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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2017-0294; FRL-9977-31]

***Duddingtonia flagrans* strain IAH 1297; Exemption from the Requirement of a Tolerance**

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes an exemption from the requirement of a tolerance for residues of *Duddingtonia flagrans* strain IAH 1297 in or on all food commodities when used in accordance with label directions and good agricultural practices. International Animal Health Products Pty. Ltd. submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), requesting an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of *Duddingtonia flagrans* strain IAH 1297 under FFDCA.

DATES: This regulation is effective [*insert date of publication in the* **Federal Register**]. Objections and requests for hearings must be received on or before [*insert date 60 days after date of publication in the* **Federal Register**], 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-2017-0294, 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 review the visitor instructions and additional information about the docket available at *http://www.epa.gov/dockets*.

FOR FURTHER INFORMATION CONTACT: Robert McNally, 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 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-2017-0294 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 [*insert date 60 days after date of publication in the* **Federal Register**]. 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-2017-0294, 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 October 23, 2017 (82 FR 49022) (FRL-9967-37), 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 6F8531) by International Animal Health Products Pty. Ltd., 18 Healey Circuit, Huntingwood, New South Wales 2148, Australia (in care of SciReg. Inc., 12733 Director's Loop, Woodbridge, VA 22192). The petition requested that 40 CFR part 180 be amended by establishing an exemption from the requirement of a tolerance for residues of *Duddingtonia flagrans* strain IAH 1297 in or on all raw and processed agricultural commodities. That document referenced a summary of the petition prepared by the petitioner International Animal Health Products Pty. Ltd., which is available in the docket via *http://www.regulations.gov*. There were no comments received in response to the notice of filing.

EPA changed the commodity to be reflected in the tolerance expression from "in or on all raw and processed agricultural commodities" to "in or on all food commodities." The reason for this change is explained in Unit VII.B.

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 or tolerance exemption 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 EPA 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, for microbial pesticides, EPA determines the pathogenicity and toxicity of the pesticide. Second, EPA examines exposure to the pesticide through food, drinking water, and other exposures that occur as a result of pesticide use in residential settings, as well as other non-occupational exposure to the substance.

III. Toxicological Profile

Consistent with FFDCA section 408(b)(2)(D), EPA reviewed the available scientific data and other relevant information on *Duddingtonia flagrans* strain IAH 1297 and considered their validity, completeness, and reliability, as well as the relationship of this information to human risk. EPA also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children.

A. Overview of Duddingtonia flagrans strain IAH 1297 (Refs. 1 and 2)

Duddingtonia flagrans is a fungus commonly found worldwide in soils, various plant materials, and animal feces that, in the presence of nematodes, forms looped adhesive network traps in animal feces in pasture when the diet of grazing animals is supplemented with the fungus' chlamydospores or the chlamydospores are acquired naturally from soil or plant material while the animals graze. *Duddingtonia flagrans* strain IAH 1297 chlamydospores can survive passage through the rumen and gastrointestinal tract after ingestion by grazing animals and then germinate on pasture (i.e., the chlamydospores do not germinate in animals and cannot grow at normal body temperature or under anaerobic conditions). Nematode eggs excreted by pastured or wild animals hatch in the presence of *Duddingtonia flagrans* strain IAH 1297. Thereafter, *Duddingtonia flagrans* strain IAH 1297 passively traps nematodes, penetrates the nematode cuticle and kills them within 4-8 hours, occupies the nematode body with hyphae within 20-36 hours, and consumes nematodes within 48 hours, thus breaking the infection excretion and reinfection cycle of nematodes. *Duddingtonia flagrans* strain IAH 1297's use as a feed-through nematicide comes as growing anthelmintic (antiparasitic drug) resistance and general lack of new drug options to treat affected animals is becoming a concern.

B. Microbial Pesticide Toxicology Data Requirements

All applicable mammalian toxicology data requirements supporting the request for an exemption from the requirement of a tolerance for residues of *Duddingtonia flagrans* strain IAH 1297 in or on all food commodities have been fulfilled with data submitted by the petitioner or data waiver requests that have been granted by EPA. The toxicity tests (acute oral and dermal) and the primary dermal irritation test that address potential routes of exposure to the active ingredient are all classified in Toxicity Category IV (see section II of Ref. 3) and reveal no toxicity or irritation attributed to *Duddingtonia flagrans* strain IAH 1297. Moreover, during typical toxicity/pathogenicity testing done with microbial pesticides, *Duddingtonia flagrans* strain IAH

1297 showed no toxicity, pathogenicity, or infectivity via the pulmonary route of exposure. The conclusions and classifications from all toxicological information associated with the active ingredient and submitted by the petitioner are briefly described below.

1. *Acute oral toxicity – rat (Harmonized Guideline 870.1100; Master Record Identification Number (MRID) No. 503887-01)*. An acceptable acute oral toxicity study demonstrated that *Duddingtonia flagrans* strain IAH 1297 is not toxic to female rats when dosed via the oral route at 5,000 milligrams per kilogram (mg/kg) of bodyweight. The oral median lethal dose (LD_{50}), which is a statistically derived single dose that can be expected to cause death in 50% of test animals, was greater than 5,000 mg/kg of bodyweight for female rats (Toxicity Category IV). (Refs. 1 and 2).

2. *Acute oral toxicity/pathogenicity (Harmonized Guideline 885.3050; MRID Nos. 501117-14 and 501117-27).* An acceptable scientific rationale was submitted by the petitioner; therefore, EPA waived acute oral toxicity/pathogenicity testing for *Duddingtonia flagrans* strain IAH 1297. An acute oral toxicity study conducted on female rats (MRID No. 503887-01) demonstrated that *Duddingtonia flagrans* strain IAH 1297 was not toxic (LD_{50} greater than 5,000 mg/kg; Toxicity Category IV). Further, field studies were conducted on animal groups in Australia under direction of veterinarians. A 56-day study using young cattle demonstrated that a test substance containing *Duddingtonia flagrans* strain IAH 1297 had no discernible health effects when given with feed at 125 grams per 100 kilograms of bodyweight per day (representing 10X the label use rate). A 42-day study using Merino ewes had no findings attributable to treatment with a test substance containing *Duddingtonia flagrans* strain IAH 1297, and both groups had

statistically similar weight gains throughout at 1 kilogram per group per day (representing 5X the label use rate). A 56-day study using horses demonstrated that a test substance containing *Duddingtonia flagrans* strain IAH 1297 had no discernible health effects when given with feed at 1 gram per kilogram bodyweight per day (representing 10X the label use rate). No signs of any infection were observed during these lengthy studies. EPA believes these data, when taken together, indicate that this fungus would not be toxic, infective, and/or pathogenic through the oral route of exposure and that further testing is not necessary. (Refs. 1 and 2).

3. *Acute pulmonary toxicity/pathogenicity – rat (Harmonized Guideline 885.3150; MRID Nos. 501117-15, 501117-16, 505317-00, and 505318-00)*. An acceptable acute pulmonary toxicity/pathogenicity study performed with *Duddingtonia flagrans* strain IAH 1297 did not induce signs of toxicity, infectivity, or pathogenicity when administered to rats as a single, intratracheal dose of 5.8×10^4 spores per animal. Additionally, clearance was established by day 42 of the test. (Refs. 1, 2, and 4).

4. *Acute injection toxicity/pathogenicity (Harmonized Guideline 885.3200; MRID No. 501117-17)*. An acceptable scientific rationale was submitted by the petitioner; therefore, EPA waived acute injection toxicity/pathogenicity testing for *Duddingtonia flagrans* strain IAH 1297. Intratracheal pulmonary administration of the highest possible dose of *Duddingtonia flagrans* strain IAH 1297 did not show any sign of infection or pathogenicity (MRID No. 501117-16). Lengthy oral dosing of cattle, sheep, and horses demonstrated no effects at doses of 5-10X the label use rates (MRID No. 501117-27), and an oral dose of 5,000 mg/kg of bodyweight to female rats also demonstrated no effects (MRID No. 503887-01). Further, injection is expected to result in minimal breakdown of spores, and the relatively large size of the spores makes injection

testing impractical. The lack of growth when *Duddingtonia flagrans* strain IAH 1297 was tested at 37°C (oral dosing) also allays the need to test infectivity and pathogenicity by the injection route. *Duddingtonia flagrans* strain IAH 1297 has not shown any ability to germinate or grow when mammals were exposed by various other routes, and injection of these large spores is not expected to result in infection even if possible to perform the test. Thus, EPA believes these data and information, when taken together, indicate that this fungus would not be toxic, infective, and/or pathogenic through the injection route of exposure and that further testing is not necessary. (Refs. 1 and 2).

5. *Acute dermal toxicity – rat (Harmonized Guideline 870.1200; MRID No. 501113-05)*. An acceptable acute dermal toxicity study conducted using a test substance containing *Duddingtonia flagrans* strain IAH 1297 demonstrated that the fungus was not toxic to rats when dosed at 5,000 mg/kg of bodyweight for 24 hours to a body surface area of approximately 10 percent. Following exposure, animals were observed for 14 days. All animals survived, gained weight, appeared active and healthy, and had no signs of dermal irritation throughout the study. No observable abnormalities were found in any animal at necropsy. The dermal LD_{50} for male and female rats combined was greater than 5,000 mg/kg of bodyweight (Toxicity Category IV). (Refs. 1 and 2).

6. *Primary dermal irritation – rabbit (Harmonized Guideline 870.2500; MRID No. 501113-07*). An acceptable primary dermal irritation study conducted using a test substance containing *Duddingtonia flagrans* strain IAH 1297 demonstrated that the fungus was non-irritating to the skin of rabbits. No dermal erythema, edema, or irritation was noted on any animal during the study. The primary irritation index was 0.0, and all animals gained weight normally during the study (Toxicity Category IV). (Refs. 1 and 2).

IV. Aggregate Exposure

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).

A. Dietary Exposure (Refs. 1 and 2)

1. *Food exposure*. The proposed use of *Duddingtonia flagrans* strain IAH 1297 is as a feed-through product for grazing animals such as sheep, goats, cattle, horses, deer, alpacas and zoo animals. As *Duddingtonia flagrans* is naturally present in soils and commonly found in various plant materials, it is likely that grazing animals have natural background exposure to the fungus. No adverse effects have been reported as a result of these types of exposures. Studies performed with *Duddingtonia flagrans* strain IAH 1297 have not shown that this strain has the ability to germinate or grow when mammals are exposed by various routes, including the oral route. Further, no foodborne disease outbreaks or cases of mammalian toxin production from *Duddingtonia flagrans* have been reported. As a result, dietary exposure to *Duddingtonia flagrans* strain IAH 1297 through agricultural commodities is not anticipated from use of the pesticide products as the spores and/or components of the spores are unlikely to remain in the treated animals. Should *Duddingtonia flagrans* strain IAH 1297 be present in food, however, supporting toxicological data and information indicate that no toxicity, pathogenicity, or infectivity is likely to occur with this type of exposure resulting from the use of this microbial pesticide when applied in accordance with label directions and good agricultural practices.

2. *Drinking water exposure*. Since *Duddingtonia flagrans* is naturally present in the environment and *Duddingtonia flagrans* strain IAH 1297 will be present in the feces of treated animals, exposure to surface and possibly groundwater can be expected. Water treatment

processes should remove any *Duddingtonia flagrans* or *Duddingtonia flagrans* strain IAH 1297 present in these water sources, and no adverse effects have been reported from exposure to *Duddingtonia flagrans* through drinking water. As a result, dietary exposure to *Duddingtonia flagrans* strain IAH 1297 through drinking water is not anticipated from use of the pesticide products as the spores and/or components of the spores are unlikely to survive the water treatment process. Should *Duddingtonia flagrans* strain IAH 1297 be present in water, however, supporting toxicological data and information indicate that no toxicity, pathogenicity, or infectivity is likely to occur with this type of exposure resulting from the use of this microbial pesticide when applied in accordance with label directions and good agricultural practices.

B. Other Non-Occupational Exposure

The pesticide products containing *Duddingtonia flagrans* strain IAH 1297 are proposed for agricultural use sites and zoos. As a result, residential exposures resulting from use of these products are not anticipated. Nevertheless, *Duddingtonia flagrans* strain IAH 1297 was not toxic or irritating by dermal exposure and was not toxic, infective, or pathogenic by pulmonary exposure. Further, the products are mixed into feed ingredients at 2-34.6% so it is not in pure form, and the spore size is at the upper end of the respirable range so human exposures to *Duddingtonia flagrans* strain IAH 1297 by inhalation from contact with animal feed supplements is unlikely.

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, EPA consider "available information concerning the cumulative effects of [a particular pesticide's] . . . residues and other substances that have a common mechanism of toxicity."

Duddingtonia flagrans strain IAH 1297 is not toxic and does not have a common mechanism of toxicity with other substances. Consequently, FFDCA section 408(b)(2)(D)(v) does not apply.

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

A. U.S. Population.

For all of the reasons discussed previously, EPA concludes that there is reasonable certainty that no harm will result to the U.S. population, including infants and children, from aggregate exposure to residues of *Duddingtonia flagrans* strain IAH 1297. This includes all anticipated dietary exposures and all other exposures for which there is reliable information.

B. Infants and Children

FFDCA section 408(b)(2)(C) provides that EPA shall apply an additional tenfold (10X) margin of 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 based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the Food Quality Protection Act Safety Factor. 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. As discussed above, EPA has concluded that *Duddingtonia flagrans* strain IAH 1297 is not toxic, pathogenic, or infective to mammals, including infants and children. Because there are no threshold levels of concern to infants, children, and adults when *Duddingtonia flagrans* strain IAH 1297 is used in accordance with label directions and good agricultural practices, EPA concludes that no additional margin of safety is necessary to protect infants and children.

VII. Other Considerations

A. Analytical Enforcement Methodology

An analytical method is not required for enforcement purposes because EPA is establishing an exemption from the requirement of a tolerance without any numerical limitation.

B. Revisions to Requested Tolerance Exemption

One modification has been made to the requested tolerance exemption. EPA is changing "in or on all raw and processed agricultural commodities" to "in or on all food commodities" to align with the terminology the Agency currently uses when establishing tolerance exemptions for residues of other like active ingredients.

VIII. Conclusions

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 residues of *Duddingtonia flagrans* strain IAH 1297. Therefore, an exemption from the requirement of a tolerance is established for residues of *Duddingtonia flagrans* strain IAH 1297 in or on all food commodities when used in accordance with label directions and good agricultural practices.

IX. References

1. U.S. EPA. 2017. *Duddingtonia flagrans* strain IAH 1297. Memorandum from J.V. Gagliardi, Ph.D. through M.J. Perry to M. Glikes, dated October 17, 2017 (available as a "Supporting Document" within Docket ID Number EPA-HQ-OPP-2017-0296 at *http://www.regulations.gov*).

2. U.S. EPA. 2018. *Duddingtonia flagrans* strain IAH-1297 (PC Code 033000) – Human Health Risk Assessment Summary. Memorandum from M. Perry through J. Kough, Ph.D. to C. Kendrick, dated March 26, 2018 (available as a "Supporting Document" within Docket ID Number EPA-HQ-OPP-2017-0296 at *http://www.regulations.gov*).

3. U.S. EPA. 2014. Chapter 7 of the Label Review Manual (Precautionary Statements) (Revised July 2014). Available from *https://www.epa.gov/sites/production/files/2015-03/documents/chap-07-jul-2014.pdf*.

4. U.S. EPA. 2018. *Duddingtonia flagrans* strain IAH-1297. Memorandum from J.V. Gagliardi, Ph.D. through J.L. Kough, Ph.D. to C. Kendrick, dated March 27, 2018 (available as a "Supporting Document" within Docket ID Number EPA-HQ-OPP-2017-0296 at *http://www.regulations.gov*).

X. Statutory and Executive Order Reviews

This action establishes a tolerance exemption under FFDCA section 408(d) in response to a petition submitted to EPA. 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). 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 tolerance exemption in this action, 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. As a result, this action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, EPA 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, EPA 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 EPA's 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: April 26, 2018.

Wynne Miller,
Acting Director, 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. Add § 180.1355 to subpart D to read as follows:

§180.1355 *Duddingtonia flagrans* strain IAH 1297; exemption from the requirement of a tolerance.

An exemption from the requirement of a tolerance is established for residues of *Duddingtonia flagrans* strain IAH 1297 in or on all food commodities when used in accordance with label directions and good agricultural practices.

[FR Doc. 2018-09647 Filed: 5/4/2018 8:45 am; Publication Date: 5/7/2018]