DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 174, 175, and 177

[Docket No. FDA–2022–F–1108]

Environmental Defense Fund, Maricel Maffini, Breast Cancer Prevention Partners, Clean Water Action/Clean Water Fund, Consumer Reports, Endocrine Society, Environmental Working Group, Healthy Babies Bright Futures, Linda Birnbaum, and the Nicholas School of the Environment at Duke University; Filing of Food Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification of petition.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing that we have filed a petition, submitted by Environmental Defense Fund, Maricel Maffini, Breast Cancer Prevention Partners, Clean Water Action/Clean Water Fund, Consumer Reports, Endocrine Society, Environmental Working Group, Healthy Babies Bright Futures, Linda Birnbaum, and the Nicholas School of the Environment at Duke University, proposing that the food additive regulations be amended to remove or restrict authorizations for the use of bisphenol A (BPA).

DATES: The food additive petition was filed on May 2, 2022. Submit either electronic or written comments on the filing notice by September 9, 2022.

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 September 9, 2022. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is 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–2022–F–1108 for ''Environmental Defense Fund, Maricel Maffini, Breast Cancer Prevention Partners, Clean Water Action/Clean Water Fund, Consumer Reports, Endocrine Society, Environmental Working Group, Healthy Babies Bright Futures, Linda Birnbaum, and the Nicholas School of the Environment at Duke University; Filing of Food Additive Petition.'' Received comments, those filed in a timely manner (see **DATES**), 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: Marissa Santos, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–8160.

SUPPLEMENTARY INFORMATION:

I. Background

Under section 409(b)(5) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 348(b)(5)), we are giving notice that we have filed a food additive petition (FAP 2B4831), submitted by Environmental Defense Fund, Maricel Maffini, Breast Cancer Prevention Partners, Clean Water Action/Clean Water Fund, Consumer Reports, Endocrine Society, Environmental Working Group, Healthy Babies Bright Futures, Linda Birnbaum, and the Nicholas School of the Environment at Duke University, c/o Mr. Thomas Neltner, 1875 Connecticut Ave. NW, Washington, DC 20009. The petition proposes to amend the food additive regulations in §§ 175.105, 175.300, 177.1440, 177.1580, 177.1585, 177.2280, and 177.2440 (21 CFR 175.105, 175.300, 177.1440, 177.1580, 177.1585, 177.2280, and 177.2440); Indirect Food Additives: General (part 174 (21 CFR part 174)); Indirect Food Additives: Adhesives and Components of Coatings (21 CFR part 175); and

Indirect Food Additives: Polymers (21 CFR part 177), to remove authorizations for the use of BPA in §§ 175.105, 175.300, and 177.2440; establish a migration limit for BPA from the authorized uses of BPA in food contact articles in §§ 177.1440, 177.1580, 177.1585, and 177.2280; and add a new provision to part 174 with a restriction on the use of BPA, stating that the substance is subject to a specific migration limit of 0.5 nanograms per kilogram of food. The petition is available in Docket No. FDA–2022–F–1108.

II. Amendment of §§ 175.105, 175.300, 177.1440, 177.1580, 177.1585, 177.2280, and 177.2440 and Addition of New Provision With BPA Restriction

In accordance with the procedures for amending or repealing a food additive regulation in § 171.130 (21 CFR 171.130), the petition asks us to amend §§ 175.105, 175.300, 177.1440, 177.1580, 177.1585, 177.2280, and 177.2440 to remove authorizations for the use of BPA in §§ 175.105, 175.300, and 177.2440; establish a migration limit for BPA from the authorized uses of BPA in food contact articles in §§ 177.1440, 177.1580, 177.1585, and 177.2280; and add a new provision to part 174 with a restriction on the use of BPA. The petitioners cite, as evidence, a draft opinion by the European Food Safety Authority (EFSA), which analyzed studies related to the health effects of dietary BPA exposure that were published between January 1, 2013, through October 15, 2018. EFSA's draft opinion entitled ''Re-evaluation of the risks to public health related to the presence of bisphenol (BPA) in foodstuffs,'' was published in December 2021 for public comment. Based on the analysis in the draft EFSA opinion, the petitioners conclude that the use of BPA in food and food contact articles is toxic and disrupts the ''proper functioning of the immune and reproductive systems.'' To support their conclusion, the petitioners also cite publications referred to in comments to EFSA on the draft opinion and an epidemiology study that petitioners assert show an association of in utero exposure to BPA with an increased risk of asthma and wheezing in school-age girls.

We invite comments, additional scientific data, and other information related to the issues raised by this petition. If we determine that the available data justify removing authorizations for the use of BPA as listed under §§ 175.105, 175.300, and 177.2440; establishing a migration limit for BPA from authorized uses of BPA in food contact articles as listed under §§ 177.1440, 177.1580, 177.1585, and 177.2280; or adding a new provision with a restriction on the use of BPA, we will publish our decision in the **Federal Register** in accordance with § 171.130.

The petitioners have claimed that this action is categorically excluded under 21 CFR 25.32(m) because this action would prohibit or otherwise restrict the use of a substance in food packaging. In addition, the petitioners have stated that, to their knowledge, no extraordinary circumstances exist. If FDA determines a categorical exclusion applies, neither an environmental assessment nor an environmental impact statement is required. If FDA determines a categorical exclusion does not apply, we will request an environmental assessment and make it available for public inspection.

Dated: July 1, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–14682 Filed 7–8–22; 8:45 am]

BILLING CODE 4164–01–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R04–OAR–2021–0342; FRL–9971–01–R4]

Air Plan Approval; Georgia; Vehicle Inspection and Maintenance Program

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing to approve State Implementation Plan (SIP) revisions submitted by the State of Georgia through the Georgia Department of Natural Resources (GA DNR), Environmental Protection Division (GA EPD) on April 30, 2021. The revisions remove obsolete references and provisions, update and clarify the State's inspection and maintenance (I/M) requirements, and update terminology, in part to reflect advances in test and vehicle technology. EPA has evaluated the SIP revisions and has preliminarily determined the changes will not increase emissions under the Georgia
I/M program. EPA is proposing to approve these changes pursuant to the Clean Air Act (CAA).

DATES: Comments must be received on or before August 10, 2022.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R04–OAR–2021–0342 at *www.regulations.gov.* Follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from *Regulations.gov*. EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.,* on the web, cloud, or other file sharing system). For additional submission methods, the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit *www2.epa.gov/dockets/commenting-epa-dockets.*

FOR FURTHER INFORMATION CONTACT: Kelly Sheckler, Air Regulatory Management Section, Air Planning and Implementation Branch, Air and Radiation Division, U.S. Environmental Protection Agency, Region 4, 61 Forsyth Street SW, Atlanta, Georgia 30303–8960. The telephone number is (404) 562–9222. Ms. Sheckler can also be reached via electronic mail at *sheckler.kelly@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. What is the background of Georgia's SIP-approved I/M program?

The CAA requires areas that are designated as moderate, serious, severe, or extreme ozone nonattainment areas to establish a motor vehicle I/M program to ensure regular monitoring of gasoline fueled motor vehicle emissions. *See* CAA sections 182(b)(4), (c)(3). The required monitoring is performed by periodic emissions testing of vehicles. *See* CAA sections 182(a)(2)(B), (c)(3). This emissions testing ensures that vehicles are well maintained, operating as designed, and do not exceed established vehicle pollutant limits. A basic I/M program is required for moderate ozone nonattainment areas, and an enhanced I/M program is required for serious, severe, or extreme ozone nonattainment areas.

In 1991, EPA classified a 13-county area in and around the Atlanta, Georgia, metropolitan area as a serious ozone nonattainment area for the 1979 1-hour ozone national ambient air quality standards (NAAQS), triggering the requirement for the State to establish an