consultation with State, local, and tribal government officials as specified by Executive Order 12875, entitled *Enhancing the Intergovernmental Partnership* (58 FR 58093, October 28, 1993) and Executive Order 13084, entitled *Consultation and Coordination with Indian Tribal Governments* (63 FR 27655, May 19, 1998), or special consideration of environmental justice related issues under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994) or 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). The Agency has determined that this action will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 12612, entitled *Federalism* (52 FR 41685, October 30, 1987). This action directly regulates growers, food processors, food handlers and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 346a(b)(4). This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104–113, section 12(d) (15 U.S.C. 272 note). 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.

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 to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this rule in the **Federal Register**. This rule is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

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

Dated: October 12, 1999.

James Jones,

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 § 180.482, by adding text to paragraph (d) to read as follows:

§ 180.482 Tebufenozide; tolerances for residues.

* * * * *

(d) *Indirect or inadvertent residues.* Tolerances are established for the indirect or inadvertent combined residues of tebufenozide benzoic acid, 3,5-dimethyl-1-(1,1-dimethylethyl)-2-(4-ethylbenzoyl)hydrazide and its metabolite benzoic acid, 3,5-dimethyl-1-(1,1-dimethylethyl)-2- [4-(1-hydroxyethyl)benzoyl]hydrazide in or on the raw agricultural commodities when present therin as a result of the application of tebufenozide to growing crops listed in paragraph (a) of this section to read as follows:

Commodity	Parts per million	Expiration/ Revocation Date
Foliage of legume vegetables.	0.1	9/30/03
Forage, fodder, hay and straw of cereal grains.	0.5	9/30/03
Forage, fodder, straw and hay of non-grass animal feeds.	0.5	9/30/03
Grass forage, fodder and hay.	0.5	9/30/03

[FR Doc. 99–27393 Filed 10–20–99; 8:45 am]

Billing Code 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300932; FRL–6385–9]

RIN 2070–AB78

Sethoxydim; Pesticide Tolerances for Emergency Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a time-limited tolerance for combined residues of sethoxydim and its metabolites containing the 2-cyclohexen-1-one moiety (calculated as the herbicide) in or on buckwheat. This action is in connection with a crisis exemption declared under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act authorizing use of the pesticide on buckwheat. This regulation establishes a maximum permissible level for residues of sethoxydim in this food commodity. The tolerance will expire and is revoked on December 31, 2001.

DATES: This regulation is effective October 21, 1999. Objections and requests for hearings, identified by docket control number OPP–300932, must be received by EPA on or before December 20, 1999.

ADDRESSES: Written objections and hearing requests may be submitted by mail, in person, or by courier. Please follow the detailed instructions for each method as provided in Unit VII. of the ''SUPPLEMENTARY INFORMATION.'' To ensure proper receipt by EPA, your objections and hearing requests must identify docket control number OPP–300932 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Libby Pemberton, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460; telephone number: (703) 308–9364; and e-mail address: pemberton.libby@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially

affected categories and entities may include, but are not limited to:

Categories	NAICS	Examples of Potentially Affected Entities
Industry	111	Crop production
	112	Animal production
	311	Food manufacturing
	32532	Pesticide manufacturing

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

B. How Can I Get Additional Information, Including Copies of This Document and Other Related Documents?

1. *Electronically*.You may obtain electronic copies of this document, and certain other related documents that might be available electronically, from the EPA Internet Home Page at http://www.epa.gov/. To access this document, on the Home Page select ''Laws and Regulations'' and then look up the entry for this document under the ''**Federal Register**--Environmental Documents.'' You can also go directly to the **Federal Register** listings at http://www.epa.gov/fedrgstr/.

2. *In person*. The Agency has established an official record for this action under docket control number OPP–300932. The official record consists of the documents specifically referenced in this action, and other information related to this action, including any information claimed as Confidential Business Information (CBI). This official record includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents. The public version of the official record does not include any information claimed as CBI. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period is available for inspection in the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305–5805.

II. Background and Statutory Findings

EPA, on its own initiative, in accordance with sections 408 (l)(6) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a, is establishing a tolerance 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 buckwheat at 10 part per million (ppm). This tolerance will expire and is revoked on December 31, 2001. EPA will publish a document in the **Federal Register** to remove the revoked tolerance from the Code of Federal Regulations.

Section 408(l)(6) of the FFDCA requires EPA to establish a time-limited tolerance or exemption from the requirement for a tolerance for pesticide chemical residues in food that will result from the use of a pesticide under an emergency exemption granted by EPA under section 18 of FIFRA. Such tolerances can be established without providing notice or period for public comment. EPA does not intend for its actions on section 18 related tolerances to set binding precedents for the application of section 408 and the new safety standard to other tolerances and exemptions.

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....''

Section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) authorizes EPA to exempt any Federal or State agency from any provision of FIFRA, if EPA determines that ''emergency conditions exist which require such exemption.'' This provision was not amended by the Food Quality Protection Act (FQPA). EPA has established regulations governing such emergency exemptions in 40 CFR part 166.

III. Emergency Exemption for Sethoxydim on Buckwheat and FFDCA Tolerances

On June 18, 1999, the North Dakota Department of Agriculture availed itself of the authority to declare the existence of a crisis situation within the state, thereby authorizing use under FIFRA section 18 of sethoxydim on buckwheat for control of volunteer grains, foxtail, and quackgrass. Abnormal weather consisting of above average rainfall and cooler temperatures combined with a lack of labeled products available for grass control in buckwheat has resulted in increased germination of volunteer cereal grains, foxtail and quackgrass. The densities of these pests would cause economic loss if not controlled.

As part of its assessment of this emergency exemption, EPA assessed the potential risks presented by residues of sethoxydim in or on buckwheat. In doing so, EPA considered the safety standard in FFDCA section 408(b)(2), and EPA decided that the necessary tolerance under FFDCA section 408(l)(6) would be consistent with the safety standard and with FIFRA section 18. Consistent with the need to move quickly on the emergency exemption in order to address an urgent non-routine situation and to ensure that the resulting food is safe and lawful, EPA is issuing this tolerance without notice and opportunity for public comment as provided in section 408(l)(6). Although this tolerance will expire and is revoked on December 31, 2001, under FFDCA section 408(l)(5), residues of the pesticide not in excess of the amounts specified in the tolerance remaining in or on buckwheat after that date will not be unlawful, provided the pesticide is applied in a manner that was lawful under FIFRA, and the residues do not exceed a level that was authorized by this tolerance at the time of that application. EPA will take action to revoke this tolerance earlier if any experience with, scientific data on, or other relevant information on this pesticide indicate that the residues are not safe.

Because this tolerance is being approved under emergency conditions, EPA has not made any decisions about whether sethoxydim meets EPA's registration requirements for use on buckwheat or whether a permanent

tolerance for this use would be appropriate. Under these circumstances, EPA does not believe that this tolerance serves as a basis for registration of sethoxydim by a State for special local needs under FIFRA section 24(c). Nor does this tolerance serve as the basis for any State other than North Dakota to use this pesticide on this crop under section 18 of FIFRA without following all provisions of EPA's regulations implementing section 18 as identified in 40 CFR part 166. For additional information regarding the emergency exemption for sethoxydim, contact the Agency's Registration Division at the address provided under ''FOR FURTHER INFORMATION CONTACT.''

IV. Aggregate Risk Assessment and Determination of Safety

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).

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 time-limited tolerance for combined residues of sethoxydim (2-[1-(ethoxyimino]butyl)-5-[2-(ethylthio)propyl]-3-hydroxy-2-cyclohexen-1-one) and its metabolites containing the 2-cyclohexen-1-one moiety (calculated as the herbicide) on buckwheat at 10 ppm. EPA's assessment of the dietary exposures and risks associated with establishing the tolerance follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. The nature of the toxic effects caused by sethoxydim are discussed in this unit.

B. Toxicological Endpoint

1. *Acute toxicity*. In a rat developmental study rats received doses of 0, 50, 180, 650, and 1,000 milligrams/kilogram/day (mg/kg/day). The maternal toxicity no-observed-adverse-effect level (NOAEL) was 180 mg/kg/day and the lowest-observed-adverse-effect level (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 were conducted by EPA to assess dietary exposures and risks from sethoxydim 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 utero* exposure and is not a postnatal effect. Since the effects occur during *in utero* 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 can not 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	0.03966	44
All Infants	0.06666	74
Nursing Infants	0.02027	22
Non-Nursing Infants (< 1 year old)	0.08619	96
Children (1–6 years old)	0.08635	95
Children (7–12 years old)	0.05859	65
Female (13+, nursing)	0.04115	46
Males (13–19 years old)	0.04074	45
U.S Population (Autumn Season)	0.04115	46
Northeast Region	0.04121	46
Hispanics	0.04016	45
Non-Hispanic Others	0.04119	46

The subgroups listed above are (1) the U.S. population (48 states); (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. *From drinking water.* Based on information available, sethoxydim is a non-persistent, but highly mobile compound in soil and water environments. There are no Maximum Contaminant Levels or Health Advisories established for sethoxydim residues in drinking water.

For this proposed Section 18 use, EPA used the Screening Concentration In GROund Water (SCI-GROW) model to estimate the concentration of sethoxydim residues in ground water. The maximum long-term estimated concentration is not expected to exceed 3 parts per billion (ppb) (chronic), and the maximum residue concentration using an average anaerobic half-life of 85 days, is predicted to be 33 ppb (acute); EPA used the generic expected environmental concentration (GENEEC) model to estimate the concentration of sethoxydim residues in surface water. The peak expected environmental concentration (EEC) was 42 ppb (acute), while the 56-day average EEC was 27 ppb (chronic).

3. *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 (12/18/98). The proposed postapplication aggregate exposure assessment takes into account chronic dietary exposure plus outdoor residential exposures. These exposure assessments assume that 20 percent 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 3400) for hand to mouth transfer for treated lawns (toddlers), 0.0012 mg/kg/day (MOE of 150,000) 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 than or equal to 100 do not exceed the Agency's level of concern.

4. *Cumulative exposure to substances with a 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 more 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 non persistent, 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 percent 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.

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 post-application exposure to sethoxydim on turf and ornamental plants taking into account chronic exposure from food and the acute dietary NOAEL. The resulting MOEs (1390-2350) are not of concern to the Agency.

4. *Aggregate cancer risk for U.S. population*. Sethoxydim has not ben 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 during 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 prenatal 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 MOE and uncertainty factor (usually 100 for combined interspecies and intraspecies 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. *Prenatal 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 highest dose tested (LOAEL).

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 database for sethoxydim and exposure data is complete or is 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 safety factor is needed. However, it was determined that the 10X safety factor need not be retained, instead, the safety factor 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 highest dose tested (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 (highest dose tested); 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 is 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 post-application 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 utero* exposure and is not a postnatal effect. Since the effects occur during *in utero* 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 utero* effect and can not result from postnatal exposure. The FQPA safety factor is not applicable to the post-application 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*. 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 post-application 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.

V. 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

Adequate enforcement methodology (gas-liquid chromatography GLC with flame photometric detection) is available (Method I, PAM II) to enforce the tolerance expression.

C. Magnitude of Residues

Residues of sethoxydim and its metabolites containing the 2-cyclohexen-1-one moiety are not expected to exceed 10.0 ppm in/on buckwheat or its processed commodity flour as a result of this Section 18 use. Secondary residues are not expected in animal commodities as no feed items are associated with this Section 18 use.

D. International Residue Limits

There are no Codex, Canadian, or Mexican residue limits for sethoxydim on buckwheat. Therefore, harmonization is not an issue for this Section 18 use.

E. Rotational Crop Restrictions

No rotational crop restrictions are specified in the Section 18 or Federal label.

VI. Conclusion

Therefore, the tolerance is 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 buckwheat at 10 ppm.

VII. Objections and Hearing Requests

Under section 408(g) of the FFDCA, as amended by the FQPA, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. The EPA procedural regulations which govern the submission of objections and requests for hearings appear in 40 CFR part 178. Although the procedures in those regulations require some modification to reflect the amendments made to the FFDCA by the FQPA of 1996, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) provides essentially the same process for persons to ''object'' to a regulation for an exemption from the requirement of a tolerance issued by EPA under new section 408(d), as was provided in the old FFDCA sections 408 and 409. However, the period for filing objections is now 60 days, rather than 30 days.

A. What Do I Need to Do to File an Objection or Request a Hearing?

You must file your objection or request a hearing on this regulation in accordance with the instructions provided in this unit and in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket control number OPP–300932 in the subject line on the first page of your submission. All requests must be in writing, and must be mailed or delivered to the Hearing Clerk on or before December 20, 1999.

1. *Filing the request.* Your objection must specify the specific provisions in the regulation that you object to, and the grounds for the objections (40 CFR 178.25). If a hearing is requested, the objections must include a statement of the factual issues(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). 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.

Mail your written request to: Office of the Hearing Clerk (1900), Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. You may also deliver your request to the Office of the Hearing Clerk in Rm. M3708, Waterside Mall, 401 M St., SW., Washington, DC 20460. The Office of the Hearing Clerk is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Office of the Hearing Clerk is (202) 260–4865.

2. *Tolerance fee payment.* If you file an objection or request a hearing, you must also pay the fee prescribed by 40 CFR 180.33(i) or request a waiver of that fee pursuant to 40 CFR 180.33(m). You must mail the fee to: EPA Headquarters Accounting Operations Branch, Office of Pesticide Programs, P.O. Box 360277M, Pittsburgh, PA 15251. Please identify the fee submission by labeling it ''Tolerance Petition Fees.''

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 the waiver of these fees, you may contact James Tompkins by phone at (703) 305–5697, by e-mail at tompkins.jim@epa.gov, or by mailing a request for information to Mr. Tompkins at Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460.

If you would like to request a waiver of the tolerance objection fees, you must mail your request for such a waiver to: James Hollins, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460.

3. *Copies for the Docket.* In addition to filing an objection or hearing request with the Hearing Clerk as described in Unit VII.A., you should also send a copy of your request to the PIRIB for its inclusion in the official record that is described in Unit I.B.2. Mail your copies, identified by the docket control number OPP-300932, 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 or by courier, bring a copy to the location of the PIRIB described in Unit I.B.2. You may also send an electronic copy of your request via e-mail to: opp-

docket@epa.gov. Please use an ASCII file format and avoid the use of special characters and any form of encryption. Copies of electronic objections and hearing requests will also be accepted on disks in WordPerfect 6.1/8.0 file format or ASCII file format. Do not include any CBI in your electronic copy. You may also submit an electronic copy of your request at many Federal Depository Libraries.

B. When Will the Agency Grant a Request for a Hearing?

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 issues(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32).

VIII. Regulatory Assessment Requirements

This final rule establishes a tolerance under section 408 of the FFDCA. 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) (Public Law 104–4). Nor does it require prior consultation with State, local, and tribal government officials as specified by Executive Order 12875, entitled *Enhancing the Intergovernmental Partnership* (58 FR 58093, October 28, 1993) and Executive Order 13084, entitled *Consultation and Coordination with Indian Tribal Governments* (63 FR 27655, May 19, 1998), or special consideration of environmental justice related issues under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994) or 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). The Agency has determined that this action will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 12612, entitled *Federalism* (52 FR 41685, October 30, 1987). This action directly regulates growers, food processors, food handlers and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 346a(n)(4). This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104–113, section 12(d) (15 U.S.C. 272 note). In addition, since tolerances and exemptions that are established under FFDCA section 408(l)(6), 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.

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

List of Subjects in 40 CFR Part 180

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

Dated: October 5, 1999.

James Jones,

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), 346(a) and 371.

2. In § 180.412, the table in paragraph (b) is amended by adding an entry for ''buckwheat'' to read as follows:

§ 180.412 Sethoxydim; tolerances for residues.

* * * * *

(b) * * *

Commodity	Parts per million	Expiration/revocation date
Buckwheat	10	12/31/01
* * *	* * *	*

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[FR Doc. 99–27391 Filed 10–20–99; 8:45 am]

BILLING CODE 6560–50–F

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[MM Docket No. 93–279; RM–8368 and RM–8385]

Radio Broadcasting Services; Cal-Nev-Ari, NV.

AGENCY: Federal Communications Commission.

ACTION: Final rule; application for review.

SUMMARY: This document grants an appeal filed by Richard W. Myers of a *Report and Order*, 60 FR 37623 (July 21, 1995), which concluded that Cal-Nev-Ari, Nevada, did not qualify as a ''community'' for allotment purposes. The Commission finds that Cal-Nev-Ari constitutes a ''community'' for allotment purposes and adds Channel 285A to Cal-Nev-Ari, Nevada, as its first local aural transmission facility. The coordinates for Channel 285A at Cal-Nev-Ari are: North Latitude 35–17–12 and West Longitude 114–51–57. With this action, this proceeding is terminated.

EFFECTIVE DATE: November 22, 1999.

FOR FURTHER INFORMATION CONTACT: R. Barthen Gorman, Mass Media Bureau, (202) 418–2180.

SUPPLEMENTARY INFORMATION: This is a synopsis of the Commission's *Memorandum Opinion and Order*, MM