

INITIAL STATEMENT OF REASONS AND PUBLIC REPORT
DEPARTMENT OF PESTICIDE REGULATION

Title 3. California Code of Regulations
Adopt Sections 6310, 6312, and 6314, and Amend Section 6170
Pertaining to Data Cost-Sharing

This is the Initial Statement of Reasons required by Government Code section 11346.2 and the public report specified in section 6110 of Title 3, California Code of Regulations (3 CCR). Section 6110 meets the requirements of Title 14, CCR section 15252, and Public Resources Code section 21080.5 pertaining to certified state regulatory programs under the California Environmental Quality Act.

SUMMARY OF PROPOSED ACTION/PESTICIDE REGULATORY PROGRAM
ACTIVITIES AFFECTED

The Department of Pesticide Regulation (DPR) proposes to adopt Article 15, Data Cost-Sharing, sections 6310, 6312, and 6314, and amend section 6170 in 3 CCR. The pesticide regulatory program activities that will be affected by the proposal are those pertaining to pesticide product registration. In summary, the proposed action would prescribe in detail the proceeding authorized by Food and Agricultural Code (FAC) section 12811.5 to resolve disputes over the terms and amount of data cost-sharing. Proposed sections 6310 and 6170 are currently in effect as emergency regulations. This proposed regulatory action would make sections 6310 and 6170 permanent.

SPECIFIC PURPOSE AND FACTUAL BASIS

Existing law requires every manufacturer, importer, or dealer of any pesticide to obtain a certificate of registration from DPR before the pesticide is offered for sale. In support of the registration, an applicant for registration must submit human health and environmental fate data.

Until January 1, 2006, FAC section 12811.5 provided that if an applicant did not submit its own data to fulfill DPR's data requirements for a new pesticide product or an amendment to a currently registered pesticide product, and the applicant wished to rely upon data owned by another company, DPR needed written authorization (letter of authorization) from the appropriate data owner. If an applicant did not wish to, or could not, obtain a letter of authorization from a current data owner, then the applicant had to submit its own duplicate data to DPR.

Assembly Bill 1011 (Chapter 612, Statutes of 2005) changed state law regarding how DPR treats data submitted in support of product registration. FAC section 12811.5 now allows DPR to consider evaluations of all data it has on file, regardless of the source of the data. The new law did not change any of DPR's data requirements. Applicants may still submit their own data in support of a registration application. However, if an applicant does not do so, and instead relies on another company's data to support its registration application, the applicant may be required to make an offer to pay the data owner.

FAC section 12811.5 allows DPR to rely upon any evaluations of previously submitted data with respect to an application for registration, an amendment to a registration, or to maintain a registration. DPR is not required to monitor or police data ownership when making registration decisions. The law specifically states that, when making registration decisions, DPR can rely on evaluations of any data on file, regardless of data ownership.

FAC section 12811.5 states that if the applicant or the source of the applicant's product is required to make an offer to pay a data owner, this offer must be made by the date an application is submitted to DPR. The specific terms and amount of payment shall be fixed by agreement between the applicant and the owner, but shall not delay approval of the applicant's application. However, if the applicant and the data owner cannot agree on the amount and terms of compensation within 90 days of the offer, either party may initiate a proceeding under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) pursuant to emergency regulations adopted by DPR to resolve disputes concerning compensation. Further, if a party fails to make an offer to pay, or refuses to participate in a proceeding or abide by a resulting award, the statute provides for a determination by the Director that could result in cancellation of the disputed registration.

DPR filed sections 6310 and 6170 as emergency regulations with the Office of Administrative Law (OAL File No. 06-0313-04E) to establish a proceeding to resolve disputes over the terms and amount of payment required under this new law if agreement cannot be reached at any time more than 90 days after issuance of an irrevocable offer to pay. Emergency regulation section 6310 provides that 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. Section 6170 was amended to be consistent with FAC 12811.5. The emergency regulations were approved and became effective on March 23, 2006.

DPR proposes to permanently adopt Article 15, Data Cost-Sharing, section 6310. Proposed section 6310 would allow the proceeding to be combined with any dispute resolution process taking place between the same parties and conducted under FIFRA; require the decisionmaker to consider that the data owner recovered all or part of its costs of generating data by having an exclusive right to sell the pesticide for some period of time; specify that the finding of the decisionmaker shall be final and conclusive; and that the parties to the dispute resolution proceedings equally share in the payment of fees and expenses.

FAC section 12811.5(g) specifies that if the applicant fails to promptly make an offer to pay or contests the obligation, the data owner and the applicant have 30 days to submit written evidence to DPR supporting their respective positions. Proposed section 6312 covers notification procedures to the Director of an applicant's failure to comply with its obligation under FAC section 12811.5(a-d).

Upon receipt of such notification, proposed section 6314 specifies that DPR shall issue a written finding within 60 days of deadline for the parties' submissions. Additionally, if the Director determines that the applicant has not met its obligations under FAC section 12811.5(a-d), the

Director will cancel the registration of the applicant's product no later than 45 days of issuing the written finding. These time frames have been established pursuant to FAC section 12811.5(g).

DPR proposes to permanently amend section 6170 to be consistent with the changes to FAC section 12811.5.

ALTERNATIVES TO THE PROPOSED REGULATORY ACTION

DPR has not identified any feasible alternatives to the proposed regulatory action that would lessen any adverse impacts, including any impacts on small businesses, and invites the submission of suggested alternatives.

EFFORTS TO AVOID UNNECESSARY DUPLICATION WITH FEDERAL REGULATIONS

The proposed regulatory action does not duplicate or conflict with any regulations contained within the Code of Federal Regulations.

DOCUMENTS RELIED UPON

There are no documents upon which DPR is relying in proposing this regulation other than the provisions of California law.