

Environmental Protection Agency

§ 725.80

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

§ 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 and correct, and to audit data submitted to EPA under this part.

Subpart C—Confidentiality and Public Access to Information

§ 725.80 General provisions for confidentiality claims.

(a) A person may assert a claim of confidentiality for any information submitted to EPA under this part. However,

(1) Any person who asserts a claim of confidentiality for portions of the specific microorganism identity must provide the information as described in § 725.85.

(2) Any person who asserts a claim of confidentiality for a use of a microorganism must provide the information as described in § 725.88.

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(3) Any person who asserts a claim of confidentiality for information contained in a health and safety study of a microorganism must provide the information described in § 725.92.

(b) Any claim of confidentiality must accompany the information when it is submitted to EPA.

(1) When a person submits any information under this part, including any attachments, for which claims of confidentiality are made, the claim(s) must be asserted by circling the specific information which is claimed and marking the page on which that information appears with an appropriate designation such as “trade secret,” “TSCA CBI,” or “confidential business information.”

(2) If any information is claimed confidential, the person must submit two copies of the document including the claimed information.

(i) One copy of the document must be complete. In that copy, the submitter must mark the information which is claimed as confidential in the manner prescribed in paragraph (b)(1) of this section.

(ii) The second copy must be complete except that all information claimed as confidential in the first copy must be deleted. EPA will place the second copy in the public file.

(iii) If the submitter does not provide the second copy, the submission is incomplete and the review period does not begin to run until EPA receives the second copy, in accordance with § 725.33.

(iv) Any information contained within the copy submitted under paragraph (b)(2)(ii) of this section which has been in the public file for more than 30 days will be presumed to be in the public domain, notwithstanding any assertion of confidentiality made under this section.

(3) A person who submits information to EPA under this part must reassert a claim of confidentiality and substantiate the claim each time the information is submitted to EPA.

(c) Any person asserting a claim of confidentiality under this part must substantiate each claim in accordance with the requirements in § 725.94.

(d) EPA will disclose information that is subject to a claim of confiden-

tiality asserted under this section only to the extent permitted by the Act, this subpart, and part 2 of this title.

(e) If a submitter does not assert a claim of confidentiality for information at the time it is submitted to EPA, EPA may make the information public and place it in the public file without further notice to the submitter.

§ 725.85 **Microorganism identity.**

(a) *Claims applicable to the period prior to commencement of manufacture or import for general commercial use*—(1) *When to make a claim.* (i) A person who submits information to EPA under this part may assert a claim of confidentiality for portions of the specific microorganism identity at the time of submission of the information. This claim will apply only to the period prior to the commencement of manufacture or import for general commercial use.

(ii) A person who submits information to EPA under this part must reassert a claim of confidentiality and substantiate the claim each time the information is submitted to EPA. For example, if a person claims certain information confidential in a TERA submission and wishes the same information to remain confidential in a subsequent TERA or MCAN submission, the person must reassert and resubstantiate the claim in the subsequent submission.

(2) *Assertion of claim.* (i) A submitter may assert a claim of confidentiality only if the submitter believes that public disclosure prior to commencement of manufacture or import for general commercial use of the fact that anyone is initiating research and development activities pertaining to the specific microorganism or intends to manufacture or import the specific microorganism for general commercial use would reveal confidential business information. Claims must be substantiated in accordance with the requirements of § 725.94(a).

(ii) If the submission includes a health and safety study concerning the microorganism and if the claim for confidentiality with respect to the specific identity is denied in accordance with § 725.92(c), EPA will deny a claim