

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: September 21, 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 180.463 is amended by alphabetically adding the following commodities to the table in paragraph (a) to read as follows:

§ 180.463 Quinclorac; tolerances for residues.

(a) * * *

Commodity	Parts per million
Barley, grain	2.0
* * * * *	* * *

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[FR Doc. E7-19227 Filed 9-27-07; 8:45 am]

BILLING CODE 6560-50-S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2006-0993; FRL-8148-4]

Florasulam; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a tolerance for florasulam in or on barley, grain at 0.01 ppm, barley, hay at 0.05 ppm, barley straw at 0.05 ppm, oat, grain at 0.01 ppm, oat, forage at 0.05 ppm, oat, hay at 0.05 ppm, oat, straw at 0.05 ppm, rye, grain at 0.01 ppm, rye, forage at 0.05 ppm, rye, straw at 0.05 ppm, wheat, grain at 0.01 ppm, wheat, forage at 0.05 ppm, wheat, hay at 0.05 ppm, and wheat, straw at 0.05 ppm. Dow AgroSciences LLC requested this tolerance under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective September 28, 2007. Objections and requests for hearings must be received

on or before November 27, 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-2006-0993. 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](http://www.regulations.gov) website to view the docket index or access available documents. All documents in the docket are listed in the docket index available in [regulations.gov](http://www.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 in the electronic docket at <http://www.regulations.gov>, or, if only available in hard copy, at the OPP Regulatory 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: Joanne I. Miller, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 305-6224; e-mail address: miller.joanne@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 those engaged in the following activities:

- Crop production (NAICS code 111), e.g., agricultural workers; greenhouse, nursery, and floriculture workers; farmers.
- Animal production (NAICS code 112), e.g., cattle ranchers and farmers, dairy cattle farmers, livestock farmers.
- Food manufacturing (NAICS code 311), e.g., agricultural workers; farmers;

greenhouse, nursery, and floriculture workers; ranchers; pesticide applicators.

- Pesticide manufacturing (NAICS code 32532), e.g., agricultural workers; commercial applicators; farmers; greenhouse, nursery, and floriculture workers; residential users.

This listing is not intended to be exhaustive, but rather to provide 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 EPA's tolerance regulations at 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 FFDCA, 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-2006-0993 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 as required by 40 CFR part 178 on or before November 27, 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 this copy, identified by docket ID number EPA-

HQ-OPP-2006-0993, 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. Petition for Tolerance

In the **Federal Register** of January 24, 2007 (72 FR 3132) (FRL-8110-9), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 6F7061) by Dow AgroSciences, LLC, 9330 Zionsville Road, Indianapolis, IN 46268. The petition requested that 40 CFR part 180 be amended by establishing a tolerance for residues of the herbicide florasulam N-(2,6-difluorophenyl)-8-fluoro-5-methoxy(1,2,4)triazolo(1,5-c)pyrimidine-2-sulfonamide, in or on barley, grain at 0.01 parts per million (ppm), barley, forage at 0.05 ppm, barley, hay at 0.05 ppm, barley straw at 0.05 ppm, oats, grain at 0.01 ppm, oats, forage at 0.05 ppm, oats, hay at 0.05 ppm, oats, straw at 0.05 ppm, rye, grain at 0.01 ppm, rye, forage at 0.05 ppm, rye, hay at 0.05 ppm, rye, straw at 0.05 ppm, triticale, grain at 0.01 ppm, triticale, forage at 0.05 ppm, triticale, hay at 0.05 ppm, triticale, straw at 0.05 ppm, wheat, grain at 0.01 ppm, wheat, forage at 0.05 ppm, wheat, hay at 0.05 ppm, and wheat, straw at 0.05 ppm. That notice referenced a summary of the petition prepared by Dow AgroSciences, LLC, the registrant, which is available to the public in the docket, <http://www.regulations.gov>. Comments were received on the notice of filing. B. Sachau commented that there are health implications listed for this chemical and a new pesticide should not be approved because the safety tests required by the EPA are insufficient. EPA's response to these comments is discussed in Unit IV.C. of this document.

EPA is not establishing the proposed tolerances for barley, forage and rye, hay because EPA does not consider these

items to be significant food commodities as noted in Table 1 of the OPPTS 860 guidelines. EPA is also not establishing the proposed tolerances for triticale. Triticale is covered by the tolerance for wheat as specified in 40 CFR 180.1(g).

III. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is "safe." Section 408(b)(2)(A)(ii) of FFDCA defines "safe" to mean that "there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information." This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to "ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue...." These provisions were added to FFDCA by the Food Quality Protection Act (FQPA) of 1996.

Consistent with FFDCA section 408(b)(2)(D), and the factors specified in FFDCA section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for the petitioned-for tolerance for residues of florasulam, N-(2,6-difluorophenyl)-8-fluoro-5-methoxy(1,2,4)triazolo(1,5-c)pyrimidine-2-sulfonamide, on barley, grain at 0.01 ppm, barley, hay at 0.05 ppm, barley, straw at 0.05 ppm, oat, grain at 0.01 ppm, oat, forage at 0.05 ppm, oat, hay at 0.05 ppm, oat, straw at 0.05 ppm, rye, grain at 0.01 ppm, rye, forage at 0.05 ppm, rye, straw at 0.05 ppm, wheat, grain at 0.01 ppm, wheat, forage at 0.05 ppm, wheat, hay at 0.05 ppm, and wheat, straw at 0.05 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 adverse effects caused by florasulam as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies can be found at <http://www.regulations.gov>. The human health risk assessment document is available in the docket established by this action, which is described under **ADDRESSES**, and is identified as EPA-HQ-OPP-2006-0993 in that docket.

B. Toxicological Endpoints

For hazards that have a threshold below which there is no appreciable risk, the toxicological level of concern (LOC) is derived from the highest dose at which no adverse effects are observed (the NOAEL) in the toxicology study identified as appropriate for use in risk assessment. However, if a NOAEL cannot be determined, the lowest dose at which adverse effects of concern are identified (the LOAEL) is sometimes used for risk assessment. Uncertainty/safety factors (UFs) are used in conjunction with the LOC to take into account 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. Safety is assessed for acute and chronic risks by comparing aggregate exposure to the pesticide to the acute population adjusted dose (aPAD) and chronic population adjusted dose (cPAD). The aPAD and cPAD are calculated by dividing the LOC by all applicable UFs. Short-, intermediate-, and long-term risks are evaluated by comparing aggregate exposure to the LOC to ensure that the margin of exposure (MOE) called for by the product of all applicable UFs is not exceeded.

For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk and estimates risk in terms of the probability of occurrence of additional adverse cases. Generally, cancer risks are considered non-threshold. 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/fedrgstr/EPA-PEST/1997/November/Day-26/p30948.htm>.

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

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

Exposure/Scenario	Point of Departure	Uncertainty Factors/ FQPA Safety Factors/ RfD, PAD, Level of Concern for Risk Assessment	Study and Toxicological Effects
Acute dietary (Females 13–49 years of age)	N/A	N/A	No appropriate endpoint identified.
Acute dietary (General population including infants and children)	N/A	N/A	No appropriate endpoint identified. The effects observed in an acute neurotoxicity study were seen at a very high dose 2,000 mg/kg/day) that is considered not applicable to human exposure.
Chronic dietary (All populations)	NOAEL= 5 mg/kg/day	UF _A = 10X UF _H = 10X I FQPA SF = 1X cPAD = 0.05 mg/kg/day	Chronic toxicity – dogs. LOAEL = 50 mg/kg/day, based on decreased body weights (17%), body weight gains (68%), and food consumption in the females; adverse liver alterations; slight vacuolation of the zona reticularis and zona fasciculate in the adrenal gland (fatty change) in both sexes.
Short-term dermal (1 to 30 days) (Residential)	N/A	N/A	No appropriate endpoint identified. 28–day dermal toxicity study – rats. LOAEL = not determined, no systemic effect up to the limit dose of 1,000 mg/kg/day.
Inhalation Short-term (1-30 days)	NOAEL = 5 mg/kg/day IAF = 100%	UF _A = 10X UF _H = 10X FQPA SF = 1X Residential LOC for MOE = 100 (Residential)	90–day oral toxicity – dogs. LOAEL = 50 mg/kg/day based on increased incidence/severity of hepatic vacuolation in both sexes.
Cancer (oral, dermal, inhalation)	“Not likely to be Carcinogenic to Humans”		

NOAEL = no observed adverse effect level. LOAEL = lowest observed adverse effect level. UF = uncertainty factor. UFA = extrapolation from animal to human (interspecies). UFH = potential variation in sensitivity among members of the human population (intraspecies). FQPA SF = FQPA Safety Factor. PAD = population adjusted dose (a = acute, c = chronic). RfD = reference dose. N/A = not applicable. LOC = level of concern. MOE = margin of exposure.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to florasulam, EPA considered exposure under the petitioned-for tolerances. EPA assessed dietary exposures from florasulam in food as follows:

i. *Acute exposure.* Quantitative acute dietary exposure and risk assessments are performed for a food-use pesticide, if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1–day or single exposure.

No such effects were identified in the toxicological studies for florasulam; therefore, a quantitative acute dietary exposure assessment is unnecessary.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the Dietary Exposure Evaluation Method (DEEM-FCID) and the food consumption data from the USDA 1994–1996, and 1998 CSFII. As to residue levels in food, EPA assumed all foods for which there are tolerances were treated and contain tolerance-level residues.

iii. *Cancer.* There were no treatment-related tumors observed in carcinogenicity studies in rats and mice. Because EPA has concluded that florasulam is not a carcinogen, a cancer exposure assessment was not needed.

iv. *Anticipated residue and percent crop treated (PCT) information.* The chronic analyses assumed tolerance level residues, 100% crop treated (CT), and DEEM™ default processing factors

for all registered and proposed commodities. For those processed commodities in the DEEM-FCID™ residue list which were not in DEEM™, a processing factor of 1 was assumed.

2. *Dietary exposure from drinking water.* The Agency lacks sufficient monitoring data to complete a comprehensive dietary exposure analysis and risk assessment for florasulam in drinking water. Because the Agency does not have comprehensive monitoring data, drinking water concentration estimates are made by reliance on simulation or modeling taking into account data on the environmental fate characteristics of florasulam. 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 5-OH degradate formed by demethylation of florasulam is by far the predominant environmental residue reaching maximum levels of 70% of applied material in the hydrolysis and metabolism (soil, aquatic) studies. This degradate is assumed to be of comparable toxicity to the parent. On this basis, the residues of concern in drinking water are the parent and 5-OH degradate. The Agency determined separate estimated drinking water concentrations (EDWCs) for these two compounds using FIRST (FQPA Index Reservoir Screening Tool) and SCI-GROW2 (Screening Concentration in Ground Water) models.

The modeled water residues were incorporated in the DEEM-FCID into the food categories "water, direct, all sources" and "water, indirect, all sources." To arrive at the total EDWC, the maximum chronic surface water value for the parent was added to the maximum chronic surface water value for the major degradate. For the parent, the chronic aerial spray value (16.8 ppTr) was higher than the ground spray value. For the degradate, the ground spray value was the higher of the two (217.5 ppTr). Adding the 2 values (16.8 + 217.5) results in the total chronic EDWC of 234 ppTr, or 0.234 ppb. This information can be found under docket identification (ID) number EPA-HQ-OPP-2006-0993.

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).

Florasulam is not registered for use on any sites that would result in residential exposure. Therefore, a residential exposure assessment was not conducted.

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."

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 florasulam and any other substances and florasulam does not appear to

produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has not assumed that florasulam has a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's website at <http://www.epa.gov/pesticides/cumulative>.

D. Safety Factor for Infants and Children

1. *In general.* Section 408 of FFDCA provides that EPA shall apply an additional ("10X") 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 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. In applying this provision, EPA either retains the default value of 10X when reliable data do not support the choice of a different factor, or, if reliable data are available, EPA uses a different additional FQPA safety factor value based on the use of traditional UFs and/or special FQPA safety factors, as appropriate.

2. *Prenatal and postnatal sensitivity.* There was no evidence of increased susceptibility and no residual uncertainties with regard to pre- and/or postnatal toxicity following *in utero* exposure to rats or rabbits and pre and/or post-natal exposures to rats.

3. *Conclusion.* EPA has determined that reliable data show that it would be safe for infants and children to reduce the FQPA safety factor to 1X. That decision is based on the following findings:

i. The toxicity database for florasulam is complete.

ii. There is no indication that florasulam 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 florasulam results in increased susceptibility following *in utero* exposure to 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 assessments were performed based on 100% CT and tolerance-level residues. Conservative ground and surface water modeling

estimates were used. These assessments will not underestimate the dietary exposure and risks posed by florasulam. There are no registered or proposed residential uses of florasulam.

E. Aggregate Risks and Determination of Safety

Safety is assessed for acute and chronic risks by comparing aggregate exposure to the pesticide to the aPAD and cPAD. The aPAD and cPAD are calculated by dividing the LOC by all applicable UFs. For linear cancer risks, EPA calculates the probability of additional cancer cases given aggregate exposure. Short-, intermediate-, and long-term risks are evaluated by comparing aggregate exposure to the LOC to ensure that the MOE called for by the product of all applicable UFs is not exceeded.

1. *Acute risk.* No acute dietary endpoint was identified; therefore, florasulam is not expected to pose an acute risk.

2. *Chronic risk.* The chronic dietary exposure analysis included both food and drinking water. The general U.S. population and all population subgroups have risk estimates that are below the level of concern. The most highly exposed population subgroup is children (1-2 years) which utilizes < 1% of the cPAD. The general U.S. population utilizes <1% of the cPAD. There are no residential uses for florasulam that result in chronic residential exposure to florasulam.

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

Florasulam is not registered for use on any sites that would result in residential exposure. Therefore, short-term and intermediate-term aggregate risk assessments were not conducted.

4. *Aggregate cancer risk for U.S. population.* Exposure to florasulam did not result in a treatment-related increase in tumor formation in rats or mice; therefore, florasulam is not expected to pose a cancer risk.

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, or to infants and children from aggregate exposure to florasulam residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology (capillary gas chromatography with mass selective detection (GC/MSD) 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

Maximum residue levels (MRLs) are established in Canada for residues of florasulam in barley, oats, and wheat grain at 0.01 ppm. No harmonization issues exist since the same tolerance level is recommended for the use in the United States. There are no Codex MRLs.

C. Response to Comments

One comment was received in response to the notice of filing from B. Sachau, 15 Elm St., Florham Park, NJ 07932. The commenter objected to the sale or use of this product and the acceptance of anything except a zero tolerance. The commenter also indicated health implications from this chemical. However, the comment contained no scientific data or evidence to rebut the Agency's conclusion that there is a reasonable certainty that no harm will result from aggregate exposure to florasulam, including all anticipated dietary exposure and all other exposures for which there is reliable information. The commenter also questioned the rigor of the safety testing submitted on florasulam; however, the comment was in the form of a conclusory statement and provided no supporting documentation or rationale for the position taken.

V. Conclusion

Therefore, the tolerance is established for residues of florasulam, N-(2,6-difluorophenyl)-8-fluoro-5-methoxy(1,2,4)triazolo(1,5-c)pyrimidine-2-sulfonamide, in or on barley, grain at 0.01 ppm, barley, hay at 0.05 ppm, barley, straw at 0.05 ppm, oat, grain at 0.01 ppm, oat, forage at 0.05 ppm, oat, hay at 0.05 ppm, oat, straw at 0.05 ppm, rye, grain at 0.01 ppm, rye, forage at 0.05 ppm, rye, straw at 0.05 ppm, wheat, grain at 0.01 ppm, wheat, forage at 0.05 ppm, wheat, hay at 0.05 ppm, and wheat, straw at 0.05 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: September 23, 2007.

Debra Edwards,
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 180.633 is added to read as follows:

§ 180.633 Florasulam; tolerances for residues.

(a) *General.* Tolerances are established for residues of the herbicide florasulam N-(2,6-difluorophenyl)-8-fluoro-5-methoxy(1,2,4)triazolo(1,5-c)pyrimidine-2-sulfonamide in or on the following commodities:

Commodity	Parts per million
Barley, grain	0.01
Barley, hay	0.05
Barley, straw	0.05
Oat, forage	0.05
Oat, grain	0.01
Oat, hay	0.05
Oat, straw	0.05
Rye, forage	0.05
Rye, grain	0.01

Commodity	Parts per million
Rye, straw	0.05
Wheat, forage	0.05
Wheat, grain	0.01
Wheat, hay	0.05
Wheat, straw	0.05

(b) Section 18 emergency exemptions.
[Reserved]

(c) Tolerances with regional registrations. [Reserved]

(d) Indirect or inadvertent residues.
[Reserved]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2006-0072; FRL-8148-2]

Tembotrione; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for combined residues of tembotrione, 2-[2-chloro-4-(methylsulfonyl)-3-[(2,2,2-trifluoroethoxy)methyl]benzoyl]-1,3-cyclohexanedione and its metabolite (M5); 2-[2-chloro-4-(methylsulfonyl)-3-[(2,2,2-trifluoroethoxy)methyl]benzoyl]-4,6-dihydroxy-1,3-cyclohexanedione in or on corn (field, sweet and pop) and livestock commodities. Bayer CropScience requested those tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective September 28, 2007. Objections and requests for hearings must be received on or before November 27, 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-2006-0072. 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 website 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 in the electronic docket at <http://www.regulations.gov>, or, if only available in hard copy, at the OPP Regulatory 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:

Eugene Wilson, Registration Division, Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 305-6103; e-mail address: wilson.eugene@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 those engaged in the following activities:

- Crop production (NAICS code 111), e.g., agricultural workers; greenhouse, nursery, and floriculture workers; farmers.
- Animal production (NAICS code 112), e.g., cattle ranchers and farmers, dairy cattle farmers, livestock farmers.
- Food manufacturing (NAICS code 311), e.g., agricultural workers; farmers; greenhouse, nursery, and floriculture workers; ranchers; pesticide applicators.
- Pesticide manufacturing (NAICS code 32532), e.g., agricultural workers; commercial applicators; farmers; greenhouse, nursery, and floriculture workers; residential users.

This listing is not intended to be exhaustive, but rather to provide 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 EPA's tolerance regulations at 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 FFDCA, 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-2006-0072 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 as required by 40 CFR part 178 on or before November 27, 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 this copy, identified by docket ID number EPA-HQ-OPP-2006-0072, 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.