The authority citation for part 180 Pesticide Programs.

1. The authority citation for part 180.

2. In §180.632, amend the table in paragraph (a) as follows:

<table>
<thead>
<tr>
<th>Commodity</th>
<th>Parts per million</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hop, dried cones</td>
<td>30.0</td>
</tr>
<tr>
<td>Pineapple</td>
<td>0.20</td>
</tr>
<tr>
<td>Nuts, Tree, Group 14–12</td>
<td>0.02</td>
</tr>
<tr>
<td>Tea, dried</td>
<td>9.0</td>
</tr>
</tbody>
</table>

* * * * *

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180


Isopyrazam; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of isopyrazam in or on pepper, bell; tomato; and vegetable, cucumber, subgroup 9A. Syngenta Crop Protection, LLC, requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective May 25, 2017. Objections and requests for hearings must be received on or before July 24, 2017, 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–2016–0143, 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?


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–2016–0143 in the subject line on the first page of your submission. All
providing for the rolling adjustments of rates. In 40 CFR 178.105(c), the agency provides for the rolling adjustments of rates. It is important to note that the rates are regularly adjusted based on changes in the cost of living and other factors.

E. General Exemptions

In 40 CFR 178.105(d), the agency provides for the general exemptions from the payment of the rates. These exemptions are based on the size of the shipment and the distance it is transported. The agency also provides for exemptions for different types of shipments, such as those for hazardous materials.

F. Enforcement and Compliance

In 40 CFR 178.105(e), the agency provides for the enforcement and compliance of the requirements for the rolling adjustments of rates. The agency has established a program to ensure compliance with the requirements, and it conducts regular inspections to verify that the rates are being properly applied.

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 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)(ID), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient information to evaluate the hazards of and to make a determination on aggregate exposure for isopyrazam including exposure resulting from the tolerances established by this action. EPA’s assessment of exposures and risks associated with isopyrazam 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 oral toxicity studies in the rat, mouse, rabbit and dog demonstrate that the primary target organ for isopyrazam is the liver (increased organ weight and centrilobular hepatocyte hypertrophy). Liver toxicity is usually accompanied by reduced food consumption. Isopyrazam did not cause reproductive toxicity. Effects seen in the offspring (decreased bodyweight during lactation and increased liver weight at weaning) in the rat reproduction study occurred at the same doses that cause general toxicity in the parents.

Developmental effects described as small eyes and/or microphthalmia were observed in both the Himalayan and New Zealand rabbit strains. However, in the Himalayan strain, the intraocular abnormalities occur in the absence of maternal toxicity while in the New Zealand strain, the ocular abnormalities occurred at doses that were maternally toxic. Developmental effects observed in the rat (increased post-implantation loss, reduced fetal weight, and a non- or incomplete ossification or retardation of ossification) occurred at doses that also produced maternal toxicity (mortality, decreased body weights, body weight gains, and food consumption, increased liver weights and microscopic findings in the liver).

No evidence of specific neurotoxicity was seen in acute and subchronic oral neurotoxicity studies in rats. Clinical signs seen in two subchronic dog studies (side-to-side head wobble, ataxia, reduced stability) are consistent with neurotoxic effects. However, detailed and specific neuropathological analyses were not conducted for the dog studies (i.e., functional observational battery, motor activity, detailed histopathology with special stains).

Consequently, there is uncertainty regarding whether the effects seen in the dog studies are in fact signs of neurotoxicity. However, clear no observed adverse effect levels (NOAELs)/lowest adverse effect levels (LOAELs) were established for both subchronic dog studies. The point of departure selected for the acute dietary assessment is based on clinical signs seen on day 2 in one of four males in the subchronic dog study. This study provides the lowest NOAEL in the database (most sensitive endpoint) for a single dose effect. The dose used for the chronic dietary risk assessment is eight times lower than the dose at which clinical effects were seen at four weeks in the second subchronic dog study.

There is no evidence of immunotoxicity based on a 28-day dietary immunotoxicity study in mice. The LOAEL for immunotoxicity was not identified and the NOAEL for immunotoxicity was 1,356 milligrams/kilograms (mg/kg).

Isopyrazam is classified as “ Likely to be Carcinogenic to Humans” based on increased incidence of uterine endometrial adenocarcinomas and liver hepatocellular adenomas in female rats and increased incidence of thyroid follicular cell adenomas and/or...
cancerous in male rats. Isopyrazam is not carcinogenic in the mouse. There is no evidence of genotoxicity, mutagenicity, or clastogenicity in the in vivo and in vitro studies. There are no structural relationships with other known carcinogens. A linear low-dose approach (Q*1) was used to extrapolate experimental animal tumor data for the quantification of human cancer risk.

Isopyrazam is of low acute toxicity by the oral, dermal, and inhalation routes and is not a skin or eye irritant. Specific information on the studies received and the nature of the adverse effects caused by isopyrazam 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 “Isopyrazam: Human Health Risk Assessment for the Establishment of Tolerances With No U.S. Registrations in/on Cucurbit Vegetables Crop, Subgroup 9A, Bell Pepper and Tomato Import and Use in the United States” in docket ID number EPA–HQ–OPP–2016–0143.

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 isopyrazam used for human risk assessment is discussed in Table 1 of the final rule published in the Federal Register of December 27, 2013 (78 FR 78740) (FRL–9903–53).

C. Exposure Assessment

1. Dietary exposure from food and feed uses. In evaluating dietary exposure to isopyrazam, EPA considered exposure under the petitioned-for tolerances as well as all existing isopyrazam tolerances in 40 CFR 180.654. EPA assessed dietary exposures from isopyrazam 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 isopyrazam. In estimating acute dietary exposure, EPA used food consumption information from the United States Department of Agriculture (USDA) 2003–2008 National Health and Nutrition Examination Survey, What We Eat in America, (NHANES/WWEIA). As to residue levels in food, maximum residues from field trials conducted at the maximum use rates were used to estimate isopyrazam residues of concern and 100 percent crop treated (PCT) assumptions were used. Dietary Exposure Evaluation Model (DEEM) default processing factors were used for all processed commodities including dried apple (8.0), apple juice/cider (1.3), dried banana/plantain (3.9), peanut butter (1.89), dried tomato (14.3), tomato juice (1.5), tomato paste (5.4), and tomato puree (3.3). In the absence of peanut processing data, the maximum theoretical concentration factor was used for peanut oil (2.8).

   ii. Chronic exposure. In conducting the chronic dietary exposure assessment EPA used the food consumption data from the USDA 2003–2008 NHANES/WWEIA. As to residue levels in food, EPA used the average residues from field trials conducted at the maximum use rates were used to estimate isopyrazam residues and the same processing factors and PCT assumptions as in the acute dietary exposure analysis. *1 Bears the number 1.

   iii. Cancer. Based on the data summarized in Unit III.A., EPA has concluded that isopyrazam should be classified as “Likely to be Carcinogenic to Humans” and a linear approach has been used to quantify cancer risk. In evaluating the cancer risk, EPA used the same residue levels, processing factors, and PCT assumptions as in the chronic dietary exposure analysis.
Adequate enforcement methodology (GRM006.01B) 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) 305–2005; 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 MRLs for isopyrazam in/on vegetable, cucumber, subgroup 9A; pepper, bell; and tomato.

C. Revisions to Petitioned-For Tolerances

Based on the residue levels observed in the field trial studies, EPA is establishing a tolerance of 0.50 ppm in/on tomato, bell pepper, in lieu of the 0.6 ppm as requested by the petitioner. The tolerance requested for Cucurbit Crop Group 9A is also being established as Vegetable, cucumber, subgroup 9A, which is the standard commodity description for these commodities. The petitioned-for tolerances for residues of isopyrazam in/on cucurbit crop group 9A (0.3 ppm) and tomato (0.5 ppm) are set at 0.30 ppm and 0.50 ppm, respectively, consistent with the current practices for setting tolerances.

V. Conclusion

Therefore, tolerances are established for residues of isopyrazam, (3-((difluoromethyl)-1-methyl-N-[1,2,3,4-tetrahydro-9-(1-methylthyl)-1,4-methanomethenaphthalen-5-yl]-1H-pyrazole-4-carboxamide) and anti-isomer (3-((difluoromethyl)-1-methyl-N-[1,2,3,4-tetrahydro-9-(1-methylthyl)-1,4-methanomethenaphthalen-5-yl]-1H-pyrazole-4-carboxamide), in or on vegetable, cucumber, subgroup 9A at 0.30 ppm; pepper, bell at 0.50 ppm; and tomato at 0.50 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 (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.


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:


2. In §180.654, add alphabetically the entries “Pepper, bell”, “Tomato”, and “Vegetable, cucumber, subgroup 9A” to the table in paragraph (a), and revise footnote 1 at the end of the table to read as follows:

§180.654 Isopyrazam; tolerances for residues.

(a) * * *
### DEPARTMENT OF HOMELAND SECURITY

**Federal Emergency Management Agency**

**44 CFR Part 64**

[Docket ID FEMA–2017–0002; Internal Agency Docket No. FEMA–8481]

**Suspension of Community Eligibility**

**AGENCY:** Federal Emergency Management Agency, DHS.

**ACTION:** Final rule.

**SUMMARY:** This rule identifies communities where the sale of flood insurance has been authorized under the National Flood Insurance Program (NFIP) that are scheduled for suspension on the effective dates listed within this rule because of noncompliance with the floodplain management requirements of the program. If the Federal Emergency Management Agency (FEMA) receives documentation that the community has adopted the required floodplain management measures prior to the effective suspension date given in this rule, the suspension will not occur and a notice of this will be provided by publication in the Federal Register on a subsequent date. Also, information identifying the current participation status of a community can be obtained from FEMA’s Community Status Book (CSB). The CSB is available at [https://www.fema.gov/national-flood-insurance-program-community-status-book](https://www.fema.gov/national-flood-insurance-program-community-status-book).

**DATES:** The effective date of each community’s scheduled suspension is the third date (“Sus.”) listed in the third column of the tables in the amendment.

**FOR FURTHER INFORMATION CONTACT:** If you want to determine whether a particular community was suspended on the suspension date or for further information, contact Patricia Suber, Federal Insurance and Mitigation Administration, Federal Emergency Management Agency, 400 C Street SW., Washington, DC 20472, (202) 646–4149.

**SUPPLEMENTARY INFORMATION:** The NFIP enables property owners to purchase Federal flood insurance that is not otherwise generally available from private insurers. In return, communities agree to adopt and administer local floodplain management measures aimed at protecting lives and new construction from future flooding. Section 1315 of the National Flood Insurance Act of 1968, as amended, 42 U.S.C. 4022, prohibits the sale of NFIP flood insurance unless an appropriate public body adopts adequate floodplain management measures with effective enforcement measures. The communities listed in this document no longer meet that statutory requirement for compliance with program regulations, 44 CFR part 59. Accordingly, the communities will be suspended on the effective date in the third column. As of that date, flood insurance will no longer be available in the community. We recognize that some of these communities may adopt and submit the required documentation of legally enforceable floodplain management measures after this rule is published but prior to the actual suspension date. These communities will not be suspended and will continue to be eligible for the sale of NFIP flood insurance. A notice withdrawing the suspension of such communities will be published in the Federal Register.

In addition, FEMA publishes a Flood Insurance Rate Map (FIRM) that identifies the Special Flood Hazard Areas (SFHAs) in these communities. The date of the FIRM, if one has been published, is indicated in the fourth column of the table. No direct Federal financial assistance (except assistance pursuant to the Robert T. Stafford Disaster Relief and Emergency Assistance Act not in connection with a flood) may be provided for construction or acquisition of buildings in identified SFHAs for communities not participating in the NFIP and identified for more than a year on FEMA’s initial FIRM for the community as having flood-prone areas (section 202(a) of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4106(a), as amended). This prohibition against certain types of Federal assistance becomes effective for the communities listed on the date shown in the last column. The Administrator finds that notice and public comment procedures under 5 U.S.C. 553(b), are impracticable and unnecessary because communities listed in this final rule have been adequately notified.

Each community receives 6-month, 90-day, and 30-day notification letters addressed to the Chief Executive Officer stating that the community will be suspended unless the required floodplain management measures are met prior to the effective suspension date. Since these notifications were made, this final rule may take effect within less than 30 days.

**National Environmental Policy Act.** FEMA has determined that the community suspension(s) included in this rule is a non-discretionary action and therefore the National Environmental Policy Act of 1969 (42 U.S.C. 4321 et seq.) does not apply.

**Regulatory Flexibility Act.** The Administrator has determined that this rule is exempt from the requirements of the Regulatory Flexibility Act because the National Flood Insurance Act of 1968, as amended, Section 1315, 42 U.S.C. 4022, prohibits flood insurance coverage unless an appropriate public body adopts adequate floodplain management measures with effective enforcement measures. The communities listed no longer comply with the statutory requirements, and after the effective date, flood insurance will no longer be available in the communities unless remedial action takes place.

**Regulatory Classification.** This final rule is not a significant regulatory action under the criteria of section 3(f) of Executive Order 12866 of September 30, 1993, Regulatory Planning and Review, 58 FR 51735.

**Executive Order 13132, Federalism.** This rule involves no policies that have federalism implications under Executive Order 13132.

**Executive Order 12988, Civil Justice Reform.** This rule meets the applicable standards of Executive Order 12988.

**Paperwork Reduction Act.** This rule does not involve any collection of information for purposes of the Paperwork Reduction Act, 44 U.S.C. 3501 et seq.

**List of Subjects in 44 CFR Part 64**

Flood insurance, Floodplains.

Accordingly, 44 CFR part 64 is amended as follows:

**PART 64—AMENDED**

1. The authority citation for Part 64 continues to read as follows:


<table>
<thead>
<tr>
<th>Commodity</th>
<th>Parts per million</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pepper, bell</td>
<td>0.50</td>
</tr>
<tr>
<td>Tomato</td>
<td>0.50</td>
</tr>
<tr>
<td>Vegetable, cucurbit, subgroup</td>
<td>0.30</td>
</tr>
</tbody>
</table>

There are no U.S. registrations for use of isopyrazam on these commodities.