

**§ 180.571 Mesotrione; tolerances for residues.**

(a) General. Tolerances are established for residues of the herbicide mesotrione, 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

mesotrione, 2-[4-(methylsulfonyl)-2-nitrobenzoyl]-1,3-cyclohexanedione, in or on the following raw agricultural commodities:

Commodity	Parts per million
Soybean, seed .....	0.01

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## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 180

[EPA-HQ-OPP-2009-0005; FRL-8797-9]

#### Tribenuron methyl; Pesticide Tolerances

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

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes tolerances for residues of tribenuron methyl and its metabolites and degradates in or on grain, aspirated fractions; soybean, forage; soybean, hay; and soybean, hulls; and revises existing tolerances for residues for tribenuron methyl and its metabolites and degradates in or on corn, field, forage; corn, field, grain; corn, field, stover; and soybean, seed. E.I. du Pont de Nemours and Company requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

**DATES:** This regulation is effective December 18, 2009. Objections and requests for hearings must be received on or before February 16, 2010, 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-2009-0005. 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 Test Guidelines referenced in this document, go directly to the guidelines at <http://www.epa.gov/oppts> and select “Test Methods & Guidelines” on the left side navigation menu.

###### 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-2009-0005 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 February 16, 2010.

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-2009-0005, 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 8F7432 and PP 8F7441) by E.I. du Pont de Nemours and Company, Laurel Run Plaza, P.O. Box 80038, Wilmington, DE 19880-0038. The petitions requested that 40 CFR 180.451 be amended by establishing tolerances for residues of the herbicide tribenuron methyl, methyl-2-[[[N-(4-methoxy-6-methyl-1,3,5-triazin-2-yl)methylamino] carbonyl] amino] sulfonyl benzoate, (in PP 8F7441) in or on corn, field, grain at 0.01 parts per million (ppm); corn, field, forage at 0.2 ppm; corn, field, stover at 1.1 ppm; and corn, aspirated grain fractions at 3.55 ppm; and (in PP 8F7432) in or on soybean, seed at 0.01 ppm; soybean, forage at 0.06 ppm; soybean, hulls at 0.04 ppm; soybean, aspirated grain fractions at 3.46 ppm; and soybean, hay at 0.25 ppm. That notice referenced a summary of the petitions prepared by E.I. du Pont de Nemours and 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 has increased the proposed tolerances on soybean hay and forage, decreased the proposed tolerance on field corn forage, and determined that a tolerance should be established for "grain, aspirated fractions", in lieu of the proposed tolerances on "soybean, aspirated grain fractions" and "corn, field, aspirated grain fractions." EPA has also revised the tribenuron methyl tolerance expression for all existing and new tolerances. 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 tribenuron methyl and its metabolites and degradates on corn, field, forage at 0.15 ppm; corn, field, grain at 0.01 ppm; corn, field, stover at 1.1 ppm; grain, aspirated fractions at 1.5 ppm; soybean, forage at 0.07 ppm; soybean, hay at 0.35 ppm; soybean, hulls at 0.04 ppm and soybean, seed at 0.01 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.

Tribenuron methyl has low to moderate acute toxicity via the oral, inhalation, and dermal routes of exposure. It is not a dermal irritant, but was found to be mildly irritating to the eye and is a skin sensitizer.

Repeated dose oral toxicity studies in rats and dogs resulted primarily in

decreased body weights and body weight gains accompanied by decreased food consumption. There is no evidence that tribenuron methyl targets specific organs following repeated oral exposure. There is no evidence that tribenuron methyl is neurotoxic. Although increased spleen weights were observed in the 90-day oral toxicity study in rats and decreased spleen weights were observed in the reproduction study (both potential indications of immunotoxicity), these effects occurred in the absence of other potential indicators of immunotoxicity.

EPA has classified tribenuron methyl as a Group C (possible human) carcinogen, based on statistically significant increases in mammary gland adenocarcinomas in female rats at the highest dose tested (HDT) (76 milligram/kilogram/day (mg/kg/day)). There was no evidence of carcinogenicity observed in the mouse carcinogenicity study. Quantitative cancer risk assessment is not recommended for tribenuron methyl because the tumors observed in rats occurred at a dose resulting in excessive toxicity (i.e., greater than the maximum tolerated dose), there was no evidence of genotoxicity, and structurally similar compounds are not known to be carcinogenic in rats and mice. The no observed adverse effect level (NOAEL) (0.8 mg/kg/day) selected for chronic risk assessment is considered to be protective of any potential cancer risk.

Developmental and reproductive toxicity studies indicated no increased susceptibility of offspring to tribenuron methyl. At the lowest observed adverse effect level (LOAEL) of 125 mg/kg/day in the developmental study in rats, decreased fetal weights were observed in the presence of decreased maternal body weights. At the HDT (500 mg/kg/day), increased resorptions, fetal deaths, and incomplete ossifications were observed, but these effects may be secondary to maternal toxicity. In the developmental rabbit study, maternal toxicity consisted of decreased food consumption and abortions at the HDT. At this same dose there was a 10% decrease in fetal body weights (not statistically significant). Since the number of dead fetuses and resorptions per litter were not correlated with the dosing level, the increased incidence of abortions in the high dose group is likely due to maternal toxicity. In a two-generation reproduction study, reproductive effects of tribenuron methyl were limited to decreased body weight gain during lactation. There was no evidence of increased susceptibility, as parental, offspring and reproduction

NOAELs and LOAELs were established at similar levels.

Specific information on the studies received and the nature of the adverse effects caused by tribenuron methyl as well as the NOAEL and the LOAEL from the toxicity studies can be found at <http://www.regulations.gov> in the document "Tribenuron methyl. Human Health Risk Assessment for the Proposed Use of Tribenuron methyl on Corn and Soybean," page 33 in docket ID number EPA-HQ-OPP-2009-0005.

#### B. Toxicological Endpoints

For hazards that have a threshold below which there is no appreciable risk, a toxicological point of departure (POD) is identified as the basis for derivation of reference values for risk assessment. The POD may be defined as the highest dose at which no adverse effects are observed (the NOAEL) in the toxicology study identified as appropriate for use in risk assessment. However, if a NOAEL cannot be determined, the lowest dose at which adverse effects of concern are identified (the LOAEL) or a Benchmark Dose (BMD) approach is sometimes used for risk assessment. Uncertainty/safety factors (UFs) are used in conjunction with the POD to take into account uncertainties inherent in the extrapolation from laboratory animal data to humans and in the variations in sensitivity among members of the human population as well as other unknowns. Safety is assessed for acute and chronic dietary risks by comparing aggregate food and water exposure to the pesticide to the acute population adjusted dose (aPAD) and chronic population adjusted dose (cPAD). The aPAD and cPAD are calculated by dividing the POD by all applicable UFs. Aggregate short-term, intermediate-term, and chronic-term risks are evaluated by comparing food, water, and residential exposure to the POD to ensure that the margin of exposure (MOE) called for by the product of all applicable UFs is not exceeded. This latter value is referred to as the Level of Concern (LOC).

For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect greater than that expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see <http://www.epa.gov/pesticides/factsheets/riskassess.htm>.

A summary of the toxicological endpoints for tribenuron methyl used for human risk assessment can be found

at <http://www.regulations.gov> in the document "Tribenuron methyl. Human Health Risk Assessment for the Proposed Use of Tribenuron methyl on Corn and Soybean," page 20 in docket ID number EPA-HQ-OPP-2009-0005.

#### C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to tribenuron methyl, EPA considered exposure under the petitioned-for tolerances as well as all existing tribenuron methyl tolerances in 40 CFR 180.451. EPA assessed dietary exposures from tribenuron methyl 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 tribenuron methyl; therefore, a quantitative acute dietary exposure assessment is unnecessary.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the food consumption data from the U.S Department of Agriculture (USDA) 1994–1996 and 1998 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 tribenuron methyl. DEEM™ 7.81 default concentration factors were used to estimate residues of tribenuron methyl in processed commodities.

iii. *Cancer.* EPA classified tribenuron methyl as a Group C, possible human, carcinogen and determined that the chronic dietary risk assessment based on the cPAD would be protective of any potential cancer effects. Therefore, a separate exposure assessment to evaluate cancer risk is unnecessary. The weight of the evidence supporting this determination is discussed in Unit III.A.

iv. *Anticipated residue and percent crop treated (PCT) information.* EPA did not use anticipated residue or PCT information in the dietary assessment for tribenuron methyl. Tolerance level residues and 100 PCT were assumed for all food commodities.

2. *Dietary exposure from drinking water.* The Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for tribenuron methyl in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of tribenuron methyl. 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 First Index Reservoir Screening Tool (FIRST) and Screening Concentration in Ground Water (SCI-GROW) models, the Estimated Drinking Water Concentrations (EDWCs) of tribenuron methyl for acute exposures are estimated to be 4.1 parts per billion (ppb) for surface water and 6.8 ppb for ground water. For chronic exposures for non-cancer assessments EDWCs are estimated to be 2.7 ppb for surface water and 6.8 ppb for ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For chronic dietary risk assessment, the only dietary exposure scenario for which a toxicological endpoint of concern was identified, the water concentration value of 6.8 ppb was used to assess the contribution to drinking water.

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). Tribenuron methyl 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."

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

#### D. Safety Factor for Infants and Children

1. *In general.* Section 408(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 SF. In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor 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 tribenuron methyl includes guideline rat and rabbit developmental toxicity studies and a two-generation reproduction toxicity study in rats. As discussed in Unit III.A., there is no quantitative or qualitative evidence of increased susceptibility of fetuses or offspring in any of these studies.

3. *Conclusion.* EPA has determined that reliable data show the safety of infants and children would be adequately protected if the FQPA SF were reduced to 1X. That decision is based on the following findings:

i. The toxicity database for tribenuron methyl is adequate to assess prenatal and postnatal toxicity. In accordance with Part 158 Toxicology Data requirements, an immunotoxicity study (OPPTS Test Guideline 870.7800) and acute and subchronic neurotoxicity studies (OPPTS Test Guideline 870.6200) are required for tribenuron methyl. In the absence of specific immunotoxicity and neurotoxicity studies, EPA has evaluated the available tribenuron methyl toxicity data to determine whether an additional database uncertainty factor is needed to account for the lack of these studies.

a. *Immunotoxicity:* Increased spleen weights were observed in the 90-day oral toxicity study in rats at 118/135 (Male/Female) mg/kg/day, and decreased absolute spleen weights were observed in the offspring in the reproduction study at 250 mg/kg/day. These effects occurred in the absence of other potential indicators of immunotoxicity, including histopathology and alterations in hematology, and there were no accompanying effects on thymus weights. Finally, the dose selected for chronic risk assessment (cPAD of 0.008 mg/kg/day from the chronic dog toxicity study) is protective of any potential immunotoxicity (i.e., decreased spleen weights) from exposure to tribenuron methyl. Therefore, an additional UF is not needed to account for the lack of an immunotoxicity study.

b. *Neurotoxicity:* No evidence of neurotoxicity or neuropathology was observed in any of the toxicology studies for tribenuron methyl. Therefore, EPA has concluded that there is no need for a developmental neurotoxicity study or additional UFs to account for the lack of specific acute/subchronic neurotoxicity studies.

ii. There is no evidence that tribenuron methyl results in increased susceptibility *in utero* rats or rabbits in the prenatal developmental studies or in young rats in the 2-generation reproduction study.

iii. There are no residual uncertainties identified in the exposure databases. The dietary food exposure assessments were performed assuming 100 PCT and tolerance-level residues. EPA made conservative (protective) assumptions in the ground water and surface water modeling used to assess exposure to tribenuron methyl in drinking water. Residential exposure to tribenuron methyl is not expected. These assessments will not underestimate the exposure and risks posed by tribenuron methyl.

#### *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 margin of exposure (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. No adverse effect resulting from a single oral exposure was identified and no acute dietary endpoint was selected. Therefore, tribenuron methyl is not expected to pose an acute risk.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to tribenuron methyl from food and water will utilize less than 4% of the cPAD for the general U.S. population and less than 8% of the cPAD for infants less than 1 year old, the population group receiving the

greatest exposure. There are no residential uses for tribenuron methyl.

3. *Short-term/intermediate-term risk.* Short-term/intermediate term aggregate exposure takes into account short-term/intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Tribenuron methyl is not registered for any use patterns that would result in residential exposure. Therefore, the short-term/intermediate-term aggregate risk is the sum of the risk from exposure to tribenuron methyl 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 tribenuron methyl. Based on the results of the chronic risk assessment discussed above in Unit III.E.2, EPA concludes that tribenuron methyl 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 tribenuron methyl residues.

## **IV. Other Considerations**

### *A. Analytical Enforcement Methodology*

Adequate enforcement methodology (liquid chromatography with tandem mass-spectrometric detection (LC/MS/MS) method, DuPont Method 13412 (Revision 1)) 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 (MRLs) established on the commodities associated with these petitions.

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

EPA has increased the proposed tolerance on soybean, hay from 0.25 ppm to 0.35 ppm; increased the tolerance on soybean, forage from 0.06 ppm to 0.07 ppm; and decreased the proposed tolerance on corn, field, forage from 0.2 ppm to 0.15 ppm. EPA revised these tolerance levels based on analyses of the residue field trial data using the

Agency's Tolerance Spreadsheet in accordance with the Agency's Guidance for Setting Pesticide Tolerances Based on Field Trial Data. EPA also determined that a single tolerance at 1.5 ppm should be established for "grain, aspirated fractions", in lieu of the separately proposed tolerances of 3.46 ppm on "soybean, aspirated grain fractions" and 3.55 ppm on "corn, field, aspirated grain fractions." The tolerance on grain, aspirated fractions (AGF) will cover residues on aspirated fractions of both corn and soybean. The tolerance level of 1.5 ppm was determined based on data for soybean indicating a concentration factor of 150x for AGF and the highest average field trial (HAFT) residue for of 0.01 ppm. Residues in corn AGF are expected to be lower, based on a concentration factor of only 13x and a HAFT of 0.01 ppm.

Finally, EPA has revised the tribenuron methyl tolerance expression for all existing and new commodities 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 tolerances cover "residues of tribenuron methyl and its metabolites and degradates," but that compliance with the tolerance levels will be determined by measuring only "tribenuron methyl, methyl-2-[[[N-(4-methoxy-6-methyl-1,3,5-triazin-2-yl) methylamino] carbonyl] amino] sulfonyl] benzoate, in or on the commodities.

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 tribenuron methyl and its metabolites and degradates in or on corn, field, forage at 0.15 ppm; corn, field, grain at 0.01 ppm; corn, field, stover at 1.1 ppm; grain, aspirated fractions at 1.5 ppm; soybean, forage at 0.07 ppm; soybean, hay at 0.35 ppm; soybean, hulls at 0.04 ppm and soybean, seed at 0.01 ppm. Compliance with these tolerances will be determined by measuring only tribenuron methyl, methyl-2-[[[N-(4-methoxy-6-methyl-1,3,5-triazin-2-yl) methylamino] carbonyl] amino] sulfonyl] benzoate, in or on the commodities.

## 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: December 8, 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 180.451 is amended by revising the introductory text in paragraph (a); revising the existing tolerances in paragraph (a) for corn, field, forage; corn, field, grain; corn, field, stover; and soybean, seed; and alphabetically adding the commodities grain, aspirated fractions; soybean, forage; soybean, hay; and soybean, hulls to the table in paragraph (a) to read as follows:

### § 180.451 Tribenuron methyl; tolerances for residues.

(a) *General.* Tolerances are established for residues of the herbicide tribenuron methyl and its metabolites and degradates in or on the commodities in the following table. Compliance with the tolerance levels specified below is to be determined by measuring only tribenuron methyl,

methyl-2-[[[N-(4-methoxy-6-methyl-1,3,5-triazin-2-yl) methylamino] carbonyl] amino] sulfonyl] benzoate, in or on the following commodities:

Commodity	Parts per million
Corn, field, forage	0.15
Corn, field, grain	0.01
Corn, field, stover	1.1
Grain, aspirated fractions	1.5
Soybean, forage	0.07
Soybean, hay	0.35
Soybean, hulls	0.04
Soybean, seed	0.01

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## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 180

[EPA-HQ-OPP-2008-0385; FRL-8408-1]

#### Glyphosate; Pesticide Tolerances

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

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes a new tolerance for a plant commodity, and revises other tolerances for glyphosate and its metabolite *N*-acetyl-glyphosate and revises one tolerance for glyphosate *per se*. These changes are detailed in Unit II. of this document. E.I. DuPont de Nemours and Company requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

**DATES:** This regulation is effective December 18, 2009. Objections and requests for hearings must be received on or before February 16, 2010, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION** ).

**ADDRESSES:** EPA has established a docket for this action under docket identification (ID) number EPA-HQ-OPP-2008-0385. 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:** Dan Kenny, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 305-7546; e-mail address: [kenny.dan@epa.gov](mailto:kenny.dan@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 Get Electronic Access to Other Related Information?

You may 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>.

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

Under section 408(g) of FFDCA, 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2008-0385 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 February 16, 2010.

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please