

TITLE 3. DEPARTMENT OF PESTICIDE REGULATION  
Data Cost-Sharing  
DPR Regulation No. 06-003

NOTICE OF PROPOSED REGULATORY ACTION

The Department of Pesticide Regulation (DPR) proposes to adopt Article 15, Data Cost-Sharing, sections 6310, 6312, and 6314, and amend section 6170 in Title 3, California Code of Regulations (3 CCR) to 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.

SUBMITTAL OF COMMENTS

Any interested person may present comments in writing about the proposed action to the agency contact person named below. Written comments must be received no later than 5:00 p.m. on June 19, 2006. Comments regarding this proposed action may also be submitted via e-mail <[dpr06003@cdpr.ca.gov](mailto:dpr06003@cdpr.ca.gov)>, or by facsimile (FAX) transmission at (916) 324-5872.

A public hearing is not scheduled; however, a public hearing will be scheduled if any interested person submits a written request for a public hearing to DPR no later than 15 days prior to the close of the written comment period.<sup>1</sup>

EFFECT ON SMALL BUSINESS

DPR has determined that the proposed regulatory action may affect certain types of small businesses. The types of businesses that may be affected by the proposed regulatory change include companies that register pesticide products for sale and use in California.

INFORMATIVE DIGEST/POLICY STATEMENT OVERVIEW

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.

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<sup>1</sup> If you have special accommodation or language needs, please include this in your request for a public hearing. TTY/TTD speech-to-speech users may dial 7-1-1 for the California Relay Service.

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.

Pursuant to FAC section 12811.5(d), DPR filed sections 6310 and 6170 as emergency regulations with the Office of Administrative Law (OAL File No. 06-0313-04E) to prescribe in more detail the proceeding authorized by the statute to resolve disputes over the terms and amount of cost-sharing required by FAC section 12811.5. The emergency regulations became effective on March 23, 2006.

DPR proposes to permanently adopt Article 15, Data Cost-Sharing, sections 6310, 6312, and 6314. Specifically, the proposal would:

- Allow the proceeding to be combined with any dispute resolution process taking place between the same parties and conducted under the Federal Insecticide, Fungicide, and Rodenticide Act; 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, the parties to the dispute resolution proceedings equally share in the payment of fees and expenses.
- 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, specify 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.

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

#### IMPACT ON LOCAL AGENCIES OR SCHOOL DISTRICTS

DPR has determined that the proposed regulatory action does not impose a mandate on local agencies or school districts, nor does it require reimbursement by the state pursuant to Part 7 (commencing with section 17500) of Division 4 of the Government Code because the regulatory action does not constitute a "new program or higher level of service of an existing program" within the meaning of section 6 of Article XIII of the California Constitution. DPR has also determined that no nondiscretionary costs or savings to local agencies or school districts will result from the proposed regulatory action.

## COSTS OR SAVINGS TO STATE AGENCIES

DPR has determined that any increased costs to DPR due to the increased level of service provided under the proposed regulatory action are absorbable in the current budget. However, should costs increase in the future, DPR may need additional funding. The proposed regulatory change may reduce workload in the area of scientific data review; however, the workload of reviewing application is expected to increase and, due to personnel cuts and DPR's backlog, any savings from the proposed regulatory change will be put towards reducing the backlog of applications. No positions will be eliminated. The workload of DPR's legal staff may also increase dependent upon how many companies submit noncompliance determinations. DPR has determined that no increased costs or savings to any other state agency will result from the proposed regulatory action.

## EFFECT ON FEDERAL FUNDING TO THE STATE

DPR has determined that no costs or savings in federal funding to the state will result from the proposed action.

## EFFECT ON HOUSING COSTS

DPR has made an initial determination that the proposed action will have no effect on housing costs.

## SIGNIFICANT STATEWIDE ADVERSE ECONOMIC IMPACT DIRECTLY AFFECTING BUSINESSES

DPR has made an initial determination that the adoption of this regulation will not have a significant statewide adverse economic impact directly affecting businesses, including the ability of California businesses to compete with business in other states.

## COST IMPACT ON REPRESENTATIVE PRIVATE PERSONS OR BUSINESSES

DPR has made an initial determination that the adoption of this regulation will not have a significant cost impact on representative private persons or businesses. The agency is not aware of any cost impacts that a representative private person or business would necessarily incur in reasonable compliance with the proposed action.

## IMPACT ON THE CREATION, ELIMINATION, OR EXPANSION OF JOBS/BUSINESSES

DPR has determined it is unlikely that the proposed regulatory action will impact the creation or elimination of jobs, the creation of new businesses or the elimination of existing businesses, or the expansion of businesses currently doing business within the State of California.

## CONSIDERATION OF ALTERNATIVES

DPR must determine that no reasonable alternative considered by the agency, or that has otherwise been identified and brought to the attention of the agency, would be more effective in carrying out the purpose for which the action is proposed or would be as effective and less burdensome to affected private persons or businesses. For this regulation, alternatives are not applicable because the statute requires DPR to adopt these regulations.

## AUTHORITY

This regulatory action is being taken pursuant to authority vested by FAC sections 12781 and 12811.5.

## REFERENCE

This regulatory action implements, interprets, or makes specific FAC sections 12811, 12812, 12815, 12816, and 12811.5.

## AVAILABILITY OF STATEMENT OF REASONS AND TEXT OF PROPOSED REGULATIONS

DPR has prepared an Initial Statement of Reasons and has available the express terms of the proposed action, all of the information upon which the proposal is based, and a rulemaking file. A copy of the Initial Statement of Reasons and the proposed text of the regulations may be obtained from the agency contact person named in this notice. The information upon which DPR relied in preparing this proposal and the rulemaking file are available for review at the address specified below.

## AVAILABILITY OF CHANGED OR MODIFIED TEXT

After the close of the comment period, DPR may make the regulations permanent if they remain substantially the same as described in the Informative Digest. If DPR does make substantial changes to the regulations, the modified text will be made available for at least 15 days prior to adoption. Requests for the modified text should be addressed to the agency contact person named in this notice. DPR will accept written comments only on any changes for 15 days after the modified text is made available.

## AGENCY CONTACT

Written comments about the proposed regulatory action; requests for a copy of the Initial Statement of Reasons; the proposed text of the regulation; and a public hearing; inquiries regarding the rulemaking file; or questions on the substance of the proposed regulatory action may be directed to:

Polly Frenkel, Chief Counsel  
Department of Pesticide Regulation  
Office of Legal Affairs  
1001 I Street, P.O. Box 4015  
Sacramento, California 95812-4015  
(916) 324-2666

Note: In the event the contact person is unavailable, inquiries should be directed to the following backup contact person at the same address as above.

Linda Irokawa-Otani, Regulations Coordinator  
Office of Legislation and Regulations  
(916) 445-3991

This Notice of Proposed Action, the Initial Statement of Reasons, and the proposed text of the regulation are also available on DPR's Internet Home Page <<http://www.cdpr.ca.gov>>.

AVAILABILITY OF FINAL STATEMENT OF REASONS

Following its preparation, a copy of the Final Statement of Reasons mandated by Government Code section 11346.9(a) may be obtained from the contact person named above. In addition, the Final Statement of Reasons will be posted on DPR's Internet Home Page and accessed at <<http://www.cdpr.ca.gov>>.

DEPARTMENT OF PESTICIDE REGULATION

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Director

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Date