are positive, or not available within 2 weeks as specified in § 610.46.

(b) *Notification of recipients of prior transfusions.* If the transfusion service has administered any unit of blood as described in paragraph (a) of this section, the transfusion service shall notify the recipients' attending physician (physician of record) and ask him or her to inform the recipient of the need for HIV testing and counseling. The physician may notify another authorized person, such as a parent or guardian of the recipient, if the reasons to do so are documented pursuant to § 606.160 of this chapter. If the physician is unavailable or declines to notify the recipient, the transfusion service shall notify the recipient and inform the recipient of the need for HIV testing and counseling. The transfusion service is responsible for notification, including basic explanations to the recipient and referral for counseling, and shall document the notification or attempts to notify the attending physician or the recipient, pursuant to § 606.160 of this chapter.

Dated: March 26, 1993.

David A. Kessler,

Commissioner of Food and Drugs.

Donna E. Shalala,

Secretary of Health and Human Services.

[FR Doc. 93–15400 Filed 6–29–93; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[EE–14–81]

RIN 1545–AD81

Deductions and Reductions in Earnings and Profits (or Accumulated Profits) With Respect to Certain Foreign Deferred Compensation Plans Maintained by Certain Foreign Corporations or by Foreign Branches of Domestic Corporations; Correction

AGENCY: Internal Revenue Service, Treasury.

ACTION: Correction to notice of proposed rulemaking.

SUMMARY: This document contains corrections to the notice of proposed rulemaking (EE–14–81), which was published in the **Federal Register** for Friday, May 7, 1993 (58 FR 27219). The proposed regulations relate to the limitations on deductions and adjustments to earnings and profits (or accumulated profits) with respect to certain foreign deferred compensation plans.

FOR FURTHER INFORMATION CONTACT: Elizabeth A. Purcell, (202) 622–6080 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

The notice of proposed rulemaking that is the subject of these corrections contain proposed amendments to the Income Tax Regulations (26 CFR part 1) under sections 404A and 7805(a) of the Internal Revenue Code.

Need for Correction

As published, the proposed regulations contain errors which may prove to be misleading and are in need of clarification.

Correction of Publication

Accordingly, the publication of the proposed regulations (EE–14–81), which was the subject of FR Doc. 93–10743, is corrected as follows:

1. On page 27224, column 3, in the preamble under the heading "Section 481(a) Adjustment", second line from the bottom of the paragraph continued from column 2, the language "plan as the beginning of the year of a" is corrected to read "plan as of the beginning of the year of a".

§ 1.404–A–7 [Connected]

2. On page 27248, column 3, § 1.404A–7(d)(5), *Example 3*, eleventh line following the table, the language "as provided paragraph (d) of this section," is corrected to read "as provided in paragraph (d) of this section,".

3. On page 27249, column 2, § 1.404A–7(f)(1)(i), sixth line from the bottom of the paragraph, the language "this section, however. Furthermore, the" is corrected to read "this section. Furthermore, the".

Cynthia E. Grigsby,

Alternate Federal Register Liaison Officer, Assistant Chief Counsel (Corporate).

[FR Doc. 93–15302 Filed 6–29–93; 8:45 am]

BILLING CODE 4830–01–U

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 85

[FRL–4672–6]

Emission Defect Reporting Requirements; Public Workshop

AGENCY: Environmental Protection Agency.

ACTION: Notice of public workshop and request for comments.

SUMMARY: The Environmental Protection Agency (EPA) is currently considering possible revisions to its motor vehicle and engine Emission Defect Reporting Requirements, promulgated under the Clean air Act. To aid the Agency in this process, a public workshop will be held on various issues relevant to revising the current defect reporting regulations. The Agency is also inviting written comment on these issues. All interested parties are invited to attend the public workshop and provide input on the relevant issues.

DATES: The workshop will be held on Tuesday, July 27, from 10 a.m. to 5 p.m. in Washington, DC. Persons interested in making presentations at the workshop are requested to notify the Agency contact below at least two weeks prior to the workshop so that a final agenda can be prepared. Written comments may be submitted to the same Agency contact until August 27, 1993.

ADDRESSES: The workshop will be held at the EPA Judiciary Square building in the first floor conference room, 501 3rd Street NW., Washington, DC.

FOR FURTHER INFORMATION CONTACT: Mary Ann Stumbaugh, Recall Branch, Manufacturers Operations Division (6405J), U.S. Environmental Protection Agency, 401 M St. SW., Washington, DC 20460. Telephone: (202) 233–9324.

SUPPLEMENTARY INFORMATION:

I. Background

The Federal Motor Vehicle Emissions Control Program established under title II of the Clean Air Act and EPA's implementing regulations are structured to insure that manufacturers build motor vehicles an engines that conform to the applicable emission standards for the vehicles' or engines' useful lives. This program includes requirements for certification based on pre-production testing, assembly line testing, recall of non-complying in-use vehicles, as well as emission warranties for individual owners. In addition, section 208(a) of the Clean Air Act provides the Administrator with the authority to require a manufacturer to "make reports and provide information the Administrator may reasonably require to determine whether the manufacturer or other person has acted or is acting in compliance with" Parts A and C of Title II of the Clean Air Act and regulations thereunder.

The "Emission Defect Reporting Requirements," 40 CFR 85.1901–85.1908, are an important component of EPA's programs to detect potential emission nonconformities of in-use vehicles and engines. Current regulations require manufacturers to

submit a defect information report to EPA whenever a specific emission related defect is found to exist in 25 or more vehicles or engines of the same model year.

Defect information reports alert EPA to potential emissions nonconformities among in-use vehicles or engines. Manufacturers are currently required to submit defect information reports whenever a defect is found in the required number of vehicles or engines. However, manufacturers often do not actively search for possible emission related defects, or monitor available data to track defects. EPA is considering amendments to the regulations that would require manufacturers to collect, analyze, and submit data on potential emission-related defects. This would provide for more thorough and accurate identification of emission-related defects.

II. Issues

EPA is interested in obtaining more information on the issues described below. Parties submitting written comments may assert a business confidentiality claim covering all or part of the information provided. A claim of business confidentiality regarding any information submitted should be made in a manner consistent with 40 CFR 2.203(b). Information covered by such a claim will be disclosed by EPA only to the extent, and by means of the procedures set forth in 40 CFR part 2, subpart B. If no claim accompanies the information when it is received by EPA, it may be made available to the public without further notice to the submitting party.

Data Sources for Identification of Emissions Defects

The Agency's goal in defect reporting is to accurately identify emissions defects that occur during the useful life of vehicles and engines. One means of monitoring potential emissions defects is through warranty claims. Other possible means of tracking defects include, but are not limited to, part sales, repair records (both warranty and non-warranty), and manufacturers' own in-use testing.

EPA requests comments from manufacturers regarding data tracking. Persons providing comment to the Agency on this issue are requested to include in their comments responses to the following questions:

(1) In order to implement a system to effectively identify defective components during the entire useful life or a vehicle, what data should be collected? How and from whom would the data be collected?

(2) Given options of (a) tracking data for a shorter period of time (2 years/ 24,000 miles, for example) while meeting more stringent triggers for further action (providing the Agency with a report when defect levels reach 4%, perhaps), or (b) monitoring for a longer period of time and having less stringent triggers for further action, which option is preferable?

California Procedures for Reporting Failures of Emission-Related Components

In February 1990, amendments to the California Air Resources Board's (CARB's) Recall Regulations went into effect. These amendments include revisions to the procedures for reporting failures of emission-related components. Manufacturers of California-certified vehicles are now required to review and compile warranty claim data, and to submit (to (CARB) quarterly reports based on warranty claims for emission-related components. If the number of warranty claims for a specific component of an engine family exceeds a specified percentage of total sales for that engine family, further investigation into the validity of the warranty claims data and the effects of the component failure on emissions is required. EPA requests specific data on the burden this requirement has on manufacturers. Affected parties providing comment to the Agency on this issue are requested to address the following questions:

(1) On average, prior to model year 1990, how many voluntary recalls (per model year) were initiated due to information submitted to CARB under CARB's defect reporting regulations?

(2) Since model year 1990, how many voluntary recalls (per model year) have been initiated due to the collection of warranty claim information?

(3) Are data collected from all California dealerships, or is a sample used to project the data from the entire state? If a sample is used, what criteria are used for selecting the representative dealerships? What percentage of California dealerships does the sample represent? What percentage of California sales?

(4) What methods are used to validate warranty claims in order to determine the level of actual component failures (as needed to trigger a field information report)?

(5) What methods are used to project the number of validated component defects for an engine family (as required in the field information report)?

(6) What methods are used (or would be used) to determine the emissions impact of a validated component defect (as required in the emissions impact report)?

In addition to the questions above, commenters are encouraged to provide date and comments on any issues not specified above that are pertinent to the impact of the California warranty reporting requirements.

Electronic reporting

In an effort to reduce the volume of paper handled by both manufacturers and EPA, the Agency is considering making electronic communication the primary method for submission of reports related to defective components. EPA requests information on the hardware, operating systems, and software currently being used by manufacturers for collecting, analyzing, and distributing data and information. Persons presenting or submitting comments are asked to answer the following questions:

(1) What types of hardware (IBM PC, mainframe, etc.) are currently being used? What operating systems (DOS 5.0, UNIX, etc.) are used?

(2) What commercial software packages are used?

(3) What method (electronic or other) is used to distribute information (such as technical service bulletins) in dealerships?

(4) What method (electronic or other) is used to receive information (such as warranty claims) from dealerships?

(5) What method (electronic or other) is used to exchange information between other common contacts (such as part suppliers, different plants, etc.)?

(6) What would be the preferred method for transporting defect data to EPA? What medium (floppy disk, magnetic tape, modem, etc.) would be used with this method? What is this method preferable over other methods?

III. Workshop Structure

EPA will arrange the workshop agenda to accommodate those persons who what to make presentations and who notify the Agency contact listed above at least two weeks prior to the workshop. EPA will allot time to address the issues outlined in this notice, as well as other relevant issues from the comments received prior to the workshop. Persons who have not previously contacted the Agency but who wish to make oral presentations on the day of the workshop may do so to the extent time permits. Written comments may also be submitted to the

Agency for 30 days after the workshop, to the Agency contact listed above.

Jerry A. Kurtzweg,

Acting Assistant Administrator for Air Radiation.

[FR Doc. 93-15259 Filed 6-29-93; 8:45 am]

BILLING CODE 6560-50-M

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40 CFR Part 180

[OPP-300287; FRL 4587-5]

RIN No. 2070-AC18

Boric Acid and its Salts, Borax (Sodium Borate Decahydrate), Disodium Octaborate Tetrahydrate, Boric Oxide (Boric Anhydride), Sodium Borate and Sodium Metaborate; Tolerance Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: This document proposes that an exemption from the requirement of a tolerance be established for residues of boric acid and its salts, borax (sodium borate decahydrate), disodium octaborate tetrahydrate, boric oxide (boric anhydride), sodium borate, and sodium metaborate, in or on raw agricultural commodities when used as an active ingredient in insecticides, herbicides, or fungicides preharvest or postharvest in accordance with good agricultural practices. This proposed regulation was requested by Bushwacker Associates, Galveston, TX. The proposed tolerance exemption would supersede the tolerances for boron established under 40 CFR 180.271; therefore, this document also proposes to remove § 180.271.

DATES: Written comments, identified by the document control number, [OPP-300287], must be received on or before July 30, 1993.

ADDRESSES: By mail, submit comments to: Public Docket and Freedom of Information Section, Field Operations Division (H7506C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring comments to: Rm. 1128, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA 22202.

Information submitted as a comment concerning this document may be claimed confidential by marking any part or all of that information as "Confidential Business Information" (CBI). Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the 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. 1128 at the address given above, from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays.

FOR FURTHER INFORMATION CONTACT: By mail, Robert A. Forrest, Product Manager (PM 14), Registration Division (H7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location and telephone number: Rm. 219, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA, (703)-305-6600.

SUPPLEMENTARY INFORMATION: Bushwacker Associates, Inc., Division of Bethurum Research & Development, Inc., P.O. Box 3436, Galveston, TX 77552, submitted pesticide petition (PP) 2F4132 requesting that the Administrator, pursuant to section 408(e) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 346a(e), propose to amend 40 CFR part 180 by establishing an exemption from the requirement of a tolerance for residues of boric acid and its salts, borax (sodium borate decahydrate), disodium octaborate tetrahydrate, boric oxide (boric anhydride), sodium borate, and sodium metaborate in or on raw agricultural commodities when used as an active ingredient in insecticides, herbicides, or fungicides preharvest or postharvest in accordance with good agricultural practices.

The data submitted in the petition and other relevant material have been evaluated. The pesticide is considered useful for the purpose for which the exemption is sought.

The petition requested that an exemption from the requirement of a tolerance be established as a result of the use of boric acid as a fire ant control bait in agricultural areas. The product is to be applied as a broadcast via ground or air at a rate of 0.5 lb ai/acre. A second application may be made 5 days after initial treatment.

Boron occurs naturally in water, fruits, vegetables, and forage crops, and is an essential nutrient for plants. In pears and strawberries the levels may reach 160 ppm, and in red cabbage occasionally as high as 200 to 300 ppm. The increment of added boron residues resulting from pesticide use of boric acid and the boron-containing salts is insignificant compared to levels of naturally occurring boron in citrus and cottonseeed. For example, lemons average 1 ppm incremental boron due to treatment, compared with 2.5 ppm boron which is endogenous.

Based on a review of the toxicology data it has been determined that even with an increase of exposure there would be no increase in hazard because boric acid and its salts are benign.

Based upon the above information and review of its use, EPA has found that, when used in accordance with good agricultural practice, this active ingredient is useful and a tolerance is not necessry to protect the public health. Therefore, EPA proposes that the exemption from the requirement of a tolerance be established as set forth below, and as the tolerance exemption would supersede tolerances for boron established under 40 CFR 180.271, it is also proposed that § 180.271 be removed.

Any person who has registered or submitted an application for registration of a pesticide under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) as amended that contains any of the ingredients listed herein may request within 30 days after publication of this document in the **Federal Register** that this rulemaking proposal be referred to an Advisory Committee in accordance with section 408(e) of the Federal Food, Drug, and Cosmetic Act.

Interested persons are invited to submit written comments on the proposed regulations. Comments must bear a notation indicating the document control number, [OPP-300287]. All written comments filed in response to this petition will be available in the Public Information Branch, at the address given above, from 8 a.m. to 4 p.m., Monday through Friday, except legal holidays.

The Office of Management and Budget has exempted this rule from the requirements of section 3 of Executive Order 12291.

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

Administrative practice and procedure, Agricultural commodities, Pesticides and pests.

Dated: June 17, 1993.

Lawrence E. Culleen,

Acting Director, Registration Division, Office of Pesticide Programs.

Therefore, it is proposed that part 180 be amended as follows:

PART 180—[AMENDED]

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

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

§180.271 [Removed]

2. In subpart C, § 180.271 *Boron; tolerances for residues* is removed.

3. In subpart D, by adding new § 180.1121, to read as follows:

§180.1121 Boric acid and its salts, borax (sodium borate decahydrate), disodium octaborate tetrahydrate, boric oxide (boric anhydride), sodium borate and sodium metaborate; exemption from the requirement of a tolerance.

An exemption from the requirement of a tolerance is established for residues of the pesticidal chemical boric acid and its salts, borax (sodium borate decahydrate), disodium octaborate tetrahydrate, boric oxide (boric anhydride), sodium borate and sodium metaborate, in or on raw agricultural commodities when used as an active ingredient in insecticides, herbicides, or fungicides preharvest or postharvest in accordance with good agricultural practices.

[FR Doc. 93–15415 Filed 6–29–93; 8:45 am]

BILLING CODE 6560–50–F

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40 CFR Part 180

[OPP–300290; FRL–4627–3]

[RIN 2070–AC18]

C.I. Pigment Violet #23 (Carbazole Violet), C.I. Pigment Blue #15, C.I. Pigment Green #7, and FD & C Red No. 40; Tolerance Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: This document proposes that an exemption from the requirement of a tolerance be established for residues of C.I. Pigment Violet #23 (Carbazole Violet; CAS Registry No. 6358-30-1), C.I. Pigment Blue #15 (CAS Registry No. 147-14-8), C.I. Pigment Green #7 (CAS Registry No. 1328-53-6), and FD & C Red No. 40 (CAS Reg. No. 25956-17-6) when used as inert ingredients (dyes, coloring agents) in pesticide formulations applied to growing crops only. This proposed regulation was requested by Becker-Underwood, Inc., and responds to a comment by Gustafson, Inc., to a proposed rule on FD & C Red No. 40 regarding the use and amount of FD & C Red No. 40 exempt from the requirement of a tolerance.

DATES: Comments, identified by the document control number [OPP-300290], must be received on or before July 30, 1993.

ADDRESSES: By mail, submit written comments to: Public Response and Program Resources Branch, Field Operations Division (H7506C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, deliver comments to: Rm. 1128, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA 22202. Information submitted as a comment concerning this document may be claimed confidential by marking any part or all of that information as "Confidential Business Information" (CBI).

Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the comment that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential will be included in the public docket by the EPA without prior notice. The public docket is available for public inspection in Rm. 1128 at the address given above, from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays.

FOR FURTHER INFORMATION CONTATCT: By mail: Connie Welch, Registration Support Branch, Registration Division (H7505W), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location and telephone number: 2800 Crystal Drive, North Tower, Arlington, VA 22202, (703) 308-8320.

SUPPLEMENTARY INFORMATION: Becker-Underwood, Inc., 801 Dayton Ave., Ames, IA 50010, submitted pesticide petitions (PP) 2E4129, 2E4130, and 2E4131 requesting that the Administrator, pursuant to section 408(e) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 346a(e), amend 40 CFR 180.1001(d) by establishing an exemption from the requirement of a tolerance for residues of C.I. Pigment Violet #23 (Carbazole Violet; CAS Registry No. 6358-30-1), C.I. Pigment Blue #15 (CAS Registry No. 147-14-8), and C.I. Pigment Green #7 (CAS Registry No. 1328-53-6) when used as inert ingredients (dyes, coloring agents) in pesticide formulations applied to growing crops only.

Gustafson, Inc., P.O. Box 660065, Dallas, TX 75266-0065, submitted a comment to OPP-300277 (58 FR 12200, March 3, 1993) requesting the Administrator to expand the proposed tolerance exemption for FD & C Red No. 40 (CAS Reg. No. 25956-17-6), principally disodium salt of 6-hydroxy-5-[(2-methoxy-5-methyl-4sulfophenyl)azo]-2-naphthalenesulfonic acid. EPA had proposed to exempt FD & C Red No. 40 from the requirement of a tolerance when used as an inert ingredient (dye, coloring agent) in pesticide formulations applied to growing crops or to raw agricultural commodities after harvest with the limitation that the dye was not to exceed 0.002% by weight in the formulation. Gustafson, Inc., requested that the limitation be raised to 2% by weight in pesticide formulations so that the dye could be used for seed treatment. Two percent by weight of the pesticide formulation is needed for FD & C Red No. 40 in seed treatment to distinguish treated seed from untreated seed. Since the original request did not involve seed treatment, it was finalized, as proposed, at the lower limit and this proposal for the seed treatment application was developed for use on growing crops only.

Inert ingredients are all ingredients that are not active ingredients as defined in 40 CFR 153.125, and include, but are not limited to, the following types of ingredients (except when they have a pesticidal efficacy of their own): solvents such as alcohols and hydrocarbons; surfactants such as polyoxyethylene polymers and fatty acids; carriers such as clay and diatomaceous earth; thickeners such as carrageenan and modified cellulose; wetting, spreading, and dispersing agents; propellants in aerosol dispensers; microencapsulating agents; and emulsifiers. The term "inert" is not intended to imply nontoxicity; the ingredient may or may not be chemically active.

The data submitted in the petition and other relevant material have been evaluated. As part of the EPA policy statement on inert ingredients published in the **Federal Register** of April 22, 1987 (52 FR 13305), the Agency established data requirements which will be used to evaluate the risks posed by the presence of an inert ingredient in a pesticide formulation. Exemptions from some or all of the requirements may be granted if it can be determined that the inert ingredient will present minimal or no risk.

The Agency has decided that the data normally required to support the proposed tolerance exemptions for C.I.

Pigment Violet #23 (Carbazole Violet; CAS Reg. No. 6358-30-1), C.I. Pigment Blue #15 (CAS Registry No. 147-14-8), C.I. Pigment Green #7 (CAS Registry No. 1328-53-6), and FD & C Red No. 40 (CAS Reg. No. 25956-17-6) will not need to be submitted. The rationale for this decision is described below.

1. C.I. Pigment Violet #23 is not expected to be absorbed by any route based on a review of the acute oral, dermal, and subchronic data submitted, thus eliminating concerns for oncogenicity, mutagenicity, or developmental toxicity.

2. C.I. Pigment Violet #23 has a reported acute oral LD_{50} of 10 gm/kg or greater in mice. No signs of skin or eye irritation were observed after application of C.I. Pigment Violet #23.

3. In a 43-day feeding study, rats fed 1 gm/kg of C.I. Pigment Violet #23 in aqueous dispersion did not demonstrate any abnormal pathology.

4. A series of cytotoxicity studies were conducted indicating that C.I. Pigment Violet #23 is noncytotoxic.

5. C.I. Pigment Green #7 and C.I. Pigment Blue #15 both have a reported acute oral LD_{50} of 10 gm/kg or greater in rats. No signs of skin or eye irritation were observed after application of C.I. Pigment Green #7, and no signs of skin or mucosal irritation were observed after application of C.I. Pigment Blue #15.

6. A 2-year NTP Bioassay study conducted on C.I. Pigment Green #7 and C.I. Pigment Blue #15 was dropped based on lack of absorption or adverse effects in a 90-day feeding study in rats and mice.

7. In vitro screening tests for mutagenicity conducted on C.I. Pigment Green #7 and C.I. Pigment Blue #15 were negative.

8. C.I. Pigment Green #7 is approved for use as a colorant in food-contact resinous and polymeric coatings under 21 CFR 175.300.

9. C.I. Pigment Green #7 is approved for use as a colorant in contact lenses under 21 CFR 73.3124.

10. C.I. Pigment Green #7 is approved for use as a pigment in rubber products intended for repeated food-contact use under 21 CFR 177.2600.

11. C.I. Pigment Blue #15 is approved by the Food and Drug Administration for use as a colorant in polypropylene sutures, polybutester nonabsorbable sutures, nonabsorbable polybutylene terephthalate monofilament sutures for general and ophthalmic surgery, and for intraocular lenses under 21 CFR 74.3045.

12. C.I. Pigment Blue #15 is approved for use as a colorant for contact lenses under 21 CFR 74.3045.

13. C.I. Pigment Blue #15 is approved for use as a pigment in polyurethane resins used as food-contact surfaces for dry food under 21 CFR 177.1680.

14. C.I. Pigment Blue #15 is approved for use as a colorant in food-contact polymers under 21 CFR 178.3297.

15. FD & C Red No. 40 is considered safe for use in coloring foods under 21 CFR 74.340.

16. FD & C Red No. 40 is considered safe for use in coloring drugs under 21 CFR 74.1340.

17. FD & C Red No. 40 is considered safe for use in coloring cosmetics under 21 CFR 74.2340.

18. FD & C Red No. 40 was the subject of an Interagency Working Group chaired by the Food and Drug Administration. The Working Group, which included scientists and statisticians from academia and government, including EPA, reviewed the design and conduct of an *in utero*-exposed lifetime rat study and two *in utero*-exposed lifetime mouse studies. In the unpublished "Report of the Interagency Working Group on FD C Red No. 40," June 1981, EPA MRID 412365-03, the Working Group concluded:

> The results from the two mouse studies and the rat study were analyzed statistically both for tumor incidence and time-to-tumor. No pattern of statistically significant increases in the incidence of cancer in relation to FD C & Red No. 40 has been found in any of the three studies.... We find no substantial question of safety and at this time see no need for additional testing in chronic rodent studies.

19. FD & C Red No. 40 would be an alternative to another frequently used seed colorant, Rhodamine B, which is a List 1, "Inerts of Toxicological Concern." Registrants have been encouraged to remove any List 1 inert ingredient from their pesticide formulation.

Based upon the above information and review of the ingredients' use, EPA has found that, when used in accordance with good agricultural practice, these ingredients are useful and a tolerance is not necessary to protect the public health. Therefore, EPA proposes that the exemption from the requirement of a tolerance be established as set forth below.

Any person who has registered or submitted an application for registration of a pesticide, under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) as amended, which contains any of the ingredients listed herein, may request within 30 days after publication of this document in the **Federal Register** that this rulemaking proposal be referred to an Advisory Committee in accordance with section 408(e) of the Federal Food, Drug, and Cosmetic Act.

Interested persons are invited to submit written comments on the proposed regulation. Comments must bear a notation indicating the document control number, [OPP-300290]. All written comments filed in response to this petition will be available in the Public Response and Program Resources Branch, at the address given above from 8 a.m. to 4 p.m., Monday through Friday, except legal holidays.

The Office of Management and Budget has exempted this rule from the requirements of section 3 of Executive Order 12291.

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

Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Recording and recordkeeping requirements.

Dated: June 17, 1993.

Lawrence E. Culleen,

Acting Director, Registration Division, Office of Pesticide Programs.

Therefore, it is proposed that 40 CFR part 180 be 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 180.1001(d) is amended by adding and alphabetically inserting the inert ingredients, to read as follows:

§ 180.1001 Exemptions from the requirement of a tolerance.

* * * * *

(d) * * *

Inert ingradients	Limits	Uses
* * *	* * *	* * *
C.I. Pigment Blue #15 (CAS Reg. No. 147-14-8)	.....	Dye, coloring agent
C.I. Pigment Green #7 (CAS Reg. No. 1328-53-6)	.....	Dye, coloring agent
C.I. Pigment Violet #23 (CAS Reg. No. 6358-30-1)	.....	Dye, coloring agent
* * *	* * *	* * *
C.I. Pigment Red No. 40 (CAS Reg. No. 25956-17-6) conforming to 21 CFR 74.340.	For seed treatment use only. Not to exceed 2% by weight of pesticide formulation..	Dye, coloring agent
* * *	* * *	* * *

* * * * *

[FR Doc. 93–15417 Filed 6–29–93; 8:45 am]
BILLING CODE 6560–50–F

40 CFR Part 180

[PP 5F3177/P561; FRL–4628–3]

RIN 2070–AC18

Pesticide Tolerance for Cyromazine

AGENCY: Environmental Protection Agency

ACTION: Proposed rule.

SUMMARY: EPA proposes to establish a tolerance for residues of the insect growth regulator cyromazine (*N*-cyclopropyl-1,3,5-triazine-2,4,6-triamine) (Armor) and its metabolite melamine (1,3,5-triazine-2,4,6-triamine), calculated as cyromazine, in or on mushrooms at 10.0 parts per million (ppm). This regulation to establish maximum permissible levels for residues of the insecticide was requested pursuant to a petition submitted by Ciba-Geigy Corp.

DATES: Written comments must be received by July 21, 1993.

ADDRESSES: Comments, in triplicate, should bear the docket control number, [PP 5F3177/P561], and be submitted to: Public Response and Program Resources Branch, Field Operations Division (H7506C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person bring comments to: Rm. 1128, Crystal Mall #2, 1921 Jefferson Davis Hwy., Crystal City, VA 22202.

Information submitted in any comment concerning this document may be claimed confidential by marking any part or all of that information as "Confidential Business Information" (CBI). Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the 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 to the submitter. Written comments will be available for public inspection in Rm. 1128 at the Virginia address given above, from 8 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays.

FOR FURTHER INFORMATION CONTACT: By mail: Phillip O. Hutton, Product Manager (PM) 18, Registration Division (H7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location and telephone number: Rm. 202, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA 22202, (703)-557-2386.

SUPPLEMENTARY INFORMATION: In the Federal Register of January 30, 1985 (50 FR 4265), EPA issued a notice which announced that Ciba-Geigy Corp., P.O. Box 18300, Greensboro, NC 27419, had submitted a pesticide petition (PP 5F3177) to EPA proposing to amend 40 CFR part 180 by establishing a tolerance, under section 408 of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 346a, for residues of the insecticide cyromazine (*N*-cyclo-propyl-1,3,5-triazine-2,4,6-triamine) and its metabolite melamine (1,3,5-triazine-2,4,6-triamine) in or on mushrooms at 10.0 ppm. Further, in the Federal Register of September 25, 1985 (50 FR 38895), EPA issued a notice which announced that Ciba-Geigy Corp. had revised the petition so that Ciba-Geigy Corp. proposed amending 40 CFR part 180 by establishing a tolerance for the combined residues of the insecticide cyromazine (*N*-cyclopropyl-1,3,5-triazine-2,4,6-triamine) and its principal metabolite, melamine (1,3,5-triazine-2,4,6-triamine), calculated as cyromazine in or on the commodity mushrooms at 10.0 ppm. The proposed analytical method for determining residues is gas chromatography.

There were no comments or requests for referral to an advisory committee received in response to these notices of filing. Because these notices of filing were issued 8 years ago, EPA is publishing a proposal in regard to the petition rather than proceeding directly to a final rule.

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 (49 FR 18120) and in the Notice of Conditional Registration for Larvadex 0.3% Premix, published in the Federal Register of May 15, 1985 (50 FR 20373) Subsequent to these documents being published, the Agency has reevaluated both the developmental toxicity of cyromazine and the carcinogenic potential of its metabolite melamine.

Cyromazine has been classified by the Office of Pesticide Programs' Health Effects Division's Carcinogenicity Peer Review Committee (PRC) as Group C, i.e., possible human carcinogen. Mammary tumors in the mouse occurred at a dose that may have been insufficient for an adequate assessment of carcinogenic potential. However, the incidence of mammary tumors was almost three times the historical controls. These data were also supported by the same tumor type in the rat, although the dosing may have been excessive in this species. In addition, cyromazine has some structural similarities to other mammary tumor-producing analogs, although the relationship was not considered to be strong. Although the evidence from the rat study alone was not conclusive, in combination with the mouse study the weight-of-the-evidence for the carcinogenicity of cyromazine pointed toward a Group C classification. Because the rat study alone does not carry much weight (there may have been excessive dosing and because the incidence of mammary tumors was within the historical control range), the