

(g) A manufacturer or importer may only proceed after receipt of EPA approval.

Subparts H–K [Reserved]

Subpart L—Additional Procedures for Reporting on Significant New Uses of Microorganisms

§ 725.900 Scope and purpose.

(a) This subpart describes additional provisions governing submission of MCANs for microorganisms subject to significant new use rules identified in subpart M of this part.

(b) Manufacturers, importers, and processors described in § 725.105(c) must submit a MCAN under subpart D of this part for significant new uses of microorganisms described in subpart M of this part, unless they are excluded under §§ 725.910 or 725.912.

(c) Section 725.920 discusses exports and imports.

(d) Additional recordkeeping requirements specific to significant new uses of microorganisms are described in § 725.950.

(e) Section 725.975 describes how EPA will approve alternative means of complying with significant new use requirements designated in subpart M of this part.

(f) Expedited procedures for promulgating significant new use requirements under subpart M of this part for microorganisms subject to section 5(e) orders are discussed in §§ 725.980 and 725.984.

(g) This subpart L contains provisions governing submission and review of notices for the microorganisms and significant new uses identified in subpart M of this part. The provisions of this subpart L apply to the microorganisms and significant new uses identified in subpart M of this part, except to the extent that they are specifically modified or supplanted by specific requirements in subpart M of this part. In the event of a conflict between the provisions of this subpart L and the provisions of subpart M of this part, the provisions of subpart M of this part shall govern.

(h) The provisions of subparts A through F of this part also apply to

subparts L and M of this part. For purposes of subparts L and M of this part, wherever the words “microorganism” or “new microorganism” appear in subparts A through F of this part, it shall mean the microorganism subject to subparts L and M of this part. In the event of a conflict between the provisions of subparts A through F and the provisions of subparts L and M of this part, the provisions of subparts L and M of this part shall govern.

§ 725.910 Persons excluded from reporting significant new uses.

(a) A person who intends to manufacture, import, or process a microorganism identified in subpart M of this part and who intends to distribute it in commerce is not required to submit a MCAN under subpart D of this part, if that person can document one or more of the following as to each recipient of the microorganism from that person:

(1) That the person has notified the recipient, in writing, of the specific section in subpart M of this part which identifies the microorganism and its designated significant new uses, or

(2) That the recipient has knowledge of the specific section in subpart M of this part which identifies the microorganism and its designated significant new uses, or

(3) That the recipient cannot undertake any significant new use described in the specific section in subpart M of this part.

(b) The manufacturer, importer, or processor described in paragraph (a) of this section must submit a MCAN under subpart D of this part, if such person has knowledge at the time of commercial distribution of the microorganism identified in the specific section in subpart M of this part that a recipient intends to engage in a designated significant new use of that microorganism without submitting a MCAN under this part.

(c) A person who processes a microorganism identified in a specific section in subpart M of this part for a significant new use of that microorganism is not required to submit a MCAN if that person can document each of the following:

Environmental Protection Agency

§ 725.912

(1) That the person does not know the specific microorganism identity of the microorganism being processed, and

(2) That the person is processing the microorganism without knowledge that the microorganism is identified in subpart M of this part.

(d)(1) If at any time after commencing distribution in commerce of a microorganism identified in a specific section in subpart M of this part, a person who manufactures, imports, or processes a microorganism described in subpart M of this part and distributes it in commerce has knowledge that a recipient of the microorganism is engaging in a significant new use of that microorganism designated in that section without submitting a MCAN under this part, the person is required to cease supplying the microorganism to that recipient and to submit a MCAN for that microorganism and significant new use, unless the person is able to document each of the following:

(i) That the person has notified the recipient and EPA enforcement authorities (at the address in paragraph (d)(1)(iii) of this section), in writing within 15 working days of the time the person develops knowledge that the recipient is engaging in a significant new use, that the recipient is engaging in a significant new use without submitting a MCAN.

(ii) That, within 15 working days of notifying the recipient as described in paragraph (d)(1)(i) of this section, the person received from the recipient, in writing, a statement of assurance that the recipient is aware of the terms of the applicable section in subpart M of this part and will not engage in the significant new use.

(iii) That the person has promptly provided EPA enforcement authorities with a copy of the recipient's statement of assurance described in paragraph (d)(1)(ii) of this section. The copy must be sent to the Director, Office of Compliance (2221A), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

(2) If EPA notifies the manufacturer, importer, or processor that the recipient is engaging in a significant new use after providing the statement of assurance described in paragraph (d)(1)(ii) of this section and without submitting a

MCAN under this part, the manufacturer, importer, or processor shall immediately cease distribution to that recipient until the manufacturer, importer, or processor or the recipient has submitted a MCAN under this part and the MCAN review period has ended.

(3) If, after receiving a statement of assurance from a recipient under paragraph (d)(1)(ii) of this section, a manufacturer, importer, or processor has knowledge that the recipient is engaging in a significant new use without submitting a MCAN under this part, the manufacturer, importer, or processor must immediately cease distributing the microorganism to that recipient and notify EPA enforcement authorities at the address identified in paragraph (d)(1)(iii) of this section. The manufacturer, importer, or processor may not resume distribution to that recipient until any one of the following has occurred:

(i) The manufacturer, importer, or processor has submitted a MCAN under this part and the MCAN review period has ended.

(ii) The recipient has submitted a MCAN under this part and the MCAN review period has ended.

(iii) The manufacturer, importer, or processor has received notice from EPA enforcement authorities that it may resume distribution to that recipient.

§ 725.912 Exemptions.

Persons identified in § 725.105(c) are not required to submit a MCAN under subpart D of this part for a microorganism identified in subpart M of this part, unless otherwise specified in a specific section in subpart M, if:

(a) The person submits a MCAN for the microorganism prior to the promulgation date of the section in subpart M of this part which identifies the microorganism, and the person receives written notification of compliance from EPA prior to the effective date of such section. The MCAN submitter must comply with any applicable requirement of section 5(b) of the Act. The MCAN must include the information and test data specified in section 5(d)(1) of the Act. For purposes of this exemption, the specific section in subpart M of this part which identifies the microorganism and §§ 725.3, 725.15,

§ 725.920

725.65, 725.70, 725.75, 725.100, and 725.900 apply; after the effective date of the section in subpart M of this part which identifies the microorganism, §§ 725.105 and 725.910 apply and § 725.920 continues to apply. EPA will provide the MCAN submitter with written notification of compliance only if one of the following occurs:

(1) EPA is unable to make the finding that the activities described in the MCAN will or may present an unreasonable risk of injury to health or the environment under reasonably foreseeable circumstances, or

(2) EPA and the person negotiate a consent order under section 5(e) of the Act, such order to take effect on the effective date of the section in subpart M of this part which identifies the microorganism.

(b) The person is operating under the terms of a consent order issued under section 5(e) of the Act applicable to that person. If a provision of such section 5(e) order is inconsistent with a specific significant new use identified in subpart M of this part, abiding by the provision of the section 5(e) order exempts the person from submitting a MCAN for that specific significant new use.

§ 725.920 Exports and imports.

(a) *Exports.* Persons who intend to export a microorganism identified in subpart M of this part, or in any proposed rule which would amend subpart M of this part, are subject to the export notification provisions of section 12(b) of the Act. The regulations that interpret section 12(b) appear at part 707 of this chapter.

(b) *Imports.* Persons who import a substance identified in a specific section in subpart M of this part are subject to the import certification requirements under section 13 of the Act, which are codified at 19 CFR §§ 12.118 through 12.127 and 127.28(i). The EPA policy in support of the import certification requirements appears at part 707 of this chapter.

§ 725.950 Additional recordkeeping requirements.

Persons submitting a MCAN for a significant new use of a microorganism must comply with the recordkeeping

40 CFR Ch. I (7-1-12 Edition)

requirements of § 725.65. In addition, the following requirements apply:

(a) At the time EPA adds a microorganism to subpart M of this part, EPA may specify appropriate recordkeeping requirements. Each manufacturer, importer, and processor of the microorganism shall maintain the records for 3 years from the date of their creation.

(b) The records required to be maintained under this section may include the following:

(1) Records documenting the information contained in the MCAN submitted to EPA.

(2) Records documenting the manufacture and importation volume of the microorganism and the corresponding dates of manufacture and import.

(3) Records documenting volumes of the microorganism purchased domestically by processors of the microorganism, names and addresses of suppliers and corresponding dates of purchase.

(4) Records documenting the names and addresses (including shipment destination address, if different) of all persons outside the site of manufacture or import to whom the manufacturer, importer, or processor directly sells or transfers the microorganism, the date of each sale or transfer, and the quantity of the microorganism sold or transferred on such date.

§ 725.975 EPA approval of alternative control measures.

(a) In certain sections of subpart M of this part, significant new uses for the identified microorganisms are described as the failure to establish and implement programs providing for the use of either: specific measures to control worker exposure to or release of microorganisms which are identified in such sections, or alternative measures to control worker exposure or environmental release which EPA has determined provide substantially the same degree of protection as the specified control measures. Persons who manufacture, import, or process a microorganism identified in such sections and who intend to employ alternative measures to control worker exposure or environmental release must submit a request to EPA for a determination of equivalency before commencing

Environmental Protection Agency

§ 725.980

manufacture, import, or processing involving the alternative control measures.

(b) Persons submitting a request for a determination of equivalency to EPA under this part, unless allowed by § 725.25(c) (1), (2), or (3), must submit the request to EPA via EPA's Central Data Exchange (CDX) using EPA-provided e-PMN software in the manner set forth in § 725.25(c). See 40 CFR 720.40(a)(2)(iv) for information on how to obtain e-PMN software. Support documents related to these requests must also be submitted to EPA via CDX using e-PMN software. If submitted on paper, requests must be submitted either via U.S. mail to the Document Control Office (DCO) (7407M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; ATTN: SNUR Equivalency Determination or submitted via courier to the Environmental Protection Agency, OPPT Document Control Office (DCO), EPA East Bldg., 1201 Constitution Ave., NW., Rm. 6428, Washington, DC 20004; ATTN: SNUR Equivalency Determination. Optical discs containing electronic requests must be submitted by courier to the Environmental Protection Agency, OPPT Document Control Office (DCO), EPA East Bldg., 1201 Constitution Ave., NW., Rm. 6428, Washington, DC 20004; ATTN: SNUR Equivalency Determination. A request for a determination of equivalency must contain:

- (1) The name of the submitter.
- (2) The specific identity of the microorganism.
- (3) The citation for the specific section in subpart M of this part which pertains to the microorganism for which the request is being submitted.
- (4) A detailed description of the activities involved.
- (5) The specifications of the alternative worker exposure control measures or environmental release control measures.
- (6) A detailed analysis explaining why such alternative control measures provide substantially the same degree of protection as the specific control measures identified in the specific section in subpart M of this part which

pertains to the microorganism for which the request is being submitted.

(7) The data and information described in §§ 725.155 and 725.160. If such data and information have already been submitted to EPA's Office of Pollution Prevention and Toxics, the submitter need only document that it was previously submitted, to whom, and the date it was submitted.

(c) Requests for determinations of equivalency will be reviewed by EPA within 45 days. Determinations under this paragraph will be made by the Director, or a designee. Notice of the results of such determinations will be mailed to the submitter.

(d) If EPA notifies the submitter under paragraph (c) of this section that EPA has determined that the alternative control measures provide substantially the same degree of protection as the specified control measures identified in the specific section of subpart M of this part which pertains to the microorganism for which the request is being submitted, the submitter may commence manufacture, import, or processing in accordance with the specifications for alternative worker exposure control measures or environmental release control measures identified in the submitter's request, and may alter any corresponding notification to workers to reflect such alternative controls. Deviations from the activities described in the EPA notification constitute a significant new use and are subject to the requirements of this part.

[62 FR 17932, April 11, 1997, as amended at 75 FR 790, Jan. 6, 2010]

§ 725.980 Expedited procedures for issuing significant new use rules for microorganisms subject to section 5(e) orders.

(a) *Selection of microorganisms.* (1) In accordance with the expedited process specified in this section, EPA will issue significant new use notification requirements for each new microorganism that, after MCAN review under subpart D of this part, becomes subject to a final order issued under section 5(e) of the Act, except for an order that prohibits manufacture and import of

the microorganism, unless EPA determines that significant new use notification requirements are not needed for the microorganism.

(2) If EPA determines that significant new use notifications requirements are not needed for a microorganism that is subject to a final order issued under section 5(e) of the Act, EPA will issue a notice in the FEDERAL REGISTER explaining why the significant new use requirements are not needed.

(b) *Designation of requirements.* (1) The significant new use notification and other specific requirements will be based on and be consistent with the provisions included in the final order issued for the microorganism under section 5(e) of the Act. EPA may also designate additional activities as significant new uses which will be subject to notification.

(2) Significant new use requirements and other specific requirements designated under this section will be listed in subpart M of this part. For each microorganism, subpart M of this part will identify:

(i) The microorganism name.

(ii) The activities designated as significant new uses.

(iii) Other specific requirements applicable to the microorganism, including recordkeeping requirements or any other requirements included in the final section 5(e) order.

(c) *Procedures for issuing significant new use rules*—(1) *Possible processes.* EPA will issue significant new use rules (SNURs) under this section by one of the following three processes: direct final rulemaking, interim final rulemaking, or notice and comment rulemaking. EPA will use the direct final rulemaking process to issue significant new use rules unless it determines that, in a particular case, one of the other processes is more appropriate.

(2) *Notice in the Federal Register.* FEDERAL REGISTER documents issued to propose or establish significant new uses under this section will contain the following:

(i) The microorganism identity or, if its specific identity is claimed confidential, an appropriate generic micro-

organism name and an accession number assigned by EPA.

(ii) The MCAN number.

(iii) A summary of EPA's findings under section 5(e)(1)(A) of the Act for the final order issued under section 5(e).

(iv) Designation of the significant new uses subject to, or proposed to be subject to, notification and any other applicable requirements.

(v) Any modification of subpart L of this part applicable to the specific microorganism and significant new uses.

(vi) If the FEDERAL REGISTER document establishes a final rule, or notifies the public that a final rule will not be issued after public comment has been received, the document will describe comments received and EPA's response.

(3) *Direct final rulemaking.* (i) EPA will use direct final rulemaking to issue a significant new use rule, when specific requirements will be based on and be consistent with the provisions included in the final order issued for the microorganism under section 5(e) of the Act. EPA will issue a final rule in the FEDERAL REGISTER following its decision to develop a significant new use rule under this section for a specific new microorganism.

(ii) The FEDERAL REGISTER document will state that, unless written notice is received by EPA within 30 days of publication that someone wishes to submit adverse or critical comments, the rule will be effective 60 days from the date of publication. The written notice of intent to submit adverse or critical comments should state which SNUR(s) will be the subject of the adverse or critical comments, if several SNURs are established through the direct final rule. If notice is received within 30 days that someone wishes to submit adverse or critical comments, the section(s) of the direct final rule containing the SNUR(s) for which a notice of intent to comment was received will be withdrawn by EPA issuing a document in the final rule section of the FEDERAL REGISTER, and a proposal will be published in the proposed rule section of the FEDERAL REGISTER. The proposal will establish a 30-day comment period.

(iii) If EPA, having considered any timely comments submitted in response to the proposal, decides to establish notification requirements under this section, EPA will issue a final rule adding the microorganism to subpart M of this part and designating the significant new uses subject to notification.

(4) *Interim final rulemaking.* (i) EPA will use the interim final rulemaking procedure to issue a significant new use rule, when specific requirements will be based on and be consistent with the provisions included in the final order issued for the microorganism under section 5(e) of the Act. The Agency will issue an interim final rule in the FEDERAL REGISTER following its decision to develop a significant new use rule for a specific new microorganism. The document will state EPA's reasons for using the interim final rulemaking procedure.

(A) The significant new use rule will take effect on the date of publication.

(B) Persons will be given 30 days from the date of publication to submit comments.

(ii) Interim final rules issued under this section shall cease to be in effect 180 days after publication unless, within the 180-day period, EPA issues a final rule in the FEDERAL REGISTER responding to any written comments received during the 30-day comment period specified in paragraph (c)(4)(i)(B) of this section and promulgating final significant new use notification requirements and other requirements for the microorganism.

(5) *Notice and comment rulemaking.* (i) EPA will use a notice and comment procedure to issue a significant new use rule, when EPA is designating additional activities which are not provisions included in the final order issued for the microorganism under section 5(e) of the Act as significant new uses which will be subject to notification. EPA will issue a proposal in the FEDERAL REGISTER following its decision to develop a significant new use rule under this section for a specific new microorganism. Persons will be given 30 days to comment on whether EPA should establish notification requirements for the microorganism under this part.

(ii) If EPA, having considered any timely comments, decides to establish notification requirements under this section, EPA will issue a final rule adding the microorganism to subpart M of this part and designating the significant new uses subject to notification.

(d) *Schedule for issuing significant new use rules.* (1) Unless EPA determines that a significant new use rule should not be issued under this section, EPA will issue a proposed rule, a direct final rule, or an interim final rule within 180 days of receipt of a valid notice of commencement under § 725.190.

(2) If EPA receives adverse or critical significant comments following publication of a proposed or interim final rule, EPA will either withdraw the rule or issue a final rule addressing the comments received.

§ 725.984 Modification or revocation of certain notification requirements.

(a) *Criteria for modification or revocation.* EPA may at any time modify or revoke significant new use notification requirements for a microorganism which has been added to subpart M of this part using the procedures of § 725.980. Such action may be taken under this section if EPA makes one of the following determinations, unless other information shows that the requirements should be retained:

(1) Test data or other information obtained by EPA provide a reasonable basis for concluding that activities designated as significant new uses of the microorganism will not present an unreasonable risk of injury to health or the environment.

(2) EPA has promulgated a rule under section 4 or 6 of the Act, or EPA or another agency has taken action under another law, for the microorganism that eliminates the need for significant new use notification under section 5(a)(2) of the Act.

(3) EPA has received MCANs for some or all of the activities designated as significant new uses of the microorganism and, after reviewing such MCANs, concluded that there is no need to require additional notice from persons who propose to engage in identical or similar activities.

(4) EPA has examined new information, or has reexamined the test data

§ 725.1000

40 CFR Ch. I (7–1–12 Edition)

or other information supporting its finding under section 5(e)(1)(A)(ii)(I) of the Act and has concluded that a rational basis no longer exists for the findings that activities involving the microorganism may present an unreasonable risk of injury to health or the environment required under section 5(e)(1)(A) of the Act.

(5) Certain activities involving the microorganism have been designated as significant new uses pending the completion of testing, and adequate test data developed in accordance with applicable procedures and criteria have been submitted to EPA.

(b) *Procedures for limitation or revocation.* Modification or revocation of significant new use notification requirements for a microorganism that has been added to subpart M of this part using the procedures described in § 725.980 may occur either at EPA's initiative or in response to a written request.

(1) Any affected person may request modification or revocation of significant new use notification requirements for a microorganism that has been added to subpart M of this part using the procedures described in § 725.980 by writing to the Director, or a designee, and stating the basis for such request. The request must be accompanied by information sufficient to support the request. Persons submitting a request to EPA under this part, unless allowed by § 725.25(c)(1), (c)(2), or (c)(3), must submit the request to EPA via EPA's Central Data Exchange (CDX) using EPA-provided e-PMN reporting software in the manner set forth in § 725.25(c). See 40 CFR 720.40(a)(2)(iv) for information on how to obtain the e-PMN software. Support documents related to these requests must also be submitted to EPA via CDX using e-PMN software. Paper requests must be submitted either via U.S. mail to the Document Control Office (DCO) (7407M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; ATTN: Request to Amend SNUR or submitted via courier to the Environmental Protection Agency, OPPT Document Control Office (DCO), EPA East Bldg., 1201 Constitution Ave., NW., Rm. 6428, Wash-

ington, DC 20004; ATTN: Request to Amend SNUR. Optical discs containing electronic requests must be submitted by courier to the Environmental Protection Agency, OPPT Document Control Office (DCO), EPA East Bldg., 1201 Constitution Ave., NW., Rm. 6428, Washington, DC 20004; ATTN: Request to Amend SNUR.

(2) The Director, or a designee, will consider the request, make a determination whether to initiate rulemaking to modify the requirements, and notify the requester of that determination by certified letter. If the request is denied, the letter will explain why EPA has concluded that the significant new use notification requirements for that microorganism should remain in effect.

(3) If EPA concludes that significant new use notification requirements for a microorganism should be limited or revoked, EPA will propose the changes in a notice in the FEDERAL REGISTER, briefly describe the grounds for the action, and provide interested parties an opportunity to comment.

[62 FR 17932, April 11, 1997, as amended at 75 FR 790, Jan. 6, 2010]

Subpart M—Significant New Uses for Specific Microorganisms

§ 725.1000 Scope.

This subpart identifies uses of microorganisms which EPA has determined to be significant new uses under the authority of section 5(a)(2) of the Toxic Substances Control Act.

§ 725.1075 *Burkholderia cepacia* complex.

(a) *Microorganism and significant new uses subject to reporting.* (1) The microorganisms identified as the *Burkholderia cepacia* complex defined as containing the following nine species, *Burkholderia cepacia*, *Burkholderia multivorans*, *Burkholderia stabilis*, *Burkholderia vietnamiensis*, *Burkholderia ambifaria*, *Burkholderia pyrrocinia*, *Burkholderia cepacia* genomovar VIII (*Burkholderia anthina*), and *Burkholderia cepacia* genomovars III and VI are subject to reporting under this section for the significant new