

TITLE 3. DEPARTMENT OF PESTICIDE REGULATION
Research Authorizations
DPR Regulation No. 15-001

NOTICE OF PROPOSED REGULATORY ACTION

The Department of Pesticide Regulation (DPR) proposes to amend sections 6260, 6262, 6264, and 6266 of Title 3, California Code of Regulations. The proposed actions will clarify the information required on the research authorization application and reporting forms, and will revise the notification requirements. DPR proposes to incorporate by reference the following application forms: Pesticide Research Authorization [(DPR-REG-027a, Est. 4/15)], Pesticide Research Authorization (Additional Pesticides) [(DPR-REG-027b, Est. 4/15)], Experimental Trial Report [(DPR-REG-029, Est. 4/15)], Experimental Pesticide Use Report [(DPR-REG-028a, Est. 4/15)], and Experimental Pesticide Use Report (Continued) [(DPR-REG-028b, Est. 4/15)]. Copies of these forms are included in the rulemaking file and are available upon request.

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 August 24, 2015. Comments regarding this proposed action may also be transmitted via e-mail to <dpr15001@cdpr.ca.gov> or by facsimile at 916-324-1491.

A public hearing is not scheduled. However, one will be scheduled if any interested person submits a written request 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 affect small businesses.

INFORMATIVE DIGEST/POLICY STATEMENT OVERVIEW

DPR protects human health and the environment by regulating pesticide sales and use and by fostering reduced-risk pest management. DPR's strict oversight includes: product evaluation and registration; statewide licensing of commercial and private applicators, pest control businesses, dealers, and advisers; environmental monitoring; and residue testing of fresh produce. This statutory scheme is set forth primarily in Food and Agricultural Code (FAC) Divisions 6 and 7.

Pesticides must be registered (licensed for sale and use) with the U.S. Environmental Protection Agency (U.S. EPA) before they can be registered in California. DPR's preregistration evaluation is in addition to, and complements, U.S. EPA's evaluation. Before U.S. EPA and DPR register a pesticide or a new use of a registered pesticide, both agencies require data on a product's: toxicology and chemistry to evaluate how it may impact human health and the environment; effectiveness against targeted pests; potential to pose hazards to nontarget organisms; effect on

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

fish and wildlife; and potential for worker exposure. Some data, such as certain efficacy (proof that the product will work when used in accordance with use directions), environmental fate, and worker exposure data, must be generated under field conditions. As part of its certified regulatory program under the California Environmental Quality Act, DPR requires that these data be generated specifically under California use conditions. Because registrants must conduct these field studies in California to collect the data, federal and state law allow registrants to apply for limited use of unregistered pesticides.

With few exceptions, section 6260 requires a researcher to obtain approval from DPR before any unregistered use of a pesticide occurs in California. A research authorization allows registrants and researchers to conduct limited field trials with products that are not registered or are not registered for a particular use pattern in California. Field data collected under the research authorization are used to support the California registration of a pesticide product or new use of a currently registered product. Prior to issuing a research authorization, DPR conducts an evaluation of the potential hazards of the pesticide to human health and the environment and determines what kind of restrictions should be imposed on the research. When trials are conducted on crops, the research authorization program also prevents produce bearing an illegal pesticide residue from entering the food chain.

There are several relevant points about research authorizations that should be noted. First, they are not always implemented. For example, in 2014, approximately 700 research authorizations were issued, but only 550 were completed. Second, the research typically involves a limited area. According to pesticide use reports, of the 550 trials conducted in 2014, 95 percent were conducted on a total area of 10 acres or less, with 89 percent of the trials conducted on a total area of one acre or less. Only 3 percent of trials were conducted on a total area of more than 10 acres. The remaining 2 percent of trials reported use in units other than acres or square footage (such as number of trees or vines).

Section 6262 specifies the information a researcher must provide to DPR on the application form, such as: brand name, common name, or ID number of the pesticide being applied; U.S. EPA registration number; dosage of active ingredient; any existing residue tolerances; type of site or commodity being treated; size of the trials; and proposed disposition for the treated crop. DPR may also require additional data to assess potential adverse effects to workers, the public, or the environment. Currently, these elements do not require the researcher to provide certain details that would assist DPR and the CAC's evaluation of the pesticide and application.

DPR proposes to delete the elements listed in section 6262, and incorporate by reference, the Pesticide Research Authorization form (DPR-REG-027a, Est. 4/15) to include these elements and additional information including the active ingredient, product formulation, and other information to ensure that all the necessary information to evaluate the pesticide application is obtained from the researcher. Because of the limited space on DPR-REG-027(a), incorporated by reference within this form is the Pesticide Research Authorization (Additional Pesticides) form (DPR-REG-27b, Est. 4/15) that, if necessary, the applicant can list additional pesticide products that will be used in the same research trial.

Currently, the active ingredient is not required to be provided when applying for a research authorization. However, the identity of the active ingredient is critical to DPR's evaluation of the

pesticide since the active ingredient is the principle way U.S. EPA and DPR classify a pesticide. In order to address concerns about disclosing the identity of unregistered, newly developed active ingredients on the application form in certain situations when confidentiality is warranted, DPR proposes to add criteria that must be met in order to justify a researcher from omitting certain unregistered active ingredients on the application form. If such criteria are met, DPR will allow the pesticide registrant to provide DPR with the identity of the active ingredient in a separate statement from the application form and it will be maintained by DPR as confidential business information.

Currently, section 6264 requires the researcher to notify the CAC at least 24 hours before the research authorization field trial begins and provide the CAC with a copy of the approved research authorization (application form with DPR approval and conditions of approval). The county where the pesticide will be applied may not be known at the time the research authorization is approved by DPR, and this 24-hour notice of application may be the first time the CAC is aware that a pesticide research trial may be occurring in his/her county. In some cases, 24 hours may not be adequate notice for the CAC to fully assess the potential impacts of the application and contact DPR if there are any concerns about the research authorization. Therefore, DPR proposes to require the researcher to provide a notice of application to the CAC at least 72 hours before the application unless the CAC approves less than 72 hours' notice based on a determination that a shorter time period is adequate to evaluate the intended pesticide application. Additionally, at the time a research authorization application is submitted to DPR, the researcher may not know specific information about the crop, number of acres, date of application, etc. As part of the notice, the researcher would be required to submit this information, in addition to the location of each trial on a plot map and a map or aerial photograph designating sensitive sites, to assist CACs with their evaluation of the research authorization.

Section 6266 requires the researcher to submit an experimental trial report to the CAC after completing the final pesticide application and an experimental pesticide use report to DPR two weeks following the expiration date of the research authorization. Currently, subsection (a) lists the required elements that the researcher must provide on the experimental trial report. DPR proposes to delete the listed elements and incorporate by reference, Experimental Trial Report form (DPR-REG-029, Est. 4/15), to include the current elements and additional clarifying information that would be helpful to CACs. Subsection (b) lists the required elements that the researcher must provide on the experimental pesticide use report. DPR proposes to delete the listed elements in subsection (b) and incorporate by reference, Experimental Pesticide Use Report form (DPR-REG-028a, Est. 4/15), to include some of those elements as well as additional clarifying information. Incorporated by reference within this form is the Experimental Pesticide Use Report (Continued) form (DPR-REG-028b, Est. 4/15) where additional use information may be reported on the same research trial, if necessary.

In summary, revising the research authorization regulations as proposed will provide additional measures to protect human health and the environment. The proposed revisions would ensure that DPR has the necessary information to authorize research being conducted on unregistered pesticide use in California. The proposed revisions would provide CACs, the local enforcers of pesticide laws and regulations, with more time to ensure compliance with the conditions and limitations of the research authorization and evaluate potential impacts that may occur from the pesticide application. These changes would also ensure that DPR has all the specific details

pertaining to the pesticide application at the same time the CAC is notified of the intended application.

Adoption of these regulations will provide a benefit to public health, worker safety, and the environment by ensuring that all necessary information regarding a pesticide application is reported in a timely manner to the CACs, the primary enforcer of pesticide laws and regulations that impact human health and the environment.

During the process of developing these regulations, DPR conducted a search of any similar regulations on this topic and has concluded that these proposed regulations are neither inconsistent nor incompatible with existing state regulations. DPR is the only state agency that has the authority to regulate pesticides. No other state agency has the authority to regulate research authorizations.

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 are expected to 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 ECONOMIC IMPACT DIRECTLY AFFECTING BUSINESSES

DPR has made an initial determination that 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 businesses in other states.

COST IMPACTS ON REPRESENTATIVE PRIVATE PERSONS OR BUSINESSES

DPR has made an initial determination that the adoption of this regulation is unlikely to have a significant cost impact on representative private persons or businesses. The additional costs faced by pesticide registrants and their researchers should not significantly affect their operations or have any adverse economic impact on the sector.

RESULTS OF THE ECONOMIC IMPACT ANALYSIS

Benefit to the environment, worker safety, and the health of California residents: The proposed regulations are intended to increase protection to residents, agricultural workers, and the environment by ensuring that all the necessary information regarding a pesticide application is reported in a timely manner to the CAC and DPR.

Impact on the Creation, Elimination, or Expansion of Job/Businesses: DPR has determined it is unlikely 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 with 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, would be as effective and less burdensome to affected private persons than the proposed regulatory action, or would be more cost-effective to affected private persons and equally effective in implementing the statutory policy or other provision of the law.

AUTHORITY

This regulatory action is taken pursuant to the authority vested by FAC sections 11456, 12781, and 12976.

REFERENCE

This regulatory action is to implement, interpret, or make specific FAC sections 12995 and 14006.6.

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 regulation 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 regulation permanent if it remains substantially the same as described in the Informative Digest. If DPR does make substantial changes to the regulation, 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 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, and the proposed text of the regulation; and inquiries regarding the rulemaking file may be directed to:

Linda Irokawa-Otani, Regulations Coordinator
Department of Pesticide Regulation
1001 I Street, P.O. Box 4015
Sacramento, California 95812-4015
916-445-3991

Note: In the event the contact person is unavailable, questions on the substance of the proposed regulatory action may be directed to the following back-up person at the same address as noted below:

Ann Hanger, Senior Environmental Scientist
Pesticide Registration Branch
916-324-3535

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>>. Upon request, the documents can be made available in another language, or an alternate form as a disability-related accommodation.

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