Inert ingredients	Limits	Uses
* * *	* * *	* * *
Poly(oxy-1,2-ethanediyl), α-isotridecyl-ω-methoxy (CAS Reg. No. 345642-79-7)	At a maximum of 10% in formulation	Surfactant
* * *	* * *	* * *

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2010–0528; FRL–8834–8]

Pyraclostrobin; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of pyraclostrobin in or on alfalfa and poultry, and increases tolerances for residues in or on soybean. BASF Corporation requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective July 21, 2010. Objections and requests for hearings must be received on or before September 20, 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–2010–0528. 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: Shaunta Hill, Registration Division (7504P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 347–8961; e-mail address: *hill.shaunta@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 site at *http://www.gpoaccess.gov/ecfr*.

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

Under FFDCA section 408(g), 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–2010–0528 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before September 20, 2010. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

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. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit a copy of your non-CBI objection or hearing request, identified by docket ID number EPA–HQ–OPP–2010–0528, 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. Summary of Petitioned-For Tolerance

In the **Federal Register** of February 4, 2010 (75 FR 5792) (FRL–9110–5) and June 8, 2010 (75 FR 32465) (FRL–8827–5), EPA issued notices pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of pesticide petitions PP 9F7590 and PP 9F7528, respectively, by BASF Corporation, P.O. Box 13528, Research

Triangle Park, NC 27709. The petitions requested that 40 CFR 180.582 be amended by increasing tolerances for residues of the fungicide pyraclostrobin, carbamic acid, [2-[[[1-(4-chlorophenyl)-1H-pyrazol-3-yl]oxy]methyl]phenyl]methoxy-, methyl ester, in or on soybean, forage at 11.0 parts per million (ppm) (PP 9F7590), and soybean, hay at 14.0 ppm (PP 9F7590), and by establishing tolerances for residues for alfalfa, forage at 10 ppm (PP 9F7528), alfalfa, hay at 30 ppm (PP 9F7528), poultry, fat at 0.1 ppm (PP 9F7528); poultry, meat byproducts at 0.1 ppm (PP 9F7528); poultry, meat at 0.1 ppm (PP 9F7528); and poultry, eggs at 0.1 ppm (PP 9F7528). These notices referenced a summary of the petition prepared by BASF Corporation, the registrant, which is available in the docket at *http://www.regulations.gov*. There were no comments received in response to the notice of filing.

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 pyraclostrobin including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with pyraclostrobin 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.

Pyraclostrobin has a low to moderate acute toxicity via the oral, dermal, and inhalation routes of exposure. Pyraclostrobin produces moderate eye irritation, is a moderate dermal irritant, and is not a dermal sensitizer. The main target organs for pyraclostrobin are the upper gastrointestinal tract (mainly the duodenum and stomach), the spleen/hematopoiesis, and the liver. In the 90–day mouse oral toxicity study, thymus atrophy was seen at doses of 30 milligrams/kilogram (mg/kg) or above, but similar effect was not found in the mouse carcinogenicity study at doses as high as 33 mg/kg. In reproductive and developmental studies, there was evidence of increased qualitative susceptibility following *in utero* exposure in the rabbit, but not in rats. In both the acute and subchronic neurotoxicity studies, there were no indications of treatment-related neurotoxicity. EPA classified pyraclostrobin as "Not Likely to be Carcinogenic to Humans" based on no treatment-related increase in tumors in both sexes of rats and mice, which were tested at doses that were adequate to assess carcinogenicity, and the lack of evidence of mutagenicity.

Specific information on the studies received and the nature of the adverse effects caused by pyraclostrobin 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 document "Revised Pyraclostrobin: Human Health Risk Assessment for Proposed Uses on Cotton and Belgian Endive" at page 15 in docket ID number EPA–HQ–OPP–2006–0522.

B. Toxicological Points of Departure/Levels of Concern

Once a pesticide's toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which no adverse effects are observed (the NOAEL) and the lowest dose at which adverse effects of concern are identified (the LOAEL). Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level—generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD)—and a safe margin of exposure (MOE). 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 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 pyraclostrobin used for human risk assessment can be found at *http://www.regulations.gov* in document "Pyraclostrobin: Human Health Risk Assessment for Proposed Uses on Grain Sorghum (PP#8F7385); Increase of Tolerance for the Stone Fruit Crop Group 12 to Satisfy European Union (EU) Import Requirement (PP#8F7390); and Establishment of a Permanent Import Tolerance for Coffee (PP#8E7394)" at page 17 in docket ID number EPA–HQ–OPP–2008–0713.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to pyraclostrobin, EPA considered exposure under the petitioned-for tolerances as well as all existing pyraclostrobin tolerances in 40 CFR 180.582. EPA assessed dietary exposures from pyraclostrobin in food as follows:

i. *Acute exposure.* Quantitative acute dietary exposure and risk assessments are performed for a food-use pesticide, if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1–day or single exposure.

In estimating acute dietary exposure, EPA used food consumption information from the United States Department of Agriculture (USDA) 1994–1996 and 1998 Nationwide Continuing Surveys of Food Intake by Individuals (CSFII). As to residue levels in food, EPA performed a slightly refined acute dietary exposure assessment for pyraclostrobin. EPA assumed that 100% of crops covered by existing or proposed tolerances were treated with pyraclostrobin and that these crops either had tolerance-level residues or residues at the highest level found in field trials. Experimentally

derived processing factors were used for fruit juices, tomato, and wheat commodities but for all other processed commodities Dietary Exposure Evaluation Model (DEEM™) default processing factors were assumed.

ii. *Chronic exposure*. In conducting the chronic dietary exposure assessment, EPA used the food consumption data from the USDA 1994–1996 and 1998 CSFII. As to residue levels in food, EPA performed a refined chronic dietary exposure assessment for pyraclostrobin. EPA used data on average percent crop treated (PCT) (when available) and either tolerance-level residues or average field trial residues. Experimentally derived processing factors were used for fruit juices, tomato, and wheat commodities, but for all other processed commodities DEEM™ default processing factors were assumed.

iii. *Cancer*. EPA classified pyraclostrobin as "Not Likely to be Carcinogenic to Humans" based on no treatment-related increase in tumors in both sexes of rats and mice, which were tested at doses that were adequate to assess carcinogenicity, and the lack of evidence of mutagenicity. Accordingly, an exposure assessment to evaluate cancer risk is unnecessary.

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

Section 408(b)(2)(F) of FFDCA states that the Agency may use data on the actual percent of food treated for assessing chronic dietary risk only if:

- Condition a: The data used are reliable and provide a valid basis to show what percentage of the food derived from such crop is likely to contain the pesticide residue.
- Condition b: The exposure estimate does not underestimate exposure for any significant subpopulation group.
- Condition c: Data are available on pesticide use and food consumption in a particular area, the exposure estimate does not understate exposure for the population in such area.

In addition, the Agency must provide for periodic evaluation of any estimates used. To provide for the periodic evaluation of the estimate of PCT as required by FFDCA section 408(b)(2)(F), EPA may require registrants to submit data on PCT.

The Agency estimated the PCT for existing uses as follows:

Commodity	PCT
Almond	35%
Apple	10%
Apricot	10%
Barley	1%
Bell pepper	10%
Black bean seed	5%
Blackberry	20%
Blueberry	20%
Broad bean (succulent)	2.5%
Broad bean seed	5%
Broccoli	5%
Cabbage	10%
Cantaloupe	15%
Carrot	25%
Celery	2.5%
Cherry	30%
Chinese mustard cabbage	10%
Cowpea seed	5%
Cowpea (succulent)	2.5%
Cucumber	5%
Currant	5%
Dry bulb onion	15%
Field corn	5%
Filbert	10%
Garlic	10%
Grape	25%
Grapefruit	25%
Great northern bean seed	5%
Green onion	15%
Head lettuce	5%
Leaf lettuce	5%
Kidney bean seed	5%
Lima bean seed	5%
Lima bean (succulent)	2.5%
Mung bean seed	5%
Napa cabbage	10%
Navy bean seed	5%
Nectarine	15%
Non-bell pepper	10%
Orange	5%
Peach	15%
Peanut	25%
Pear	10%
Pecan	2.5%
Pigeon pea (succulent)	5%
Pink bean seed	5%
Pinto bean seed	5%
Pistachio	25%
Plum	5%
Pop corn	5%
Potato	10%
Pumpkin	20%
Raspberry	35%
Snap bean (succulent)	2.5%
Soybean	5%
Spinach	10%
Strawberry	50%
Succulent pea	5%
Sugar beet	35%
Summer squash	10%
Sweet corn	5%
Tangerine	15%
Tomato	20%
Watermelon	30%
Wheat	5%
Winter squash	10%

In most cases, EPA uses available data from USDA/National Agricultural Statistics Service (USDA/NASS), proprietary market surveys, and the National Pesticide Use Database for the chemical/crop combination for the most recent 6–7 years. EPA uses an average PCT for chronic dietary risk analysis. The average PCT figure for each existing use is derived by combining available public and private market survey data for that use, averaging across all observations, and rounding to the nearest 5%, except for those situations in which the average PCT is less than one. In those cases, 1% is used as the average PCT and 2.5% is used as the maximum PCT. EPA uses a maximum PCT for acute dietary risk analysis. The maximum PCT figure is the highest observed maximum value reported within the recent 6 years of available public and private market survey data for the existing use and rounded up to the nearest multiple of 5%.

The Agency believes that the three conditions discussed in Unit III.C.1.iv. have been met. With respect to Condition a, PCT estimates are derived from Federal and private market survey data, which are reliable and have a valid basis. The Agency is reasonably certain that the percentage of the food treated is not likely to be an underestimation. As to Conditions b and c, regional consumption information and consumption information for significant subpopulations is taken into account through EPA's computer-based model for evaluating the exposure of significant subpopulations including several regional groups. Use of this consumption information in EPA's risk assessment process ensures that EPA's exposure estimate does not understate exposure for any significant subpopulation group and allows the Agency to be reasonably certain that no regional population is exposed to residue levels higher than those estimated by the Agency. Other than the data available through national food consumption surveys, EPA does not have available reliable information on the regional consumption of food to which pyraclostrobin may be applied in a particular area.

2. *Dietary exposure from drinking water*. The Agency used screening level water exposure models in the dietary exposure analysis and risk assessment

for pyraclostrobin in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of pyraclostrobin. 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, the estimated drinking water concentrations (EDWCs) of pyraclostrobin for acute exposures are estimated to be 35.6 parts per billion (ppb) for surface water and 0.02 ppb for ground water and for chronic exposures for non-cancer assessments are estimated to be 2.3 ppb for surface water and 0.02 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 35.6 ppb was used to assess the contribution to drinking water. For chronic dietary risk assessment, the water concentration of value 2.3 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).

Pyraclostrobin is currently registered for the following uses that could result in residential exposures: Residential turf grass and recreational sites. EPA assessed residential exposure using the following assumptions: Residential and recreational turf applications are applied by professional pest control operators (PCOs) only and, therefore, residential handler exposures do not occur. There is, however, a potential for short- and intermediate-term post-application exposure of adults and children entering lawn and recreation areas previously treated with pyraclostrobin. Exposures from treated recreational sites are expected to be similar to, or in many cases lower than, those from treated residential turf sites so a separate exposure assessment for recreational turf sites was not conducted. EPA assessed exposures from the following residential turf post-application scenarios:

(1) Short-/intermediate-term adult and toddler post-application dermal exposure from contact with treated lawns.

(2) Short-/intermediate-term toddlers' incidental ingestion of pesticide residues on lawns from hand-to-mouth transfer.

(3) Short-/intermediate-term toddlers' object-to-mouth transfer from mouthing of pesticide-treated turfgrass.

(4) Short-/intermediate-term toddlers' incidental ingestion of soil from pesticide-treated residential areas. The post-application risk assessment was conducted in accordance with the Residential Standard Operating Procedures and recommended approaches of the Health Effects Division's Science Advisory Council for 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 pyraclostrobin to share a common mechanism of toxicity with any other substances, and pyraclostrobin does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that pyraclostrobin 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 pre-natal and post-natal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the FQPA Safety Factor (SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

2. *Pre-natal and post-natal sensitivity*. The pre-natal and post-natal toxicology database for pyraclostrobin includes the rat and rabbit developmental toxicity studies and the 2–generation reproduction toxicity study in rats. In reproductive and developmental studies there was evidence of increased qualitative susceptibility following *in utero* exposure in the rabbit, but not in rats. In the 2-generation reproduction study, the highest dose tested did not cause maternal systemic toxicity, nor did it elicit reproductive or offspring toxicity. There is low concern for pre-natal developmental effects seen in the rabbit because there are clear NOAELs for maternal and developmental effects, this toxicity endpoint is used to establish the acute dietary RfD, and the developmental effect was seen at the same dose level as that produced for the maternal effect.

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 pyraclostrobin is considered adequate to support toxicity endpoint selection for risk assessment and FQPA evaluation. However, under the current 40 CFR 158.500 data requirement guidelines, the immunotoxicity data (780.7800) is required as a condition of approval. In the absence of specific immunotoxicity studies, EPA has evaluated the available pyraclostrobin toxicity data to determine whether an additional database uncertainty factor is needed to account for potential immunotoxicity. For pyraclostrobin, a complete battery of subchronic, chronic, carcinogenicity, developmental and reproductive studies, and acute and subchronic neurotoxicity screening studies are available for consideration. The immunotoxic potential of pyraclostrobin has been well characterized in relationship to other adverse effects seen in the submitted toxicity studies. Under the conditions of the studies, the results do not indicate the immune system to be the primary target. Other than the high-dose thymus effects seen in the 90-day mouse study, no significant evidence of pyraclostrobin-induced immunotoxicity was demonstrated in the studies conducted either in adult animals or in the offspring following pre-natal and post-natal exposures. Increased spleen weights observed in 28-day and 90-day rat studies were accompanied with mild hemolytic anemia (a hematopoieses response) indicating these effects are unrelated to an immunotoxic response. Currently, the point of departure in establishing the chronic RfD is 3.4 mg/kg/day. The Agency does not believe that conducting a special series 870.7800 immunotoxicity study will result in a NOAEL less than 3.4 mg/kg/

day. A similar conclusion was reached in an earlier action on pyraclostrobin. (See 72 FR 52108, 52120 (September 12, 2007)) (FRL–8144–4). In light of these conclusions, EPA does not believe an additional uncertainty or safety factor is needed to address the lack of the required immunotoxicity study.

ii. There is no indication that pyraclostrobin 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 pyraclostrobin results in increased quantitative susceptibility in *in utero* rats or rabbits in the prenatal developmental studies or in young rats in the 2-generation reproduction study. Although there is qualitative evidence of increased susceptibility in the prenatal development study in rabbits, the Agency did not identify any residual uncertainties after establishing toxicity endpoints and traditional UFs to be used in the risk assessment of pyraclostrobin. The degree of concern for pre-natal and/or post-natal toxicity is low.

iv. There are no residual uncertainties identified in the exposure databases. The acute dietary food exposure assessments were performed using tolerance-level or highest field trial residues and 100% crop treated. The chronic dietary food exposure assessments were performed using tolerance-level or average field trial residues and 100% CT or average PCT. Average PCT is conservatively derived from multiple data sources and is averaged by year and then across all years. The field trials represent maximum application rates and minimum PHIs. A limited number of experimentally derived processing factors from pyraclostrobin processing studies were also used to refine the analysis. The results of the refined chronic dietary analysis are based on reliable data and will not underestimate the exposure and risk. Conservative surface water modeling estimates were used. EPA used similarly conservative assumptions to assess post-application exposure of children as well as incidental oral exposure of toddlers. These assessments will not underestimate the exposure and risks posed by pyraclostrobin.

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*. Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food and water to pyraclostrobin will occupy 81% of the aPAD for females 13 to 49 years old, and 3% of the aPAD for children 1–2 years old, the population group receiving the greatest exposure.

2. *Chronic risk*. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to pyraclostrobin from food and water will utilize 24% of the cPAD for children 1 to 2 years old the population group receiving the greatest exposure. Based on the explanation in Unit III.C.3., regarding residential use patterns, chronic residential exposure to residues of pyraclostrobin is not expected.

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).

Pyraclostrobin is currently registered for uses 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 pyraclostrobin.

Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded the combined short-term food, water, and residential exposures result in aggregate MOEs of 230 for adults and 120 for children 1 to 2 years old. The aggregate MOE for adults is based on the residential turf scenario and includes combined food, drinking water, and post-application dermal exposures. The aggregate MOE for children includes food, drinking water, and post-application dermal and incidental oral exposures from entering turf areas previously treated with pyraclostrobin. MOEs above 100 are considered to be of no 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).

Pyraclostrobin is currently registered for uses that could result in intermediate-term residential exposure, and the Agency has determined that it is appropriate to aggregate chronic exposure through food and water with intermediate-term residential exposures to pyraclostrobin.

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 result in aggregate MOEs of 230 for adults and 120 for children 1 to 2 years old. The endpoints and points of departure (NOAELs) are identical for short- and intermediate-term exposures, so the aggregate MOEs for intermediate-term exposure are the same as those for short-term exposure. MOEs above 100 are considered to be of no concern.

5. *Aggregate cancer risk for U.S. population*. Based on the lack of evidence of carcinogenicity in two adequate rodent carcinogenicity studies, pyraclostrobin 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 pyraclostrobin residues.

IV. Other Considerations

Analytical Enforcement Methodology

There are adequate residue analytical methods for tolerance enforcement. The analytical methods for plant commodities are liquid chromatography with tandem mass spectroscopy/mass spectroscopy detector (LC/MS/MS) and high pressure liquid chromatography with ultraviolet detector (HPLC/UV), which both measure pyraclostrobin and its desmethoxy metabolite. The analytical methods for live stock commodities, gas chromatography with mass spectroscopy detector (GC/MS) and LC/MS/MS, convert pyraclostrobin and related metabolites to chlorophenylpyrazolol (BF 500–5) and hydroxylated chlorophenylpyrazolol (BF 500–8) in goats and chlorophenylpyrazolol (BF 500–5) and hydroxylated chlorophenylpyrazolol (BF 500–9) in poultry.

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 currently no proposed or established Codex, Canadian, or Mexican Maximum Residue Limits (MRLs) for residues of pyraclostrobin on alfalfa and soybeans. However, there are Canadian MRLs for various livestock commodities, including poultry meat, meat byproducts and eggs. The U.S. tolerance and Canadian MRL expressions are the same for both plant and livestock commodities, but several of the recommended changes in tolerances on livestock commodities will result in differences between the U.S. tolerances and the respective Canadian MRLs, due to increase in poultry dietary burden as a result of registration of alfalfa.

V. Conclusion

Therefore, tolerances are established for residues of pyraclostrobin, carbamic acid, [2-[[[1-(4-chlorophenyl)-1H-pyrazol-3-yl]oxy]methyl] phenyl]methoxy-, methyl ester, in or on alfafa, forage at 10 ppm; alfalfa, hay at 30 ppm; poultry, fat at 0.1 ppm; poultry, meat byproducts at 0.1 ppm; poultry, meat at 0.1 ppm; poultry, eggs at 0.1 ppm; and tolerances are increased for residues in or on soybean; forage at 11 ppm; and soybean, hay; at 14 ppm.

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 tolerances 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: July 12, 2010.

Lois Ann 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 180.582 is amended as follows:

a. Revise the introductory text of paragraph (a)(1).

b. Add alphabetically the commodities "Alfalfa, forage" and "Alfalfa, hay" to the table in paragraph (a)(1).

c. Revise the entries for "Soybean, forage" and "Soybean, hay." in the table in paragraph (a)(1).

d. Add alphabetically four commodities to the table in paragraph (a)(2).

§ 180.582 Pyraclostrobin; tolerances for residues.

(a) *General.* (1) Tolerances are established for residues of the fungicide pyradostrobin, 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 the sum of pyraclostrobin (carbamic acid, [2-[[[1-(4-chlorophenyl)-1H-pyrazol-3-yl]oxy] methyl]phenyl]methoxy-, methyl ester) and its desmethoxy metabolite (methyl-N-[[[1-(4-chlorophenyl)-1H-pyrazol-3-yl]oxy]methyl] phenylcarbamate), calculated as the stoichiometric equivalent of pyraclostrobin, in or on the commodity.

Commodity	Parts per million
Alfalfa, forage	10
Alfalfa, hay	30
* * * * *	
Soybean, forage	11
Soybean, hay	14
* * * * *	

* * * * *

(2) * * *

Commodity	Parts per million
* * * * *	
Poultry, eggs	0.10

Commodity	Parts per million
Poultry, fat	0.10
Poultry, meat	0.10
Poultry, meat by-products	0.10

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[FR Doc. 2010–17793 Filed 7–20–10; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 721

[EPA–HQ–OPPT–2008–0483; FRL–8832–2]

RIN 2070–AJ36

Elemental Mercury Used in Flow Meters, Natural Gas Manometers, and Pyrometers; Significant New Use Rule

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: EPA is promulgating a significant new use rule (SNUR) under section 5(a)(2) of the Toxic Substances Control Act (TSCA) for elemental mercury (CAS No. 7439–97–6) for use in flow meters, natural gas manometers, and pyrometers, except for use in these articles when they are in service as of September 11, 2009. This action will require persons who intend to manufacture (including import) or process elemental mercury for an activity that is designated as a significant new use by this rule to notify EPA at least 90 days before commencing that activity. Persons subject to the provisions of this rule will not be exempt from significant new use reporting if they import into the United States or process elemental mercury as part of an article. The required notification will provide EPA with the opportunity to evaluate the intended use and, if necessary, to prohibit or limit that activity before it occurs.

DATES: This final rule is effective August 20, 2010.

ADDRESSES: EPA has established a docket for this action under docket identification (ID) number EPA–HQ–OPPT–2008–0483. 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 OPPT Docket. The OPPT Docket is located in the EPA Docket Center (EPA/DC) at Rm. 3334, EPA West Bldg., 1301 Constitution Ave., NW., Washington, DC. The EPA/DC Public Reading Room hours of operation are 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number of the EPA/DC Public Reading Room is (202) 566–1744, and the telephone number for the OPPT Docket is (202) 566–0280. Docket visitors are required to show photographic identification, pass through a metal detector, and sign the EPA visitor log. All visitor bags are processed through an X-ray machine and subject to search. Visitors will be provided an EPA/DC badge that must be visible at all times in the building and returned upon departure.

FOR FURTHER INFORMATION CONTACT: *For technical information contact*: Peter Gimlin, National Program Chemicals Division (7404T), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (202) 566–0515; e-mail address: *gimlin.peter@epa.gov*.

For general information contact: The TSCA-Hotline, ABVI-Goodwill, 422 South Clinton Ave., Rochester, NY 14620; telephone number: (202) 554–1404; e-mail address: *TSCA-Hotline@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. Does this Action Apply to Me?

You may be potentially affected by this action if you manufacture (defined by statute to include import) or process elemental mercury used in flow meters, natural gas manometers, or pyrometers. Potentially affected entities may include, but are not limited to, manufacturers of instruments and related products for measuring, displaying, and controlling industrial process variables (North American Industrial Classification System (NAICS) code 334513). This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The NAICS codes have been provided to assist you and others in determining whether this action might apply to certain entities. To determine whether you or your business may be affected by this action, you should carefully examine the applicability provisions in 40 CFR 721.5 for SNUR-related obligations. If you have any questions regarding the applicability of this action to a particular entity, consult the technical person listed under **FOR FURTHER INFORMATION CONTACT.**

This action may also affect certain entities through pre-existing import certification and export notification rules under TSCA. Persons who import any chemical substance governed by a final SNUR are subject to the TSCA section 13 (15 U.S.C. 2612) import certification requirements and the corresponding regulations at 19 CFR 12.118 through 12.127 and 19 CFR 127.28. Those persons must certify that the shipment of the chemical substance complies with all applicable rules and orders under TSCA, including any SNUR requirements. The EPA policy in support of import certification appears at 40 CFR part 707, subpart B. In addition, TSCA section 12(b) (15 U.S.C. 2611(b)) export notification requirements are triggered by publication of a proposed SNUR. Therefore, on or after October 11, 2009, any persons who export or intend to export elemental mercury are subject to the export notification provisions of TSCA section 12(b) (see 40 CFR 721.20) and must comply with the export notification requirements in 40 CFR part 707, subpart D. EPA also notes that, pursuant to the Mercury Export Ban Act of 2008 (Pub. L. 110–414), the export of elemental mercury from the United States will be prohibited as of January 1, 2013, unless an exemption is obtained under TSCA section 12(c)(4).

II. Background

A. What Action is the Agency Taking?

EPA proposed this SNUR for elemental mercury used in flow meters, natural gas manometers, and pyrometers on September 11, 2009 (74 FR 46707) (FRL–8432–3). EPA's response to public comments received on the proposed rule appear in Unit III.C. Please consult the September 11, 2009, **Federal Register** document for further background information for this final rule.

This final SNUR will require persons to notify EPA at least 90 days before commencing the manufacture, import, or processing of elemental mercury for any of the following significant new uses: Flow meters, natural gas manometers, or pyrometers. This rule does not affect the manufacturing and processing of elemental mercury for use in these articles when they are in service as of September 11, 2009. EPA