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(4) At the time any information is furnished to a contractor, subcontractor, or State or local government agency under this paragraph (h), the EPA office furnishing the information to the contractor, subcontractor, or State or local government agency shall notify the contractor, subcontractor, or State or local government agency that the information may be entitled to confidential treatment and that any knowing and willful disclosure of the information may subject the contractor, subcontractor, or State or local government agency and its employees to penalties in section 3001(b)(3)(B), 3007(b)(2), or 9005(b)(1) of the Act (42 U.S.C. 6921(b)(3)(B), 6927(b), or 6995(b)).

[43 FR 40003, Sept. 8, 1978, as amended at 50 FR 51662, Dec. 18, 1985]

§ 2.306 Special rules governing certain information obtained under the Toxic Substances Control Act.

(a) *Definitions.* For the purposes of this section:

(1) *Act* means the Toxic Substances Control Act, 15 U.S.C. 2601 *et seq.*

(2) *Chemical substance* has the meaning given it in section 3(2) of the Act, 15 U.S.C. 2602(2).

(3)(i) *Health and safety data* means the information described in paragraphs (a)(3)(i) (A), (B), and (C) of this section with respect to any chemical substance or mixture offered for commercial distribution (including for test marketing purposes and for use in research and development), any chemical substance included on the inventory of chemical substances under section 8 of the Act (15 U.S.C. 2607), or any chemical substance or mixture for which testing is required under section 4 of the Act (15 U.S.C. 2603) or for which notification is required under section 5 of the Act (15 U.S.C. 2604).

(A) Any study of any effect of a chemical substance or mixture on health, on the environment, or on both, including underlying data and epidemiological studies; studies of occupational exposure to a chemical substance or mixture; and toxicological, clinical, and ecological studies of a chemical substance or mixture;

(B) Any test performed under the Act; and

(C) Any data reported to, or otherwise obtained by, EPA from a study described in paragraph (a)(3)(i)(A) of this section or a test described in paragraph (a)(3)(i)(B) of this section.

(ii) Notwithstanding paragraph (a)(3)(i) of this section, no information shall be considered to be *health and safety data* if disclosure of the information would—

(A) In the case of a chemical substance or mixture, disclose processes used in the manufacturing or processing the chemical substance or mixture or,

(B) In the case of a mixture, disclose the portion of the mixture comprised by any of the chemical substances in the mixture.

(4) [Reserved]

(5) *Mixture* has the meaning given it in section 3(8) of the Act, 15 U.S.C. 2602(8).

(6) *Proceeding* means any rulemaking, adjudication, or licensing conducted by EPA under the Act or under regulations which implement the Act, except for determinations under this subpart.

(b) *Applicability.* This section applies to all information submitted to EPA for the purpose of satisfying some requirement or condition of the Act or of regulations which implement the Act, including information originally submitted to EPA for some other purpose and either relied upon to avoid some requirement or condition of the Act or incorporated into a submission in order to satisfy some requirement or condition of the Act or of regulations which implement the Act. Information will be considered to have been provided under the Act if the information could have been obtained under authority of the Act, whether the Act was cited as authority or not, and whether the information was provided directly to EPA or through some third person.

(c) *Basic rules which apply without change.* Sections 2.201 through 2.203, 2.206, 2.207, and 2.210 through 2.215 apply without change to information to which this section applies.

(d) *Initial action by EPA office.* Section 2.204 applies to information to which this section applies, except that the provisions of paragraph (e)(3) of this section regarding the time allowed

for seeking judicial review shall be reflected in any notice furnished to a business under § 2.204(d)(2).

(e) *Final confidentiality determination by EPA legal office.* Section 2.205 applies to information to which this section applies, except that—

(1) Notwithstanding § 2.205(i), the General Counsel (or his designee), rather than the regional counsel, shall make the determinations and take the actions required by § 2.205;

(2) In addition to the statement prescribed by the second sentence of § 2.205(f)(2), the notice of denial of a business confidentiality claim shall state that under section 20(a) of the Act, 15 U.S.C. 2619, the business may commence an action in an appropriate Federal district court to prevent disclosure.

(3) The following sentence is substituted for the third sentence of § 2.205(f)(2): ''With respect to EPA's implementation of the determination, the notice shall state that (subject to § 2.210) EPA will make the information available to the public on the thirty-first (31st) calendar day after the date of the business' receipt of the written notice (or on such later date as is established in lieu thereof under paragraph (f)(3) of this section), unless the EPA legal office has first been notified of the business' commencement of an action in a Federal court to obtain judicial review of the determination and to obtain preliminary injunctive relief against disclosure.''; and

(4) Notwithstanding § 2.205(g), the 31 calendar day period prescribed by § 2.205(f)(2), as modified by paragraph (e)(3) of this section, shall not be shortened without the consent of the business.

(f) [Reserved]

(g) *Substantive criteria for use in confidentiality determinations.* Section 2.208 applies without change to information to which this section applies, except that health and safety data are not eligible for confidential treatment. No information to which this section applies is voluntarily submitted information.

(h) *Disclosure in special circumstances.* Section 2.209 applies to information to which this section applies, except that the following two additional provisions apply to § 2.209(c):

(1) The official purpose for which the information is needed must be in connection with the agency's duties under any law for protection of health or the environment or for specific law enforcement purposes; and

(2) EPA notifies the other agency that the information was acquired under authority of the Act and that any knowing disclosure of the information may subject the officers and employees of the other agency to the penalties in section 14(d) of the Act (15 U.S.C. 2613(d)).

(i) *Disclosure of information relevant in a proceeding.* (1) Under section 14(a)(4) of the Act (15 U.S.C. 2613(a)(4)), any information to which this section applies may be disclosed by EPA when the information is relevant in a proceeding under the Act, notwithstanding the fact that the information otherwise might be entitled to confidential treatment under this subpart. However, any such disclosure shall be made in a manner that preserves the confidentiality of the information to the extent practicable without impairing the proceeding. Disclosure of information to which this section applies because of its relevance in a proceeding shall be made only in accordance with this paragraph (i).

(2)–(4) The provisions of § 2.301(g) (2), (3), and (4) are incorporated by reference as paragraphs (i) (2), (3), and (4), respectively, of this section.

(j) *Disclosure of information to contractors and subcontractors.* (1) Under section 14(a)(2) of the Act (15 U.S.C. 2613(a)(2)), any information to which this section applies may be disclosed by EPA to a contractor or subcontractor of the United States performing work under the Act, notwithstanding the fact that the information otherwise might be entitled to confidential treatment under this subpart. Subject to the limitations in this paragraph (j), information to which this section applies may be disclosed:

(i) To a contractor or subcontractor with EPA, if the EPA program office managing the contract first determines in writing that such disclosure is necessary for the satisfactory performance by the contractor or subcontractor of the contract or subcontract; or

(ii) To a contractor or subcontractor with an agency other than EPA, if the EPA program office which provides the information to that agency, contractor, or subcontractor first determines in writing, in consultation with the General Counsel, that such disclosure is necessary for the satisfactory performance by the contractor or subcontractor of the contract or subcontract.

(2)–(4) The provisions of § 2.301(h)(2)(ii), (iii), and (iv) are incorporated by reference as paragraphs (j) (2), (3), and (4), respectively, of this section.

(5) At the time any information is furnished to a contractor or subcontractor under this paragraph (j), the EPA office furnishing the information to the contractor or subcontractor shall notify the contractor or subcontractor that the information was acquired under authority of the Act and that any knowing disclosure of the information may subject the contractor or subcontractor and its employees to the penalties in section 14(d) of the Act (15 U.S.C. 2613(d)).

(k) *Disclosure of information when necessary to protect health or the environment against an unreasonable risk of injury.* (1) Under section 14(a)(3) of the Act (15 U.S.C 2613(a)(3)), any information to which this section applies may be disclosed by EPA when disclosure is necessary to protect health or the environment against an unreasonable risk of injury to health or the environment. However, any disclosure shall be made in a manner that preserves the confidentiality of the information to the extent not inconsistent with protecting health or the environment against the unreasonable risk of injury. Disclosure of information to which this section applies because of the need to protect health or the environment against an unreasonable risk of injury shall be made only in accordance with this paragraph (k).

(2) If any EPA office determines that there is an unreasonable risk of injury to health or the environment and that to protect health or the environment against the unreasonable risk of injury it is necessary to disclose information to which this section applies that otherwise might be entitled to confidential treatment under this subpart, the EPA office shall notify the General Counsel in writing of the nature of the unreasonable risk of injury, the extent of the disclosure proposed, how the proposed disclosure will serve to protect health or the environment against the unreasonable risk of injury, and the proposed date of disclosure. Such notification shall be made as soon as practicable after discovery of the unreasonable risk of injury. If the EPA office determines that the risk of injury is so imminent that it is impracticable to furnish written notification to the General Counsel, the EPA office shall notify the General Counsel orally.

(3) Upon receipt of notification under paragraph (k)(2) of this section, the General Counsel shall make a determination in writing whether disclosure of information to which this section applies that otherwise might be entitled to confidential treatment is necessary to protect health or the environment against an unreasonable risk of injury. The General Counsel shall also determine the extent of disclosure necessary to protect against the unreasonable risk of injury as well as when the disclosure must be made to protect against the unreasonable risk of injury.

(4) If the General Counsel determines that disclosure of information to which this section applies that otherwise might be entitled to confidential treatment is necessary to protect health or the environment against an unreasonable risk of injury, the General Counsel shall furnish notice to each affected business of the contemplated disclosure and of the General Counsel's determination. Such notice shall be made in writing by certified mail, return receipt requested, at least 15 days before the disclosure is to be made. The notice shall state the date upon which disclosure will be made. However, if the General Counsel determines that the risk of injury is so imminent that it is impracticable to furnish such notice 15 days before the proposed date of disclosure, the General Counsel may provide notice by means that will provide receipt of the notice by the affected business at least 24 hours before the disclosure is to be made. This may be done

by telegram, telephone, or other reasonably rapid means.

[43 FR 40003, Sept. 8, 1978, as amended at 44 FR 17674, Mar. 23, 1979; 58 FR 462, Jan. 5, 1993]

§ 2.307 Special rules governing certain information obtained under the Federal Insecticide, Fungicide and Rodenticide Act.

(a) *Definitions.* For the purposes of this section;

(1) *Act* means the Federal Insecticide, Fungicide and Rodenticide Act, as amended, 7 U.S.C. 136 *et seq.*, and its predecessor, 7 U.S.C. 135 *et seq.*

(2) *Applicant* means any person who has submitted to EPA (or to a predecessor agency with responsibility for administering the Act) a registration statement or application for registration under the Act of a pesticide or of an establishment.

(3) *Registrant* means any person who has obtained registration under the Act of a pesticide or of an establishment.

(b) *Applicability.* This section applies to all information submitted to EPA by an applicant or registrant for the purpose of satisfying some requirement or condition of the Act or of regulations which implement the Act, including information originally submitted to EPA for some other purpose but incorporated by the applicant or registrant into a submission in order to satisfy some requirement or condition of the Act or of regulations which implement the Act. This section does not apply to information supplied to EPA by a petitioner in support of a petition for a tolerance under 21 U.S.C. 346a(d), unless the information is also described by the first sentence of this paragraph.

(c) *Basic rules which apply without change.* Sections 2.201 through 2.203, 2.206, 2.207, and 2.210 through 2.215 apply without change to information to which this section applies.

(d) *Initial action by EPA office.* Section 2.204 applies to information to which this section applies, except that the provisions of paragraph (e) of this section regarding the time allowed for seeking judicial review shall be reflected in any notice furnished to a business under § 2.204(d)(2).

(e) *Final confidentiality determination by EPA legal office.* Section 2.205 applies to information to which this section applies, except that—

(1) Notwithstanding § 2.205(i), the General Counsel (or his designee), rather than the Regional Counsel, shall make the determinations and take the actions required by § 2.205;

(2) In addition to the statement prescribed by the second sentence of § 2.205(f)(2), the notice of denial of a business confidentiality claim shall state that under section 10(c) of the Act, 7 U.S.C. 136h(c), the business may commence an action in an appropriate Federal district court for a declaratory judgment;

(3) The following sentence is substituted for the third sentence of § 2.205(f)(2): ''With respect to EPA's implementation of the determination, the notice shall state that (subject to § 2.210) EPA will make the information available to the public on the thirty-first (31st) calendar day after the date of the business's receipt of the written notice (or on such later date as is established in lieu thereof under paragraph (f)(3) of this section), unless the EPA legal office has first been notified of the business's commencement of an action in a Federal court to obtain judicial review of the determination or to obtain a declaratory judgment under section 10(c) of the Act and to obtain preliminary injunctive relief against disclosure.''; and

(4) Notwithstanding § 2.205(g), the 31 calendar day period prescribed by § 2.205(f)(2), as modified by paragraph (e)(3) of this section, shall not be shortened without the consent of the business.

(f) [Reserved]

(g) *Substantive criteria for use in confidentiality determinations.* Section 2.208 applies without change to information to which this section applies; however, no information to which this section applies is voluntarily submitted information.

(h) *Disclosure in special circumstances.* (1) Section 2.209 applies without change to information to which this section applies. In addition, under section 12(a)(2)(D) of the Act, 7 U.S.C. 136j(a)(2)(D), EPA possesses authority to disclose any information to which this section applies to physicians,