the confidential attachment, the submitter waives a claim of confidentiality for such information under FIFRA sec. 10(d)(1) (A), (B), or (C).

(2) The attachment must have a cover page which is clearly marked to indicate that the material contained in the attachment falls within the scope of FIFRA sec. 10(d)(1) (A), (B), or (C).

(3) Each item in the attachment must be numbered. For each item, the submitter must cite the applicable portion of FIFRA sec. 10(d)(1) (A), (B), or (C) on which the claim of confidentiality is based. In addition, for each item, the submitter must provide a list of page numbers in the study where the item is cited (*i.e.*, identified by number).

(4) Each item in the attachment must be referenced in the body of the study by its number in the attachment.

(5) The following statement must appear on the Statement of Data Confidentiality Claims:

> Information claimed confidential on the basis of its falling within the scope of FIFRA sec. 10(d)(1)(A), (B), or (C) has been removed to a confidential appendix, and is cited by cross-reference number in the body of the study.

The statement must bear the name, title, and signature of the submitter or his properly designated agent, and the date of signature.

(c) *No claim of confidentiality under FIFRA sec. 10(d)(1)(A), (B), or (C).* If no claim of confidentiality is being made for information described by FIFRA sec. 10(d)(1)(A), (B), or (C), or if such information is not contained in the body of the study, the Statement of Data Confidentiality Claims must include the following statement:

> No claim of confidentiality is made for any information contained in this study on the basis of its falling within the scope of FIFRA sec. 10(d)(1)(A), (B), or (C).

This statement must bear the name, title and signature of the submitter or his properly designated agent, and the date of signature.

(d) *Claim of confidentiality for information not described by FIFRA sec. 10(d)(1) (A), (B), or (C).* Any information not described by FIFRA sec. 10(d)(1) (A), (B), or (C) for which a claim of confidentiality is made must be submitted in accordance with the following procedures:

(1) The information must be clearly marked in the body of the study as being claimed confidential.

(2) A separate Supplemental Statement of Data Confidentiality Claims must be submitted identifying by page and line number the location within the study of each item claimed confidential, and stating the basis for the claim.

(3) The Supplemental Statement of Data Confidentiality Claims must bear the name, title, and signature of the submitter or his properly designated agent, and the date of signature.

[53 FR 15991, May 4, 1988]

§ 161.34 Flagging of studies for potential adverse effects.

(a) Any person who submits a study of a type listed in paragraph (b) of this section to support an application for new or amended registration, or to satisfy a requirement imposed under FIFRA sec. 3(c)(2)(B), must submit with the study a statement in accordance with paragraph (c) of this section.

(b) The following table indicates that study types and the criteria to be applied to each. Column 1 lists the study types by name. Column 2 lists the associated Pesticide Assessment Guideline number. Column 3 lists the criteria applicable to each type of study. Column 4 lists the reporting code to be included in the statement specified in paragraph (c) of this section when any criterion is met or exceeded.

TABLE—FLAGGING CRITERIA

Toxicity studies	Pesticide assessment guidelines No.	Criteria	Reporting code
Oncogenicity [or combined oncogenicity/chronic feeding study]	83–2	Treated animals show any of the following:	

TABLE—FLAGGING CRITERIA—Continued

Toxicity studies	Pesticide assessment guidelines No.	Criteria	Reporting code
or Subchronic feeding study	82–1	An incidence of neoplasms in male or female animals which increases with dose; or A statistically significant ($p \leq 0.05$) incidence of any type of neoplasm in any test group (male or female animals at any dose level) compared to concurrent control animals of the same sex; or An increase in any type of uncommon or rare neoplasms in any test group (male or female animals at any dose level) compared to concurrent control animals or A decrease in the time to development of any type of neoplasms in any test group (male or female animals at any dose level) compared to concurrent control animals	1 2 3 4
Teratogenicity	83–3	When compared with concurrent controls, treated animals show a dose-related increase in malformations (or deaths) on a litter basis in the absence of significant maternal toxicity at the same dose levels	5
Neurotoxicity	81–7	When compared with controls, treated animals show a response indicative of acute delayed neurotoxicity	6
Chronic feeding study or combined chronic feeding/oncogenicity study	83–1	Cholinesterase inhibition NOEL less than 10 times the current existing ADI. or General (systemic) toxicity NOEL less than 100 times the current existing ADI.	7 8
Reproduction study	83–4	Reproductive effects NOEL less than 100 times the current ADI	9
Subchronic feeding study	82–1	Cholinesterase inhibition NOEL less than 100 times the current existing ADI. or General (systemic) toxicity NOEL less than 1000 times the current existing ADI.	10 11

(c) *Identification of studies.* For each study of a type identified in paragraph (b) of this section, the applicant (or registrant in the case of information submitted under FIFRA sec. 3(c)(2)(B)) shall include the appropriate one of the following two statements, together with the signature of the authorized representative of the company, and the date of signature:

(1) ''I have applied the criteria of 40 CFR 161.34 for flagging studies for potential adverse effects to the results of the attached study. This study neither meets nor exceeds any of the applicable criteria.''

(2) ''I have applied the criteria of 40 CFR 161.34 for flagging studies for potential adverse effects to the results of the attached study. This study meets or exceeds the criteria numbered [insert all applicable reporting codes.]''

[53 FR 15992, May 4, 1988, as amended at 58 FR 34203, June 23, 1993]

§ 161.35 Flexibility of the data requirements.

Several provisions of this part provide EPA flexibility in requiring (or not requiring) data and information for the purposes specified in §161.20(b). These provisions are summarized in this section and discussed elsewhere in this part.

(a) The Agency encourages each applicant, particularly a person applying for registration for the first time, to consult with the Product Manager for