

**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: June 11, 2009.

**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 180.364 is amended by revising the following entry in the table in paragraph (a)(1) to read as follows:

**§ 180.364 Glyphosate; tolerances for residues.**

(a) *General.* (1) \* \* \*

Commodity	Parts per million
* * *	* *
Cotton, gin byproducts ...	210
* * *	* *

\* \* \* \* \*

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**ENVIRONMENTAL PROTECTION AGENCY**

**40 CFR Part 180**

[EPA-HQ-OPP-2008-0384; FRL-8417-8]

**Acetochlor; Pesticide Tolerances**

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

**ACTION:** Final rule.

**SUMMARY:** This regulation modifies tolerances for residues of acetochlor and its metabolites in or on the commodities corn, field, forage; corn, field, stover; and corn, pop, stover. The modifications are detailed in Unit II. of this document. Monsanto Company requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

**DATES:** This regulation is effective June 24, 2009. Objections and requests for hearings must be received on or before August 24, 2009, 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-2008-0384. All documents in the docket are listed in the docket index available at <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:** Vickie Walters, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 305-5704; e-mail address: [walters.vickie@epa.gov](mailto:walters.vickie@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).
- 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 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?*

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*C. Can I File an Objection or Hearing Request?*

Under section 408(g) of FFDCA, 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2008-0384 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 August 24, 2009.

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-2008-0384 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 Facility'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 June 13, 2008 (73 FR 33814) (FRL-8367-3), 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 7F7306) by Monsanto Company (a member of the Acetochlor Registration Partnership (ARP), 1300 I St., NW., Suite 450 East, Washington, DC 20005). The petition requested that 40 CFR 180.470 be amended by establishing tolerances for the herbicide acetochlor, (2-chloro-2'-methyl-6'-ethyl-N-ethoxymethylacetanilide) and its metabolites containing either the 2-ethyl-6-methylaniline (EMA) or the 2-(1-hydroxyethyl-6-methyl-aniline (HEMA) moiety, to be expressed as acetochlor in or on the food commodities when present therein as a result of the application of acetochlor to growing crops: Corn, field, forage at 4.5 parts per million (ppm) and corn, field, stover at 3.0 ppm. That notice referenced a summary of the petition prepared by Monsanto Company, the registrant, which is available to the public in the docket, <http://www.regulations.gov>. Comments were received on the notice of filing. EPA's response to these comments is discussed in Unit IV.C.

Monsanto Company has requested an amendment to its registration for acetochlor under Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) which would modify the use pattern for post-emergence application by allowing application of acetochlor to corn up to 30 inches in height. Current products are registered for post-emergence application up to 11 inches in height. The petitioner is requesting that tolerances be increased to support this use pattern.

Based upon review of the data supporting the petition, EPA has determined that the proposed tolerances in this petition should remain in

§ 180.470 (a) which reads: "Tolerances are established for residues of acetochlor; 2-chloro-2'-methyl-6-ethyl-N-ethoxymethylacetanilide, and its metabolites containing the ethyl methyl aniline (EMA) and the hydroxyethyl methyl aniline (HEMA) moiety, to be analyzed as acetochlor and expressed as acetochlor equivalents, in or on the following raw agricultural commodities." Also, the Agency has determined that available data support tolerances of 2.5 ppm for corn, field, stover, and that the current tolerance for corn, pop, stover must be increased to 2.5 ppm. The proposed numerical value for the tolerance on corn, field, forage remains at 4.5 ppm. The reasons for these changes are explained in Unit IV.D.

## III. Aggregate Risk Assessment and Determination of Safety

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

Consistent with section 408(b)(2)(D) of FFDCA, and the factors specified in section 408(b)(2)(D) of 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 for the petitioned-for tolerances for residues of acetochlor on corn, field, forage at 2.5 ppm, corn, field, stover at 2.5 ppm, and corn, pop, stover at 2.5 ppm. EPA's assessment of exposures and risks associated with establishing tolerances 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 acetochlor as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies can be found at <http://www.regulations.gov> in the document entitled "Acetochlor- RED Phase 2 Revised HED Chapter of the TRED" and is available in docket ID number EPA-HQ-OPP-2005-0227 identified as document 0004.

### B. Toxicological Endpoints

For hazards that have a threshold below which there is no appreciable risk, a toxicological point of departure (POD) is identified as the basis for derivation of reference values for risk assessment. The POD may be defined as 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) or a Benchmark Dose (BMD) approach is sometimes used for risk assessment. Uncertainty/safety factors (UFs) are used in conjunction with the POD 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 dietary risks by comparing aggregate food and water 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 POD by all applicable UFs. Aggregate short-, intermediate-, and chronic-term risks are evaluated by comparing food, water, and residential exposure to the POD to ensure that the margin of exposure (MOE) called for by the product of all applicable UFs is not exceeded. This latter value is referred to as the level of concern (LOC).

For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect greater than that expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete

description of the risk assessment process, see <http://www.epa.gov/pesticides/factsheets/riskassess.htm>.

A summary of the toxicological endpoints for acetochlor used for human risk assessment can be found at <http://www.regulations.gov> in document "Acetochlor: Human Health Risk Assessment to Support the Proposed Uses on Sorghum and Sweet Corn and Rotational Crops of Nongrass Animal Feeds (Group 18), Sugar Beets, Dried Shelled Beans and Peas (Subgroup 6C), Sunflowers, Potatoes, Cereal Grains (Group 15), and Forage, Fodder, and Straw of Cereal Grains (Group 16)," page 11 in Docket ID number EPA-HQ-OPP-2006-0203.

#### C. Exposure Assessment

The increased tolerances proposed in this rule do not result in changes in the exposures or risk assessments reported in the previous risk assessments or in the final rule published in the **Federal Register** of May 16, 2007 (72 FR 27463) (FRL-8126-2). The changed use pattern and increased tolerances are only applicable to animal feed commodities and not human food. Currently, the available data show that acetochlor residues in animal feed are unlikely to result in finite amounts of acetochlor in animal commodities for human consumption. This will not change with the changed use pattern and increase in tolerance levels. EPA has calculated the maximum theoretical dietary burden for livestock based on the increased tolerances and compared those with the results from livestock feeding studies with acetochlor-impregnated feed. That comparison showed that finite residues in animal commodities for human consumption remain unlikely. The data supporting this conclusion are set forth in the Agency review entitled "Acetochlor. Petition for Increased Tolerances for Field Corn Forage and Stover to Support Amended Use on Field Corn, Summary of Analytical Chemistry and Residue Data," available at [www.regulations.gov](http://www.regulations.gov) in Docket ID number EPA-HQ-OPP-2008-0384 and identified as document EPA-HQ-OPP-2008-0384-0003. Further, the changed use pattern for acetochlor will not result in higher estimated levels in drinking water because other registered acetochlor uses on corn allow greater application amounts.

Accordingly, based on the risk assessments, and findings made in May 16, 2007 final rule for acetochlor, 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 acetochlor residues.

#### IV. Other Considerations

##### A. Analytical Enforcement Methodology

An adequate high performance liquid chromatography with oxidative coulometric electrochemical detector (HPLC/OCED) method is available for enforcement of tolerances for acetochlor and its metabolites in plant commodities including corn, field, forage; corn, field, stover, and corn, pop, stover. This method is listed as Method I for plants in PAM Vol. II.

##### B. International Residue Limits

There are no Codex or Canadian Maximum Residue Levels (MRLs) established for acetochlor on agricultural Commodities. A Mexican MRL is established for residues of acetochlor *per se*, as "acetochlor" in/on corn (maize) at 0.04 ppm. The acetochlor tolerances EPA is establishing in this action differ from the tolerance expression for the Mexican MRL, because of the inclusion of the EMA and HEMA metabolites in the tolerance expression. At this time harmonization between the U.S. tolerances and Mexican MRL can not be achieved because of the inclusion of the EMA and HEMA metabolites in the EPA tolerance expression are necessary to support use patterns in the United States.

##### C. Response to Comments

One commenter submitted a comment stating a general opposition to all genetically engineered foods. This comment is non-responsive to the proposed action in that Monsanto petitioned for modification of a tolerance for pesticide residues and not approval of a genetically engineered food.

##### D. Revisions to Petitioned-For Tolerances

The tolerance spreadsheet in the Agency's Guidance for Setting Tolerances Based on Field Trial Data was utilized in determining appropriate tolerance levels for field corn forage and stover. The available data supports the proposed tolerance for field corn forage at 4.5 ppm, but indicates that the proposed tolerance for field corn stover of 3.0 ppm is too high. The data support a tolerance of 2.5 ppm for field corn stover. The Agency previously concluded that field corn trial data would support tolerances on pop corn; therefore, the available field trial data will also support a tolerance of 2.5 ppm for pop corn stover. Therefore, EPA is revising these tolerances to agree with levels the field trial data support.

#### V. Conclusion

Therefore, tolerances are established for residues of acetochlor; 2-chloro-2'-methyl-6-ethyl-N-ethoxymethylacetanilide, and its metabolites containing the ethyl methyl aniline (EMA) and the hydroxyethyl methyl aniline (HEMA) moiety, to be analyzed as acetochlor and expressed as acetochlor equivalents, in or on corn, field, forage at 4.5 ppm; corn, field, stover at 2.5 ppm; and corn, pop, stover at 2.5 ppm.

#### VI. 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 final rule has been exempted from review under Executive Order 12866, this final rule is not subject to Executive Order 13211, entitled *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, nor does it require any special considerations under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established 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 9, 2000) do not apply to this final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (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: June 11, 2009.

**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 180.470 is amended by revising the following entries in the table in paragraph (a) to read as follows:

#### § 180.470 Acetochlor; tolerances for residues.

(a) \* \* \*

Commodity	Parts per million
Corn, field, forage .....	4.5
* * *	* *
Corn, field, stover .....	2.5
* * *	* *
Corn, pop, stover .....	2.5
* * *	* *

\* \* \* \* \*

[FR Doc. E9-14581 Filed 6-23-09; 8:45 am]

**BILLING CODE 6560-50-S**

## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 180

[EPA-HQ-OPP-2008-0856; FRL-8418-8]

#### Starch, oxidized, polymers with Bu acrylate, tert-Bu acrylate and styrene; Tolerance Exemption

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

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes an exemption from the requirement of a tolerance for residues of starch, oxidized, polymers with Bu acrylate, tert-Bu acrylate and styrene, minimum number average molecular weight (in amu) 10,000, (CAS Reg. No. 204142-80-3) when used as an inert ingredient in a pesticide chemical formulation under 40 CFR 180.960. Kemira Chemicals, Inc., submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), requesting an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of starch, oxidized, polymers with Bu acrylate, tert-Bu acrylate and styrene, on food or feed commodities.

**DATES:** This regulation is effective June 24, 2009. Objections and requests for hearings must be received on or before August 24, 2009, 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-2008-0856. All documents in the docket are listed in the docket index available at <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:

Deirdre Sunderland, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 603-0851; e-mail address: [sunderland.deirdre@epa.gov](mailto:sunderland.deirdre@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:

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- 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**.

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