E 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2021-0339; FRL-9298-02-OCSPP]

Pyridate; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of pyridate in or on lentil, dry, seed and rapeseed subgroup 20A. Belchim Crop Production US Corporation 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-2021-0339, is available online at *https://www.regulations.gov* or in-person 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 and the OPP Docket is (202) 566-1744. Please review the visitor instructions and additional information about the docket available at *https://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: Marietta Echeverria, Acting Director, Registration Division (7505T), Office of Pesticide Programs, Environmental Protection Agency,

1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; main telephone number: (202) 566-1030; 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 Office of the Federal Register's e-CFR site at *https://www.ecfr.gov/current/title-40.*

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-2021-0339 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-2021-0339, by one of the following methods:

• *Federal eRulemaking Portal*: *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/contacts.html.* 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 June 28, 2021 (86 FR 33922) (FRL-10025-08), 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 0F8885) by Belchim Crop Protection N.V./S.A., c/o Belchim Crop Protection US Corporation, 2751 Centreville Rd., Suite 100, Wilmington, DE 19808. The petition requested that 40 CFR 180.462 be amended to establish tolerances for residues of the herbicide pyridate calculated as the stoichiometric equivalent of pyridate, in or on the commodities lentils at 0.40 parts per million (ppm) and Rapeseed Subgroup (Crop Subgroup 20A) at 0.015 ppm. That document referenced a summary of the petitioned prepared by Belchim

Crop Protection, the registrant, which is available in the docket, *https://www.regulations.gov.* There were no comments received in response to the Notice of Filing.

Based upon review of the data supporting the petition and in accordance with its authority under FFDCA section 408(d)(4)(A)(i), EPA is establishing the tolerance for rapeseed crop subgroup 20A at a different level than petitioned-for and is revising the commodity definition. 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 in 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 pyridate including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with pyridate follows.

A. Toxicological Profile

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.

The toxicological database for pyridate is adequate for hazard characterization, toxicity endpoint selection, and Food Quality Protection Act (FQPA) Safety Factor (SF) consideration. The available toxicity database for pyridate indicates that the nervous system is the toxicological target in studies where pyridate was administered via gavage or capsules, with the dog and the rat showing similar levels of sensitivity once bodyweight scaling is considered. The neurotoxic effects were associated with the peak plasma concentrations, occurred within a few hours of treatment, and resolved in less than 24 hours of the bolus dose from gavage or capsule administration. The neurobehavioral effects do not appear to be accumulative or progressive since the effects in the subchronic dog study occurred at approximately the same dose where effects were seen in the chronic dog study and were generally resolved within 6 hours of treatment. No evidence of neurotoxicity was observed in the studies where pyridate was administered via the diet (feed) following subchronic or chronic dietary exposure. Effects observed following dietary (feed) exposure were generally limited to systemic toxicity, primarily reductions in bodyweight. Additionally, there were no effects seen at the limit dose in the dermal toxicity study.

There was no evidence of increased susceptibility to the fetus or offspring in the available developmental and reproduction toxicity studies. Developmental (missing and unossified sternebrae and decreased bodyweight in fetuses) and offspring effects (decreased bodyweights) were seen in the presence of maternal toxicity in rats. An increased incidence of abortions was also noted in the developmental toxicity study in rabbits at the highest dose tested.

Pyridate is classified as “Not Likely to be Carcinogenic to Humans.”

Specific information on the studies received and the nature of the adverse effects caused by pyridate 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

https://www.regulations.gov in the document titled "Pyridate. Human Health Risk Assessment for the Proposed New Section 3 Registration on Lentils, Rapeseed Subgroup 20A, Popcorn, and Seed Corn." (hereinafter referred to as "Pyridate Human Health Risk Assessment") on pages 25-27 in docket ID number EPA-HQ-OPP-2021-0339.

B. Toxicological Points of Departure/Levels of Concern

Once a pesticide's toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which no adverse effects are observed (the NOAEL) and the lowest dose at which adverse effects of concern are identified (the LOAEL). Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level - generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD) - and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/standard-operating-procedures-residential-pesticide.

A summary of the toxicological endpoints for pyridate used for human risk assessment can be found in the Pyridate Human Health Risk Assessment on pages 13-16.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses*. In evaluating dietary exposure to pyridate, EPA considered exposure under the petitioned-for tolerances as well as all existing pyridate tolerances in 40 CFR 180.462. EPA assessed dietary exposures from pyridate in food as follows:

i. *Acute exposure*. Quantitative acute dietary exposure and risk assessments are performed for a food-use pesticide, if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1-day or single exposure. Such effects were identified for pyridate.

In conducting the acute dietary exposure assessment, EPA used the 2005-2010 food consumption data from the U.S. Department of Agriculture's (USDA's) National Health and Nutrition Examination Survey, What We Eat in America (NHANES/WWEIA). The acute dietary exposure assessment is unrefined, assuming tolerance-level residues, 100% crop treated (100 PCT) for all commodities, and default processing factors.

ii. *Chronic exposure*. In conducting the chronic dietary exposure assessment EPA used the food consumption data from the USDA 2005-2010 food consumption data from the NHANES/WWEIA. The chronic dietary exposure assessment is unrefined, assuming tolerance-level residues, 100 PCT for all commodities, and default processing factors.

iii. *Cancer*. EPA has classified pyridate as "Not Likely to be Carcinogenic to Humans" as there was no evidence carcinogenicity in either of the rodent cancer studies; therefore, a cancer dietary assessment was not performed.

2. *Dietary exposure from drinking water*. The Agency used screening-level water exposure models in the dietary exposure analysis and risk assessment for pyridate in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of pyridate. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at *https://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/about-water-exposure-medels-used-pesticide.*

Based on the Pesticides in Water Calculator (PWC; version 1.52), the estimated drinking water concentrations (EDWCs) of pyridate are estimated to be 363 parts per billion (ppb) for acute dietary exposures and 256 ppb for chronic dietary exposures.

3. *From non-dietary exposure*. The term "residential exposure" is used in this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets). Pyridate is not registered for any specific use patterns that would result in residential exposure.

4. *Cumulative effects from substances with a common mechanism of toxicity*. Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider "available information" concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity."

Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding as to pyridate and any other substances and pyridate does not appear to produce a toxic metabolite produced by other substances. For the purposes of this action, therefore, EPA has not assumed that pyridate has a common mechanism of toxicity with other substances.

D. Safety Factor for Infants and Children

1. In general. 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.

2. Prenatal and postnatal sensitivity. There was no evidence of increased susceptibility to the fetus or offspring in the available developmental and reproduction toxicity studies. Developmental (missing and unossified sternebrae and decreased bodyweight in fetuses) and

offspring effects (decreased bodyweights) were seen in the presence of maternal toxicity in rats. An increased incidence of abortions was also noted in the developmental toxicity study in rabbits at the highest dose tested. Since these effects occurred in the presence of comparable or more severe maternal toxicity, they were not considered evidence of qualitative susceptibility. Furthermore, the selected points of departure are protective of these effects.

3. Conclusion. 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 for all exposure scenarios. That decision is based on the following findings:

i. The toxicology database for pyridate is complete and includes acceptable developmental and reproductive toxicity studies for evaluating sensitivity for infants and children.

ii. There are adverse neurotoxic effects observed in the database for pyridate both in the acute neurotoxicity (ACN) and in other studies, including the subchronic rat and chronic and subchronic dog, with effects such as emesis, ataxia, salivation, dyspnea, tremors, and prostration in dogs; and hypoactivity and excessive salivation in rats. However, these effects were only observed in studies where the test animals were exposed to a concentrated bolus of the chemical (gavage/capsule) and not in studies in which animals were exposed through the diet. These neurotoxic effects increased rapidly in incidence within 1-3 hours after dosing and gradually resolved over the next 8-12 hours and do not show progression in chronic studies. EPA concluded based upon a weight-of-evidence approach that the subchronic neurotoxicity study was not required for risk assessment at this time. Although there is evidence of neurotoxicity, concern is low since the selected endpoints for this chemical are protective of these effects.

iii. There was no evidence of increased quantitative or qualitative susceptibility in the developmental toxicity studies in rabbits or rats or the reproduction toxicity study in rats.

iv. There is no residual uncertainty in the exposure database. The dietary assessment is based on high-end assumptions such as modeled, high-end estimates of residues in drinking water, assuming 100 PCT and tolerance-level residues. In addition, there are no residential uses proposed for pyridate at this time. These assessments will not underestimate the exposure and risks posed by pyridate.

E. 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 water. Using the exposure estimates from dietary consumption of food and drinking water, EPA has concluded that acute exposure to pyridate from food and water will utilize 33% of the aPAD for all infants less than 1-year old, the most highly exposed population subgroup.

2. Chronic risk. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure of pyridate from food and water will utilize 18% of the cPAD for all infants less than 1-year old, the population group receiving the greatest exposure.

3. Short- and intermediate-term risks. Short- and intermediate-term exposure takes into account short- and intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). A short-term adverse effect and an intermediate-term adverse effect were identified; however, pyridate is not registered for any use patterns that would result in short- or intermediate-term residential exposure. Short- and

intermediate-term risk is assessed based on short- and intermediate-term residential exposure plus chronic dietary exposure. Because there is no short- or intermediate-term residential exposure and chronic dietary exposure has already been assessed under the appropriately protective cPAD (which is at least as protective as the POD used to assess short-term risk), no further assessment of short-term risk is necessary, and EPA relies on the chronic dietary risk assessment for evaluating short- and intermediate-term risk for pyridate**.**

4. Aggregate cancer risk for U.S. population. Based on the lack of evidence of carcinogenicity in two adequate rodent carcinogenicity studies, pyridate is not expected to pose a cancer risk to humans.

5. *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 pyridate residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology (high-performance liquid chromatography with ultraviolet detection (UV-HPLC)) 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).

Codex has not established an MRL for pyridate in/on lentils or rapeseed subgroup 20A.

C. Revisions to Petitioned-For Tolerances

For rapeseed subgroup 20A, the registrant proposed a tolerance of 0.015 ppm, which is less than the limit of quantitation (LOQ) of the enforcement method. Therefore, EPA is establishing a tolerance of 0.05 ppm for rapeseed subgroup 20A, which is the LOQ of the method employed in the crop field trials. EPA also adjusted the commodity definition for rapeseed subgroup 20A to use standard terminology. In addition, EPA dropped the trailing zero from the lentil tolerance value to be consistent with current Agency rounding practices.

V. Conclusion

Therefore, tolerances are established for residues of pyridate, in or on lentil, dry, seed at 0.4 ppm and rapeseed subgroup 20A at 0.05 ppm.

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). 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 19, 2022.

Marietta Echeverria,

Acting Director, Registration Division, Office of Pesticide Programs.

Therefore, for the reasons stated in the preamble, EPA is amending 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 §180.462, the table in paragraph (a) is amended by:

a. Adding a table heading; and

b. Adding the commodities "Lentil, dry, seed" and "Rapeseed subgroup 20A" to the table in alphabetical order.

The additions read as follows:

§ 180.462 Pyridate; tolerances for residues.

(a) * * *

Table 1 to Paragraph (a)

Commodity	Parts per million
* * * * * * *	
Lentil, dry, seed	0.4
* * * * * * *	
Rapeseed subgroup 20A	0.05
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