inserting USCG–2012–0965 in the ''Keyword'' box and then clicking ''Search''. They are also available for inspection or copying at the Docket Management Facility (M–30), U.S. Department of Transportation, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or email David H. Sulouff, Chief, Bridge Section, Eleventh Coast Guard District; telephone 510–437–3516, email *David.H.Sulouff@uscg.mil* If you have questions on viewing the docket, call Renee V. Wright, Program Manager, Docket Operations, telephone 202–366–9826.

SUPPLEMENTARY INFORMATION: The City of San Francisco requested a temporary change to the operation of the Third Street Drawbridge, mile 0.0, over China Basin, at San Francisco, CA. The Third Street Drawbridge navigation span provides a vertical clearance of 7 feet above Mean High Water in the closed-to-navigation position. The draw opens on signal if at least one hour notice is given as required by 33 CFR 117.149. Navigation on the waterway is recreational.

The drawspan will be secured in the closed-to-navigation position 9 a.m. to 6 p.m. on November 10, 2012, to allow spectators to the RedBull Flugtag to cross the bridge during the event. This temporary deviation has been coordinated with the waterway users. No objections to the proposed temporary deviation were raised. The drawspan can be operated upon 30 minutes advance notice for emergencies requiring the passage of waterway traffic.

Vessels that can transit the bridge, while in the closed-to-navigation position, may continue to do so at any time.

In accordance with 33 CFR 117.35(e), the drawbridge must return to its regular operating schedule immediately at the end of the designated time period. This deviation from the operating regulations is authorized under 33 CFR 117.35.

Dated: October 23, 2012.

D.H. Sulouff,

Bridge Section Chief, Eleventh Coast Guard District.

[FR Doc. 2012–27242 Filed 11–6–12; 8:45 am]

BILLING CODE 9110–04–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R09–OAR–2011–0492; FRL– 9749–4]

Approval and Promulgation of Implementation Plans; California; Determinations of Attainment for the 1997 8-Hour Ozone Standard

AGENCY: Environmental Protection Agency (EPA).

ACTION: Withdrawal of direct final rule.

SUMMARY: Due to the receipt of an adverse comment, EPA is withdrawing the September 14, 2012, direct final rule that makes several determinations relating to certain 1997 8-hour ozone nonattainment areas in California. EPA will address the comment in a subsequent final action based upon the proposed rulemaking action, also published on September 14, 2012. EPA will not institute a second comment period on this action.

DATES: The direct final rule published at 77 FR 56775 on September 14, 2012, is withdrawn as of November 7, 2012.

FOR FURTHER INFORMATION CONTACT: John Ungvarsky, Air Planning Office, AIR–2, EPA Region IX, 75 Hawthorne Street, San Francisco, CA 94105–3901, telephone number (415) 972–3963, or email *ungvarsky.john@epa.gov*.

SUPPLEMENTARY INFORMATION: EPA is withdrawing the September 14, 2012 (77 FR 56775), direct final rule that makes several determinations relating to 1997 8-hour ozone nonattainment areas in California and thereby suspending certain attainment-related requirements for as long as these areas continue to meet the 1997 8-hour ozone national ambient air quality standard. The subject areas include Amador and Calaveras Counties, Chico, Kern County, Mariposa and Tuolumne Counties, Nevada County, Sutter County, and Ventura County. In the direct final rule, EPA stated that if adverse comments were received by October 15, 2012, the rule would be withdrawn and not take effect. On September 10, 2012, EPA received a comment, which it interprets as adverse and, therefore, EPA is withdrawing the direct final rule. EPA will address the comment in a subsequent final action based upon the proposed rulemaking action, also published on September 14, 2012 (77 FR 56797). EPA will not institute a second comment period on this action.

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Intergovernmental relations, Nitrogen dioxide, Ozone, Reporting and recordkeeping requirements, Volatile organic compounds.

Dated: October 29, 2012.

Jared Blumenfeld,

Regional Administrator, Region IX.

Accordingly, the amendment to 40 CFR 52.282 published in the **Federal Register** on September 14, 2012 (77 FR 56775) on page 56782 is withdrawn as of November 7, 2012.

[FR Doc. 2012–27054 Filed 11–6–12; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2012–0756; FRL–9366–8]

Fluridone; Pesticide Tolerances for Emergency Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes time-limited tolerances for residues of fluridone in or on cotton. This action is in response to EPA's granting of an emergency exemption under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) authorizing use of the pesticide on cotton. This regulation establishes a maximum permissible level for residues of fluridone in or on cotton commodities. The time-limited tolerances expire on December 31, 2014.

DATES: This regulation is effective November 7, 2012. Objections and requests for hearings must be received on or before January 7, 2013, 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–2012–0756, 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), EPA West 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: Debra Rate, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001; telephone number: (703) 306–0309; email address: *rate.debra@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 40 CFR part 180 through the Government Printing Office's e-CFR site at: *http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl.*

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, 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–2012–0756 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 January 7, 2013. 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–2012–0756, 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.htm.*

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *http://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(1)(6), is establishing time-limited tolerances for residues of fluridone, 1-methyl-3-phenyl-5-(3-(trifluoromethyl)phenyl)-4(1*H*)-pyridinone, its metabolites and degradates, in or on cotton, undelinted seed at 0.1 parts per million (ppm). These time-limited tolerances expire on December 31, 2014.

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 food that will result from the use of a pesticide under an emergency exemption granted by EPA under FIFRA section 18. Such tolerances 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 Exemption for Fluridone on Cotton and FFDCA Tolerances

This is the first section 18 request received for the use of fluridone on cotton. Since the introduction of glyphosate resistant cotton in 1997, twenty-one weed species have developed resistance to glyphosate. Glyphosate-resistant palmer amaranth is the most serious of these species across all the major agronomic crops in the southern U.S. Glyphosate-resistant palmer amaranth was confirmed in Arkansas in 2006. Since 2006, it has become the most severe weed problem that Arkansas cotton producers face. Greater than 95% of Arkansas cotton and 80% of soybean contain the glyphosate tolerant gene and thus glyphosate is the base herbicide for weed control. A significant economic loss is expected to occur on nearly 25% of acres grown or about 160,000 acres.

After having reviewed the Arkansas emergency exemption application, EPA determined that an emergency condition exists for this State, and that the criteria for approval of an emergency exemption are met. EPA has authorized a specific exemption under FIFRA section 18 for the use of fluridone on cotton for control of glyphosate-resistant palmer amaranth in Arkansas.

As part of its evaluation of the emergency exemption application, EPA

assessed the potential risks presented by residues of fluridone in or on cotton. In doing so, EPA considered the safety standard in FFDCA section 408(b)(2), and EPA decided that the necessary tolerance 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 exemption in order to address an urgent non-routine situation and to ensure that the resulting food is safe and lawful, EPA is issuing this tolerance without notice and opportunity for public comment as provided in FFDCA section 408(l)(6). Although these time-limited tolerances expire on December 31, 2014, under FFDCA section 408(l)(5), residues of the pesticide not in excess of the amounts specified in the tolerance remaining in or on cotton, undelinted seed 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 fluridone meets FIFRA's registration requirements for use on cotton or whether permanent tolerances for this use would be appropriate. Under these circumstances, EPA does not believe that this time-limited tolerance decision serves as a basis for registration of fluridone by a State for special local needs under FIFRA section 24(c). Nor does this tolerance by itself serve as the authority for persons in any State other than Arkansas 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 the emergency exemption for fluridone, 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 this emergency exemption request and the time-limited tolerances for residues of fluridone on cotton, undelinted seed 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 non-threshold risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see *http://www.epa.gov/pesticides/factsheets/riskassess.htm.*

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 (females 13–49 years of age).	NOAEL = 125 mg/kg/day. UF_A = 10x UF_H = 10x FQPA SF = 1X	aRfD = 1.25 mg/kg/day. aPAD = 1.25 mg/kg/day.	Developmental toxicity—rabbit. LOAEL = 300 mg/kg/day based on increased incidences of abortions.
Chronic dietary (All populations)	NOAEL = 15 mg/kg/day. UF_A = 10x UF_H = 10x FQPA SF = 1X	cRfD = 0.15 mg/kg/day. cPAD = 0.15 mg/kg/day.	2 yr. cancer study in mice. LOAEL = 50 mg/kg/day based on increased alkaline phosphatase activity and increased incidence of heptocellular hyperplasia.

TABLE 1—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR FLURIDONE FOR USE IN HUMAN HEALTH RISK ASSESSMENT—Continued

Exposure/scenario	Point of departure and uncertainty/ safety factors	RfD, PAD, LOC for risk assessment	Study and toxicological effects
Incidental oral short-term (1–30 days) and intermediate-term (1–6 months) oral, dermal, and inhalation exposures.	NOAEL = 15 mg/kg/ day. UF_A = 10x UF_H = 10x	LOC for MOE = 100	2 yr. cancer study in mice (same as above).
Cancer (oral, dermal, inhalation).	Fluridone is classified as ''not likely'' to be a human carcinogen, based on the lack of evidence of carcinogenicity in mice and rats. 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).

B. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to fluridone, EPA considered exposure under the time-limited tolerances established by this action 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.* Such effects were identified for fluridone. In estimating acute dietary exposure for the subpopulation, females 13–49 years, EPA used food consumption information from the United States Department of Agriculture (USDA) 1994–1996 and 1998 Nationwide Continuing Surveys of Food Intake by Individuals (CSFII). As to residue levels in food, EPA used tolerance level residues, DEEM (Ver. 7.81) default processing factors (as necessary) and 100 percent crop treated (PCT) for all commodities.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the food consumption data from the USDA 1994–1996 and 1998 CSFII. As to residue levels in food, EPA used tolerance level residues, DEEM (Ver. 7.81) default processing factors (as necessary) and 100 PCT for all commodities.

iii. *Cancer.* Based on the data summarized in Unit IV.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 or PCT information in the dietary assessment for fluridone. 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 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://www.epa.gov/oppefed1/models/water/index.htm.*

Based on the FQPA Index Reservoir Screening Tool (FIRST) and Screening Concentration in Ground Water (SCI–GROW) models, the estimated drinking water concentrations (EDWCs) of fluridone for acute exposures are estimated to be 9.6 parts per billion (ppb) for surface water and 0.67 ppb for ground water. EDWCs of fluridone for chronic exposures for non-cancer assessments are estimated to be 2.5 ppb for surface water and 0.67 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 9.6 ppb was used to assess the contribution to drinking water. For chronic dietary risk assessment, the water concentration of value 2.5 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, swimming in treated water, and flea and tick control on pets).

Fluridone is currently registered for one use that could result in residential handler and residential post-application exposures: Consumer use to control aquatic weeds in ponds. EPA assessed residential exposure using the following assumptions: Residents or consumers may experience short-term (1–30 days) skin contact or inhalation exposures. These exposures are assessed through residential handler scenarios. Post-application exposures of children and adults through contact with treated swimming ponds are also anticipated. These exposures are expected to be short- and intermediate-term (1–6 months) in duration through dermal, ingestion, aural, buccal/sublingual, and nasal/orbital exposure. All residential handler and post-application scenarios from the uses of fluridone have been assessed and no risks of concern have been identified (MOE ≤100). The scenarios for residential handler and post-application exposure (combined dermal and inhalation) resulted in MOEs of 1,800 and 23,000, respectively.

Further information regarding EPA standard assumptions and generic inputs for residential exposures may be found at: *http://www.epa.gov/pesticides/trac/science/trac6a05.pdf.*

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 Web site at

http://www.epa.gov/pesticides/cumulative.

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 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.* Based on the results in the developmental toxicity studies in rats and rabbits and in a three-generation reproduction study, no increased sensitivity of fetuses or pups (as compared to adults) was demonstrated for fluridone. There are no concerns or residual uncertainties for prenatal/postnatal toxicity following exposure to fluridone.

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 fluridone is complete except for the lack of an immunotoxicity study and a neurotoxicity battery (*i.e.,* acute and subchronic neurotoxicity) that meets the new data requirements in 40 CFR part 158 for conventional pesticide registration. However, the existing toxicology database for fluridone does not show any evidence of treatment-related effects on either the nervous or the immune system. In addition, fluridone does not belong to any class of compounds (*e.g.,* the organotins, heavy metals, or halogenated aromatic hydrocarbons) that would be expected to be immunotoxic. Based on the currently available data for fluridone, the Agency expects that findings from the additional studies will not result in a lower point of departure POD than that currently in use for overall risk assessment, and therefore, a database uncertainty factor is not needed to account for the lack of these studies.

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

iii. There is no evidence that fluridone results in increased susceptibility in *in utero* rats or rabbits in the prenatal developmental studies or in young rats in the 2-generation reproduction study.

iv. There are no residual uncertainties identified in the exposure databases. The dietary food exposure assessment utilized 100 PCT and tolerance-level residues (established or recommended). 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 post-application exposure of children as well as incidental oral exposure of toddlers. These assessments will not underestimate the exposure and risks posed by fluridone.

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 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.* An acute aggregate risk assessment takes into account acute exposure estimates from dietary consumption of food and drinking water. An adverse effect resulting from a single oral exposure was identified for only the subpopulation females 13–49 years. Using the exposure assumptions described in this unit for acute exposure, EPA has concluded that acute exposure to fluridone from food and water will utilize less than 1% of the aPAD for females 13–49 years. Therefore, fluridone is not expected to pose an acute risk.

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

3. *Short-and Intermediate-term risk.* Short- and intermediate-term aggregate exposure takes into account short-term residential exposure or intermediate-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- and intermediate-term residential exposure, and the Agency has determined that it is appropriate to aggregate chronic exposure through food and water with short- and intermediate-term residential exposures to fluridone.

Using the exposure assumptions described in this unit for short-term and intermediate-term exposures, EPA has concluded the combined short-term food, water, and residential exposures and the intermediate-term food, water, and residential exposures each result in aggregate MOEs of 290 (liquids for pouring applications + swimming exposure) to 340 (liquids for garden hose end sprayer + swimming exposure). Because EPA's level of concern for fluridone is a MOE of 100 or below, these MOEs are not of concern.

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.

V. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodologies (enzyme-linked immunosorbant assay (ELISA), high performance liquid chromatography with ultraviolet detection (HLPC/UV), and liquid chromatography with tandem mass spectroscopy (LC–MSMS)) are 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.*

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 an MRL for fluridone.

VI. Conclusion

Therefore, time-limited tolerances are established for residues of fluridone, 1-methyl-3-phenyl-5-(3-(trifluoromethyl)phenyl)-4(1*H*)-pyridinone, including its metabolites and degradates, in or on cotton, undelinted seed at 0.1 ppm. This tolerance expires on December 31, 2014.

VII. Statutory and Executive Order Reviews

This final rule 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 final rule has been exempted from review under Executive Order 12866, this final rule 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 final rule 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 final rule 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 final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (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 of 1995 (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: October 26, 2012.

Daniel J. Rosenblatt,

Acting Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR part 180 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, revise paragraph (b) to read as follows:

§ 180.420 Fluridone; tolerances for residues.

* * * * *

(b) *Section 18 emergency exemptions.* Time-limited tolerances specified in the following table are established for residues of the herbicide fluridone, 1-methyl-3-phenyl-5-(3-(trifluoromethyl)phenyl)-4(1*H*)-pyridinone, including its metabolites and degradates in or on the specified agricultural commodities, resulting from use of the pesticide pursuant to the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) section 18 emergency exemptions. Compliance with the tolerance levels specified below is to be determined by measuring only fluridone. The tolerances expire on the date specified in the table.

Commodity	Parts per million	Expiration date
Cotton, undelinted seed	0.1	12/31/14

* * * * *

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