



Mary-Ann Warmerdam
Director

Arnold Schwarzenegger
Governor

California Notice 2005-10

TO: PESTICIDE REGISTRANTS

SUBJECT: ELIMINATION OF LETTER OF AUTHORIZATION

CONCURRENT SUBMISSION OF PESTICIDE PRODUCTS CONTAINING
NEW ACTIVE INGREDIENTS TO THE DEPARTMENT OF PESTICIDE
REGULATION AND THE U.S. ENVIRONMENTAL PROTECTION AGENCY

ELECTRONIC DATA SUBMISSIONS – NEW ACTIVE INGREDIENTS

Effective January 1, 2006, applicants that wish to rely on data on file with the Department of Pesticide Regulation (DPR) to register new pesticide products or amend currently registered pesticide products will no longer need a letter of authorization from the owner of the data. In addition, effective January 1, 2006, DPR will accept applications for registration of new pesticide products containing new active ingredients concurrently with submission of an application to the U.S. Environmental Protection Agency (U.S. EPA) for federal registration. Also, DPR is requesting that applicants provide both hard and electronic copies of scientific data submitted to DPR to support the registration of pesticide products containing new active ingredients.

LETTER OF AUTHORIZATION

Assembly Bill 1011 (AB 1011, Chapter 612, Statutes of 2005) amended Food and Agricultural Code (FAC) section 12811.5, prompting several changes in DPR's registration process. (For a copy of the legislation, go to <www.aroundthecapitol.com/Bills/AB_1011/>) Previously, DPR had to obtain written permission from the data owner before considering data owned by that company to support another company's application for registration or amendment.

AB 1011 has removed this requirement, effective January 1, 2006. FAC section 12811.5 now states that DPR "...may rely upon any evaluations of previously submitted data to determine whether to accept an application for registration of a new pesticide product, an amendment to a registered pesticide product, or to maintain the registration of a pesticide product regardless of the ownership of the data previously evaluated" (*emphasis added*).

Please note the new statute did not change or reduce DPR's data requirements.

Effective January 1, 2006, an applicant for registration of a new pesticide product where the product label specifies uses (including application rate, target pest, etc.) similar to uses previously approved by DPR for another pesticide product(s) containing the same active ingredient, is not required to submit or cite additional data to meet DPR's data requirements. The same is true of an applicant that wishes to amend the formulation and/or add a new use to a



currently registered pesticide product. If the formulation and/or new use were previously approved by DPR for a pesticide product containing the same active ingredient, then no new data are required to be submitted or cited to meet DPR's data requirements.

To receive the most expeditious processing of such applications, applicants for registration or amendment must identify by brand name and U.S. EPA registration number one or more DPR registered pesticide products containing the same active ingredient(s) and intended for the same or similar uses, including application rate, target pest, etc. Please note in your cover letter that you will not be submitting your own data, but instead are asking the Department to rely upon data already on file and include information identifying the previously approved product(s).

Applicants to register additional brand names and distributor registrations are still required to submit all pertinent U.S. EPA documentation.

DPR is aware that an applicant for registration or amendment cannot determine whether another company's pesticide product(s) contains the same or toxicologically similar inert ingredients to the applicant's product. DPR will make this determination.

With regard to applications submitted to DPR prior to January 1, 2006 that are still under review, applicants must inform DPR if they want their application considered under the new law. If you would like your application to be considered under the new statute, please inform your registration specialist in writing and identify by brand name and U.S. EPA registration number, one or more registered pesticide products containing the same active ingredient(s) and intended for the same or similar uses.

Applicants should be aware that, under the new FAC section 12811.5, they have certain obligations to data owners who have registered similar products in specifically defined situations (described in the legislation). These obligations arise with respect to data currently required by DPR to support registration or amendment of the applicant's product (section 12811.5[a]). They also arise with respect to data that, although not currently required by DPR to support registration or amendment of the applicant's product, were previously required by DPR to obtain, amend, or maintain the registration of a similar product of a data owner (section 12811.5[b]). Additional information will be forthcoming from the Department.

If you do not want to rely upon data on file and owned by other companies to support your product registration or amendment, please clearly state this in your cover letter. You must submit data to meet DPR's data requirements or cite data previously submitted by your company that meets DPR's data requirements. In addition, if you choose to submit your own data to meet the requirements of FAC section 12811.5(b), please clearly identify such data and indicate in your cover letter that the data are being submitted pursuant to FAC section 12811.5(b).

Please note that in order to assist data owners in identifying new and amended products which may be subject to the data authorization/cost sharing provisions of new FAC section 12811.5, DPR will post the proposed and final registrations of new and amended pesticide products, including distributor products, on its website at <http://www.cdpr.ca.gov/docs/nod/nodmenu.htm>.

NEW ACTIVE INGREDIENTS

Effective January 1, 2006, DPR will accept the following types of applications concurrently with submission of an application to U.S. EPA for federal registration:

1. Applications to register new pesticide products containing new active ingredients;

DPR will also continue to accept:

2. Applications to register or amend Experimental Use Permit pesticide products;
3. Applications to register new "antimicrobial pesticides" that are intended to control pests that pose a threat to human health and requests to amend registered "antimicrobial pesticides" if the amendment adds a use to the product to control pests that pose a threat to human health.
4. Applications to register new "public health pesticides" and requests to amend registered pesticides if the amendment adds a public health use to the product label. For purposes of this notice, a "public health pesticide" is a minor use pesticide that is labeled for use in a public health program or is used predominately in a public health program by a public health agency. The term "public health pesticide" does not include products intended for use by homeowners. If the "public health pesticide" is not labeled for use by a public health agency, the applicant must submit documentation from a public health agency of how the agency uses the product in California to qualify for concurrent submission.

Please note that in accordance with FAC section 12836, DPR will strive, as resources allow, to review submissions concurrently in time with the review conducted by U.S. EPA for (a) requests to register new pesticide products meeting the criteria of #3 and #4 above, that also either: (i) contain a new active ingredient; or (ii) list a public health threat use for which there are no effective alternatives to control the public health pest; and (b) requests to amend registered pesticide products meeting the criteria of #3 and #4 where the label amendment adds a public health threat use for which there are no effective alternatives. In all instances, the applicant must provide DPR with documentation that no effective alternatives exist.

If you are submitting an application concurrently, please clearly note in your cover letter that the product is not yet federally registered and indicate which of the above criteria the product meets.

For the most part, DPR reviews concurrent submissions in the order received, along with all other applications for registration of pesticide products. DPR may prioritize the review of any type of submission as needed for use in California.

The acceptance of registration requests before federal registration of a product, or issuance of a federal experimental use permit is not a reduction in any of DPR's data requirements. All required data and information must still be submitted with the registration request. After federal registration, it is the applicant's responsibility to submit a copy of U.S. EPA's registration letter, the U.S. EPA stamped-accepted label, and any additional data submitted to U.S. EPA by the applicant. California registration of the product will not be granted until U.S. EPA's stamped accepted label and accompanying letter are received and the label is approved by DPR.

This Notice revises and replaces California Notice 2002-5.

ELECTRONIC DATA SUBMISSIONS- NEW ACTIVE INGREDIENTS

To reduce storage space needed by the Department, DPR is requesting that applicants for registration of new pesticide products containing new active ingredients submit both a hard copy and an electronic copy of all required data. Please use Adobe Portable Document Format (PDF) as the standard file format and compact disks (CDs) as the transport medium. Please use the same file formats, naming conventions, fonts, conversion options, etc. suggested by U.S. EPA in the following guidance documents: <http://www.epa.gov/oppfead1/eds/esr_guidance.htm>.

Further details regarding the electronic submission of data will be forthcoming in a separate California Notice.

If you have any questions regarding this notice, please contact Ms. Ann Prichard, Senior Environmental Research Scientist, by e-mail at <aprichard@cdpr.ca.gov> or by telephone at (916) 324-3931. For questions regarding submission of an application for registration and required data, please contact your registration specialist.

Original signed by

November 14, 2005

Barry Cortez, Chief
Pesticide Registration Branch
(916) 445-4377

Date

Enclosure

cc: Ms. Ann Prichard