IX. Regulatory Assessment Requirements

Under Executive Order 12866 (58 FR 51735, October 4, 1993), this action is not a ''significant regulatory action'' and, since this action does not impose any information collection requirements as defined by the Paperwork Reduction Act, 44 U.S.C. 3501 et seq., it is not subject to review by the Office of Management and Budget. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4), or require prior consultation with State officials as specified by Executive Order 12875 (58 FR 58093, October 28, 1993), or special considerations as required by Executive Order 12898 (59 FR 7629, February 16, 1994). Because FFDCA section 408(l)(6) permits establishment of this regulation without a notice of proposed rulemaking, the regulatory flexibility analysis requirements of the Regulatory Flexibility Act, 5 U.S.C. 604(a), do not apply.

Under 5 U.S.C. 801(a)(1)(A) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Title II of Pub. L. 104–121, 110 Stat. 847), EPA submitted 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 General Accounting Office prior to publication of the rule in today's **Federal Register**. This rule is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects

40 CFR Part 180

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

40 CFR Part 185

Environmental protection, Food and additives, Pesticides and pest.

40 CFR Part 186

Environmental protection, Animal feeds Pesticides and pest.

Dated: April 4, 1997.

Penelope A. Fenner-Crisp,

Acting Director, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

1. In part 180:

a. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 346a and 371.

b. Section 180.443 is amended as follows:

i. In paragraph (a) by adding the heading.

ii. In paragraph (b) by transferring and alphabetically adding the entry in the table to the table in paragraph (a) and by removing the remaining text.

iii. In paragraph (c) by transferring and alphabetically adding the entries in the table to the table in paragraph (a) and by removing the remaining text.

iv. By redesignating paragraph (d) as paragraph (b) and by revising newly redesignated paragraph (b).

v. By adding the headings and reserving new paragraphs (c) and (d).

§ 180.443 Myclobutanil; tolerances for residues.

(a) *General.* * * *

(b) *Section 18 emergency exemptions.* Time-limited tolerances are established for residues of the fungicide myclobutanil, in connection with use of the pesticide under section 18 emergency exemption granted by EPA. The tolerances are specified in the following table. These tolerances expire and are automatically revoked on the date specified in the table.

Commodity	Parts per million	Expiration/Revocation Date
Cucurbit vegetables	0.3	November 30, 1997
Strawberries	0.5	March 31, 1998

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

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

PART 185—[AMENDED]

2. In part 185:

a. The authority citation for part 185 continues to read as follows:

Authority: 21 U.S.C. 346a and 348.

§ 185.4350 [Removed]

b. The entries in the table to § 185.4350 are transferred and added alphabetically to the table in paragraph (a) of § 180.443; the remainder of § 185.4350 is removed.

PART 186—[AMENDED]

3. In part 186:

a. The authority citation for part 186 continues to read as follows:

Authority: 21 U.S.C.342, 348, and 701.

§ 186.4350 [Removed]

b. The entries in the table to § 186.4350 are transferred and added alphabetically to the table in paragraph (a) of § 180.443; the remainder of § 186.4350 is removed.

[FR Doc. 97–9378 Filed 4–11–97; 8:45 am]

BILLING CODE 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 180, 185, and 186

[OPP–300467; FRL–5598–7]

RIN 2070–AB78

Sethoxydim; Extension of Time-limited Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This document extends the effective dates for the established time-limited tolerances for combined residues of the herbicide 2-[1-(ethoxyimino)butyl]-5-[2-(ethylthio)propyl]-3-hydroxy-2-cyclohexen-1-one (also referred to in this document as sethoxydim) and its metabolites in or on various raw agricultural commodities. The Interregional Research Project Number 4 (IR-4) requested these time extensions under the Federal Food, Drug and Cosmetic Act, as amended by the Food Quality Protection Act of 1996.

DATES: This regulation becomes effective April 11, 1997. Objections and hearing request must be received by June 10, 1997.

ADDRESSES: Written objections and hearing requests, identified by the docket control number, [OPP–300467; PP 0E3909, 2E4052, 2E4065, 2E4092, and 3E4162], may 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 should be identified by the docket control number and submitted to: Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring copy of objections and hearing requests to: Rm. 1132, CM #2, 1921 Jefferson Davis Highway, Arlington, VA 22202.

A copy of objections and hearing requests filed with the Hearing Clerk may also be submitted electronically to the OPP by sending electronic mail (e-mail) to: opp-docket@epamail.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 in 5.1 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–300467; PP 0E3909, 2E4052, 2E4065, 2E4092, and 3E4162]. 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. Additional information on electronic submissions can be found in Unit IV. of this document.

FOR FURTHER INFORMATION CONTACT: By mail: Hoyt L. Jamerson, Registration Division (7505W), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number and e-mail address: Sixth Floor, Crystal Station #1, 2800 Jefferson Davis Highway, Arlington, VA 22202, (703) 308–8783, e-mail:jamerson.hoyt@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of January 8, 1997 (62 FR 1114)(FRL–5582–6), EPA issued a notice pursuant to section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a, announcing the filing of amendments to pesticide petitions (PP) for tolerances by the Interregional Research Project No. 4 (IR-4), New Jersey Agricultural Experiment Station, P.O. Box 231, Rutgers University, New Brunswick, NJ 08903. This 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 amended petitions requested that 40 CFR 180.412 be amended by extending the effective dates to expire on December 31, 1998, for the time-limited tolerances established for combined residues of the herbicide 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 parts per million (ppm), carrot at 1.0 ppm, cranberry and endive at 2.0 ppm, and peppermint and spearmint at 30.0 ppm. Registration for use of sethoxydim on endive is limited to Florida based on the geographical representation of the residue data submitted. Additional residue data will be required to expand the area of usage. Persons seeking geographically broader registration should contact the Agency's Registration Division at the address provided above.

These tolerances were established as time-limited tolerances since an acceptable carcinogenicity study is needed in one rodent species. A repeat chronic feeding/carcinogenicity study in rats was submitted to EPA in November of 1995 and is awaiting review. The Agency will reassess sethoxydim tolerances based on the outcome of the rat chronic feeding/carcinogenicity study and, if appropriate, will establish permanent tolerances for asparagus, carrot, cranberry, endive, peppermint and spearmint.

I. Risk Assessment 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, 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....''

A. Method of Determining Risks

Dietary exposure to residues of a pesticide in a food commodity are estimated by multiplying the average daily consumption of the food forms of that commodity by the tolerance level or the anticipated pesticide residue level. The Theoretical Maximum Residue Contribution (TMRC) is an estimate of the level of residues consumed daily if each food item contained pesticide residues equal to the tolerance. The TMRC is a ''worst case'' estimate since it is based on the assumptions that food contains pesticide residues at the tolerance level and that 100 percent of the crop is treated by pesticides that have established tolerances. If the TMRC exceeds the Reference Dose (RfD) or poses a lifetime cancer risk that is greater than approximately one in a million, EPA attempts to derive a more accurate exposure estimate for the pesticide by evaluating additional types of information (anticipated residue data and/or percent of crop treated data) which show, generally, that pesticide residues in most foods when they are eaten are well below established tolerances and that the total acreages for all crops with established tolerances are seldom treated with the pesticide.

The RfD is assumed to be the exposure at or below which daily aggregate exposure over a lifetime will not pose an appreciable risk to human health. To assure the adequacy of the RfD, the Agency uses an uncertainty factor in deriving it. The factor is usually 100, based on the assumption that certain segments of the human population could be as much as 100 times more sensitive than the species represented by the toxicology data. The aggregate daily exposure to a pesticide residue at or below the RfD (expressed as l00 percent of the RfD) is generally considered acceptable by EPA.

If the pesticide is determined to be a human carcinogen, the toxicological end-point must be determined based on the nature of the carcinogenic response and a knowledge of its mode of action. The Agency uses a weight of evidence approach in classifying the potential of the pesticide as a human carcinogen.

In addition to assessing long-term, chronic exposure to pesticide residues in food, the Agency also evaluates single-day or single event, acute exposure. Acute dietary exposure to residues of a pesticide in a food commodity is estimated by multiplying individual, single-day consumption estimates of that food by the tolerance level or the anticipated pesticide residue level. Each individual's daily exposure to a pesticide is the sum of the

food commodities that individual consumed on that given day multiplied by the residue assumed to be present on each food commodity consumed. Using this method, a distribution of possible daily exposures for a given population is established.

From this distribution, an upper end estimate of exposure is chosen and compared to the most sensitive no-observed-effect level (NOEL) from studies relating to the toxicological effect of acute concern (usually developmental toxicity or neurotoxicity) to derive a Margin of Exposure (MOE). The MOE is a measure of the level of safety that exists between the estimated exposure to a highly exposed individual and the level below which effects were observed in the available toxicological studies.

B. Toxicological Profile

1. A 1–year feeding study with dogs fed diets containing 0, 8.86/9.41, 17.5/19.9, and 110/129 milligrams per kilogram per day (mg/kg/day) (males/females) with a NOEL 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.

2. 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 NOEL 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.

3. A 2–year chronic feeding/carcinogenic study with rats fed diets containing 0, 2, 6, and 18 mg/kg/day with a systemic NOEL greater than or equal to 18 mg/kg/day (highest dose tested). 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 an MTD was not achieved.

4. A second chronic feeding/carcinogenic study with rats fed diets containing 0, 360, and 1,080 ppm (equivalent to 18.2/23.0, and 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 an MTD or define a lowest effect level (LEL). Slight decreases in body weight in rats at the 1,080-ppm dose level, although not biologically significant, support a free-standing no-observed-adverse-effect-level (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.

5. A developmental toxicity study in rats fed dosages of 0, 50, 180, 650, and 1,000 mg/kg/day with a maternal NOAEL of 180 mg/kg/day and a maternal LEL 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 LEL of 650 mg/kg/day (21 to 22 percent 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 metatarsals, and pubes).

6. A developmental toxicity study in rabbits fed doses of 0, 80, 160, 320, and 400 mg/kg/day with a maternal NOEL of 320 mg/kg/day and a maternal lowest observed effect level (LOEL) of 400 mg/kg/day (37 percent reduction in body weight gain without significant differences in group mean body weights and decreased food consumption during dosing); and a developmental NOEL greater than 400 mg/kg/day (highest dose tested).

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

8. Mutagenicity studies including: Ames assays were negative for gene mutation in *Salmonella typhimurium* strains TA98, TA100, TA1535, and TA1537, 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*; and 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 percent.

9. In a rat metabolism study, excretion was extremely rapid and tissue accumulation was negligible.

C. Toxicological Endpoints

1. *Dietary*— i. *Chronic risk*. The RfD for sethoxydim is calculated at 0.09 milligrams per kilogram of body weight per day (mg/kg/ bwt/day. The RfD is based on a NOEL of 8.86 mg/kg/day from a 1–year feeding study in dogs and an uncertainty factor of 100. This study demonstrated equivocal anemia in male dogs at the LOEL of 17.5 mg/kg/day.

ii. *Acute risk*. EPA has determined that an NOEL of 180 mg/kg/day from a developmental toxicity study in rats should be used to assess acute dietary risk. Decreased fetal weights, filamentous tail, lack of tail, and delayed ossification were observed at the LOEL of 650 mg/kg/day. The population of concern for this risk assessment are females 13+ years old.

iii. *Cancer risk*. EPA has not fully determined the carcinogenic potential of sethoxydim. No positive tumor findings have been reported at this time in the evaluations of rat or mouse carcinogenicity studies. A repeat carcinogenicity study in rats was submitted by the registrant and is under evaluation by EPA. There was no reported carcinogenicity in the repeat rat study.

2. *Non-dietary*. i. *Short- and intermediate-term risk*. A risk assessment is not needed since no effects were observed in a 21–day dermal toxicity study in rabbits at the highest dose tested (1,000 mg/kg/day) or in a developmental toxicity study in rabbits at the highest dose tested (400 mg/kg/day).

ii. *Chronic risk*. Chronic risk estimates are not required since non-dietary (occupational/residential) exposure will not be chronic.

D. Aggregate Exposures and Risks

1. *From food*. Food exposure to sethoxydim will be from ingestion of raw and processed agricultural commodities, as listed in 40 CFR 180.412 and 185.2800. The existing sethoxydim tolerances (published, including the current time-limited tolerances) result in a TMRC that is equivalent to the following percentages of the RfD:

U.S Population	36%
Non-Nursing Infants (<1 year old)	61%
Children (1 to 6 years old)	72%

The chronic dietary risk assessment used conservative assumptions resulting in risk estimates as high as 72% of the reference dose. Actual risks using more realistic assumptions would likely result in significantly lower risk estimates.

The acute dietary risk assessment resulted in a MOE of 1,200 for females (13+ years old), the population of concern. The assumptions in this assessment were: (1) All tolerance level residues, (2) 100% crop treated, (3) no mixing of commodities, and (4) all foods consumed in a day by a person had tolerance level residues. These

assumptions are extremely conservative; risk assessment using more realistic assumptions would result in an estimated MOE significantly greater than 1,200.

2. *From drinking water.* There is presently no established Maximum Concentration Level (MCL) for residues of sethoxydim in drinking water, and no health advisory levels for sethoxydim in drinking water have been established. Available monitoring studies, however, indicate that sethoxydim residues may migrate to ground water and surface water. In addition, the available data are inadequate to determine whether residues of the degradates of sethoxydim are likely to occur in water. Therefore, assessments of the risks posed to human health from exposure to potential sethoxydim residues in drinking water was conducted.

The data used to estimate exposure in water wells are from one study conducted in Missouri involving 40 rural domestic drinking water wells and 25 public supply drinking water wells. All of the available monitoring data show nondetectable residues of sethoxydim. Therefore, to estimate sethoxydim exposure for the purposes of exposure and risk assessment, a value equal to one-half of the limit of detection for the analytical methods was used to determine sethoxydim residues in the drinking water samples. Samples from the rural domestic drinking water wells and the public supply drinking water wells were analyzed with different analytical methods with different limits of detection (0.2 parts per billion (ppb) and 2 ppb, respectively). This risk assessment assumes exposure to be at 1 ppb based on one-half of the higher limit of detection (2 ppb). Exposure and risk was also estimated based on the highest sethoxydim residues (42 ppb) detected in ground water.

Exposures and risks to residues of sethoxydim in drinking water were calculated using the following formulas:

Adults (male): Exposure = (chemical concentration in micrograms (µg)/liter (L) in consumed water) × (l0^{-3} mg/micrograms (µg)) divided by (70 kg body weight) × (2 L water consumed/day).

Children (1 to 6 years): Exposure = (chemical concentration in µg/L in consumed water) × (l0^{-3} mg/µg)) divided by (10 kg body weight) × (1 L water consumed/day).

i. *Chronic exposures and risks from drinking water.* a. Adult (male) exposure (based on estimated residues in public water wells) = (1µg/L) × (10^{-3} mg/µg) divided by (70 kg body weight) × (2 L/day) = 2.85 × 10^{-5} mg/kg/day, which accounts for < 1% of the RfD.

b. Adult (male) exposure (based on highest concentration detected in ground water) = (42 µg/L) × (10^{-3} mg/µg) divided by (70 kg body weight) × (2 L/day) = 1.2 × 10^{-3} mg/kg/day, which accounts for 1% of the RfD.

c. Children (1 to 6 years old) exposure (based on estimated residues in public water wells) = (1 µg)/L) × (10^{-3} mg/µg) divided by (10 kg body weight) × (1 L/day) = 1 × 10^{-4} mg/kg/day, which accounts for < 1% of the RfD.

d. Children (1 to 6 years old) exposure (based on highest concentration detected in ground water) = (42 µg)/L) × (10^{-3} mg/µg) divided by (10 kg body weight) × (1 L/day) = 4.2 × 10^{-3} mg/kg/day, which accounts for 5% of the RfD.

ii. *Acute risk from drinking water.* a. Acute risk from residues of sethoxydim in drinking water were calculated as follows: Exposure = (chemical concentration in µg)/L in consumed water) × (10^{-3} mg/µg) divided by (kg body weight) × (liters (L) of water consumed/day).

b. Adult (female) exposure (based on highest concentration of sethoxydim detected in ground water) = (42 µg)/L) × (10^{-3} mg/µg) divided by (60 kg body weight) × (2 L/day) = 1.4 × 10^{-3} µg)/kg/day.

c. Children (1 to 6 years old) exposure (based on highest concentration of sethoxydim detected in ground water) = (42 µg)/L) × (10^{-3} mg/µg) divided by 10 kg body weight) × (1 L/day) = 4.2 × 10^{-3}.

d. Margins of Exposure were calculated based on the above exposure estimates as follows:

(i) For female adults consuming water containing 42 µg/L of sethoxydim the MOE is equal to 180/1.4 × 10^{-3} = 130,000.

(ii) For children (1 to 6 years old) consuming water containing 42 µg)/L of sethoxydim the MOE is equal to 180/1.4 × 10^{-3} = 43,000.

3. *From non-dietary (residential) exposure.* Sethoxydim is currently registered for use by homeowners on the following residential use sites: vegetables, fruits, flowers, shrubs, trees, and bedding plants. However, this risk assessment is not required.

4. *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.'' The Agency believes that ''available information'' in this context might include not only toxicity, chemistry, and exposure data, but also scientific policies and methodologies for understanding common mechanisms of toxicity and conducting cumulative risk assessments. For most pesticides, although the Agency has some information in its files that may turn out to be helpful in eventually determining whether a pesticide shares a common mechanism of toxicity with any other substances, EPA does not at this time have the methodologies to resolve the complex scientific issues concerning common mechanism of toxicity in a meaningful way. EPA has begun a pilot process to study this issue further through the examination of particular classes of pesticides. The Agency hopes that the results of this pilot process will increase the Agency's scientific understanding of this question such that EPA will be able to develop and apply scientific principles for better determining which chemicals have a common mechanism of toxicity and evaluating the cumulative effects of such chemicals. The Agency anticipates, however, that even as its understanding of the science of common mechanisms increases, decisions on specific classes of chemicals will be heavily dependent on chemical specific data, much of which may not be presently available.

Although at present the Agency does not know how to apply the information in its files concerning common mechanism issues to most risk assessments, there are pesticides as to which the common mechanism issues can be resolved. These pesticides include pesticides that are toxicologically dissimilar to existing chemical substances (in which case the Agency can conclude that it is unlikely that a pesticide shares a common mechanism of activity with other substances) and pesticides that produce a common toxic metabolite (in which case common mechanism of activity will be assumed).

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 subtances.

E. Determination of Safety for Infants and Children

FFDCA section 408 provides that EPA shall apply an additional tenfold MOE (safety) for infants and children in the

case of threshold effects to account for pre-and post-natal toxicity and the completeness of the database unless EPA determines that a different MOE (safety) will be safe for infants and children. Margins of exposure (safety) are often referred to as uncertainty (safety) factors. EPA believes that reliable data support using the standard MOE (usually 100x for combined inter- and intra-species variability)) and not the additional tenfold MOE 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.

The data base for sethoxydim realtive to pre- and post-natal toxicity is complete and is summarized as follows:

1. *Developmental toxicity studies.* In the rat developmental toxicity study the maternal (systemic) NOEL is established at 180 mg/kg/day, based on irregular gait, decreased activity, excessive salivation and anogenital staining at 650 mg/kg/day. The developmental (pup) NOEL is 180 mg/kg/day, based on decreased fetal weights, filamentous tail, lack of tail, and delayed-ossification at 650 mg/kg/day.

In the rabbit developmental toxicity study the maternal (systemic) NOEL is established at 320 mg/kg/day, based on a 37% reduction in body weight gain without significant differences in group mean body weights and food consumption at 400 mg/kg/day. The developmental (pup) NOEL is ≥400 mg/kg/day (highest dose tested).

2. *Reproduction studies.* In a 2-generation reproduction study in the rat the maternal/reproductive NOEL is approximately 150 mg/kg/day, the highest dose tested. This study did not fully meet the requirements of achieving toxicity as defined by the Pesticide Assessment Guidelines (OPPTS-870); however, this study is considered usable for regulatory purposes and a freestanding NOEL is established at approximately 150 mg/kg/day (LOEL not established). There were no indications of toxicity, dose-related effects on fertility, or difficult deliveries in either parental generation.

Conclusions. The toxicological database for evaluating pre- and postnatal toxicity for sethoxydim is complete. Available data indicate that no developmental toxicity was observed in the rabbit study at the highest dose tested (400 mg/kg/day). Maternal toxicity was observed in the rabbit at the highest dose tested and consisted of significant reductions in body weight gain and food consumption. In the rat developmental study developmental toxicity was observed in the presence of significant maternal toxicity at a high dose level (650 mg/kg/day). There was no parental or reproductive toxicity observed in a multigeneration reproduction study at doses up to 150 mg/kg/day (highest dose tested). These data taken together suggest minimal concern for developmental or reproductive toxicity and do not indicate any increased pre- or postnatal sensitivity; and no additional uncertainty factor for increased sensitivity in infants and children is appropriate. Therefore, EPA concludes that reliable data support using a hundredfold uncertainty factor and that uncertainty factor will protect the safety of infants and children without an additional tenfold uncertainty factor. Based on very conservative exposure assumptions, EPA concludes that aggregate exposure to children and infants will not exceed the RfD. EPA concludes that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure.

F. Other Considerations

1. *Endocrine effects.* An evaluation of the potential effects on the endocrine systems of mammals has not been determined; however, no evidence of such effects were reported in the chronic toxicology studies described above. There were no observed pathology of the endocrine organs in these studies. There is no evidence at this time that sethoxydim causes endocrine effects.

2. *Metabolism in plants and animals.* The metabolism of sethoxydim in plants and animals is adequately understood for the purposes of these tolerances. The residues of concern in plants and animals are sethoxydim and its metabolites containing the 2-cyclohexen-l-one moiety calculated as sethoxydim, as specified in 40 CFR 180.412.

3. *Secondary residues.* Carrot culls are the only animal feed items associated with these uses. Secondary residues in animal commodities are not expected to exceed existing tolerances as a result of this use.

4. *Analytical method.* There is a practical analytical method for detecting and measuring levels of sethoxydim and its metabolites in or on food with a limit of detection that allows monitoring of food with residues at or above the levels set in this tolerance. Method 30G, is available in PAM, Vol II to enforce the tolerance expression. Method 30G is a capillary gas chromatography method which uses flame photometric detection in the sulfur mode and determines total residues of sethoxydim and its metabolites containing the 2-cyclohexen-l-one moiety.

5. *International tolerances.* There are no Codex, Canadian, or Mexican Maximum Residue Levels or tolerances established for sethoxydim in/on asparagus, endive, carrots, cranberry, or mint.

II. Summary of Findings

Both the chronic and acute dietary risk assessments are conservative and represent overestimates of risk because they assume tolerance level residues and 100% crop treated for all commodities having sethoxydim tolerances. Refinement of dietary exposure estimates using percent crop treated data and/or anticipated residue data would result in significantly lower dietary exposure estimates. Aggregate chronic risks are estimated at 37% of the RfD (36% for food and 1% for water) for the general population, and 77% of the RfD (72% for food and 5% for water for children (1 to 6 years old)). For acute dietary risks, the calculated MOE's for the population subgroup of concern (females 13+ years old) is 1,200 from residues of sethoxydim in food and > 130,000 for residues in drinking water. The aggregate MOE is also 1,200.

Based on the information cited above, the Agency has determined that the establishment of the time-limited tolerances by amending 40 CFR 180.412 will be safe; therefore, the time-limited tolerances are established as set forth below.

In addition to the time-limited tolerances being amended, since for purposes of establishing tolerances FQPA has eliminated all distinctions between raw and processed food, EPA is combining the tolerances that now appear in §§ 185.2800 and 186.2800 with the tolerances in § 180.412 and is eliminating §§ 185.2800 and 186.2800.

III. Objections and Hearing Requests

The new FFDCA section 408(g) provides essentially the same process for persons to ''object'' to a tolerance regulation issued by EPA under new section 408(e) and (1)(6) 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 governs 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 June 10, 1997 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 above (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 rulemaking. 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). If a hearing is requested, the objections must include a statement of the factual issue(s) on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the objector (40 CFR 178.27). A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is a genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established, resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issue(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32). Information submitted in connection with an objection or hearing request may be claimed confidential by marking any part or all of that information as Confidential Business Information (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.

IV. Public Docket

A record has been established for this rulemaking under docket number [OPP–300467; PP 0E3909, 2E4052, 2E4065, 2E4092, and 3E4162]. A public version of this record, 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 1132 of the Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA.

The official record for this rulemaking, as well as the public version, as described above, is kept in paper form. Accordingly, in the event there are objections and hearing requests, 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 rulemaking record. The official rulemaking record is the paper record maintained at the address in ''ADDRESSES'' at the beginning of this document.

V. Regulatory Assessment Requirements

Under Executive Order 12866 (58 FR 51735, Oct. 4, 1993), this action is not a ''significant regulatory action'' and since this action does not impose any information collection requirements subject to approval under the Paperwork Reduction Act, 44 U.S.C. 3501 et seq., it is not subject to review by the Office of Management and Budget. In addition, this action does not impose any enforceable duty, or contain any ''unfunded mandates'' as described in Title II of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4), or require prior consultation as specified by Executive Order 12875 (58 FR 58093, October 28, l993), or special considerations as required by Executive Order 12898 (59 FR 7629, February 16, l994).

Because tolerances established on the basis of a petition under section 408(d) of FFDCA do not require issuance of a proposed rule, the regulatory flexibility analysis requirements of the Regulatory Flexibility Act (RFA), 5 U.S.C. 604(a), do not apply. Prior to the recent amendment of the FFDCA, EPA had treated such rulemakings as subject to the RFA; however, the amendments to the FFDCA clarify that no proposal is required for such rulemakings and hence that the RFA is inapplicable. Nonetheless, the Agency has previously assessed whether establishing tolerances or exemptions from tolerance, raising tolerance levels, or expanding exemptions adversely impact small entities and concluded, as a generic matter, that there is no adverse impact. (46 FR 24950) (May 4, 1981).

Pursuant to 5 U.S.C. 801(a)(1)(A), EPA submitted 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 General Accounting Office prior to publication of the rule in today's **Federal Register**. This rule is not a major rule as defined by 5 U.S.C. 804(2).

List of Subjects

40 CFR Part 180

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

40 CFR Part 185

Environmental protection, Food additives, Pesticides and pests.

40 CFR Part 186

Environmental protection, Animal feeds, Pesticides and pests.

Dated: April 4, 1997.

Penelope A. Fenner-Crisp,

Acting Director, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180— [AMENDED]

1. In part 180:

a. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 346a and 371.

b. Section 180.412 is amended as follows:

i. By revising the section heading to read as set forth below.

ii. By revising paragraph (a).

iii. In paragraph (b) by removing the text and by adding the heading ''*Section 18 emergency exemptions.*'', and reserving it.

iv. By revising paragraph (c).

v. By removing the text of paragraph (d), adding a heading entitled ''*Indirect and inadvertent residues.*'' and reserving it.

§ 180.412 Sethoxydim; tolerances for residues.

(a) *General.* Tolerances are established for combined residues of the herbicide 2-[1-(ethoxyimino)butyl]-5-[2-(ethylthio)propyl]-3-hydroxy-2-cyclohexen-1-one (CAS Reg. No. 74051–80–2) and its metabolites containing the 2-cyclohexen-1-one moiety (calculated as the herbicide) in or on the following commodities:

Commodity	Parts per million	Expiration/Revocation Date
Alfalfa, forage	40.0	None
Alfalfa, hay	40.0	None
Almond hulls	2.0	None
Apple pomace, wet and dry	0.8	None
Asparagus	4.0	December 31, 1998
Beans, dry	20.0	None
Beans, forage	10.0	None
Beans, hay	50.0	None
Beans, succulent	5.0	None
Blueberries	4.0	None
Brassica leafy vegetables	5.0	None
Bulb vegetables	1.0	None
Canola/rapeseed, meal	40.0	None
Canola/rapeseed	35.0	None
Carrot	1.0	December 31, 1998
Cattle, fat	0.2	None
Cattle, mbyp	0.2	None
Cattle, meat	0.2	None
Celery	1.0	None
Citrus fruits	0.5	None
Citrus molasses	1.5	None
Citrus pulp, dried	1.5	None
Clover, forage	35.0	None
Clover, hay	50.0	None
Cottonseed soapstock	15	None
Corn, field, grain	0.5	None
Corn fodder	2.5	None
Corn forage	2.0	None
Corn, sweet (K+CWHR)	0.2	None
Cranberry	2.0	December 31, 1998
Cottonseed	5.0	None
Cucurbits vegetables	4.0	None
Eggs	2.0	None
Flaxseed	5.0	None
Flaxseed meal	7	None
Flax straw	2.0	None
Fruiting vegetables	4.0	None
Goats, fat	0.2	None
Goats, mbyp	0.2	None
Goats, meat	0.2	None
Grape pomace, wet and dry	6.0	None
Grapes	0.2	None
Hogs, fat	0.2	None
Hogs, mbyp	0.2	None
Hogs, meat	0.2	None
Horses, fat	0.2	None
Horses, mbyp	0.2	None
Horses, meat	0.2	None
Lentils	30.0	None
Lettuce, head	1.0	None
Lettuce, leaf	2.0	None
Milk	0.05 (N)	None
Peanuts	25.0	None
Peanuts, hull	5.0	None
Peanut soapstock	75.0	None
Peas, dry	40.0	None
Peas, forage	20.0	None
Peas, hay	40.0	None
Peas, succulent	10.0	None
Peppermint, tops (stems and leaves)	30.0	December 31, 1998
Pome fruits	0.2	None
Potatoes	4.0	None
Potato flakes	8.0	None
Potato granules	8.0	None
Potato waste, processed (wet and dry)	8.0	None
Poultry, fat	0.2	None
Poultry, mbyp	2.0	None
Poultry, meat	0.2	None
Raisins	1.0	None
Raisin waste	1.0	None
Raspberries	5.0	None

Commodity	Parts per million	Expiration/Revocation Date
Sheep, fat	0.2	None
Sheep, mbyp	0.2	None
Sheep, meat	0.2	None
Soybean, hay	10.0	None
Soybeans	10.0	None
Spearmint, tops (stems and leaves)	30.0	December 31, 1998
Spinach	4.0	None
Strawberries	10.0	None
Sugar beet molasses	10.0	None
Sugar beet, roots	1.0	None
Sugar beet, tops	3.0	None
Sunflower meal	20.0	None
Sunflower seeds	7.0	None
Sweet potato	4.0	None
Tomato pomace, dried	12.0	None
Tomato products, concentrated	24	None
Tree nuts	0.2	None

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

(c) *Tolerances with regional registration.* Tolerances with regional registration, as defined in § 180.1(n), are established for the combined residues of the herbicide 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 the following commodities:

Commodity	Parts per million	Expiration/Revocation Date
Artichokes	3.0	None
Endive	2.0	December 31, 1998
Rhubarb	0.3	None

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

PART 185—[AMENDED]

2. In part 185:

a. The authority citation for part 185 continues to read as follows:

Authority: 21 U.S.C. 346a and 348.

§ 185.2800 [Removed]

b. Section 185.2800 is removed.

PART 186—[AMENDED]

3. In part 186:

a. The authority citation for part 186 continues to read as follows:

Authority: 21 U.S.C.342, 348, and 701.

§ 186.2800 [Removed]

b. Section 186.2800 is removed.

[FR Doc. 97–9374 Filed 4–10–97; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 180, 185, and 186

[OPP–300470; FRL–5598–2]

RIN 2070–AC78

Norflurazon; Pesticide Tolerance for Emergency Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes time-limited tolerances for residues of the herbicide norflurazon in or on the raw agricultural commodities bermudagrass hay and forage in connection with EPA's granting of emergency exemptions under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act authorizing use of norflurazon on bermudagrass in the states of Alabama, Georgia, Louisiana, Mississippi, and Texas. This regulation establishes maximum permissible levels for residues of norflurazon in these foods pursuant to section 408(l)(6) of the Federal Food, Drug, and Cosmetic Act, as amended by the Food Quality Protection Act of 1996. The tolerances will expire and be revoked by EPA on November 30, 1998.

DATES: This regulation becomes effective April 11, 1997. Objections and requests for hearings must be received by EPA on or before June 10, 1997.

ADDRESSES: Written objections and hearing requests, identified by the docket control number, [OPP–300470], 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 document control number, [OPP–300470], must also be submitted to: Public Response and Program Resources Branch, Field Operations Division (7506C), 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. 1132, CM #2,