

California Registration Program Streamlining Aims to Improve Review Times and Cut Costs

In the wake of huge budget shortfalls and Governor Schwarzenegger's Performance Review initiative, numerous changes are underway within the California Department of Pesticide Regulation (DPR) and more are being considered. The California Performance Review (CPR), which has produced recommendations for the abolition or consolidation of many state offices, has recommended that DPR be maintained as one of six functional divisions within the California Environmental Protection Agency (Cal-EPA). Although DPR will maintain its separate identity and functions within Cal-EPA, the CPR has recommended significant changes to how it operates.

Letters of Authorization Blamed for Program Inefficiencies

The CPR, in Resolution 16 of the CPR's Final Report, reserves its harshest criticisms for the current requirement mandating that applicants for state registrations must submit all required data or obtain a letter of authorization (LOA) from the owner of data already in CPR's files. Resolution 16 states that the current process "requires staff time and resources for activities that primarily protect the business interest of data owners, duplicates federal registration processes that already provide adequate protection to data owners, and creates marketplace barriers for pesticide products." The Resolution adds that "this duplication of effort does nothing to improve public health or the environment."

The Resolution recommends that the Governor work with the Legislature to repeal Section 128115 of the Food and Agriculture Code, which prohibits DPR from considering data it has already reviewed unless it has the written permission of the original data submitter. The CPR has set the stage for the repeal by making very strong arguments that the current law diverts resources from the government's core obligations of protecting public health and the environment and wastes significant government and industry resources in the process. Nonetheless, there is likely to be opposition from pesticide registrants that have invested considerable time and money in data packages on file with the state. Consequently, changes to the LOA process may be a future possibility at best and not offer opportunities for near-term streamlining.

Efficacy Data Reviews to Be Eliminated for Some Pesticides

DPR requires that registrants submit efficacy data to support every use site claimed for its California registration. The requirements have been stringently applied, with an onerous degree of specificity applied to the data mandated for non-agricultural use sites. One of the main results of the efficacy requirements has been a bottleneck in the registration review process. The CPR views efficacy reviews as a consumer protection function, which has diluted DPR's mission to protect public health and the environment. In fact, the CPR charges that California, by continuing to require efficacy reviews, has resisted the trend in pesticide regulation to evolve from consumer protection to environmental protection.

Consistent with the CPR recommendations, DPR on July 27 announced its intention to amend its regulations to provide "more discretion and flexibility on reviewing efficacy data." Presumably, its proposed regulatory changes will be consistent with the CPR's, which would be to review

efficacy data only for public health pesticides, described in Resolution 16 as “sanitizers, disinfectants, and sterilants.”

The Resolution further recommends that DPR should review EPA evaluations of efficacy data for public health pesticides and refer to the data only when there are questions about the EPA evaluation. In fact, consistent with this recommendation, DPR issue California Notice 2004-6 in June, encouraging applicants to submit EPA evaluations of all types of data, not just efficacy data. In that notice, the department committed to limit its routine reviews to the evaluations, and to refer to the underlying data only on an “as-needed” basis.

DPR Commits to Register Pesticides in 60 Days

According to Resolution 16, “DPR’s goal and commitment to the pesticide industry is to register pesticides within 60 days of receiving the registration application.” This would be a significant change, given that registration delays of six months are typical and delays of a year or more are common. However, the CPR Resolution notes that DPR management estimates that 75 to 90 percent of all product registrations and label amendments could meet the 60-day turnaround goal, *but only if* the LOA requirement is eliminated and efficacy review regulations are amended.

But Only After Regulations Are Revised and Laws Repealed

DPR management reportedly is working on a proposal to amend its regulations on efficacy data reviews. Even if this process is expedited, it is likely to take at least six months and probably longer before revised regulations are promulgated. Any change in the requirement for LOAs is dependent on repealing an existing provision of law, which is dependent on cooperation between the Democratic-controlled Senate and Assembly and the Republican Governor. Interested parties will be staking out their positions and seeking to influence the upcoming debates on these issues.