into interstate commerce and may be kept as original records, as true copies, or as electronic records. Manufacturers must provide those records to us for examination and copying during an inspection upon request.

(5) When a scientifically valid method pursuant to paragraph (c)(1) of this section is not available because the food is distilled, FDA will evaluate compliance with paragraph (b) of this section by verifying the absence of protein in the distilled component using scientifically valid analytical methods that can reliably detect the presence or absence of protein or protein fragments in the food.

* * * * *

Dated: July 29, 2020.

Stephen M. Hahn,

Commissioner of Food and Drugs.

[FR Doc. 2020–17088 Filed 8–12–20; 8:45 am]

BILLING CODE 4164–01–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2019–0249; FRL–10011–78]

Novaluron; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes and modifies tolerances for residues of novaluron in or on multiple commodities which are identified and discussed later in this document. Interregional Research Project Number 4 (IR–4) requested these tolerances and modifications under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective August 13, 2020. Objections and requests for hearings must be received on or before October 13, 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–2019–0249, 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: Michael Goodis, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001; main telephone number: (703) 305–7090; email address: *RDFRNotices@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 EPA's tolerance regulations at 40 CFR part 180 through the Government Printing 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(g), 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–2019–0249 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 October 13, 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–2019–0249, 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. Summary of Petitioned-For Tolerance

In the **Federal Register** of August 30, 2019 (84 FR 45702) (FRL–9998–15), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 9E8746) by IR–4, IR–4 Project Headquarters, Rutgers, The State University of New Jersey, 500 College Road East, Suite 201 W, Princeton, NJ 08540. The petition requested to amend 40 CFR 180.598 by establishing tolerances for residues of the insecticide novaluron, including its metabolites and degradates, in or on the following commodities: *Brassica,* leafy greens, subgroup 4–16B at 25 parts per million (ppm); cottonseed subgroup 20C at 0.6 ppm; kohlrabi at 0.7 ppm; sunflower subgroup 20B at 0.07 ppm; tropical and subtropical, small fruit, inedible peel, subgroup 24A at 9 ppm;

and vegetable, *brassica,* head and stem, group 5–16 at 0.7 ppm; and by modifying the existing tolerance on vegetable, fruiting, group 8–10 from 1.0 ppm to 1.5 ppm due to the proposed use on greenhouse grown peppers. The document also requested to remove the established tolerances in or on the following commodities: *Brassica,* head and stem, subgroup 5A at 0.50 ppm; *brassica,* leafy greens, subgroup 5B at 25 ppm; cotton, undelinted seed at 0.60 ppm; and turnip, greens at 25 ppm because these commodities would be covered by the new tolerances established for the crop group expansions and conversions above.

That document referenced a summary of the petition prepared by Makhteshim (d/b/a ADAMA), the registrant, which is available in the docket, *http://www.regulations.gov.* A comment was received in response to the notice of filing. EPA's response to this comment is discussed in Unit IV.C.

Based upon review of the data supporting the petition, EPA is establishing and modifying tolerances that vary from what was requested. The reason for these changes is explained in Unit IV.D.

III. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of the FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is ''safe.'' Section 408(b)(2)(A)(ii) of the 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. Section 408(b)(2)(C) of the FFDCA requires 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. . . .''

Consistent with FFDCA section 408(b)(2)(D) and the factors specified therein, EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for novaluron, including exposure resulting from the tolerances established or modified by this action. EPA's assessment of exposures and risks associated with novaluron follows.

On July 22, 2015, EPA published in the **Federal Register** a final rule establishing tolerances for residues of novaluron in or on multiple agricultural commodities based on the Agency's conclusion that aggregate exposure to novaluron is safe for the general population, including infants and children. *See* 80 FR 43329 (FRL–9929–57). EPA is incorporating the following portions of that document by reference here, as they have not changed in the Agency's current assessment of exposures and risks associated with novaluron: The toxicological profile and points of departure, certain assumptions for exposure assessment, cumulative effects from substances with a common mechanism of toxicity, and the Agency's determination regarding the children's safety factor.

EPA's dietary exposure assessments have been updated to include the additional exposure from the new uses of novaluron on the tropical and subtropical, small fruit, inedible peel, subgroup 24A, the sunflower subgroup 20B, and greenhouse-grown peppers; the crop group expansion for the cottonseed subgroup 20C; and the crop group conversions for *Brassica,* leafy greens, subgroup 4–16B, the vegetable, *Brassica,* head and stem, group 5–16, and kohlrabi. An acute dietary exposure assessment was not performed as there are no appropriate toxicological effects attributable to a single exposure (dose). A partially refined chronic dietary (food and drinking water) exposure and risk assessment was conducted that incorporated tolerance-level residues for the proposed new uses, crop group expansions, and crop group conversions. The chronic analysis also incorporated average percent crop treated (PCT) data for several registered commodities. For the remaining commodities, 100 PCT was assumed. Anticipated residues for meat, milk, hog, and poultry commodities were incorporated as well. A cancer dietary assessment was not conducted because novaluron is classified as ''not likely to be carcinogenic to humans.'' In addition, the chronic dietary exposure and risk assessment incorporated the highest total estimated drinking water concentration of 8.4 parts per billion into this dietary assessment. EPA's aggregate exposure assessment incorporated this additional assumed dietary exposure in food and drinking water and residential exposure for existing uses; the residential exposure assessment has not changed since the 2015 final rule because no new residential uses are being added by this action.

Chronic dietary risks are below the Agency's level of concern of 100% of the chronic population adjusted dose (cPAD); they are estimated to be 50% of the cPAD for children 1 to 2 years old, the population subgroup with the highest exposure estimate. Short- and intermediate-term aggregate (dietary and residential) margins of exposure (MOEs) are 3,400 for adults and 420 for children 1–2 years old, which are not of concern because they are greater than EPA's levels of concern (MOEs less than or equal to 100). There are no anticipated long-term exposures because the pet spot-on use of novaluron was voluntarily cancelled in 2017, so the long-term aggregate assessment is equivalent to the chronic dietary.

Therefore, based on the risk assessments and information described above, EPA concludes there is a reasonable certainty that no harm will result to the general population, or to infants and children, from aggregate exposure to novaluron residues. Further information about EPA's risk assessment and determination of safety supporting the tolerances established and modified in this regulation can be found at *http://www.regulations.gov* in the document titled, ''*Novaluron. Human Health Risk Assessment for Proposed New Uses on Tropical and Subtropical, Small Fruit, Inedible Peel, Subgroup 24A; Sunflower Subgroup 20B; and Greenhouse-Grown Peppers; and Crop Group Expansion for Cottonseed Subgroup 20C, and Crop Group Conversions for Brassica, Leafy Greens, Subgroup 4–16B, Vegetable, Brassica, Head and Stem, Group 5–16, and Kohlrabi*'' dated June 30, 2020 in docket ID number EPA–HQ–OPP–2019–0249.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology (gas chromatography/electron-capture detection (GC/ECD) and high-performance liquid chromatography/ultraviolet (HPLC/UV)) is available to enforce the tolerance expression.

The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755–5350; telephone number: (410) 305–2905; email address: *residuemethods@epa.gov.*

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food

safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex is a joint United Nations Food and Agriculture Organization/ World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

Codex MRLs are established for residues of novaluron in mustard greens (part of the *Brassica,* leafy greens, subgroup 4–16B), the group of *Brassica* vegetables (which includes the commodities in the vegetable, *Brassica,* head and stem, group 5–16 and kohlrabi), and cotton seed (part of the cottonseed subgroup 20C) at the same levels as the U.S. tolerances and are thus harmonized. There are no Codex MRLs for any of the commodities in the tropical and subtropical, small fruit, inedible peel, subgroup 24A or sunflower subgroup 20B and therefore harmonization is not an issue. There are Canadian MRLs at 1 ppm and Codex MRLs at 0.7 ppm for pepper, bell; pepper, non-bell; and tomato, which are the representative commodities in the vegetable, fruiting, group 8–10. Based on the data submitted with this petition, EPA is revising the existing tolerance in/on the vegetable, fruiting, group 8–10 to be 2 ppm. Harmonization with the Canada or Codex MRLs is not possible because lowering the tolerance could cause U.S. growers to have violative residues despite using the pesticide according to the label.

C. Response to Comments

One comment was received in response to the notice of filing that stated in part that ''increasing the tolerance so that more pesticide junk can be on brassica and turnips—that is a very bad idea.''

Although the Agency recognizes that some individuals believe that pesticides should be banned on agricultural crops, the existing legal framework provided by section 408 of the FFDCA authorizes EPA to establish tolerances when it determines that the tolerance is safe. Upon consideration of the validity, completeness, and reliability of the available data as well as other factors the FFDCA requires EPA to consider, EPA has determined that the novaluron residue tolerances established and modified by this action are safe. The commenter has provided no information supporting a contrary conclusion.

D. Revisions to Petitioned-For Tolerances

The Agency is modifying the tolerance for vegetable, fruiting, group 8–10 to 2 ppm, rather than 1.5 ppm as proposed by the petitioner. The petitioner did not use the Organization for Economic Cooperation and Development (OECD) tolerance calculator and instead estimated the proposed tolerance level. To be conservative, EPA utilized all of the submitted field trial data for greenhouse pepper (which is a representative commodity in the vegetable, fruiting, group 8–10) at the pre-harvest interval (PHI) which gave the highest residue levels, because data showed that residues increased with increasing PHI. These values were input into the OECD calculator.

Also, although the petitioner proposed a 0.6 ppm tolerance for the cottonseed subgroup 20C, the Agency is establishing the tolerance at 0.5 ppm for harmonization with Codex. While the OECD calculator determined a rounded tolerance of 0.6 ppm based on previously submitted cotton field trial data, EPA concludes that a 0.5 ppm tolerance is appropriate because it is based on the following conservative tolerance-setting assumptions: Cottonseed is a blended commodity (therefore, residues are likely to be lower), and field trials are based on maximum application rates (which provides a ''worst-case'' residue level). Furthermore, the OECD calculator provided an unrounded maximum residue limit (MRL) of 0.52 ppm, which is close to 0.5 ppm.

V. Conclusion

Therefore, tolerances are established for residues of novaluron in or on *Brassica,* leafy greens, subgroup 4–16B at 25 ppm; cottonseed subgroup 20C at 0.5 ppm; kohlrabi at 0.7 ppm; sunflower subgroup 20B at 0.07 ppm; tropical and subtropical, small fruit, inedible peel, subgroup 24A at 9 ppm; and vegetable, *Brassica,* head and stem, Group 5–16 at 0.7 ppm. Furthermore, the existing tolerance for vegetable, fruiting, group 8–10 is modified from 1.0 ppm to 2 ppm. Lastly, the following tolerances are removed as unnecessary due to the establishment of the above tolerances: *Brassica,* head and stem, subgroup 5A; *Brassica,* leafy greens, subgroup 5B; cotton, undelinted seed; and turnip greens.

VI. Statutory and Executive Order Reviews

This action establishes and modifies tolerances 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 tolerances and modifications 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).

VII. 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: July 16, 2020.

Michael Goodis,

Director, Registration Division, Office of Pesticide Programs.

Therefore, for the reasons states in the preamble, the EPA amend 40 CFR chapter I as follows:

PART 180—TOLERANCES AND EXEMPTIONS FOR PESTICIDE CHEMICAL RESIDUES IN FOOD

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

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

■ 2. In § 180.598, amend the table in paragraph (a) by:

■ a. Removing the entry for ''*Brassica,* head and stem, subgroup 5A'';

■ b. Adding in alphabetical order an entry for ''*Brassica,* leafy greens, subgroup 4–16B'';

■ c. Removing the entries for ''*Brassica,* leafy greens, subgroup 5B'' and ''Cotton, undelinted seed'';

■ d. Adding in alphabetical order entries for ''Cottonseed subgroup 20C,'' ''Kohlrabi,'' ''Sunflower subgroup 20B,'' ''Tropical and subtropical, small fruit, inedible peel, subgroup 24A'';

■ e. Removing the entry for ''Turnip greens'';

■ f. Adding in alphabetical order an entry for ''Vegetable, *Brassica,* head and stem, Group 5–16''; and

■ g. Revising the entry for ''Vegetable, fruiting, group 8–10''.

The additions and revision read as follows:

§ 180.598 Novaluron; tolerances for residues.

(a) * * *

Commodity	Parts per million
* * * * * * *	
Brassica, leafy greens, subgroup 4–16B	25
* * * * * * *	
Cottonseed subgroup 20C	0.5
* * * * * * *	
Kohlrabi	0.7
* * * * * * *	
Sunflower subgroup 20B	0.07
* * * * * * *	
Tropical and subtropical, small fruit, inedible peel, subgroup 24A	9
Vegetable, *Brassica,* head and stem, Group 5–16	0.7
* * * * * * *	
Vegetable, fruiting, group 8–10	2
* * * * * * *	

* * * * *

[FR Doc. 2020–16457 Filed 8–12–20; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 600

[CMS–2432–FN]

RIN 0938–ZB56

Basic Health Program; Federal Funding Methodology for Program Year 2021

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Final methodology.

SUMMARY: This document finalizes the methodology and data sources necessary to determine federal payment amounts to be made for program year 2021 to states that elect to establish a Basic Health Program under the Patient Protection and Affordable Care Act to offer health benefits coverage to low-income individuals otherwise eligible to purchase coverage through Affordable Insurance Exchanges.

DATES: The methodology and data sources announced in this notice are effective on January 1, 2021.

FOR FURTHER INFORMATION CONTACT: Christopher Truffer, (410) 786–1264; or Cassandra Lagorio, (410) 786–4554.