ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2018–0194; FRL–9998–87]

Cyclaniliprole; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of cyclaniliprole in or on multiple commodities that are identified and discussed later in this document. ISK Biosciences Corporation requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective September 26, 2019. Objections and requests for hearings must be received on or before November 25, 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–2018–0194, 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 Goodis, Director, 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.* To access the OCSPP test guidelines referenced in this document electronically, please go to *http://www.epa.gov/ocspp* and select ''Test Methods and Guidelines.''

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–2018–0194 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing and must be received by the Hearing Clerk on or before November 25, 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–2018–0194, 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 Tuesday, July 24, 2018 (83 FR 34968) (FRL–9980–31), 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 7F8651) by ISK Biosciences Corporation, 7470 Auburn Rd, Suite A, Concord, OH 44077. The petition requested that 40 CFR 180.694 be amended by establishing tolerances for residues of the insecticide cyclaniliprole, 3-bromo-N-[2-bromo-4-chloro-6-[[(1-cyclopropylethyl)amino] carbonyl]phenyl]-1-(3-chloro-2-pyridinyl)-1H-pyrazole-5-carboxamide, in or on the following commodities: Citrus fruit (crop group 10–10) at 0.5 parts per million (ppm); tuberous & corm vegetables (crop group 1C) at 0.01 ppm; and berry & small fruit (crop subgroup 13–07A, 13–07B, 13–07E except grape, and 13–07G) at 1.5 ppm. That document referenced a summary of the petition prepared by ISK Biosciences Corporation, 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 tolerances that vary from the levels requested as allowed by section 408(d)(4)(A)(i) of FFDCA. The reason for these changes 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 cyclaniliprole including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with cyclaniliprole is summarized as follows.

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children.

No single or repeated dose study performed by any route of exposure produced an adverse effect following cyclaniliprole exposure at dose levels below, at, or above the limit dose (1,000 milligrams/kilogram/day (mg/kg/day)). Although the oral toxicity studies in dogs were conducted at approximately a third of the limit dose, no adverse effects were seen. It is unlikely that cyclaniliprole would produce adverse liver effects, if tested at higher doses in dogs as a structurally related chemical, chlorantraniliprole, was tested up to the limit dose in dogs and did not demonstrate liver effects. There is no evidence that cyclaniliprole produces increased susceptibility with prenatal or postnatal exposures. Cyclaniliprole is considered not likely to be carcinogenic based on no increase in treatment-related tumor incidence in carcinogenicity studies in rats and mice and no genotoxicity.

Specific information on the studies received for cyclaniliprole as well as the no-observed-adverse-effect-level (NOAEL) from the toxicity studies can be found at *http://www.regulations.gov* in document, ''Cyclaniliprole: Human Health Risk Assessment for the Proposed New Uses on Bushberry Subgroup 13–07B; Caneberry Subgroup 13–07A; Citrus Fruit Crop Group 10–10; Low Growing Berry Subgroup 13–07G; Small Fruit Vine Climbing (except Grape) Subgroup 13–07E; and Tuberous and Corm Vegetables Crop Subgroup 1C.'', dated October 17, 2018 in docket ID number EPA–HQ–OPP–2018–0194.

Based on the review of the available cyclaniliprole toxicological studies, no toxicity endpoints or points of departure were selected for risk assessment. Based on the toxicological profile of cyclaniliprole, EPA has concluded that the FFDCA requirements to retain an additional safety factor for protection of infants and children and to consider cumulative effects do not apply. Section 408(b)(2)(C) requires an additional tenfold margin of safety in the case of threshold risks, which cyclaniliprole does not present. Section 408(b)(2)(D)(v) requires consideration of information concerning cumulative effects of substances that have a common mechanism of toxicity, which cyclaniliprole does not have.

There is a potential for exposure to cyclaniliprole residues via food and drinking water based on existing uses and the proposed uses for cyclaniliprole application directly to growing crops. These applications can also result in cyclaniliprole reaching surface and ground water, both of which can serve as sources of drinking water. Moreover, there are no proposed uses in residential settings; therefore, there are no anticipated residential exposures.

Determination of safety. Based on the available data indicating a lack of adverse effects from exposure to cyclaniliprole, 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 cyclaniliprole.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methods have been proposed for plants (Method JSM0269) and livestock commodities (Method JSM0277). For plants and livestock, cyclaniliprole residues are extracted using acetonitrile, cleaned up and analyzed by liquid chromatography with tandem mass spectrometry (LC–MS/MS). The validated limit of quantitation (LOQ) was 0.01 ppm for plants and livestock commodities. All concurrent recoveries of cyclaniliprole at the fortification level of 0.01 ppm in the field trials and processing studies were within the acceptable range of 70–120%. The method is considered suitable for enforcement purposes. Adequate independent laboratory validation (ILV) and adequate radio-validation studies were conducted for the methods.

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 MRLs for cyclaniliprole.

C. Revisions to Petitioned-For Tolerances

Tolerances were requested for citrus fruit (crop group 10–10) at 0.5 ppm; tuberous & corm vegetables (crop group 1C) at 0.01 ppm; and berry & small fruit (crop subgroup 13–07A, 13–07B, 13–07E except grape, and 13–07G) at 1.5 ppm.

EPA considered commodity definitions and additional information provided by ISK Biosciences Corporation, including field trial residues that were adjusted by proportionality to reflect the proposed used pattern and used the Organization for Economic Cooperation and Development (OECD) statistical calculation procedures to determine the appropriate tolerance value which resulted in a different tolerance value for each of these subgroups than what the petitioner requested.

EPA is establishing separate subgroup tolerances for fruit, citrus, group 10–10, in anticipation of the establishment of subgroup MRLs by Codex, rather than a single group MRL. For citrus fruit crop group 10–10, EPA is establishing tolerances for orange subgroup 10–10A at 0.4 ppm, lemon/lime subgroup 10–10B at 0.3 ppm, and grapefruit subgroup 10–10C at 0.2 ppm. Based on processing studies, EPA is further establishing tolerances for fruit, citrus, group 10–10, oil at 30 ppm in accordance with its regulatory requirement to establish tolerances for processed commodities made necessary by the use of the

pesticide on the commodities in the underlying crop group.

For tuberous & corm vegetables (crop group 1C), EPA is establishing the tolerance at 0.01 ppm. Based on processing information and in accordance with 40 CFR 180.40(f), EPA is further establishing a tolerance for potato (wet peel) at 0.06 ppm.

For the berries, the registrant proposed tolerances as berry and small fruit (Crop Subgroups 13–07A, 13–07B, 13–07E (except grape), and 13–07G at 1.5 ppm. HED is recommending for individual crop subgroup tolerances, with the tolerance level based on the representative commodities for the specific subgroups. For the berry and small fruit subgroups, EPA is establishing the tolerance for caneberry subgroup 13–07A at 0.8 ppm; bushberry subgroup 13–07B at 1.5 ppm; fruit, small vine climbing (except grape) subgroup 13–07E at 1 ppm; and berry, low growing, subgroup 13–07G at 0.4 ppm.

V. Conclusion

Although the lack of toxicity supports a safety finding for an exemption from the requirement of tolerance for all crops, EPA is establishing tolerances for residues resulting from direct applications to certain commodities because the petitioner requested them for international trade purposes. Tolerances are established for residues of cyclaniliprole, 3-bromo-N-[2-bromo-4-chloro-6-[[(1-cyclopropylethyl)amino]carbonyl] phenyl]-1-(3-chloro-2-pyridinyl)-1Hpyrazole-5-carboxamide in or on orange subgroup 10–10A at 0.4 ppm; lemon/lime subgroup 10–10B at 0.3 ppm; grapefruit subgroup 10–10C at 0.2 ppm; and fruit, citrus, group 10–10, oil at 30 ppm; vegetable, tuberous and corm, subgroup 1C at 0.01 ppm; and potato, wet peel at 0.06 ppm; caneberry subgroup 13–07A at 0.8 ppm; bushberry subgroup 13–07B at 1.5 ppm; fruit, small, vine climbing, except grape, subgroup 13–07E at 1 ppm; and berry, low growing, subgroup 13–07G at 0.4 ppm.

VI. Statutory and Executive Order Reviews

This action establishes 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 10, 2019.

Michael Goodis,

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 § 180.694, add alphabetically the following commodities to the table in paragraph (a) to read as follows:

§ 180.694 Cyclaniliprole; tolerances for residues.

(a) * * *

Commodity	Parts per million
* * * * *	
Berry, low growing, subgroup 13–07G	0.4
Bushberry subgroup 13–07B	1.5
Caneberry subgroup 13–07A	0.8
* * * * *	
Fruit, citrus, group 10–10, oil	30
* * * * *	
Fruit, small, vine climbing, except grape, subgroup 13–07E	1
* * * * *	
Grapefruit subgroup 10–10C	0.2
* * * * *	
Lemon/lime subgroup 10–10B	0.3
* * * * *	
Orange subgroup 10–10A	0.4
Potato, wet peel	0.06
* * * * *	
Vegetable, tuberous and corm, subgroup 1C	0.01

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