

Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(d), establish a tolerance for residues of the insecticide benzoic acid, 3,5-dimethyl-1,1-(1,1-dimethylethyl)-2-(4-ethylbenzoyl)hydrazide, in or on the raw agricultural commodity walnuts at 0.1 part per million (ppm).

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 1-year dog feeding study with a lowest-observable-effect level (LOEL) of 250 ppm (9 mg/kg/day for male and female dogs) based on decreases in RBC, HCT, and HGB, increases in Heinz bodies, methemoglobin, MCV, MCH, reticulocytes, platelets, plasma total bilirubin, spleen weight, and spleen/body weight ratio, and liver weight and liver/body weight ratio. Hematopoiesis and sinusoidal engorgement occurred in the spleen, and hyperplasia occurred in the marrow of the femur and sternum. The liver showed an increased pigment in the Kupffer cells. The no-observable-effect level (NOEL) for systemic toxicity in both sexes is 50 ppm (1.9 mg/kg/day).

2. An 18-month mouse carcinogenicity study with no carcinogenicity observed at dosage levels up to and including 1,000 ppm.

3. A 2-year rat carcinogenicity study with no carcinogenicity observed at dosage levels up to and including 2,000 ppm (97 mg/kg/day and 125 mg/kg/day for males and females, respectively).

4. A two-generation rat reproduction study with a NOEL of 150 ppm (12.1 mg/kg/day) for reproductive effects compared to a systemic NOEL of 10 ppm (0.85 mg/kg/day).

5. A rat developmental study with a NOEL of 1,000 mg/kg/day for developmental toxicity.

6. A rabbit developmental study with a NOEL of 1,000 mg/kg/day for developmental toxicity.

7. Several mutagenicity tests which were all negative. These include an Ames assay with and without metabolic activation, an *in vivo* cytogenetic assay in rat bone marrow cells, an *in vitro* chromosome aberration assay in CHO cells, a CHO/HGPRT assay, a reverse mutation assay with *E. coli*, and an unscheduled DNA synthesis assay (UDS) in rat hepatocytes.

The reference dose (RfD), for chronic toxicity as defined in a 1-year chronic dog study is 0.019 mg/kg/day based upon a NOEL of 1.9 mg/kg/day in dogs of both sexes and applying an uncertainty factor of 100. The theoretical maximum residue contribution (TMRC) for this first food use of benzoic acid, 3,5-dimethyl-1-(1,1-dimethylethyl)-2-(4-

ethylbenzoyl)hydrazide on walnuts for the overall U.S. population is less than 0.000001 mg/kg/day and represents 0.003% of the RfD. The TMRC for the highest exposed subgroup, children (ages 1-6 years old), is less than 0.000001 mg/kg/day and represents 0.008% of the RfD.

The metabolism of benzoic acid, 3,5-dimethyl-1-(1,1-dimethylethyl)-2-(4-ethylbenzoyl)hydrazide, is adequately understood. An adequate analytical method, HPLC separation with UV detection, is available for enforcement purposes and is being provided to FDA for inclusion in the Pesticide Analytical manual, Vol. II.

There are currently no actions pending against the registration of this chemical. There is no expectation of residues occurring in meat, milk, poultry, or eggs from this tolerance.

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 docket number [PP 4F4280/R2135] (including objections and hearing requests 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 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The public record is located in Rm. 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.

Written objections and hearing requests, identified by the document control number [PP 4F4280/R2135], may be submitted to the Hearing Clerk (1900), Environmental Protection Agency, Rm. 3708, 401 M St., SW., Washington, DC 20460.

A copy of electronic objections and hearing requests can be sent directly to EPA at:

opp-Docket@epamail.epa.gov

A copy of electronic objections and hearing requests must be submitted as an ASCII file avoiding the use of special characters and any form of encryption.

The official record for this rulemaking, as well as the public version, as described above will be kept in paper form. Accordingly, EPA will transfer any 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 objections and hearing requests 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: May 12, 1995.

Daniel M. Barolo,
Director, 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. By adding new § 180.842, to read as follows:

§ 180.842 Benzoic acid; tolerances for residues.

A tolerance is established for residues of the insecticide benzoic acid, 3,5-dimethyl-1-(1,1-dimethylethyl)-2-(4-ethylbenzoyl)hydrazide, in or on the following raw agricultural commodity:

Commodity	Parts per million
Walnuts	0.1

40 CFR Part 180

[PP 2E4051/R2136; FRL-4955-5]

RIN 2070-AB78

Difenoconazole; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This document establishes import tolerances for residues of the fungicide difenoconazole in or on the raw agricultural commodities barley grain, rye grain, and wheat grain at 0.1 part per million (ppm); fat, meat, and meat byproducts of cattle, goats, hogs, horses, poultry, and sheep and eggs at 0.05 ppm; and milk at 0.01 ppm. Ciba-Geigy Corp. requested this regulation pursuant to the Federal Food, Drug and Cosmetic Act (FFDCA). The regulation establishes the maximum permissible level for residues of the fungicide in or on the commodities.

EFFECTIVE DATE: This regulation becomes effective May 31, 1995.

ADDRESSES: Written objections and hearing requests, identified by the document control number, [PP 2E4051/R2136], 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 2E4051/R2136]. 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: James Stone, Acting Product Manager (PM) 22, Registration Division (7505C), Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location and telephone number: Rm. 259, 1921 Jefferson Davis Hwy., Arlington, VA 22202, (703)-305-7391; e-mail: stone.james@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of April 12, 1995 (60 FR 18555), EPA issued a proposed rule that gave notice that Ciba-Geigy Corp., P.O. Box 18300, Greensboro, NC 27419-8300, had petitioned EPA under section 408 of the FFDCA, 21 U.S.C. 346a, to establish import tolerances under 40 CFR 180.475 for residues of the fungicide difenoconazole, [(2S,4R)/(2R,4S)]/[(2R,4R/2S,4S)] 1-[2-[4-(4-chlorophenoxy)-2-chlorophenyl]-4-methyl-1,3-dioxolan-2-yl-methyl]-1H-1,2,4-triazole, in or on the raw agricultural commodities (RACs) barley grain, rye grain, and wheat grain at 0.1 ppm; fat, meat, and meat byproducts (mbyp) of cattle, goats, hogs, horses, poultry, and sheep and eggs at 0.04 ppm; and milk at 0.01 ppm.

There were no comments or requests for referral to an advisory committee received in response to the proposed rule.

The data submitted with the proposal and other relevant material have been evaluated and discussed in the proposed rule. Based on the data and information considered, the Agency concludes that the tolerances will protect the public health. Therefore, the tolerances are 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 and/or request a hearing 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