IX. 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 final rule has been exempted from review under Executive Order 12866, this final 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) or Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, nor does it require any special considerations under Executive Order 12898, entitled Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under section 408(d) of FFDCA, such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply.

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of FFDCA. As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, *entitled Federalism* (64 FR 43255, August 10, 1999) and Executive Order 13175, *entitled Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 9, 2000) do not apply to this final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104–4).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104–113, section 12(d) (15 U.S.C. 272 note).

X. 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: April 23, 2008.

Debra Edwards,

Director, 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 180.1282 is added to read as follows:

§ 180.1282 Bacillus firmus I-1582; exemption from the requirement of a tolerance.

An exemption from the requirement of a tolerance is established in/on all food/feed commodities, for residues of *Bacillus firmus* I-1582 when used as a soil application or seed treatment.

[FR Doc. E8–10121 Filed 5–6–08; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2004–0306; FRL–8361–4]

Pyridalyl; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of pyridalyl in or on vegetables, leafy, except *Brassica*, group 4; *Brassica*, head and stem, subgroup 5A; vegetables, fruiting, group 8; mustard greens; and turnip greens. Valent U.S.A. Corporation and the International Research Project Number 4 (IR-4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective May 7, 2008. Objections and requests for hearings must be received on or before July 7, 2008, 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–2004–0306. To access the electronic docket, go to *http://www.regulations.gov*, select ''Advanced Search,'' then ''Docket Search.'' Insert the docket ID number where indicated and select the ''Submit'' button. Follow the instructions on the regulations.gov website to view the docket index or access available documents. All documents in the docket are listed in the docket index available in 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: Olga Odiott, Registration Division (7505P),

Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 308–9369; e-mail address: *odiott.olga@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected entities may include, but are not limited to those engaged in the following activities:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

This listing is not intended to be exhaustive, but rather to provide a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How Can I Access Electronic Copies of this Document?

In addition to accessing an electronic copy of this **Federal Register** document through the electronic docket at *http://www.regulations.gov*, you may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at *http://www.epa.gov/fedrgstr*. You may also access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's pilot e-CFR site at *http://www.gpoaccess.gov/ecfr*.

C. Can I File an Objection or Hearing Request?

Under section 408(g) of FFDCA, 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–2004–0306 in the subject line on the first page of your submission. All requests must be in writing, and must be mailed or delivered to the Hearing Clerk as required by 40 CFR part 178 on or before July 7, 2008.

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing that does not contain any CBI for inclusion in the public docket that is described in **ADDRESSES**. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit this copy, identified by docket ID number EPA–HQ–OPP–2004–0306, 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's normal hours of operation (8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays). Special arrangements should be made for deliveries of boxed information. The Docket Facility telephone number is (703) 305–5805.

II. Petition for Tolerance

In the **Federal Register** of December 5, 2003 (68 FR 68044) (FRL–7344–6), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of pesticide petitions (PP 2F6459 and 3E6592) (petition 3E6592 was inadvertently referred to as 2E6592 in the December, 2003 FR notice) by Valent U.S.A. Corporation, 1600 Riviera Ave., Suite 200, Walnut Creek, California 94596–8025 and the International Research Project Number 4 (IR-4), 681 U.S Highway #1 South, North Brunswick, NJ, 08902–3390. Petition 2F6459 requested that 40 CFR 180 be amended by establishing tolerances for residues of the insecticide pyridalyl, (pyridine, 2-[3-[2,6-dichloro-4-[(3,3-dichloro-2-propenyl)oxy]phenoxy]propoxy]-5-(trifluoromethyl), in or on vegetables, leafy, except *Brassica*, group 4, at 20.0 parts per million (ppm); vegetables, fruiting, group 8, at 1.1 ppm; *Brassica*, head and stem, subgroup 5A, at 5.0 ppm; cotton seed at 0.4 ppm; meat at 0.04 ppm; meat by-products at 0.05 ppm; animal fat at 1.0 ppm; and whole milk at 0.1 ppm; and to establish tolerances for residues of pyridalyl plus the metabolite 3,5-dichloro-4-[3-(5-trifluoromethyl-2-pyridyloxy)]propoxy phenol (S-1812-DP) in or on the raw agricultural commodity cotton, gin byproducts at 23.0 ppm. Petition 3E6592 requested that 40 CFR 180 Part be amended by establishing tolerances for residues of pyridalyl in or on the raw agricultural commodities: *Brassica*, leafy greens, subgroup 5B, at 30 ppm; and turnip greens at 30 ppm. That notice referenced a summary of the petition prepared by Valent U.S.A. Corporation, the registrant, which is available to the public in the docket, *http://www.regulations.gov*. There were no comments received in response to the notice of filing.

Based upon review of the data supporting the petitions, EPA has determined that the proposed tolerances for *Brassica*, head and stem, subgroup 5A, and vegetables, fruiting, group 8, should be reduced to 3.5 ppm; and 1.0 ppm respectively; that a tolerance for mustard greens at 30 ppm; should be proposed; and that the proposed tolerance for *Brassica*, leafy greens, subgroup 5B should be deleted. The reasons for these changes are explained in Unit IV.C. The Agency is evaluating additional environmental fate data and has not yet made a decision to register the outdoor uses associated with the proposed tolerances for cotton and related commodities. A decision to establish these tolerances will be made at such time when the Agency makes the determination to register these outdoor uses.

III. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is ''safe.'' Section 408(b)(2)(A)(ii) of FFDCA defines ''safe'' to mean that ''there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to ''ensure that there is a

reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue....''

Consistent with section 408(b)(2)(D) of FFDCA, and the factors specified in section 408(b)(2)(D) of FFDCA, EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for the following petitioned-for tolerances for residues of pyridalyl *per se* in or on vegetables, leafy, except *Brassica*, group 4, at 20 ppm; *Brassica*, head and stem, subgroup 5A at 3.5 ppm; vegetables, fruiting, group 8, at 1.0 ppm; mustard greens at 30 ppm; and turnip greens at 30 ppm. EPA's assessment of exposures and risks associated with establishing tolerances follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children.

Pyridalyl has low acute toxicity via the oral, dermal and inhalation routes of exposure but is a dermal sensitizer. There was no evidence of neurotoxicity seen in either the sub-chronic and chronic toxicity studies or the developmental and reproductive studies. There is low concern for prenatal and/or postnatal toxicity resulting from exposure to pyridalyl. Pyridalyl is classified as ''Not Likely to be Carcinogenic to Humans'' based on lack of carcinogenicity in mice and rats and overall negative findings in various mutagenicity studies.

Specific information on the studies received and the nature of the adverse effects caused by pyridalyl 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 pyridalyl in/on cotton, fruiting vegetables, leafy vegetables, head and stem *Brassica* vegetables, *Brassica* leafy greens, and turnip greens, shrubs, ornamentals and non-bearing trees. HED Risk Assessment on page number 26 in docket ID number EPA–HQ–OPP–2004–0306.

B. Toxicological Endpoints

For hazards that have a threshold below which there is no appreciable risk, a toxicological point of departure (POD) is identified as the basis for derivation of reference values for risk assessment. The POD may be defined as the highest dose at which no adverse effects are observed 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 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 pyridalyl used for human risk assessment is shown in Table 1 of this unit.

TABLE 1.—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR PYRIDALYL FOR USE IN HUMAN RISK ASSESSMENT

Exposure/Scenario	Point of Departure and Uncertainty/Safety Factors	RfD, PAD, LOC for Risk Assessment	Study and Toxicological Effects
Acute dietary (females 13–50 years of age) Acute dietary (general population including infants and children)	An effect of concern attributable to a single exposure (dose) was not identified from the oral toxicity studies, including the developmental toxicity studies in rats and rabbits.		
Chronic dietary (All populations)	NOAEL= 3.4 mg/kg/day UF_A = 10x UF_H = 10x FQPA SF = 1x	cPAD = 0.034 mg/kg/day	Combined chronic toxicity/carcinogenicity study-rats LOAEL = 17.1 miligrams/kilogram/day (mg/kg/day) on males and 21.1 mg/kg/day on females based on decreased body weights, weight gain, and food efficiency.
Cancer (oral, dermal, inhalation)	Classified as ''Not likely to be Carcinogenic to Humans''		

UF_A = extrapolation from animal to human (interspecies). UF_H = potential variation in sensitivity among members of the human population (intraspecies). FQPA SF = FQPA Safety Factor. PAD = population adjusted dose (a = acute, c = chronic). RfD = reference dose. LOC = level of concern.

C. Exposure Assessment

Pyridalyl residues of concern for tolerance expression and risk assessment were determined to be: 3,5-dichloro-4-[3-(5-trifluoromethyl-2-pyridyloxy)]propoxy phenol (S-1812-DP), 2-hydroxy-5-trifluoromethylpyridine (HTFP), and 3-hydroxy-5-trifluoromethylpyridone (HPDO).

Pyridalyl is the predominant residue in crops and livestock. S-1812-DP is the only major metabolite observed in any of the metabolism studies and is found at significant levels in the cotton gin byproduct field trials. The toxicity of S-1812-DP is assumed to be comparable to the parent compound.

Rotational crops did not take up parent pyridalyl or its metabolite S-1812-DP from the soil, but did take up metabolite HTFP. HTFP was then metabolized in rotational crops via oxidation to HPDO. Metabolites HTFP and HPDO are assumed to be of equivalent toxicity to the parent compound and are included as residues of concern.

Pyridalyl is expected to be persistent in both soil and aquatic environments. However, S-1812-DP and HTFP, the major metabolites in the terrestrial field-dissipation studies, are expected to be more soluble and mobile than the parent compound, and therefore are included in the drinking water assessment.

1. *Dietary exposure from food and feed uses*. In evaluating dietary exposure to pyridalyl, EPA considered exposure under the petitioned-for tolerances for pyridalyl. EPA assessed dietary exposures from pyridalyl in food as follows:

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

No such effects were identified in the toxicological studies for pyridalyl; therefore, a quantitative acute dietary exposure assessment is unnecessary.

ii. *Chronic exposure*. In conducting the chronic dietary exposure assessment EPA used the food consumption data from the United States Department of Agricuulture (USDA) 1994–1996 and 1998 Continuing Surveys of Food Intake by Individuals (CSFII). As to residue levels in food, EPA used tolerance level residues and 100 percent crop treated (PCT) information for all commodities. In addition, Dietary Exposure Evaluation (DEEM/™) (version 7.76) default processing factors were used for all processed commodities.

iii. *Anticipated residue and PCT information*. EPA did not use anticipated residue and/or PCT information in the dietary assessment for pyridalyl.

2. *Dietary exposure from drinking water*. The Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for pyridalyl in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of pyridalyl. 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*.

The Agency used estimated environmental concentrations (EECs), which are the model estimates of a pesticide's concentration in water, to quantify pyridalyl drinking water exposure and risk as a Percent Reference Dose (%RfD) or %PAD. Drinking water levels of comparison (DWLOCs) were calculated and used as a point of comparison against the model estimates of the pesticide's concentration in water. DWLOCs are theoretical upper limits on a pesticide's concentration in drinking water in light of total aggregate exposure to a pesticide in food, and from residential uses. Since DWLOCs address total aggregate exposure to pyridalyl they are further discussed in the aggregate risk sections in Unit E.

Based on the Pesticide Root Zone Model/Exposure Analysis Modeling System (PRZM/EXAMS) and Screening Concentration in Ground Water (SCI-GROW) models the EECs of pyridalyl for chronic exposures are estimated to be 1.64 parts per billion (ppb) for surface water and 3.4 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).

Pyridalyl is not registered for any specific use patterns that would result in residential exposure.

4. *Cumulative effects from substances with a common mechanism of toxicity*. Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider ''available information'' concerning the cumulative effects of a particular pesticide's residues and ''other substances that have a common mechanism of toxicity.''

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

D. Safety Factor for Infants and Children

1. *In general*. Section 408(b)(2)(c) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the FQPA 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. *Prenatal and postnatal sensitivity*. There was low concern for the quantitative susceptibility in the 2-generation reproduction study, since there was clear NOAEL for the offspring toxicity, the effects of concern were well defined and used for risk assessment. Therefore, there are no concerns and no residual uncertainties with regard to prenatal and/or postnatal toxicity.

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 pyridalyl is complete.

ii. There is no indication that pyridalyl is a neurotoxic chemical and there is no need for a developmental neurotoxicity study or additional UFs to account for neurotoxicity.

iii. There are no concerns and no residual uncertainties with regard to prenatal and/or postnatal toxicity.

iv. There are no residual uncertainties identified in the exposure databases. The dietary food exposure assessments were performed based on 100% CT and tolerance-level residues. EPA made conservative (protective) assumptions in the ground water and surface water modeling used to assess exposure to pyridalyl in drinking water. These

assessments will not underestimate the exposure and risks posed by pyridalyl.

E. Aggregate Risks and Determination of Safety

To estimate total aggregate exposure to pyridalyl from food, drinking water, and residential uses, the Agency calculated DWLOCs which are used as a point of comparison against EECs. DWLOC values are not regulatory standards for drinking water. DWLOCs are theoretical upper limits on a pesticide's concentration in drinking water in light of total aggregate exposure to a pesticide in food and residential uses. In calculating a DWLOC, the Agency determines how much of the acceptable exposure (i.e., the PAD) is available for exposure through drinking water [e.g., allowable chronic water exposure (mg/kg/day) = cPAD - (average food + residential exposure)]. This allowable exposure through drinking water is used to calculate a DWLOC.

A DWLOC will vary depending on the toxic endpoint, drinking water consumption, and body weights. Default body weights and consumption values as used by the EPA's Office of Water are used to calculate DWLOCs: 2 liter (L)/70 kg (adult male), 2L/60 kg (adult female), and 1L/10 kg (child). Default body weights and drinking water consumption values vary on an individual basis. This variation will be taken into account in more refined screening-level and quantitative drinking water exposure assessments. Different populations will have different DWLOCs. Generally, a DWLOC is calculated for each type of risk assessment used: Acute, short-term, intermediate-term, chronic term, and cancer.

When EECs for surface water and ground water are less than the calculated DWLOCs, EPA concludes with reasonable certainty that exposures to the pesticide in drinking water (when considered along with other sources of exposure for which EPA has reliable data) would not result in unacceptable levels of aggregate human health risk at this time. Because EPA considers the aggregate risk resulting from multiple exposure pathways associated with a pesticide's uses, levels of comparison in drinking water may vary as those uses change. If new uses are added in the future, EPA will reassess the potential impacts of residues of the pesticide in drinking water as a part of the aggregate risk assessment process.

1. *Acute risk*. An acute aggregate risk assessment takes into account exposure estimates from acute dietary consumption of food and drinking water. No adverse effect resulting from a single-oral exposure was identified and no acute dietary endpoint was selected. Therefore, pyridalyl is not expected to pose an acute risk.

2. *Chronic risk*. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to pyridalyl from food will utilize 35% of the cPAD for the U.S. population, 20% of the cPAD for all infants, and 59% of the cPAD for children 1-2 years old, the children subpopulation at greatest exposure. There are no residential uses for pyridalyl. There is potential for chronic dietary exposure to pyridalyl and its metabolites in drinking water. After calculating DWLOCs and comparing them to the EECs for surface water and ground water, EPA does not expect the aggregate exposure to exceed 100% of the cPAD, as shown in the following Table:

TABLE 2.—AGGREGATE RISK ASSESSMENT FOR CHRONIC (NON-CANCER) EXPOSURE TO PYRIDALYL

Population Sub-group	cPAD mg/kg/day	%cPAD (Food)	Surface Water EEC[a](ppb)	Ground Water EEC[b](ppb)	Chronic DWLOC (ppb)
U.S. population	0.034	35	1.64	3.4	780
All infants (< 1 yr)	0.034	20	1.64	3.4	270
Children 1-2 yrs.	0.034	59	1.64	3.4	140

[a] Tier II PRZM-EXAMS - Index reservoir model, pyridalyl plus HTFP and S-1812-DP.
[b] Tier 1 SCI-GROW model, HTFP (highest value).

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).

Pyridalyl is not registered for any use patterns that would result in residential exposure. Therefore, the short-term aggregate risk is the sum of the risk from exposure to pyridalyl through food and water and will not be greater than the chronic aggregate risk.

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).

Pyridalyl is not registered for any use patterns that would result in intermediate-term residential exposure. Therefore, the intermediate-term aggregate risk is the sum of the risk from exposure to pyridalyl through food and water, which has already been addressed, and will not be greater than the chronic aggregate risk.

5. *Aggregate cancer risk for U.S. population*. Pyridalyl is classified as ''not likely to be carcinogenic to humans'' by all relevant routes of exposure based on adequate studies in mice and rats and overall negative findings in various mutagenicity assays. Therefore, pyridalyl 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 pyridalyl residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology (gas chromatography/nitrogen-phosphorus detector (GC/NPD) methods RM-38P-1-1, RM-38M-1, and RM-38M-1-1 for plant commodities; and RM-38P-2 and RM-38P-3-1 for livestock commodities) is available to enforce the tolerance expression. 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*. FDA multiresidue methods (protocols B, D, E, and F) are also available for enforcement of the tolerances (PAM Vol.I, Appendix II, 1/94).

B. International Residue Limits

There are currently no U.S. or international Codex tolerances established for pyridalyl.

C. Revisions to Petitioned-For Tolerances

Based on its review of submitted crop field trial data, EPA determined that the proposed tolerances for *Brassica* head and stem, subgroup 5A; and for fruiting vegetables, group 8 should be reduced to 3.5 and 1.0 ppm, respectively. The Agency determined also that the data were not sufficient to support the proposed tolerance for Brassica leafy greens, subgroup 5B; although a mustard green tolerance at 30 ppm was supported by the data.

V. Conclusion

Therefore, tolerances are established for residues of pyridalyl *per se*, in or on vegetables, leafy, except *Brassica*, group 4 at 20 ppm; *Brassica*, head and stem, subgroup 5A at 3.5 ppm; vegetables, fruiting, group 8 at 1.0 ppm; mustard greens at 30 ppm; and turnip greens at 30 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, Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled Protection of Children from Environmental Health Risks and Safety Risks (62 FR 19885, April 23, 1997). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, nor does it require any special considerations under Executive Order 12898, entitled Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under section 408(d) of FFDCA, such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply.

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of FFDCA. As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled Federalism (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled Consultation and Coordination with Indian Tribal Governments (65 FR 67249, November 9, 2000) do not apply to this final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104–4).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104–113, section 12(d) (15 U.S.C. 272 note).

VII. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this final rule in the **Federal Register**. This final rule is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: April 23, 2008.

Debra Edwards,

Director, 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 180.640 is added to read as follows:

180.640 Pyridalyl; tolerances for residues.

(a) *General*. Tolerances are established for residues of pyridalyl, pyridine,2-[3-[2,6-dichloro-4-[(3,3-dichloro-2-propenyl)oxy]phenoxy]propoxy]-5-(trifluoromethyl, in or on the following raw agricultural commodities:)

Commodity	Parts per million
Brassica, head and stem, subgroup 5A	3.5
Mustard greens	30
Turnip greens	30
Vegetable, fruiting, group 8	1.0
Vegetables, leafy, except *Brassica*, group 4	20

(b) *Section 18 emergency exemption*. [Reserved]

(c) *Tolerances with regional registration*. [Reserved]

(d) *Indirect or inadvertent residues*. [Reserved]

[FR Doc. E8–9823Filed 5–6–08; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2007–0398; FRL–8362–2]

Spirodiclofen; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a tolerance for residues of spirodiclofen in or on hop, dried cones. Interregional Research Project Number 4 (IR–4) requested this tolerance under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective May 7, 2008. Objections and requests for hearings must be received on or before July 7, 2008, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also