

Environmental Protection Agency

§ 152.96

§ 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 to 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)(F);

(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 contact information, including a telephone number and email address.

(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.

[49 FR 30903, Aug. 1, 1984, as amended at 73 FR 75595, Dec. 12, 2008; 79 FR 6825, Feb. 5, 2014]

§ 152.96 Claim of data gap.

(a) *When a data gap may be claimed.* Except as provided in paragraph (b) of this section, an applicant may defer his obligation to satisfy an applicable data requirement until the Agency requires the data if no other person has previously submitted to the Agency a valid study that would satisfy the data requirement in question.

(b) *When a data gap may not be claimed—*(1) *Product containing a new active ingredient.* An applicant for registration of a product containing a new active ingredient may not defer his obligation by claiming a data gap 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 the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) section 3(c)(7)(C).

(2) *Product not containing a new active ingredient.* An applicant for registration of a product under FIFRA sections 3(c)(7)(A) or (B) (a product not containing a new active ingredient) may not defer his obligation by claiming a data gap if the data are:

(i) Data needed to determine whether the product is identical or substantially similar to another currently registered product or differs only in ways that would substantially increase the risk of unreasonable adverse effects on the environment.

(ii) Efficacy data specific to the product, if required to be submitted to the Agency.

(iii) If a new use is proposed for a product that is identical or substantially similar to an existing product, data to demonstrate whether the new use would substantially increase the risk of unreasonable adverse effects on the environment.

(c) *Approval of application with a data gap claim—*(1) In accordance with