to the Chief Counsel for Advocacy of the Small Business Administration.

B. Executive Order 12875

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

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

C. Executive Order 13084

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

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

IX. Submission to Congress and the Comptroller General

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

List of Subjects in 40 CFR Part 180

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

Dated: April 2, 1999.

Donald Stubbs,

Acting Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

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

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

2. In §180.532, by revising paragraph (b) to read as follows:

§180.532 Cyprodinil; tolerances for residues.

* * * * *

(b) *Section 18 emergency exemptions.* Time-limited tolerances are established for residues of the fungicide cyprodinil (4-cyclopropyl-6-methyl-*N*-phenyl-2-pyrimidinamine) in connection with use of the pesticide under section 18 emergency exemptions granted by EPA. The tolerances will expire and are revoked on the dates specified in the following table:

Commodity	Parts per million	Expiration/ revocation date
Strawberries	5.0	5/31/00

* * * * *

[FR Doc. 99–9059 Filed 4-13-99; 8:45 am]
BILLING CODE 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300829; FRL 6072–2]

RIN 2070–AB78

Fluthiacet-methyl; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a tolerance for residues of fluthiacet-methyl in or on soybean seed. Novartis Crop Protection, Inc. 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 April 14, 1999. Objections and requests for hearings must be received by EPA on or before June 14, 1999.

ADDRESSES: Written objections and hearing requests, identified by the docket control number, [OPP–300829], must be submitted to: Hearing Clerk (1900), Environmental Protection Agency, Rm. M3708, 401 M St., SW., Washington, DC 20460. Fees accompanying objections and hearing requests shall be labeled ''Tolerance Petition Fees'' and forwarded to: EPA Headquarters Accounting Operations Branch, OPP (Tolerance Fees), P.O. Box 360277M, Pittsburgh, PA 15251. A copy of any objections and hearing requests filed with the Hearing Clerk identified by the docket control number, [OPP–300829], must also be submitted to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring a copy of objections and hearing requests to Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA.

A copy of objections and hearing requests filed with the Hearing Clerk may be submitted electronically by sending electronic mail (e-mail) to: opp-

docket@epa.gov. Copies of objections and hearing requests must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Copies of objections and hearing requests will also be accepted on disks in WordPerfect 5.1/6.1 or ASCII file format. All copies of objections and hearing requests in electronic form must be identified by the docket control number [OPP–300829]. No Confidential Business Information (CBI) should be submitted through e-mail. Electronic copies of objections and hearing requests on this rule may be filed online at many Federal Depository Libraries.

FOR FURTHER INFORMATION CONTACT: By mail: James A. Tompkins, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number, and e-mail address: Rm. 239, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, 703–305–5697; tompkins.jim@epa.gov.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of March 26, 1997 (62 FR 14426) (FRL–5595–6), 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) (Pub. L. 104–170) announcing the filing of a pesticide petition (PP) 6F4614, for tolerance by Novartis Crop Protection, Inc., P.O. Box 18300, Greensboro, NC 27419. This notice included a summary of the petition prepared by Novartis Crop Protection, Inc., 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 a tolerance for residues of the herbicide, fluthiacet-methyl, acetic acid [[2-chloro-4-fluoro-5-[(tetrahydro-3-oxo-1*H*,3*H*-[1,3,4]thiadiazolo[3,4-α]pyridazin-1-ylidene)amino]phenyl]thio]-methyl ester, in or on soybeans at 0.01 part per million (ppm).

I. Background and Statutory Findings

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

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

II. Aggregate Risk Assessment and Determination of Safety

Consistent with section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of fluthiacet-methyl and to make a determination on aggregate exposure, consistent with section 408(b)(2), for a tolerance for residues of fluthiacet-methyl on soybean seed at 0.01 ppm. EPA's assessment of the dietary exposures and risks associated with establishing the tolerance follows.

A. Toxicological Profile

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

1. A rat acute oral study with a LD_{50} greater than (>) 5,000 milligrams (mg)/kilogram (kg) for males and females.

2. A 90-day rat feeding study with a no observed adverse effect level (NOAEL) of 100 ppm 6.19 mg/kg/day for males and 6.80 mg/kg/day for females and a lowest observed adverse effect level (LOAEL) of 3,500 ppm 216 mg/kg/day for males and 249 mg/kg/day for females based on decreased body weight gains as well as effects on hematology, clinical chemistry, urinalysis parameters, liver weights and microscopic pathology.

3. A 90-day mouse feeding study with a NOAEL of 10 ppm (1.3 mg/kg/day for males and 1.6 mg/kg/day for females) and a LOAEL of 500 ppm (66 mg/kg/day for males and 83 mg/kg/day for females) based on effects on the erythropoietic system and the liver.

4. A 6-week dog dietary study with a NOAEL of 236 mg/kg/day for males and 77.7 mg/kg/day for females and a LOAEL of 709 mg/kg/day for males and 232 mg/kg/day for females based on decreased body weight gain.

5. A 28-day rat dermal study with a NOAEL of 1,000 mg/kg/day, the highest dose tested (HDT).

6. A 1-year dog chronic feeding study with a NOAEL of 57.6 mg/kg/day in males and 30.3 mg/kg/day for females and a LOAEL of 582 mg/kg/day for males and 145 mg/kg/day for females based on effects observed in the erythropoietic system and the liver.

7. A rat chronic feeding/carcinogenicity study with a NOAEL for systemic toxicity of 50 ppm (2.1 mg/kg/day in males and 2.5 mg/kg/day in females) and a LOAEL for systemic toxicity of 3,000 ppm (130 mg/kg/day in males and 154 mg/kg/day in females) based on decreased body weights, liver toxicity, pancreatic toxicity and microcytic anemia in males; and liver toxicity, uterine toxicity and slight microcytic anemia in females. In males only at 3,000 and 5,000 ppm (130 and 219 mg/kg/day, respectively) there was an increase in the trend toward pancreatic exocrine adenomas and pancreatic islet cell adenomas.

8. A mouse carcinogenicity study with a NOAEL for systemic toxicity of 1 ppm (0.1 mg/kg/day in males and females) and a LOAEL for systemic toxicity of 10 ppm (1.0 mg/kg/day in males and 1.2 mg/kg/day in females) based on non-neoplastic liver findings. In males (and possibly females) at 100 (10 mg/kg/day for males and 12 mg/kg/day for females) and 300 ppm (32 mg/kg/day for males and 37 mg /kg/day for females) there was an increase in the number of mice with hepatocellular adenomas, carcinomas and/or adenomas/carcinomas.

9. A 2-generation rat reproduction study with a parental systemic NOAEL of 25 ppm (1.59 mg/kg/day for males and 1.73 mg/kg/day for females) and a systemic LOAEL of 500 ppm (31.8 mg/kg/day for males and 35.2 mg/kg/day for females) based on reduction in male body weights/gains and hepatic pathology; and the reproductive NOAEL of 500 ppm (31.8 mg/kg/day for males and 37.1 mg/kg/day for females) and the reproductive LOAEL of 5,000 ppm (313 mg/kg/day for males and 388 mg/kg/day for females) based on decreases in mean litter body weights.

10. A rat developmental study with a maternal NOAEL and reproductive NOAEL equal to or greater than 1,000 mg/kg/day HDT.

11. A rabbit developmental study with a maternal and developmental NOAEL of 1,000 mg/kg/day HDT and with a developmental NOAEL of 300 mg/kg/day and with a developmental LOAEL of 1,000 mg/kg/day based on slight non-significant increased incidence of irregularly shaped sternebrae attributed to a delay in fetal development.

12. An acute rat neurotoxicity study with a NOAEL of 2,000 mg/kg HDT.

13. A rat subchronic neurotoxicity study with a systemic NOAEL of 10 ppm (0.576 mg/kg/day) in males and 20,000 ppm (1,354 mg/kg/day), HDT in females and a systemic LOAEL of 10,000 (556 mg/kg/day) in males based on decreased body weight and food consumption and with a neurotoxicity NOAEL of 20,000 ppm (1,128 mg/kg/day for males and 1,354 mg/kg/day for females), HDT.

14. Fluthiacet-methyl was negative for mutagenic/genotoxic effects in bacterial or cultured mammalian cells and did not cause DNA damage in bacterial or primary rat hepatocytes. *In vitro* cytogenetic assays performed with two different mammalian cell lines demonstrated that fluthiacet-methyl is clastogenic both in the presence and absence of S9 activation. Although the test substance is negative for micronuclei induction in mouse bone marrow, a significant increase in micronuclei is seen in stimulated rat liver cells following *in vivo* exposure.

15. Based on the results of the rat metabolism studies, fluthiacet-methyl was absorbed rapidly at both the low and high dose for both male and female rats. Repeated oral dosing had no effect on extent of absorption. Tissue levels of ^{14}C-fluthiacet-methyl derived radioactivity in the single and repeated low dose groups did not exceed 0.018 ppm for any tissue. At the single high dose, female rats showed higher levels of ^{14}C-fluthiacet-methyl derived radioactivity in tissues than males except for muscle, brain, fat and plasma. Excretion in males was predominantly in feces for all dose groups, with between 67–87% of administered radioactivity excreted by this route. In females, the percentage of administered radioactivity in urine across all dose groups 40–48% was approximately equivalent to the percent excreted in feces 39–52%. The greater fecal excretion in males was based on a greater percentage excretion in bile for males 37% vs. females 19%.

B. Toxicological Endpoints

1. *Acute toxicity*. EPA could not identify any toxicological effects that could be attributable to a single oral exposure (dose) in any of the available toxicological studies.

2. *Short- and intermediate-term toxicity*. EPA could not identify any toxicological effects that could be attributable to short- or intermediate-term dietary exposure .

3. *Chronic toxicity*. EPA has established the RfD for fluthiacet-methyl at 0.001 mg/kg/day. This Reference Dose (RfD) is based on the NOAEL of 0.1 mg/kg/day in the mouse carcinogenicity study and using an uncertainty factor of 100 (10x for inter-species extrapolation, 10x for intra-species variability). The LOAEL in this study, 1.0 and 1.2 mg/kg/day for males and females, respectively, was based on non-neoplastic liver findings (centrilobular necrosis, centrilobular cell degeneration, histiocytic pigmentation and karyomegaly).

4. *Carcinogenicity*. The Health Effects Division Cancer Assessment Review Committee has classified fluthiacet-methyl in accordance with the Agency's *Proposed Guidelines for Carcinogen Risk Assessment* (April 10, 1996) as ''likely to be a human carcinogen.'' Evidence for carcinogenicity was demonstrated by the presence of pancreatic tumors (exocrine adenomas, islet cell adenomas and combined islet cell adenomas + carcinomas) in male rats and liver tumors (adenomas and combined adenomas + carcinomas) in male and female mice. The Committee recommended a linear low-dose approach (Q_1*) for human characterization and determined that extrapolation should be based on the combined hepatocellular tumors (adenomas and carcinomas) in male mice.

C. Exposures and Risks

1. *From food and feed uses.* The proposed tolerance in or on the raw agricultural commodity: soybean seed at 0.01 ppm is the first to be established for residues of the herbicide, fluthiacet-methyl, acetic acid, [[2-chloro-4-fluoro-5-[(tetrahydro-3-oxo-1*H*,3*H*-[1,3,4]thiadiazolo[3,4-α]pyridazin-1-ylidene)amino]phenyl]thio]-methyl ester. There is no reasonable expectation of residues of fluthiacet-methyl occurring in meat, milk, poultry, or eggs from its use on soybeans. Risk assessments were conducted by EPA to assess dietary exposures from fluthiacet-methyl as follows:

Section 408(b)(2)(F) states that the Agency may use data on the actual percent of food treated (PCT) for assessing chronic dietary risk only if the Agency can make the following findings: That the data used are reliable and provide a valid basis to show what percentage of the food derived from such crop is likely to contain such pesticide residue; that the exposure estimate does not underestimate exposure for any significant subpopulation group; and if data are available on pesticide use and food consumption in a particular area, the exposure estimate does not understate exposure for the population in such area. In addition, the Agency must provide for periodic evaluation of any estimates used. To provide for the periodic evaluation of the estimate of percent of crop treated as required by the section 408(b)(2)(F), EPA may require registrants to submit data on PCT.

The Agency used PCT information as follows:

A chronic exposure analysis for soybeans was conducted assuming 25% of the soybean crop is treated. EPA estimates that 25% of the total soybeans crop acres will not be exceeded by this new broadleaf herbicide within the next 5 years.

The Agency believes that the three conditions, discussed in section 408 (b)(2)(F) in this unit concerning the Agency's responsibilities in assessing chronic dietary risk findings, have been met. EPA finds that the PCT information is reliable and has a valid basis. Before the petitioner can increase production of product for treatment of greater than 25% of total soybean acres, permission from the Agency must be obtained. The regional consumption information and consumption information for significant subpopulations is taken into account through EPA's computer-based model for evaluating the exposure of significant subpopulations including several regional groups. Use of this consumption information in EPA's risk assessment process ensures that EPA's exposure estimate does not understate exposure for any significant subpopulation group and allows the Agency to be reasonably certain that no regional population is exposed to residue levels higher than those estimated by the Agency. Other than the data available through national food consumption surveys, EPA does not have available information on the consumption of food bearing fluthiacet-methyl in a particular area.

i. *Acute exposure and risk*. EPA could not identify any toxicological effects that could be attributable to a single oral exposure (dose) in any of the available

toxicological studies. This risk assessment is not needed.

ii. *Chronic exposure and risk.* The Reference Dose (RfD) for fluthiacet-methyl is 0.001 mg/kg/day. This value is based on the systemic NOAEL of 0.1 mg/kg/day in the mouse carcinogenicity study with a 100-fold safety factor to account for interspecies extrapolation (10x) and intraspecies variability (10x).

A Dietary Exposure Evaluation Model (DEEM) chronic exposure analysis was conducted using tolerance levels for soybeans assuming that 25% of the crop is treated to estimate dietary exposure for the general population and 22 subgroups. The chronic analysis showed that exposures from the tolerance level residues in or on soybeans for non-nursing infants less than 1 years old (the subgroup with the highest exposure) would be 0.6% of the RfD. The exposure for the general U.S. population would be 0.1% of the RfD.

A lifetime dietary carcinogenicity exposure analysis was conducted for fluthiacet-methyl using the proposed tolerances along with the assumption of 25 percent of the crop treated and a Q* of 2.07×10^{-1} $(mg/kg/day)^{-1}$. A lifetime risk exposure analysis was also conducted using the DEEM computer analysis. The estimated cancer risk (2.06×10^{-7}) is less than the level that the Agency usually considers negligible for cancer risk estimates.

2. *From drinking water.* Drinking water estimated concentrations (DWECs) for surface water were calculated by generic expected environmental concentration (GENEEC) computer models to be an average of 0.3 parts per billion (ppb). The DWECs for ground water based on the computer model screening concentration in ground water (SCI-GROW) were calculated to be an average of 0.002 ppb.

3. *From non-dietary exposure.* There are no non-food uses of fluthiacet-methyl currently registered under the Federal Insecticide, Fungicide and Rodenticide Act, as amended. No non-dietary exposures are expected for the general population.

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

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

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

1. *Acute risk.* EPA could not identify any toxicological effects that could be attributable to a single oral exposure (dose) in any of the available toxicological studies.

2. *Chronic risk.* Using the DEEM chronic exposure assumptions described in this unit, EPA has concluded that aggregate exposure to fluthiacet-methyl from food will utilize 0.1% of the RfD for the U.S. population. The major identifiable subgroup with the highest aggregate exposure, non-nursing infants less than 1 year old, utilize 0.6% of the RfD. EPA generally has no concern for exposures below 100% of the RfD because the RfD represents the level at or below which daily aggregate exposure over a lifetime will not pose appreciable risks to human health. The drinking water level of comparisons (DWLOCs) for chronic exposure to fluthiacet-methyl in drinking water calculated for the U.S. population was 35 ppb and for non-nursing infants less than 1 year old the DWLOC was 10 ppb. The estimated average concentration in surface water for fluthiacet-methyl is 0.3 ppb and for ground water is 0.002 ppb. EPA's chronic drinking water levels of comparison are well above the estimated exposures for fluthiacet-methyl in water for the U.S. population and the subgroup of concern. Conservative model estimates (GENEEC and SCI-GROW) of the concentrations of fluthiacet-methyl in surface and ground water indicate that exposure will be minimal.

3. *Short- and intermediate-term risk.* EPA could not identify any toxicological effects that could be attributable to short or intermediate-term dermal or inhalation exposure. No systemic effects were observed in available dermal studies. In addition, no endpoints for short or intermediate-term exposure could be identified from available oral studies. A short- and intermediate-term risk assessment is not needed.

4. *Aggregate cancer risk for U.S. population—combined food and water.* A lifetime dietary carcinogenicity exposure analysis for fluthiacet-methyl estimated the cancer risk to be 2.06×10^{-7}, a level that the Agency usually considers negligible for cancer risk estimates. A DWLOC for cancer was calculated as 0.133 ppb. The estimated concentration in surface water and groundwater for fluthiacet-methyl for chronic exposure are 0.1 ppb (0.3 ppb (the 56-day concentration)/3) and 0.002 ppb, respectively. The model exposure estimates are less than the cancer DWLOC.

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

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

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

FFDCA section 408 provides that EPA shall apply an additional tenfold margin of safety for infants and children in the case of threshold effects to account for pre- and post-natal toxicity and the completeness of the database unless EPA determines that a different margin of safety will be safe for infants and children. Margins of safety are incorporated into EPA risk assessments either directly through use of a margin of exposure (MOE) analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans. EPA believes that reliable data support using the standard uncertainty factor (usually 100 for combined inter- and intra-species variability) and not the additional tenfold MOE/uncertainty factor when EPA has a complete data base under existing guidelines and when the severity of the effect in infants or children or the potency or unusual

toxic properties of a compound do not raise concerns regarding the adequacy of the standard MOE/safety factor.

In the prenatal developmental study with rabbits, *in utero* exposure did not result in maternal toxicity at 1,000 mg/kg/day. Developmental toxicity, however, was seen at this dose as a non-statistical increase in irregular sternebrae (an effect attributed to a delay in fetal development, a variation which is reversible). The occurrence of developmental toxicity at a dose at which no maternal toxicity was noted indicates an apparent susceptibility. EPA; however, determined that the apparent susceptibility is not convincing for the following reasons:

a. The increased incidence of irregular sternebrae was not statistically significant when compared to concurrent controls.

b. The increase occurred primarily at the limit-dose (1,000 mg/kg/day).

c. It was the only anomaly observed in the study (i.e., a single variation).

d. The dose response was not strong since there was only a small increase in the litter incidences between the low-dose (5 mg/kg/day) and the high-dose (1,000 mg/kg/day), with the mid- and high-dose groups having 8 litters with this variation.

e. This endpoint is considered appropriate to establish a LOAEL, but not appropriate for risk assessments.

Based on these factors, the Agency concluded that there is no increased susceptibility in the rabbit study.

The Agency concluded that an extra safety factor to protect infants and children is not needed based on the following considerations:

The available hazard assessment studies indicated no increased susceptibility of rats or rabbits to *in utero* and/or postnatal exposure to fluthiacet-methyl, and exposure assessments do not indicate a concern for potential risk to infants and children, based upon the very low application rates and quick dissipation of fluthiacet-methyl; the dietary exposure estimates using field study data result in an overestimate of dietary exposure; modeling data are used for ground and surface source drinking water exposure assessments resulting in estimates considered to be upper-bound concentrations; and there are currently no registered residential uses for fluthiacet-methyl.

2. *Conclusion*. There is a complete toxicity database for fluthiacet-methyl and exposure data is complete or is estimated based on data that reasonably accounts for potential exposures.

III. Other Considerations

A. Metabolism In Plants and Animals

The nature of the residue in soybeans, rotational crops, and livestock is adequately understood. The residues of concern for the tolerance expression are parent per se. Based on the results of animal metabolism studies it is unlikely that secondary residues would occur in animal commodities from the use of fluthiacet-methyl on soybeans.

B. Analytical Enforcement Methodology

Adequate enforcement methodology (gas-liquid chromatography) is available to enforce the tolerance expression. The method may be requested from: Calvin Furlow, PIRIB, IRSD (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location and telephone number: Rm 101FF, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, (703) 305–5229.

C. Magnitude of Residues

Based on the results of animal metabolism studies it is unlikely that significant residues would occur in secondary animal commodities from the use of fluthiacet-methyl on soybeans. Residues of fluthiacet-methyl in all treated and untreated samples of soybeans, hulls, meal, crude oil, refined oil and aspirated grain fractions were less than the method level of quantification (LOQ). The nature of the residue in plants is adequately understood for the purposes of these tolerances

D. International Residue Limits

There are no Codex Alimentarius Commission (Codex), Canadian, or Mexican Maximum Residue Levels (MRLs) for fluthiacet-methyl at this time.

E. Rotational Crop Restrictions

No tolerances for inadvertent residues of fluthiacet-methyl are required in rotational crops.

IV. Conclusion

Therefore, the tolerance is established for residues of fluthiacet-methyl in soybeans seeds at 0.01 ppm.

V. Objections and Hearing Requests

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

Any person may, by June 14, 1999, file written objections to any aspect of this regulation and may also request a hearing on those objections. Objections and hearing requests must be filed with the Hearing Clerk, at the address given under the ''ADDRESSES'' section (40 CFR 178.20). A copy of the objections and/or hearing requests filed with the Hearing Clerk should be submitted to the OPP docket for this regulation. The objections submitted must specify the provisions of the regulation deemed objectionable and the grounds for the objections (40 CFR 178.25). Each objection must be accompanied by the fee prescribed by 40 CFR 180.33(i). EPA is authorized to waive any fee requirement ''when in the judgement of the Administrator such a waiver or refund is equitable and not contrary to the purpose of this subsection.'' For additional information regarding tolerance objection fee waivers, contact James Tompkins, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number, and e-mail address: Rm. 239, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, (703) 305–5697, tompkins.jim@epa.gov. Requests for waiver of tolerance objection fees should be sent to James Hollins, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460.

If a hearing is requested, the objections must include a statement of the factual issues on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the requestor (40 CFR 178.27). A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established, resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issues in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32). Information submitted in connection

with an objection or hearing request may be claimed confidential by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the information that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice.

VI. Public Record and Electronic Submissions

EPA has established a record for this regulation under docket control number [OPP–300829] (including any comments and data submitted electronically). A public version of this record, including printed, paper versions of electronic comments, which does not include any information claimed as CBI, is available for inspection from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The public record is located in Room 119 of the Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA.

Objections and hearing requests may be sent by e-mail directly to EPA at:
opp-docket@epa.gov.

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

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

VII. Regulatory Assessment Requirements

A. Certain Acts and Executive Orders

This final rule establishes a tolerance under section 408(d) of the FFDCA in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Pub. L. 104–4). Nor does it require any prior consultation as specified by Executive Order 12875, entitled *Enhancing the Intergovernmental Partnership* (58 FR 58093, October 28, 1993), or special considerations as required by Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994), or require OMB review in accordance with Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997).

In addition, since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerance/exemption in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply. Nevertheless, the Agency previously assessed whether establishing tolerances, exemptions from tolerances, raising tolerance levels or expanding exemptions might adversely impact small entities and concluded, as a generic matter, that there is no adverse economic impact. The factual basis for the Agency's generic certification for tolerance actions published on May 4, 1981 (46 FR 24950), and was provided to the Chief Counsel for Advocacy of the Small Business Administration.

B. Executive Order 12875

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

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

C. Executive Order 13084

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

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

VIII. Submission to Congress and the Comptroller General

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the Agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and the Comptroller General of the United States. EPA will submit a report containing this rule and other

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

List of Subjects in 40 CFR Part 180

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

Dated: March 31, 1999.

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 180.551 is added to read as follows.

§180.551 Fluthiacet-methyl; tolerances for residues.

(a) *General.* A tolerance is established for residues of the herbicide, fluthiacet-methyl, acetic acid [[2-chloro-4-fluoro-5-[(tetrahydro-3-oxo-1*H*,3*H*-[1,3,4]thiadiazolo[3,4-α]pyridazin-1-ylidene)amino]phenyl]thio]-methyl ester, in or on the food commodity:

Commodity	Parts per million
Soybean seed	0.01

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

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

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

[FR Doc. 99–9057 Filed 4–13–99; 8:45 am]
BILLING CODE 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300831; FRL–6072–3]

RIN 2070–AB78

Cyromazine; Extension of Tolerance for Emergency Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation extends a time-limited tolerance for combined residues of the insecticide cyromazine and its metabolites in or on lima beans at 5.0 part per million (ppm) for an additional 2–year period.This tolerance will expire and is revoked on December 31, 2001. This action is in response to EPA's granting of an emergency exemption under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) authorizing use of the pesticide on lima beans. Section 408(l)(6) of the Federal Food, Drug, and Cosmetic Act requires EPA to establish a time-limited tolerance or exemption from the requirement for a tolerance for pesticide chemical residues in food that will result from the use of a pesticide under an emergency exemption granted by EPA under FIFRA section 18.

DATES: This regulation becomes effective April 14, 1999. Objections and requests for hearings must be received by EPA, on or before June 14, 1999.

ADDRESSES: Written objections and hearing requests, identified by the docket control number [OPP–300831], must be submitted to: Hearing Clerk (1900), Environmental Protection Agency, Rm. M3708, 401 M St., SW., Washington, DC 20460. Fees accompanying objections and hearing requests shall be labeled ''Tolerance Petition Fees'' and forwarded to: EPA Headquarters Accounting Operations Branch, OPP (Tolerance Fees), P.O. Box 360277M, Pittsburgh, PA 15251. A copy of any objections and hearing requests filed with the Hearing Clerk identified by the docket control number, [OPP–300831], must also be submitted to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring a copy of objections and hearing requests to Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA.

A copy of objections and hearing requests filed with the Hearing Clerk may also be submitted electronically by sending electronic mail (e-mail) to: opp-docket@epa.gov. Copies of electronic objections and hearing requests must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Copies of objections and hearing requests will also be accepted on disks in WordPerfect 5.1/6.1 or ASCII file format. All copies of electronic objections and hearing requests must be identified by the docket control number [OPP-300831]. No Confidential Business Information (CBI) should be submitted through e-mail. Copies of electronic objections and hearing requests on this rule may be filed online at many Federal Depository Libraries.

FOR FURTHER INFORMATION CONTACT: By mail: Andrew Ertman, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number, and e-mail address: Rm. 280, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, (703) 308–9367; ertman.andrew@epa.gov.

SUPPLEMENTARY INFORMATION: EPA issued a final rule, published in the **Federal Register** of December 10, 1997 (62 FR 65030) (FRL–5758–2), which announced that on its own initiative under section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(e) and (l)(6), as amended by the Food Quality Protection Act of 1996 (FQPA) (Pub. L. 104–170) it established a time-limited tolerance for the combined residues of cyromazine and its metabolites in or on lima beans at 5.0 ppm, with an expiration date of December 31, 1998. EPA established the tolerance because section 408(l)(6) of the FFDCA requires EPA to establish a time-limited tolerance or exemption from the requirement for a tolerance for pesticide chemical residues in food that will result from the use of a pesticide under an emergency exemption granted by EPA under FIFRA section 18. Such tolerances can be established without providing notice or period for public comment.

EPA received a request to extend the use of cyromazine on lima beans for this years growing season due to the continuing emergency situation in California. Insect pressure from the leafminer has increased over the past several years due to the rapid increase in the insect's resistance to currently registered insecticides and the resulting increase in insect populations. With the end of the California drought, overwintering has occurred in leafminer populations and mild weather has added to the resistance population with outbreaks increasing in the summer and carrying through the end of the harvest season.

The damage caused by the leafminer in lima beans begins in the leaf tissue of the plant. The adult leafminers lay eggs in the leaf tissue, and then the eggs hatch and the larvae eat the leaf tissue underneath the epidermis and cuticle, leaving tracks or mines. These mines damage or kill the plant leaf, which in