



## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 180

[EPA-HQ-OPP-2022-0257; FRL-12388-01-OCSP]

### Pyridate; Pesticide Tolerances

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes tolerances for residues of pyridate in or on Pea, field, forage; Pea, field, hay; Soybean, forage; Soybean, hay; Soybean, seed; and Vegetable, legume, pulse, pea, dried shelled, subgroup 6-22F. Belchim Crop Protection 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-2022-0257, is available at <https://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 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:** Charles Smith, Director, Registration

Division (7505P), 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 *Federal Register* Office'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(g), 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-2022-0257 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-2022-0257, 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/where-send-comments-epa-dockets>.

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 March 22, 2022 (87 FR 16133) (FRL-9410-11-OCSP), EPA issued a document pursuant to FFDCFA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 1F8978) by Belchim Crop Protection US Corporation, 2751 Centreville Road, Suite 100, Wilmington, Delaware 19808. The petition requested that 40 CFR part 180 be amended by establishing tolerances for residues of the herbicide pyridate in or on dry peas and soybeans at 0.05 parts per million (ppm). That document referenced a summary of the

petition prepared by Belchim Crop Protection US Corporation, the registrant, which is available in the docket at <https://www.regulations.gov>. Comments were received on the notice of filing. EPA's response to these comments is discussed in Unit IV.C.

Based upon review of the data supporting the petition, EPA has revised tolerance levels and corrected commodity definitions. The registrant proposed tolerances of dry pea vines, dry pea hay, dry pea seed (dried), soybean forage, soybean hay, and soybean seed (dried) at 0.05 ppm. The proposed dry pea seed (dried) was revised to vegetable, legume, pulse, pea, dried shelled, subgroup 6-22F. The proposed dry pea vines at 0.05 ppm were revised to pea, field, forage at 2 ppm. The proposed dry pea hay at 0.05 ppm was revised to 5 ppm. The proposed soybean forage at 0.05 was revised to soybean, forage at 0.4 ppm. The proposed soybean hay at 0.05 ppm was revised to soybean, hay at 0.8 ppm, and the proposed Soybean Seed (dried) was revised to Soybean, seed. The reason for these changes is explained in Unit IV.D.

In the *Federal Register* of October 26, 2023 (88 FR 73571) (FRL-10579-09-OCSP), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a revised pesticide petition (PP 1F8978) by Belchim Crop Protection US Corporation. The revised petition requested that 40 CFR part 180 be amended by establishing tolerances for residues of the herbicide pyridate in or on dry pea vines, dry pea hay, dry pea seed (dried), soybean forage, soybean hay, and soybean seed (dried) at 0.05 ppm. That document referenced a revised summary of the petition prepared by Belchim Crop Protection US Corporation, the registrant, which is available in the docket at <https://www.regulations.gov>. No comments were received on the revised 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 therein, 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.

In an effort to streamline its publications in the *Federal Register*, EPA is not reprinting sections that repeat what has been previously published in tolerance rulemakings for the same pesticide chemical. Where scientific information concerning a particular chemical remains unchanged, the content of those sections would not vary between tolerance rulemakings, and EPA considers referral back to those sections as sufficient to provide an explanation of the information EPA considered in making its safety determination for the new rulemaking.

In the *Federal Register* of May 25, 2022 (87 FR 31738) (FRL-9298-02), EPA published a final rule establishing tolerances for residues of pyridate in which EPA concluded, based on available information, that there is a reasonable certainty that no harm would result from aggregate exposure to pyridate. EPA is incorporating previously published sections from that rulemaking as described further in this rulemaking, as they have not changed.

*Toxicological profile.* For a discussion of the toxicological profile of pyridate, see Unit III.A. of the May 25, 2022, rulemaking.

*Toxicological points of departure/levels of concern.* For a summary of the toxicological points of departure/levels of concern for pyridate used for human health risk assessment, see

Unit III.B. of the May 25, 2022, rulemaking.

*Exposure assessment.* Much of the exposure assessment for pyridate remains unchanged from the discussion in Unit III.C. of the May 25, 2022, rulemaking, except as described in the following paragraphs.

*Dietary exposure from food and feed uses.* The exposure assessment has been updated to include the additional dietary exposure from the proposed new uses of pyridate on dry pea and soybean commodities using the same previous assumptions of tolerance-level residues and 100 percent crop treated (PCT) described in Unit III.C.1. of the May 25, 2022, rulemaking.

*Drinking water and non-occupational exposures.* Although drinking water and residential exposures are not impacted by the proposed new uses of pyridate on dry pea and soybean commodities, there are proposed new uses of pyridate for control of annual broadleaf weeds on residential turfgrass. In the *Federal Register* of April 26, 2022 (87 FR 24556; FRL-9408-03-OCSP), EPA issued a document pursuant to the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), providing notice of receipt and opportunity to comment on the application to register these new uses on turfgrass. EPA updated the estimated drinking water concentrations (EDWCs) of pyridate to evaluate potential drinking water exposure from use on residential turfgrass. Based on the Pesticides in Water Calculator (PWC; version 2.001), the EDWCs of pyridate are estimated to be 0.580 ppm for acute dietary exposures and 0.454 ppm for chronic dietary exposures.

EPA also assessed residential post-application exposure from contacting lawns and turf treated with pyridate using default assumptions in lieu of chemical-specific turf transfer residue data. The residential exposures used in the aggregate assessment are incidental oral exposures (hand-to-mouth, object-to-mouth, and soil ingestion) from post-application exposure to treated lawns and turf for children 1 to < 2 years old. Although dermal exposures are also expected, no dermal toxicological point of departure was selected.

*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.

*Safety factor for infants and children.* EPA continues to conclude that there are reliable data to support the reduction of the Food Quality Protection Act (FQPA) safety factor from 10X to 1X. See Unit III.D. of the May 25, 2022, rulemaking for a discussion of the Agency’s rationale for that determination.

*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 population adjusted dose (aPAD) and chronic population adjusted dose (cPAD). Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate points of departure to ensure that an adequate margin of exposure (MOE) exists. For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure.

The acute aggregate risk assessment considers exposures from food and drinking water only and is equivalent to the acute dietary risk estimates. Acute dietary risks are below the Agency’s level of concern: 53% of the aPAD for all infants less than 1 year old, the population group of concern. There are no registered or proposed uses of pyridate that result in long-term residential exposures. Therefore, the chronic aggregate risk assessment considers exposures from food and drinking water only. Chronic dietary risks are below the Agency’s level of concern:

31% of the cPAD for all infants less than 1 year old, the group with the highest exposure.

The short-term aggregate risk assessment considers dietary (food and drinking water) and residential exposures. No residential handler exposure is expected, and only post-application dermal and incidental oral exposures are expected from the proposed uses of pyridate in residential areas. Residential post-application inhalation exposures are not expected. Using the exposure assumptions described for short-term exposures, EPA has concluded that the combined short-term food, water, and residential exposures result in aggregate MOEs above 100. These MOEs are not of concern, as the level of concern for all scenarios assessed is an MOE less than 100. Intermediate-term residential exposure is not expected so no intermediate term aggregate assessment was conducted.

Pyridate is classified as “Not Likely to Be Carcinogenic to Humans.” Therefore, EPA does not expect pyridate exposures to pose an aggregate cancer risk.

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 pyridate residues. More detailed information on the subject action to establish tolerances in or on dry pea and soybean commodities can be found in the document titled “Pyridate. Human Health Risk Assessment for the Proposed New Section 3 Registration on Soybeans and Dry Peas.” available at <https://www.regulations.gov> in docket ID number EPA-HQ-OPP-2022-0257.

#### **IV. Other Considerations**

##### *A. Analytical Enforcement Methodology*

Adequate analytical 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](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). Codex 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. The Codex has not established MRLs for residues of pyridate in dry pea and soybean raw agricultural commodities.

### *C. Response to Comments*

EPA received one comment in response to the notice of filing. The commenter opposed any tolerances for pyridate and expressed a general opposition to the use of “toxic chemicals” on food. Although the Agency recognizes that some individuals believe that pesticide chemicals should not be permitted on food, the existing legal framework provided by section 408 of the FFDCA authorizes EPA to establish tolerances when it determines the tolerances are safe. Upon consideration of the validity, completeness, and reliability of the available data as well as other factors the FFDCA requires EPA to consider, EPA has determined that the pyridate tolerances are safe. The commenter has provided no information indicating that a safety determination cannot be supported.

### *D. Revisions to Petitioned-For Tolerances*

For dry pea vines and hay and soybean forage and hay, the petitioner proposed a tolerance level equal to the LOQ of the enforcement method, which is not appropriate as quantifiable residues were found in these commodities. The recommended tolerance level for dry

pea vines and hay and soybean forage and hay was determined through use of the Organization for Economic Co-operation and Development (OECD) calculation procedures. Commodity definitions were updated to EPA standards.

## **V. Conclusion**

Therefore, tolerances are established for residues of pyridate, in or on Vegetable, legume, pulse, pea, dried shelled, subgroup 6-22F at 0.05 ppm; Pea, field, forage at 2.0 ppm; Pea, field, hay at 5.0 ppm; Soybean, forage at 0.4 ppm; Soybean, hay at 0.8 ppm; and Soybean, seed at 0.5 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, titled “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, titled “Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use” (66 FR 28355, May 22, 2001) or Executive Order 13045, titled “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.*).

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, titled “Federalism” (64 FR 43255, August 10, 1999) and Executive Order 13175, titled “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: March 14, 2025.

**Charles Smith,**

*Director, Registration Division, Office of Pesticide Programs.*

Therefore, for the reasons stated in the preamble, 40 CFR chapter I is amended 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. Amend § 180.462, by adding in alphabetical order the entries “Pea, field, forage”, “Pea, field, hay”, “Soybean, forage”, “Soybean, hay”, “Soybean, seed”, and “Vegetable, legume, pulse, pea, dried shelled, subgroup 6-22F” to table 1 to paragraph (a) to read as follows:

**§ 180.462 Pyridate; tolerances for residues.**

(a) \* \* \*

**Table 1 to Paragraph (a)**

<b>Commodity</b>	<b>Parts per million</b>
* * * * *	
Pea, field, forage	2
Pea, field, hay	5
* * * * *	
Soybean, forage	0.4
Soybean, hay	0.8
Soybean, seed	0.05
* * * * *	
Vegetable, legume, pulse, pea, dried shelled, subgroup 6-22F	0.05

\* \* \* \* \*