§ 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>
<thead>
<tr>
<th>Toxicity studies</th>
<th>Pesticide assessment guidelines No.</th>
<th>Criteria</th>
<th>Reporting code</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oncogenicity (or combined oncogenicity/chronic feeding study)</td>
<td>83–2</td>
<td>Treated animals show any of the following:</td>
<td></td>
</tr>
</tbody>
</table>

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]
(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.]”

§ 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...