

§ 152.94

40 CFR Ch. I (7-1-07 Edition)

§ 152.94 Citation of a public literature study or study generated at government expense.

(a) An applicant may demonstrate compliance for a data requirement by citing, and submitting to the Agency, one of the following:

(1) A valid study from the public literature.

(2) A valid study generated by, or at the expense of, any government (Federal, State, or local) agency.

(b) In no circumstances does submission of a public literature study or government-generated study confer any rights on the data submitter to exclusive use of data or compensation under FIFRA section 3(c)(1)(D).

§ 152.95 Citation of all studies in the Agency's files pertinent to a specific data requirement.

An applicant normally may demonstrate compliance for a data requirement by citation of all studies in the Agency's files pertinent of that data requirement. The applicant who selects this cite-all option must submit to the Agency:

(a) A general offer to pay statement having the same wording as that specified in §152.86(c) except that the offer to pay may be limited to apply only to data pertinent to the specific data requirement(s) for which the cite-all method of support has been selected;

(b) A certification that:

(1) For each person who is included on the Data Submitters List as an original data submitter of exclusive use data for the active ingredient in question, the applicant has obtained a written authorization containing the information required by §152.86(a) for the use the any exclusive use study that would be pertinent to the applicant's product; and

(2) For each person included on the current Data Submitters List as an original data submitter of data that are not exclusive use for the active ingredient in question, the applicant has furnished:

(i) A notification of the applicant's intent to apply for registration, including the name of the proposed product, and a list of the product's active ingredients;

(ii) Identification of the specific data requirement(s) for which the offer to pay for data is being made;

(iii) An offer to pay the person compensation to the extent required by FIFRA section 3(c)(1)(D);

(iv) An offer to commence negotiations to determine the amount and terms of compensation, if any, to be paid for use of any study; and

(v) The applicant's name, address and telephone number; and

(c) An acknowledgment having the same wording as that specified in §152.86(d), except that it may be limited to apply only to data pertinent to the specific data requirement(s) for which the cite-all method of support has been selected.

§ 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