

TEXT OF PROPOSED REGULATIONS

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

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

ARTICLE 2. REGISTRATION REQUIREMENTS

Amend section 6170 to read:

6170. Application.

(a) Each application for registration of a pesticide product shall be made on the Application for Pesticide Registration Form 39-030 (Rev. 9/03), prescribed by the director and described in section 6170.5. The application is incomplete and may be returned by the Director if the application is not accompanied by the fee required by section 6148, six copies of the product labeling, and the data required to be submitted by sections 6159, 6170, 6172, 6176-6179, 6180(a), 6181-6192, and 6200 when applicable to support registration of the product. All data submitted by the applicant to the U.S. EPA in support of federal registration shall be submitted and all studies shall be submitted in full. The product labeling should be printer's proof, final labels, or legible photocopies, thereof. If typescript labels are submitted with the application, printer's proof, final labels, or legible photocopies, thereof, must be submitted before a Certificate of Registration (License) for the product will be issued. If the label has been approved by a federal agency, proof of such approval shall be submitted with the application.

(b) An application to amend the labeling (including a special local needs labeling) of a pesticide product is incomplete and may be returned by the Director if the application is not accompanied by the fee required by 6148.5, six copies of the labeling and the data required to be submitted by sections 6159, 6170, 6172, 6176-6179, 6180(a), 6181-6192, and 6200 when applicable to the amendment. The application to amend the labeling shall be accompanied by all data submitted by the applicant to the U.S. EPA in support of the federal amended labeling and all studies shall be submitted in full. The product labeling should be printer's proof, final labels or legible photocopies; thereof. If typescript labels are submitted, printer's proof, final labels or legible photocopies; thereof, must be submitted before the amended label will be accepted for use. If the amended labeling has been approved by a federal agency, proof of such approval shall be submitted with the amendment application.

(c) In lieu of submitting data pursuant to subsections (a) and (b) of this section, ~~the registrant~~ an applicant for registration or amendment may reference appropriate data previously submitted to the ~~d~~Director by the registrant. ~~Data previously submitted to the director may be used by any applicant when an authorization is submitted in writing to the Department, by the owner of that data or a pesticide product(s) previously approved by the Director that would be subject to some or all of the same data requirements as applicable to the applicant's product.~~

(d) If an applicant does not submit or reference its own data to support its application for registration or amendment, it is subject to the requirements imposed under Food and Agricultural Code section 12811.5.

NOTE: Authority cited: Section 12781, Food and Agricultural Code.

Reference: Sections 12811, 12812, 12815 and 12816, Food and Agricultural Code.

Adopt Article 15 to read:

ARTICLE 15. DATA COST-SHARING

Adopt section 6310 to read:

6310. Dispute Resolution Proceedings.

If agreement cannot be reached about the terms and amount of payment required pursuant to Food and Agricultural Code section 12811.5, at any time more than 90 days after the issuance of an irrevocable offer to pay, either the applicant, source, or data owner may initiate or with the consent of all parties, join a binding dispute resolution proceeding under the rules prescribed under Title 29 Code of Federal Regulations, Part 1440, or its successor provision, if any, or other rules to which the applicant and data owner may agree.

(a) To the extent feasible, and upon mutual consent of the parties, the proceeding may be consolidated with any dispute resolution process taking place between the same parties and being conducted pursuant to the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. Sec 136a et.seq.).

(b) In determining the amount due under this section, the decisionmaker(s) of a dispute resolution proceeding shall consider, among other factors, that the data owner's exclusive right to sell the pesticide resulted in the data owner recovering all or part of the costs of generating the data.

(c) The finding of the decisionmaker(s) in a dispute resolution proceeding shall be final and conclusive, and no official or court shall have power or jurisdiction to review that finding and determination, except for fraud, misrepresentation, or other misconduct by one of the parties to the dispute resolution proceeding or by the decisionmaker(s) where there is a verified complaint with supporting affidavits attesting to specific instances of fraud, misrepresentation, or misconduct.

(d) The parties to the dispute resolution proceeding shall share equally in the payment of fees and expenses of the dispute resolution process, except that each party shall bear its legal fees and its expenses.

NOTE: Authority cited: Section 12811.5, Food and Agricultural Code.

Reference: Section 12811.5, Food and Agricultural Code.

Adopt section 6312 to read:

6312. Noncompliance Notification.

Pursuant to Food and Agricultural Code section 12811.5(g), any notification to the Director of an applicant's failure to comply with its obligation under Food and Agricultural Code section 12811.5(a-d) shall be in writing and shall include, organized by the subsection and subparagraph below to which it is responsive:

- (a) Identification of the applicant and the product registration challenged, including:
 - (1) Applicant name and address;
 - (2) Brand name and U.S. Environmental Protection Agency Registration Number of the product;
 - (3) Date of the Department's registration of the product; and
 - (4) Identification of each current and/or past Department data requirement for which you claim the applicant failed to submit a study or otherwise satisfy, and for which the applicant failed to make your company an offer to pay.
- (b) With respect to the data for which the data owner claims the applicant failed to make an offer to pay:
 - (1) Identification of the Department's exact data requirement to obtain, amend, or maintain the data owner's product that the data was submitted to satisfy;
 - (2) Identification of each study (including DPR document number and study record number) submitted and the corresponding data requirement it satisfied; and
 - (3) The date each study was submitted to the Department and, if applicable, to the U.S. Environmental Protection Agency (including the Master Record Identification Number - MRID).
- (c) A statement setting forth with specificity the contention that the data requirements applicable to the product registration or amendment can only be satisfied by the data for which cost sharing is sought, and all documents supporting that contention.
- (d) Proof that, prior to making the notification to the Director pursuant to Food and Agricultural Code section 12811.5(g), the data owner has informed the applicant of its claim, provided the applicant with the information required in (a), (b), and (c), and allowed the applicant an opportunity of at least ten days to promptly make an offer to pay for the data that serves as a basis of the data owner's claim. This proof shall include copies of all correspondence between the data owner and the applicant related to this issue.
- (e) Proof that at the same time the data owner filed its notification to the Director of the applicant's failure to meet its obligation under Food and Agricultural Code section 12811.5(a-d), the data owner sent a copy of the notification and all accompanying data and information by certified mail to the applicant.
- (f) With respect to a claim that the applicant has failed to participate in a proceeding for reaching an agreement on compensation, failed to comply with an agreement related to compensation, or failed to pay an award resulting from a proceeding to determine compensation, proof of such failure including, but not limited to, all correspondence between the parties on the issue and a copy of the award resulting from a proceeding on compensation, if any.

NOTE: Authority cited: Section 12811.5, Food and Agricultural Code.
Reference: Section 12811.5, Food and Agricultural Code.

Adopt section 6314 to read:

6314. Determination.

All parties shall have 30 days from receipt of the copy of the notification to the Director to submit additional evidence and written arguments to the Director. The Director may rely solely on the information provided by the two parties involved in the dispute, without conducting any further investigation. The Director shall provide a written finding within 60 days of the deadline for the parties' submissions. If the Director determines that the applicant has not met its obligations under Food and Agricultural Code section 12811.5(a-d), the Director shall cancel the applicant's product registration, without further hearing, no later than 45 days after issuing the written finding.

NOTE: Authority cited: Section 12811.5, Food and Agricultural Code.

Reference: Section 12811.5, Food and Agricultural Code.