

TABLE 9 TO PARAGRAPH (d)(2)(vii)—DELEGATION STATUS FOR NEW SOURCE PERFORMANCE STANDARDS FOR SAN DIEGO COUNTY APCD, SAN JOAQUIN VALLEY UNIFIED APCD, SAN LUIS OBISPO COUNTY APCD, AND SANTA BARBARA COUNTY APCD—Continued

|            | Subpart  | Air pollution control agency |                                 |                             |                           |
|------------|--|------------------------------|---------------------------------|-----------------------------|---------------------------|
|            |  | San Diego County APCD        | San Joaquin Valley Unified APCD | San Luis Obispo County APCD | Santa Barbara County APCD |
| QQQQ ..... | Standards of Performance for New Residential Hydronic Heaters and Forced-Air Furnaces. | X                            | .....                           | .....                       | .....                     |
| TTTT ..... | Standards of Performance for Greenhouse Gas Emissions for Electric Generating Units.   | X                            | .....                           | .....                       | .....                     |

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**ENVIRONMENTAL PROTECTION AGENCY**

**40 CFR Part 180**

[EPA-HQ-OPP-2021-0604; FRL-9657-01-OCSP]

**Sodium Salt of Acifluorfen; Pesticide Tolerances for Emergency Exemptions**

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

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes time-limited tolerances for residues of sodium salt of acifluorfen in or on beet, sugar, roots and beet, sugar, leaves. This action is in response to EPA’s granting of emergency exemptions under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) authorizing use of the pesticide on sugarbeets. This regulation establishes a maximum permissible level for residues of sodium salt of acifluorfen in or on these commodities. These time-limited tolerances expire on December 31, 2024.

**DATES:** This regulation is effective March 31, 2022. Objections and requests for hearings must be received on or before May 31, 2022, 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-2021-0604, is available at <https://www.regulations.gov> or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave. NW, Washington, DC 20460-0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal

holidays. The telephone number for the Public Reading Room and the OPP Docket is (202) 566-1744.

Due to the public health concerns related to COVID-19, the EPA Docket Center (EPA/DC) and Reading Room is open to visitors by appointment only. For the latest status information on EPA/DC services and access, visit <https://www.epa.gov/dockets>.

**FOR FURTHER INFORMATION CONTACT:** Marietta Echeverria, Acting Director, 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: [RDfRNtices@epa.gov](mailto:RDfRNtices@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 Office of the Federal Register’s e-CFR site at <https://www.ecfr.gov/current/title-40>.

*C. How can I file an objection or hearing request?*

Under section 408(g) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(g), any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2021-0604 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 May 31, 2022. 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-2021-0604, by one of the following methods:

- **Federal eRulemaking Portal:** <https://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.
- **Mail:** OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave. NW, Washington, DC 20460-0001.
- **Hand Delivery:** To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at <https://www.epa.gov/dockets/where-send-comments-epa-dockets>.

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <https://www.epa.gov/dockets>.

## II. Background and Statutory Findings

EPA, on its own initiative, in accordance with FFDCA sections 408(e) and 408(l)(6) of, 21 U.S.C. 346a(e) and 346a(l)(6), is establishing time-limited tolerances for residues of sodium salt of acifluorfen, in or on beet, sugar, roots at 0.1 parts per million (ppm), and beet, sugar, leaves at 0.1 ppm. These time-limited tolerances expire on December 31, 2024.

Section 408(l)(6) of FFDCA requires EPA to establish a time-limited tolerance or exemption from the requirement for a tolerance for pesticide chemical residues in or on food that will result from the use of a pesticide under an emergency exemption granted by EPA under FIFRA section 18. Such tolerances or exemptions can be established without providing notice or period for public comment. EPA does not intend for its actions on FIFRA section 18-related time-limited tolerances to set binding precedents for the application of FFDCA section 408 and the safety standard to other tolerances and exemptions. Section 408(e) of FFDCA allows EPA to establish a tolerance or an exemption from the requirement of a tolerance on its own initiative, *i.e.*, without having received any petition from an outside party.

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. . . .”

Section 18 of FIFRA authorizes EPA to exempt any Federal or State agency from any provision of FIFRA, if EPA determines that “emergency conditions

exist which require such exemption.” EPA has established regulations governing such emergency exemptions in 40 CFR part 166.

## III. Emergency Exemptions for Sodium Salt of Acifluorfen on Sugarbeets and FFDCA Tolerances

The Colorado, Michigan, Minnesota, Nebraska, and North Dakota Departments of Agriculture requested specific emergency exemptions for postemergence use of acifluorfen to control glyphosate-resistant pigweed species, Palmer amaranth and waterhemp, on sugarbeets. According to the States, glyphosate-resistant Palmer amaranth and waterhemp have reached population levels so high that sugarbeet production is severely impacted. They assert that without a viable alternative tool for postemergence control, growers are unable to contain infestations in their sugarbeet fields and are expected to experience significant economic loss.

After having reviewed the applications, EPA determined that an emergency condition exists for these States, and that the criteria for approval of these emergency exemptions are met. EPA authorized specific exemptions under FIFRA section 18 for the use of sodium salt of acifluorfen on sugarbeets for postemergence control of glyphosate-resistant pigweed species in Colorado, Michigan, Minnesota, Nebraska, and North Dakota.

As part of its evaluation of the emergency exemption applications, EPA assessed the potential risks presented by residues of sodium salt of acifluorfen in or on sugarbeets. In doing so, EPA considered the safety standard in FFDCA section 408(b)(2), and EPA decided that the necessary tolerances under FFDCA section 408(l)(6) would be consistent with the safety standard and with FIFRA section 18. Consistent with the need to move quickly on the emergency exemptions in order to address the urgent non-routine situation in these States and to ensure that the resulting food is safe and lawful, EPA is issuing these tolerances without notice and opportunity for public comment as provided in FFDCA section 408(l)(6). Although these time-limited tolerances expire on December 31, 2024, under FFDCA section 408(l)(5), residues of the pesticide not in excess of the amounts specified in the tolerances remaining in or on sugarbeets after that date will not be unlawful, provided the pesticide was applied in a manner that was lawful under FIFRA, and the residues do not exceed a level that was authorized by these time-limited tolerances at the time of that application. EPA will take action to revoke these time-limited tolerances

earlier if any experience with, scientific data on, or other relevant information on this pesticide indicate that the residues are not safe.

Because these time-limited tolerances are being approved under emergency conditions, EPA has not made any decisions about whether sodium salt of acifluorfen meets FIFRA’s registration requirements for use on sugarbeets or whether permanent tolerances for this use would be appropriate. Under these circumstances, EPA does not believe that these time-limited tolerance decisions serve as a basis for registration of sodium salt of acifluorfen by a State for special local needs under FIFRA section 24(c). Nor do these tolerances by themselves serve as the authority for persons in any State other than Colorado, Michigan, Minnesota, Nebraska, and North Dakota to use this pesticide on the applicable crops under FIFRA section 18 absent the issuance of an emergency exemption applicable within that State. For additional information regarding these emergency exemptions for sodium salt of acifluorfen, contact the Agency’s Registration Division at the address provided under **FOR FURTHER INFORMATION CONTACT**.

## IV. 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 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 expected as a result of these emergency exemption requests

and the time-limited tolerances for residues of sodium salt of acifluorfen on beet, sugar, roots at 0.1 parts per million (ppm), and beet, sugar, leaves at 0.1 ppm. EPA's assessment of exposures and risks associated with establishing time-limited tolerances follows.

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

A summary of the toxicological endpoints for sodium salt of acifluorfen used for human health risk assessment is shown in Table 1 of this unit.

**TABLE 1—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR SODIUM SALT OF ACIFLUORFEN FOR USE IN HUMAN HEALTH RISK ASSESSMENT**

| Exposure/scenario  | Point of departure and uncertainty/safety factors  | RfD, PAD, LOC for risk assessment  | Study and toxicological effects   |
|--|--|--|---|
| Acute dietary (Females 13–50 years of age).                        | NOAEL = 20 mg/kg/day.<br>UF <sub>A</sub> = 10x<br>UF <sub>H</sub> = 10x<br>FQPA SF = 1x  | Acute RfD = aPAD = 0.20 mg/kg/day.   | Rat Developmental Study: LOAEL = 90 mg/kg/day based on increased incidence of slightly dilated lateral ventricles of the brain.   |
| Acute dietary (General population including infants and children). | NOAEL = 293 mg/kg/day.<br>UF <sub>A</sub> = 10x<br>UF <sub>H</sub> = 10x<br>FQPA SF = 1x   | Acute RfD = aPAD = 2.9 mg/kg/day.  | Acute Neurotoxicity Study: LOAEL = 440 mg/kg/day based on decreased motor activity in females.  |
| Chronic dietary (All populations)                                  | NOAEL = 1.25 mg/kg/day.<br>UF <sub>A</sub> = 10x<br>UF <sub>H</sub> = 10x<br>FQPA SF = 1x  | Chronic RfD = cPAD = 0.013 mg/kg/day.  | Rat Parental Reproduction Study: LOAEL = 25 mg/kg/day based on dilatation of tubules in the outer medulla of kidneys in parental females of both generations (33/35 (P1) and 28/40 (F1) treated parents vs 0/35–41 controls); one occurrence of tubular epithelial necrosis was noted in the P1 females (compared to 0 controls). |
| Incidental oral short-term (1 to 30 days).                         | NOAEL = 25 mg/kg/day.<br>UF <sub>A</sub> = 10x<br>UF <sub>H</sub> = 10x<br>FQPA SF = 1x  | Residential LOC for MOE = 100.<br>No residential uses.<br>Accounts for spray drift | Rat Offspring Reproduction Study: LOAEL = 125 mg/kg/day based on decreased body weight (both generations; ↓6–26%) and increased incidence of dilatation of the renal pelvis in the F2 generation.   |
| Dermal short-term (1 to 30 days).                                  | NOAEL = 25 mg/kg/day.<br>DAF = 18%<br>UF <sub>A</sub> = 10x<br>UF <sub>H</sub> = 10x<br>FQPA SF = 1x   | Residential LOC for MOE = 100.<br>No residential uses.<br>Accounts for spray drift | Rat Offspring Reproduction Study: LOAEL = 125 mg/kg/day based on decreased body weight (both generations; ↓6–26%) and increased incidence of dilatation of the renal pelvis in the F2 generation. Rat Developmental Study is supportive.  |
| Cancer (Oral, dermal, inhalation).                                 | Classification: Likely to be carcinogenic to humans at high enough doses to cause the biochemical and histopathological changes in livers of rodents, but unlikely to be carcinogenic at doses below those causing these changes. The non-linear RfD approach will be protective for chronic effects, including carcinogenicity. |  |   |

DAF = dermal absorption factor. FQPA SF = FQPA Safety Factor. LOAEL = lowest observed adverse effect level. LOC = level of concern. NOAEL = no observed adverse effect level. PAD = population adjusted dose (a = acute, c = chronic). Point of Departure (POD) = A data point or an estimated point that is derived from observed dose-response data and used to mark the beginning of extrapolation to determine risk associated with lower environmentally relevant human exposures. RfD = reference dose. MOE = margin of exposure. UF = uncertainty factor. UF<sub>A</sub> = extrapolation from animal to human (interspecies). UF<sub>H</sub> = potential variation in sensitivity among members of the human population (intraspecies).

**B. Exposure Assessment**

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to sodium salt of acifluorfen, EPA considered exposure under the

time-limited tolerances established by this action as well as all existing sodium salt of acifluorfen tolerances in 40 CFR 180.383. EPA assessed dietary

exposures from sodium salt of acifluorfen in food as follows:

- i. *Acute exposure.* Such effects were identified for sodium salt of acifluorfen. In estimating acute dietary exposure,

EPA used food consumption information from the Dietary Exposure Evaluation and Model-Food Commodity Intake Database (DEEM-FCID). As to residue levels in food, EPA assumed that sodium acifluorfen residues were present at tolerance levels in all commodities for which tolerances have been established or proposed and that 100% of the crops were treated with sodium salt of acifluorfen.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment, EPA used the food consumption data from the Dietary Exposure Evaluation and Model-Food Commodity Intake Database (DEEM-FCID). As to residue levels in food, EPA assumed that acifluorfen residues were present at tolerance levels in all commodities for which tolerances have been identified or proposed and that 100% of the crops were treated with sodium salt of acifluorfen.

iii. *Cancer.* EPA determines whether quantitative cancer exposure and risk assessments are appropriate for a food-use pesticide based on the weight of the evidence from cancer studies and other relevant data. Cancer risk is quantified using a linear or nonlinear approach. If sufficient information on the carcinogenic mode of action is available, a threshold or nonlinear approach is used and a cancer RfD is calculated based on an earlier noncancer key event. If carcinogenic mode of action data are not available, or if the mode of action data determines a mutagenic mode of action, a default linear cancer slope factor approach is utilized. Based on the data summarized in Unit IV.A., EPA has concluded that a nonlinear RfD approach is appropriate for assessing cancer risk to sodium salt of acifluorfen. Cancer risk was assessed using the same exposure estimates as discussed in Unit IV.B.1.ii., *chronic exposure.*

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

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

[pesticide-risks/about-water-exposure-models-used-pesticide](https://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/about-water-exposure-models-used-pesticide).

Based on the groundwater modeling results from Pesticide Root Zone Model Ground Water (PRZM GW), the estimated drinking water concentrations (EDWCs) of sodium salt of acifluorfen for acute exposures are estimated to be 66.8 parts per billion (ppb) for surface water and 146 ppb for ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For acute and chronic (non-cancer) dietary risk assessments, the water concentration value of 146 ppb was used to assess the contribution to drinking water.

3. *From non-dietary exposure.* The term “residential exposure” is used in this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets).

Sodium salt of acifluorfen is not registered for any specific use patterns that would result in residential exposure.

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

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

At this time, there is not sufficient information to determine if any other pesticides share a common mechanism of toxicity with sodium salt of acifluorfen. For purposes of this time-limited tolerance action, EPA has assumed that sodium salt of acifluorfen does not share a common mechanism of toxicity with any 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 <https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/cumulative-assessment-risks-pesticides>.

### C. 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 Food Quality Protection Act (FQPA) Safety Factor (SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional SF when reliable data available to EPA support the choice of a different factor.

#### 2. *Prenatal and postnatal sensitivity.*

There is evidence of increased susceptibility following in utero exposure to sodium acifluorfen in the Sprague Dawley rat developmental toxicity study. However, there is low concern because effects are well characterized with clear NOAEL/LOAEL values and the chosen points of departure for risk assessment for each scenario are protective of these effects.

3. *Conclusion.* EPA has determined that reliable data show that 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 sodium salt of acifluorfen is complete.

ii. There is some indication that sodium salt of acifluorfen is a neurotoxic chemical, however, the chosen points of departure for risk assessment are protective of these effects, and there is no need for a developmental neurotoxicity study or additional UFs to account for neurotoxicity.

iii. There is evidence that sodium salt of acifluorfen results in increased susceptibility following exposure *in utero* rats in the Sprague Dawley rat prenatal developmental study. However, there is low concern because effects are well characterized with clear NOAEL/LOAEL values and the chosen points of departure for risk assessment for each scenario are protective of these effects.

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

#### D. Aggregate Risks and Determination of Safety

EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute population adjusted dose (aPAD) and chronic population adjusted dose (cPAD). For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure. Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate PODs to ensure that an adequate MOE exists.

1. *Acute risk.* Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food and water to sodium salt of acifluorfen will occupy 4.0% of the aPAD for females 13–49 years old, the population group receiving the greatest exposure. There are no registered residential uses of sodium salt of acifluorfen, and so acute aggregate risk is equivalent to acute dietary risk, which is not of concern.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to sodium salt of acifluorfen from food and water will utilize 63% of the cPAD for all infants <1 year old, the population group receiving the greatest exposure. There are no registered residential uses of sodium salt of acifluorfen, and so chronic aggregate risk is equivalent to chronic dietary risk, which is not of concern.

3. *Short-term risk.* Short-term aggregate exposure takes into account short-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Sodium salt of acifluorfen is not currently registered for a use that could result in short-term (non-occupational) residential exposure. Because there are no registered residential uses, short-term aggregate risk is equivalent to chronic dietary risk, which is not of concern.

4. *Intermediate-term risk.* Intermediate-term aggregate exposure takes into account intermediate-term non-dietary, non-occupational exposure plus chronic exposure to food and water (considered to be a background exposure level). Because there are no registered residential uses, intermediate-term risk is equivalent to chronic dietary risk, which is not of concern.

5. *Aggregate cancer risk for U.S. population.* Sodium salt of acifluorfen is classified as “likely to be carcinogenic

to humans at doses high enough to cause the biochemical and histopathological changes in livers of rodents, but unlikely to be carcinogenic at doses below those causing these changes.” EPA determined that non-linear extrapolation be used in this assessment instead of a separate Q1\* based cancer aggregate assessment.” A non-cancer dietary assessment was completed that resulted in risk levels below the LOC of 100%. These levels are considered protective for both non-cancer and cancer risk because EPA regulates at doses below those where initiation of tumor formation is expected.

6. *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 sodium salt of acifluorfen residues. More detailed information on the subject action to establish time-limited tolerances in or on beet, sugar, roots and beet, sugar, leaves can be found at <https://www.regulations.gov> in the document entitled “Sodium Acifluorfen: Human Health Risk Assessment for Section 18 Emergency Exemptions for the Use on Sugarbeets in Nebraska and Colorado.” This document can be found in docket ID number EPA–HQ–OPP–2021–0604.

#### V. Other Considerations

##### A. Analytical Enforcement Methodology

Adequate enforcement methodology, the Pesticide Analytical Manual (PAM) Volume II gas chromatography/electron capture detector (GC/ECD) method, is available to enforce the tolerance expression.

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

##### B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). Codex is a joint United Nations Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-

setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

Codex has not established a MRL for sodium salt of acifluorfen.

#### VI. Conclusion

Therefore, time-limited tolerances are established for residues of sodium salt of acifluorfen, in or on beet, sugar, roots at 0.1 parts per million (ppm), and beet, sugar, leaves at 0.1 ppm. These tolerances expire on December 31, 2024.

#### VII. Statutory and Executive Order Reviews

This action establishes tolerances under FFDCA sections 408(e) and 408(l)(6). 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 (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 in accordance with FFDCA sections 408(e) and 408(l)(6), such as the tolerances in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply.

This action directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the

relationship between the National Government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, 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).

**VIII. Congressional Review Act**

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a "major rule" as defined by 5 U.S.C. 804(2).

**List of Subjects in 40 CFR Part 180**

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: March 25, 2022.

**Marietta Echeverria,**

*Acting Director, Registration Division, 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. Section 180.383(b) is added to read as follows:

**§ 180.383 Sodium salt of acifluorfen; tolerances for residues.**

\* \* \* \* \*

(b) *Section 18 emergency exemptions.* Time-limited tolerances are established

for residues of the herbicide sodium salt of acifluorfen, including its metabolites and degradates, in or on the specified agricultural commodities in the following table, resulting from use of the pesticide pursuant to FIFRA section 18 emergency exemptions. Compliance with the tolerance levels specified in the following table is to be determined by measuring only the sum of acifluorfen acid, (5-[2-chloro-4-(trifluoromethyl)phenoxy]-2-nitrobenzoate), acifluorfen amine methyl ester (methyl 5-[2-chloro-4(trifluoromethyl)phenoxy]-2-aminobenzoate), calculated as the stoichiometric equivalent of acifluorfen acid in or on the commodities. The tolerances expire on the date specified in the table.

TABLE 2 TO PARAGRAPH (b)

| Commodity                 | Parts per million | Expiration date |
|---------------------------|-------------------|-----------------|
| Beet, sugar, roots .....  | 0.1               | 12/31/2024      |
| Beet, sugar, leaves ..... | 0.1               | 12/31/2024      |

\* \* \* \* \*

[FR Doc. 2022-06817 Filed 3-30-22; 8:45 am]

**BILLING CODE 6560-50-P**

**DEPARTMENT OF THE INTERIOR**

**Fish and Wildlife Service**

**50 CFR Part 17**

[Docket No. FWS-R8-ES-2018-0042; FXES1113090FEDR-223-FF09E42000]

**RIN 1018-BD00**

**Endangered and Threatened Wildlife and Plants; Reclassification of the Endangered Layia carnosa (Beach Layia) to Threatened With Section 4(d) Rule**

**AGENCY:** Fish and Wildlife Service, Interior.

**ACTION:** Final rule.

**SUMMARY:** We, the U.S. Fish and Wildlife Service (Service), are reclassifying the plant beach layia (*Layia carnosa*) from an endangered to a threatened species under the Endangered Species Act of 1973, as amended (Act), due to substantial improvements in the species' overall status since its original listing as endangered in 1992. This action is based on a thorough review of the best scientific and commercial data available, which indicates that beach layia no longer meets the definition of an endangered species under the Act. Beach layia will remain protected as a threatened species under the Act. We

are also finalizing a rule under section 4(d) of the Act that provides for the conservation of beach layia.

**DATES:** This rule is effective May 2, 2022.

**ADDRESSES:** This final rule, supporting documents we used in preparing this rule, and public comments we received are available on the internet at <https://www.regulations.gov> at Docket No. FWS-R8-ES-2018-0042.

**FOR FURTHER INFORMATION CONTACT:** Tanya Sommer, Field Supervisor, Arcata Fish and Wildlife Office, 1655 Heindon Rd., Arcata, CA 95521; telephone 707-822-7201.

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**SUPPLEMENTARY INFORMATION:**

**Previous Federal Actions**

On June 22, 1992, we listed the beach layia as an endangered species (57 FR 27848). On September 29, 1998, we finalized a recovery plan for this and six other coastal species (Service 1998, entire). In 2011, we completed a 5-year review (Service 2011, entire) and concluded that there was evidence to support a decision to reclassify beach layia from an endangered species to a threatened species under the Act. We announced the availability of this review on April 27, 2012 (77 FR 25112).

On September 30, 2020, we proposed to reclassify beach layia from an endangered species to a threatened species with a rule issued under section 4(d) of the Act ("4(d) rule") to provide for the conservation of beach layia (85 FR 61684). On April 13, 2021, we reopened the public comment period for the proposed rule and announced a public informational meeting and public hearing (86 FR 19184), which we held on April 29, 2021.

**Summary of Changes From the Proposed Rule**

In this rule, we make certain nonsubstantive, editorial changes to some text that we presented in the proposed rule, and we include a minor amount of new information (e.g., some updated abundance information and new references) that we received or that became available since the proposed rule published. However, this new information did not change our analysis, rationales, or determination for either