1981 (46 FR 24950), and was provided to the Chief Counsel for Advocacy of the Small Business Administration.

B. Executive Order 12875

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

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

C. Executive Order 13084

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

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

VIII. Submission to Congress and the Comptroller General

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

List of Subjects in 40 CFR Part 180

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

Dated: May 25, 1999.

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. 321(q), (346a) and 371.

2. Section 180.475 is revised to read as follows:

§ 180.475 Difenoconazole; tolerances for residues.

(a) *General.* Tolerances are established for residues of the fungicide difenoconazole (((2*S*,4*R*)/(2*R*,4*S*)/(2*R*,4*R*)/(2*S*,4*S*)) (1–((2–(2-chloro-4–(4-chlorophenoxy)phenyl)-4-methyl-1,3-dioxolan-2-yl)methyl)-1*H*–1,2,4-triazole) in or on the following raw agricultural commodities:

Commodity	Parts per million
Cattle, fat	0.05
Cattle, meat	0.05
Cattle, meat by-products	0.05
Eggs	0.05
Goats, fat	0.05
Goats, meat	0.05
Goats, meat by-products	0.05
Hogs, fat	0.05
Hogs, meat	0.05
Hogs, meat by-products	0.05
Horses, fat	0.05
Horses, meat	0.05
Horses, meat by-products	0.05
Milk	0.01
Poultry, fat	0.05
Poultry, meat	0.05
Poultry, meat by-products	0.05
Sheep, fat	0.05
Sheep, meat	0.05
Sheep, meat by-products	0.05
Wheat, forage	0.1
Wheat, grain	0.1
Wheat, straw	0.1

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

(c) *Tolerances with regional registrations.*

Commodity	Parts per million
Bananas[1]	0.2

[1]There are no U.S. registrations.

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

[FR Doc. 99–13947 Filed 6–1–99; 8:45 am]

BILLING CODE 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 180, 185 and 186

[OPP–300807; FRL 6064–5]

RIN 2070–AB78

Iprodione; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a tolerance for combined residues of iprodione, 3-(3,5-dichlorophenyl)-*N*-(1-methylethyl)-2,4-dioxo-1-imidazolidinecarboxamide, its isomer, 3-(1-methylethyl)-*N*-(3,5-

dichlorophenyl)-2,4-dioxo-1-imidazolidinecarboxamide and its metabolite, 3-(3,5-dichlorophenyl)-2,4-dioxo-1-imidazolidinecarboxamide in or on cottonseed. Rhone-Poulenc Ag Company requested this tolerance under the Federal Food, Drug, and Cosmetic Act, as amended by the Food Quality Protection Act of 1996.

DATES: This regulation is effective June 2, 1999. Objections and requests for hearings must be received by EPA on or before August 2, 1999.

ADDRESSES: Written objections and hearing requests, identified by the docket control number, [OPP–300807], 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–300807], must also be submitted to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring a copy of objections and hearing requests to Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA.

A copy of objections and hearing requests filed with the Hearing Clerk may be submitted electronically by sending electronic mail (e-mail) to: opp-docket@epa.gov. Copies of objections and hearing requests must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Copies of objections and hearing requests will also be accepted on disks in WordPerfect 5.1/6.1 or ASCII file format. All copies of objections and hearing requests in electronic form must be identified by the docket control number [OPP–300807]. No Confidential Business Information (CBI) should be submitted through e-mail. Electronic copies of objections and hearing requests on this rule may be filed online at many Federal Depository Libraries.

FOR FURTHER INFORMATION CONTACT: By mail: Mary L. Waller, Product Manager (21), Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number, and e-mail address: Rm. 249, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, (703) 308–9354, waller.mary@epa.gov.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of January 24, 1997 (62 FR 3696) (FRL 5582–7), EPA issued a notice pursuant to section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a as amended by the Food Quality Protection Act of 1996 (FQPA) (Pub. L. 104–170) announcing the filing of a pesticide petition (PP) for tolerance by Rhone-Poulenc Ag Company, P.O. Box 12014, 2 T.W. Alexander Drive, Research Triangle Park, NC 27709. This notice included a summary of the petition prepared by Rhone-Poulenc Ag Company, the registrant. There were no comments received in response to the notice of filing.

The petition requested that 40 CFR 180.399 be amended by establishing a tolerance for combined residues of the fungicide iprodione, 3-(3,5-dichlorophenyl)-*N*-(1-methylethyl)-2,4-dioxo-1-imidazolidinecarboxamide, its isomer, 3-(1-methylethyl)-*N*-(3,5-dichlorophenyl)-2,4-dioxo-1-imidazolidinecarboxamide and its metabolite, 3-(3,5-dichlorophenyl)-2,4-dioxo-1-imidazolidinecarboxamide], in or on cottonseed at 0.10 part per million (ppm).

I. Background and Statutory Findings

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

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

II. Aggregate Risk Assessment and Determination of Safety

Consistent with section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of iprodione and to make a determination on aggregate exposure, consistent with section 408(b)(2), for a tolerance for combined residues of iprodione, 3-(3,5-dichlorophenyl)-*N*-(1-methylethyl)-2,4-dioxo-1-imidazolidinecarboxamide, its isomer, 3-(1-methylethyl)-*N*-(3,5-dichlorophenyl)-2,4-dioxo-1-imidazolidinecarboxamide and its metabolite, 3-(3,5-dichlorophenyl)-2,4-dioxo-1-imidazolidinecarboxamide on cottonseed at 0.10 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 iprodione are discussed in this unit.

1. *Acute studies*. Iprodione is not acutely toxic by oral, dermal, inhalation, or ocular routes of exposure. Acute oral, acute dermal and primary eye irritation studies were in toxicity category III. Acute inhalation and primary skin irritation studies were in toxicity category IV. Iprodione is not a dermal sensitizer.

2. *Subchronic toxicity testing*—a. In a dermal toxicity study, rabbits were administered iprodione on the skin at dose levels of 0, 100, 500, and 1,000 mg/kg/day for 21 days. There were no deaths or clinical signs of toxicity and no adverse effects were observed on body weight, food consumption, the skin, liver or kidneys. The NOAEL was 1,000 mg/kg/day, the highest dose tested.

b. In a 90–day subchronic feeding study, rats were administered iprodione in the diet at doses of 0, 1,000, 2,000, 3,000 and 5,000 ppm (0, 78, 151, 252 and 355 mg/kg/day for males and 0, 89, 189, 266 and 408 mg/kg/day for females). The NOAEL in this study was 1,000 ppm (78 mg/kg/day for males and

89 mg/kg/day for females). The LOAEL was 2,000 ppm (151 mg/kg/day for males and 189 mg/kg/day for females), based on decreased body weight gain, decreased food consumption and food utilization, organ weight effects, and microscopic lesions in the sex organs.

3. *Chronic toxicity studies*—a. In a chronic feeding study, dogs were administered iprodione in the diet at dose levels of 0, 100 ppm (4.1 mg/kg/day for males and 4.3 mg/kg/day for females), 600 ppm (24.9 mg/kg/day for males and 28.3 mg/kg/day for females) and 3,600 ppm (145.3 mg/kg/day for males and 152.5 mg/kg/day for females) for one year. The NOAEL was 100 ppm (4.1 mg/kg/day for males and 4.3 mg/kg/day for females, and the LOAEL was 600 ppm (24.9 mg/kg/day for males and 28.3 mg/kg/day for females) based on decreased prostate weight and an increased incidence of erythrocytes with Heinz bodies.

b. A second chronic feeding study designed to compliment the above study was conducted using dose levels of 0, 200 ppm (7.8 mg/kg/day for males and 9.1 mg/kg/day for females), 300 ppm (12.4 mg/kg/day for males and 13.1 mg/kg/day for females), 400 ppm (17.5 mg/kg/day for males and 18.4 mg/kg/day for females) and 600 ppm (24.6 mg/kg/day for males and 26.4 mg/kg/day for females) for 12 months. The NOAEL for systemic toxicity is 400 ppm (17.5 mg/kg/day for males and 18.4 mg/kg/day for females). The LOAEL is 600 ppm (24.6 mg/kg/day for males and 26.4 mg/kg/day for females) based on decreased red blood cell values. When both chronic dog studies are considered together, the NOAEL is 400 ppm (18 mg/kg/day).

4. *Carcinogenicity*—a. In a combined chronic toxicity/carcinogenicity study in rats, iprodione was administered in the diet of rats at dose levels of 0, 150, 300 and 1,600 ppm (6.1, 12.4, and 69 mg/kg/day for males and 8.4, 16.5, and 95 mg/kg/day for females, respectively) for 24 months. The NOAEL for non-neoplastic changes in this study was 150 ppm (6.1 mg/kg/day for males and 8.4 mg/kg/day for females). The LOAEL was 300 ppm (12.4 mg/kg/day for males and 16.5 mg/kg/day for females) based on increases in generalized enlargement of the cells of the zona glomerulosa in males and females, in fine vacuolation of the zona fasciculata and in generalized fine vacuolation of the zona reticularis in males in the adrenal cortex, an increased incidence of interstitial cell hyperplasia, reduced spermatozoa in the epididymides, reduced secretion of the seminal vesicles, increased hemosiderosis in the spleen in females, and increased liver weight.

b. In a carcinogenicity study, iprodione was administered in the diet to mice for 99 weeks at dose levels of 0, 160, 800, and 4,000 ppm (0, 23, 115, and 604 mg/kg/day for males and 0, 27, 138, and 793 mg/kg/day for females, respectively). The NOAEL for this study was 160 ppm (23 mg/kg/day for males and 27 mg/kg/day for females). The LOAEL was 800 ppm (115 mg/kg/day for males and 138 mg/kg/day for females) based on the increased incidence of centrilobular hepatocyte enlargement in females and the increased incidence of generalized vacuolation/hypertrophy of the interstitial cells in the testes of males.

5. *Developmental toxicity*—a. In a developmental toxicity study, pregnant rats were administered iprodione at dose levels of 0, 40, 90, and 200 mg/kg/day by gavage from day 6 through 15 of gestation. There were no significant differences observed in the mean number of viable fetuses, implantations, corpora lutea, resorptions, and pre- and post-implantation losses were comparable among the groups. There was no evidence of maternal toxicity at any dose level. The developmental NOAEL was 90 mg/kg/day and the developmental toxicity LOAEL was 200 mg/kg/day, based on delayed fetal development (slightly reduced fetal body weight and increased incidences of space between the body wall and organs in the fetuses).

b. In a special prenatal developmental toxicity study, pregnant rats received iprodione by gavage at dose levels of 0, 20, 120 or 250 mg/kg/day during gestation days 6 through 19. For maternal toxicity, the NOAEL was 20 mg/kg/day and the LOAEL was 120 mg/kg/day based on decreased body-weight gain and decreased food efficiency. For developmental toxicity, the NOAEL was 20 mg/kg/day and the LOAEL was 120 mg/kg/day, based on decreased anogenital distance in the male pups.

c. In a prenatal developmental toxicity study on rabbits, dosed by gavage with iprodione at 0, 20, 60 or 200 mg/kg/day during gestation days 6 through 18, the NOAEL for maternal toxicity was 20 mg/kg/day and the LOAEL was 60 mg/kg/day based on decreased body weight gain. For developmental toxicity, the NOAEL was 60 mg/kg/day and the LOAEL was 200 mg/kg/day based upon increased skeletal variations.

6. *Reproductive toxicity*. In a 2-generation reproduction study, male and female rats received diets containing iprodione at 0, 300, 1,000, or 3,000/2,000 ppm (0, 18.5, 61.4, or 154.8 mg/kg/day for males and 22.49, 76.2, or 201.2 mg/kg/day for females). For parental systemic toxicity, the NOAEL was 300 ppm (21 mg/kg/day) and the LOAEL was 1,000 ppm (69 mg/kg/day), based on decreased body weight, body weight gain, and food consumption in both sexes and generations. For offspring toxicity, the NOAEL was 1,000 ppm (69 mg/kg/day) and the LOAEL was 3,000/2,000 ppm (178 mg/kg/day), based on decreased pup viability (as evidenced by an increased number of still born pups and decreased survival during postnatal days 0–4), decreased pup body weight throughout lactation, and an increased incidence in clinical signs (smallness, reduced mobility, unkempt appearance, hunching and or tremors) in pups during the lactation period.

7. *Mutagenicity*. Several mutagenicity studies were conducted. Iprodione was negative for induction of reverse gene mutations at the histidine locus in *Salmonella typhimurium* strains, both in the presence and absence of S9 activation. Iprodione did not induce mutation with or without metabolic activation in the *in vitro* forward gene mutation (CHO/HGPRT) assay at adequate dose levels. Iprodione was negative in an *in vitro* chromosomal aberration assay in Chinese hamster ovary (CHO) cells both in the presence and absence of metabolic activation. In an *in vivo* mouse micronucleus assay, iprodione was administered by oral gavage once at dose levels of 750, 1,500, and 3,000 mg/kg. Bone marrow cells were collected for micronucleated polychromatic erythrocytes (MPEs). One male and eight females died at the high dose. Dose-related cytotoxic effects on the target tissue were also seen at 48 hours post dose. The positive control induced the expected high yield of MPEs in both sexes. There was no evidence of a clastogenic or aneugenic effect at any dose or harvest time. Iprodione was negative in a sister chromatid exchange assay in Chinese hamster ovary cells both with and without metabolic activation. Iprodione was tested against 19 strain of *Bacillus subtilis* both with and without metabolic activation. Iprodione was positive both with and without metabolic activation.

8. *Metabolism*. A general metabolic pathway for iprodione in the rat indicates that biotransformation results in hydroxylation of the aromatic ring, degradation of the isopropylcarbamoyl chain, and rearrangement followed by cleavage of the hydantoin moiety. Additionally, structural isomers of iprodione resulting from molecular rearrangement, as well as intermediates in the pathway, were detected.

9. *Neurotoxicity* Neurotoxicity studies are not required since iprodione is not an organophosphate nor structurally related to compounds that are known to induce neurotoxicity.

10. *Other toxicological considerations*. In a dermal penetration study, rats were exposed dermally to a single dose of iprodione at dose levels of 0.4, 4.0, and 40 mg/rat for 0.5, 1, 2, 4, 10, and 24 hours. Skin residues increased with the duration of exposure to 5–10% of the applied dose, although there was no apparent dose response. The portion of the test material absorbed increased with the duration of exposure to 7.41%, 3.16% and 0.19% of the applied dose at 0.4, 4.0 and 40 mg/rat, respectively. Absorption appears to be saturated at the two highest dose levels. Following a 10–hour exposure period, about 5% iprodione is absorbed.

B. Toxicological Endpoints

1. *Acute toxicity*. The Agency determined that the developmental NOAEL of 20 mg/kg/day based on decreased anogenital distance (AGD) in male fetuses at 120 mg/kg/day (LOAEL) should be used for acute dietary risk assessment). This NOAEL is from a special rat developmental study which was designed to determine the impact of iprodione on sexual differentiation. This endpoint applies only for females 13 years or older because the endpoint (decreased AGD) is an *in utero* effect occurring during prenatal exposure. An appropriate endpoint attributable to a single dose was not identified for the general population including infants and children. The target acute dietary margin of exposure (MOE) for iprodione is 300, based on uncertainty factors of 10x for interspecies variability, 10x for intraspecies variability, and 3x for added protection of infants and children. The acute RfD is 0.06 mg/kg/day based on the 20 mg/kg/day NOAEL and an uncertainty factor of 300.

2. *Short- and intermediate-term toxicity*. The Agency determined that short- and intermediate-term dermal risk assessments are not required since no dermal or systemic toxicity was seen. It was concluded that there is no potential hazard by the dermal route because of lack of systemic toxicity at the limit-dose (1,000 mg/kg/day) and the demonstration of low (5%) absorption by the dermal route. For short-term inhalation exposure, the developmental NOAEL of 20 mg/kg/day from the special rat developmental toxicity study was selected. This NOAEL is based on decreased AGD in male fetuses at 120 mg/kg/day. For intermediate-term inhalation exposure, the NOAEL of 6.1 mg/kg/day from the rat combined chronic toxicity/carcinogenicity study was selected. This NOAEL is based on histopathological lesions in the male reproductive system and effects on the adrenal glands in males at 12.4 mg/kg/day and in females at 16.5 mg/kg/day (LOAEL). The inhalation unit exposures (in ug ai/lb/day) should be converted to an equivalent oral dose (mg/kg/day) using a 100% absorption rate (default value). The converted oral doses should then be compared to the NOAELs identified above.

3. *Chronic toxicity*. EPA has established the RfD for iprodione at 0.02 milligrams/kilogram/day (mg/kg/day). This Reference Dose (RfD) is based on a NOAEL of 6.1 mg/kg/day from the rat combined chronic toxicity/carcinogenicity study in which histopathological lesions occurred in the male reproductive system and there were effects on the adrenal glands in males at 12.4 mg/kg/day and in females at 16.5 mg/kg/day (LOAEL). The NOAEL was adjusted with an uncertainty factor of 300 (10x for interspecies extrapolation, 10x for intraspecies extrapolation and 3x for added protection for infants and children).

4. *Carcinogenicity*. In accordance with the EPA Proposed Guidelines for Carcinogenic Risk Assessment (April 10, 1996), iprodione was classified as a ''likely'' human carcinogen based on the combined hepatocellular adenomas/carcinomas in mice and testicular tumors in male rats with a linear low-dose extrapolation approach and a 3/4s interspecies scaling factor for human risk characterization. For the combined hepatocellular adenomas/carcinomas, the Q_1*s are 8.7 x 10^{-3} mg/kg/day for the male mouse and 5.07 x 10^{-3} mg/kg/day for the female mouse. The Leydig cell tumor Q_1* is 4.3 x 10^{-2} mg/kg/day which was determined to be appropriate for estimating carcinogenic risk.

C. Exposures and Risks

1. *From food and feed uses.* Tolerances have been established (40 CFR 180.399) for the combined residues of iprodione, 3-(3,5-dichlorophenyl)-*N*-(1-methylethyl)-2,4-dioxo-1-imidazolidinecarboxamide, its isomer, 3-(1-methylethyl)-*N*-(3,5-dichlorophenyl)-2,4-dioxo-1-imidazolidinecarboxamide and its metabolite, 3-(3,5-dichlorophenyl)-2,4-dioxo-1-imidazolidinecarboxamide, in or on a variety of raw agricultural commodities. Commodities include various vegetable crops, field crops, stone fruits, small fruit and berry crops and commodities of animal origin (meat, milk, poultry and eggs). Risk assessments were conducted by EPA to assess dietary exposures from iprodione as follows:

Dietary exposures for iprodione were reevaluated as part of the reregistration process. The risk assessment in the Reregistration Eligibility Decision (RED) document is being used to establish the tolerance for iprodione on cottonseed. The resulting estimates included refinements using both anticipated residues and percent crop treated for many crops but not for cottonseed. The requirements indicated below regarding anticipated residues and percent crop treated apply to both iprodione and its 3,5- dichloroaniline metabolite.

Section 408(b)(2)(e) authorizes EPA to use available data and information on the anticipated residue levels of pesticide residues in food and the actual levels of pesticide chemicals that have been measured in food. If EPA relies on such information, EPA must require that data be provided 5 years after the tolerance is established, modified, or left in effect, demonstrating that the levels in food are not above the levels anticipated. Following the initial data submission, EPA is authorized to require similar data on a time frame it deems appropriate. As required by section 408(b)(2)(e), EPA will issue a data call-in for information relating to anticipated residues to be submitted no later than 5 years from the date of issuance of this tolerance.

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

The Agency used PCT information as follows: PCT was used for various crops in reevaluating dietary exposures for iprodione as part of the reregistration process. For cottonseed, it was considered that 100% of the crop would be treated with iprodione.

The Agency believes that the three conditions, discussed in section 408 (b)(2)(f) in this unit concerning the Agency's responsibilities in assessing chronic dietary risk findings, have been met. The PCT estimates are derived from Federal and private market survey data, which are reliable and have a valid basis. 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 the PCT, the Agency is reasonably certain that the percentage of the food treated is not likely to be underestimated. The regional consumption information and consumption information for significant subpopulations is taken into account through EPA's computer-based model for evaluating the exposure of significant subpopulations including several regional groups. Use of this consumption information in EPA's risk assessment process ensures that EPA's exposure estimate does not understate exposure for any significant subpopulation group and allows the Agency to be reasonably certain that no regional population is exposed to residue levels higher than those estimated by the Agency. Other than the data available through national food consumption surveys, EPA does not have available information on the regional consumption of food to which iprodione may be applied in a particular area.

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 risk for iprodione was reevaluated as part of the reregistration process. The target margin of exposure (MOE) for dietary risk for iprodione is 300. MOEs above 300 are not considered to be of concern. Prior to the reevaluation, dietary MOEs were 111 for existing tolerances and 66.6 for existing and proposed tolerances. Following reevaluation, which included risk mitigation measures imposed in the Reregistration Eligibility Decision (RED) document, the acute dietary MOE was calculated to be 351 for the population subgroup of concern (females 13 years old or older).

ii. *Chronic exposure and risk.* The total dietary exposure for iprodione, expressed as percent of the RfD for the chronic (non-carcinogenic) risk was calculated based on the theoretical maximum residue contribution (TMRC) and the RfD of 0.02 mg/kg/day to be less than 1% for all populations from the registered uses. The additional use on cotton would not increase the chronic (non-carcinogenic) risk to an unacceptable level. The upper bound carcinogenic risk from food uses of iprodione for the general U.S. population was calculated using the equation: upper bound cancer risk equals dietary exposure (anticipated residue contribution) multiplied by the Q1*. Based on a Q_1* of 0.0439 $(mg/kg/day)^{-1}$ the upper bound cancer risk for all commodities with proposed and established tolerances was calculated to be 3.9×10^{-6}. This risk estimate is above the range the Agency generally considers negligible for excess life-time cancer risk. During the reregistration process, the upper bound cancer risk was reevaluated, taking into consideration the risk mitigation measures imposed in the RED. The reevaluated dietary cancer risk for iprodione with mitigation measures in place is estimated to be approximately 1.8×10^{-6} and is within the range the Agency generally considers negligible for excess life-time cancer risk. The upper bound cancer risk attributed to the use of iprodione on cotton was calculated to be 1.8×10^{-8}.

2. *From drinking water.* In the absence of reliable, available monitoring data, EPA uses models to estimate concentrations of pesticides in ground and surface water. For iprodione, modeling was used to estimate surface water concentrations because of very limited surface water monitoring data. However, EPA does not use these model estimates to quantify risk. Currently, EPA uses drinking water levels of comparison (DWLOCs) as a surrogate to capture risk associated with exposure to pesticides in drinking water. A DWLOC is the concentration of a pesticide in drinking water that would be acceptable as an upper limit in light of total aggregate exposure to that pesticide from food, water, and residential uses (if any). A DWLOC will vary depending on the residue level in foods, the toxicity endpoint and with drinking water consumption patterns and body weights for specific subpopulations. The calculated DWLOC is compared with the model estimate from PRZM 2.3/EXAMS 2.94 model estimates. If the estimates are below the DWLOC, the risks are not considered to be of concern. EPA believes the PRZM 2.3/EXAMS 2.94 model estimates to be overestimations of concentrations of iprodione expected in drinking water. Iprodione is strongly absorbed to sediment and is expected to be removed through treatment. Given low concentrations estimated in surface water (1–3 ppb), expected absorption to sediments, and the likelihood of removal through treatment, the Agency does not believe iprodione will be present in drinking water.

i. *Acute exposure and risk.* The acute DWLOC for iprodione was calculated for the population subgroup females 13 years old or older to be 324 µg/L. Conservative model estimates of maximum concentrations in surface water associated with use of iprodione range from 10–15 ppb (µg/L). The estimated concentrations in surface water are much lower than EPA's DWLOC of 324 µg/L for the population of females 13 years old or older. Therefore, acute drinking water exposures and risks are not of concern.

ii. *Chronic exposure and risk.* The chronic DWLOC was calculated for adult males, adult females and children. The DWLOCs were 693 µg/L for adult males, 594 µg/L for adult females and 197 µg/L for children. Conservative model estimates of a long-term average concentration of iprodione in surface water range up to a few parts per billion (1–3 µg/L) The estimated concentrations in surface water are much lower than EPA's calculated DWLOCs for the above subpopulations for chronic exposure and risk assessments. Therefore, chronic drinking water exposures and risks are not of concern.

iii. *Carcinogenic exposure and risk.* Because cancer risk estimates (without risk mitigation) for exposure to iprodione residues through food and residential uses each exceeded EPA's level of concern individually, combined exposures through these routes resulted in an aggregate risk that further exceeded the level of concern. Any additional exposure through drinking water would result in aggregate risks that further exceed the level of concern. In effect, the drinking water level of comparison (DWLOC) is zero. So, effectively, with risk reduction measures is place, exposures from food, residential uses and through drinking water would be below the level of concern.

3. *From non-dietary exposure.* Iprodione is currently registered for use on the following residential non-food sites: ornamental plants including shade trees, evergreens and shrubs, and turfgrass. As one of the risk mitigation measures included in the RED, the registrant has agreed to cancel all residential uses for iprodione. Therefore, there will be no exposure or risk from residential uses.

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.

Although at present the Agency is still considering how to apply the information in its files concerning common mechanism issues to most risk assessments, there are pesticides for 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).

Iprodione is structurally related to vinclozolin and procymidone, which belong to the imide class of fungicides. Each of these three pesticides can metabolize to 3,5-dichloroaniline (3,5-DCA). FQPA requires EPA to estimate cumulative risk from consumption of food and water containing 3,5-DCA derived from iprodione, vinclozolin, and procymidone.

The Agency has determined that it is not necessary to include exposure to DCA derived from vinclozolin and procymidone in a cumulative exposure assessment for iprodione *per se*. Based on available metabolism data (discussed below), the contribution of DCA from vinclozolin and procymidone to the total chronic iprodione dietary exposure is less than an order of magnitude. Therefore, inclusion of DCA from vinclozolin and procymidone in the iprodione chronic exposure assessment would not have a significant impact on the risk estimates. A similar negligible contribution is expected for acute dietary exposure. Iprodione residues are measured as DCA by the analytical method, thus, any DCA formed from iprodione is already accounted for in the iprodione exposure assessment.

3,5-DCA is not a registered pesticide; therefore, there are no FIFRA toxicology data for this compound so EPA has used the Q_1* for *p*-chloroaniline (PCA) to assess the carcinogenic risk for other structurally related chloroanilines. The EPA policy on chloroanilines specifies that chloroaniline metabolites should be considered to be toxicologically equivalent to PCA unless there is sufficient evidence that the metabolite is not carcinogenic. No other toxicological endpoints have been identified for DCA. A Q_1* of 6.38×10^{-2} $(mg/kg/day)^{-1}$ in human equivalents has been calculated for p-chloroaniline. This is based on the spleen sarcoma rate in male rats from an NTP bioassay, linearized low dose multistage model, and the 3/4s interspecies scaling factor.

i. *3,5-DCA residues in food and wine*—a. For iprodione, metabolism data submitted to fulfill reregistration data requirements indicated that 3,5-DCA represented 1% of the total radioactive residue (TRR) in eggs, smaller proportions in other livestock commodities, and was not detected in primary or rotational crops. The total estimated exposure to iprodione-derived 3,5-DCA in food is 0.00000009219 mg/kg/day.

b. For vinclozolin, metabolism data indicated that DCA represented 9.6% TRR in peaches, smaller proportions in strawberries and was not detected in lettuce or grapes. Therefore, EPA assumed that 10% vinclozolin residues would be appropriate for use in an assessment for 3,5-DCA. Wine was included in the analysis because the metabolism studies for procymidone showed that the 3,5-DCA metabolite is formed in wine even though it is not detected in grapes. The total estimated exposure to vinclozolin-derived 3,5-DCA in food is 0.000143224 mg/kg/day.

c. Procymidone is not registered for use in the U.S. so only imported wine was considered under the procymidone tolerance for wine grapes. The 3,5-DCA metabolite was not detected in grapes, but occurs during fermentation. Residues in wine were 0.3 ppm for parent procymidone and 0.06 ppm for 3,5-DCA. The estimated exposure to procymidone-derived 3,5 DCA in wine is 0.0000058 mg/kg/day using tolerance levels and 100% of crop treated.

ii. *3,5-DCA residues in water*—a. EPA estimated the concentration of iprodione in surface water as a result of an application to peaches for a chronic exposure to be 1.5 parts per billion (ppb). This assessment was refined by assuming that only some of the iprodione will convert to 3,5-DCA. A soil photolysis study indicated that a value of 30% would be reasonable to account for the iprodione that is actually converted. The concentration of 3,5-DCA was estimated to be 0.45 ppb in surface water.

b. A tier 1 estimated environmental concentration (EEC) was calculated for 3,5-DCA from degradation of vinclozolin when applied to peaches. EPA estimated the concentration of vinclozolin in surface water for a chronic exposure to be 2.6 ppb. The maximum of the parent vinclozolin that would be expected to convert to 3,5-DCA based on a field dissipation study is 20%. The concentration of 3,5-DCA in surface water was estimated to be 0.52 ppb.

c. There are no U.S. registrations for procymidone; therefore, an evaluation of exposure to procymidone-derived 3,5-DCA in water is not appropriate.

iii. *Cumulative risk from all sources of 3,5-DCA*. The cumulative carcinogenic risk estimate for consumption of food and wine containing residues of 3,5-DCA as a result of use of iprodione, vinclozolin and procymidone is 9.5×10^{-7}. This can be considered to be a conservative estimate. Metabolism studies for iprodione and vinclozolin were used to estimate the amount of 3,5-DCA present in various commodities by using total radioactive residues to convert iprodione or vinclozolin exposures to 3,5-DCA exposures. There is another uncertainty in the risk estimate in that a surrogate Q_1* is being used for 3,5-DCA. However, due to the structural similarities of 3,5-DCA and PCA, EPA believes that for 3,5-DCA, the use of the PCA Q_1* represents an upper-bound estimate. This risk estimate is within the range the Agency generally considers negligible for excess life-time cancer risk. Because drinking water data on DCA residues in water are not available, EPA compared the conservative screening-level model estimates of iprodione concentrations in surface water to drinking water levels of comparison (DWLOCs) for DCA. The estimated concentrations of 3,5-DCA from iprodione applications in water was 0.22 ppb and is less than the DWLOC calculated for the cancer risk assessment. From applications of vinclozolin, the model estimated the concentration of DCA in water at 0.37 ppb. This is above the DWLOC calculated for the cancer risk assessment. However, the Agency recognizes that the model estimates are very conservative (upper bound estimates with a high degree of uncertainty) and are not likely to be representative of what might be expected in drinking water. When model estimates for water exceed DWLOCs, EPA makes an attempt to gather monitoring data (required for surface water). These data are used to confirm or deny the model estimate. The RED for iprodione requires that registrants develop and submit surface water monitoring data to confirm or deny the model estimates. The risks indicated for 3,5-DCA are not added to

those for the parent compounds since the risk estimates for the parent already include the 3,5-DCA component.

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

1. *Acute risk.* The aggregate acute dietary risk estimate includes exposure to iprodione residues in foods and water. Iprodione uses are not expected to impact ground water. Upper bound estimates of iprodione in surface waters from conservative screening models indicate concentrations of a few parts per billion. For the acute dietary exposure and risk assessment, the toxic endpoint selected for risk assessment was the NOAEL of 20 mg/kg/day based on decreased anogenital distance (AGD) in male offspring observed in the developmental study in rats, in which the LOAEL was 120 mg/kg/day. The FQPA safety factor is applied for acute dietary risk assessment for only females 13+ because the endpoint (decreased AGD) is an in utero effect occurring during prenatal exposures. The MOE for this subgroup was calculated to be 351.

2. *Chronic risk.* The chronic aggregate risk assessment for iprodione includes risk estimates associated with exposure through food, water, and registered residential uses. Using anticipated residues and percent crop-treated data for commodities with published tolerances results in an exposure to iprodione through food that will utilize 1% of the RfD for the U.S. population. The major identifiable subgroup with the highest aggregate exposure is non-nursing infants less than 1 year old, (discussed below) which represents up to 1.6% of the chronic FQPA RfD. Exposure to all other groups is less than or equal to 1% of the chronic FQPA RfD. EPA generally has no concern for exposures below 100% of the RfD because the RfD represents the level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to human beings. Chronic aggregate risk from iprodione in food and drinking water associated with registered uses of iprodione is not of concern. Estimated average concentrations of iprodione in ground water were not available for comparison against DWLOC values; however, based on iprodione's physical/chemical characteristics and available, but limited monitoring data, iprodione is not expected to impact ground water. No chronic exposure scenarios for residential uses of iprodione were identified; therefore, no chronic exposure from residential uses was included in the aggregate risk estimate.

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.

4. *Short-term aggregate risk.* Aggregate risk estimates associated with short-term risk include exposures to average residues of iprodione in the diet (food and water) and inhalation exposure (1 to 7 days in duration) through the residential application of iprodione. The resulting risk, calculated without any risk mitigation, represented 3.6% of the acute FQPA RfD for the U.S. population representing the most exposed population of adult males and females. It was assumed that children and infants do not apply pesticides. The Agency believes that iprodione's impact on drinking water will not affect the aggregate short-term risk significantly. Therefore, the Agency concluded with reasonable certainty that residues of iprodione in drinking water (when considered along with exposure from food and residential uses) would not result in an unacceptable short-term aggregate human health risk estimate. Since residential uses will be canceled, short-term risk would be even lower.

5. *Intermediate-term aggregate risk.* Aggregate risk estimates associated with intermediate-term risk include exposures to average residues of iprodione in the diet (food and water) and inhalation exposure (7 days to several months in duration) through the residential application of iprodione. The resulting risk, calculated without mitigation measures, was 9.5% of the chronic FQPA RfD for the U.S. population representing the most exposed population of adult males and females. It was assumed that children and infants do not apply pesticides. The Agency believes that iprodione's impact on drinking water will not affect the aggregate intermediate-term risk significantly. Therefore, The Agency concluded with reasonable certainty that residues of iprodione in drinking water (when considered along with exposure from food and residential uses) would not result in an unacceptable intermediate-term aggregate human health risk estimate. Since residential uses of iprodione will be canceled, intermediate-term risk would be even lower. Assuming that the conditions imposed by the RED are met by the registrant, the Agency concludes that aggregate risks for the general population resulting from iprodione uses are not of concern.

6. *Aggregate cancer risk for U.S. population.* Without risk mitigation measures in place, combined exposure and the risk estimates for each of the residential exposure scenarios plus dietary exposure to iprodione residues results in cancer risk estimates that are all greater than 10^{-6}. The first step in reducing the cancer aggregate risk is to make ineligible for reregistration all those residential uses which are greater than 10^{-6}. Therefore, the Agency has decided, based on the current risk assessment, that residential use of iprodione on vegetable/small fruit gardens is ineligible for reregistration; use of iprodione on residential turf and lawns will be reclassified as restricted-use (professional application only); and, residential use of iprodione on ornamentals using a garden hose end-sprayer is ineligible for reregistration. The registrant has agreed to cancel these uses. With these mitigation measures in place cancer risks from residential uses of iprodione are expected to be negligible.

For dietary cancer risk, with no risk mitigation measures in place, the upper bound dietary cancer risk estimate (3.9×10^{-6}) exceeds EPA's level of concern. With risk mitigation measures in place, the upper bound dietary cancer risk estimate is approximately 1.8×10^{-6} and is within the range the Agency generally considers negligible for excess life-time cancer risk. This risk estimate is based the new use patterns which include the risk mitigation measures in the RED, which is based on a refined estimate of dietary exposure using the most recent percent crop-treated data (1995) and anticipated residue data from monitoring programs (USDA's PDP) and field trials. Residues of iprodione, including its metabolites, are not expected to exceed the Agency's drinking water level of comparison as indicated above.

7. *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 iprodione 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 iprodione, EPA considered data from developmental toxicity studies in the rat and rabbit and a 2-generation reproduction study in the rat. The developmental toxicity studies are designed to evaluate adverse effects on the developing organism resulting from maternal pesticide exposure gestation. Reproduction studies provide information relating to effects from exposure to the pesticide on the

reproductive capability of mating animals and data on systemic toxicity.

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

ii. *Conclusion*. Based on developmental and reproductive data for iprodione, EPA determined that an additional 10x safety factor for the protection of infants and children (as required by FQPA) should be reduced to 3x. The rationale for reducing the 10x factor to 3x is as follows: No enhanced susceptibility was seen in rat and rabbit developmental and 2–generation reproduction study in rats.

a. The critical endpoint for acute dietary risk assessment (decreased AGD) was seen at a high dose (120 mg/kg/day) and there were only marginal differences in the degree of decreased AGD between the doses 20 mg/kg/day, 120 mg/kg/day and 250 mg/kg/day , thus indicating the ''true'' NOAEL could be higher than the one established at 20 mg/kg/day.

b. The proposed mode of action of iprodione is disruption of testosterone biosynthesis with a corresponding increase in plasma luteinizing hormone to dose levels which induce benign Leydig cell tumors. The dose response for this type of hormonally-mediated effect would be expected to be non-linear.

c. The use of realistic dietary exposure data (refined using monitoring data and percent crop treated).

d. The endpoints selected for both the acute (AGD) and the chronic (histopathology of the male reproductive system) risk assessments are based on developmental/ reproductive effects and therefore, these effects are already adequately considered in the risk evaluation. These factors favor removal of the safety factor but, although the data base for iprodione is complete, the Agency still has questions about any effects that iprodione may have on the developing reproductive system. The Agency is requiring an additional pre/post exposure study to assess the effects of iprodione on the male reproductive system. A safety factor of 3x is being retained pending completion of this additional study. There is a complete toxicity database for [iprodione] and exposure data is complete or is estimated based on data that reasonably accounts for potential exposures.

2. *Acute risk*. The acute dietary risk for iprodione was calculated and the MOE was determined to be 351. Using the 3x safety factor for protection of infants and children, MOEs above 300 are not considered to be of concern. For drinking water, the estimated concentrations in surface water are much lower than the DWLOC of 324 µg/ L for the population subgroup females 13 years old or older, so no acute risk concerns are posed by drinking water. There will be no residential exposure.

3. *Chronic risk*. Using the exposure assumptions described in this unit, EPA has concluded that aggregate exposure to iprodione from food will utilize 1.6% of the RfD for non-nursing infants less than 1 year old and less than 1% for all other population subgroups. 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. Since the potential for exposure to iprodione in drinking water is low and there will be no risk from non-dietary, non-occupational exposure, EPA does not expect the aggregate exposure to exceed 100% of the RfD.

4. *Short- or intermediate-term risk*. EPA has concluded that there are no short- or intermediate-term risk factors associated with infants and children. Residential handler exposure scenarios for short- and intermediate-term inhalation exposures are not applicable to children.

5. *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 iprodione residues.

III. Other Considerations

A. Metabolism In Plants and Animals

1. *Plants*. The metabolism of iprodione in plants is well understood. EPA concluded that the residues of concern in plants are the parent, its isomer 3-(1-methylethyl)-*N*-(3,5-dichlorophenyl)-2,4--dioxo-1-imidazolidinecarboxamide, and its metabolite 3-(3,5-dichlorophenyl)-2,4-dioxo-1-imidazolidinecarboxamide.

2. *Animals*. In rats, radio-labeled iprodione was absorbed readily from the gastrointestinal tract, metabolized and excreted by rats of both sexes. Peak blood levels were observed at 4 and 2 hours, respectively, in the low-dose males and females and at 6 hours in the high dose rats of both sexes. The elimination from the blood was slower in males than in females. Although radioactivity was found in most tissues monitored, the levels were <0.05% of the total amount administered. The primary route of elimination following single and repeat low-dose exposure was the urine, and the feces was the primary route following high-dose exposure. Dealkylation and cleavage of the hydantoin ring were the two primary steps in the metabolism of iprodione. Hydroxylation of the phenyl ring and oxidation of the alkyl chain also occurred. The nature of residues in animals is adequately understood for the use on cotton since the dietary contribution for animals from cottonseed as a result of the use on cotton will be small and the secondary residues in animal commodities would be expected to be nondetectable. The residues of concern in animal commodities are the parent, its isomer 3-(1-methylethyl)-*N*-(3,5-dichlorophenyl)-2,4-dioxo-1-imidazolidinecarboxamide and its metabolites 3-(3,5-dichlorophenyl)-2,4-dioxo-1-imidazolidinecarboxamide and *N*-(3,5-dichloro-4-hydroxyphenyl)-ureidocarboxamide.

B. Analytical Enforcement Methodology

An adequate analytical method, gas-liquid chromatography using an electron-capture detector, is available in the Pesticide Analytical Manual, Vol. II, for enforcement purposes.

C. Magnitude of Residues

The combined residues of iprodione, its isomer and its metabolite resulting from the use of iprodione on cotton will not exceed the tolerance level of 0.10 ppm.

D. International Residue Limits

There are no Codex, Canadian, or Mexican tolerances for iprodione on cottonseed. Therefore, no compatibility questions exist for cottonseed with respect to Codex.

E. Rotational Crop Restrictions

The following crops may be rotated after harvest: beans, broccoli, carrots, Chinese mustard, cotton, dry bulb onions, garlic, lettuce, peanuts, potatoes and rice.

IV. Conclusion

Therefore, the tolerance is established for combined residues of iprodione, 3-(3,5-dichlorophenyl)-*N*-(1-methylethyl)-2,4-dioxo-1-imidazolidinecarboxamide, its isomer, 3-(1-methylethyl)-*N*-(3,5-dichlorophenyl)-2,4-dioxo-1-imidazolidinecarboxamide and its metabolite, 3-(3,5-dichlorophenyl)-2,4-dioxo-1-imidazolidinecarboxamide, in cottonseed at 0.10 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 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 August 2, 1999, file written objections to any aspect of this regulation and may also request a hearing on those objections. Objections and hearing requests must be filed with the Hearing Clerk, at the address given under the ''ADDRESSES'' section (40 CFR 178.20). A copy of the objections and/or hearing requests filed with the Hearing Clerk should be submitted to the OPP docket for this regulation. The objections submitted must specify the provisions of the regulation deemed objectionable and the grounds for the objections (40 CFR 178.25). Each objection must be accompanied by the fee prescribed by 40 CFR 180.33(i). EPA is authorized to waive any fee requirement ''when in the judgement of the Administrator such a waiver or refund is equitable and not contrary to the purpose of this subsection.'' For additional information regarding tolerance objection fee waivers, contact James Tompkins, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number, and e-mail address: Rm. 239, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, (703) 305–5697, tompkins.jim@epa.gov. Requests for waiver of tolerance objection fees should be sent to James Hollins, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460.

If a hearing is requested, the objections must include a statement of the factual issues on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the requestor (40 CFR 178.27). A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established, resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issues in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32). Information submitted in connection with an objection or hearing request may be claimed confidential by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the information that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice.

VI. Public Record and Electronic Submissions

EPA has established a record for this regulation under docket control number [OPP–300807] (including any comments and data submitted electronically). A public version of this record, including printed, paper versions of electronic comments, which does not include any information claimed as CBI, is available for inspection from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The public record is located in Room 119 of the Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA.

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

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

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

VII. Regulatory Assessment Requirements

A. Certain Acts and Executive Orders

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

In addition, since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the [tolerance] in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (R.A.) (5 U.S.C. 601 *et seq.*) do not apply. Nevertheless, the Agency previously assessed whether establishing tolerances, exemptions from tolerances, raising tolerance levels or expanding exemptions might adversely impact small entities and concluded, as a

generic matter, that there is no adverse economic impact. The factual basis for the Agency's generic certification for tolerance actions published on May 4, 1981 (46 FR 24950), and was provided to the Chief Counsel for Advocacy of the Small Business Administration.

B. Executive Order 12875

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

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

C. Executive Order 13084

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

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

VIII. Submission to Congress and the Comptroller General

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

List of Subjects in 40 CFR Parts 180, 185 and 186

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

Dated: April 16, 1999.

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. 321(q), 346a and 371.

2. Section 180.399 is amended as follows:

a. By revising the phrase ''raw agricultural commodities'' or ''raw agricultural commodity'' to read ''food commodities'' or ''food commodity'', respectively, wherever it appears.

b. By adding a paragraph heading to paragraph (a), and redesignating the text following the heading as paragraph (a)(1).

c. By adding alphabetically to the table in paragraph (a)(1) the entries: Cottonseed at 0.10 ppm; Ginseng, dried 4.0 ppm; Raisins 300 ppm; Rice bran 30.0 ppm and Rice hulls 50.0 ppm.

d. By redesignating paragraph (b) as paragraph (a)(2).

e. By adding a paragraph heading to paragraph (c).

f. By adding and reserving with a paragraph heading, new paragraph (b), and by removing and reserving paragraph (d) with a paragraph heading to read as follows:

The additions read as follows:

§ 180.399 Iprodione; tolerances for residues.

(a) *General.* (1) * * *

* * * * * * *

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

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

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

PART 185 — [AMENDED]

2. In part 185:

a. The authority citation for part 185 continues to read as follows:

Authority: 21 U.S.C. 348.

§185.3750 [Removed]

b. Section 185.3750 is removed.

PART 186 — [AMENDED]

3. In part 186:

a. The authority citiation for part 186 continues to read as follows:

Authority 21 U.S.C. 342, 348, and 371.

§186.3750 [Removed]

b. Section 186.3750 is removed.

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FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 51

[CC Docket No. 98–147; FCC 99–48]

Deployment of Wireline Services Offering Advanced Telecommunications Capability

AGENCY: Federal Communications Commission.

ACTION: Final rule; announcement of effective date.

SUMMARY: The Commission amended its rules relating to local competition. The