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: June 24, 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 180.641 is added to read as follows:

§ 180.641 Spirotetramat; tolerances for residues.

(a) *General.* (1) Tolerances are established for residues of the insecticide spirotetramat (cis-3-(2,5-dimethlyphenyl)-8-methoxy-2-oxo-1-azaspiro [4.5] dec-3-en-4-yl-ethyl carbonate) and its metabolites BYI 08330-enol (cis-3-(2,5-dimethylphenyl)-4-hydroxy-8-methoxy-1-azaspiro 4.5 dec-3-en-2-one), BYI 08330-ketohydroxy (cis-3-(2,5-dimethylphenyl)-3-hydroxy-8-methoxy-1-azaspiro 4.5 decane-2,4-dione), BYI08330-enol-Glc (cis-3-(2,5-dimethylphenyl)-8-methoxy-2-oxo-1-azaspiro 4.5 dec-3-en-4-yl beta-D-glucopyranoside), and BYI 08330-monohydroxy (cis-3-(2,5-dimethylphenyl)-4-hydroxy-8-methoxy-1-azaspiro 4.5 decan-2-one), calculated as spirotetramat equivalents, in or on the following raw agricultural commodities:

Commodity	Parts per million
Almond, hulls	9.0
Brassica, head and stem, subgroup 5A	2.5
Brassica, leafy, subgroup 5B	8.0
Citrus, oil	6.0
Fruit, citrus, group 10	0.60
Fruit, pome, group 11	0.70
Fruit, stone, group 12	4.5
Grape, raisin	3.0
Hop, dried cones	10.0
Nut, tree, group 14	0.25
Onion, bulb, subgroup 3A-07	0.3
Potato, flakes	1.6
Small fruit vine climbing subgroup, except fuzzy kiwifruit, subgroup 13-07F	1.3
Strawberry	0.40
Vegetable, cucurbit, group 9	0.30
Vegetable, fruiting, group 8	2.5
Vegetable, leafy, except Brassica, group 4	9.0
Vegetable, tuberous and corm, subgroup 1C	0.60

(2) Tolerances are also established for the combined residues of spirotetramat (cis-3-(2,5-dimethlyphenyl)-8-methoxy-2-oxo-1-azaspiro [4.5] dec-3-en-4-yl-ethyl carbonate) and its metabolite BYI 08330-enol (cis-3-(2,5-dimethylphenyl)-4-hydroxy-8-methoxy-1-azaspiro 4.5 dec-3-en-2-one), calculated as spirotetramat equivalents, in or on the following commodities:

Commodity	Parts per million
Cattle, fat	0.02
Cattle, meat	0.02
Cattle, meat byproducts	0.02
Goat, fat	0.02
Goat, meat	0.02
Goat, meat byproducts	0.02
Horse, fat	0.02
Horse, meat	0.02
Horse, meat byproducts	0.02
Milk	0.01
Sheep, fat	0.02
Sheep, meat	0.02
Sheep, meat byproducts	0.02

(b) Section 18 emergency exemptions. [Reserved]

(c) Tolerances with regional registrations. [Resereved]

(d) Indirect or inadvertant residues. [Reserved]

[FR Doc. E8–15521 Filed 7–8–08; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2007–0893; FRL–8370–9]

Sethoxydim; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for combined residues of sethoxydim and its metabolites containing the 2-cyclohexen-1-one moiety, in or on various oilseed commodities. Interregional Research Project Number 4 (IR-4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective July 9, 2008. Objections and requests for hearings must be received on or before September 8, 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–2007–0893. 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: Susan Stanton, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 305–5218; e-mail address: *stanton.susan@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–2007–0893 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 September 8, 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–2007–0893, 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 September 28, 2007 (72 FR 55204) (FRL–8147–1), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 7E7232) by Interregional Research Project Number 4 (IR–4), 500 College Road East, Suite 201W, Princeton, NJ 08540. The petition 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 (calculated as the herbicide), in or on cuphea, seed at 35.0 parts per million (ppm); echium, seed at 35.0 ppm; gold of pleasure, seed at 35.0 ppm; gold of pleasure, meal at 40.0 ppm; hare's ear mustard, seed at 35.0 ppm; lesquerella, seed at 35.0 ppm; lunaria, seed at 35.0 ppm; meadowfoam, seed at 35.0 ppm; milkweed, seed at 35.0 ppm; mustard, seed at 35.0 ppm; oil radish, seed at 35.0 ppm; poppy, seed at 35.0 ppm; sesame, seed at 35.0 ppm; sweet rocket, seed at 35.0 ppm; crambe, seed at 35.0 ppm; and crambe, meal at 40.0 ppm. That notice referenced a summary of the petition prepared by BASF, the registrant, on behalf of IR–4, 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.

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 petitioned-for tolerances for combined residues of sethoxydim and its metabolites containing the 2-cyclohexen-1-one moiety on crambe, meal at 40.0 ppm; crambe, seed at 35.0 ppm; cuphea, seed at 35.0 ppm; echium, seed at 35.0 ppm; gold of pleasure, meal at 40.0 ppm; gold of pleasure, seed at 35.0 ppm; hare's ear mustard, seed at 35.0 ppm; lesquerella, seed at 35.0 ppm; lunaria, seed at 35.0 ppm; meadowfoam, seed at 35.0 ppm; milkweed, seed at 35.0 ppm; mustard, seed at 35.0 ppm; oil radish, seed at 35.0 ppm; poppy, seed at 35.0 ppm; sesame, seed at 35.0 ppm; and sweet rocket, seed at 35.0 ppm. EPA's assessment of exposures and risks associated with establishing these 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.

The acute toxicity data indicate that sethoxydim is minimally toxic via oral, dermal and inhalation routes of exposure. It is neither irritating to the eye nor the skin. With repeated dosing, the primary target organ for this chemical is the liver. In the chronic toxicity study in dogs, there were significantly increased absolute and

relative liver weights accompanied by supportive clinical chemistry and histopathology. Dose-related clinical chemistry abnormalities were observed in both sexes and included increased alkaline phosphatase and aspartate aminotransferase (ALT) and decreased albumin and cholesterol synthesis. Dose-related histopathologic lesions were found in the liver, spleen and bone marrow. A mild hepatocellular cytoplasmic alteration was found in males at all doses and in females at the mid and high doses. Adverse liver effects were also observed via the oral route in mice and via the inhalation route in rats. There was no evidence of carcinogenicity in studies in rats and mice and no evidence of mutagencity, immunotoxicity or endocrine disruption in the toxicity database for sethoxydim. In the prenatal developmental studies in rats and rabbits and reproductive toxicity study in rats, the primary effects noted in the young were fetal skeletal variations and decreases in body weight. Although effects suggestive of neurotoxicity were noted in adult and young rats in the developmental and/or reproductive toxicity studies, EPA has concluded that sethoxydim is not a neurotoxic chemical. The weight of evidence EPA considered in making this determination is discussed in more detail in Unit III.D.3.ii.

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 (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies can be found in the final rule published in the **Federal Register** of September 29, 2003 (68 FR 55858) (FRL–7238–6)(*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, 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 NOAEL in the toxicology study identified as appropriate for use in risk assessment. However, if a NOAEL cannot be determined, the LOAEL or a Benchmark Dose (BMD) approach is sometimes used for risk assessment. Uncertainty/safety factors (UFs) are used in conjunction with the POD to take into account uncertainties inherent in the extrapolation from laboratory animal data to humans and in the variations in sensitivity among members of the human population as well as other unknowns. Safety is assessed for acute and chronic dietary risks by comparing aggregate food and water exposure to the pesticide to the acute population adjusted dose (aPAD) and chronic population adjusted dose (cPAD). The aPAD and cPAD are calculated by dividing the POD by all applicable UFs. Aggregate short-term, intermediate-term, and chronic-term risks are evaluated by comparing food, water, and residential exposure to the POD to ensure that the margin of exposure (MOE) called for by the product of all applicable UFs is not exceeded. This latter value is referred to as the Level of Concern (LOC).

For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect greater than that expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see *http://www.epa.gov/pesticides/factsheets/riskassess.htm*.

A summary of the toxicological endpoints for sethoxydim used for human risk assessment can be found at *http://www.regulations.gov* in the document *Sethoxydim: Amended human health risk assessment to support uses on the Rapeseed Crop Subgroup 20A* at page 10 in docket ID number EPA–HQ–OPP–2007–0893.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses*. In evaluating dietary exposure to sethoxydim, EPA considered exposure under the petitioned-for tolerances as well as all existing sethoxydim tolerances in 40 CFR 180.412. EPA assessed 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 1–day or single exposure.

In estimating acute dietary exposure, EPA used food consumption information from the United States Department of Agriculture (USDA) 1994–1996 and 1998 Nationwide Continuing Surveys of Food Intake by Individuals (CSFII). As to residue levels in food, EPA assumed that 100 percent of all crops with existing or pending tolerances are treated with sethoxydim and contain tolerance-level residues.

ii. *Chronic exposure*. In conducting the chronic dietary exposure assessment EPA used the food consumption data from the USDA 1994–1996 and 1998 CSFII. As to residue levels in food, EPA assumed that 100 percent of all crops with existing or pending tolerances are treated with sethoxydim and contain tolerance-level residues.

iii. *Cancer*. Based on the results of carcinogenicity studies in rats and mice, EPA classified sethoxydim as ''not likely to be carcinogenic to humans''; therefore, an exposure assessment for evaluating cancer risk is not needed for this chemical.

iv. *Anticipated residue and percent crop treated (PCT) information*. EPA did not use anticipated residue or PCT information in the dietary assessment for sethoxydim. Tolerance level residues and 100 PCT were assumed for all food commodities.

2. *Dietary exposure from drinking water*. The Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for sethoxydim in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport 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 Reservoir Screening Tool (FIRST) and Screening Concentration in Ground Water (SCI-GROW) models, the estimated drinking water concentrations (EDWCs) of sethoxydim for acute exposures are estimated to be 130 parts per billion (ppb) for surface water and 1.5 ppb for ground water; and for chronic exposures for non-cancer assessments 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 of value 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 the following uses that could result in residential exposures: Ornamentals and flowering plants, recreational areas, and buildings/structures (outdoor). EPA assessed residential handler and

postapplication exposures using the following assumptions:

Homeowners who apply sethoxydim to ornamental gardens and turf may be exposed for short-term durations via the dermal and inhalation routes. Dermal endpoints of concern were not identified for sethoxydim; therefore, dermal exposure and risk assessments are not appropriate. Short-term inhalation exposure was assessed for residential handlers who mix, load and apply liquid sethoxydim products using low-pressure hand wands, backpack sprayers and garden hose-end sprayers.

Sethoxydim can be used in areas, such as home lawns, that may be frequented by adults and children. There is potential for dermal exposure of adults and children as well as incidental oral exposure of children following application of sethoxydim to such areas. Post-application inhalation exposure of adults and children is expected to be negligible. Since there are no dermal endpoints of concern for sethoxydim, only post-application incidental oral exposure of children was assessed. EPA assessed incidental oral exposure of toddlers from hand-to-mouth, object-to-mouth and incidental soil ingestion activities using Standard Operating Procedures for Residential Exposure Assessments.

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 sethoxydim to share a common mechanism of toxicity with 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 assumed that sethoxydim 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*. The prenatal and postnatal toxicity database for sethoxydim includes rat and rabbit developmental toxicity studies and a 2–generation reproduction toxicity study in rats. There was no evidence of increased quantitative or qualitative susceptibility of *in utero* rabbit fetuses following exposure to sethoxydim in the rabbit developmental study; however, evidence of increased susceptibility was noted in the rat developmental and reproduction toxicity studies as described below:

There was some evidence of qualitative susceptibility in the rat developmental study with the occurrence of more severe effects in the fetuses (delayed ossification and tail abnormalities) than in the maternal animals (transient clinical signs including: Irregular gait and decreased activity) at the same dose. The degree of concern for increased susceptibility in this study is low and there are no residual uncertainties for the following reasons: The effects in the pups were of low incidence and only observed at a high dose that is considered to be close to a limit dose. In addition, these effects were seen in the presence of clear maternal toxicity and clear NOAELs and LOAELs were established for both maternal and developmental toxicities.

In the 2–generation reproduction study in rats, pups showed decreases in body weight (11 to 13%) during lactation at the high dose. At the same dose, adult female animals exhibited body weight losses (8 to 10%) that are considered too small to qualify as an adverse effect. The determination that body weight effects occurred in pups at a dose that did not result in maternal toxicity is technically an indication of quantitative susceptibility. However, the degree of concern for the body weight changes in pups is low, since the weight changes are considered minimal and the differences observed in body weight losses between the adult and young animals are marginal. Characterization of the body weight changes as an adverse effect in the pups is considered conservative (protective).

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 sethoxydim is complete.

ii. Sethoxydim is not considered to be a neurotoxic chemical and there is no need for a developmental neurotoxicity study or additional UFs to account for neurotoxicity. Clinical signs suggestive of neurotoxicity (including irregular gait, decreased activity, excessive salivation, and anogenital staining) were observed in adult rats in the developmental toxicity study. 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 a high dose. An increased incidence of fetal skeletal variations due to delayed ossification was seen in young rats in the developmental and reproductive toxicity studies. 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 and at high treatment doses. In the 2–generation reproduction study in rats, 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 neural tube effect. In the rat prenatal study, there is no description of any effect on neural tube-derived structures. No other effects suggestive of neurotoxicity were seen in toxicology studies conducted with sethoxydim. Furthermore, cyclohexones, the class of compounds that includes sethoxydim, are not known to cause neurotoxicity or developmental malformations of the nervous system. Based on the weight of the evidence, EPA concluded that sethoxydim is not neurotoxic.

iii. There is no evidence that sethoxydim results in increased susceptibility in *in utero* rabbits in the prenatal developmental study. Although there is qualitative evidence of increased susceptibility in the prenatal developmental study in rats and equivocal evidence of quantitative susceptibility in the 2–generation

reproduction study in rats, the degree of concern is low, and the Agency did not identify any residual uncertainties after establishing toxicity endpoints and traditional UFs to be used in the risk assessment of sethoxydim.

iv. There are no residual uncertainties identified in the exposure databases. The dietary food exposure assessments were performed assuming 100 PCT and tolerance-level residues. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to sethoxydim in drinking water. EPA used similarly conservative assumptions to assess postapplication exposure of 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

EPA determines whether acute and chronic pesticide exposures are safe by comparing aggregate exposure estimates to the aPAD and cPAD. The aPAD and cPAD represent the highest safe exposures, taking into account all appropriate SFs. EPA calculates the aPAD and cPAD by dividing the POD by all applicable UFs. For linear cancer risks, EPA calculates the probability of additional cancer cases given the estimated aggregate exposure. Short-term, intermediate-term, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the POD to ensure that the MOE called for by the product of all applicable UFs is not exceeded.

1. *Acute risk*. An acute aggregate risk assessment takes into account exposure estimates from acute dietary consumption of food and drinking water. Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food and water to sethoxydim will occupy 17% of the aPAD for children, 1 to 2 years old, the population group receiving the greatest exposure.

2. *Chronic risk*. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to sethoxydim from food and water will utilize 94% of the cPAD for children, 1 to 2 years old, the population group receiving the greatest exposure. Based on the explanation in Unit III.C.3., regarding residential use patterns, chronic residential exposure to residues of sethoxydim is not expected.

3. *Short-term risk*. Short-term aggregate exposure takes into account short-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Sethoxydim is currently registered for uses that could result in short-term residential exposure and the Agency has determined that it is appropriate to aggregate chronic exposure through food and water with short-term residential exposures to sethoxydim, except residential inhalation exposures. It is not appropriate to aggregate dietary (i.e., oral) exposures and inhalation exposures because the toxic effects identified for the oral and inhalation exposure pathways differ.

Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded the combined short-term food, water, and residential exposures aggregated result in an aggregate MOE of 1,300 for children 1 to 2 years old (toddlers). The aggregate MOE for children includes food, drinking water and post-application incidental oral exposures from entering turf areas previously treated with sethoxydim. Adult residential handler MOEs, based on inhalation exposure of adults who mix, load and apply liquid sethoxydim products using low-pressure hand wands, backpack sprayers or garden hose-end sprayers, range from 1.4×10^6 to 1.6×10^6, with hose-end sprayers resulting in the lowest MOE. As noted in the previous paragraph, it is not appropriate to aggregate chronic exposure from food and water with inhalation exposures. Post-application inhalation exposure of adults and children is expected to be negligible.

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). Sethoxydim 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 sethoxydim 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*. EPA has classified sethoxydim into the category ''Not Likely to be Carcinogenic to Humans.'' 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, or to infants and children from aggregate exposure to sethoxydim residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology (gas chromatography with flame photometric detection in the sulfur mode; BASF Wyandotte Corporation's Method No. 30; 3/15/82; MRID 44864501; Method I, Pesticide Analytical Methods Vol. II) is available to enforce these oilseed tolerances.

B. International Residue Limits

There are no CODEX, Canadian or Mexican maximum residue limits (MRLs) established on the commodities associated with this petition.

V. Conclusion

Therefore, tolerances are 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, in or on crambe, meal at 40.0 ppm; crambe, seed at 35.0 ppm; cuphea, seed at 35.0 ppm; echium, seed at 35.0 ppm; gold of pleasure, meal at 40.0 ppm; gold of pleasure, seed at 35.0 ppm; hare's ear mustard, seed at 35.0 ppm; lesquerella, seed at 35.0 ppm; lunaria, seed at 35.0 ppm; meadowfoam, seed at 35.0 ppm; milkweed, seed at 35.0 ppm; mustard, seed at 35.0 ppm; oil radish, seed at 35.0 ppm; poppy, seed at 35.0 ppm; sesame, seed at 35.0 ppm; and sweet rocket, seed at 35.0 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: June 30, 2008.

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 by alphabetically adding the following commodities to the table in paragraph (a) to read as follows:

§ 180.412 Sethoxydim; tolerances for residues.

(a) * * *

Commodity	Parts per million
* * *	* *
Crambe, meal	40.0
Crambe, seed	35.0
* * *	* *
Cuphea, seed	35.0
* * *	* *
Echium, seed	35.0
* * *	* *
Gold of pleasure, meal	40.0
Gold of pleasure, seed	35.0
* * *	* *
Hare's ear mustard, seed	35.0
* * *	* *
Lesquerella, seed	35.0
* * *	* *
Lunaria, seed	35.0
Meadowfoam, seed	35.0
* * *	* *
Milkweed, seed	35.0
Mustard, seed	35.0
* * *	* *
Oil radish, seed	35.0
* * *	* *
Poppy, seed	35.0
* * *	* *
Sesame, seed	35.0
* * *	* *
Sweet rocket, seed	35.0
* * *	* *

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2007–0096; FRL–8372–6]

Gamma-cyhalothrin; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of Gamma-cyhalothrin in or on all food commodities (other than those already covered by a higher tolerance as a result of use on growing crops) in food-handling establishments where food products are held, processed or prepared, pistachio and okra. Pytech Chemicals GmbH and Interregional Research Project No. 4 (IR-4) requested this tolerance under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective July 9, 2008. Objections and requests for hearings must be received on or before September 8, 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–2007–0096. 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.),