(1) If a Registration Standard has been issued for any active ingredient, the applicant must list the applicable data requirements enumerated in that Standard for the active ingredient and, if end use products are covered by the Registration Standard, for such products containing that active ingredient.

(2) If a Registration Standard has not been issued, or if an issued Registration Standard does not cover all data requirements for products containing the active ingredient in question, the applicant must list the applicable requirements as prescribed by 40 CFR part 158 or part 161, as applicable. All required (R) studies, and any studies that could be conditionally required (CR) based upon composition, use pattern, or the results of required studies, are to be listed. The applicant may demonstrate via the data gap procedures in §152.96 that a conditional requirement need not be satisfied by the submission or citation of data at the time of application.

(b) *Methods of demonstrating compliance*. The applicant must state for each data requirement on the list required by paragraph (a) of this section which of the following methods of compliance with the requirement he is using, and shall provide the supporting documentation specified in the referenced section.

(1) Existence of or granting of a data waiver. Refer to §152.91.

(2) Submission of a new valid study. Refer to §152.92.

(3) Citation of a specific valid study previously submitted to the Agency by the applicant or another person, with any necessary written authorizations or offers to pay. Refer to §152.93.

(4) Citation of a public literature study. Refer to §152.94.

(5) Citation of all pertinent studies previously submitted to the Agency, with any necessary written authorizations or offers to pay. Refer to §152.95.

(6) Documentation of a data gap. Refer to §152.96.

[49 FR 30903, Aug. 1, 1984, as amended at 72 FR 61028, Oct. 26, 2007]

§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 extension of an existing waiver*. An applicant may claim that a waiver previously granted by the Agency also applies to a data requirement for his 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 Registration Standard, and must explain why that waiver should apply to his 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*. If the request for a new waiver or extension of an existing waiver is denied by the Agency, 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]

§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