(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (i) and (k) are applicable to manufacturers and processors of this substance.

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

(3) *Determining whether a specific use is subject to this section.* The provisions of § 721.1725(b)(1) apply to paragraph (a)(2)(iii) of this section.

[FR Doc. 2019–23389 Filed 10–25–19; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2019–0062; FRL–9999–56]

Mandipropamid; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of mandipropamid in or on cacao, dried bean. Syngenta Crop Protection, LLC requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective October 28, 2019. Objections and requests for hearings must be received on or before December 27, 2019 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–2019–0062, 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: Michael L. Goodis, P.E., 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, 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–2019–0062 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 December 27, 2019. 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–2019–0062, 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 June 7, 2019 (84 FR 26630) (FRL–9993–93), 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 9F8733) by Syngenta Crop Protection, LLC, P.O. Box 18300, Greensboro, NC 27419. The petition requested that 40 CFR 180.637 be amended by establishing tolerances for residues of the fungicide mandipropamid in or on cocoa bean at 0.05 parts per million (ppm). That document referenced a summary of the petition prepared by Syngenta Crop Protection, LLC, the registrant, which is available in the docket, *http://www.regulations.gov.* There were no comments received in response to the notice of filing.

Based upon review of the data supporting the petition, EPA is establishing the tolerance at 0.06 ppm in or on cacao, dried bean. The reason for this change is explained in Unit IV.C.

III. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of 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 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 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 in FFDCA section 408(b)(2)(D), 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 mandipropamid including exposure resulting from the tolerances established by this action.

A. Risk Assessment

In the **Federal Register** of March 22, 2019 (84 FR 10695) (FRL–9987–25), EPA established tolerances for residues of mandipropamid in or on several commodities. Because much of the safety assessment of mandipropamid for the current action remains the same, EPA is incorporating several aspects of that previous rule and relying in part upon the findings made in the March 22, 2019 final rule in support of this action.

A summary of the toxicological profile and endpoints used for human risk assessment is discussed in Units III.A. and III.B of the March 22, 2019 final rule. In evaluating dietary exposure for this action, EPA considered exposure under the petitioned-for tolerances as well as all existing mandipropamid tolerances in 40 CFR 180.637. The exposure assumptions used to assess the mandipropamid tolerances remain the same as discussed in the March 22, 2019 final rule, except to incorporate the exposure associated with the tolerance on cacao, dried beans, for which the Agency assumed 100 percent crop treated and tolerance-level residues. For a summary of those exposure assumptions, see Unit III.C.1 of the March 22, 2019 final rule. In addition, because there is no U.S. registration associated with the use of mandipropamid on cacao, dried beans, the estimated drinking water exposures reported in the March 22, 2019 final rule remain the same for this rule. A summary of EPA's assessment of drinking water exposure is discussed in Unit III.C.2. of the March 22, 2019 final rule. Similarly, the Agency's assessment of cumulative risks remains the same as in the March 22, 2019 final rule.

Because there have been no changes to the potential for prenatal and postnatal toxicity or in the completeness of data with respect to toxicity and exposure, EPA has determined that reliable data show the safety of infants and children would be adequately protected if the additional tenfold (10X) margin of safety required under section 408(b)(2)(C) (''FQPA safety factor'') were reduced to 1X. A summary of EPA's rationale for this determination is discussed in Unit III.D. of the March 22, 2019 final rule.

B. Determination of Safety

EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute population-adjusted dose (aPAD) and chronic population-adjusted dose (cPAD). Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate points of departure to ensure that an adequate margin of exposure exists.

No acute effects were identified in the toxicological studies for mandipropamid; therefore, a quantitative acute dietary exposure assessment was not conducted. The chronic dietary risk is 31% of the cPAD for the general U.S. population and 49% of the cPAD for children 1 to 2 years old, the population subgroup with the highest estimated chronic dietary exposure to mandipropamid. The Agency level of concern is percentage numbers greater than 100% of the cPAD. Mandipropamid is not registered for any specific use patterns that would result in residential exposure. Therefore, all aggregate risk estimates are expected to be equivalent to the dietary (food and drinking water) risk estimates mentioned above.

Therefore, EPA concludes that there is a reasonable certainty that no harm will result to the general population, or to infants and children from aggregate exposure to mandipropamid residues.

Mandipropamid is classified as ''Not Likely to be Carcinogenic to Humans.'' Therefore, a dietary exposure assessment for the purpose of assessing cancer risk is unnecessary.

For a detailed discussion of the aggregate risk assessments and determination of safety for these tolerances, please refer both to the March 22, 2019 final rule and its supporting documents, available at *http://www.regulations.gov* in docket ID number EPA–HQ–OPP–2017–0671, and to the risk assessment for this current action, ''*Mandipropamid. Human Health Risk Assessment to Support the Proposed Establishment of a Tolerance for the Fungicide (without Section 3 Registration) in/on Imported Cacao Beans.*'' in docket ID number EPA–HQ–OPP–2019–0062.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology, using method RAM 415/02, for the determination of mandipropamid using high-performance liquid chromatography with tandem mass spectrometric detection (LC/MS/MS), is available to enforce the tolerance. The method has been adequately validated by an independent laboratory, with a validated limit of quantitation (LOQ) of 0.010 ppm and a limit of detection (LOD) of 0.002 ppm in the crops tested.

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 Alimentarius 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.

The Codex has not established an MRL for mandipropamid in cacao, dried bean.

C. Revisions to Petitioned-For Tolerances

The tolerance definition was revised from ''cocoa bean'' to ''cacao, dried bean'' in accordance with tolerance naming conventions. EPA has revised the tolerance level for mandipropamid residues in cacao, dried bean based on the review conducted by the European Food Safety Authority (EFSA) (*Setting*

of an import tolerance for mandipropamid in cocoa beans; A. Brancato *et al;* 31 October 2018). The EFSA review addresses the same use pattern and residue data submitted to the EPA to support this use, so the tolerance being established is harmonized with EFSA's recommended MRL (0.06 mg/kg).

V. Conclusion

Therefore, tolerances are established for residues of mandipropamid, in or on cacao, dried bean at 0.06 ppm.

VI. Statutory and Executive Order Reviews

This action establishes 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 tolerance 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: October 11, 2019.

Daniel Rosenblatt,

Acting Director, Registration 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. In § 180.637, add alphabetically the commodity ''Cacao, dried bean'' to the table in paragraph (a) to read as follows:

§ 180.637 Mandipropamid; tolerances for residues.

(a) * * *

Commodity	Parts per million
* * * * *	
Cacao, dried bean [1]	0.06
* * * * *	

[1] There are no U.S. registrations allowing use of mandipropamid on cacao as of October 28, 2019.

* * * * *

[FR Doc. 2019–23360 Filed 10–25–19; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

45 CFR Part 162

[CMS–0054–F]

RIN 0938–AT42

Administrative Simplification: Rescinding the Adoption of the Standard Unique Health Plan Identifier and Other Entity Identifier

AGENCY: Office of the Secretary, HHS.

ACTION: Final rule.

SUMMARY: This final rule rescinds the adopted standard unique health plan identifier (HPID) and the implementation specifications and requirements for its use and the other entity identifier (OEID) and implementation specifications for its use. This final rule also removes the definitions for the ''Controlling health plan'' (CHP) and ''Subhealth plan'' (SHP).

DATES: This final rule is effective on December 27, 2019.

FOR FURTHER INFORMATION CONTACT: Lorraine Doo, (410) 786–6597 or *Lorraine.Doo@cms.hhs.gov*.

Brian James, (301) 492–4234 or *Brian.James@cms.hhs.gov* for questions regarding the Health Plan and Other Entity Enumeration System (HPOES).

SUPPLEMENTARY INFORMATION:

I. Background

Section 262 of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) (Pub. L. 104–191) added section 1173 to the Social Security Act (the Act), which requires that the Secretary of the Department of Health and Human Services (HHS or the Secretary) adopt a standard unique health plan identifier.

Congress renewed the requirement for the Secretary to adopt a standard unique