Environmental Protection Agency

§ 2.308 Special rules governing certain information obtained under the Federal Food, Drug and Cosmetic Act.

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


(2) Petition means a petition for the issuance of a regulation establishing a tolerance for a pesticide chemical or exempting the pesticide chemical from the necessity of a tolerance, pursuant to section 408(b)(2) of the Act, 21 U.S.C. 346a(d).

(3) Petitioner means a person who has submitted a petition to EPA (or to a predecessor agency).

(b) Applicability. (1) This section applies only to business information submitted to EPA (or to an advisory committee established under the Act) by a petitioner, solely in support of a petition which has not been acted on by EPA before the publication by EPA of a regulation establishing a tolerance for a pesticide chemical or exempting the pesticide chemical from the necessity of a tolerance, as provided in section 408(d) (2) or (3) of the Act, 21 U.S.C. 346a(d) (2) or (3).

(2) Section 2.307, rather than this section, applies to information described by the first sentence of § 2.307(b) (material incorporated into submissions in order to satisfy the requirements of the Federal Insecticide, Fungicide and Rodenticide Act, as amended), even though such information was originally submitted by a petitioner in support of a petition.

(3) This section does not apply to information gathered by EPA under a proceeding initiated by EPA to establish a tolerance under section 408(e) of the Act, 21 U.S.C. 346a(e).

(c) Basic rules which apply without change. Sections 2.201, 2.202, 2.206, 2.207, and 2.210 through 2.215 apply without change to information to which this section applies.

(d) Effect of submission of information without claim. Section 2.203 (a) and (b) apply without change to information to which this section applies. A petitioner's failure to assert a
claim when initially submitting a petition shall not constitute a waiver of any claim the petitioner may have.

(e) Initial action by EPA office. Section 2.204 applies to information to which this section applies, except that—

(1) Unless the EPA office has on file a written waiver of a petitioner's claim, a petitioner shall be regarded as an affected business, a petition shall be treated as if it were covered by a business confidentiality claim, and an EPA office acting under § 2.204(d) shall determine that the information in the petition is or may be entitled to confidential treatment and shall take action in accordance with § 2.204(d)(1);

(2) In addition to other required provisions of any notice furnished to a petitioner under § 2.204(e), such notice shall state that—

(i) Section 408(f) of the Act, 21 U.S.C. 346a(f), affords absolute confidentiality to information to which this section applies, but after publication by EPA of a regulation establishing a tolerance (or exempting the pesticide chemical from the necessity of a tolerance) neither the Act nor this section affords any protection to the information;

(ii) Information submitted in support of a petition which is also incorporated into a submission in order to satisfy a requirement or condition of the Federal Insecticide, Fungicide and Rodenticide Act, as amended, 7 U.S.C. 136 et seq., is regarded by EPA as being governed, with respect to business confidentiality, by § 2.307 rather than by this section;

(iii) Although it appears that this section may apply to the information at this time, EPA is presently engaged in determining whether for any reason the information is entitled to confidential treatment or will be entitled to such treatment if and when this section no longer applies to the information; and

(iv) Information determined by EPA to be covered by this section will not be disclosed for as long as this section continues to apply, but will be made available to the public thereafter (subject to § 2.210) unless the business furnishes timely comments in response to the notice;

(f) 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 in all cases make the determinations and take the actions required by § 2.205;

(2) In addition to the circumstances mentioned in § 2.205(f)(1), notice in the form prescribed by § 2.205(f)(2) shall be furnished to each affected business whenever information is found to be entitled to confidential treatment under section 408(f) of the Act but not otherwise entitled to confidential treatment. With respect to such cases, the following sentences shall be 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 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 and to obtain preliminary injunctive relief against disclosure; provided, that the information will not be made available to the public for so long as it is entitled to confidential treatment under section 408(f) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. 346a(f),’’;

and

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

(g) [Reserved]

(h) Substantive criteria for use in confidentiality determinations. Section 2.206 does not apply to information to which this section applies. Such information shall be determined to be entitled to confidential treatment for so long as this section continues to apply to it.

(1) Disclosure in special circumstances. (1) Section 2.209 applies to information to which this section applies. In addition, under Section 408(f) of the Act, 21

(a) Definitions. For purposes of this section:


(2) Person has the meaning given it in section 101(21) of the Act, 42 U.S.C. 9601(21).

(3) Facility has the meaning given it in section 101(9) of the Act, 42 U.S.C. 9601(9).

(4) Hazardous substance has the meaning given it in section 101(14) of the Act, 42 U.S.C. 9601(14).

(5) Release has the meaning given it in section 101(22) of the Act, 42 U.S.C. 9601(22).

(6) Proceeding means any rulemaking or adjudication conducted by EPA under the Act or under regulations which implement the Act (including the issuance of administrative orders under section 106 of the Act and cost recovery pre-litigation settlement negotiations under sections 107 or 122 of the Act), any cost recovery litigation under section 107 of the Act, or any administrative determination made under section 104 of the Act, but not including determinations under this subpart.

(b) Applicability. This section applies only to information provided to or obtained by EPA under section 104 of the Act, 42 U.S.C. 9604, by or from any person who stores, treats, or disposes of hazardous wastes; or where necessary to ascertain facts not available at the facility where such hazardous substances are located, by or from any person who generates, transports, or otherwise handles or has handled hazardous substances, or by or from any