354, 94 Stat. 1164, 5 U.S.C. 601–612), the Administrator has determined that regulations establishing new tolerances or raising tolerance levels or establishing exemptions from tolerance requirements do not have a significant economic impact on a substantial number of small entities. A certification statement to this effect was published in the Federal Register of May 4, 1981 (46 FR 24950).

List of Subjects in 40 CFR Part 180

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

Dated: April 18, 1996.

Stephen L. Johnson,

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR part 180 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 § 180.414 the table in paragraph (e) is amended by adding alphabetically the following raw agricultural commodity:

§ 180.414 Cyromazine; tolerances for residues.

* * * * *

Commodity	Parts per million
* * * * *	
Tomato	1.0

[FR Doc. 96–10922 Filed 5–2–96; 8:45 am]

BILLING CODE 6560–50–F

40 CFR Part 180

[PP 2F4111/R2226; FRL–5360–3]

RIN 2070–AB78

Pesticide Tolerance for Iprodione

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This rule establishes a time-limited tolerance for the combined residues of the fungicide iprodione in or on the raw agricultural commodity cottonseed. The regulation to establish a maximum permissible level for residues of iprodione was requested in a petition submitted by Rhone-Poulenc Ag Company.

EFFECTIVE DATE: This regulation becomes effective March 18, 1996.

ADDRESSES: Written objections and hearing requests, identified by the document control number, [PP 2F4111/R2226], may 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 should be identified by the document control number and submitted to: Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring copy of objections and hearing requests to: Rm. 1132, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA 22202.

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 in 5.1 file format or ASCII file format. All copies of objections and hearing requests in electronic form must be identified by the docket number [PP 2F4111/R2226]. 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. Additional information on electronic submissions can be found below in this document.

FOR FURTHER INFORMATION CONTACT: By mail: Connie B. Welch, Product Manager (PM) 21, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location and telephone number: Rm. 227, CM #2, 1921 Jefferson Davis Highway, Arlington, VA 22202 (703) 305-6900; e-mail: welch.connie@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: Rhone-Poulenc Ag Co., P.O. Box 12014,2 T.W. Alexander Drive, Research Triangle Park, NC 27709, has submittedpesticide petition (PP) 2F4111 to EPA requesting that the Administrator,pursuant to section 408(d) of the Federal Food, Drug, and Cosmetic Act(FFDCA), 21 U.S.C. 346a(d), establish a tolerance for the 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 the raw agricultural commodity cottonseed at 0.10 parts per million (ppm).

Through an oversight, an announcement of receipt of this petition by the Agency was not published in the Federal Register as required by regulation in 40 CFR 177.88. In lieu of the 30-day comment period prior to establishing the tolerance requested, this tolerance is being established with the provision that any comments received within 30 days after publication in the Federal Register which contain objections will be reviewed and if the objections are substantial, the tolerance will be withdrawn, if justified. The publication of this notice is deemed to be in the public interest and is justified by the fact that the resulting changes in the use pattern for iprodione, which resulted from an agreement between Rhone-Poulenc Ag Co. and the Agency, will significantly lower the overall use of iprodione and consequently reduce the risk to the public posed by its current uses.

The scientific data submitted in the petition and other relevant material have been evaluated. The toxicological data considered in support of the tolerance include:

1. A three-generation rat reproduction study using dosage levels of 0, 250, 500 and 2,000 ppm with a no-observed-effect level (NOEL) of 500 ppm (25 milligrams/kilogram(mg/kg) body weight (bwt)/day), a reproductive lowest effect level (LEL) of 2,000 ppm (100 mg/kg/day), and a systemic NOEL equal to or greater than 2,000 ppm (100 mg/kg/day).

2. A rabbit developmental toxicity study in which the following doses were administered by gavage; 0, 20, 60, and 200 mg/kg bwt, resulting in a developmental toxicity NOEL equal to or greater than 60 mg/kg bwt, and an LEL of 200 mg/kg bwt.

3. A rat developmental toxicity study in which the following doses were administered by gavage: 0, 40, 90, and

200 mg/kg bwt, with a developmental toxicity NOEL equal to or greater than 90 mg/kg bwt, and an LEL of 200 mg/kg bwt.

4. A 24-month feeding/oncogenicity study in rats using dosage levels of 125, 250 and 1,000 ppm (6.25, 12.5 and 50 mg/kg/day) which showed no treatment-related tumors were reported but testicular intersticial cell tumors were observed.

5. A repeated 24-month rat feeding study at dose levels of 0, 150, 300 and 1,600 ppm which showed non-neoplastic changes such as intersticial cell hyperplasia in the testes of males and tubular hyperplasia in the ovaries and increased sciatic nerve fiber degeneration in females. The NOEL for non-neoplastic changes was 150 ppm (6.1 mg/kg/day for males and 8.4 mg/kg/day for females) and an LEL of 300 ppm (12.4 mg/kg/day for males and 16.5 mg/kg/day for females).

6. An 18-month oncogenicity study in mice using dosage levels of 200, 500 and 1,250 ppm (28.6, 71.4 and 178.6 mg/kg/day, which showed no carcinogenicity.

7. A repeated mouse feeding study of 99 weeks at dose levels of 0, 160, 800, and 4,000 ppm in which there was a significantly increased incidence of single and multiple areas of enlarged eosinophilic hepatocytes and focal fat-containing hepatocytes in both males and females. In males there was an increased incidence of generalized vacuolation/hypertrophy of the interstitial cells of the testes in the mid- and high-dose mice. There was a dose-related increase in female mice displaying luteinization of the interstitial cell of the ovary, but statistical significance was not attained at any dose level. The NOEL for non-neoplastic changes was 160 ppm (23 mg/kg/day for males and 27 mg/kg/day for females) and the LEL was 800 ppm (115 mg/kg/day for males and 138 mg/kg/day for females).

8. A 1-year dog feeding study using dosage levels of 100, 600 and 3,600 ppm (4.2, 15, and 90 mg/kg/day) with a NOEL of 100 ppm (4.2 mg/kg/day) and an LEL of 600 ppm (15 mg/kg/day) based on decreased prostate weight and an increased number of erythrocytes with Heinz bodies in males.

9. Another 1-year dog feeding study at dosage levels of 200, 300, 400 and 600 ppm in which the NOEL was set at 400 ppm (17.5 mg/kg for males and 18.4 mg/kg for females and an LEL set at 600 ppm (24.6 mg/kg for males and 26.4 mg/kg for females) based on depressed red blood cell parameters.

10. A 90-day feeding study in dogs using dosage levels of 800, 2,400 and 7,200 ppm (20, 60, and 180 mg/kg/day) with a NOEL of 2,400 ppm (60 mg/kg/day) and an LEL of 7,200 ppm (180 mg/kg/day) based on liver hypertrophy and increased SAP.

11. Iprodione was tested in several mutagenicity studies. The chemical was negative in the Ames assay; CHO/HGPRT mammalian cell forward mutation assay, with and without metabolic activation; *in vitro* chromosome aberration assay in CHO cells; *in vitro* sister chromatid exchange assay in CHO cells; and dominant lethal test in mice. Iprodione was positive in the *Bacillus subtilis* assay for DNA damage without metabolic activation.

The Reference Dose (RfD) of 0.06 mg/kg/day based on a NOEL of 6.1 mg/kg/day and an uncertainty factor of 100 was used in the chronic risk analysis for iprodione. Using percent crop treated data and the Anticipated Residue Contribution (ARC), the Theoretical Maximum Residue Contribution (TMRC) for the overall U.S. population is 0.015134 mg/kg/day and utilizes 25% of the RfD. For the most highly exposed subgroup, non-nursing infants, the TMRC is 0.045389 mg/kg/day and utilizes 76% of the RfD. The calculated percentage of the RfD is within a safe margin and the chronic dietary risk posed from iprodione is not of concern.

In analyzing for the acute dietary risk tolerance level, residues were used to calculate the exposure of the highest exposed individual for the females (13 years old or older) which was compared to the developmental NOEL of 60 mg/kg/day from the rabbit study to determine the Margin of Exposure (MOE). The MOE was calculated to be 333. The Agency is not generally concerned with acute risk unless the MOE is below 100 when the NOEL is taken from an animal study.

The Health Effects Division (HED) Cancer Peer Review Committee determined that iprodione should be classified as a group B2 carcinogen (probable human carcinogen). Calculations of $Q1^*$ from the rat study used in the risk analysis was based upon interstitial cell benign tumor rates and was calculated to be 0.0439 $(mg/kg/day)^{-1}$. In the dietary cancer risk assessment, the upper bound cancer risk was calculated for all registered commodities when using anticipated residues to be 6.0×10^{-6}. This upper bound cancer risk estimate exceeds the Agency's generally accepted level of concern for dietary risk, even when anticipated residues are used and adjustments for percent crop treated are made. In an agreement between the Agency and Rhone-Poulenc Ag Co., various changes in the use pattern of iprodione will be made to reduce the residues of iprodione in or on several crops. Although data are not available to quantitatively determine the amount of reduction, the overall quantity of iprodione used will be reduced enough to significantly affect the amount of residues. This reduction is expected to lower the upper bound cancer risk estimate to an acceptable level.

The upper bound cancer risk attributed to the use of iprodione on cotton was calculated to be 1.8×10^{-8}. Therefore, the added use would be unlikely to significantly affect the overall cancer risk estimate. The tolerance being established for cottonseed is time-limited and the time limitation is being imposed on the condition that sufficient data are submitted within the time period to demonstrate that the risk has been reduced to an acceptable level through the changes in the use pattern of iprodione containing products.

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

There are presently no actions pending against the continued registration of this chemical. The pesticide is considered useful for the purpose for which the tolerance is sought.

Based on the information and data considered, the Agency has determined that the tolerance established by amending 40 CFR part 180 will protect the public health. Therefore, the tolerance is established as set forth below.

Any person adversely affected by this regulation may, within 30 days after publication of this document in the Federal Register, file written objections to the 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 issue(s) on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the objector (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 issue(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32).

EPA has established a record for this rulemaking under docket number [PP 2F4111/R2226] (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 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The public record is located in Room 1132 of the Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA.

Electronic comments may be sent directly to EPA at:

opp-docket@epamail.epa.gov.

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

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

Under Executive Order 12866 (58 FR 51735, October 4, 1993), the Agency must determine whether the regulatory action is ''significant'' and therefore subject to all the requirements of the Executive Order (i.e., Regulatory Impact Analysis, review by the Office of Management and Budget (OMB)). Under section 3(f), the order defines ''significant'' as those actions likely to lead to a rule (1) having an annual effect on the economy of $100 million or more, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local or tribal governments or communities (also known as ''economically significant''); (2) creating serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement, grants, user fees, or loan programs; or (4) raising novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in this Executive Order.

Pursuant to the terms of this Executive Order, EPA has determined that this rule is not ''significant'' and is therefore not subject to OMB review.

Pursuant to the requirements of the Regulatory Flexibility Act (Pub. L. 96–354, 94 Stat. 1164, 5 U.S.C. 601–612), the Administrator has determined that regulations establishing new tolerances or raising tolerance levels or establishing exemptions from tolerance requirements do not have a significant economic impact on a substantial number of small entities. A certification statement to this effect was published in the Federal Register of May 4, 1981 (46 FR 24950).

List of Subjects in 40 CFR Part 180

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

Dated: March 18, 1996.

Stephen L. Johnson,

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR part 180 is amended as follows:

PART 180—[AMENDED]

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

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

2. Section 180.399, is amended by adding paragraph (d) to read as follows:

§ 180.399 Iprodione; tolerances for residues.

* * * * *

(d)(1) A time-limited tolerance, to expire March 15, 1997, is established permitting the 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 the following raw agricultural commodity:

Commodity	Parts per million
Cottonseed	0.10

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

[FR Doc. 96–10921 Filed 5–2–96; 8:45 am]

BILLING CODE 6560–50–F

40 CFR Part 180

[OPP–300403A; FRL–4995–8]

RIN 2070–AB78

Tebuthiuron; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final Rule.

SUMMARY: This final regulation establishes lower tolerances for residues of Tebuthiuron on grass hay and grass rangeland forage and changes the commodity name grass, rangeland forage to grass, forage. These changes are based on the Reregistration Eligibility Decision tolerance assessment for Tebuthiuron.

EFFECTIVE DATE: This regulation becomes effective July 2, 1996.

ADDRESSES: Written objections and hearing requests, identified by the document control number, [OPP–300403A], may 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 should be identified by the document control number and submitted to: Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring copy of objections and hearing requests to Rm. 1132, CM #2,