

INITIAL STATEMENT OF REASONS AND PUBLIC REPORT  
DEPARTMENT OF PESTICIDE REGULATION

Title 3. California Code of Regulations  
Amend sections 6186, 6200, and 6222  
Pertaining to Changes to Efficacy Data Requirements  
for Pesticide Products

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 (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 amend sections 6186, 6200, and 6222. The pesticide regulatory program activities that will be affected by the proposal are those pertaining to efficacy data submission requirements to support the registration of new pesticide products and the amendment of currently registered products.

SPECIFIC PURPOSE AND FACTUAL BASIS

Food and Agricultural Code (FAC) section 12753 defines a "pesticide" as: (1) any spray adjuvant; and (2) any substance, or mixture of substances, that is intended to be used for defoliating plants, regulating plant growth, or for preventing, destroying, repelling, or mitigating any pest, as defined in FAC section 12754.5, that may infest or be detrimental to vegetation, man, animals, or households, or be present in any agricultural or nonagricultural environment. FAC section 11501 requires DPR "to assure users that pesticides are properly labeled and are appropriate for the use designated by the label." FAC section 12824 requires DPR to endeavor to eliminate from use in California any pesticide not beneficial for the purposes for which it is sold. FAC section 12825 authorizes DPR to cancel the registration of any pesticide "that is of little or no value for the purpose for which it is intended."

Adopted in 1980, 3 CCR section 6186 requires each application for registration of a new pesticide product to be accompanied by data supporting each efficacy claim on the pesticide product label, and each application to amend the label of a pesticide product to be accompanied by data supporting each new efficacy claim. The applicant must submit the efficacy data to DPR, unless the applicant already has the data on file with DPR. DPR evaluates efficacy data prior to registration of the pesticide product or acceptance of the amended label. DPR returns to the applicant any application not accompanied by efficacy data or a reference to data on file, including a letter of authorization if another company owns the referenced data. If, after review of the efficacy data, DPR determines that the data do not support the claims on the pesticide product label, DPR will not register the product or accept the amended label.

Under the proposed regulation, only efficacy claims that are "significantly different" from efficacy claims on other currently registered products would require the submission of efficacy data to support each such claim. However, the proposed regulation change would also authorize the Director, at any time, to require the submission of efficacy data for any label claim on a pesticide product either during evaluation or after registration of the pesticide product.

In 1996, DPR opened the subject of efficacy data requirements for pesticide products to the public for comment. DPR held workshops throughout the State and received a number of written comments. In 1997, based upon the comments received at the workshops, DPR proposed amendments to its efficacy data requirement regulations. DPR received numerous comments in response to the proposed regulation change. However, because a substantial number of the comments opposed the regulatory change, DPR withdrew the proposed regulation. As a part of DPR's 2004 pesticide product registration reform initiative, DPR is once again proposing amendments to pesticide product efficacy data requirements.

The U.S. Environmental Protection Agency (U.S. EPA) currently requires that each registrant ensure through testing that a pesticide product will be efficacious when used in accordance with label directions and commonly accepted pest control practices. However, U.S. EPA requires the submission of, and evaluates, efficacy data to support the registration or amendment of pesticide products that bear claims to control pest organisms that pose a threat to human health. Such pests include: (a) microorganisms which are infectious to man in any area of the inanimate environment, (b) vertebrates (e.g., rodents, birds, bats, dogs, and skunks) that may directly or indirectly transmit diseases to or injure humans, and (c) insects that carry human diseases (e.g., mosquitoes, ticks, etc.). On a case-by-case basis, U.S. EPA may require the submission of efficacy data to substantiate other types of efficacy claims. Current efficacy data submission requirements in California exceed those of U.S. EPA and any other state.

### 3 CCR, Section 6186

In order to implement the change in efficacy data requirements, DPR proposes to amend section 6186. DPR proposes to divide section 6186 into five subsections.

When registering a new pesticide product or amending the label of a registered pesticide product, proposed subsection (a) would require an applicant to submit efficacy data supporting each new efficacy claim on the product label, if the efficacy claim(s) is significantly different from efficacy claims on one or more currently registered pesticide products. If an efficacy claim is not significantly different and DPR has no information indicating that the registered product(s) is ineffective, then there would not be a need for DPR to require duplicative efficacy studies. This would eliminate the submission of duplicative

sets of efficacy data for the same type of efficacy claim to DPR. At the same time, the proposed regulation change would ensure that DPR continues to receive efficacy data for all unique pesticide products and unique uses of a pesticide product.

Proposed subsection (b) provides a definition for the term "significantly different," as used in subsection (a). DPR would consider a pesticide product efficacy claim to be "significantly different" from a claim on another currently registered pesticide product(s), if:

- (1) the products contain different active ingredients;
- (2) the label of the new product or amendment claims control of a new target pest or a different life stage of the target pest; or
- (3) the label claims or use directions of the new product or amendment differ substantially from the efficacy claims or use directions of other currently registered products in any of the following ways:
  - (A) rates of application (amount of active ingredient per treatment area);
  - (B) method of application;
  - (C) site of application; or
  - (D) claims increased level of control of the pest.

Under proposed subsection (b)(1), a pesticide product containing a new active ingredient would qualify as "significantly different" from other currently registered pesticide products. Therefore, an applicant for registration of a product containing a new active ingredient must still submit efficacy data for each efficacy claim on its product label.

Pursuant to proposed subsection (b)(2), efficacy data would also be required if a new pesticide product or an amendment to a registered product contained the same active ingredient, but the new product or amendment was intended for use on a new target pest or a different life stage of a target pest. A pesticide active ingredient that is effective in controlling one type of pest (i.e., aphids) will not necessarily be effective in controlling an entirely different type of pest (i.e., stink bugs). Likewise, a pesticide active ingredient that controls the adult life stage of an insect pest will not necessarily be effective in controlling the egg or larval stage of the same insect.

Proposed subsection (b)(3) is necessary to clarify that even if the new or amended pesticide product contains the same active ingredient and claims control of the same stage of target pest as one or more currently registered product(s), if the new product's use directions call for a significantly different rate of application (amount of active ingredient per treatment area), method of application, site of application, or claim an increased level of control of the pest, then the applicant would be required to submit efficacy data for each such efficacy claim. Proposed subsection (b)(3)(A) is necessary because a pesticide active ingredient, which is effective at controlling a pest at a given rate of application, may not be as effective at controlling the same pest at a lower application rate. Proposed subsection (b)(3)(B) is

necessary to reflect the fact that different methods of application can also affect the efficacy of a pesticide product. For example, a pesticide product that is currently labeled for application by air equipment will not necessarily be as effective if applied at the same rate through a drip irrigation system. Similarly, proposed subsection (b)(3)(C) is necessary because different sites of application may have an effect on efficacy. For example, an antimicrobial pesticide product that is effective on a hard nonporous surface will not necessarily be as effective, all other variables remaining the same, on a porous surface. Proposed subsection (b)(3)(D) is necessary to reflect the fact that if the new or amended pesticide product label claims an increased level of pest control, efficacy data showing that increased level of control must be submitted to support that claim.

Proposed subsection (c) provides that the Director may, at any time, require the submission of efficacy data for any product registered or proposed for registration. This provision will allow DPR to require the submission of efficacy data whenever a concern arises regarding the efficacy of a pesticide product.

The amendments to subsections (d) and (e) are editorial in nature. DPR is also proposing to clarify and update the authority and reference citations of section 6186.

In order to fully implement the changes in efficacy data requirements, DPR is proposing to make corresponding amendments to sections 6200 and 6222.

### 3 CCR, Section 6200

Section 6200 allows DPR to conditionally register, for a limited period of time, new pesticide products for which applicants have not yet submitted all required scientific data.

Section 6200(c)(6) prohibits DPR from granting a conditional registration unless the applicant has submitted "preliminary efficacy data indicating the product is effective for the proposed use." DPR is proposing to amend section 6200(c)(6) to clarify that if a pesticide efficacy claim is exempt from the requirement to submit efficacy data pursuant to section 6186, the label claim is also exempt from the requirement to submit "preliminary" efficacy data in order to obtain a conditional registration. This proposed amendment is necessary to conform section 6200 to the proposed amendments to section 6186. All other proposed amendments to section 6200 are editorial in nature.

### 3 CCR, Section 6222

Sections 6220 through 6225 establish DPR's reevaluation process. Title 3 CCR section 6221 lists "lack of efficacy" as one of many criteria that could result in the initiation of a reevaluation. Section 6222 states that during reevaluation, DPR ". . . shall require submission of all data required for registration of a new pesticide by the U.S. EPA and by sections 6159, 6170, 6176-6179, 6180(a),

6181-6192, and 6200 which is relevant to the focus of the reevaluation . . . " Under proposed section 6186, efficacy data would no longer be required for certain types of efficacy claims; therefore, DPR would not be able to require registrants to submit efficacy data for those efficacy claims pursuant to a reevaluation. DPR proposes to amend 6222(a) to retain DPR's authority to call in efficacy data for any pesticide product label claim regardless of whether U.S. EPA or DPR required the applicant during initial registration or amendment of the product to submit efficacy data for the label claim. DPR is also proposing to clarify and update the authority and reference citations of section 6222, as well as minor editorial corrections.

#### ALTERNATIVES TO THE PROPOSED REGULATORY ACTION (GOVERNMENT CODE SECTION 11346.2(b))

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

As discussed in the Notice of Proposed Regulatory Action, published in the California Regulatory Notice Register, DPR has determined that the adoption of this regulation will not have a significant impact on private persons or businesses.

#### IDENTIFICATION OF AN SIGNIFICANT ADVERSE ENVIRONMENTAL EFFECT THAT CAN REASONABLY BE EXPECTED TO OCCUR FROM IMPLEMENTING THIS PROPOSAL

DPR has not identified any significant adverse environmental effect from the proposed regulatory action.

#### 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. Title 40, Code of Federal Regulations, Part 158 - Data Requirements for Registration.