

Dated: October 5, 1999.

Carol M. Browner,
Administrator.

For the reasons set out in the preamble, title 40, chapter I of the Code of Federal Regulations is amended as follows:

PART 76—[AMENDED]

1. The authority citation for part 76 continues to read as follows:

Authority: 42 U.S.C. 7601 and 7651, *et seq.*

2. Section 76.6 is amended by removing from paragraph (a)(1) the words "after November 15, 1990" and the entire last sentence.

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP-300915; FRL-6380-4]

RIN 2070-AB78

Rhizobium Inoculants; 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 *Rhizobium* inoculants (pure strains of *Rhizobium spp.* bacteria [e.g. *Sinorhizobium*, *Bradyrhizobium* & *Rhizobium*]; hereinafter referred to as *Rhizobium* inoculants) when used as inert ingredients in pesticide formulations applied to all leguminous food commodities. This would not include strains expressing rhizobitoxine or strains deliberately altered to expand the range of antibiotic resistance. EPA is establishing this regulation on its own initiative. EPA submitted a proposed rule under the Federal Food, Drug, and Cosmetic Act, as amended by the Food Quality Protection Act of 1996 requesting an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of *Rhizobium* inoculants.

DATES: This regulation is effective October 15, 1999. Objections and requests for hearings, identified by docket control number OPP-300915, must be received by EPA on or before December 14, 1999.

ADDRESSES: Written objections and hearing requests may be submitted by

mail, in person, or by courier. Please follow the detailed instructions for each method as provided in Unit VIII. of the "SUPPLEMENTARY INFORMATION" section. To ensure proper receipt by EPA, your objections and hearing requests must identify docket control number OPP-300915 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Edward Allen, Biological Pesticides and Pollution Prevention Division (7511C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number and e-mail: 9th Floor, Crystal Mall 2 (CM #2), 1921 Jefferson Davis Hwy., Arlington, VA, (703) 308-8699; e-mail: allen.edward@epamail.epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does This Action Apply to Me?

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

Cat-egories	NAICS	Examples of Potentially Affected Entities
Industry	111 112 311 32532	Crop production Animal production Food manufacturing Pesticide manufacturing

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 the table could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether or not this action might apply to certain entities. If you have questions regarding the applicability of this action to a particular entity, consult the person listed in the "FOR FURTHER INFORMATION CONTACT" section.

B. How Can I Get Additional Information, Including Copies of This Document and Other Related Documents?

1. *Electronically.* You may obtain electronic copies of this document, and certain other related documents that might be available electronically, from the EPA Internet Home Page at <http://www.epa.gov/>. To access this document, on the Home Page select

"Laws and Regulations" and then look up the entry for this document under the "Federal Register--Environmental Documents." You can also go directly to the **Federal Register** listings at <http://www.epa.gov/fedrgstr/>.

2. *In person.* The Agency has established an official record for this action under docket control number OPP-300915. The official record consists of the documents specifically referenced in this action, and other information related to this action, including any information claimed as Confidential Business Information (CBI). This official record includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents. The public version of the official record does not include any information claimed as CBI. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period is available for inspection in the Public Information and Records Integrity Branch (PIRIB), Rm. 119, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305-5805.

II. Background and Statutory Findings

In the **Federal Register** of May 19, 1999 (64 FR 27223) (FRL-6074-3), EPA issued a proposed rule pursuant to section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a, as amended by the Food Quality Protection Act (FQPA) (Public Law 104-170). This rule was proposed by EPA on its own initiative. The rule included a summary of the petition prepared by EPA. There were no comments received in response to the proposed rule.

The petition requested that 40 CFR 180.1001(c) be amended by establishing an exemption from the requirement of a tolerance for residues of *Rhizobium* inoculants.

Section 408(b)(2)(A)(i) of the 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 tolerance is "safe." Section 408(b)(2)(A)(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(b)(2)(C) 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 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. The nature of the toxic effects caused by *Rhizobium* inoculants are discussed in this unit.

The inoculants that are the subject of this exemption are pure stains of bacteria in the genera *Rhizobium*, *Sinorhizobium* or *Bradyrhizobium*. *Rhizobium* species are found naturally in soil and are agriculturally important as they form a symbiosis with the roots of leguminous plants such as green beans, alfalfa and soybeans. This symbiosis is a controlled bacterial infection of the root cortical cells and results in root nodules formation. These root nodules biologically fix atmospheric nitrogen into a form readily useable by plants.

There are no reports in the literature of these *Rhizobium* bacteria causing disease or injury to man or other animals (USEPA/OPPT "Risk Assessment, Commercialization Request for P-92-403, *Sinorhizobium* (*Rhizobium*) meliloti RMBPC-2," May 1997). There are reports of *Rhizobium* bacteria producing a toxin (rhizobitoxine) that can affect the growth of legume plants nodulated with these strains. It is unlikely that any *Rhizobium* inoculants that are the subject of this exemption would be developed which express rhizobitoxine due to the adverse effects they have on the host plant. However, EPA feels it is appropriate to exclude *Rhizobium* strains intentionally developed to

express rhizobitoxine from this inert clearance because of possible additional human exposure to rhizobitoxine.

EPA believes that any intentional alteration in the range of antibiotic resistance of *Rhizobium* species should be considered for its impact on the proliferation of antibiotic resistance traits in clinically important pathogenic bacteria. It is common knowledge that all bacteria, including these *Rhizobium* species, have inherent resistance to certain antibiotics. It is also known that bacteria, especially clinical strains, have developed or acquired antibiotic resistance due to widespread use of antibiotics. The exclusion of *Rhizobium* strains with altered antibiotic resistance from this tolerance exemption discourages the use of antibiotic resistance genes, especially those genes with resistance to clinically important antibiotics. EPA therefore excludes any *Rhizobium* species with an intentionally expanded range of antibiotic resistance traits from this exemption.

IV. Aggregate Exposures

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, including drinking water from ground water or surface water and exposure through pesticide use in gardens, lawns, or buildings (residential and other indoor uses).

Consistent with section 408(c)(2)(B) of FFDCA, EPA has reviewed the available scientific data and other relevant information in support of the proposed action. EPA has sufficient data to assess the hazards of *Rhizobium* inoculants in or on all leguminous food commodities. EPA's assessment of the dietary exposures and risks associated with establishing these tolerances are as follows.

The data available in the public literature, EPA's Biotechnology Science Advisory Committee's reports on genetically engineered *Rhizobium* species and other relevant material have been evaluated. As part of the EPA policy statement on inert ingredients published in the **Federal Register** of April 22, 1987 (52 FR 13305), EPA set forth a list of studies which would generally be used to evaluate the risks posed by the presence of an inert ingredient in a pesticide formulation. However, where it can be determined that the inert ingredient will present minimal or no risk, EPA generally does not require some or all of the listed studies to rule on the proposed tolerance or exemption from the

requirement of a tolerance for an inert ingredient.

Dietary Exposure

For the purposes of assessing the potential dietary exposure under this exemption, EPA considered that under this exemption *Rhizobium* inoculants could be present in all raw and processed agricultural commodities and drinking water and that non-occupational, non-dietary exposure was possible. The intended use pattern as a seed or soil inoculant lessens the likelihood of contact with humans other than occupational exposure. The likelihood that a soil bacterium such as *Rhizobium* will enter drinking water in significant numbers is remote considering the natural filtration of the soil profile as water percolates to the water table and the fact that many water supplies are treated prior to distribution in municipal systems (USEPA/OPPT, Exposure Assessment for Commercialization of a Recombinant Strain of *Rhizobium* meliloti, RMBPC-2, December 1994). Even if exposure occurred, the lack of reports of disease in man or animals indicates there is no risk for these exposures. Therefore, EPA concluded that, based on this inoculant's use, there are no concerns for risks associated with any potential exposure scenarios that are reasonably foreseeable.

V. Cumulative Effects

Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance or tolerance exemption, the Agency consider "available information" concerning the cumulative effects of a particular chemical's residues and "other substances that have a common mechanism of toxicity." In the case of the *Rhizobium* inoculants, as limited, there is lack of toxicity to humans and other animal species as well as no information in the literature indicating a cumulative effect with any other compound. Therefore, a cumulative risk assessment is not necessary.

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

Based on the information in this preamble, EPA concludes that there is a reasonable certainty of no harm from aggregate exposure to *Rhizobium* inoculants residues. Accordingly, EPA finds that exempting *Rhizobium* inoculants from the requirement of a tolerance will be safe. EPA believes these bacteria present no dietary risk under any reasonably foreseeable circumstances.

FFDCA section 408 provides that EPA shall apply an additional tenfold margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the data base unless EPA concludes that a different margin of safety will be safe for infants and children. Margins of safety are incorporated into EPA risk assessments either directly through the use of margin of exposure analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans.

VII. Other Considerations

A. Endocrine Disruptors

The Agency has no information to suggest that *Rhizobium* inoculants will adversely affect the immune or endocrine systems. The Agency is not requiring information on the endocrine effects of this microbial 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.

B. International Tolerances

There are no CODEX tolerances or international tolerance exemptions for *Rhizobium* inoculants at this time.

VIII. Objections and Hearing Requests

Under section 408(g) of the FFDCA, as amended by the FQPA, 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. Although the procedures in those regulations require some modification to reflect the amendments made to the FFDCA by the FQPA of 1996, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) provides essentially the same process for persons to "object" to a regulation for an exemption from the requirement of a tolerance issued by EPA under new section 408(d), as was provided in the old FFDCA sections 408 and 409. However, the period for filing objections is now 60 days, rather than 30 days.

A. What Do I Need To Do To File an Objection or Request a Hearing?

You must file your objection or request a hearing on this regulation in accordance with the instructions provided in this unit and in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket control number OPP-300915 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 14, 1999.

1. *Filing the request.* Your objection must specify the specific provisions in the regulation that you object to, and the grounds for the objections (40 CFR 178.25). If a hearing is requested, the objections must include a statement of the factual issues(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). 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.

Mail your written request to: Office of the Hearing Clerk (1900), Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. You may also deliver your request to the Office of the Hearing Clerk in Rm. M3708, Waterside Mall, 401 M St., SW., Washington, DC 20460. The Office of the Hearing Clerk is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Office of the Hearing Clerk is (202) 260-4865.

2. *Tolerance fee payment.* If you file an objection or request a hearing, you must also pay the fee prescribed by 40 CFR 180.33(i) or request a waiver of that fee pursuant to 40 CFR 180.33(m). You must mail the fee to: EPA Headquarters Accounting Operations Branch, Office of Pesticide Programs, P.O. Box 360277M, Pittsburgh, PA 15251. Please identify the fee submission by labeling it "Tolerance Petition Fees."

EPA is authorized to waive any fee requirement "when in the judgement of the Administrator such a waiver or refund is equitable and not contrary to the purpose of this subsection." For additional information regarding the waiver of these fees, you may contact James Tompkins by phone at (703) 305-5697, by e-mail at tompkins.jim@epa.gov, or by mailing a request for information to Mr. Tompkins at Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460.

If you would like to request a waiver of the tolerance objection fees, you must mail your request for such a waiver to:

James Hollins, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460.

3. *Copies for the Docket.* In addition to filing an objection or hearing request with the Hearing Clerk as described in Unit VIII.A. of this preamble, you should also send a copy of your request to the PIRIB for its inclusion in the official record that is described in Unit I.B.2. of this preamble. Mail your copies, identified by docket number OPP-300915, 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 or by courier, bring a copy to the location of the PIRIB described in Unit I.B.2. of this preamble. You may also send an electronic copy of your request via e-mail to: opp-docket@epa.gov. Please use an ASCII file format and avoid 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 6.1/8.0 file format or ASCII file format. Do not include any CBI in your electronic copy. You may also submit an electronic copy of your request at many Federal Depository Libraries.

B. When Will the Agency Grant a Request for a Hearing?

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 issues(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32).

IX. Regulatory Assessment Requirements

This final rule establishes an exemption from the tolerance requirement under section 408(d) of the 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). 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) (Public Law 104-4). Nor does it require prior consultation with State, local, and tribal government officials as specified by Executive Order 12875, entitled *Enhancing the Intergovernmental Partnership* (58 FR 58093, October 28, 1993) and Executive Order 13084, entitled *Consultation and Coordination with Indian Tribal Governments* (63 FR 27655, May 19, 1998), or special consideration of environmental justice related issues under 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). The Agency has determined that this action will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 12612, entitled *Federalism* (52 FR 41685, October 30, 1987). This action does not alter the relationships or distribution of power

and responsibilities established by Congress in the preemption provisions of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 346a(b)(4). This action directly regulates growers, food processors, food handlers and food retailers, not States. 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). In addition, since tolerances and 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.

X. 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 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 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: September 29, 1999.

Marcia E. Mulkey,
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), 346(a) and 371.

2. In section 180.1001, the table in paragraph (c) is amended by adding alphabetically the following inert ingredient:

§ 180.1001 Exemptions from the requirement of a tolerance.

*	*	*	*	*
(c)	*	*	*	*

Inert ingredients	Limits	Uses
*	* * * * *	*
<i>Rhizobium</i> inoculants (e.g. <i>Sinorhizobium</i> , <i>Bradyrhizobium</i> & <i>Rhizobium</i>).	All leguminous food commodities
*	* * * * *	*

[FR Doc. 99-26862 Filed 10-14-99; 8:45 am]
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COMMITTEE FOR PURCHASE FROM PEOPLE WHO ARE BLIND OR SEVERELY DISABLED

41 CFR Parts 51-2 and 51-5

Miscellaneous Amendments to Committee Regulations

AGENCY: Committee for Purchase From People Who Are Blind or Severely Disabled.

ACTION: Final rule.

SUMMARY: The Committee is changing its pricing and shipping regulations to

make them consistent with new Committee pricing policies reflecting a preference for negotiated rather than formula-based fair market prices.

EFFECTIVE DATE: November 15, 1999.

ADDRESSES: Committee for Purchase From People Who Are Blind or Severely Disabled, Crystal Gateway 3, Suite 310, 1215 Jefferson Davis Highway, Arlington, Virginia 22202-4302.

FOR FURTHER INFORMATION CONTACT: G. John Heyer (703) 603-0665. Copies of this notice will be made available on request in computer diskette format.

SUPPLEMENTARY INFORMATION: The Committee is revising 41 CFR 51-2.7, the Committee's general fair market pricing regulation, to reflect the

preference for negotiated prices set forth in the Committee's recently-adopted pricing policies and the methods of price-setting established by those policies. Paragraph (a) of 41 CFR 51-5.5 is revised to emphasize the statutory nature of the Committee's price-setting authority. This revision is intended to emphasize the exemption of the Committee's prices from a statutory requirement that cost or pricing data be submitted to contracting activities before a price can be negotiated and recommended to the Committee. Paragraph (d)(2) of 41 CFR 51-5.5 is revised to change the minimum time for a contracting activity to submit required wage determination paperwork to the appropriate central nonprofit agency