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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2018-0047; FRL-10000-79]

Isotianil; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a tolerance for residues of isotianil in or on banana. Bayer CropScience 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-2018-0047, 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 L. Goodis, P.E., 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*. To access the OCSPP test guidelines referenced in this document electronically, please go to *http://www.epa.gov/ocspp* and select "Test Methods and Guidelines."

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-2018-0047 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-2018-0047, 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 April 11, 2018 (83 FR 15528) (FRL-9975-57), 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 7E8656) by Bayer CropScience, 2 T.W. Alexander Drive, Research Triangle Park, NC 27709. The petition requested that 40 CFR part 180 be amended by establishing a tolerance for residues of the fungicide isotianil in or on banana at 0.01 parts per million (ppm). That document referenced a summary of the petition prepared by Bayer CropScience, 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 has recommended the tolerance be set at 0.02 ppm in or on banana. The reason for this change is 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 isotianil including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with isotianil 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.

Subchronic and chronic studies indicate that the liver is the primary target organ for isotianil in all species except for rats, in which the primary target organ for isotianil was the forestomach. Liver effects include organ weight increases, histopathology alterations, and associated enzyme and cholesterol increases. Hyperplasia was observed in the forestomach of rats in longer duration studies. Kidney effects, seen in dogs and rats, included chronic nephropathy and organ weight increases with longer exposure durations. Altered hematological profiles and spleen weight changes were also seen near the limit dose in longer duration studies of dogs and rats. Skin effects/hair loss were seen at high doses, but either occurred above the lowest-observed-adverse-effect-level (LOAEL) or were considered not adverse. Lung bronchiolization of the alveolar wall was observed in the longer duration dietary rat studies.

No evidence of neurotoxicity was observed in the isotianil guideline studies. The

database does not include any guideline neurotoxicity studies but limited functional observational battery and motor activity-related measurements were incorporated in the design of the available subchronic and chronic rat and dog guideline studies. No signs of neurotoxicity were noted at any dose in the database.

Evidence of quantitative susceptibility was observed in the developmental rabbit and two-generation rat reproductive toxicity studies. The 2-generation reproductive toxicity study in rats showed no parental or reproductive effects up to the highest dose tested; however, both generations of offspring exhibited decreased body weight in both sexes. Decreased fetal weights were observed in the absence of maternal toxicity in the developmental rabbit study. The immunotoxicity study was waived based on the available hazard and exposure data.

There was a slight increase in liver tumors in male mice at the highest dose tested, but the rat carcinogenicity study did not show an increased incidence of tumors in either sex. Studies showed no evidence of mutagenicity or genotoxicity. Therefore, isotianil is classified as "not likely to be carcinogenic to humans."

Additional studies were available for the select metabolites of isotianil, DCIT-acid and anthranilonitrile. In a subchronic rat oral toxicity study, DCIT-acid showed no evidence of toxic effects up to 349 mg/kg and DCIT-acid was not mutagenic with or without metabolic activation. A developmental study with DCIT-acid noted toxicity in both the maternal (mortality, clinical signs) and fetal (decreased fetal weight) groups at 250 mg/kg, with a no-observed-adverse-effect-level (NOAEL) of 50 mg/kg. Anthranilonitrile was not mutagenic with or without metabolic activation.

Specific information on the studies received and the nature of the adverse effects caused by isotianil as well as the NOAEL and the LOAEL from the toxicity studies can be found at

http://www.regulations.gov in document "Isotianil. Human Health Risk Assessment of the Proposed Tolerance for Residues on Imported Bananas without a U.S. Registration" on pages 21-25 in docket ID number EPA-HQ-OPP-2018-0047.

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 the reference value 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 endpoint for isotianil used for human risk assessment is shown in Table 1 of this unit.

Table 1. -- Summary of Toxicological Dose and Endpoint for Isotianil for Use in Human Health Risk Assessment

Exposure/Scenario	Point of Departure and Uncertainty/Safety Factors	PAD for Risk Assessment	Study and Toxicological Effects
Acute dietary (General population, including females 13 to 49 years of age)	An appropriate endpoint was not identified for acute exposure.		
Chronic dietary (All populations)	NOAEL= 27 mg/kg/day UF_A = 10x UF_H = 10x FQPA SF = 1x	cPAD = 0.27 mg/kg/day	Chronic Dog LOAEL = 107/110 (M/F) mg/kg/day based on clinical chemistry, hematology, liver weight and histopathology, spleen weight and appearance, increased hematopoiesis, and kidney weight and histopathology
Cancer (Oral, dermal, inhalation)	Classification: "Not Likely to be Carcinogenic to Humans."		

FQPA SF = Food Quality Protection Act Safety Factor. LOAEL = lowest-observed-adverse-effect-level. mg/kg/day = milligram/kilogram/day. NOAEL = no-observed-adverse-effect-level. PAD = population adjusted dose (c = chronic). UF = uncertainty factor. UF_A = extrapolation from animal to human (interspecies). UF_H = potential variation in sensitivity among members of the human population (intraspecies).

C. Exposure Assessment

1. *Dietary exposure from food and feed uses*. In evaluating dietary exposure to isotianil, EPA considered exposure under the petitioned-for tolerance. EPA assessed the dietary exposure to isotianil 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.

No such effects were identified in the toxicological studies for isotianil; therefore, a quantitative acute dietary exposure assessment was unnecessary.

ii. *Chronic exposure*. In conducting the chronic dietary exposure assessment, EPA used the Dietary Exposure Evaluation Model software with the Food Commodity Intake Database (DEEM-FCID) Version 3.16, which uses 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) from 2003 through 2008. As to residue levels in food, EPA used the tolerance value for parent isotianil (0.02 ppm) plus the maximum observed residue value of the DCIT-acid metabolite from the magnitude of the residue study. The maximum DCIT-acid residue observed in the magnitude of the residue study was <0.010 ppm, so the total isotianil residue estimate used in the chronic assessment was 0.030 ppm. It is EPA's typical practice to include plantains in dietary assessments that include bananas, so EPA used the banana residue data to estimate a value for residues of isotianil in/on plantains. The chronic assessment made use of EPA's 2018 default processing factor for dried bananas and dried plantains (processing factor of 4.8x). HED assumed 100% crop treated (PCT) for all commodities in the chronic assessment.

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

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

2. *Dietary exposure from drinking water*. Isotianil is not registered for use in the U.S. Therefore, residues are not expected in groundwater or surface water sources of drinking water, and no exposure to isotianil through drinking water is anticipated.

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).

Isotianil is not currently registered for any uses that could result in residential exposures.

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 isotianil to share a common mechanism of toxicity with any other substances, and isotianil does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that isotianil 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://www.epa.gov/pesticides/cumulative*.

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 safety factor when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity*. Quantitative susceptibility was observed in the 2-generation rat reproductive toxicity study in rats and in the developmental rabbit study. In the rat reproduction study, decreased pup body weights were observed in the absence of parental toxicity. The developmental rabbit study noted decreased fetal weights in the absence of maternal effects at the highest dose tested (1,000 mg/kg/day). Although susceptibility was observed, clear NOAELs were observed and the doses selected for risk assessment are protective of the observed susceptibility; therefore, there are no residual uncertainties with respect to pre- or postnatal toxicity.

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. That decision is based on the following findings:

i. The toxicity database for isotianil is complete.

ii. There is no indication that isotianil is a neurotoxic chemical and there is no need for a developmental neurotoxicity study or additional UFs to account for neurotoxicity.

iii. There was evidence of quantitative susceptibility in the database, observed in the rabbit developmental toxicity study and the rat reproductive toxicity study; however, the degree of concern is low because clear NOAELs were identified, and the endpoint selected for risk assessment is protective of the observed susceptibility.

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. These assessments will not underestimate the exposure and risks posed by isotianil.

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.

There are no residential uses for isotianil, and therefore aggregate exposure and risk estimates are equivalent to dietary exposure and risk estimates, which are not of concern.

1. *Acute risk*. An acute aggregate risk assessment takes into account acute exposure estimates from dietary consumption of food and drinking water. No adverse effect resulting from a single oral exposure was identified and no acute dietary endpoint was selected. Therefore, isotianil is not expected to pose an acute risk.

2. *Chronic risk*. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to isotianil from food is not of concern for the general U.S. population and all population subgroups. The population subgroup that received the greatest exposure estimate was the children 1to 2 years old subgroup, which utilized <1% of the cPAD. There are no residential uses for isotianil, so aggregate risk is equivalent to dietary risk, and is not of concern.

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

4. *Determination of safety*. Based on this risk assessment, 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 isotianil residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology (Method 01390, a high-performance liquid chromatography with tandem mass spectrometry (HPLC-MS/MS method) is adequate to measure residues of isotianil in/on plant matrices. Method 01390 has a limit of quantification (LOQ) of 0.01 ppm for isotianil.

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 Codex has not established an MRL for isotianil.

C. Revisions to Petitioned-For Tolerances

The petitioner's requested tolerance of 0.01 ppm for residues of isotianil in/on banana is based on magnitude of the residue data collected for bagged bananas. EPA standard practice is to use unbagged banana residue data for tolerance establishment. Based on magnitude of the residue data collected for unbagged bananas and the Organization for Economic Development and Cooperation (OECD) tolerance calculation procedure, EPA is establishing a tolerance of 0.02 ppm for residues of isotianil in or on banana.

V. Conclusion

Therefore, tolerances are established for residues of isotianil in or on banana at 0.02 ppm.

VI. Statutory and Executive Order Reviews

This action establishes a tolerance under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled "Regulatory Planning and Review" (58 FR 51735, October 4, 1993). Because this action has been exempted from review under Executive Order 12866, this action is not subject to Executive Order 13211, entitled "Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use" (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled "Protection of Children from Environmental Health Risks and Safety Risks" (62 FR 19885, April 23, 1997), nor is it considered a regulatory action under Executive Order 13771, entitled "Reducing Regulations and Controlling Regulatory Costs" (82 FR 9339, February 3, 2017). This action does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq*.), nor does it require any special considerations under Executive Order 12898, entitled "Federal Actions to Address Environmental Justice in Minority Populations and Low-

Income Populations" (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the 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 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: October 10, 2019.

Daniel Rosenblatt,

Acting 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. Add § 180.708 to subpart C to read as follows:

§ 180.708 Isotianil; tolerances for residues.

(a) *General*. Tolerances are established for residues of isotianil, including its metabolites and degradates, in or on the commodities in the table below. Compliance with the tolerance level specified in the table in this paragraph (a) is to be determined by measuring only isotianil (3,4-dichloro-N-(2-cyanophenyl)-5-isothiazolecarboxamide) in or on the commodity.

Commodity	Parts per million
Banana[1]	0.02

[1]There are no US registrations for bananas as of [*insert date of publication in the* **Federal Register**].

(b) [Reserved]

[FR Doc. 2019-23385 Filed: 10/31/2019 8:45 am; Publication Date: 11/1/2019]