

INITIAL STATEMENT OF REASONS AND PUBLIC REPORT
DEPARTMENT OF PESTICIDE REGULATION

Title 3. California Code of Regulations
Amend Sections 6260, 6262, 6264, and 6266
Relating to Research Authorizations

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 requirement of Title 14, CCR section 15252 and Public Resources Code section 21080.5 pertaining to state regulatory programs certified under the California Environmental Quality Act (CEQA).

SUMMARY OF PROPOSED ACTION/PESTICIDE REGULATORY PROGRAM
ACTIVITIES AFFECTED

The Department of Pesticide Regulation (DPR) proposes to amend 3 CCR sections 6260, 6262, 6264, and 6266. This proposal will affect the pesticide regulatory program activities pertaining to research authorizations. In summary, the proposed action will clarify the information required on the research authorization application and reporting forms, and will revise the notification requirements. These changes are intended to ensure that DPR and the county agricultural commissioners (CACs) have the necessary information to evaluate pesticides applied under the research authorization program.

SPECIFIC PURPOSE AND FACTUAL BASIS

Background

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 pesticide 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 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 CEQA, 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 a few exceptions noted in section 6268, 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. Prior to issuing a research authorization, DPR conducts an evaluation of the potential hazards of the pesticide to human health and the environment. Section 6262(b) gives DPR the authority to require any necessary data to assess the potential adverse effects of the pesticide to workers, the public, and/or the environment. If the pesticide active ingredient is not present in a pesticide product that has already been evaluated and registered in California, DPR requests information about the toxicity of the pesticide. After reviewing the provided toxicity information and other data submitted on the pesticide, DPR decides whether to issue the research authorization, and if so, determines what kind of restrictions should be imposed on the research to protect human health and the environment. These restrictions also prevent 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).

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. For example, DPR requires registrants to provide efficacy data for all products submitted for registration. In contrast, U.S. EPA does not require registrants to provide data showing the pesticide product is effective unless it bears a claim to control public health pests. As a result, approximately 90 percent of the approximately 700 research authorizations DPR issued in 2014 were intended to collect efficacy data or data demonstrating the product was effective and would not cause harm to plants (phytotoxicity) under California use conditions. The remaining 10 percent of research authorizations were issued to collect residue data (6 percent) and phytotoxicity data (4 percent). Phytotoxicity data are required for registration to ensure harm from the new product to both the target crop and nontarget adjacent crops is prevented. Residue data are required for registration to estimate the amount and nature of pesticide residues likely to be present in food or animal feed and to set and enforce tolerances for pesticide residues in food or feed.

If a research authorization is issued for a product containing an active ingredient not registered at U.S. EPA, testing under a research authorization is limited statewide to 10 acres or less on land or one surface acre or less of water, unless the registrant obtains a federal experimental use permit (EUP) from U.S. EPA. Before issuing an EUP for a product containing an unregistered active ingredient, U.S. EPA conducts a comprehensive review and evaluates detailed information

on the proposed testing program parameters and label, in addition to the product's formulation; chemical and physical properties; available data on the decline of residues with other information about safe worker re-entry; and available toxicity and exposure data, including epidemiological data. Based on the information, U.S. EPA establishes the maximum allowable area for the federal EUP.

In 2014, out of the approximately 700 research authorizations issued in California, five research authorizations were issued for products that had federal EUPs. Four of the five EUPs were issued for new uses of currently registered active ingredients at U.S. EPA. Only one EUP was issued for an unregistered active ingredient at U.S. EPA, and the use of this product was limited to five acres.

Section 6260 authorizes DPR to terminate, amend, or refuse to issue a research authorization if the research may involve a hazard to human health or the environment, is used for purposes unrelated to pesticide data development, violates current or previous authorizations, or violates pesticide laws and regulations in connection with the research.

Current Research Authorization Application Process and Conditions of Approval

Section 6262(a) 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 pursuant to subsection (b).

If the pesticide is applied to a harvestable crop and there is no applicable residue tolerance or exemption from tolerance for the crop, federal regulations governing experimental uses specify that the crop must be destroyed or fed only to experimental animals for testing purposes (Title 40 Code of Federal Regulations sections 172.3(ii) and 172.24.) Additionally, DPR may impose other use restrictions, if necessary.

Current Notification and Reporting Requirements

Section 6264(a) currently 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). If not submitted with the notice, the researcher must submit a plot map of the exact location of each trial within seven days after the initial application of the pesticide.

After the final application of a pesticide in a particular research authorization trial location, and at least 24 hours prior to either harvest or crop destruction, section 6266(a) requires the researcher to submit an experimental trial report to the CAC.

Within two weeks following the expiration date of the research authorization, section 6266(b) requires the researcher to submit an experimental pesticide use report to DPR.

Proposed Changes to Research Authorization Program

DPR is proposing to amend the research authorization requirements in sections 6260, 6262, 6264, and 6266 to address the following concerns:

Currently, the elements listed in section 6262 pertaining to the application for a research authorization do not require the researcher to provide certain details that would assist DPR and the CAC’s evaluation of the pesticide and application.

To address these concerns, DPR proposes to delete the elements listed in section 6262(a) and instead incorporate by reference, Pesticide Research Authorization form (DPR-REG-027a, Est. 4/15). The researcher would be required to provide additional or clarifying information on the proposed form about the pesticide and application 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. The modifications are described in the table below:

Section 6262 Application for Research Authorization

Section 6262(a)(1-8) Current Requirements		Proposed Pesticide Research Authorization Form (DPR-REG-027a Est. 4/15)	
		Modification/Addition (Box Number on Form)	Reason Modified/Added
(1) Name, mailing address, and telephone number of applicant		-Clarify “Name” as researcher name and firm name (box 1). -Add mobile phone field (box 1). -Add e-mail address field (box 1).	Provides more options to contact researcher.
(2) Pesticide to be applied	(A) Brand name, common name, or ID number	Clarify brand name as “product name” (box 2) and common name as “active ingredient” (box 6).	Provides specific information about the pesticide being evaluated.
	(B) Residue tolerance established	Unchanged	Not applicable
	(C) U.S. EPA Registration Number	-Clarify U.S. EPA registration number or experimental use permit number, if any (box 3). -Add registration type (federal, California, both, or unregistered) (box 4).	Clarifies type of registration at both federal and state levels.

Section 6262(a)(1-8) Current Requirements		Proposed Pesticide Research Authorization Form (DPR-REG-027a Est. 4/15)	
		Modification/Addition (Box Number on Form)	Reason Modified/Added
(2) Pesticide to be applied (cont.)	(D) Dosage of active ingredient	Clarify dosage as maximum rate for the active ingredient: “Maximum Rate (A.I.)” (box 7).	Clarifies the maximum rate of AI per area or unit being applied.
	(E) Method of application	Unchanged	Not applicable
	(F) Type of pesticide	-Add fumigant question (box 5). -Add formulation field (box 10).	Provides additional information about type of pesticide applied.
(3) Type of site or commodity and stage of growth at which pesticide will be applied		Add “or crop group” to type of commodity or site being treated (box 17).	Stating crop group prevents researcher from being limited to treating one specific commodity.
(4) Size, number, and total area of trials		-Add yes/no question asking if multiple applications are intended (box 12). -Add county of use, if known (box 23).	-Multiple applications can explain if a maximum rate appears to have been exceeded. -Ensures the appropriate CAC is identified and county-specific requirements are followed.
(5) Date of first and last applications		Add trial completion date (box 22).	An Experimental Pesticide Use Report must be submitted to DPR within two weeks following trial completion date pursuant to section 6266(b). Since the last application date may differ from the trial completion date, this information will help DPR verify timely submissions of reports.
(6) Type of data sought		Unchanged	Not applicable
(7) Planned disposition of treated commodity		Unchanged	Not applicable
(8) Signature and title of persons responsible for trials		Add date.	Provides date of request.

Incorporated by reference within this form is the Pesticide Research Authorization (Additional Pesticides) form (DPR-REG-27b, Est. 4/15). Since research trials may involve multiple pesticides, this form will allow additional space for researchers to enter the complete information on all the pesticide products that will be used during the same research trial. This form will provide DPR with the same information required in boxes 2-18 on form DPR-REG-27a.

Currently, the researcher is not required to provide the name of the active ingredient 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. For this reason, DPR is proposing to require identification of the active ingredient as part of the research authorization application process. 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 in proposed subsection (b) that must be met in order to justify a researcher from omitting certain unregistered active ingredients on the application form. If the active ingredient is not contained in any pesticide products currently registered by U.S. EPA or in any spray adjuvants currently registered by DPR, proposed subsection (c) 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 submit a notice of intent (NOI) to the CAC at least 24 hours prior to the intended pesticide application. The current elements required in the notice of pesticide application under the research authorization program are specified in section 6434(b), which are the required elements for a notice of pesticide application permitted under the restricted materials program. Since the requirements listed in section 6434(b) pertain to the restricted materials program, some of the listed elements are not applicable or not appropriate for a pesticide trial conducted under the research authorization program.

For restricted materials, the CAC is aware that a potential pesticide application may occur in his/her county when the CAC office approves the restricted materials permit. For research authorizations, the county where the pesticide will be applied may not be known at the time the research authorization is approved by DPR. Therefore, the 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. For example, the CAC may need to conduct pre-application inspections, identify potential sensitive sites, or make arrangements to be present at the site during the application to ensure the conditions and limitations of the research authorization are adequately met. In addition, under current requirements, the CAC may not receive a plot map with the exact location of the trial until up to seven days after the first pesticide application. Furthermore, although DPR issues the research authorization, there is no current requirement to notify DPR when the application is expected to occur.

To address these concerns about the lack of timely, site-specific information about the pesticide application, DPR proposes the following:

- Proposed subsection (a) would require the researcher to provide a notice of application to the CAC at least 72 hours before the application. This would provide the CAC adequate time to fully assess the potential impacts of the application. However, proposed subsection (b) would provide the CAC discretion to approve less than 72 hours' notice if the CAC determines a shorter time period is adequate to evaluate the intended pesticide application.

- In addition to requiring the researcher to provide the CAC with a copy of the approved research authorization pursuant to proposed subsection (a)(1), DPR proposes to list the specific elements of the notice of application that are relevant to a DPR-issued research authorization within proposed subsection (a)(2). Currently, the regulations refer to the required elements for a NOI submitted for a CAC-issued restricted materials permit under section 6434(b) if the information is not provided on an approved research authorization. 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.
- Additionally, proposed section 6264 is amended to refer to the research authorization notice as “notice of application” instead of a “notice of intent” which is defined in section 6000 as notification specified by the CAC and prior to the use of a pesticide pursuant to a restricted materials permit. In the case of research authorizations, the notification is specified by DPR and the application is not under the restricted materials program.
- Proposed subsection (c) would require the researcher to notify DPR at the same time notification is required by the CAC so that DPR is informed about when and where the actual research is being conducted.
- Current subsection (b) has been relettered to subsection (d).

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 as described below:

Section 6266(a) Experimental Trial Report

Section 6266(a)(1-7) Current Requirements	Proposed Experimental Trial Report Form (DPR-REG-029, Est. 4/15)	
	Modification/Addition	Reason Modified/Added
(1) Firm name	Unchanged	Not applicable
(2) Authorization number	Unchanged	Not applicable
(3) Commodity or site treated	Unchanged	Not applicable
(4) Date of report	Unchanged	Not applicable
(5) Trial location	-Add county -Add “Map No.”	-Indicates which county should receive report. -Geographical map number gives CACs specific location of the trial based on parcel map for future

Section 6266(a)(1-7) Current Requirements	Proposed Experimental Trial Report Form (DPR-REG-029, Est. 4/15)	
	Modification/Addition	Reason Modified/Added
		reference. This location information is in addition to the location information provided in the notice of application.
(6) Date and method of planned disposition of treated commodity	Clarify “date” as “date harvest will begin.”	Providing the harvest date puts CACs on notice that disposition will be occurring if any follow-up is needed prior to crop disposition.
(7) Name and telephone number of researcher or representative responsible for crop disposition	Add line for researcher’s signature.	Holds researcher accountable for information on the form.

Section 6266(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 as described below:

Section 6266(b) Experimental Pesticide Use Report

Section 6266(b)(1-9) Current Requirements	Proposed Experimental Pesticide Use Report Form (DPR-REG-028a, Est. 4/15)	
	Modification/Addition (Box Number on Form)	Reason Modified/Added
(1) Research authorization number	Unchanged	Not applicable
(2) Pesticide products applied	-Clarify as “product name” (box 2) and “active ingredient” (box 8) -Add formulation field (box 3).	Additional information to characterize type of pesticide.
(3) Commodity or site treated	Unchanged	Not applicable
(4) Rate of active ingredient per acre or unit	No longer required.	Rate can be determined from the provided amounts of active ingredient used and area/units treated.
(5) Total amount of active ingredient used	Unchanged	Not applicable
(6) Total acres or units treated	Specify as “area or units treated” (box 4).	Changing acres to area is broader in scope.
(7) Counties where trials were conducted	Unchanged	Not applicable

Section 6266(b)(1-9) Current Requirements	Proposed Experimental Pesticide Use Report Form (DPR-REG-028a, Est. 4/15)	
	Modification/Addition (Box Number on Form)	Reason Modified/Added
(8) Name, address and phone number of researcher	Add "Firm Name" field (box 1).	Firm name further identifies researcher.
(9) Certification that the commodity was harvested/disposed of as required by the authorization	-Clarify by adding crop disposition field (box 6). -Broaden certification to apply to all information provided on the form with signature, title, and date (box 10).	-Confirm crop disposition consistent with research authorization application form -Confirm all information provided on form is correct.

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. This form requires the same information required in boxes 2-9 on form DPR-REG-28a.

Finally, DPR proposes to make minor, nonsubstantive changes to section 6260.

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. In addition, 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. CACs would have the option to reduce the amount of notice required from the researcher at their discretion. 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.

This proposal meets DPR's duty as laid out in FAC section 11501(b) to protect the environment from environmentally harmful pesticides by prohibiting, regulating, or ensuring proper stewardship of those pesticides. This proposal is also consistent with the intent and provisions of Public Resources Code section 21080.5 that requires that the process used by DPR to propose regulations governing pesticide use has among its principal purposes the protection of the environment.

CONSULTATION WITH OTHER AGENCIES

DPR consulted with the CACs, University of California, and Western Plant Health Association during the development of the text of the proposed regulation.

ALTERNATIVES TO THE PROPOSED REGULATORY ACTION [GOVERNMENT CODE SECTION 11346.2(b)(5)]

DPR has not identified any feasible alternatives to the proposed regulatory action that would achieve the purpose of the regulations with fewer possible adverse economic impacts, including any impacts on small businesses, and invites the submission of suggested alternatives.

The proposed regulations are intended to make improvements to the existing research authorization application and notification process and enhance communication with CACs, the primary enforcer of pesticide laws and regulations.

ECONOMIC IMPACT ON BUSINESSES [GOVERNMENT CODE SECTION 11346.2(b)(5)(A)]

This proposed regulatory action may result in minor economic impacts to the regulated public. The time required for researchers to provide additional information on the application and reporting forms is insignificant, but there may be minor costs associated with the need to identify an application site sufficiently in advance and provide this information to the CAC 72 hours before the application. Since site conditions may change within 72 hours, it is possible that some applications may not be able to proceed as planned. However, the proposed regulations provide CACs with the flexibility to reduce this notice at their discretion, so it is possible there may be no change in impact to researchers, or even less impact, as a result of this added flexibility.

The document relied upon to make this determination is listed in the “Documents Relied Upon” section of this initial statement of reasons and is available from DPR.

ECONOMIC IMPACT ASSESSMENT PURSUANT TO SECTION 11346.3(b)

Creation or Elimination of Jobs with the State of California: The proposed action would not create or eliminate jobs in California because the action only impacts reporting and notification requirements.

Creation of New Business or the Elimination of Existing Businesses with the State of California: This proposed action would not create or eliminate businesses. The intent of the proposed action is to update and clarify the existing application, notification, and reporting requirements.

The Expansion of Businesses Currently Doing Business within the State of California: This proposal will not result in an expansion of business since it only makes minor revisions to the existing process.

The Benefits of the Regulation to the Health and Welfare of California Residents, Worker Safety, and the State's Environment: This proposal is intended to increase protection to residents, workers, 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.

IDENTIFICATION OF ANY SIGNIFICANT ADVERSE ENVIRONMENTAL EFFECT THAT CAN REASONABLY BE EXPECTED TO OCCUR FROM IMPLEMENTING THE PROPOSAL [3 CCR SECTION 6110]

DPR has determined that there is no significant adverse environmental effect to water, air, nontarget species or human health that can reasonably be expected to occur, directly or indirectly, from the proposed regulatory action. The proposed action, rather than causing an adverse environmental effect, is intended to be more protective of the environment by providing more detailed and timely information about pesticide applications to the CACs, the primary enforcer of pesticide laws and regulations that impact human health and the environment. Therefore, there is no significant adverse environmental effect and no alternatives or mitigation measures are proposed to lessen any significant adverse effects on the environment.

EFFORTS TO AVOID UNNECESSARY DUPLICATION WITH FEDERAL REGULATIONS

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

DOCUMENTS RELIED UPON

1. Economic Analysis for the Department of Pesticide Regulation Amendment to Title 3 CCR Sections 6260, 6262, 6264, and 6266. California Environmental Protection Agency, Agencywide Economic Studies Section, Air Resources Board. Memorandum from Stephen Storelli to Linda Irokawa-Otani, Regulations Coordinator, DPR. April 9, 2015.