

Environmental Protection Agency

§ 158.33

submission must be in the form of individual documents or studies. Previously submitted documents should not be resubmitted unless specifically requested by the Agency, but should be cited with adequate information to identify the previously submitted document. Each study or document should include the following:

(1) A title page including the following information:

(i) The title of the study, including identification of the substance(s) tested and the test name or data requirement addressed.

(ii) The author(s) of the study.

(iii) The date the study was completed.

(iv) If the study was performed in a laboratory, the name and address of the laboratory, project numbers or other identifying codes.

(v) If the study is a commentary on or supplement to another previously submitted study, full identification of the other study with which it should be associated in review.

(vi) If the study is a reprint of a published document, all relevant facts of publication, such as the journal title, volume, issue, inclusive page numbers, and date of publication.

(2) The appropriate statement(s) regarding any data confidentiality claims as described in § 158.33.

(3) A statement of compliance or non-compliance with respect to Good Laboratory Practice Standards as required by 40 CFR 160.12, if applicable.

(4) A complete and accurate English translation must be included for any information that is not in English.

(5) A flagging statement as prescribed by § 158.34, if applicable.

§ 158.33 Confidential data.

(a) *Definitions.* For the purposes of this section:

(1) *Registered or previously registered pesticide* means any pesticide containing an active ingredient contained in a product that is, or has ever been, an active ingredient in a product registered under sec. 3 of FIFRA. A registered pesticide that is the subject of an application for a new use falls within the category of “registered or previously registered pesticide.”

(2) *Safety and efficacy information* means information concerning the objectives, methodology, results, or significance of any test or experiment performed on or with a registered or previously registered pesticide or its separate ingredients, impurities, or degradation products, and any information concerning the effects of such pesticide on any organism or the behavior of such pesticide in the environment, including, but not limited to, data on safety to fish and wildlife, humans and other mammals, plants, animals, and soil, and studies on persistence, translocation and fate in the environment, and metabolism.

(b) *Applicability.* (1) This section applies to information submitted pursuant to this part. It supplements the general confidentiality procedures in 40 CFR part 2, subpart B, including FIFRA confidentiality procedures at 40 CFR 2.307. To the extent that provisions in this section conflict with those in 40 CFR part 2, subpart B, the provisions in this section take precedence. The provisions of 40 CFR 2.308 do not apply to information to which this section applies. In addition to complying with the requirements of this section, any confidentiality claims for information subject to 40 CFR part 174 (plant-incorporated protectants) must be substantiated at the time of submission as described in § 174.9 of this chapter.

(2) FFDCA sec. 408(i) protects confidential information submitted in connection with an application for a tolerance or exemption to the same extent as FIFRA sec. 10. References in this section to FIFRA sec. 10 are deemed to apply equally to information submitted pursuant to FFDCA sec. 408, pursuant to the authority in sec. 408(i).

(c) *Method of asserting business confidentiality claims—*(1) *Claim required.* Information to which this section applies (and which is submitted on or after the effective date of this regulation) will be deemed as not subject to a confidentiality claim unless a claim for that information is made in accordance with the procedures specified in this paragraph. Information not subject to a confidentiality claim may be made available to the public without further notice, subject to the requirements of FIFRA sec. 10(g).

(2) *Statement required.* Upon submission to EPA, each document must be accompanied by a signed and dated document containing either the statements in paragraph (c)(2)(i) or (ii) of this section. No claims or markings on the document or any attachments, other than these statements and attachments submitted in accordance with paragraph (c)(3) of this section, will be recognized as asserting a claim of confidentiality. The format of data submissions is set forth in § 158.32.

(i) *No claim of confidentiality.*

No claim of confidentiality, on any basis whatsoever, is made for any information contained in this document. I acknowledge that information not designated as within the scope of FIFRA sec. 10(d)(1)(A), (B), or (C) and which pertains to a registered or previously registered pesticide is not entitled to confidential treatment and may be released to the public, subject to the provisions regarding disclosure to multinational entities under FIFRA sec. 10(g).

(ii) *Claim of confidentiality.*

Information claimed as confidential has been removed to a confidential attachment.

(3) *Confidential attachment.* (i) All information claimed as confidential must be submitted in a separate confidential attachment to the document and cross referenced to the specific location in the document from which it was removed. The confidential attachment must have its own title page and be paginated separately from the non-confidential document.

(ii) All information in the confidential attachment that consists of (or whose disclosure would in turn disclose) manufacturing or quality control processes must be individually identified in the confidential attachment as a claim for information within the scope of FIFRA sec. 10(d)(1)(A).

(iii) All information in the confidential attachment that consists of (or whose disclosure would in turn disclose) the details of any methods for testing, detecting, or measuring the quantity of any deliberately added inert ingredient of a pesticide, must be individually identified in the confidential attachment as a claim for information within the scope of FIFRA sec. 10(d)(1)(B).

(iv) All information in the confidential attachment that consists of (or whose disclosure would in turn dis-

close) the identity or percentage quantity of any deliberately added inert ingredient of a pesticide must be individually identified in the confidential attachment as a claim for information within the scope of FIFRA sec. 10(d)(1)(C).

(v) Information in the confidential attachment that is designated in accordance with paragraphs (c)(3)(ii) - (iv) of this section must be on a separate page from information that is not so designated.

(4) *Voluntary release of information to States and foreign governments.* (i) Submitters are encouraged to include with the statement required under paragraph (c)(2) of this section an additional statement to allow EPA to share information with State and foreign governments. EPA will not consider such a statement to be a waiver of confidentiality or proprietary claims for the information. The statement is as follows:

I authorize the Environmental Protection Agency to release any information contained in this document to State or foreign governments, without relinquishing proprietary rights or any confidentiality claims asserted above.

(ii) Information designated as releasable to state or foreign governments in accordance with this section may be released to such a government without further notice to the submitter. EPA will inform the State or foreign government of any of the confidentiality claims associated with the information.

(d) *Release of information.* (1) Safety and efficacy information that was submitted to EPA on or after May 4, 1988 and that has not been designated by the submitter as FIFRA sec. 10(d)(1)(A), (B), or (C) information in accordance with the applicable requirements of this section is not entitled to confidential treatment and may be disclosed to the public without further notice to the submitter, in accordance with paragraph (d)(2) of this section. Safety and efficacy information which has been designated by the submitter as FIFRA sec. 10(d)(1) (A), (B), or (C) information is entitled to confidential treatment only to the extent provided by FIFRA sec. 10(b), this section, and 40 CFR 2.208.

(2) Information that is not entitled to be protected as confidential in accordance with FIFRA sec. 10(b), this section and with EPA confidentiality regulations at 40 CFR part 2, subpart B, may be released to the public without the affirmation of non-multinational status provided under FIFRA sec. 10(g), provided that the information does not contain or consist of any complete unpublished report submitted to EPA, or excerpts or restatements of any such report which reveal the full methodology and complete results of the study, test, or experiment, and all explanatory information necessary to understand the methodology or interpret the results.

§ 158.34 Flagging of studies for potential adverse effects.

(a) Any applicant who submits a study of a type listed in paragraph (b) of this section must submit with the study a statement in accordance with paragraph (c) of this section.

(b) The following table indicates the 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

Study Type(s)	Guideline No.	Criteria: Treated animals show any of the following:	Criteria No.
Carcinogenicity or combined carcinogenicity/chronic feeding study.	870.4200	An incidence of neoplasms in males or females which increases with dose (positive trend $p \leq 0.05$); or	1
	870.4300	A statistically significant (pairwise $p \leq 0.05$) increase of any type of neoplasm in any test group, males or females at any dose level, compared to concurrent control animals of the same sex; or	2
		An increase in any type of uncommon or rare neoplasms in any test group, males or females animals at any dose level, compared to concurrent controls of the same sex; or	3
		A decrease in the time to development of any type of neoplasms in any test group, males or females at any dose level, compared to concurrent controls of the same sex.	4
Prenatal developmental toxicity Reproduction and fertility Developmental neurotoxicity	870.3700 870.3800 870.6300	When compared to concurrent controls, treated offspring show a dose-related increase in malformations, pre- or post-natal deaths, or persistent functional or behavioral changes on a litter basis in the absence of significant maternal toxicity at the same dose level.	5
Neurotoxicity	870.6100 870.6200	When compared to concurrent controls, treated animals show a statistically or biologically significant increase in neuropathological lesions or persistent functional or behavioral changes.	6
Chronic feeding Carcinogenicity Reproduction and fertility Prenatal developmental toxicity Developmental neurotoxicity Acute or 90-day neurotoxicity	870.4100 870.4200 870.3800 870.3700 870.6300 870.6200	The no observed adverse effect level (NOAEL) from one of these studies is less than the NOAEL currently used by the Agency as the basis for either the acute or chronic reference dose.	7

(c) *Identification of studies.* For each study of a type identified in paragraph (b) of this section, the applicant shall include the appropriate one of the following two statements, together with the signature of the authorized rep-

resentative of the company, and the date of signature:

(1) Study does not meet or exceed criteria.

I have applied the criteria of 40 CFR 158.34 for flagging studies for potential adverse effects to the results of the attached study.