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: February 12, 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 180.361 is amended by revising paragraph (b) to read as follows:

§ 180.361 Pendimethalin; tolerances for residues

* * * * *

(b) *Section 18 emergency exemptions.* Time-limited tolerances specified in the following table are established for combined residues of the herbicide pendimethalin, [*N*-(1-ethylpropyl)-3,4-dimethyl-2,6-dinitrobenzenamine], and its metabolite 4-[(1-ethylpropyl)amino]-2-methyl-3,5-dinitrobenzyl alcohol, in or on the specified agricultural commodities, resulting from use of the pesticide pursuant to FIFRA section 18 emergency exemptions. The tolerances expire and are revoked on the date specified in the table.

Commodity	Parts per million	Expiration/revocation date
Bermuda grass, forage	25	12/31/09
Bermuda grass, hay	60	12/31/09

* * * * *

[FR Doc. E9–5831 Filed 3–17–09; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2008–0936; FRL–8402–8]

Pyraclostrobin; Pesticide Tolerances for Emergency Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes time-limited tolerances for combined residues of pyraclostrobin and its desmethoxy metabolite in or on sugarcane, cane and sugarcane, molasses. This action is in response to EPA's granting of an emergency exemption under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) authorizing use of the pesticide on sugarcane. This regulation establishes a maximum permissible level for residues of pyraclostrobin and its desmethoxy metabolite in these food. The time-limited tolerances expire and are revoked on December 31, 2011.

DATES: This regulation is effective March 18, 2009. Objections and requests for hearings must be received on or before May 18, 2009, 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–2008–0936. All documents in the docket are listed in the docket index available in *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: Libby Pemberton, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 308–9364; e-mail address: *pemberton.libby@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:

- 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 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 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 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 the Federal Food, Drug, and Cosmetic Act (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. The EPA procedural regulations which govern the submission of objections and requests for hearings appear in 40 CFR part 178. 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–2008–0936 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 on or before May 18, 2009.

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 your copies, identified by docket ID number EPA–HQ–OPP–2008–0936, 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. Background and Statutory Findings

EPA, on its own initiative, in accordance with sections 408(e) and 408(l)(6) of FFDCA, 21 U.S.C. 346a(e) and 346a(1)(6), is establishing time-limited tolerances for combined residues of the fungicide, 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, expressed as parent compound, in or on sugarcane, cane at 0.02 parts per million (ppm) and sugarcane, molasses at 0.4 ppm. These time-limited tolerances expire and are revoked on December 31, 2011. EPA will publish a document in the **Federal Register** to remove the revoked tolerances from the CFR.

Section 408(l)(6) of FFDCA requires EPA to establish a time-limited tolerance or exemption from the requirement for a tolerance for pesticide chemical residues in food that will result from the use of a pesticide under an emergency exemption granted by EPA under section 18 of FIFRA. Such tolerances can be established without providing notice or period for public comment. EPA does not intend for its actions on section 18 related time-limited tolerances to set binding precedents for the application of section 408 of FFDCA and the new safety standard to other tolerances and exemptions. Section 408(e) of FFDCA allows EPA to establish a tolerance or an exemption from the requirement of a tolerance on its own initiative, i.e., without having received any petition from an outside party.

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. . . .''

Section 18 of FIFRA authorizes EPA to exempt any Federal or State agency from any provision of FIFRA, if EPA determines that ''emergency conditions exist which require such exemption.'' EPA has established regulations governing such emergency exemptions in 40 CFR part 166.

III. Emergency Exemption for Pyraclostrobin on Sugarcane, cane and Sugarcane, molasses and FFDCA Tolerances

Florida and Louisiana declared a crisis exemption under FIFRA section 18 for the use of pyraclostrobin on sugarcane for control of Orange Rust (*Puccinia Keuhnii*) and/or Brown Rust (*Puccinia melanocephala*). EPA concurs that emergency conditions exist for these States, and that the criteria for an emergency exemption are met.

As part of its evaluation of the emergency exemption application, EPA assessed the potential risks presented by residues of pyraclostrobin in or on sugarcane, cane and sugarcane, molasses. In doing so, EPA considered the safety standard in section 408(b)(2) of FFDCA, and EPA decided that the necessary tolerance under section 408(l)(6) of FFDCA would be consistent with the safety standard and with FIFRA section 18. Consistent with the need to move quickly on the emergency exemption in order to address an urgent non-routine situation and to ensure that the resulting food is safe and lawful, EPA is issuing this tolerance without notice and opportunity for public comment as provided in section 408(l)(6) of FFDCA. Although these time-limited tolerances expire and are revoked on December 31, 2011, under section 408(l)(5) of FFDCA, residues of the pesticide not in excess of the amounts specified in the tolerance remaining in or on sugarcane, cane and sugarcane, molasses. after that date will not be unlawful, provided the pesticide was applied in a manner that was lawful under FIFRA, and the residues do not exceed a level that was authorized by these time-limited tolerances at the time of that application. EPA will take action to revoke these time-limited tolerances earlier if any experience with, scientific data on, or other relevant information on this pesticide indicate that the residues are not safe.

Because these time-limited tolerances are being approved under emergency conditions, EPA has not made any decisions about whether pyraclostrobin meets FIFRA's registration requirements for use on sugarcane, cane and sugarcane, molasses or whether permanent tolerances for this use would be appropriate. Under these circumstances, EPA does not believe that this time-limited tolerance decision serves as a basis for registration of pyraclostrobin by a State for special local needs under FIFRA section 24(c). Nor does this tolerance serve as the basis for persons in any State other than Florida and Louisiana to use this pesticide on these crops under FIFRA section 18 absent the issuance of an emergency exemption applicable within that State. For additional information regarding the emergency exemption for pyraclostrobin, contact the Agency's Registration Division at the address

provided under **FOR FURTHER INFORMATION CONTACT**.

IV. 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 the factors specified in FFDCA section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure expected as a result of this emergency exemption request and the time-limited tolerances for combined residues of the fungicide, 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, expressed as parent compound, in or on sugarcane, cane at 0.02 ppm and sugarcane, molasses at 0.4 ppm. EPA's assessment of exposures and risks associated with establishing time-limited tolerances follows.

A. 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 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 Oats, Oilseed Group (Canola and Flax), Plus Seed Treatment on Oats, Canola, and Flax; Tropical Fruits (Avocado, Black Sapote, Canistel, Mamey Sapote, Mango; Papaya, Sapodilla, and Star Apple);Increased Tolerance on Barley; Adding Aerial Application to Turf and Ornamentals; and Adding In-Furrow Applications to Corn, Soybean, and Sugar Beets* pages 21 to 23 in docket ID number EPA–HQ–OPP–2007–0906–0004.

B. Exposure Assessment

1. *Dietary exposure from food and feed uses*. In evaluating dietary exposure to pyraclostrobin, EPA considered exposure under the time-limited tolerances established by this action 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. EPA identified such an effect for the general population (decreased body weight gain seen after a single oral dose in the rat acute neurotoxicity study) and for females 13 to 49 years old (increased resorptions/litter and increased total resorptions seen in the rabbit developmental toxicity study that are presumed to occur after a single exposure). The aPAD for the general population has been established at 3.0 milligrams/kilogram/day (mg/kg/day); whereas, the aPAD for females 13 to 49 years old is significantly lower (0.05 mg/kg/day), due to the more sensitive endpoint on which it is based. In estimating acute dietary exposure, EPA used food consumption information from the U.S. Department of Agriculture (USDA) 1994–1996 and 1998 Nationwide Continuing Surveys of Food Intake by Individuals (CSFII). As to residue levels in food, EPA assumed that residues are present at tolerance levels or for some commodities (amaranth, leafy; arugula; chrysanthemum; cress, garden; cress, upland; dandelion, leaves; fennel; parsley, leaves; radicchio; rhubarb; spinach; swiss chard; beans, dry; celery; lettuce, head; lettuce, leaf; and pea, dry) at the highest residue level found in residue field trials. One hundred percent crop treated (PCT) was assumed for all commodities in the assessment. Default processing factors were applied to all commodities except those for which experimentally-derived processing factors were available: Apple juice, grape juice, citrus juices, cottonseed oil, tomato paste, tomato puree, wheat flour, and wheat germ.

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 assumed that residues are present at tolerance levels in all crops except apple, broccoli, celery, collard, grape, lettuce, citrus, pepper, mustard green and tomato. EPA relied on anticipated residues (average residues from field trials) for these crops. One hundred PCT was assumed for all commodities in the assessment. Default processing factors were applied to all commodities except those for which experimentally-derived processing factors were available: Apple juice, grape juice, citrus juices, tomato paste, tomato puree, wheat flour, and wheat germ.

iii. *Cancer*. Based on the results of carcinogenicity studies in rats and mice, EPA has concluded that pyraclostrobin is ''not likely to be carcinogenic to humans.'' Consequently, a quantitative cancer exposure and risk assessment is not appropriate for pyraclostrobin.

iv. *Anticipated residue 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.

2. *Dietary exposure from drinking water*. The Agency lacks sufficient monitoring data to complete a comprehensive dietary exposure analysis and risk assessment for pyraclostrobin in drinking water. Because the Agency does not have comprehensive monitoring data, drinking water concentration estimates are made by reliance on simulation or modeling taking into account data on the environmental fate characteristics of 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 environmental concentrations (EECs) 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. The EECs for chronic exposures 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 riskassessment, the water concentration value of 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 residential non-dietary sites: Residential and recreational turf grass. 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-term and intermediate-term postapplication 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; therefore, a separate exposure assessment for recreational turf sites was not conducted. EPA assessed exposures from the following residential turf post application scenarios:

i. Adult and toddler post application dermal exposure from contact with treated lawns

ii. Toddlers' incidental ingestion of pesticide residues on lawns from hand-to-mouth transfer

iii. Toddlers' object-to-mouth transfer from mouthing of pesticide-treated turf grass, and:

iv. 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 (SOPs) and recommended approaches of the Health Effects Division's (HED's) Science Advisory Council for Exposure (Expo SAC).

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 the policy statements released by EPA's Office of Pesticide Programs concerning common mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism on EPA's website at *http://www.epa.gov/pesticides/cumulative*.

C. 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 safety factor (SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional SF when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity*. The prenatal and postnatal toxicology database for pyraclostrobin includes the rat and rabbit developmental toxicity studies and the 2-generation reproduction toxicity study in rats. There was no evidence of increased quantitative or qualitative susceptibility of *in utero* rats or offspring following exposure to pyraclostrobin in the rat developmental and reproduction studies. In the rabbit developmental study, there was evidence of increased qualitative susceptibility of *in utero* rabbits following exposure to pyraclostrobin (increases in resorptions/litter and post-implantation losses). However, this qualitative susceptibility seen in the rabbit developmental study does not indicate a heightened risk for infants or children because: The developmental effects were seen in the presence of maternal toxicity; there are clear NOAELs for maternal and developmental toxicities; and this endpoint is used in the acute dietary reference dose (RfD) exposure assessment for females, 13 years and older, as well as for short-term and intermediate-term dermal risk assessments.

3. *Conclusion*. EPA has determined that reliable data show that it would be safe for infants and children to reduce the FQPA safety factor to 1X. This

determination was exhaustively discussed in a prior order concerning pyraclostrobin, September 12, 2007 (72 FR 52108) (FRL–8144–4). In summary, the safety factor decision is based on the following findings:

i. The toxicity database for pyraclostrobin is complete.

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 susceptibility *in utero* rats in the prenatal developmental study orin young rats in the 2-generation reproduction study. Although there is qualitative evidence of increased susceptibility in the prenatal developmental 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 prenatal toxicity is low.

iv. There are no residual uncertainties identified in the exposure databases. The dietary food exposure assessments were performed based on 100 PCT and tolerance-level residues or anticipated residues derived from reliable field trial data. Conservative ground water and surface water modeling estimates were used. Similarly, conservative assumptions were used to assess post-application dermal exposure of children as well as incidental oral exposure of toddlers. These assessments will not underestimate the exposure and risks posed by pyraclostrobin.

D. 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 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 80% of the aPAD for (females 13–49 years) 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 48% of the cPAD for (children 1–2 years,) the population group receiving the greatest exposure. Based on the explanation in the unit 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 food and water and short-term exposures for pyraclostrobin. Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded that the aggregated food, water, and residential exposures result in aggregate MOEs of 200 for adults and 100 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, post-application dermal and incidental oral exposures from entering turf are as previously treated with pyraclostrobin.

4. *Intermediate-term risk*. Intermediate-term aggregate exposure takes into account residential exposure plus chronic exposure to food and water (considered to be a background exposure level). 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 food and water and intermediate-term exposures for pyraclostrobin. Since the endpoints and points of departure NOAELs are identical for short-term and intermediate-term exposures, the aggregate MOEs for intermediate-term exposure are the same as those for short-term exposure (200 for adults and 100 for children, 1 to 2 years old).

5. *Aggregate cancer risk for U.S. population*. EPA has classified pyraclostrobin into the category ''Not Likely to be Carcinogenic to Humans.'' Pyraclostrobin is not expected to pose a cancer risk.

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.

V. Other Considerations

A. Analytical Enforcement Methodology

Two adequate enforcement methodologies (a Liquid Chromatography/Mass Spectrometry (LC/MS/MS) method (BASF Method D9808), and a High Performance Liquid Chromatography using Untraviolet Detection (HPLC/UV) method (BASF Method D9904)) are available to enforce the tolerance expression in/on plant commodities. Two more adequate methods have also been proposed for enforcing tolerances for livestock commodities: HPLC/UV method 439/0 and method 446 (consisting of CAS Chromatography/Mass Spectroscopy (GC/MS) method 446/0 and LC/MS/MS method 446/1) The methods may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755–5350; telephone number: (410) 305–2905; e-mail address: *residuemethods@epa.gov*.

B. International Residue Limits

No Codex maximum residue levels have been established for residues of pyraclostrobin in or on these commodities.

VI. Conclusion

Therefore, time-limited tolerances are established for combined residues of the fungicide, 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, expressed as parent compound, in or on sugarcane, cane at 0.02 ppm and sugarcane, molasses at 0.4 ppm. These tolerances expire and are revoked on December 31, 2011.

VII. Statutory and Executive Order Reviews

This final rule establishes tolerances under sections 408(e) and 408(l)(6) 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 in accordance with sections 408(e) and 408(l)(6) 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).

VIII. 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: February 24, 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 180.582 is amended by alphabetically adding commodities to the table in paragraph (b) to read as follows:

§ 180.582 Pyraclostrobin; tolerances for residues.

* * * * *

(b) * * *

Commodity	Parts per million	Expiration/revocation date
* * * *	*	
Sugarcane, cane	0.02	December 31, 2011
Sugarcane, molasses	0.4	December 31, 2011

* * * * *

[FR Doc. E9–5834 Filed 3–17–09; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2008–0794; FRL–8399–5]

Formaldehyde, Polymer with 2-Methyloxirane and 4-Nonylphenol; Tolerance Exemption

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes an exemption from the requirement of a tolerance for residues of formaldehyde, polymer with 2-methyloxirane and 4-nonylphenol (CAS Reg. No. 37523–33–4); when used as an inert ingredient in a pesticide chemical formulation. Akzo Nobel Surface Chemistry, LLC, submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), requesting an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of formaldehyde, polymer with 2-methyloxirane and 4-nonylphenol on food or feed commodities.

DATES: This regulation is effective March 18, 2009. Objections and requests for hearings must be received on or before May 18, 2009, 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–2008–0794. 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