August 10, 1999). Executive Order 13132 requires EPA to develop an accountable process to ensure ''meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.'' ''Policies that have federalism implications'' is defined in the Executive Order to include regulations that have ''substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.'' This final rule directly regulates growers, food processors, food handlers and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of FFDCA. For these same reasons, the Agency has determined that this rule does not have any ''tribal implications'' as described in Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000). Executive Order 13175, requires EPA to develop an accountable process to ensure ''meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.'' ''Policies that have tribal implications'' is defined in the Executive Order to include regulations that have ''substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and the Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.'' This rule will not have substantial direct effects on tribal governments, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this rule.

VIII. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, 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: March 27, 2006.

Losi 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 180.598 is amended by alphabetically adding the following commodity to the table in paragraph (a) to read as follows:

§ 180.598 Novaluron; tolerances for residues.

(a) * * *

Commodity	Parts per million
* * *	* *
Brassica, head and stem, subgroup 5A	0.50
* * *	* *

[FR Doc. 06–3261 Filed 4–4–06; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2004–0292; FRL–7772–8]

Pyraclostrobin; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for combined residues 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), expressed as parent compound, in or on bean, succulent, shelled; legume vegetables group, foliage, in crop group 7; mango (import); and papaya (import). This final rule also increases the tolerances for almond, hulls; pea and bean, dried shelled, except soybean, subgroup 6C; and strawberry. BASF Corporation requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA).

DATES: This regulation is effective April 5, 2006. Objections and requests for hearings must be received on or before June 5, 2006.

ADDRESSES: To submit a written objection or hearing request follow the detailed instructions as provided in Unit VI. of the **SUPPLEMENTARY INFORMATION**. EPA has established a docket for this action under docket identification (ID) number EPA–HQ–OPP–2004–0292. All documents in the docket are listed on the regulations.gov website. (EDOCKET, EPA's electronic public docket and comment system was replaced on November 25, 2005, by an enhanced Federal-wide electronic docket management and comment system located at *http://www.regulations.gov*. Follow the on-line instructions.) Although listed in the index, some information is not publicly available, e.g., 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 either electronically through regulations.gov or in hard copy at the Public Information and Records Integrity Branch(PIRIB), Rm. 119, Crystal Mall #2, 1801 S. Bell St., Arlington, VA. This Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: Tony Kish, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 308–9443; e-mail address: *kish.tony@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), e.g., agricultural workers; greenhouse, nursery, and floriculture workers; farmers.
- Animal production (NAICS code 112), e.g., cattle ranchers and farmers, dairy cattle farmers, livestock farmers.
- Food manufacturing (NAICS code 311), e.g., agricultural workers; farmers; greenhouse, nursery, and floriculture workers; ranchers; pesticide applicators.
- Pesticide manufacturing (NAICS code 32532), e.g., agricultural workers; commercial applicators; farmers; greenhouse, nursery, and floriculture workers; residential users.

This listing is not intended to be exhaustive, but rather 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 and Other Related Information?

In addition to using 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*. A frequently updated electronic version of 40 CFR part 180 is available on E-CFR Beta Site Two at *http://www.gpoaccess.gov/ecfr*.

II. Background and Statutory Findings

In the **Federal Register** of August 27, 2004 (69 FR 52670) (FRL–7676–9), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of three pesticide petitions by BASF Corporation (0F6139, 2F6431, and 3F6581) of Research Triangle Park, NC 27709 and one petition (3E6774) by the Interregional Research Project Number 4 (IR-4), 681 US Highway #1 South, North Brunswick, NJ, 08902-3390. These petitions requested that 40 CFR 180.582 be amended by establishing tolerances for combined residues of the fungicide pyraclostrobin and its desmethoxy metabolite, expressed as parent compound, in or on a large number of crops. Most, but not all of the proposed new tolerances requested in the four petitions mentioned in this unit were established in a final rule published in the **Federal Register** of October 29, 2004 (69 FR 63083) (FRL-7681-9). The following tolerances were requested, but not included in the October 29, 2004 final rule, and thus are included herein: Bean, succulent, shelled; legume vegetables group, foliage, in crop group 7; mango (import); and papaya (import).

Additionally, in the **Federal Register** of February 15, 2006 (71 FR 7955) (FRL–7759–4), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of a revised pesticide petition by BASF Corporation (5F6906) of Research Triangle Park, NC 27709. That notice included a summary of the pesticide petition prepared by BASF, the registrant. This petition requested that 40 CFR 180.582 be amended by revising established tolerances for combined residues of the fungicide pyraclostrobin and its desmethoxy metabolite, expressed as parent compound, in or on pea and bean, dried shelled, except soybean, subgroup 6C, and strawberry.

The October 29, 2004 final rule previously established tolerances for pea and bean, dried shelled, except soybean, subgroup 6C, and for strawberry. However, the existing 0.3 parts per million (ppm) tolerance in this rule for pea and bean, dried shelled, except soybean, subgroup 6C, was based on submission of confirmatory field trial data. These confirmatory data were submitted and reviewed, and result in the tolerance being increased herein from 0.3 ppm to 0.5 ppm. Hence, a revised notice of filing/petition was submitted.

Furthermore, the existing 1.5 ppm time-limited tolerance established for strawberry in that final rule expired December 31, 2005. Upon this expiration, the tolerance reverted back to the permanent 0.4 ppm tolerance. Based on submission of recent field trial data, the permanent strawberry tolerance is being increased from 0.4 ppm to 1.2 ppm. Hence, a revised notice of filing/petition was submitted. No comments were received on the notice of filing.

In the **Federal Register** of January 27, 2006, (71 FR 4579) (FRL–7758–8), 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 by BASF Corporation (5F6906) of Research Triangle Park, NC 27709. That notice included a summary of the pesticide petition prepared by BASF, the registrant. This petition requested that 40 CFR 180.582 be amended by increasing the tolerance for combined residues of the fungicide pyraclostrobin and its desmethoxy metabolite, expressed as parent compound, in or on almonds, hulls. Comments were received on the notice of filing. EPA's response to these comments is discussed in Unit IV.C.

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....''

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. For further discussion of the regulatory requirements of section 408 of FFDCA and a complete description of the risk assessment process, see *http://www.epa.gov/fedrgstr/EPA-PEST/1997/November/Day-26/p30948.htm*.

III. Aggregate Risk Assessment and Determination of Safety

Consistent with 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, consistent with section 408(b)(2) of FFDCA, for tolerances for combined residues of pyraclostrobin and its desmethoxy metabolite, expressed as parent compound, on almond, hulls at 7.0 ppm; bean, succulent, shelled at 0.5 ppm; legume vegetables group, foliage, in crop group 7, at 25 ppm; mango (import) at 0.1 ppm; papaya (import) at 0.1 ppm; pea and bean, dried shelled, except soybean, subgroup 6C at 0.5 ppm; and strawberry at 1.2 ppm.

EPA's assessment of exposures and risks associated with establishing the tolerances follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also

considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. Specific information on the studies received and the nature of the toxic effects caused by pyraclostrobin as well as the no-observed-adverse-effect-levels (NOAELs) and the lowest-observed-adverse-effect-levels (LOAELs) from the toxicity studies can be found in the October 29, 2004 final rule.

B. Toxicological Endpoints

For hazards that have a threshold below which there is no appreciable risk, the dose at which no adverse effects are observed (the NOAEL) from the toxicology study identified as appropriate for use in risk assessment is used to estimate the toxicological level of concern (LOC). However, the lowest dose at which adverse effects of concern are identified (the LOAEL) is sometimes used for risk assessment if no NOAEL was achieved in the toxicology study selected. An uncertainty factor (UF) is applied to reflect 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.

The linear default risk methodology (Q*) is the primary method currently used by the Agency to quantify non-threshold hazards such as cancer. The Q* approach assumes that any amount of exposure will lead to some degree of cancer risk, estimates risk in terms of the probability of occurrence of additional cancer cases.

A summary of the toxicological endpoints for pyraclostrobin used for human risk assessment is discussed in Unit III.B. of the October 29, 2004 final rule.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* Tolerances have previously been established (40 CFR 180.582) for the combined residues of pyraclostrobin and its desmethoxy metabolite, expressed as parent compound, in or on a variety of raw agricultural commodities. Risk assessments were conducted by EPA to assess 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.

The Dietary Exposure Evaluation Model (DEEM™) analysis evaluated the individual food consumption as reported by respondents in the U.S. Department of Agriculture (USDA) 1994–1996 and 1998 Nationwide Continuing Surveys of Food Intake by Individuals (CSFII) and accumulated exposure to the chemical for each commodity. The following assumptions were made for the acute exposure assessments:

Values corresponding to the HAFT (highest average field trial), instead of the tolerance level, were used for crops in the leafy vegetables crop group and for the dry shelled peas and beans subgroup. For all other crops, residue values corresponding to tolerance levels were used. A 100% percent crop treated (PCT) estimate was used for all crops.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the DEEM™ software with the Food Commodity Intake Database (DEEM-FCID™), which incorporates food consumption data as reported by respondents in the USDA 1994–1996 and 1998 Nationwide CSFII, and accumulated exposure to the chemical for each commodity. The following assumptions were made for the chronic exposure assessments:

Residues corresponding to tolerance level for all crops other than apple and pear (average values from field trials), and PCT were used in this assessment.

iii. *Cancer.* The assessment assumed residues corresponding to tolerance level, or average residue from field trials (apple and pear), and PCT.

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 chemicals that have been measured in food. If EPA relies on such information, EPA must pursuant to FFDCA section 408(f)(1) require 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. Following the initial data submission, EPA is authorized to require similar data on a time frame it deems appropriate. For the present action, EPA will issue such data call-ins for information relating to anticipated residues as are required by FFDCA section 408(b)(2)(E) and authorized under FFDCA section 408(f)(1). Such data call-ins will be required to be submitted no later than 5 years from the date of issuance of this tolerance.

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 the Agency can make the following findings: Condition 1, that 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 such pesticide residue; Condition 2, that the exposure estimate does not underestimate exposure for any significant subpopulation group; and Condition 3, if 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 used PCT information in Table 1 of this unit.

TABLE 1.—VALUES FOR PERCENT CROP TREATED

Commodity	PCT
Root and Tuber Vegetables	
Beet, garden	41*
Beet, sugar	55*
Carrot	31*
Potato	66*
Radish	8*
Sweet potato	2*
Yam	1*
Other root and tuber	6
Bulb Vegetables	
Onion	17
Other bulbs	17
Leafy Vegetables	
Celery	44*
Lettuce (leaf)	58*
Lettuce (head)	58*
Spinach	40*
Swiss chard	9*
Other leafy	5
Brassica Vegetables	
Broccoli	7*
Brussels sprouts	43*

TABLE 1.—VALUES FOR PERCENT CROP TREATED—Continued

Commodity	PCT
Cabbage	40*
Cauliflower	31*
Other head and stem	2
Collards	41
Kale	20*
Mustard green	15*
Turnip green	15*
Other leafy	2
Legume Vegetables	
Beans, lima	24*
Beans, snap	36*
Other beans, succulent	1
Beans, dry	1
Peas, green or succulent	1*
Peas, dry	2*
Soybean (dry)	1*
Fruiting Vegetables	
Pepper	18
Tomato	18
Other fruiting	18
Cucurbit Vegetables	
Cantaloupe	37
Cucumber	37
Other cucurbit vegetables	37
Citrus Fruits	
Grapefruit	6
Oranges	6
Other citrus	6
Pome Fruits	
Apple	41*
Pears	49*
Other pome	7
Stone Fruits	
Cherry	53
Peach	28
Plum	28

TABLE 1.—VALUES FOR PERCENT CROP TREATED—Continued

Commodity	PCT
Other stone	28
Berries	
All berries	2
Tree Nuts	
All nuts	1
Pistachio	6
Grains	
Barley	2
Corn, field	1*
Corn, pop	2
Corn, sweet	16*
Rye	2
Wheat (triticale)	2
Miscellaneous Commodities	
Banana/plantain	100
Grape	16
Grape, raisin	16
Hop	48*
Mango	100
Papaya	100
Peanut	19
Mint	6*
Strawberry	80
Sunflower	3*
Edible Animal Tissue (Cattle, Goat, Hog, Horse and Sheep)	
Meat	100
Meat byproduct/kidney	100
Liver	100
Fat	100
Milk	100
Drinking Water	
Water, direct	100
Water, indirect	100

* Projected figures.

The Agency believes that the three conditions listed in Unit III.C.1.iv have been met. With respect to Condition 1, PCT estimates for existing uses 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 2 and 3, 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 information on the regional consumption of food to which pyraclostrobin may be applied in a particular area.

EPA estimates projected percent crop treated (PPCT) for a new pesticide use by assuming that the PCT during the pesticide's initial 5 years of use on a specific use site will not exceed the average PCT of the dominant pesticide (i.e., the one with the greatest PCT) on that site over the three most recent surveys. Comparisons are only made among pesticides of the same pesticide types (i.e., the dominant fungicide on the use site is selected for comparison with a new fungicide). The PCTs included in the average may be each for the same pesticide or for different pesticides since the same or different pesticides may dominate for each year selected. Typically, EPA uses USDA/National Agricultural Statistics Service (NASS) as the source for raw PCT data because it is publicly available and does not have to be calculated from available data sources. When a specific use site is not surveyed by USDA/NASS, EPA uses proprietary data and calculates the estimated PCT.

This estimated PPCT, based on the average PCT of the market leader is appropriate for use in the chronic dietary risk assessment. This method of estimating a PPCT for a new use of a registered pesticide or a new pesticide, produces a high-end estimate that is unlikely, in most cases, to be exceeded during the initial 5 years of actual use. The predominant factor that bears on whether the estimated PPCT could be exceeded is whether the new pesticide use is more efficacious or controls a broader spectrum of pests than the dominant pesticide(s). All information

currently available has been considered for pyraclostrobin, and based on that information EPA concludes that it is unlikely that actual PCT for pyraclostrobin will exceed the estimated PPCT during the next 5 years.

2. *Dietary exposure from drinking water*. The Agency lacks sufficient monitoring exposure 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 physical characteristics of pyraclostrobin. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found in the October 29, 2004 final rule.

Based on the Tier II Pesticide Root Zone Mode/Exposure Analysis Modeling System (PRZM/EXAMS) and Screening Concentration in Groundwater (SCI-GROW) models, the estimated drinking water concentrations (EDWCs) of pyraclostrobin for acute exposures are estimated to be 10.2 parts per billion (ppb) for surface water and 0.02 ppb for ground water. The EDWCs for chronic exposures are estimated to be 0.8 ppb for surface water and 0.02 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).

Pyraclostrobin is currently registered for use on the following residential non-dietary sites: Residential and recreational turfgrass sites and golf course turf. The risk assessment was conducted using the following residential exposure assumptions: Residential and recreational turf applications are applied by professional pest control operators (PCOs) only, and therefore, residential handler exposure is not expected, and was not evaluated. There is, however, a potential for exposure to homeowners in residential settings from entering previously treated lawns where children might play and adults might work or play. As a result, risk assessments have been completed for postapplication scenarios. Recreational nonresidential exposures are expected to be similar to, or in many cases less than, those evaluated for residential postapplication exposure and risk; and therefore, a separate recreational nonresidential exposure assessment was not conducted. Refer to the October 29, 2004 final rule, for a detailed discussion of residential/recreational 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.''

Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding as to pyraclostrobin and 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 not assumed that pyraclostrobin has 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*.

D. Safety Factor for Infants and Children

1.*In general*. Section 408 of FFDCA provides that EPA shall apply an additional tenfold margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. Margins of safety are incorporated into EPA risk assessments either directly through use of a margin of exposure (MOE) analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans. In applying this provision, EPA either retains the default value of 10X when reliable data do not support the choice of a different factor, or, if reliable data are available, EPA uses a different additional safety factor value based on the use of traditional UFs and/or special FQPA SF, as appropriate.

2. *Prenatal and postnatal sensitivity*. There was no substantial evidence of increased prenatal or postnatal susceptibility following *in utero* exposure to rats. A complete discussion can be found in the October 29, 2004 final rule.

3. *Conclusion*. There is an adequate toxicity database for the selection of doses and endpoints for use in risk assessment for pyraclostrobin. Exposure data are complete or are estimated based on data that reasonably accounts for potential exposures. EPA previously evaluated the available studies and established acute and chronic reference doses (RfDs), as well as doses and endpoints for the cancer and occupational and residential risk assessments. EPA has evaluated and reevaluated the potential for increased susceptibility of infants and children to pyraclostrobin and has concluded that there are reliable data to support reducing the FQPA SF to 1X for all potential pyraclostrobin exposure scenarios because the toxicity and exposure databases are adequate, there are no residual uncertainties for pre- or postnatal toxicity, and there is no substantial evidence of increased sensitivity of infants and children to pyraclostrobin. For a detailed discussion, refer to the October 29, 2004 final rule.

E. Aggregate Risks and Determination of Safety

1. *Acute risk*. The total combined MOEs from dietary (food + water) and non-occupational/residential exposures, are 100 and 160 for children 1–2 yrs, and the general U.S. population, respectively, and therefore are not of concern. This aggregate exposure risk assessment is considered a very conservative estimate, that should not underestimate risks, because of the following inputs:

i. Dietary inputs primarily used tolerance level residues.

ii. Crop specific (turf) screening level drinking water modeling data were used (i.e., Tier II surface water model).

iii. Maximum application rates and minimum application intervals were used

iv. Conservative standard operating procedures (SOPs) and upper level estimates of exposure were employed.

2. *Chronic risk*. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to pyraclostrobin from food and drinking water will utilize 21% of the chronic population adjusted dose (cPAD) for the U.S. population, and 33% of the cPAD for children 1–2 years of age, the most highly exposed population subgroup. Based on the use pattern, chronic residential exposure to

residues of pyraclostrobin is not expected. Drinking water was incorporated directly into the dietary assessment using the 1 in 10 year annual mean concentration for surface water generated by the PRZM-EXAMS model. EPA does not expect the aggregate exposure to exceed 100% of the cPAD for any population subgroup.

3. *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 use(s) 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.

Using the exposure assumptions for intermediate-term exposures, EPA has concluded that food and residential exposures aggregated result in aggregate MOEs of 100 or above for all population subgroups. These aggregate MOEs do not exceed the Agency's level of concern for aggregate exposure to food and residential uses.

4. *Aggregate cancer risk for U.S. population*. The Agency has calculated aggregate MOEs (food and drinking water exposure) for pyraclostrobin. In general, acceptable study results indicate that pyraclostrobin is unlikely to be a carcinogen. However, the Agency has also concluded that the carcinogenicity data available for pyraclostrobin are inadequate to allow full assessment of the human carcinogenic potential of this pesticide because the highest dosing levels for females in the mouse carcinogenicity study were not great enough to produce significant toxicological effects (that is, the highest dose tested (HDT), is the NOAEL for female mice in this study). The company is performing an additional carcinogenicity study in female mice to remedy this deficiency. Because neither of the rat nor mouse cancer studies show any evidence of carcinogenicity, a non-threshold (Q-star) approach cannot be used to estimate cancer risk. Instead, a regulatory MOE has been chosen as a tool for bounding any potential chronic dietary cancer risk from pyraclostrobin that may exist. The regulatory MOE is derived from the HDT in female mice (a NOAEL of 32.8 milligram/kilogram/day (mg/kg/day) and is 10 times higher than the NOAEL used for chronic non-cancer risk. The MOE for cancer is estimated to be 4,500. It is derived from the highest dose tested in female mice (32.8 mg/kg/day) in the inadequate mouse oncogenicity study, divided by the chronic dietary exposure (food + water) for the U.S. general population (0.00727 mg/kg/day). Drinking water was incorporated directly into the dietary assessment using the 1 in 30 annual mean concentration for surface water generated by the PRZM-EXAMS model.

5. *Determination of safety*. Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, and to infants and children from aggregate exposure to pyraclostrobin residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology (gas chromatography/mass spectrometry) 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

The Codex Alimentarius Commission has established maximum residue limits (MRLS) for pyraclostrobin in or on almond, hulls at 2.0 ppm; strawberry at 0.5 ppm; beans (dry) at 0.2 ppm; lentil (dry) at 0.5 ppm; and peas (dry) at 0.3 ppm. The U.S. tolerances differ from the Codex MRLS because the U.S. residue definitions include both the parent compound (pyraclostrobin), and its desmethoxy metabolite, whereas the Codex MRLS only include the parent compound.

C. Response to Comments

Comments were received from B. Sachau on petition 5F6906 for almond, hulls. The comments stated general opposition to Agency approval of tolerances and exemptions other than zero, for pesticides. The commenter opposes any residue left on a treated crop. The comments contained no scientific data or evidence to rebut the Agency's conclusion that there is a reasonable certainty that no harm will result from aggregate exposure to pyraclostrobin, including all anticipated dietary exposures and other exposures for which there is reliable information. These same or similar comments from this responder have been addressed by the Agency on several prior occasions. See the October 29, 2004 and January 7, 2005 (70 FR 1349) (FRL-7691-4) final rules.

V. Conclusion

Therefore, the tolerances are established for combined residues of pyraclostrobin and its desmethoxy metabolite, expressed as parent compound, in or on bean, succulent, shelled at 0.5 ppm; legume vegetables group, foliage, in crop group 7 at 25 ppm; mango (import) at 0.1 ppm; and papaya (import) at 0.1 ppm.

Existing tolerances are being increased almond, hulls from 1.6 ppm to 7.0 ppm; pea and bean, dried shelled, except soybean, subgroup 6C, from 0.3 ppm to 0.5 ppm; strawberry from 0.4 ppm to 1.2 ppm.

VI. Objections and Hearing Requests

Under section 408(g) of FFDCA, as amended by FQPA, 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. Although the procedures in those regulations require some modification to reflect the amendments made to FFDCA by FQPA, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) of FFDCA provides essentially the same process for persons to ''object'' to a regulation for an exemption from the requirement of a tolerance issued by EPA under new section 408(d) of FFDCA, as was provided in the old sections 408 and 409 of FFDCA. However, the period for filing objections is now 60 days, rather than 30 days.

A. What Do I Need to Do to File an Objection or Request a Hearing?

You must file your objection or request a hearing on this regulation in accordance with the instructions provided in this unit and in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number HQ–EPA–OPP–2004–0292 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 June 5, 2006.

1. *Filing the request*. Your objection must specify the specific provisions in the regulation that you object to, and the grounds for the objections (40 CFR 178.25). If a hearing is requested, the objections must include a statement of the factual issue(s) on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the objector (40

CFR 178.27). Information submitted in connection with an objection or hearing request may be claimed confidential by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the information that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice.

Mail your written request to: Office of the Hearing Clerk (1900L), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001. You may also deliver your request to the Office of the Hearing Clerk in Suite 350, 1099 14th St., NW., Washington, DC 20005. The Office of the Hearing Clerk is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Office of the Hearing Clerk is (202) 564–6255.

2. *Copies for the Docket*. In addition to filing an objection or hearing request with the Hearing Clerk as described in Unit VI.A., you should also send a copy of your request to the PIRIB for its inclusion in the official record that is described in **ADDRESSES**. Mail your copies, identified by docket ID number HQ–EPA–OPP–2004–0292, to: Public Information and Records Integrity Branch, Information Technology and Resource Management Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–-0001. In person or by courier, bring a copy to the location of the PIRIB described in **ADDRESSES**. Please use an ASCII file format and avoid the use of special characters and any form of encryption. Copies of electronic objections and hearing requests will also be accepted on disks in WordPerfect 6.1/8.0 or ASCII file format. Do not include any CBI in your electronic copy. You may also submit an electronic copy of your request at many Federal Depository Libraries.

B. When Will the Agency Grant a Request for a Hearing?

A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is a genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issue(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32).

VII. Statutory and Executive Order Reviews

This final rule establishes a tolerance under section 408(d) of FFDCA in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). Because this rule has been exempted from review under Executive Order 12866 due to its lack of significance, this rule is not subject to Executive Order 13211, *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001). 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.*, or 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). 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); or OMB review or any Agency action under Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). 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). 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. In addition, the Agency has determined that this action will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999). Executive Order 13132 requires EPA to develop an accountable process to ensure ''meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.'' ''Policies that have federalism implications'' is defined in the Executive order to include regulations that have ''substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.'' This final rule directly regulates growers, food processors, food handlers, and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of FFDCA. For these same reasons, the Agency has determined that this rule does not have any ''tribal implications'' as described in Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000). Executive Order 13175, requires EPA to develop an accountable process to ensure ''meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.'' ''Policies that have tribal implications'' is defined in the Executive order to include regulations that have ''substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and the Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.'' This rule will not have substantial direct effects on tribal governments, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this rule.

VIII. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, 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: March 29, 2006.

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:
■ a. Removing in the introductory text of paragraph (a)(1) the phrase ''carbamic acid, [2-[[[1-(4-chlorophenyl)-1H-pyrazol-3-yl]oxy]methyl]phenyl]methoxy-, methyl ester and its desmethoxy metabolite methyl 2-[[[1-(4-chlorophenyl)-1H-pyrazol-3-yl]oxy]methyl]phenyl carbamate'' and adding in its place ''(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).''
■
■ b. Revising the commodities ''almond, hulls; pea and bean, dried shelled, except soybean, subgroup; and strawberry'' and adding alphabetically the remaining commodities listed below to the table in paragraph (a)(1). The amended table reads as set forth below.
■ c. Removing paragraph (a)(3).

§ 180.582 Pyraclostrobin; tolerances for residues.

(a) * * *
(1) * * *

Commodity	Parts per million
Almond, hulls	7.0
* * * * *	
Bean, succulent shelled	0.5
* * * * *	
Mango[1]	0.1
* * * * *	
Papaya[1]	0.1
* * * * *	
Pea and bean, dried shelled, except soybean, subgroup 6C	0.5
* * * * *	
Strawberry	1.2
* * * * *	
Vegetables, foliage of legume, group 7	25
* * * * *	

[1] There are no U.S. registrations on mango or papaya as of April 5, 2006.

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[FR Doc. 06–3262 Filed 4–4–06; 8:45 am]

BILLING CODE 6560–50–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 410

[CMS–3017–F]

RIN 0938–AM74

Medicare Program; Conditions for Payment of Power Mobility Devices, Including Power Wheelchairs and Power-Operated Vehicles

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Final rule.

SUMMARY: This final rule conforms our regulations to section 302(a)(2)(E)(iv) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003. This rule defines the term power mobility devices (PMDs) as power wheelchairs and power operated vehicles (POVs or scooters). It sets forth revised conditions for Medicare payment of PMDs and defines who may prescribe PMDs. This rule also requires a face-to-face examination of the beneficiary by the physician or treating practitioner, a written prescription, and receipt of pertinent parts of the medical record by the supplier within 45 days after the face-to-face examination that the durable medical equipment suppliers maintain in their records and make available to CMS or its agents upon request. Finally, this rule discusses CMS' policy on documentation that may be requested by CMS or its agents to support a Medicare claim for payment, as well as the elimination of the Certificate of Medical Necessity (CMN) for PMDs.

DATES: *Effective Date:* These regulations are effective on June 5, 2006.

FOR FURTHER INFORMATION CONTACT: Karen Rinker, (410) 786–0189. Camille Soondar, (410) 786–9370 for CMN issues.

SUPPLEMENTARY INFORMATION:

I. Background

Section 902 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173) amended section 1871(a) of the Act and requires the Secretary, in consultation with the Director of the Office of Management and Budget, to establish and publish timelines for the publication of Medicare final regulations based on the previous publication of a Medicare proposed or interim final regulation. Section 902 of the MMA also states that the timelines for these regulations may vary but shall not exceed 3 years after publication of the preceding proposed or interim final regulation except under exceptional circumstances.

This final rule finalizes provisions set forth in August 26, 2005 (70 FR 50940) interim final regulation.

In addition, this final rule has been published within the 3-year time limit imposed by section 902 of the MMA. Therefore, we believe that the final rule is in accordance with Congress's intent to ensure timely publication of final regulations.

Sections 1832(a)(1) and 1861(s)(6) of the Social Security Act (the Act) established that the provision of durable medical equipment (DME) is a covered benefit under Part B of the Medicare program. Section 1834(a)(1)(A) of the Act provides that Medicare will pay for covered items defined in section 1834(a)(13) which, in turn, defines the term ''covered item'' to include DME defined in section 1861(n). Section 1861(n) provides that DME includes wheelchairs, including power-operated vehicles that may appropriately be used as wheelchairs, that are necessary based on the beneficiary's medical and physical condition, meet safety requirements prescribed by the Secretary, and are used in the beneficiary's home, including an institution used as the beneficiary's home other than a hospital described in section 1861(e)(1) or a skilled nursing facility described in section 1819(a)(1) of the Act. Section 414.202 of our regulations further defines DME as equipment that can withstand repeated use, is primarily and customarily used to serve a medical purpose, generally is not useful to a person in the absence of an illness or injury, and is appropriate for use in the home. We have interpreted the term wheelchair to include both power wheelchairs and power-operated vehicles (POVs or scooters), and we collectively refer to power wheelchairs and power-operated vehicles as power mobility devices (PMDs).