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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2017-0694; FRL-10004-23]

Cyantraniliprole; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

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SUMMARY: This regulation establishes a tolerance for residues of

cyantraniliprole in or on strawberry. The Interregional Research

Project No. 4 (IR-4) requested this tolerance under the Federal Food,

Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective February 14, 2020. Objections and

requests for hearings must be received on or before April 14, 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-2017-0694, is available at

[https://www.regulations.gov](https://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 <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](mailto: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>. To access the OCSPP

test guidelines referenced in this document electronically, please go

to <https://www.epa.gov/aboutepa/about-office-chemical-safety-and-pollution-prevention-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-2017-0694 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

April 14, 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

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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-2017-0694, by one of the following methods:

Federal eRulemaking Portal: [https://www.regulations.gov](https://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 <https://www.epa.gov/dockets/where-send-comments-epa-dockets>.

Additional instructions on commenting or visiting the docket, along

with more information about dockets generally, is available at <https://www.epa.gov/dockets>.

II. Summary of Petitioned-For Tolerance

In the Federal Register of August 2, 2019 (84 FR 37818) (FRL-9996-

78), 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

9E8739) by The Interregional Research Project No. 4 (IR-4), Rutgers,

The State University of New Jersey, 500 College Road East, Suite 201 W,

Princeton, NJ 08540. The petition requested that 40 CFR 180.672 be

amended by establishing a tolerance for residues of the insecticide,

cyantraniliprole, 3-bromo-1-(3-chloro-2-pyridinyl)-N-[4-cyano-2-methyl-

6-[((methylamino)carbonyl]phenyl]-1H-pyrazole-5-carboxamide, in or on

strawberry at 1.5 parts per million (ppm). Upon the establishment of

the above tolerance, IR-4 proposed to remove the existing tolerance in

40 CFR 180.672 in or on strawberry at 1.0 ppm. That document referenced

a summary of the petition prepared by DuPont Crop Protection, the

registrant, which is available in the docket, [https://www.regulations.gov](https://www.regulations.gov/). No comments were received on the notice of filing.

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 cyantraniliprole including

exposure resulting from the tolerance established by this action. EPA's

assessment of exposures and risks associated with cyantraniliprole

follows.

A. Toxicological Profile and Points of Departure/Levels of Concern

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.

A summary of the toxicological profile for cyantraniliprole is

discussed in Unit III.A. of the final rule published in the Federal

Register of November 13, 2018 (84 FR 56262) (FRL-9985-32). A summary of

the toxicological endpoints for cyantraniliprole used for human risk

assessment is discussed in Unit III.B of the final rule published in

the Federal Register of February 5, 2014 (79 FR 6826) (FRL-9388-7).

Specific information on the studies received and the nature of the

adverse effects caused by cyantraniliprole as well as the no-observed-

adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-

level (LOAEL) from the toxicity studies can be found at [http://www.regulations.gov](http://www.regulations.gov/) in document ``Cyantraniliprole. Human Health Risk

Assessment for Proposed Uses and Tolerance Requests on Coffee;

Caneberry Subgroup 13-07A; Low Growing Berry Subgroup 13-07H, Except

Strawberry, Lowbush Blueberry and Lingonberry; Brassica Leafy Greens

Subgroup 4-16A; Leafy Greens Subgroup 4-16B; Brassica Head and Stem

Vegetable Group 5-16; Leaf Petiole Vegetable Subgroup 22B; Celtuce;

Florence Fennel; Kohlrabi; Rice; Soybean; and Aspirated Grain

Fractions'' on pages 36-45 in docket ID number EPA-HQ-OPP-2017-0694.

B. Exposure Assessment

A summary of EPA's consideration of dietary exposure under the

petitioned-for tolerance as well as existing cyantraniliprole

tolerances, as well as non-dietary exposure and exposure to substances

with a common mechanism of toxicity is discussed in Unit III.C. of the

November 13, 2018 final rule published in the Federal Register.

C. Safety Factor for Infants and Children

Section 408(b)(2)(C) of FFDCA 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 FQPA Safety Factor (SF). 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.

EPA has determined that reliable data show the safety of infants

and children would be adequately protected if the FQPA SF were reduced

to 1X. That decision is based on the findings summarized in Unit III.D.

of the November 13, 2018 final rule.

D. Aggregate Risks and Determination of Safety

EPA determines whether acute and chronic dietary pesticide

exposures are safe by comparing aggregate exposure estimates to the

acute PAD (aPAD) and chronic PAD (cPAD). For linear cancer risks, EPA

calculates the lifetime probability of acquiring cancer given the

estimated aggregate exposure. Short-, intermediate-, and chronic-term

risks are evaluated by comparing the estimated aggregate food, water,

and residential exposure to the appropriate PODs to ensure that an

adequate MOE exists.

1. Acute risk. An acute aggregate risk assessment takes into

account acute exposure estimates from dietary consumption of food and

drinking

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water. No adverse effect resulting from a single oral exposure was

identified and no acute dietary endpoint was selected. Therefore,

cyantraniliprole is not expected to pose an acute risk.

2. Chronic risk. Using the exposure assumptions cited in this unit

for chronic exposure, EPA has concluded that chronic exposure to

cyantraniliprole from food and water will utilize 99% of the cPAD for

children 1 to 2 years old, the population group receiving the greatest

exposure. Based on the explanation cited in Unit III.B., regarding

residential use patterns, chronic residential exposure to residues of

cyantraniliprole is not expected.

3. Short-term risk. Short-term aggregate exposure takes into

account short-term residential exposure plus chronic exposure to food

and water (considered to be a background exposure level).

Cyantraniliprole is currently registered for uses that could result in

short-term residential exposure, and the Agency has determined that it

is appropriate to aggregate chronic exposure through food and water

with short-term residential exposures to cyantraniliprole.

Using the exposure assumptions cited in this unit for short-term

exposures, EPA has concluded the combined short-term food, water, and

residential exposures result in an aggregate MOE of 149 for children 1

to 2 years old. For adults, the oral and inhalation routes of exposure

are not appropriate to be aggregated since the endpoints of concern are

not common. Because EPA's level of concern for cyantraniliprole is an

MOE of 100 or below, this MOE is not of concern.

4. Intermediate-term risk. Intermediate-term aggregate exposure

takes into account intermediate-term residential exposure plus chronic

exposure to food and water (considered to be a background exposure

level). Cyantraniliprole is currently registered for uses that could

result in intermediate-term residential exposure, however, the short-

term aggregate risk estimate described above is protective of potential

intermediate-term exposures and risks in children.

5. Aggregate cancer risk for U.S. population. Based on the lack of

evidence of carcinogenicity in two adequate rodent carcinogenicity

studies, cyantraniliprole is not expected to pose a cancer risk to

humans.

6. Determination of safety. Based on these risk assessments, 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 cyantraniliprole residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology (liquid chromatography with tandem

mass spectroscopy (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](mailto: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.

Codex has not established an MRL for cyantraniliprole residues in

or on strawberry.

V. Conclusion

Therefore, the existing tolerance for residues of cyantraniliprole,

3-bromo-1-(3-chloro-2-pyridinyl)-N-[4-cyano-2-methyl-6-

[((methylamino)carbonyl]phenyl]-1H-pyrazole-5-carboxamide, in or on

strawberry is modified from 1.0 ppm to 1.5 ppm.

VI. Statutory and Executive Order Reviews

This action modifies 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).

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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: January 24, 2020.

Michael Goodis,

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180--[AMENDED]

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

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

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2. In Sec. 180.672, revise the entry for ``Strawberry'' in the table

in paragraph (a) to read as follows:

Sec. 180.672 Cyantraniliprole; tolerances for residues.

(a) \* \* \*

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Parts per

Commodity million

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\* \* \* \* \*

Strawberry.................................................. 1.5

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[FR Doc. 2020-02238 Filed 2-13-20; 8:45 am]

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