

TITLE 3. DEPARTMENT OF PESTICIDE REGULATION
Pesticide Product Registration
DPR Regulation No. 06-004

NOTICE OF PROPOSED REGULATORY ACTION

The Department of Pesticide Regulation (DPR) proposes to amend sections 6170(a) and (b), 6172(a), and 6200(c) in Title 3, California Code of Regulations (3 CCR). The proposed regulatory action would clarify regulations related to data requirements for pesticide product registration consistent with past and current practices of the Department.

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 September 18, 2006. Comments regarding this proposed action may also be submitted via e-mail <dpr06004@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.¹

EFFECT ON SMALL BUSINESS

DPR has determined that the proposed regulatory action does not affect small businesses. The proposed minor changes only clarify regulations consistent with past and current pesticide product registration practices.

INFORMATIVE DIGEST/POLICY STATEMENT OVERVIEW

DPR is proposing amendments to sections 6170(a) and (b), 6172(a), and 6200(c). The Office of Administrative Law (OAL) initially approved these proposed changes on June 5, 2002 (OAL File No. 02-0423-03N) and August 14, 2002 (OAL File No. 02-0729-01N), respectively, as changes without regulatory effect. However, a recent Appellate Court ruling (*Syngenta Crop Protection, Inc. v. Helliker* [2006] 136 Cal.App.4th 1464), found the changes to be substantive and subject to the rulemaking procedures of Chapter 3.5, Article 5 of the Administrative Procedures Act (APA). The Court ruled that, even though these amendments were consistent with DPR's practice under the former regulations, DPR was required to inform the public of the proposed amendments.

Title 1 CCR section 100(a)(3) states that an agency may revise text published in CCR without complying with the rulemaking procedure specified in article 5 of the APA to delete a regulatory provision held invalid in a judgment that has become final, entered by a California court of competent jurisdiction, a U.S. District Court located in California, the U.S. Court of Appeals for

¹ 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.

the Ninth Circuit, or U.S. Supreme Court. Therefore, even though the Court ruled that the amendments were adopted in violation of the APA and are invalid, the text in the existing 3 CCR reflects the language that was approved on June 5 and August 14, 2002, and will not be revised until judgment becomes final. However, DPR is proceeding to adopt these proposed amendments under the rulemaking procedures of Chapter 3.5, Article 5 of the APA. Therefore, the text of the proposed regulations does not reflect what is currently published in 3 CCR. The proposed regulations are presented as if the additions and deletions are being made to the text that existed prior to the changes made in 2002.

DPR proposes to amend the following sections:

- DPR proposes to add the phrase "by the applicant" to subsections 6170(a) and (b). The proposed change will further clarify that the data that must be submitted to DPR with each application for product registration or label amendment are the data that the applicant submitted to the U.S. Environmental Protection Agency (U.S. EPA) to support federal registration or amendment of the product that the applicant is requesting to register or amend in California. Additionally, to correct an unintentional omission that occurred in 1990 when section 6170 was amended (OAL File No. 90-0621-02) DPR is restoring the reference to sections 6181-6192 in the second sentence of 6170(a) to correspond to their reference in subsection (b). The word or term "product" and "of the product" has been added to subsections (a) and (b) to be consistent with the use of the terms elsewhere in section 6170.
- DPR proposes to delete the phrase "and active ingredients" in sections 6172(a)(1) and (3) and 6200(c)(1) and (3) because the phrase is redundant and potentially confusing to the regulated public. DPR requires applicants for registration of a pesticide product to submit acute toxicity studies conducted on the formulation of the product that is intended to be sold for use in California. If the product is a manufacturing use product containing only the technical grade chemical active ingredient, then the acute toxicity studies must be conducted using the technical grade chemical active ingredient. If the product contains other ingredients, in addition to the chemical active ingredient (i.e., the product has been formulated), then the acute toxicity studies must be conducted using the product as formulated. Because the term "product" is applicable to both formulated products and products containing only active ingredients, the additional reference to "active ingredient" is redundant and potentially confusing to the regulated public.
- Clarify the agency being referenced by replacing all references to the previous acronym for U.S. Environmental Protection Agency "EPA" with the acronym "U.S. EPA" in sections 6170 and 6172.

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 no savings or increased costs to any 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 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 action makes only clarifying changes to existing regulation.

AUTHORITY

This regulatory action is being taken pursuant to authority vested by Food and Agricultural Code sections 11456, 12781, and 12824.

REFERENCE

This regulatory action implements, interprets, or makes specific Food and Agricultural Code sections 11501, 12811, 12812, 12815, 12816, and 12824-12825.

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

Director

Date