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 the FFDCA, such as the exemption 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 the 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.

XII. 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 rule in the **Federal Register**. This 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 14, 2007.

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: 1 U.S.C. 321(q), 346a and 371.

■ 2. In § 180.960 the table is amended by alphabetically adding a polymer to read as follows:

§ 180.960 Polymers; exemptions from the requirement of a tolerance.

Polymer	CAS No.
* * * * *	
2-Propenoic acid, methyl ester, polymer with ethenyl acetate, hydrolyzed, sodium salts..	886993–11–9
* * * * *	

[FR Doc. E7–3118 Filed 2–27–07; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2006–0321; FRL–8115–8]

Sethoxydim; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for combined residues of sethoxydim {2-[1-(ethoxyimino)butyl]-5-[2-(ethylthio)propyl]-3-hydroxy-2-cyclohexen-1-one }and its metabolites containing the 2-cyclohexen-1-one moiety (calculated as sethoxydim) in or on buckwheat grain, buckwheat flour, okra, borage seed, borage meal, fresh dillweed leaves, radish tops, turnip greens, and vegetable, root and tuber, group 1. Interregional Research Project No. 4 (IR-4) 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 February 28, 2007. Objections and requests for hearings must be received on or before April 30, 2007, 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–2006–0321. All documents in the docket are listed in the index for the docket. 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 Building), 2777 S. Crystal Drive, Arlington, VA. The 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: Barbara Madden, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 305-6463; e-mail address: *Madden.Barbara@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 111), e.g., agricultural workers; greenhouse, nursery, and floriculture workers; farmers.
- Animal production (NAICS 112), e.g., cattle ranchers and farmers, dairy cattle farmers, livestock farmers.
- Food manufacturing (NAICS 311), e.g., agricultural workers; farmers; greenhouse, nursery, and floriculture workers; ranchers; pesticide applicators.
- Pesticide manufacturing (NAICS 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?

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 40 CFR part 180 through the Government Printing Office's pilot e-CFR site at *http://www.gpoaccess.gov/ecfr*. To access the OPPTS Harmonized Guidelines referenced in this document, go directly to the guidelines at *http://www.epa.gpo/opptsfrs/home/guidelin.htm*.

C. Can I File an Objection or Hearing Request?

Under section 408(g) of the FFDCA, as amended by the 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. 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–2006–0321 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 April 30, 2007.

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–2006–0321, 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 Building), 2777 S. Crystal Drive, 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 telephone number is (703) 305-5805.

II. Background and Statutory Findings

In the **Federal Register** of July 5, 2006 (71 FR 38154) (FRL–8074–7), 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 0E6204 and 4E6885) by IR-4, 500 College Road East, Suite 201 W, Princeton, NJ 08540. The petitions requested that 40 CFR 180.412 be amended by establishing tolerances for combined residues of the herbicide sethoxydim {2-[1-(ethoxyimino)butyl]-5-[2-(ethylthio)propyl]-3-hydroxy-2-cyclohexen-1-one} and its metabolites containing the 2-cyclohexen-1-one moiety in or on turnip tops at 5.0 parts per million (ppm) (PP 0E6204) and buckwheat, grain at 20 ppm; buckwheat, flour at 20 ppm; borage; seed at 5.0 ppm; borage, meal at 40 ppm; borage, oil at 40 ppm; dill, fresh leaves at 10 ppm; dill, dried leaves at 10 ppm; okra at 4.0 ppm; vegetable root, except sugar beet, group 1B at 4.0 ppm; and radish tops at 5.0 ppm (4E6885). That notice referenced a summary of the petition prepared by BASF Corporation, the registrant, that is available in EPA's electronic docket. There were no comments received in response to the notice of filing.

Upon completing review of the current sethoxydim database, the Agency concluded that the appropriate tolerance levels and preferred commodity terms for sethoxydim residues in or on pending crops should be established as follows: Buckwheat, grain at 19 ppm; buckwheat, flour at 25 ppm; okra at 2.5 ppm; borage, seed at 6.0 ppm; borage, meal at 10 ppm; dillweed, fresh leaves at 10 ppm; radish, tops at 4.5 ppm; turnip, greens at 5.0 ppm and Vegetable, root and tuber, group 1 at 4.0 ppm. Vegetable, root and tuber, group 1 incorporates both the request for vegetable root, except sugar beet, group 1B at 4.0 ppm and existing tolerances for carrot, roots at 1.0 ppm; horseradish at 4.0 ppm; beet, garden at 1.0 ppm; beet, sugar, root at 1.0 ppm; and tuberous and corm vegetable subgroup 1D at 4.0 ppm. Turnip, greens replaces the term turnip tops. In addition, the proposed tolerance for borage oil was withdrawn because no separate tolerance is required since oil is covered by the borage seed tolerance and the proposed tolerance for dill, dried leaves was withdrawn because no separate tolerance is required since dried dillweed is covered by the fresh dillweed tolerance.

EPA is also deleting several established tolerances in section 180.412(a) that are no longer needed as a result of this action. The revisions to section 180.412(a) are as follows: Delete beet, garden at 1.0 ppm; beet, sugar, roots at 1.0 ppm; carrot, roots at 1.0 ppm; horseradish at 4.0 ppm; and tuberous and corm vegetable crop subgroup at 4.0 ppm. All of these tolerances are replaced with vegetable, root and tuber, group 1 at 4.0 ppm.

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 the FFDCA and a complete description of the risk assessment process, see *http://www.epa.gov/fedrgstr/EPA-PEST/1997/November/Day-26/p30948.htm* and *http://www.epa.gov/fedrgstr/EPA-PEST/2003/July/Day-30/p19357.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 sethoxydim and its metabolites containing the 2-cyclohexen-1-one moiety on buckwheat, grain at 19 ppm; buckwheat, flour at 25 ppm; okra at 2.5 ppm; borage, seed at 6.0 ppm; borage, meal at 10 ppm; dillweed, fresh leaves at 10 ppm; radish, tops at 4.5 ppm; turnip, greens at 5.0 ppm and vegetable, root and tuber, group 1 at 4.0 ppm. EPA's assessment of exposures and risks associated with establishing the tolerance 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 sethoxydim as well as the no-observed-adverse-effect-level (the NOAEL) and the lowest-observed-adverse-effect-level (the LOAEL) from the toxicity studies can be found in the final rule published in the **Federal Register** of September 29, 2003 (68 FR 55858) *(http://www.epa.gov/EPA-PEST/2003/September/Day-29/p24562.htm).*

B. Toxicological Endpoints

For hazards that have a threshold below which there is no appreciable risk, the dose at which 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 (LOAEL) of concern are identified 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. More information can be found on the general principles EPA uses in risk characterization at be found on the general principles EPA uses in risk characterization at *http://www.epa.gov/pesticides/health/human.htm.*

A summary of the toxicological endpoints for sethoxydim used for human risk assessment can be found at www.regulations.gov in document 0003 (page 9) in Docket ID EPA–HQ–OPP–2006–0321. To locate this information on the Regulations.gov website follow these steps:

Select ''Advanced Search'', then ''Docket Search.''

In the ''Keyword'' field type the chemical name or insert the applicable ''Docket ID number.'' (example: EPA–HQ–OPP–2005–9999).

Click the ''Submit''button.

Follow the instructions on the regulations.gov web site to view the index for the docket and access available documents.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* Tolerances have been established (40 CFR 180.412) for the combined residues of sethoxydim and its 2-cyclohexen-1-one moiety containing metabolites, in or on a variety of raw agricultural commodities. Tolerances have also been established for combined residues of sethoxydim in or on milk, egg, and fat, meat, and meat byproducts of cattle, goat, hog, horse, poultry and sheep. Risk assessments were conducted by EPA to assess dietary exposures from sethoxydim 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 one-day or single exposure.

In conducting the acute dietary exposure assessment EPA used the Dietary Exposure Evaluation Model 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 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: For all proposed new uses and for all commodities in Vegetable, root and tuber, group 1, tolerance level residues and 100 percent crop treated (PCT) were assumed. For the remaining crops with existing tolerances available maximum PCT values were used. Tolerance level residues were assumed for most crops except for grapes, oranges, potatoes, tomatoes, strawberries, apples, pears and other pome fruits where anticipated residues were calculated through the incorporation of field trial data. Empirical processing data for apples, grapes, tomatoes, potatoes and oranges were used, and were sometimes translated to other members of the crop group. For livestock commodities, the available PCT information was incorporated into the dietary burden calculation and the feeding studies were used to determine the appropriate residue level, however at least one food item in each diet was assumed to be 100 PCT. PCT information was incorporated into the acute exposure and risk assessments through use of probabilistic risk assessment model.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the DEEM™ software with the Food Commodity Intake Database, which incorporates food consumption data as reported by respondents in the United States 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 chronic exposure assessments: For the proposed new uses and all commodities in Vegetable, root and tuber, group 1 tolerance level residues and 100% CT were assumed. For most of the crops with existing tolerances, tolerance level residues and average PCT values were assumed. PCT data for some livestock feeds were incorporated into the calculations of the theoretical dietary burdens for livestock, which were then used in conjunction with the available feeding studies to determine the anticipated residues in livestock commodities.

iii. *Cancer*. The Agency has classified sethoxydim as not likely to be a human carcinogen based on lack of evidence of carcinogenicity in rats and mice. Therefore, a cancer dietary exposure assessment was not performed

iv. *Anticipated residue and PCT information*. Section 408(b)(2)(E) of the 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 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 section 408(b)(2)(F) of FFDCA, EPA may require registrants to submit data on PCT.

The Agency used PCT information for the chronic dietary risk assessment as follows: 1% apples, 1% apricots, 6% globe artichokes, 5% asparagus, 14% dry beans, 9% lima beans, 8% snap beans, 5% garden beet tops, 1% broccoli, 5% cabbage, 8% cantaloupes, 2% cauliflower, 1% cherries, 2% collards, 1% corn, 1% cotton, 8% cranberries, 6% cucumbers, 5% eggplants, 38% flax, 1% grapes, 1% grapefruits, 5% lemons, 1% lettuce, 1% nectarines, 3% oranges, 2% succulent peas, 14% dry peas, 1% peaches, 5% peanuts, 1% pears, 3% bell peppers, 6% nonbell peppers, 4% potatoes, 8% pumpkins, 4% rapeseed, 6% rhubarb, 2% soybeans, 1% spinach, 8% summer squash, 5% strawberry, 14% sunflower, 4% tomatoes, 5% turnip greens, and 12% watermelons.

EPA uses an average PCT for chronic dietary risk analysis. The average PCT figure for each existing use is derived by combining available Federal, State, and private market survey data for that use, averaging by year, averaging across all years, and rounding up to the nearest multiple of five percent except for those situations in which the average PCT is less than one. In those cases <1% is used as the average and <2.5% is used as the maximum. EPA uses a maximum PCT for acute dietary risk analysis. The maximum PCT figure is the single maximum value reported overall from available federal, state, and private market survey data on the existing use, across all years, and rounded up to the nearest multiple of five percent. In most cases, EPA uses available data from United States Department of Agriculture/National Agricultural Statistics Service (USDA/NASS), Proprietary Market Surveys, and the National Center for Food and Agriculture Policy (NCFAP) for the most recent six years.

The Agency believes that the three conditions listed III.C.1.iv. have been met. With respect to Condition 1, PCT estimates are derived from Federal and private market survey data, which are reliable and have a valid basis. The Agency is reasonably certain that the percentage of the food treated is not likely to be an underestimation. As to Conditions 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 sethoxydim may be applied in a particular area.

2. *Dietary exposure from drinking water*. The Agency lacks sufficient monitoring exposure data to complete a comprehensive dietary exposure analysis and risk assessment for sethoxydim 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 sethoxydim. 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 First Index Screening Tool Reservoir (FIRST) and Screening Concentration in Groundwater (SCI-GROW) models, the estimated environmental concentrations (EECs) of sethoxydim for acute exposures are estimated to be 130 parts per billion (ppb) for surface water and 1.5 ppb for ground water. The EECs for chronic exposures are estimated to be 16 ppb for surface water and 1.5 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 130 ppb was used to assess the contribution to drinking water. For chronic dietary risk assessment, the water concentration value of 16 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).

Sethoxydim is currently registered for use on the following residential non-dietary sites: Ornamentals and flowering

plants, recreational areas, rights-of-way, along fences and hedgerows, and public and commercial buildings/structures (non-agricultural-outdoors). The risk assessment was conducted using the following residential exposure assumptions: Homeowners who apply sethoxydim to ornamental gardens and turf may be exposed for short-term (up to 30 days) durations via the dermal and inhalation routes. Short-term post application exposures to children may result from incidental oral contact via hand-to-mouth, turf-to-mouth, and soil-to-mouth activities with treated turf. No dermal toxicity endpoints were identified, therefore, only exposure from inhalation (adult handlers) and incidental ingestion (children) were assessed. For short-term and intermediate-term aggregate exposure, the inhalation exposures estimated for adult handlers cannot be combined with dietary exposure due to lack of common toxicity via the oral [transitory clinical signs: Irregular gait at doses of 650 milligrams/kilogram (mg/kg) and 1,000 mg/kg and inhalation (hepatotoxicity)] routes of exposure. Therefore, only short-term aggregate exposures from incidental ingestion for children via hand-to-mouth, turf-to-mouth, and soil-to-mouth activities with treated turf were assessed.

4. *Cumulative effects from substances with a common mechanism of toxicity*. Section 408(b)(2)(D)(v) of the 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 sethoxydim and any other substances and sethoxydim 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 sethoxydim 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 data base 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 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 uncertainty factors and/or special FQPA safety factors, as appropriate.

2. *Prenatal and postnatal sensitivity*. Since there is evidence of increased susceptibility of the young following exposure to sethoxydim in the rat developmental study and the rat reproduction study, the EPA performed a Degree of Concern Analysis to: 1. Determine the level of concern for the effects observed when considered in the context of all available toxicity data; and 2. Identify any residual uncertainties after establishing toxicity endpoints and traditional uncertainty factors to be used in the risk assessment of this chemical. If residual uncertainties are identified, EPA examines whether these residual uncertainties can be addressed by a special FQPA safety factor and, if so, the size of the factor needed. The results of Degree of Concern analysis for sethoxydim are presented as follows:

The degree of concern is low for the fetal effects in the developmental rat study since the fetal anomalies were seen only at the high dose (650 mg/kg/day) which is close to the Limit Dose (1,000 mg/kg/day), they were seen in the presence of maternal toxicity (irregular gait) and clear NOAELs/LOAELs were established for maternal and developmental toxicities.

EPA has determined that the degree of concern was low for prenatal and/or postnatal toxicity resulting from exposure to sethoxydim toxicity.

3. *Conclusion*. In the final rule published in the **Federal Register** of September 29, 2003 (68 FR 55858) (FRL–7328–6) (*http://www.epa.gov/EPA-PEST/2003/September/Day-29/p24562.htm*). EPA retained the additional 10X FQPA safety factor in the form of a Data base Uncertainty Factor because EPA had required submission of subchronic and developmental neurotoxicity studies due to various clinical signs in the rat developmental study and evidence of developmental abnormalities in the rat developmental and reproductive studies. In December of 2004, the EPA revisited the requirement for the subchronic and developmental neurotoxicity studies and determined that the evidence does not support the need for neurotoxicity studies for the reasons discussed below.

First, EPA concluded that the clinical signs seen in the rat developmental study were not neurotoxicity. The clinical signs following sethoxydim exposure in that study were irregular gait, decreased activity, excessive salivation, and anogenital staining. These effects were only observed in animals receiving very high doses of sethoxydim (650 mg/kg/day and 1,000 mg/kg/day). Irregular gait was observed in 12/24 dams at 650 mg/kg/day and 10/10 dams at 1,000 mg/kg/day on the first day of dosing, after 3 doses the signs began to dissipate. Decreased activity was noted in 1/34 dams at 650 mg/kg/day and in 4/10 dams at 1,000 mg/kg/day and reversed after several days. Excessive salivation was noted in 23/34 dams at 650 mg/kg/day and 10/10 dams at 1,000 mg/kg/day. Anogenital staining was documented in 13/34 dams at 650 mg/kg/day and 7/10 dams at 1,000 mg/kg/day. All clinical signs reported were transient, with the exception of the anogenital staining which did not reverse. Because the clinical signs occurred shortly after dosing, only occurred at very high treatment doses (over one half the limit dose) and were transitory, it is unlikely that the signs observed are the result of a primary systemic effect on the nervous system but, rather, are reflective of the general toxicity at the high dose. It should be noted that clinical signs indicative of nervous system effects were not observed in any other standard toxicity study for sethoxydim. Although none of these other studies dosed up to 650 and 1,000 mg/kg/day, a maximum tested dose was reached because of evidence of other toxicities (e.g., liver effects or body weight reductions).

Second, EPA found that there were no developmental effects seen in the rat and rabbit prenatal studies indicative of an effect on the nervous system. The main effect seen in the rat and rabbit prenatal studies was an increased incidence of fetal skeletal variations due

to delayed ossification. In the rat prenatal study, tail abnormalities (filamentous tail or lack of a tail) were noted. These abnormalities were observed at a very low incidence (10 fetuses in 7 litters, 650 milligrams/kilogram/body weight/day (mg/kg/bwt/day and at high treatment doses (650 and 1,000 mg/kg/day). In the 2-generation reproduction study in rat, a tail anomaly (short, thread-like tail, no anal opening, hindlimbs curved toward central midline) was found in one pup in the F2b generation (1/344 total pups; in 1/4 litters). Tail abnormalities are sometimes thought to relate to central nervous system (CNS) malformations; however, in this case, these tail abnormalities are not likely to be the result of a primary neurotube effect. In the rat prenatal study, there is no description of any effect on neural tube derived structures. Furthermore, the class of compounds, cyclohexones (which sethoxydim is a member), do not demonstrate neurotoxicity or developmental malformations of the nervous system.

Therefore, after a weight-of-evidence examination of all the toxicological studies available in the data base, the previous requirement for a neurotoxicity studies have been waived.

In light of its finding that neurotoxicity studies are not needed, EPA has now determined that reliable data show that it would be safe for infants and children to reduce the FQPA safety factor to 1X. That decision is based on the following findings:

1. The toxicity database for sethoxydim is complete.

2. There is no indication that sethoxydim is a neurotoxic chemical and there is no need for a developmental neurotoxicity study or additional uncertainty factors to account for neurotoxicity.

3. Although there is qualitative evidence of increased susceptibility in the prenatal developmental studies in rats and rabbits, the risk assessment team did not identify any residual uncertainties after establishing toxicity endpoints and traditional uncertainty factors to be used in the risk assessment for sethoxydim. The degree of concern for pre-and/or postnatal toxicity is low.

4. There are no residual uncertainties identified in the exposure databases. The dietary food exposure assessments were performed based on tolerance level residues and 100 PCT for all proposed new uses and for all commodities in Vegetable, root and tuber, group 1. For most of the remaining crops available maximum PCT treated values were used for acute dietary assessment and average PCT values were assumed for chronic dietary assessment. Tolerance level residues were assumed for crops with existing tolerances or anticipated residues were calculated through the incorporation of field trial data. Conservative ground and surface water modeling estimates were used. Similarly conservative Residential SOPs were used to assess post-application exposure to children as well as incidental oral exposure of toddlers. These assessments will not underestimate the exposure and risks posed by sethoxydim.

E. Aggregate Risks and Determination of Safety

Safety is assessed for acute and chronic risks by comparing aggregate 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 LOC by all applicable uncertainty/safety factors. For linear cancer risks, EPA calculates the probability of additional cancer cases given aggregate exposure. Short-term, intermediate, and long-term risks are evaluated by comparing aggregate exposure to the LOC to ensure that the margin of exposure (''MOE'') called for by the product of all applicable uncertainty/safety factors 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 sethoxydim will occupy 11% of the aPAD for the U.S. population, 7.2% of the aPAD for females 13 years and older, 14% of the aPAD for all infants (<1 year old), and 20% of the aPAD for children 1-2 years old, the subpopulation at greatest exposure

2. *Chronic risk*. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to sethoxydim from food and water will utilize 6.9% of the cPAD for the U.S. population, 15% of the cPAD for all infants (<1 year old), and 16% of the cPAD for children 1-2 years old, the subpopulation at greatest exposure. Based on the use pattern, chronic residential exposure to residues of sethoxydim is not expected.

3. *Short-term risk*. Short-term aggregate exposure takes into account residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Sethoxydim is currently registered for use 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 sethoxydim.

Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded that food, water and residential exposures aggregated result in aggregate MOEs of 5,700 for children/toddlers 1-2 years of age. Since this is the subpopulation with the highest estimated food and water exposures and the calculated MOE of 5,700 is substantially greater than the target MOE of 100 EPA has no concern for short-term aggregate risk for other subpopulations as well.

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).

Though residential exposure could occur with the use of sethoxydim intermediate-term exposures are not expected. Only risks associated with short-term exposures of up to 30 days were assessed.

5. *Aggregate cancer risk for U.S. population*. The Agency has classified sethoxydim as not likely to be a human carcinogen based on lack of evidence of carcinogenicity in rats and mice. Sethoxydim 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, and to infants and children from aggregate exposure to sethoxydim residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology (gas-liquid chromatography with flame photometric detection in the sulfur mode) is available BASF Wyandotte Corporations' (BWCs) Method No. 30, 3/15/82; MRID 44864501; Method I, PAM II to enforce the tolerance expression for the purpose of this request.

B. International Residue Limits

There are currently no Codex maximum residue levels for sethoxydim.

V. Conclusion

Therefore, the tolerance is established for combined residues of sethoxydim {2-[1-(ethoxyimino)butyl]-5-[2-(ethylthio)propyl]-3-hydroxy-2-cyclohexen-1-one}and its metabolites containing the 2-cyclohexen-1-one moiety (calculated as sethoxydim), in or on buckwheat, grain at 19 ppm; buckwheat, flour at 25 ppm; okra at 2.5 ppm; borage, seed at 6.0 ppm; borage, meal at 10 ppm; dillweed, fresh leaves

at 10 ppm; radish, tops at 4.5 ppm; turnip, greens at 5.0 ppm and vegetable, root and tuber, group 1 at 4.0 ppm.

VI. 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.

VII. 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: February 13, 2007.

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 180.412 is amended in paragraph (a), in the table, by removing the commodities ''Beet, garden'', ''Beet, sugar, roots'', ''Carrot, roots'' ''Horseradish'', and ''Tuberous and corm vegetable crop subgroup''; and alphabetically adding commodities to read as follows:

§180.412 Sethoxydim: Tolerances for residues.

(a) * * *

Commodity	Parts per million
* * * * *	
Borage, meal	10
Borage, seed	6.0
Buckwheat, flour	25
Buckwheat, grain	19
* * * * *	
Dillweed, fresh leaves	10
* * * * *	
Okra	2.5

Commodity	Parts per million
* * * * *	
Radish, tops	4.5
* * * * *	
Turnip, greens	5.0
* * * * *	
Vegetable, root and tuber, group 1	4.0

[FR Doc. E7–3010 Filed 2–27–07; 8:45 am]
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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2006–0205; FRL–8113–8]

Halosulfuron-methyl; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of halosulfuron-methyl in or on the commodities alfalfa, forage at 1.0 parts per million (ppm) and alfalfa, hay at 2.0 ppm. Gowan Company requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA). The Agency is also correcting the tolerance expression for 40 CFR 180.479(a)(1) with this regulation. The tolerance expression is being corrected because the metabolites were inadvertently deleted from the most recent edition of 40 CFR 180.479.

DATES: This regulation is effective February 28, 2007. Objections and requests for hearings must be received on or before April 30, 2007, 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–2006–0205. 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: Vickie Walters, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 305–5704; e-mail address: *walters.vickie@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 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?

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 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, 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. 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–2006–0205 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 April 30, 2007.

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–2006–0205, by one of the following methods: