

40 C.F.R. § 725.100

Scope and purpose.

(a) This subpart establishes procedures for submission of a notice to EPA under section 5(a) of the Act for persons who manufacture, import, or process microorganisms for commercial purposes. This notice is called a Microbial Commercial Activity Notice (MCAN). It is expected that MCANs will in general only be submitted for microorganisms intended for general commercial use. Persons who manufacture, import, or process a microorganism in small quantities solely for research and development as defined in § 725.3 are not required to submit a notice to EPA. Persons who manufacture, import, or process a microorganism for research and development activities that do not fit the definition of small quantities solely for research and development may nonetheless qualify for more limited reporting requirements in subpart E, including the TERA which can be used for review of research and development involving environmental release.

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