(ii) Any data, including test data, which are not in the submitter's possession or control, but which are known to or reasonably ascertainable by the submitter. For the purposes of this section, data are known to or reasonably ascertainable by the submitter if the data are known to any of its employees or other agents who are associated with the research and development, test marketing, or commercial marketing of the microorganism.

(2) Data that must be described include data concerning the new microorganism in a pure culture or formulated form as used or as intended to be used in one of the activities listed in paragraph (b)(1) of this section.

(3) The description of data reported under paragraph (b) of this section must include:

(i) If the data appear in the open scientific literature, a standard literature citation, which includes the author, title, periodical name, date of publication, volume, and pages.

(ii) If the data are not available in the open scientific literature, a description of the type of data and summary of the results, if available, and the names and addresses of persons the submitter believes may have possession or control of the data.

(4) All data described in paragraph (b) of this section are subject to these requirements, regardless of their age, quality, or results; and regardless of whether they are complete at the time the MCAN is submitted.

§ 725.170 EPA review of the MCAN.

General procedures for review of all submissions under this part are contained in §§ 725.28 through 725.60. In addition, the following procedures apply to EPA review of MCANs submitted under this subpart:

(a) Length of the review period. The MCAN review period specified in section 5(a) of the Act runs for 90 days from the date the Document Control Officer for the Office of Pollution Prevention and Toxics receives a complete MCAN, or the date EPA determines the MCAN is complete under § 725.33, unless the Agency extends the period under section 5(c) of the Act and § 725.56.

(b) Notice of expiration of MCAN review period. (1) EPA will notify the submitter that the MCAN review period has expired or that EPA has completed its review of the MCAN. Expiration of the review period does not constitute EPA approval or certification of the new microorganism, and does not mean that EPA may not take regulatory action against the microorganism in the future.

(2) After expiration of the MCAN review period, in the absence of regulatory action by EPA under section 5(e), 5(f), or 6(a) of the Act, the submitter may manufacture or import the microorganism even if the submitter has not received notice of expiration.

(3) Early notification that EPA has completed its review does not permit commencement of manufacture or import prior to the expiration of the 90–day MCAN review period.

(c) No person submitting a MCAN in response to the requirements of this subpart may manufacture, import, or process a microorganism subject to this subpart until the review period, including all extensions and suspensions, has expired.

§ 725.190 Notice of commencement of manufacture or import.

(a) *Applicability.* Any person who commences the manufacture or import of a new microorganism for nonexempt, commercial purposes for which that person previously submitted a section 5(a) notice under this part must submit a notice of commencement (NOC) of manufacture or import.

(b) *When to report.* (1) If manufacture or import for nonexempt, commercial purposes begins on or after May 27, 1997, the submitter must submit the NOC to EPA no later than 30 calendar days after the first day of such manufacture or import.

(2) If manufacture or import for nonexempt, commercial purposes began or will begin before May 27, 1997, the submitter must submit the NOC by May 27, 1997.

(3) Submission of an NOC prior to the commencement of manufacture or import is a violation of section 15 of the Act.

(c) *Information to be reported.* The NOC must contain the following information: Specific microorganism identity, MCAN number, and the date when

manufacture or import commences. If the person claimed microorganism identity confidential in the MCAN, and wants the identity to be listed on the confidential Inventory, the claim must be reasserted and resubstantiated in accordance with § 725.85(b). Otherwise, EPA will list the specific microorganism identity on the public Inventory.

(d) *How to submit.* All notices of commencement must be generated, completed, and submitted 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.

[62 FR 17932, Apr. 11, 1997, as amended at 75 FR 789, Jan. 6, 2010; 78 FR 72828, Dec. 4, 2013]

EFFECTIVE DATE NOTE: At 88 FR 37174, June 7, 2023, § 725.190 was amended by revising paragraph (c) and adding paragraphs (e) and (f), effective Aug. 7, 2023. For the convenience of the user, the added and revised text is set forth as follows:

§ 725.190 Notice of commencement of manufacture or import.

* * * * *

(c) *Information to be reported.* The NOC must contain the following information: Specific microorganism identity, MCAN number, and the date when manufacture or import commences. If the person claims any information on the form as confidential, the claim must be asserted and substantiated in accordance with the requirements described in part 703 of this subchapter and § 725.80, as indicated in EPA Form 7710–56. If the submitter wants the microorganism identity to be listed on the confidential portion of the TSCA Inventory, the microorganism identity must be claimed as confidential and also follow the certification, substantiation, and generic name requirements described in part 703 of this subchapter and paragraphs (e) and (f) of this section.

* * * * *

(e) *Requirements for assertion.* Any person who asserts a confidentiality claim for microorganism identity must:

(1) Comply with the requirements of paragraph (f) of this section regarding submission of a generic name.

(2) Agree that EPA may disclose to a person with a *bona fide* intent to manufacture or import the microorganism the fact that the particular microorganism is included on the confidential TSCA Inventory for purposes of notification under section 5(a)(1)(A) of the Act.

(3) Have available and agree to furnish to EPA upon request the taxonomic designations and supplemental information required by § 725.12.

(4) Make claims of confidentiality in accordance with the procedures described in 40 CFR part 703.

(f) *Generic name.* If a submitter asserts a claim of confidentiality for microorganism identity in a notice of commencement, they must provide a generic name.

(1) Generic names must:

(i) Be structurally descriptive (e.g., not a trade name); and

(ii) Be consistent with guidance on the determination of structurally descriptive generic names, developed in accordance with section 14(c)(4)(A) of the Act (e.g., *Guidance for Creating Generic Names for Confidential Chemical Substance Identity Reporting under TSCA*). Generic names for microorganisms may only mask the portion of microorganism identity that the submitter believes is proprietary (considering that the identity of a microorganism to be listed on the TSCA Inventory must include taxonomic designations (genus, species, and strain), key phenotypic traits, key genotypic traits and modifications, genetic material that has been introduced or modified, any vector constructs used, cellular location of introduced or modified genes, number and type of genes introduced or modified, and method of construction or modification). Taxonomic designation (in most cases down to strain) must be included in the generic name except where the submitter claims the taxonomic designation confidential, in which case the person making such claim must provide an explanation of why such masking is necessary to protect proprietary information. Additionally, the generic microorganism identity must include a statement regarding the function and stability of the genetic construct. This includes an indication of whether the introduced or modified genes are present on the chromosome or extrachromosomal.

(2) Generic names will be reviewed by EPA at the time of submission.

(i) If EPA concludes that a proposed generic name meets the criteria in paragraph (f)(1) of this section, EPA will include that generic name in the public TSCA Inventory listing for that substance.

(ii) If the proposed generic name does not meet the criteria in paragraph (f)(1) of this section, EPA will notify the submitter concerning the deficiency via CDX, as described in § 703.5(h) of this subchapter. EPA will provide ten business days to correct the deficiency and provide an alternative generic name that would be acceptable to EPA. If the alternative generic name proposed by EPA is acceptable to the submitter (or if the submitter does not respond within the ten-day period), EPA will place that alternative

generic name on the public TSCA Inventory. If the alternative generic name proposed by EPA is not acceptable to the submitter, the submitter must submit a revised generic name that meets the criteria in paragraph (f)(1) of this section and an explanation of how EPA's proposed generic name reveals confidential information. If EPA concludes that the revised generic name also does not meet the criteria in paragraph (f)(1) of this section, EPA will hold the notice of commencement for a period of up to 10 business days. Reporting requirements will not be considered to have been met and the microorganism will not be added to the TSCA Inventory during this period. If the submission remains deficient after this 10-day period, EPA will proceed with CBI review of the microorganism identity claim and will likely deny the claim.

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