Crime, Infants and children, Law enforcement, Penalties, Privacy, Seizures and forfeitures.

Accordingly, 39 CFR 233 is amended as set forth below.

PART 233—INSPECTION SERVICE/ INSPECTOR GENERAL AUTHORITY

1. The authority citation for part 233 is changed to read as follows:

Authority: 39 U.S.C. 101, 102, 202, 204, 401, 402, 403, 404, 406, 410, 411, 1003, 3005(e)(1); 12 U.S.C. 3401–3422; 18 U.S.C. 981, 1956, 1957, 2254, 3061; 21 U.S.C. 881; Omnibus Budget Reconciliation Act of 1996, sec. 662 (Pub. L. No. 104–208).

§ 233.2 [Amended]

2. In § 233.2 amend the Note in paragraph (b)(2) as follows:

a. In the third paragraph, remove ''Assault on Postal Employees, $15,000'' and add ''Assault on Postal Employees, $50,000'' in its place.

b. In the fourth paragraph, remove ''Bombs or Explosives, $50,000'' and add ''Bombs or Explosives, $100,000'' in its place.

c. In the sixth paragraph, remove ''Robbery, $25,000'' and add ''Robbery, $50,000'' in its place.

d. In the eleventh paragraph, remove ''Child Pornography, $10,000'' and add ''Child Pornography, $50,000'' in its place.

e. In the last paragraph, remove ''10,000'' and add $50,000'' in its place.

Stanley F. Mires,

Chief Counsel, Legislative.

[FR Doc. 98–25802 Filed 9–29–98; 8:45 am]

BILLING CODE 7710–12–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300724; FRL–6033–4]

RIN 2070–AB78

Fluroxypyr; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for combined residues of fluroxypyr 1-methylheptyl ester [1-methylheptyl ((4-amino-3,5-dichloro-6-fluoro-2-pyridinyl)oxy)acetate] and its metabolite fluroxypyr [((4-amino-3,5-dichloro-6-fluoro-2-pyridinyl)oxy)acetic acid] in or on the raw agricultural commodities (RAC) wheat, barley, and oats as follows: 0.5 ppm (grain), 12 ppm (straw and forage), 20 ppm (hay), and 0.6 ppm (aspirated grain fractions). Because residues of fluroxypyr 1-methylheptyl ester and its metabolite fluroxypyr, free and conjugated, may occur in animal feeds derived from wheat, barley, and oats, the following meat and milk tolerances are also being established: 0.1 ppm (meat, fat, milk, and meat byproducts except for kidney) and 0.5 ppm (kidney). Dow AgroSciences LLC requested this tolerance under the Federal Food, Drug and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (Pub. L. 104–170).

DATES: This regulation is effective September 30, 1998. [Objections and requests for hearings must be received by EPA on or before November 30, 1998.

ADDRESSES: Written objections and hearing requests, identified by the docket control number [OPP–300724, 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–300724, 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 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–300724]. 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: Joanne I. Miller, 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) 305–6224, e-mail: miller.joanne@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of December 17, 1997 (62 FR 66083)(FRL–5759–1), 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) 6F4772 for tolerance by Dow AgroSciences LLC, 9330 Zionsville Road, Indianapolis, IN 46268. This notice included a summary of the petition prepared by Dow AgroSciences LLC, the registrant. There were no comments received in response to the notice of filing.

In the **Federal Register** of August 14, 1998 (63 FR 43710)(FRL–6023–3), 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 an amended pesticide petition (PP) 6F4772 for this tolerance petition. The revised petition requested that 40 CFR part 180 be amended by establishing a tolerance for combined residues of the herbicide fluroxypyr 1-methylheptyl ester [1-methylheptyl ((4-amino-3,5-dichloro-6-fluoro-2-pyridinyl)oxy)acetate] and its metabolite fluroxypyr [((4-amino-3,5-dichloro-6-fluoro-2-pyridinyl)oxy)acetic acid] in or on the raw agricultural commodities wheat, barley, and oats as follows: 0.5 ppm (grain), 12 ppm (straw and forage), 20 ppm (hay), and 0.6 ppm (aspirated grain fractions). Because residues of fluroxypyr 1-methylheptyl ester and its metabolite fluroxypyr, free and conjugated, may occur in animal feeds derived from wheat, barley, and oats, the following meat and milk tolerances are also being established: 0.1 ppm (meat, fat, milk, and meat byproducts except for kidney) and 0.5 ppm (kidney).

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 adverse effect level'' or ''NOAEL'').

Once a study has been evaluated and the observed effects have been determined to be threshold effects, EPA generally divides the NOAEL from the study with the lowest NOAEL 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 NOAEL 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 NOAEL) 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 three 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/NOAEL 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.

Percent of crop treated estimates are derived from federal and private market survey data. Typically, a range of estimates are supplied and the upper end of this range is assumed for the exposure assessment. By using this upper end estimate of percent of crop treated, the Agency is reasonably certain that exposure is not understated for any significant subpopulation group. Further, regional consumption information is taken into account through EPA's computer-based model for evaluating the exposure of significant subpopulations including several regional groups, to pesticide residues. For this pesticide, the most highly exposed population subgroup was not regionally based.

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 fluroxypyr and to make a determination on aggregate exposure, consistent with section 408(b)(2), for tolerances for combined residues of fluroxypyr 1-methylheptyl ester [1-methylheptyl ((4-amino-3,5-dichloro-6-fluoro-2-pyridinyl)oxy)acetate] and its metabolite fluroxypyr [((4-amino-3,5-dichloro-6-fluoro-2-pyridinyl)oxy)acetic acid] in or on the raw agricultural commodities wheat, barley, and oats as follows: 0.5 ppm (grain), 12 ppm (straw and forage), 20 ppm (hay), and 0.6 ppm (aspirated grain fractions), and residues of fluroxypyr 1-methylheptyl ester and its metabolite fluroxypyr, free and conjugated, in meat, fat, milk, and meat byproducts except for kidney at 0.1 ppm and kidney at 0.5 ppm. on at 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 fluroxypyr are discussed below.

1. Several acute toxicology studies places the technical-grade herbicide in Toxicity Category II.

2. A 90–day feeding study in Wistar rats (10/sex/group) administered fluroxypyr (98.5% a.i.) in the diet at 0, 80, 750, 1,000 or 1,500 milligrams/kilogram/day (mg/kg/day) for 13 weeks. Significant nephrotoxicity and deaths were observed at 1,000 and 1,500 mg/kg/day in both sexes, and in males at 750 mg/kg/day. Death was due to renal papillary necrosis. Also observed were signs of ill health, emaciation, decreased food intake, increased kidney weight, histopathological lesions and decreased renal function. Histological changes were observed in the adrenals in both sexes at 1,000 and 1,500 mg/kg/day. In males the NOAEL for this study is 80 mg/kg/day, and the LOEL is 750 mg/kg/day based on kidney effects and death. In females the NOAEL is 750 mg/kg/day, with the LOEL at 1,000 mg/kg/day based on kidney effects and death.

3. A 90–day feeding study in mice (12/sex/group) administered fluroxypyr (99.3% active ingredient (a.i.)) in the diet at levels of 0, 200, 500, 2,500 or 10,000 ppm (males: 0, 26.7, 67.7, 330 or 1,342 mg/kg/day; females: 0, 32.5, 81.7, 418, or 1,748 mg/kg/day) for 13 weeks. Under the conditions of the study, no significant effects were observed at any dose level. The NOAELs are therefore 1,342 and 1,748 mg/kg/day in males and females, respectively, the highest dose level tested, and above the 1,000 mg/kg limit dose. A LOEL could not be established.

4. A 28–day feeding study in Beagle dogs administered Fluroxypyr 98.0% a.i. in the diet at levels of 0, 50, 150 or 450 mg/kg/day for 28 days. Dogs at 500 mg/kg/day exhibited ataxia and hind limb weakness as well as decreases in body weight and food consumption and were sacrificed on days 16/17 of the study. Histopathology showed moderate acute tubular nephrosis and a slight to moderate acute gastroenteritis. Some early signs of acute tubular nephrosis were also seen in both sexes of dogs at 150 mg/kg/day. The NOAEL for the study was 50 mg/kg/day, the LOEL was 150 mg/kg/day based on histopathological lesions in the kidneys, decreased testes weights, and increased adrenal weights in both sexes.

5. In a 21–day dermal study, fluroxypyr (98.5% a.i.) was administered to New Zealand white rabbits (5/sex/group) at levels of 0, 100, 300, or 1,000 mg/kg/day for 3 weeks. Administration was 6 hr/day to an area approx. 10 x 15 cm (10% of body surface area). No dermal or systemic toxicity was observed at any dose level. The NOAEL for males and females is therefore 1,000 mg/kg/day. A LOEL could not be established.

6. In the combined chronic toxicity/carcinogenicity study in rats, fluroxypyr 99.0% a.i. was administered to 50 Fischer 344 rats/sex/dose via the diet at dose levels of 0, 100, 500, and 1,000, females only, mg/kg/day for 24 months 10 rats/sex/dose for 12 months. There was no apparent increase in the incidence of kidney tumors in either sex. With the exception of an increased incidence of parafollicular cell adenomas, single only, in males at 500 mg/kg/day, at the doses tested, there was no apparent treatment-related increase in any tumor type in either sex. The LOEL is 500 mg/kg/day, based on increased kidney weight in both sexes, increased incidence of atrophy, adipose tissue mesenteric tissues in males and an increase in the severity of chronic progressive glomerulonephropathy in the kidney in both sexes. The NOAEL is 100 mg/kg/day. Deaths occurred at 1,000 mg/kg/day in males within the first 90 days on test 2 by day 28 and 3 more by day 56.

7. In the carcinogenicity study in mice, fluroxypyr 98.92% a.i. was administered to 60 CD–1 mice/sex/dose via the diet at dose levels of 0, 100, 300, and 1,000 mg/kg/day for 18 months. There was no apparent treatment-related increase in the incidence of any tumor type in either sex. The LOEL is 1,000 mg/kg/day, based on decreased body weight/gain in males and an increased incidence of kidney lesions in females. The NOAEL is 300 mg/kg/day.

8. In a 1–year chronic feeding study, fluroxypyr 98.0% a.i. was administered to Beagle dogs (4/sex/group) in the diet at 0, 20, 50 or 150 mg/kg/day for 12 months. No adverse effects were observed at any dose level. No abnormalities in hematology, clinical chemistry or urinalysis. No abnormal findings were made at necropsy, nor were there any significant changes in food consumption or body weight. The NOAEL for this study is 150 mg/kg/day, the highest dose level tested. The LOEL could not be established.

9. In a developmental toxicity study, pregnant rats (six/dose group) were administered fluroxypyr (99% a.i.) at oral dose levels of 0, 125, 250, or 500 mg/kg/day in 1% methyl cellulose on days 6 through 19 of gestation. Clinical signs such as salivation and brown facial staining were observed at 250 and 500 mg/kg/day; a 10% increase in mean kidney weight was observed at 500 mg/kg/day, along with renal pelvic dilatation. No adverse effects were observed on food consumption, body weight gain, live young, embryonic deaths, implants, corpora lutea, pre- or post-implantation loss, litter weight or mean fetal weight. In pups, reduced skeletal ossification was observed at the 500 mg/kg/day. No other significant effects were observed on the conceptus. The maternal NOAEL is 125 mg/kg/day, and the LOEL is 250 mg/kg/day based on clinical signs. The developmental NOAEL is 250 mg/kg/day, the LOEL is 500 mg/kg/day based on reduced ossification.

10. In a developmental toxicity study in rats, fluroxypyr methylheptyl ester 95.8% a.i. was administered to 28 naturally-mated female Sprague-Dawley rats/group via gavage at dose levels of 0, 100, 300, and 600 mg/kg/day from days 6 through 15 of gestation. The maternal NOAEL is 300 mg/kg/day, the LOEL is 600 mg/kg/day, based on deaths and decreased body-weight gain and food consumption. The developmental toxicity NOAEL is 300 mg/kg/day, and the LOEL is 600 mg/kg/day, based on an increase in two ossification variations incompletely ossified cervical vertebral transverse processes and pubes.

11. In a developmental toxicity study in rabbits, fluroxypyr methylheptyl ester 95.8% a.i. was administered to 20 naturally-inseminated New Zealand female rabbits/group via gavage at dose levels of 0, 100, 500, and 1,000 mg/kg/day from days 7 through 19 of gestation. The maternal/developmental LOEL is 1,000 mg/kg/day, based on an increased incidence of abortions. The maternal NOAEL is 500 mg/kg/day.

12. In a prenatal developmental toxicity study in rabbits, pregnant New Zealand White rabbits received oral (gavage) administration of fluroxypyr at dose levels of 0, 25, 100, or 400 mg/kg/day during gestation days 6 through 19. Due to a large number of maternal deaths in the 400 mg/kg/day group, a dose level of 250 mg/kg/day was added to the study, and the 400 mg/kg/day dose level was discontinued early. For maternal toxicity, the NOAEL was 250 mg/kg/day and the LOEL was 400 mg/kg/day based on maternal deaths. For developmental toxicity, the NOAEL was 100 mg/kg/day and the LOEL was 250 mg/kg/day, based on increased postimplantation loss.

13. In a 2–generation reproduction study, fluroxypyr 99.0% a.i. was administered to 30 Sprague-Dawley rats/sex/dose via the diet at dose levels of 0, 100, 500, and 750 mg/kg/day males and 0, 100, 500, and 1,000 mg/kg/day females during the pre-mating period of 10 weeks (F_1 generation) 12 weeks (F_2 generation). There was one litter (F_1) in the first generation and two litters (F_{2A} and F_{2B}) in the second generation. The NOAEL for maternal/paternal toxicity is 500/100 mg/kg/day, and the LOEL is 1,000/500 mg/kg/day, based on death in females and increased kidney weight with corresponding gross and microscopic findings papillary atrophy, edema, necrosis, hyperplasia of the pelvic epithelium, degeneration/regeneration of the tubular epithelium, tubulo-interstitial nephritis, and dilatation of the tubules in both sexes. The reproductive NOAEL is 1,000/750 mg/kg/day, the highest dose tested. The neonatal NOAEL is 500 mg/kg/day, and the LOEL is 1,000 mg/kg/day, based on decreased pup body weight/body-weight gain and slightly lower survival.

14. In a *Salmonella typhimurium* reverse gene mutation assay, fluroxypyr was not mutagenic up to a cytotoxic dose (10,000 µg/plate +S9). In a *Salmonella typhimurium/Escherichia* coli reverse gene mutation assay with fluroxypyr methylheptyl ester, independent trials were negative up to insoluble doses with or without S9 activation (≧ 2,500 µg/plate).

15. In a Chinese hamster ovary (CHO) cell Hypoxanthine guanine phosphoribosyl transferase (HGPRT) forward gene mutation assay), fluroxypyr was negative up a cytotoxic concentration (2,000 µg/mL +/-S9). In a Chinese hamster ovary (CHO) cell HGPRT forward gene mutation assay with fluroxypyr methylheptyl ester, independent trials were negative up to cytotoxic concentrations without S9 activation (≧ 30 µg/mL -S9). In the presence of S9 activation, the test was also negative over the entire dose range investigated (100–1,200 µg/mL) in two trials.

16. An *in vitro* chromosome aberration assay in CHO cells with fluroxypyr was negative for damage to structural chromosomes up to doses causing moderate cytotoxicity (500 and 1,000 µg/mL +/-S9). There was, however, marginal and nondose-related evidence of polyploidy under nonactivated and S9-activated conditions. Also, in an *in vitro* unscheduled DNA synthesis (UDS) assay in human embryonic lung fibroblasts, cell line no. 2002 was negative up to nonactivated and S9-activated doses causing precipitation and moderate cytotoxicity. For fluroxypyr methylheptyl ester, in an *in vitro* chromosome aberration assay with rat lymphocytes, independent trials were negative up to cytotoxic concentrations (≧ 270 µg/mL +/-S9). Also, in an *in vivo* bone marrow micronucleus assay, negative results were obtained in CD–1 (ICR) male and female mice receiving single oral gavage administrations of 225–900 mg/kg. Lethality and other clinical signs of toxicity were noted at 900 mg/kg. There was, however, no evidence of bone marrow cytotoxicity at any dose.

17. In a metabolism study, fluroxypyr ^{14}C-methylheptyl ester 95.8% a.i. unlabeled; radiochemical purity 99%; labeled on the methylheptanol portion of the molecule or ^{14}C- methylheptanol 98.9% unlabeled; radiochemical purity 97.5% was administered to 5 plasma/3 balance male Fischer 344 rats/group in single oral equimolar doses of 50 mg fluroxypyr methylheptyl ester/kg body weight or 17.7 mg methylheptanol/kg body weight. The total recovery of the administered dose was 105% and 104%, with the principal route of excretion being expired $^{14}CO_2$, which contained approxiamately (≈) 61% and 63% of the radioactivity for the fluroxypyr and methylheptanol balance groups, respectively. The urine contained ≈ 30% and 27% and the feces contained 5% and 7% of the administered dose for the fluroxypyr and Methylheptanol groups, respectively. At 48 hours post dose, ≈ 7% of the administered dose was recovered in the blood, carcass, and skin of both groups. The overall rates and routes of elimination were comparable between the groups. Each was extensively absorbed and rapidly eliminated. Approximately 52% and 54% of the administered fluroxypyr and Methylheptanol, respectively, was absorbed and expired as $^{14}CO_2$ within 12 hours post dose, and an additional 18% of the administered dose was excreted in the urine within 12 hours post dose. Based on the percentage of the dose in the expired $^{14}CO_2$, urine, and tissues, ≈ 90% of the dose was absorbed by the rats in each case. Once absorbed, both were extensively metabolized (20–22 metabolites) and rapidly expired as $^{14}CO_2$ and eliminated in the urine with a half-life of 6 hours. Fluroxypyr displayed a slower absorption rate than Methylheptanol, but once absorbed, the pharmacokinetic parameters were similar. Peak plasma concentrations of ^{14}C-radioactivity were attained by 7 and 10 hours post dose, and the half-lives for the elimination

phase were ≈ 18.2 and 17.4 hours for fluroxypyr and Methylheptanol, respectively. It was stated that the percentage of radioactivity recovered in the tissues and carcass ≈ 7% suggests ^{14}C-incorporation into the carbon pool that may account for the longer half life in plasma as compared to the urinary half-life of 6 hours. Average area under the curve values were 140 µg equivalent hours/gram (eq hr/g) and 163 µg eq hr/g for the fluroxypyr and Methylheptanol groups, respectively. Clearance values were comparable for these groups also 2.1 and 1.8 mL/min kg. These pharmacokinetic parameters indicate no difference in kinetics of Methylheptanol, based on whether it is labeled alone or as part of the fluroxypyr molecule. Urine profiles were similar and indicated extensive metabolism (20–22 metabolites). Unchanged fluroxypyr was not detected in any of the samples, and the author stated that this ''is consistent with the majority of the dose metabolized to CO_2.'' The data indicate that the fluroxypyr bond is readily hydrolyzed and that the methylheptyl ester portion of fluroxypyr is bioequivalent to Methylheptanol.

B. Toxicological Endpoints

1. *Acute toxicity*. In a prenatal developmental toxicity study, pregnant New Zealand White rabbits received oral (gavage) administration of fluroxypyr (unspecified purity) in 0.5% carboxymethylcellulose (5 mL/kg) at dose levels of 0, 25, 100, or 400 mg/kg/day during gestation days 6 through 19. Due to a large number of maternal deaths in the 400 mg/kg/day group, a dose level of 250 mg/kg/day was added to the study, and the 400 mg/kg/day dose levels was discontinued early. For maternal toxicity, the NOAEL was 250 mg/kg/day and the LOEL was 400 mg/kg/day based on maternal deaths. For developmental toxicity, the NOAEL was 100 mg/kg/day and the LOEL was 250 mg/kg/day, based on increased postimplantation loss. The postimplantation loss is presumed to occur after a single exposure (dose). Appropriate endpoints attributable to a single exposure (dose) for this population were not seen in oral toxicity studies including maternal toxicity in the developmental toxicity studies in rats and rabbits.

EPA determined that the 10X factor to protect infants and children (as required by FQPA) should be reduced to 3X. This conclusion was based on the fact that the developmental toxicity study in rats showed no increased sensitivity in fetuses as compared to maternal animals following *in utero* exposures, the 2–generation reproduction toxicity study in rats showed no increased sensitivity in pups when compared to adults, and the toxicology data base is complete (i.e., no data gaps). However, EPA determined that an uncertainty factor of 300 is required because, in the prenatal developmental toxicity study in rabbits, there is an indication of additional susceptibility following prenatal exposure to fluroxypyr since the developmental NOAEL was less than the maternal NOAEL. The confidence in these data, however, were minimized by the fact that the value is only slightly above the historical control, and because no statistical significance was indicated. Additionally, susceptibility to the offspring was not observed in any of the other prenatal developmental toxicity studies examined, and there is always the possibility that maternal toxicity may have been present (as kidney pathology) but that the relevant endpoint was not examined.

For acute dietary risk assessment, a Margin of Exposure (MOE) of 300 is required. This includes the conventional 100X for inter- and intra-species variation, and 3X for FQPA. This risk assessment is required for females 13+ only, since the endpoint is based on an *in utero* effect. The available data, which include developmental studies in rats and rabbits, a 3–month feeding rat study and a 28–day mouse feeding study, did not demonstrate toxicity which can be observed following one exposure only.

2. *Short - and intermediate - term toxicity*. i. *Dermal absorption*. A dermal absorption study was not available for review. Therefore an absorption factor of 100% will be assumed.

ii. *Short-term toxicity*. Although a 21–day dermal toxicity study with fluroxypyr methylheptyl ester (98.5%) in New Zealand White rabbits with a NOAEL of > 1,000 mg/kg/day is available, the developmental NOAEL from an oral study with fluroxypyr in the same species (rabbits) was selected for this risk assessment because of the concern for developmental effects seen in the oral study with the acid which was not studied with the ester, and because developmental effects are not evaluated in the dermal toxicity study (i.e., the consequence of these effects can not be ascertained for the dermal route of exposure. Since an oral dose was identified, a dermal absorption rate of 100% should be used for dermal risk assessments, to convert to oral equivalents. Therefore, a developmental NOAEL of 100 mg/kg/day based on increased postimplantation loss at 250 mg/kg/day (LOEL) was used for risk assessment.

iii. *Intermediate-term toxicity*. For the reasons discussed above with short-term toxicity, a developmental NOAEL of 100 mg/kg/day based on increased postimplantation loss at 250 mg/kg/day (LOEL) was used for risk assessment.

3. *Chronic toxicity*. EPA has established the RfD for fluroxypyr at 0.5 mg/kg/day. This RfD is based on histopathological lesions in the kidneys, decreased testes weights, and increased adrenal weights in both sexes observed in a 4–week range-finding feeding study in the dog with a NOAEL of 50 mg/kg/day. An uncertainty factor of 100 was used in calculating the RfD to account for both inter- and intra-species variations.

4. *Carcinogenicity*. Based on the lack of evidence of carcinogenicity in mice and rats at doses that were judged to be adequate to assess the carcinogenic potential, fluroxypyr was classified as a ''not likely'' human carcinogen by the EPA's Hazard Identification Assessment Review Committee (document dated December 1, 1997) according to EPA Proposed Guidelines for Carcinogen Risk Assessment (document dated April 10, 1996).

B. Exposures and Risks

1. *From food and feed uses*. No previous tolerances have been established for the combined residues of fluroxypyr 1-methylheptyl ester and its metabolite fluroxypyr. Risk assessments were conducted by EPA to assess dietary exposures and risks from fluroxypyr as follows:

i. *Acute exposure and risk*. Acute dietary risk assessments are performed for a food-use pesticide if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1 day or single exposure. The acute dietary (food only) risk assessment used the theoretical maximum residue contribution (TMRC). By using TMRC in conducting this chronic dietary risk assessment, EPA has made very conservative assumptions: 100% of wheat, oats, and barley RACs having fluroxypyr tolerances will contain fluroxypyr residues and those residues will be at the level of the established tolerance. This results in an overestimate of human dietary exposure. Thus, in making a safety determination for this tolerance, EPA is taking into account this conservative exposure assessment. The exposure estimate for females (13+ years old) results in a dietary (food only) MOE of 50,000. This should be viewed as a conservative risk estimate; refinement using anticipated residue values and percent crop-treated data in conjunction with Monte Carlo analysis would result

in a lower acute dietary exposure estimate.

ii. *Chronic exposure and risk.* In conducting this chronic dietary risk assessment, EPA has made very conservative assumptions -- 100% of wheat, barley, oats and all other commodities having fluroxypyr 1-methylheptyl ester tolerances will contain fluroxypyr 1-methylheptyl ester residues and those residues would be at the level of the tolerance -- which result in an overestimation of human dietary exposure. Thus, in making a safety determination for this tolerance, EPA is taking into account this conservative exposure assessment.

The fluroxypyr 1-methylheptyl ester tolerances result in a TMRC that is equivalent to the following percentages of the RfD:

U.S. Population (48 States)	0.41%
U.S. Population - Fall Season	0.43%
U.S. Population - Winter Season	0.43%
Northeast Region	0.43%
North Central Region	0.43%
Western Region	0.44%
Hispanics	0.48%
Non-Hispanic Whites	0.42%
Non-Hispanic Others	0.43%
Nursing Infants (< 1 year old)	0.39%
Non-Nursing Infants (< 1 year old)	1.55%
Children (1–6 years old)	1.06%
Children (7–12 years old)	0.69%
Males (13–19 years old)	0.46%

The subgroups listed above are: (1) the U.S. population (48 states); (2) those for infants and children; and, (3) the other subgroups for which the percentage of the RfD occupied is greater than that occupied by the subgroup U.S. population (48 states).

2. *From drinking water.* In terrestrial and aquatic environments, fluroxypyr 1-methylheptyl ester is rapidly hydrolyzed to fluroxypyr. Fluroxypyr is further degraded (although less rapidly) by microbes to 4-amino-3,5-dichloro-6-fluoro-pyridin-2-ol (''pyridinol'') and 4-amino-3,5-dichloro-6-fluoro-2-methoxypyridine (''methoxypyridine''). In aerobic environments, fluroxypyr, pyridinol, and methoxypyridine are ultimately degraded to carbon dioxide.

There are no established Maximum Contaminant Levels for residues of fluroxypyr 1-methylheptyl ester in drinking water. No health advisory levels for fluroxypyr 1-methylheptyl ester in drinking water have been established. The assessment used SCI-GROW2 for groundwater assessment and Generic expected environmental concentration (GENEEC) Version 1.2 for acute and chronic surface water assessments. Estimated environmental concentrations (EEC's) in surface water reflecting 0.25 lb acid equivalents/A/yr applied by air were 11.2 µg/L for acute and 3.9 µg/L for chronic. EEC's for groundwater were 0.025 µg/L parts per billion (ppb) for acute and chronic. The computer generated EECs represent conservative estimates and should be used only for screening.

i. *Acute exposure and risk.* EPA has calculated drinking water levels of concern (DWLOCs) for acute exposure to fluroxypyr in drinking water for the only relevant population subgroup, females (13+ years old): 9,930 µg/L.

To calculate the DWLOCs for acute exposure relative to an acute toxicity endpoint, the acute dietary food exposure (from the Dietary Exposure Evaluation System (DRES) analysis) was subtracted from the ratio of the acute NOAEL (used for acute dietary assessments) to the acceptable MOE for aggregate exposure to obtain the acceptable acute exposure to fluroxypyr in drinking water. DWLOCs were then calculated using default body weights and drinking water consumption figures.

Estimated maximum concentrations of fluroxypyr in surface and ground water are 11.2 ppb and 0.025 ppb, respectively and the DWLOC is 9,930 µg/L. The estimated maximum concentrations of fluroxypyr in surface and ground water are less than EPA's level of concern for fluroxypyr in drinking water as a contribution to acute aggregate exposure.

Therefore, taking into account present uses and uses proposed in this action, EPA concludes with reasonable certainty that residues of fluroxypyr in drinking water (when considered along with other sources of exposure for which EPA has reliable data) would not result in unacceptable levels of aggregate human health risk at this time.

ii. *Chronic exposure and risk.* The ''Interim Guidance for Conducting Drinking Water Exposure and Risk Assessments'' issued on November 24, 1997 was followed for this assessment. Thus, the GENEEC model and the SCI-GROW model were run to produce estimates of fluroxypyr concentrations in surface and ground water, respectively. The primary use of these models is to provide a coarse screen for sorting out pesticides for which EPA has a high degree of confidence that the true levels of the pesticide in drinking water will be less than the human health DWLOCs. A DWLOC is the concentration of a pesticide in drinking water which would be acceptable as an upper limit in light of total aggregate exposure to that chemical from food, water, and non-occupational (residential) sources. The DWLOC for chronic exposure is the concentration in drinking water as a part of the aggregate chronic exposure that occupies no more than 100% of the RfD. The Agency's default body weights and water consumption values used to calculate DWLOCs are as follows: 70 kg/2L (adult male), 60 kg/2L (adult female), and 10 kg/1L (child).

For chronic (non-cancer) exposure to fluroxypyr in surface and ground water, the drinking water levels of concern are 17,400 µg/L for the U.S. population, 14,900 µg/L for females (13+ years old), and 4,950 µg/L for children (1–6 years old). To calculate the DWLOC for chronic (non-cancer) exposure relative to a chronic toxicity endpoint, the chronic dietary food exposure (from DRES) was subtracted from the RfD to obtain the acceptable chronic (non-cancer) exposure to fluroxypyr in drinking water. DWLOCs were then calculated using default body weights and drinking consumption figures.

Estimated average concentrations of fluroxypyr in surface and ground water are 3.9 ppb and 0.025 ppb, respectively. The DWLOCs are 17,400 µg/L for the U.S. population, 14,900 µg/L for females (13+ years old), and 4,950 µg/L for children (1–6 years old). The estimated average concentrations of fluroxypyr in surface and ground water are less than EPA's level of concern for fluroxypyr in drinking water as a contribution to chronic aggregate exposure.

3. *From non-dietary exposure.* There are no registered or proposed residential uses for fluroxypyr 1-methylheptyl ester or its metabolite fluroxypyr.

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).

EPA does not have, at this time, available data to determine whether fluroxypyr 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, fluroxypyr 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 fluroxypyr has a common mechanism of toxicity with other substances.

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

1. *Acute risk.* For the population subgroup of concern, females 13+ years old, the calculated MOE value (food) is 50,000. The Agency acknowledges the potential for exposure to fluroxypyr 1-methylheptyl ester in drinking water, but does not expect that exposure would result in an aggregate MOE (food plus water) that would exceed the Agency's level of concern for acute dietary exposure.

2. *Chronic risk.* Using the TMRC exposure assumptions described Unit II.B.1. of this preamble, EPA has concluded that aggregate exposure to fluroxypyr from food will utilize 0.41% of the RfD for the U.S. population. The major identifiable subgroup with the highest aggregate exposure is discussed below. EPA generally has no concern for exposures below 100% of the RfD because the RfD represents the level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to human health. Despite the potential for exposure to fluroxypyr in drinking water and from non-dietary, non-occupational exposure, EPA does not expect the aggregate exposure to exceed 100% of the RfD.

3. *Short- and intermediate-term risk.* Short- and intermediate-term aggregate exposure takes into account chronic dietary food and water (considered to be a background exposure level) plus indoor and outdoor residential exposure. There are no proposed residential uses for fluroxypyr. Therefore, the short and intermediate aggregate risks are adequately addressed by the chronic aggregate dietary risk assessment.

4. *Aggregate cancer risk for U.S. population.* Fluroxypyr has been classified as a ''not likely'' carcinogenic chemical by the Agency

5. *Conclusion.* EPA concludes that there is a reasonable certainty that no harm will result from aggregate exposure to fluroxypyr residues.

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

1. *Safety factor for infants and children*— a. *In general.* In assessing the potential for additional sensitivity of infants and children to residues of fluroxypyr, 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 analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans. In either case, EPA generally defines the level of appreciable risk as exposure that is greater than 1/100 of the no observed effect level in the animal study appropriate to the particular risk assessment. This hundredfold uncertainty (safety) factor/margin of exposure (safety) is designed to account for inter-species extrapolation and intra-species variability. EPA believes that reliable data support using the hundredfold margin/factor, rather than the thousandfold margin/factor, when EPA has a complete data base under existing guidelines, and when the severity of the effect in infants or children, the potency or unusual toxic properties of a compound, or the quality of the exposure data do not raise concerns regarding the adequacy of the standard margin/factor.

In the case of fluroxypyr, EPA determined that the 10X factor to protect infants and children (as required by FQPA) should be reduced to 3X. This conclusion was based on the fact that the developmental toxicity study in rats showed no increased sensitivity in fetuses as compared to maternal animals following *in utero* exposures, the 2–generation reproduction toxicity study in rats showed no increased sensitivity in pups when compared to adults, and the toxicology data base is complete (i.e., no data gaps). However, EPA determined that an uncertainty factor of 300 is required because, in the prenatal developmental toxicity study in rabbits, there is an indication of additional susceptibility following prenatal exposure to fluroxypyr since the developmental NOAEL was less than the maternal NOAEL. The confidence in these data, however, were minimized by the fact that the value is only slightly above the historical control, and because no statistical significance was indicated. Additionally, susceptibility to the offspring was not observed in any of the other prenatal developmental toxicity studies examined, and there is always the possibility that maternal toxicity may have been present (as kidney pathology) but that the relevant endpoint was not examined.

b. *Developmental toxicity studies.* In the developmental study in rats, the maternal (systemic) NOAEL was 125 mg/kg/day, based on clinical signs at the LOEL of 250 mg/kg/day. The developmental (fetal) NOAEL was 250 mg/kg/day, based on reduced ossification at the LOEL of 500 mg/kg/day.

In the developmental toxicity study in rabbits, the maternal (systemic) NOAEL was 250 mg/kg/day, based on maternal

deaths at the LOEL of 400 mg/kg/day. The developmental (pup) NOAEL was 125 mg/kg/day, based on increased postimplantation loss at the LOEL of 250 mg/kg/day.

c. *Reproductive toxicity study.* In the 2–generation reproductive toxicity study in rats, the maternal (systemic) NOAEL was 100 mg/kg/day, based on increased kidney weights and kidney histopathology at the LOEL of 500 mg/kg/day. The developmental (pup) NOAEL was 500 mg/kg/day, based on decreased body weight at the LOEL of 1,000 mg/kg/day. The reproductive NOAEL was 1,000 mg/kg/day Highest Dose Tested.

d. *Pre- and post-natal sensitivity.* The toxicological data base for evaluating pre- and post-natal toxicity for fluroxypyr is complete with respect to current data requirements. Based on the results of the rabbit developmental toxicity study for fluroxypyr there does appear to be an extra sensitivity for pre-natal effects.

e. *Conclusion.* Based on the above, EPA concludes that reliable data support use of a 300-fold margin of exposure/uncertainty factor, rather than the standard thousandfold margin/factor, to protect infants and children.

2. *Acute risk.* The acute dietary MOE (food) was calculated to be 6,666 for infants (< 1 year old), 10,000 for children (1–6 years old), and 50,000 females 13+ years old (accounts for both maternal and fetal exposure). These MOE calculations were based on the developmental NOAEL in rabbits of 100 mg/kg/day. This risk assessment assumed 100% crop-treated with tolerance level residues on all treated crops consumed, resulting in a significant over estimation of dietary exposure. The large acute dietary MOE calculated for females 13+ years old and the infants < 1 year old subgroup (lowest MOE) provides assurance that there is a reasonable certainty of no harm for females 13+ years old, infants, and children.

EPA acknowledges the potential for exposure to fluroxypyr 1-methylheptyl ester in drinking water, but does not expect that exposure would result in aggregate MOEs (food plus water) that would exceed the Agency's level of concern for acute dietary exposure.

3. *Chronic risk.* Using the conservative exposure assumptions described above, EPA has concluded that aggregate exposure to fluroxypyr from food will utilize from 0.39% of the RfD for nursing infants (< 1 year old) up to 1.55% of the RfD for non-nursing infants (< 1 year old). EPA generally has no concern for exposures below 100% of the RfD because the RfD represents the level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to human health. Despite the potential for exposure to fluroxypyr in drinking water. EPA does not expect the aggregate exposure to exceed 100% of the RfD. EPA concludes that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to fluroxypyr residues.

4. *Short- or intermediate-term risk.* Short- and intermediate-term aggregate exposure takes into account chronic dietary food and water (considered to be a background exposure level) plus indoor and outdoor residential uses. There are no proposed residential uses for fluroxypyr. Therefore, the short and intermediate aggregate risks are adequately addressed by the chronic aggregate dietary risk assessment.

III. Other Considerations

A. Metabolism In Plants and Animals

The nature of the residue in plants and animals is adequately understood. The residues of concern in plants and animals are fluroxypyr 1-methylheptyl ester and its metabolite fluroxypyr, free and conjugated, all expressed as fluroxypyr .

B. Analytical Enforcement Methodology

Adequate enforcement methodology is available for plants (gas chromatography/mass spectrometry (GC/MS) and capillary gas chromatography/MS) to enforce the tolerance expression. The petitioner validated the limit of quantitation at 0.01 ppm for cereal grains and 0.05 ppm for forage, straw, and hay of cereal grains.

Adequate enforcement methodology is available for livestock (gas chromatography/electron capture detection (GC/ECD) and capillary gas chromatography with mass selective detection) to enforce the tolerance expression. The petitioner validated the limit of quantitation of Method GRM 96.03 at 0.01 ppm for all animal substrates.

C. Magnitude of Residues

Residues of fluroxypyr 1-methylheptyl ester and fluroxypyr are not expected to exceed the established tolerance levels in RAC's and processed commodities of wheat, barley, oats, and animal commodities as a result of this use.

D. International Residue Limits

There are no CODEX, Canadian, or Mexican tolerances for residues of fluoroxypyr 1-methylheptyl ester on wheat, barley, or oats.

E. Rotational Crop Restrictions

A confined rotational crop study was conducted in which fluroxypyr was applied at the rate of 8.8 oz acid equivalent/acre (ae/A). Residues in crops planted 120 days after soil treatment were 0.01 to 0.08 ppm; however, based on this study and the use rates, residues of fluroxypyr 1-methylheptyl ester and fluroxypyr are not expected to occur in rotational crops at levels > 0.01 ppm at the 120–day plant-back interval. The end-use product label will contain a statement limiting the planting of rotational crops for at least 120 days after application.

IV. Conclusion

Therefore, the tolerances is are established for combined residues of fluroxypyr 1-methylheptyl ester and its metabolite fluroxypyr in wheat, barley, and oats as follows: 0.5 ppm (grain), 12 ppm (straw and forage), 20 ppm (hay), and 0.6 ppm (aspirated grain fractions), and residues of fluroxypyr 1-methylheptyl ester and its metabolite fluroxypyr, free and conjugated, in meat, fat, milk, and meat byproducts except for kidney at 0.1 ppm and kidney at 0.5 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 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 November 30, 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 or a request for a waiver as specified 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 Confidential Business Information (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 rulemaking under docket control number [OPP–300724 (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 1132 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

A. Certain Acts and Executive Orders

This final rule establishes tolerances 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 tolerances 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.

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 to 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: September 23, 1998.

Marcia E. Mulkey,

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 revising § 180.535 to read as follows:

§ 180.535 Fluroxypyr 1-methylheptyl ester; tolerances for residues.

(a) *General* . Tolerances are established for combined residues of fluroxypyr 1-methylheptyl ester [1-methylheptyl ((4-amino-3,5-dichloro-6-fluoro-2-pyridinyl)oxy)acetate] and its metabolite fluroxypyr [((4-amino-3,5-dichloro-6-fluoro-2-pyridinyl)oxy)acetic acid] in or on the following raw agricultural commodities.

Commodity	Parts per million
Aspirated grain fractions	0.6
Barley, grain	0.5
Barley, forage	12.0
Barley, hay	20.0
Barley, straw	12.0
Cattle, fat	0.1
Cattle, kidney	0.5
Cattle, meat	0.1
Cattle, meat byproducts	0.1
Goats, fat	0.1
Goats, kidney	0.5
Goats, meat	0.1
Goats, meat byproducts	0.1
Hogs, fat	0.1
Hogs, kidney	0.5
Hogs, meat	0.1
Hogs, meat byproducts	0.1
Horses, fat	0.1
Horses, kidney	0.5
Horses, meat	0.1
Horses, meat byproducts	0.1
Milk	0.1
Oats, forage	12.0
Oats, grain	0.5
Oats, hay	20.0
Oats, straw	12.0
Sheep, fat	0.1
Sheep, kidney	0.5
Sheep, meat	0.1
Sheep, meat byproducts	0.1
Wheat, forage	12.0
Wheat, grain	0.5
Wheat, hay	20.0
Wheat, straw	12.0

(b) *Section 18 emergency exemptions.* Time-limited tolerances are established for the combined residues of fluroxypyr 1-methylheptyl ester and its metabolite fluroxypyr, 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
Corn, field, forage	2.0	12/1/99
Corn, field, grain	0.05	12/1/99
Corn, field, stover	2.5	12/1/99
Corn, sweet, forage	2.0	12/1/99
Corn, sweet, K + CWHR	0.05	12/1/99
Corn, sweet, stover	2.5	12/1/99

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

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

[FR Doc. 98–26002 Filed 9–29–98; 8:45 am]

BILLING CODE 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300721; FRL–6033–3]

RIN 2070–AB78

Tebufenozide; Pesticide Tolerances for Emergency Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a time-limited tolerance for residues of tebufenozide in or on cranberries. This action is in response to EPA's granting of emergency exemptions under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act authorizing use of the pesticide on cranberries. This regulation establishes a maximum permissible level for residues of tebufenozide in this food commodity pursuant to section 408(l)(6) of the Federal Food, Drug, and Cosmetic Act, as amended by the Food Quality Protection Act of 1996. The tolerance will expire and is revoked on September 30, 1999.

DATES: This regulation is effective September 30, 1998. Objections and requests for hearings must be received by EPA on or before November 30, 1998.

ADDRESSES: Written objections and hearing requests, identified by the docket control number, [OPP–300721], 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–300721], 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@epamail.epa.gov.