approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, nor does it require any special considerations under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under section 408(d) of FFDCA, 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.

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of FFDCA. As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 9, 2000) do not apply to this final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104–4).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104–113, section 12(d) (15 U.S.C. 272 note).

X. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report to each House of the Congress and to 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 this final rule in the **Federal Register**. This final 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: October 18, 2009.

Debra Edwards,

Director, Office of Pesticide Programs.

■ Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

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

Authority: 21 U.S.C. 321(q), 346a and 371.

■ 2. Section 180.1292 is added to subpart D to read as follows:

§ 180.1292 Ulocladium oudemansii (U3 Strain); exemption from the requirement of a tolerance.

An exemption from the requirement of a tolerance is established in/on all food commodities for residues of *Ulocladium oudemansii* (U3 Strain), when applied or used pre-harvest-only, excluding applications made post-harvest or to processed commodities, as a microbial fungicide in accordance with good agricultural practices.

[FR Doc. E9–25969 Filed 10–27–09; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2007–1025; FRL–8434–5]

Cold Pressed Neem Oil; Exemption from the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes an exemption from the requirement of a tolerance for residues of the biochemical pesticide, cold pressed neem oil on all food commodities when applied/used on/in food commodities. Plasma Power Limited of India submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), requesting an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of cold pressed neem oil.

DATES: This regulation is effective October 28, 2009. Objections and requests for hearings must be received on or before December 28, 2009, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: EPA has established a docket for this action under docket identification (ID) number EPA–HQ–OPP–2007–1025. All documents in the docket are listed in the docket index available at *http://www.regulations.gov*. Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available in the electronic docket at *http://www.regulations.gov*, or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S-4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: Driss Benmhend, Biopesticides and Pollution Prevention Division (7511P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 308–9525; e-mail address: *benmhend.driss@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected entities may include, but are not limited to:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American

Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How Can I Access Electronic Copies of this Document?

In addition to accessing electronically available documents at *http://www.regulations.gov*, you may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at *http://www.epa.gov/fedrgstr*. You may also access a frequently updated electronic version of 40 CFR part 180 through the Government Printing Office's e-CFR site at *http://www.gpoaccess.gov/ecfr*. To access the OPPTS Harmonized Guidelines referenced in this document, go directly to the guidelines at *http://www.epa.gov/opptsfrs/home/guidelin.htm*.

C. Can I File an Objection or Hearing Request?

Under section 408(g) of FFDCA, 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. The EPA procedural regulations which govern the submission of objections and requests for hearings appear in 40 CFR part 178. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2007–1025 in the subject line on the first page of your submission. All requests must be in writing, and must be mailed or delivered to the Hearing Clerk on or before December 28, 2009.

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing that does not contain any CBI for inclusion in the public docket that is described in **ADDRESSES**. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit your copies, identified by docket ID number EPA–HQ–OPP–2007–1025, by one of the following methods.

- *Federal eRulemaking Portal*: *http://www.regulations.gov*. Follow the on-line instructions for submitting comments.
- *Mail*: Office of Pesticide Programs (OPP) Regulatory Public Docket (7502P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.
- *Delivery*: OPP Regulatory Public Docket (7502P), Environmental Protection Agency, Rm. S-4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. Deliveries are only accepted during the Docket Facility's normal hours of operation (8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays). Special arrangements should be made for deliveries of boxed information. The Docket Facility telephone number is (703) 305–5805.

II. Background and Statutory Findings

In the **Federal Register** of November 2, 2007 (72 FR 62237) (FRL–8153–8), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide tolerance petition (PP 7F7249) by Plasma Power Limited of India, c/o OMC Ag Consulting, 828 Tanglewood Lane, East Lansing, MI 48823. The petition requested that 40 CFR part 180 be amended by establishing an exemption from the requirement of a tolerance for residues of cold pressed neem oil. The notice included a summary of the petition prepared by the petitioner, Plasma Power Limited of India. One comment was received in response to the notice of filing. The commenter objected to the petition and expressed concerns about EPA's regulation of human exposure to toxic chemicals. The Agency understands the commenter's concerns regarding toxic chemicals and the potential effects to humans when exposed to toxic chemicals. Pursuant to its authority under the FFDCA, and as discussed further in this unit, EPA conducted a comprehensive assessment of cold pressed neem oil, including a review of acute toxicity, mutagenicity and developmental studies. Based on these data, the Agency has concluded that there is a reasonable certainty that no harm will result from dietary exposure to residues of cold pressed neem oil when used in or on the food and feed commodities.

Section 408(c)(2)(A)(i) of FFDCA allows EPA to establish an exemption from the requirement for a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the exemption is ''safe.'' Section 408(c)(2)(A)(ii) of FFDCA 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. Pursuant to section 408(c)(2)(B) of FFDCA, in establishing or maintaining in effect an exemption from the requirement of a tolerance, EPA must take into account the factors set forth in sections 408(b)(2)(C) and (D) of FFDCA, which require 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. . . .'' Additionally, section 408(b)(2)(D) of FFDCA requires that the Agency consider ''available information concerning the cumulative effects'' of a particular pesticide's residues and ''other substances that have a common mechanism of toxicity.''

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 available scientific data and other relevant information in support of this action and considered its validity, completeness, and reliability and the relationship of this information 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.

Cold pressed neem oil is pressed directly from seeds of the neem tree (azadirachta indica), which is a tropical evergreen tree native to India and also found in other Southeast Asian and African countries. Cold pressed neem oil has a brown color, a bitter taste and a garlic/sulfur smell. A single seed may contain up to 50% oil by weight. Cold pressed neem oil contains various compounds that have insecticidal and medicinal properties. It is used in making shampoos, toothpaste, soaps, cosmetics, mosquito repellants, creams, lotions, and pet products such as pet shampoo. It also contains vitamin E, other essential amino acids and some percentages of fatty acids. Cold pressed neem oil is used for treating many skin diseases viz, eczema, psoriasis, skin allergies, etc. and is being studied for

making contraceptives in India (DAI, 2009).

Cold pressed neem oil is a mixture of several C26 terpenoids which are naturally occurring organic compounds composed of a five-carbon skeleton (simple terpenoids) or complex terpenoids with structures that possess between 20 and 40 carbon atoms. Azadirachtin is the most common terpenoid in cold pressed neem oil, the most thoroughly characterized and is a federally registered active ingredient pesticide. Cold pressed neem oil also contains steroids, fatty acids, and a number of essential oils.

Cold pressed neem oil has been used for hundreds of years in controlling plant pests and diseases (DAI, 2009). Research has demonstrated that the spray solution of cold pressed neem oil helps to control common pests such as white flies, aphids, scales, mealy bugs, spider mites, locusts, thrips, and Japanese beetles. Cold pressed neem oil is also used as a fungicide and helps control powdery mildew. Data submitted and reviewed by EPA show that cold pressed neem oil acts by affecting the insect's growth, thus preventing the larval stage to molt into an adult. It also acts as a repellent and feeding inhibitor by leaving a very bitter taste on sprayed plants, making them very distasteful for the insects to feed on.

Based on all the data submitted and available in the literature, the Agency determined that cold pressed neem oil and its components have low toxicity via all routes of exposure. Moreover, EPA conducted further modeling of potential residue on sprayed fruits and vegetables with 100% cold pressed neem oil and concluded that residues of cold pressed neem oil are very low and that these residues will decline rapidly (details in Unit III.A.)

All the data requirements to support a tolerance exemption were fulfilled by the applicant. EPA concluded that the data are acceptable and that no data gaps exist and no additional data are required. No acute, subchronic, or chronic toxicity endpoints were identified in guideline studies or in data obtained from the open technical literature. Moreover, cold pressed neem oil is not a mutagen, and is not a developmental toxicant. There are no known effects on endocrine systems via oral, dermal, or inhalation exposure.

1. *Acute toxicity (OPPTS Harmonized Guideline 870.1100–870.2600).* Tier I toxicity data submitted and reviewed showed that cold pressed neem oil is a Toxicity Category IV (low toxicity) compound via acute oral and acute inhalation routes of exposure. Cold pressed neem oil is in Toxicity Category III (slightly toxic) for acute dermal irritation. Cold pressed neem oil is not an eye or skin irritant, and it is not a dermal sensitizer.

2. *90–Day oral feeding (OPPTS Harmonized Guideline 870.3100).* To address this data requirement, the applicant submitted data obtained from the technical public literature in lieu of a guideline study. The study showed that test animals did not exhibit any clinical signs of toxicity that were statistically different from untreated controls. There were no significant changes in body weight, serum liver damage indicators, direct bilirubin and total bilirubin, or other blood parameters during the 90–day study period. The 90–day oral feeding LD_{50} is higher than 5,000 milligrams (mg) crude cold pressed neem oil/kilogram (kg) body weight. Based on the review of this data, EPA concluded that no subchronic oral toxicity is expected to occur when this compound is used in accordance with good agricultural practices.

3. *Tier I developmental toxicity (teratogenicity) (OPPTS Harmonized Guideline 870.3500).* Several technical public literature studies were submitted in lieu of guideline studies to satisfy the developmental toxicity data requirement.

In vitro studies showed that cold pressed neem oil may inhibit the development of two-cell mouse embryos (Juneja and Williams, 1993; Juneja *et al.*, 1994) and mouse sperm-egg interaction (Juneja and Williams, 1993). Sharma *et al.* (1996) found that a cold pressed neem oil fraction (designated NIM-76) placed in contact with cells *in vitro* selectively killed human sperm but did not affect normal cells of monkey kidney, human fetal lung, or peritoneal macrophages. In *in vivo* studies, Upadhyay *et al.* (1990) found that a single intrauterine dose of 100 µL of cold pressed neem oil inhibited pre-implantation in Wistar rats for up to 180 days. However, the effect was reversible, as treated rats regained fertility and delivered normal litters within 5 months post-treatment. A later study (Kaushic and Upadhyay, 1995) in rats showed that the anti-fertility effect of cold pressed neem oil was localized and 100 µL administered to one uterine horn produced abnormal cleavage. Subcutaneous application of cold pressed neem oil to cyclic rats produced significant damage to the luminal epithelium of the uterus and to the uterine glands (Tewari *et al.*, 1989). Glycogen and total protein in the ovary and uterus were also decreased. Ovariectomized rats administered cold pressed neem oil also showed decreased glycogen and protein content in the uterus, but when cold pressed neem oil was administered with or without estradiol dipropionate or progesterone, there were no significant differences between rats receiving cold pressed neem oil alone or in conjunction with the hormones. Tewari *et al.* (1989) concluded that the histological and biochemical changes seen were due to the toxicological potential of the cold pressed neem oil rather than to hormonal properties. Intravaginal application of a formulated product containing cold pressed neem oil (praneem polyherbal cream) was an effective contraceptive in rabbits up to 1 hour post-application, but was less effective after 90 minutes and ineffective after 12 hours (Garg *et al.*, 1993). The conception rate of monkeys receiving the cream was only 2.27%. In a three-generation reproduction study (Chinnasamy *et al.* (1993)) in which rats were fed a diet containing 10% cold pressed neem oil or 10% groundnut oil, the results from both matings in all three-generations did not show any adverse effects on the reproductive parameters of rats fed cold pressed neem oil compared to groundnut oil. No other toxicological effects were reported.

Based on the *in vitro* and *in vivo* studies, and subcutaneous and intravaginal applications of cold pressed neem oil, it seems that developmental toxicity may occur when exposure to cold pressed neem oil occurs by intravaginal, intrauterine, subcutaneous injection, or by direct exposure to mammalian sperm and eggs in *in vitro* laboratory studies. However, the three-generation study in rats fed cold pressed neem oil in the diet demonstrates that chronic oral ingestion of food commodities containing cold pressed neem oil residues will not result in any mammalian developmental toxicity. Therefore, no developmental toxicity is expected to occur from the use of cold pressed neem oil as a pesticide.

4. *Mutagenicity testing (OPPTS Harmonized Guideline 870.5100, 870.5300, and 870.5375).* The technical documents from the public literature and the guideline study submitted, performed using the TGAI as the test substance, showed no mutagenicity/genotoxicity effects.

Cold pressed neem oil and its components are not structurally related to known mutagens, nor do they belong to any chemical class of compounds containing known mutagens. Humans are regularly exposed to this substance via oral exposure (as a traditional folk medicinal product) and dermal exposure (when used on skin and hair)

at levels that are significantly greater than that which would be expected from the product as a pesticide under conditions of use. In addition, an extensive literature search of several scientific databases (i.e., ChemIDPlus, HSDB, Toxline, CCCRIS, DART, GENETOX, IRIS, ITER, LactMed, Multi-Database, TRI, HazMap, Household Products, TOXMAP and TOXNET) for the period 1980 to 2008 using cold pressed neem oil as the search parameter was unable to locate any other data/information regarding mutagenicity or genotoxicity of cold pressed neem oil. As a result, EPA concludes that cold pressed neem oil is not mutagenic or genotoxic.

IV. Aggregate Exposures

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

There is reasonable certainty that no harm to the U.S. population will result from aggregate exposure to residues of 100% cold pressed neem oil. This includes all exposures for which there is reliable information. The Agency arrived at this conclusion based on the low level of toxicity of cold pressed neem oil and the current use of cold pressed neem oil on skin in traditional medicinal products, cosmetics, and shampoos at levels that are substantially greater than that which would be expected from the product as a pesticide under conditions of use. The risks from aggregate exposure via oral, dermal and inhalation exposure are a compilation of three low-risk exposure scenarios (oral, dermal, and inhalation) and are negligible. Since there are no threshold effects of concern, and no known toxic endpoints, the provision requiring an additional margin of safety does not apply. Therefore, the Agency has not used a margin of exposure (MOE) (safety) approach to assess the safety of cold pressed neem oil.

A. Dietary Exposure

1. *Food*. The most likely human exposure to cold pressed neem oil will occur via dietary exposure (consumption) to treated fruits, seeds, or leafy vegetables. EPA modeling (using the terrestrial exposure model (T-REX; EPA, 2005) of potential residues of cold pressed neem oil following terrestrial treatments indicated that following 12 consecutive applications of 100% cold pressed neem oil at 7–day intervals, the maximum dietary residues present would be approximately 881 parts per million (ppm) on broadleaf plant foliage; and approximately 98 ppm on fruits, pods, and seeds (see table below). The modeling indicated that residues would decline rapidly between foliar applications (approximately 245–440 ppm on broadleaf foliage; and 27–49 ppm on fruits, pods, and seeds) and following the final application (see table below). As stated in Unit III.1. cold pressed neem oil is a Toxicity Category IV for oral exposure (LD_{50} = >5,000 mg/kg). The estimated maximum theoretical residues likely to be present on edible commodities are 882 ppm. This residue level is approximately 5-fold less than the highest doses used in acute and subchronic laboratory testing (5,000 mg/kg) and approximately 20-fold less than chronic laboratory testing (10% in the diet) at which no mortalities or other signs of clinical toxicity were observed.

Therefore, based on a lack of acute, subchronic, or chronic toxicity in laboratory testing, estimated maximum residues that are well below the doses used in laboratory testing, and the rapid degradation of neem oil in the environment, it is highly unlikely that that there will be any adverse effects to humans resulting from dietary exposure to neem oil.

ESTIMATED COLD PRESS NEEM OIL RESIDUES ON TERRESTRIAL MATRICES USING THE TERRESTRIAL EXPOSURE MODEL (T-REX; EPA, 2005)

Terrestrial Matrix	Dietary-based Estimated Environmental Concentrations		
	0 Days After Last App	86 Days After Last App	106 Days After Last App
Edible Broadleaf Plant Folage	881.20	0.04	0.00
Fruits. Pods, and Seeds	97.91	0.00	0.00

Moreover, humans are regularly exposed to this compound via consumption of cold pressed neem oil medicinal products, and at levels that are significantly greater than what would be expected from pesticide applications. The Agency is not concerned about dietary exposure because of the low toxicity of this active ingredient and the history of its use without any reports of adverse effects.

2. *Drinking water exposure*. No significant drinking water exposure or residues are expected to result from the pesticidal usage of cold pressed neem oil. The active ingredient is intended for use as a foliar application on food commodities and not to be applied directly to water or to areas where surface water is present. If used in accordance with EPA-approved labeling, is not likely to accumulate in drinking water. In the unlikely event that exposure via drinking water did occur from accidental spraying, the health risk would be expected to be minimal, based on the low acute oral toxicity and the long history of human exposure to cold pressed neem oil without adverse effects. As a result, dietary and drinking water exposure to residue of cold pressed neem oil are expected to be minimal.

B. Other Non-Occupational Exposure

There are no residential, school or day care uses proposed for this product. Since the proposed use pattern is for all food commodities, the potential for non-occupational, non-dietary exposures to cold pressed neem oil by the general population, including infants and children, is highly unlikely.

1. *Dermal exposure*. Humans are regularly exposed to cold pressed neem oil via dermal exposure when used on skin and hair at levels that are significantly greater than that which would be expected from the product use as a pesticide. Non-occupational dermal exposures to cold pressed neem oil when used as a pesticide are expected to be negligible because it is limited to agricultural use.

2. *Inhalation exposure*. Non-occupational inhalation exposures to cold pressed neem oil when used as a pesticide are expected to be negligible because it is limited to agricultural use.

V. Cumulative Effects

Section 408(b)(2)(D)(v) of the FFDCA requires that, when considering whether to establish an exemption from a tolerance, the Agency consider ''available information concerning the cumulative effects of a [particular pesticide's residues] and other substances that have a common mechanism of toxicity.'' These considerations include the possible cumulative effects of such residues on infants and children.

EPA has considered the potential for cumulative effects of cold pressed neem oil and other substances in relation to a common mechanism of toxicity. However, because of its low toxicity to mammalian systems, the Agency does not expect any cumulative or incremental effects from exposure to residues of cold pressed neem oil when applied/used as directed on the label and in accordance with good agricultural practices.

VI. Determination of Safety for U.S. Population, Infants and Children

There is reasonable certainty that no harm will result from aggregate exposure to residues of cold pressed neem oil to the U.S. population, infants, and children. This includes all anticipated dietary exposures and all other exposures for which there is reliable information. The Agency arrived at this conclusion based on the low level of toxicity of cold pressed neem oil and the already widespread human use and exposure to cold pressed neem oil without any reported adverse effects on human health. The risks from aggregate exposure via oral, dermal and inhalation exposure are a compilation of three low-risk exposure scenarios and are negligible. Since there are no threshold effects of concern, the provision requiring an additional margin of safety does not apply. Moreover, cold pressed neem oil is widely used in cosmetics (soap, hair products, hand creams, etc.), traditional medicine (acne, fevers, rheumatism, diuretics, inflammations, etc.), as an insect repellent and an insecticide, as a nematicide and fungicide, and as a fertilizer. Humans have had frequent physical contact with cold pressed neem oil with no negative health effects. Therefore, the Agency has not used a MOE (safety) approach to assess the safety of cold pressed neem oil.

VII. Other Considerations

A. Endocrine Disruptors

EPA is required under section 408(p) of the FFDCA, as amended by the Food Quality Protection Act (FQPA), to develop a screening program to determine whether certain substances (including all pesticide active and other ingredients) ''may have an effect in humans that is similar to an effect produced by a naturally-occurring estrogen, or such other endocrine effect as the Administrator may designate.''

Cold pressed neem oil is not a known endocrine disruptor nor is it related to any class of known endocrine disruptors. Thus, there is no impact via endocrine-related effects on the Agency's safety finding set forth in this final rule for cold pressed neem oil.

B. Analytical Methods

Through this action, the Agency proposes to establish an exemption from the requirement of a tolerance for cold pressed neem oil when used on fruit and vegetable crops. For the same reasons that support the granting of this tolerance exemption, the Agency has concluded that an analytical method is not required for enforcement purposes for these proposed uses of cold pressed neem oil.

C. Codex Maximum Residue Level

There are no codex maximum residue levels established for cold pressed neem oil.

VIII. Conclusions

There are no human health concerns when end use products containing the active ingredient cold pressed neem oil are applied according to label use directions. The data submitted by the applicant and reviewed by the Agency support the petition for an exemption from the requirement of tolerances for cold pressed neem oil on food when the product is applied/used as directed on the label and in accordance with good agricultural practices. The toxicology data submitted are sufficient to demonstrate that no foreseeable human health hazard is likely to arise from the use of cold pressed neem oil.

IX. Statutory and Executive Order Reviews

This final rule establishes a tolerance under section 408(d) of FFDCA 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). Because this final rule has been exempted from review under Executive Order 12866, this final rule is not subject to Executive Order 13211, entitled *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). 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.*, nor does it require any special considerations under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under section 408(d) of FFDCA, such as the tolerance 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.

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of FFDCA. As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 9, 2000) do not apply to this final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104–4).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104–113, section 12(d) (15 U.S.C. 272 note).

X. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report to each House of the Congress and to 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 this final rule in the **Federal Register**. This final 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: October 15, 2009.

Keith A. Matthews,

Acting Director, Biopesticides and Pollution Prevention Division, Office of Pesticide Programs.

■ Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

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

Authority: 21 U.S.C. 321(q), 346a and 371.

■ 2. Section 180.1291 is added to subpart D to read as follows:

§ 180.1291 Cold pressed neem oil; exemption from the requirement of a tolerance.

Residues of the biochemical pesticide cold pressed neem oil are exempt from the requirement of a tolerance in or on all food commodities.

[FR Doc. E9–25455 Filed 10–27–09; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2009–0018; FRL–8795–3]

Pyriproxyfen; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of pyriproxyfen in or on artichoke, globe; asparagus; fruit, small, vine climbing subgroup, except grape 13–07E; vegetable, foliage of legume, group 7; vegetable, leafy, except brassica, group 4; vegetable, leaves of root and tuber, group 2; and watercress. It also removes the section 18 time-limited tolerances on succulent bean, celery and strawberry since these tolerances have expired. Interregional Research Project Number 4 (IR-4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective October 28, 2009. Objections and requests for hearings must be received on or before December 28, 2009, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: EPA has established a docket for this action under docket identification (ID) number EPA–HQ–OPP–2009–0018. All documents in the docket are listed in the docket index available at *http://www.regulations.gov*. Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available in the electronic docket at *http://www.regulations.gov*, or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: Barbara Madden, Registration Division, Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 305–6463; e-mail address: *madden.barbara@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected entities may include, but are not limited to those engaged in the following activities:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

This listing is not intended to be exhaustive, but rather to provide a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How Can I Access Electronic Copies of this Document?

In addition to accessing electronically available documents at *http://www.regulations.gov*, you may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at *http://www.epa.gov/fedrgstr*. You may also access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's e-CFR cite at *http://www.gpoaccess.gov/ecfr*. To access the OPPTS Harmonized Test Guidelines referenced in this document, go directly to the guidelines at *http://www.epa.gov/oppts* and select ''Test Methods & Guidelines'' on the left side navigation menu.

C. Can I File an Objection or Hearing Request?

Under section 408(g) of FFDCA, 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2009–0018 in the subject line on the first page of your submission. All requests must be in writing, and must be mailed or delivered to the Hearing Clerk as required by 40 CFR part 178 on or before December 28, 2009.

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing that does not contain any CBI for inclusion in the public docket that is described in **ADDRESSES**. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit this copy, identified by docket ID number EPA–HQ–OPP–2009–0018, by one of the following methods:

- *Federal eRulemaking Portal*: *http://www.regulations.gov*. Follow the on-line instructions for submitting comments.