(c) *Tolerances with regional registrations*. Tolerances with regional registrations, as defined in § 180.1(m), are established for the combined residues of the insecticide oxydemeton-methyl (S-(2-(ethylsulfinyl)-ethyl) O,O-dimethyl phosphorothioate) and its metabolite oxydemeton-methyl sulfone in or on the following food commodities:

Commodity	Parts per million
Broccoli raab	2.0

(d) *Indirect or inadvertent residues*. [Reserved]

■ 4. Section 180.404 is amended by revising paragraph (a) to read as follows:

§ 180.404 Profenofos; tolerances for residues.

(a) *General*. Tolerances are established for residues of the insecticide profenofos (O-(4-bromo-2-chlorophenyl)-O-ethyl-S-propyl phosphorothioate) in or on the following food commodities:

Commodity	Parts per million
Cattle, fat	0.05
Cattle, meat	0.05
Cattle, meat byproducts	0.05
Cotton, gin byproducts	55.0
Cotton, undelinted seed	2.0
Goat, fat	0.05
Goat, meat	0.05
Goat, meat byproducts	0.05
Horse, fat	0.05
Horse, meat	0.05
Horse, meat byproducts	0.05
Milk	0.01
Sheep, fat	0.05
Sheep, meat	0.05
Sheep, meat byproducts	0.05

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[FR Doc. E7–18869 Filed 9–25–07; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2007–0146; FRL–8147–2]

Alachlor; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation revises and separates the tolerances for alachlor in § 180.249 into paragraphs (a) through (d). This regulation also establishes several new tolerances under paragraph (a). It further establishes several new tolerances under paragraph (d). Details of these changes are outlined in Unit II. of this document. 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 September 26, 2007. Objections and requests for hearings must be received on or before November 26, 2007, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: EPA has established a docket for this action under docket identification (ID) number EPA–HQ–OPP–2007–0146. To access the electronic docket, go to *http://www.regulations.gov*, select ''Advanced Search,'' then ''Docket Search.'' Insert the docket ID number where indicated and select the ''Submit'' button. Follow the instructions on the regulations.gov website to view the docket index or access available documents. All documents in the docket are listed in the docket index available in regulations.gov. Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available in the electronic docket at *http://www.regulations.gov*, or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: 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–2007–0146 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 26, 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–2007–0146, by one of the following methods:

- *Federal eRulemaking Portal*: *http://www.regulations.gov*. Follow the on-line instructions for submitting comments.
- *Mail*: Office of Pesticide Programs (OPP) Regulatory Public Docket (7502P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.
- *Delivery*: OPP Regulatory Public Docket (7502P), Environmental Protection Agency, Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. Deliveries are only accepted during the Docket's normal hours of operation (8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays). Special arrangements should be made for deliveries of boxed information. The Docket Facility telephone number is (703) 305–5805.

II. Petition for Tolerance

In the **Federal Register** of May 9, 2007 (72 FR 26372) (FRL–8121–5), 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 0F2348, 9F3776, 3F4179, 8F5000, 8F5025) by Monsanto Company, 1300 I St., NW., Suite 450 East, Washington, DC 2005. The petitions requested that 40 CFR 180.249 be amended by establishing a tolerance for residues of the herbicide alachlor (2-chloro-2',6'-diethyl-*N*-(methoxymethyl)acetanilide)and its metabolites which can be converted to 2,6-diethylaniline (DEA) or 2-ethyl-6-(1-hydroxyethyl)aniline (HEEA) upon basic hydrolysis, calculated as alachlor, in or on corn, fodder, and corn, forage at 2.0 ppm (0F2348); soybean at 1.0 ppm (9F3776); beans, dry and beans, succulent lima at 0.1 ppm; cowpea, forage and cowpea, hay at 5.0 ppm (3F4179); cotton, gin byproducts at 0.7 ppm; cotton, undelinted seed at 0.03 ppm; sunflower, seed at 2.5 ppm; and in the processed commodity sunflower, seed meal at 3.4 ppm (8F5000); grain, cereal group 15, except corn, rice, and sorghum forage at 0.05 ppm; grain, cereal, forage, fodder, and straw, group 16, except corn, rice, and sorghum forage at 0.6 ppm; hay and straw at 0.8 ppm; and nongrass animal feed, crop group 18, forage at 1.4 ppm and hay at 1.2 ppm (8F5025). PP 3F4179 also proposed that the current tolerances for bean, forage and bean, hay at 0.2 ppm be revoked, as these are no longer significant animal feed commodities. That notice referenced a summary of the petitions 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 petitions, EPA is increasing the tolerance for peanut to 0.5 ppm. This tolerance will be listed in § 180.249(a). The Agency is correcting the tolerance expression for § 180.249(a) to read ''Tolerances are established for combined residues of the herbicide alachlor (2-chloro-2',6'-diethyl-*N*-(methoxymethyl)acetanilide) and its metabolites which can be converted to 2,6-diethylaniline (DEA) or 2-ethyl-6-(1-hydroxyethyl)aniline (1-HEEA) upon basic hydrolysis, calculated as alachlor in or on the following food commodities:'' The terminology for the current listings of corn, fresh, kernel plus cob with husk removed; sorghum, forage; and sorghum, grain (milo); are being updated to read corn, sweet (K+CWHR); sorghum, grain, forage; and sorghum, grain, grain; to conform to Agency procedures. Pending tolerances for beans, dry at 0.1 ppm and beans, succulent lima at 0.1 will replace the current entries for bean, dry, seed and bean, lima, succulent. These tolerances will be listed in paragraph (a).

Based upon Agency procedures concerning commodity names, the Agency is correcting the pending crops under § 180.249(a) as follows: Corn, field, forage at 2.0 ppm; corn, field, grain at 0.2 ppm; corn, field, stover at 2.0 ppm; corn, field, pop at 0.2 ppm; corn, pop, stover at 2.0 ppm; corn, sweet, forage at 2.0 ppm; corn, sweet, stover at 2.0 ppm; soybeans, seed at 1.0 ppm and sunflower, meal at 3.4 ppm. These listings will replace current listings for corn, forage; corn, grain; corn, stover; and soybean.

The Agency also determined that the pending rotational crop tolerances should be placed in § 180.249(d) *Indirect and inadvertent residues*. The tolerance expression and commodity listing for § 180.249 (d) is revised to read: Tolerances are also established for indirect or inadvertent residues of alachlor (2-chloro-2',6'-diethyl-*N*-(methoxymethyl)acetanilide) and its metabolites which can be converted to 2,6-diethylaniline (DEA) or 2-ethyl-6-(1-hydroxyethyl)aniline (1-HEEA) upon basic hydrolysis, calculated as alachlor in or on the following raw agricultural commodities when present therein as a result of application of alachlor to the growing crops listed in paragraph (a) of this section animal feed, nongrass, group 18, forage at 1.4 ppm; animal feed, nongrass, group 18, hay at 1.2 ppm; grain, cereal, group 15 except corn, sorghum, rice at 0.05 ppm; grain, cereal, forage, fodder, and straw, group 16 except corn, sorghum, and rice, forage at 0.6 ppm; grain, cereal, forage, fodder and straw, group 16 except corn, sorghum, and rice, hay at 0.8 ppm; and grain, cereal, forage, fodder, and straw, group 16 except corn, sorghum, and rice, straw at 0.8 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 FFDCA section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for the petitioned-for tolerances for combined residues of alachlor (2-chloro-2',6'-diethyl-*N*-(methoxymethyl)acetanilide) and its metabolites which can be converted to 2,6-diethylaniline (DEA) or 2-ethyl-6-(1-hydroxyethyl)aniline (1-HEEA) upon basic hydrolysis, calculated as alachlor. EPA's assessment of exposures and risks associated with establishing the 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 alachlor 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 FQPA Human Health Risk Assessment for Section 3 New Uses on Cotton, Sunflower, and for Inadvertent Tolerances on Various Rotational Crops (Cereal Grains and Nongrass Animal Feeds and is available in the docket established by this action, which is described under **ADDRESSES**, and is identified as EPA–HQ–OPP–2007–0146–003 in that docket.

B. Toxicological Endpoints

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

For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk and estimates risk in terms of the probability of occurrence of additional adverse cases. Generally, cancer risks are considered non-threshold. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see *http://www.epa.gov/fedrgstr/EPA-PEST/1997/November/Day-26/p30948.htm*.

A summary of the toxicological endpoints for alachlor used for human risk assessment can be found at *http://www.regulations.gov* in document ''FQPA Human Health Risk Assessment for Section 3 New Uses on Cotton, Sunflower, and for Inadvertent Tolerances on Various Rotational Crops (Cereal Grains and Nongrass Animal Feeds'' on page 50 in docket ID number EPA–HQ–OPP–2007–0146.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses*. In evaluating dietary exposure to alachlor, EPA considered exposure under the petitioned-for tolerances as well as all reassessed tolerances and existing alachlor tolerances in (40 CFR 180.249). EPA assessed dietary exposures from alachlor in food as follows:

i. *Acute exposure*. Quantitative acute dietary exposure and risk assessments are performed for a food-use pesticide, if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1–day or single exposure. No such effects were identified in the toxicological studies for alachlor in the general population. Therefore, a quantitative acute dietary exposure is unnecessary for the general population. An effect attributable to a single dose was identified for females 13-49 in the developmental study in rats. In estimating acute dietary exposure for females 13-49, EPA used food consumption information from the U.S. Department of Agriculture (USDA) 1994–1996 or 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 were treated and contain tolerance-level residues. Percent crop treated (PCT) or anticipated residues were not used.

ii. *Chronic exposure*. In conducting the chronic dietary exposure assessment EPA used the food consumption data from the USDA 1994–1996, or 1998 CSFII. As to residue levels in food, EPA assumed all foods for which there are tolerances were treated and contain tolerance level residues. PCT or anticipated residues were not used.

iii. *Cancer*. Alachlor has been classified as ''likely to be carcinogenic to humans at high dose, but not at low doses'', based on treatment-related increases in nasal olfactory epithelial thyroid, and gastric tumors at higher dose levels. The Agency used the MOE approach for quantification of cancer risk. The target MOE is 100. For nasal tumors, the point of departure selected was 0.5 milligrams/kilograms/day (mg/kg/day), based on nasal tumors at 2.5 mg/kg/day in rats. For gastric tumors, a point of departure of 14 mg/kg/day was selected, based on stomach tumors seen at 42 mg/kg/day in rats. The cancer assessment was conducted using tolerance levels and 100% crop treated for all existing and proposed uses.

2. *Dietary exposure from drinking water*. The Agency lacks sufficient monitoring data to complete a comprehensive dietary exposure analysis and risk assessment for alachlor in drinking water. Because the Agency does not have comprehensive monitoring data, drinking water concentration estimates are made by reliance on simulation or modeling taking into account data on the environmental fate characteristics of alachlor. 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) and Screening Concentration in Groundwater (SCI-GROW) models, the estimated drinking water concentrations (EDWCs) of alachlor for acute exposures are estimated to be 123 parts per billion (ppb) for surface water and 2.48 ppb for ground water. The EDWCs for chronic exposures are estimated to be 75 ppb for surface water and <2.48 ppb for ground 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 123 ppb was used to access the contribution to drinking water. For chronic dietary risk assessment, the water concentration value of 75 ppb was used to access the contribution to drinking water. For the cancer risk assessment, the 30–year mean concentration of 64 ppb was used.

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).

Alachlor 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.''

Alachlor is a member of the chloroacetanilide cumulative assessment group (CAG) which includes alachlor, acetochlor, 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.regulations.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 the Agency's level of concern of 100.

A revised cumulative risk assessment was performed based on the new uses for alachlor addressed in this rule and the new uses for acetochlor established in the final rule published in the **Federal Register** of May 16, 2007 (72 FR 27463) (FRL–8126–2). The revised risk assessment includes only food and water, since there are no residential uses registered for these two chemicals. Because the endpoint of interest is a cancer endpoint that arises via a mode of action that requires prolonged exposure, only a chronic dietary analysis was performed. For food exposure, tolerance levels and some average residues were used. Acetochlor residues were converted to alachlor equivalents by multiplying a factor of 0.05. The total alachlor residues were obtained by adding the alachlor residues to acetochlor (alachlor equivalents) residues for crop that have both alachlor and acetochlor tolerances. DEEM default processing factors from DEEM (Version 7.81) were used for all processed commodities that do not have individual tolerances, except for soybeans and sunflower, where processing factors from available processing studies were used. For soybeans, processing factors used in DEEM are: 0.17 for soybean oil, 0.32 for soybean protein concentrate, and 0.21 for soybean protein isolate. For sunflower, a processing factor of 0.07 was used for sunflower oil. For drinking water exposure, the 30 year mean concentration of 63.6 ppb from modeling for alachlor and degradates, plus 0.11 ppb (alachlor equivalent) from monitoring for acetochlor, totaling 64 ppb was used.

The dietary exposure assessment was conducted using the Dietary Exposure Evaluation Model (DEEM-FCID, Version 2.03) which uses food consumption data from the USDA's CSFII from 1994–1996 and 1998. It was assumed that 100% crop treated (%CT) for all commodities. The MOE for nasal tumor (the most sensitive cancer endpoint among the group) for the general U.S. population is 330 which is greater than the target MOE of 100. Therefore, the cumulative risk is below EPA's level of concern. This analysis is considered conservative dietary exposure assessment with the use of average residues for some crops, 100% crop treated, and the use of drinking water modeling data. Based on the DEEM commodity analysis, the drinking water exposure from alachlor modeling value counts for 90% of the total risk. This risk assessment is fully discussed in the document entitled ''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). The referenced document is available in the docket established by this action which is described under **ADDRESSES** and is identified as EPA–HQ–OPP–2007–0146–004 in that docket.

D. Safety Factor for Infants and Children

1. *In general*. Section 408 of FFDCA provides that EPA shall apply an additional (''10X'') tenfold margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the FQPA safety factor. In applying this provision, EPA either retains the default value of 10X when reliable data do not support the choice of a different factor, or, if reliable data are available, EPA uses a different additional FQPA safety factor value based on the use of traditional UFs and/or special FQPA safety factors, as appropriate.

2. *Prenatal and postnatal sensitivity*. Available developmental toxicity in two species and multi–generation reproductive toxicity study in rat do not show evidence of increased susceptibility of the offspring. These studies, along with guideline toxicity studies in the adult animal, do not show evidence of neurotoxicity. Concern for increased susceptibility is low since toxicity to offspring was observed only at maternally toxic doses in the developmental toxicity studies in the rat and rabbit and in a rat multi–generation reproductive toxicity study. Clear NOELs for offspring and adults were observed in all studies.

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

i. The toxicity database for alachlor is complete.

ii. There is no indication that alachlor is a neurotoxic chemical and there is no need for a developmental neurotoxicity study or additional UFs to account for neurotoxicity.

iii. There is no evidence that alachlor 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.

iv. There are no residual uncertainties identified in the exposure databases. The dietary food exposure assessments were performed based on 100%CT and tolerance-level residues. Conservative ground and surface water modeling estimates were used. These assessments will not underestimate the exposure and risks posed by alachlor.

E. Aggregate Risks and Determination of Safety

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

1. *Acute risk*. Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food and water to

alachlor will occupy 0.3% of the aPAD for the population group females (13-49) receiving the greatest exposure.

2. *Chronic risk*. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to alachlor from food and water will utilize 16% of the cPAD for the U.S. general population and 33% of the cPAD for children 1-2 years old. There are no residential uses for alachlor that result in chronic residential exposure to alachlor.

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).

Alachlor is not registered for use on any sites that would result in residential exposure. Therefore, the aggregate risk is the sum of the risk from food and water.

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).

Alachlor is not registered for use on any sites that would result in residential exposure. Therefore, the aggregate risk is the sum of the risk from food and water, which do not exceed the Agency's level of concern.

5. *Aggregate cancer risk for U.S. population*. Using the exposure assumptions discussed in this unit for cancer risk, EPA has determined that the MOE for the U.S. population is 330 which does not exceed the EPA's level of concern (a MOE of 100).

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 alachlor residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

There are adequate analytical methods for the purposes of tolerance enforcement and data collection. An HPLC method which determines DEA- and 1-HEEA-yeilding metabolites have been validated has been validated by the Agency and is considered acceptable for enforcement purposes. The method uses HPLC with oxidative coulometric electrochemical detection (HPLC-OCED) of both DEA and 1-HEEA-producing residues, and was recommended for inclusion in PAM Vol. II as Method III, the limit of detection is 0.01 ppm for each metabolite class.

Adequate enforcement methodology (HPLC-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*.

B. International Residue Limits

No maximum residue limits (MRLs) for alachlor have been established by CODEX for any agricultural commodity.

V. Conclusion

Therefore, the tolerance is established for combined residues of alachlor (2-chloro-2',6'-diethyl-*N*-(methoxymethyl)acetanilide) and its metabolites which can be converted to 2,6-diethylaniline (DEA) or 2-ethyl-6-(1-hydroxyethyl)aniline (1-HEEA) upon basic hydrolysis, calculated as alachlor, 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: September 13, 2007.

Lois Rossi,

Director, Registration Division, Office of Pesticide Programs.

■ Therefore, 40 CFR chapter I is amended as follows:

PART 180—AMENDED

■ 1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

■ 2. Section 180.249 is revised to read as follows:

§ 180.249 Alachlor; tolerances for residues.

(a) *General.* Tolerances are established for combined residues of alachlor (2-chloro-2',6'-diethyl-*N*-(methoxymethyl)acetanilide) and its metabolites which can be converted to 2,6-diethylaniline (DEA) or 2-ethyl-6-(1-hydroxyethyl)aniline (1-HEEA) upon basic hydrolysis, calculated as alachlor in or on the following raw agricultural commodities.

Commodity	Parts per million
Beans, dry	0.1
Beans, succulent lima	0.1
Cattle, fat	0.02
Cattle, meat byproducts	0.02
Cattle, meat	0.02
Corn, field, forage	2.0
Corn, field, grain	0.2
Corn, field, pop	0.2
Corn, field, stover	2.0
Corn, pop, stover	2.0
Corn, sweet (K+CWHR)	0.05
Corn, sweet, stover	2.0
Cotton, gin byproducts	0.7
Cotton, undelinted seed	0.03
Cowpea, forage	5.0
Cowpea, hay	5.0
Egg	0.02
Goat, fat	0.02
Goat, meat byproducts	0.02
Goat, meat	0.02
Hog, fat	0.02
Hog meat byproducts	0.02
Hog, meat	0.02
Horse, fat	0.02
Horse, meat byproducts	0.02
Horse, meat	0.02
Milk	0.02
Peanut	0.5
Poultry, fat	0.02
Poultry, meat byproducts	0.02
Poultry, meat	0.02
Sheep, fat	0.02
Sheep, meat byproducts	0.02
Sheep, meat	0.02
Sorghum grain, forage	2.0
Sorghum, grain, grain	0.1
Sorghum, grain, stover	1.0
Soybeans, seed	1.0
Sunflower, meal	3.4
Sunflower, seed	2.5

(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 alachlor (2-chloro-2',6'-diethyl-*N*-(methoxymethyl)acetanilide) and its metabolites which can be converted to 2,6-diethylaniline (DEA) or 2-ethyl-6-(1-hydroxyethyl)aniline (1-HEEA) upon basic hydrolysis, calculated as alachlor, in or on the following raw agricultural commodities when present therein as a result of the application of alachlor to the growing crops in paragraph (a) of this section:

Commodity	Parts per million
Animal feed, nongrass, group 18, forage	1.4
Animal feed, nongrass, group 18, hay	1.2
Grain, cereal, forage, and straw, group 16 except corn, sorghum, rice, straw	0.8
Grain, cereal, forage, fodder and straw, group 16 except corn, sorghum, rice, forage	0.6
Grain, cereal, forage, fodder, and straw, group 16 except for corn, sorghum, rice, hay	0.8
Grain, cereal, group 15 except corn, sorghum, rice	0.05

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2007–0145; FRL–8148–1]

Tepraloxydim; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a tolerance for residues of tepraloxydim in or on imported flax, seed; lentil, seed; and pea, dry seed. BASF requested this tolerance under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective September 26, 2007. Objections and requests for hearings must be received on or before November 26, 2007, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: EPA has established a docket for this action under docket identification (ID) number EPA–HQ–OPP–2007–0145. To access the electronic docket, go to *http://www.regulations.gov*, select ''Advanced Search,'' then ''Docket Search.'' Insert the docket ID number where indicated and select the ''Submit'' button. Follow the instructions on the regulations.gov website to view the docket index or access available documents. All documents in the docket are listed in the docket index available in regulations.gov. Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available in the electronic docket at *http://www.regulations.gov*, or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: Jim Tompkins, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 305–5697; e-mail address: *tompkins.jim@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