section 3(b) of Executive Order 13084 do not apply to this rule.

IV. Submission to Congress and the Comptroller General

The Congressional Review Act, 5 U.S.C. 801 *et seq*., as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the Agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this 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 28, 1998.

Arnold E. Layne,

Acting Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180 — [AMENDED]

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

Authority: 21 U.S.C. 346a and 371.

§ 180.442 [Amended]

2. In §180.442, by amending the entry for ''Canola, seed'' in the table in paragraph (b) by changing the date ''9/30/98'' to read ''3/30/00.''

[FR Doc. 98–26901 Filed 10–6–98; 8:45 am]

BILLING CODE 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300738; FRL–6036–8]

RIN 2070–AB78

Fludioxonil; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of fludioxonil (4-(2,2-difluoro 1,3 benzodioxol-4-yl)-1*H*-pyrrole-3-carbonitrile) in or on the following raw agricultural commodities (RACs): rape seed, rape forage, peanuts, meat (hulls removed), peanut hay, sunflower seed, leafy vegetables except brassica, brassica leafy vegetables, legume vegetables, foliage of legume vegetables, fruiting vegetables except cucurbits, cucurbit vegetables, forage, fodder, and straw of cereal grains, grass, forage, fodder, and hay, and non-grass animal feeds at 0.01 parts per million (ppm); root and tuber vegetables, leaves of root and tuber vegetables, bulb vegetables, cereal grains, and herbs and spices at 0.02 ppm; and cotton seed and cotton gin byproducts at 0.05 ppm. Novartis Crop Protection, Inc, 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 October 7, 1998. Objections and requests for hearings must be received by EPA on or before December 7, 1998.

ADDRESSES: Written objections and hearing requests, identified by the docket control number, [OPP–300738], 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–300738], 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. 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–300738]. 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 Waller, 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 August 26, 1998 63 FR 45497 (FRL–6023–4), EPA issued a notice pursuant to section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a announcing the filing of a pesticide petition (PP 8F4978) for tolerances by Novartis Crop Protection, Inc., 410 Swing Road, Greensboro, NC 27419. This notice included a summary of the petition prepared by Novartis Crop Protection Inc., the registrant. There were no comments received in response to the Notice of Filing.

The petition requested that 40 CFR 180.516 be amended by establishing tolerances for residues of fludioxonil in or on the following RACs: rape seed and rape forage (reported as canola in the Notice of Filing), peanuts, meat (hulls removed) and peanut hay (reported as peanuts in the Notice of Filing), sunflower seed, leafy vegetables except brassica (Crop Group 4); brassica leafy vegetables (Crop Group 5); legume vegetables (Crop Group 6); foliage of legume vegetables (Crop Group 7); fruiting vegetables except cucurbits (Crop Group 8); cucurbit vegetables (Crop Group 9); forage, fodder, and straw of cereal grains (Crop Group 16); grass, forage, fodder, and hay (Crop Group 17); and non-grass animal feeds (Crop Group 18) at 0.01 ppm; root and tuber vegetables (Crop Group 1); leaves of root and tuber vegetables (Crop Group 2); bulb vegetables (Crop Group 3); cereal grains (Crop Group 15); and herbs and spices (Crop Group 19) at 0.02 ppm; cotton seed, and cotton gin byproducts at 0.05 ppm.

I. Risk Assessment and Statutory Findings

Section 408(b)(2)(A)(i) of the FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is ''safe.'' Section 408(b)(2)(A)(ii) defines ''safe'' to

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

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

II. Aggregate Risk Assessment and Determination of Safety

Consistent with section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of fludioxonil and to make a determination on aggregate exposure, consistent with section 408(b)(2), for tolerances in or on the following raw agricultural commodities (RACs): rape seed, rape forage, peanuts, meat (hulls removed), peanut hay, sunflower seed, leafy vegetables except brassica, brassica leafy vegetables, legume vegetables, foliage of legume vegetables, fruiting vegetables except cucurbits, cucurbit vegetables, forage, fodder, and straw of cereal grains, grass, forage, fodder, and hay, and non-grass animal feeds at 0.01 ppm; root and tuber vegetables, leaves of root and tuber vegetables, bulb vegetables, cereal grains, and herbs and spices at 0.02 ppm; and cotton seed and cotton gin byproducts at 0.05 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 fludioxonil are discussed below.

1. A battery of acute toxicity studies place technical fludioxonil in Toxicity Category IV for oral, inhalation, and dermal irritation studies, and Category III for dermal and eye irritation studies. Fludioxonil is not a skin sensitizer.

2. A subchronic oral toxicity study in rats dosed orally with technical fludioxonil at levels of 0, 0.8, 6.6, 64, 428, and 1,283 mg/kg/day (males); 0, 1.0, 7.1, 70, 462, and 1,288 mg/kg/day (females) resulted in the Lowest-Observed-Adverse-Effect Level (LOAEL) of 428 mg/kg/day in males and 462 mg/kg/day in females, based on the increased incidence of microscopic pathology of the kidney and liver and the deceased body weight gain. The No-Observed-Adverse-Effect level (NOAEL) is 64 mg/kg/day in males; 70 mg/kg/day in females.

3. In a subchronic oral toxicity study, fludioxonil technical was administered to dogs for 13 weeks at 0, 200, 2,000, and 15,000/10,000 ppm (15,000 ppm for 17 days and 10,000 ppm from day 18 until study termination). These dose levels correspond to nominal doses of 0, 5, 50, or 375/250 mg/kg/day, as actual intake data were not provided. A LOAEL of 2,000 ppm in males and females was determined based on the observation of diarrhea. The NOAEL is 5 mg/kg/day in males and females.

4. In a subchronic oral toxicity study, technical fludioxonil was administered to mice at doses of 0, 1.3, 13.9, 144, 445, or 1,052 mg/kg/day (males); 0, 1.9, 16.8, 178, 559, or 1,307 mg/kg/day (females). The LOAEL is 1,052 mg/kg/day in males, and 1,307 mg/kg/day in females, based on decreased body weight gain in female mice, changes in serum chemistry in male and female mice, increased liver to body weight ratio, and the increased incidence of nephropathy and centrilobular hypertrophy of the liver in both sexes. The NOAEL is 445 mg/kg/day in males and 559 mg/kg/day in females.

5. In a 28 day repeated dermal toxicity test, rats were dosed with technical fludioxonil under occlusive dressing (6 hrs/day, 5 days/week, for 4 weeks) at 0, 40, 200, and 1,000 mg/kg/day. The dermal irritation LOAEL and NOAEL are both greater than 1,000 mg/kg for males and females. The systemic toxicity LOAEL is 1,000 mg/kg for females based on increased AST and adrenal weight, and 1,000 mg/kg for males based on increased creatinine and adrenal weight and the systemic toxicity NOAEL is 200 mg/kg/day for males and females.

6. In a chronic oral toxicity study, dogs were dosed with technical fludioxonil for 52 weeks at 0, 3.1, 33.1, and 297.8 mg/kg/day (males); 3.3, 35.5, and 330.7 mg/kg/day (females). The LOAEL for male dogs is 297.8 mg/kg/day based on decreased body weight, hematology alterations (increased platelets and fibrin), clinical chemistry alterations (increased cholesterol and alkaline phosphatase) and increased liver weight. The LOAEL for female dogs is 35.5 mg/kg/day based on a marked decrease in body weight gain for weeks 1–13 and 1–52 of the study. The NOAEL is 33.1 mg/kg/day for male dogs and 3.3 mg/kg/day for female dogs.

7. In a combined chronic toxicity/carcinogenicity study, rats were fed technical fludioxonil at 0, 10, 30, 100, 1,000, and 3,000 ppm (males: 0, 0.37, 1.1, 3.7, 37 and 113 mg/kg/day; females: 0, 0.44, 1.3, 4.4, 44, and 141 mg/kg/day) for either 12 or 24 months. In addition, rats from the control and 3,000 ppm groups were fed the test diets for 12 months and then allowed to recover for 1 month prior to sacrifice. There was no treatment related effect on food or water consumption. Males dosed at 1,000 and 3,000 ppm and females dosed at 3,000 ppm exhibited a number of effects including higher incidence of dark stool and urine, staining (mostly blue) around the pelvic region and abdomen, higher frequency of diarrhea (males only), and decreased body weight gain. Females dosed at 3,000 ppm had some evidence of slight anemia at the 12 month evaluation. At necropsy, males at the 3,000 ppm dose level exhibited an increased incidence of enlarged livers and kidneys with discolored foci or general discoloration and an increased severity of progressive nephropathy; kidneys with cysts were reported at both the 1,000 and 3,000 ppm dose levels. For females in the 1,000 and 3,000 ppm dose levels there was an increase incidence of discoloration of the kidneys. Males and females in the 3,000 ppm group had an increased incidence and more severe grade of histopathological changes in the liver. There was an increased incidence of hepatocellular tumors in both sexes of the 3,000 ppm group; however, the increase in males was not statistically significant. The statistically significant finding in females was an increase in combined adenomas and carcinomas (0/70, 1/60, 0/60, 1/60, 2/60 and 5/70 in the 0, 10, 30, 100, 1,000 and 3,000 ppm groups, respectively). Males and females in the 3,000 ppm group had an increased incidence of basophilic foci in the liver; males also had an increase in hepatocellular hypertrophy. The LOAEL

for males and females was 113 and 141 mg/kg/day, respectively (3,000 ppm) based on decreased body weight and weight gain, slight anemia in females at 12 months, and increased incidence and severity of histopathology changes in the liver. The NOAEL for males and females was 37 and 44 mg/kg/day, respectively. Fludioxonil technical was not carcinogenic in male rats. There was a statistically significant increase in the incidence of combined adenomas and adenocarcinomas of the liver in female rats in the 3,000 ppm group. The 3,000 ppm level is considered adequate for carcinogenicity testing based on decreased body weight and weight gain in both sexes, slight anemia in females at 12 months, and an increased incidence and severity of liver histopathology changes in both sexes.

8. A carcinogenicity study in mice administered technical fludioxonil in the diet at 0, 10, 100, 1,000, and 3,000 ppm (0, 1.1, 11.3, 112, and 360 mg/kg/day for males and 0, 1.4, 13.5, 133, and 417 mg/kg/day for females). Male mice at 360 mg/kg/day level exhibited clinical toxicity in the form of an incidence of ''convulsed'' when handled. No significant effects on body weight, weight gain, food consumption, hematology, or microscopic non neoplastic pathology were reported in either sex. Increased liver weight (9%) and spleen weight (34%) were observed in male mice at the 360 mg/kg/day dose level, which correlated with the macroscopic observations of enlarged spleen and raised foci of liver. Female mice showed a statistically significant increase in liver weight at the 417 mg/kg dose level and this is also supported by the macroscopic observation of enlarged liver. Other macroscopic changes in female mice were an increased incidence of enlarged thymus, spleen, mediastinal lymph node, and liver and an increased incidence of lymphoma in these organs. The LOAEL is 112 mg/kg/day for male mice, based on the increased incidence of clinical toxicity and 417 mg/kg/day for female mice, based on the increased liver weight and the increased incidence of macroscopic pathology. The NOAEL is 11.3 mg/kg/day and 133 mg/kg/day in male and female mice, respectively. There was evidence of carcinogenicity in female mice based on increased incidence of lymphomas, which contributed to death. This effect was due to the early onset and high incidence of lymphoma at the 3,000 ppm dose relative to the control group. Total incidence of lymphoma was 11/59, 10/59, 13/60, 12/60, and 18/60 for the 0, 10, 100, 1,000, and 3,000 ppm dose levels in female mice, respectively. This increase in total lymphoma was significant by a trend test, but not by a pair wise comparison. Whether an adequate dose level was used in this study to assess the carcinogenic potential of fludioxonil is complicated by the observation of an increased lymphoma incidence at the 3,000 ppm dose level. This dose level produced some systemic effects, such as an increased incidence of male mice which ''convulsed'' when handled and macroscopic pathology in both sexes. But this dose level produced no significant effects on body weight gain, food consumption, hematology, or microscopic non neoplastic pathology in either sex.

In a second carcinogenicity study in mice fludioxonil technical was administered in the diet at nominal dose levels of 0, 3, 30, 5,000, and 7,000 ppm (0, 0.33, 3.3, 590, and 851 mg/kg/ day in males; 0, 0.41, 4.1, 715, and 1,008 mg/kg/day for females). The 7,000 ppm dose level in males and females produced significant systemic effects in addition to significant nephropathy, which contributed to death in a majority of test animals. Survival in female mice was below 25% and exceeded the guideline criteria for survival in a mouse carcinogenicity study. Changes in liver weights were observed in both sexes at the 5,000 and 7,000 ppm dose levels, but could not be related to histological alterations in the liver. The LOAEL is estimated at 851 mg/kg/day in males, and 1,008 mg/kg/day in females. The NOAEL is 590 mg/kg/day in males, and 715 mg/kg/day in females. The 7,000 ppm dose is adequate for testing carcinogenic potential in male mice, based on the significant systemic effects and nephropathy observed at this dose. For female mice, the 7,000 ppm dose level is considered excessive, based on the reduction in survival of the test animals. There was no evidence of increased incidence of tumors in this study for male or female mice.

9. In a developmental toxicity (teratology) study, pregnant rats (gestation days 6–15 inclusive) were administered technical fludioxonil at 0, 10, 100, and 1,000 mg/kg/day by oral gavage. Maternal toxicity was evident at 1,000 mg/kg/day with a 16% reduction in corrected body weight gain. Developmental toxicity was evident at the 1,000 mg/kg/day dose with increased fetal and litter incidence of dilated renal pelvis and dilated ureter. Based on these observations, the Maternal LOAEL and Developmental toxicity LOAEL are at 1,000 mg/kg/day and the Maternal NOAEL and Developmental toxicity NOAEL are at 100 mg/kg/day.

10. In another developmental toxicity study, rabbits (gestation days 6 through 18) were dosed with technical fludioxonil by oral gavage at 0, 10, 100, and 300 mg/kg/day. Minimal maternal toxicity was noted in the mid and high dose groups as less body weight during the dosing period (gestation days 6 through 18) and dosing plus post dosing period (gestation days 6 through 28). The high dose group consumed less food than the control group during the dosing period, the post dosing period (gestation days 19 through 28), the dosing plus post dosing period, and for the overall gestation period. However, food efficiency was decreased in the mid and high dosed groups during the dosing plus post dosing periods, and for the entire gestation period. The Maternal Toxicity LOAEL is 100 mg/kg/day and the Maternal Toxicity NOAEL is 10 mg/kg/day based on decreased body weight gains and decreased food efficiency. No developmental toxicity was noted at the dose levels tested. The Developmental Toxicity LOAEL is greater than 300 mg/kg/day and the Developmental Toxicity NOAEL is equal to or greater than 300 mg/kg/day.

11. In a reproductive toxicity study, rats received 0, 2.19, 22.13, and 221.61 mg/kg/day (males) and 0, 2.45, 24.24, and 249.67 mg/kg/day (females) fludioxonil technical in the diet for 2 generations. The Parental Systemic Toxicity LOAEL is 221.61 mg/kg/day for males and 249.67 mg/kg/day for females. The Parental Systemic Toxicity NOAEL is 22.13 mg/kg/day for males, and 24.24 mg/kg/day for females based on clinical observations, reduced body weight and weight gains, and reduced food consumption. The Reproductive/Developmental Toxicity LOAEL is 221.61 mg/kg/day for males and 249.67 mg/kg/day for females. The Reproductive/Developmental Toxicity NOAEL is 22.13 mg/kg/day for males and 24.24 mg/kg/day for females based on reduced pup body weights.

12. Gene mutation and other genotoxic effects were studied using fludioxonil technical:

i. Ames Salmonella assay with and without metabolic activation provided evidence of cytotoxicity at 1,250 and 5,000 micrograms/plate (µg/plate) concentrations.

ii. Unscheduled DNA Synthesis assay (*in vitro*) indicated cytotoxicity at 313 µg/ml.

iii. Chromosome aberrations assay (*in vitro*) in Chinese hamster ovary (CHO) cells with and without S9 activation provided convincing evidence that

fludioxonil is a clastogen and polyploidy inducer.

iv. Chromosome Aberrations assay (*in vitro*) in Chinese hamster bone marrow cells noted occurrence of hyperploidy in one mid-dose female and trisomy in one high dose male.

v. Micro nucleus assay (*in vitro*) using rat hepatocytes provided no definitive conclusions as to dose related increase in micro nucleate hepatocytes and therefore, this study will be repeated.

vi. Dominant Lethal assay indicated no test material induced dominant lethal mutations in male mouse germinal cells sampled over the entire period of spermatogenesis.

vii. Point Mutation test in CHO cells (*in vitro*) with and without S9 activation produced no increase in the number of thioguanine resistant colonies, mutant frequency, or mutant factor.

viii. Mouse Micro nucleus assay using mouse bone morrow Micro nucleus test produced no statistically significant increase in number of micronucleated polychromatic erythrocytes in male and female mice.

B. Toxicological Endpoints

1. *Acute toxicity.* Fludioxonil exhibits very low mammalian toxicity when tested by the oral route. There is no concern for an acute dietary risk. The available data do not indicate any evidence of significant toxicity from 1 day or single event exposure by oral route.

2. *Short and intermediate term toxicity.* Subchronic studies conducted with fludioxonil contain no end points suggesting the need for short term occupational or residential risk assessments for the dermal route of exposure. For intermediate term, the recommended LOAEL and NOAEL are 50 mg/kg/day and 5 mg/kg/day, respectively from the 13 week oral toxicity study in dogs. For the intermediate term risk assessment, the 50 mg/kg/day is used as the NOAEL, since the effects of concern are believed to occur at doses in excess of 50 mg/kg/day.

3. *Chronic toxicity.* EPA has established the RfD for fludioxonil at 0.03 mg/kg/day. This RfD is based on the 1 year oral toxicity study in dogs with a NOAEL of 3.3 mg/kg/day in females and an uncertainly factor of 100 to account for both interspecies extrapolation and intraspecies variability.

4. *Carcinogenicity.* Fludioxonil has been classified as a Group D chemical not classifiable as to human carcinogenicity. That is, the evidence is inadequate and cannot be interpreted as showing either the presence or absence of a carcinogenic effect.

C. Exposures and Risks

1. *From food and feed uses.* Tolerances have been established at 40 CFR 180.516 for residues of fludioxonil in or on potatoes and time limited tolerances under the Section 18 program have been established for apricot, nectarines, peaches, and plums. Risk assessments were conducted by EPA to assess dietary exposures from fludioxonil 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. There is no concern for an acute dietary exposure to fludioxonil. The available data do not indicate any evidence of significant toxicity from 1 day or single event exposure by oral route.

ii. *Chronic exposure and risk.* Fludioxonil is currently registered for seed treatment uses on corn, sorghum, and potatoes and for greenhouse uses on non food crops. Section 18 requests have been approved for post harvest treatment on apricots, nectarines, peaches, and plums. There is no reasonable expectation of residues on corn and sorghum as a result of treatment of corn and sorgham seed, therefore, these uses did not require tolerances and no exposure was assumed to result from these registered uses. Potatoes has a tolerance of 0.02 ppm and apricots, nectarines, peaches, plums have a time limited tolerance of 5 ppm. There are no residential uses for fludioxonil; therefore no chronic residential exposure is expected. Based on a Novigen Dietary Exposure Evaluation Model (DEEM) and using conservative assumptions (100% of crops treated and tolerance level residues) and a chronic RfD of 0.03 mg/kg/day, EPA estimates the chronic exposure to fludioxonil from food will utilize 22% of the chronic RfD for the most highly exposed population subgroup, (non-nursing infants < 1 year old). All other population subgroups have risk estimates below that of the non-nursing infants.

2. *From drinking water.* There are no maximum contaminant levels or health advisory levels established for residues of fludioxonil in drinking water. In view of the currently registered use patterns and the proposed seed treatment of food and feed crops at very low levels (1.13 to 2.26 grams of active ingredient (ai) per 100 lbs seed), fludioxonil is not expected to impact ground or surface waters. Thus the likelihood of residues of fludioxonil entering in drinking water is considered negligible.

3. *From non-dietary exposure.* Fludioxonil is not currently registered for any residential non-food uses. Therefore, oral, dermal, and inhalation exposure from residential uses is not expected.

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.''

Fludioxonil is a representative of a new class of plant protection agents derived from the structure of a naturally occurring plant antibiotic called pyrrolnitrin. EPA does not have, at this time, available data to determine whether fludioxonil 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, fludioxonil 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 fludioxonil has a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the Final Rule for Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997).

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

1. *Chronic risk.* Using the Theoretical Maximum Residue Contribution (TMRC) exposure assumptions described in this preamble, EPA has concluded that aggregate exposure to fludioxonil from food will utilize 22% of the RfD for the most highly exposed population subgroup. The major identifiable subgroup with the highest aggregate exposure is the 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.

2. *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. Fludioxonil is not registered for indoor uses. Based on registered and proposed uses, exposure to fludioxonil from drinking water is not expected.

3. *Aggregate cancer risk for U.S. population*. Fludioxonil has been classified as a Group D chemical not classifiable as to human carcinogenicity. The available carcinogenicity studies in the rat and mouse show some increase in the combined tumors only in the female rat above that in the concurrent controls. However, this statistical increase in liver tumors in female rats was only at the high dose. Some of this significant increase was due to the lack of any liver tumors in the concurrent control, whereas the historical control from the same lab indicated a range of 1.4 to 15% for combined liver tumors. Therefore, based on available information, EPA believes that this pesticide does not pose a significant cancer risk.

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

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

1. *Safety factor for infants and children*— i. *In general.* In assessing the potential for additional sensitivity of infants and children to residues of fludioxonil, 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 during gestation. Reproduction studies provide information relating to effects from exposure to the pesticide on the reproductive capability of mating animals and data on systemic toxicity.

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

ii. *Pre- and post-natal sensitivity*. The toxicity data base for fludioxonil includes acceptable prenatal developmental toxicity studies in rats and rabbits and an acceptable 2–generation reproduction study in rats. The data did not suggest any additional sensitivity to the embryo or neonate following *in utero* or early postnatal exposure to fludioxonil. In the rat developmental study, the Maternal NOAEL and the Developmental (fetal and pup) NOAEL were both 100 mg/kg/day. In the rabbit developmental study, the Maternal NOAEL was 10 mg/kg/day. No developmental toxicity was noted at any dosing level. The Developmental NOAEL was set equal to or greater than 300 mg/kg/day, the highest dose tested. Results from the 2–generation reproduction study for rats indicated a Developmental/Reproduction NOAEL of 22.13 mg/kg/day for males and 24.24 mg/kg/day for females. The Developmental/Reproductive NOAEL is at least 600 fold higher then the RfD (0.03 mg/kg/day), and should be protective for infants and children.

iii. *Conclusion*. There is a complete toxicity data base for fludioxonil and exposure data is complete or is estimated based on data that reasonably accounts for potential exposures.

2. *Chronic risk*. Using the exposure assumptions described in Unit II.C. of this preaamble, EPA has concluded that aggregate exposure to fludioxonil from food will utilize 22% of the RfD for infants and children. 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. As exposure from drinking water, non-dietary, or non-occupational sources are not anticipated, EPA does not expect aggregate exposure to exceed 100% of RfD.

3. *Determination of safety*. Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to fludioxonil residues.

III. Other Considerations

A. Metabolism In Plants and Animals

Plant metabolism studies in potatoes, rice, and wheat were previously submitted. Additional studies on cotton and soybeans were provided in conjunction with the proposed use. There is minimal uptake of the active ingredient when applied as a seed treatment. Based on these studies, EPA concludes that the nature of fludioxonil residues in plants are adequately understood and the residue of concern is the parent compound. Two animal metabolism studies conducted in ruminant and poultry indicate that there is no reasonable expectation of finite residues of fludioxonil in ruminant tissues, milk, poultry tissues, and eggs.

B. Analytical Enforcement Methodology

The Ciba-Geigy Analytical Method AG–597B has been adequately validated for use in enforcing the proposed tolerances. The method may be requested from: Calvin Furlow, PRRIB, IRSD (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location and telephone number: Rm 101FF, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA 22202, (703–305–5229).

C. Magnitude of Residues

The submitted field trial data on cucumber, leaf lettuce, radish, succulent peas, and wheat indicate that residue levels were less than the limit of quantitation (LOQ) in each crop. The submitted residue data support the following proposed tolerance levels of fludioxonil. The RAC and the respective tolerance ppm are: rape seed (0.01 ppm), rape forage (0.01 ppm), sunflower seed (0.01 ppm), peanuts, meat (hulls removed) (0.01 ppm), peanut hay (0.01 ppm), leafy vegetables except brassica (0.01 ppm), brassica (cole) leafy vegetables (0.01 ppm), legume vegetables (0.01 ppm), foliage of legume vegetables (0.01 ppm), fruiting vegetables except cucurbits (0.01 ppm), cucurbit vegetables (0.01 ppm), forage, fodder, and straw of cereal grains (0.01 ppm), grass, forage, fodder, and hay (0.01 ppm), non-grass animal feeds (0.01 ppm), root and tuber vegetables (0.02 ppm), leaves and roots of tuber vegetables (0.02 ppm), bulb vegetables, (0.02 ppm), cereal grains (0.02 ppm), herbs and spices (0.02 ppm), cotton, undelinted seed (0.05 ppm), and cotton gin byproducts (0.05 ppm).

D. International Residue Limits

There are currently no established or proposed maximum residue limits

(MRLs) in Canada, CODEX, or Mexico for fludioxonil residues in/on crops and crop groups included in this submission. Therefore, problems with compatibility of tolerances/MRLs do not exist.

IV. Conclusion

Therefore, tolerances are established for residues of fludioxonil in the following RACs at (ppm): rape seed (0.01 ppm), rape forage (0.01 ppm), sunflower seed (0.01 ppm), peanuts, meat (hulls removed) (0.01 ppm), peanut hay (0.01 ppm), leafy vegetables except brassica (0.01 ppm), brassica (cole) leafy vegetables (0.01 ppm), legume vegetables (0.01 ppm), foliage of legume vegetables (0.01 ppm), fruiting vegetables except cucurbits (0.01 ppm), cucurbit vegetables (0.01 ppm), forage, fodder, and straw of cereal grains (0.01 ppm), grass, forage, fodder, and hay (0.01 ppm), non-grass animal feeds (0.01 ppm), root and tuber vegetables (0.02 ppm), leaves and roots of tuber vegetables (0.02 ppm), bulb vegetables, (0.02 ppm), cereal grains (0.02 ppm), herbs and spices (0.02 ppm), cotton, undelinted seed (0.05 ppm), and cotton gin byproducts (0.05 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 December 7, 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 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-300738] (including any comments and data submitted electronically). A public version of this record, including printed, paper versions of electronic comments, which does not include any information claimed as CBI, is available for inspection from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The public record is located in Room 119 of the Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA.

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 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.

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 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: September 29, 1998.

James Jones,

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

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

Authority: 21 U.S.C. 346a and 371.

2. In § 180.516 by revising paragraph (a) to read as follows:

§ 180.516 Fludioxonil; tolerances for residues.

(a) *General.* Tolerances are established for residues of the fungicide fludioxonil (4-(2,2-difluoro-1,3-benzodioxol-4-yl)-1*H*-pyrrole-3-carbonitrile) in or on the following commodities:

Commodity	Parts per million
Bassica (cole) leafy vegetables	0.01
Bulb vegetables	0.02
Cereal grains	0.02
Cotton gin byproducts	0.05
Cotton, undelinted seed	0.05
Cucurbit vegetables	0.01
Foliage of legume vegetables	0.01
Forage, fodder, and straw of cereal grains	0.01
Fruiting vegetables except cucurbits	0.01
Grass, forage, fodder, and hay	0.01
Herbs and spices	0.02
Leafy vegetables except Brassica	0.01
Leaves and roots of tuber vegetables	0.02
Legume vegetables	0.01
Non-grass animal feeds	0.01
Peanut hay	0.01
Peanuts, meat (hulls removed)	0.01
Rape forage	0.01
Rape seed	0.01
Root and tuber vegetables	0.02
Sunflower seed	0.01

* * * * *

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300743; FRL–6037–2]
RIN 2070-AB78

Imidacloprid; Extension of Tolerance for Emergency Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This rule extends the time-limited tolerances for residues of the insecticide imidacloprid and its metabolites in or on the citrus fruits crop group at 1.0 part per million (ppm), dried citrus pulp at 5.0 ppm, beet roots at 0.3 ppm, turnip roots at 0.3 ppm, and turnip tops 3.5 ppm for an additional 18-month period, to June 30, 2000. This action is in response to EPA's granting of emergency exemptions under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) authorizing use of the pesticide on citrus, table beets and turnip greens. Section 408(l)(6) of the Federal Food, Drug, and Cosmetic Act (FFDCA) requires EPA to establish a time-limited tolerance or exemption from the requirement for a tolerance for pesticide chemical residues in food that will result from the use of a pesticide under an emergency exemption granted by EPA under section 18 of FIFRA.

DATES: This regulation becomes effective October 7, 1998. Objections