Alaska

(a) * * *

(1) The following State of Alaska requirements are applicable to OCS Sources, September 15, 2018, Alaska Administrative Code—Department of Environmental Conservation. The following sections of Title 18, Chapter 50:

Article 1. Ambient Air Quality Management

18 AAC 50.005. Purpose and Applicability of Chapter (effective 10/01/2004)
18 AAC 50.010. Ambient Air Quality Standards (effective 08/20/2016)
18 AAC 50.015. Air Quality Designations, Classification, and Control Regions (effective 04/17/2015) except (b)(3) and (d)(2)
Table 1. Air Quality Classifications
18 AAC 50.020. Baseline Dates and Maximum Allowable Increases (effective 08/20/2016)
Table 2. Baseline Areas and Dates
Table 3. Maximum Allowable Increases
18 AAC 50.025. Visibility and Other Special Protection Areas (effective 09/15/2018)
18 AAC 50.030. State Air Quality Control Plan (effective 09/15/2018)
18 AAC 50.035. Documents, Procedures, and Methods Adopted by Reference (effective 09/15/2018)
18 AAC 50.040. Federal Standards Adopted by Reference (effective 09/15/2018) except (h)(2)
18 AAC 50.045. Prohibitions (effective 10/01/2004)
18 AAC 50.050. Incinerator Emissions Standards (effective 07/25/2008)
Table 4. Particulate Matter Standards for Incinerators
18 AAC 50.055. Industrial Processes and Fuel-Burning Equipment (effective 09/15/2018) except (a)(4) through (a)(6), (a)(9), (b)(2)(A), (b)(3), (b)(5), and (e)
18 AAC 50.065. Open Burning (effective 03/06/2016)
18 AAC 50.070. Marine Vessel Visible Emission Standards (effective 06/21/1998)
18 AAC 50.080. Ice Fog Standards (effective 01/18/1997)
18 AAC 50.085. Volatile Liquid Storage Tank Emission Standards (effective 01/18/1997)
18 AAC 50.100. Nonroad Engines (effective 10/01/2004)
18 AAC 50.110. Air Pollution Prohibited (effective 05/26/1972)

Article 2. Program Administration

18 AAC 50.200. Information Requests (effective 10/01/2004)
18 AAC 50.201. Ambient Air Quality Investigation (effective 10/01/2004)
18 AAC 50.205. Certification (effective 10/01/2004) except (b)
18 AAC 50.215. Ambient Air Quality Analysis Methods (effective 09/15/2018)
Table 5. Significant Impact Levels (SILs)
18 AAC 50.220. Enforceable Test Methods (effective 09/15/2018)
18 AAC 50.225 Owner-Requested Limits (effective 09/15/2018) except (c) through (g)
18 AAC 50.230. Preapproved Emission Limits (effective 09/15/2018) except (d)
18 AAC 50.235. Unavoidable Emergencies and Malfunctions (effective 09/15/2018)
18 AAC 50.240. Excess Emissions (effective 12/29/2016)
18 AAC 50.245. Air Quality Episodes and Advisories for Air Pollution Other Than PM 2.5 (effective 02/28/2015)
Table 6. Concentrations Triggering an Air Quality Episode for Air Pollution Other Than PM 2.5
18 AAC 50.246. Air Quality Episodes and Advisories for PM 2.5 (effective 02/28/2015)
Table 6a. Concentrations Triggering an Air Quality Episode for PM 2.5

Article 3. Major Stationary Source Permits

18 AAC 50.302. Construction Permits (effective 09/14/2012)
18 AAC 50.306. Prevention of Significant Deterioration (PSD) Permits (effective 01/04/2013) except (c) and (e)
18 AAC 50.311. Nonattainment Area Major Stationary Source Permits (effective 09/15/2018) except (c)
18 AAC 50.316. Preconstruction Review for Construction or Reconstruction of a Major Source of Hazardous Air Pollutants (effective 12/01/2004) except (c)
18 AAC 50.321. Case-By-Case Maximum Achievable Control Technology (effective 10/06/2013)
18 AAC 50.326. Title V Operating Permits (effective 09/15/2018) except (c)(1), (h), (i)(3), (j)(5), (j)(6), (k)(1), (k)(3), (k)(5), and (k)(6)
18 AAC 50.345. Construction, Minor and Operating Permits: Standard Permit Conditions (effective 09/15/2018)
18 AAC 50.346. Construction and Operating Permits: Other Permit Conditions (effective 09/15/2018)
Table 7. Standard Operating Permit Condition

Article 4. User Fees

18 AAC 50.400. Permit Administration Fees (effective 09/15/2018) except (a)(2) through (a)(4), (a)(6), (a)(8), (i)(1), (i)(4), (i)(8), and (i)(9)
18 AAC 50.403. Negotiated Service Agreements (effective 09/26/2015)
18 AAC 50.410. Emission Fees (effective 09/15/2018)
18 AAC 50.499. Definition for User Fee Requirements (effective 09/26/2015)

Article 5. Minor Permits

18 AAC 50.502. Minor Permits for Air Quality Protection (effective 09/15/2018) except (b)(1) through (b)(3), (b)(5), (d)(1)(A) and (d)(2)(A)
18 AAC 50.508. Minor Permits Requested by the Owner or Operator (effective 12/09/2010)
18 AAC 50.510. Minor Permit—Title V Permit Interface (effective 12/09/2010)
18 AAC 50.540. Minor Permit: Application (effective 09/15/2018)
18 AAC 50.542. Minor Permit: Review and Issuance (effective 09/15/2018) except (a), (b), (c), and (d)
18 AAC 50.544. Minor Permits: Content (effective 12/09/2010)
18 AAC 50.546. Minor Permit Revision (effective 7/25/08)
18 AAC 50.560. General Minor Permits (effective 09/15/2018) except (b)

Article 9. General Provisions

18 AAC 50.990. Definitions (effective 09/15/2018)

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2019–0413; FRL–10013–02]

Tiafenacil; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of tiafenacil in or on multiple commodities which are identified and discussed later in this document. ISK Biosciences Corporation requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective September 8, 2020. Objections and requests for hearings must be received on or before November 9, 2020, 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–2019–0413, 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. Due to the public health concerns related to COVID–19, the EPA Docket Center (EPA/DC) and Reading Room is closed to visitors with limited exceptions. The staff continues to provide remote customer service via email, phone, and webform. For the latest status information on EPA/DC services and docket access, visit *https://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: Marietta Echeverria, 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/test-guidelines-pesticides-and-toxic-substances.*

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–2019–0413 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 November 9, 2020. 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–2019–0413, 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/where-send-comments-epa-dockets.*

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 August 30, 2019 (84 FR 45702) (FRL–9998–15), 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 8F8676) by ISK Biosciences Corporation, 7470 Auburn Road, Suite A., Concord, OH 44077. The petition requested that 40 CFR part 180 be amended by establishing tolerances for residues of the herbicide tiafenacil, methyl *N*-[2-[[2-chloro-5-[3,6-dihydro-3-methyl-2,6-dioxo-4-(trifluoromethyl)-1(2*H*)-pyrimidinyl]-4-fluorophenyl]thio]-1-oxopropyl]-β-alaninate, including its metabolites and degradates, in or on corn, which includes field corn and popcorn, at 0.01 parts per million (ppm); cottonseed subgroup 20C, gin byproducts at 3.0 ppm; cottonseed subgroup 20C, undelinted seed at 0.5 ppm; grape at 0.01 ppm; grape, raisin at 0.01 ppm; soybean seed at 0.01 ppm; and wheat grain at 0.01 ppm. That document referenced a summary of the petition prepared by ISK Biosciences Corporation, 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 revised the tolerance expressions, revised tolerance values and definitions for some commodities, and established tolerances on livestock feed commodities. The reasons for these changes are explained in Unit IV.C.

III. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is ''safe.'' Section 408(b)(2)(A)(ii) of FFDCA defines ''safe'' to mean that ''there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to ''ensure that there is a reasonable certainty that no harm will result 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 tiafenacil including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with tiafenacil follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children.

The available data indicate that exposure to tiafenacil caused consistent decreases in absolute body weights, alterations in the erythropoietic system, minor clinical chemical changes, and histopathological changes in the liver, bone marrow and the spleen of mice, rats and dogs. There was no evidence of carcinogenicity, genotoxicity, mutagenicity, dermal toxicity, neurotoxicity, or immunotoxicity.

There was evidence of an increased fetal quantitative susceptibility in rats

but not rabbits. In rats, no maternal effects were observed up to the highest dose tested, while there was a decrease in fetal weights at the high dose. The decrease in fetal body weights is not considered a single dose effect. No adverse effects were observed in rabbits in maternal or fetal animals. There was no evidence of increased postnatal susceptibility in the 2-generation reproductive study up to the highest dose tested. Increased levels of porphyrin were observed in the liver at the highest doses tested in parents and offspring. While not adverse, this effect is consistent with the hematotoxicity observed throughout the database at higher doses. At the highest dose in the 1-generation reproductive study, parental effects included pale skin, decreased body weight and food consumption, low hemoglobin concentrations, hematocrit, mean corpuscular volume, and mean corpuscular hemoglobin and platelet count. F1 offspring were not generated based upon the effects in adults as it was predicted that similar effects and increased mortality would occur.

Tiafenacil has low acute lethality through oral, dermal, and inhalation routes. It is not an ocular or dermal irritant, nor is it a dermal sensitizer.

Specific information on the studies received and the nature of the adverse effects caused by tiafenacil 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 the document, ''Tiafenacil. Human Health Risk Assessment for the Section 3 Registration Action of the New Active Ingredient on Grapes, Corn, Cotton, Soybeans, and Wheat''. First Food Use. in docket ID number EPA–HQ–OPP–2019–0413.

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://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/assessing-human-health-risk-pesticides.*

The toxicological endpoints used to assess safety of exposures to tiafenacil are discussed in the Human Health Risk Assessment mentioned above.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to tiafenacil, EPA considered exposure under the petitioned-for tolerances. EPA assessed dietary exposures from tiafenacil 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 tiafenacil; therefore, a quantitative acute dietary exposure assessment is unnecessary.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment, EPA used the food consumption data from the United States Department of Agriculture (USDA) National Health and Nutrition Examination Survey, What We Eat in America, (NHANES/WWEIA; 2003–2008). As to residue levels in food, EPA assumed 100% CT and tolerance-level residues for all commodities.

iii. *Cancer.* Based on the data summarized in Unit III.A., EPA has concluded that tiafenacil 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 and/or PCT information in the dietary assessment for tiafenacil. Tolerance level residues and/or 100% CT 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 tiafenacil in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of tiafenacil. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at *http://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/about-water-exposure-models-used-pesticide.*

Modeled estimates of drinking water concentrations based on the Pesticides in Water Calculator (PWC) version 1.52 were directly entered into the dietary exposure model. For chronic dietary risk assessment, the highest estimated drinking water concentration of 66 parts per billion was used to assess the contribution to drinking water from groundwater sources.

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). There are no uses for tiafenacil that will result in residential exposure.

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

EPA has not found tiafenacil to share a common mechanism of toxicity with any other substances, and tiafenacil does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that tiafenacil 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/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.* There is evidence from a rat developmental study of an increased quantitative fetal susceptibility following *in utero* exposure to tiafenacil in rats. Although a 2-generation reproductive study would typically further characterize this susceptibility, no effects were observed in parents and offspring in the definitive study. Therefore, EPA conducted a weight-of-evidence (WOE) analysis taking into consideration a 1-generation reproductive study and determined that the concern for the observed effects is low because: (1) The effects are well characterized and clear NOAELs were established; (2) the PODs selected for risk assessment are protective for the effects observed in the rat developmental and 1-generation reproductive studies; (3) the 2-generation reproductive study and the 1-generation reproductive study are considered co-critical based upon similar doses allowing them to be considered together; (4) the parental effects were observed in the 1-generation reproductive study are six to seven-fold higher than the NOAEL; (5) increased porphyrin levels which are thought to be a precursor to hematotoxicity occur at the same dose in parental animals and offspring in the 2-generation reproductive study and not the lower two doses; and (6) quantitative susceptibility was not observed in the two-generation reproductive study for a similar chemical saflufenacil.

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 tiafenacil is complete.

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

iii. The selected endpoints are protective of the observed increased fetal and offspring susceptibilities in rats. They are also protective of potential offspring effects which are expected to occur at the same dose as parental effects or higher.

iv. There are no residual uncertainties identified in the exposure databases. The dietary food exposure assessments were performed based on 100% CT and tolerance-level residues. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to tiafenacil in drinking water. These assessments will not underestimate the exposure and risks posed by tiafenacil.

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 tiafenacil.

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, tiafenacil 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 tiafenacil from food and water will utilize 14% of the cPAD for the general population, and 36% of the cPAD for infants (<1 year old), the population group receiving the greatest exposure.

3. *Short- and intermediate-term risks.* Short- and intermediate-term aggregate exposures takes into account short- and intermediate-term residential exposures plus chronic exposure to food and water (considered to be a background exposure level). Because there are no residential uses for tiafenacil, short- and intermediate-term aggregate exposures are equivalent to the chronic dietary exposure.

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

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology (high-performance liquid chromatography method with tandem mass spectrometry detection (LC/MS/MS), Method No. GPL–MTH–113) is available to enforce the tolerance expression for determination of residues of tiafenacil and metabolites M–36 (2-(2-chloro-4-fluoro-5-(3-methyl-2,6-dioxo-4-(trifluoromethyl)-2,3-dihydropyrimidin-1(6*H*)-yl)phenylsulfinyl)propanoic acid) and M–56 (2-(2-chloro-5-(2,6-dioxo-4-(trifluoromethyl)-2,3-dihydropyrimidin-1(6*H*)-yl)-4-fluorophenylsulfinyl)propanoic acid) in crop commodities.

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 any MRL for tiafenacil.

C. Revisions to Petitioned-for Tolerances

Based upon review of supporting residue data, EPA has made several modifications to the petition. The petitioner did not propose tolerances for residues in or on the livestock feed raw agricultural commodities (RACs) associated with the use of tiafenacil on corn, wheat, and soybeans; however, EPA has determined that tolerances for

residues in these RACs are needed based on the tolerances requested, as the crop field trial data showed quantifiable residues of tiafenacil and its metabolites. For livestock feed items (both preplant and desiccation), significant amounts of metabolites M–01, M–10, M–52, M–53, M–36, and/or M–56 were found in the corn, cotton, soybean, and wheat field trials. For tolerance enforcement in livestock feed items, tiafenacil, M–36, and M–56 are appropriate marker compounds as the metabolites are common to these RACs following preplant use and tiafenacil is the major residue following desiccation treatment. Therefore, EPA is establishing a separate tolerance expression for livestock feed RACs by including the sum of tiafenacil, M–36, and M–56 for compliance with the tolerance values specified. In addition to establishing the petitioned-for tolerance on cotton gin byproducts under this separate tolerance expression, EPA also established tolerances on livestock RACs for corn (field, forage and stover; pop, stover), soybean (forage and hay), and wheat (forage, hay, straw). The tolerance values for cottonseed subgroup 20C undelinted seed and cottonseed subgroup 20C gin byproducts were corrected by removing the trailing zero to be consistent with EPA's Rounding Class Practice and the commodity definitions were revised to be consistent with Agency practice. All livestock feed RAC tolerance values were calculated using the Organization for Economic Co-operation and Development's (OECD) MRL calculation procedures.

The proposed tolerance expression was revised for primary crops by removing the metabolite M–01 (3-(2-(2-chloro-4-fluoro-5-(3-methyl-2,6-dioxo-4-(trifluoromethyl)-2,3-dihydropyrimidin-1(6*H*)-yl)phenylthio)propanamido)propanoic acid), as parent tiafenacil was the predominant residue and is thus the residue of concern for tolerance enforcement purposes. Residues in these human consumption commodities (seeds, grains, and fruits) will result only from desiccation use.

A lower tolerance value was established for the cottonseed subgroup 20C after adjusting the residue levels using proportionality to account for the exaggerated rate used in the cotton field trials and using the OECD MRL calculation procedures. The submitted processing studies indicate that a tolerance for residues of tiafenacil is not required for grape, raisin (*i.e.,* no concentration of residues was observed).

V. Conclusion

Therefore, tolerances are established for residues of tiafenacil, methyl *N*-[2-[[2-chloro-5-[3,6-dihydro-3-methyl-2,6-dioxo-4-(trifluoromethyl)-1(2*H*)-pyrimidinyl]-4-fluorophenyl]thio]-1-oxopropyl]-β-alaninate, including its metabolites and degradates, in or on Corn, field, forage at 0.05 ppm; Corn, field, grain at 0.01 ppm; Corn, field, stover at 0.05 ppm; Corn, pop, grain at 0.01 ppm; Corn, pop, stover at 0.05 ppm; Cotton, gin byproducts at 3 ppm; Cottonseed subgroup 20C at 0.3 ppm; Grape at 0.01 ppm; Soybean, forage at 0.15 ppm; Soybean, hay at 0.3 ppm; Soybean, seed at 0.01 ppm; Wheat, forage at 0.05 ppm; Wheat, grain at 0.01 ppm; Wheat, hay at 0.08 ppm; and Wheat, straw at 0.07 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), or 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: August 23, 2020.

Edward Messina,

Acting Director, Office of Pesticide Programs.

Therefore, for the reasons stated in the preamble, EPA is amending 40 CFR chapter I as follows:

PART 180—TOLERANCES AND EXEMPTIONS FOR PESTICIDE CHEMICAL RESIDUES IN FOOD

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

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

■ 2. Add § 180.713 to subpart C to read as follows:

§ 180.713 Tiafenacil; tolerances for residues.

(a) *General.* (1) Tolerances are established for residues of the herbicide tiafenacil, 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 only tiafenacil, methyl *N*-[2-[[2-chloro-5-[3,6-dihydro-3-methyl-2,6-dioxo-4-(trifluoromethyl)-1(2*H*)-pyrimidinyl]-4-fluorophenyl]thio]-1-oxopropyl]-β-alaninate, in or on the following commodities:

TABLE 1 TO PARAGRAPH (a)(1)

Commodity	Parts per million
Corn, field, grain	0.01
Corn, pop, grain	0.01
Cottonseed subgroup 20C	0.3
Grape	0.01
Soybean, seed	0.01
Wheat, grain	0.01

(2) Tolerances are established for residues of the herbicide tiafenacil, 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 only the sum of tiafenacil, methyl *N*-[2-[[2-chloro-5-[3,6-dihydro-3-methyl-2,6-dioxo-4-(trifluoromethyl)-1(2*H*)-pyrimidinyl]-4-fluorophenyl]thio]-1-oxopropyl]-β-alaninate and its metabolites 2-(2-chloro-4-fluoro-5-(3-methyl-2,6-dioxo-4-(trifluoromethyl)-2,3-dihydropyrimidin-1(6*H*)-yl)phenylsulfinyl)propanoic acid and 2-(2-chloro-5-(2,6-dioxo-4-(trifluoromethyl)-2,3-dihydropyrimidin-1(6*H*)-yl)-4-fluorophenylsulfinyl)propanoic acid, calculated as the stoichiometric equivalent of tiafenacil, in or on the following commodities:

TABLE 2 TO PARAGRAPH (a)(2)

Commodity	Parts per million
Cotton, gin byproducts	3
Corn, field, forage	0.05
Corn, field, stover	0.05
Corn, pop, stover	0.05
Soybean, forage	0.15
Soybean, hay	0.3
Wheat, forage	0.05
Wheat, hay	0.08
Wheat, straw	0.07

(b)–(d) [Reserved]

[FR Doc. 2020–19673 Filed 9–4–20; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 402, 403, 411, 412, 422, 423, 460, 483, 488, and 493

[CMS–6076–RCN2]

RIN 0991–AC07

Medicare and Medicaid Programs; Adjustment of Civil Monetary Penalties for Inflation; Continuation of Effectiveness and Extension of Timeline for Publication of the Final Rule

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Continuation of effectiveness and extension of timeline for publication of the final rule.

SUMMARY: This document announces the continuation of, effectiveness of, and the extension of the timeline for publication of a final rule. We are issuing this document in accordance with section 1871(a)(3)(C) of the Social Security Act (the Act), which allows an interim final rule to remain in effect after the expiration of the timeline specified in section 1871(a)(3)(B) of the Act if the Secretary publishes a notice of continuation explaining why we did not comply with the regular publication timeline.

DATES: Effective September 4, 2020, the Medicare provisions adopted in the interim final rule published on September 6, 2016 (81 FR 61538), continue in effect and the regular timeline for publication of the final rule is extended for an additional year, until September 6, 2021.

FOR FURTHER INFORMATION CONTACT: Steve Forry (410) 786–1564 or Jaqueline Cipa (410) 786–3259.

SUPPLEMENTARY INFORMATION: Section 1871(a) of the Social Security Act (the Act) sets forth certain procedures for promulgating regulations necessary to carry out the administration of the insurance programs under Title XVIII of the Act. Section 1871(a)(3)(A) of the Act requires the Secretary, in consultation with the Director of the Office of Management and Budget (OMB), to establish a regular timeline for the publication of final regulations based on the previous publication of a proposed rule or an interim final rule. In accordance with section 1871(a)(3)(B) of the Act, such timeline may vary among different rules, based on the complexity of the rule, the number and scope of the comments received, and other relevant factors. However, the timeline for publishing the final rule, cannot exceed 3 years from the date of publication of the proposed or interim final rule, unless there are exceptional circumstances. After consultation with the Director of OMB, the Secretary published a document, which appeared in the December 30, 2004 **Federal Register** on (69 FR 78442), establishing a general 3-year timeline for publishing Medicare final rules after the publication of a proposed or interim final rule.

Section 1871(a)(3)(C) of the Act states that upon expiration of the regular timeline for the publication of a final regulation after opportunity for public comment, a Medicare interim final rule shall not continue in effect unless the Secretary publishes a notice of continuation of the regulation that includes an explanation of why the regular timeline was not met. Upon publication of such notice, the regular timeline for publication of the final regulation is treated as having been extended for 1 additional year.

On September 6, 2016 **Federal Register** (81 FR 61538), the Department of Health and Human Services (HHS) issued a department-wide interim final rule titled ''Adjustment of Civil Monetary Penalties for Inflation'' that established new regulations at 45 CFR part 102 to adjust for inflation the maximum civil monetary penalty amounts for the various civil monetary penalty authorities for all agencies within the Department. HHS took this action to comply with the Federal Civil Penalties Inflation Adjustment Act of 1990 (the Inflation Adjustment Act) (28 U.S.C. 2461 note 2(a)), as amended by the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 (section 701 of the Bipartisan Budget Act of 2015, (Pub. L. 114–74), enacted on November 2, 2015). In addition, this September 2016 interim final rule included updates to certain agency-specific regulations to reflect the new provisions governing the adjustment of civil monetary penalties for inflation in 45 CFR part 102.

One of the purposes of the Inflation Adjustment Act was to create a mechanism to allow for regular inflationary adjustments to federal civil monetary penalties. Section 2(b)(1) of the Inflation Adjustment Act. The 2015 amendments removed an inflation update exclusion that previously