The increased incidence in tumors in both rats and mice was only observed when animals were treated at or above the MTD. For all three tumor sites (testes, liver, ovary) tumors only develop on pre-existing non-neoplastic lesions (cell hypertrophy/vacuolation, hyperplasia) and a clear threshold level exist for both non-neoplastic lesions and tumors. Those thresholds are far in excess of those levels of iprodione that the general public would be exposed to.

Conclusion. Rhone-Poulenc believes that iprodione would not be expected to induce any adverse effects related to endocrine disruption in members of the general population via the consumption of food crops containing residues of this compound.

II. Public Record

EPA invites interested persons to submit comments on this notice of filing. Comments must bear a notation indicating the docket control number, [PF-689].

A record has been established for this notice of filing under docket control number [PF-689] (including comments and data submitted electronically as described below). A public version of this record, including printed, paper versions of electronic comments, which does not include any information claimed as CBI, is available for inspection from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The public record is located in Room 1132 of the Public 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 can be sent directly to EPA at:
opp-docket@epamail.epa.gov

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

The official record for this notice of filing, as well as the public version, as described above will be kept in paper form. Accordingly, EPA will transfer all comments 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.

List of Subjects

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

Dated: January 15, 1997.

Stephen L. Johnson,

Director, Registration Division, Office of Pesticide Programs.

[FR Doc. 97–1752 Filed 1–23–97; 8:45 am]
BILLING CODE 6560–50–F

[PF-691; FRL-5583-6]

Rhone-Poulenc Ag Company; Pesticide Tolerance Petition Filing

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of filing.

SUMMARY: This notice announces the filing of a pesticide petition proposing the extension of the time-limited 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] (CAS Number 36734-19-7, PC Code 109801) in or on the raw agricultural commodity (RAC) cottonseed at 0.10 parts per million (ppm). The notice includes a summary of the petition prepared by the petitioner, Rhone-Poulenc Ag Company.

DATES: Comments, identified by the docket number [PF-691], must be received on or before February 24, 1997.

ADDRESSES: By mail, submit written comments 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 comments to Rm. 1132, CM #2, 1921 Jefferson Davis Highway, Arlington, VA.

Comments and data may also be submitted electronically by sending electronic mail (e-mail) to: 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. Comments and data will also be accepted on disks in WordPerfect 5.1 file format or ASCII file format. All comments and data in electronic form must be identified by the docket number [PF-691]. Electronic comments on this notice of filing may be filed online at many Federal Depository Libraries. Additional information on electronic submissions can be found in Unit II. of this document.

Information submitted as comments concerning this document may be claimed confidential by marking any part or all of that information as ''Confidential Business Information'' (CBI). CBI should not be submitted through e-mail. Information marked as CBI will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the comment 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. All written comments will be available for public inspection in Rm. 1132 at the address given above, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays.

FOR FURTHER INFORMATION CONTACT: By mail: Connie Welch, Product Manager (PM 21), Registration Division (7505W), 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, Room 227, 1921 Jefferson Davis Highway, Arlington, VA, 703-305-6226, e-mail: welch.connie@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: EPA has received a pesticide petition (PP 2F4111) from Rhone-Poulenc Ag Company (Rhone-Poulenc), P.O. Box 12014, T.W. Alexander Drive, Research Triangle Park, NC 27709 proposing pursuant to section 408(d) of the Federal Food, Drug and Cosmetic Act (FFDCA), 21 U.S.C. 346(d), to amend 40 CFR part 180 by extending the time-limited tolerance for 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 RAC cottonseed at 0.10 ppm. The current time-limited tolerance was established under pesticide petition (PP) 2F4111 and expires on March 15, 1997. EPA has determined that the petition contains data or information regarding the elements set forth in section 408(d)(2) of the FFDCA; however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data supports granting of the petition. Additional data may be needed before EPA rules on the petition.

As required by section 408(d) of the FFDCA, as recently amended by the Food Quality Protection Act, Rhone-Poulenc included in the petition a summary of the petition and authorization for the summary to be published in the Federal Register in a notice of receipt of the petition. The summary represents the views of Rhone-Poulenc. EPA is in the process of evaluating the petition. As required by section 408(d)(3) of the FFDCA, EPA is including the summary as a part of this notice of filing. EPA may have made minor edits to the summary for the purpose of clarity.

I. Petition Summary

There is an extensive data base supporting the registration of iprodione. All the studies required under the reregistration process mandated by the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) 88 have been submitted. Most of these studies have been reviewed by the Agency and accepted.

The time-limited tolerance for iprodione on cottonseed at 0.10 ppm is considered adequate to cover residues resulting from the use of iprodione on cotton. No residues were detected in cottonseed field trial studies. A processing study conducted at 12x the label rate showed no detectable residues. The nature of the residue in plants is adequately defined. Plant metabolism studies have been reviewed in connection with previous petitions for tolerances. The residues of concern are iprodione, its isomer RP30228, and its metabolite RP32490. The Phase IV Review concluded that additional plant metabolism studies are not needed.

The nature of the residue in animals is adequately understood for the proposed use of iprodione on cotton. Dietary contribution for animals from cottonseed as a result of the proposed use will be very small and secondary residues in animal commodities (ruminant and poultry) are expected to be nondetectable (i.e. <0.01 ppm in milk and <0.05 ppm in other animal commodities). A restriction is included in the use directions for cotton prohibiting grazing and feeding of cotton forage to livestock. Furthermore, based on market share information, only approximately 3% of the cotton crop is expected to be treated with iprodione in 1997. The established tolerances for iprodione and its metabolites in meat, milk, poultry, and eggs are therefore adequate to cover secondary residues in animal commodities resulting from the use on cotton.

An adequate analytical method, gas liquid chromatography using an electron-capture detector, is available in the Pesticide Analytical Manual, Vol. II, for enforcement purposes. In the Phase IV Review, EPA requested that a substitute for benzene be used in the method of analysis used in new crop field trials. In response to this request, Rhone-Poulenc developed a common moiety GC method with a 0.05 ppm limit of quantitation (LOQ). An independent laboratory validation for this method was submitted.

Iprodione is an important product for growers of several minor crops. These include garlic, ginseng, chinese mustard, broccoli, caneberries (blackberries, loganberries, and raspberries), and bushberries (blueberries, currant, elderberries, gooseberries, and huckleberries).

Iprodione is also an important tool for cotton growers in controlling *Rhizoctonia solani*, a seedling disease. The Cotton Disease Loss Estimate Committee of the National Cotton Council ranks seedling diseases as the most important cotton disease. Furthermore, based on the cotton use directions for iprodione products, the maximum amount of product applied would be 0.2 lb active ingredient/acre on a 40 inch row and 13,000 linear row ft. This is a five- to six-fold decrease in active ingredient concentration compared to that required for competitive soil applied cotton fungicides which control *Rhizoctonia solani*. This allows for reduction of total pesticide usage in cotton production and thus reduces pesticide exposure in the environment. Another benefit is that iprodione is efficacious against all five anastomosis groups of *Rhizoctonia solani*. Currently, there are no registered products which possess this characteristic.

There are no Codex tolerances for iprodione on cottonseed.

The following mammalian toxicity studies have been conducted to support the extension of the tolerance for iprodione on cotton.

A. Toxicological Profile

Rhone-Poulenc's explanation of the toxicological profile of iprodione is being published elsewhere in today's issue of the Federal Register in another notice of filing [PF-689] for a tolerance for iprodione.

B. Aggregate Exposure

Rhone-Poulenc's explanation concerning aggregate exposure to residues of iprodione is being published elsewhere in today's issue of the Federal Register in another notice of filing [PF-689] for a tolerance.

C. Safety Determination

1. DRES—US population—infants—children (1-6 yrs old). According to EPA's Dietary Risk Evaluation System (DRES) chronic analysis, the percent RfD falls within a safe margin even when considering tolerance levels and 100% crop treated. For the overall U.S. population, dietary exposure to iprodione uses 0.353% of the RfD when using Anticipated Residue Contribution (ARC) or 54.22 % of the RfD when using tolerance levels. These figures remain the same when cotton is included in the analysis. Exposure to iprodione resulting from the use of the product on cotton is negligible considering that:

i. Residues above the LOQ (0.05 ppm) were not observed in cotton field trial studies.

ii. A processing study conducted at 12x the label rate showed no detectable residues.

iii. Only 3% of the cotton crop is expected to be treated with iprodione.

A DRES detailed acute exposure analysis was performed by EPA using conservative values. The resulting high end margin of exposure value of 100 for the DRES subgroup of concern (females 13 + years) is above the acceptable level and demonstrates no acute dietary concern.

For the reasons stated in Unit I.A.5. in a notice of filing for iprodione published elsewhere in this issue of the Federal Register, Rhone-Poulenc considers the use of a low dose quantitative risk assessment for iprodione to be inappropriate. As previously indicated Rhone-Poulenc recommends the use of a safety factor approach and a RfD of 0.0725—mg/kg/day. The use of the Q* (Q star) value of 0.0439 $(mg/kg/day)^{-1}$ previously calculated by EPA represents a very conservative estimate of the lifetime cancer risk from potential residues of iprodione.

Nevertheless, an assessment of the lifetime cancer risk from iprodione residues in food using a Q* value of 0.0439 $(mg/kg/day)^{-1}$ has been conducted to specifically demonstrate that the use of iprodione on cotton does not measurably increase exposure above that estimated for current uses. The upper bound cancer risk attributed to the use of iprodione on cotton is calculated to be 1.8×10^{-8}. This assessment also indicates the total cancer risk to be in the *de minimus* range of 10^{-6}, even with a very conservative Q* value.

Based on results of the analyses, Rhone-Poulenc concludes that the added use on cotton will not measurably increase the cancer risk

estimate for any population subgroup, and iprodione residues in currently registered foods would not be expected to result in significant levels of chronic toxicity to any segment of the U.S. population.

2. Infants and children—adequate margin of safety. In assessing the potential for additional sensitivity of infants and children to residues of iprodione, the available teratology and reproductive toxicity studies and the potential for endocrine modulation by iprodione were considered.

Developmental studies in two species indicate that iprodione has no teratogenic potential, even at maternally toxic dose levels. Maternal and developmental no observed effect levels and lowest observed effect levels were generally comparable indicating no increased susceptibility of developing organisms. Multigeneration rodent reproduction studies indicated that iprodione has no adverse effects on reproductive performance, fertility, fecundity or sex ratio. Effects on pup weight and viability were only noted in the presence of severe parental toxicity.

The mechanism of endocrine modulation associated with iprodione (inhibition of testosterone biosynthesis) appears to be distinct from that of anti-androgens acting at the level of the androgen receptor and may help to explain the lack of adverse effects on reproductive function observed with iprodione.

Therefore, based upon the completeness and reliability of the toxicity data and the conservative exposure assessment, Rhone-Poulenc believes that there is a reasonable certainty that no harm will result to infants and children from exposure to residues of iprodione and no additional uncertainty factor is warranted.

3. Endocrine discussion and conclusion. As indicated in Unit I.A.5. in a notice of filing for iprodione published elsewhere in this issue of the Federal Register, the primary lesion at the level of the target organs (testes, ovaries adrenals) is likely to be related to an inhibition of steroid/androgen biosynthesis. The resulting endocrine toxic effect due to iprodione is fairly moderate compared to that produced by potent endocrine disruptors such as flutamide (and other structural analogs) and is insufficiently potent to produce effects on reproduction or development.

The increased incidence in tumors in both rats and mice was only observed when animals were treated at or above the MTD. For all three tumor sites (testis, liver, ovary) tumors only develop on pre-existing non-neoplastic lesions (cell hypertrophy/vacuolation, hyperplasia) and a clear threshold level exist for both non-neoplastic lesions and tumors. Those thresholds are far in excess of those levels of iprodione that the general public would be exposed to.

Conclusion. Rhone-Poulenc believes that iprodione would not be expected to induce any adverse effects related to endocrine disruption in members of the general population via the consumption of food crops containing residues of this compound.

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Electronic comments can be sent directly to EPA at:

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List of Subjects

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

Dated: January 15, 1997.

Stephen L. Johnson,

Director, Registration Division, Office of Pesticide Programs.

[FR Doc. 97-1765 Filed 1-23-97; 8:45 am]

BILLING CODE 6560-50-F

FEDERAL RESERVE SYSTEM

Formations of, Acquisitions by, and Mergers of Bank Holding Companies

The companies listed in this notice have applied to the Board for approval, pursuant to the Bank Holding Company Act of 1956 (12 U.S.C. 1841 *et seq*.) (BHC Act), Regulation Y (12 CFR Part 225), and all other applicable statutes and regulations to become a bank holding company and/or to acquire the assets or the ownership of, control of, or the power to vote shares of a bank or bank holding company and all of the banks and nonbanking companies owned by the bank holding company, including the companies listed below.

The applications listed below, as well as other related filings required by the Board, are available for immediate inspection at the Federal Reserve Bank indicated. Once the application has been accepted for processing, it will also be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the standards enumerated in the BHC Act (12 U.S.C. 1842(c)). If the proposal also involves the acquisition of a nonbanking company, the review also includes whether the acquisition of the nonbanking company complies with the standards in section 4 of the BHC Act, including whether the acquisition of the nonbanking company can ''reasonably be expected to produce benefits to the public, such as greater convenience, increased competition, or gains in efficiency, that outweigh possible adverse effects, such as undue concentration of resources, decreased or unfair competition, conflicts of interests, or unsound banking practices'' (12 U.S.C. 1843). Unless otherwise noted, nonbanking activities will be conducted throughout the United States.

Unless otherwise noted, comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than February 18, 1997.

A. Federal Reserve Bank of Boston (Robert M. Brady, Vice President) 600 Atlantic Avenue, Boston, Massachusetts 02106-2204: