



BILLING CODE 6560-50-P

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.

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 [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. Objections and requests for hearings must be received on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*] 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> 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.

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 FFDCFA 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 [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. 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>. 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>. 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 10-10, 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> 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>. 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.

VI. Statutory and Executive Order Reviews

This action establishes tolerances under FFDCFA 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

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

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

2. In § 180.350, 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:

§ 180.350 Nitrapyrin; tolerances for residues.

(a) * * *

Commodity	Parts per million
****	***
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
****	***

* * * * *