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## 40 C.F.R. § 2.308

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

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

(1) *Act* means the Federal Food, Drug and Cosmetic Act, as amended, 21 U.S.C. 301*et seq.*

(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(d) 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 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.

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