for at least five (5) years after the last sale of the product by the manufacturer or importer.

(g) The certificate of conformity and documentation must be completed prior to a product's introduction into commerce.

§ 143.20 Compliance provisions.

(a) Noncompliance with the Safe Drinking Water Act or this subpart may be subject to enforcement. Enforcement actions may include seeking injunctive or declaratory relief, civil penalties, or criminal penalties.

(b) The Administrator may, on a case-by-case basis, request any information, such as records deemed necessary to determine whether a person has acted or is acting in compliance with section 1417 of the Safe Drinking Water Act and this subpart. Information, such as records requested, must be provided to the Administrator at a time and in a format as may be reasonably determined by the Administrator.

[FR Doc. 2020–16869 Filed 8–31–20; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2019–0182; FRL–10011–47]

Citrus Tristeza Virus Expressing Spinach Defensin Proteins 2, 7, and 8; Temporary Exemption From the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation amends and extends a temporary exemption from the requirement of a tolerance for residues of the *Citrus tristeza* virus expressing spinach defensin proteins 2, 7, and 8 alone or in various combinations on citrus fruit (*Citrus* spp., *Fortunella* spp., Crop Group 10–10) when applied/used as a microbial pesticide in accordance with the terms of Experimental Use Permit (EUP) No. 88232–EUP–2. Southern Gardens Citrus submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), requesting extension of the temporary tolerance exemption. This regulation eliminates the need to establish a maximum permissible level for residues of *Citrus tristeza* virus expressing spinach defensin proteins 2, 7, and 8 alone or in various combinations. The temporary tolerance exemption expires on August 31, 2023.

DATES: This regulation is effective August 31, 2020. Objections and requests for hearings must be received on or before November 2, 2020, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA–HQ–OPP–2019–0182, is available at *http://www.regulations.gov* or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave. NW, Washington, DC 20460–0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the OPP Docket is (703) 305–5805.

Please note that due to the public health emergency the EPA Docket Center (EPA/DC) and Reading Room was closed to public visitors on March 31, 2020. Our EPA/DC staff will continue to provide customer service via email, phone, and webform. For further information on EPA/DC services, docket contact information and the current status of the EPA/DC and Reading Room, please visit *https://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: Jean Overstreet, Acting Director, Biopesticides and Pollution Prevention Division (7511P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001; main telephone number: (703) 305–7090; email address: *BPPDFRNotices@epa.gov.*

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. How can I get electronic access to other related information?

You may access a frequently updated electronic version of 40 CFR part 180 through the Government Publishing Office's e-CFR site at *http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl.*

C. How can I file an objection or hearing request?

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2019–0182 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before November 2, 2020. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA–HQ–OPP–2019–0182, 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 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.*

II. Background and Statutory Findings

In the **Federal Register** of June 28, 2019 (84 FR 30976) (FRL–9995–27), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide tolerance petition (PP 9G8741) by Southern Gardens Citrus, 1820 County Road 833, Clewiston, FL 33440. The petition requested that 40 CFR 180.1337 be amended to extend a temporary exemption from the requirement of a tolerance for residues of *Citrus tristeza* virus expressing spinach defensin proteins 2, 7, and 8 in or on the commodities in fruit, citrus group 10–10 from August 31, 2020, to August 31, 2023. That document contains a summary of the petition prepared by the petitioner Southern Gardens Citrus, which is available in the docket, *http://www.regulations.gov.* One comment was received on the notice of filing. EPA's response to this comment is discussed in Unit VII.C.

Section 408(c)(2)(A)(i) of FFDCA allows EPA to establish an exemption from the requirement for a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the exemption is ''safe.'' Section 408(c)(2)(A)(ii) of FFDCA defines ''safe '' to mean that ''there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Pursuant to FFDCA section 408(c)(2)(B), in establishing or maintaining in effect an exemption from the requirement of a tolerance, EPA must take into account the factors set forth in FFDCA section 408(b)(2)(C), which require EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to ''ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue . . . .'' Additionally, FFDCA section 408(b)(2)(D) requires that the Agency consider ''available information concerning the cumulative effects of a particular pesticide's residues'' and ''other substances that have a common mechanism of toxicity.''

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. First, EPA determines the toxicity of pesticides. Second, EPA examines exposure to the pesticide through food, drinking water, and through other exposures that occur as a result of pesticide use in residential settings.

III. Toxicological Profile

Consistent with FFDCA section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action and considered its validity, completeness and reliability, and the relationship of this information to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children.

The pesticide chemical is a genetically altered *Citrus tristeza* virus that expresses spinach defensin proteins 2 (SoD2), 7 (SoD7), and 8 (SoD8) to combat citrus greening disease. Although EPA did not receive data on the altered virus itself, EPA has sufficient data to evaluate each component of the pesticide individually—*i.e.,* the *Citrus tristeza* virus and the spinach defensin proteins 2, 7, and 8. Assessing overall risk based on the virus and spinach defensin proteins' individual risks is reasonable because the antimicrobial spinach defensin proteins are unlikely to change the host range of the plant virus and the plant virus is unlikely to affect the toxicity or allergenicity profile of the antimicrobial spinach defensin proteins.

Citrus whole fruits and juices have been an important part of the American and international diets for centuries. ''History of Citrus,'' All Foods Natural (2013) (available online at: *http://www.allfoodnatural.com/article/history-of-citrus.html*). The U.S. human population has been exposed to the *Citrus tristeza* (*C. tristeza*) virus in citrus products for at least two decades since its discovery as being widespread in the Florida citrus industry in the mid-1990s. No adverse effects from this exposure in people have been reported. This lack of adverse effects is consistent with the fact that *C. tristeza* is a plant virus, and plant viruses do not cause disease in humans; human intestines commonly harbor plant viruses without any adverse effect. (Ref. 1.)

Spinach defensin proteins are naturally found in every spinach plant, and oral exposure to the spinach plant provides exposure to these proteins. There is a long history of mammalian consumption of the entire spinach plant (both raw and cooked) as food, without causing any known deleterious human health effects or any evidence of toxicity. Spinach plant leaves have long been part of the human diet, and there have been no findings that indicate toxicity or allergenicity of spinach proteins.

Diverse defensin proteins are expressed by most eukaryotic species to combat various bacterial and fungal organisms. Bioinformatic sequence comparisons to assess the toxicity potential of spinach defensin 2 (SoD2), spinach defensin 7 (SoD7), and spinach defensin 8 (SoD8) were conducted for this tolerance exemption extension and yielded no potential significant toxicity matches. Furthermore, literature searches did not produce any papers that showed any mammalian toxicity associated with spinach or spinach defensins. In addition, available data demonstrate that SoD2, SoD7, and SoD8 proteins have very low oral toxicity. In an acute oral toxicity study conducted with a single dose of 5,000 milligram/kilogram (mg/kg) of microbial-produced SoD2 protein, no evidence of toxic or adverse effects was observed. Due to the high similarity between SoD2, SoD7, and SoD8, the toxicity assessment is applicable to all three proteins.

Because SoD2, SoD7, and SoD8 are proteins, EPA also evaluated their potential for allergenicity. An updated bioinformatics analysis was conducted for this EUP extension in which sequence comparisons were made between the novel proteins from spinach against those of known and putative allergens in a search of the *AllergenOnline.org* database based on the 35% amino acid identity criterion established by Codex (Ref. 2). The analysis (Ref. 3) indicated that there are no sequence homology matches that are of concern with known allergens based on the Codex criterion.

In an *in vitro* study, microbial produced SoD2 and SoD7 proteins were rapidly and extensively hydrolyzed in stimulated gastric and intestinal conditions in the presence of pepsin (at pH 1.2) and pancreatin, respectively. Both microbial-produced SoD2 and SoD7 proteins demonstrated half-lives of approximately five minutes when subjected to pepsin digest, and both proteins were completely proteolyzed to amino acids and small peptide fragments in less than one minute in the presence of 0.15 milligram/liter (mg/ml) pancreatin. These results indicate that both the SoD2 and SoD7 proteins are highly susceptible to degradation in conditions similar to the human digestive tract.

An evaluation of the similarities of SoD8 compared to SoD2 and SoD7 proteins to estimate SoD8 protein digestibility was conducted. The sequences are homologous, but SoD8 is longer on both N and C terminal ends. The proteins were found to be nearly

identical in major overlapping sequences, while SoD8 has one more pepsin cleavage site compared to SoD2 and SoD7. This analysis indicates that SoD8 should be digested very similarly to SoD2 and SoD7.

Based on the source, bioinformatics, and digestibility of these proteins, EPA concludes that these spinach defensin proteins will not pose any allergenicity concerns. In sum, EPA concludes that due to the lack of toxicity and pathogenicity concerns for *C. tristeza* and any toxicity or allergenicity concerns for the spinach defensin proteins 2, 7, and 8, the altered *C. tristeza* virus expressing these spinach defensin proteins does not pose any toxicity, pathogenicity, or allergenicity concerns. Therefore, EPA did not identify any points of departure for regulating exposure, and a qualitative assessment was conducted. For further information about EPA's assessment of the *Citrus tristeza* virus that has been genetically altered to express spinach defensin proteins 2 (SoD2), 7 (SoD7), and 8 (SoD8), see the *C. tristeza* SoD2, SoD7, and SoD8 March 2016 Human Health Review found in Docket ID EPA–HQ–OPP–2016–0034 and the August 2020 review found in Docket ID No. EPA–HQ–OPP–2019–0182.

IV. Aggregate Exposures

In examining aggregate exposure, FFDCA section 408 directs EPA to consider available information concerning exposures from the pesticide residue in food and all other non-occupational exposures, including drinking water from ground water or surface water and exposure through pesticide use in gardens, lawns, or buildings (residential and other indoor uses).

The Agency has considered available information on the aggregate exposure levels of consumers (and major identifiable subgroups of consumers) to the pesticide chemical residue and to other related substances. These considerations include dietary exposure under the tolerance exemption and all other tolerances or exemptions in effect for residue from genetically engineered *C. tristeza* expressing spinach defensins SoD2, SoD7, and SoD8 (*i.e.,* including 88232–EUP–1), and exposure from non-occupational sources.

The Agency anticipates that there may be dietary exposure to *Citrus tristeza* virus expressing spinach defensin proteins 2, 7, and 8 (either alone or in combinations with each other) from the consumption of citrus products treated with this pesticide. Significant dietary exposure to spinach defensin proteins 2, 7, and 8 (either alone or in combinations with each other) from use of this pesticide is not expected due to the very low expression of the defensin proteins from the *C. tristeza* vector. Dietary exposure to spinach defensins from consumption of treated citrus products containing them will be far below the amount consumed from raw and cooked spinach. Recent U.S. consumption statistics indicate that, on average, 2 lbs. of spinach are consumed per person per year in the United States. ''Spinach Profile,'' Agricultural Marketing Resource Center (June 2013). (*http://www.agmrc.org/commodities_products/vegetables/spinach-profile/*). EPA has also approved another experimental use permit (88232–EUP–1) involving use of defensin proteins SoD2 and SoD7, to which people may be exposed. A total of 75 kg of SoD proteins was authorized for treatment of 720 acres in Florida and Texas. May 6, 2015 (80 FR 25943) (FRL–9926–99) and August 28, 2015 (80 FR52270) (FRL–9931–26). In terms of nonpesticidal dietary exposure, the U.S. population will continue to be exposed to *C. tristeza* virus through infected citrus plants and will continue to be exposed to these spinach defensin proteins through consumption of spinach plants. Exposure to the *C. tristeza* vector and spinach defensin proteins is likely; however, risk via consumption is unlikely due to the low toxicity and high digestibility of the active ingredients.

Residues in drinking water from use of this pesticide will be extremely low or non-existent since the pesticide will be present only in the vascular tissue of citrus trees and is applied under the bark; therefore, it is highly unlikely that any environmental exposure will occur.

The Agency does not expect there to be any non-occupational exposure to this pesticide chemical residue. Exposure via the skin or inhalation is not likely since the viral vector will be phloem limited in citrus trees, and very little phloem is present in citrus fruit, which essentially eliminates these exposure routes or reduces these exposure routes to negligible.

V. Cumulative Effects From Substances With a Common Mechanism of Toxicity

Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider ''available information'' concerning the cumulative effects of a particular pesticide's residues and ''other substances that have a common mechanism of toxicity.''

Citrus tristeza virus expressing spinach defensin proteins 2, 7, and 8 (either alone or in combinations with each other) is not toxic and does not have a common mechanism of toxicity with any other substances. Consequently, section 408(b)(2)(D)(v) does not apply.

VI. Determination of Safety for U.S. Population, Infants and Children

FFDCA section 408(b)(2)(C) provides that, in considering the establishment of a tolerance or tolerance exemption for a pesticide chemical residue, EPA shall assess the available information about consumption patterns among infants and children, special susceptibility of infants and children to pesticide chemical residues, and the cumulative effects on infants and children of the residues and other substances with a common mechanism of toxicity. In addition, FFDCA section 408(b)(2)(C) provides that EPA shall apply an additional tenfold (10X) margin of exposure (safety) for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines that a different margin of exposure (safety) will be safe for infants and children. This additional margin of exposure (safety) is commonly referred to as the Food Quality Protection Act Safety Factor (FQPA SF).

In applying this provision, EPA either retains the default value of 10X or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor. Based on the information discussed in Unit III, EPA concludes that there are no threshold effects of concern to infants, children, or adults from exposure to the spinach defensing proteins SoD2, SoD7, and SoD8. As a result, EPA concludes that no additional margin of exposure (safety) is necessary to protect infants and children and that not adding any additional margin of exposure (safety) will be safe for infants and children.

Based on the discussion in this document and supporting documents, EPA concludes that there is a reasonable certainty that no harm will result to the U.S. population, including infants and children, from aggregate exposure to the residues of *C. tristeza* expressing spinach defensin proteins SoD2, SoD7, and SoD8. Such exposure includes all anticipated dietary exposures and all other exposures for which there is reliable information. The Agency has arrived at this conclusion based on a lack of toxicity and anticipated low likelihood of allergenicity of the *C. tristeza* expressing spinach defensin proteins SoD2, SoD7, and SoD8.

VII. Other Considerations

A. Analytical Enforcement Methodology

An analytical method is not required for enforcement purposes since the Agency is establishing an exemption from the requirement of a tolerance without any numerical limitation based on the lack of any toxicity or allergenicity of the *C. tristeza* virus expressing spinach defensin proteins 2, 7, and 8.

B. Response to Comments

One comment was received in response to the Notice of Filing. The submitted comment suggested that *Citrus tristeza* virus expressing spinach defensin proteins 2, 7, and 8 could be correlated with Creutzfeldt-Jakob disease and dementia.

Creutzfeldt-Jakob disease (CJD) is caused by misfolding of human protein PrP, which can occur genetically, sporadically, or through infection, not from exposure to *Citrus tristeza* or SoD nucleic acids or proteins. Inherited form is not caused by any external infectious agent but by mutation in the gene. The epidemiological evidence strongly suggests that sporadic form of CJD is also not acquired from an external infectious source. Infectious CJD is associated with exposure to the tissues of an affected person via surgical procedures or medical treatments, or dietary exposure to bovine spongiform encephalopathy via consumption of contaminated beef meat or other products. Presently, there is no concern about any association between CJD and *Citrus tristeza* or SoD nucleic acids or proteins.

Dementia is a symptom rather than a disease and can occur as a result of multiple diseases and disorders, in particular, as a result of CJD. There is no evidence at all that any form of dementia can be associated with CTV or SoD nucleic acids or protein consumption or exposure by other routes.

EPA has no evidence of the consumption *Citrus tristeza* virus or spinach has led to adverse outcomes. The U.S. human population has been exposed to the *Citrus tristeza* virus in citrus products for at least two decades since its discovery as being widespread in the Florida citrus industry in the mid-1990s. Also, there is a long history of mammalian consumption of the entire spinach plant (both raw and cooked) as food, without causing any known deleterious human health effects or any evidence of toxicity. Furthermore, diverse defensin proteins are expressed by most eukaryotic species to combat various bacterial and fungal organisms.

VIII. Conclusion

Therefore, the expiration date for the current temporary exemption for residues of *Citrus tristeza* virus expressing spinach defensin proteins 2, 7, and 8 associated with Experimental Use Permit No. 88232–EUP–2 is extended from August 31, 2020, to August 31, 2023.

IX. References

1. U.S. Environmental Protection Agency. Meeting Minutes of the FIFRA Scientific Advisory Panel Meeting Held December 6–8, 2005 on Plant-Incorporated Protectants Based on Virus Coat Protein Genes: Science Issues Associated with the Proposed Rule, *http://www.regulations.gov.* Docket No. EPA–HQ–OPP–2005–0249–12.
2. Codex Alimentarius Commission. 2003. Alinorm 03/34: Appendix III. Guideline for the conduct of food safety assessment of foods derived from recombinant DNA plants. Annex IV. Annex on the assessment of possible allergenicity, Rome, Italy.
3. Updated bioinformatics analysis for extension of experimental use permit 88232–EUP–2 and extension of the associated temporary tolerance exemption for *Citrus tristeza* virus expressing spinach defensin proteins 2, 7 and 8 at 40 CFR part 180.1337 for additional 3 years. Memorandum from N. Baranova through J. Kough to K. Welch, dated June 23, 2020. *http://www.regulations.gov.* Docket No. EPA–HQ–OPP–2019–0182.

X. Statutory and Executive Order Reviews

This action modifies an exemption from the requirement of a tolerance under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled ''Regulatory Planning and Review'' (58 FR 51735, October 4, 1993). Because this action has been exempted from review under Executive Order 12866, this action is not subject to Executive Order 13211, entitled ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use'' (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled ''Protection of Children from Environmental Health Risks and Safety Risks'' (62 FR 19885, April 23, 1997), nor is it considered a regulatory action under Executive Order 13771, entitled ''Reducing Regulations and Controlling Regulatory Costs'' (82 FR 9339, February 3, 2017). This action does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), nor does it require any special considerations under Executive Order 12898, entitled ''Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations'' (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the exemption in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), do not apply.

This action directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled ''Federalism'' (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled ''Consultation and Coordination with Indian Tribal Governments'' (65 FR 67249, November 9, 2000) do not apply to this action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 *et seq.*).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note).

XI. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: August 26, 2020.

Jean Overstreet,

Acting Director, Biopesticides and Pollution Prevention Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

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

Authority: 21 U.S.C. 321(q), 346a and 371.

■ 2. Revise § 180.1337 to read as follows:

§ 180.1337 Citrus tristeza virus expressing spinach defensin proteins 2, 7, and 8; exemption from the requirement of a tolerance.

A temporary exemption from the requirement of a tolerance is established for residues of the microbial pesticide *Citrus tristeza* virus expressing spinach defensin proteins 2, 7, and 8 (either alone or in combinations with each other) in or on the commodities listed in fruit, citrus group 10–10, when used in accordance with the terms of Experimental Use Permit No. 88232–EUP–2. This temporary exemption from the requirement of a tolerance expires on August 31, 2023.

[FR Doc. 2020–19351 Filed 8–28–20; 4:15 pm]

BILLING CODE 6560–50–P

OFFICE OF MANAGEMENT AND BUDGET

41 CFR Part 201

Federal Acquisition Supply Chain Security Act

AGENCY: Office of Management and Budget, OMB.

ACTION: Interim final rule with request for comments.

SUMMARY: As authorized by the Federal Acquisition Supply Chain Security Act of 2018 (FASCSA), the Federal Acquisition Security Council (FASC) is issuing this interim final rule to implement the requirements of the laws that govern the operation of the FASC, the sharing of supply chain risk information, and the exercise of its authorities to recommend issuance of removal and exclusion orders to address supply chain security risks.

DATES: Effective September 1, 2020. Written comments must be received on or before November 2, 2020.

ADDRESSES: Interested parties should provide comments via electronic mail to the following inbox: *OFCIO@omb.eop.gov.* The Office of Management and Budget is located at 725 17th Street NW, Washington, DC 20503. No physical copies will be accepted.

Instructions: Comments sent by any other method, to any other address or individual, or received after the end of the comment period, may not be considered. Comments submitted in response to this notice may be made publically available and are subject to disclosure under the Freedom of Information Act. For this reason, please do not include in your comments information of a confidential nature, such as sensitive personal information or proprietary information, or any information that you would not want publicly disclosed. Summary information of the public comments received, including any specific comments, may be posted on *regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Lisa N. Barr, 202–395–3015, *Lisa.N.Barr@omb.eop.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

Information and communications technology and services (ICTS) are essential to the proper functioning of U.S. government information systems. The U. S. government's efforts to evaluate threats to and vulnerabilities in ICTS supply chains have historically been undertaken by individual or small groups of agencies to address specific supply chain security risks. Because of the scale of supply chain risks faced by government agencies, and the need for better coordination among a broader group of agencies, there was an organized effort within the executive branch to support Congressional efforts in 2018 to pass new legislation to improve executive branch coordination, supply chain information sharing, and actions to address supply chain risks.

The Federal Acquisition Supply Chain Security Act of 2018 (FASCSA or Act) (Title II of Pub. L. 115–390), signed into law on December 21, 2018, established the Federal Acquisition Security Council (FASC). The FASC is an executive branch interagency council, chaired by a senior-level official from the Office of Management and Budget (OMB), and includes representatives from the General Services Administration (GSA); Department of Homeland Security (DHS); Office of the Director of National Intelligence (ODNI); Department of Justice; Department of Defense (DoD); and Department of Commerce (Commerce).

Pursuant to subsection 202(d) of the FASCSA, the FASC is required to prescribe this IFR to implement subchapter III of chapter 13 of title 41, U.S. Code. This IFR is organized in three subparts. Subpart A explains the scope of this IFR, provides definitions for relevant terms, and establishes the membership of the FASC. Subpart B establishes the role of the FASC's Information Sharing Agency (ISA). DHS, acting primarily through the Cybersecurity and Infrastructure Security Agency, will serve as the ISA. The ISA will standardize processes and procedures for submission and dissemination of supply chain information, and will facilitate the operations of a Supply Chain Risk Management (SCRM) Task Force under the FASC. This FASC Task Force (hereafter referred to as ''Task Force'') will be comprised of designated technical experts that will assist the FASC in implementing its information sharing, risk analysis, and risk assessment functions. Subpart B also prescribes mandatory and voluntary information sharing criteria and associated information protection requirements. Subpart C provides the criteria and procedures by which the FASC will evaluate supply chain risk from sources and covered articles and recommend issuance of orders requiring removal of covered articles from executive agency information systems (removal orders) and orders excluding sources or covered articles from future procurements (exclusion orders). Subpart C also provides the process for issuance of removal orders and exclusion orders and agency requests for waivers from such orders.

II. Analysis of Part 201

Subpart A—General

Subpart A establishes regulations generally applicable to the operations of the FASC. Subpart A, § 201.101(a) summarizes the scope of subparts A, B, and C, which generally govern the activities of federal agencies, and not non-federal entities. § 201.101(b) clarifies that nothing in these regulations require non-federal entities to share supply chain risk information with the federal government. In addition, because subpart C provides for the issuance of exclusion orders and removal orders, which affect the supply and use of products and services supplied by non-federal entities,