[Federal Register Volume 85, Number 156 (Wednesday, August 12, 2020)]

[Rules and Regulations]

[Pages 48651-48654]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2019-0232; FRL-10009-42]

Nitrapyrin; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

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SUMMARY: This regulation establishes tolerances for residues of

nitrapyrin in or on sugar beet molasses, sugar beet roots, sugar beet

tops, rapeseed seed, and the vegetable, tuberous and corm, crop

subgroup 1C. Dow AgroSciences LLC requested these tolerances under the

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

DATES: This regulation is effective August 12, 2020. Objections and

requests for hearings must be received on or before October 13, 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-2019-0232, 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

[[Page 48652]]

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

Printing 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-2019-0232 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

October 13, 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-2019-0232, 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 October 28, 2019 (84 FR 57685) (FRL-

10001-11), 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

8F8723) by Dow AgroSciences LLC, 9330 Zionsville Road, Indianapolis, IN

46268. The petition requested that 40 CFR part 180 be amended by

establishing tolerances for residues nitrapyrin in or on beet, sugar,

roots at 0.30 parts per million (ppm); beet, sugar, molasses at 0.70

ppm; beet, sugar, tops at 0.70 ppm; canola, seed at 0.30 ppm; canola,

meal at 0.80 ppm; potato, processed potato waste at 1.50 ppm; and

vegetable, tuberous and corm, subgroup at 0.60 ppm. That document

referenced a summary of the petition prepared by Dow AgroSciences, 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 is

establishing some tolerances at different levels than requested and in

some cases is establishing tolerances for different commodities than

requested. The reasons for these changes are explained in Unit IV.C.

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 nitrapyrin including exposure

resulting from the tolerances established by this action.

On August 27, 2019 EPA published in the Federal Register a final

rule establishing tolerances for residues of nitrapyrin in or on

several fruit and vegetable commodities. See 84 FR 44708 (FRL-9996-85).

That document contains a summary of the toxicological profile,

assumptions for dietary exposure assessment, cumulative risk, and the

safety factor for children, which, except for the cancer classification

of nitrapyrin, have not changed.

In the analysis supporting the August 27, 2019 rule, EPA had

concluded that nitrapyrin was appropriately classified as ``suggestive

evidence of carcinogenic potential'' (See the document ``Nitrapyrin.

Human Health Risk Assessment for New Uses in/on Vegetable, Bulb, Crop

Group 3-07; Vegetable Leafy, Crop Group 4-16; Vegetable, Brassica, Head

and Stem Crop Group 5-16; Fruit, Citrus, Crop Group 10-10; Fruit,

Citrus, Group 10-10, Dried Pulp; Fruit, Citrus, Group 10-

[[Page 48653]]

10, Oil; and Leaf Petiole Subgroup 22B'' dated July 16, 2019 in docket

ID EPA-HQ-OPP-2018-0095). The toxicological endpoints table noted that

the chronic RfD would be protective of any potential cancer risk. Since

that time, EPA has reassessed the carcinogenic potential of nitrapyrin

(May 8, 2018 document titled, ``Nitrapyrin: Sixth Report of the Cancer

Assessment Review Committee''). Based on information submitted by the

registrant, nitrapyrin is now classified as ``not likely to be

carcinogenic to humans at doses that do not result in CAR activation as

indicated by Cyp2b10 expression.'' Quantification of cancer risk using

a non-linear RfD approach adequately accounts for all chronic toxicity,

including carcinogenicity that could result from exposure to

nitrapyrin; therefore, a separate cancer dietary exposure and risk

assessment was not conducted.

A summary of the toxicological endpoints for nitrapyrin used for

human risk assessment can be found in the document titled ``Nitrapyrin.

Human Health Risk Assessment for New Uses in/on Canola, Tuberous and

Corm Vegetables (Crop Subgroup 1C), Sugar Beets, and Sorghum'' dated

May 1, 2020 in docket number EPA-HQ-OPP-2019-0232.

Further information about EPA's risk assessment and determination

of safety supporting the tolerances established in the August 27, 2019

Federal Register action can be found at [http://www.regulations.gov](http://www.regulations.gov/) in

the documents titled, ``Nitrapyrin. Human Health Risk Assessment for

New Uses in/on Vegetable, Bulb, Crop Group 3-07; Vegetable Leafy, Crop

Group 4-16; Vegetable, Brassica, Head and Stem Crop Group 5-16; Fruit,

Citrus, Crop Group 10-10; Fruit, Citrus, Group 10-10, Dried Pulp;

Fruit, Citrus, Group 10-10, Oil; and Leaf Petiole Subgroup 22B'' dated

July 16, 2019. The document can be found in docket ID EPA-HQ-OPP-2018-

0095.

The Agency conducted a revised risk assessment to incorporate

exposure to residues of nitrapyrin from use on canola, tuberous and

corm vegetables (crop subgroup 1C), and sugar beets. EPA's aggregate

exposure assessment incorporated this additional dietary exposure, as

well as exposure in drinking water, although the latter exposure is not

impacted by the new uses. Acute dietary risks are below the Agency's

level of concern: 10% of the aPAD for all infants less than one year

old, the most highly exposed population subgroup. Chronic dietary risks

are below the Agency's level of concern: 22% of the cPAD for children

1-2 years old, the most highly exposed population subgroup. There are

no residential uses for nitrapyrin, so there is no short- or

intermediate-term residential exposure to aggregate with the chronic

dietary exposures. Finally, as indicated previously in this document,

EPA does not expect any cancer risk below doses that do not result in

CAR activation as indicated by Cyp2b10 expression. Because the chronic

RfD is below those levels, precluding doses that would result in CAR

activation, EPA does not expect any cancer risk from aggregate exposure

to nitrapyrin.

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 nitrapyrin residues.

More detailed information on the subject action to establish a

tolerance in or on canola, tuberous and corm vegetables (crop subgroup

1C), and sugar beets can be found in the document titled, ``Nitrapyrin.

Human Health Risk Assessment for New Uses in/on Canola, Tuberous and

Corm Vegetables (Crop Subgroup 1C), Sugar Beets, and Sorghum,'' dated

May 1, 2020 by going to [http://www.regulations.gov](http://www.regulations.gov/). The referenced

document is available in the docket EPA-HQ-OPP-2019-0232.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology (gas chromatography with electron

capture detection) is available to enforce the tolerance expression.

Seven analytical methods are available in Volume II of the Pesticide

Analytical Manual (PAM II--Pesticide Reg. Sec. 180.350) for tolerance

enforcement for nitrapyrin and/or for metabolite 6-CPA.

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 any MRLs for residues of nitrapyrin.

C. Revisions to Petitioned-For Tolerances

EPA is establishing a tolerance on ``rapeseed, seed'' rather than

the requested tolerance on ``canola, seed'' to be consistent with the

terminology the Agency uses for that commodity. Also, although the

petitioner requested a separate tolerance for canola, meal, EPA has

determined that the tolerance established for rapeseed, seed will

adequately cover residues in canola, meal. Based on the highest average

field trial (HAFT) value from canola seed raw agricultural commodity

(RAC) field trials, including combined residues of nitrapyrin and 6-CPA

(0.151 ppm), and utilizing the processing factor (1.5X), the expected

residues in meal are lower than the tolerance on rapeseed, seed.

Therefore, the separate tolerance on canola meal is unnecessary.

Similarly, although the petitioner requested a tolerance on potato,

processed potato waste at 1.50 ppm, EPA has determined that the

tolerance established for tuberous and corm vegetables, subgroup 1C

will adequately cover residues in processed potato waste. Based on HAFT

(0.309 ppm) value from potato RAC and the median processing factor in

potato processed commodities (1.0x), the expected residues in processed

potato waste are lower than the tolerance for subgroup 1C. Therefore,

the tolerance for potato, potato processed waste is not needed.

For beet, sugar, molasses, EPA calculated tolerance value based on

the HAFT value from sugar beet root RAC for combined residues of

nitrapyrin and 6-CPA (0.123 ppm) and the processing factor (2.9X); the

result is expected residues lower than the tolerance requested for

sugar beet roots. Therefore, the tolerance is being established at 0.5

ppm rather than as requested at 0.70 ppm.

Lastly, several of the tolerance values have been corrected to be

consistent with the Agency's rounding class practice.

V. Conclusion

Therefore, tolerances are established for residues of nitrapyrin in

or on beet, sugar, molasses at 0.5 ppm; beet, sugar, roots at 0.3 ppm;

beet, sugar, tops at 0.7 ppm; rapeseed, seed at 0.3 ppm; and vegetable,

tuberous and corm, crop subgroup 1C at 0.6 ppm.

[[Page 48654]]

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 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: July 2, 2020.

Michael Goodis,

Director, Registration Division, Office of Pesticide Programs.

Therefore, for the reasons stated in the preamble, the EPA amends

40 CFR chapter I as follows:

PART 180--TOLERANCES AND EXEMPTIONS FOR PESTICIDE CHEMICAL RESIDUES

IN FOOD

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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. 180.350, amend paragraph (a) by adding to the table, in

alphabetical order, the commodities, ``Beet, sugar, molasses'', ``Beet,

sugar, roots'', ``Beet, sugar, tops'', ``Rapeseed, seed'', and

``Vegetable, tuberous and corm, crop subgroup 1C'' to read as follows:

Sec. 180.350 Nitrapyrin; tolerances for residues.

(a) \* \* \*

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Parts per

Commodity million

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\* \* \* \* \*

Beet, sugar, molasses....................................... 0.5

Beet, sugar, roots.......................................... 0.3

Beet, sugar, tops........................................... 0.7

\* \* \* \* \*

Rapeseed, seed.............................................. 0.3

\* \* \* \* \*

Vegetable, tuberous and corm, crop subgroup 1C.............. 0.6

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[FR Doc. 2020-16456 Filed 8-11-20; 8:45 am]

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