■ 2. Amend § 601.2 by adding paragraphs (g), (h), (i), and (j) to read as follows:

§ 601.2 Applications for biologics licenses; procedures for filing.

* * * * *

(g) Except as provided in paragraph (h) of this section, an application for a biological product submitted to the Food and Drug Administration for licensure under section 351 of the Public Health Service Act; licensed under section 351 of the Public Health Service Act; or deemed, under section 7002(e) of the Biologics Price Competition and Innovation Act of 2009, to be licensed under section 351 of the Public Health Service Act may not incorporate by reference drug substance, drug substance intermediate, or drug product information contained in a master file, including a drug master file submitted under § 314.420 of this chapter. Amendments and supplements submitted in support of these applications also may not incorporate by reference such information contained in a master file.

(h) An application for a biological product that:

(1) Was approved under section 505 of the Federal Food, Drug, and Cosmetic Act;

(2) Was deemed on March 23, 2020, to be a license for the biological product under section 351 of the Public Health Service Act; and

(3) On March 23, 2020, incorporated by reference drug substance, drug substance intermediate, and/or drug product information contained in a drug master file submitted under § 314.420 of this chapter may continue to incorporate by reference the information contained in that drug master file after March 23, 2020. Amendments and supplements submitted in support of these applications may also incorporate by reference the information contained in that drug master file.

(i) Nothing in paragraph (g) of this section limits or restricts an application for a biological product submitted to the Food and Drug Administration for licensure under section 351 of the Public Health Service Act; licensed under section 351 of the Public Health Service Act; or deemed, under section 7002(e) of the Biologics Price Competition and Innovation Act of 2009, to be licensed under section 351 of the Public Health Service Act from incorporating by reference information contained in any master file, including a drug master file submitted under § 314.420 of this chapter, that is not drug substance, drug substance intermediate, or drug product information. Amendments and supplements submitted in support of these applications may also incorporate by reference such information contained in a master file.

(j) Nothing in paragraph (g) of this section limits or restricts an investigational new drug application for a biological product from incorporating by reference any information, including drug substance, drug substance intermediate, and drug product information, contained in a master file, including a drug master file submitted under § 314.420 of this chapter.

Dated: June 17, 2019.

Norman E. Sharpless,

Acting Commissioner of Food and Drugs.

Dated: June 21, 2019.

Eric D. Hargan,

Deputy Secretary, Department of Health and Human Services.

[FR Doc. 2019–13753 Filed 6–27–19; 8:45 am]

BILLING CODE 4164–01–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 174 and 180

[EPA–HQ–OPP–2019–0041; FRL–9995–27]

Receipt of Several Pesticide Petitions Filed for Residues of Pesticide Chemicals In or On Various Commodities (May 2019)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of filing of petitions and request for comment.

SUMMARY: This document announces the Agency's receipt of several initial filings of pesticide petitions requesting the establishment or modification of regulations for residues of pesticide chemicals in or on various commodities.

DATES: Comments must be received on or before July 29, 2019.

ADDRESSES: Submit your comments, identified by the docket identification (ID) number and pesticide petition number (PP) of interest as shown in the body of this document, by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.
- *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001.
- *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *http://www.epa.gov/dockets/contacts.html.*

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *http://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: Michael Goodis, Registration Division (RD) (7505P), main telephone number: (703) 305–7090, email address: *RDFRNotices@epa.gov;* or Robert McNally, Biopesticides and Pollution Prevention Division (BPPD) (7511P), main telephone number: (703) 305–7090, email address: *BPPDFRNotices@epa.gov.* The mailing address for each contact person is: Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001. As part of the mailing address, include the contact person's name, division, and mail code. The division to contact is listed at the end of each pesticide petition summary.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

B. What should I consider as I prepare my comments for EPA?

1. *Submitting CBI.* Do not submit this information to EPA through regulations.gov or email. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD–ROM that you mail to EPA, mark the outside of the disk or CD–ROM as CBI and then identify electronically within the disk or CD–ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI

must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for preparing your comments.* When preparing and submitting your comments, see the commenting tips at *http://www.epa.gov/dockets/comments.html.*

3. *Environmental justice.* EPA seeks to achieve environmental justice, the fair treatment and meaningful involvement of any group, including minority and/or low-income populations, in the development, implementation, and enforcement of environmental laws, regulations, and policies. To help address potential environmental justice issues, the Agency seeks information on any groups or segments of the population who, as a result of their location, cultural practices, or other factors, may have atypical or disproportionately high and adverse human health impacts or environmental effects from exposure to the pesticides discussed in this document, compared to the general population.

II. What action is the Agency taking?

EPA is announcing its receipt of several pesticide petitions filed under section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a, requesting the establishment or modification of regulations in 40 CFR part 174 or 180 for residues of pesticide chemicals in or on various food commodities. The Agency is taking public comment on the requests before responding to the petitioners. EPA is not proposing any particular action at this time. EPA has determined that the pesticide petitions described in this document contain data or information prescribed in FFDCA section 408(d)(2), 21 U.S.C. 346a(d)(2); however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data support granting of the pesticide petitions. After considering the public comments, EPA intends to evaluate whether and what action may be warranted. Additional data may be needed before EPA can make a final determination on these pesticide petitions.

Pursuant to 40 CFR 180.7(f), a summary of each of the petitions that are the subject of this document, prepared by the petitioner, is included in a docket EPA has created for each rulemaking. The docket for each of the petitions is available at *http://www.regulations.gov.*

As specified in FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), EPA is publishing notice of the petitions so that the public has an opportunity to comment on these requests for the establishment or modification of regulations for residues of pesticides in or on food commodities. Further information on the petitions may be obtained through the petition summaries referenced in this unit.

Amended Tolerance Exemptions for Non-Inerts (Except PIPS)

PP 9G8741. (EPA–HQ–OPP–2019–0182). Southern Gardens Citrus Nursery, LLC, 1820 County Rd. 833, Clewiston, FL 33440, requests to amend a temporary exemption from the requirement of a tolerance in 40 CFR 180.1337 for residues of the microbial pesticide *Citrus tristeza* virus expressing spinach defensin proteins 2, 7, and 8 in or on the commodities listed in fruit, citrus group 10–10 by extending the expiration date from August 31, 2020, to August 31, 2023. The petitioner believes no analytical method is needed because it is not practical, and there is no need for removal of residues of *Citrus tristeza* virus or residues of spinach defensin proteins 2, 7, and 8 from citrus tissues and commodities, as a continued exemption from the requirement of a tolerance at 40 CFR 180.1337 is requested for these proteins when expressed in citrus. Contact: BPPD.

New Tolerance Exemptions for PIPS

PP 8F8722. (EPA–HQ–OPP–2019–0097). BASF Corporation, 26 Davis Dr., Research Triangle Park, NC 27709, requests to establish an exemption from the requirement of a tolerance in 40 CFR part 174 for residues of the plant-incorporated protectant (PIP) *Bacillus thuringiensis* Cry14Ab-1 protein in soybean. An analytical method utilizing ELISA and an independent laboratory validation of the method were submitted to EPA for the detection and measurement of the pesticide residues. Contact: BPPD.

New Tolerances for Non-Inerts

PP 9F8758. (EPA–HQ–OPP–2019–0297). Taminco US LLC, a subsidiary of Eastman Chemical Company, 200 S Wilcox Drive, Kingsport, TN 37660–5147, requests to amend the tolerance in 40 CFR 180.698 for residues of the plant regulator, chlormequat chloride in or on the raw agricultural commodity oat grain at 30.0 parts per million (ppm).The LC–MS/MS method is used to measure and evaluate the chemical chlormequat chloride. Contact: RD.

Authority: 21 U.S.C. 346a.

Dated: June 12, 2019.

Delores Barber,

Director, Information Technology and Resources Management Division, Office of Pesticide Programs.

[FR Doc. 2019–13774 Filed 6–27–19; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 257

[EPA–HQ–OLEM–2018–0533; FRL–9995–82–OLEM]

Georgia: Approval of State Coal Combustion Residuals Permit Program

AGENCY: Environmental Protection Agency (EPA).

ACTION: Announcment of availability; request for comment.

SUMMARY: Pursuant to the Resource Conservation and Recovery Act (RCRA or the Act), the Environmental Protection Agency (EPA) is proposing to partially approve the Georgia Coal Combustion Residuals (CCR) state permit program. After reviewing the state permit program application, submitted by the Georgia Environmental Protection Division (GA EPD), EPA has preliminarily determined that Georgia's CCR state permit program meets the standard for partial approval under RCRA. If approved, Georgia's CCR state permit program will operate in lieu of the Federal CCR program, with the exception of certain provisions noted below. The State's CCR state permit program requirements and resulting permit provisions will also be subject to EPA's information gathering and enforcement authorities under RCRA and other applicable statutory and regulatory provisions as discussed below. This document announces that EPA is seeking comment on this proposal during a 60-day public comment period and will be holding a public hearing on EPA's preliminary approval of Georgia's CCR state permitting program.

DATES: Comments must be received on or before August 27, 2019. *Public Hearing:* A public hearing will be held on August 6, 2019, 8 a.m. to 5:30 p.m.

ADDRESSES: The EPA has established a docket for this action under Docket ID No. EPA–HQ–OLEM–2018–0533. All documents in the docket are listed in the *https://www.regulations.gov* index. Publicly available docket materials are available either electronically at *https://www.regulations.gov* or in hard copy at the EPA Docket Center. The Public Reading Room is open from 8:30 a.m. to