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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2017-0476; FRL-9991-75]

Bentazon; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a tolerance for residues of bentazon in or on pea, dry, seed. Interregional Project Number 4 (IR-4) requested this tolerance 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-2017-0476, 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 review the visitor instructions and additional information about the docket available at <http://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT: Michael Goodis, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; main telephone number: (703) 305-7090; email address: RDFRNotices@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

B. How Can I Get Electronic Access to Other Related Information?

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Publishing Office's e-CFR site at

http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl.

C. How Can I File an Objection or Hearing Request?

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2017-0476 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-2017-0476, 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 December 15, 2017 (82 FR 59604) (FRL-9970-50), 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 7E8597) by IR-4, Rutgers, The State University of New Jersey, 500 College Road East, Suite 201 W, Princeton, NJ 08540. The petition requested that 40 CFR 180.355 be amended by increasing the existing tolerance for residues of the herbicide bentazon, (3-isopropyl-1*H*-2,1,3-benzothiadiazin-4(3*H*)-one-2,2-dioxide) and its 6- and 8-hydroxy metabolites, in or on Pea, dry, seed to 3.0 parts per million (ppm). That document referenced a summary of the petition prepared by BASF Corporation, the registrant, which is now available in the docket, <http://www.regulations.gov>. There were no comments received in response to the notice of filing.

III. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of FFDCFA 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 FFDCFA 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 FFDCFA 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 bentazon including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with bentazon follows.

A. Toxicological Profile

EPA has evaluated the available toxicity database 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.

Bentazon elicits low acute lethality by the oral, inhalation, and dermal routes of exposure. It is moderately irritating to the eye, slightly irritating to the skin and is also a dermal sensitizer. In a 21-day dermal toxicity study of bentazon, no effects were observed up to 1,000 mg/kg/day.

In the acute neurotoxicity study, a clear NOAEL was established for the effect observed in decreased motor activity at the mid- and high-dose groups in males on day 0. There were no effects in the subchronic neurotoxicity study, and no evidence of neurotoxicity observed in the rest of the toxicology database.

In subchronic studies in rats and dogs and in chronic studies in all species, the most toxicologically significant effects were changes in hematological/coagulation parameters following oral administration of bentazon. In rats, subchronic oral exposure caused increased thromboplastin and prothrombin times (PT). In dogs, hemoglobin, hematocrit, and erythrocyte counts were significantly reduced in animals at both 6 weeks and at term. PT and reticulocytes

were also elevated.

The effects in the chronic studies in rats, mice and dogs were similar to those in subchronic studies. In a chronic/oncogenicity study in mice, PT were elevated. In addition, the incidence of hemorrhage in liver and heart was increased. In a chronic/oncogenicity study in rats, partial thromboplastin times (PTT) were elevated. In a one-year feeding study in dogs, at the highest dose tested, there were clinical signs (emaciation, dehydration, bloody stool, pale mucous membranes, moderated activity) and a slight to severe anemia (decreased hemoglobin, hematocrit, and erythrocyte count, decreased reticulocytes, platelets, leukocytes, PTT, and abnormal red cell morphology) during the first 13 weeks.

In the rat developmental toxicity study, maternal effects consisted of increased post-implantation loss and fetal resorptions, and developmental effects consisted of skeletal variations and reduced fetal weights. In the rabbit developmental toxicity study, at the highest dose tested, maternal effects consisted of partial abortions with resorptions, and developmental effects consisted of an increased incidence of no living fetuses. In the two-generation reproductive toxicity study in rats, there was an increased quantitative offspring susceptibility. Offspring toxicity manifested as reduced absolute pup weights during lactation at a dose lower than where parental systemic toxicity was observed. The sole parental effect was an increased incidence of kidney mineralization and liver microgranuloma. In rats and rabbits, fetal effects occurred at doses that caused maternal toxicity.

Bentazon was found not to be mutagenic. It is classified as a Group "E" chemical (evidence of non-carcinogenicity for humans) based upon lack of evidence of carcinogenicity in rats and mice.

Specific information on the studies received and the nature of the adverse effects caused by bentazon 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 <http://www.regulations.gov> in document **SUBJECT: Sodium Bentazon – Preliminary Human Health Risk Assessment for Registration Review** at page 32 in docket ID number EPA-HQ-OPP-2017-0476.

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 <http://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/assessing-human-health-risk-pesticides>.

A summary of the toxicological endpoints for bentazon used for human risk assessment is

shown in the Table of this unit.

Table - Summary of Toxicological Doses and Endpoints for bentazon for Use in Human Health Risk Assessment

Exposure/Scenario	Point of Departure and Uncertainty/Safety Factors	RfD, PAD, LOC for Risk Assessment	Study and Toxicological Effects
Acute dietary (General population, including infants and children)	NOAEL = 50 mg/kg/day UF _A = 10x UF _H = 10x FQPA SF = 1x	Acute RfD = 0.5 mg/kg/day aPAD = 0.05 mg/kg/day	Acute neurotoxicity-Rat LOAEL = 150 mg/kg/day based on decreased motor activity in males on study day 0.
Chronic dietary (All populations)	NOAEL = 15 mg/kg/day UF _A = 10x UF _H = 10x FQPA SF = 1x	Chronic RfD = 0.15 mg/kg/day cPAD = 0.15 mg/kg/day	Reproduction and fertility effects - Rat Offspring LOAEL = 62 mg/kg/day based on decreased absolute pup body weights during lactation.
Incidental oral short- (1-30 days) and Intermediate – term (1-6 months)	NOAEL = 15 mg/kg/day UF _A = 10X UF _H = 10X FQPA SF = 1X	Residential LOC for MOE = 100	Reproduction and fertility effects - Rat Offspring LOAEL = 62 mg/kg/day based on decreased absolute pup body weights during lactation.
Inhalation short- (1-30 days) and Intermediate-term (1-6 months)	NOAEL = 15 mg/kg/day UF _A = 10x UF _H = 10x FQPA SF = 1x	Residential LOC for MOE = 100	Reproduction and fertility effects - Rat Offspring LOAEL = 62 mg/kg/day based on decreased absolute pup body weights during lactation.
Cancer (Oral, dermal, inhalation)	Bentazon is classified as a Group “E” chemical (evidence of non-carcinogenicity for humans) based upon lack of evidence of carcinogenicity in rats and mice		

FQPA SF = Food Quality Protection Act Safety Factor. LOAEL = lowest-observed-adverse-effect-level. LOC = level of concern. mg/kg/day = milligram/kilogram/day. MOE = margin of exposure. NOAEL = no-observed-adverse-effect-level. PAD = population adjusted dose (a = acute, c = chronic). RfD = reference dose. UF = uncertainty factor. UF_A = extrapolation from animal to human (interspecies). UF_{DB} = to account for the absence of data or other data

deficiency. UF_H = potential variation in sensitivity among members of the human population (intraspecies). UF_L = use of a LOAEL to extrapolate a NOAEL. UF_S = use of a short-term study for long-term risk assessment.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to bentazon, EPA considered exposure under the petitioned-for tolerances as well as all existing bentazon tolerances in 40 CFR 180.355. EPA assessed dietary exposures from bentazon 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 bentazon. In estimating acute dietary exposure, EPA used 2003-2008 food consumption information from the United States Department of Agriculture (USDA) National Health and Nutrition Survey/What We Eat in America (NHANES/WWEIA). The acute dietary (food and drinking water) exposure assessment was conducted using the Dietary Exposure Evaluation Model software with the Food Commodity Intake Database (DEEM-FCID), Version 3.16. As to residue levels in food, EPA assumed 100 percent crop treated (PCT) and tolerance-level residues for all existing and proposed commodities.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the 2003-2008 food consumption information from the USDA NHANES/WWEIA. The chronic dietary (food and drinking water) exposure assessment was conducted using DEEM-FCID, Version 3.16. As to residue levels in food, EPA assumed 100 PCT and tolerance-level residues for all existing and proposed commodities.

iii. *Cancer*. Based on the data summarized in Unit III.A., EPA has concluded that bentazon does not pose a cancer risk to humans. Therefore, a dietary exposure assessment for the purpose of assessing cancer risk is unnecessary.

iv. *Anticipated residue and percent crop treated (PCT) information*. EPA did not use anticipated residue or PCT information in the dietary assessment for bentazon. Tolerance level residues and 100 PCT were assumed for all food commodities.

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

Based on the Tier 1 Rice Model and application rate of two applications of 1.1 pounds (lbs) active ingredient (ai) per acre for a total application of 2.2 lbs ai/acre/year and a soil adsorption coefficient of 0.898, the estimated drinking water concentrations (EDWCs) of bentazon for acute and chronic exposures are estimated to be 2,112 parts per billion (ppb) for surface water which represents “worst case”. The Agency believes all of the other uses of bentazon would produce EDWCs lower than this conservative value for both surface and groundwater because the Tier 1 Rice Model does not consider degradation in the rice paddy and EDWCs will not be adjusted by the percent crop adjustment (PCA) factors.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For acute dietary risk assessment, the water concentration value of 2,112 ppb

was used to assess the contribution to drinking water. For chronic dietary risk assessment, the water concentration of value 2,112 ppb was used to assess the contribution to drinking water.

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).

Bentazon is currently registered for the following uses that could result in residential exposures: turf and ornamentals. EPA developed a quantitative exposure assessment for adult residential handlers and post-application exposure to children, based on the following scenarios.

For adult residential handler exposure estimates, these three scenarios were assessed: (1) mixing/loading/applying liquids to turf and gardens/trees with manually-pressurized handwand; (2) mixing/loading/applying liquids to turf and gardens/trees with hose-end sprayer; and (3) mixing/loading/applying liquids turf and gardens/trees with backpack.

Since there is no dermal hazard, a quantitative residential handler dermal assessment was not conducted. The inhalation exposure risk estimates for residential handlers at baseline for all scenarios resulted in all MOEs $\geq 75,000$. EPA’s level of concern for bentazon is an MOE < 100 .

The quantitative exposure assessment for residential post-application exposures, i.e., hand-to-mouth; object to mouth; and short- and intermediate-term incidental soil ingestion, is based on the scenario of physical activities on turf for children 1 to < 2 years old (incidental oral).

The lifestages selected for each post-application scenario are based on an analysis provided in EPA’s 2012 Residential Standard Operating Procedures (SOPs). While not the only lifestage potentially exposed for these post-application scenarios, the lifestage that is included in the quantitative assessment is health protective for the exposures estimates for any other

potentially exposed lifestage. All risk estimates for post-application exposure resulted in MOEs $\geq 1,000$ for children.

Further information regarding EPA standard assumptions and generic inputs for residential exposures may be found at <http://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/standard-operating-procedures-residential-pesticide>.

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.”

EPA has not found bentazon to share a common mechanism of toxicity with any other substances, and bentazon does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that bentazon does not have a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's website at <http://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/cumulative-assessment-risk-pesticides>.

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.* In the rat developmental toxicity study, skeletal variations and reduced fetal weights were observed. In the two-generation reproductive toxicity study in rats, there was evidence of increased quantitative offspring susceptibility based on low pup weights. In the rabbit developmental toxicity study, developmental effects resulted in an increased incidence of no living fetuses at the highest dose tested. Offspring toxicity manifested as reduced absolute pup weights during lactation at a dose lower than where parental systemic toxicity was observed. In rats and rabbits, fetal effects occurred at doses that caused maternal toxicity.

3. *Conclusion.* EPA has concluded that reliable data show the safety of infants and children would be adequately protected if the FQPA SF were reduced to 1X. That decision is based on the following findings:

- i. The available toxicity database for bentazon is complete for FQPA evaluation. Developmental toxicity studies in rats and rabbits, a 2-generation reproduction study in rats, and neurotoxicity studies in rats are available for FQPA consideration.
- ii. There is no indication that bentazon should be classified as a neurotoxic chemical. The acute neurotoxicity study established a clear NOAEL for the observed effect (decreased motor activity). However, no evidence of neurotoxicity was observed in the remaining toxicology database, including the subchronic neurotoxicity study. There is no need for a developmental neurotoxicity study or additional UFs to account for neurotoxicity.

iii. There is evidence of increased quantitative offspring susceptibility. However, the concern is low because of (1) a clear NOAEL is established in the offspring; (2) the dose-response for these effects are well defined and characterized; and (3) endpoints selected for risk assessment are protective of the observed offspring and developmental effects. There are no residual uncertainties for pre- and post-natal toxicity.

iv. There are no residual uncertainties identified in the exposure databases. The dietary food exposure assessments were performed based on 100 PCT and tolerance-level residues. The residential exposure assessment is considered health-protective. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to bentazon in drinking water. EPA used similarly conservative assumptions to assess post-application exposure of children as well as incidental oral exposure. These assessments will not underestimate the exposure and risks posed by bentazon.

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.* Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food and water to bentazon will occupy 73% of the aPAD for all infants less than one year old, the population group receiving the greatest exposure.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to bentazon from food and water will utilize 78% of the cPAD for all infants less than one year old, the population group receiving the greatest exposure. None of the residential exposure scenarios described in Unit III.C.3 result in long-term exposure. Therefore, the chronic risk aggregate risk assessment is equivalent to the chronic dietary risk assessment.

3. *Short- and Intermediate-term risk.* Short- and intermediate-term aggregate exposure takes into account short- and intermediate-term aggregate residential exposure plus chronic exposure to food and water (considered to be a background exposure level).

Bentazon is currently registered for uses on turf and ornamentals that could result in short-term residential exposures only, as intermediate-term residential exposures are not expected from registered uses. Therefore, EPA determined that it is appropriate to aggregate chronic exposure through food and water with short-term residential exposures to bentazon.

For short-term exposures, incidental oral and inhalation exposure risk assessments are appropriate to aggregate since the PODs for these routes are based on the same study/effects. The short-term incidental oral and inhalation exposures are combined (where appropriate) with chronic dietary (food and water) exposure for determination of aggregate short-term exposures.

Adults are potentially exposed to bentazon through dermal, inhalation, and dietary (food and drinking water) routes. However, dermal hazard was not identified, so dermal risk estimates were not assessed and are not included in the aggregate. Adult handler inhalation exposures have been aggregated with dietary (food and water) exposures for the short-term duration. The backpack scenario for mixing and loading liquids is the exposure scenario with the greatest exposure; therefore, the exposure estimates for this scenario are protective of other exposure

scenarios.

For young children, due primarily to their hand-to-mouth activities, short-term oral (non-dietary) exposures are expected along with dermal and dietary (food and drinking water) exposures. Only the incidental oral exposures have been aggregated with dietary exposures since a dermal hazard was not identified. The non-dietary residential exposures for children 1-2 years old are included in the aggregate assessment and are considered health protective for exposures and risk estimates for other potentially exposed lifestages.

The short-term aggregate risk estimates for children 1-2 years old and adults are aggregate MOEs of 180 and 330, respectively, and therefore, not of concern to EPA.

4. *Aggregate cancer risk for U.S. population.* Based on the lack of evidence of carcinogenicity in two adequate rodent carcinogenicity studies, bentazon 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 bentazon residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methods are available for the determination of residues of bentazon and its 6- and 8-hydroxy metabolites in/on plant commodities. The Pesticide Analytical Method Volume II (PAM II) lists Method II, a gas liquid chromatography (GLC) method with flame photometric detection for the determination of bentazon and its hydroxy metabolites in/on corn, rice, and soybeans; the limit of detection (LOD) for each compound is 0.05 ppm. Method III, modified from Method II, is available for the determination of bentazon

and its hydroxy metabolites in/on peanuts and seed and pod vegetables with a LOD of 0.05 ppm for each compound. A validated analytical method for enforcement of the residue definition is also available, with a combined limit of quantitation (LOQ) of 0.03 ppm in high water content, high oil content, acidic, and dry commodities

(<http://www.efsa.europa.eu/en/efsajournal/doc/2822.pdf>).

The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755-5350; telephone number: (410) 305-2905; email address: *residuemethods@epa.gov*.

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCa section 408(b)(4). The Codex Alimentarius is a joint United Nations Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCa section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

The current U.S. tolerance of 1.0 ppm for sodium bentazon on pea, dry, seed is harmonized with the current Codex MRL, including having identical residue expressions. However, in 2018, the Joint FAO/WHO Meeting on Pesticide Residues (JMPR) recommended that Codex revise the tolerance expression for sodium bentazon to include only the parent

chemical and to decrease the MRL for pea, dry, seed to 0.5 ppm. These changes are expected to be finalized during 2019. Since the metabolite residues included in the U.S. tolerance expression are the major residues in some commodities, EPA concluded that it is not appropriate to eliminate these compounds from the U.S. tolerance expression to harmonize with Codex. Because the new dry pea data resulted in residues greater than the current tolerance, EPA is increasing the pea, dry, seed tolerance from 1 ppm to 3 ppm. The new tolerance level and tolerance expression are harmonized with Canada.

V. Conclusion

Therefore, tolerances are established for residues of bentazon, including its metabolites and degradates, in or on Pea, dry, seed at 3 ppm.

In addition to establishing the requested tolerance, EPA is revising the tolerance expression to clarify (1) that, as provided in FFDCA section 408(a)(3), the tolerance covers metabolites and degradates of bentazon not specifically mentioned; and (2) that compliance with the specified tolerance levels is to be determined by measuring only the specific compounds mentioned in the tolerance expression. EPA has determined that it is reasonable to make this change final without prior proposal and opportunity for comment, because public comment is not necessary, in that the change has no substantive effect on the tolerance, but rather is merely intended to clarify the existing tolerance expression.

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 FFDCFA section 408(d), such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), do not apply.

This action directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCFA 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: April 24, 2019.

Michael Goodis,

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180--[AMENDED]

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

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

2. In § 180.355(a)(1):

a. Revise the introductory text.

b. Revise the entry for “Pea, dry, seed” in the table.

The revisions read as follows:

§ 180.355 Bentazon; tolerances for residues.

(a) *General.* (1) Tolerances are established for residues of bentazon, including its metabolites and degradates, in or on the commodities in the table below. Compliance with the tolerance levels specified below is to be determined by measuring for only the sum of bentazon (3-(1-methylethyl)-1*H*-2,1,3-benzothiadiazin-4(3*H*)-one 2,2-dioxide), 6-hydroxy-3-isopropyl-1*H*-2,1,3-benzothiadiazin-4(3*H*)-one 2,2-dioxide, and 8-hydroxy-3-isopropyl-1*H*-2,1,3-benzothiadiazin-4(3*H*)-one 2,2-dioxide calculated as the stoichiometric equivalent of bentazon.

Commodity	Parts per million
* * *	* * *
Pea, dry, seed	3
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