Federal standard, and does not alter the relationship or the distribution of power and responsibilities established in the Clean Air Act. This rule also is not subject to Executive Order 13045 ''Protection of Children from Environmental Health Risks and Safety Risks'' (62 FR 19885, April 23, 1997), because it is not economically significant.

In reviewing SIP submissions, EPA's role is to approve state choices, provided that they meet the criteria of the Clean Air Act. In this context, in the absence of a prior existing requirement for the State to use voluntary consensus standards (VCS), EPA has no authority to disapprove a SIP submission for failure to use VCS. It would thus be inconsistent with applicable law for EPA, when it reviews a SIP submission, to use VCS in place of a SIP submission that otherwise satisfies the provisions of the Clean Air Act. Thus, the requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) do not apply. This rule does not impose an information collection burden under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

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. Section 804 exempts from section 801 the following types of rules: (1) Rules of particular applicability; (2) rules relating to agency management or personnel; and (3) rules of agency organization, procedure, or practice that do not substantially affect the rights or obligations of non-agency parties. 5 U.S.C. 804(3). EPA is not required to submit a rule report regarding this action under section 801 because this is a rule of particular applicability.

Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by February 7, 2003. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this rule for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. (*See* section 307(b)(2).)

List of Subjects in 40 CFR Part 52

Environmental protection, Administrative practice and procedure, Air pollution control, Incorporation by reference, Intergovernmental relations, Particulate matter, Reporting and recordkeeping requirements.

Dated: November 7, 2002.

Bharat Mathur,

Acting Regional Administrator, Region 5.

For the reasons stated in the preamble, part 52, chapter I, title 40 of the Code of Federal Regulations is amended as follows:

PART 52—[AMENDED]

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

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

Subpart P—Indiana

2. Section 52.770 is amended by adding paragraph (c)(155) to read as follows:

§ 52.770 Identification of plan.

(c) * * *

(155) On October 17, 2002, the State submitted revised particulate matter emission limits for the Knauf Fiber Glass in Shelby County for incorporation into the Indiana SIP.

(i) Incoropration by reference.

(A) Indiana Administrative Code Title 326: Air Pollution Control Board, Article 11 Emission Limitations for Specific Types of Operations, Rule 4 Fiberglass Insulation Manufacturing, Paragraph 5 Shelby County (326 IAC 11–4–5). Adopted by the Indiana Air Pollution Control Board on May 1, 2002. Filed with the Secretary of State on August 28, 2002. Published in the *Indiana Register*, Volume 26, Number 1, October 1, 2002, effective September 27, 2002.

[FR Doc. 02–30937 Filed 12–6–02; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2002–0326; FRL–7282–1]

Carboxin; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a tolerance for combined residues of carboxin (5,6-dihydro-2-methyl-N-phenyl-1,4-oxathiin-3-carboxamide) and its metabolite 5,6-dihydro-3-carboxanilide-2-methyl-1,4-oxathiin-4-oxide (calculated as carboxin) (from treatment of seed prior to planting) in or on canola, seed. Gustafson LLC requested this tolerance under the Federal Food, Drug, and Cosmetic Act (FFDCA) , as amended by the Food Quality Protection Act of 1996 (FQPA).

DATES: This regulation is effective December 9, 2002. Objections and requests for hearings, identified by docket ID number OPP–2002–0326, must be received on or before February 7, 2003.

ADDRESSES: Written objections and hearing requests may be submitted electronically, by mail, or through hand delivery/courier. Follow the detailed instructions as provided in Unit VI. of the **SUPPLEMENTARY INFORMATION**.

FOR FURTHER INFORMATION CONTACT: Mary Waller, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 308–9354; e-mail address: *waller.mary@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected entities may include, but are not limited to:

- Crop production (NAICS Code 111)
- Animal production (NAICS Code 112)
- Food manufacturing (NAICS Code 311)
- Pesticide manufacturing (NAICS Code 32532)

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

B. How Can I Get Copies of this Document and Other Related Information?

1. *Docket*. EPA has established an official public docket for this action under docket identification (ID) number OPP–2002–0326. The official public docket consists of the documents specifically referenced in this action, any public comments received, and other information related to this action. Although a part of the official docket, the public docket does not include Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. The official public docket is the collection of materials that is available for public viewing at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305–5805.

2. *Electronic access*. You may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at *http://www.epa.gov/fedrgstr/*. A frequently updated electronic version of 40 CFR part 180 is available at *http://www.access.gpo.gov/nara/cfr/cfrhtml_00/Title_40/40cfr180_00.html*, a beta site currently under development. To access the OPPTS Harmonized Guidelines referenced in this document, go directly to the guidelines at *http://www.epa.gov/opptsfrs/home/guidelin.htm*.

An electronic version of the public docket is available through EPA's electronic public docket and comment system, EPA Dockets. You may use EPA Dockets at *http://www.epa.gov/edocket/* to submit or view public comments, access the index listing of the contents of the official public docket, and to access those documents in the public docket that are available electronically. Although not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the docket facility identified in Unit I.B.1. Once in the system, select ''search,'' then key in the appropriate docket ID number.

II. Background and Statutory Findings

In the **Federal Register** of February 23, 2000 (65 FR 8970) (FRL–6390–1), EPA issued a notice pursuant to section 408 of FFDCA, 21 U.S.C. 346a, as amended by FQPA (Public Law 104–170), announcing the filing of a pesticide petition (PP 9F6036) by Gustafson LLC, 1400 Preston Road, Suite 400, Plano, Texas 75093. That notice included a summary of the petition prepared by Gustafson, LLC, the registrant. There were no comments received in response to the notice of filing.

The petition requested that 40 CFR 180.301 be amended by establishing a tolerance for combined residues of the fungicide carboxin, 5,6-dihydro-2-methyl-1,4-oxathiin-3-carboxanilide] and its sulfoxide metabolite 5,6-dihydro-3-carboxanilide-2-methyl-1,4-oxathiin-4-oxide], each expressed as the parent compound], in or on canola, seed at 0.03 parts per million (ppm).

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) of the FFDCA defines ''safe'' to mean that ''there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of the FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to ''ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue....''

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. For further discussion of the regulatory requirements of section 408 of the FFDCA and a complete description of the risk assessment process, see the final rule on Bifenthrin Pesticide Tolerances November 26, 1997 (62 FR 62961) (FRL–5754–7).

III. Aggregate Risk Assessment and Determination of Safety

Consistent with section 408(b)(2)(D) of the FFDCA, EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure, consistent with section 408(b)(2) of the FFDCA, for a tolerance for combined residues of carboxin (5,6-dihydro-2-methyl-N-phenyl-1,4-oxathiin-3-carboxamide) and its metabolite 5,6-dihydro-3-carboxanilide-2-methyl-1,4-oxathiin-4-oxide (calculated as carboxin) (from treatment of seed prior to planting) on canola, seed at 0.03 ppm. EPA's assessment of exposures and risks associated with establishing the tolerance follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. The nature of the toxic effects caused by carboxin are discussed in Table 1 of this unit as well as the no observed adverse effect level (NOAEL) and the lowest observed adverse effect level (LOAEL) from the toxicity studies reviewed.

TABLE 1.— SUBCHRONIC, CHRONIC, AND OTHER TOXICITY

Guideline No.	Study Type	Results
870.3100	90–Day oral toxicity in rats	NOAEL = Males: not identified; Females: 10 mg/kg/day LOAEL = Males: 10 mg/kg/day based on chronic nephritis, increased urea nitrogen, increased creatinine; Females: 40 mg/kg/day based on chronic nephritis
870.3200	21/28–Day dermal toxicity	Not available
870.3465	90–Day inhalation toxicity	Not available

TABLE 1.— SUBCHRONIC, CHRONIC, AND OTHER TOXICITY—Continued

Guideline No.	Study Type	Results
870.3700	Prenatal developmental in rats	Maternal NOAEL = 10 milligrams/kilogram/day (mg/kg/day) LOAEL = 90 mg/kg/day based on decreased body weights and body weight gain, decreased food consumption, and increased hair loss Developmental NOAEL = 175 mg/kg/day LOAEL = not identified
870.3700	Prenatal developmental in rabbits	Maternal NOAEL = 75 mg/kg/day LOAEL = 375 mg/kg/day based on increased abortions Developmental NOAEL = 75 mg/kg/day LOAEL = 375 mg/kg/day based on increased abortions
870.3800	Reproduction and fertility effects in rats	Parental NOAEL = Males and Females: 1 mg/kg/day LOAEL = Males: 10 mg/kg/day based on decreased body weight gains in F1 parents, gross and histopathological changes in kidneys; Females: 15 mg/kg/day based on equivocal histopathological changes in kidneys Reproductive NOAEL = Males: 10 mg/kg/day; Females: 15 mg/kg/day LOAEL = Males: 20 mg/kg/day; Females: 30 mg/kg/day based on decreased fertility indices for F1b parents due to decreased number of pregnancies for F2b generation Offspring NOAEL = Males: 10 mg/kg/day; Females: 15 mg/kg/day LOAEL = Males: 20 mg/kg/day; Females: 30 mg/kg/day based on decreased body weights for F2b male pups
870.4100	Chronic toxicity in dogs	NOAEL = Males: 16 mg/kg/day; Females: 1.3 mg/kg/day LOAEL = Males: 158 mg/kg/day based on decreased RBC, hematocrit and hemoglobin, increased MCH and MCV, increased alkaline phosphatase and cholesterol, increased liver weights; Females: 15 mg/kg/day based on decreased body weight gains
870.4300	Combined Chronic/ Carcinogenicity in rats	NOAEL = Males: 0.8 mg/kg/day; Females: 1.0 mg/kg/day LOAEL = Males: 9 mg/kg/day based on decreased body weight and body weight gain, increased urea nitrogen and creatinine, increased water consumption and urine volume, decreased urine specific gravity, histopathological changes in kidneys; Females: 16 mg/kg/day based on histopathological changes in kidneys Negative for carcinogenicity
870.4200	Carcino-genicity in mice	NOAEL = Males: 752 mg/kg/day; Females: 9 mg/kg/day LOAEL = Males: not identified; Females: 451 mg/kg/day based on increased mortality Negative for carcinogenicity
870.5100	Bacterial reverse mutation assay (Ames test)	Negative with or without S-9 activation at 5.000 μg/plate and less
870.5375	*In vitro* mammalian chromosome aberration (CHO cells)	Negative without S-9 activation Positive with S-9 activation. Highly significant increases in chromosomal aberrations at several toxic dose levels ranging from 400 to 1,400 Fg/mL
870.5385	*In vivo* mammalian chromosome aberration (rat bone marrow)	Negative at all dose levels up to 48-hours post-dosing Study is unacceptable due to lack of clinical toxicity, lack of a multiple dosing schedule, and/or lack of evidence of transport to target tissue
870.5385	*In vivo* mammalian chromosome aberration (rat bone marrow)	Negative at all dose levels tested
870.5385	*In vivo* mammalian chromosome aberration (rat bone marrow)	Positive. Dose-related statistically significant increased percent of aberrant cells at 191 mg/kg/day
870.5450	Dominant lethal assay in rats	Not available

TABLE 1.— SUBCHRONIC, CHRONIC, AND OTHER TOXICITY—Continued

Guideline No.	Study Type	Results
870.5550	UDS in primary rat hepatocytes	Positive. Dose-dependent positive responses were observed at treatment levels from 5.13 to 103 μg/mL in the absence of moderate to severe toxicity
870.7485	Metabolism and pharmaco kinetics in rats	Following oral treatment of rats with phenyl-UL-C^{14} carboxin, approximately 78.3–81.1% and 77.0–81.5% of the low and high doses, respectively, were recovered. Urine was the major route of excretion. The major urinary metabolites were 4-acetamidophenol and its glucuronide, acetanilide, and hydroxylated carboxin sulfoxide

B. Toxicological Endpoints

The dose at which NOAEL from the toxicology study identified as appropriate for use in risk assessment is used to estimate the toxicological level of concern (LOC). However, the lowest dose at which adverse effects of concern are identified the LOAEL is sometimes used for risk assessment if no NOAEL was achieved in the toxicology study selected. An uncertainty factor (UF) is applied to reflect uncertainties inherent in the extrapolation from laboratory animal data to humans and in the variations in sensitivity among members of the human population as well as other unknowns. An UF of 100 is routinely used, 10X to account for interspecies differences and 10X for intra species differences.

For dietary risk assessment (other than cancer) the Agency uses the UF to calculate an acute or chronic reference dose (acute RfD or chronic RfD) where the RfD is equal to the NOAEL divided by the appropriate UF (RfD = NOAEL/UF). Where an additional safety factors (SF) is retained due to concerns unique to the FQPA, this additional factor is applied to the RfD by dividing the RfD by such additional factor. The acute or chronic Population Adjusted Dose (aPAD or cPAD) is a modification of the RfD to accommodate this type of FQPA SF.

For non-dietary risk assessments (other than cancer) the UF is used to determine the LOC. For example, when 100 is the appropriate UF (10X to account for interspecies differences and 10X for intraspecies differences) the LOC is 100. To estimate risk, a ratio of the NOAEL to exposures (margin of exposure (MOE) = NOAEL/exposure) is calculated and compared to the LOC.

The linear default risk methodology (Q*) is the primary method currently used by the Agency to quantify carcinogenic risk. The Q* approach assumes that any amount of exposure will lead to some degree of cancer risk. A Q* is calculated and used to estimate risk which represents a probability of occurrence of additional cancer cases (e.g., risk is expressed as 1×10^{-6} or one in a million). Under certain specific circumstances, MOE calculations will be used for the carcinogenic risk assessment. In this non-linear approach, a ''point of departure'' is identified below which carcinogenic effects are not expected. The point of departure is typically a NOAEL based on an endpoint related to cancer effects though it may be a different value derived from the dose response curve. To estimate risk, a ratio of the point of departure to exposure (MOE_{cancer} = point of departure/exposures) is calculated. A summary of the toxicological endpoints for carboxin used for human risk assessment is shown in Table 2 of this unit:

TABLE 2.—SUMMARY OF TOXICOLOGICAL DOSE AND ENDPOINTS FOR CARBOXIN FOR USE IN HUMAN RISK ASSESSMENT

Exposure Scenario	Dose Used in Risk Assessment, UF	FQPA SF* and Level of Concern for Risk Assessment	Study and Toxicological Effects
Acute dietary all populations	Acute RfD = not required	No toxicological endpoint attributable to a single exposure was identified	None
Chronic dietary all populations	NOAEL = 0.8 mg/kg/day UF = 100 Chronic RfD = 0.008 mg/kg/day	FQPA SF = 3 cPAD = chr RfD FQPA SF = 0.00267 mg/kg/day	Combined chronic/carcinogenicity - rat LOAEL = Males: 9 mg/kg/day based on decreased body weight and body weight gain, increased urea nitrogen and creatinine, increased water consumption and urine volume, decreased urine specific gravity, histopathological changes in kidneys; Females: 16 mg/kg/day based on histopathological changes in kidneys
Cancer (oral, dermal, inhalation)	Not likely to be carcinogenic to humans	Negative for carcinogenicity in rats and mice	Combined chronic/carcinogenicity - rat and carcinogenicity - mouse

* The reference to the FQPA SF refers to any additional SF retained due to concerns unique to the FQPA.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* Tolerances have been established (40 CFR 180.301) for the combined residues of carboxin and its sulfoxide metabolite, in or on a variety of raw agricultural commodities (RAC). Risk assessments were conducted by EPA to assess dietary exposures from

carboxin and its sulfoxide metabolite in food as follows:

i. *Acute exposure*. 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. No toxicological endpoint attributable to a single exposure was identified in the available toxicology studies on carboxin. As a result, an acute endpoint was not identified and an acute dietary exposure assessment was not performed.

ii. *Chronic exposure*. In conducting this chronic dietary risk assessment the Dietary Exposure Evaluation Model (DEEM™) analysis evaluated the individual food consumption as reported by respondents in the Department of Agriculture (USDA) 1989–1992 nationwide Continuing Surveys of Food Intake by Individuals (CSFII) and accumulated exposure to the chemical for each commodity. The chronic dietary exposure analysis was an unrefined assessment. Tolerance level residues and 100% crop treated assumptions were used.

iii. *Cancer*. Carboxin was classified as ''not likely to be carcinogenic to humans.'' Therefore, a cancer dietary exposure assessment was not performed.

2. *Dietary exposure from drinking water*. The Agency lacks sufficient monitoring exposure data to complete a comprehensive dietary exposure analysis and risk assessment for carboxin and its sulfoxide metabolite] in drinking water. Because the Agency does not have comprehensive monitoring data, drinking water concentration estimates are made by reliance on simulation or modeling taking into account data on the physical characteristics of carboxin and its sulfoxide metabolite.

The Agency uses the First Index Reservoir Screening Tool (FIRST) or the Pesticide Root Zone/Exposure Analysis Modeling System (PRZM/EXAMS), to produce estimates of pesticide concentrations in an index reservoir. The SCI-GROW model is used to predict pesticide concentrations in shallow ground water. For a screening-level assessment for surface water EPA will use FIRST (a tier 1 model) before using PRZM/EXAMS (a tier 2 model). The FIRST model is a subset of the PRZM/EXAMS model that uses a specific high-end runoff scenario for pesticides. While both FIRST and PRZM/EXAMS incorporate an index reservoir environment, the PRZM/EXAMS model includes a percent crop (PC) area factor as an adjustment to account for the maximum PC coverage within a watershed or drainage basin.

None of these models include consideration of the impact processing (mixing, dilution, or treatment) of raw water for distribution as drinking water would likely have on the removal of pesticides from the source water. The primary use of these models by the Agency at this stage is to provide a coarse screen for sorting out pesticides for which it is highly unlikely that drinking water concentrations would ever exceed human health levels of concern.

Since the models used are considered to be screening tools in the risk assessment process, the Agency does not use estimated environmental concentrations (EECs) from these models to quantify drinking water exposure and risk as a %RfD or %PAD. Instead drinking water levels of comparison (DWLOCs) are calculated and used as a point of comparison against the model estimates of a pesticide's concentration in water. DWLOCs are theoretical upper limits on a pesticide's concentration in drinking water in light of total aggregate exposure to a pesticide in food, and from residential uses. Since DWLOCs address total aggregate exposure to carboxin and its sulfoxide metabolite they are further discussed in the aggregate risk sectionsin Unit E.

Based on the FIRST and SCI-GROW models the estimated environmental concentrations (EECs) of carboxin and its sulfoxide metabolite for acute exposures are estimated to be 29.6 parts per billion (ppb) for surface water and 0.09 ppb for ground water. The EECs for chronic exposures are estimated to be 0.63 ppb for surface water and 0.09 ppb for ground water.

3. *From non-dietary exposure*. The term ''residential exposure'' is used in this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets). Carboxin is not registered for use on any sites that would result in residential exposure.

4. *Cumulative exposure to substances with a common mechanism of toxicity*. Section 408(b)(2)(D)(v) of the FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider ''available information'' concerning the cumulative effects of a particular pesticide's residues and ''other substances that have a common mechanism of toxicity.''

EPA does not have, at this time, available data to determine whether carboxin 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, carboxin 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 carboxin has a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the final rule for Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997).

D. Safety Factor for Infants and Children

1. *In general*. Section 408 of the FFDCA provides that EPA shall apply an additional tenfold margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure 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 MOE analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans.

2. *Prenatal and postnatal sensitivity*. The developmental toxicity and reproduction studies performed with carboxin did not indicate evidence for enhanced susceptibility to the fetuses/offspring of rats or rabbits. Neither quantitative nor qualitative increased susceptibility was observed in the developmental toxicity study in rats, the developmental toxicity study in rabbits, or the 2-generation reproduction toxicity study in rats. In none of the toxicity studies on carboxin was there any toxicologically significant evidence of treatment-related neurotoxicity. A developmental neurotoxicity study in rats is not required. There is, however, a concern for possible germinal cell toxicity.

In genotoxicity studies, carboxin demonstrated clear evidence of clastogenic potential. It was also noted that in the 2-generation reproduction study in rats, treatment-related decreased fertility indices for the F1b male and female parents (due to a decreased number of pregnancies for the F2b generation) were observed. Based on these considerations, the registrant will be required to submit a germinal

cell assay, specifically a dominant lethal assay in rats, to the Agency in order to evaluate possible interaction between carboxin and germinal cell targets.

3. *Conclusion*. Based upon clear evidence of clastogenic activity and the requirement for a dominant lethal study, EPA concluded that a FQPA safety factor of 3X is appropriate for this risk assessment. The safety factor of 10X was reduced to 3X because: i. There is no indication of quantitative or qualitative increased susceptibility of rats or rabbits to *in utero* and/or postnatal exposure; ii. A developmental neurotoxicity study is not required; iii. The dietary (food and drinking water) exposure assessments will not underestimate the potential for exposures to infants and children; and iv. There are no registered residential uses for carboxin.

E. Aggregate Risks and Determination of Safety

To estimate total aggregate exposure to a pesticide from food, drinking water, and residential uses, the Agency calculates DWLOCs which are used as a point of comparison against the model EECs of a pesticide. DWLOC values are not regulatory standards for drinking water. DWLOCs are theoretical upper limits on a pesticide's concentration in drinking water in light of total aggregate exposure to a pesticide in food and residential uses. In calculating a DWLOC, the Agency determines how much of the acceptable exposure (i.e., the PAD) is available for exposure through drinking water e.g., allowable chronic water exposure (mg/kg/day) = cPAD - (average food + residential exposure). This allowable exposure through drinking water is used to calculate a DWLOC.

A DWLOC will vary depending on the toxic endpoint, drinking water consumption, and body weights. Default body weights and consumption values as used by the USEPA Office of Water are used to calculate DWLOCs: 2 liter (L)/70 kg (adult male), 2L/60 kg (adult female), and 1L/10 kg (child). Default body weights and drinking water consumption values vary on an individual basis. This variation will be taken into account in more refined screening-level and quantitative drinking water exposure assessments. Different populations will have different DWLOCs. Generally, a DWLOC is calculated for each type of risk assessment used: Acute, short-term, intermediate-term, chronic, and cancer.

When EECs for surface water and ground water are less than the calculated DWLOCs, EPA concludes with reasonable certainty that exposures to the pesticide in drinking water (when considered along with other sources of exposure for which EPA has reliable data) would not result in unacceptable levels of aggregate human health risk at this time. Because EPA considers the aggregate risk resulting from multiple exposure pathways associated with a pesticide's uses, levels of comparison in drinking water may vary as those uses change. If new uses are added in the future, EPA will reassess the potential impacts of residues of the pesticide in drinking water as a part of the aggregate risk assessment process.

1. *Acute risk*. No toxicological endpoint attributable to a single exposure was identified in the available toxicology studies on carboxin. As a result, carboxin is not expected to pose an acute risk.

2. *Chronic risk*. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to carboxin and its sulfoxide metabolite from food will utilize 41% of the cPAD for the U.S. population and 92% of the cPAD for children 1–6 years, the most highly exposed population. There are no residential uses for carboxin. In addition, there is potential for chronic dietary exposure to carboxin and its sulfoxide metabolite in drinking water. After calculating DWLOCs and comparing them to the EECs for surface and ground water, EPA does not expect the aggregate exposure to exceed 100% of the cPAD, as shown in the following Table 3:

TABLE 3.—AGGREGATE RISK ASSESSMENT FOR CHRONIC (NON-CANCER) EXPOSURE TO CARBOXIN AND ITS SULFOXIDE METABOLITE

Population Subgroup	cPAD mg/kg/day	%cPAD (Food)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Chronic DWLOC (ppb)
U.S. population	0.00267	41	0.63	0.09	56
Children 1–6 years	0.00267	92	0.63	0.09	2

3. *Short-term and Intermediate-term risk*. Both short-term aggregate exposure and intermediate-term aggregate exposure take into account residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Since carboxin is not registered for use on any sites that would result in residential exposure. Therefore, the aggregate risk is the sum of the risk from food and water, which do not exceed the Agency's level of concern as described in Table 3.

4. *Aggregate cancer risk for U.S. population*. Carboxin was classified as ''not likely to be carcinogenic to humans.'' Therefore, carboxin is not expected to pose a cancer risk.

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

IV. Other Considerations

A. Endocrine Disruptor Effects

FQPA requires EPA to develop a screening program to determine whether certain substances (including all pesticides and inerts or inactive ingredients) ''may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen, or such other endocrine effect...'' EPA has been working with interested stakeholders to develop a screening and testing program as well as a priority setting scheme. In the available toxicity studies for carboxin, there is no evidence of endocrine disruptor effects. When appropriate screening and/or testing protocols being considered under the Agency's Endocrine Disruptor Screening Program have been developed, carboxin may be subjected to further screening and/or testing to better characterize effects related to endocrine disruption.

B. Analytical Enforcement Methodology

The current available enforcement methods for tolerances of the combined residues of carboxin and its carboxin sulfoxide metabolite are described in the Pesticide Analytical Manual (PAM)

Vol. II. Method I is a colorimetric method which is used for determination of residues in or on corn, peanuts, rice, rice straw, sorghum, soybeans, eggs, meat, and milk. Method II and its modification, Method A, are gas liquid chromatography (GLC) methods which are used for wheat, oats, barley, peanuts, peanut oil and meal, sorghum, cottonseed, and cottonseed oil and meal. Adequate recovery data were submitted to validate the methods used in the canola field trials. Residues in canola seeds were converted to aniline, which was derivatized with heptafluorobutyric anhydride prior to gas chromatography mass selective detector (GC/MSD) analysis. Recoveries were 100–103% for 0.025 ppm fortifications in canola seeds.

Adequate enforcement methodology is available to enforce the tolerance expression. The method may be requested from: Francis Griffith, Analytical Chemistry Branch, Environmental Science Center, U.S. Environmental Protection Agency, 701 Mapes Road, Fort George G. Meade, MD 20755–5350; telephone number: (410) 305–2905; e-mail address: griffith.francis@epa.gov.

C. International Residue Limits

There are no CODEX, Canadian, or Mexican maximum residue levels (MRLs) for carboxin in/on onion seed. As a result, harmonization of tolerances is not an issue.

V. Conclusion

Therefore, the tolerance is established for combined residues of carboxin, (5,6 dihydro-2-methyl-N-phenyl-1,4-oxathiin-3-carboxamide) and its metabolite 5,6-dihydro-3-carboxanilide-2-methyl-1,4-oxathiin-4-oxide (calculated as carboxin) (from treatment of seed prior to planting) insert regulated chemical, in or on canola, seed at 0.03 ppm.

VI. 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, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) of the FFDCA 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) of FFDCA, as was provided in the old sections 408 and 409 of the FFDCA. 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 ID number OPP–2002–0326 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 February 7, 2003.

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 (1900C), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001. You may also deliver your request to the Office of the Hearing Clerk in Rm.104, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA;. 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 (703) 603–0061.

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, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.

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, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.

3. *Copies for the Docket.* In addition to filing an objection or hearing request with the Hearing Clerk as described in Unit VI.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.1. Mail your copies, identified by docket ID number OPP–2002–0326, to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001. In person or by courier, bring a copy to the location of the PIRIB described in Unit I.B.1. 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 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).

VII. Regulatory Assessment Requirements

This final rule establishes a tolerance under section 408(d) of the FFDCA in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). Because this rule has been exempted from review under Executive Order 12866 due to its lack of significance, this rule is not subject to Executive Order 13211, *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104–4). Nor does it require any special considerations under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994); or OMB review or any Agency action under Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104–113, section 12(d) (15 U.S.C. 272 note). Since tolerances and exemptions that are established on the basis of a petition under section 408(d) of the FFDCA, such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply. In addition, the Agency has determined that this action will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999). Executive Order 13132 requires EPA to develop an accountable process to ensure ''meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.'' ''Policies that have federalism implications'' is defined in the Executive order to include regulations that have ''substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.'' This final rule directly regulates growers, food processors, food handlers and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of the FFDCA. For these same reasons, the Agency has determined that this rule does not have any ''tribal implications'' as described in Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000). Executive Order 13175, requires EPA to develop an accountable process to ensure ''meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.'' ''Policies that have tribal implications'' is defined in the Executive order to include regulations that have ''substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and the Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.'' This rule will not have substantial direct effects on tribal governments, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this rule.

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

List of Subjects in 40 CFR Part 180

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

Dated: November 26, 2002.

Peter Caulkins,

Acting Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180— [AMENDED]

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

Authority: 21 U.S.C. 321(q), 346(a) and 371.

2. Section 180.301 is amended by alphabetically adding the commodity ''canola, seed'' to the table in paragraph (a) to read as follows:

§ 180.301 Carboxin; tolerances for residues.

(a) * * *

Commodity	Parts per million
* * * * *	*
Canola, seed	0.03
* * * * *	*

* * * * *

[FR Doc. 02–31010 Filed 12–6–02; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 721

[OPPT–2002–0043; FRL–7279–1]

RIN 2070–AD43

Perfluoroalkyl Sulfonates; Significant New Use Rule

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: EPA is issuing a significant new use rule (SNUR) under section 5(a)(2) of the Toxic Substances Control Act (TSCA) for 75 substances including perfluorooctanesulfonic acid (PFOSH) and certain of its salts (PFOSS), perfluorooctanesulfonyl fluoride (POSF), certain higher and lower homologues of PFOSH and POSF, and certain other chemical substances, including polymers, that are derived from PFOSH and its homologues. These chemicals are collectively referred to as perfluoroalkyl sulfonates, or PFAS. This rule requires manufacturers and importers to notify EPA at least 90 days before commencing the manufacture or import of these chemical substances for the significant new uses described in this document. EPA believes that this action is necessary because the PFOSH component of these chemical substances may be hazardous to human health and the environment. The required notice will provide EPA with the opportunity to evaluate an intended new use and associated activities and, if necessary, to prohibit or limit that activity before it occurs.

DATES: This final rule is effective on January 8, 2003.

FOR FURTHER INFORMATION CONTACT: *For general information contact*: Barbara Cunningham, Acting Director, Environmental Assistance Division (7408M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (202) 554–1404; e-mail address: TSCA-Hotline@epa.gov.

For technical information contact: Mary Dominiak, Chemical Control Division (7405M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (202) 564–8104; e-mail address: dominiak.mary@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you manufacture (defined by statute to include import) any of the chemical substances that are listed in Table 1 of this unit. Persons who intend to import any chemical substance governed by a final SNUR are subject to TSCA section 13 (15 U.S.C. 2612) import certification requirements, and to the regulations codified at 19 CFR 12.118 through 12.127 and 12.728. Those persons must certify that they are in compliance with the SNUR requirements. The EPA policy in support of import certification appears at 40 CFR part 707, subpart B. In addition, any persons who export or intend to export any of the chemical substances listed in Table 1 are subject to the export notification provisions of TSCA section 12(b) (15 U.S.C. 2611(b)), and must comply with the export notification requirements in 40 CFR 721.20 and 40 CFR part 707, subpart D.Potentially affected entities may include, but are not limited to:

- Chemical manufacturers or importers (NAICS 325), e.g., persons who manufacture (defined by statute to include import) one or more of the subject chemical substances.
- Chemical exporters (NAICS 325), e.g., persons who export, or intend to export, one or more of the subject chemical substances.

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. To determine whether you or your business may be affected by this action, you should carefully examine the applicability provisions in 40 CFR 721.5 for SNUR-related obligations. Also, consult Unit II. If you have any questions regarding the applicability of this action to a particular entity, consult the technical person listed under **FOR FURTHER INFORMATION CONTACT**.

TABLE 1.—CHEMICAL SUBSTANCES COVERED BY THIS RULE

CAS No./PMN	CAS Ninth Collective Index Name
307–35–7	1-Octanesulfonyl fluoride, 1,1,2,2,3,3,4,4,5,5,6,6,7,7,8,8,8-heptadecafluoro-
307–51–7	1-Decanesulfonyl fluoride, 1,1,2,2,3,3,4,4,5,5,6,6,7,7,8,8,9,9,10,10,10-heneicosafluoro-
376–14–7	2-Propenoic acid, 2-methyl-, 2-[ethyl[(heptadecafluorooctyl)sulfonyl]amino]ethyl ester
383–07–3	2-Propenoic acid, 2-[butyl[(heptadecafluorooctyl)sulfonyl]amino]ethyl ester
423–50–7	1-Hexanesulfonyl fluoride, 1,1,2,2,3,3,4,4,5,5,6,6,6-tridecafluoro-
423–82–5	2-Propenoic acid, 2-[ethyl[(heptadecafluorooctyl)sulfonyl]amino]ethyl ester
754–91–6	1-Octanesulfonamide, 1,1,2,2,3,3,4,4,5,5,6,6,7,7,8,8,8-heptadecafluoro-
1652–63–7	1-Propanaminium, 3-[[(heptadecafluorooctyl)sulfonyl]amino]-N,N,N-trimethyl-, iodide
1691–99–2	1-Octanesulfonamide, N-ethyl-1,1,2,2,3,3,4,4,5,5,6,6,7,7,8,8,8-heptadecafluoro-N-(2-hydroxyethyl)-
1763–23–1	1-Octanesulfonic acid, 1,1,2,2,3,3,4,4,5,5,6,6,7,7,8,8,8-heptadecafluoro-
2795–39–3	1-Octanesulfonic acid, 1,1,2,2,3,3,4,4,5,5,6,6,7,7,8,8,8-heptadecafluoro-, potassium salt