

Environmental Protection Agency

§ 725.75

the Assistant Administrator for Prevention, Pesticides and Toxic Substances makes a preliminary determination that the new microorganism will not present an unreasonable risk of injury to health or the environment, the Assistant Administrator will propose a rule to grant the exemption using the applicable procedures in part 750 of this chapter.

(2) *Denial of the application.* If the Assistant Administrator decides that the preliminary determination described in paragraph (b)(1) of this section cannot be made, the application will be denied by sending the applicant a written statement with the Assistant Administrator's reasons for denial.

(c) *Processing of the exemption*—(1) *Unreasonable risk standard.* Granting a section 5(h)(4) exemption requires a determination that the activities will not present an unreasonable risk of injury to health or the environment.

(i) An unreasonable risk determination under the Act is an administrative judgment that requires balancing of the harm to health or the environment that a chemical substance may cause and the magnitude and severity of that harm, against the social and economic effects on society of EPA action to reduce that harm.

(ii) A determination of unreasonable risk under section 5(h)(4) of the Act will examine the reasonably ascertainable economic and social consequences of granting or denying the exemption after consideration of the effect on the national economy, small business, technological innovation, the environment, and public health.

(2) *Grant of the exemption.* The exemption will be granted if the Assistant Administrator determines, after consideration of all relevant evidence presented in the rulemaking proceeding described in paragraph (b)(1) of this section, that the new microorganism will not present an unreasonable risk of injury to health or the environment.

(3) *Denial of the exemption.* The exemption will be denied if the Assistant Administrator determines, after consideration of all relevant evidence presented in the rulemaking proceeding described in paragraph (b)(1) of this section, that the determination described in paragraph (c)(2) of this sec-

tion cannot be made. A final decision terminating the rulemaking proceeding will be published in the FEDERAL REGISTER.

[62 FR 17932, April 11, 1997, as amended at 75 FR 789, Jan. 6, 2010]

§ 725.70 Compliance.

(a) Failure to comply with any provision of this part is a violation of section 15 of the Act (15 U.S.C. 2614).

(b) A person who manufactures or imports a microorganism before a MCAN is submitted and the MCAN review period expires is in violation of section 15 of the Act even if that person was not required to submit the MCAN under § 725.105.

(c) Using a microorganism which a person knew or had reason to know was manufactured, processed, or distributed in commerce in violation of section 5 of the Act or this part is a violation of section 15 of the Act (15 U.S.C. 2614).

(d) Failure or refusal to establish and maintain records or to permit access to or copying of records, as required by the Act, is a violation of section 15 of the Act (15 U.S.C. 2614).

(e) Failure or refusal to permit entry or inspection as required by section 11 of the Act is a violation of section 15 of the Act (15 U.S.C. 2614).

(f) Violators may be subject to the civil and criminal penalties in section 16 of the Act (15 U.S.C. 2615) for each violation. Persons who submit materially misleading or false information in connection with the requirements of any provision of this part may be subject to penalties calculated as if they never filed their submissions.

(g) EPA may seek to enjoin the manufacture or processing of a microorganism in violation of this part or act to seize any microorganism manufactured or processed in violation of this part or take other actions under the authority of section 7 of the Act (15 U.S.C. 2606) or section 17 of the Act (15 U.S.C. 2616).

§ 725.75 Inspections.

EPA will conduct inspections under section 11 of the Act to assure compliance with section 5 of the Act and this part, to verify that information required by EPA under this part is true