California Department of Pesticide Regulation

Pesticide Product Registration Reform Initiative

DRAFT

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Goals of the Registration Reform Initiative

- Shorten the timeframe for registration decisions.
- Eliminate unnecessary workload and costs for registrants and DPR.
- Expedite the introduction of lower-risk pesticides.
- Eliminate activities unrelated to protection of public health and the environment.

Results of the Registration Reform Initiative

California's pesticide product registration process has served to assure that pesticides sold in California are effective and would not pose unacceptable risk to public health or the environment. Some of the registration processes that have been established via statute, regulation, and policy were designed to address issues that were inadequately managed by the U.S. Environmental Protection Agency (U.S. EPA). Over the past decade, many positive changes have occurred at U.S. EPA that now allow DPR to reconsider how it conducts the pesticide registration process. DPR's goal in this review is to ensure timely decisions, while enhancing protection of people and the environment.

As DPR implements changes in its business processes, staff will be freed up to reduce the backlog in registration decisions and improve the overall timeliness of registration reviews. DPR also expects to expand its work-sharing activities with U.S. EPA. DPR has had tremendous success in sharing review work with U.S. EPA on a select number of new active ingredients and evaluating residues for the Interregional Research Project No. 4 (IR-4) projects. DPR's goal is to expand this work-sharing arrangement as broadly as possible to optimize the joint expenditure of staff time at U.S. EPA and DPR in evaluating data for pesticides proposed for use in California.

Consultative Process

On March 26, 2004, DPR released the first draft of the Registration Initiative. It was discussed at the Pest Management Advisory Committee meeting on March 26, and Committee members and other participants offered many suggestions for improvements to the initiative and further actions DPR should take. DPR also received comments from various organizations. Those comments are posted on DPR's Web site, at <www.cdpr.ca.gov/docs/planning/planning.htm>.

Based on the comments and discussion, DPR has revised its Registration Initiative, which is described in the rest of this document. As in the March 26 proposal, some items can be initiated immediately, while others require more analysis and discussion, and ultimately perhaps modification to regulations or statutes. DPR will continue to meet with stakeholders on these proposals as it proceeds to implement the initiative.

Planned Reforms

Accept U.S. EPA Reviews - DPR will be issuing a notice to registrants regarding its policy of accepting U.S. EPA data evaluation reports. Under the new policy, registrants would need to include a copy of the U.S. EPA written evaluation with their data submission. DPR will then review the U.S. EPA evaluation and only refer to the underlying data on an as-needed basis. This policy would result in a reduction in evaluation time, because less time is needed to review U.S. EPA's evaluation than the entire study. Unfortunately, only some registration requests will benefit from this policy because U.S. EPA produces formal reviews for only a portion of the products that it registers.

Registration Status e-Notification Pilot Project - DPR has conducted a pilot project that provides electronic updates to registrants on the status of their registration requests. DPR plans to launch a full-scale implementation of this system, which will provide registrants with better and timelier information, and a reduction in the time DPR staff spend answering queries from registrants. The information provided by this system will allow the registrants to resolve registration review issues expeditiously and better gauge when their products will be available for the California marketplace.

Consultation with Organic Agriculture - Since the passage of the National Organic Standard, efforts have been put in place to foster the growing organic production sector. DPR is looking at ways to remove barriers, if present, to the registration of pesticide products needed by California organic growers. DPR will be scheduling meetings with representatives of the organic agricultural industry to determine areas of particular concern to that industry sector. One item DPR will propose is to accept applications for registration of new pesticide products intended for use in organic production concurrently with the applicant's submission of an application to U.S. EPA for federal registration. Currently, DPR accepts concurrent applications for four other categories of pesticides.

California Conditions - DPR will issue a policy to clarify that applicants for registration of the first agricultural use of an active ingredient no longer have to conduct one of the two required environmental fate dissipation studies in California. Food and Agricultural Code (FAC) section 13143 is the basis of this requirement and mandates that registrants conduct field dissipation studies under California or similar use conditions. When the statute was enacted, U.S. EPA did not have specific environmental fate data that would meet California standards. To date, DPR has required that one of the two required field dissipation studies be conducted in California. In most instances, the same studies that the registrant submits to U.S. EPA will fulfill California requirements. DPR's experience with the environmental fate dissipation studies, required by U.S. EPA and generated by the registrants, indicates that removing the requirement to conduct studies in California will not compromise the usefulness of the data submitted. The change in policy will not affect DPR's scientific determination of whether an active ingredient is likely to move into ground water.

Proposed Reform Topics

Residue Data - For decades, the review of residue data reflective of California uses was a key element of the pesticide registration program. The residue review involves determining whether the labeled uses of a specific pesticide on a specific food or feed crop will result in residues at the time of harvest above the established tolerance level. This review was intended to assure that California's food supply would be protected from illegal residues on produce, to protect consumers, and to assist growers in complying with the law. DPR's review was particularly critical at a time when the tolerances set by U.S. EPA were not based on acceptable risks and the states had the authority to set tolerances.

Today, both of these factors have changed. The Food Quality Protection Act (FQPA) now preempts states from establishing tolerances. In addition, FQPA requires U.S. EPA to set tolerances specifically to ensure that all food uses of a pesticide active ingredient pose a reasonable certainty of no harm. For a number of pesticide active ingredients, U.S. EPA has established tolerances for individual food crops at a level far more stringent than necessary to protect public health. The tolerances are set low in order to leave room in the "risk-cup" for use of the same active ingredient on other food crops. For these pesticides, when DPR finds residues above the tolerance for an individual food crop, no appreciable health threat results, but the produce cannot enter the channels of trade. This results in a potentially devastating economic impact on the grower, despite his/her full compliance with pesticide label requirements. What has not changed is that DPR and U.S. EPA both continue to conduct reviews of pesticide residue data.

With respect to residue data requirements, DPR is proposing three concepts for discussion:

1. No change to DPR's current requirement that residue data for each food or feed use on the pesticide product label must be submitted with California registration applications.
2. Not require the submission of residue data after U.S. EPA establishes a standardized method for developing tolerances using data from residue field trials. U.S. EPA, Canada, DPR, and the European Union are jointly working on a project to develop a statistical method for tolerance establishment. The current methodology of reviewing residue data is generally similar between U.S. EPA and California.
3. Not require the submission of residue data and rely on the federal data reviews.

Repeal California's Data Ownership Laws (Letters of Authorization) - Federal statute provides a 15-year window of protection to registrants for data they generate to support a proposal to U.S. EPA to register a pesticide. If another registrant wants to use this data to support the registration of its product, it must get permission from the data owner, or offer to compensate the data owner. California statute requires that during, and even after, the 15-year window of federal protection has expired, applicants for registration of the same pesticide product in California must submit a letter of authorization to use data generated by another registrant. This proposal would rescind California law (FAC section 12811.5) and the regulation covering letters of authorization [Title 3 California Code of Regulations (3CCR) section 6170 (c)]. Eliminating this additional authorization would allow DPR to use any data on file and would accelerate its

decisionmaking process on registration requests. This proposal would require a change in California statute.

Efficacy Reviews - Pesticide regulatory programs at the state and federal level were designed to ensure that products are effective, although U.S. EPA does not require the submission of most efficacy data. Over the years, the focus of the pesticide regulatory program has evolved to focus on protection of human health and the environment.

Efficacy data submission requirements in California exceed those of the federal government and any other state. The regulations (3 CCR section 6186) require each applicant for registration to submit data supporting each efficacy claim. DPR based this regulation on FAC section 11501, which 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."

DPR plans to streamline the production of evaluation reports by allowing evaluation scientists to simplify their review of pesticide products if no significant issues arise. This procedure may reduce the final evaluation time. In addition, DPR will facilitate the citation of efficacy data in the public domain. Many older pesticides have a considerable amount of data in the public domain that could be relied upon in lieu of submission of efficacy data. The existing law makes accommodations for registrants to be able to cite data in the public domain. DPR will encourage registrants to cite data in the public domain and will prepare a public domain citable section for pesticides.

DPR has also identified four potential efficacy data requirement options:

1. No change to the current regulations or practice.
2. Amend DPR's regulations regarding the submission of efficacy data (CCR section 6186) to maintain the existing requirement, except for certain classes of pesticides that are determined to not need efficacy review. These classes will be defined by DPR in regulations, pursuant to completion of consultations with interested parties. If a registrant submits a U.S. EPA review of efficacy data for any pesticide for which data are still required, DPR will review that evaluation and only refer to the efficacy data if there are any questions DPR has about the U.S. EPAEPA evaluation. DPR would reserve the right to require efficacy data to be submitted upon request prior to, or anytime after, registration.
3. Amend DPR's regulations regarding the submission of efficacy data to be consistent with U.S. EPA procedures. If a registrant submits a U.S. EPA review of efficacy data for any pesticide for which data are still required, DPR will review that evaluation and only refer to the efficacy data if there are any questions DPR has about the U.S. EPA evaluation. DPR would reserve the right to require efficacy data to be submitted upon request prior to, or anytime after, registration.
4. Conditionally register pesticide products, without preliminary efficacy data, pending submittal of complete efficacy data packages. Conditionally registering pesticide products

would allow users access to the products while registrants complete the process of developing data to support specific label claims regarding efficacy.

Enhancing Workshare Opportunities - In 2003, DPR ended its longstanding policy of accepting reduced-risk pesticide products concurrently with submission to U.S. EPA for federal registration. DPR limited concurrent acceptance to biochemicals, microbials, certain antimicrobials, federal experimental use permits, and a limited number of pesticides products that were on U.S. EPA's annual work plan. The new process allowed for greater work sharing opportunities with U.S. EPA. With the enactment of the 2004 federal appropriations bill, the laws governing the pesticide product fees and the federal registration process changed dramatically. DPR intends to work closely with U.S. EPA as they redesign their pesticide registration process and find ways to create opportunities to share the registration workload and minimize the timeframe decisions on registration requests for California.

ACCOUNTABILITY

DPR will issue a biannual report beginning on January 1, 2005, on the status of the pesticide product registration reform initiatives, the performance of the registration process, current allocation of resources, and any improvements resulting from the initiative.

REFERENCES

Challenge and Change (1991)
Western Crop Protection Association (1995)
New Point Report (2001)
AB 780 Report (2003)