

## Environmental Protection Agency

## § 158.34

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 disclose) 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

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(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 870.4300	An incidence of neoplasms in males or females which increases with dose (positive trend $p \leq 0.05$ ); or	1
		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 representative 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. This study neither meets nor exceeds any of the applicable criteria.

(2) Study meets or exceeds 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. This study meets or exceeds the criteria numbered [insert all applicable reporting codes].

§ 158.45 Waivers.

(a) The data requirements specified in this part as applicable to a category of products will not always be appropriate for every product in that category. Some products may have unusual physical, chemical, or biological properties or atypical use patterns which would make particular data requirements inappropriate, either because it would not be possible to generate the required data or because the data would not be useful in the Agency's evaluation of the risks or benefits of the product. The Agency will waive data requirements it finds are inappropriate, but will ensure that sufficient data are available to make the determinations required by the applicable statutory standards.

(b)(1) Applicants are encouraged to discuss a data waiver request with the