

40 C.F.R. § 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 ecological, 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.

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