[Federal Register Volume 85, Number 45 (Friday, March 6, 2020)]

[Rules and Regulations]

[Pages 13059-13062]

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

[FR Doc No: 2020-04208]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2019-0130; FRL-10004-08]

Trifloxystrobin; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

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SUMMARY: This regulation establishes a tolerance for residues of

trifloxystrobin in or on pea and bean, dried shelled, except soybean,

subgroup 6C. Bayer CropScience requested this tolerance under the

Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective March 6, 2020. Objections and

requests for hearings must be received on or before May 5, 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-2019-0130, 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 review the visitor instructions and

additional information about the docket available at <http://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.

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-2019-0130 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

May 5, 2020. Addresses for mail and hand delivery of objections and

hearing requests are provided in 40 CFR 178.25(b).

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 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-2019-0130, 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 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

8F8729) by Bayer CropScience, 2 T.W. Alexander Drive, P.O. Box 12014,

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

part 180 be amended by establishing tolerances for residues of the

fungicide, trifloxystrobin (benzeneacetic acid, (E,E)-alpha-

(methoxyimino)-2-[[[[1-[3-(trifluoromethyl)

phenyl]ethylidene]amino]oxy]methyl]-methyl ester) and the free form of

its acid metabolite CGA-321113 ((E,E)-methoxyimino-[2-[1-(3-

trifluoromethylphenyl)-ethylideneaminooxymethyl]-phenyl]acetic acid) in

or on dried shelled pea and bean (except soybean) subgroup 6C at 0.06

parts per million (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.

 Based upon review of the data supporting the petition, EPA has

modified the crop group name to be consistent with Agency nomenclature.

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 trifloxystrobin including

exposure resulting from the tolerances established by this action.

EPA's assessment of exposures and risks associated with trifloxystrobin

follows.

 On February 15, 2019 (84 FR 4340) (FRL-9985-23), EPA published in

the Federal Register a final rule establishing a tolerance for residues

of the fungicide trifloxystrobin in or on flax seed and amending an

existing tolerance for aspirated grain fractions based on the Agency's

conclusion that aggregate exposure to trifloxystrobin is safe for the

general population, including infants and children. See 84 FR 4340

(FRL-9985-23). That document contains a summary of the toxicological

profile and points of departure, assumptions for exposure assessment,

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

which have not changed. The Agency conducted a revised risk assessment

to incorporate additional exposure to residues of trifloxystrobin

approved since that rulemaking and including the use on pea and bean,

dried shelled, except soybean, subgroup 6C.

 EPA's exposure assessments have been updated to include the

additional exposure from use of trifloxystrobin from use on pea and

bean, dried shelled, except soybean, subgroup 6C, i.e., reliance on

tolerance-level residues 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 pea and bean 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

February 15, 2019 Federal Register action, as well as the new

trifloxystrobin tolerance can be found at [http://www.regulations.gov](http://www.regulations.gov/) in

the document entitled ``Trifloxystrobin. Human Health Risk Assessment

for the Proposed New Use on Flax Seed and Increase of Established

Tolerance on Aspirated Grain Fractions,'' dated October 31, 2018, in

docket ID EPA-HQ-OPP-2017-0532.

 Acute dietary risks are below the Agency's level of concern: 3.4%

of the acute population adjusted dose (aPAD) for females 13 to 49 years

old, the only population group of concern. Chronic dietary risks are

below the Agency's level of concern: 58% of the chronic population

adjusted dose (cPAD) for all infants less than 1 year old, the group

with the highest exposure. There is not expected to be any handler

exposure, and there is no adverse systemic hazard via the dermal route

of exposure, so the only residential post-application scenario assessed

was for the incidental short-term oral exposure of children 1 to less

than 2 years old. Using the exposure assumptions described for short-

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

and residential exposures result in aggregate MOEs above the 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 trifloxystrobin residues. More detailed

information on the subject action to establish a tolerance in or on pea

and bean, dried shelled, except soybean, subgroup 6C can be found in

the document entitled, ``Trifloxystrobin. Human Health Aggregate Risk

Assessment for New Use on Dry Beans and Proposed Crop Group Expansion

from Dry Pea to Crop

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Subgroup 6C'' 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-2019-0130.

IV. Other Considerations

A. Analytical Enforcement Methodology

 Adequate enforcement methodology (gas chromatography method with

nitrogen phosphorus detection (GC/NPD)) 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.

 Codex has established an MRL of 0.01 ppm for several of the

commodities in subgroup 6C with the exception of broad bean, chickpea,

cowpea, guar, lupin, blackeyed pea, crowder pea, pigeon pea and

southern pea for which no MRL is established. U.S. tolerances for

residues in the commodities of subgroup 6C are not harmonized with

Codex. Since the Codex MRL is significantly lower for some commodities,

harmonization is not possible because lowering the U.S. tolerance could

cause U.S. growers to have violative residues despite legal use of the

pesticide.

V. Conclusion

 Therefore, tolerances are established for residues of

trifloxystrobin in or on pea and bean, dried shelled, except soybean,

subgroup 6C at 0.06 ppm. Additionally, the existing tolerance on ``pea,

dry, seed'' is removed as unnecessary since it is part of the new

subgroup 6C tolerance.

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: February 6, 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. 180.555, amend the table in paragraph (a) as follows:

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a. Add alphabetically the entry for ``Pea and bean, dried shelled,

except soybean, subgroup 6C''; and

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b. Remove the entry for ``Pea, dry, seed''.

 The addition reads as follows:

Sec. 180.555 Trifloxystrobin; tolerances for residues.

 (a) \* \* \*

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 Parts per

 Commodity million

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Pea and bean, dried shelled, except soybean, subgroup 6C.... 0.06

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[FR Doc. 2020-04208 Filed 3-5-20; 8:45 am]

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