

## Environmental Protection Agency

## § 725.12

for a research and development activity, which is not eligible for a full exemption from reporting under § 725.232, 725.234, or 725.238, submitted to EPA in accordance with subpart E of this part.

*Well-characterized* for introduced genetic material means that the following have been determined:

(1) The function of all of the products expressed from the structural gene(s).

(2) The function of sequences that participate in the regulation of expression of the structural gene(s).

(3) The presence or absence of associated nucleotide sequences and their associated functions, where associated nucleotide sequences are those sequences needed to move genetic material including linkers, homopolymers, adaptors, transposons, insertion sequences, and restriction enzyme sites.

### § 725.8 Coverage of this part.

(a) *Microorganisms subject to this part.* Only microorganisms which are manufactured, imported, or processed for commercial purposes, as defined in § 725.3, are subject to the requirements of this part.

(b) *Microorganisms automatically included on the Inventory.* Microorganisms that are not intergeneric are automatically included on the Inventory.

(c) *Microorganisms not subject to this part.* The following microorganisms are not subject to this part, either because they are not subject to jurisdiction under the Act or are not subject to reporting under section 5 of the Act.

(1) Any microorganism which would be excluded from the definition of "chemical substance" in section 3 of the Act and § 720.3(e) of this chapter.

(2) Any microbial mixture as defined in § 725.3. This exclusion applies only to a microbial mixture as a whole and not to any microorganisms and other chemical substances which are part of the microbial mixture.

(3) Any microorganism that is manufactured and processed solely for export if the following conditions are met:

(i) The microorganism is labeled in accordance with section 12(a)(1)(B) of the Act, when the microorganism is distributed in commerce.

(ii) The manufacturer and processor can document at the commencement of manufacturing or processing that the person to whom the microorganism will be distributed intends to export it or process it solely for export as defined in § 721.3 of this chapter.

### § 725.12 Identification of microorganisms for Inventory and other listing purposes.

To identify and list microorganisms on the Inventory, both taxonomic designations and supplemental information will be used. The supplemental information required in paragraph (b) of this section will be used to specifically describe an individual microorganism on the Inventory. Submitters must provide the supplemental information required by paragraph (b) of this section to the extent necessary to enable a microorganism to be accurately and unambiguously identified on the Inventory.

(a) *Taxonomic designation.* The taxonomic designation of a microorganism must be provided for the donor organism and the recipient microorganism to the level of strain, as appropriate. These designations must be substantiated by a letter from a culture collection, literature references, or the results of tests conducted for the purpose of taxonomic classification. Upon EPA's request to the submitter, data supporting the taxonomic designation must be provided to EPA. The genetic history of the recipient microorganism should be documented back to the isolate from which it was derived.

(b) *Supplemental information.* The supplemental information described in paragraphs (b)(1) and (b)(2) of this section is required to the extent that it enables a microorganism to be accurately and unambiguously identified.

(1) *Phenotypic information.* Phenotypic information means pertinent traits that result from the interaction of a microorganism's genotype and the environment in which it is intended to be used and may include intentionally added biochemical and physiological traits.

(2) *Genotypic information.* Genotypic information means the pertinent and distinguishing genotypic characteristics of a microorganism, such as the

identity of the introduced genetic material and the methods used to construct the reported microorganism. This also may include information on the vector construct, the cellular location, and the number of copies of the introduced genetic material.

**§ 725.15 Determining applicability when microorganism identity or use is confidential or uncertain.**

(a) *Consulting EPA.* Persons intending to conduct activities involving microorganisms may determine their obligations under this part by consulting the Inventory or the microorganisms and uses specified in § 725.239 or in subpart M of this part. This section establishes procedures for EPA to assist persons in determining whether the microorganism or the use is listed on the Inventory, in § 725.239 or in subpart M of this part.

(1) Confidential identity or use. In some cases it may not be possible to directly determine if a specific microorganism is listed, because portions of that entry may contain generic information to protect confidential business information (CBI). If any portion of the microorganism's identity or use has been claimed as CBI, that portion does not appear on the public version of the Inventory, in § 725.239 or in subpart M of this part. Instead, it is contained in a confidential version held in EPA's Confidential Business Information Center (CBIC). The public versions contain generic information which masks the confidential business information. A person who intends to conduct an activity involving a microorganism or use whose entry is described with generic information will need to inquire of EPA whether the unreported microorganism or use is on the confidential version.

(2) Uncertain microorganism identity. The current state of scientific knowledge leads to some imprecision in describing a microorganism. As the state of knowledge increases, EPA will be developing policies to determine whether one microorganism is equivalent to another. Persons intending to conduct activities involving microorganisms may inquire of EPA whether the microorganisms they intend to manufacture, import, or process are

equivalent to specific microorganisms described on the Inventory, in § 725.239, or in subpart M of this part.

(b) *Requirement of bona fide intent.* (1) EPA will answer the inquiries described in paragraph (a) of this section only if the Agency determines that the person has a *bona fide* intent to conduct the activity for which reporting is required or for which any exemption may apply.

(2) To establish a *bona fide* intent to manufacture, import, or process a microorganism, the person who intends to manufacture, import, or process the microorganism must submit the following information in writing to the Office of Pollution Prevention and Toxics, Document Control Officer, 7407, 1200 Pennsylvania Ave., NW., Washington, DC 20460, ATTN: BIOTECH *bona fide* submission.

(i) Taxonomic designations and supplemental information required by § 725.12.

(ii) A signed statement certifying that the submitter intends to manufacture, import, or process the microorganism for commercial purposes.

(iii) A description of research and development activities conducted with the microorganism to date, demonstration of the submitter's ability to produce or obtain the microorganism from a foreign manufacturer, and the purpose for which the person will manufacture, import, or process the microorganism.

(iv) An indication of whether a related microorganism was previously reviewed by EPA to the extent known by the submitter.

(v) A specific description of the major intended application or use of the microorganism.

(c) If an importer or processor cannot provide all the information required by paragraph (b) of this section, because it is claimed as confidential business information by its foreign manufacturer or supplier, the foreign manufacturer or supplier may supply the information directly to EPA.

(d) EPA will review the information submitted by the manufacturer, importer, or processor under this paragraph to determine whether that person has shown a *bona fide* intent to manufacture, import, or process the