scientific methodology and that EPA
has not determined to be invalid.
[49 FR 30903, Aug. 1, 1984, as amended at 73
FR 75959, Dec. 12, 2008]

§ 152.84 When materials must be sub-
mitted to the Agency.
All information required by this sub-
part should be submitted with the ap-
lication, 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 deter-
mines either that the application is not
subject to these requirements or that
all required materials have been sub-
mitted and are acceptable.

§ 152.85 Formulators’ exemption.
(a) Statutory provision. FIFRA section
3(c)(2)(D) excuses an applicant from the
requirement to submit or cite data per-
taining to any pesticide contained in
his product that is derived solely from
one or more EPA-registered products
which the applicant purchases from an-
other person. This provision is com-
monly referred to as the formulators’
exemption.
(b) Applicability of the formulators’ ex-
emption. (1) The formulators’ exemp-
tion applies only to data concerning
the purchased product or its ingredi-
ents. These data may include, but are
not limited to, product chemistry,
toxicology, residue chemistry, expo-
sure, environmental fate, and ecologi-
ocal effects.
(2) The data to which the formu-
lators’ exemption applies usually will
concern the safety of one or more of
the product’s active ingredients, spe-
cifically, 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 formu-
lators’ exemption.
(3) The formulators’ exemption gen-
erally 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 iden-
tical to the purchased product. In gen-
eral, data for which the required test
substance is the product proposed for
registration are not eligible for the for-
mulators’ exemption.
(c) Limitation of the formulators’ ex-
emption. EPA interprets FIFRA section
3(c)(2)(D) as allowing an applicant to
use the formulators’ exemption with
respect to data concerning an ingre-
dient 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 in-
gredient and the use of the purchased
product in formulating the product; and
(2) The purchased product is a reg-
istered 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 reg-
istered end-use product labeled for
each use for which the applicant’s
product will be labeled.
(d) Claiming eligibility for the exemp-
tion. (1) If the product contains one or
more ingredients eligible for the for-
mulators’ 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 sub-
mits to the Agency a certification
statement containing the following in-
formation (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.
(iii) A statement that the listed in-
gredients meet the requirements for
the formulators’ exemption.
(iv) A statement that the applicant
has submitted (either previously or
with the current application) a com-
plete, accurate and current Confiden-
tial Statement of Formula.
(v) The name, title and signature of
the applicant or his authorized rep-
resentative and the date of signature.
(2) An applicant for amended reg-
istration is not required to submit a
§ 152.86 The cite-all method.

An applicant may comply with this subpart by citing all data in Agency files that are pertinent to its consideration of the requested registration under FIFRA section 3(c)(5), in accordance with the procedures in this section, as applicable.

(a) Exclusive use studies. The applicant must certify to the Agency that he has obtained, from each person listed on the Data Submitters List as an exclusive use data submitter for the chemical in question, a written authorization that contains at least the following information:

(1) Identification of the applicant to whom the authorization is granted;
(2) Authorization to the applicant to use all pertinent studies in satisfaction of data requirements for the application in question; and
(3) The signature and title of the original data submitter or his authorized representative and date of the authorization.

If the Agency identifies any exclusive use data submitter not on the Data Submitters List, the applicant will be required prior to registration to obtain the necessary written authorization from such person.

(b) Other studies. The applicant must certify to the Agency that, with respect to each other person on the Data Submitters List for the chemical in question:

(1) He has obtained from that person a written authorization that contains the information required by paragraphs (a) (1) through (3) of this section; or
(2) He has furnished to that person:

(i) A notification of his intent to apply for registration, including the name of the proposed product, and a list of the product’s active ingredients;
(ii) An offer to pay the person compensation to the extent required by FIFRA section 3(c)(1)(F) for any data on which the application relies;
(iii) An offer to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of any study; and
(iv) His name, address and telephone number.

(c) General offer to pay statement. The applicant must submit to the Agency the following general offer to pay statement:

[Name of applicant] hereby offers and agrees to pay compensation to other persons, with regard to the approval of this application, to the extent required by FIFRA section 3(c)(1)(F) of the Federal Insecticide, Fungicide and Rodenticide Act.

(d) Acknowledgement of reliance on data. Each application filed under this section shall include an acknowledgement that for purposes of FIFRA section 3(c)(1)(F) the application relies on the following data:

(1) All data submitted with or specifically cited in the application; and
(2) Each other item of data in the Agency’s files which:

(i) Concerns the properties or effects of the applicant’s product, of any product which is identical or substantially similar to the applicant’s product, or of one or more of the active ingredients in the applicant’s product; and
(ii) Is one of the types of data that EPA would require to be submitted if the application sought the initial registration under FIFRA section 3(c)(5) of a product with composition and intended uses identical or substantially similar to the applicant’s product, under the data requirements in effect on the date EPA approves the applicant’s present application.

§ 152.90 The selective method.

An applicant may comply with this subpart by listing the specific data requirements that apply to his product, its active ingredients, and use patterns, and demonstrating his compliance for each data requirement by submitting or citing individual studies, or by demonstrating that no study has