

**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 17, 2007.

**Lois Rossi,**

*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. Section 180.495 is amended by alphabetically adding the following commodities to the table in paragraph (a) to read as follows:

**§ 180.495 Spinosad; tolerances for residues.**

(a) \* \* \*

Commodity	Parts per million	Expiration/Revocation Date
Fish .....	4.0	* None
Fish-shellfish, crustacean .....	4.0	* None
Fish-shellfish, mollusc .....	4.0	* None

\* \* \* \* \*

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**ENVIRONMENTAL PROTECTION AGENCY**

**40 CFR Part 180**

[EPA-HQ-OPP-2007-0428; FRL-8138-6]

**Flusilazole; Pesticide Tolerances for Emergency Exemptions**

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

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes time-limited tolerances for residues of flusilazole in or on soybean seed, soybean aspirated grain fractions, and soybean oil. This action is in response to EPA’s granting of emergency exemptions under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) authorizing use of the pesticide on soybeans. This regulation establishes maximum permissible levels for residues of flusilazole in these food commodities. The tolerances expire and are 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-2007-0428. 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 Office of Pesticide Programs (OPP) Regulatory Public Docket in Rm. S-4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The hours of operation of this Docket Facility are 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:** Andrea Conrath, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 308-9356; e-mail address: [conrath.andrea@epa.gov](mailto:conrath.andrea@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-2007-0428 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-2007-0428, 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, is establishing tolerances for residues of the fungicide flusilazole, (1-[[bis(4-

fluorophenyl)methylsilyl]methyl]-1H-1,2,4-triazole), in or on soybean seed at 0.04 parts per million (ppm), soybean aspirated grain fractions at 2.6 ppm, and soybean oil at 0.10 ppm. These tolerances expire and are revoked on December 31, 2010. EPA will publish a document in the **Federal Register** to remove the revoked tolerances from the Code of Federal Regulations (CFR).

Section 408(l)(6) of the 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 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 (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. . . ."

Section 18 of the 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." This provision was not amended by the Food Quality Protection Act of 1996 (FQPA). EPA has established regulations governing such emergency exemptions in 40 CFR part 166.

## III. Emergency Exemption for Flusilazole on Soybeans and FFDCA Tolerances

Australasian soybean rust (SBR) is a plant disease caused by 2 fungal species, *Phakopsora pachyrhizi* and *P. meibomia*, and is spread primarily by windborne spores that can be transported over long distances. SBR models suggest that most of the soybean acreage in the U.S. could be compromised by an SBR epidemic. In accordance with the 2002 Agricultural Bioterrorism Protection Act, SBR was identified by the United States Department of Agriculture (USDA) as a select biological agent with the potential to pose a severe threat to the soybean industry and livestock production, in general. As such, USDA has invested in extensive readiness and outreach activities among soybean producers. EPA has authorized under FIFRA section 18 the use of flusilazole on soybeans for control of Australasian Soybean Rust in Minnesota and South Dakota. After having reviewed the states' submissions, EPA concurs that emergency conditions exist for these States.

As part of its assessment of these emergency exemptions, EPA assessed the potential risks presented by residues of flusilazole in or on soybean seed, aspirated grain fractions, and oil. In doing so, EPA considered the safety standard in section 408(b)(2) of the FFDCA, and EPA decided that the necessary tolerances under section 408(l)(6) of the FFDCA 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 these tolerances without notice and opportunity for public comment as provided in section 408(l)(6) of the FFDCA. Although these tolerances expire and are 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 tolerances remaining in or on soybean seed, aspirated grain fractions, and oil 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 levels that were authorized by these tolerances at the time of that application. EPA will take action to revoke these 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 tolerances are being approved under emergency conditions, EPA has not made any decisions about whether flusilazole meets EPA's registration requirements for use on soybean or whether permanent tolerances for this use would be appropriate. Under these circumstances, EPA does not believe that these tolerances serve as the basis for registration of flusilazole by a State for special local needs under FIFRA section 24(c). Nor do these tolerances serve as the basis for use of this pesticide on this crop under section 18 of FIFRA by any State 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 flusilazole, 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 flusilazole and to make a determination on aggregate exposure, consistent with section 408(b)(2) of the FFDCA, for time-limited tolerances for residues of flusilazole in or on soybean seed at 0.04 ppm, soybean aspirated grain fractions at 2.6 ppm, and soybean oil at 0.10 ppm. EPA's assessment of the dietary exposures and risks associated with establishing the tolerances follows.

##### A. Toxicological Endpoints

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 endpoint. However, the lowest dose at which adverse effects of concern are identified (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. An UF of 100 is routinely used, 10X to account for interspecies differences and 10X for intraspecies differences.

For dietary risk assessment (other than cancer) the Agency uses the UF to calculate an acute or chronic reference dose (acute RfD or chronic RfD) where the RfD is equal to the NOAEL divided by the appropriate UF (RfD = NOAEL/UF). Where an additional safety factor is applied in order to protect infants and children, this additional factor is applied to the RfD by dividing the RfD by such additional factor. The acute or chronic Population Adjusted Dose (aPAD or cPAD) is a modification of the RfD to accommodate this type of FQPA SF.

For non-dietary risk assessments (other than cancer) the UF is used to determine the level of concern (LOC). For example, when 100 is the appropriate UF (10X to account for interspecies differences and 10X for intraspecies differences) the LOC is 100. To estimate risk, a ratio of the NOAEL to exposures (margin of exposure (MOE) = NOAEL/exposure) is calculated and compared to the LOC.

The linear default risk methodology (Q\*) is the primary method currently used by the Agency to quantify carcinogenic risk. The Q\* approach assumes that any amount of exposure will lead to some degree of cancer risk. A Q\* is calculated and used to estimate risk which represents a probability of occurrence of additional cancer cases (e.g., risk is expressed as  $1 \times 10^6$  or one in a million). Under certain specific circumstances, 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 ( $MOE_{\text{cancer}} = \text{point of departure/exposures}$ ) is calculated.

A summary of the toxicological endpoints for flusilazole used for human risk assessment is discussed in Table 2.3 on page 15 of the human health risk assessment found at <http://www.regulations.gov> Docket No. EPA-HQ-OPP-2007-0428-0001.

##### B. Exposure Assessment

1. *Dietary exposure from food and feed uses.* There are currently no tolerances established for this chemical, and it is not registered in the US. Risk assessments were conducted by EPA to

assess dietary exposures from flusilazole in food as follows:

i. *Acute exposure.* Acute dietary 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. EPA used the Dietary Exposure Evaluation Model (DEEM™) and data on individual food consumption as reported by respondents in the USDA 1994–1996 and 1998 nationwide Continuing Surveys of Food Intake by Individuals (CSFII) to estimate exposure to the chemical for each commodity. This acute risk assessment used conservative and high end assumptions to estimate acute exposure and risk, as follows: It was assumed that flusilazole residues in soybean commodities would be at proposed tolerance levels or higher; default processing factors were applied to account for effects that may occur on flusilazole residues from processing into soybean oil; an additional factor was incorporated to account for potential residues of the metabolite of flusilazole, which may occur in soybean commodities; and it was assumed that 100% of the soybean crop grown in the US would be treated. No refinements such as incorporating anticipated residue values or percent of crop treated (PCT) assumptions were used. A high-end estimate for contribution to dietary exposure from residues occurring in drinking water, was incorporated directly into the dietary assessment using the 30-year average annual concentration for surface water generated by the Agency's computer simulation, the Pesticide Root Zone/Exposure Analysis Modeling System (PRZM-EXAMS).

ii. *Chronic exposure.* In conducting this chronic dietary risk assessment EPA used the DEEM™ and data on individual food consumption as reported by respondents in the USDA 1994–1996 and 1998 nationwide CSFII to estimate exposure to the chemical for each commodity. The chronic risk assessment also used the same conservative and high-end assumptions as described above in Unit IV.B.1.i., for calculation of the acute exposure estimates and risk.

iii. *Cancer.* The cancer risk assessment incorporated the same dietary exposure estimates as used for the chronic assessment, and used conservative and high-end assumptions to calculate cancer risk estimates over a lifetime of exposure, as described above in Unit IV.B.1.i.

2. *Dietary exposure from drinking water.* Since this exemption is the only use of a new pesticide in the US, there

are no residues in drinking water, and thus there are no monitoring exposure data to use for a comprehensive dietary exposure analysis and risk assessment for flusilazole in drinking water.

Because of this, the Agency calculated drinking water concentration estimates which may occur from this use, by reliance on simulation or modeling taking into account data on the physical characteristics of flusilazole.

None of the models include consideration of the impact processing (mixing, dilution, or treatment) of raw water for distribution as drinking water would likely have on the removal of pesticides from the source water. The primary use of these models by the Agency at this stage is to provide a coarse screen for sorting out pesticides for which it is highly unlikely that drinking water concentrations would ever exceed human health LOC.

Based on available data, and for this section 18 use only, the Agency determined that the residue of concern for drinking water is flusilazole *per se*. Some surface and ground water contamination may occur based on the proposed application rates and the environmental fate properties of flusilazole, although mobility in soil is expected to be low.

Based on Tier II screening-level surface water modeling for drinking water, the Agency estimated concentrations in surface water to be used for acute, chronic non-cancer, and cancer exposure assessment. Tier II surface water concentrations for parent flusilazole were calculated using PRZM-EXAMS. PRZM/EXAMS incorporates an index reservoir environment and includes a percent crop area factor as an adjustment to account for the maximum percent crop coverage within a watershed or drainage basin. EPA used the Screening Concentration Ground Water (SCI-GROW2) model to estimate ground water concentrations. These results for both surface and ground water are consistent with the fate and transport properties of flusilazole.

Modeled estimates of drinking water concentrations were incorporated directly into the dietary assessments using the estimated drinking water concentrations (EDWC) for surface water generated by the PRZM-EXAMS model. For the acute assessment, the peak concentration of 1.81 parts per billion (ppb) was used to assess the contribution to surface drinking water; for the chronic assessment, the annual mean value of 0.92 ppb was used to assess the contribution to surface drinking water. The EDWC for groundwater was estimated by SCI-GROW2 at 0.05 ppb. Since the EDWC

estimated by SCI-GROW2 for groundwater was lower, at 0.05 ppb, the higher, more conservative, surface water estimate of 1.81 ppb was used for assessing contribution to dietary exposures.

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). Flusilazole 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."

Flusilazole is a member of the triazole-containing class of pesticides. Although triazole pesticides act similarly in plants (fungi) by inhibiting ergosterol biosynthesis, there is not necessarily a relationship between this 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 triazoles 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 triazoles 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 triazoles share common mechanisms of toxicity and EPA is not following a cumulative risk approach based on a common mechanism of toxicity for the triazole pesticides. 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>.

Flusilazole is a triazole-derived pesticide. This class of compounds can form the common metabolites 1,2,4-

triazole conjugates (triazole alanine and triazole acetic acid). To support existing tolerances and to establish new tolerances for triazole-derived pesticides, 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 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, on the assessment involving the 1,2,4-triazole metabolites, 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 may be found at <http://www.epa.gov/oppr001/factsheets/tetraHHRA.pdf>.

In that risk assessment, EPA concluded that, based upon the available information and on conservative estimates of hazard and exposure, there are no human health risk issues associated with 1,2,4-triazole or its metabolites that would preclude re-registration of the triazole-derivative fungicides registered to date or conditional registrations of the triazole-derivative fungicides that have been proposed as of September 1, 2005, which included the use of flusilazole on soybean.

### C. 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 prenatal and postnatal 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. *Developmental and Reproductive toxicity studies.* There are several developmental and 2-generation reproduction studies in rats and rabbits that provide evidence of increased susceptibility to in utero and/or pre-, postnatal exposure to flusilazole.

Developmental effects such as cleft palate, resorption and skeletal malformations were observed in rats. In rabbits, increased resorptions were observed. In both species, these effects occurred either in the absence of maternal toxicity and/or at a dose that caused only marginal maternal toxicity (decreased food consumption, body weight gain). In a multi-generation reproduction study in rats a decrease in pup viability at birth and decreased post-natal survival were observed either in the absence of maternal toxicity and/or at a dose that caused only marginal maternal toxicity.

3. *Prenatal and postnatal sensitivity.* The evidence of increased susceptibility observed in rats and rabbits is off-set because EPA has set the acute (0.02 milligrams/kilograms (mg/kg) and chronic (0.002 mg/kg) RfDs below the dose at which these developmental effects were observed, and these are therefore protective with respect to these effects. Although NOAELs were not identified in some developmental and 2-generation reproduction studies, there are well established NOAELs in most of the developmental and 2-generation reproduction studies, and the RfDs are below these NOAELs. Because EPA has set the RfDs well below the levels at which developmental effects are observed, the increased susceptibility seen in these studies does not warrant retaining the 10X FQPA safety factor (i.e., it is 1X).

4. *Conclusion.* For the purpose of this emergency quarantine exemption, EPA relied on studies reviewed by the European Union as well as some preliminary internal study reviews. Therefore, the stated toxicological endpoints are applicable for this emergency section 18 use only, since upon detailed review of the new and existing data, the final conclusions may change. EPA determined that, in terms of hazard, there are low concerns and no residual uncertainties with regard to pre-and/or post-natal toxicity. EPA determined that the FQPA 10X safety factor to protect infants and children should be removed (reduced to 1X) based on the following:

i. The toxicity database for flusilazole is complete.

ii. The dietary food exposure assessment utilizes proposed tolerance-level or higher residues and 100% CT information for all commodities. By using these screening-level assessments, acute and chronic exposures/risks will not be underestimated.

iii. The dietary drinking water assessment (Tier 2 estimates) utilizes values generated by model and associated modeling parameters which are designed to provide conservative, health-protective, high-end estimates of water concentrations.

iv. There are no residential uses of flusilazole.

*D. Aggregate Risks and Determination of Safety*

The Agency currently has two ways to estimate total aggregate exposure to a pesticide from food, drinking water, and residential uses. First, a screening assessment can be used, in which the Agency calculates drinking water levels of comparison (DWLOCs), which are used as a point of comparison against estimated drinking water concentrations (EDWCs). The DWLOC values are not regulatory standards for drinking water, but are theoretical upper limits on a pesticide's concentration in drinking water in light of total aggregate exposure to a pesticide in food and residential uses. More information on the use of DWLOCs in dietary aggregate risk assessments can be found at <http://www.epa.gov/oppfead1/trac/science/screeningsop.pdf>.

More recently, the Agency has used another approach to estimate aggregate exposure through food, residential and drinking water pathways. In this approach, modeled surface water and ground water EDWCs are directly incorporated into the dietary exposure analysis, along with food. This approach provides a more realistic estimate of exposure because actual body weights and water exposures are then added to estimates and water consumption from the CSFII are used. The combined food and water exposures are then added to estimated exposure from residential sources to calculate aggregate risks. The resulting exposure and risk estimates are still considered to be high end, due to the assumptions used in developing

drinking water modeling inputs. The risk assessment for flusilazole used in this tolerance document uses this approach of incorporating water exposure directly into the dietary exposure analysis.

There are no registered or proposed uses of flusilazole, which result in residential exposures, so the aggregate exposure assessment required by FFDCA section 408(b)(2)(D)(vi) consists solely of dietary (food + drinking water) exposures.

Aggregate exposure risk assessments were conducted by incorporating the drinking water concentrations directly into the dietary exposure assessment for the acute and chronic aggregate exposures (food + drinking water). These aggregate exposures do not exceed the Agency's LOC since they were less than 100% of the acute and chronic population adjusted doses (PADs).

1. *Acute risk.* Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food and drinking water to flusilazole is estimated at 0.000326 mg/kg/day, and occupies 1.6% of the aPAD for females 13–49 years, the population subgroup of concern. There were no acute toxicity concerns for other population subgroups noted, based upon the available toxicology studies, and therefore, no acute toxicology endpoints assigned. Therefore, EPA does not expect aggregate dietary exposure for this population subgroup of concern to exceed the LOC of 100% of the aPAD.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to flusilazole from food and water will utilize 8.1% of the cPAD for the U.S. population, 21% of the cPAD for All Infants <1 year old (the most highly exposed subpopulation), and 17% of the cPAD for Children 1–2 years old, and Children 3–5 years old (both subgroups). Flusilazole is unregistered, and therefore there are no residential uses or exposures. EPA does not expect the aggregate exposure to exceed 100% of the cPAD, as shown in the following Table of this unit:

**AGGREGATE RISK ASSESSMENT FOR CHRONIC (NON-CANCER) DIETARY (FOOD + WATER) EXPOSURE TO FLUSILAZOLE**

Population Subgroup	Dietary exposure (mg/kg/day)	% cPAD utilized
General U.S. Population .....	0.000162	8.1
All Infants (< 1 year old) .....	0.000429	21
Children 1–2 years old .....	0.000334	17

AGGREGATE RISK ASSESSMENT FOR CHRONIC (NON-CANCER) DIETARY (FOOD + WATER) EXPOSURE TO FLUSILAZOLE—  
Continued

Population Subgroup	Dietary exposure (mg/kg/day)	% cPAD utilized
Children 3–5 years old .....	0.000338	17
Children 6–12 years old .....	0.000243	12
Youth 13–19 years old .....	0.000161	8.0
Adults 20–49 years old .....	0.000143	6.7
Adults 50+ years old .....	0.000110	5.5
Females 13–49 years old	0.000128	6.4

3. *Short-term and intermediate risks.* Short-term and intermediate aggregate exposures take into account residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Flusilazole is not registered for use on any sites that would result in residential exposure. Therefore, the aggregate risk is the sum of the risk from food and water, which were previously addressed.

4. *Aggregate cancer risk for U.S. population.* In its cancer analysis, EPA assumed 100% of the soybean crop in the US would be treated with flusilazole. EPA used the DEEM 7.81 default processing factors to estimate residues that might occur in processed commodities (i.e. soybean oil) and assumed that flusilazole residues in or on soybean commodities would be equal to the proposed tolerance levels. Drinking water was incorporated directly into the dietary assessment using the 30-year average annual concentration for surface water generated by the PRZM-EXAMS model as a high-end estimate. The resulting cancer risk estimate for the general U.S. population ( $4.5 \times 10^{-7}$ ) was less than EPA's LOC (generally  $1 \times 10^{-6}$ ).

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 flusilazole residues.

**V. Other Considerations**

*A. Analytical Enforcement Methodology*

Adequate enforcement methodologies (gas chromatography/nitrogen-phosphorus detector; and gas chromatography/mass-selective detector) are available to enforce the tolerance expression. The methods may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755–5350; telephone

number: (410) 305–2905; e-mail address: *residuemethods@epa.gov*.

*B. International Residue Limits*

There are no Codex, Canadian, or Mexican maximum residue limits (MRLs) for the residues of flusilazole on soybean commodities. Therefore, there are no international harmonization concerns at this time.

**VI. Conclusion**

Therefore, the tolerances are established for residues of flusilazole, (1-[[bis(4-fluorophenyl)methylsilyl]methyl]-1H-1,2,4-triazole), in or on soybean seed at 0.04 parts per million (ppm), soybean aspirated grain fractions at 2.6 ppm, and soybean oil at 0.10 ppm.

**VII. Statutory and Executive Order Reviews**

This final rule establishes tolerances 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 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 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).

**VIII. 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 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]

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**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](mailto: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