

## Environmental Protection Agency

## § 152.93

with any necessary written authorizations or offers to pay. Refer to §152.95.

(6) Claim of data gap. Refer to §152.96.

[49 FR 30903, Aug. 1, 1984, as amended at 72 FR 61028, Oct. 26, 2007; 79 FR 6825, Feb. 5, 2014]

### § 152.91 Waiver of a data requirement.

The applicant may demonstrate compliance for a data requirement by documenting the existence of a waiver in accordance with paragraph (a) of this section, or by being granted a new waiver requested in accordance with paragraph (b) of this section.

(a) *Request for an extension of an existing waiver.* An applicant may claim that a waiver previously granted by the Agency also applies to a data requirement for the product. To document this claim, the applicant must provide a reference to the Agency record that describes the previously granted waiver, such as an Agency list of waivers or an applicable Reregistration Eligibility Decision (RED) document or registration review decision document, and explain why that waiver should apply to the product.

(b) *Request for a new waiver.* An applicant who requests a waiver to satisfy a data requirement must submit the information specified in 40 CFR 158.45 or 40 CFR 161.45.

(c) *Effect of denial of waiver request.* A decision by the Agency to deny a written request for a new waiver or an extension of an existing waiver is a final Agency action. Following denial, the applicant must choose another method of satisfying the data requirement.

[49 FR 30903, Aug. 1, 1984, as amended at 72 FR 61028, Oct. 26, 2007; 79 FR 6825, Feb. 5, 2014]

### § 152.92 Submission of a new valid study.

An applicant may demonstrate compliance for a data requirement by submitting a valid study that has not previously been submitted to the Agency. A study previously submitted to the 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)(F)(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: