

Environmental Protection Agency

§ 152.94

Agency should not be resubmitted but should be cited in accordance with §152.93.

§ 152.93 Citation of a previously submitted valid study.

An applicant may demonstrate compliance for a data requirement by citing a valid study previously submitted to the Agency. The study is not to be submitted to the Agency with the application.

(a) *Study originally submitted by the applicant.* If the applicant certifies that he is the original data submitter, no documentation other than the citation is necessary.

(b) *Study previously submitted by another person.* If the applicant is not the original data submitter, the applicant may cite the study only in accordance with paragraphs (b) (1) through (3) of this section.

(1) *Citation with authorization of original data submitter.* The applicant may cite any valid study for which he has obtained the written authorization of the original data submitter. The applicant must obtain written authorization to cite any study that is an exclusive use study. The applicant must certify that he has obtained from the original data submitter a written authorization that contains at least the following information:

(i) Identification of the applicant to whom the authorization is granted;

(ii) Identification by title, EPA Accession Number or Master Record Identification Number, and date of submission, of the study or studies for which the authorization is granted;

(iii) Authorization to the applicant to use the specified study in satisfaction of the data requirement for the application in question; and

(iv) The signature and title of the original data submitter or his authorized representative, and date of the authorization.

(2) *Citation with offer to pay compensation to the original data submitter.* The applicant may cite any valid study that is not subject to the exclusive use provisions of FIFRA section 3(c)(1)(D)(i) without written authorization from the original data submitter if the applicant certifies to the Agency

that he has furnished to the original data submitter:

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

(ii) Identification of the specific data requirement involved and of the study for which the offer to pay is made (by title, EPA Accession Number or Master Record Identification Number, and date of submission, if possible);

(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 the use of the study; and

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

(3) *Citation without authorization or offer to pay.* The applicant may cite any valid study without written authorization from, or offer to pay to, the original data submitter, if:

(i) The study was originally submitted to the Agency on or before December 31, 1969; or

(ii) The study was originally submitted to the Agency on or before the date that is 15 years before the date of the application for which it is cited, and the study is not an exclusive use study, as defined in §152.83(c).

§ 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).