additional costs to State, local, or tribal governments, or to the private sector, result from this action.

G. Submission to Congress and the Comptroller General

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 the rule in the **Federal Register**. This rule is not a ''major rule'' as defined by 5 U.S.C. 804(2).

H. Petitions for Judicial Review

Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of this action, pertaining to Delaware's NO_X RACT regulation, must be filed in the United States Court of Appeals for the appropriate circuit by August 16, 1999. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this rule for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2).)

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Intergovernmental relations, Nitrogen dioxide, Ozone, Reporting and recordkeeping requirements.

Dated: May 27, 1999.

W. Michael McCabe,

Regional Administrator, Region III.

40 CFR part 52 is amended as follows:

PART 52—[AMENDED]

1. The authority citation for part 52 continues to read as follows:

Authority: 42 U.S.C. 7401 *et seq.*

Subpart I—Delaware

2. In § 52.420, the table in paragraph (c) is amended by adding in numerical order a new entry for ''Regulation 12'' to read as follows:

§ 52.420 Identification of plan.

* * * * *

(c) * * *

EPA-APPROVED REGULATIONS IN THE DELAWARE SIP

State citation	Title subject	State effective date	EPA approval date	Comments
*	*	*	*	*
Regulation 12—Control of Nitrogen Oxide Emissions				
Section 1	Applicability	11/24/93	June 16, 1999 [*Federal Register* cite]	Limited approval.
Section 2	Definitions	11/24/93	June 16, 1999 [*Federal Register* cite]	Limited approval.
Section 3	Standards	11/24/93	June 16, 1999 [*Federal Register* cite]	Limited approval.
Section 4	Exemptions	11/24/93	June 16, 1999 [*Federal Register* cite]	Limited approval.
Section 5	Alternative and Equivalent RACT Determinations.	11/24/93	June 16, 1999 [*Federal Register* cite]	Limited approval.
Section 6	RACT Proposals	11/24/93	June 16, 1999 [*Federal Register* cite]	Limited approval.
Section 7	Compliance Certification, Record Keeping, and Reporting Requirements.	11/24/93	June 16, 1999 [*Federal Register* cite]	Limited approval.
*	*	*	*	*

* * * * *

3. Section 52.424 is amended by adding paragraph (d) to read as follows:

§ 52.424 Conditional approval.

* * * * *

(d) Revisions to the Delaware State Implementation Plan, Regulation No. 12, pertaining to NO_X RACT requirements on major sources submitted on January 11, 1993 and amended on January 20, 1994 by the Delaware Department of Natural Resources and Environmental Control, is conditionally approved. Delaware must meet the following condition by no later than July 17, 2000, in accordance with criteria defined in the EPA Memorandum dated November 7, 1996 from the Director of the Air Quality Strategies and Standards Division of the Office of Air Planning and Standards, entitled ''Approval Options for Generic RACT Rules Submitted to Meet the Non-CTG VOC RACT Requirement and Certain NO_X RACT Requirements.'' This memorandum is available, upon request, at the office of the U.S. Environmental Protection Agency, Region III, 1650 Arch Street, Philadelphia, PA 19103.

This condition is:

(1) The DNREC must certify, in writing, that it has submitted, as SIP revisions, RACT determinations for all sources subject to source-specific NO_X RACT requirements.

[FR Doc. 99–15015 Filed 6–15–99; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300859; FRL–6080–9]

RIN 2070–AB78

Sethoxydim; Pesticide Tolerance

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 (calculated as the herbicide) in or on asparagus, carrot, cranberry, horseradish, peppermint tops and spearmint tops. The Interregional

Research Project Number 4 (IR-4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act, as amended by the Food Quality Protection Act of 1996.

DATES: This regulation is effective June 16, 1999. Objections and requests for hearings must be received by EPA on or before August 16, 1999.

ADDRESSES: Written objections and hearing requests, identified by the docket control number, [OPP–300859], must be submitted to: Hearing Clerk (1900), Environmental Protection Agency, Rm. M3708, 401 M St., SW., Washington, DC 20460. Fees accompanying objections and hearing requests shall be labeled ''Tolerance Petition Fees'' and forwarded to: EPA Headquarters Accounting Operations Branch, OPP (Tolerance Fees), P.O. Box 360277M, Pittsburgh, PA 15251. A copy of any objections and hearing requests filed with the Hearing Clerk identified by the docket control number, [OPP–300859], must also be submitted to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring a copy of objections and hearing requests to Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA.

A copy of objections and hearing requests filed with the Hearing Clerk may be submitted electronically by sending electronic mail (e-mail) to: opp-docket@epa.gov. Copies of objections and hearing requests must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Copies of objections and hearing requests will also be accepted on disks in WordPerfect 5.1/6.1 file format or ASCII file format. All copies of objections and hearing requests in electronic form must be identified by the docket control number [OPP–300859]. No Confidential Business Information (CBI) should be submitted through e-mail. Electronic copies of objections and hearing requests on this rule may be filed online at many Federal Depository Libraries.

FOR FURTHER INFORMATION CONTACT: By mail: Hoyt Jamerson, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number, and e-mail address: Rm. 272, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, (703) 308–9368, jamerson.hoyt@epa.gov.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of December 30, 1998 (63 FR 71920) (FRL–6050–1), EPA issued a notice pursuant to section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a as amended by the Food Quality Protection Act of 1996 (FQPA) (Pub. L. 104–170) announcing the filing of pesticide petitions (PP 3E4162, 2E4092, 0E3909, and 2E4052) for tolerances by Interregional Research Project Number 4 (IR-4), New Jersey Agricultural Experiment Station, Rutgers University, New Brunswick, New Jersey 08903. The notice included a summary of the petitions prepared by BASF Corporation, the registrant. There were no comments received in response to the notice of filing.

The petitions requested that 40 CFR 180.412 be amended by removing the time limitations (expiration dates) on established 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 asparagus (PP 3E4162) at 4.0 parts per million (ppm), carrot (PP 2E4092) at 1.0 ppm, cranberry (PP 0E3909) at 2.0 ppm, and peppermint and spearmint tops (PP 2E4052) at 30 ppm. Since the tolerances for asparagus, carrot, cranberry, peppermint and spearmint tops expired December 31, 1998, after the notice of filing was published in the **Federal Register**, this rule establishes the tolerances without time limitations. In addition, in the **Federal Register** of January 29, 1999 (64 FR 4650) (FRL–6055–8), PP 9E5049 proposed to amend 40 CFR 180.412 by establishing a tolerance for residues of sethoxydim and its metabolites in or on horseradish at 4 ppm.

I. Background and Statutory Findings

Section 408(b)(2)(A)(i) of the 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) 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) 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 and a complete description of the risk assessment process, see the final rule on Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997) (FRL–5754–7).

II. Aggregate Risk Assessment and Determination of Safety

Consistent with section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of sethoxydim and to make a determination on aggregate exposure, consistent with section 408(b)(2), for a tolerance for combined residues of (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 asparagus, carrot, cranberry, horseradish, and peppermint and spearmint tops. EPA's assessments of the dietary exposures and risks associated with establishing the tolerances are as 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 nature of the toxic effects caused by sethoxydim are discussed in this unit.

1. *Acute toxicity*. Based on the available acute toxicity data, sethoxydim does not pose any acute dietary risks. A summary of the acute toxicity studies follows:

i. *Acute oral toxicity, rat*: Toxicity Category III; LD_{50}=3,125 milligrams/kilograms (mg/kg) (male), 2,676 mg/kg (female).

ii. Acute dermal toxicity, rat: Toxicity Category III; LD_{50} >5,000 mg/kg (male and female).

iii. *Acute inhalation toxicity, rat*: Toxicity Category III; LC_{50} (4-hour)=6.03 mg/liter (L) (male), 6.28 mg/L (female).

iv. *Primary eye irritation, rabbit*: Toxicity Category IV; no irritation.

v. *Primary dermal irritation, rabbit*: Toxicity Category IV; no irritation.

vi. *Dermal sensitization, guinea pig*: Waived because no sensitization was seen in guinea pigs dosed with the end-use product Poast (18% active ingredient).

2. *Genotoxicity*. Ames assays were negative for gene mutation in *Salmonella typhimurium* strains TA98, TA100, TA1535, and TA 1537, with and without metabolic activity. A Chinese hamster bone marrow cytogenetic assay was negative for structural chromosomal aberrations at doses up to 5,000 mg/kg in Chinese hamster bone marrow cells *in vivo*. Recombinant assays and forward mutations tests in *Bacillus subtilis*, *Escherichia coli*, and *S. typhimurium* were all negative for genotoxic effects at concentrations of greater than or equal to 100%.

3. *Reproductive and developmental toxicity*. A 2-generation reproduction study with rats fed diets containing 0, 150, 600, or 3,000 ppm (approximately 0, 7.5, 30, or 150 mg/kg/day) with no reproductive effects observed under the conditions of the study.

A developmental toxicity study in rats fed dosages of 0, 50, 180, 650, or 1,000 mg/kg/day with a maternal no-observed-adverse-effect level (NOAEL) of 180 mg/kg/day and a maternal lowest-adverse-effect level (LAEL) of 650 mg/kg/day (irregular gait, decreased activity, excessive salivation, and anogenital staining); and a developmental NOAEL of 180 mg/kg/day, and a developmental LAEL of 650 mg/kg/day, based on a 21 to 22% decrease in fetal weights, filamentous tail, and lack of tail due to the absence of sacral and/or caudal vertebrae, and delayed ossification in the hyoids, vertebral centrum and/or transverse processes, sternebrae and/or metatarsal, and pubes). A developmental toxicity study in rabbits fed doses of 0, 80, 160, 320, or 400 mg/kg/day with a maternal NOAEL of 320 mg/kg/day and a maternal lowest-observed-adverse-effect level (LOAEL) of 400 mg/kg/day (37% reduction in body weight gain without significant differences in group mean body weights and decreased food consumption during dosing); and a developmental NOAEL greater than 400 mg/kg/day highest dose tested (HDT).

4. *Subchronic toxicity*. A 21-day dermal study in rabbits with a NOAEL of >1,000 mg/kg/day (limit dose). The only dose-related finding was slight epidermal hyperplasia at the dosing site in nearly all males and females dosed at 1,000 mg/kg/day. This was probably an adaptive response.

5. *Chronic toxicity*. A 1-year feeding study with dogs fed diets containing 0, 8.86/9.41, 17.5/19.9, and 110/129 mg/kg/day (males/females) with a NOAEL of 8.86/9.41 mg/kg/day (males/females) based on equivocal anemia in male dogs at the 17.5-mg/kg/day dose level.

A 2-year chronic feeding/carcinogenicity study with mice fed diets containing 0, 40, 120, 360, and 1,080 ppm (equivalent to 0, 6, 18, 54, and 162 mg/kg/day) with a systemic NOAEL of 120 ppm (18 mg/kg/day) based on non-neoplastic liver lesions in male mice at the 360-ppm (54 mg/kg/day) dose level. There were no carcinogenic effects observed under the conditions of the study. The maximum tolerated dose (MTD) was not achieved in female mice. The need for a new study will be based on the adequacy of the rat study currently under review.

A 2-year chronic feeding/carcinogenic study with rats fed diets containing 0, 2, 6, and 18 mg/kg/day with a systemic NOAEL greater than or equal to 18 mg/kg/day HDT. There were no carcinogenic effects observed under the conditions of the study. This study was reviewed under current guidelines and was found to be unacceptable because the doses used were insufficient to induce a toxic response and the MTD was not achieved.

A second chronic feeding/carcinogenic study with rats fed diets containing 0, 360, or 1,080 ppm (equivalent to 18.2/23.0, or 55.9/71.8 mg/kg/day (males/females). The dose levels were too low to elicit a toxic response in the test animals and failed to achieve the MTD or to define a LAEL. Slight decreases in body weight in rats at the 1,080-ppm dose level, although not biologically significant, support a free-standing NOAEL of 1,080 ppm (55.9/71.8 mg/kg/day (males/females)). There were no carcinogenic effects observed under the conditions of the study.

A third chronic feeding/carcinogenicity study in rats has been submitted. Male and female rats were dosed at nominal concentrations of 0, 300, 1,000, or 3,000 ppm. Clinical findings at the high-dose included changes in food consumption, food efficiency, body weight, and liver pathology. Upon initial review, it appears that the dose selection was adequate, and that there was no evidence of carcinogenicity.

6. *Animal metabolism*. In a rat metabolism study, excretion was extremely rapid and tissue accumulation was negligible.

B. Toxicological Endpoints

1. *Acute toxicity*. In a rat developmental study rats received doses of 0, 50, 180, 650, and 1,000 mg/kg/day. The maternal toxicity NOAEL was 180 mg/kg/day and the LOAEL was 650 mg/kg/day based on irregular gait, decreased activity, excessive salivation, and ano-genital staining. For developmental toxicity the NOAEL was 180 mg/kg/day and the LOAEL was 650 mg/kg/day based on 21-22% decrease in fetal weights, filamentous tail and lack of tail due to the absence of accral and /or caudal vertebrae, and delayed ossification in the hyoids, vertebral centrum and/or transverse processes, sternebrae and/or metatarsal, and pubes. The end point for use in the risk assessment is the maternal NOAEL of 180 mg/kg/day. The end point is set on maternal effects because the NOAEL for developmental effects is also 180 mg/kg/day.

2. *Short- and intermediate-term toxicity*. No short or intermediate dermal or inhalation endpoints were identified. In a 21-day dermal study with rabbits dosed at 0, 40, 200, or 1,000 mg/kg/day, there was no evidence of compound related toxicity on clinical signs, body weights, food consumption, food efficiency, eye health, clinical pathology, organ weights, or gross pathology. The NOAEL was greater than 1,000 mg/kg/day (limit dose). In the acute inhalation study with rats the LC_{50} was 6.03 mg/L (males) and 6.28 mg/L (females placing sethoxydim in category IV.

3. *Chronic toxicity*. EPA has established the Reference Dose (RfD) for sethoxydim at 0.9 mg/kg/day. This RfD is based on a finding of equivocal anemia in the 1-year dog study. The NOAEL was 8.86 mg/kg in males and 9.41 mg/kg in females.

4. *Carcinogenicity*. Sethoxydim is not classified. Available studies show no evidence of carcinogenicity in rats or mice.

C. Exposures and Risks

1. *From food and feed uses*. Tolerances have been established (40 CFR 180.412) for the combined residues of (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 a variety of raw agricultural commodities. Risk assessments conducted by EPA to assess dietary exposures from sethoxydim are as follows:

i. *Acute exposure and risk*. Acute dietary risk assessments are performed

for a food-use pesticide if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1-day or single exposure. The acute dietary endpoint is 180 mg/kg/day based on NOAEL's of 180 mg/kg/day for maternal and developmental effects in the rabbit developmental study. The FQPA safety factor of 3x was applied to females 13+ only because the endpoint (based on decrease in fetal weights, filamentous tail and lack of tail due to absence of sacral and/or caudal vertebrae, delayed ossification in the hyoids, vertebral centrum and/or transverse processes, sternebrae and/or metatarsal) occurs only during in urtero exposure and is not a postnatal effect. Since the effects occur during in urtero exposure, it is not an appropriate endpoint for acute dietary risk assessment of infants and children.

In conducting this acute dietary risk assessment, the Agency made very conservative assumptions--100% of all commodities having sethoxydim tolerances will contain sethoxydim regulable residues and those residues will be at the level of the tolerance which result in an over estimation of human dietary exposure.

From the acute dietary (food only) risk assessment, a high-end exposure estimate of 0.2 mg/kg/day was calculated. This exposure yielded dietary (food only) margins of exposure (MOEs) ranging from 420 for children (1-6 years old) to 622 for female 13+ and greater than 500 for all other subgroups.

ii. *Chronic exposure and risk.* The FQPA Safety Factor will not be applied for chronic dietary risk assessment because the endpoint is based on anemia in male dogs. The endpoint for which the FQPA safety factor is based is an in utero effect and cannot result from postnatal exposure. There was no indication of increased susceptibility in the prenatal developmental study in rabbits following in utero exposure. In the 2-generation reproduction study in rats, effects in offspring were observed only at above treatment levels which resulted in evidence of appreciable parental toxicity. No increased susceptibility was demonstrated in the developmental toxicity study with rats when the maternal and developmental NOAELs/LOAELs were compared. In conducting this chronic dietary risk assessment, the Agency has made very conservative assumptions no percent crop-treated data were used and all commodities having sethoxydim tolerances will contain sethoxydim residues and those residues will be at the level of the tolerance which will result in an overestimate of human dietary exposure.

The sethoxydim tolerances (published and pending) result in a Theoretical Maximum Residue Contribution (TMRC) that is equivalent to the following percentages of the RfD:

Subgroup	TMRC	%RFD
U.S. Population	0.039187	44
Nursing Infants	00.018957	21
Non-Nursing Infants (<1 year old)	00.072949	81
Children (1-6 years old)	00.085308	95
Children (7-12 years old)	00.058101	65
Female (13+, nursing)	00.040144	45
Males (13-19 years old)	00.040429	45
U.S Population (Summer Season)	00.039408	44
Hispanics	00.039428	44
Non-Hispanic Others	00.040452	45
Non-Hispanic Whites	00.039238	44

The subgroups listed above are: (1) the U.S. population (48 states); and (2) those for infants, children, females, 13+ nursing; and other subgroups for which the percentage of RfD occupied is greater than occupied by the subgroup U.S. population.

2. *Carcinogenic risk.* Sethoxydim has not been classified. At the present time, studies do not show evidence of carcinogenicity in rats or mice.

3. *From drinking water.* Limited monitoring data of ground water and surface water are available for sethoxydim. The modeling data estimates maximum concentrations in ground water of 0.84 microgram (µg)/liter (L) and in surface water 59.4 µg/L and 56-day EECs of 37.3 µg/L. The modeling data were compared to the results of the following equations used to calculate acute and chronic drinking water level of concern (DWLOC) for sethoxydim in ground and surface water (Standard Operating Procedures for Drinking Water Exposure and Risk Assessments, November 20, 1997). Models used were SCI-GROW and GENEC to provide estimates of ground and surface water contamination respectively from sethoxydim, but did not consider the behavior of degradates. Agency default weights and water consumption used in the calculations were 70 kg(2L) for adult males, 60 kg(2L) for adult females, and 10 kg (1L) for child.

i. *Acute exposure and risk.* Based on acute dietary exposure and using default body weights and water consumption values stated above, acute DWLOC were calculated using the following equation.

DWLOC (acute) = (NOAEL divided by uncertainty factor) - (acute food + residential exposure (mg/kg/day) x (body weight) divided by consumption(L) x 10^{-3} mg/µg.

Acute dietary water levels of concern were calculated to be 525,000 µg/L for the U.S. population, 56,000 µg/L for adult males 13+, 12,000 µg/L for adult females 13+ (including 3x safety factor) and 14,000 µg/L for child (infant < 1 year old).

ii. *Chronic exposure and risk.* Based on acute dietary exposure and using default body weights and water consumption values stated above, acute DWLOC were calculated using the following equation.

DWLOC (chronic) = (NOEL divided by uncertainty factor) - (chronic food + residential exposure (mg/kg/day) x (body weight) divided by consumption(L) x 10^{-3} mg/µg.

Chronic DWLOCs were calculated to be 1,760 µg/L for the U.S. population, 1,780 µg/L for adult males 13+, 1,700 µg/L for adult females 13+ (including 3x safety factor) and 14,000 µg/L for child (infant < 1 year old).

4. *From non-dietary exposure.* Sethoxydim is currently registered for use on the following residential non-food sites: ornamentals and flowering plants, recreational areas, and buildings/structures (outdoor non-agricultural). These residential uses comprise a short- and intermediate-term exposure scenario, but do not comprise a chronic exposure scenario.

i. *Acute exposure and risk.* There is a potential for exposure to sethoxydim by homeowner mixers/applicators. However, since no endpoints for dermal or inhalation were selected, the use on residential non-food sites is not

expected to pose an unacceptable acute risk.

ii. *Chronic exposure and risk.* The registered uses for sethoxydim do not comprise a chronic exposure scenario. A chronic non-dietary endpoint was not selected; therefore, the use on residential non-food sites is not expected to pose an unacceptable chronic risk.

iii. *Short- and intermediate-term exposure and risk.* Short-term or intermediate term endpoints were not identified. However, the following scenarios may result if herbicides containing sethoxydim are applied to residential turf, and/or ornamental plants: incidental non-dietary ingestion of residues on lawns from hand-to-mouth transfer, ingestion of pesticide-treated turfgrass, and incidental ingestion of soil from treated lawns. A residential exposure estimate and risk assessment was conducted for postapplication exposure following the application of sethoxydim on turf and ornamental gardens. The acute dietary endpoint was used for this risk assessment because the acute dietary endpoint provides the worst case estimate of risk and exposure for these use patterns. The assessment was performed using Draft SOPs for Residential Exposure Assessments (December 18, 1998). The proposed postapplication aggregate exposure assessment takes into account chronic dietary exposure plus outdoor residential exposures. These exposure assessments assume that 20% of the application rate is available from the turf grass as dislodgeable residue and 2 hours as the duration of exposure. These assumptions are considered conservative and protective.

Exposures and MOEs were calculated to be 0.053 mg/kg/day (MOE of 3,400) for hand to mouth transfer for treated lawns (toddlers), 0.0012 mg/kg/day (MOE of 15,000) for ingestion of treated turf grass (toddler), and 0.000025 (MOE of 7,000,000) for incidental ingestion of soil (toddlers). MOEs exceeded 100 for all three scenarios. MOEs greater or equal to 100 do not exceed the Agency's level of concern.

5. *Cumulative exposure to substances with common mechanism of toxicity.* Section 408(b)(2)(D)(v) 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 does not have, at this time, available data to determine whether sethoxydim has a common mechanism of toxicity with other substances or how to include this pesticide in a cumulative risk assessment. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, 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 final rule for Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997).

D. Aggregate Risks and Determination of Safety for U.S. Population

1. *Acute risk.* Using the published and pending tolerances, the dietary (food only) acute MOEs range from 420 for children (1-6 year) to 622 for females 13+ years. The level of concern for females 13+ years is 300 (includes 3x safety factor) for acute sethoxydim exposure and 100 for all other population subgroups. This risk estimate should be viewed as highly conservative; refinement using anticipated residue values and percent crop treated data in conjunction with Monte Carlo analysis will result in a lower acute dietary exposure estimate. The dietary exposure does not exceed the Agency's level of concern.

Sethoxydim is a nonpersistent, but highly mobile compound in soil and water environments. The modeling data for sethoxydim in drinking water indicate levels less than OPP's DWLOC for acute exposure. Since a refined acute risk for food only would not exceed EPA's levels of concern for acute dietary exposures and the monitoring and modeling levels in water are less than the acute DWLOC, EPA does not expect aggregate acute exposure to sethoxydim will pose an unacceptable risk to human health.

2. *Chronic risk.* Using the TMRC exposure assumptions described in this unit, EPA has concluded that aggregate exposure to sethoxydim from food will utilize 44% of the RfD for the U.S. population. The major identifiable subgroup with the highest aggregate exposure is 95% for children 1 to 6 years; discussed below. EPA generally has no concern for exposures below 100% of the RfD because the RfD represents the level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to human health. Despite the potential for exposure to sethoxydim in drinking water and from non-dietary, non-occupational exposure, EPA does not expect the aggregate exposure to exceed 100% of the RfD. EPA concludes that there is a reasonable certainty that no harm will result from aggregate exposure to sethoxydim residues.

3. *Short- and intermediate-term risk.* Short- and intermediate-term aggregate exposure takes into account chronic dietary food and water (considered to be a background exposure level) plus indoor and outdoor residential exposure.

Endpoints for short or intermediate term were not selected. An aggregate exposure estimate and risk assessment was conducted for postapplication exposure to sethoxydim on turf and ornamental plants taking into account chronic exposure from food and the acute dietary NOAEL. The resulting MOEs (1,390–2,350) are not of concern to the Agency.

4. *Aggregate cancer risk for U.S. population.* Sethoxydim has not been classified. Available studies do not show evidence of carcinogenicity in rats or mice.

5. *Determination of safety.* Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result from aggregate exposure to sethoxydim residues.

E. Aggregate Risks and Determination of Safety for Infants and Children

1. *Safety factor for infants and children*— i. *In general.* In assessing the potential for additional sensitivity of infants and children to residues of sethoxydim, EPA considered data from developmental toxicity studies in the rat and rabbit and a 2-generation reproduction study in the rat. The developmental toxicity studies are designed to evaluate adverse effects on the developing organism resulting from maternal pesticide exposure gestation. Reproduction studies provide information relating to effects from exposure to the pesticide on the reproductive capability of mating animals and data on systemic toxicity.

FFDCA section 408 provides that EPA shall apply an additional tenfold margin of safety for infants and children in the case of threshold effects to account for pre- and postnatal toxicity and the completeness of the data base unless EPA determines that a different margin of safety will be safe for infants and children. Margins of safety are incorporated into EPA risk assessments either directly through use of a margin of exposure (MOE) analysis or through using uncertainty (safety) factors in calculating a dose level that poses no

appreciable risk to humans. EPA believes that reliable data support using the standard uncertainty factor (usually 100 for combined inter- and intra-species variability) and not the additional tenfold MOE/uncertainty factor when EPA has a complete data base under existing guidelines and when the severity of the effect in infants or children or the potency or unusual toxic properties of a compound do not raise concerns regarding the adequacy of the standard MOE/safety factor.

ii. *Pre- and postnatal sensitivity.* There was no indication of increased susceptibility in the prenatal developmental toxicity study in rabbits following in utero exposure. In the 2-generation reproduction study in rats, effects in the offspring were observed only at or above treatment levels which resulted in evidence of appreciable parental toxicity. No increased susceptibility was demonstrated in the developmental toxicity studies; however developmental toxic effects, were observed at the HDT.

Acceptable developmental toxicity studies have been performed in rats and rabbits; an acceptable 2-generation reproduction study has also been performed in rats. A chronic feeding/carcinogenicity guideline study in rats has been submitted and is currently undergoing review. An initial examination of the study supports the current findings of no evidence of carcinogenicity. There is a complete toxicity data base for sethoxydim and exposure data are complete or are estimated based on data that reasonably accounts for potential exposures.

The FQPA Safety Factor is to be retained in case of developmental toxicity in the absence of maternal toxicity. Since malformations were seen in the rat study at levels that produced minimal maternal toxicity. The Agency concluded that an FQPA factor is needed. However, it was determined that the 10x factor need not be retained, instead should be reduced to 3x based on the following weight of evidence considerations: (1) developmental toxicity was seen in only one species, in the presence of maternal toxicity, and at a very high dose (650 mg/kg/day) that approached the Limit-Dose of 1,000 mg/kg/day; (2) no developmental toxicity was observed in the rabbit study at the HDT (400 mg/kg/day); (3) there was no increased susceptibility seen in the 2-generation reproduction study in rats at doses up to 150 mg/kg/day HDT; and (4) lack of concern for structure activity relationship (i.e., no significant developmental or reproductive toxicity was seen with the structural analog, clethodim.)

Exposure assessments do not indicate a concern for potential risk to infants and children based on: (1) the dietary exposure assessments use field study data and assume 100% crop treated which results in an overestimate of dietary exposure; (2) limited monitoring data are used for ground and surface source drinking water exposure assessments, resulting in estimates considered to be reasonable upper-bound concentrations; (3) there is a potential for postapplication hand-to-mouth exposure to toddlers associated with lawn use; however, the use of conservative models and/or assumptions in the residential exposure assessment provide adequate protection of infants and children.

The FQPA safety factor is applicable for acute dietary risk assessment for females 13+ because the endpoint occurs only during in urtero exposure and is not a postnatal effect. Since the effects occur during in urtero exposure, it is not an appropriate endpoint for acute dietary risk assessment of infants and children. The FQPA safety factor is not applied for chronic risk assessment because the endpoint is an in urtero effect and cannot result from postnatal exposure. The FQPA safety factor is not applicable to the postapplication hand-to-mouth exposure associated with the lawn use since this exposure scenario would only be expected for toddlers and not for females 13+.

iii. *Conclusion.* Acceptable developmental toxicity studies have been performed in rats and rabbits; an acceptable 2-generation reproduction study has also been performed in rats. A chronic feeding/carcinogenicity guideline study in rats has been submitted and is currently undergoing review. An initial examination of the study supports the current findings of no evidence of carcinogenicity. There is a complete toxicity data base for sethoxydim and exposure data are complete or are estimated based on data that reasonably accounts for potential exposures.

2. *Acute risk.* Using the conservative exposure assumptions that 100% of the commodities having sethoxydim tolerances will contain sethoxydim regulable residues and that those residues will be at the level of the tolerance, EPA calculated acute dietary (food only) MOEs ranging from 420 for children (1-6 years old) to 622 for females 13+ years. The level of concern is 300 (3x safety factor x 100) for females 13+ years and 100 for all other subgroups.

3. *Chronic risk.* Using the exposure assumptions described in this unit, EPA has concluded that aggregate exposure to sethoxydim from food will utilize less than 100% of the RfD for nursing infants, non-nursing infants (<1 years old), children (1-6 years old), and children (7-12 years old). EPA generally has no concern for exposures below 100% of the RfD because the RfD represents the level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to human health. Despite the potential for exposure to sethoxydim in drinking water and from non-dietary, non-occupational exposure, EPA does not expect the aggregate exposure to exceed 100% of the RfD.

4. *Short- or intermediate-term risk.* An aggregate exposure estimate and risk assessment was conducted for postapplication exposure to sethoxydim on turf and ornamental plants taking into account chronic exposure from food and the acute dietary NOAEL. The resulting MOEs (1,390–2,350) are not of concern to EPA.

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

III. Other Considerations

A. Metabolism In Plants and Animals

The metabolism of sethoxydim in plants and animals is understood, the tolerances for plant and animal commodities are expressed as the combined residues of sethoxydim and its metabolites containing the 2-cyclohexen-1-one moiety (calculated as the herbicide).

B. Analytical Enforcement Methodology

BASF Method 30 as published in PAM Vol. II is adequate for tolerance enforcement in all raw agricultural commodities. Quantitation is accomplished by gas chromatography with flame photometric detection in the sulfur mode. Sethoxydim and its metabolites are not recovered or not likely to be recovered by FDA multiresidue methods.

C. Magnitude of Residues

The available crop field data support the established tolerances for asparagus at 4.0 ppm, carrot at 1.0 ppm, cranberry at 2.0 ppm, and peppermint and spearmint tops at 30 ppm. Residue data submitted in support of existing tolerances for carrot at 1.0 ppm, potato at 4.0 ppm, sugar beet at 1.0 ppm, and sweet potato at 4.0 ppm support the establishment of a tolerance for horseradish at 4.0 ppm.

D. International Residue Limits

Maximum Residue Levels (MRLs) have not been established for residues of sethoxydim on asparagus, carrot, cranberry, horseradish, peppermint, or spearmint tops.

IV. Conclusion

Therefore, the tolerances are established for combined residues of (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 asparagus at 4.0 ppm, carrot at 1.0 ppm, cranberry at 2.0 ppm, horseradish at 4.0 ppm, and peppermint and spearmint tops at 30 ppm. at ppm.

V. Objections and Hearing Requests

The new FFDCA section 408(g) provides essentially the same process for persons to ''object'' to a tolerance regulation as was provided in the old section 408 and in section 409. However, the period for filing objections is 60 days, rather than 30 days. EPA currently has procedural regulations which govern the submission of objections and hearing requests. These regulations will require some modification to reflect the new law. However, until those modifications can be made, EPA will continue to use those procedural regulations with appropriate adjustments to reflect the new law.

Any person may, by August 16, 1999, file written objections to any aspect of this regulation and may also request a hearing on those objections. Objections and hearing requests must be filed with the Hearing Clerk, at the address given under the ''ADDRESSES'' section (40 CFR 178.20). A copy of the objections and/or hearing requests filed with the Hearing Clerk should be submitted to the OPP docket for this regulation. The objections submitted must specify the provisions of the regulation deemed objectionable and the grounds for the objections (40 CFR 178.25). Each objection must be accompanied by the fee prescribed by 40 CFR 180.33(i). EPA is authorized to waive any fee requirement ''when in the judgement of the Administrator such a waiver or refund is equitable and not contrary to the purpose of this subsection.'' For additional information regarding tolerance objection fee waivers, contact James Tompkins, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number, and e-mail address: Rm. 239, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, (703) 305–5697, tompkins.jim@epa.gov. Requests for waiver of tolerance objection fees should be sent to James Hollins, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460.

If a hearing is requested, the objections must include a statement of the factual issues on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the requestor (40 CFR 178.27). A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established, resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issues in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32). Information submitted in connection with an objection or hearing request may be claimed confidential by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the information that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice.

VI. Public Record and Electronic Submissions

EPA has established a record for this regulation under docket control number [OPP–300859] (including any comments and data submitted electronically). A public version of this record, including printed, paper versions of electronic comments, which does not include any information claimed as CBI, is available for inspection from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The public record is located in Room 119 of the Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA.

Objections and hearing requests may be sent by e-mail directly to EPA at:

opp-docket@epa.gov

E-mailed objections and hearing requests must be submitted as an ASCII file avoiding the use of special characters and any form of encryption.

The official record for this regulation, as well as the public version, as described in this unit will be kept in paper form. Accordingly, EPA will transfer any copies of objections and hearing requests received electronically into printed, paper form as they are received and will place the paper copies in the official record which will also include all comments submitted directly in writing. The official record is the paper record maintained at the Virginia address in ''ADDRESSES'' at the beginning of this document.

VII. Regulatory Assessment Requirements

A. Certain Acts and Executive Orders

This final rule establishes a tolerance under section 408(d) of the 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). 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) (Pub. L. 104–4). Nor does it require any prior consultation as specified by Executive Order 12875, entitled *Enhancing the Intergovernmental Partnership* (58 FR 58093, October 28, 1993), or special considerations as required by Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994), or require OMB review in accordance with Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997).

In addition, since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), 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. Nevertheless, the Agency previously assessed whether establishing tolerances, exemptions from tolerances, raising tolerance levels or expanding exemptions might adversely impact small entities and concluded, as a

generic matter, that there is no adverse economic impact. The factual basis for the Agency's generic certification for tolerance actions published on May 4, 1981 (46 FR 24950), and was provided to the Chief Counsel for Advocacy of the Small Business Administration.

B. Executive Order 12875

Under Executive Order 12875, entitled *Enhancing the Intergovernmental Partnership* (58 FR 58093, October 28, 1993), EPA may not issue a regulation that is not required by statute and that creates a mandate upon a State, local or tribal government, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by those governments. If the mandate is unfunded, EPA must provide to OMB a description of the extent of EPA's prior consultation with representatives of affected State, local, and tribal governments, the nature of their concerns, copies of any written communications from the governments, and a statement supporting the need to issue the regulation. In addition, Executive Order 12875 requires EPA to develop an effective process permitting elected officials and other representatives of State, local, and tribal governments ''to provide meaningful and timely input in the development of regulatory proposals containing significant unfunded mandates.''

Today's rule does not create an unfunded Federal mandate on State, local, or tribal governments. The rule does not impose any enforceable duties on these entities. Accordingly, the requirements of section 1(a) of Executive Order 12875 do not apply to this rule.

C. Executive Order 13084

Under Executive Order 13084, entitled *Consultation and Coordination with Indian Tribal Governments* (63 FR 27655, May 19, 1998), EPA may not issue a regulation that is not required by statute, that significantly or uniquely affects the communities of Indian tribal governments, and that imposes substantial direct compliance costs on those communities, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by the tribal governments. If the mandate is unfunded, EPA must provide OMB, in a separately identified section of the preamble to the rule, a description of the extent of EPA's prior consultation with representatives of affected tribal governments, a summary of the nature of their concerns, and a statement supporting the need to issue the regulation. In addition, Executive Order 13084 requires EPA to develop an effective process permitting elected officials and other representatives of Indian tribal governments ''to provide meaningful and timely input in the development of regulatory policies on matters that significantly or uniquely affect their communities.''

Today's rule does not significantly or uniquely affect the communities of Indian tribal governments. This action does not involve or impose any requirements that affect Indian tribes. Accordingly, the requirements of section 3(b) of Executive Order 13084 do not apply to this rule.

VIII. Submission to Congress and the Comptroller General

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 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 the 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: May 20, 1999.

Peter Caulkins,

Acting 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. In § 180.412(a), by removing the expiration date for the entries asparagus, carrot, cranberry, peppermint, tops and spearmint tops and inserting ≥None≥ in each place and adding a new entry for horseradish at 4.0 ppm to read as follows:

§ 180.412 Sethoxydim; tolerances for residues.

(a) * * *

Commodity	Parts per million	Expiration/ Revocation Date
* *	* *	*
Horseradish	4.0	None
* *	* *	*

* * * * *

[FR Doc. 99–14865 Filed 6–15–99; 8:45 am]

BILLING CODE 6560–50–F

GENERAL SERVICES ADMINISTRATION

41 CFR Part 101–35

[FPMR Amendment F–1]

RIN 3090–AG79

User Fees; Network Registration Services

AGENCY: Office of Governmentwide Policy, GSA.

ACTION: Final rule.

SUMMARY: This final rule establishes fees for network registration services offered by the General Services Administration (GSA) to Government agencies and commercial organizations. These services include establishing and maintaining unique global names and network addresses for X.400 Private Management Domains (PMRD), X.500 Organizational Units (OU), Administrative Authority Identifiers (AAI), and Internet Domain names. This rule will allow State and local governments to be registered within the DOT–GOV.

EFFECTIVE DATE: June 16, 1999.

FOR FURTHER INFORMATION CONTACT: Mr. Jack L. Finley, Director, Electronic Messaging, Directories and Registrations Branch (TOI), 202–501–3932, *jack.finley@fed.gov*.

SUPPLEMENTARY INFORMATION:

A. Background

The following outlines GSA's responsibilities with regard to assigning and managing network registrations.

X.400 PRMD

X.400 is a series of international standards that define components and protocols for electronic Messaging Handling Systems (MHS). Within X.400, top-level Management Domains (MD) are assigned and delegated to