

activities described in the EPA notification constitute a significant new use and are subject to the requirements of this part.

**§ 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 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