

Environmental Protection Agency

§ 725.1

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Subpart A—General Provisions and Applicability

§ 725.1 Scope and purpose.

(a) This part establishes all reporting requirements under section 5 of TSCA for manufacturers, importers, and processors of microorganisms subject to TSCA jurisdiction for commercial purposes, including research and development for commercial purposes. New microorganisms for which manufacturers and importers are required to report under section 5(a)(1)(A) of TSCA are those that are intergeneric. In addition, under section 5(a)(1)(B) of TSCA, manufacturers, importers, and processors may be required to report for any microorganism that EPA determines by rule is being manufactured, imported, or processed for a significant new use.

(b) Any manufacturer, importer, or processor required to report under section 5 of TSCA (see § 725.100 for new microorganisms and § 725.900 for significant new uses) must file a Microbial Commercial Activity Notice (MCAN) with EPA, unless the activity is eligible for a specific exemption as described in this part. The general procedures for filing MCANs are described in subpart D of this part. The exemptions from the requirement to file a MCAN are for certain kinds of contained activities (see §§ 725.424 and 725.428), test marketing activities (see § 725.300), and research and development activities described in paragraph (c) of this section.

(c) Any manufacturer, importer, or processor required to file a MCAN for research and development (R&D) activities may instead file a TSCA Experimental Release Application (TERA) for a specific test (see § 725.250). A TERA is not required for certain R&D activities; however a TERA exemption does not extend beyond the research and development stage, to general commercial use of the microorganism, for which compliance with MCAN requirements is required. The TERA exemptions are for R&D activities subject to other Federal agencies or programs (see § 725.232), certain kinds of contained R&D activities (see § 725.234), and R&D activities using certain listed microorganisms (see § 725.238).

(d) New microorganisms will be added to the Inventory established under section 8 of TSCA once a MCAN has been received, the MCAN review period has expired, and EPA receives a Notice of Commencement (NOC) indicating that manufacture or importation has actually begun. New microorganisms approved for use under a TERA will not be added to the Inventory until a MCAN has been received, the MCAN review period has expired, and EPA has received an NOC.

§ 725.3 Definitions.

Definitions in section 3 of the Act (15 U.S.C. 2602), as well as definitions contained in §§ 704.3, 720.3, and 721.3 of this chapter, apply to this part unless otherwise specified in this section. In addition, the following definitions apply to this part:

Consolidated microbial commercial activity notice or *consolidated MCAN* means any MCAN submitted to EPA that covers more than one microorganism (each being assigned a separate MCAN number by EPA) as a result of a prenotice agreement with EPA.

Containment and/or inactivation controls means any combination of engineering, mechanical, procedural, or biological controls designed and operated to restrict environmental release of viable microorganisms from a structure.

Director means the Director of the EPA Office of Pollution Prevention and Toxics.

Exemption request means any application submitted to EPA under subparts E, F, or G of this part.

General commercial use means use for commercial purposes other than research and development.

Genome means the sum total of chromosomal and extrachromosomal genetic material of an isolate and any descendants derived under pure culture conditions from that isolate.

Health and safety study of a microorganism or *health and safety study* means any study of any effect of a microorganism or microbial mixture on health or the environment or on both, including underlying data and epidemiological studies, studies of occupational exposure to a microorganism or microbial mixture, toxicological, clinical, and ec-

ological, or other studies of a microorganism or microbial mixture, and any test performed under the Act. Microorganism identity is always part of a health and safety study of a microorganism.

(1) It is intended that the term “health and safety study of a microorganism” be interpreted broadly. Not only is information which arises as a result of a formal, disciplined study included, but other information relating to the effects of a microorganism or microbial mixture on health or the environment is also included. Any data that bear on the effects of a microorganism on health or the environment would be included.

(2) Examples include:

(i) Tests for ecological or other environmental effects on invertebrates, fish, or other animals, and plants, including: Acute toxicity tests, chronic toxicity tests, critical life stage tests, behavioral tests, algal growth tests, seed germination tests, plant growth or damage tests, microbial function tests, bioconcentration or bioaccumulation tests, and model ecosystem (microcosm) studies.

(ii) Long- and short-term tests of mutagenicity, carcinogenicity, or teratogenicity; dermatotoxicity; cumulative, additive, and synergistic effects; and acute, subchronic, and chronic effects.

(iii) Assessments of human and environmental exposure, including workplace exposure, and impacts of a particular microorganism or microbial mixture on the environment, including surveys, tests, and studies of: Survival and transport in air, water, and soil; ability to exchange genetic material with other microorganisms, ability to colonize human or animal guts, and ability to colonize plants.

(iv) Monitoring data, when they have been aggregated and analyzed to measure the exposure of humans or the environment to a microorganism.

(v) Any assessments of risk to health and the environment resulting from the manufacture, processing, distribution in commerce, use, or disposal of the microorganism.

Inactivation means that living microorganisms are rendered nonviable.