

### F. Petitions for Judicial Review

Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by July 31, 1998. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this rule for the purposes of judicial review nor does it extend the time within which a petition for judicial review must be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements (see section 307(b)(2)).

### G. Executive Order 13045

Protection of Children from Environmental Health Risks and Safety Risks. Executive Order 13045 (62 FR 19885, April 23, 1997), applies to any rule that is (1) likely to be "economically significant" as defined under Executive Order 12866, and (2) the Agency has reason to believe that the environmental health or safety risk addressed by the rule may have a disproportionate effect on children. If a regulatory action meets both criteria, the Agency must evaluate the environmental health or safety effects of the planned rule on children, and explain why the planned regulation is preferable to other potentially effective and reasonably feasible alternatives considered by the Agency.

This rule is not subject to E.O. 13045, "Protection of Children from Environmental Health Risks and Safety Risks" because this is not an "economically significant" regulatory action as defined by E.O. 12866, and because it does not involve decisions on environmental health or safety risks that may disproportionately affect children.

### List of Subjects in 40 CFR Part 62

Environmental protection, Administrative practice and procedure, Air pollution control, Intergovernmental relations, Methane, Municipal solid waste landfills, Nonmethane organic compounds, Reporting and recordkeeping requirements.

Dated: May 21, 1998.

**Carol Rushin,**

*Acting Regional Administrator, Region VIII.*

40 CFR part 62 is amended as follows:

### PART 62—[AMENDED]

1. The authority citation for part 62 continues to read as follows:

**Authority:** 42 U.S.C. 7401-7642.

2. Subpart ZZ is added to read as follows:

### Subpart ZZ—Wyoming

Sec.

- 62.12600 Identification of plan.
- 62.12601 Identification of sources.
- 62.12602 Effective date.

### Subpart ZZ—Wyoming

#### Landfill Gas Emissions From Existing Municipal Solid Waste Landfills

##### § 62.12600 Identification of plan.

Section 35, "Municipal Solid Waste Landfills," of the Wyoming Air Quality Standards and Regulations and associated documentation submitted by the State on February 13, 1998.

##### § 62.12601 Identification of sources.

The plan applies to all existing municipal solid waste landfills for which construction, reconstruction, or modification was commenced before May 30, 1991 that accepted waste at any time since November 8, 1987 or that have additional capacity available for future waste deposition, as described in 40 CFR part 60, subpart CC.

##### § 62.12602 Effective date.

The effective date of the plan for municipal solid waste landfills is July 31, 1998.

[FR Doc. 98-14435 Filed 5-29-98; 8:45 am]

BILLING CODE 6560-50-P

## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 721

[OPPTS-50630A; FRL-5789-5]

RIN 2070-AB27

#### Sinorhizobium meliloti strain RMBPC-2; Significant New Use Rule

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** EPA is issuing 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 rule will require 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:** This rule is effective July 1, 1998.

#### FOR FURTHER INFORMATION CONTACT:

Susan B. Hazen, Director, Environmental Assistance Division (7408), Office of Pollution Prevention and Toxics, Environmental Protection Agency, Rm. E-531, 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/fedrgrstr/>).

This 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 microorganisms as stated in the **Federal Register** of April 11, 1997 (62 FR 17910) (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 TSCA section 5(b) and (d)(1), the exemptions authorized by TSCA 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 TSCA 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 published a proposed SNUR for the microorganism described as *Sinorhizobium meliloti* strain RMBPC-2, which is the subject of premanufacture notice (PMN) P-92-403, in the **Federal Register** of March 10, 1998 (63 FR 11643) (FRL-5765-6). The background and reasons for the SNUR are set forth in the preamble to the proposed rule. EPA proposed the significant new use 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 pounds (lbs) in any consecutive 12-month period.

The Agency received no public comment concerning the proposed rule. As a result EPA is issuing the final rule as proposed.

## IV. Objectives and Rationale of the 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 microorganism 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 the 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 final rule (OPPTS-50630A).

## 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-50630A (including comments and data submitted electronically). In addition, extensive information for this microorganism can also be found in OPPTS docket number 51786, which contains materials concerning the TSCA section 5(a) review of PMN P-92-403. A public version of this record, including printed, paper versions of electronic comments, which does not include any information claimed as Confidential Business Information (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.

## 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 (UMRA) (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. Submission to Congress and the General Accounting Office

Under 5 U.S.C. 801(a)(1)(A), as added by the Small Business Regulatory Enforcement Fairness Act of 1996, the Agency has submitted 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 General Accounting Office prior to publication of this rule in today's **Federal Register**. This is not a major rule as defined by 5 U.S.C. 804(2).

#### List of Subjects in 40 CFR Part 721

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

Dated: May 20, 1998.

**Charles M. Auer,**

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

Therefore, 40 CFR part 721 is amended as follows:

#### PART 721—[AMENDED]

1. The authority citation for part 721 continues 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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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Care Financing Administration

#### 42 CFR Parts 441 and 489

[HCFA-1152-1-F]

RIN 0938-A186

#### Medicare and Medicaid Programs; Surety Bond Requirements for Home Health Agencies

**AGENCY:** Health Care Financing Administration (HCFA), HHS.

**ACTION:** Final rule.

**SUMMARY:** This final rule revises several provisions of an earlier final rule concerning surety bond requirements published in the **Federal Register** on January 5, 1998 (63 FR 292). This rule also establishes the surety bond submission compliance date, as described in a notice of intent and in a final rule concerning surety bond requirements published in the **Federal Register** on March 4, 1998 (63 FR 10730 and 10732). The March 4 documents advised the public that we intended to