

§ 725.975

40 CFR Ch. I (7-1-14 Edition)

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

(b) Persons submitting a request for a determination of equivalency to EPA under this part must submit the request to EPA (via CDX) using e-PMN

software. See 40 CFR 720.40(a)(2)(ii) 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. 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, Apr. 11, 1997, as amended at 75 FR 790, Jan. 6, 2010; 78 FR 72828, Dec. 4, 2013]

§ 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 microorganism 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