early in the process of developing the proposed regulation.

This rule will not 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, as specified in Executive Order 13132, because it merely approves a state rule implementing a federal standard, and does not alter the relationship or the distribution of power and responsibilities established in the Clean Air Act. Thus, the requirements of section 6 of the Executive Order do not apply to this rule.

E. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) generally requires an agency to conduct a regulatory flexibility analysis of any rule subject to notice and comment rulemaking requirements unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. Small entities include small businesses, small not-for-profit enterprises, and small governmental jurisdictions. This final rule will not have a significant impact on a substantial number of small entities because SIP approvals under section 110 and subchapter I, part D of the CAA do not create any new requirements but simply approve requirements that the State is already imposing. Therefore, because the Federal SIP approval does not create any new requirements, EPA certifies that this action will not have a significant economic impact on a substantial number of small entities.

Moreover, due to the nature of the Federal-State relationship under the CAA, preparation of flexibility analysis would constitute Federal inquiry into the economic reasonableness of state action. The CAA forbids EPA to base its actions concerning SIPs on such grounds. *Union Electric Co.* v. *U.S. EPA,* 427 U.S. 246, 255–66 (1976); 42 U.S.C. 7410(a)(2).

F. Unfunded Mandates

Under section 202 of the Unfunded Mandates Reform Act of 1995 (''Unfunded Mandates Act''), signed into law on March 22, 1995, EPA must prepare a budgetary impact statement to accompany any proposed or final rule that includes a federal mandate that may result in estimated annual costs to state, local, or tribal governments in the aggregate; or to private sector, of $100 million or more. Under section 205, EPA must select the most cost-effective and least burdensome alternative that achieves the objectives of the rule and is consistent with statutory requirements. Section 203 requires EPA to establish a plan for informing and advising any small governments that may be significantly or uniquely impacted by the rule.

EPA has determined that the final approval action does not include a federal mandate that may result in estimated annual costs of $100 million or more to either state, local, or tribal governments in the aggregate, or to the private sector. This federal action approves pre-existing requirements under state or local law, and imposes no new requirements. Accordingly, no additional costs to state, local, or tribal governments, or to the private sector, result from this action.

G. Submission to Congress and the Comptroller General

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This rule is not a ''major'' rule as defined by 5 U.S.C. 804(2).

H. Petitions for Judicial Review

Under section 307(b)(1) of the CAA, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by November 28, 2000. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this rule for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2).)

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Intergovernmental relations, Nitrogen oxides, Ozone, Reporting and recordkeeping requirements, Volatile organic compounds.

Dated: August 21, 2000.

William J. Muszynski,

Acting Regional Administrator, Region 2.

40 CFR Part 52 is amended as follows:

PART 52—[AMENDED]

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

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

Subpart HH—New York

2. Section 52.1683 is amended by adding new paragraph (g) to read as follows:

§ 52.1683 Control strategy: Ozone.

* * * * *

(g) EPA approves as a revision to the New York State Implementation Plan, the Stage II gasoline vapor recovery comparability plan for upstate portions of New York State submitted by the New York State Department of Environmental Conservation on April 18, 2000.

[FR Doc. 00–24789 Filed 9–28–00; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–301052; FRL–6745–9]

RIN 2070–AB78

Flucarbazone-sodium; Time-Limited Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes time-limited tolerances for combined residues of flucarbazone-sodium, 4,5-dihydro-3-methoxy-4-methyl-5-oxo-*N*-[[2(trifluoromethoxy)phenyl] sulfonyl]-1*H*-1,2,4-triazole 1-carboxamide, sodium salt) and its *N*-desmethyl metabolite in or on wheat, forage at 0.30 parts per million (ppm); wheat, grain at 0.01 ppm; wheat, hay at 0.10 ppm; and wheat, straw at 0.05 ppm; and combined residues of flucarbazone-sodium and its metabolites converted to 2-(trifluoromethoxy)benzene sulfonamide and calculated as flucarbazone-sodium in or on milk at 0.005 ppm; meat and meat byproducts (excluding liver) of cattle, goats, hogs, horses and sheep at 0.01 ppm; and liver of cattle, goats, hogs, horses and sheep at 1.5 ppm. Bayer Corporation requested these tolerances under the Federal Food, Drug, and Cosmetic Act, as amended by the Food Quality Protection Act of 1996.

The tolerances will expire and be revoked on November 1, 2005.

DATES: This regulation is effective September 29, 2000.Objections and requests for hearings, identified by docket control number OPP–301052, must be received by EPA on or before November 28, 2000.

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 VI. of the **SUPPLEMENTARY INFORMATION.** To ensure proper receipt by EPA, your objections and hearing requests must identify docket control number OPP–301052 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Joanne I. Miller, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703)–305–6224; and e-mail address: miller.joanne@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be 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,'' ''Regulations and Proposed Rules,'' 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/. To access the OPPTS Harmonized Guidelines referenced in this document, go directly to the guidelines at http://www.epa.gov/opptsfrs/home/guidelin.htm.

2. *In person.* The Agency has established an official record for this action under docket control number OPP–301052. 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

In the **Federal Register** of October 8, 1999 (64 FR 195) (FRL–6384–2), EPA issued a notice pursuant to section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a as amended by the Food Quality Protection Act of 1996 (FQPA) (Public Law 104–170) announcing the filing of a pesticide petition (PP) for tolerance by Bayer Corporation, 8400 Hawthorne Road, Kansas City, Missouri 64120–0013. This notice included a summary of the petition prepared by Bayer Corporation, the registrant. There were no comments received in response to the notice of filing.

The petition requested that 40 CFR part 180 be amended by establishing tolerances for combined residues of the herbicide flucarbazone-sodium, 4,5-dihydro-3-methoxy-4-methyl-5-oxo-*N*-[[2(trifluoromethoxy)phenyl]sulfonyl]-1*H*-1,2,4-triazole 1-carboxamide, sodium salt) and its *N*-desmethyl metabolite in or on wheat, forage at 0.30 ppm; wheat, grain at 0.01 ppm; wheat, hay at 0.10 ppm; wheat, straw at 0.05 ppm, milk at 0.005 ppm; meat of cattle, goats, hogs, horses and sheep at 0.01 ppm; and liver of cattle, goats, hogs, horses and sheep at 0.60 ppm. As a result of its review of scientific data submitted in support of this petition, the Agency has determined that additional sulfonamide metabolites should be included in the tolerance expression for both wheat and the associated animal commodities. The submitted analytical method and residue data for livestock are sufficient to establish tolerances for livestock commodities that include the additional sulfonamide metabolites. The animal tolerances requested by Bayer Corporation for flucarbazone-sodium and its *N*-desmethyl metabolite are adequate to cover the additional metabolites, with the exception of the tolerance for liver, which EPA has determined must be raised from 0.60 ppm to 1.5 ppm. However, before EPA can establish tolerances for wheat forage, grain, hay and straw that include the sulfonamide metabolites, the registrant must submit a revised method and additional residue data that measure not only the parent and *N*-desmethyl metabolite, but also the sulfonamide metabolites of concern. Therefore, EPA is establishing time-limited tolerances for combined residues of flucarbazone-sodium, 4,5-dihydro-3-methoxy-4-methyl-5-oxo-*N*-[[2(trifluoromethoxy)phenyl] sulfonyl]-1*H*-1,2,4-triazole 1-carboxamide, sodium salt) and its *N*-desmethyl metabolite in or on wheat, forage at 0.30 ppm; wheat, grain at 0.01 ppm; wheat, hay at 0.10 ppm; and wheat, straw at 0.05 ppm; and combined residues of flucarbazone-sodium and its metabolites converted to 2-(trifluoromethoxy)benzene sulfonamide and calculated as flucarbazone-sodium in or on milk at 0.005 ppm; meat and meat byproducts (excluding liver) of cattle, goats, hogs, horses and sheep at 0.01 ppm; and liver of cattle, goats, hogs, horses and sheep at 1.5 ppm. The tolerances are being established as time-limited to allow time to develop additional analytical methodology and residue data for wheat to support revised tolerances that include the

sulfonamide metabolites. These tolerances will expire and be revoked on November 1, 2005. Although EPA does not have sufficient data to establish wheat tolerances that include the sulfonamide metabolites, sufficient data are available for the Agency to estimate human exposure and risk from these metabolites as described in the ''Exposure Assessment'' section below.

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

EPA performs a number of analyses to determine the risks from aggrege 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).

III. Aggregate Risk Assessment and Determination of Safety

Consistent with section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure, consistent with section 408(b)(2), for tolerances for combined residues of flucarbazone-sodium, 4,5-dihydro-3-methoxy-4-methyl-5-oxo-*N*-[[2(trifluoromethoxy)phenyl] sulfonyl]-1*H*-1,2,4-triazole 1-carboxamide, sodium salt) and its *N*-desmethyl metabolite in or on wheat, forage at 0.30 ppm; wheat, grain at 0.01 ppm; wheat, hay at 0.10 ppm; and wheat, straw at 0.05 ppm; and combined residues of flucarbazone-sodium and its metabolites converted to 2-(trifluoromethoxy)benzene sulfonamide and calculated as flucarbazone-sodium in or on milk at 0.005 ppm; meat and meat byproducts (excluding liver) of cattle, goats, hogs, horses and sheep at 0.01 ppm; and liver of cattle, goats, hogs, horses and sheep at 1.5 ppm. EPA's assessment of exposures and risks associated with establishing these tolerances follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. The nature of the toxic effects caused by flucarbazone-sodium are discussed in the following Table 1 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	28–Day oral toxicity in rodents (rats)	NOAEL = 27 mg/kg/day in males and 25 mg/kg/day in females. LOAEL = 266 mg/kg/day in males and 251 mg/kg/day in females based on immunological changes in both sexes
870.3100	90–Day oral toxicity in rodents (rats)	NOAEL = 73.5 mg/kg/day in males and 102 mg/kg/day in females LOAEL = 287 mg/kg/day in males and 358 mg/kg/day in females based on immunological findings in both sexes
870.3100	28–Day oral toxicity in rodents (mice)	NOAEL = > 4,554 mg/kg/day in males and 6,429 mg/kg/day in females LOAEL > 4,554 mg/kg/day in males and 6,429 mg/kg/day in females. There were no signs of toxicity attributable to treatment at any dose level
870.3100	90–Day oral toxicity in rodents (mice)	NOAEL = > 2,083 mg/kg/day in males and 3,051 mg/kg/day in females LOAEL > 2,083 mg/kg/day in males and 3,051 mg/kg/day in females. There were no signs of toxicity attributable to treatment at any dose level.
870.3150	28–Day oral toxicity in nonrodents (dogs)	NOAEL = 164 mg/kg/day in males and 171 mg/kg/day in females LOAEL = 1,614 mg/kg/day in males and 1,319 mg/kg/day in females based on decreased body weight gain, decreased food consumption, decreased T4 levels and increased thyroxine-binding capacity, induction of microsomal enzymes, increased liver weight and liver histopathology in both sexes
870.3150	90–Day oral toxicity in nonrodents (dogs)	NOAEL = 33.8 mg/kg/day in males and 35.2 mg/kg/day in females with the occurrence of slight, adaptive induction of hepatic microsomal enzymes LOAEL = 162 mg/kg/day in males and 170 mg/kg/day in females based on decreased T4 levels, increased thyroxine-binding capacity, induction of microsomal enzymes, gross pathology and histopathology in the stomach, and histopathology in the liver in both sexes
870.3200	21/28–Day dermal toxicity in rabbits	NOAEL ≥1,000 mg/kg/day for both sexes.

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

Guideline No.	Study Type	Results
		LOAEL > 1,000 mg/kg/day. There were no signs of toxicity attributable to treatment at any dose level.
870.3250	90–Day dermal toxicity in rats	Not applicable (NA)
870.3465	90–Day inhalation toxicity in rats	NA
870.3700a	Prenatal developmental toxicity in rats	Maternal NOAEL = > 1,000 mg/kg/day LOAEL > 1,000 mg/kg/day Developmental NOAEL = > 1,000 mg/kg/day LOAEL > 1,000 mg/kg/day
870.3700b	Prenatal developmental toxicity in rabbits	Maternal NOAEL = 100 mg/kg/day LOAEL = 300 mg/kg/day based on decreased food consumption and increased clinical signs Developmental NOAEL = 300 mg/kg/day LOAEL = 500 mg/kg/day based on decreased fetal weight and increased incidence of delayed fetal ossification
870.3800	Reproduction and fertility effects in rats	Parental/Systemic NOAEL = 287 mg/kg/day for males and 340 mg/kg/day for females with a slight, increased incidence of moderate cecal enlargement occurring as an adaptive response to treatment LOAEL = 800 mg/kg/day for males based on decreased liver weight and 991 mg/kg/day for females based on decreased uterine weight and increased incidence of severe cecal enlargement Reproductive/Offspring NOAEL = 287 mg/kg/day for males and 340 mg/kg/day for females LOAEL = 800 mg/kg/day for males and 991 mg/kg/day for females based on reduced pup weights, decreased liver weight in male pups, marbled liver, air filled stomach
870.4100b	Chronic toxicity in dogs	NOAEL = 35.9 mg/kg/day in males and 37.1 mg/kg/day in females. LOAEL = 183 mg/kg/day in males and 187 mg/kg/day in females based upon body weight gain depression and increased N-demethylase levels in both sexes, decreased T4 levels and marginally increased liver weight in females.
870.4300	2–Year Chronic toxicity/carcinogenicity in rats	NOAEL = 125 mg/kg/day in males and females LOAEL = 1,000 mg/kg/day in males and females based on decreased body weight and increased food consumption in females, thickened mucosa of the glandular stomach in both sexes, inflammatory infiltrates (males), vacuolation of the squamous epithelium in the fore-stomach (females) and immunological effects in males No evidence of carcinogenicity
870.4200b	2–Year Carcinogenicity in mice	NOAEL = 275 mg/kg/day in males and 459 mg/kg/day in females LOAEL = 2,066 mg/kg/day in males and 3,212 mg/kg/day in females based on decreased body weight in both sexes and increased food consumption in males. No evidence of carcinogenicity
870.5100	Gene Mutation; reverse gene mutation assay in bacteria	There was no evidence of induced mutant colonies over background.
870.5100	Gene Mutation; reverse gene mutation assay in bacteria with MKH 10868, an animal, plant, and soil metabolite	There was no evidence of induced mutant colonies over background
870.5300	Gene mutation assay in V79 cultured mammalian cells	No increase in mutant frequency above that of negative controls up to the limit dose.
870.5375	Cytogenetics; *in vitro* mammalian cytogenetics assay	No increases in aberrant metaphases were observed up to the limit dose.
870.5395	bone marrow micronucleus assay	There was no significant increase in the frequency of micronucleated polychromatic erythrocytes in bone marrow at 2,000 mg/kg.

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

Guideline No.	Study Type	Results
870.5550	Other Genotoxicity; Unscheduled DNA synthesis in primary rat hepatocytes	There was no evidence of unscheduled DNA synthesis up to cytotoxic levels.
870.6200a	Acute neurotoxicity screening battery in rats	NOAEL = 500 mg/kg/day for males and females LOAEL = 2,000 mg/kg/day based on increased incidence of perianal staining in males, decreased motor activity and locomotor activity in both sexes and increase in the incidence of animals exhibiting low levels of activity in open field in both sexes.
870.6200b	Subchronic neurotoxicity screening battery in rats	NOAEL = 147 mg/kg/day in males and 1,736 mg/kg/day in females LOAEL = 1,482 mg/kg/day based on decreased body weight, decreased body weight gain, and decreased food consumption in males. LOAEL > 1,736 mg/kg/day in females.
870.6300	Developmental neurotoxicity in rats	NA
870.7800	Antibody Plaque-forming cell assay in male rats	NOAEL = > 1,000 mg/kg/day LOAEL > 1,000 mg/kg/day
870.7800	Antibody Plaque-forming cell assay in female rats	NOAEL = > 1,000 mg/kg/day LOAEL > 1,000 mg/kg/day
870.7800	Splenic T-cells, B-cells, and NK-cell assay in male rats	NOAEL = > 1,000 mg/kg/day LOAEL > 1,000 mg/kg/day
870.7800	Splenic T-cells, B-cells, and NK-cell assay in female rats	NOAEL = > 1,000 mg/kg/day LOAEL > 1,000 mg/kg/day
870.7800	Plaque-Forming cell assay in rats	NOAEL = 2,205 mg/kg/day in males and 2,556 mg/kg/day in females LOAEL > 2,205 mg/kg/day in males and 2,556 mg/kg/day in females
870.7485	Metabolism in rats	There were no sex-related differences in the absorption, distribution, metabolism or excretion. Based on urinary excretion, absorption was 15–30% and maximum plasma concentrations were achieved within 30 minutes. At sacrifice, tissues and carcass contained less than 1% of radioactivity. The highest residue in the tissues was in the liver. Greater than 90% of the administered dose was eliminated within 24 hours. The major component in urine and feces was unchanged parent which represented 90–95% of the administered dose.
870.7485	Metabolism in rats	Major component in urine and feces was unchanged parent which represented 94% of the administered dose. Less than 1% of the administered dose was recovered in the carcass, tissues, expired air, or cage wash. Highest residue was in the liver.
870.7485	Metabolism in rats: M: 5.13 mg/kg of phenyl- UL-C^{14} MKH 6562 sulfonamide lactate (plant metabolite of MKH 6562)	Metabolized via two pathways. One pathway involved the oxidative decarboxylation of sulfonamide lactate to form sulfonamide acetate. The other pathway involved the hydrolysis of sulfonamide lactate and sulfonamide acetate to give sulfonamide.
870.7485	Metabolism in rats: M: 5 mg/kg of phenyl-C^{14} MKH 6562 sulfonamide alanine (a plant metabolite of MKH 6562)	Approximately 70% absorption and elimination with 98% recovery in urine and feces. Several metabolites in addition to parent (17%). Less than 1% of the administered dose was recovered in the carcass, tissues, expired air, or cage wash. Highest residue was in the liver.
870.7600	Dermal penetration	NA

B. Toxicological Endpoints

The dose at which no adverse effects are observed (the 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 factor 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 Safety Factor.

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 flucarbazone-sodium used for human risk assessment is shown in the following Table 2:

TABLE 2.—SUMMARY OF TOXICOLOGICAL DOSE AND ENDPOINTS FOR FLUCARBAZONE-SODIUM] 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 females 13–50 years of age	NOAEL = 300 mg/kg/day; UF = 100; Acute RfD = 3.0 mg/kg/day	FQPA SF = 1X; aPAD = acute RfD ÷ FQPA SF = 3.0 mg/kg/day	Developmental Toxicity Study - rabbit; Developmental LOAEL = 500 mg/kg/day based on decreased fetal body weight and delayed ossification.
Chronic Dietary all populations	NOAEL = 35.9 mg/kg/day; UF = 100; Chronic RfD = 0.36 mg/kg/day;	FQPA SF = 1X; cPAD = chronic RfD ÷ FQPA SF = 0.36 mg/kg/day	One year dog feeding study LOAEL = 183 mg/kg/day based on decreased body weight gain, decreased thyroxine, increased *N*-demethylase, and increased liver weight

* The reference to the FQPA Safety Factor refers to any additional safety factor retained due to concerns unique to the FQPA.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* No tolerances have previously been established for flucarbazone-sodium. Risk assessments were conducted by EPA to assess dietary exposures from flucarbazone-sodium 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. An appropriate endpoint attributable to a single exposure was not identified for the general population, including infants and children. The decreased motor and locomotor activity observed at 2,000 mg/kg on the day of dosing only in the acute neurotoxicity study in rats was reversible within 18 minutes. The NOAEL of 500 mg/kg for these findings was not considered appropriate for selection as an acute dietary endpoint for the general population. An acute dietary risk assessment was performed for flucarbazone-sodium for the population subgroup, females 13 to 50 years old, based on the results of the rabbit developmental toxicity study. The Dietary Exposure Evaluation Model (DEEM®) analysis evaluated the individual food consumption as reported by respondents in the USDA [1989–1992] nationwide Continuing Surveys of Food Intake by Individuals (CSFII) and accumulated exposure to the chemical for each commodity. The following assumptions were made for the acute exposure assessment: For all commodities, 100% crop treated was assumed. In order to account for the metabolites of concern in wheat and livestock commodities, the anticipated residue levels (parent and metabolites of concern) to be used in the dietary exposure assessment were determined. Using the ratio of the sulfonamide metabolites to the sum of the parent and *N*-desmethyl metabolite observed in the wheat metabolism study and the Highest Average Field Trial (HAFT) value from the crop field trial studies, the anticipated total residues (parent and metabolites of concern) expected to be in wheat were determined. A processed wheat food/feed study was not submitted in support of this petition. Therefore, in order to represent the worse case scenario, the wheat maximum theoretical concentration factor of 8x (Table 1, Residue Chemistry Test Guidelines OPPTS 860.1520) was used for all wheat commodities. Default concentration factors were used for all other commodities in DEEM®.

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 USDA 1989–1992 nationwide CSFII and accumulated exposure to the chemical for each commodity. The following assumptions were made for the chronic exposure assessments: For all commodities, 100% crop treated was assumed. In order to account for the metabolites of concern in wheat and livestock commodities, the anticipated residue levels (parent and metabolites of concern) to be used in the dietary exposure assessment were determined. Using the ratio of the sulfonamide metabolites to the sum of the parent and *N*-desmethyl metabolite observed in the wheat metabolism study, and the Highest Average Field Trial (HAFT)

value from the crop field trial study, the anticipated total residues (parent and metabolites of concern) expected to be in wheat were determined. A processed wheat food/feed study was not submitted in support of this petition. Therefore, in order to represent the worse case scenario, the wheat maximum theoretical concentration factor of 8x (Table 1, Residue Chemistry Test Guidelines OPPTS 860.1520) was used for all wheat commodities. Default concentration factors were used for all other commodities in DEEM®.

iii. *Cancer*. The Agency concluded that flucarbazone-sodium was negative for carcinogenic potential in mice and rats and classified flucarbazone-sodium as ''not likely'' to be a human carcinogen according to EPA Draft Guidelines for Carcinogen Risk Assessment. Therefore, a cancer dietary exposure analysis was not performed.

Section 408(b)(2)(E) authorizes EPA to use available data and information on the anticipated residue levels of pesticide residues in food and the actual levels of pesticide chemicals that have been measured in food. If EPA relies on such information, EPA must require that data be provided 5 years after the tolerance is established, modified, or left in effect, demonstrating that the levels in food are not above the levels anticipated. Following the initial data submission, EPA is authorized to require similar data on a time frame it deems appropriate. As required by section 408(b)(2)(E), EPA will issue a data call-in for information relating to anticipated residues to be submitted no later than 5 years from the date of issuance of this tolerance. EPA used anticipated residues in this case to estimate exposure to the sulfonamide metabolites of flucarbazone-sodium in wheat that are not included in the time-limited tolerance expression. As a condition of registration, EPA will require Bayer Corporation to submit revised analytical methodology and wheat residue data that measure all residues of concern, including the sulfonamide metabolites. These data must be submitted within 3 years of registration, well within the 5 year time frame specified in the regulations, and should allow the Agency to set tolerances for wheat that include these metabolites and eliminate the need for sulfonamide anticipated residue calculations in future risk assessments for flucarbazone-sodium.

2. *Dietary exposure from drinking water*. The Agency lacks sufficient monitoring exposure data to complete a comprehensive dietary exposure analysis and risk assessment for flucarbazone-sodium 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 flucarbazone-sodium.

The Agency uses the Generic Estimated Environmental Concentration (GENEEC) or the Pesticide Root Zone/ Exposure Analysis Modeling System (PRZM/EXAMS) to estimate pesticide concentrations in surface water and the Screening Concentration in Ground Water model (SCI-GROW), which predicts pesticide concentrations in groundwater. In general, EPA will use GENEEC (a tier 1 model) before using PRZM/EXAMS (a tier 2 model) for a screening-level assessment for surface water. The GENEEC model is a subset of the PRZM/EXAMS model that uses a specific high-end runoff scenario for pesticides. GENEEC incorporates a farm pond scenario, while PRZM/EXAMS incorporate an index reservoir environment in place of the previous pond scenario. The PRZM/EXAMS model includes a percent crop area factor as an adjustment to account for the maximum percent crop coverage within a watershed or drainage basin.

None of these models includes 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 flucarbazone-sodium they are further discussed in the aggregate risk sections below.

Based on the GENEEC and SCI-GROW models the EECs of flucarbazone-sodium (parent only) in surface water and ground water for acute exposures are estimated to be 1.42 parts per billion (ppb) for surface water and 0.2 ppb for ground water. The EECs for chronic exposures are estimated to be 1.25 ppb for surface water and 0.2 ppb for ground water.

Based on the GENEEC model, total flucarbazone-sodium EECs (parent plus metabolites) in surface water are not likely to exceed 1.45 ppb for acute exposures and 1.44 ppb for chronic (60-day) exposures. Agency interim policy recommends that the 60–day GENEEC value to be divided by an adjustment factor of 3 to obtain a value for chronic risk assessment calculations. Therefore, a surface water value of 0.48 ppb was used for chronic risk assessment.

Because the degradates of flucarbazone-sodium are so resistant to aerobic metabolism in soil, they lie outside the range of environmental characteristics from which SCI-GROW was developed. It was therefore not appropriate in this case to use the model to estimate total flucarbazone-sodium EECs in ground water. Instead, the concentration of total flucarbazone residues in soil porewater of the top 1-foot of soil immediately postapplication was estimated to be approximately 50 ppb. This number would be an upper limit on the amount of chemical that could be found in the soil porewater and was used by the Agency as an estimate of expected residues of flucarbazone-sodium and its metabolites in ground water for risk assessment purposes.

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).

Flucarbazone-sodium 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) 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 flucarbazone-sodium 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, flucarbazone-

sodium 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 flucarbazone-sodium 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. *Safety factor for infants and children*—i. *In general*. 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 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 margin of exposure (MOE) analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans.

ii. *Prenatal and postnatal sensitivity*. No increased quantitative or qualitative susceptibility was seen following prenatal and/or postnatal exposures. There were no developmental findings in rats up to the limit dose of 1,000 mg/kg/day. In the rabbit developmental toxicity study, the effects seen in fetuses (decreased fetal body weight and delayed ossification) are at dose levels equal to or greater than doses where maternal toxicity (increased clinical signs and decreased food consumption) were observed. In a 2-generation reproductive toxicity study in rats, the effects seen in offspring were at dose levels equal to or greater than doses where parental toxicity were seen.

iii. *Conclusion*. There is a complete toxicity data base for flucarbazone-sodium and exposure data are complete or are estimated based on data that reasonably accounts for potential exposures. EPA determined that the 10X safety factor to protect infants and children should be removed. The FQPA factor is removed because there is no indication of quantitative or qualitative increased susceptibility of rats or rabbits to *in utero* and/or postnatal exposure; a developmental neurotoxicity study is not required; the dietary (food and drinking water) exposure assessments will not underestimate the potential exposures for infants and children; and there are no registered residential uses at the current time.

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 estimates of a pesticide's concentration in water (EECs). 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: 2L/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 groundwater are less than the calculated DWLOCs, OPP concludes with reasonable certainty that exposures to the pesticide in drinking water (when considered along with other sources of exposure for which OPP has reliable data) would not result in unacceptable levels of aggregate human health risk at this time. Because OPP 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, OPP 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*. Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food to flucarbazone-sodium will occupy < 1% of the aPAD for females 13 to 50 years old. Since an appropriate endpoint attributable to a single exposure was not identified for the general population, including infants and children, an acute exposure assessment was not performed for these population subgroups. In addition, there is potential for acute dietary exposure to flucarbazone-sodium 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 aPAD for the population of concern (females 13 to 50 years old), as shown in the following Table 3:

TABLE 3.—AGGREGATE RISK ASSESSMENT FOR ACUTE EXPOSURE TO FLUCARBAZONE-SODIUM

Population Subgroup	aPAD (mg/kg)	%aPAD (Food)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Acute DWLOC (ppb)
Females, 13 to 50 years old	3	<1	1.45	50	90,000

2. *Chronic risk*. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to flucarbazone-sodium from food will utilize 1% of the cPAD for the U.S. population, <1% of the cPAD for all infants less than 1 year old and 2% of the cPAD for children 1 to 6 years old, the population subgroup with the highest estimated exposure to flucarbazone-sodium. There are no residential uses for flucarbazone-sodium that result in chronic residential exposure to flucarbazone-sodium. In addition, there is potential for chronic dietary exposure to flucarbazone-sodium in drinking water. After calculating the 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 4:

TABLE 4.—AGGREGATE RISK ASSESSMENT FOR CHRONIC (NON-CANCER) EXPOSURE TO FLUCARBAZONE-SODIUM

Population Subgroup	cPAD mg/kg/day	% cPAD (Food)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Chronic DWLOC (ppb)
U.S. Population	0.36	1	0.48	50	12,000
Infants less than 1 year old	0.36	<1	0.48	50	3,600
Children 1 to 6 years old	0.36	2	0.48	50	3,500

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

Flucarbazone-sodium 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.

4. *Intermediate-term risk*. Intermediate-term aggregate exposure takes into account residential exposure plus chronic exposure to food and water (considered to be a background exposure level).

Flucarbazone-sodium 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.

5. *Aggregate cancer risk for U.S. population*. The Agency concluded that flucarbazone-sodium was negative for carcinogenic potential in mice and rats and classified flucarbazone-sodium as ''not likely'' to be a human carcinogen according to EPA Draft Guidelines for Carcinogen Risk Assessment. Therefore, a cancer dietary exposure analysis was not performed.

6. *Determination of safety*. Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, and to infants and children from aggregate exposure to flucarbazone-sodium residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

The petitioner has proposed residue analytical methods for tolerance enforcement in wheat and livestock commodities. The analytical enforcement method for wheat employs accelerated solvent extraction, clean-up using solid phase extraction columns followed by detection and quantitation by liquid chromatography/tandem mass spectroscopy (LC/MS/MS). The analytical method for livestock commodities is a common moiety method which measures residues of flucarbazone-sodium (MKH6562) in animal tissues and milk by extracting and hydrolysing MKH 6562 and MKH 6562-related residues to MKH 6562 sulfonamide. Detection is achieved using negative ion electrospray mass spectrometry using deuterated MKH 6562 sulfonamide as an internal standard. Both methods have undergone successful validations by independent laboratories. They are currently being validated by the Analytical Chemistry Branch laboratories, BEAD (7503C), Office of Pesticide Programs. Upon successful completion of the EPA validation and the granting of this registration these methods will be forwarded to FDA for publication in a future revision of the Pesticide Analytical Manual, Vol-II (PAM-II). Prior to publication in PAM-II and upon request, the methods will be available from the Analytical Chemistry Branch (ACB), BEAD (7503C), Environmental Science Center, 701 Mapes Road, Ft George G. Meade, MD 20755–5350; contact Francis D. Griffith, Jr, telephone (410) 305–2905, e-mail griffith.francis@epa.gov. The analytical standards for these methods are also available from the EPA National Pesticide Standard Repository at the same location.

B. International Residue Limits

A default Maximum Residue Limit (MRL) of 0.01 ppm has been established in Canada for residues of flucarbazone-sodium and its *N*-desmethyl metabolite on wheat grain. This value is consistent with the tolerance being established in the United States on wheat grain. There are no Codex MRLs for this compound on wheat. Therefore, no compatibility issues exist with Codex in regard to the U.S. tolerances discussed in this review.

C. Conditions

The registration of flucarbazone-sodium will be time-limited and conditioned upon submission of a revised method and additional residue data for wheat commodities that measure all of the metabolites of concern. In addition, the registrant must submit a 28–day rat inhalation study and additional storage stability data.

V. Conclusion

Therefore, time-limited tolerances are established for combined residues of flucarbazone-sodium, 4,5-dihydro-3-methoxy-4-methyl-5-oxo-*N*-[[2(trifluoromethoxy)phenyl] sulfonyl]-1H-1,2,4-triazole 1-carboxamide, sodium salt) and its *N*-desmethyl metabolite in or on wheat, forage at 0.30 ppm; wheat, grain at 0.01 ppm; wheat, hay at 0.10 ppm; and wheat, straw at 0.05 ppm; and combined residues of flucarbazone-sodium and its metabolites converted to 2-(trifluoromethoxy)benzene sulfonamide and calculated as flucarbazone-sodium in or on milk at 0.005 ppm; meat and meat byproducts (excluding liver) of cattle, goats, hogs, horses and sheep at 0.01 ppm; and liver of cattle, goats, hogs, horses and sheep at 1.5 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 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–301052 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 November 28, 2000.

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, 1200 Pennsylvania Ave., NW., Washington, DC 20460. You may also deliver your request to the Office of the Hearing Clerk in Rm. C400, 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, 1200 Pennsylvania Ave., NW., 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, 1200 Pennsylvania Ave., NW., 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 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.2. Mail your copies, identified by docket control number OPP–301052, 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. 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 etermines 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 FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104–4). Nor does it require any prior consultation as specified by Executive Order 13084, entitled *Consultation and Coordination with Indian Tribal Governments* (63 FR 27655, May 19, 1998); special considerations as required by Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994); or require OMB review 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 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. 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 FFDCA section 408(n)(4).

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: September 21, 2000.

Susan B. Hazen,

Acting Director, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180— [AMENDED]

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

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

2. Section 180.562 is added to read as follows:

§ 180.562 Flucarbazone-sodium; tolerances for residues.

(a) *General.* (1) Time-limited tolerances are established for combined residues of the herbicide flucarbazone-sodium, 4,5-dihydro-3-methoxy-4-methyl-5-oxo-*N*-[[2(trifluoromethoxy)phenyl] sulfonyl]-1H-1,2,4-triazole 1-carboxamide, sodium salt) and its *N*-desmethyl metabolite in or on the following food commodities:

Commodity	Parts per million	Expiration/ Revocation Date
Wheat, forage	0.30	11/01/05
Wheat, grain	0.01	11/01/05
Wheat, hay	0.10	11/01/05
Wheat, straw	0.05	11/01/05

(2) Time-limited tolerances are established for combined residues of the herbicide flucarbazone-sodium, 4,5-dihydro-3-methoxy-4-methyl-5-oxo-*N*-[[2(trifluoromethoxy)phenyl] sulfonyl]-1H-1,2,4-triazole 1-carboxamide, sodium salt) and its metabolites converted to 2-(trifluoromethoxy)benzene sulfonamide and calculated as flucarbazone-sodium in or on the following food commodities:

Commodity	Parts per million	Expiration/ Revocation Date
Cattle, liver	1.50	11/01/05
Cattle, mbyp except liver	0.01	11/01/05
Cattle, meat	0.01	11/01/05
Goats, liver	1.50	11/01/05
Goats, mbyp except liver	0.01	11/01/05
Goats, meat	0.01	11/01/05
Hogs, liver	1.50	11/01/05
Hogs, mbyp except liver	0.01	11/01/05
Hogs, meat	0.01	11/01/05
Horses, liver	1.50	11/01/05
Horses, mbyp except liver	0.01	11/01/05
Horses, meat	0.01	11/01/05
Milk	0.005	11/01/05
Sheep, liver	1.50	11/01/05
Sheep, mbyp except liver	0.01	11/01/05
Sheep, meat	0.01	11/01/05

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

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

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

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–301063; FRL–6744–8]

RIN 2070–AB78

Triallate,(S-2,3,3-trichloroallyl diisopropylthiocarbamate); Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a tolerance for the combined residues of the herbicide triallate (*S*-2,3,3, trichloroallyl diisopropylthiocarbamate) and its metabolite, TCPSA (2,3,3-trichloroprop-2-ene sulfonic acid) in or on sugar beet, root; sugar beet, top; and sugar beet, pulp. Monsanto requested this tolerance under the Federal Food, Drug, and Cosmetic Act, as amended by the Food Quality Protection Act of 1996.

DATES: This regulation is effective September 29, 2000.Objections and requests for hearings, identified by docket control number OPP–301063, must be received by EPA on or before November 28, 2000.

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 VI. of the **SUPPLEMENTARY INFORMATION.** To ensure proper receipt by EPA, your objections and hearing requests must identify docket control number OPP–301063 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: James A. Tompkins (PM 25), Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: 703 305–5697; and e-mail address: Tompkins.Jim @epamail.epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be 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 codes	Examples of potentially affected entities
Industry	111 112 311 32532	Crop production Animal production Food manufacturing 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, '' ''Regulations and Proposed Rules,'' 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/. To access the OPPTS Harmonized Guidelines referenced in this document, go directly to the guidelines at http://www.epa.gov/opptsfrs/home/guidelin.htm.

2. *In person.* The Agency has established an official record for this action under docket control number OPP–301063. 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

In the **Federal Register** of May 16, 1997 (62 FR 27027) (FRL–5717–6), EPA issued a notice pursuant to section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a as amended by the Food Quality Protection Act of 1996 (FQPA) (Public Law 104–170) announcing the filing of a pesticide petition (PP 8F2128) for tolerance by Monsanto, 600 13th St., NW., Suite 660, Washington, DC 20005. This notice included a summary of the petition prepared by Monsanto, the registrant. There were no comments received in response to the notice of filing.

The petition requested that 40 CFR 180.314 be amended by establishing a tolerance for residues of the herbicide triallate, and its metabolite, TCPSA in or on sugar beet root at 0.01 part per million (ppm), sugar beet top at 0.5 ppm, and sugar beet pulp at 0.2 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) defines ''safe '' to mean that ''there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to ''ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue.... ''

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. For