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40 C.F.R. § 725.235

Conditions of exemption for activities conducted inside a structure.

(a) *Determination of risks.* To determine whether notification under § 725.234(e) is required, the manufacturer, importer, or processor must do one of the following:

(1) For research conducted in accordance with the NIH Guidelines, the manufacturer, importer, or processor must meet the conditions laid out at IV-B-4-d of the NIH Guidelines; or

(2) For all other research conducted in accordance with § 725.234, the manufacturer, importer, or processor must review and evaluate the following information to determine whether there is reason to believe there is any risk to health which may be associated with the microorganism:

(i) Information in its possession or control concerning any significant adverse reaction of persons exposed to the microorganism which may reasonably be associated with such exposure.

(ii) Information provided to the manufacturer, importer, or processor by a supplier or any other person concerning a health risk believed to be associated with the microorganism.

(iii) Health and environmental effects data in its possession or control concerning the microorganism.