

Transfer and Advancement Act of 1995 (NTTAA), Public Law 104-113, section 12(d) (15 U.S.C. 272 note).

**VII. Congressional Review Act**

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

**List of Subjects in 40 CFR Part 180**

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

Dated: August 25, 2009.

**Lois A. 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. In § 180.589, the table to paragraph (a)(1) is amended by alphabetically adding an entry for “coffee, green bean, imported”, by revising the entry for “banana, import” and by removing the entry for “cucumber” with the limit of 0.20 ppm and the entry for “vegetable, root, subgroup 1A, except sugar beet, garden beet, radish, and turnip” with the limit of 0.7 ppm. The added and revised entries read as follows:

**§ 180.589 Boscalid; tolerances for residues.**

(a)\* \* \*(1) \* \* \*

| Commodity                      | Parts per million |
|--------------------------------|-------------------|
| * * * * *                      | *                 |
| Banana, import \\\             | 0.40              |
| Coffee, green bean, import \\\ | 0.05              |

<sup>1</sup>No US registrations as of September 16, 2009.

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**ENVIRONMENTAL PROTECTION AGENCY**

**40 CFR Part 180**

[EPA-HQ-OPP-2009-0002; FRL-8434-1]

**Acetochlor; Pesticide Tolerances**

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

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes tolerances for residues of acetochlor, including its metabolites and degradates, in or on cotton, gin byproducts; cotton, undelinted seed; soybean, meal; and soybean, seed. Monsanto Company requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA). This regulation also removes the existing tolerance for indirect or inadvertent residues of acetochlor on soybean, seed. **DATES:** This regulation is effective September 16, 2009. Objections and requests for hearings must be received on or before November 16, 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-2009-0002. 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:** Susan Stanton, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200

Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 305-5218; e-mail address: [stanton.susan@epa.gov](mailto:stanton.susan@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?*

In addition to accessing electronically available documents 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 e-CFR cite at <http://www.gpoaccess.gov/ecfr>. To access the OPPTS Harmonized Guidelines referenced in this document, go directly to the guidelines at <http://www.epa.gov/opptsfrs/home/guidelin.htm>.

*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-2009-0002 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 16, 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-2009-0002, 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 April 8, 2009 (74 FR 15971) (FRL-8407-4), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of pesticide petitions (PP 8F7443 and PP 8F7448) by Monsanto Company, 1300 I St., NW., Suite 450 East, Washington DC 20052. The petitions requested that 40 CFR 180.470 be amended by establishing tolerances for combined residues of the herbicide acetochlor, 2-chloro-2'-methyl-6'-ethyl-N-ethoxymethylacetanilide, and its metabolites containing either the 2-ethyl-6-methyl-aniline (EMA) or the 2-(1-hydroxyethyl)-6-methyl-aniline (HEMA) moiety, to be expressed as acetochlor equivalents, in or on cotton, gin byproducts; and cotton, undelinted seed at 4.0 parts per million (ppm) and 0.6 ppm, respectively (PP 8F7443); and soybean, seed at 1.0 ppm (PP 8F7448). 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>. There were no comments received in response to the notice of filing.

Based upon review of the data supporting the petition, EPA has determined that a tolerance for residues of acetochlor and its metabolites is also required on soybean, meal at 1.2 ppm. EPA has also revised the tolerance expression for acetochlor to clarify the chemical moieties that are covered by the tolerances and specify how compliance with the tolerances is to be measured. The reasons for these changes are explained in Unit IV.C.

## 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, including its metabolites and degradates, on cotton, gin byproducts at 4.0 ppm; cotton, undelinted seed at 0.6 ppm; soybean, meal at 1.2 ppm; and soybean, seed at 1.0 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.

Acetochlor has low acute toxicity by the oral, dermal, and inhalation routes of exposure and is mildly irritating to the eyes. The results of two dermal irritation studies indicate that it is a mild to strong skin irritant. Acetochlor is also a strong dermal sensitizer.

Evidence of neurotoxicity was observed in acute and subchronic neurotoxicity screening studies in rats, developmental toxicity studies in rats, and subchronic and chronic studies in dogs. In addition to the nervous system, the major target organs affected in subchronic and chronic studies in rats, dogs and mice exposed to acetochlor are the liver, thyroid (secondary to liver), kidney, testes, and erythrocytes. Species-specific target organs include the nasal olfactory epithelium in rats and the lungs in mice.

There is no evidence of increased qualitative or quantitative susceptibility of fetuses or offspring to acetochlor exposure in the developmental and reproduction toxicity studies in rats and rabbits. In two developmental toxicity studies in rats, fetal effects (increased early resorptions, postimplantation loss, and decreased fetal weight) occurred at doses that also resulted in maternal toxicity (mortality, clinical signs of toxicity, and decreased maternal body weight gain). In two rabbit developmental toxicity studies there were no adverse fetal effects at the highest doses tested (HDT) (190 milligrams/kilogram/day (mg/kg/day) and 300 mg/kg/day); whereas maternal toxicity (body weight loss) was seen at 50 mg/kg/day in one study. In three reproduction toxicity studies in rats, offspring effects (decreased pup weights in the first two studies; decreased pup weights, decreased F2 litter size at birth, and focal hyperplasia and polypoid adenomata in nasal epithelium of adult F1 offspring at study termination in the third study) occurred at the same or higher doses than those resulting in parental toxicity (decreased body weight or weight gain in the first two studies; focal hyperplasia and polypoid adenomata in nasal epithelium of adult F1 offspring at study termination in the third study). There was no evidence of reproductive toxicity observed at any dose tested in two of the three reproductive toxicity studies in rats. The third reproduction study in rats showed a decreased number of implantations at the HDT of 1,750 ppm.

There was evidence of carcinogenicity in studies conducted with acetochlor in rats and mice. A 23-month mouse carcinogenicity study showed weak evidence for increased benign lung tumors in females, and a 78-week study showed weak evidence for increased benign lung tumors in males. The increases were considered equivocal, based on increases in benign tumors only, inconsistent dose-responses between the two studies, inconsistencies in the responses of males and females between the two studies, lack of pre-neoplastic lung lesions in the 23-month study (while the 78-week study showed an increase in bronchiolar hyperplasia), and the variable incidence of lung tumors known to occur in older mice.

Two carcinogenicity studies in rats showed an increase in nasal epithelial tumors and thyroid follicular cell tumors. Thyroid tumor incidence was relatively low, and there was evidence that the tumors were due to disruption of thyroid-pituitary homeostasis. There are acceptable mode of action data for the rat tumors (nasal olfactory epithelial tumors and thyroid follicular cell tumors) which are adequate to support a non-linear, margin of exposure (MOE), approach for assessment of cancer risk. The data show that, like the related compounds, alachlor and butachlor, tumor formation is dependent upon local cytotoxicity secondary to oxidative damage by a reactive quinone imine intermediate. The mechanistic data on nasal tumorigenesis of acetochlor in the rat, when considered together with the mutagenicity data on acetochlor and consistent findings in mechanistic and mutagenicity studies on the closely related compound alachlor, are considered adequate to demonstrate a cytotoxic, non-mutagenic mode of tumor induction.

Because a clear mode of action was demonstrated for the rat tumors, EPA based the cancer classification on the data from the mouse. Given the weakness of these data (benign lung tumors in male and female mice and histiocytic sarcomas in female mice), EPA has classified acetochlor as having "Suggestive Evidence of Carcinogenic Potential" and determined that linear quantification of carcinogenic potential would not be appropriate for the mouse tumors. The rat nasal tumors, with a point of departure (POD) of 10 mg/kg/day, are the most sensitive effect for cancer risk. The chronic population adjusted dose (cPAD), based on the no-observed-adverse-effect level (NOAEL) of 2.0 mg/kg/day from the chronic dog study, will be protective of both non-cancer and cancer effects, including rat

nasal tumors, thyroid tumors, and mouse tumors.

Specific information on the studies received and the nature of the adverse effects caused by acetochlor as well as the NOAEL and the lowest-observed-adverse-effect level (LOAEL) from the toxicity studies can be found at <http://www.regulations.gov> in the document *Acetochlor Human Health Risk Assessment for Proposed New Use of Acetochlor on Cotton and Soybeans*, page 41 in docket ID number EPA-HQ-OPP-2009-0002.

#### B. Toxicological Endpoints

For hazards that have a threshold below which there is no appreciable risk, a toxicological 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 cPAD. The aPAD and cPAD are calculated by dividing the POD by all applicable UFs. Aggregate short-term, intermediate-term, and chronic-term risks are evaluated by comparing food, water, and residential exposure to the POD to ensure that the 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 the

document *Acetochlor Human Health Risk Assessment for Proposed New Use of Acetochlor on Cotton and Soybeans* page 25 in docket ID number EPA-HQ-OPP-2009-0002.

#### C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to acetochlor, EPA considered exposure under the petitioned-for tolerances as well as all existing acetochlor tolerances in 40 CFR 180.470. EPA assessed dietary exposures from acetochlor 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.

In estimating acute dietary exposure, EPA used food consumption information from the U.S. Department of Agriculture (USDA) 1994-1996 and 1998 Nationwide Continuing Surveys of Food Intakes by Individuals (CSFII). As to residue levels in food, EPA assumed that residues are present in all commodities at the tolerance level and that 100% of commodities are treated with acetochlor. Dietary Exposure Evaluation Model 7.81 (DEEM™ 7.81) default concentration factors were used to estimate residues of acetochlor in processed commodities.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the food consumption data from the USDA 1994-1996 and 1998 CSFII. As to residue levels in food, EPA assumed that residues are present in soybeans and cotton at the tolerance level and that 100% of cotton and soybeans are treated with acetochlor. For existing uses of acetochlor, EPA assumed average field trial levels and 100 percent crop treated (PCT). DEEM™ 7.81 default concentration factors were used to estimate residues of acetochlor in processed commodities.

iii. *Cancer.* Based on the results of carcinogenicity studies in rats and mice, EPA classified acetochlor as having "Suggestive Evidence of Carcinogenic Potential" but determined that the chronic risk assessment will be protective of both non-cancer and cancer effects. Therefore, a separate exposure assessment to evaluate cancer risk is unnecessary.

iv. *Anticipated residue and PCT information.* EPA used anticipated residues derived from the results of field trials in the chronic dietary exposure assessment. EPA did not use PCT

information in the acute or chronic exposure assessments.

Section 408(b)(2)(E) of FFDCA authorizes EPA to use available data and information on the anticipated residue levels of pesticide residues in food and the actual levels of pesticide residues that have been measured in food. If EPA relies on such information, EPA must require pursuant to FFDCA section 408(f)(1) that data be provided 5 years after the tolerance is established, modified, or left in effect, demonstrating that the levels in food are not above the levels anticipated. For the present action, EPA will issue such Data Call-Ins as are required by FFDCA section 408(b)(2)(E) and authorized under FFDCA section 408(f)(1). Data will be required to be submitted no later than 5 years from the date of issuance of these tolerances.

2. *Dietary exposure from drinking water.* The Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for acetochlor in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of acetochlor. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at <http://www.epa.gov/oppefed1/models/water/index.htm>.

Based on the Pesticide Root Zone Model/Exposure Analysis Modeling System (PRZM/EXAMS), the estimated drinking water concentration (EDWC) of acetochlor for acute exposures is estimated to be 75 parts per billion (ppb) for surface water. The EDWC for chronic exposures for non-cancer assessments is estimated to be 4.8 ppb for surface water. Residues of parent acetochlor in ground water are expected to be insignificant compared to residues in surface water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For acute dietary risk assessment, the water concentration value of 75 ppb was used to assess the contribution to drinking water. For chronic dietary risk assessment, the water concentration of value 9.5 ppb was used to assess the contribution to drinking water. This value is higher than the modeled EDWC for chronic exposures (4.8 ppm) and was derived from preliminary modeling that was subsequently refined. Since chronic exposure estimates using the higher value are below EPA's LOC, EPA did not revise the dietary exposure assessment to reflect the final modeled EDWC.

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). Acetochlor is not registered for any specific use patterns that would result in residential exposure.

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."

The chloroacetanilides have been evaluated by the Agency and the FIFRA Scientific Advisory Panel (SAP) as a related group of chemicals for this purpose. Acetochlor is included in a Cumulative Assessment Group (CAG) of Chloroacetanilide pesticides. Structurally related chloroacetanilides include acetochlor, alachlor, butachlor, propachlor and metolachlor. For purposes of a cumulative risk assessment, it was determined that the common mechanism of toxicity group consists of alachlor, acetochlor and butachlor. Butachlor is excluded from the group for risk assessment purposes at present since there are no registered uses or tolerances for this chemical in the United States. The group was selected based on common endpoints of:

- i. Nasal turbinate tumors in rats, and a known mechanism of toxicity for development of these tumors.
- ii. Induction of hepatic UDP-Glucuronosyl Transferase (UDPGT), which results in increased incidence of thyroid follicular cell tumors secondary to disruption of pituitary-thyroid homeostasis. Thyroid effects were not included in the final cumulative assessment of the chloroacetanilide herbicides because they were determined to occur at excessively toxic dose levels, and therefore were not considered relevant to human risk assessment. Nasal tumors represent the most sensitive endpoint for both compounds.

An updated cumulative risk assessment of the Chloroacetanilide CAG pesticides, acetochlor and alachlor, was conducted in April 2007. The risk assessment "ACETOCHLOR/ALACHLOR: Revised Cumulative Risk Assessment for the Chloroacetanilides to Support the Proposed New Uses on Alachlor and Acetochlor". PP 8F05000 and 8F5025 (Alachlor), PP 6F4791, 1F6263 and 5F6918 (Acetochlor) is available in the docket established for

this action (EPA-HQ-OPP-2009-0002). Based on the most recent Chloroacetanilide CAG cumulative risk assessment, cumulative risk is not of concern. A revised quantitative cumulative assessment was not conducted for the current assessment of proposed new uses for acetochlor, because the proposed new uses on cotton and soybeans would not affect the cumulative risk results. Acetochlor is a very minor contributor to cumulative risk when compared to alachlor, and the proposed new uses (cotton and soybeans) are minor contributors to acetochlor dietary risk.

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(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the FQPA safety factor (SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional SF when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity.* The prenatal and postnatal toxicity database for acetochlor includes two rat and two rabbit developmental toxicity studies and three reproduction toxicity studies in rats. As discussed in Unit III.A., there was no evidence of qualitative or quantitative susceptibility of fetuses or offspring to acetochlor exposure in any of these studies.

3. *Conclusion.* EPA has determined that the FQPA safety factor of 10X must be retained as a database UF for acetochlor acute risk assessment. This decision is based on the following findings:

- i. The toxicity database for acetochlor is incomplete. Additional data pertaining to acetochlor's potential to cause developmental neurotoxicity (DNT) or immunotoxicity are outstanding.

- ii. Evidence of neurotoxicity was observed in acute and subchronic neurotoxicity screening studies in rats,

developmental toxicity studies in rats, and subchronic and chronic studies in dogs. Frank neuropathology was seen in a chronic study in the dog. EPA has required a DNT study in rats to assess susceptibility of offspring to neurotoxic effects relative to adult animals. Results of the DNT study could impact the current dose selected for assessing acute oral exposure, since the NOAEL used for acute dietary risk assessment (150 mg/kg/day) is greater than the NOAEL from a reproductive toxicity study (21 mg/kg/day) for acetochlor, and the DNT study will likely be conducted at dose levels similar to those of the reproductive toxicity study. The results of the DNT study are not expected to impact the dose selected for chronic risk assessment, which is based on the lower NOAEL of 2.0 mg/kg/day from the chronic dog study.

iii. In accordance with 40 CFR part 158 Toxicology Data requirements, an immunotoxicity study (870.7800) is required for acetochlor. In the absence of specific immunotoxicity studies, EPA has evaluated the available acetochlor toxicity data to determine whether an additional database UF is needed to account for potential immunotoxicity. There are no indications in the available studies that organs associated with immune function, such as the thymus and spleen, are affected by acetochlor, and acetochlor does not belong to a class of chemicals (e.g., the organotins, heavy metals, or halogenated aromatic hydrocarbons) that would be expected to be immunotoxic.

iv. There is no evidence that acetochlor results in increased susceptibility in *in utero* rats or rabbits in the prenatal developmental studies or in offspring in the 2-generation reproduction studies.

v. There are no residual uncertainties identified in the exposure databases. The dietary food exposure assessments were performed based on 100% crop treated and tolerance-level residues or average residue levels derived from reliable field trials. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to acetochlor in drinking water. Residential exposure to acetochlor is not expected. These assessments will not underestimate the exposure and risks posed by acetochlor.

After weighing this evidence, EPA retains significant uncertainty regarding potential neurotoxic effects in infants and children but does not have such concerns for immunotoxicity. Given the findings of neurotoxicity and the uncertainty regarding the sensitivity of fetal and neonatal animals to neurotoxic effects, EPA has concluded that it lacks

reliable data to remove the FQPA 10X safety factor for acute exposures. For chronic exposures, EPA concludes that reliable data show that removal of the FQPA 10X factor will be safe for infants and children. Three factors predominate here. First, given the expected dosing in the DNT study, that study is unlikely to affect the cPAD, even if effects were seen at the lowest dose tested. Second, there is no evidence of increased susceptibility in multiple studies in multiple species. Third, although neurotoxic effects have been observed in the database, at lower doses the more significant effects are not related to neurotoxicity.

#### *E. Aggregate Risks and Determination of Safety*

EPA determines whether acute and chronic pesticide exposures are safe by comparing aggregate exposure estimates to the aPAD and cPAD. The aPAD and cPAD represent the highest safe exposures, taking into account all appropriate SFs. EPA calculates the aPAD and cPAD by dividing the POD by all applicable UFs. For linear cancer risks, EPA calculates the probability of additional cancer cases given the estimated aggregate exposure. Short-term, intermediate-term, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the POD to ensure that the MOE called for by the product of all applicable UFs is not exceeded.

1. *Acute risk.* An acute aggregate risk assessment takes into account exposure estimates from acute dietary consumption of food and drinking water. Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food and water to acetochlor will occupy 11% of the aPAD for infants less than 1 year old, the population group receiving the greatest exposure.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to acetochlor from food and water will utilize 6% of the cPAD for infants less than 1 year old, the population group receiving the greatest exposure. There are no residential uses for acetochlor.

3. *Short-term/intermediate-term risk.* Short-term and intermediate-term aggregate exposure take into account short-term or intermediate-term residential exposure plus chronic exposure from food and water (considered to be a background exposure level). Acetochlor is not registered for any use patterns that would result in residential exposure.

Therefore, the short-term or intermediate-term aggregate risk is the sum of the risk from exposure to acetochlor through food and water and will not be greater than the chronic aggregate risk.

4. *Aggregate cancer risk for U.S. population.* As explained in Unit III.A., risk assessments based on the endpoint selected for chronic risk assessment are considered to be protective of any potential carcinogenic risk from exposure to acetochlor. Based on the results of the chronic risk assessment discussed above in Unit E.2., EPA concludes that acetochlor 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 acetochlor residues.

#### **IV. Other Considerations**

##### *A. Analytical Enforcement Methodology*

Adequate enforcement methodology (high performance liquid chromatography (HPLC) method with oxidative coulometric electrochemical detection (OCED)) 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](mailto:residuemethods@epa.gov).

##### *B. International Residue Limits*

There are no CODEX, Canadian or Mexican maximum residue limits established for residues of acetochlor on cotton or soybean commodities.

##### *C. Revisions to Petitioned-For Tolerances*

The registrant proposed a tolerance for residues of acetochlor and its metabolites on soybean, seed at 1.0 ppm. Based on processing data for soybean showing the potential for residues of acetochlor to concentrate in soybean meal (1.2X), EPA determined that a tolerance is also needed for soybean, meal at 1.2 ppm.

Tolerances for acetochlor are currently expressed in terms of "residues of acetochlor; 2-chloro-2'-methyl-6-ethyl-N-ethoxymethylacetanilide, and its metabolites containing the ethyl methyl aniline (EMA) moiety and the hydroxyethyl methyl aniline (HEMA) moiety, to be analyzed as acetochlor and expressed as acetochlor equivalents." EPA is revising the tolerance expression

for existing tolerances and the new tolerances on cotton and soybeans to clarify the chemical moieties that are covered by the tolerances and specify how compliance with the tolerances is to be measured. The revised tolerance expression makes clear that the tolerance covers “residues of acetochlor, including its metabolites and degradates,” and that compliance with the tolerance levels will be determined by measuring only “acetochlor, 2-chloro-2'-methyl-6-ethyl-N-ethoxymethylacetanilide, and its metabolites containing the EMA moiety and the HEMA moiety. Both parent and the named metabolites shall be determined as EMA and HEMA, and calculated as the stoichiometric equivalents of acetochlor.”

EPA has determined that it is reasonable to make this change final without prior proposal and opportunity for comment, because public comment is not necessary, in that the change has no substantive effect on the tolerance, but rather is merely intended to clarify the existing tolerance expression.

## V. Conclusion

Therefore, tolerances are established for residues of acetochlor, including its metabolites and degradates, on cotton, gin byproducts at 4.0 ppm; cotton, undelinted seed at 0.6 ppm; soybean, meal at 1.2 ppm; and soybean, seed at 1.0 ppm. Compliance with these tolerance levels is to be determined by measuring only acetochlor, 2-chloro-2'-methyl-6-ethyl-N-ethoxymethylacetanilide, and its metabolites containing the EMA moiety and the HEMA moiety. Both parent and the named metabolites shall be determined as EMA and HEMA, and calculated as the stoichiometric equivalents of acetochlor.

## 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: August 31, 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 introductory text in paragraphs (a) and (d); alphabetically adding the entries cotton, gin byproducts; cotton, undelinted seed; soybean, meal; and soybean, seed to the table in paragraph (a), and by removing the entry for “soybean, seed” from the table in paragraph (d) to read as follows.

### § 180.470 Acetochlor; tolerances for residues.

(a) *General.* Tolerances are established for residues of acetochlor, including its metabolites and degradates, in or on the commodities in the table below. Compliance with the tolerance levels specified below is to be determined by measuring only acetochlor, 2-chloro-2'-methyl-6-ethyl-N-ethoxymethylacetanilide, and its metabolites containing the ethyl methyl aniline (EMA) moiety and the hydroxyethyl methyl aniline (HEMA) moiety. Both parent and the named metabolites shall be determined as ethyl methyl aniline (EMA) and hydroxyethyl methyl aniline (HEMA), and calculated as the stoichiometric equivalents of acetochlor, in or on the following commodities:

| Commodity                     | Parts per million |
|-------------------------------|-------------------|
| Cotton, gin byproducts .....  | 4.0               |
| Cotton, undelinted seed ..... | 0.6               |
| Soybean, meal .....           | 1.2               |
| Soybean, seed .....           | 1.0               |

\* \* \* \* \*

(d) *Indirect or inadvertent residues.* Tolerances are established for indirect or inadvertent residues of acetochlor, including its metabolites and degradates, in or on the raw agricultural commodities in the table to this paragraph when present therein as a result of application of acetochlor to the growing crops in the table to paragraph (a) of this section. Compliance with the tolerance levels specified below is to be determined by measuring only acetochlor, 2-chloro-2'-methyl-6-ethyl-N-ethoxymethylacetanilide, and its metabolites containing the ethyl methyl aniline (EMA) moiety and the hydroxyethyl methyl aniline (HEMA) moiety. Both parent and the named metabolites shall be determined as ethyl methyl aniline (EMA) and hydroxyethyl methyl aniline (HEMA), and calculated as the stoichiometric equivalents of acetochlor, in or on the following commodities.

\* \* \* \* \*

[FR Doc. E9-21845 Filed 9-15-09; 8:45 am]  
 BILLING CODE 6560-50-S

**ENVIRONMENTAL PROTECTION AGENCY**

**40 CFR Part 180**

[EPA-HQ-OPP-2009-0251; FRL-8431-7]

**Ametryn, Amitraz, Ammonium Soap Salts of Higher Fatty Acids, Bitertanol, Coppers, et al.; Tolerance Actions**

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

**ACTION:** Final rule.

**SUMMARY:** EPA is revoking certain tolerances/tolerance exemptions for the fungicides pentachloronitrobenzene and triadimenol; the herbicides ametryn, fluazifop-p-butyl, and prometryn; the insecticides amitraz and mineral oil; the defoliant/desiccant sodium chlorate; and the fungicide/algicide/herbicide coppers. Also, EPA is modifying certain tolerances for the fungicide bitertanol and the insecticide malathion. In addition, EPA is establishing new tolerances/tolerance exemptions for the fungicides coppers and pentachloronitrobenzene; the herbicide

prometryn; the insecticide malathion; and the defoliant/desiccant sodium chlorate; and revising the tolerance expression for the ammonium salts of higher fatty acids (ammonium soap salts). The regulatory actions finalized in this document are in follow-up to the Agency's reregistration program under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), and tolerance reassessment program under the Federal Food, Drug, and Cosmetic Act (FFDCA), section 408(q).

**DATES:** This regulation is effective September 16, 2009. Objections and requests for hearings must be received on or before November 16, 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-2009-0251. 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:** Joseph Nevola, Pesticide Re-evaluation Division (7508P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 308-8037; e-mail address: [nevola.joseph@epa.gov](mailto:nevola.joseph@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 electronically available documents 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 e-CFR site at <http://www.gpoaccess.gov/ecfr>.

*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. 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