§ 2402.12 Disclaimer.

Nothing in this part shall be construed to entitle any person, as a right, to any service or to the disclosure of any record to which such person is not entitled under the FOIA.

Dated: October 5, 2020.

Stacy Lynn Murphy,

Operations Manager.

[FR Doc. 2020–22375 Filed 11–3–20; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2020–0046; FRL–10012–51]

Trinexapac-ethyl; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of trinexapac-ethyl in or on sugarcane, cane and sugarcane, molasses. Syngenta Crop Protection, LLC requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective November 4, 2020. Objections and requests for hearings must be received on or before January 4, 2021, 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–2020–0046, 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. Due to public health concerns related to COVID–19, the EPA Docket Center and Public Reading Room are closed for the time being, although EPA staff are continuing to provide remote assistance. Please review additional information about the docket available at *http://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: Marietta Echeverria, 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 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–2020–0046 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 January 4, 2021. 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–2020–0046, 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 March 3, 2020 (85 FR 12454) (FRL–10005–58), 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 9F8761) by Syngenta Crop Protection, LLC, P.O. Box 18300, Greensboro, NC 27419. The petition requested that 40 CFR part 180.662 be amended by establishing tolerances for residues of the herbicide trinexapac-ethyl, (4-(cyclopropyl-a-hydroxy-methylene)-3,5-dioxo-cyclohexanecarboxylic acid ethyl ester), and its primary metabolite CGA-179500 in or on sugarcane, cane at 1.5 parts per million (ppm) and sugarcane, molasses at 5.0 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.* Comments were received on the notice of filing. EPA's response to these comments is discussed in Unit IV.C.

Based upon review of the data supporting the petition, EPA is modifying the tolerance expression and the tolerance for sugarcane, molasses at a different level than petitioned-for. The reasons for these are explained in Unit IV.D.

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 Trinexapac-ethyl including exposure resulting from the tolerances established by this action.

EPA published a final rule in the **Federal Register** on May 20, 2015 (80 FR 28843) (FRL–9926–62) establishing tolerances for residues of trinexapac-ethyl in or on rice and rye commodities based on the Agency's conclusion that there is a reasonable certainty that no harm will result from aggregate exposure to trinexapac-ethyl to the general population, including infants and children. That document contains a summary of the toxicological profile, a reference to toxicological endpoints, a description of EPA's position on the potential for cumulative risk, as well as the rationale for the Agency's determination regarding the children's safety factor. As those sections continue to reflect the Agency's current position on those topics, those sections are incorporated here by reference.

EPA's exposure assessments have been updated to include the additional exposure from the increased tolerance of trinexapac-ethyl from use in or on sugarcane, cane and sugarcane, molasses. Those assessments rely on tolerance-level residues, 2019 default processing factors, and an assumption of 100% crop treated (PCT). EPA's aggregate exposure assessment incorporated this additional dietary exposure, as well as exposure in drinking water and from residential sources, although those latter exposures are not impacted by the modified use on sugarcane and thus have not changed since the last assessment.

Acute dietary risks are below the Agency's level of concern: 2.5% of the acute population adjusted dose (aPAD) for females 13 to 49 years old, the population group of concern. Chronic dietary risks are below the Agency's level of concern: 6.6% of the chronic population adjusted dose (cPAD) for children 1 to 2 years old, the population group receiving the greatest exposure. Aggregating chronic (or background) dietary exposure with short- and intermediate-term exposures, EPA has concluded that the combined food, water, and short- and intermediate-term residential exposures result in aggregate margins of exposures above the level of concern for all scenarios assessed and are not of concern. Finally, EPA has concluded that trinexapac-ethyl is not expected to pose a cancer risk, given the lack of evidence of carcinogenicity in the database.

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 trinexapac-ethyl residues. Further information about EPA's risk assessment and determination of safety can be found at *http://www.regulations.gov* in the document titled ''Trinexapac-ethyl. Human Health Risk Assessment for the Petition to Amend the Pre-Harvest Intervals on Sugarcane.'' dated July 13, 2020 in the docket ID number EPA–HQ–OPP–2020–0046.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology (Method GRM020.01A), which utilizes high performance liquid chromatography with triple-quadrupole mass spectrometry (LC–MS/MS) 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 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 established an MRL for trinexapac-ethyl in or on sugarcane at 0.5 ppm. This MRL is different than the tolerances established for trinexapac-ethyl in the United States. The United States is not able to harmonize its sugarcane tolerance with the Codex MRL; based on the reduction of the preharvest interval (PHI) from 28 to 14 days on sugarcane, the field trial data indicate that use in accordance with the label results in residues may exceed tolerances if they were harmonized with Codex.

C. Response to Comments

Two comments were received in response to the Notice of Filing. Neither comment was accompanied by any substantiation nor data supporting a conclusion that the tolerances being established in this action do not meet the FFDCA safety standard. Although EPA recognizes that some individuals would oppose any use of pesticides on food, section 408 of the FFDCA authorizes EPA to set tolerances for residues of pesticide chemicals in or on food when it determines that the tolerance meets the safety standard imposed by that statute. Upon review of the available information, EPA concludes that these tolerances would be safe.

D. Revisions to Petitioned-For Tolerances

EPA is revising the tolerance expression to include the free and conjugated forms of the parent (trinexapac-ethyl) and acid. Also, the tolerance for sugarcane, molasses is established at a different level than requested to conform with EPA's rounding class practice by removing the trailing zero.

V. Conclusion

Therefore, EPA is increasing tolerances for residues of trinexapac-ethyl, ethyl 4-(cyclopropylhydroxymethylene)-3,5-dioxocyclohexanecarboxylate, including

its metabolites and degradates, in or on sugarcane, cane at 1.5 ppm, and sugarcane, molasses at 5 ppm.

VI. Statutory and Executive Order Reviews

This action modifies existing 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 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: September 16, 2020.

Marietta Echeverria,

Acting Director, Registration Division, Office of Pesticide Programs.

Therefore, for the reasons stated in the preamble, EPA amends 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 § 180.662, amend paragraph (a) by:

■ i. Revising the Introductory text.

■ ii. Revising the existing entries in the table for ''Sugarcane, cane'' and ''Sugarcane, molasses''.

The revisions read as follows:

§ 180.662 Trinexapac-ethyl; tolerances for residues.

(a) *General.* Tolerances are established for residues of the plant growth regulator, trinexapac-ethyl, including its metabolites and degradates, in or on the commodities in the table below. Compliance with the tolerance levels specified below is to be determined by measuring only the free and conjugated forms of both trinexapac-ethyl, ethyl 4-(cyclopropylhydroxymethylene)-3,5-dioxocyclohexanecarboxylate and trinexapac, 4-(cyclopropylhydroxymethylene)-3,5-dioxocyclohexanecarboxylic acid, calculated as the stoichiometric equivalent of trinexapac-ethyl, in or on the commodity.

Commodity	Parts per million
* * * * *	
Sugarcane, cane	1.5
Sugarcane, molasses	5
* * * * *	

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[FR Doc. 2020–23040 Filed 11–3–20; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

45 CFR Parts 170 and 171

RIN 0955–AA02

Information Blocking and the ONC Health IT Certification Program: Extension of Compliance Dates and Timeframes in Response to the COVID–19 Public Health Emergency

AGENCY: Office of the National Coordinator for Health Information Technology (ONC), Department of Health and Human Services (HHS).

ACTION: Interim final rule with comment period.

SUMMARY: This interim final rule with comment period (IFC) gives health IT developers and health care providers flexibilities to effectively respond to the public health threats posed by the spread of the coronavirus disease 2019 (COVID–19). Recognizing the urgency of this situation, and understanding that caring for patients with COVID–19 is of utmost importance, ONC is issuing this IFC to extend certain compliance dates and timeframes adopted in the 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program Final Rule (ONC Cures Act Final Rule), including compliance and applicability dates for the information blocking provisions, certain 2015 Edition health IT certification criteria, and Conditions and Maintenance of Certification