ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2008–0811; FRL–8799–1]

Mesotrione; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a tolerance for residues of mesotrione in or on soybean, seed. Syngenta Crop Protection requested this tolerance 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–2008–0811. 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: Joanne Miller, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 305–6224; e-mail address: *miller.joanne@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'' in the left side margin 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–2008–0811 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–2008–0811, 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 December 3, 2008 (73 FR 73648) (FRL–8391–3), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 8F7456) by Syngenta Crop Protection, Inc., P.O. Box 18300, Greensboro, NC 27419. The petition requested that 40 CFR 180.571 be amended by establishing tolerances for residues of the herbicide, mesotrione, in or on soybeans at 0.01 parts per million (ppm). That notice referenced a summary of the petition prepared by Syngenta Crop Protection, 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.

To harmonize with the Food and Feed Commodity Vocabulary, *http://www.epa.gov/opphed01/foodfeed/index.htm/*, EPA has amended the commodity listing to read: Soybean, seed at 0.01 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.''

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 mesotrione, including its metabolites and degradates, in or on soybean, seed at 0.01 ppm. Compliance with the tolerance level is to be determined by measuring only mesotrione, 2-[4-(methylsulfonyl)-2-nitrobenzoyl]-1,3-cyclohexanedione, in the raw agricultural commodity. 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.

Mesotrione has a low acute toxicity via the oral, dermal, and inhalation routes. It is a mild eye irritant, but is not a dermal irritant or a dermal sensitizer. In subchronic and chronic oral studies, ocular lesions, liver and kidney effects, and/or body weight decrements were the major adverse effects seen in the rat, mouse, and dog. Plasma tyrosine levels were increased in the rat, mouse and dog in the chronic and reproduction studies in which levels were measured. The ocular, liver and kidney effects are believed to be mediated by the high tyrosine levels in the blood caused by inhibition of the enzyme HPPD. Even though the rat is the most sensitive species to this effect compared to the dog and the mouse, EPA concluded that the mouse is a more appropriate model for assessing human risk than is the rat.

There was no evidence of carcinogenic potential in either the rat chronic toxicity/carcinogenicity or mouse carcinogenicity studies and no concern for mutagenicity. No evidence of neurotoxicity or neuropathology was seen in the acute and subchronic neurotoxicity studies. In the multi-generation mouse reproduction study, one first generation male and one first generation female had retinal detachment with marked cataractous changes at the highest dose tested (>1,000 mg/kg/day). In the subchronic toxicity dog study, the high-dose females had decreased absolute and relative brain weights; however, no microscopic abnormalities were noted in any brain tissues from the high-dose group and effect was not observed in the chronic toxicity dog study. There is some concern about the effects of elevated plasma tyrosine levels on the developing nervous system in children due to a report that some patients with tyrosinemia III (an autosomal recessive disorder in which HPPD is deficient) were presented with mental retardation or neurological symptoms. There was evidence of increased susceptibility of rats, mice and rabbits to *in utero* and/or post-natal exposure to mesotrione.

Specific information on the studies received and the nature of the adverse effects caused by mesotrione as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies can be found at *http://www.regulations.gov* in the document ''Mesotrione: Human Health Risk Assessment for Section 3 New Uses on Soybeans'' in docket ID number EPA–HQ–OPP–2008–0811. Additionally, mesotrione toxicological data are discussed in the final rule published in the **Federal Register** of June 21, 2001 (66 FR 33187) (FRL–6787–7).

B. Toxicological Endpoints

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

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

A summary of the toxicological endpoints for mesotrione used for human risk assessment is discussed in ''Mesotrione: Human Health Risk Assessment for Section 3 New Uses on Soybeans'' in docket ID number EPA–HQ–OPP–2008–0811. Additionally, mesotrione toxicological data are discussed in the final rule published in the **Federal Register** of June 21, 2001 (66 FR 33187) (FRL–6787–7)

C. Exposure Assessment

1. *Dietary exposure from food and feed uses*. In evaluating dietary exposure to mesotrione, EPA considered exposure under the petitioned-for tolerances as well as all existing mesotrione tolerances in 40 CFR 180.571. EPA assessed dietary exposures from mesotrione 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 mesotrione; 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 USDA 1994–1996 and 1998 nationwide Continuing Surveys of Food Intake by Individuals (CSFII). As to residue levels in food, EPA assumed that all foods were treated for which there are proposed and established tolerances and that all the foods contain tolerance-level residues.

iii. *Cancer*. Mesotrione was negative for carcinogenicity in feeding studies in rats and mice and was classified as ''not likely'' to be a human carcinogen. Therefore, a quantitative exposure assessment to evaluate cancer risk is unnecessary.

2. *Dietary exposure from drinking water*. The Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for mesotrione in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of mesotrione. 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 Ground Water (SCI-GROW) models for the experimental use permit issued for an experimental program with mesotrione on soybeans (100-EUP-114), the estimated drinking water concentrations (EDWCs) of mesotrione for chronic exposures are estimated to be 5.1 parts per billion (ppb) for surface water and 0.54 ppb for ground 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).

Mesotrione is currently registered for the following uses that could result in residential exposures: Golf course, commercial and residential turf. EPA assessed residential exposure using the following assumptions: Residential adult handlers (dermal and inhalation) as well as postapplication exposure to adults (dermal), youths (dermal), and toddlers (dermal and incidental oral) to residues on treated grass was assessed.

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.''

Mesotrione, pyrasulfotole, isoxaflutole and topramezone belong to a class of herbicides that inhibit the liver enzyme, 4-hydroxyphenylpyruvate dioxygenase (HPPD), which is involved in the catabolism (metabolic breakdown) of tyrosine (an amino acid derived from proteins in the diet). Inhibition of HPPD can result in elevated tyrosine levels in the blood, a condition called tyrosinemia. HPPD-inhibiting herbicides have been found to cause a number of toxicities in laboratory animal studies including ocular, developmental, liver and kidney effects. Of these toxicities, it is the ocular effect (corneal opacity) that is highly correlated with the elevated blood tyrosine levels. In fact, rats dosed with tyrosine alone show ocular opacities similar to those seen with HPPD inhibitors. Although the other toxicities may be associated with chemically-induced tyrosinemia, other mechanisms may also be involved.

There are marked differences among species in the ocular toxicity associated with inhibition of HPPD. Ocular effects following treatment with HPPD inhibitor herbicides are seen in the rat but not in the mouse. Monkeys also seem to be recalcitrant to the ocular toxicity induced by HPPD inhibition. One explanation of this species-specific response in ocular opacity may be related to the species differences in the clearance of tyrosine. A metabolic pathway exists to remove tyrosine from the blood that involves a liver enzyme called tyrosine aminotransferase (TAT). In contrast to rats where ocular toxicity is observed following exposure to HPPD-inhibiting herbicides, mice and humans are unlikely to achieve the levels of plasma tyrosine necessary to produce ocular opacities because the activity of TAT in these species is much greater compared to rats. HPPD inhibitors (e.g., nitisinone) are used as an effective therapeutic agent to treat patients suffering from rare genetic diseases of tyrosine catabolism. Treatment starts in childhood but is often sustained throughout patient's lifetime. The human experience indicates that a therapeutic dose (1 mg/kg/day dose) of nitisinone has an excellent safety record in infants, children and adults and that serious adverse health outcomes have not been observed in a population followed for approximately a decade. Rarely, ocular effects are seen in patients with high plasma tyrosine levels; however, these effects are transient and can be readily reversed upon adherence to a restricted protein diet. This indicates that an HPPD inhibitor in and of itself cannot easily overwhelm the tyrosine-clearance mechanism in humans.

Therefore, exposure to environmental residues of HPPD-inhibiting herbicides are unlikely to result in the high blood levels of tyrosine and ocular toxicity in humans due to an efficient metabolic process to handle excess tyrosine. The Agency continues to study the complex relationships between elevated tyrosine levels and biological effects in various species. Nonetheless, as a worst case scenario, EPA has assessed aggregate exposure to mesotrione based on ocular effects in rats. For similar reasons, a semi-quantitative screening cumulative assessment was conducted using the rat ocular effects and 100% crop treated information. The results of this screening analysis did not indicate a concern. In the future, assessments of HPPD-inhibiting herbicides will consider more appropriate models and cross species extrapolation methods. For additional 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*. There is quantitative evidence of increased susceptibility of the young in the oral prenatal developmental toxicity studies in rats, mice, and rabbits and in the multi-generation reproduction study in mice. Quantitative evidence of increased susceptibility was not demonstrated in the multi-generation reproduction study in rats. The ocular discharge seen in the reproductive study in mice provided a highly conservative endpoint at 7,000 ppm. There is a well characterized NOAEL protecting

offspring in the developmental and reproductive studies in mice (relevant species for human-health risk assessment). The endpoints and dose selected for the RfD, as well as incidental exposure assessments, will be protective of the effects seen in the developmental toxicity study in rabbits.

3. *Conclusion*. EPA concluded that an additional FQPA SF is needed to address uncertainty due to reliance on a LOAEL from the mouse two-generation reproduction study in establishing the POD for mesotrione. Nonetheless, EPA determined that there is reliable data showing that the default additional safety factor value of 10X can be safely reduced to 3X. This conclusion is based on the following:

i. The toxicity database for mesotrione is complete, except for immunotoxicity testing and a deficiency in the mouse two-generation reproduction study (lack of a NOAEL). EPA began requiring functional immunotoxicity testing of all food and non-food use pesticides on December 26, 2007. These studies are not yet available for mesotrione. In the absence of specific immunotoxicity studies, EPA has evaluated the available mesotrione toxicity data to determine whether an additional database uncertainty factor is needed to account for potential immunotoxicity of mesotrione. There was no evidence of adverse effects on the organs of the immune system in any study with mesotrione. Based on these considerations, EPA does not believe that conducting a special test guideline series, 870.7800 immunotoxicity study will result in a point of departure less than the LOAEL of 2.1 mg/kg/day used in calculating the cPAD for mesotrione; therefore, an additional database uncertainty factor is not needed to account for potential immunotoxicity.

ii. The LOAEL used to establish the level of concern is based on tyrosineanemia in mice caused by excess tyrosine in the blood. Mesotrione can lead to excess tyrosine because it inhibits the liver enzyme HPPD which metabolically breaks down tyrosine. Tyrosine can also be removed from the blood by the activity of tyrosine aminotransferase (TAT). EPA reviewed comparative data on TAT in the rat, mouse and human, and concluded that the mouse and the human were similar in their ability to remove the excess tyrosine from the blood, while the rat was more limited in this ability and thus more sensitive to the effects of HPPD inhibition. Because a 10X interspecies factor has been retained despite evidence that the mouse is not less sensitive than humans to these effects, it is not necessary to retain the full tenfold FQPA factor to account for the use of a LOAEL from the mouse two-generation reproduction study. In effect, by not reducing the interspecies factor and retaining a 3X FQPA SF, EPA is retaining an additional SF for the protection of infants and children that is at least equal to 10X.

iii. There is low concern for the susceptibility seen in the developmental studies in mice (relevant species for human health risk assessment) because there is a well characterized NOAEL protecting offspring in these studies. In the developmental toxicity study in New Zealand white rabbits and in rats, no NOAEL was established for the developmental effects. However, since the effects seen in the rabbits and rat studies were at much higher doses (twentyfold) than the dose used for establishing the POD, the POD is protective of the effects seen in the developmental toxicity studies in rats and rabbits.

iv. Mesotrione exerts its toxicity via the inhibition of HPPD, causing the build-up of tyrosine levels in the blood. There are data in the published literature indicating that children with elevated plasma tyrosine levels during development due to a genetic disorder may have mental retardation or neurological symptoms. However, by protecting against the excessive build-up of tyrosine in the blood, the human health risk assessment is protective of all adult and child populations. Further, because the data show that any potential developmental neurotoxicity of mesotrione is related to the build-up of tyrosine in the blood and nervous tissues, it is not necessary to conduct a DNT study.

v. There are no residual uncertainties identified in the exposure databases. The chronic dietary food exposure assessment utilizes proposed tolerance level residues and 100% crop treated for all commodities. EPA made conservative (protective) assumptions in the residue estimates used to assess exposure to mesotrione in drinking water. EPA used similarly conservative assumptions to assess postapplication exposure of children including incidental oral exposure of toddlers. These assessments will not underestimate the exposure and risks posed by mesotrione.

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-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the POD to ensure that the MOE called for by the product of all applicable UFs is not exceeded.

1. *Acute risk*. There were no effects observed in oral toxicity studies including developmental toxicity studies in rats and rabbits that could be attributable to a single dose (exposure). Therefore, mesotrione 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 mesotrione from food and water will utilize 5.8% of the cPAD for (all infants less than 1 year old) the population group receiving the greatest exposure. Long-term aggregate risk was not calculated because residential post-application exposure over the long-term duration (more than 6 months) is not expected based on the potential residential use pattern of mesotrione.

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

Mesotrione is currently registered for use on golf course, commercial and residential turf that could result in short-term residential exposure and the Agency has determined that it is appropriate to aggregate chronic exposure through food and water with short-term residential exposures to mesotrione. Residential handler (adult only) as well as postapplication exposure to adults, youths, and toddlers to residues on treated grass was assessed. A summary of the assumptions for residential handler (dermal and inhalation) and post application dermal and incidental oral (toddlers only) exposure from mesotrione use on turf grass can be found at *http://www.regulations.gov* in document ''Mesotrione: Human-Health Risk Assessment for Section 3 New Uses on Soybeans'' at page 23 in docket ID number EPA–HQ–OPP–2006–0811.

Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded that the combined short-term food, water, and residential exposures aggregated result in aggregate MOEs of 370 for toddlers,

6,000 for youth, and 2,600 for adults. As EPA's Level of Concern (LOC) of 300 for mesotrione is below these MOEs, they are not of concern.

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

Mesotrione is currently registered for use on residential turf grass that could result in intermediate-term residential exposure to toddlers from ingestion of treated soil and the Agency has determined that it is appropriate to aggregate chronic exposure to mesotrione through food and water with intermediate-term exposures for mesotrione.

Using the exposure assumptions described in this unit for intermediate-term exposures, EPA has concluded that the combined intermediate-term food, water, and residential exposures aggregated result in aggregate MOE of 9,000 for toddlers. As EPA's LOC of 300 for mesotrione is below this MOE, it is not of concern.

5. *Aggregate cancer risk for U.S. population*. Mesotrione is classified as ''not likely'' to be carcinogenic in humans based on the results of a carcinogenicity study in mice and the combined chronic toxicity and carcinogenicity study in the rat. Therefore, mesotrione is not expected to pose a cancer risk to humans.

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 mesotrione residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology, high-pressure liquid chromatography fluorescence detector (HPLC/FLD), 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

There are no CODEX, Canadian, or Mexican tolerances/Maximum Residue Levels (MRLs) for mesotrione residues for the proposed crop. Thus, harmonization is not an issue at this time.

V. Conclusion

Therefore, a tolerance is established for residues of the herbicide, mesotrione, including its metabolites and degradates, in or on soybean, seed at 0.01 ppm. Compliance with the tolerance level is to be determined by measuring only mesotrione, 2-[4-(methylsulfonyl)-2-nitrobenzoyl]-1,3-cyclohexanedione, in the raw agricultural commodity.

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 180.571 is amended by revising introductory text of paragraph (a) and by alphabetically adding the commodity ''soybean, seed'' to the table in paragraph (a) to read as follows:

§ 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
* * * * *	*

* * * * *

[FR Doc. E9–30034 Filed 12–17–09; 8:45 am]
BILLING CODE 6560–50–S

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.*

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.