (with a discount rate of 7 percent), minus the costs of the baseline of gradual voluntary reduction, are $0.09 million to $0.23 million. The first-year costs of the proposed rule are $6.4 million to $15.9 million. We estimate the annualized reduction in BVO exposure under the proposed rule relative to the baseline of gradual voluntary reduction to be roughly 0.02 million ounces (oz).

II. Table of Abbreviations/Acronyms Used in This Document

Abbreviation/ acronym	What it means
BVO	Brominated vegetable oil.
CFR	Code of Federal Regulations.
FDA	Food and Drug Administration.
FD&C Act	Federal Food, Drug, and Cosmetic Act.
GRAS	Generally Recognized as Safe.
NCTR	National Center for Toxicological Research.
ppm	parts per million.

III. Background

Brominated vegetable oil has been used as a flavoring oil stabilizer and emulsifier since the 1920s and was generally recognized as safe (GRAS) for this use by FDA. In 1970, FDA concluded that BVO could no longer be regarded as GRAS because of toxicity concerns under the conditions of use at the time, at a level of approximately 150 parts per million (ppm) in beverages (Ref. 1). FDA removed BVO from the list of ''Substances generally recognized as safe'' in 21 CFR part 121 (now codified under 21 CFR part 182) (35 FR 1049, January 27, 1970). In response, the Flavor and Extract Manufacturers Association submitted a food additive petition (FAP 0A2532) to FDA requesting approval for use of BVO as a food additive in beverages at a maximum use level of 15 ppm. FDA reviewed the petition, including results from unpublished BVO studies, and while the available information did not indicate an immediate threat to health from the use of BVO in beverages at 15 ppm, we concluded in our petition response that additional long-term studies were needed to support the 15-ppm limit (Ref. 2).

Based on the data available at the time and the history of use of BVO in food without apparent harm, FDA determined in October 1970 that there would be an adequate margin of safety from the use of BVO in beverages at the reduced use level of 15 ppm on an interim basis while additional, longer-term safety studies with BVO were conducted (Ref. 1). FDA established an interim food additive regulation under 21 CFR 121.1234 (now codified at § 180.30) authorizing the use of BVO as a stabilizer for flavoring oils used in fruit-flavored beverages in an amount not to exceed 15 ppm in the finished beverage. FDA initially authorized this use of BVO on a 3-year interim basis pending the receipt of additional data (35 FR 12062, July 28, 1970), and then for an indefinite period to allow for completion of subsequent safety studies (39 FR 36113, October 8, 1974). BVO is not permitted for use in beverages in some jurisdictions, including Australia, the European Union, Japan, and New Zealand. Some BVO-containing products have been reformulated to replace BVO to market the products in jurisdictions that do not permit the use of BVO in those products.

Safe and authorized substitutes for BVO are available and have long been in use for the same functions as BVO. For example, sucrose acetate isobutyrate (SAIB; 21 CFR 172.833), glycerol ester of rosin (ester gum; 21 CFR 172.735), and locust (carob) bean gum (21 CFR 184.1343) are approved food additives or affirmed by FDA as GRAS when used to stabilize or adjust the density of flavoring oils in beverages. To date, FDA has not taken further regulatory action regarding BVO use in food because new data or information had not been available that was sufficient to issue a permanent food additive regulation for this use of BVO in food or to revoke authorization for this use of BVO.

IV. Regulation of Food Additives

Food additives are regulated under section 409 of the FD&C Act (21 U.S.C. 348). A food additive is deemed unsafe under section 402(a)(2)(C) of the FD&C Act (21 U.S.C. 342(a)(2)(C)), unless, in relevant part, the use of the food additive is authorized under a food additive regulation. FDA may not issue such an authorization unless the use of the food additive is safe. FDA defines ''safe,'' in relevant part, to mean that

there is a reasonable certainty in the minds of competent scientists that the substance is not harmful under the conditions of its intended use (see 21 CFR 170.3(i)). Certain food additives are authorized on an interim basis as provided under 21 CFR 180.1. Section 409(i) of the FD&C Act provides that the procedure by which food additive regulations may be amended or repealed are to be prescribed by FDA regulation and that such procedure must conform to the procedure specified in the statute for promulgating these regulations. Under § 171.130(a) (21 CFR 171.130(a)), FDA may propose the issuance of a regulation amending or repealing a regulation pertaining to a food additive or granting or repealing an exception for such additive.

V. Legal Authority

We are issuing this proposed rule under sections 409(i) and 701(a) of the FD&C Act. The FD&C Act defines ''food additive,'' in relevant part, as any substance, the intended use of which results or may reasonably be expected to result, directly or indirectly, in it becoming a component of food, if such substance is not generally recognized by qualified experts as safe under the conditions of its intended use (section 201(s) of the FD&C Act (21 U.S.C. 321(s))). Section 409(i) of the FD&C Act provides that the procedure by which food additive regulations may be amended or repealed are to be prescribed by FDA regulation and that such procedure must conform to the procedure specified in the statute for promulgating these regulations. Under § 171.130(a), FDA may propose repealing a regulation pertaining to a food additive. Section 701(a) of the FD&C Act (21 U.S.C. 371(a)) provides the authority to issue regulations for the efficient enforcement of the FD&C Act.

VI. Safety of Brominated Vegetable Oil Consumption

A. 2014 Evaluation of Safety Data

In 2014, as part of our work to reevaluate food and color additives when, for example, new safety information becomes available about an authorized substance, we reviewed all available data and information that were relevant to the safety of BVO used as a food ingredient. For this reevaluation, we also reviewed the memoranda and safety studies in our files regarding BVO and considered current scientific principles and study design practices (Ref. 3).

In our 2014 review, we identified four unresolved safety questions with respect to the use of BVO in food: the potential for thyroid toxicity, bioaccumulation, developmental neurotoxicity, and reproductive toxicity. We determined that the safety data and information available did not provide evidence of a health threat resulting from the limited permitted use of BVO as a flavoring stabilizer in fruit-flavored beverages, but many studies that we reviewed did not clearly establish safe levels of chronic use (Ref. 3). We identified deficiencies in the existing studies, including poor study design by modern standards, equivocal results, inconsistencies in measured parameters between studies, and suboptimal dose selection (Ref. 3). We concluded that high-quality data from contemporary studies, performed under current guideline standards, were needed to address the knowledge gaps regarding the safety of BVO (Ref. 3).

Therefore, through a collaboration between FDA's Center for Food Safety and Applied Nutrition, the National Center for Toxicological Research (NCTR), and the National Institute of Environmental Health Sciences' Division of Translational Toxicology (formerly the Division of the National Toxicology Program), new rodent safety studies on BVO were designed and executed with the goal of addressing two of the unresolved safety questions: the potential for thyroid toxicity and bioaccumulation. We selected these two safety questions to study first because if these studies indicated safety concerns, we would not need to conduct more complex studies on the additional outcomes to take regulatory action.

B. New Findings Do Not Support Safety of BVO Used as a Food Ingredient

The rodent safety studies conducted by NCTR were published in 2022 (Ref. 4) and confirmed previous reports that dietary exposure to BVO is toxic to the thyroid and results in bioaccumulation of lipid-bound bromine in the body at doses relevant to human exposure. To account for uncertainty in translating animal studies to humans, risk assessors evaluate the safety of food ingredients in animal studies at use levels greater than probable human dietary exposure. For example, FDA typically requires food additives to be safe in animal studies at exposures at least 100-fold higher than probable human dietary exposure (21 CFR 170.22) to account for uncertainty in applying results from animal studies to humans. Using the combined 2015–2018 National Health and Nutrition Examination Survey and the conservative assumption that all beverages labeled as containing BVO contain the 15 ppm use level permitted by § 180.30, we estimated mean and 90th percentile dietary exposures of 5 and 9 milligrams (mg) BVO/person (p)/day (d) for the U.S. population aged 2 years and older (Ref. 5), or 0.08 and 0.15 mg/kilogram (kg) body weight (bw)/d on a 60 kg bw basis. The doses of BVO used in the recently published studies more closely approximate levels of dietary exposure to BVO in humans than the doses used in many of the earlier studies.

NCTR's first 90-day study conducted in rats described adverse effects on the thyroids of test animals following dietary exposure to BVO. Histological changes in the thyroid, specifically follicular cell hypertrophy, were observed in males at all exposure levels and in females at the highest exposure level, suggestive of a sex-specific effect. The incidence of abnormal histopathological findings in male thyroids increased in a dose-dependent manner. This study also demonstrated alterations in hormone signaling along the hypothalamic-pituitary-thyroid axis as a result of dietary exposure to BVO (Ref. 6). Overall, these new data corroborate previous studies in rats and pigs that also reported thyroid toxicity after dietary exposure to BVO (Ref. 3).

Additionally, in both studies, dietary exposure to BVO led to the accumulation of inorganic and organic bromine in test animals (Ref. 6), a finding previously related to the onset of central nervous system toxicity (*i.e.,* lethargy, ataxia, and disorientation) in pigs exposed to BVO (Ref. 3). After 90 days of dietary exposure to BVO, accumulation had not reached steady state, but brominated fatty acids appeared to accumulate in a dose-dependent manner in the heart, liver, and inguinal fat of all animals fed BVO. Based on these study results, we estimated that bioaccumulated brominated fatty acids could persist in test animals for up to 587 days after BVO was removed from the diet (Ref. 6). The observed potential for brominated fatty acids to bioaccumulate in these studies confirms previous studies in laboratory animals and humans that raised safety questions with the use of BVO as a food ingredient (Ref. 3). Importantly, the bioaccumulation of lipid-bound bromine makes it difficult to estimate cumulative dietary exposure to BVO and to interpret subchronic studies that reported no adverse effect from dietary exposure to BVO (Ref. 6).

These studies provide important new data on two of the previously mentioned unresolved safety questions for BVO use in foods. In total, they demonstrate BVO consumption can result in thyroid toxicity in both male and female rats, interference with the hypothalamic-pituitary-thyroid axis in male rats, and

bioaccumulation of lipid-bound bromine in both sexes. As a result of these new data, we can no longer conclude that there is a reasonable certainty of no harm from the use of BVO as a stabilizer for flavoring oils in fruit-flavored beverages. While safety questions remain regarding the potential for developmental and reproductive toxicity resulting from dietary exposure to BVO, we do not believe that addressing these remaining unresolved safety questions is needed to conclude that there is no longer a reasonable certainty of no harm from this use. Therefore, we propose to revoke the interim authorization of BVO as a food additive.

VII. Description of the Proposed Rule

The proposed rule, if finalized, would revoke § 180.30, which authorizes on an interim basis the use of BVO as a stabilizer for flavoring oils generally used in fruit-flavored beverages, for which any applicable standards of identity do not preclude such use, in an amount not to exceed 15 ppm in the finished beverage. As we have previously determined that this use of BVO is not GRAS, the use of BVO in food will no longer be authorized. Our proposal to remove § 180.30 is supported by animal and human data, including those summarized in Ref. 3 and the new safety studies described above, which demonstrate that there is no longer a reasonable certainty of no harm from the authorized use of BVO in food.

VIII. Proposed Effective/Compliance Dates

We propose that any final rule resulting from this rulemaking be effective 30 days after the final rule's date of publication in the **Federal Register**. We also recognize that the food industry would need sufficient time to reformulate products and for these products to work their way through distribution. Therefore, the compliance date for this rule, if finalized, will be 1 year after the effective date, to provide the opportunity for companies to reformulate, relabel, and deplete the inventory of BVO-containing products prior to enforcing the requirements of the final rule.

IX. Preliminary Economic Analysis of Impacts

We have examined the impacts of the proposed rule under Executive Order 12866, Executive Order 13563, Executive Order 14094, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4).

Executive Orders 12866, 13563, and 14094 direct us to assess all benefits, costs, and transfers of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). Rules are significant under Executive Order 12866 Section 3(f)(1) (as amended by Executive Order 14094) if they ''have an annual effect on the economy of $200 million or more (adjusted every 3 years by the Administrator of the Office of Information and Regulatory Affairs [OIRA] for changes in gross domestic product); or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, territorial, or tribal governments or communities.'' OIRA has determined that this proposed rule is not a significant regulatory action under Executive Order 12866 Section 3(f)(1).

The Regulatory Flexibility Act requires us to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because we estimate that this proposed rule will impact at most 2.5 percent of small businesses within the beverage manufacturing industry, and because we believe that costly disruptions to small entities are likely to be small due to replacement formulas for BVO having been in place and widely used for decades, we propose to certify that the proposed rule will not have a significant economic impact on a substantial number of small entities.

The Unfunded Mandates Reform Act of 1995 (section 202(a)) requires us to prepare a written statement, which includes estimates of anticipated impacts, before proposing ''any rule that includes any Federal mandate that may result in the expenditure by State, local, and Tribal Governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year.'' The current threshold after adjustment for inflation is $177 million, using the most current (2022) Implicit Price Deflator for the Gross Domestic Product. This proposed rule would not result in an expenditure in any year that meets or exceeds this amount.

Food producers would not be permitted to use BVO as a food additive if the rule is finalized. For the purposes of this analysis, we assume that all products currently using BVO will be reformulated to use some other kind of stabilizer.

The costs of this proposed rule come from reformulating products currently manufactured with BVO, relabeling products currently manufactured with BVO, ingredient substitutes for BVO, and changes to sensory product properties. The benefits of this proposed rule come in the form of public health gains from reduced exposure to BVO. The annualized costs (with a discount rate of 7 percent) of this rulemaking, minus the costs of the baseline of gradual voluntary reduction, are $0.09 million to $0.23 million. The first-year costs of the proposed rule are $6.4 million to $15.9 million. We estimate the annualized reduction in BVO exposure under the proposed rule relative to the baseline of gradual voluntary reduction to be roughly 0.02 million ounces (oz). For the proposed rule to be cost effective, it would have to prevent $0.15 million worth of illness (with a discount rate of 7 percent) on an annual basis to cover the domestic costs to industry. This amounts to almost $9 worth of public health benefits per oz of reduced BVO exposure.

It is possible that the cost of reformulation and relabeling could be passed on to consumers in the form of higher prices. We do not know what percentage of the costs will be passed on to consumers. However, replacement formulas have been in place for decades and are widely used in beverage products throughout the United States and the world. The time between the publication of our proposal and any subsequent final rule as well as that rule's compliance period should minimize costly disruptions to manufacturers still using BVO.

TABLE 1—SUMMARY OF BENEFITS, COSTS AND DISTRIBUTIONAL EFFECTS OF PROPOSED RULE

Category	Primary estimate	Low estimate	High estimate	Units			Notes
				Year dollars	Discount rate (%)	Period covered	
Benefits:							
Annualized Monetized $millions/year.	.....	.....	.....	.....	7		
					3		
Annualized Quantified	0.02 million oz ...	0.01 million oz ...	0.03 million oz ...	.....	.....	2026–2045	The benefits of the proposed rule come in the form of reduction in exposure to BVO.
Qualitative	For the rule to be cost effective, it would have to prevent almost $9 worth of illness annually per oz of reduced BVO exposure.						
Costs:							
Annualized Monetized $millions/year.	$0.15	$0.09	$0.23	2022	7	2026–2045	The first-year costs are roughly $6.4 million to $15.9 million.
	$0.06	$0.03	$0.08	2022	3	2026–2045	
Annualized Quantified	.....	.....	.....	.....	7		
Qualitative	.....	.....	.....	.....	3		
Transfers:							
Federal Annualized Monetized $millions/year.	.....	.....	.....	.....	7		
	.....	.....	.....	.....	3		
From/To	From:			To:			
Other Annualized Monetized $millions/year.	.....	.....	.....	.....	7		
	.....	.....	.....	.....	3		
From/To	From: Producers			To: Consumers			We do not know what percentage of producer costs will be passed on to consumers.
Effects:							
State, Local or Tribal Government:							
Small Business:							
Wages:							
Growth:							

We have developed a comprehensive Preliminary Economic Analysis of Impacts that assesses the impacts of the proposed rule. We request comment on our estimates of benefits, costs, and transfers of this proposed rule. The full preliminary analysis of economic impacts is available in the docket for this proposed rule (Ref. 7) and at *https://www.fda.gov/about-fda/reports/economic-impact-analyses-fda-regulations.*

X. Analysis of Environmental Impacts

We have determined under 21 CFR 25.32(m) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

XI. Paperwork Reduction Act of 1995

FDA tentatively concludes that this proposed 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.

XII. Consultation and Coordination with Indian Tribal Governments

We have analyzed this proposed rule in accordance with the principles set forth in Executive Order 13175. We have tentatively determined that the rulemaking does not contain policies that would have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes. We invite comments from tribal officials on any potential impact on Indian tribes from this proposed action.

XIII. Federalism

We have analyzed this proposed rule in accordance with the principles set forth in Executive Order 13132. We have determined that the proposed rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, we conclude that the rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement is not required.

XIV. References

The following references marked with an asterisk (*) are on display at the Dockets Management Staff (see **ADDRESSES**) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they also are available electronically at *https://www.regulations.gov.* References without asterisks are not on public display at *https://www.regulations.gov*

because they have copyright restriction. Some may be available at the website address, if listed. References without asterisks are available for viewing only at the Dockets Management Staff. FDA has verified the website addresses, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

* 1. FDA Memorandum from S. Shibko to Division of Regulations and Petitions Control, May 25, 1970.

* 2. FDA Memorandum from L. Friedman to L. Buckley, Division of Regulations and Petitions Control, October 21, 1970.

* 3. FDA Memorandum from Y. Zang to T. Croce, Division of Petition Review, September 2, 2014.4. Woodling K.A., P. Chitranshi, C.C. Jacob, et al., ''Toxicological Evaluation of Brominated Vegetable Oil in Sprague Dawley Rats.'' *Food and Chemical Toxicology,* 165:113137, 2022.

* 5. FDA Memorandum from D. Doell to J. Downey, Regulatory Review Branch—Team 1, March 1, 2023.

* 6. FDA Memorandum from J. Gingrich to J. Downey, Regulatory Review Branch—Team 1, March 1, 2023.

* 7. FDA Preliminary Economic Analysis of Rule to Revoke Uses of Brominated Vegetable Oil in Foods (*https://www.fda.gov/about-fda/reports/economic-impact-analyses-fda-regulations*).

List of Subjects in 21 CFR Part 180

Food additives.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under the authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 180 be amended as follows:

PART 180—FOOD ADDITIVES PERMITTED IN FOOD OR IN CONTACT WITH FOOD ON AN INTERIM BASIS PENDING ADDITIONAL STUDY

■ 1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321, 342, 343, 348, 371; 42 U.S.C. 241.

§ 180.30 [Removed]

■ 2. Remove § 180.30.

Dated: October 25, 2023.

Robert M. Califf,

Commissioner of Food and Drugs.

[FR Doc. 2023–24084 Filed 11–2–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

30 CFR Part 950

[SATS WY–051–FOR; Docket ID: OSM–2023–0004; S1D1S SS08011000 SX064A000 223S180110; S2D2S SS08011000 SX064A000 22XS501520]

Wyoming Regulatory Program

AGENCY: Office of Surface Mining Reclamation and Enforcement, Interior.

ACTION: Proposed rule; public comment period and opportunity for public hearing on proposed amendment.

SUMMARY: We, the Office of Surface Mining Reclamation and Enforcement (OSMRE), are announcing receipt of a proposed regulatory and statutory amendment to the Wyoming coal program (Wyoming program) under the Surface Mining Control and Reclamation Act of 1977 (SMCRA or the Act). On September 25, 2018 the Wyoming Environmental Quality Council approved a number of revisions to rules governing permitting, operation, and abandonment of Class III underground injection and recovery wells associated with in situ mining of coal. Specifically, the proposed revisions update regulations to be consistent with Environmental Protection Agency Underground Injection Control regulations for class III wells, reorganize the chapter to better correlate with other key Land Quality Division (LQD) regulations and to reference existing LQD regulations and definitions, update regulations to be consistent with other Wyoming regulations pertaining to well construction, well abandonment, and aquifer exemptions, and update regulations to include current best management practices specific to in situ coal mining.

This document gives the times and locations that the Wyoming program and this proposed amendment to that program are available for your inspection, the comment period during which you may submit written comments on the amendment, and the procedures that we will follow for the public hearing, if one is requested.

DATES: We will accept written comments on this amendment until 4 p.m., M.D.T., December 4, 2023. If requested, we may hold a public hearing or meeting on the amendment on November 28, 2023. We will accept requests to speak at a hearing until 4 p.m., M.D.T., on November 20, 2023.

ADDRESSES: You may submit comments, identified by SATS No. WY–051–FOR, by any of the following methods:

- *Mail/Hand Delivery:* OSMRE, Attn: Jeffrey Fleischman, P.O. Box 11018, 100 East B Street, Room 4100, Casper, Wyoming 82602.
- *Fax:* (307) 261–6552.
- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.

Instructions: All submissions received must include the agency name and docket number for this rulemaking. For detailed instructions on submitting comments and additional information on the rulemaking process, see the ''Public Comment Procedures'' heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to review copies of the Wyoming program, this amendment, a listing of any scheduled public hearings or meetings, and all written comments received in response to this document, you must go to the address listed below during normal business hours, Monday through Friday, excluding holidays. You may receive one free copy of the amendment by contacting OSMRE's Casper Field Office or the full text of the program amendment is available for you to read at *www.regulations.gov.*

Attn: Jeffrey Fleischman, Field Office Director, Office of Surface Mining Reclamation and Enforcement, 100 East B Street, Casper, Wyoming 82602, Telephone: (307) 261–6550, Email: *jfleischman@osmre.gov*

In addition, you may review a copy of the amendment during regular business hours at the following location:

Attn: Kyle Wendtland, Administrator, Wyoming Department of Environmental Quality, Land Quality Division, 200 West 17th Street, Suite 10, Cheyenne, Wyoming 82002, Telephone: (307) 777–7046, Email: *kyle.wendtland@wyo.gov*

FOR FURTHER INFORMATION CONTACT: Jeffrey Fleischman, Field Office Director, Office of Surface Mining Reclamation and Enforcement, 100 East B Street, Casper, Wyoming 82602, Telephone: (307) 261–6550, Email: *jfleischman@osmre.gov*

SUPPLEMENTARY INFORMATION:

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I. Background on the Wyoming Program

Subject to OSMRE's oversight, section 503(a) of the Act permits a State to