

outline of the topics to be discussed and the time to be devoted to each topic (a signed original and eight (8) copies) by August 23, 1999.

A period of 10 minutes will be allotted to each person for making comments.

An agenda showing the scheduling of the speakers will be prepared after the deadline for receiving outlines has passed. Copies of the agenda will be available free of charge at the hearing.

Drafting Information

The principal author of these regulations is Kenneth Christman, Office of Assistant Chief Counsel (Financial Institutions and Products). However, other personnel from the IRS and Treasury Department participated in their development.

List of Subjects in 26 CFR Part 1

Income taxes, Reporting and recordkeeping requirements.

Proposed Amendments to the Regulations

Accordingly, 26 CFR part 1 is proposed to be amended as follows:

PART 1—INCOME TAXES

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

Authority: 26 U.S.C. 7805 * * *

§ 1.6049-7 [Amended]

Par. 2. In § 1.6049-7, paragraph (g) is removed.

Robert E. Wenzel,

Deputy Commissioner of Internal Revenue.
[FR Doc. 99-12525 Filed 5-18-99; 8:45 am]

BILLING CODE 4830-01-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[WY-001-0002b and WY-001-0003b; FRL-6344-3]

Approval and Promulgation of State Implementation Plans; Wyoming

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is proposing to approve two revisions to the Wyoming State Implementation Plan (SIP) regarding particulate matter. The SIP revisions include clarification and revisions to the particulate matter control requirements in section 25 of the Wyoming Air Quality Standards and Regulations

(WAQSR) for the FMC Corporation in the Trona Industrial Area of Wyoming, and the addition of guidelines for best available control technology (BACT) in the minor source construction permitting requirements of section 21 of the WAQSR for large mining operations.

We are also revising 40 CFR 52.2620 to list subsections 21(a)(iv), 24(a)(xix), 24(b)(iv), and 24(b)(xii)(H) of the WAQSR in the "Incorporation by reference" section. We approved these subsections in previous SIP approvals (on November 29, 1994 and on November 3, 1995, respectively) but we inadvertently neglected to identify those subsections as incorporated into the SIP in the CFR.

In the Rules and Regulations section of this **Federal Register**, we approve the State's submittals as a direct final rule without prior proposal because we view this as a noncontroversial action and anticipate no adverse comments. A detailed rationale for the approval is set forth in the preamble of the direct final rule. If no adverse comments are submitted, we will not take further action on this proposed rule. If we receive adverse comments, we will publish a timely withdrawal of the direct final rule in the **Federal Register** and it will not take effect. We will address all public comments in a subsequent final rule based on this proposed rule. We will not institute a second comment period on this action. Any parties interested in commenting must do so at this time.

DATES: Comments must be received in writing on or before June 18, 1999.

ADDRESSES: You should mail your written comments to Richard R. Long, Director, Air and Radiation Program, Mailcode 8P-AR, Environmental Protection Agency (EPA), Region VIII, 999 18th Street, Suite 500, Denver, Colorado, 80202. Copies of the documents relative to this action are available for inspection during normal business hours at the Air and Radiation Program, Environmental Protection Agency, Region VIII, 999 18th Street, Suite 500, Denver, Colorado 80202-2466. Copies of the State documents relevant to this action are available for public inspection at the Department of Environmental Quality, 122 West 25th Street, Cheyenne, Wyoming 82002.

FOR FURTHER INFORMATION CONTACT: Vicki Stamper, EPA Region VIII, (303) 312-6445.

SUPPLEMENTARY INFORMATION: See the information provided in the Direct Final action of the same title which is located in the Rules and Regulations section of this **Federal Register**.

Authority: 42 U.S.C. 7401 *et seq.*

Dated: May 7, 1999.

Jack W. McGraw,

Acting Regional Administrator, Region VIII.
[FR Doc. 99-12583 Filed 5-18-99; 8:45 am]

BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP-300838; FRL-6074-3]

RIN 2070-AC18

Rhizobium inoculants; Proposed Exemption from the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA proposes to establish an exemption from the requirement of tolerances for residues of *Rhizobium* inoculants (pure strains of *Rhizobium spp.* bacteria eg. *Sinorhizobium*, *Bradyrhizobium* & *Rhizobium*) 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 proposing this regulation on its own initiative.

DATES: Written comments should be submitted to EPA on or before July 19, 1999.

ADDRESSES: By mail, submit written comments 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, deliver comments to: Rm. 119, CM #2, 1921 Jefferson Davis Highway, Arlington, VA.

Comments and data may also be submitted electronically to: opp-docket@epamail.epa.gov. Follow the instructions under Unit VIII of this document. No Confidential Business Information (CBI) should be submitted through e-mail.

Information submitted as a comment concerning this document 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 comment that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential will be included in the public docket by

EPA without prior notice. The public docket is available for public inspection in Rm. 119 at the Virginia address given above, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays.

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, 1921, Jefferson Davis Hwy., Arlington, VA, (703) 308-8699; e-mail: allen.edward@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: EPA proposes that an exemption from the requirement of a tolerance be established for residues of *Rhizobium* inoculants when used as inert ingredients in pesticide formulations applied to all leguminous food commodities. EPA is proposing this regulation on its own initiative.

I. Electronic Availability

Electronic copies of this document and other available support documents may be obtained on the Internet from the EPA Home Page at the "**Federal Register**—Environmental Documents" entry for this document (<http://www.epa.gov/fedrgstr/EPA-PEST/1999/>).

II. Background and Statutory Authority

New section 408(c)(2)(A)(i) allows EPA to establish an exemption from the requirement of a tolerance for a pesticide chemical residue on food only if EPA determines that the exemption is "safe". Section 408(c)(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, 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 an exemption from the requirement of 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" and specifies factors EPA is to consider in establishing an exemption.

III. Inert Ingredient Definition

Inert ingredients are all ingredients that are not active ingredients as defined

in 40 CFR 153.125 and include, but are not limited to, the following types of ingredients (except when they have a pesticidal efficacy of their own): solvents such as alcohols and hydrocarbons; surfactants such as polyoxyethylene polymers and fatty acids; carriers such as clay and diatomaceous earth; thickeners such as carrageenan and modified cellulose; wetting, spreading, and dispersing agents; propellants in aerosol dispensers; microencapsulating agents; and emulsifiers. The term "inert" is not intended to imply nontoxicity or lack of chemical activity. Generally, EPA has exempted inert ingredients from the requirement of a tolerance based on the low toxicity of the individual inert ingredients.

IV. Risk Assessment and Statutory Findings

EPA establishes exemptions from the requirement of a tolerance only in those cases where it can be clearly demonstrated that the risks from aggregate exposure to pesticide chemical residues under reasonably foreseeable circumstances will pose no appreciable risks to human health. In order to determine the risks from aggregate exposure to pesticide inert ingredients, EPA considers the toxicity of the inert ingredient in conjunction with possible exposure to residues of the inert ingredient in food, drinking water, and other non-occupational exposures. If EPA is able to determine that a finite tolerance is not necessary to ensure that there is a reasonable certainty that no harm will result from aggregate exposure to the inert ingredient, an exemption from the requirement of a tolerance may be established.

V. Aggregate Risk Assessment and Determination of Safety

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.

A. Toxicological Profile

The inoculants that are the subject of this exemption are pure strains of bacteria in the genera *Rhizobium*, *Sinorhizobium* or *Bradyrhizobium* (hereafter referred to as *Rhizobium*). *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 proposes to exclude any *Rhizobium* species with an intentionally expanded range of antibiotic resistance traits from this exemption.

B. Exposures and Risks

1. *From food and feed uses, drinking water, and non-dietary exposures.* 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.

2. *Cumulative exposure to substances with a common mechanism of toxicity.* 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.

C. Aggregate Risks and Determination of Safety for U.S. Population

Based on this bacteria's toxicological profile, and its established use in common agricultural practices, EPA concludes that there is a reasonable

certainty that no harm to the U.S. population will result from aggregate exposure to *Rhizobium* inoculants. EPA believes these bacteria present no dietary risk under any reasonably foreseeable circumstances.

D. Aggregate Risks and Determination of Safety for Infants and Children

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 pre- 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.

Due to the low toxicity of these bacteria, EPA has not used a safety factor analysis in assessing a risk. For the same reasons the additional safety factor is unnecessary.

VI. Other Considerations

EPA proposes to establish an exemption from the requirement of a tolerance without any numerical limitation; therefore, EPA has concluded that analytical methods are not required for enforcement purposes *Rhizobium* inoculants. There are no Codex tolerances or international tolerance exemptions for *Rhizobium* inoculants.

VII. Conclusion

Based on the information and data considered, EPA proposes that an exemption from the requirement of a tolerance be established as set forth in this document.

VIII. Public Record and Electronic Submissions

The official record for this rulemaking, as well as the public version, has been established for this rulemaking under docket control number [OPP-300838] (including comments and data submitted electronically as described below). A public version of this record, including printed, paper versions of electronic comments, which does not include any information claimed as CBI, is available for inspection from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The official rulemaking record is located at the Virginia address in "ADDRESSES" at the beginning of this document.

Electronic comments can 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. Comment and data will also be accepted on disks in Wordperfect 5.1/6.1 or ASCII file format. All comments and data in electronic form must be identified by the docket control number [OPP-300838]. Electronic comments on this proposed rule may be filed online at many Federal Depository Libraries.

IX. Regulatory Assessment Requirements

A. Certain Acts and Executive Orders

This action proposes to establish an exemption from the tolerance requirement under FFDCA section 408(e). 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). In addition, this proposed 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 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).

In addition, under the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 et seq.), 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), and was provided to the Chief Counsel for Advocacy of the Small Business Administration.

B. Executive Order 12875

Under Executive Order 12875, entitled *Enhancing the Intergovernmental Partnership* (58 FR 58093, October 28, 1993), EPA may not issue a regulation that is not required by statute and that creates a mandate upon a State, local, or tribal government, unless the Federal government provides

the funds necessary to pay the direct compliance costs incurred by those governments. If the mandate is unfunded, EPA must provide to OMB a description of the extent of EPA's prior consultation with representatives of affected State, local, and tribal governments, the nature of their concerns, copies of any written communications from the governments, and a statement supporting the need to issue the regulation. In addition, Executive Order 12875 requires EPA to develop an effective process permitting elected officials and other representatives of State, local, and tribal governments "to provide meaningful and timely input in the development of regulatory proposals containing significant unfunded mandates."

Today's proposed rule does not create an unfunded Federal mandate on State, local, or tribal governments. The proposed rule does not impose any enforceable duties on these entities. Accordingly, the requirements of section 1(a) of Executive Order 12875 do not apply to this proposed rule.

C. Executive Order 13084

Under Executive Order 13084, entitled *Consultation and Coordination with Indian Tribal Governments* (63 FR 27655, May 19, 1998), EPA may not

issue a regulation that is not required by statute, that significantly or uniquely affects the communities of Indian tribal governments, and that imposes substantial direct compliance costs on those communities, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by the tribal governments. If the mandate is unfunded, EPA must provide OMB, in a separately identified section of the preamble to the proposed rule, a description of the extent of EPA's prior consultation with representatives of affected tribal governments, a summary of the nature of their concerns, and a statement supporting the need to issue the regulation. In addition, Executive Order 13084 requires EPA to develop an effective process permitting elected officials and other representatives of Indian tribal governments "to provide meaningful and timely input in the development of regulatory policies on matters that significantly or uniquely affect their communities."

Today's proposed rule does not significantly or uniquely affect the communities of Indian tribal governments. This action does not involve or impose any requirements that affect Indian tribes. Accordingly, the requirements of section 3(b) of

Executive Order 13084 do not apply to this proposed rule.

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural Commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: May 11, 1999.

Janet L. Andersen,

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

Therefore, it is proposed that 40 CFR chapter I be amended as follows:

PART 180—[AMENDED]

1. The authority citation for part 180 is revised to read as follows:

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

2. In § 180.1001 the tables in paragraphs (c) and (e) are amended by adding alphabetically the following inert ingredient:

§ 180.1001 Rhizobium inoculants (eg. Sinorhizobium, Bradyrhizobium & Rhizobium); Exemption from the requirements of a tolerance.

* * * * *

(c) * * *

Inert ingredient	Limit	Uses
Rhizobium inoculants (eg. <i>Sinorhizobium</i> , <i>Bradyrhizobium</i> & <i>Rhizobium</i>)	* * *	All leguminous food commodities

* * * * *

(e) * * *

Inert ingredient	Limit	Uses
Rhizobium inoculants (eg. <i>Sinorhizobium</i> , <i>Bradyrhizobium</i> & <i>Rhizobium</i>)	* * *	All leguminous food commodities