



ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2014-0913; FRL-9941-69]

Fluridone; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a tolerance for residues of fluridone in or on cotton, undelinted seed. SePRO Corporation 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-2014-0913, is available at <http://www.regulations.gov> or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the

Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave., NW., Washington, DC 20460-0001.

The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPP Docket is (703) 305-5805. Please review the visitor instructions and additional information about the docket available at <http://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT: Susan Lewis, 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 Printing Office's e-CFR site at 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 FFDCFA 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-2014-0913 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-2014-0913, by one of the following methods:

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

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

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

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

II. Summary of Petitioned-For Tolerance

In the **Federal Register** of April 6, 2015 (80 FR 18327) (FRL-9924-00), 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 4F8308) by SePRO Corporation, 11550 North Meridian Street, Suite 600, Carmel, IN 46032. The petition requested that 40 CFR part 180 be amended by establishing tolerances for residues of the herbicide fluridone, 1-methyl-3-phenyl-5-(3-(trifluoromethyl)phenyl)-4(1*H*)-pyridinone, in or on cotton, undelinted seed at 0.1 parts per million (ppm). That document referenced a summary of the petition prepared by SePRO 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.

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 fluridone including exposure resulting from the tolerance established by this action. EPA's assessment of exposures and risks associated with fluridone 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 liver and kidneys were identified as the primary target organs based on a multitude of organ specific effects noted across the toxicity database. All model species exhibited indications of liver toxicity that were often accompanied by body weight effects. Mice were the most sensitive species examined, and dogs were the most tolerant. Rat sensitivity was comparable (chronic exposure) to or slightly less (subchronic exposure) than mice; however, rats were the only species to exhibit minor kidney effects in addition to liver and body weight toxicity. Progression of toxicity from subchronic to chronic exposures was not observed in mice and was limited (2-fold difference) in rats. No evidence of fetal sensitivity was observed in rats or rabbits. Body weight effects in the F₂ rat offspring during the lactation period were suggestive of susceptibility in the young. However, this evidence is considered equivocal because the effects were isolated to the F₂ offspring, body weight of the F₂ offspring returned to control levels after the lactation period and no subsequent evidence of susceptibility was observed in progeny of the F₂ generation. Furthermore, the offspring effects occurred at doses 2 to 4.5 times higher than the target organ and body weight toxicity noted in adult rodents. While these effects are considered equivocal, susceptibility will be assumed to be present in the young in the absence of more definitive toxicity data. Behavioral anomalies, physiological effects, and locomotor impairment consistent with neurotoxicity were only observed following acute gavage exposure to doses that likely exceeded linear pharmacokinetics and were at

least 13 to 26 times higher than the lowest doses causing liver and kidney effects in rodents. No signs of neurotoxicity were identified in the rest of the toxicity database. Toxicity from repeated dose dermal exposures was limited to irritation effects on the skin (erythema, desquamation, epidermal fissures). No evidence of immunotoxicity, mutagenicity, or carcinogenicity were noted in the toxicity database. Fluridone did not demonstrate mutagenic behavior either *in vitro* or *in vivo* nor did exposure result in an increased incidence of tumors. The EPA concluded that fluridone should be classified as “not likely” to be a human carcinogen.

Specific information on the studies received and the nature of the adverse effects caused by fluridone as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies can be found at <http://www.regulations.gov> in document *Fluridone. Human Health Risk Assessment for Registration Review and to Support the Registration of the Use on Cotton* on pages 47 thru 72 in docket ID number EPA-HQ-OPP-2014-0913.

B. Toxicological Points of Departure/Levels of Concern

Once a pesticide’s toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which no adverse effects are observed (the NOAEL) and the lowest dose at which adverse

effects of concern are identified (the LOAEL). Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level - generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD) - and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see <http://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/assessing-human-health-risk-pesticides>.

The 2-year mouse study was used for the residential points of departures (PODs) for short- and intermediate-term incidental oral, dermal and inhalation exposure. The mouse chronic endpoint was considered appropriate for short-and intermediate-term fluridone exposures because mice were the most sensitive species and there was no progression of toxicity from subchronic to chronic exposure.

The guideline dermal study was not used to set endpoints for the dermal assessment, because the study did not address concerns for the possible sensitivity in the young observed in the 3-generation reproduction study. The systemic NOAEL from the dermal study is 384 milligram/kilogram/day (mg/kg/day), but there is equivocal, yet suggestive evidence of offspring toxicity at 112 mg/kg/day. The NOAEL from the 2-year mouse cancer study is 38.5 mg/kg/day after accounting for route-to-route extrapolation (dermal absorption factor of 39%) and is therefore protective of the equivocal offspring effects. The chronic mouse oral endpoint was used for the inhalation assessment as well,

because a route-specific inhalation study was not available. Without a route specific study, inhalation exposure was assumed to be equivalent to oral exposure.

A summary of the toxicological endpoints for fluridone used for human risk assessment is shown in Table 1 of this unit.

Table 1.--Summary of Toxicological Doses and Endpoints for Fluridone 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 (All populations)	NOAEL = 125 mg/kg/day $UF_A = 10x$ $UF_H = 10x$ FQPA SF = 1x	Acute RfD = 1.25 mg/kg/day aPAD = 1.25 mg/kg/day	Acute Neurotoxicity - Rat LOAEL = 650 mg/kg/day based on decreased ambulatory counts and the prevalence of functional observational battery (FOB) anomalies in males and females
Chronic dietary (All populations)	NOAEL = 15 mg/kg/day $UF_A = 10x$ $UF_H = 10x$ FQPA SF = 1x	Chronic RfD = 0.15 mg/kg/day cPAD = 0.15 mg/kg/day	2-year cancer study - Mouse LOAEL = 50 mg/kg/day based on increased alkaline phosphatase activity and increased incidence of hepatocellular hyperplasia

Incidental oral short-term (1 to 30 days) and intermediate-term	NOAEL= 15 mg/kg/day UF _A = 10x UF _H = 10x FQPA SF = 1x	LOC for MOE = 100	2-year cancer study – Mouse LOAEL = 50 mg/kg/day based on increased alkaline phosphatase activity and increased incidence of hepatocellular hyperplasia
Dermal short-term (1 to 30 days) and intermediate-term (1 to 6 months)	Oral study NOAEL = 15 mg/kg/day (dermal absorption rate = 39%) UF _A = 10x UF _H = 10x FQPA SF = 1x	LOC for MOE = 100	2-year cancer study – Mouse LOAEL = 50 mg/kg/day based on increased alkaline phosphatase activity and increased incidence of hepatocellular hyperplasia
Inhalation short-term (1 to 30 days) and intermediate-term (1 to 6 months)	Oral study NOAEL= 15 mg/kg/day (inhalation absorption rate = 100%) UF _A = 10x UF _H = 10x FQPA SF = 1x	LOC for MOE = 100	2-year cancer study – Mouse LOAEL = 50 mg/kg/day based on increased alkaline phosphatase activity and increased incidence of hepatocellular hyperplasia
Cancer (Oral, dermal, inhalation)	Fluridone is classified as “not likely” to be a human carcinogen. Quantitative cancer risk assessment is not required.		

FQPA SF = Food Quality Protection Act Safety Factor. LOAEL = lowest-observed-adverse-effect-level. LOC = level of concern. mg/kg/day = milligram/kilogram/day. MOE = margin of exposure. NOAEL = no-observed-adverse-effect-level. PAD = population adjusted dose (a = acute, c = chronic). RfD = reference dose. UF =

uncertainty factor. UF_A = extrapolation from animal to human (interspecies). UF_H = potential variation in sensitivity among members of the human population (intraspecies).

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to fluridone, EPA considered exposure under the petitioned-for tolerances as well as all existing fluridone tolerances in 40 CFR 180.420. EPA assessed dietary exposures from fluridone 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 fluridone. In estimating acute dietary exposure, EPA used food consumption information from the United States Department of Agriculture (USDA) National Health and Nutrition Examination Survey, What We Eat in America, (NHANES/WWEIA). This dietary survey was conducted from 2003 to 2008. 100 percent crop treated (PCT), tolerance residues, and default processing factors were assumed for this assessment.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the food consumption data from the USDA NHANES/WWEIA. This dietary survey was conducted from 2003 to 2008. 100 PCT, tolerance residues, and default processing factors were assumed.

iii. *Cancer*. Based on the data summarized in Unit III.A., EPA has concluded that fluridone 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 PCT information*. EPA did not use anticipated residue and/or PCT information in the dietary assessment for fluridone. Tolerance-level residues and/or 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 fluridone in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of fluridone. 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 First Index Reservoir Screening Tool (FIRST) and Pesticide Root Zone Model Ground Water (PRZM GW), the estimated drinking water concentrations (EDWCs) of fluridone for acute exposures are estimated to be 24 parts per billion (ppb) for surface water and 34 ppb for ground water. For chronic exposures they are estimated to be 21 ppb for surface water and 32 ppb for ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For acute dietary risk assessment, the water concentration value of 34 ppb was used to assess the contribution to drinking water. For chronic dietary risk

assessment, the water concentration of value 32 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).

Fluridone is currently registered for the following uses that could result in residential exposures: from use on ponds (including a homeowner use), lakes, reservoirs, and rivers. EPA assessed residential exposure using the following assumptions: Adult applicators may be exposed (dermal and inhalation) while applying the pesticide to residential ponds. Residential handler exposure is expected to be short-term in duration only. Intermediate-term and chronic exposures are not likely because of the intermittent nature of applications by homeowners. There is also potential for residential post-application exposure (dermal, inhalation and incidental ingestion) for adults and children (3 to <6 years old) swimming in treated water. Residential post-application exposure is expected to be short term in duration only.

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.”

EPA has not found fluridone to share a common mechanism of toxicity with any other substances, and fluridone does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that fluridone 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://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 Food Quality Protection Act Safety Factor (FQPA 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 was no evidence of qualitative susceptibility in fetuses in the rat and rabbit developmental study. Equivocal

susceptibility was observed in the young from the F₂ population in the reproductive study during the lactation phase (based decreased body weight); however, body weight of the F₂ offspring returned to control levels after the lactation period and no evidence of susceptibility was observed in the F₃ offspring.

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 fluridone is complete. Though EPA relied on an oral study to assess inhalation exposures, a subchronic inhalation study is not required based on a weight-of-evidence (WOE) approach that considered the physical/chemical properties of fluridone including low vapor pressure, low acute inhalation toxicity, and the large short- and intermediate-term inhalation MOEs calculated.

ii. The combination of behavioral anomalies and impaired physiological and locomotor function in the acute neurotoxicity (ACN) study were suggestive of neurotoxicity following high dose acute exposure. However, the concern for neurotoxicity is low because the adverse effects in the ACN study were only seen at relatively high gavage doses (650-2000 mg/kg/day); there were no corresponding neurohistopathological findings; there were no indications of neurotoxicity in the rest of the toxicity database; and the endpoints selected for risk assessment are protective of these adverse effects.

iii. There is no evidence that fluridone results in increased susceptibility in *in utero* rats or rabbits in the prenatal developmental studies. There was equivocal

susceptibility observed in the young from the F₂ population in the reproductive study during the lactation phase (decreased body weight); however, body weight of the F₂ offspring returned to control levels after the lactation period, and no evidence of susceptibility was observed in the F₃ offspring. The PODs selected to assess risk are protective of the equivocal susceptibility in young animals.

iv. There are no residual uncertainties identified in the exposure databases. The dietary food exposure assessments were performed based on 100 PCT and tolerance-level residues. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to fluridone in drinking water. EPA used similarly conservative assumptions to assess postapplication exposure of children as well as incidental oral exposure of toddlers. These assessments will not underestimate the exposure and risks posed by fluridone.

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 fluridone will occupy 1.3%

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 fluridone from food and water will utilize 5.5% of the cPAD for children 1-2 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 fluridone 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). Fluridone 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 fluridone. 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 1,500 for adults and 1,600 for children. Because EPA's level of concern for fluridone is a MOE of 100 or below, these MOEs are not of concern.

4. *Intermediate-term risk.* An intermediate-term adverse effect was identified; however, fluridone 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 fluridone.

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

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 fluridone residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology [high performance liquid chromatography (HPLC) method (originally submitted as method AM-AA-CA-RO52-AA-755)] is available in the Pesticide Analytical Manual (PAM) Volume II for residues of fluridone in plant commodities, including cotton.

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 a MRL for fluridone in cotton.

V. Conclusion

Therefore, a tolerance is established for residues of fluridone, 1-methyl-3-phenyl-5-(3-(trifluoromethyl)phenyl)-4(1*H*)-pyridinone, in or on cotton, undelinted seed at 0.1 ppm. Additionally, the tolerances for cotton, undelinted seed at 0.1 ppm in paragraphs (b) and (d) are removed, since they are superseded by this action.

VI. Statutory and Executive Order Reviews

This action establishes tolerances under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled “Regulatory Planning and Review” (58 FR 51735, October 4, 1993). Because this action has been exempted from review under Executive Order 12866, this action is not subject to Executive Order 13211, entitled “Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use” (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled “Protection of Children from Environmental Health Risks and Safety Risks” (62 FR 19885, April 23, 1997). This action does not contain any

information collections subject to OMB approval under the Paperwork Reduction Act (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: February 8, 2016.

Susan Lewis,

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180--[AMENDED]

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

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

2. In § 180.420, is amended:

i. By alphabetically adding “cotton, undelinted seed” to the table in paragraph (a)(2);

ii. By removing and reserving the text of paragraph (b);

iii. By removing “cotton, undelinted seed” from the table in paragraph (d).

The addition reads as follows:

§ 180.420 Fluridone; tolerances for residues.

(a) * * *

(2) * * *

Commodity	Parts per million
****	***
Cotton, undelinted seed	0.1
****	***

(b) *Section 18 emergency exemptions.* [Reserved].

* * * * *

[FR Doc. 2016-03220 Filed: 2/16/2016 8:45 am; Publication Date: 2/17/2016]