[Federal Register Volume 85, Number 122 (Wednesday, June 24, 2020)]

[Rules and Regulations]

[Pages 37760-37763]

From the Federal Register Online via the Government Publishing Office [[www.gpo.gov](http://www.gpo.gov/)]

[FR Doc No: 2020-12132]

-----------------------------------------------------------------------

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2020-0045; FRL-10008-92]

Indaziflam; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

-----------------------------------------------------------------------

SUMMARY: This regulation establishes tolerances for residues of

indaziflam in or on multiple commodities which are identified and

discussed later in this document. Bayer CropScience requested these

tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective June 24, 2020. Objections and

requests for hearings must be received on or before August 24, 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-2020-0045, is available at [http://www.regulations.gov](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 note that due to the public health emergency the EPA Docket

Center (EPA/DC) and Reading Room was closed to public visitors on March

31, 2020. Our EPA/DC staff will continue to provide customer service

via email, phone, and webform. For further information on EPA/DC

services, docket contact information and the current status of the EPA/

DC and Reading Room, please visit <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>.

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-2020-0045 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

August 24, 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 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-2020-0045, by one of

the following methods:

Federal eRulemaking Portal: [http://www.regulations.gov](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 April 15, 2020 (85 FR 20910) (FRL-10006-

54), EPA issued a document pursuant to FFDCA section 408(d)(3), 21

U.S.C. 346a(d)(3), announcing the filing of a

[[Page 37761]]

pesticide petition (PP 8F8725) by Bayer CropScience 2 T.W. Alexander

Drive, Research Triangle Park, NC 27709. The petition requested that 40

CFR part 180 be amended by establishing tolerances for residues of

indaziflam (N-[(1R,2S)-2,3-dihydro-2,6-dimethyl-1H-inden-1-yl]-6-(1-

fluoroethyl)-1,3,5-triazine-2,4-diamine) in or on grass, forage, fodder

and hay, group 17, forage at 30 parts per million (ppm); grass, forage,

fodder and hay, group 17, hay at 10 ppm; sugarcane, cane at 0.01 ppm;

cattle, goat, horse, and sheep fat at 0.07 ppm; cattle, goat, horse,

and sheep meat at 0.01 ppm; cattle, goat, horse, and sheep meat

byproducts at 0.2 ppm; milk at 0.01 ppm; and milk, fat at 0.25 ppm.

That document referenced a summary of the petition prepared by Bayer

CropScience, the registrant, which is available in the docket, [http://www.regulations.gov](http://www.regulations.gov/). There were no comments received in response to 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 indaziflam including exposure

resulting from the tolerances established by this action. EPA's

assessment of exposures and risks associated with indaziflam follows.

On October 10, 2019, EPA published in the Federal Register a final

rule establishing tolerances for residues of indaziflam in or on the

tropical and subtropical fruit (edible peel) group 23 and tropical and

subtropical fruit (inedible peel) group 24 based on the Agency's

conclusion that aggregate exposure to indaziflam is safe for the

general population, including infants and children. See 84 FR 54510

(FRL-9999-70). That document contains a summary of the toxicological

profile and points of departure, assumptions for exposure assessment,

and the Agency's determination regarding the children's safety factor,

which have not changed.

EPA's dietary exposure assessments have been updated to include the

additional exposure from use of indaziflam on grass forage, grass hay,

and sugarcane cane, and from exposure to residues in edible ruminant

commodities, i.e., reliance on tolerance-level residues for all crops,

maximum anticipated residues for all edible ruminant commodities, and

an assumption of 100 percent 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 new uses on

grass forage, grass hay, and sugarcane cane and thus have not changed

since the last assessment. Further information about EPA's risk

assessment and determination of safety supporting the tolerances

established in the October 10, 2019 Federal Register action, as well as

the new indaziflam tolerances, can be found at [http://www.regulations.gov](http://www.regulations.gov/) in the document titled ``Indaziflam--Aggregate

Human Health Risk Assessment of the Proposed New Use on Lowbush

Blueberry, and Crop Group Expansions to Tropical and Subtropical Fruit,

Edible Peel, Group 23 and Tropical and Subtropical Fruit, Inedible

Peel, Group 24.'' dated September 11, 2019 in docket ID EPA-HQ-OPP-

2018-0561 and the document titled, ``Indaziflam. Human Health Risk

Assessment in Support of the Proposed New Uses on Grasses, Sugarcane,

Wildlife Management, and Rights-of-Way'' dated April 17, 2020 in docket

ID number EPA-HQ-OPP-2020-0045.

Acute dietary risks are below the Agency's level of concern: 20% of

the acute population adjusted dose (aPAD) at the 95th percentile of

exposure for all infants less than 1 year old, the population subgroup

with the highest exposure estimate. Chronic dietary risks are below the

Agency's level of concern: 20% of the chronic population adjusted dose

(cPAD) for children 1 to 2 years old, the population subgroup with the

highest exposure estimate. The updated combined short-term food, water,

and residential exposure estimates result in aggregate margins of

exposure (MOEs) above the level of concern (LOC) of 100 for all

scenarios assessed and are not of concern.

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 indaziflam residues. More detailed information on

the subject action to establish tolerances in or on the grass forage,

grass hay, sugarcane cane, and edible ruminant commodities can be found

in the document entitled, ``Indaziflam. Human Health Risk Assessment in

Support of the Proposed New Uses on Grasses, Sugarcane, Wildlife

Management, and Rights-of-Way'' by going to [http://www.regulations.gov](http://www.regulations.gov/).

The referenced document is available in the docket established by this

action, which is described under ADDRESSES. Locate and click on the

hyperlink for docket ID number EPA-HQ-OPP-2020-0045.

IV. Other Considerations

A. Analytical Enforcement Methodology

There are adequate residue analytical methods for enforcing

tolerances for indaziflam residues of concern in/on the registered

plant and livestock commodities. Method DH-003-P07-02 is an adequate

high-performance liquid chromatography with tandem mass spectrometry

(LC-MS/MS) tolerance enforcement method for indaziflam and 1-

fluoroethyl diaminotriazine (FDAT) in crops. Method DH-009-A18-01 is an

adequate LC-MS/MS tolerance enforcement method for the determination of

indaziflam residues in livestock commodities.

These methods 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

[[Page 37762]]

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 any MRLs for indaziflam.

V. Conclusion

Therefore, tolerances are established for residues of indaziflam,

N-[(1R,2S)-2,3-dihydro-2,6-dimethyl-1H-inden-1-yl]-6-(1-fluoroethyl)-

1,3,5-triazine-2,4-diamine, including its metabolites and degradates in

or on grass, forage, fodder and hay, group 17, forage at 30 ppm; grass,

forage, fodder and hay, group 17, hay at 10 ppm; and sugarcane, cane at

0.01 ppm. Compliance with the tolerance levels specified above is to be

determined by measuring only indaziflam and FDAT, 6-[(1R)-1-

fluoroethyl]-1,3,5-triazine-2,4-diamine, calculated as the

stoichiometric equivalent of indaziflam, in or on the commodity.

Tolerances are also established for residues of indaziflam, N-

[(1R,2S)-2,3-dihydro-2,6-dimethyl-1H-inden-1-yl]-6-(1-fluoroethyl)-

1,3,5-triazine-2,4-diamine, including its metabolites and degradates in

or on cattle, fat at 0.7 ppm; cattle, meat at 0.01 ppm; cattle, meat

byproducts at 0.2 ppm; goat, fat at 0.07 ppm; goat, meat at 0.01 ppm;

goat, meat byproducts at 0.2 ppm; horse, fat at 0.07 ppm; horse, meat

at 0.01 ppm; horse, meat byproducts at 0.2 ppm; milk at 0.01 ppm; milk,

fat at 0.25 ppm; sheep, fat at 0.07 ppm; sheep, meat at 0.01 ppm; and

sheep, meat byproducts at 0.2 ppm. Compliance with the tolerance levels

specified above is to be determined by measuring only indaziflam in or

on the commodity.

Lastly, the existing tolerance in paragraph (a) for ``Sugarcane,

refined sugar'' is removed as unnecessary and the tolerances under

paragraph (b), Section 18 emergency exemptions for ``Grass, forage,

fodder, and hay, group 17 forage'', and ``Grass, forage, fodder, and

hay, group 17, hay'' are removed as unnecessary due to the

establishment of the above tolerances.

VI. Statutory and Executive Order Reviews

This action establishes and modifies 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 tolerances 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: May 26, 2020.

Michael Goodis,

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180--[AMENDED]

0

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

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

0

2. In Sec. 180.653:

0

a. Redesignate paragraph (a) as (a)(1), revise newly redesignated

paragraph (a)(1) introductory text and redesignate the table as Table 1

to paragraph (a)(1);

0

b. In the table in newly redesignated paragraph (a)(1) remove the entry

for ``Sugarcane, refined sugar'' and add alphabetically entries for

``Grass, forage, fodder and hay, group 17, forage''; ``Grass, forage,

fodder and hay, group 17, hay''; and ``Sugarcane, cane'';

0

c. Add paragraph (a)(2); and

0

d. Remove and reserve paragraph (b).

The additions and revisions read as follows:

Sec. 180.653 Indaziflam; tolerances for residues.

(a) General (1) Tolerances are established for residues of the

herbicide indaziflam, N-[(1R,2S)-2,3-dihydro-2,6-dimethyl-1H-inden-1-

yl]-6-(1-fluoroethyl)-1,3,5-triazine-2,4-diamine, including its

metabolites and degradates, in or on the commodities in the following

table. Compliance with the tolerance levels specified in the following

table is to be determined by measuring only indaziflam and FDAT,

[[Page 37763]]

6-[(1R)-1-fluoroethyl]-1,3,5-triazine-2,4-diamine, calculated as the

stoichiometric equivalent of indaziflam, in or on the commodity.

Table 1 to Paragraph (a)(1)

------------------------------------------------------------------------

Parts per

Commodity million

------------------------------------------------------------------------

\* \* \* \* \*

Grass, forage, fodder and hay, group 17, forage............. 30

Grass, forage, fodder and hay, group 17, hay................ 10

\* \* \* \* \*

Sugarcane, cane............................................. 0.01

------------------------------------------------------------------------

(2) Tolerances are established for residues of the herbicide

indaziflam, N-[(1R,2S)-2,3-dihydro-2,6-dimethyl-1H-inden-1-yl]-6-(1-

fluoroethyl)-1,3,5-triazine-2,4-diamine, including its metabolites and

degradates, in or on the commodities in the following table. Compliance

with the tolerance levels specified in the following table is to be

determined by measuring only indaziflam in or on the commodity.

Table 2 to Paragraph (a)(2)

------------------------------------------------------------------------

Parts per

Commodity million

------------------------------------------------------------------------

Cattle, fat................................................. 0.07

Cattle, meat................................................ 0.01

Cattle, meat byproducts..................................... 0.2

Goat, fat................................................... 0.07

Goat, meat.................................................. 0.01

Goat, meat byproducts....................................... 0.2

Horse, fat.................................................. 0.07

Horse, meat................................................. 0.01

Horse, meat byproducts...................................... 0.2

Milk........................................................ 0.01

Milk, fat................................................... 0.25

Sheep, fat.................................................. 0.07

Sheep, meat................................................. 0.01

Sheep, meat byproducts...................................... 0.2

------------------------------------------------------------------------

(b) [Reserved]

\* \* \* \* \*

[FR Doc. 2020-12132 Filed 6-23-20; 8:45 am]

BILLING CODE 6560-50-P