



## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 180

[EPA-HQ-OPP-2019-0233; FRL-10017-30]

#### 2,4-D; Pesticide Tolerances

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

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes tolerances for residues of 2,4-D in or on intermediate wheatgrass bran, forage, grain, and straw and sesame seed. Interregional Research Project Number 4 (IR-4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

**DATES:** This regulation is effective [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. Objections and requests for hearings must be received on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*], and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

**ADDRESSES:** The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2019-0233, 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](mailto: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](http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl).

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

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in

40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2019-0233 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA-HQ-OPP-2019-0233, by one of the following methods:

- *Federal eRulemaking Portal*: <http://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.

- *Mail*: OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

- *Hand Delivery*: To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at <http://www.epa.gov/dockets/contacts.html>.

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

## **II. Summary of Petitioned-For Tolerance**

In the *Federal Register* of September 30, 2020 (85 FR 61681) (FRL-10014-74), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of pesticide petitions (an amended PP 9E8745 and PP 0E8848) by IR-4, IR-4 Project Headquarters, Rutgers, The State University of New Jersey, 500 College Road East, Suite 201W,

Princeton, NJ 08540. This September 30, 2020 Notice supersedes the previous document the Agency published notifying the public of the filing of the IR-4 petition PP9E8745 in the *Federal Register* of August 30, 2019 (84 FR 45702) (FRL-9998-15).

The petitions requested that 40 CFR part 180 be amended by establishing tolerances for residues of 2,4-D in or on the raw agricultural commodities wheatgrass, intermediate, bran at 4 parts per million (ppm); wheatgrass, intermediate, grain at 2 ppm; wheatgrass, intermediate, straw at 50 ppm, and wheatgrass, intermediate, forage at 25 ppm (PP 9E8745) and sesame, seed at 0.05 ppm (PP 0E8848). That document referenced summaries of the petitions prepared by Nufarm and PBI Gordon, the registrants, which are available in the docket, <http://www.regulations.gov>. There was one comment received in response to the notice of filing and it was in support of the petition. Although the petitioner requested a tolerance for wheatgrass, intermediate, forage at 25 ppm, the available data indicate that a tolerance of 30 ppm is appropriate; therefore, EPA is establishing that tolerance at 30 ppm. The remaining tolerances are being established as requested.

### **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 2,4-D including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with 2,4-D 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 toxicity profile of 2,4-D shows that the principal toxic effects are changes in the kidney, thyroid, liver, adrenal, eye, and ovaries/testes in the rat following exposure to 2,4-D via the oral route at dose levels above the threshold of saturation of renal clearance; below that level, the kidneys rapidly excrete the chemical before it has any toxic effects on the body. No systemic toxicity was observed in rabbits following repeated exposure via the dermal route at dose levels up to the limit dose. Neurotoxicity was observed in the acute neurotoxicity study in rats at the high dose. In an extended 1-generation reproductive toxicity study in rats, reproductive toxicity, developmental neurotoxicity, and immunotoxicity were not observed, and the thyroid effects observed at dose levels up to/approaching renal saturation were considered treatment-related, although not adverse. Maternal and developmental toxicities were observed only at high dose levels exceeding the threshold of saturation of renal clearance. Regarding carcinogenicity, available data showed no statistically significant tumor response in rats and mice. Moreover, EPA's literature review found that, overall, there was little substantive evidence to suggest a clear associative or causal relationship between exposure to 2,4-D and cancer.

Specific information on the studies received and the nature of the adverse effects caused by 2,4-D 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 titled “2,4-D. Second Revision: Human Health Risk Assessment for Registration Review” (hereinafter “2,4-D Human Health Risk Assessment for Registration Review”) in docket ID number EPA-HQ-OPP-2019-0233.

### *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-pesticide>.

A summary of the toxicological endpoints for 2,4-D used for human risk assessment can be found in the 2,4-D Human Health Risk Assessment for Registration Review.

### *C. Exposure Assessment*

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to 2,4-D, EPA considered exposure under the petitioned-for tolerances as well as all existing 2,4-D tolerances in 40 CFR 180.142. EPA assessed dietary exposures from 2,4-D 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 2,4-D. In estimating acute dietary exposure, EPA used 2003-2008 food consumption information from the United States Department of Agriculture's (USDA's) National Health and Nutrition Examination Survey, What We Eat in America, (NHANES/WWEIA). As to residue levels in food, EPA assumed tolerance-level residues, except for transgenic soybeans and cotton (for which a value higher than the tolerance was used to account for the 2,4-DCP metabolite), and 100 percent crop treated (PCT) for all commodities, as well as empirical and default processing factors.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment, EPA used the 2003-2008 food consumption data from the USDA's NHANES/WWEIA. As to residue levels in food, EPA assumed tolerance-level residues, except for transgenic soybeans and cotton (for which a value higher than the tolerance was used to account for the 2,4-DCP metabolite), and 100 percent crop treated (PCT) for all commodities, as well as empirical and default processing factors.

iii. *Cancer.* Based on the data summarized in the 2,4-D Human Health Risk Assessment for Registration Review in docket ID number EPA-HQ-OPP-2019-0233, EPA has concluded that 2,4-D is not expected to pose a cancer risk to humans. Therefore, a dietary exposure assessment for the purpose of assessing cancer risk is unnecessary.

iv. *Anticipated residue and PCT information.* EPA did not use anticipated residue or PCT information in the dietary assessment for 2,4-D. Tolerance-level residues (except for transgenic soybeans and cotton, for which a value higher than the tolerance was used to account for the 2,4-DCP metabolite) 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 2,4-D in drinking

water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of 2,4-D. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at <http://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/about-water-exposure-models-used-pesticide>.

Based on the Surface Water Concentration Calculator (SWCC), Pesticide Root Zone Model Ground Water (PRZM GW) model, and monitoring data, the estimated drinking water concentrations (EDWCs) of 2,4-D for acute exposures are estimated to be 298 parts per billion (ppb) for surface water and 14.89 ppb for ground water, and for chronic exposures are estimated to be 34.5 ppb for surface water and 14.89 ppb for ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For the acute dietary risk assessment, the water concentration value of 298 ppb was used to assess the contribution to drinking water. For the chronic dietary risk assessment, the water concentration of value 34.5 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).

2,4-D is currently registered for the following uses that could result in residential exposures: ornamental turf, including lawns, parks, sports fields, and golf courses, as well as aquatic uses. EPA assessed residential exposure using the following assumptions: There is no potential hazard via the dermal route for 2,4-D; therefore, the handler assessment included only the inhalation route of exposure. There are registered 2,4-D products for use in residential sites (*e.g.*, lawns and turf) that have been considered in the short-term residential handler assessment for 2,4-D. As the aquatic use product labels include PPE requirements, and state that coordination and approval of local and state authorities and/or permits may be required prior to application, those applications are assumed to be made only by occupational applicators.

There is potential for short-term post-application exposure for individuals as a result of

being in an environment that has been previously treated with 2,4-D. The quantitative exposure/risk assessment for residential post-application exposures is based on the following scenarios:

- Incidental ingestion (*i.e.*, hand-to-mouth, object-to-mouth, soil ingestion exposure) from contact with treated turf (children 1 to less than 2 years old only),
- Episodic granular ingestion on treated turf (children 1 to less than 2 years old only), and
- Incidental ingestion of water during recreational swimming (both adults and children 3 to less than 6 years old).

The residential exposure scenario used in the adult and children 3 to less than 6 years aggregate assessments reflects short-term incidental oral exposure from post-application exposure swimmer scenario.

The residential exposure scenario used in the children 1 to less than 2 years old aggregate assessment reflects short-term hand-to-mouth exposures from post-application turf scenario (*i.e.*, post-application exposure to turf applications).

These scenarios are considered worst-case and are protective of all other exposure scenarios.

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

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

2,4-D is a member of the alkylphenoxy herbicide class of pesticides. This class also includes MCPA, 2,4-DB, and 2,4-DP. Unlike other pesticides for which EPA has followed a

cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding as to 2,4-D and any other substances. For the purposes of this action, therefore, EPA has not assumed that 2,4-D has 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 the policy statements released by EPA's Office of Pesticide Programs concerning common mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism on EPA's website at <http://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/cumulative-assessment-risk-pesticides>.

#### *D. Safety Factor for Infants and Children*

1. *In general.* Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the FQPA Safety Factor (SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity.* 2,4-D has been evaluated for potential developmental effects in the rat and rabbit. There is no evidence of increased susceptibility following *in utero* exposure to 2,4-D in the rabbit developmental toxicity study or following *in utero* and/or pre-/post-natal exposure in the rat extended 1-generation reproduction toxicity study. Maternal toxicity in the rabbit included decreased body weight gain, clinical signs of toxicity (decreased motor activity, ataxia, loss of righting reflex, extremities cold to the touch) and developmental toxicity includes abortions.

The rat developmental toxicity study and the rat 2-generation reproductive study indicate increased susceptibility following *in utero* exposure to 2,4-D in the rat developmental toxicity study and/or pre-/post-natal exposure in the reproductive study. In the former, maternal toxicity included decreased body weight gains at the same dose level where developmental effects (occurrence of skeletal malformations) occurred; in the latter, maternal toxicity included decreased body weight gains at the same dose level where reduced viability of the F1 pups was observed. In both the rat developmental study and the rat 2-generation reproduction study, the toxicity was observed at dose levels that exceed renal saturation. Because the toxicity was observed at those levels, EPA expects that had an examination of the kidney been done on the maternal animals in these studies, kidney effects would have been revealed at doses lower than where the developmental effects had occurred; therefore, the study findings are not considered evidence of real susceptibility.

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 2,4-D is complete.
- ii. Evidence of neurotoxicity was observed in the acute neurotoxicity study in rats, as evidenced by an increase in the incidence of in-coordination and slight gait abnormalities (forepaw flexing or knuckling) during the Functional Operational Battery assessment at the high dose in both sexes. In the subchronic neurotoxicity study, relative forelimb grip strength was significantly increased in rats of both sexes at the high-dose level, although there was no treatment-related change in absolute grip strength. Clinical signs of neurotoxicity (decreased motor activity, ataxia, loss of righting reflex, extremities cold to the touch) were observed in maternal rabbits in the developmental toxicity study. Developmental neurotoxicity was not observed in the developmental neurotoxicity cohort of the Extended One Generation Reproductive Toxicity study in rats. Neuropathological effects were not observed in any study.

iii. There is evidence of increased susceptibility following *in utero* exposure to 2,4-D in the rat developmental toxicity study and following *in utero* and/or pre-/post-natal exposure in the rat 2-generation reproduction study at dose levels that exceed renal saturation. There is no evidence of increased susceptibility following *in utero* exposure to 2,4-D in the rabbit developmental toxicity study or following *in utero* and/or pre-/post-natal exposure in the rat extended 1-generation reproduction toxicity study. Despite this conclusion, there is no residual uncertainty concerning the potential susceptibility of infants and children to effects of 2,4-D necessitating the retention of the 10X FQPA safety factor. There are no data gaps in the toxicology database, and the available reliable data provide clearly established NOAELs and LOAELs for the population of concern and the points of departure (POD) that are protective of susceptibility. Consequently, there is no need to retain the 10X FQPA safety factor to protect infants and children.

iv. There are no residual uncertainties identified in the exposure databases. The dietary exposure estimates are unrefined and reflect primarily tolerance-level residues in food and 100 PCT. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to 2,4-D in drinking water. EPA used similarly conservative assumptions to assess post-application exposure of children as well as incidental oral exposure of toddlers. These assessments will not underestimate the exposure and risks posed by 2,4-D.

#### *E. Aggregate Risks and Determination of Safety*

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

1. *Acute risk.* Using the exposure assumptions discussed in this unit for acute exposure,

the acute dietary exposure from food and water to 2,4-D will occupy 23% of the aPAD for children 1-2 years old, the population group receiving the greatest exposure.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to 2,4-D from food and water will utilize 20% of the cPAD for children 1 to 2 years old, the population group receiving the greatest exposure. Based on the explanation in Unit III.C.3., regarding residential use patterns, chronic residential exposure to residues of 2,4-D is not expected.

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).

2,4-D is currently registered for uses that could result in short-term residential exposure, and the Agency has determined that it is appropriate to aggregate chronic exposure through food and water with short-term residential exposures to 2,4-D.

Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded the combined short-term food, water, and residential exposures result in aggregate MOEs of 2000 for adults and 280 for children. Because EPA's level of concern for 2,4-D is a MOE of 100 or below, these MOEs are not of concern.

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

An intermediate-term adverse effect was identified; however, 2,4-D is not registered for any use patterns that would result in intermediate-term residential exposure. Intermediate-term risk is assessed based on intermediate-term residential exposure plus chronic dietary exposure. Because there is no intermediate-term residential exposure and chronic dietary exposure has already been assessed under the appropriately protective cPAD (which is at least as protective as the POD used to assess intermediate-term risk), no further assessment of intermediate-term risk

is necessary, and EPA relies on the chronic dietary risk assessment for evaluating intermediate-term risk for 2,4-D.

5. *Aggregate cancer risk for U.S. population.* As discussed above, EPA has concluded that 2,4-D will not pose a cancer risk.

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 2,4-D residues.

#### **IV. Other Considerations**

##### *A. Analytical Enforcement Methodology*

Adequate analytical methods are available for data collection and the enforcement of plant commodity tolerances. An adequate Gas Chromatography/Electron Capture Detector (GC/ECD) enforcement method for plants (designated as EN-CAS Method No. ENC-2/93) was submitted, which has been independently validated and radiovalidated. An enforcement method was submitted for determination of 2,4-D in livestock commodities, which has been adequately radiovalidated. The methods have been submitted to FDA for inclusion in PAM II. The 10/1997 edition of FDA PAM Volume I, Appendix I indicates that 2,4-D is partially recovered (50-80%) using Multiresidue Methods Section 402 E1 and 402 E2.

For multiresidue method analysis, 2,4-D is documented to be well-recovered through the QuEChERS (Quick, Easy, Cheap, Effective, Rugged, and Safe) streamlined extraction method.

The methods 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 has not established any MRLs for 2,4-D on intermediate wheatgrass raw agricultural commodities or sesame seed.

### *C. Response to Comments*

There was one comment received in response to the notice of filing and it was in support of the petition.

## **V. Conclusion**

Therefore, tolerances are established for residues of 2,4-D, in or on sesame, seed at 0.05 ppm; wheatgrass, intermediate, bran at 4 ppm; wheatgrass, intermediate, forage at 30 ppm; wheatgrass, intermediate, grain at 2 ppm; and wheatgrass, intermediate, straw at 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), nor is it considered a regulatory action under Executive Order 13771, entitled “Reducing Regulations and Controlling Regulatory Costs” (82 FR 9339, February 3, 2017). This action does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), nor does it require any special considerations under Executive Order 12898, entitled “Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations” (59 FR 7629, February 16, 1994).

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

## **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: December 4, 2020.

**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. In § 180.142 amend paragraph (a) by designating the table and adding, in alphabetical order, in newly designated Table 1 to paragraph (a) the entries “Sesame, seed”; “Wheatgrass, intermediate, bran”; “Wheatgrass, intermediate, forage”; “Wheatgrass, intermediate, grain”; and “Wheatgrass, intermediate, straw” to read as follows:

**§ 180.142 2,4-D; tolerances for residues.**

(a) \* \* \*

Table 1 to Paragraph (a)

Commodity	Parts per million
* * * * *	*
Sesame, seed	0.05
* * * * *	*
Wheatgrass, intermediate, bran	4
Wheatgrass, intermediate, forage	30
Wheatgrass, intermediate, grain	2
Wheatgrass, intermediate, straw	50

\* \* \* \* \*