

reclassification of nonattainment areas under section 188(b)(2) of the CAA do not in-and-of-themselves create any new requirements. Therefore, I certify that today's proposed action does not have a significant impact on small entities.

VI. Unfunded Mandates

Under sections 202, 203 and 205 of the Unfunded Mandates Reform Act of 1995 (Unfunded Mandates Act), signed into law on March 22, 1995, EPA must assess whether various actions undertaken in association with proposed or final regulations include a Federal mandate that may result in estimated costs of \$100 million or more to the private sector, or to State, local or tribal governments in the aggregate.

EPA believes, as discussed earlier in section IV of this notice, that the proposed finding of failure to attain and reclassification of the Phoenix Planning Area are factual determinations based upon air quality considerations and must occur by operation of law and, hence, do not impose any federal intergovernmental mandate, as defined in section 101 of the Unfunded Mandates Act.

List of Subjects in 40 CFR Part 81

Environmental protection, Air pollution control, Intergovernmental relations, Particulate matter.

Authority: 42 U.S.C. 7401-7671q.

Dated: May 25, 1995.

David P. Howekamp,

Acting Regional Administrator.

[FR Doc. 95-13925 Filed 6-6-95; 8:45 am]

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40 CFR Part 180

[PP 0F3885/R2142; FRL-4958-9]

RIN 2070-AC18

Burkholderia (Pseudomonas) Cepacia Type Wisconsin; Tolerance Exemption

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: This document proposes that an exemption from the requirement of a tolerance be established for residues of the biological pesticide *Burkholderia (Pseudomonas) cepacia* type Wisconsin in or on all raw agricultural commodities, resulting from use on plant roots or seedling roots. EPA is proposing this regulation on its own initiative. The proposal would amend the existing tolerance exemption for this organism, which is limited to the seed treatment use.

DATES: Comments identified by the docket number, [PP 0F3885/R2142], must be received on or before July 7, 1995.

ADDRESSES: Submit written comments by mail to: Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring comments to: Public Docket, Rm. 1132, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA 22202. Information submitted as a comment concerning this document may be claimed confidential by marking any part or all of that information as "Confidential Business Information" (CBI). Information so marked will not be disclosed except in accordance with procedures as 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. 1132 at the above address, from 8 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays.

Comments and data may also be submitted electronically by sending electronic mail (e-mail) to: 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. Comments and data will also be accepted on disks in WordPerfect in 5.1 file format or ASCII file format. All comments and data in electronic form must be identified by the docket number [PP 0F3885/R2142]. No Confidential Business Information (CBI) should be submitted through e-mail. Electronic comments on this proposed rule may be filed online at many Federal Depository Libraries. Additional information on electronic submissions can be found below in this document.

FOR FURTHER INFORMATION CONTACT: By mail: Denise Greenway, Biopesticides and Pollution Prevention Division (7501W), Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location and telephone number: Rm. CS51L6, Crystal Station #1, 2800 Crystal Drive, Arlington, VA 22202, (703)-308-8263; e-mail: greenway.denise@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of April 3, 1991 (56 FR 13642), EPA issued a notice that Stine Microbial Products, 4722 Pflaum Rd., Madison, WI 53704, had submitted pesticide petition (PP) 0F3885 to EPA

proposing to amend 40 CFR part 180 by establishing a regulation pursuant to the Federal Food, Drug and Cosmetic Act (21 U.S.C. 346a and 371), to exempt from the requirement of a tolerance the residues of the biological pesticide *Pseudomonas cepacia* type Wisconsin in or on all raw agricultural commodities when applied as a seed treatment for growing agricultural crops in accordance with good agricultural practices. There were no comments received in response to the notice.

In the **Federal Register** of December 23, 1992 (57 FR 61003), an exemption from the requirement of a tolerance was established for residues of the biological pesticide *Pseudomonas cepacia* type Wisconsin in or on all raw agricultural commodities when applied as a seed treatment for growing agricultural crops in accordance with good agricultural practices.

Stine Microbial Products has subsequently proposed a new use site, plant roots or seedling roots. Like the seed treatment use for which an exemption from the requirement of a tolerance now exists (40 CFR 180.1115), *Pseudomonas cepacia* type Wisconsin applied to plant roots or seedling roots will colonize the developing root system, and by producing antibiotics, protect the seedling or plant from a range of plant pathogenic fungi and nematodes. The Agency has determined that this presents no new hazard issues and that the following originally submitted data can support the registration for use as a soil, seed, or seedling treatment:

The organism is a naturally occurring biotype of the bacterial species *Pseudomonas cepacia* which is found world wide. The original isolates of *Pseudomonas cepacia* type Wisconsin were identified as colonizers of the roots and rhizospheres of maize. Further testing indicated that this biotype will colonize roots of many crop plants. *Pseudomonas cepacia* type Wisconsin has been shown to produce antibiotics which are effective against a diverse range of plant pathogenic fungi. *Pseudomonas cepacia* type Wisconsin is not generally regarded as a human or animal pathogen. Products containing this organism are intended to be used for formulating other end-use products or as a seed treatment (and the proposed plant root and seedling root use). When applied to seeds (or plant or seedling roots), the bacteria colonize the developing root system, and by producing antibiotics, protect the seedling from a range of plant pathogenic fungi and nematodes.

The data submitted in the petition and other relevant material have been

evaluated. The toxicological data considered in support of the exemption from the requirement of a tolerance include an acute oral toxicity/pathogenicity study, an acute dermal toxicity study, an acute pulmonary toxicity/pathogenicity study, and an acute intravenous toxicity/pathogenicity study. All studies were conducted with the rat as the test animal. A review of these studies indicated that the organism was not acutely toxic to test animals when administered via dermal and intravenous routes. The active ingredient was not infective or pathogenic to test animals when administered via the oral, pulmonary, or intravenous route. No reports of hypersensitivity have been recorded from personnel working with this organism. All of the toxicity studies submitted are considered acceptable. The toxicity data provided are sufficient to show that there are no foreseeable health hazards to humans or domestic animals likely to arise from the use of this organism as a seed (or seedling root or plant root) treatment.

Residue chemistry data were not required; such data are necessary only if the submitted toxicity studies indicate that additional Tier II or Tier III toxicology data are needed. These additional data were not needed. Therefore, no residue data are required to establish an exemption from the requirement of a tolerance for the biological pesticide *Pseudomonas cepacia* type Wisconsin in or on all raw agricultural commodities when applied to plant roots and seedling roots or used as a seed treatment for growing agricultural crops in accordance with good agricultural practices.

Acceptable daily intake (ADI) and maximum permissible intake (MPI) considerations are not relevant to this petition because the data submitted demonstrated that this biological control agent is not toxic to humans. No enforcement actions are expected. Therefore, the requirement for an analytical method for enforcement purposes is not applicable to this exemption request.

The Agency hereby takes the initiative to amend the current tolerance exemption (40 CFR 180.1115) by expanding it to include the proposed use on plant roots and seedling roots. The Agency also proposes that the exemption from the requirement of a tolerance be further amended to update the organism name. There has been a recent change in the bacterial taxonomy affecting the generic affiliation of the RNA group II pseudomonads and moving them from the genus *Pseudomonas* to the newly described

genus *Burkholderia*. To reduce confusion by completely changing the organism name, it is proposed that the former genus name be inserted parenthetically after the new one, *Burkholderia (Pseudomonas) cepacia*.

Burkholderia (Pseudomonas) cepacia type Wisconsin is considered useful for the purposes for which the exemption from the requirement of a tolerance is sought. Based on the information considered, the Agency concludes that the establishment of a tolerance is not necessary to protect the public health. Therefore, EPA proposes that an exemption from the requirement of a tolerance be established as set forth below.

Any person who has registered or submitted an application for registration of a pesticide under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) as amended, which contains the ingredient listed herein, may request within 30 days after the publication of this document in the **Federal Register** that this rulemaking proposal be referred to an Advisory Committee in accordance with section 408(e) of the Federal Food, Drug, and Cosmetic Act (FFDCA).

Interested persons are invited to submit written comments on the proposed regulation. Comments must bear a notation indicating the document control number, [PP 0F3885/R2142]. All written comments filed in response to this petition will be available in the Public Response and Program Resources Branch at the above address from 8 a.m. to 4:30 p.m., Monday through Friday, except legal holidays.

A record has been established for this rulemaking under docket number [PP 0F3885/R2142] (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 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The public record is located in Room 1132 of the Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA.

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.

The official record for this rulemaking, as well as the public version, as described above will be kept in paper form. Accordingly, EPA will transfer all comments received electronically into printed, paper form as they are received and will place the paper copies in the official rulemaking record which will also include all comments submitted directly in writing. The official rulemaking record is the paper record maintained at the address in "ADDRESSES" at the beginning of this document.

The Office of Management and Budget has exempted this document from the requirement of review pursuant to Executive Order 12866.

Pursuant to the requirements of the Regulatory Flexibility Act (Pub. L. 96-354, 94 Stat. 1164, 5 U.S.C. 601-612), the Administrator has determined that regulations establishing new tolerances or raising tolerance levels or establishing exemptions from tolerance requirements do not have a significant economic impact on a substantial number of small entities. A certification statement to this effect was published in the **Federal Register** of May 4, 1981 (46 FR 24950).

List of Subjects in 40 CFR Part 180

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

Dated: June 1, 1995.

Janet L. Andersen,

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

Therefore, it is proposed that 40 CFR part 180 be amended as follows:

PART 180—[AMENDED]

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

Authority: 21 U.S.C. 346a and 371.

2. Section 180.1115 is revised to read as follows:

§ 180.1115 *Burkholderia (Pseudomonas) cepacia* type Wisconsin; exemption from the requirement of a tolerance.

The biological pesticide *Burkholderia (Pseudomonas) cepacia* type Wisconsin is exempted from the requirement of a tolerance in or on all raw agricultural commodities when applied to plant roots and seedling roots, or as a seed treatment for growing agricultural crops

in accordance with good agricultural practices.

[FR Doc. 95-13961 Filed 6-6-95; 8:45 am]

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40 CFR Part 721

[OPPTS-50615B; FRL-4916-4]

RIN 2070-AB27

Organotin Lithium Compound; 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 chemical substance described generically as an organotin lithium compound which is the subject of premanufacture notice (PMN) P-93-1119. This proposal would require certain persons who intend to manufacture, import, or process this substance 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 July 7, 1995.

ADDRESSES: Each comment must bear the docket control number OPPTS-50615B. All comments should be sent in triplicate to: OPPT Document Control Officer (7407), Office of Pollution Prevention and Toxics, Environmental Protection Agency, Rm. E-G99, 401 M St., SW., Washington, DC 20460. All comments which are claimed confidential must be clearly marked as such. Three additional sanitized copies of any comments containing confidential business information (CBI) must also be submitted. Nonconfidential versions of comments on this proposed rule will be placed in the rulemaking record and will be available for public inspection. See Unit VII. of this document for further information.

Comments and data may also be submitted electronically by sending electronic mail (e-mail) to: 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 in 5.1

file format or ASCII file format. All comments and data in electronic form must be identified by the docket number OPPTS-50615B. No CBI should be submitted through e-mail. Electronic comments on this proposed rule may be filed online at many Federal Depository Libraries. Additional information on electronic submissions can be found in Unit VIII. of this document.

FOR FURTHER INFORMATION CONTACT:

Susan B. Hazen, Director, Environmental Assistance Division (7408), Office of Pollution Prevention and Toxics, Environmental Protection Agency, Rm. E-543B, 401 M St., SW., Washington, DC 20460, Telephone: (202) 554-1404, TDD: (202) 554-0551.

SUPPLEMENTARY INFORMATION: This proposed SNUR would require persons to notify EPA at least 90 days before commencing the manufacture, import, or processing of P-93-1119 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). 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) with respect to a category of chemical substances.

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 sections 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 significant new use notice (SNUN), EPA may take regulatory action under section 5(e), 5(f), 6, or 7 to control the activities for which it has received a SNUN. 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 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 31252), EPA promulgated a "User Fee Rule" (40 CFR part 700) under the authority of TSCA section 26(b). Provisions requiring persons submitting SNUNs 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 direct final SNUR for the chemical substance which was the subject of PMN P-93-1119 in the **Federal Register** of May 27, 1994 (59 FR 27474). EPA received adverse comments following publication for this chemical substance. Therefore, as required by 40 CFR 721.160, the final SNUR for P-93-1119 is being revoked elsewhere in this issue of the **Federal Register** and this proposed rule on the substance is being issued.

The comments were submitted by the PMN submitter's customer for this substance. The commenter proposed changing the requirements of the SNUR. Based on potential toxicity to the environment, the direct final SNUR required notification if the substance was predictably or purposefully released to surface waters. The commenter proposed a SNUR requiring notification if the substance was predictably or purposefully released to surface waters above a concentration of 1 ppb (part per billion) according to the formula in 40 CFR 721.90.

The direct final SNUR was based on the information in the PMN that manufacture and use of the PMN substance as a catalyst would not result in releases to surface waters. The commenter demonstrated through a pilot study and analytical measurements that the substance would be released to surface waters. The commenter also demonstrated that treatment at that particular plant site would result in surface water concentrations below EPA's original 1 ppb concern concentration. Because the data demonstrate that releases to water could occur but would not exceed the 1 ppb concern level at the intended site of