proposed rule. Based on the data and information considered, the Agency concludes that the tolerance 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 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 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 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 5E4464/R2185] (including any 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 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.

Written objections and hearing requests, identified by the document control number [PP 5E4464/R2185], 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, Oct. 4, 1993), the Agency must determine whether the regulatory action is ''significant'' and therefore subject to review by the Office of Management and Budget (OMB) and the requirements of the Executive Order. Under section 3(f), the order defines a ''significant regulatory action'' as an action that is likely to result in 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 referred to 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 the rights and obligations of recipients thereof; 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 the 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: November 21, 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.

2. In § 180.184, paragraph (a) is amended in the table therein by revising the entry for asparagus, to read as follows:

§ 180.184 Linuron; tolerances for residues.

* * * * *

(a) * * *

Commodity	Parts per million
Asparagus	7.0
* * * * *	

* * * * *

[FR Doc. 95–29989 Filed 12–12–95; 8:45 am]
BILLING CODE 6560–50–F

40 CFR Part 180

[PP 5F4467/R2193; FRL–4990–8]

RIN 2070–AB78

Neem Oil; Tolerance Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This rule establishes an exemption from the requirement of a tolerance for residues of clarified hydrophobic extract of neem oil when used according to good agricultural practice as a broad-spectrum fungicide/insecticide/miticide on all greenhouse and terrestrial food crops. A request for an exemption from the requirement of a tolerance was submitted by W.R. Grace Co.-Conn. This regulation eliminates the need to establish a maximum

permissible level for residues of this broad-spectrum fungicide/insecticide/miticide on all greenhouse and terrestrial food crops when used according to good agricultural practice.

EFFECTIVE DATE: This rule becomes effective on December 13, 1995.

ADDRESSES: Written objections and hearing requests, identified by the document control number, [PP 5F4467/R2193], 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 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 Highway, 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.

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 5F4467/R2193]. 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: Paul Zubkoff, Biopesticides and Pollution Prevention Division (7501W), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location and telephone number: 5th Floor, CS #1, 2800 Crystal Drive, Arlington, VA 22202, (703)-308-8694; e-mail: zubkoff.paul@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: EPA issued a notice, published in the Federal Register of September 29, 1995 (60 FR 50582), which announced that W.R. Grace Co.-Conn., 7379 Route 32, Columbia, MD 21044, had submitted a pesticide petition (PP) 5F4467 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 an exemption from the requirement of a tolerance for the use of clarified hydrophobic extract of neem oil on all greenhouse and terrestrial food crops when used according to good agricultural practice. There were no adverse comments or requests for referral to an advisory committee received in response to the notice of filing of PP 5F4467.

Existing Food Clearances

The clarified hydrophobic extract is prepared from the crude botanical extract of the seed kernels of the neem tree, *Azadiracta indica*. The constituents of clarified hydrophobic extract of neem oil are long-chain fatty acids and glycerides. Long-chain fatty acids and glycerides are Generally Recognized As Safe (GRAS) for use in foods by the U.S. Food and Drug Administration (FDA). Under title 21 of the Code of Federal Regulations (CFR) (21 CFR 172.860), oleic acid derived from tall oil fatty acids (21 CFR 172.862), and linoleic acid (21 CFR 184.1065), glyceryl monooleate (21 CFR 184.1323), glyceryl monostearate (21 CFR 184.1324), and mono- and diglycerides (21 CFR 184.1505) are considered as GRAS.

Natural Occurrence

Long-chain fatty acids and glycerides are readily synthesized by most forms of life and are common constituents of human, avian, and other mammalian diets. In most soil and aquatic environments, these constituents of clarified hydrophobic extract of neem oil would be readily metabolized by endemic microbial populations and should not accumulate. Because clarified hydrophobic extract of neem oil is a naturally occurring compound which displays a nontoxic mode of action to the target pest, the Agency classified the active ingredient as a biochemical pesticide.

Toxicology Assessment

All studies submitted for acute mammalian toxicology support the registration of the technical manufacturing product (Reg. No. 11688-8) and the end-use product for use on all terrestrial and greenhouse food crops. Summarized below are data and information for the registration of clarified hydrophobic extract of neem oil. EPA has examined the acute mammalian toxicology data related to human health submitted for clarified hydrophobic extract of neem oil. The mammalian toxicology data for clarified hydrophobic extract of neem oil indicate low acute toxicity following all routes of exposure. With the exceptions of the primary eye irritation study (toxicity category III) and the acute dermal study (toxicity category III), all other acute studies (oral, dermal irritation, and inhalation toxicity) were classified toxicity category IV. Based on the results from the sensitization test (Buehler), the clarified hydrophobic extract of neem oil is considered to be a mild (minimal) contact sensitizer. In addition, clarified hydrophobic extract of neem oil was shown not to be cytotoxic or mutagenic via the Ames test (Salmonella/reverse mutation assay). Further genotoxicity tests to address structural chromosomal aberrations and forward mutations have been waived based on the known composition (fatty acids and glycerides) and GRAS status of the technical manufacturing product (clarified hydrophobic extract of neem oil, the lack of mammalian and avian toxicity, and the negative results observed in the Ames tests). Consequently, at levels used on plants, human exposure is expected to be negligible and acute toxicity from such exposure is not expected.

Tolerance exemptions are usually, in part, based on the results of subchronic (90-day) feeding and developmental toxicity studies submitted to support registration. However, these studies were waived for clarified hydrophobic extract of neem oil because of the low demonstrated acute toxicity, the GRAS nature of the naturally occurring components (saturated fatty acids and glycerides) of the active pesticidal ingredient, and the negligible exposure to humans and the environment owing to the low use rates. Such use rates would not significantly increase dietary intake over routine exposure from general consumption of fatty acids in foods. Moreover, the Agency knows of no reported cases of adverse effects from exposure to low amounts of fatty acids.

Residue Chemistry Data

Residue chemistry data are usually required for biochemical pesticides only if the submitted mammalian toxicology studies indicate that additional Tier II or Tier III toxicology data would be required as specified in 40 CFR 158.165(e). The submitted toxicology data for this use indicate that the product is of low mammalian toxicity; it has naturally occurring components in many food plants and, therefore, it is

a component of the normal human diet. Therefore, Tier II or Tier III data are not required. Based on the information considered, the Agency concludes that the establishment of a tolerance for the active ingredient, clarified hydrophobic extract of neem oil, is not necessary to protect the public health from food residues expected from the use of clarified hydrophobic extract of neem oil. Since this rule establishes an exemption from the requirement of a tolerance, the Agency has concluded that an analytical method is not required for enforcement purposes for clarified hydrophobic extract of neem oil.

Metabolism

Clarified hydrophobic extract of neem oil consists of naturally occurring fatty acids and glycerides that are considered GRAS by the FDA. The oxidative degradation of fatty acids is a central metabolic pathway in animals, plants, and microbes. Glycerides are degraded into glycerol and fatty acids of varying chain lengths. Glycerol is readily metabolized or used as an energy source or as a precursor to other carbohydrates, lipids, or amino acids. Fatty acids are metabolized into two-carbon fragments through a sequence of enzyme-catalyzed reactions. The metabolic products are then incorporated into fats, carbohydrates, and amino acids.

Conclusion

Based on the information considered, the Agency concludes that establishment of a tolerance for clarified hydrophobic extract of neem oil (Reg. No. 11688-8) is not necessary to protect the public health. Therefore, the exemption from 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 rule-making. 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, a summary of any evidence relied upon by the objector as well as the other materials required by 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 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 5F4467/R2193] (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 5F4467/R2193], 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: November 30, 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. In subpart D, by adding new § 180.1161, to read as follows:

§ 180.1161 Clarified hydrophobic extract of neem oil; exemption from the requirement of a tolerance.

Clarified hydrophobic extract of neem oil (Reg. No. 11688-8) is exempt from the requirement of a tolerance on all raw agricultural commodities when used as a botanical fungicide/insecticide/miticide.

[FR Doc. 95–29991 Filed 12–12–95; 8:45 am]
BILLING CODE 6560–50–F

40 CFR Part 180

[PP 8E3574/R2165; FRL–4973–5]

RIN 2070–AB78

Terbufos; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This document extends the time-limited tolerance for combined residues of the insecticide/nematicide terbufos and its cholinesterase-inhibiting metabolites in or on the raw agricultural commodity (RAC) green coffee beans for an additional 2 years. American Cyanamid Co. submitted a petition under the Federal Food, Drug and Cosmetic Act (FFDCA) requesting the regulation to establish a maximum permissible level for combined residues of the insecticide/nematicide in or on the commodity.

EFFECTIVE DATE: This regulation becomes effective December 13, 1995.

ADDRESSES: Written objections and hearing requests, identified by the document control number, [PP 8E3574/R2165], 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 8E3574/R 2165]. 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: Robert A. Forrest, Product Manager (PM) 14, Registration Division (7505C), 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 22202, (703)-305-6600; e-mail: forrest.robert@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: In the Federal Register of August 2, 1995 (60 FR 39299), EPA issued a proposed rule (FRL-4963-5) that gave notice that the American Cyanamid Co. had submitted data and a request under the FFDCA that a time-limited tolerance for residues of the insecticide/nematicide terbufos on coffee beans be changed to permanent status. The Agency proposed an extension of the time-limited tolerance to allow it to complete its in-depth reassessment of the current established tolerances for terbufos.

The following comments were received from the petitioner, American Cyanamid.

1. American Cyanamid believes that since the acceptance of the new rat metabolism study fulfills the condition of the time-limited coffee bean tolerance, it is sufficient to establish the regulation as permanent, regardless of any on-going analysis of tolerances for reregistration purposes.

2. Additionally, American Cyanamid believes that ''the toxicological end-point of a no-observable-effect level (NOEL) based upon plasma cholinesterase (ChE) inhibition, as mentioned in the proposed rule, is of equivocal value when used in risk assesments'' and that ''A NOEL based upon alternative tox endpoints such as red blood cell ChE inhibition, brain ChE inhibition, or clinical signs would be more appropriately used to establish reference dose for regulatory purposes.''

American Cyanamid has requested a reevaluation of plasma cholinesterase as a suitable endpoint.

The Agency acknowledges that the condition upon which the initial time-limited tolerance was based, i.e., the lack of an acceptable guideline rat metabolism study, has now been fulfilled.

However, as described in the proposed rule referenced above, the Agency currently has concern over the potential acute dietary risk posed by the current established tolerances based on the estimated margins of exposure (MOE). In light of this concern, the Agency believes that it is prudent to limit the period of time in which the coffee bean tolerance is in effect pending the Agency reassessment of the tolerances.

The Agency will take American Cyanamid's comments relative to the toxicological endpoint into consideration in its reassessment of the established tolerances.

There were no 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 time-limited tolerance will protect the public health. Therefore, the time-limited 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 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 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 a genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the