

Environmental Protection Agency

§ 350.11

any time by EPA if EPA desires to determine whether chemical identity information claimed as trade secret is entitled to trade secret treatment, even though no request for release of the information has been received.

(c) If EPA initiates a determination as to the validity of a trade secrecy claim, the procedures set forth in §§ 350.11, 350.15, and 350.17 shall be followed in making the determination.

(d) When EPA receives a petition requesting disclosure of trade secret chemical identity or if EPA decides to initiate a determination of the validity of a trade secrecy claim for chemical identity, EPA shall first make a determination that the chemical identity claimed as trade secret is not the subject of a prior trade secret determination by EPA concerning the same submitter and facility, or if it is, that the prior determination upheld the submitter's claim of trade secrecy for that chemical identity at that facility.

(1) If EPA determines that the chemical identity claimed as trade secret is not the subject of a prior trade secret determination by EPA concerning the same submitter and the same facility, or if it is, that the prior determination upheld the submitter's claim of trade secrecy, then EPA shall review the submitter's claim according to § 350.11.

(2) If such a prior determination held that the submitter's claim for that chemical identity is invalid, and such determination was not challenged by appeal to the General Counsel, or by review in the District Court, or, if challenged, was upheld, EPA shall notify the submitter by certified mail (return receipt requested) that the chemical identity claimed as trade secret is the subject of a prior, final Agency determination concerning the same facility in which it was held that such a claim was invalid. In this notification EPA shall include notice of intent to disclose chemical identity within 10 days pursuant to § 350.18(c) of this subpart. EPA shall also notify the petitioner by regular mail of the action taken pursuant to this section.

§ 350.11 Review of claim.

(a) *Determination of sufficiency.* When EPA receives a petition submitted pursuant to § 350.15, or if EPA initiates a

determination of the validity of a trade secrecy claim for chemical identity, and EPA has made a determination, as required in paragraph (d)(1) of § 350.9, then EPA shall determine whether the submitter has presented sufficient support for its claim of trade secrecy in its substantiation. EPA must make such a determination within 30 days of receipt of a petition. A claim of trade secrecy for chemical identity will be considered sufficient if, assuming all of the information presented in the substantiation is true, this supporting information could support a valid claim of trade secrecy. A claim is sufficient if it meets the criteria set forth in § 350.13.

(1) *Sufficient claim.* If the claim meets the criteria of sufficiency set forth in § 350.13, EPA shall notify the submitter in writing, by certified mail (return receipt requested), that it has 30 days from the date of receipt of the notice to submit supplemental information in writing in accordance with § 350.7(e), to support the truth of the facts asserted in the substantiation. EPA will not accept any supplemental information, in response to this notice, submitted after the 30 day period has expired. The notice required by this section shall include the address to which supplemental information must be sent. The notice may specifically request supplemental information in particular areas relating to the submitter's claim. The notice must also inform the submitter of his right to claim any trade secret or confidential business information as confidential, and shall include a reference to § 350.7(e) of this regulation as the source for the proper procedure for claiming trade secrecy for trade secret or confidential business information submitted in the supplemental information requested by EPA.

(2) *Insufficient claim.* If the claim does not meet the criteria of sufficiency set forth in § 350.13, EPA shall notify the submitter in writing of this fact by certified mail (return receipt requested). Upon receipt of this notice, the submitter may either file an appeal of the matter to the General Counsel under paragraph (a)(2)(i) of this section, or, for good cause shown, submit additional material in support of its claim

§ 350.11

40 CFR Ch. I (7-1-08 Edition)

of trade secrecy to EPA under paragraph (a)(2)(ii) of this section. The notice required by this section shall include the reasons for EPA's decision that the submitter's claim is insufficient, and shall inform the submitter of its rights within 30 days of receiving notice to file an appeal with EPA's General Counsel or to amend its original substantiation for good cause shown. The notice shall include the address of the General Counsel, and the address of the office to which an amendment for good cause shown should be sent. The notice shall also include a reference to §350.11(a)(2)(i)-(iv) of this subpart as the source on the proper procedures for filing an appeal or for amending the original substantiation.

(i) *Appeal.* The submitter may file an appeal of a determination of insufficiency with the General Counsel within 30 days of receipt of the notice of insufficiency, in accordance with the procedures set forth in §350.17.

(ii) *Good Cause.* In lieu of an appeal to the General Counsel, the submitter may send additional material in support of its trade secrecy claim, for good cause shown, within 30 days of receipt of the notice of insufficiency. To do so, the submitter shall notify EPA by letter of its contentions as to good cause, and shall include in that letter the additional supporting material.

(iii) Good cause is limited to one or more of the following reasons:

(A) The submitter was not aware of the facts underlying the additional information at the time the substantiation was submitted, and could not reasonably have known the facts at that time; or

(B) EPA regulations and other EPA guidance did not call for such information at the time the substantiation was submitted; or

(C) The submitter had made a good faith effort to submit a complete substantiation, but failed to do so due to an inadvertent omission or clerical error.

(iv) If EPA determines that the submitter has met the standard for good cause, then EPA shall decide, pursuant to paragraph (a) of this section, whether the submitter's claim meets the

Agency's standards of sufficiency set forth in §350.13.

(A) If after receipt of additional material for good cause, EPA decides the claim is sufficient, EPA will determine whether the claim presents a valid claim of trade secrecy according to the procedures set forth in paragraph (b) of this section.

(B) If after receipt of additional material for good cause, EPA decides the claim is insufficient, EPA will notify the submitter by certified mail (return receipt requested) and the submitter may seek review in U.S. District Court within 30 days of receipt of the notice. The notice required by this paragraph shall include EPA's reasons for its determination, and shall inform the submitter of its right to seek review in U.S. District Court within 30 days of receipt of the notice. The petitioner shall be notified of EPA's decision by regular mail.

(v) If EPA determines that the submitter has not met the standard for good cause, then EPA shall notify the submitter by certified mail (return receipt requested). The submitter may seek review of EPA's decision in U.S. District Court within 30 days of receipt of the notice. The notice required in this paragraph shall include EPA's reasons for its determination, and shall inform the submitter of its right to seek review in U.S. District Court within 30 days of receipt of the notice. The petitioner shall be notified of EPA's decision by regular mail.

(b) Determination of trade secrecy. Once a claim has been determined to be sufficient under paragraph (a) of this section, EPA must decide whether the claim is entitled to trade secrecy.

(1) If EPA determines that the information submitted in support of the trade secrecy claim is true and that the chemical identity is a trade secret, the petitioner shall be notified by certified mail (return receipt requested) of EPA's determination and may bring an action in U.S. District Court within 30 days of receipt of such notice. The notice required in this paragraph shall include the reasons why EPA has determined that the chemical identity is a trade secret and shall inform the petitioner of its right to seek review in U.S. District Court within 30 days of

Environmental Protection Agency

§ 350.13

receipt of the notice. The submitter shall be notified of EPA's decision by regular mail.

(2) If EPA decides that the information submitted in support of the trade secrecy claim is not true and that the chemical identity is not a trade secret:

(i) The submitter shall be notified by certified mail (return receipt requested) of EPA's determination and may appeal to the General Counsel within 30 days of receipt of such notice, in accordance with the procedures set forth in §350.17. The notice required by this paragraph shall include the reasons why EPA has determined that the chemical identity is not a trade secret and shall inform the submitter of its appeal rights to EPA's General Counsel. The notice shall include the address to which an appeal should be sent and the procedure for filing an appeal, as set forth in §350.17(a) of this subpart. The petitioner shall be notified of EPA's decision by regular mail.

(ii) The General Counsel shall notify the submitter by certified mail (return receipt requested) of its decision on appeal pursuant to the requirements in §350.17. The notice required by this paragraph shall include the reasons for EPA's determination. If the General Counsel affirms the decision that the chemical identity is not a trade secret, then the submitter shall have 30 days from the date it receives notice of the General Counsel's decision to bring an action in U.S. District Court. If the General Counsel decides that the chemical identity is a trade secret, then EPA shall follow the procedure set forth in paragraph (b)(1) of this section.

§ 350.13 Sufficiency of assertions.

(a) A substantiation submitted under §350.7 will be determined to be insufficient to support a claim of trade secrecy unless the answers to the questions in the substantiation submitted under §350.7 support all of the following conclusions. This substantiation must include, where applicable, specific facts.

(1) The submitter has not disclosed the information to any other person, other than a member of a local emergency planning committee, an officer or employee of the United States or a State or local government, an em-

ployee of such person, or a person who is bound by a confidentiality agreement, and such person has taken reasonable measures to protect the confidentiality of such information and intends to continue to take such measures. To support this conclusion, the facts asserted must show all of the following:

(i) The submitter has taken reasonable measures to prevent unauthorized disclosure of the specific chemical identity and will continue to take such measures.

(ii) The submitter has not disclosed the specific chemical identity to any person who is not bound by an agreement to refrain from disclosing the information.

(iii) The submitter has not previously disclosed the specific chemical identity to a local, State, or Federal government entity without asserting a confidentiality claim.

(2) The information is not required to be disclosed, or otherwise made available, to the public under any other Federal or State law.

(3) Disclosure of the information is likely to cause substantial harm to the competitive position of such person. To support this conclusion, the facts asserted must show all of the following:

(i) *Either*: (A) Competitors do not know or the submitter is not aware that competitors know that the chemical whose identity is being claimed trade secret can be used in the fashion that the submitter uses it, and competitors cannot easily duplicate the specific use of this chemical through their own research and development activities; or

(B) Competitors are not aware or the submitter does not know whether competitors are aware that the submitter is using this chemical in this fashion.

(ii) The fact that the submitter manufactures, imports or otherwise uses this chemical in a particular fashion is not contained in any publication or other information source (of which the submitter is aware) available to competitors or the public.

(iii) The non-confidential version of the submission under this title does not contain sufficient information to enable competitors to determine the