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 special 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, under the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 et seq.), 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.

VI. Submission to Congress and the General Accounting Office

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).

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, 1998.

Stephen L. Johnson,

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. 346a and 371.

2. Section 180.222 is amended as follows:

i. By adding a heading to paragraph (a).

ii. By alphabetically adding the raw agricultural commodity ''carrots'' to the table in paragraph (a).

iii. By designating the text in paragraph (b) as paragraph (c), and adding a heading to newly designated paragraph (c).

iv. By adding and reserving with headings new paragraphs (b) and (d).

The additions read as follows:

§ 180.222 Prometryn; tolerances for residues.

(a) *General.* * * *

Commodity	Parts per million
Carrots[1]	0.1

* * * *

[1] There are no U.S. registrations as of April 10, 1998 for use on carrots.

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

(c) *Tolerances with regional registrations.* * * *

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

[FR Doc. 98–9548 Filed 4–9–98; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300636; FRL–5782–9]

RIN 2070–AB78

N-(4-fluorophenyl)-N-(1-methylethyl)-2-[[5-(trifluoromethyl)-1,3,4-thiadiazol-2-yl]oxy]acetamide; Time-Limited Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a time-limited tolerances for the combined residues of the herbicide *N*-(4-fluorophenyl)-*N*-(1-methylethyl)-2-[[5-(trifluoromethyl)-1,3,4-thiadiazol-2-yl]oxy]acetamide and its metabolites containing the 4-fluoro-*N*-methylethyl benzenamine moiety [hereafter referred to as flufenacet, the proposed common chemical name] in or on certain raw agricultural commodities. Bayer Corporation requested this tolerance under the Federal Food, Drug and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (Pub. L. 104–70). The tolerance will expire on April 30, 2003.

DATES: This regulation is effective April 10, 1998. Objections and requests for hearings must be received by EPA on or before June 9, 1998.

ADDRESSES: Written objections and hearing requests, identified by the docket control number, [OPP–300636], 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–300636], 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, CM #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@epamail.epa.gov. Copies of objections and hearing requests must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Copies of objections and hearing requests will also be accepted on disks in WordPerfect 5.1/6.1 file format or ASCII file format. All copies of objections and hearing requests in electronic form must be identified by the docket control number [OPP–300636]. 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: Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, (703) 305–5697, e-mail: tompkins.jim@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of April 2, 1997 (62 FR 15690)(5593–9), EPA issued a notice pursuant to section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(e) announcing the filing of a pesticide petition (PP 6F4631) for

tolerances by Bayer Corporation, P.O. Box 4913, Kansas City, MO 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, FOE 5043, *N*-(4-fluorophenyl)-*N*-(1-methylethyl)-2-[[5-(trifluoromethyl)-1,3,4-thiadiazol-2-yl]oxy]acetamide in or on field corn grain at 0.05 parts per million (ppm), field corn forage at 0.4 ppm, field corn stover (fodder) at 0.4 ppm, soybean seed at 0.1 ppm, milk at 0.01 ppm, meat at 0.05 ppm, and meat by-products at 0.05 ppm. Bayer subsequently amended the petition by deleting the proposed milk, meat and meat by-products tolerances. The tolerance expression is also being editorially amended to read: *N*-(4-fluorophenyl)-*N*-(1-methylethyl)-2-[[5-(trifluoromethyl)-1,3,4-thiadiazol-2-yl]oxy]acetamide and its metabolites containing the 4-fluoro-*N*-methylethyl benzenamine moiety. The tolerances will expire and will be revoked on April 30, 2003.

I. Risk Assessment and Statutory Findings

New 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. First, EPA determines the toxicity of pesticides based primarily on toxicological studies using laboratory animals. These studies address many adverse health effects, including (but not limited to) reproductive effects, developmental toxicity, toxicity to the nervous system, and carcinogenicity. Second, EPA examines exposure to the pesticide through the diet (e.g., food and drinking water) and through exposures that occur as a result of pesticide use in residential settings.

A. Toxicity

1. *Threshold and non-threshold effects.* For many animal studies, a dose response relationship can be determined, which provides a dose that causes adverse effects (threshold effects) and doses causing no observed effects (the ''no-observed effect level'' or ''NOEL'').

Once a study has been evaluated and the observed effects have been determined to be threshold effects, EPA generally divides the NOEL from the study with the lowest NOEL by an uncertainty factor (usually 100 or more) to determine the Reference Dose (RfD). The RfD is a level at or below which daily aggregate exposure over a lifetime will not pose appreciable risks to human health. An uncertainty factor (sometimes called a ''safety factor'') of 100 is commonly used since it is assumed that people may be up to 10 times more sensitive to pesticides than the test animals, and that one person or subgroup of the population (such as infants and children) could be up to 10 times more sensitive to a pesticide than another. In addition, EPA assesses the potential risks to infants and children based on the weight of the evidence of the toxicology studies and determines whether an additional uncertainty factor is warranted. Thus, an aggregate daily exposure to a pesticide residue at or below the RfD (expressed as 100 percent or less of the RfD) is generally considered acceptable by EPA. EPA generally uses the RfD to evaluate the chronic risks posed by pesticide exposure. For shorter term risks, EPA calculates a margin of exposure (MOE) by dividing the estimated human exposure into the NOEL from the appropriate animal study. Commonly, EPA finds MOEs lower than 100 to be unacceptable. This hundredfold MOE is based on the same rationale as the hundredfold uncertainty factor.

Lifetime feeding studies in two species of laboratory animals are conducted to screen pesticides for cancer effects. When evidence of increased cancer is noted in these studies, the Agency conducts a weight of the evidence review of all relevant toxicological data including short-term and mutagenicity studies and structure activity relationship. Once a pesticide has been classified as a potential human carcinogen, different types of risk assessments (e.g., linear low dose extrapolations or MOE calculation based on the appropriate NOEL) will be carried out based on the nature of the carcinogenic response and the Agency's knowledge of its mode of action.

2. *Differences in toxic effect due to exposure duration.* The toxicological effects of a pesticide can vary with different exposure durations. EPA considers the entire toxicity data base, and based on the effects seen for different durations and routes of exposure, determines which risk assessments should be done to assure that the public is adequately protected from any pesticide exposure scenario. Both short and long durations of exposure are always considered. Typically, risk assessments include ''acute,'' ''short-term,'' ''intermediate term,'' and ''chronic'' risks. These assessments are defined by the Agency as follows.

Acute risk, by the Agency's definition, results from 1–day consumption of food and water, and reflects toxicity which could be expressed following a single oral exposure to the pesticide residues. High end exposure to food and water residues are typically assumed.

Short-term risk results from exposure to the pesticide for a period of 1–7 days, and therefore overlaps with the acute risk assessment. Historically, this risk assessment was intended to address primarily dermal and inhalation exposure which could result, for example, from residential pesticide applications. However, since enaction of FQPA, this assessment has been expanded to include both dietary and non-dietary sources of exposure, and will typically consider exposure from food, water, and residential uses when reliable data are available. In this assessment, risks from average food and water exposure, and high-end residential exposure, are aggregated. High-end exposures from all 3 sources are not typically added because of the very low probability of this occurring in most cases, and because the other conservative assumptions built into the assessment assure adequate protection of public health. However, for cases in which high-end exposure can reasonably be expected from multiple sources (e.g. frequent and widespread homeowner use in a specific geographical area), multiple high-end risks will be aggregated and presented as part of the comprehensive risk assessment/characterization. Since the toxicological endpoint considered in this assessment reflects exposure over a period of at least 7 days, an additional degree of conservatism is built into the assessment; i.e., the risk assessment nominally covers 1–7 days exposure,

and the toxicological endpoint/NOEL is selected to be adequate for at least 7 days of exposure. (Toxicity results at lower levels when the dosing duration is increased.)

Intermediate-term risk results from exposure for 7 days to several months. This assessment is handled in a manner similar to the short-term risk assessment.

Chronic risk assessment describes risk which could result from several months to a lifetime of exposure. For this assessment, risks are aggregated considering average exposure from all sources for representative population subgroups including infants and children.

B. Aggregate Exposure

In examining aggregate exposure, FFDCA section 408 requires that EPA take into account available and reliable information concerning exposure from the pesticide residue in the food in question, residues in other foods for which there are tolerances, residues in groundwater or surface water that is consumed as drinking water, and other non-occupational exposures through pesticide use in gardens, lawns, or buildings (residential and other indoor uses). Dietary exposure to residues of a pesticide in a food commodity are estimated by multiplying the average daily consumption of the food forms of that commodity by the tolerance level or the anticipated pesticide residue level. The Theoretical Maximum Residue Contribution (TMRC) is an estimate of the level of residues consumed daily if each food item contained pesticide residues equal to the tolerance. In evaluating food exposures, EPA takes into account varying consumption patterns of major identifiable subgroups of consumers, including infants and children. The TMRC is a ''worst case'' estimate since it is based on the assumptions that food contains pesticide residues at the tolerance level and that 100% of the crop is treated by pesticides that have established tolerances. If the TMRC exceeds the RfD or poses a lifetime cancer risk that is greater than approximately one in a million, EPA attempts to derive a more accurate exposure estimate for the pesticide by evaluating additional types of information (anticipated residue data and/or percent of crop treated data) which show, generally, that pesticide residues in most foods when they are eaten are well below established tolerances.

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 flufenacet and to make a determination on aggregate exposure, consistent with section 408(b)(2), for a time-limited tolerance for combined residues of flufenacet and its metabolites. 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 flufenacet are discussed below.

1. A rat acute oral study with a LD_{50} of 1,617 milligrams (mg)/kilogram (kg) for males and 589 mg/kg for females.

2. A 84–day rat feeding study with a No Observed Effect Level (NOEL) less than 100 ppm [6.0 mg/kg/day] for males and a NOEL of 100 ppm [7.2 mg/kg/day] for females and with a Lowest Observed Effect Level (LOEL) of 100 ppm [6.8 mg/kg/day] for males based on suppression of thyroxine (T4) level and a LOEL of 400 ppm [28.8 mg/kg/day] for females based on hematology and clinical chemistry findings.

3. A 13–week mouse feeding study with a NOEL of 100 ppm [18.2 mg/kg/day for males and 24.5 mg/kg/day for females] and a LOEL of 400 ppm [64.2 mg/kg/day for males and 91.3 mg/kg/day for females] based on histopathology of the liver, spleen and thyroid.

4. A 13–week dog dietary study with a NOEL of 50 ppm [1.70 mg/kg/day for males and 1.67 mg/kg/day for females] and a LOEL of 200 ppm [6.90 mg/kg/day for males and 7.20 mg/kg/day for females] based on evidence that the biotransformation capacity of the liver has been exceeded, (as indicated by increase in LDH, liver weight, ALK and hepatomegaly), globulin and spleen pigment in females, decreased T4 and ALT values in both sexes, decreased albumin in males, and decreased serum glucose in females.

5. A 21–day rabbit dermal study with the dermal irritation NOEL of 1,000 mg/kg/day for males and females and a systemic NOEL of 20 mg/kg/day for males and 150 mg/kg/day for females and a systemic LOEL of 150 mg/kg/day for males and 1,000 mg/kg/day for females based on clinical chemistry data (decreased T4 and FT4 levels in both sexes) and centrilobular hepatocytomegaly in females.

6. A 1–year dog chronic feeding study with a NOEL was 40 ppm [1.29 mg/kg/day in males and 1.14 mg/kg/day in females] and a LOEL of 800 ppm [27.75 mg/kg/day in males and 26.82 mg/kg/day in females] based on increased alkaline phosphatase, kidney, and liver weight in both sexes, increased cholesterol in males, decreased T2, T4 and ALT values in both sexes, and increased incidences of microscopic lesions in the brain, eye, kidney, spinal cord, sciatic nerve and liver.

7. A rat chronic feeding/carcinogenicity study with a NOEL less than 25 ppm [1.2 mg/kg/day in males and 1.5 mg/kg/day in females] and a LOEL of 25 ppm [1.2 mg/kg/day in males and 1.5 mg/kg/day in females] based on methemoglobinemia and multi-organ effects in blood, kidney, spleen, heart, and uterus. Under experimental conditions the treatment did not alter the spontaneous tumor profile.

8. In a mouse carcinogenicity study the NOEL was less than 50 ppm [7.4 mg/kg/day] for males and the NOEL was 50 ppm [9.4 mg/kg/day] for females and the LOEL was 50 ppm [7.4 mg/kg/day] for males and the LOEL was 200 ppm [38.4 mg/kg/day] for females based on cataract incidence and severity. There was no evidence of carcinogenicity for flufenacet in this study.

9. A two-generation rat reproduction study with a parental systemic NOEL of 20 ppm [1.4 mg/kg/day in males and 1.5 mg/kg/day in females] and a reproductive NOEL of 20 ppm [1.3 mg/kg/day] and a parental systemic LOEL of 100 ppm [7.4 mg/kg/day in males and 8.2 mg/kg/day in females] based on increased liver weight in F_1 females and hepatocytomegaly in F_1 males and a reproductive LOEL of 100 ppm [6.9 mg/kg/day] based on increased pup death in early lactation (including cannibalism) for F_1 litters and the same effects in both F_1 and F_2 pups at the high dose level of 500 ppm [37.2 mg/kg/day in F_1 males and 41.5 mg/kg/day in F_1 females, respectively].

10. A rat developmental study with a maternal NOEL of 25 mg/kg/day and with a maternal LOEL of 125 mg/kg/day based on decreased body weight gain initially and a developmental NOEL of 25 mg/kg/day and a developmental LOEL of 125 mg/kg/day based on decreased fetal body weight, delayed

development [mainly delays in ossification in the skull, vertebrae, sternebrae, and appendages], and an increase in the incidence of extra ribs.

11. A rabbit developmental study with a maternal NOEL of 5 mg/kg/day and a maternal LOEL of 25 mg/kg/day based on histopathological finds in the liver and a developmental NOEL of 25 mg/kg/day and a developmental LOEL of 125 mg/kg/day based on increased skeletal variations.

12. An acute rat neurotoxicity study with a NOEL less than 75 mg/kg/day and a LOEL of 75 mg/kg/day based on decreased motor activity in males.

13. A rat subchronic neurotoxicity study with a NOEL of 120 ppm [7.3 mg/kg/day in males and 8.4 mg/kg/day in females] and a LOEL of 600 [38.1 mg/kg/day in males and 42.6 mg/kg/day in females] based on microscopic lesions in the cerebellum/medulla and spinal cords.

14. Flufenacet was negative for mutagenic/genotoxic effects in a Gene mutation/*In vitro* assay in bacteria, a Gene mutation/*In vitro* assay in chinese hamster lung fibroblasts cells, a Cytogenetics/*In vitro* assay in chinese hamster ovary cells, a Cytogenetics/*In vivo* mouse micronucleus assay, and an *In vitro* unscheduled DNA synthesis assay in primary rat hepatocytes.

15 A rat metabolism study showed that radio-labeled flufenacet was rapidly absorbed and metabolized by both sexes. Urine was the major route of excretion at all dose levels and smaller amounts were excreted via the feces.

16. A 55–day dog study with subcutaneous administration of Thiadone [flufenacet metabolite] supports the hypothesis that limitations in glutathione interdependent pathways and antioxidant stress result in metabolic lesions in the brain and heart following flufenacet exposure.

B. Toxicological Endpoints

1. *Acute toxicity*. EPA has concluded that a risk estimate is required based on the LOEL of 75 mg/kg/day established in the acute neurotoxicity study. For this risk assessment a Margin of Exposure (MOE) of 900 is required based on 10 X for inter-species extrapolation, 10 X for intra-species variation, 3 X required to protect infants and children, and 3 X for the use of a LOEL.

2. *Short - and intermediate-term toxicity*. EPA has concluded that available evidence does not indicate any evidence of significant toxicity from short-term and intermediate-term dietary exposure.

3. *Chronic toxicity*. EPA has established the RfD for flufenacet at 0.004 mg/kg/day. This RfD is based on a LOEL of 1.2 mg/kg/day in the combined chronic toxicity/carcinogenicity study in rats with a 300-fold safety factor to account for inter-species extrapolation (10 X), intra-species variability (10 X), and a lack of a NOEL in a critical study (3 X). An extra safety factor to protect infants and children is not needed because the NOEL used in deriving the RfD is based on methemoglobinema and multi-organ effects (not developmental or neurotoxic effects) in adult rats after chronic exposure and thus are not relevant for enhanced sensitivity to infants and children.

4. *Carcinogenicity*. The Health Effects Division RfD/Peer Review Committee has classified flufenacet as ''not likely'' to be carcinogenic to humans based on the lack of carcinogenicity in rats and mice.

C. Exposures and Risks

1. *From food and feed uses.* Tolerances have not been established (40 CFR part 180) previously for the residues of flufenacet, in or on raw agricultural commodities. There is no reasonable expectation of residues of flufenacet or its metabolites occurring in meat, milk, poultry, or eggs. Risk assessments were conducted by EPA to assess dietary exposures and risks from flufenacet from the proposed use on soybeans and field corn as follows:

i. *Acute exposure and risk.* Acute dietary risk assessments are performed for a food-use pesticide if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1–day or single exposure. An acute dietary risk assessment was conducted for flufenacet and its metabolites containing the 4-fluoro-*N*-methylethyl benzenamine moiety based on the LOEL of 75.0 mg/kg/day from the acute neurotoxicity study. The acute analysis estimates the distribution of single-day exposures for the overall U.S. population and certain subgroups. The Margin of Exposure (MOE) is a measure of how closely the exposure comes to the LOEL and is calculated as a ratio of the LOEL to the exposure. The calculated MOE for acute risk of flufenacet and its metabolites for the general U. S. population was 50,000 and for the most exposed subgroups, infants (< 1 year old) and children (1–6 years old), the MOE was 37,500. These figures are above the MOE of 900 which is the level of concern based on interspecies extrapolation (10 X), intraspecies variability (10 X), the lack of a NOEL in the acute neurotoxicity study (3 X), and providing additional protection to infants and children (3 X).

ii. *Chronic exposure and risk.* The Reference Dose (RfD) for flufenacet is 0.004 mg/kg/day. This value is based on the systemic LOEL of 1.2 mg/kg/day in the rat chronic feeding/carcinogenicity study with a 300–fold safety factor to account for interspecies extrapolation (10 X), intraspecies variability (10 X), the lack of a NOEL in the rat chronic feeding/carcinogenicity study (3 X).

A DRES chronic exposure analysis was conducted using tolerance levels for field corn and soybeans and percent crop treated information to estimate dietary exposure for the general population and 22 subgroups. The chronic analysis showed that exposure from the tolerances in or on field corn, soybeans and rotated crops for non-nursing infants (the subgroup with the highest exposure) would be 6.5% of the Reference Dose (RfD). The exposure for the general U.S. population would be 2.6% of the RfD.

Section 408(b)(2)(F) states that the Agency may use data on the actual percent of food treated for assessing chronic dietary risk only if the Agency can make the following findings: (a) 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; (b) That the exposure estimate does not underestimate exposure for any significant subpopulation group; and (c) 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.

The Agency used percent crop treated (PCT) information as follows. A routine chronic dietary exposure analysis for flufenacet was based on 16% of field corn crop treated and 26% of the soybean crop treated. The Agency believes that the three conditions listed above have been met. With respect to Unit II.B.1.ii.(a) of this preamble, EPA finds that the (PCT) information described above for flufenacet used on field corn is reliable and has a valid basis. Bayer Corporation's flufenacet production capacity does not exceed that needed to treat 16% of the total corn and 26% of the total soybean acres planted in the United States at the average application rates for products containing flufenacet. Before the petitioner can increase production of product, permission from the Agency must be obtained. As to Unit II.B.1.ii.(b) and (c) of this preamble, 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 regional consumption of food to which flufenacet may be applied in a particular area.

2. *From drinking water.* Drinking water estimated concentrations (DWECs) for groundwater (parent flufenacet and degradate thiadone) were calculated from the monitoring data to be 0.18 parts per billion (ppb) for acute and 0.03 ppb for chronic concentrations. The DWECs for surface water based on the computer models PRZM 2.3 and EXAMS 2.97.5 were calculated to be 17.0 ppb for the acute concentration and 14.2 ppb for chronic concentration (parent flufenacet and degradate thiadone).

3. *From non-dietary exposure.* There are no non-food uses of flufenacet 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.'' The Agency believes that ''available information'' in this context might include not only toxicity, chemistry, and exposure data, but also scientific policies and methodologies for understanding common mechanisms of toxicity and conducting cumulative risk assessments. For most pesticides, although the Agency has some information in its files that may turn out to be helpful in eventually determining whether a pesticide shares a common mechanism of toxicity with any other substances, EPA does not at this time have the methodologies to resolve the complex scientific issues concerning common mechanism of toxicity in a meaningful way. EPA has begun a pilot process to study this issue further through the examination of particular classes of pesticides. The Agency hopes that the results of this pilot process will increase the Agency's scientific understanding of this question such that EPA will be able to develop and apply scientific principles for better determining which chemicals have a common mechanism of toxicity and evaluating the cumulative effects of such chemicals. The Agency anticipates, however, that even as its understanding of the science of common mechanisms increases, decisions on specific classes of chemicals will be heavily dependent on chemical specific data, much of which may not be presently available.

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

Flufenacet is structurally a thiadiazole. EPA is not aware of any other pesticides with this structure. For flufenacet, EPA has not yet conducted a detailed review of common mechanisms to determine whether it is appropriate, or how to include this chemical in a cumulative risk assessment. After EPA develops a methodology to address common mechanism of toxicity issues to risk assessments, the Agency will develop a process (either as part of the periodic review of pesticides or otherwise) to reexamine these tolerance decisions. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, flufenacet does not appear to produce a toxic metabolite produced by other substances. For the purposes of these tolerance actions; therefore, EPA has not assumed that flufenacet has a common mechanism of toxicity with other substances.

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

1. *Acute risk.* The acute endpoint for flufenacet and its metabolites is 75 mg/kg/day. The acute exposure for flufenacet and its metabolites is 0.0015 mg/kg/day for the general U.S. population and 0.002 mg/kg/day for children 1–6 years of age. The drinking water level of concerns (DWLOCs) for acute exposure to flufenacet in drinking water calculated for the U.S. population was 2.87 ppm and for children (1–6 years old) was 813 ppb. These figures were calculated as follows. First, the acceptable acute exposure to flufenacet in drinking water was obtained by subtracting the acute dietary food exposures from the ratio of the acute LOEL to the acceptable MOE for aggregate exposure. Then, the DWLOCs were calculated by multiplying the acceptable exposure to flufencet in drinking water by estimated body weight (70 kg for adults, 10 kg for children) and then dividing by the estimated daily drinking water consumption (2 L/day for adults, 1 L/day for children). The Agency's SCI-Grow model estimates peak levels of flufenacet and its metabolite thiadone in groundwater to be 15.3 ppb. PRZM/EXAMS estimates peak levels of flufenacet and its metabolite thiadone in surface water to be 17 ppb. EPA's acute drinking water level of concern are well above the estimated exposures for flufenacet in water for the U.S. population and subgroup with highest estimated exposure.

2. *Chronic risk.* The chronic endpoint for flufenacet is 0.004 mg/kg body weight(bwt)/day. Using tolerance levels and percent crop treated, the residues in the diet (food only) are calculated to be 0.0001 mg/kg bwt/day or 2.6% of the RfD for the general U.S. population and 0.00023 mg/kg bwt/day or 5.8% of the RfD for children aged 1–6 years. Therefore, residues of flufenacet in drinking water may comprise up to 0.0039 mg/kg bwt/day (0.0040–0.0001 mg/kg bwt/day) for the U.S. population and 0.0038 mg/kg bwt/day (0.00400–0.00023 mg/kg bwt/day) for children 1–6 years old (the group exposed to the highest level of flufencet residues in both food and water).

The drinking water level of concerns (DWLOCs) for chronic exposure to flufenacet in drinking water calculated for the U.S. population was 136 ppb assuming that an adult weighs 70 kg and consumes a maximum of 2 liters of water per day. For children (1–6 years old), the DWLOC was 37.7 ppb assuming that a child weighs 10 kg and consumes a maximum of 1 liter of water per day.

The drinking water estimated concentration (DWECs) for groundwater (parent flufenacet and degradate thiadone) calculated from the monitoring data is 0.03 ppb for chronic concentrations which does not exceed DWLOC of 37.7 ppb for children (1–6 years old). The DWEC for surface water based on the computer models PRZM

2.3 and EXAMS 2.97.5 was calculated to be 14.2 ppb for chronic concentration (parent flufenacet and degradate thiadone) which does not exceed the DWLOC of 37.7 ppb for children (1–6 years old).

EPA concludes that there is a reasonable certainty that no harm will result from aggregate exposure to flufenacet residues.

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

In assessing the potential for additional sensitivity of infants and children to residues of flufenacet, EPA considered data from developmental toxicity studies in the rat and rabbit and a two-generation reproduction study in the rat. The developmental toxicity studies are designed to evaluate adverse effects on the developing organism resulting from pesticide exposure during prenatal development to one or both parents. 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. Although there is no indication of increased sensitivity to young rats or rabbits following pre- and/or post-natal exposure to flufenacet in the standard developmental and reproductive toxicity studies, an additional developmental neurotoxicity study, which is not normally required, is needed to access the susceptiblity of the offspring in function/neurological development. Therefore, EPA has required that a developmental neurotoxicty study be conducted with flufenacet and a threefold safety factor for children and infants will be used in the aggregate dietary acute and chronic risk assessment. Although there is no indication of additional sensitivity to young rats or rabbits following pre- and/or post-natal exposure to flufenacet in the developmental and reproductive toxicity studies; the Agency concluded that the FQPA safety factor should not be removed but instead reduced because: (1) There was no assessment of susceptibility of the offspring in functional/neurological developmental and reproductive studies. (2) There is evidence of neurotoxicity in mice, rats, and dogs. (3) There is concern for thyroid hormone disruption.

III. Other Considerations

A. Metabolism in Plants and Animals

The nature of the residue in field corn, soybeans and livestock is adequately understood. The residues of concern for the tolerance expression are parent and metabolites containing the 4-fluoro-*N*-methylethyl benzenamine moiety. Based on the results of animal metabolism studies it is unlikely that secondary residues would occur in animal commodities from the use on field corn and soybeans.

B. Analytical Enforcement Methodology

An adequate analytical method, gas chromatography/mass spectrometry with selected ion monitoring, is available for enforcement purposes. Because of the long lead time from establishing these tolerances to publication of the enforcement methodology in the Pesticide Analytical Manual, Vol. II, the analytical methodology is being made available in the interim to anyone interested in pesticide enforcement when requested from: Calvin Furlow, 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. Office location and telephone number: Room 119E, CM #2, 1921 Jefferson Davis Highway, Arlington, VA 22202, (703–305–5937).

C. Endocrine effects

EPA is required to develop a screening program to determine whether certain substances (including all pesticides and inerts) ''may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen, or such other effect***.'' The Agency is currently working with interested stakeholders, including other government agencies, public interest groups, industry and research scientists in developing a screening and testing program and a priority setting scheme to implement this program. Congress has allowed 3 years from the passage of FQPA (August 3, 1999) to implement this program. At that time, EPA may require further testing of this active ingredient and end use products for endocrine disrupter effects. Based on the toxicological findings for flufenacet relating to endocrine disruption effects, flufenacet should be considered as a candidate for evaluation as an endocrine disrupter when the criteria are established.

D. 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 on corn and soybeans. EPA believes it is inappropriate to establish permanent tolerances for the uses of flufenacet at this time due to the exitence of data gaps. These data gaps are: (1) Data regarding the stability of the glucoside conjugate and the malonylalanine conjugate of thiadone and subsequent bioavailability of any released free thiadone or thiadone glucuronide in meat, poultry, eggs, and milk commodities. The glucoside and malonylalanine conjugates of thiadone are metabolies of parent flufenacet that are present in plant commodites. Data are needed to ensure that these metabolites are not further converted to free thiadone or thiadone glucuronide in animal commodities. (2) A revised analytical method incorporating editorial changes specified in the Agency review. (3) Validation of the product chemistry enforcement analytical methods. (4) Data for additional rotational crops. (5) A developmental neurotoxicity study. EPA believes that the existing data support time-limited tolerances to April 30, 2003. The nature of the residue in plants is adequately understood for the purposes of these time-limited tolerances.

E. International Residue Limits

There are no Codex Alimentarius Commission (Codex) Maximum Residue Levels (MRLs) for flufenacet.

F. Rotational Crop Restrictions.

No tolerances for inadvertent residues of flufenacet are required in rotational crops. The restrictions that appear on the labeling proposed for registration under the Federal Insecticide Fungicide and Rodenticide Act (FIFRA), as amended, will prevent inadvertent residues that may occur in rotational crops for the use on field corn and soybeans.

IV. Conclusion

The analysis for flufenacet and its metabolites using crop tolerances, percentage of crop estimates, and estimated drinking water concentrations for all population subgroups examined by EPA shows the use on soybeans and corn will not cause exposure at which the Agency believes there is an appreciable risk during the period of time for the time-limited tolerance. Therefore EPA concludes there is a reasonable certainty of no harm from aggregate exposure to flufenacet. Based

on the information cited above, EPA has determined that establishing time-limited tolerances for the combined residues of the herbicide, *N*-(4-fluorophenyl)-*N*-(1-methylethyl)-2-[[5-(trifluoromethyl)-1,3,4-thiadiazol-2-yl]oxy]acetamide and its metabolites containing the 4-fluoro-*N*-methylethyl benzenamine moiety in or on field corn grain at 0.05 ppm, field corn forage at 0.4 ppm, field corn stover at 0.4 ppm, and soybean seed at 0.1 ppm will be safe. This time-limited tolerance will expire on April 30, 2003. Therefore, the tolerances are established as set forth below.

V. Objections and Hearing Requests

The new FFDCA section 408(g) provides essentially the same process for persons to ''object'' to a tolerance regulation issued by EPA under new section 408(e) and (l)(6) as was provided in the old section 408 and in section 409. However, the period for filing objections is 60 days, rather than 30 days. EPA currently has procedural regulations which 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 9, 1998, file written objections to any aspect of this regulation and may also request a hearing on those objections. Objections and hearing requests must be filed with the Hearing Clerk, at the address given above (40 CFR 178.20). A copy of the objections and/or hearing requests filed with the Hearing Clerk should be submitted to the OPP docket for this rulemaking. The objections submitted must specify the provisions of the regulation deemed objectionable and the grounds for the objections (40 CFR 178.25). Each objection must be accompanied by the fee prescribed by 40 CFR 180.33(i). If a hearing is requested, the objections must include a statement of the factual 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 Docket and Electronic Submissions

EPA has established a record for this rulemaking under docket control number [OPP–300636] (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 Highway, Arlington, VA.

Electronic comments may be sent directly to EPA at:

opp-docket@epamail.epa.gov.

Electronic comments must be submitted as an ASCII file avoiding the use of special characters and any form of encryption.

The official record for this rulemaking, as well as the public version, as described above 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 rulemaking record which will also include all comments submitted directly in writing. The official rulemaking record is the paper record maintained at the Virginia address in **ADDRESSES** at the beginning of this document.

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) (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 these 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. Nevertheless, the Agency has 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.

VIII. Submission to Congress and the General Accounting Office

The Congressional Review Act, 5 U.S.C. 801 et seq., as added by the Small Bussiness 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 oher 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 3, 1998.

Stephen L. Johnson,

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. 346a and 371.

2. By adding § 180.527, to read as follows:

§ 180.527 N-(4-fluorophenyl)-N-(1-methylethyl)-2-[[5-(trifluoromethyl)-1,3,4-thiadiazol-2-yl]oxy]acetamide; tolerances for residues.

(a) *General.* (1) Time-limited tolerances are established for combined residues of the herbicide, *N*-(4-fluorophenyl)-*N*-(1-methylethyl)-2-[[5-(trifluoromethyl)-1,3,4-thiadiazol-2-yl]oxy]acetamide and its metabolites containing the 4-fluoro-*N*-methylethyl benzenamine moiety in or on the following raw agricultural commodities:

Commodity	Parts per million	Expiration/Revocation Date
Corn, field, forage ..	0.05	4/30/03
Corn, field, grain	0.4	4/30/03
Corn, field, stover ...	0.4	4/30/03
Soybean seed	0.1	4/30/03

(2) Residues in these commodities not in excess of the established tolerance resulting from the use described in paragraph (a) of this section remaining after expiration of the time-limited tolerance will not be considered to be actionable if the herbicide is applied during the term of and in accordance with the provisions of the above regulation.

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

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

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

[FR Doc. 98–9549 Filed 4–7–98; 4:39 pm]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300643; FRL–5785–1]

RIN 2070–AB78

Cyprodinil; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of cyprodinil, 4-cyclopropyl-6-methyl-*N*-phenyl-2-pyrimidinamine in or on the folowing commodities: almond hulls at 0.05 ppm; almond nutmeats at 0.02 ppm; apple pomace, wet at 0.15 ppm; grapes at 2.0 ppm; pome fruit at 0.1 ppm; raisins at 3.0 ppm and stone fruit at 2.0 ppm. Novartis Crop Protection, Inc. requested these tolerances under the Federal Food, Drug and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (Pub. L. 104–170).

DATES: This regulation is effective April 10, 1998. Objections and requests for hearings must be received by EPA on or before June 9, 1998.

ADDRESSES: Written objections and hearing requests, identified by the docket control number, [OPP–300643], 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–300643], 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, CM #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@epamail.epa.gov. Copies of objections and hearing requests must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Copies of objections and hearing requests will also be accepted on disks in WordPerfect 5.1/6.1 file format or ASCII file format. All copies of objections and hearing requests in electronic form must be identified by the docket control number [OPP–300643]. 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: Mary L. Waller, Acting Product Manager (PM) 21, 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: Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, (703) 308–9354, e-mail: waller.mary@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of April 2, 1997 (64 FR 15690)(FRL–5593–9) EPA issued a notice pursuant to section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(e) announcing the filing of pesticide petitions (PP 6F4656 and 6H5746) for tolerances by Novartis Crop Protection, Inc. Greensboro, NC 27419 (formerly Ciba Crop Protection). This notice included a summary of the petitions prepared by Novartis Crop Protection, Inc., the registrant. There were no comments received in response to the notice of filing.

The petitions requested that 40 CFR part 180 be amended by establishing tolerances for residues of the fungicide cyprodinil, 4-cyclopropyl-6-methyl-*N*-phenyl-2-pyrimidinamine in or on the following commodities: almond hulls at 0.05 ppm; almond nutmeats at 0.02 ppm; apple pomace, wet at 0.15 ppm; grapes at 2.0 ppm; pome fruit at 0.1 ppm; raisins at 3.0 ppm and stone fruit at 2.0 ppm.

Note that the scientific assessments relevant to establishing these tolerances for cyprodinil were conducted jointly between EPA and the Pest Management Regulatory Agency (PMRA) of Canada as a pilot project under the North American Free Trade Agreement (NAFTA) and the Canadian United States Trade Agreement (CUSTA). Cyprodinil qualified as the first candidate for such a pilot program due to its classification as a reduced risk pesticide.

I. Risk Assessment and Statutory Findings

New 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