Discussion of Regulation

This regulation is necessary to ensure the safety of contestant and spectator vessels involved with the 3rd Annual Dana Point Challenge powerboat race. The planned course of the race is approximately one mile offshore and extends from Capistrano Beach to San Mateo Point, California. Many spectator vessels (estimated 500–600 in 1995) have previously attended this event. In past years, contestants (approximately 20–25) had to speed around spectator vessels which had wandered into the race lanes. By deterring the large amount of expected spectator vessel traffic from entering into the designated race lanes, the risk of high speed collisions can be greatly reduced from that of previous Dana Point Challenges. This safety zone will be enforced by U.S. Coast Guard personnel. The Coast Guard Auxiliary, the Dana Point Harbor Patrol and the Dana Point Challenge event staff will assist in the enforcement of the safety zone. Persons and vessels are prohibited from entering into, transiting through, or anchoring within the Safety Zone unless authorized by the Captain of the Port of his designated representative.

Regulatory Evaluation

This rule is not a significant regulatory action under section 3(f) of Executive Order 12866 and does not require an assessment of potential costs and benefits under section 6(a)(3) of that order. It has been exempted from review by the Office of Management and Budget under that order. It is not significant under the regulatory policies and procedures of the Department of Transportation (44 FR 11040; February 26, 1979). The Coast Guard expects the economic impact of this regulation to be so minimal that a full Regulatory Evaluation under paragraph 10(e) of the regulatory policies and procedures of the Department of Transportation is unnecessary.

Collection of Information

This regulation contains no collection of information requirements under the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*).

Federalism

The Coast Guard has analyzed this regulation under the principles and criteria contained in Executive Order 12612, and has determined that this rule does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

Environmental Assessment

The Coast Guard has considered the environmental impact of this regulation and concluded that under section 2.B.2. of Commandant Instruction M16475.1B it will have no significant environmental impact and it is categorically excluded from further environmental documentation. An environmental analysis checklist has been completed and a Marine Event permit has been issued.

List of Subject in 33 CFR Part 165

Harbors, Marine safety, Navigation (water), Reporting and recordkeeping requirements, Security Measures, Waterways.

Regulation

In consideration of the foregoing, Subpart F of Part 165 of Title 33, Code of Federal Regulations, is amended as follows:

PART 165—[AMENDED]

1. The authority citation for 33 CFR part 165 continues to read as follows:

Authority: 33 U.S.C. 1231; 50 U.S.C. 191; 33 CFR 1.05–1(g), 6.04–1, 6.04–6 and 160.5; 49 CFR 1.46.

2. A new section 165.T11–057 is added to read as follows:

§ 165.T1157 Safety Zone: Dana Point, CA

(a) *Location.* The following area constitutes a safety zone on the navigable waters in the vicinity of Capistrano Beach and San Mateo Point, California, specifically:

North-West corner: 33°26.0′ N, 117°42.0′ W;
North-East corner: 33°27.0′ N, 117°41.3′ W;
North-East corner: 33°24.0′ N, 117°37.0′ W;
North-West corner: 33°23.2′ N, 117°38.0′ W.

This area measures approximately five nautical miles by one nautical mile. (Datum: NAD 83)

(b) *Effective Date.* This safety zone is effective at 10 A.M. PDT and terminates at 2 P.M. PDT on May 19, 1996 unless canceled earlier by the Captain of the Port.

(c) *Regulations.* The general regulations governing safety zones contained in 33 CFR 165.23 apply. No person or vessel may enter or remain within the safety zone without the permission of the Captain of the Port Los Angeles-Long Beach, California or his designated representative.

Dated: April 24, 1996.

E. E. Page,

Captain, U.S. Coast Guard, Captain of the Port, Los Angeles-Long Beach, California.

[FR Doc. 96–10998 Filed 5–2–96; 8:45 am]

BILLING CODE 4910–14–M

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[PP 6F3333 and FAP2H5640/R2234; FRL–5365–6]

RIN 2070–AB78

Cyromazine; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final Rule.

SUMMARY: This rule establishes a tolerance for combined residues of the insecticide cyromazine (*N*-cyclopropyl-1,3,5-triazine-2,4,6-triamine) and its major metabolite melamine, 1,3,5-triazine-2,4-6-triamine calculated as cyromazine in or on the raw agricultural commodity (RAC) tomato. The regulation to establish a maximum permissible level for residues of the insecticide was requested in a petition submitted by the CIBA-Geigy Corporation, P.O. Box 18300, Greensboro, NC 27419.

EFFECTIVE DATE: This regulation becomes effective May 3, 1996.

ADDRESSES: Written objections and hearing requests, identified by the document control number, [PP 6F3333 and FAP2H5640/R2234], may be submitted to: Hearing Clerk (1900), Environmental Protection Agency, Rm. M3708, 401 M St., SW., Washington, DC 20460. 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. Fees accompanying objections shall be labeled ''Tolerance Petition Fees'' and forwarded to: EPA Headquarters Accounting Operations Branch, OPP (Tolerance Fees), P.O. Box 360277M, Pittsburgh, PA 15251. An electronic copy of objections and hearing requests filed with the Hearing Clerk may be submitted to OPP by sending electronic mail (e-mail) to: opp-docket@epamail.epa.gov.

Copies of electronic objections and hearing requests must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Copies of electronic objections and hearing requests must be identified by the docket number [PP 6F3333 and

FAP2H5640/R2234]. No Confidential Business Information (CBI) should be submitted through e-mail. Copies of electronic objections and hearing requests on this rule may be filed online at many Federal Depository Libraries. Additional information on electronic submissions can be found below in this document.

FOR FURTHER INFORMATION CONTACT: By mail: George LaRocca, Product Manager (PM) [13], Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location and telephone number: Rm. 204, CM#2, 1921 Jefferson Davis Highway, Arlington, VA 22202. (703) 305-6100; e-mail: glarocca@epamail.epa.gov

SUPPLEMENTARY INFORMATION: In the Federal Register of March 19, 1986 (51 FR 9511) and June 10, 1992 (57 FR 2467) EPA issued notices of filing which announced that Ciba-Geigy Corp. (CIBA), P.O. Box 18300, Greensboro, NC 27419 had submitted pesticide petition (PP 6F3333) and Food/Feed Additive Petition (FAP) 2H5640 to EPA proposing to amend 40 CFR 180.414 by establishing a tolerance under section 408 (d) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a, for residues of the insecticide cyromazine (*N*-cyclopropyl-1,3,5-triazine-2,4,6-triamine) plus its major metabolite melamine, 1,3,5-triazine-2,4-6-triamine calculated as cyromazine in or on the raw agricultural commodity tomato at 1.0 parts per million (ppm) and proposing to amend 40 CFR parts 185 and 186 by establishing a food/feed additive regulation under section 409(e) of FEDCA 21 U.S.C. 348(b) for combined residues of cyromazine and its metabolite in/on processed tomato products at 1.2 ppm and dried tomato pomace at 1.6 ppm. Further in the Federal Register of March 10, 1993 (58 FR 13261), Ciba amended PP 6F3333 by lowering the tolerance for combined residues of the insecticide cyromazine plus its metabolite melamine, in or on the raw agricultural commodity tomato from 1.0 ppm to 0.5 ppm. The petitions for tomato and processed tomato products were again amended in the Federal Register of October 25, 1995 (60 FR 54689) by proposing to raise the tolerance in tomatoes to 1.0 ppm and proposing tolerances in or on processed tomato products (excluding juice) at 2.5 ppm and tomato pomace, wet and dry at 2.5 ppm. In addition Ciba proposed to amend 40 CFR 180.414 by:

(1) Establishing separate tolerances for residues of cyromazine and its major metabolite melamine, calculated as cyromazine, in meat, fat, and meat by-products (including liver and kidney) of cattle, goats, hogs, horses, and sheep at 0.05 ppm and milk at 0.02 ppm under Sections 180.414(b) and (c) respectively.

(2) Establish as a separate tolerance for residues of the metabolite 1-methylcyromazine (1-methyl-*N*-cyclopropyl-1,3,5-triazine-2,4,6-triamine), calculated as cyromazine, in liver and kidney of cattle, goats, hogs, horses and sheep at 0.05 ppm, and

(3) Amending the established tolerances for cyromazine and melamine in or on fat, meat and meat-by-products of chickens, under 40 CFR 180.414 (b) and (c) by removal of the restriction ''from chicken layer hens and chicken breeder hens only''.

There were no comments or requests for referral to an advisory committee received in response to these notices of filing.

The scientific data submitted in the petition and other relevant material have been evaluated. A discussion of the toxicological data considered in support of the tolerance as well as a discussion of the risk of cyromazine and its metabolite melamine can be found in a rule (FAP 2H5355/P344) published in the Federal Register of April 27, 1984 (48 FR 18120); in the Notice of Conditional Registration for Larvadex 0.3% Premix, published in the Federal Register of May 15, 1985 (50 FR 20373); and in the proposed rule regarding the establishment of a tolerance for residues of cyromazine and its metabolite melamine, calculated as cyromazine, in or on mushroom at 10.0 ppm in the Federal Register of June 30, 1993 (58 FR 34972).

A chronic dietary exposure/risk assessment has been performed for cyromazine using a reference dose (RfD) of 0.0075 mg/kg bwt/day. The reference dose is based on the no-observable-effect-level (NOEL) of 0.75 mg/kg bwt/day from a 6–month dog feeding study with an uncertainty factor (UF) of 100 that demonstrated decreased hematocrit and hemoglobin levels. Granting the tolerance on tomato will increase the theoretical maximum residue contribution (TMRC) for the overall (average) U.S. population for cyromazine from 0.001788 mg/kg/day to 0.002011 mg/kg/day. The percentage of the RfD used is increased from 24 percent to approximately 26.8%. Generally speaking the Agency has no concern if dietary exposure is less than the Rfd for all published and proposed tolerances.

Cyromazine was previously classified by the Agency as a Group C-possible human carcinogen, with the Reference Dose (RfD) methodology recommended for estimation of human risk (see the Federal Register of June 30, 1993 (58 FR 34972)). Ciba subsequently submitted a reexamination (by a reviewing pathologist and a pathology working group) of the tissues from the cyromazine chronic feeding and carcinogenicity studies in both rat and mouse. Based on a review of this information by the Health Effects Division Carcinogenicity Peer Review Committee (CPRC) of the Office of Pesticide Programs, the Agency has determined that cyromazine should be reclassified to Group E-no evidence for carcinogenicity in humans. The consensus of the CPRC was that the reexamination of mammary gland tissues in the mouse and rat was performed in an acceptable manner and based on these revised data, there were no statistically significant increases in tumors in the treated groups, and there were no statistically significant trends. Therefore, the classification of cyromazine has been revised to Group E in accordance with Agency guidelines, published in the Federal Register of September 24, 1986 (51 FR 33992).

The Agency has modified and updated its policy concerning whether concentration occurs in processed foods. In the past, EPA has found that a food additive tolerance (section 409) is necessary whenever a pesticide concentrates in the processed food (i.e., the levels in parts per million are greater in the processed food than in the raw food). The National Food Processors Association (NFPA) raised a number of concerns with the Agency's traditional approach to determining whether concentration occurs. EPA concluded that modifications can be made to its policy to ensure better predictions of concentration. Although information from processing studies will remain the most important information in determining whether concentration occurs EPA will now also take into account information concerning mixing and blending of crops information pertaining to average residues.

As a result of this change in policy the Agency has reevaluated the processing data for tomato and has concluded that a food additive tolerance is not needed for cyromazine residues including the metabolite melamine in processed tomato products. Tolerances are needed to prevent processed foods from being deemed adulterated when the processed food when ready to eat contains a pesticide residue at a level greater than permitted by the corresponding section 408 tolerance 21 U.S.C. 342(a)(2). In 1993, EPA had concluded that a 409 tolerance for processed tomato products was needed due to a processing study

that showed levels of cyromazine in tomato paste (the tomato byproduct with the highest concentration) 2.2 times the level in tomato (i.e., a concentration factor 2.2X). However, other processing studies showed that processing tomato paste resulted in a reduction of cyromazine residues or a lower concentration factor than 2.2X. In accordance with the Agency's revised concentration policy when the results from all processing studies for tomato paste were averaged, the concentration factor was lowered to 1X. Given the variability in analytical methods and this lower concentration factor, EPA believes that it is unlikely that any tomato paste or other processed tomato products derived from tomatoes containing legal levels of cyromazine could be reliably determined to have levels of cyromazine above the tomato tolerance. Because it is unlikely that processed tomato products will have levels of cyromazine above the section 408 tolerance, no section 409 tolerance is needed. In a letter dated November 21, 1995 Ciba requested withdrawal of the food additive proposal in processed tomato products.

In the same November 21, 1995 letter Ciba also requested withdrawal of the feed additive proposal in or on tomato pomaces; withdrawal of tolerance for cyromazine and melamine in milk, meat, fat and meat byproducts of cattle, goats, hogs, horses and sheep; withdrawal of the tolerance for the metabolite, 1-methycyromazine in the liver and kidney of cattle, goats, hogs, horses and sheep and withdrawal of the request to remove the restriction ''from chicken layer and breeder hens only''. Ciba's withdrawal of these tolerances were submitted in response to EPA's latest revision (unpublished) to Table II (September 1995) of the Pesticide Assessment Guidelines, Subdivision O (Residue Chemistry) titled Raw Agricultural and Processed Commodities and Livestock Feeds Derived from Field Crops and Ciba's voluntary withdrawal of a companion proposed tolerance request for use of cyromazine and its metabolite melamine in or on carrot (PP 6F3329)(See 60 FR 54689, October 25, 1995). With respect to the feed additive proposal for tomato pomace EPA has concluded that tomato pomaces (wet and dry) are no longer considered feedstuffs. Withdrawal of the proposed use of cyromazine on carrot eliminated potential residues from the feedstuff carrot culls. Thus based upon the decision that tomato pomaces are no longer feedstuffs and withdrawal of the carrot tolerance (carrot culls), feed additive tolerances in animal commodities are not necessary for this proposed use.

An adequate analytical method, AG-584A, is available 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).

A record has been established for this rulemaking under the docket number [PP 6F3333 and FAP2H5640/R2234] (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.

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 rule-making 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. In addition, this action does not impose any enforceable duty, or contain any ''unfunded mandates'' as described in Title II of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4), or require prior consultation as specified by Executive Order 12875 (58 FR 58093, October 28, 1993), entitled Enhancing the Intergovernmental Partnership, or special considerations as required by Executive Order 12898 (59 FR 7629, February 16, 1994).

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: 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