

§ 152.84

40 CFR Ch. I (7-1-00 Edition)

(a) *Data gap* means the absence of any valid study or studies in the Agency's files which would satisfy a specific data requirement for a particular pesticide product.

(b) *Data Submitters List* means the current Agency list, entitled "Pesticide Data Submitters by Chemical," of persons who have submitted data to the Agency.

(c) *Exclusive use study* means a study that meets each of the following requirements:

(1) The study pertains to a new active ingredient (new chemical) or new combination of active ingredients (new combination) first registered after September 30, 1978;

(2) The study was submitted in support of, or as a condition of approval of, the application resulting in the first registration of a product containing such new chemical or new combination (first registration), or an application to amend such registration to add a new use; and

(3) The study was not submitted to satisfy a data requirement imposed under FIFRA section 3(c)(2)(B);

Provided that, a study is an exclusive use study only during the 10-year period following the date of the first registration.

(d) *Original data submitter* means the person who possesses all rights to exclusive use or compensation under FIFRA section 3(c)(1)(D) in a study originally submitted in support of an application for registration, amended registration, reregistration, or experimental use permit, or to maintain an existing registration in effect. The term includes the person who originally submitted the study, any person to whom the rights under FIFRA section 3(c)(1)(D) have been transferred, or the authorized representative of a group of joint data developers.

(e) *Valid study* means a study that has been conducted in accordance with the Good Laboratory Practice standards of 40 CFR part 160 or generally accepted scientific methodology and that EPA has not determined to be invalid.

§ 152.84 When materials must be submitted to the Agency.

All information required by this subpart should be submitted with the ap-

plication, but may be submitted at any later time prior to EPA's approval of the application. The Agency will not approve any application until it determines either that the application is not subject to these requirements or that all required materials have been submitted and are acceptable.

§ 152.85 Formulators' exemption.

(a) FIFRA section 3(c)(2)(D) excuses an applicant from the requirement to submit or cite data pertaining to the safety of any ingredient (or mixture of ingredients) contained in his product that is derived solely from one or more EPA-registered products which the applicant purchases from another producer.

(b) If the product contains one or more ingredients eligible for the formulators' exemption, the applicant need not comply with the requirements of §§ 152.90 through 152.96 with respect to any data requirements pertaining to the safety of any such ingredient, provided that he submits to the Agency a certification statement containing the following information (a form for this purpose is available from the Agency):

(1) Identification of the applicant, and of the product by EPA registration number or file symbol;

(2) Identification of each ingredient in the pesticide that is eligible for the formulators' exemption, and the EPA registration number of the product that is the source of that ingredient;

(3) A statement that the listed ingredients meet the requirements for the formulators' exemption;

(4) A statement that the applicant has submitted (either previously or with the current application) a complete, accurate and current Confidential Statement of Formula; and

(5) The name, title and signature of the applicant or his authorized representative and the date of signature.

(c) An applicant for amended registration is not required to submit a new formulators' exemption statement, if the current statement in Agency files is complete and accurate.

[49 FR 30903, Aug. 1, 1984, as amended at 58 FR 34203, June 23, 1993; 60 FR 32096, June 19, 1995]