EPA will list the specific microorganism identity on the public Inventory.

(d) *Where to submit.* All notices of commencement must be submitted to EPA in a manner set forth in this paragraph.

(1) *Older notices.* Notices of commencement for a MCAN submitted before April 6, 2010 must be submitted on paper 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 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.

(2) *Newer notices.* For MCANs submitted on or after April 6, 2010, EPA will accept notices of commencement only if submitted in accordance with this paragraph:

(i) Notices of commencement may be submitted on paper on or before April 6, 2011. All paper-based notices of commencement must be generated using e-PMN reporting software and be completed through the finalization step of the software, and e-PMN software must be used to print the statement of withdrawal for submission to EPA. Paper notices of commencement 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 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.

(ii) Notices of commencement may be submitted as electronic files on optical disc on or before April 6, 2012. All notices of commencement submitted as electronic files on optical disc must be generated using e-PMN reporting software and be completed through the finalization step of the software. Optical discs containing electronic notices of commencement 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.

(iii) Notices of commencement may be submitted electronically to EPA via CDX on or after April 6, 2010. After April 6, 2012 all notices of commencement must be submitted electronically to EPA via CDX. Prior to submission to EPA via CDX, such notices of commencement must be generated and completed using e-PMN reporting software. See 40 CFR 720.40(a)(2)(iv) for information on how to obtain e-PMN software.

[62 FR 17932, April 11, 1997, as amended at 75 FR 789, Jan. 6, 2010]

Subpart E—Exemptions for Research and Development Activities

§ 725.200 Scope and purpose.

(a) This subpart describes exemptions from the reporting requirements under subpart D of this part for research and development activities involving microorganisms.

(b) In lieu of complying with subpart D of this part, persons described in § 725.205 may submit a TSCA Experimental Release Application (TERA) for research and development activities involving microorganisms or otherwise comply with this subpart.

(c) Exemptions from part 725 are provided at §§ 725.232, 725.234, and 725.238.

(d) Submission requirements specific for TERAs are described at § 725.250.

(e) Data requirements for TERAs are set forth in §§ 725.255 and 725.260.

(f) EPA review procedures specific for TERAs are set forth in §§ 725.270 and 725.288.

(g) Subparts A through C of this part apply to any submission under this subpart.

§ 725.205 Persons who may report under this subpart.

(a) Commercial research and development activities involving new microorganisms or significant new uses of microorganisms are subject to reporting under this part unless they qualify for an exemption under this part.

(b) Commercial purposes for research and development means that the activities are conducted with the purpose

of obtaining an immediate or eventual commercial advantage for the researcher and would include:

(1) All research and development activities which are funded directly, in whole or in part, by a commercial entity regardless of who is actually conducting the research. Indications that the research and development activities are funded directly, in whole or in part, may include, but are not limited to:

(i) Situations in which a commercial entity contracts directly with a university or researcher; or

(ii) Situations in which a commercial entity gives a conditional grant where the commercial entity holds patent rights, or establishes a joint venture where the commercial entity holds patent or licensing rights; or

(iii) Any other situation in which the commercial entity intends to obtain an immediate or eventual commercial advantage for the commercial entity and/or the researcher.

(2) Research and development activities that are not funded directly by a commercial entity, if the researcher intends to obtain an immediate or eventual commercial advantage. Indications that the researcher intends to obtain an immediate or eventual commercial advantage may include, but are not limited to:

(i) The research is directed toward developing a commercially viable improvement of a product already on the market; or

(ii) The researcher has sought or is seeking commercial funding for the purpose of developing a commercial application; or

(iii) The researcher or university has sought or is seeking a patent to protect a commercial application which the research is developing; or

(iv) Other evidence that the researcher is aware of a commercial application for the research and has directed the research toward developing that application.

(c) Certain research and development activities involving microorganisms subject to jurisdiction under the Act are exempt from reporting under this part. A person conducting research and development activities which meet the conditions for the exemptions described in §§ 725.232, 725.234, or 725.238 is exempt from TERA reporting under this subpart.

(d) A microorganism is not exempt from reporting under subpart D of this part if any amount of the microorganism, including as part of a mixture, is processed, distributed in commerce, or used, for any commercial purpose other than research and development.

(e) Quantities of the inactivated microorganism, or mixtures or articles containing the inactivated microorganism, remaining after completion of research and development activities may be disposed of as a waste in accordance with applicable Federal, State, and local regulations.

(f) A person who manufactures, imports, or processes a microorganism solely for research and development is not required to comply with the requirements of this section if:

(1) The person is manufacturing a microbial pesticide identified in § 172.45(c), or

(2) The person is manufacturing a microbial pesticide for which an Experimental Use Permit is required, pursuant to § 172.3; or

(3) The person is manufacturing a microbial pesticide for which a notification or an Experimental Use Permit is not required to be submitted.

§ 725.232 Activities subject to the jurisdiction of other Federal programs or agencies.

This part does not apply to any research and development activity that meets all of the following conditions.

(a) The microorganism is manufactured, imported, or processed solely for research and development activities.

(b) There is no intentional testing of a microorganism outside of a structure, as structure is defined in § 725.3.

(c)(1) The person receives research funds from another Federal agency, and the funds are awarded on the condition that the research will be conducted in accordance with the relevant portions of the NIH Guidelines, or

(2) A Federal agency or program otherwise imposes the legally binding requirement that the research is to be conducted in accordance with relevant portions of the NIH Guidelines.