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.

§ 161.75 Requirements for additional data.

(a) *General policy.* The data routinely required by part 161 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 Administrator 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]

§ 161.80 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 fulfill the purposes of the requirements as described in this paragraph.

(b) *Previously developed data.* The Agency will consider that data developed prior to the effective date of this part would be satisfactory to support applications provided good laboratory practices were followed, the data meet the purposes of this part, and the data

permit sound scientific judgments to be made. Such data will not be rejected merely because they were not developed in accordance with suggested protocols.

(c) *Data developed in foreign countries.* The Agency considers all applicable data developed from laboratory and field studies anywhere to be suitable to support pesticide registrations except for data from tests which involved field test sites or a test material, such as a native soil, plant, or animal, that is not characteristic of the United States. When studies at test sites or with materials of this type are anticipated, applicants should take steps to assure that United States materials are used or be prepared to supply data or information to demonstrate the lack of substantial or relevant differences between the selected material or test site and the United States material or test site. Once comparability has been established, the Agency will assess the acceptability of the data as described in paragraph (a) of this section.

(d) *Data from monitoring studies.* Certain data are developed to meet the monitoring requirements of FIFRA sections 5, 8 or 20. Applicants may wish to determine whether some of these data may meet the requirements of this part. In addition, data developed independently of FIFRA regulations or requirements may also satisfy data requirements in this part. Consultation with appropriate EPA Product Managers would be helpful if applicants are unsure about suitability of such data.

§ 161.85 Revision of data requirements and guidelines.

(a) Data requirements will be revised from time to time to keep up with policy changes and technology. Revisions to this part will be made in accordance with the Administrative Procedure Act (5 U.S.C. 551 *et seq.*). Changes having a significant impact on the registration process, applicants, testers, or other parties, or on the outcome and evaluation of studies, will be made only after public notice and opportunity for comment. Until final rules reflecting a change have been promulgated, the Agency can implement changes in the data requirements on a case-by-case basis.

(b) The Agency invites registration applicants, registrants, and the general public to suggest changes in the data requirements or the Pesticide Assessment Guidelines. Suggestions may be submitted at any time. Those making suggestions are requested to contact, in writing, the Director of the Hazard Evaluation Division. When suggestions consist of new suggested methods, representative test results should accompany the submittals.

Subpart B—How To Use Data Tables

SOURCE: 49 FR 42881, Oct. 24, 1984, unless otherwise noted. Redesignated and amended at 72 FR 60253–60255, Oct. 24, 2007.

§ 161.100 How to determine registration data requirements.

To determine the specific kinds of data needed to support the registration of each pesticide product, the registration applicant should:

(a) Refer to subparts C and D (§§ 161.150 through 161.640). These subparts describe the data requirements, including data tables for each subject area. The corresponding subdivisions in the Pesticide Assessment Guidelines are listed in § 161.108.

(b) Select the general use pattern(s) that best covers the use pattern(s) specified on the pesticide product label. Selection of the appropriate general use pattern(s) will usually be obvious. However, unique or ambiguous cases will arise occasionally. These situations may be clarified by reference to the Use Pattern Index presented in the appendix to the Data Requirements for Registration. The applicant can look up a specific use pattern in appendix A and it will be cross referenced to the appropriate general use patterns to be used in each Data Requirement table.

(c) Proceed down the appropriate general use pattern column in the table and note which tests (listed along the left hand side of the table) are required (''R''), conditionally required (''CR'') or usually not required (''—''). After reading through each data requirement table, the applicant will have a complete list of required and conditionally required data for the pesticide product