Notwithstanding the preceding sentence, compliance with this subpart is required if the Administrator has, by written notice under §152.46, determined that the modification may not be accomplished by notification or non-notification.

(6) Any type of amendment if the Administrator determines, by written finding, that Agency consideration of data would not be necessary in order to approve the amendment under FIFRA section 3(c)(5).

(7) Compliance with Agency regulations, adjudicatory hearing decisions, notices, or other Agency announcements that unless the registration is amended in the manner the Agency proposes, the product's registration will be suspended or canceled, or that a hearing will be held under FIFRA section 6. However, this paragraph does not apply to amendments designed to avoid cancellation or suspension threatened under FIFRA section 3(c)(2)(B) or because of failure to submit data.

[79 FR 6824, Feb. 5, 2014]

§152.82 Definitions.

For the purposes of this subpart, the definitions set forth in the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), in §152.3, and in this section apply. In addition, the term ''exclusive use study'' shall have the meaning set forth in §152.83.

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.

Data Submitters List means the current Agency list, entitled ''Pesticide Data Submitters by Chemical,'' of persons who have submitted data to the Agency.

Original data submitter means the person who possesses all rights to exclusive use or compensation under FIFRA section 3(c)(1)(F) 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)(F) have been transferred, or the authorized representative of a group of joint data developers.

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.

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

§152.83 Definition of exclusive use study.

A study is an exclusive use study if it meets the conditions of either paragraph (a) or paragraph (b) of this section.

(a) *Initial exclusive use period.* A study submitted to support the registration of a product containing a new active ingredient (new chemical) or a new combination of active ingredients (new combination) is an exclusive use study if all the following conditions are met:

(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, or an application to amend such registration to add a new use.

(3) Less than 10 years have passed (or up to 13 years, if the period of exclusive use protection has been extended under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) section 3(c)(1)(F)(ii)) since the issuance of the registration for which the data were submitted.

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

(b) *Exclusive use period for certain minor use data.* A study submitted by an applicant or registrant to support an amendment adding a new minor use to an existing registration that does not retain any period of exclusive use under paragraph (b)(1) of this section is an exclusive study under FIFRA section 3(c)(1)(F)(vi) if all the following conditions are met:

(1) The study relates solely to a minor use of a pesticide.

(2) The applicant or registrant at the time the new use is requested has notified the Administrator that any exclusive use period for the pesticide has expired and that the study is eligible for exclusive use treatment.

(3) Less than 10 years have passed since the study was submitted to EPA.

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

(5) The minor use supported by the data has not been voluntarily canceled nor have such data been used to support a non-minor use.

[79 FR 6825, Feb. 5, 2014]

§ 152.84 When materials must be submitted to the Agency.

Information and materials required by this subpart must be submitted at the time of application, unless the application is determined not to be subject to the requirements of this subpart.

[79 FR 6825, Feb. 5, 2014]

§ 152.85 Formulators' exemption.

(a) *Statutory provision.* FIFRA section 3(c)(2)(D) excuses an applicant from the requirement to submit or cite data pertaining to any pesticide contained in his product that is derived solely from one or more EPA-registered products which the applicant purchases from another person. This provision is commonly referred to as the formulators' exemption.

(b) *Applicability of the formulators' exemption.* (1) The formulators' exemption applies only to data concerning the purchased product or its ingredients. These data may include, but are not limited to, product chemistry, toxicology, residue chemistry, exposure, environmental fate, and ecological effects.

(2) The data to which the formulators' exemption applies usually will concern the safety of one or more of the product's active ingredients, specifically, those active ingredients which are contained in the purchased product. In general, data for which the required test substance is the technical grade of the active ingredient, the pure active ingredient, the radiolabeled pure active ingredient, or a typical end-use product are eligible for the formulators' exemption.

(3) The formulators' exemption generally does not apply to data on the applicant's product itself, including the safety or efficacy of the product, unless the composition of the product is identical to the purchased product. In general, data for which the required test substance is the product proposed for registration are not eligible for the formulators' exemption.

(c) *Limitation of the formulators' exemption.* EPA interprets FIFRA section 3(c)(2)(D) as allowing an applicant to use the formulators' exemption with respect to data concerning an ingredient of his product only if:

(1) The application indicates that the ingredient's presence in the product is attributable solely to the purchase from another person of an identified, registered product containing that ingredient and the use of the purchased product in formulating the product; and

(2) The purchased product is a registered manufacturing-use product whose label does not prohibit its use for making an end-use product labeled for any use for which the applicant's product will be labeled; or

(3) The purchased product is a registered end-use product labeled for each use for which the applicant's product will be labeled.

(d) *Claiming eligibility for the exemption.* (1) 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 requirement pertaining to 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):

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

(ii) 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.