2-[1-(ethoxyimino)butyl]-5-[2-(ethylthio)propyl]-3-hydroxy-2-cyclohexen-1-one and its metabolites containing the 2-cyclohexen-1-one moiety (calculated as the herbicide) in or on the following raw agricultural commodities:

Commodity	Parts per million
Endive	2.0

[FR Doc. 95–12744 Filed 5–23–95; 8:45 am]

BILLING CODE 6560–50–F

40 CFR Part 180

[PP 2F4154/R2136; FRL–4955–3]

RIN 2070–AB78

Fenbuconazole; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a time-limited tolerance for combined residues of the fungicide fenbuconazole, *alpha*-[2-(4-chlorophenyl)ethyl]-*alpha*-phenyl-3-(1*H*-1,2,4-triazole)-1-propanenitrile, and its metabolites *cis*-5-(4-chlorophenyl)dihydro-3-phenyl-3-(1*H*-1,2,4-triazole-1-ylmethyl)-2-3*H*-furanone and *trans*-5-(4-chlorophenyl)dihydro-3-phenyl-3-(1*H*-1,2,4-triazole-1-ylmethyl)-2-3*H*-furanone, expressed as fenbuconazole, in or on the raw agricultural commodity bananas (whole fruit) at 0.3 ppm of which not more than 0.05 ppm is contained in the banana pulp. Rohm & Haas Co. submitted petitions for this regulation to establish a maximum permissible level for residues of the fungicide.

EFFECTIVE DATE: This regulation becomes effective May 24, 1995..

ADDRESSES: Written objections and hearing requests, identified by the document control number, [PP 2F4154/R2136], may be submitted to: Hearing Clerk (1900), Environmental Protection Agency, Rm. M3708, 401 M St., SW., Washington, DC 20460. Fees accompanying objections shall be labeled ''Tolerance Petition Fees'' and forwarded to: EPA Headquarters Accounting Operations Branch (Tolerance Fees), P.O. Box 360277M, Pittsburgh, PA 15251. A copy of any objections and hearing request 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 (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20450. In person, bring copy of objections and hearing request 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: oppdocket@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 2F4154/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 M. Stone, Acting Product Manager (PM) 22, Registration Division, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location and telephone number: Rm. 229, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA 22202, (703)- 305-5540; e-mail: stone.james@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: EPA issued a notice, published in the **Federal Register** of December 30, 1992 (57 FR 62334), which announced that Rohm & Haas, Agricultural Chemicals, Independence Mall West, Philadelphia, PA 19105, had submitted a pesticide petition (PP) 2F4154, 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), amend 40 CFR part 180 by establishing a regulation to permit residues of fenbuconazole, *alpha*-[2-(4-chlorophenyl)ethyl]-*alpha*-phenyl-3-(1*H*-1,2,4-triazole)-1-propanenitrile, and its metabolites [5-(4-chlorophenyl)-dihydro-3-phenyl-3-(methyl-1*H*-1,2,4-triazole-1-yl)-2-3*H*-furanone] in or on bananas (pulp) at 0.05 part per million (ppm) and bananas (peel) at 0.3 ppm. Subsequently, on June 29, 1994 (59 FR 33503), EPA announced that Rohm & Haas had amended the petition to propose amending 40 CFR part 180 by establishing a regulation to permit residues of fenbuconazole, *alpha*-(2-(4-chlorophenyl)ethyl)-*alpha*-phenyl-3-(1*H*-1,2,4-triazole)-1-propanenitrile, and its metabolites *cis*-5-(4-chlorophenyl)dihydro-3-phenyl-3-(1*H*-1,2,4-triazole-1-4-ylmethyl)-2-3*H*-furanone and *trans*-5-(4-chlorophenyl)dihydro-3-phenyl-3-(1*H*-1,2,4-triazole-1-ylmethyl)-2-3*H*-furanone in or on bananas (whole fruit) at 0.3 ppm of which not more than 0.05 ppm is contained in banana pulp.

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 petitions and all other relevant material have been evaluated. The toxicology data considered in support of the tolerances include:

1. A rat acute oral study with an LD_{50} greater than 2 grams (g)/kilogram (kg).

2. A 13-week rat feeding study with a no-observed-effect level (NOEL) of 20 ppm (1.3 milligrams(mg)/kg/day males and 1.5 mg/kg/day females) and a lowest-observed-effect level (LOEL) of 80 ppm (5.1 mg/kg/day males and 6.3 mg/kg/day females) based on hepatotoxicity.

3. A 3-month mouse feeding study with a NOEL of 20 ppm (3.8 mg/kg/day males and 5.7 mg/kg/day females) and a LOEL of 60 ppm (11.1 mg/kg/day males and 17.6 mg/kg/day females) based on hepatotoxicity.

4. A 3-month dog feeding study with a NOEL of 100 ppm (3.3 mg/kg/day males and 3.5 mg/kg/day females) and LOEL of 400 ppm (13.3 mg/kg/day males and 14.0 mg/kg/day females), based hepatocellular hypertrophy.

5. A 21-day rat dermal study with a NOEL greater than 1,000 mg/kg/day (limit dose).

6. A 78-week dietary carcinogenicity study in mice with a NOEL of 1.43 mg/kg/day and a LOEL of 28.6 mg/kg/day (males) and 92.9 mg/kg/day (females) based on hepatocellular enlargement and a greater incidence and severity of hepatocellular vacuolation. There was evidence of carcinogenicity based on the occurrence of increased trend for malignant liver tumors in males and an increase in benign and malignant liver tumors in females. The carcinogenic effects observed are discussed below.

7. A 24-month rat chronic feeding/carcinogenicity study with a NOEL of 80 ppm (3.03 mg/kg/day for males and 4.02 mg/kg/day for females) for systemic effects and an LEL of 800 ppm (30.62 mg/kg/day for males and 43.07 mg/kg/day for females) based on decreased in body weights in females, and increased liver weighs in females and males along with hepatocellular enlargement and

vacuolization. There was also an increase in thyroid weights with slight increases in thyroid focal cystic hyperplasia and follicular cell neoplasia in both sexes. A LOEL was not established for males. There was evidence of carcinogenicity based on the increased occurrence of thyroid follicular cell benign and malignant tumors in males. The carcinogenic effects observed are discussed further below.

8. A 24-month male rat chronic feeding/carcinogenicity study with a NOEL of less than 800 ppm (30.41 mg/kg/day) and a LOEL is 800 ppm (30.41 mg/kg/day) based on increased liver with centrilobular to midzonal hepatocellular enlargement and vacuolization, decreased body weight gain, and increased thyroid weights. There was evidence of carcinogenicity based on the increased occurrence of thyroid follicular cell benign and malignant tumors. The carcinogenic effects observed are discussed further below.

9. A 1-year dog chronic feeding study with a NOEL of 150 ppm (3.75 mg/kg/day) and the LOEL, based on decreases in body weight gain and increased liver weight, of 1,200 ppm (30 mg/kg/day).

10. A two generation reproduction study in rats with a parental NOEL of 4 mg/kg/day (80 ppm) and a LOEL of 40 mg/kg/day (800 ppm), based on decreased body weight, decreased food consumption, increased number of dams not delivering viable or delivering nonviable offspring, and increases in adrenal and thyroid weights. The reproductive NOEL is greater than 40 mg/kg/day (800 ppm) [(highest dose tested (HDT)].

11. A developmental toxicity study in rabbits with a maternal NOEL of 10 mg/kg/day, and a developmental NOEL of 30 mg/kg/day, and a maternal LOEL of 30 mg/kg/day due to only 1/19 (5%) of the pregnant does producing a viable fetus, and no developmental LOEL (greater than 30 mg/kg/day).

12. A developmental toxicity study in rats with a maternal NOEL and developmental NOEL of 30 mg/kg/day and a LEL of 75 mg/kg/day due to decrease in maternal body weight compared to controls and increase in early and late resorption with a decrease in number of live fetuses per dam.

13. No evidence of gene mutation was observed in a test for induction of gene mutation at the HGPRT locus in Chinese hamster ovary cells. No increase in the number of cells with aberrations or observations per cell were noted in an *in vivo* cytogenetics assay using bone marrow from treated rats. No increase in unscheduled DNA synthesis in rat primary hepatocyte study was observed.

14. A rat metabolism study showed that radiolabeled fenbuconazole is rapidly absorbed, distributed, and excreted following oral administration in rats. Biliary excretion data indicated that systemic absorption of fenbuconazole was high for all dosing groups. The feces was the major route of excretion. Tissue distribution and bioaccumulation of fenbuconazole appeared to be minimal.

The Health Effects Division Carcinogenicity Peer Review Committee has concluded that the available data provide limited evidence of the carcinogenicity of fenbuconazole in mice and rats and has classified fenbuconazole as a Group C (possible human carcinogen with limited evidence of carcinogenicity in animals) in accordance with Agency guidelines, published in the **Federal Register** in 1986 (51 FR 33992; Sept. 24, 1986) and recommended that for the purpose of risk characterization a low-dose extrapolation model should be applied to the experimental animal tumor data for quantification for human risk ($Q1^*$). This decision was based on the induction of thyroid follicular cell adenomas and/or combined adenomas-carcinomas in male rats in two studies, both by pairwise comparison with controls and by trend analysis. The studies were combined for the purpose of deriving the $Q1^*$. The $Q1^*$ for fenbuconazole based on a recalculation with a 3/4's power safety factor is 1.06×10^{-2} $(mg/kg/day)^{-1}$ in human equivalents.

Based on (1) the established pecan and stone fruit group (except plums and prunes) tolerances, (2) the limitation of production of the only fenbuconazole product registered under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) for use on stone fruit to 28,500 pounds of active ingredient per year (calculated to be equivalent to treating 12.8% of the total U.S acreage of apricots, cherries, nectarines, and peaches per year), and (3) the proposed banana tolerances, the upper-bound limit of the dietary carcinogenic risk is calculated in the range of 1 incidence in 1 million (9×10^{-7}).

Processing studies for bananas are not required. Therefore, food/feed additive tolerances are not needed in conjunction with these uses.

Using the NOEL of 3.0 mg/kg/day from the most sensitive species in the rat chronic feeding study with a 100-fold safety factor, the Reference Dose (RfD) for systemic effects is 0.03 mg/kg/day. The theoretical maximum residue contribution (TMRC) from the established and proposed tolerances is 0.000616 mg/kg/day and utilizes 2 percent of the RfD for the overall U.S. population. For exposure of the most highly exposed subgroups in the population, non-nursing infants (less than 1-year old), the TMRC is 0.00522 mg/kg/day and utilizes 17 percent of the RfD.

The metabolism of fenbuconazole in plants is adequately understood. Due to the following chemistry data gap, magnitude of the residue: Crop field trials with unbagged bananas (two in Hawaii and two in Puerto Rico) [GLN 171-4], EPA believes it is inappropriate to establish permanent tolerances for the uses of fenbuconazole at this time. However, based on trials with bagged bananas and one side-by-side trial with bagged and unbagged bananas, EPA believes that the existing data support time-limited tolerances to December 31, 1998.

The nature of the residue in plants is adequately understood for the purposes of these time-limited tolerances. An analytical method, gas-liquid chromatography with a thermionic-specific detector with nitrogen selectivity, is available for enforcement purposes. The enforcement methodology has been submitted to the Food and Drug Administration for publication in the Pesticide Analytical Manual, Vol. II (PAM II). Because of the long lead time for publication of the method in PAM II, the analytical methodology is being made available in the interim to anyone interested in pesticide enforcement when requested from: Calvin Furlow, Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location and telephone number: Rm. 1132, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA 22202, (703)-305-5232.

There is no reasonable expectation that secondary residues will occur in milk, eggs, or meat of livestock and poultry since there are no livestock feed items associated with this action. 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 time-limited tolerance established by amending 40 CFR part 180 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 fees provided 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, and the requestor's contentions on each such issue, and a summary of the evidence relied upon by the objection (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 a 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 2F4154/R2136] (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, 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 2F4154/R2136], 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 filed with the Hearing Clerk can be sent directly to EPA at:

opp-Docket@epamail.epa.gov

A copy of electronic objections and hearing requests filed with the Hearing Clerk 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 10, 1995.

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.

b. In § 180.480, by amending paragraph (a) in the table therein by adding and alphabetically inserting the raw agricultural commodity bananas, to read as follows:

§ 180.480 Fenbuconazole; tolerances for residues.

(a) * * *

Commodity	Parts per million
Bananas (whole fruit)	0.3 (of which not more than 0.05 ppm is contained in the banana pulp).
* * *	* *

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[FR Doc. 95–12743 Filed 5–23–95; 8:45 am]

BILLING CODE 6560–50–F

40 CFR Part 180

[PP 4E4359/R2127; FRL–4936–3]

RIN 2070–AB78

Paraquat; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This document establishes tolerances for residues of the desiccant, defoliant, and herbicide paraquat in or on the raw agricultural commodities lentils, lentil forage, and lentil hay. The Interregional Research Project No. 4 (IR-4) requested this regulation to establish the maximum permissible levels for residues of paraquat in or on the commodities, and EPA has found that paraquat is useful and safe for the requested tolerances.

EFFECTIVE DATE: This regulation becomes effective May 24, 1995.

ADDRESSES: Written objections and hearing requests, identified by the document control number, [PP 4E4359/R2127], may be submitted to: Hearing Clerk (1900), Environmental Protection Agency, Rm. M3708, 401 M St., SW., Washington, DC 20460. Fees