
40 C.F.R. § 725.160

Submission of health and environmental effects data.

(a) *Test data on the new microorganism in the possession or control of the submitter.* (1) Except as provided in § 725.25(h), and in addition to the information required by § 725.155(d)(3), each MCAN must contain all test data in the submitter's possession or control which are related to the effects on health or the environment of any manufacture, processing, distribution in commerce, use, or disposal of the new microorganism or any microbial mixture or article containing the new microorganism, or any combination of such activities. This includes test 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 above.

(2) A full report or standard literature citation must be submitted for the following types of test data:

(i) Health effects data.

(ii) Ecological effects data.

(iii) Physical and chemical properties data.

(iv) Environmental fate characteristics.

(v) Monitoring data and other test data related to human exposure to or environmental release of the new microorganism.

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