

TEXT OF PROPOSED REGULATION

Current wording is indicated by regular type.
Proposed deletions are indicated by ~~strikeout~~.
Proposed additions are indicated by underline.

TITLE 3. CALIFORNIA CODE OF REGULATIONS DIVISION 6. PESTICIDES AND PEST CONTROL OPERATIONS CHAPTER 2. PESTICIDE SUBCHAPTER 1. PESTICIDE REGISTRATION ARTICLE 3. SUPPLEMENTAL DATA REQUIREMENTS

Amend section 6186 to read:

6186. Efficacy.

(a) Each application for registration or amendment to the labeling of a pesticide product that contains an efficacy claim that the Director determines is significantly different from efficacy claims on other currently registered pesticide products shall be accompanied by data supporting each such efficacy claim on the pesticide product label.

(b) An efficacy claim is considered to be "significantly different" from a claim on another currently registered pesticide product(s), if:

(1) The product contains different active ingredients;

(2) The label of the new product or amendment claims control of a new target pest or a different life stage of the target pest; or

(3) The label claim(s) or use direction(s) of the new product or amendment differs substantially from other currently registered products in any of the following ways:

(A) Rates of Application (amount of active ingredient per treatment area);

(B) Method of Application;

(C) Site of Application; or

(D) Claims increased level of control of the pest.

(c) Notwithstanding subsection (a), the Director may at any time, require the submission of efficacy data for any label claim on a pesticide product registered or proposed for registration.

(d) If data supporting efficacy ~~such~~ claims are in the public domain, and copies of the data are provided, the submission of such data may satisfy the requirements of this section.

(e) Such Efficacy data studies shall be ~~obtained~~ conducted under California or similar environmental use conditions and shall take into consideration differences in plants, soils, climate conditions, and application techniques.

NOTE: Authority cited: Sections 11456, and 12781 ~~14004.5 and 14006.7~~, Food and Agricultural Code. Reference: Sections 11501, ~~12561~~, 12824, 12825, and 12854, Food and Agricultural Code.

ARTICLE 4. CONDITIONAL REGISTRATION

Amend section 6200 to read:

6200. Conditional Registration.

The ~~d~~Director may waive specific data requirements in this subchapter for a period reasonably sufficient, not to exceed three years, for the generation and submission of such required data provided:

(a) The pesticide product is registered pursuant to the Federal Insecticide, Fungicide, and Rodenticide Act, the product is to be used under a Federal Experimental Use Permit, or the product is for use in California only.

(b) The applicant has provided the ~~d~~Director with all data the applicant has available required by the U.S. EPA and by this subchapter to support registration of the pesticide product.

(c) No conditional registration shall be granted unless the data includes all of the following:

(1) Acute oral and dermal LD₅₀ data on the product.

(2) Acute LC₅₀ data on products which produce respirable aerosols or gases.

(3) Primary eye and skin irritation data on the product.

(4) When human contact is likely with soils or foliage containing residues, foliar and soil residue data as specified in ~~S~~sections 6181 and 6182, sufficient to establish safe reentry level or interval.

(5) Analytical methods to determine residues of (1) each active ingredient and (2) each toxic metabolite that may result from the active ingredient for which a tolerance has been established by the U.S. EPA in the Code of ~~the~~ Federal Regulations. Test methods shall, as applicable, allow the ~~d~~Director to determine residues in or on plant tissue, soil, and water.

(6) ~~If required pursuant to section 6186, P~~preliminary efficacy data indicating the product is effective for the proposed use.

(d) The ~~d~~Director complies with ~~S~~section 6158.

(e) That each item of data waived is for a specific period.

Such period shall be no more than necessary for the applicant using good faith efforts to develop the ~~information required by Sections 6176-6179, 6180(a), 6181-6183~~ required data.

(f) The ~~d~~Director makes a written finding, supported by substantial evidence, that the use of the pesticide during the periods while data are being developed, is not expected to cause any significant adverse effect on the environment, that a clear need for the use of the product in California exists while the data ~~is~~ are being developed, and that specified benefits of using the pesticide outweigh specified risks to human health and the environment.

(g) The ~~d~~Director requires the use of the best pest control methods and technology available including, but not limited to, methods of application to protect human health and the environment, and limitations to mitigate adverse effects to nontarget organisms or areas.

(h) Each registrant be required to submit a report to the ~~d~~Director annually (with product renewal application if such a waiver extends over January 1 of any year) and whenever specifically requested by the ~~d~~Director, detailing progress made towards development of each item of the waived data.

(i) Where the application is for a pesticide product containing a new active ingredient, the applicant has provided the ~~d~~Director with the following data in addition to the data required by section 6200(c), (1)-(6) when required by the U.S. EPA to support the full unconditional registration of the product pursuant to ~~S~~section 3 of the Federal Insecticide, Fungicide, and Rodenticide Act and when specifically requested by the ~~d~~Director:

(1) Results of a two-year feeding study on oncogenicity on active ingredients in at least one animal species.

(2) Results of a teratogenicity study and one generation of a two-generation combined male-female reproductive study on active ingredients.

(3) Results of three mutagenicity studies on active ingredients that detect gene mutations, chromosomal aberrations, and DNA damage/repair.

(4) Data to support medical management of poisoning or injury.

NOTE: Authority cited: Sections 11456 and 12781, Food and Agricultural Code.

Reference: Sections 11501 and 12824-12825, Food and Agricultural Code.

ARTICLE 8. REEVALUATION CRITERIA

Amend section 6222 to read:

6222. Reevaluation Data Requirements.

(a) During a reevaluation, the ~~e~~Director shall require submission of all data required for registration of a new pesticide by the U.S. EPA and by sections 6159, 6170, 6176-6179, 6180(a), 6181-6192, and 6200 which ~~is~~ are relevant to the focus of the reevaluation and ~~has~~ have not previously been submitted to the department. If relevant to the reevaluation, the Director may require the submission of efficacy data not previously required pursuant to section 6186. The ~~e~~Director shall allow a reasonable time for the development and submission of such data, not to exceed a period of two years. Notwithstanding the lack of such data, the ~~e~~Director shall act expeditiously to protect against risks to human health and the environment.

(b) If information is obtained from an individual or organization indicating possible adverse effect from the use of a pesticide, the ~~e~~Director shall respond in writing to the individual or organization indicating the reasons for his or her decision either to reevaluate or not reevaluate the pesticide registration based upon the information submitted.

NOTE: Authority cited: Sections 11456, ~~11502, 12005, 12111, 12531, 12561, and~~ 12781, ~~12976, 12981, 14005 and 14006.7,~~ Food and Agricultural Code. Reference: Sections ~~11401 12121, 12501 12671, 12751 13102 and 14001 14104,~~ 11501, 12824, 12825, 12825.5, 12826, and 12827, Food and Agricultural Code.