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).

IX. 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: May 4, 2007.

Janet L. Andersen,

Director, Biopesticides and Pollution Prevention 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 180.1254 is amended by designating the existing text as paragraph (a) and by adding paragraph (b) to read as follows:

§ 180.1254 Aspergillus flavus NRRL 21882; exemption from requirement of a tolerance.

(a) * * *

(b) *Aspergillus flavus* NRRL 21882 is temporarily exempt from the requirement of a tolerance on corn when used in accordance with the Experimental Use Permit 75624–EUP–2. This temporary exemption from tolerance will expire on May 2, 2009.

[FR Doc. E7–9427 Filed 5–15–07; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2006–0203; FRL–8126–2]

Acetochlor; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation revises and separates the tolerances for acetochlor in 180.470 into paragraphs (a) through (d) and reassigns many of the current entries from paragraph (a) to paragraph (d), which applies to tolerances for indirect and inadvertent residues. This regulation also establishes several new tolerances and amends several existing tolerances under paragraph (a). It further establishes several new tolerances under paragraph (d); and amends and revises two tolerances moved to that paragraph. Details of these changes are outlined in Unit II. of this document. The Acetochlor Registration Partnership (ARP) and Monsanto Company requested these changes as submitted by petitions to EPA pursuant to the Federal Food, Drug and Cosmetic Act (FFDCA).

DATES: This regulation is effective May 16, 2007. Objections and requests for hearings must be received on or before July 16, 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–2006–0203. To access the electronic docket, go to *http://www.regulations.gov*, select ''Advanced Search,'' then ''Docket Search.'' Insert the docket ID number where indicated and select the ''Submit'' button. Follow the instructions on the regulations.gov web site to view the docket index or access available documents. All documents in the docket are listed in the docket index available in regulations.gov. Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available 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 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*.

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–2006–0203 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 July 16, 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–2006–0203, 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 telephone number is (703) 305–5805.

II. Petition for Tolerance

In the **Federal Register** of February 7, 2007 (72 FR 5706) (FRL–8111–8, 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 1F6263, 4F4505, 6F4791) by the Acetochlor Registration Partnership (ARP) and Monsanto Company, 1300 ''I'' St., NW., Washington, DC 20005, and PP 5F6918 by Monsanto Company, 1300 ''I'' St., NW., Suite 450 East, Washington, DC 20005. The petitions requested that 40 CFR 180.470(a) be amended by establishing tolerances for residues of the herbicide, acetochlor [2-chloro-2-methyl-6-ethyl-*N*-ethoxymethylacetamide) and its metabolites containing the ethyl methyl aniline (EMA) moiety and the hydroxyethyl methyl-aniline (HEMA) moiety, and expressed as acetochlor equivalents in or on the food commodities corn, field, forage at 3.0 ppm (5F4505) corn, pop, grain at 0.05 part per million (ppm); corn, pop, stover at 1.5 ppm (PP 1F6263); corn, sweet, fodder and forage at 1.5 ppm; and corn, sweet, kernels plus cob with husks removed at 0.05 ppm (6F4791); sorghum, forage at 1.0 ppm; sorghum, grain at 0.05 ppm; and sorghum, grain, stover at 1.5 ppm (5F6918). These petitions also requested that 40 CFR 180.470(d) be amended by establishing tolerances for residues of the herbicide, acetochlor (2-chloro-2-methyl-6-ethyl-*N*-ethoxymethylacetamide) and its metabolites containing the ethyl methyl aniline (EMA) moiety and the hydroxyethyl methyl-aniline (HEMA) moiety, and expressed as acetochlor equivalents in or on the food commodities beet, sugar, root and tops/pea and bean (except soybean) dried and shelled (subgroup 6C)/potato/ and grain, cereal (except rice) (group 15),at 0.05 ppm; grain, grain, cereal (except rice), forage/fodder/straw (group 16) forage at 0.5 ppm; grain, cereal (except rice) forage/fodder/straw (group 16) hay at 2.0 ppm; grain, cereal (except rice) forage/fodder/straw (group 16) stover at 0.1 ppm; grain, cereal (except rice) forage/fodder/straw (group 16), straw at 0.3 ppm (1F6263); non-grass animal feeds (group 18) forage at 1.3 ppm; and non-grass animal feeds (group 18) hay at 3.5ppm (6F4791). That notice referenced a summary of the petitions prepared by Acetochlor Registration Partnership and Monsanto Company, the registrants, which have been placed in the public 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 petitions EPA is reassigning the entries for soybean, forage at 0.7 ppm; soybean, grain at 0.1 ppm; soybean, hay at1.0 ppm; wheat, forage at 0.5 ppm; wheat, grain at 0.02 ppm; and wheat, straw at 0.1 ppm; from 180.470(a) to 180.470(d) and establishing a tolerance for wheat, hay at 2.0 ppm under 40.CFR 180.470(d). The terminology for soybean, grain is being updated to read soybean, seed to conform to Agency procedures. Additionally, EPA is increasing the tolerance for corn, field, forage to 3.0 from 1.0 ppm. This tolerance will be listed in 180.470(a).

Based upon review of the data submitted and Agency procedures concerning commodity names, the Agency is correcting the terminology for pending crops under 40 CFR 180.470(a) as follows: corn, field, forage at 3.0 ppm; corn, pop, grain at 0.05 ppm; corn, pop, stover at 1.5 ppm; corn, sweet, kernels plus cob with husks removed at 0.05 ppm; corn, sweet, forage at 1.5 ppm; and sorghum, grain, grain at 0.05 ppm. The Agency is also correcting the tolerance levels and terminology for pending crops under 40 CFR 180.470(a) as follows: corn, sweet, stover at 1.0 ppm; sorghum, grain, forage at 1.6 ppm; sorghum, grain, grain at 0.05 ppm; and sorghum, grain, stover at 1.7 ppm. The above listings for corn, field, forage; sorghum, grain, forage; sorghum, grain, grain; and sorghum, grain, stover; replace the current listings for corn, field forage; sorghum, forage; sorghum, grain; and sorghum, grain, stover.

The Agency also determined that the tolerance expression and correct terminology for the pending crops under 40 CFR 180.470(d) should be written as follows: Tolerances are also established for indirect or inadvertent residues of acetochlor (2-chloro-2'-methyl-6-ethyl-*N*-ethoxymethylacetamide) 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, in or on the following raw agricultural commodities when present therein as a

result of application of acetochlor to growing crops listed in paragraph (a) of this section: Animal feed, nongrass, group 18, forage at 1.3 ppm; animal feed, nongrass, group 18, hay at 3.5 ppm; beet, sugar, root at 0.05 ppm; beet, sugar, tops at 0.05 ppm; grain, cereal, group 15 except for corn, grain sorghum, rice and wheat, grain at 0.05 ppm; grain, cereal, forage, fodder and straw, group 16 except for corn, grain sorghum, rice and wheat, forage at 0.5 ppm; grain, cereal, forage, fodder and straw, group 16,except corn, grain sorghum, rice and wheat, hay at 2.0 ppm; grain, cereal, forage, fodder and straw, Group 16, except corn, grain sorghum, rice and wheat, stover at 0.1 ppm; grain, cereal, forage, fodder and straw, group 16, except corn, grain sorghum, rice and wheat, straw at 0.3 ppm; pea and bean, dried shelled, except soybean, subgroup 6C at 0.05 ppm; potato at 0.05; sunflower, seed at 0.05 ppm and wheat, hay at 2.0 ppm.

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 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 tolerances and amendments for tolerances for residues of acetochlor (2-chloro-2'-methyl-6-ethyl-*N*-ethoxymethylacetamide) 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.

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*. The referenced document is entitled ''Acetochlor-RED Phase 2 Revised HED Chapter of the TRED'' and is available in the docket (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, 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 (UF) 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 uncertainty/safety factors. 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 uncertainty/safety factors 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 acetochlor used for human risk assessment can be found at *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) on page 11 in Docket ID EPA–HQ–OPP–2006–0203.

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 USDA 1994–1996 and 1998 Nationwide Continuing Surveys of Food Intake by Individuals (CSFII). As to residue levels in food, EPA assumed all foods for which there are tolerances or for which tolerances are proposed, were treated and contain tolerance-level residues. Experimentally derived processing factors were used for cereal grain commodities. Default values were used for all other 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; Nationwide CSFII. As to residue levels in food, EPA chronic dietary analysis included anticipated residues from field trial data and assumed that all crop were treated. Experimentally derived processing factors were used for cereal grain commodities. Default values were used for all other processed commodities.

iii. *Cancer*. Previously, EPA has treated acetochlor as a non-threshold

carcinogen and conducted a linear low-dose quantitative cancer risk assessment in evaluating its safety. The determination that a quantitative linear low-dose cancer assessment was appropriate was based on findings that acetochlor caused mouse lung tumors and histiocytic sarcomas in female mice. The Agency has reexamined the data and concluded they do not support use of a quantitative linear low-dose cancer assessment. The Agency determined that the relationship of the mouse lung tumors to treatment was equivocal, due to some inconsistencies in dose-response between the two available mouse studies, the relatively frequent occurrence of the tumor in older mice and the lack of evidence of direct genotoxicity of acetochlor. Further the Agency found that the increase in the histiocytic sarcomas in female mice in one study was also equivocal. EPA concludes that this equivocal evidence of cancer shows no greater than a negligible risk of cancer. Nonetheless, acetochlor has been associated with nasal tumors in the rats and these tumors remain as a tumor of concern for human exposure to acetochlor. Because, however, the nasal tumors have been found to be a threshold effect, EPA has not used quantitative linear low-dose cancer assessment in assessing this cancer risk. Rather, EPA has relied on the chronic risk assessment because the chronic Reference Dose (cRfD), which is based on a NOAEL of 2 milligrams/kilograms/day (mg/kg/day), is considered to be protective of nasal tumors for which a point of departure of 10 mg/kg/day was identified. EPA has used the same exposure assumptions in assessing cancer risk as in assessing other chronic risks.

iv. *Anticipated residue and percent crop treated (PCT) information.* 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 pursuant to section 408(f)(1) of FFDCA require 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 section 408(b)(2)(E) of FFDCA and authorized under section 408(f)(1) of FFDCA. Data will be required to be submitted no later than 5 years from the date of issuance of this tolerance.

2. *Dietary exposure from drinking water.* The drinking water values used in the dietary risk assessments were based on information provided by the Acetochlor Registration Partner ship water monitoring program to support the current use on field corn. The Agency has determined that the new uses of acetochlor are not likely to result in concentrations exceeding those seen in the field corn monitoring data; therefore this data can be used to estimate drinking water concentrations resulting from the new uses on sweet corn and sorghum. In the monitoring data, exposure to acetochlor parent was significantly higher in the surface water monitoring sites than the ground water monitoring sites; therefore, the concentration used in the acute dietary assessment was from a surface water monitoring site that produced the highest concentration of 0.01821 ppm. The drinking water value used in the chronic dietary risk assessment was from a surface water monitoring site that produced the highest time-weighted annualized mean (TWAM) concentration for a single year of 0.00143 ppm.

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 use on any sites that would result in residential exposure.

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

Acetochlor is a member of the chloroacetanilide cumulative assessment group (CAG) which includes alachlor and butachlor. The Agency previously conducted a cumulative risk assessment for the CAG based on a common mode of action for the production of tumors of the nasal olfactory epithelium in rats. Butachlor was determined to be part of the CAG, however, there are currently no U.S. registrations for the chemical; therefore, it was excluded from the cumulative risk assessment. This risk assessment is fully discussed in the document: *Cumulative Risks from Chloroacetanilide Pesticides* dated March 6, 2006 identified as document EPA–HQ–OPP–2005–0050–0061 which is available on the internet at *http://www.regulaions.gov* in docket number EPA–HQ–OPP–2005–0050. Based on that cumulative risk assessment (CRA), the Agency concluded that the cumulative risks from alachlor and acetochlor did not exceed the Agency's level of concern since cumulative MOEs were above 13,000 for all populations compared to a cumulative level of concern of 100.

For this risk assessment the Agency believes that the cumulative risk from these new uses in addition to the current existing uses of acetochlor and alachlor will not exceed The Agency's level of concern. Individual risk assessments were conducted based on a point of departure of 10 mg/kg/day for nasal tumors. Anticipated residues based on field trial data and 100% crop treated was assumed for all existing and new uses for acetochlor. The individual acetochlor assessment from food resulted in MOEs raging from 49,000 for children 1-2 years old and children 3-5 years old to 179,000 for adults 50+. The addition of water to the assessment using surrogate data from the corn monitoring studies, resulted in MOEs ranging from 40,000 for children 1-2 years old to 116,000 for adults 50+. The MOEs for the General U.S. population were 111,000 from food and 83,000 from both food and water.

As noted in the March, 2006 cumulative risk assessment for the chloroacetanilide chemicals, alachlor is the index chemical and acetochlor is included in the assessment with a relative potency of 1/20th of alachlor. Further, as noted in the cumulative risk assessment, acetochlor commodities were not considered to be risk drivers in the chloroacetanilide CRA; therefore given the individual MOEs for acetochlor, it is unlikely that the addition of the new uses for acetochlor will cause an unacceptable cumulative risk when considered with the existing alachlor and acetochlor uses.

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 data base 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 uncertainty/safety factors and/or special FQPA safety factors, as appropriate.

2. *Prenatal and postnatal sensitivity*. Concern for prenatal and postnatal susceptibility is low for acetochlor since toxicity to offspring was observed only at maternal toxic doses in developmental toxicity studies in the rat and rabbit and in three multi-generation reproductive toxicity studies in the rat. In addition, clear NOAELS were established in all of these three studies.

3. *Conclusion*. A 10X FQPA safety factor was applied to the acute dietary risk in the form of a database uncertainty factor to account for the lack of a developmental neurotoxicity study. The following findings support this determination.

i. The toxicity database for acetochlor is not complete at this time. A developmental neurotoxicity study is required based on neurological observations, primarily in the dog or an alternative test which addresses the sensitivity of the dog to neurological effects. In addition, submission of positive control studies for validation of the laboratory methodology used in the acute and subchronic rat oral neurotoxicity screening studies is required as confirmatory data and to upgrade those studies to acceptable.

ii. Evidence of neurotoxicity from exposure to acetochlor was observed in several studies. Salvation and other clinical signs (anogential staining, diarrhea) were reported in some studies in both the rat (two developmental studies) and the dog (subchronic and chronic oral). The dog appears to be more sensitive than the rat or mouse to effects on the nervous system, in that salivation occurred at lower dose levels and frank neuropathology of the brain was observed in one study. In the 1–year oral toxicity study in the dog pronounced neurological signs (ataxia, abnormal head movements, tremor, depressed righting, hoping and flexor reflexes, exaggerated tonic neck reflex and stiffness and rigidity of the hindlimbs) were observed at the high dose and were associated with degenerative lesions of the cerebellum. Other evidence of neurotoxicity is discussed on page 46 of the document entitled ''Acetochlor-RED Phase 2 Revised HED Chapter of the TRED'' which is available on the internet at *http://www.regulaions.gov* in the docket identified as EPA–HQ–OPP–2005–0227 document 0004.

iii. The acute dietary endpoint of concern for the general population including females 13-49 years of age, was derived from an acute oral neurotoxicity screening study in rats (NOAEL of 150 mg/kg/day based on decreased motor activity in females. Given the likely dosing in the developmental neurotoxicity study, it is possible that this study could lower the acute RfD by a factor of 10.

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

- The toxicity database for acetochlor is complete other than the lack of a developmental neurotoxicity study.

- Given likely dosing in the developmental neurotoxicity study, it is unlikely that this study would lower the cRFD. The chronic dietary endpoint of concern for all populations was derived from the chronic oral toxicity study in dogs with a NOAEL of 2 mg/kg/day based on the increased salivation and histopathology in testes, kidney and liver at 10 mg/kg/day. The cRFD of 2.0 mg/kg/day is less than the NOAELs in the reproductive study of 21 mg/kg/day. A developmental neurotoxicity study will likely be conducted at dose levels similar to those of the 2–generation rat reproduction study. No evidence of neuropathology or overt neurobehavioral effects were observed in the 2–generation reproductive study with rats.

- There is no evidence that acetochlor results in increased susceptibility in *in utero* rats or rabbits in the prenatal developmental studies or in young rats in the 2–generation reproduction study. The FQPA safety factor was reduces to 1X.

- There are no residual uncertainties identified in the chronic exposure database. The chronic dietary food exposure assessment was based on the assumption of all crops treated and anticipated residues from acceptable field trial data for all commodities. For chronic dietary food exposure assessments, experimentally derived processing factors were used for cereal grain commodities and default processing factors were used for all other processed commodities. The drinking water values used in the dietary risk assessments were based on information provided by the Acetochlor Registration Partnership water monitoring program to support the current use on field corn. These assessments will not underestimate the exposure and risks posed by acetochlor.

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 uncertainty/safety factors. 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 uncertainty/safety factors is not exceeded.

1. *Acute risk*. Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food and water to acetochlor will occupy <1% of the aPAD at the 95th percentile for the U.S. population and 2.6% of the aPAD at the 95th percentile for all infants, the population subgroup receiving the greatest exposure.

2. *Chronic risk*. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to acetochlor from food and water will utilize <1% of the cPAD for the U.S. population and 1.2 % of the cPAD for children 1-2 years old, the population subgroup receiving the greatest exposure. There are no residential uses for acetochlor that result in chronic residential exposure to acetochlor.

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

Acetochlor is not registered for use on any sites that would result in residential exposure. Therefore, an aggregate risk assessment for this duration is not appropriate.

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

Acetochlor is not registered for use on any sites that would result in residential exposure. Therefore, an aggregate risk assessment for this duration is not appropriate.

5. *Aggregate cancer risk for U.S. population*. As explained above, in Unit III.C.iii., the cRfD is considered to be protective of any cancer risk posed by acetochlor and as discussed in Unit E2, EPA has found that chronic acetochlor exposure does not exceed the cRfD; therefore, aggregate cancer risks are not of concern.

6. *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

An adequate high performance liquid chromatography with oxidative coulometric electrochemical detector (HPLC/OCED) method is available for enforcing new tolerances for acetochlor and its metabolites in sweet corn, sorghum, and rotational crops. This method is listed as Method I for plants in PAM Vol. II.

B. International Residue Limits

There are no Codex Maximum Residue Levels established for acetochlor on agricultural commodities.

V. Conclusion

Therefore, tolerances are established for residues of acetochlor (2-chloro-2'-methyl-6-ethyl-*N*-ethoxymethylacetamide) 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 as discussed in Unit II.

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: May 8, 2007.

Donald R. Stubbs,

Acting 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 revised to read as follows:

§ 180.470 Acetochlor; tolerances for residues.

(a) *General*. Tolerances are established for 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, in or on the following raw agricultural commodities.

Commodity	Parts per million
Corn, field, forage	3.0
Corn, field, grain	0.05
Corn, field, stover	1.5
Corn, pop, grain	0.05
Corn, pop, stover	1.5
Corn, sweet, forage	1.5
Corn, sweet, kernels plus cob with husks removed	0.05
Corn, sweet, stover	1.0
Sorghum, grain, forage	1.6
Sorghum, grain, grain	0.05
Sorghum, grain, stover	1.7

(b) *Section 18 emergency exemptions*. [Reserved].

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

(d) *Indirect or inadvertent residues*. Tolerances are established for indirect or inadvertent 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, in or on the following raw agricultural commodities when present therein as a result of application of acetochlor to the growing crops in paragraph (a) of this section:

Commodity	Parts per million
Animal feed, nongrass, group 18, forage	1.3
Animal feed, nongrass, group 18, hay	3.5
Beet, sugar, root	0.05
Beet, sugar, tops	0.05
Grain, cereal, forage, fodder and straw, group 16, except corn, grain sorghum, rice and wheat, forage	0.5
Grain, cereal, forage, fodder and straw, group 16, except corn, grain sorghum, rice and wheat, hay	2.0
Grain, cereal, forage, fodder and straw, group 16, except corn, grain sorghum, rice and wheat, stover	0.1
Grain, cereal, forage, fodder and straw, group 16, except corn, grain sorghum, rice and wheat, straw	0.3
Grain, cereal, group 15, except corn, grain sorghum, rice, and wheat, grain	0.05
Pea and bean, dried shelled, except soybean, subgroup 6C	0.05
Potato	0.05
Soybean, forage	0.7
Soybean, hay	1.0
Soybean, seed	0.1
Sunflower, seed	0.05
Wheat, forage	0.5
Wheat, grain	0.02
Wheat, hay	2.0
Wheat, straw	0.1

[FR Doc. E7–9430 Filed 5–15–07; 8:45 am]

BILLING CODE 6560–50–S