Total Annual Burden Hours: 960.

Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. This includes the time needed to: review instructions; develop, acquire, install, and utilize technology and systems for the purposes of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; adjust the existing ways to comply with any previously applicable instructions and requirements; train personnel to be able to respond to a collection of information; search data sources; complete and review the collection of information; and transmit or otherwise disclose the information.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for EPA's regulations are listed in 40 CFR Part 9 and 48 CFR Chapter 15.

V. National Technology Transfer and Advancement Act

Under the National Technology Transfer and Advancement Act, 15 U.S.C. 272 note, EPA must use voluntary consensus standards to carry out policy objectives or activities unless it would be impractical to do so. In this case, such standards, applicable to this regulation, do not exist. Accordingly, the use of such standards is not required.

VI. Submission to Congress and the Comptroller General

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that, before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this direct amendment to interim final rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the direct amendment to interim final rule in the **Federal Register**. This direct final rule is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 8

Environmental protection, Antarctica, Enforcement, Environmental documentation, Environmental impact assessment, Penalties, Prohibited acts.

Dated: April 2, 1998.

Steven A. Herman,

Assistant Administrator, Office of Enforcement and Compliance Assurance.

Therefore, for the reasons set out in the preamble, title 40 chapter 1 of the Code of Federal Regulations is amended as follows:

PART 8—ENVIRONMENTAL IMPACT ASSESSMENT OF NONGOVERNMENTAL ACTIVITIES IN ANTARCTICA

1. The authority citation for part 8 continues to read as follows:

Authority: 16 U.S.C. 2401 *et seq.*, as amended, 16 U.S.C. 2403a.

2. Section 8.2 is amended by revising paragraph (d) to read as follows:

§ 8.2 Applicability and effect.

* * * * *

(d) This part is effective on April 30, 1997. This part will expire upon the earlier of the end of the 2000–2001 austral summer season or upon issuance of a final regulation.

3. Section 8.8 is amended by revising paragraphs (b)(1) and (b)(2) to read as follows:

§ 8.8 Comprehensive environmental evaluation.

* * * * *

(b) *Submission of Draft CEE to the EPA and Circulation to Other Parties.* (1) For the 1998–1999, 1999–2000, and 2000–2001 austral seasons, any operator who plans a nongovernmental expedition which would require a CEE must submit a draft of the CEE by December 1, 1997, December 1, 1998, and December 1, 1999, respectively. Within fifteen (15) days of receipt of the draft CEE, EPA will: send it to the Department of State which will circulate it to all Parties to the Protocol and forward it to the Committee for Environmental Protection established by the Protocol, and publish notice of receipt of the CEE and request for comments on the CEE in the **Federal Register**, and will provide copies to any person upon request. The EPA will accept public comments on the CEE for a period of ninety (90) days following notice in the **Federal Register**. The EPA, in consultation with other interested federal agencies, will evaluate the CEE to determine if the CEE meets the requirements under Article 8 and Annex I to the Protocol and the provisions of this part and will transmit its comments to the operator within 120 days following publication in the **Federal Register** of the notice of availability of the CEE.

(2) The operator shall send a final CEE to EPA at least seventy-five (75) days before commencement of the proposed activity in the Antarctic Treaty area. The CEE must include (or summarize) any comments on the draft CEE received from EPA, the public, and the Parties, including comments offered at the XXII Antarctic Treaty Consultative Meeting in 1998, the XXIII Antarctic Treaty Consultative Meeting in 1999, and the XXIV Antarctic Treaty Consultative Meeting in 2000 for CEEs submitted for the 1998–1999, 1999–2000, and 2000–2001 austral seasons, respectively. Following the final response from the operator, the EPA will inform the operator if EPA, with the concurrence of the National Science Foundation, makes the finding that the environmental documentation submitted does not meet the requirements of Article 8 and Annex I of the Protocol and the provisions of this part. This notification will occur within fifteen (15) days of submittal of the final CEE by the operator if the final CEE is submitted by the operator within the time limits set out in this section. If no final CEE is submitted or the operator fails to meet these time limits, EPA will provide such notification sixty (60) days prior to departure of the expedition. If EPA does not provide such notice, the operator will be deemed to have met the requirements of this part provided that procedures, which include appropriate monitoring, are put in place to assess and verify the impact of the activity. The EPA will transmit the CEE, along with a notice of any decisions by the operator relating thereto, to the Department of State which shall circulate it to all Parties no later than sixty (60) days before commencement of the proposed activity in the Antarctic Treaty area. The EPA will also publish a notice of availability of the final CEE in the **Federal Register**.

* * * * *

[FR Doc. 98–10006 Filed 4–14–98; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300623; FRL–5773–9]

2070–AB78

Canola Oil; Exemption from the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This rule establishes an exemption from the requirement of a tolerance for residues of canola oil, i.e., low erucic acid rapeseed oil (containing no more than 2% erucic acid), when used as an insecticide in or on all food commodities. W. Neudorff GmbH KG submitted a petition to the EPA under the Federal Food, Drug and Cosmetic Act (FFDCA) as amended by the Food Quality Protection Act (FQPA) of 1996 requesting the exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of this insecticide in or on all food commodities.

EFFECTIVE DATE: This regulation is effective April 15, 1998. Objections and requests for hearings must be received on or before June 15, 1998.

ADDRESSES: Written objections and hearing requests, identified by the docket control number [OPP–300623], 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 docket control number [OPP–300623] and submitted to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), 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. 119, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA.

A copy of objections and hearing requests filed with the Hearing Clerk may be submitted electronically by sending electronic mail (e-mail) to: opp-docket@epamail.epa.gov. Copies of electronic objections and hearing requests must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Copies of electronic objections and hearing requests will also be accepted on disks in WordPerfect 5.1 or 6.1 file format or ASCII file format. All copies of electronic objections and hearing requests must be identified by the docket control number [OPP–300623]. No Confidential Business Information (CBI) should be submitted through e-mail. Copies of electronic objections and hearing requests on this rule may be filed online at many Federal Depository Libraries.

FOR FURTHER INFORMATION CONTACT: By mail: Susanne Cerrelli, c/o Product Manager (PM) 90, Biopesticides and Pollution Prevention Division (7511W), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460, Office location and telephone number and e-mail address: CS1 Rm. 5-W31, 2800 Crystal Drive, Arlington, VA, 703–308–8077, e-mail: cerrelli.susanne@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: W. Neudorff GmbH KG, c/o Walter G. Telarek, PC, 1008 Riva Ridge Drive, Great Falls, VA, has requested in pesticide petition PP 7F4804 the establishment of an exemption from the requirement of a tolerance for residues of canola oil. A notice of filing (FRL–5597–6) was published in the **Federal Register** (62 FR 17812) on April 11, 1997, and the notice announced that the comment period would end on May 11, 1997; no comments were received. This exemption from the requirement of a tolerance will permit the marketing of raw agricultural commodities when treated in accordance with EPA Reg No. 67702–U, which is being issued under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended (Pub. L. 95–396, 92 Stat. 819; 7 U.S.C. 136). The data submitted in the petition and all other relevant material have been evaluated. The following is a summary of EPA's findings regarding this petition.

I. Product Identity

NEU 1160 Vegetable Oil Insecticide (EPA file symbol No. 067702–U) is the first pesticide product containing low erucic acid rapeseed oil as the active ingredient. The rapeseed oil in this product contains less than 2% erucic acid and conforms with 21 CFR 184.1555(c). Canola oil is the common name of this active ingredient. Canola oil is the full refined edible oil obtained from certain varieties of plants, i.e. *Brassica campetris*, or *B. napus*, of the family Cruciferae.

II. Risk Assessment and Statutory Findings

New section 408(c)(2)(a)(i) of FFDCA allows EPA to establish an exemption from the requirement of a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is ''safe.'' Section 408(c)(2)(ii) defines ''safe'' to mean that ''there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(c)(2)(b) requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to ''ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue***.'' EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. First, EPA determines the toxicity of pesticides. Second, EPA examines exposure to the pesticide through food, drinking water, and through other exposures that occur as a result of pesticide use in residential settings.

III. Toxicological Profile

Consistent with section 408(b)(2)(d) of FFDCA, EPA has reviewed the scientific data and other relevant information in support of this action and considered its validity, completeness, reliability, and relationship to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. Data waivers were requested for acute oral, dermal, inhalation, and eye toxicity, dermal sensitization, genotoxicity, reproductive and developmental toxicity, subchronic (90–day) oral and inhalation toxicity, and teratogenicity. The waivers were accepted based on the long history of use of canola as an edible fat and oil in food without any indication of deleterious effects; its low toxicity; its natural occurrence as an oil extracted from plants; its low erucic acid (less than 2%) content; its conformity with 21 CFR 184.1555(c); and its classification by FDA as ''generally recognized as safe'' (GRAS) for use as an edible fat or oil in human food. Available toxicity data on vegetable oils from the open literature and the Reregistration Eligibility Decision document for Flower and Vegetable Oils (EPA 738–R–93–031) support this finding.

IV. Residue Chemistry

A waiver was requested and granted for the following residue data requirements: (1) Magnitude of residue anticipated at the time of harvest, and (2) method used to determine the residue. These are waived based on the rationale presented in Unit III of this preamble.

V. Aggregate Exposure

In examining aggregate exposure, FFDCA section 408 directs EPA to consider available information concerning exposures from the pesticide residue in food and all other non-occupational exposures. The primary non-food sources of exposure the Agency considers include drinking water or groundwater, and exposure through pesticide use in gardens, lawns, or buildings (residential and other indoor uses).

Dietary exposure of canola oil via food consumption exists due to its use as a fat and oil in food. Residues from use of the biochemical pesticide, canola oil, are expected to increase the current dietary exposures only minimally because the application rates for canola are very low. In addition, because the current uses of low erucic acid canola oil have low toxicity, the Agency has determined that the aggregate dietary risk from adding the pesticidal uses of canola would be minimal.

Exposure by the inhalation route would be negligible because canola oil has low volatility, and the maximum concentration applied to plants is 2% canola oil. In summary, the potential aggregate exposure, derived from non-dietary and non-occupational exposure, should be minimal.

VI. Cumulative Effects

Canola oil shares a common dietary metabolic disposition with other edible fats and oils. Canola oil and other cooking grade oils have been used for many years without reported toxicity. These fats and oils are not known to cause any direct toxic effects when part of a balanced diet.

VII. Endocrine Disruptors

The Agency has no information to suggest that canola oil has any effect on the immune and endocrine systems. The Agency is not requiring information on the endocrine effects of this biochemical pesticide at this time; Congress has allowed 3 years after August 3, 1996, for the Agency to implement a screening program with respect to endocrine effects. Nevertheless, the above discussion on exposure from all sources combined with the low toxicity of canola oil would indicate such testing would not be necessary.

VIII. Safety Determination for U.S. Population, Infants and Children

Based on the information discussed in Unit V of this preamble, EPA concludes that there is reasonable certainty that no harm will result from aggregate exposure to the U.S. population, including infants and children, to residues of canola oil. This includes all anticipated dietary exposures and all other exposures for which there is reliable information. The Agency has arrived at this conclusion because, as discussed in Unit III of this preamble, the toxicity of canola oil to mammals is very low and under reasonably foreseeable circumstances it does not pose a risk. FFDCA section 408 provides that EPA shall apply an additional ten-fold margin of exposure (safety) for infants and children in the case of threshold effects to account for pre- and post-natal toxicity and the completeness of the database, unless EPA determines that a different margin of exposure (safety) will be safe for infants and children. Margins of exposure (safety) are often referred to as uncertainty (safety) factors. In this instance, the Agency believes there is reliable data to support the conclusion that canola oil is practically non-toxic to mammals, including infants and children, and, thus, there are no threshold effects; therefore, EPA has not used a margin of exposure (safety) approach to assess the safety of canola oil. As a result, the provision requiring an additional margin of exposure (safety) does not apply.

IX. Other Considerations

1. *Analytical method.* The Agency proposes to establish an exemption from the requirement of a tolerance without any numerical limitation; therefore, an analytical method is not required for enforcement purposes for canola oil residues.

2. *Codex maximum residue level.* There are no CODEX tolerances nor international tolerance exemptions established for canola oil at this time.

X. Conclusion

Based on the information discussed above, EPA establishes an exemption from the requirement of a tolerance for Canola oil (low erucic acid rapeseed oil containing no more than 2% erucic acid). This exemption from the requirement of a tolerance will be revoked if any experience with or scientific data on this pesticide indicate that the tolerance is not safe.

XI. Objections and Hearing Requests

The new FFDCA section 408(g) provides essentially the same process for persons to ''object'' to a tolerance exemption regulation issued by EPA under new section 408(e) as was provided in the old section 408. However, the period for filing objections is 60 days, rather than 30 days. EPA currently has procedural regulations which govern the submission of objections and hearing requests. These regulations will require some modification to reflect the new law. However, until those modifications can be made, EPA will continue to use those procedural regulations with appropriate adjustments to reflect the new law.

Any person adversely affected by this regulation may, by June 15, 1998, 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 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). Information submitted in connection with an objection or hearing request may be claimed confidential by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the information 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.

XII. Public Docket and Electronic Submissions

EPA has established a record for this rulemaking under docket control number [OPP–300623] (including any comments and data submitted electronically). A public version of this record, including printed, paper versions of electronic comments, which does not include any information

claimed as CBI, is available for inspection from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The public record is located in Room 119 of the Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA.

Electronic comments may be sent directly to EPA at:

opp-docket@epamail.epa.gov.

Electronic comments 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 copies of objections and hearing requests received electronically into printed, paper form as they are received and will place the paper copies in the official rulemaking record which will also include all comments submitted directly in writing. The official rulemaking record is the paper record maintained at the Virginia address in ''ADDRESSES'' at the beginning of this document.

XIII. Regulatory Assessment Requirements

This final rule establishes an exemption from the tolerance requirement under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled Regulatory Planning and Review (58 FR 51735, October 4, 1993). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 et seq., or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Pub. L. 104–4). Nor does it require any prior consultation as specified by Executive Order 12875, entitled Enhancing the Intergovernmental Partnership (58 FR 58093, October 28, 1993), or special considerations as required by Executive Order 12898, entitled Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations (59 FR 7629), February 16, 1994), or require OMB review in accordance with Executive Order 13045, entitled Protection of Children from Environmental Health Risks and Safety Risks (62 FR 19885, April 23, 1997).

In addition, since tolerance exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the exemption in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 et seq.) do not apply. Nevertheless, the Agency previously assessed whether establishing tolerances, exemptions from tolerances, raising tolerance levels or expanding exemptions might adversely impact small entities and concluded, as a generic matter, that there is no adverse economic impact. The factual basis for the Agency's generic certification for tolerance actions published on May 4, 1981 (46 FR 24950) was provided to the Chief Counsel for Advocacy of the Small Business.

XIV. Submission to Congress and the Comptroller General

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the Agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This rule is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, pesticides and pests, Reporting and recordkeeping requirements.

Dated: April 3, 1998.

Marcia E. Mulkey,

Director, Office of Pesticide Programs.

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 180.1194 is added to read as follows:

§ 180.1194 Canola oil; exemption from the requirement of a tolerance.

An exemption from the requirement of a tolerance is established for residues of the biochemical pesticide, canola oil, conforming to the following definition when used as an insecticide, in or on all food commodities: Canola oil, also known as low erucic rapeseed oil, is the fully refined, bleached, and deodorized edible oil obtained from certain varieties of *Brassica Napus* or *B. Campestris* of the family Cruciferae. Canola oil contains no more than 2 percent erucic acid.

[FR Doc. 98–10013 Filed 4–14–98; 8:45 am]

BILLING CODE 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300644; FRL–5785–7]

RIN 2070–AB78

Spinosad; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes permanent tolerances for residues of spinosad in or on almonds at 0.02 parts per million (ppm); almond hulls at 2.0 ppm; apples at 0.2 ppm; apple pomace, wet at 0.5 ppm; citrus fruits group at 0.3 ppm; citrus pulp, dried at 0.5 ppm; citrus oil at 3.0 ppm; cottonseed at 0.02 ppm; cotton gin byproducts at 1.5 ppm; fruiting vegetables (except cucurbits) group at 0.4 ppm; Brassica (cole), leafy vegetables, head and stem subgroup at 2.0 ppm; Brassica (cole), leafy vegetables, greens subgroup at 10.0 ppm; leafy vegetables (except Brassica vegetables) group at 8.0 ppm; fat of cattle, goats, hogs, horses, and sheep at 0.6 ppm; meat of cattle, goats, hogs, horses, and sheep at 0.04; meat byproducts of cattle, goats, hogs, horses, and sheep at 0.2 ppm; milk fat at 0.5 ppm; and whole milk at 0.04 ppm. This regulation also removes the time limitation for the tolerance for residues of spinosad on cottonseed which expires on November 15, 1999. DowElanco requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA) (Pub. L. 104-170). In addition, this regulation removes time-limited tolerances set under section 408(1)(6) of the FFDCA, as amended by the FQPA for residues of spinosad on fruiting vegetables (except cucurbits) group, tomato paste, leafy vegetables (except Brassica vegetables) group, and Brassica (cole), leafy vegetables, group at 0.25, 0.50, 10.0, and 10.0 ppm, respectively. These tolerances were set under the