that before a rule may take effect, the agency promulgating the rule must submit a rule report to each House of the Congress and to the Comptroller General of the United States. 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 this final rule in the **Federal Register**. This final rule is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

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

Dated: August 22, 2007.

Martha Monell,

Acting Director, 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. Section 180.630 is added to read as follows:

§ 180.630 Flusilazole; tolerances for residues.

(a) *General.* [Reserved]

(b) *Section 18 emergency exemptions.* Time-limited tolerances are established for residues of the fungicide, flusilazole, (1-[[bis(4-fluorophenyl)methylsilyl]methyl]-1H-1,2,4-triazole) in connection with use of the pesticide under Section 18 emergency exemptions granted by EPA. The tolerances expire and are revoked on the dates specified in the following table.

Commodity	Parts per million	Expiration/revocation date
Soybean, aspirated grain fractions	2.6	12/31/2010
Soybean, seed	0.04	12/31/2010
Soybean, oil	0.10	12/31/2010

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertant residues.* [Reserved]

[FR Doc. E7–17110 Filed 8–28–07; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2007–0327; FRL–8135–6]

Flutriafol; Time-Limited Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a time-limited tolerance for residues of flutriafol *per se* in or on soybean. 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 soybean. This regulation establishes a maximum permissible level for residues of flutriafol *per se* in this food commodity. The tolerance will expire and is revoked on December 31, 2010.

DATES: This regulation is effective August 29, 2007. Objections and requests for hearings must be received on or before October 29, 2007, 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: EPA has established a docket for this action under docket identification (ID) number EPA–HQ–OPP–2007–0327. To access the electronic docket, go to *http://www.regulations.gov*, select ''Advanced Search,'' then ''Docket Search.'' Insert the docket ID number where indicated and select the ''Submit'' button. Follow the instructions on the regulations.gov web site to view the docket index or access available documents. All documents in the docket are listed in the docket index available in regulations.gov. Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either in the electronic docket at *http://www.regulations.gov*, or, if only available in hard copy, at the OPP Public Docket, in Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: Princess Campbell, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 308–8033; e-mail address:*campbell.princess@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. Potentially affected entities may include, but are not limited to:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How Can I Access Electronic Copies of this Document?

In addition to accessing an electronic copy of this **Federal Register** document through the electronic docket at *http://www.regulations.gov*, you may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at

http://www.epa.gov/fedrgstr. You may also access a frequently updated electronic version of 40 CFR part 180 through the Government Printing Office's pilot e-CFR site at *http://www.gpoaccess.gov/ecfr*.

C. Can I File an Objection or Hearing Request?

Under section 408(g) of the FFDCA, as amended by the FQPA, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. The EPA procedural regulations which govern the submission of objections and requests for hearings appear in 40 CFR part 178. 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–2007–0327 in the subject line on the first page of your submission. All requests must be in writing, and must be mailed or delivered to the Hearing Clerk on or before October 29, 2007.

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 that does not contain any CBI for inclusion in the public docket that is described in **ADDRESSES**. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit your copies, identified by docket ID number EPA–HQ–OPP–2007–0327, by one of the following methods:

- *Federal eRulemaking Portal*: *http://www.regulations.gov*. Follow the on-line instructions for submitting comments.
- *Mail*: Office of Pesticide Programs (OPP) Regulatory Public Docket (7502P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.
- *Delivery*: OPP Regulatory Public Docket (7502P), Environmental Protection Agency, Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. Deliveries are only accepted during the Docket's normal hours of operation (8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays). Special arrangements should be made for deliveries of boxed information. The Docket Facility telephone number is (703) 305–5805.

II. Background and Statutory Findings

EPA, on its own initiative, in accordance with sections 408 (e) and 408 (l)(6) of the Federal Food, Drug and Cosmetic Act (FFDCA), 21 U.S.C. 346a 21 U.S.C. 346a, is establishing a time-limited tolerance for residues of the fungicide flutriafol *per se* in or on soybean at 0.10 parts per million (ppm). The tolerance will expire and is revoked on December 31, 2010.

Section 408(l)(6) of the FFDCA allows 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 section 18 of FIFRA. Such tolerances can be established without providing notice or period for public comment. EPA does not intend for its actions on section 18 related tolerances to set binding precedents for the application of section 408 of the FFDCA and the new safety standard to other tolerances and exemptions. Section 408(e) of the 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 the FFDCA allows EPA to establish a tolerance or exemption from the requirement for a tolerance for pesticide (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 the 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 the 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. . . .''

III. Emergency Exemption for Flutriafol on Soybeans and FFDCA Tolerances

EPA has authorized under section 18 of FIFRA the use of flutriafol on soybeans for control of Australasian soybean rust initially in Minnesota and South Dakota and subsequently in multiple states. After having reviewed the submissions, EPA concurs that emergency conditions exist for these States.

As part of its assessment of this emergency exemption, EPA assessed the potential risks presented by residues of flutriafol *per se* in or on soybean seed. In doing so, EPA considered the safety standard in section 408(b)(2) of the FFDCA, and EPA decided that the necessary tolerance under section 408(l)(6) of the FFDCA would be consistent with the safety standard and with section 18 of FIFRA. 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 section 408(l)(6) of the FFDCA. Although this tolerance will expire and is revoked on December 31, 2010, under section 408(l)(5) of the FFDCA, residues of the pesticide not in excess of the amounts specified in the tolerance remaining in or on soybean after that date will not be unlawful, provided the pesticide is applied in a manner that was lawful under FIFRA, and the residues do not exceed a level that was authorized by this tolerance at the time of that application. EPA will take action to revoke this tolerance earlier if any experience with, scientific data on, or other relevant information on this pesticide indicates that the residues are not safe.

Because this tolerance is being approved under emergency conditions EPA has not made any decisions about whether flutriafol meets EPA's registration requirements for use on soybeans or whether a permanent tolerance for this use would be appropriate. Under these circumstances, EPA does not believe that this tolerance serves as a basis for registration of flutriafol by a State for special local needs under section 24(c) of FIFRA. Nor does this tolerance serve as the basis for any States other than those following all provisions of EPA's regulations implementing FIFRA section 18 as identified in 40 CFR part 166. For additional information regarding the emergency exemption for flutriafol, contact the Agency's Registration Division at the address provided under **FOR FURTHER INFORMATION CONTACT**.

IV. Aggregate Risk Assessment and Determination of Safety

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. For further discussion of the regulatory requirements of section 408 of the FFDCA and a complete description of the risk assessment process, see *http://www.epa.gov/fedrgstr/EPA-PEST/1997/November/Day-26/p30948.htm*.

Consistent with section 408(b)(2)(D) of the FFDCA, 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, consistent with section 408(b)(2) of the FFDCA, for a tolerance for residues of flutriafol *per se* on soybean at 0.10 ppm. EPA's assessment of exposures and risks associated with establishing the tolerance 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. Specific information on the studies received and the nature of the toxic effects caused by flutriafol 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 in the docket at *http://www.regulations.gov*, docket ID number EPA–HQ–OPP–2007–0327 (see memo from Tyler, *et al.* dated March 30, 2006).

B. Toxicological Endpoints

For hazards that have a threshold below which there is no appreciable risk, the dose at which no adverse effects are observed (the NOAEL) from the toxicology study identified as appropriate for use in risk assessment is used to estimate the toxicological level of concern (LOC). However, the LOAEL is sometimes used for risk assessment if no NOAEL was achieved in the toxicology study selected. An uncertainty factor (UF) is applied to reflect uncertainties inherent in the extrapolation from laboratory animal data to humans and in the variations in sensitivity among members of the human population as well as other unknowns.

The linear default risk methodology (Q*) is the primary method currently used by the Agency to quantify non-threshold hazards such as cancer. The Q* approach assumes that any amount of exposure will lead to some degree of cancer risk, and estimates risk in terms of the probability of occurrence of additional cancer cases. Under certain specific circumstances, margin of exposure (MOE) calculations will be used for the carcinogenic risk assessment. In this non-linear approach, a ''point of departure'' is identified below which carcinogenic effects are not expected. The point of departure is typically a NOAEL based on an endpoint related to cancer effects though it may be a different value derived from the dose response curve. To estimate risk, a ratio of the point of departure to exposure (MOE_{cancer} = point of departure/exposures) is calculated. A summary of the toxicological endpoints for flutriafol used for human risk assessment is shown as follows:

TABLE 1.—SUMMARY OF TOXICOLOGICAL DOSE AND ENDPOINTS FOR FLUTRIAFOL FOR USE IN HUMAN RISK ASSESSMENT

Exposure/Scenario	Dose used in risk assessment, UF	FQPA SF* and level of concern for risk assessment	Study and toxicological effects
Acute dietary (Females 13–50 years of age)	NOAEL = <10.0 millgrams/kilogram/day (mg/kg/day) UF = 1,000X Acute RfD = 0.01 mg/kg/day	FQPA SF = 10X acute population adjusted dose (aPAD) = acute Reference Dose (RfD)	Developmental toxicity - rat LOAEL = 10.0 mg/kg/day based on increased number of unossified odontoids, variations in occipitals and calcanea of hindlimbs and increased scores of m,anus and pes
Acute dietary (General population including infants and children)	NOAEL = Not applicable	FQPA SF = Not applicable	An endpoint of concern attributable to a single dose for general population was not identified
Chronic dietary (All populations)	NOAEL = <10.0 mg/kg/day UF = 1,000X Chronic RfD = 0.01 mg/kg/day	FQPA SF = 10X cPAD = chronic RfD	Developmental toxicity-rat LOAEL = 10.0 mg/kg/day based on increased number of unossified odontoids, variations in occipitals and calcanea of hindlimbs and increased scores of m,anus and pes
Short-term dermal (1 to 7 days) (Residential)	Dermal (or oral) study NOAEL = <10.0 mg/kg/day (Dermal absorption rate = 11.0%)	LOC for MOE = 1,000 (residential)	Developmental toxicity -rat LOAEL = 10.0 mg/kg/day based on increased number of unossified odontoids, variations in occipitals and calcanea of hindlimbs and increased scores of m,anus and pes
Intermediate-term dermal (1 week to several months) (Residential)	Dermal (or oral) study NOAEL = <10.0 mg/kg/day (Dermal absorption rate = 11.0%	LOC for MOE = 1,000 (residential)	Developmental toxicity -rat LOAEL = 10.0 mg/kg/day based on increased number of unossified odontoids, variations in occipitals and calcanea of hindlimbs and increased scores of m,anus and pes
Long-term dermal (Several months to lifetime) (Residential)	Dermal (or oral) study NOAEL = <10.0 mg/kg/day (Dermal absorption rate = 11.0% when appropriate)	LOC for MOE = 1,000 (residential)	Developmental toxicity -rat LOAEL = 10.0 mg/kg/day based on increased number of unossified odontoids, variations in occipitals and calcanea of hindlimbs and increased scores of m,anus and pes
Short-term inhalation (1 to 7 days) (Residential)	Inhalation (or oral) study NOAEL = <10.0 mg/kg/day (Inhalation absorption rate = 100%)	LOC for MOE = 1,000 (residential)	Developmental toxicity -rat LOAEL = 10.0 mg/kg/day based on increased number of unossified odontoids, variations in occipitals and calcanea of hindlimbs and increased scores of m,anus and pes

TABLE 1.—SUMMARY OF TOXICOLOGICAL DOSE AND ENDPOINTS FOR FLUTRIAFOL FOR USE IN HUMAN RISK ASSESSMENT—Continued

Exposure/Scenario	Dose used in risk assessment, UF	FQPA SF* and level of concern for risk assessment	Study and toxicological effects
Intermediate-term inhalation (1 week to several months) (Residential)	Inhalation (or oral) study NOAEL = <10.0 mg/kg/day (Inhalation absorption rate = 100%)	LOC for MOE = 1,000 (residential)	Developmental toxicity - rat LOAEL = 10.0 mg/kg/day based on increased number of unossified odontoids, variations in occipitals and calcanea of hindlimbs and increased scores of m,anus and pes
Long-term inhalation (several months to lifetime) (Residential)	Inhalation (or oral) study NOAEL = <10.0 mg/kg/day (inhalation absorption rate = 100%)	LOC for MOE = 1,000 (residential)	Developmental toxicity -rat LOAEL = 10.0 mg/kg/day based on increased number of unossified odontoids, variations in occipitals and calcanea of hindlimbs and increased scores of m,anus and pes
Cancer (oral, dermal, inhalation)	NA. not carcinogenic to humans based on the lack of evidence for carcinogenicity in mice and rats	NA	NA

* The reference to the FQPA SF refers to any additional safety factor retained. UF = uncertainty factor; FQPA SF = Special FQPA safety factor; NOAEL = no observed adverse effect level; LOAEL = lowest observed adverse effect level; PAD = population adjusted dose (a = acute, c = chronic); RfD = reference dose; MOE = margin of exposure; and LOC = level of concern.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses*. Flutriafol is a new pesticide ingredient for the U.S. Therefore, there are no existing tolerances for flutriafol in 40 CFR part 180. Based on the available residue data on soybeans, residues of flutriafol are not expected to exceed 0.10 ppm on soybeans that have been treated in accordance with the emergency exemption use directions. Risk assessments were conducted by EPA to assess dietary exposures from flutriafol 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 one day or single exposure. The Dietary Exposure Evaluation Model (DEEM™) analysis evaluated the individual food consumption as reported by respondents in the United States Department of Agriculture (USDA) Nationwide Continuing Surveys of Food Intake by Individuals (CSFII) and accumulated exposure to the chemical for each commodity. The following assumptions were made for the acute exposure assessments: An acute dietary exposure assessment was performed for females 13-49 years old using tolerance level residue, and 100 per cent treated (PCT) information for all soybean commodities. Dietary Exposure and Risk Assessment, DP#322530, J. Tyler, 3/30/06.

This assessment concludes that the acute dietary exposure estimates are below the Agency's level of concern (<100% aPAD) for the general U.S. population and all population subgroups.

ii. *Chronic exposure*. In conducting this chronic dietary exposure and risk assessment the DEEM™ analysis evaluated the individual food consumption as reported by respondents in the USDA Nationwide CSFII and accumulated exposure to the chemical for each commodity. The following assumptions were made for the chronic exposure assessments: A chronic dietary exposure assessment was performed for the general U.S. population and various population subgroups using tolerance level residue, and 100% CT information for all soybean commodities.

This assessment concludes that the chronic dietary exposure estimates are below the Agency's level of concern (<100% cPAD) for the general U.S. population and all population subgroups. The most highly exposed population subgroup is all infants (<1 year old) at 2.7% cPAD

iii. *Cancer*. Preliminary analysis of tumor data indicated a significant increased trend in combined adenomas and carcinomas in male rat liver tumors. However, there were no significant differences noted in pair-wise comparison with controls in either male or female liver tumors. Thus, based on lack of evidence of carcinogenicity in both rats and mice carcinogenicity studies, the chemical was considered as ''not likely'' to be carcinogenic to humans.

2. *Dietary exposure from drinking water*. This emergency exemption use of flutriafol is the first use for this fungicide in the U.S. As such, there are no monitoring exposure data for water for this ingredient. Thus, in this risk assessment, drinking water concentration estimates are made by reliance on simulation or modeling taking into account data on the physical characteristics of flutriafol. 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*.

The Pesticide Root Zone Model/Exposure Analysis Modeling System (PRZM/EXAMS) and (SCI-GROW) screening models were used to estimate surface water and ground water concentrations of flutriafol. Based on the PRZM/EXAMS and SCI-GROW models the estimated environmental concentrations (EECs) of flutriafol for acute exposures are estimated to be 4.0 µg/L for surface water and 2.0 µg/L for ground water. The EECs of flutriafol for chronic exposures are estimated to be 2.0 µg/L for surface water and 1.0µg/L 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 4.0 µg/L was used to assess the contribution to drinking water. For chronic dietary risk assessment, the water concentration of value 2.0 µg/L 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).

Flutriafol is not registered for use on any sites that would result in residential exposure.

4. *Cumulative effects from substances with a common mechanism of toxicity*. Section 408(b)(2)(D)(v) of the 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.''

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 flutriafol and any other substances Flutriafol is a member of the triazole-containing class of pesticides commonly referred to as the conazoles. Although conazoles act similarly in plants (fungi) by inhibiting ergosterol biosynthesis, there is not necessarily a relationship between their pesticidal activity and their mechanism of toxicity in mammals. Structural similarities do not constitute a common mechanism of toxicity. Evidence is needed to establish that the chemicals operate by the same, or essentially the same, sequence of major biochemical events (EPA, 2002). In conazoles, however, a variable pattern of toxicological responses is found. Some are hepatotoxic and hepatocarcinogenic in mice. Some induce thyroid tumors in rats. Some induce developmental, reproductive, and neurological effects in rodents. Furthermore, the conazoles produce a diverse range of biochemical events including altered cholesterol levels, stress responses, and altered DNA methylation. It is not clearly understood whether these biochemical events are directly connected to their toxicological outcomes. Thus, there is currently no evidence to indicate that conazoles share common mechanisms of toxicity and EPA is not following a cumulative risk approach based on a common mechanism of toxicity for the conazoles. For information regarding EPA's procedures for cumulating effects from substances found to have a common mechanism of toxicity, see EPA's website at *http://www.epa.gov/pesticides/cumulative/*.

Flutriafol is a triazole-derived pesticide. This class of compounds can form the common metabolite 1,2,4-triazole and two triazole conjugates (triazole alanine and triazole acetic acid). To support existing tolerances and to establish new tolerances for triazole-derivative pesticides. U.S. EPA conducted a human health risk assessment for exposure to 1,2,4-triazole, triazole alanine, and triazole acetic acid resulting from the use of all current and pending uses of any triazole-derived fungicide. The risk assessment is a highly conservative, screening-level evaluation in terms of hazards associated with common metabolites (e.g., use of a maximum combination of uncertainty factors) and potential dietary and non-dietary exposures (i.e., high end estimates of both dietary and non-dietary exposures). In addition, in assessing the risks for this group of chemicals the Agency retained the additional 10X FQPA safety factor for the protection of infants and children. The assessment includes evaluations of risks for various subgroups, including those comprised of infants and children. The Agency's complete risk assessment for the conazole group is found in the propiconazole reregistration docket at *http://www.regulations.gov*, Docket ID Number EPA–HQ–OPP–2005–0497.

D. Safety Factor for Infants and Children

1. *In general*. Section 408 of the FFDCA provides that EPA shall apply an additional tenfold margin of safety for infants and children in the case of threshold effects to account for pre-natal and post-natal toxicity and the completeness of the data base on toxicity and exposure unless EPA determines that a different margin of safety will be safe for infants and children. Margins of safety are incorporated into EPA risk assessments either directly through use of a MOE analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans.

2. *Pre-natal and post-natal sensitivity*. There is no evidence of increased susceptibility in the developmental study in rabbits or in the 2-generation reproduction study in the rat. Although some effects were seen in the rat developmental study, in the rat 2-generation reproduction toxicity study the effects occurred at the same dose that caused maternal toxicity indicating there was no increased susceptibility. These effects were considered to be study variations, and the Agency also retained the 10X safety factor to account for these variations due to the lack of a well defined NOAEL in the critical study. Therefore, there is no residual uncertainty for pre-natal and/or post-natal susceptibility. (See memo from Tyler, *et al*. dated March 30, 2006.

3. *Conclusion*. The Agency evaluated the quality of the hazard and exposure data and determined that based on the available hazard and exposure data, the FQPA SF should be retained.

E. Aggregate Risks and Determination of Safety

EPA conducted human-health risk assessments for acute and chronic dietary exposures (food and drinking water only). Because there are no uses of flutriafol that are expected to result in residential exposures, this aggregate risk assessment takes into consideration dietary food and drinking water exposure only. Therefore, the acute and chronic aggregate estimates would be the same as the dietary exposure results. All aggregate exposure and risk estimates are below EPA's level of concern.

1. *Acute risk*. Including the proposed use on soybeans, human-health risk assessments have been conducted for the following exposure scenarios: Acute and chronic dietary exposures (food and drinking water only). All aggregate exposure and risk estimates are below the Agency's level of concern. Because there are no uses of flutriafol that are expected to result in residential exposures, this aggregate risk assessment takes into consideration dietary food and drinking water exposure only. The acute (95th percentile) dietary exposure estimates are below HED's level of concern <100% aPAD for females 13-49 year old (10% aPAD).

2. *Chronic risk*. The chronic dietary exposures estimates are below HED's level of concern <100% chronic population adjusted dose (cPAD) for the general population and all population subgroups. The most highly-exposed population subgroup is all infants (<1 year old) at 2.7% cPAD:

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

4. *Aggregate cancer risk for U.S. population*. For this assessment, EPA has concluded that flutriafol is, ''not likely to be carcinogenic to humans.''

5. *Determination of safety*. Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, and to infants and children from aggregate exposure to flutriafol residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology (Method RAM 219/04) submitted by the registrant, (email from C. Rodia to J. Tyler, 3/23/06) is available to enforce

the tolerance expression. The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755–5350; telephone number: (410) 305–2905; e-mail address: *residuemethods@epa.gov*.

B. International Residue Limits

There are currently tolerances of 0.10 ppm for soybean in Brazil and South Africa.

V. Conclusion

Therefore, the tolerance is established for residues of flutriafol, in or on soybean at 0.10 ppm.

VI. Statutory and Executive Order Reviews

This final rule establishes a tolerance under section 408(d) of FFDCA 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 rule has been exempted from review under Executive Order 12866, this rule is not subject to Executive Order 13211, *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 on the basis of a petition under section 408(d) of FFDCA, 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 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 section 408(n)(4) of FFDCA. 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 6, 2000) do not apply to this rule. In addition, This 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) (Public Law 104–4).

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), Public Law 104–113, section 12(d) (15 U.S.C. 272 note).

VII. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report to each House of the Congress and to the Comptroller General of the United States. 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 this final rule in the **Federal Register**. This final rule is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

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

Dated: August 22, 2007.

Martha Monell,

Acting Director, Office 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. Section 180.629 is added to read as follows:

§ 180.629 Flutriafol; tolerance for residues.

(a) *General*. [Reserved]

(b) *Section 18 emergency exemptions*. Time-limited tolerances specifed in the above table are established for residues of the fungicide flutriafol *per se* (2,4'-difluoro-α-(1H -1,2,4-triazol-1-yl-methyl)-benzhydryl alcohol) in or on the specified agricultural commodities, resulting from use of the pesticide pursuant to section 18 emergency exemptions. The tolerances expire and are revoked on the date specified in the following table.

	Parts per million	Expiration/revocation date
Soybean	0.10	December 31, 2010

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[FR Doc. E7–17112 Filed 8–28–07; 8:45 am]

BILLING CODE 6560–50–S

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

46 CFR Parts 67 and 68

[USCG–2005–20258]

RIN 1625–AA95

Vessel Documentation: Lease Financing for Vessels Engaged in the Coastwise Trade

AGENCY: Coast Guard, DHS.

ACTION: Final rule; announcement of effective date for collection of information requirements.

SUMMARY: In the final rule with this same title published October 18, 2006, we noted that the Office of Management and Budget (OMB) had not approved a collection-of-information associated with the amendments by §§ 68.65, 68.70, 68.75, 68.100, 68.107, and 68.109, to the collection-of-information requirements for vessel owners and charterers applying to engage in the coastwise trade under the lease financing provisions of 46 U.S.C. 12119 (formerly 46 U.S.C. 12106(e)). OMB has since approved that collection-of-information and the portions of the rule with these requirements are effective August 29, 2007.

DATES: *Effective Date:* The amendments to 46 CFR 68.65, 68.70, 68.75, 68.100, 68.107, and 68.109, as published in the **Federal Register** on October 18, 2006 (71 FR 61413) are effective August 29, 2007.

FOR FURTHER INFORMATION CONTACT: If you have questions on this document, call Patricia Williams, Deputy Director, National Vessel Documentation Center, U.S. Coast Guard, telephone 304–271–2506. If you have questions on viewing the docket (USCG–2005–20258), call Renee V. Wright, Program Manager, Docket Operations, telephone 202–493–0402.

SUPPLEMENTARY INFORMATION: A final rule concerning applications to engage in the coastwise trade under the lease financing provisions of 46 U.S.C. 12119 became effective on November 17, 2006, with the exception of the collection of information requirements in the amendments to 46 CFR 68.65, 68.70, 68.75, 68.100, 68.107, and 68.109. Title 46 CFR 68.65 requires a vessel owner who seeks an initial, or renewal of, coastwise endorsement, to submit a certification of ownership in writing to the Director of the NVDC. 46 CFR 68.70 requires an owner of a vessel other than a barge qualified to engage in coastwise trade under the lease financing provisions of 46 U.S.C. 12119 to submit a certified application for the coastwise operation of a vessel under a demise charter. 46 CFR 68.75 requires an owner of a barge qualified to engage in coastwise trade under the lease financing provisions of 46 U.S.C. 12119 to submit certifications and documents supporting an application for the coastwise operation of a barge under a demise charter. 46 CFR 68.100 sets out applicability provisions and phase-in dates. 46 CFR 68.107 requires an owner of a vessel other than a barge qualified to engage in coastwise trade under the lease financing provisions of 46 U.S.C. 12119 to submit certifications, certain supporting documents, and a certified application for the coastwise operation of a vessel under a demise charter. 46 CFR 68.109 requires an owner of a barge qualified to engage in coastwise trade under the lease financing provisions of 46 U.S.C. 12119 to submit certifications, certain supporting documents, and a certified application for the coastwise operation of a vessel under a demise charter.

The final rule that contained the provisions for these certifications, supporting documents and applications was published in the **Federal Register** on October 18, 2006 (71 FR 61413), and is available electronically through the docket (USCG–2005–20258) at *http://dms.dot.gov/.* As required by 44 U.S.C. 3507(d), we submitted a copy of the final rule to OMB for its review. On January 10, 2007, after reviewing the rule, OMB approved the collection-of-information required in §§ 68.65, 68.70, 68.75, 68.100, 68.107, and 68.109 of the final rule under OMB control number 1625–0027.

Dated: August 22, 2007.

J.G. Lantz,

Acting Assistant Commandant for Prevention, U.S. Coast Guard.

[FR Doc. E7–17075 Filed 8–28–07; 8:45 am]

BILLING CODE 4910–15–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[DA 07–3556; MB Docket No. 07–79; RM–11362]

Radio Broadcasting Service; Dinosaur, CO

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: The Audio Division grants a petition for rule making filed by Cumulus Licensing LLC (''Petitioner'') to allot Channel 262C0 at Dinosaur, Colorado. Channel 262C0 can be allotted at Dinosaur in compliance with the Commission's minimum distance separation requirements at 40–03–26 North Latitude and 108–39–46 West Longitude with a site restriction of 36.4 kilometers (22.6 miles) southeast of the community's reference. A filing window for Channel 262C0 at Dinosaur, Colorado will not be opened at this time. Instead, the issue of opening a filing window for this channel will be addressed by the Commission in a subsequent order.

DATES: Effective September 24, 2007.

ADDRESSES: Secretary, Federal Communications Commission, 445 Twelfth Street, SW., Washington, DC 20554.

FOR FURTHER INFORMATION CONTACT: Helen McLean, Media Bureau, (202) 418–2738.

SUPPLEMENTARY INFORMATION: This is a synopsis of the Commission's *Report and Order,* MB Docket No. 07–79, adopted August 8, 2007, and released August 10, 2007. The full text of this Commission decision is available for inspection and copying during regular business hours at the FCC's Reference Information Center, Portals II, 445 Twelfth Street, SW., Room CY–A257, Washington, DC 20554. The complete text of this decision may also be purchased from the Commission's duplicating contractor, Best Copy and Printing, Inc., 445 12th Street, SW., Room CY–B402, Washington, DC 20554, telephone 1–800–378–3160 or *www.BCPIWEB.com.* The Commission will send a copy of this *Report and Order* in a report to be sent to Congress and the Government Accountability Office pursuant to the Congressional Review Act, *see* 5 U.S.C. 801(a)(1)(A).

List of Subjects in 47 CFR Part 73

Radio, Radio broadcasting.