rulemaking on the proposal (CGD08–97–007).

Dated: February 18, 1998.

T.W. Josiah,

Rear Admiral, U.S. Coast Guard, Commander, Eighth Coast Guard District.

[FR Doc. 98–6006 Filed 3–9–98; 8:45 am]

BILLING CODE 4910–14–M

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[NH–9–1–5823b; A–1–FRL–5969–5]

Approval and Promulgation of Air Quality Implementation Plans; New Hampshire; Revised Regulations and Source-Specific Reasonably Available Control Technology Plans Controlling Volatile Organic Compound Emissions and Emission Statement Requirements

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is proposing to approve State Implementation Plan (SIP) revisions submitted by the State of New Hampshire. These revisions consist of the State's volatile organic compound (VOC) regulations in Chapter Env–A 1204 (except 1204.06), certain testing and monitoring requirements in Chapter Env–A 800, and recordkeeping and reporting requirements in Chapter Env–A 900, all of which require the implementation of reasonably available control technology (RACT) for certain sources of volatile organic compounds (VOCs), as required by the Clean Air Act. These revisions also consist of source specific VOC RACT determinations for L.W. Packard and Company, Textile Tapes Corporation, and Kalwall Corporation. In the Final Rules Section of this **Federal Register**, EPA is approving the State's SIP revisions as a direct final rule without prior proposal because the Agency views these amendments as a noncontroversial revision and anticipates no adverse comments. A detailed rationale for the approval is set forth in the direct final rule. If no adverse comments are received in response to that direct final rule, no further activity is contemplated in relation to this proposed rule. If EPA receives relevant adverse comments, the direct final rule will not take effect and all public comments received will be addressed in a subsequent final rule based on this proposed rule. EPA will not institute a second comment period on this proposal. Any parties interested in commenting on this proposal should do so at this time.

DATES: Comments must be received on or before April 9, 1998.

ADDRESSES: Comments may be mailed to Susan Studlien, Deputy Director, Office of Ecosystem Protection (mail code CAA), U.S. Environmental Protection Agency, Region I, JFK Federal Bldg., Boston, MA 02203. Copies of the State submittal and EPA's technical support document are available for public inspection during normal business hours, by appointment at the Office of Ecosystem Protection, U.S. Environmental Protection Agency, Region I, One Congress Street, 11th floor, Boston, MA and Air Resources Division, Department of Environmental Services, 64 North Main Street, Caller Box 2033, Concord, NH 03302–2033.

FOR FURTHER INFORMATION CONTACT: Jeanne Cosgrove, (617) 565–9451.

SUPPLEMENTARY INFORMATION: For additional information, see the direct final rule which is located in the Rules Section of this **Federal Register**.

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

Dated: February 9, 1998.

John P. DeVillars,

Regional Administrator, Region I.

[FR Doc. 98–5315 Filed 3–9–98; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 62

[AR–2–2–5972b; FRL–5954–3]

Approval and Promulgation of State Plans for Designated Facilities and Pollutants Arkansas; Revisions of Regulations

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: This action proposes to approve a recodification and revisions of the regulations for the Arkansas Plan for Designated Facilities and Pollutants (111(d) Plan) under section 111(d) of the Federal Clean Air Act. In the Rules and Regulations section of this **Federal Register**, EPA is approving this revision to the Arkansas 111(d) Plan as a direct final rule without prior proposal because the Agency views this as a noncontroversial revision and anticipates no adverse comments. The rationale for the approval is set forth in the direct final rule. If no adverse comments are received in response to this proposed rule, no further activity is contemplated in relation to this rule. If EPA receives adverse comments, the direct final rule will be withdrawn, and all public comments received during the 30-day comment period set forth below will be addressed in a subsequent final rule based on this proposed rule. Any parties interested in commenting on this action should do so at this time.

DATES: Comments on this proposed rule must be received in writing by April 9, 1998.

ADDRESSES: Written comments on this action should be addressed to Mr. Thomas H. Diggs, Chief, Planning Section, at the EPA Region 6 office listed below. Copies of documents relevant to this action are available for public inspection during normal business hours at the following locations. Anyone wanting to examine these documents should make an appointment with the appropriate office at least two working days in advance.

Environmental Protection Agency, Region 6, Air Planning Section (6PD–L), 1445 Ross Avenue, Dallas, Texas 75202–2733.

Arkansas Department of Pollution Control and Ecology, Division of Air Pollution Control, 8001 National Drive, P.O. Box 8913, Little Rock, Arkansas 72219–8913.

FOR FURTHER INFORMATION CONTACT: Bill Deese of the Air Planning Section (6PD–L) at (214) 665–7253 of the EPA Region 6 Office and at the address above.

SUPPLEMENTARY INFORMATION: For additional information, see the direct final rule which is published in the Rules and Regulations section of this **Federal Register**.

Authority: 42 U.S.C. 7401–7671q.

Dated: January 15, 1998.

Lynda F. Carroll,

Acting Regional Administrator, Region 6.

[FR Doc. 98–5849 Filed 3–9–98; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 721

[OPPTS–50630; FRL–5765–6]

RIN 2070–AB27

Sinorhizobium Meliloti Strain RMBPC–2; Proposed Significant New Use Rule

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is proposing a significant new use rule (SNUR) under section 5(a)(2) of the Toxic Substances Control Act (TSCA) for the microorganism

described as *Sinorhizobium meliloti* strain RMBPC–2 which is the subject of premanufacture notice (PMN) P–92–403. This proposal would require certain persons who intend to manufacture, import, or process this microorganism for a significant new use to notify EPA at least 90 days before commencing any manufacturing, importing, or processing activities for a use designated by this SNUR as a significant new use. The required notice would provide EPA with the opportunity to evaluate the intended use and, if necessary, to prohibit or limit that activity before it can occur.

DATES: Written comments must be received by EPA by April 9, 1998.

ADDRESSES: Each comment must bear the docket control number OPPTS–50630. All comments should be sent in triplicate to: OPPT Document Control Officer (7407), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 401 M St., SW., Rm. G–099, East Tower, Washington, DC 20460.

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

All comments which contain information claimed as CBI must be clearly marked as such. Three sanitized copies of any comments containing information claimed as CBI must also be submitted and will be placed in the public record for this rulemaking. Persons submitting information on any portion of which they believe is entitled to treatment as CBI by EPA must assert a business confidentiality claim in accordance with 40 CFR 2.203(b) for each portion. This claim must be made at the time that the information is submitted to EPA . If a submitter does not assert a confidentiality claim at the time of submission, EPA will consider this as a waiver of any confidentiality claim, and the information may be made available to the public by EPA without further notice to the submitter.

FOR FURTHER INFORMATION CONTACT: Susan B. Hazen, Director, Environmental Assistance Division (7408), Office of Pollution Prevention and Toxics, Environmental Protection Agency, Rm. E–543A, 401 M St., SW., Washington, DC 20460, telephone: (202) 554–1404, TDD: (202) 554–0551; e-mail: TSCA-Hotline@epamail.epa.gov.

SUPPLEMENTARY INFORMATION:

Electronic Availability: Electronic copies of this document are available from the EPA Home Page at the **Federal Register**-Environmental Documents entry for this document under ''Laws and Regulations'' (http://www.epa.gov/fedrgstr/).

This proposed SNUR would require persons to notify EPA at least 90 days before commencing the manufacture, import, or processing of the microorganism identified in PMN P–92–403 for the significant new uses designated herein. The required notice would provide EPA with information with which to evaluate an intended use and associated activities.

I. Authority

Section 5(a)(2) of TSCA (15 U.S.C. 2604(a)(2)) authorizes EPA to determine that a use of a chemical substance is a ''significant new use''. EPA must make this determination by rule after considering all relevant factors, including those listed in section 5(a)(2) of TSCA. Once EPA determines that a use of a chemical substance is a significant new use, section 5(a)(1)(B) of TSCA requires persons to submit a notice to EPA at least 90 days before they manufacture, import, or process the chemical substance for that use. Section 26(c) of TSCA authorizes EPA to take action under section 5(a)(2) of TSCA with respect to a category of chemical substances. EPA interprets the definition of ''chemical substance'' under TSCA to include intergeneric microorganisms as stated in the **Federal Register** of April 11, 1997 (62 FR 17913) (FRL–5577–2), June 26, 1986 (51 FR 23324), and December 31, 1984 (49 FR 50886).

Persons subject to this SNUR would comply with the same notice requirements and EPA regulatory procedures as submitters of premanufacture notices under section 5(a)(1) of TSCA. In particular, these requirements include the information submission requirements of section 5(b) and (d)(1), the exemptions authorized by section 5(h)(1), (h)(2), (h)(3), and (h)(5), and the regulations at 40 CFR part 720. Once EPA receives a SNUR notice, EPA may take regulatory action under section 5(e), 5(f), 6, or 7 to control the activities for which it has received a SNUR notice. If EPA does not take action, section 5(g) of TSCA requires EPA to explain in the **Federal Register** its reasons for not taking action.

Persons who intend to export a substance identified in a proposed or final SNUR are subject to the export notification provisions of TSCA section 12(b). The regulations that interpret TSCA section 12(b) appear at 40 CFR part 707.

II. Applicability of General Provisions

General regulatory provisions applicable to SNURs are codified at 40 CFR part 721, subpart A. On July 27, 1988 (53 FR 28354) and July 27, 1989 (54 FR 31298), EPA promulgated amendments to the general provisions which apply to this SNUR. In the **Federal Register** of August 17, 1988 (53 FR 31248), EPA promulgated a ''User Fee Rule'' (40 CFR part 700) under the authority of TSCA section 26(b). Provisions requiring persons submitting SNUR notices to submit certain fees to EPA are discussed in detail in that **Federal Register** document. Interested persons should refer to these documents for further information.

III. Background

EPA interprets the definition of ''chemical substance'' under TSCA to include intergeneric microorganisms. In the **Federal Register** of December 31, 1984 (49 FR 50880), EPA published a notice document entitled ''Proposed Policy Regarding Certain Microbial Products'', where EPA discussed how reporting requirements of section 5 of TSCA could be applied to microorganisms. This document was published as part of another notice document entitled ''Proposal for a Coordinated Framework for Regulation of Biotechnology'', which was published in the **Federal Register** of December 31, 1984 (49 FR 50856) by the Office of Science and Technology Policy (OSTP). In the **Federal Register** of June 26, 1986 (51 FR 23313), EPA published a notice document entitled ''Statement of Policy; Microbial Products Subject to the Federal Insecticide, Fungicide, and Rodenticide Act and the Toxic Substances Control Act'', in which EPA stated that intergeneric microorganisms would be considered ''new'' for purposes of section 5 of TSCA. This document was published as part of another notice document entitled ''Coordinated Framework for Regulation of Biotechnology'', which was published in the **Federal Register** of June 26, 1986 (51 FR 23302) by OSTP. In the **Federal Register** of April 11, 1997 (62 FR 17910) (FRL–5577–2) EPA published a final rule entitled ''Microbial Products of Biotechnology; Final Regulation Under the Toxic Substances Control Act'', in which EPA reiterated that TSCA applies to intergeneric microorganisms.

In 1992, Research Seeds, Inc. (the company), located in St. Joseph, MO, submitted several PMNs to EPA pursuant to section 5(a) of TSCA for various intergeneric strains of *Rhizobium meliloti*. *Rhizobium meliloti*

has been renamed as *Sinorhizobium meliloti*. The company conducted several small and large scale field trials with various of these strains, including the microorganism which is the subject of PMN P–92–403. These field trials are subject to a consent order issued by EPA pursuant to its authority under section 5(e) of TSCA. The consent order, as amended, limited use by the company of the intergeneric strains of *Rhizobium meliloti*, including P–92–403, to specific sites and only for research and development (R&D) purposes. The consent order (''the order'') went into effect on April 28, 1992, and was subsequently modified on June 21, 1993, November 22, 1993, April 4, 1994, and May 4, 1995 to permit additional field trials at different sites.

On May 26, 1994, Research Seeds, Inc. submitted a request to commercialize *Rhizobium meliloti* strain RMBPC–2 (PMN P–92–403). On January 4, 1995, a subcommittee of the Biotechnology Science Advisory Committee (BSAC) met to review the Agency's draft risk assessment. The BSAC submitted its report on March 6, 1995. The Agency's risk assessment, the report of the BSAC Subcommittee, and other materials relevant to EPA's review are included in the public docket for this matter (see Unit VII. of this preamble). The Agency's risk assessment and the recommendations of the BSAC report are summarized in Unit III. of this preamble.

On September 16, 1997, EPA modified the order for P–92–403 allowing limited manufacture, import, and processing for commercial purposes. The order requires that the company submit a significant new use notice (SNUN) to EPA at least 90 days before manufacture, processing, or importation of P–92–403 will exceed a production volume of 500,000 pounds (lbs) during any consecutive 12-month period.

Because the order applies only to the company, once the substance is on the TSCA Chemical Substances Inventory (maintained by EPA pursuant to section 8(a) of TSCA), it is no longer a ''new'' chemical substance subject to PMN requirements. Therefore, any other manufacturer, importer, or processor may commercialize the microorganism without restriction unless EPA takes independent action to regulate the substance. The purpose of this SNUR is to extend the requirements of the TSCA section 5(e) consent order to all manufacturers and importers of this particular microorganism.

If the SNUR were to allow several manufacturers or importers to manufacture or import up to 500,000 lbs of the microorganism during any consecutive 12-month period without further notification, much more than 500,000 lbs of the microorganism could be produced in a single year. Under the terms of such a SNUR the potential would exist for the microorganism to penetrate the entire market of inoculant on alfalfa seed without any further notification to EPA. Before allowing any potential environmental releases of the microorganism above 500,000 lbs in a 12-month period, EPA wants to evaluate further the need for any additional testing of *Sinorhizobium meliloti* strain RMBPC–2 (see Unit III.D.2. of this preamble). This was the basis for allowing only limited commercial production under the terms of a TSCA section 5(e) consent order and proposing this rule.

To ensure that no potential environmental releases of the microorganism above 500,000 lbs in a 12-month period occur before EPA receives 90-day notification, EPA is proposing the SNUR as follows: Any manufacturer or importer who has not previously submitted a premanufacture notice or significant new use notice for this microorganism must submit a significant new use notice 90 days before engaging in any commercial activity, while any manufacturer or importer who has previously submitted a premanufacture notice or a significant new use notice for this microorganism must submit a significant new use notice before manufacturing, importing, or processing greater than a maximum production volume of 500,000 lbs in any consecutive 12-month period. If and when EPA receives a significant new use notice for this microorganism, it will evaluate the need for further environmental testing based on the information in the notice and all other available relevant information.

A. Identity of the Microorganism

Rhizobium meliloti was reclassified in 1994 as *Sinorhizobium meliloti* (De Lajudie et al., 1994, see Unit IX.1. of this preamble). The microorganism which is the subject of the consent order modification is now identified as *Sinorhizobium meliloti* strain RMBPC–2. Because only the taxonomic designation of the microorganism has changed, and not the microorganism itself, *Sinorhizobium meliloti* strain RMBPC–2, is identical to that which was the subject of PMN P–92–403, and continues to be covered by the consent order.

B. Use

The company intends to use the microorganism as an inoculant on alfalfa seed. The microorganism will initially be sold in a clay-based carrier directly to farmers for use in coating their own alfalfa seed prior to planting, and subsequently, if commercially successful, would be sold to seed processors for use in coating alfalfa seed prior to sale of the seed to farmers. The company plans to sell strain RMBPC–2 as an alfalfa seed inoculant in all states, as well as for export. According to the commercialization request submitted by the company to EPA, the company initially plans to produce no more than 27,000 lbs of inoculant packaged in individual 8 ounce (oz) bags during the first year of commercial manufacture. This would be sufficient to treat approximately 3.2 million lbs of alfalfa seed or approximately 178,000 acres. The bags would be sold directly to farmers who would treat their own alfalfa seed prior to planting. During the second year of commercial manufacture, the company plans to produce 54,000 lbs of inoculant packaged in individual 8 oz bags. This would be sufficient to treat approximately 6.4 million lbs of seed or approximately 355,000 acres. The company projects that their production of the inoculant could reach 500,000 lbs by the third year of commercialization.

The following is a summary of the determinations reached on each major issue addressed in development of the risk assessment for this microorganism. A complete discussion of each component of the risk assessment is included in the final document entitled ''Risk Assessment: Commercialization Request for P–92–403 *Sinorhizobium* (*Rhizobium*) *meliloti* strain RMBPC–2'', which is included in the public docket OPPTS–51786 for this matter.

C. Human Health Issues

Concerns about human health effects associated with strain RMBPC–2 relate to three issues: Concern about inherent pathogenicity or toxicity of naturally-occurring strains of *Sinorhizobium meliloti*, the ability of the introduced DNA to impart pathogenic properties to *Sinorhizobium meliloti* strain RMBPC–2, and the ability of the introduced antibiotic resistance genes to transfer to other microorganisms which are human pathogens.

The BSAC subcommittee stated that ''there is no likelihood that naturally-occurring members of the species *Rhizobium meliloti* could colonize humans or have human pathogenic and/or toxic effects''. Similarly, the subcommittee concluded that there was no likelihood that the introduced gene fragments ''could change the behavior of RMBPC–2 with regard to human

pathogenicity or toxicity'' (Biotechnology Science Advisory Committee, page 9, 1995, see Unit IX.2. of this preamble). The conclusions of the BSAC subcommittee and of the risk assessment with respect to each of these issues are summarized in Unit III.C.1., C.2., and C.3. of this preamble.

1. *Inherent pathogenicity of Sinorhizobium meliloti.* Naturally occurring strains of *Sinorhizobium meliloti* have been in use in the United States as commercial seed inoculants for over 100 years. A thorough search for references to pathogenic effects of these microorganisms has not disclosed any reports of adverse human health effects.

2. *Pathogenic properties of Sinorhizobium meliloti.* The genetic material introduced into the host strain to produce strain RMBPC–2 is very well-characterized and contains no sequences encoding for toxin production or for traits associated with an ability to colonize humans or cause mammalian pathogenicity.

3. *Transfer of antibiotic resistance traits to human pathogens.* There is a very low probability of transfer of the aadA gene, which encodes for resistance to the antibiotics streptomycin and spectinomycin, to other microorganisms which are potential human pathogens. This is due to two reasons: The aadA gene fragment is stably inserted into the second megaplasmid of *Sinorhizobium meliloti.* Megaplasmids are such large genetic segments that they are often referred to as ''mini-chromosomes''. As such, their ability to transfer into other microorganisms, even to other closely related species, is very limited, and *Sinorhizobium meliloti* does not share habitats with other microorganisms which are potential human pathogens. As a result, the physical proximity necessary for gene transfer is not present.

The BSAC subcommittee also concluded that RMBPC–2 satisfied the criteria developed in 1989 by the BSAC subcommittee on antibiotic resistance, which had identified criteria for assessing the conditions under which intergeneric microorganisms containing antibiotic resistance markers might be approved for commercial use in the environment. The criteria enumerated in 1989 were that the antibiotic resistance markers should be located on the chromosome and be non-transposable and that the antibiotics involved should have limited or no clinical use. The BSAC subcommittee concluded that in the case of strain RMBPC–2 these criteria were satisfied because of the low probability of transfer of the *Sinorhizobium meliloti* megaplasmid and because clinical use of both antibiotics was limited and not likely to increase in the future.

The BSAC subcommittee also noted the very high levels of resistance to streptomycin and spectinomycin already present in microbial populations in the environment. The subcommittee noted that other microorganisms are much more likely sources of resistance genes than *Sinorhizobium meliloti* strain RMBPC–2.

D. Environmental Effects Issues

Environmental effects issues are grouped into four major categories: Survival and dissemination of the microorganisms in the environment, competitiveness of the microorganisms, effects on yield, and ability to nodulate non-target plants. Each of these issues is addressed in Unit III.D.1., D.2., D.3., and D.4. of this preamble.

1. *Survival and dissemination of RMBPC–2 in the environment. Sinorhizobium meliloti* strain RMBPC–2 is expected to survive in the soil once introduced into the environment. Literature studies show that strains of *Sinorhizobium meliloti* can persist in low numbers in the soil for many years and that populations can be stimulated by the presence of host plants. Data on other intergeneric strains of *Sinorhizobium meliloti* closely related to strain RMBPC–2 show that the microorganisms can persist in the soil at detectable levels in the absence of plant roots, sometimes for up to 1 year or more after termination of the field trial.

EPA required collection of monitoring data during the initial field trials of intergeneric strains of *Sinorhizobium meliloti* which are closely related to strain RMBPC–2. Monitoring data on RMBPC–2 was not specifically collected because this strain was not field tested until later in the overall field testing program. These data show that there is very little movement of intergeneric strains of this microorganism in the soil. Vertical movement of the microorganism was associated with growth of the alfalfa root system. Population densities of the microorganism decreased with increasing soil depth. Thus, dissemination of these microorganisms is limited to the rhizosphere of the associated host alfalfa plants.

2. *Competitiveness of RMBPC–2.* Analysis of the data collected on the competitiveness of strain RMBPC–2, the ability of the strain to nodulate the roots of alfalfa plants, has shown this strain to be comparable to other strains derived from the host strain *Sinorhizobium meliloti* strain RMBPC–2. The genes affecting the nodulation capability of *Sinorhizobium meliloti* were not modified in developing strain RMBPC–2. The BSAC stated that ''[t]he nodule occupancy data indicate that RMBPC–2 is similar in competitiveness to other PC-based strains, indicating that the introduced genes in RMBPC–2 had no major effects on nodulation competitiveness'' (Biotechnology Science Advisory Committee, page 8, 1995, see Unit IX.2. of this preamble). Thus, there is no expected change in either the competitiveness of the microorganism or in its host range.

The BSAC subcommittee were of divided opinion concerning the need for additional testing on the persistence, dissemination, competitiveness, and genetic stability of strain RMBPC–2. In an appendix to the subcommittee's final report, it was suggested that data specific to RMBPC–2 be accumulated by reseeding test plots in which the microorganism had been previously used (Biotechnology Science Advisory Committee, pages 15 and 18–19, 1995, see Unit IX.2. of this preamble). This was recommended because ''little or no data were presented on the behavior of RMBPC–2 itself'' with respect to these characteristics (Biotechnology Science Advisory Committe, page 15, 1995, see Unit IX.2. of this preamble).

EPA states in its risk assessment that although data specific to RMBPC–2 pertaining to some of its environmental characteristics were not collected, all genetic permutations which contributed to the construction of strain RMBPC–2 were evaluated by EPA, either during the early stages of the rhizobia field trials or during testing of strain RMBPC–2 itself. In addition, genetic modifications to strain RMBPC–2 are not likely to have modified the behavior of the microorganism compared to that observed with earlier constructs. Moreover, reseeding the original test plots is no longer possible because all tests have been terminated and the plots have been returned to normal agricultural use.

3. *Effect on yield of alfalfa plants.* Data were also collected and analyzed relating to the ability of *Sinorhizobium meliloti* strain RMBPC–2 to affect the yield of alfalfa plants. These data, encompassing up to 4 years at some sites, demonstrated that RMBPC–2 is sometimes able to significantly increase alfalfa yield under conditions of low nitrogen content of the soil and low indigenous rhizobial populations. However, the yield increases realized are modest and not outside the range of yields encountered in commercial alfalfa production using naturally occurring rhizobial inoculants. The BSAC agreed that, overall, RMBPC–2

was shown to perform within the normal range expected of naturally occurring commercial inoculants. Thus, there were no adverse effects on alfalfa yield from use of RMBPC–2.

4. *Effect on non-target plants.* The process of nodulation of leguminous plants by various strains of *Sinorhizobium meliloti* is highly specific. *Sinorhizobium meliloti* has been reported to preferentially nodulate various species of alfalfa, sweet clover, and fenugreek. Collectively, these leguminous species are referred to as the ''cross-inoculation'' group for *Sinorhizobium meliloti*. Various studies have suggested that *Sinorhizobium meliloti* may also be able to nodulate certain other leguminous plants outside of its normal cross-inoculation group such as mesquite.

In considering the potential for *Sinorhizobium meliloti* to nodulate leguminous plants other than alfalfa, the BSAC subcommittee was of divided opinion on whether to recommend additional testing of strain RMBPC–2. An appendix to the BSAC report described testing which some members of the subcommittee felt would provide additional assurance that strain RMBPC–2 would behave as other *Sinorhizobium meliloti* inoculants (Biotechnology Science Advisory Committee, pages 15 and 18–19, 1995, see Unit IX.2. of this preamble). The additional testing involved greenhouse testing of RMBPC–2 along with other control strains on various cultivars of sweet clover and several of the major mesquite species.

EPA addressed these issues in its risk assessment. With respect to the concern for increased weediness of sweet clover, EPA believes that there is no incremental hazard if RMBPC–2 were to replace indigenous or commercial strains of sweet clover inoculants. As noted in the previous two paragraphs, the ability of RMBPC–2 to nodulate plants within its cross-inoculation group is comparable to that of other commercial inoculants, and thus would be unlikely to impart a competitive advantage to sweet clover plants. In addition, agricultural management practices in alfalfa fields, which involve mowing alfalfa plants at a low height, are detrimental to sweet clover growth and would consequently control sweet clover growth in alfalfa fields, even if the sweet clover was inoculated by RMBPC–2. Finally, the Agency noted that nodulation data collected under greenhouse conditions may not accurately reflect the reality of competitive field conditions.

With respect to mesquite, there is considerable disparity between the geographic regions of the country in which mesquite and alfalfa are grown. Thus, there would be little opportunity for strain RMBPC–2 to come into contact with mesquite plants. In addition, mesquite is nodulated by a consortium of species and genera of nitrogen-fixing microorganisms, including various species of *Rhizobium* and *Bradyrhizobium*. As a result, strain RMBPC–2 would need to out-compete all such species in order to have any observable effect on individual mesquite plants, which is highly unlikely.

IV. Objectives and Rationale of the Proposed Rule

EPA is issuing this SNUR for a specific microorganism which has undergone premanufacture review to ensure that:

(1) EPA will receive notice of any company's intent to manufacture, import, or process the microorganism for a significant new use before that activity begins.

(2) EPA will have an opportunity to review and evaluate data submitted in a significant new use notice (SNUN) before the notice submitter begins manufacturing, importing, or processing the microorganism for a significant new use.

(3) When necessary to prevent potential unreasonable risks, EPA will be able to respond to a SNUN by issuing a TSCA section 5(e) consent order to regulate prospective manufacturers, importers, or processors of the microorganism before a significant new use of that substance occurs.

(4) All manufacturers, importers, and processors of the same microorganism which is subject to a TSCA section 5(e) consent order are subject to similar requirements.

Issuance of a SNUR for a microorganism does not signify that the substance is listed on the TSCA Inventory and that its manufacture would not require a PMN. Manufacturers, importers, and processors are responsible for ensuring that a new chemical substance subject to a final SNUR is listed on the TSCA Inventory.

V. Applicability of SNUR to Uses Occurring Before Effective Date of the Final SNUR

EPA has decided that the intent of section 5(a)(1)(B) of TSCA is best served by designating a use as a ''significant new use'' as of the date of proposal, rather than as of the effective date of the rule. If uses which had commenced between the date of proposal and the effective date of this rulemaking were considered ongoing, rather than new, any person could defeat the SNUR by initiating a significant new use before the effective date. This would make it difficult for EPA to establish SNUR notice requirements. Thus, persons who begin commercial manufacture, import, or processing of the microorganism for uses that would be regulated through this SNUR after the proposal date, would have to cease any such activity before the effective date of this rule. To resume their activities, such persons would have to comply with all applicable SNUR notice requirements and wait until the notice review period, including all extensions, expires. EPA, not wishing to unnecessarily disrupt the activities of persons who begin commercial manufacture, import, or processing for a proposed significant new use before the effective date of the SNUR, has promulgated provisions to allow such persons to comply with this proposed SNUR before it is promulgated. If a person meets the conditions of advance compliance as codified at § 721.45(h) (53 FR 28354, July 17, 1988), the person is considered to have met the requirements of the final SNUR for those activities. If persons who begin commercial manufacture, import, or processing of the microorganism between proposal and the effective date of the SNUR do not meet the conditions of advance compliance, they must cease that activity before the effective date of the rule. To resume their activities, these persons would have to comply with all applicable SNUR notice requirements and wait until the notice review period, including all extensions, expires.

VI. Economic Analysis

EPA has evaluated the potential costs of establishing significant new use notice requirements for potential manufacturers, importers, and processors of the microorganism subject to this rule. EPA's complete economic analysis is available in the rulemaking record for this proposed rule (OPPTS–50630).

VII. 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 OPPTS–50630 (including comments and data submitted electronically as described below). In addition, extensive information for this microorganism can also be found in OPPTS docket number 51786. This docket contains materials concerning the TSCA section 5(a) review of P–92–403. 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 12 noon to 4 p.m., Monday through Friday, excluding legal holidays. The official rulemaking record is located in the TSCA Nonconfidential Information Center Rm. NE–B607, 401 M St., SW., Washington, DC.

Electronic comments can be sent directly to EPA at:

oppt.ncic@epamail.epa.gov

Electronic comments must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Comments 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 OPPTS–50630. Electronic comments on this proposed rule may be filed online at many Federal Depository Libraries.

VIII. Regulatory Assessment Requirements

Under Executive Order 12866, entitled ''Regulatory Planning and Review'' (58 FR 51735, October 4, 1993), this action is not a ''significant regulatory action'' subject to review by the Office of Management and Budget (OMB). In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4), or require prior consultation with State officials as also specified in Executive Order 12875, entitled ''Enhancing the Intergovernmental Partnership'' (58 FR 58093, October 28, 1993). Nor does it involve special considerations of environmental justice related issues 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 additional 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).

According to the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq*., an agency may not conduct or sponsor, and a person is not required to respond to a collection of information that requires OMB approval under the PRA, unless it has been approved by OMB and displays a currently valid OMB control number. The OMB control numbers for EPA's regulations, after initial display in the preamble of the final rules, are listed in 40 CFR part 9. The information collection requirements related to this action have already been approved by OMB pursuant to the PRA under OMB control number 2070–0012 (EPA ICR No. 574). This action does not impose any burden requiring additional OMB approval.

If an entity were to submit a significant new use notice to the Agency, the annual burden is estimated to average between 30 and 170 hours per response. This burden estimate includes the time needed to review instructions, search existing data sources, gather and maintain the data needed, and complete, review, and submit the required significant new use notice.

Send any comments about the accuracy of the burden estimate and any suggested methods for minimizing respondent burden, including through the use of automated collection techniques, to the Director, OPPE Regulatory Information Division, U.S. Environmental Protection Agency (Mail Code 2137), 401 M St., SW., Washington, DC 20460, with a copy to the Office of Information and Regulatory Affairs, Office of Management and Budget, 725 17th St., NW., Washington, DC 20503, marked ''Attention: Desk Officer for EPA''. Please remember to include the OMB control number in any correspondence, but do not submit any completed forms to these addresses.

In addition, pursuant to section 605(b) of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq*.), the Agency has previously certified, as a generic matter, that the promulgation of a SNUR does not have a significant adverse economic impact on a substantial number of small entities. The Agency's generic certification for promulgation of new SNURs appears on June 2, 1997 (62 FR 29684) (FRL–5597–1) and was provided to the Chief Counsel for Advocacy of the Small Business Administration.

IX. References

1. De Lajudie, P. et al. ''Polyphasic Taxonomy of Rhizobia: Emendation of the Genus *Sinorhizobium* and Description of *Sinorhizobium meliloti* comb. nov., *Sinorhizobium saheli* sp. nov., and *Sinorhizobium teranga* sp. nov.''. Int'l J. of Systematic Bacteriology, October 1994, pp. 715–733.

2. Final report of the Biotechnology Science Advisory Committee Subcommittee on Premanufacture Notification; Review of Nitrogen Fixing *Rhizobium meliloti*, March 6, 1995.

List of Subjects in 40 CFR Part 721

Environmental protection, Chemicals, Hazardous substances, Reporting and recordkeeping requirements.

Dated: February 27, 1998.

Charles M. Auer,

Director, Chemical Control Division, Office of Pollution Prevention and Toxics.

Therefore, it is proposed that 40 CFR part 721 be amended as follows:

PART 721—[AMENDED]

1. The authority citation for part 721 would continue to read as follows:

Authority: 15 U.S.C. 2604, 2607, and 2625(c).

2. By adding new § 721.9518 to subpart E to read as follows:

§ 721.9518 Sinorhizobium meliloti strain RMBPC–2.

(a) *Microorganism and significant new uses subject to reporting.* (1) The microorganism identified as *Sinorhizobium meliloti* strain RMBPC–2 (PMN P–92–403) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Commercial activities before submitting a TSCA section 5(a) notice.* For any manufacturer or importer who has not previously submitted a premanufacture notice or significant new use notice for this microorganism, the significant new use is any use.

(ii) *Commercial activities after submitting a TSCA section 5(a) notice.* For any manufacturer or importer who has previously submitted a premanufacture notice or a significant new use notice for this microorganism, the significant new use is manufacture, import, or processing greater than a maximum production volume of 500,000 lbs in any consecutive 12-month period.

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph.

(1) *Persons who must report.* Section 721.5 applies to this section except for § 721.5(a)(2). A person who intends to manufacture or import this substance for commercial purposes must have submitted a premanufacture notice or submit a significant new use notice.

(2) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125 (a) and (i) are applicable to manufacturers and importers of this substance.

(3) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

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