

Environmental Protection Agency

§ 158.80

test if another appropriate methodology is used.

(b) *Organization for Economic Cooperation and Development (OECD) Protocols.* Tests conducted in accordance with the requirements and recommendations of the applicable OECD protocols can be used to develop data necessary to meet the requirements specified in this part. Readers should note, however, that certain of the OECD recommended test standards, such as test duration and selection of test species, are less restrictive than those recommended by EPA. Therefore, when using the OECD protocols, care should be taken to observe the test standards in a manner such that the data generated by the study will satisfy the requirements of this part.

(c) *Procedures for requesting advice on protocols.* Normally, all contact between the Agency and applicants or registrants is handled by the assigned Product Manager in the Registration Division of the Office of Pesticide Programs. Accordingly, questions concerning protocols should be directed, preferably in writing, to the Product Manager responsible for the registration or application which would be affected.

§ 158.75 Requirements for additional data.

(a) *General policy.* The data routinely required by part 158 may not be sufficient to permit EPA to evaluate every pesticide product. If the information required under this part is not sufficient to evaluate the potential of the product to cause unreasonable adverse effects on man or the environment, additional data requirements will be imposed. However, EPA expects that the information required by this part will be adequate in most cases for an assessment of the properties of pesticide.

(b) *Policy on test substance.* In general, where the technical grade of the active ingredient is specified as the substance to be tested, tests may be performed using a technical grade which is substantially similar to the technical grade used in the product for which registration is sought. In addition to or in lieu of the testing required in subparts C and D of this part the Adminis-

trator will, on a case-by-case basis, require testing to be conducted with:

(1) An analytical pure grade of an active ingredient, with or without radioactive tagging.

(2) The technical grade of an active ingredient.

(3) The representative technical grade of an active ingredient.

(4) An intentionally added inert ingredient in a pesticide product.

(5) A contaminant or impurity of an active or inert ingredient.

(6) A plant or animal metabolite or degradation product of an active or inert ingredient.

(7) The end-use pesticide product.

(8) The end-use pesticide product plus any recommended vehicles and adjuvants.

(9) Any additional substance which could act as a synergist to the product for which registration is sought.

(10) Any combination of substances in paragraphs (b) (1) through (9) of this section.

[49 FR 42881, Oct. 24, 1984, as amended at 53 FR 15999, May 4, 1988; 58 FR 34203, June 23, 1993]

§ 158.80 Acceptability of data.

(a) *General policy.* The Agency will determine whether the data submitted to fulfill the data requirements specified in this part are acceptable. This determination will be based on the design and conduct of the experiment from which the data were derived, and an evaluation of whether the data fulfill the purpose(s) of the data requirement. In evaluating experimental design, the Agency will consider whether generally accepted methods were used, sufficient numbers of measurements were made to achieve statistical reliability, and sufficient controls were built into all phases of the experiment. The Agency will evaluate the conduct of each experiment in terms of whether the study was conducted in conformance with the design, good laboratory practices were observed, and results were reproducible. The Agency will not reject data merely because they were derived from studies which, when initiated were in accordance with an Agency-recommended protocol, even if the Agency subsequently recommends a different protocol, as long as the data