

FINAL STATEMENT OF REASONS AND PUBLIC REPORT
DEPARTMENT OF PESTICIDE REGULATION

Title 3. California Code of Regulations
Amend Sections 6170(a) and (b), 6172(a), and 6200(c)
Pertaining to Pesticide Product Registration

UPDATE OF THE INITIAL STATEMENT OF REASONS

The originally proposed regulatory action was noticed in the *California Regulatory Notice Register* on August 4, 2006.

During the 45-day public comment period, the Department of Pesticide Regulation (DPR) received one letter of comment on the proposed text. The comments are discussed under the heading "SUMMARY AND RESPONSE TO COMMENTS RECEIVED" of this Final Statement of Reasons. These comments have been added to the rulemaking file.

DPR has amended sections 6170(a) and (b), 6172(a), and 6200(c) in Title 3 of the California Code of Regulations (CCR). The pesticide regulatory program activities that will be affected by the proposal are those pertaining to pesticide product registration. In summary, this action clarifies regulations related to data requirements for pesticide product registration consistent with past and current practices of the Department.

The Office of Administrative Law (OAL) initially approved these 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 (*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 Procedure Act (APA). The Court ruled that even if these amendments were consistent with DPR's practice under the former regulations, DPR was required to inform the public of these 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 the Ninth Circuit, or the 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 proceeded to adopt these 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. These regulations were presented as if the additions and deletions are being made to the text that existed prior to the changes made in 2002.

- DPR added the phrase "by the applicant" to subsections 6170(a) and (b). This change further clarifies 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 restored 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 deleted 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.
- Also, since the creation of the California Environmental Protection Agency, there has at times been confusion in the regulated community over whether the reference to "EPA" in DPR's regulations refers to U.S. EPA or the California Environmental Protection Agency. In order to clarify the agency being referenced, DPR replaced all references to the previous acronym for U.S. EPA--"EPA" with the acronym "U.S. EPA" in sections 6170 and 6172.

SUMMARY AND RESPONSE TO COMMENTS RECEIVED

DPR received one letter of comments from McKenna Long and Aldridge, Attorneys at Law, writing on behalf of BASF Corporation, Bayer CropScience LP, Dow AgroSciences, LLC, E.I. du Pont de Nemours and Company, Monsanto Company, and Syngenta Crop Protection, Inc., regarding the proposed regulations.

Comment No. 1: The proposed regulations are inconsistent with law. The proposed regulations conflict with the provisions of Assembly Bill (AB) 1011 (amended Food and Agricultural Code (FAC) section 12811.5) and will diminish the rights of data owners to obtain offers to pay. The proposed regulations will conflict with the statutory bases for the Pesticide Regulatory Program.

Response: Contrary to the commentor's position that the proposed regulations are inconsistent with amended FAC section 12811.5, the changes these regulation propose simply reinstate the regulations to the form that existed when the Legislature passed AB 1011 in November 2005

(effective in January 2006). The ruling in *Syngenta v. Helliker* (136 Cal.App. 4th 1464) that found the earlier regulatory amendments invalid for failure to comply with the procedural requirements of the APA was not issued until April 2006. It is that court decision that necessitates these proposed amendments to readopt the earlier amendments under the full notice and 45-day comment provisions of the APA.

The issue of how DPR interpreted and implemented its regulatory program with respect to the data it required from applicants and when it required letters of authorization from those applicants for data previously submitted to DPR by others was the subject matter of the *Syngenta* case. In that litigation, the former FAC section 12811.5 was the statutory underpinning of the plaintiff data owners' position that DPR was illegally considering certain data they had submitted in making its registration decisions on generic products by not requiring letters of authorization for the use of certain data in violation of their property rights. The meaning and implementation of the law and regulations and how that impacted the data protection afforded the plaintiffs were extensively argued and briefed by the plaintiff data owners, the generic real-party-in-interest, and DPR in that litigation. AB 1011 arose from this background, and resulted in the new FAC 12811.5 that both allows DPR to rely on evaluations of any data in its possession in making pesticide registration decisions regardless of data ownership, and defines what data will be protected and the mechanism by which it will be protected. The statute's development and final form was the subject of extensive discussions between all the stakeholders whose interests and concerns were voiced during the legislative process. This occurred with the backdrop of the then existing regulations. It is DPR's intent to return the regulations to the state that existed when the statute was passed to assure that the court decision does not impact the legislative solution to the data compensation issue.

DPR also disagrees that these proposed amendments readopting the earlier clarifications of its regulations in any way conflicts with the requirements of its regulatory program. DPR will continue to evaluate all pesticide products submitted to it for registration, taking into consideration all the factors outlined in both statute and regulation as it has in the past. The proposed amendments in no way affect that process. In the litigation, Syngenta challenged these clarifications of our data requirements because they were seen as weakening the legal argument made by the plaintiff data owners. However, the new statute now resolves the issues of that litigation by setting out a legal framework that determines when an applicant must make an offer to pay, and what will happen if it does not (cancellation of the registration after a determination by the Director at the request of the data submitter).

The new FAC section 12811.5 provides protection (mandatory cost-sharing) for data submitted to DPR to obtain, amend, or maintain a product registration for the prescribed time period (15 or 17 years). If an applicant does not submit its own data to comply with DPR's data requirements, has not received authorization to use another company's data, or obtained the product from an entity that has or has not entered a cost-sharing agreement for the data in connection with federal registration, the applicant must make an offer to pay the owner of such data [FAC section 12811.5 (a)]. Even data that do not meet a current data requirement at the time of an application, but were submitted by a data owner to fulfill a previous specific requirement to obtain, amend, or maintain the registration of a similar product, are protected and subject to an offer to pay [FAC section 12811.5 (b)].

The resolution of the data protection issue by AB 1011 was made by the Legislature not only with the backdrop of the California law and regulations related to pesticide registration then in place, but with the backdrop of federal law. At the federal level, the protection afforded to data submitted to U.S. EPA to obtain federal registration of a pesticide, a prerequisite to registration in California (with the exception of a small class of products called spray adjuvants that are only registered in California), is ten years of exclusive use, with an additional five-year period during which use can be made of any data submitted as long as there is an offer to pay. After 15 years, there is no longer any protection of the data at the federal level. Therefore, by the time a generic pesticide is submitted for registration in California, a data submitter has already enjoyed at least ten years of exclusive use of the data as a basis for federal and California registration, and has received an offer to pay for use of the data to support the generic registration of the product at the federal level.

Comment No. 2: The Notice of Proposed Rulemaking and Initial Statement of Reasons fail to comply with APA and CEQA.

Response: As stated in the Initial Statement of Reasons and Public Report, the need for the proposed rulemaking is the ruling in the *Syngenta* case that found that the same amendments to the regulations proposed by this rulemaking that were previously made as nonsubstantive changes, were substantive and should have been made under the procedures of Chapter 3.5, Article 5 of the APA. The issue of whether or not the changes were consistent with DPR's practice played no role in the court's reasoning on that issue and is irrelevant to the need to re-adopt these amendments. The primary ruling in that case, related to DPR's use of data, has effectively been mooted for all future registration decisions by the Legislature's enactment of AB 1011 amending FAC section 12811.5. The regulated community is affected by the new legislation, and would be affected even more without the adoption of the proposed rulemaking amending the regulations to their state at the time the legislation was passed.

The Initial Statement and Public Report further does not violate CEQA. The report clearly describes what the amendments are intended to do--clarify what data must be submitted to DPR in connection with an application for the registration of a pesticide product. Given the fact that the data submitters sued DPR for considering data they submitted in evaluating the registration application of another company's products in the past and in light of the new statute allowing DPR to do precisely that without regard to data ownership in the future, it is unclear how these changes to the regulation could possibly have any significant adverse environmental impact. FAC section 12811.5 authorizes DPR to take into account all data in its possession in making its registration decision. The proposed amendments will have no impact on the ability of DPR to use all the data related to all the factors it must consider outlined in both statute and regulation in its possession when making those decisions in compliance with its CEQA obligations.

PUBLIC HEARING

DPR received no requests to hold a public hearing and no hearing was scheduled or held.

MANDATE 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 requiring 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 B 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.

ALTERNATIVES DETERMINATION

The Director has determined that no alternative considered by DPR would be more effective in carrying out the purpose for which this regulation is proposed, or would be as effective and less burdensome to affected private persons or businesses than the proposed regulatory change.

POSTING REQUIREMENT

In 3 CCR, section 6110, it states in part that, "The public report shall be posted on the official bulletin boards of the Department, and of each commissioner's office, and in each District office of the DPR [Division of Pest Management, Environmental Protection and Worker Safety] for 45 days." DPR has posted its Initial Statement of Reasons and Public Report on its official bulletin board, which consists of the Department's Internet Home Page <http://www.cdpr.ca.gov>. In addition, copies were provided to the offices listed above for posting.