Environmental Protection Agency

§ 152.96 Documentation of a data gap.

Except as provided in paragraph (a) of this section, an applicant may defer his obligation to satisfy an applicable data requirement until the Agency requests the data if he can demonstrate, by the procedure in this section, that no other person has previously submitted to the Agency a study that would satisfy the data requirement in question.

(a) When data gap procedures may not be used. (1) An applicant for registration of a product containing a new chemical may not defer his obligation by the procedure in this section, unless he can demonstrate to the Agency’s satisfaction that the data requirement was imposed so recently that insufficient time has elapsed for the study to have been completed and that, in the public interest, the product should be registered during the limited period of time required to complete the study. Refer to FIFRA section 3(c)(7)(C).

(2) An applicant for registration of a product under FIFRA section 3(c)(7) (A) or (B) may not defer his obligation by the procedure in this section if the Agency requires the data to determine:

(i) Whether the product is identical or substantially similar to another currently registered product or differs only in ways that would not substantially increase the risk of unreasonable adverse effects on the environment;

(ii) If efficacy data are required, whether the product is efficacious; or

(iii) Whether the new use would substantially increase the risk of unreasonable adverse effects on the environment, usually required when the application involves a new use of a product which is identical or substantially similar to a currently registered product.

(b) Data gap listed in a Registration Standard. The applicant may rely on a data gap that is documented by a Registration Standard without submitting the certification required by paragraph (c) of this section. If the data gap listed in the Registration Standard has been filled since the issuance of the Standard, the Agency will notify the applicant and require him to choose another method of demonstrating compliance.

(c) Certification of a data gap. Except as provided by paragraph (b) of this section, an applicant who wishes to claim that a data gap exists must certify to the Agency that:

(1) The applicant has furnished, by certified mail, to each original data submitter on the current Data Submitters List for the active ingredient in question, a notice containing the following information:

(i) The name and address of the applicant;

(ii) The name of the product, and a statement that the applicant intends to apply for registration of that product;

(iii) The name(s) of the active ingredient(s) in the product;

(iv) A list of the data requirements for which the applicant intends to claim under this section that a data gap exists; and
§ 152.97 Rights and obligations of data submitters.

(a) Right to be listed on Data Submitters List. (1) Each original data submitter shall have the right to be included on the Agency’s Data Submitters List.

(2) Each original data submitter who wishes to have his name added to the current Data Submitters List must submit to the Agency the following information:
   (i) Name and current address;
   (ii) Chemical name and common name (if any) of the active ingredient(s), with respect to which he is an original data submitter;
   (iii) For each such active ingredient, the type(s) of study he has previously submitted (corresponding to Guidelines reference numbers given in tables in 40 CFR part 158 or part 161, as applicable), the date of submission, and the EPA registration number, file symbol, or other identifying reference for which it was submitted.

(b) Obligation to respond to data gap letters. An applicant who chooses to defer his obligation by demonstrating the existence of a data gap must write to each original data submitter for confirmation that the data submitter has not submitted a valid study that would satisfy the requirement. The original data submitter is not required to respond to such letters. However, if he fails to respond, the applicant is entitled to assume (and the Agency will act on the assumption) that the original data submitter has not submitted a study to satisfy the requirement. The data submitter may thereby limit his right to later challenge the applicant’s claim if he fails respond in writing delivered to the applicant within 60 days of receipt of the applicant’s data gap letter.

§ 152.98 Procedures for transfer of exclusive use or compensation rights to another person.

A person who possesses rights to exclusive use or compensation under FIFRA section 3(c)(1)(F) may transfer such rights to another person in accordance with this section.

(a) The original data submitter must submit to the Agency a transfer document that contains the following information:

(1) The name, address and state of incorporation (if any) of the original data submitter (the transferor);

(2) The name, address and state of incorporation (if any) of the person to whom the data rights are being transferred (the transferee);

(3) Identification of each item of data transferred including:
   (i) The name of the study or item of data;
   (ii) Whether the study is an exclusive use study, and, if so, when the period of exclusive use protection expires;
   (iii) The name of the person or laboratory that conducted the study;