

**Generics Thwarted and Basic Registrants' Rights Upheld as California's Letter of Authorization Requirement Found Not to Frustrate the Purpose and Implementation of FIFRA**

The California "exclusive use" rights of basic pesticide producers to their test data were upheld in a recent court decision. In a [May 12, 2004 order](#), a U.S. District Court ruled that Section 12811.5 of the California Food and Agricultural Code does not conflict with the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), and therefore is not preempted. The decision upholds California's "letter of access" system, and means that California registration is not likely to become any easier or less expensive for generic producers.

Under the federal pesticide statute, FIFRA, data submitters are entitled to a 10 year "exclusive use" period following the first registration of a new active ingredient, and up to 15 years of data compensation for all other data. If a follow-on applicant seeks to rely on data the original applicant previously submitted to the EPA, it must pay compensation in an amount that is negotiated or determined through arbitration. California law contains its own protection of data submitters, which is more favorable than that under FIFRA. Food and Agriculture Code Section 12811.5 does not limit the duration of the original applicant's exclusive use period, does not contain a mandatory licensing scheme, does not require that disputes be resolved in binding arbitration and does not allow the registration process to proceed while the original applicants and generic applicants resolve their disputes. As the Court noted, "the California scheme, in short, makes it costlier for generic applicants to qualify for registration."

According to Chemical Producers and Distributors Association (CPDA), the Plaintiff in the recent challenge, Section 12811.5 permits original applicants to demand excessive amounts of money from generic applicants who want to rely on their test data, to delay the registration of generic pesticides and/or to force generic applicants to duplicate their test data at great expense. CPDA argued that these provisions erect an entry barrier that Congress intended to tear down in enacting FIFRA, and, as a result, Section 12811.5 conflicts with FIFRA and is preempted. CPDA, which represents registrants of generic pesticides, specifically objected to the granting of "exclusive use" rights of indefinite duration to original applicants by Section 12811.5. CPDA sought to limit California's authority to require additional compensation to ten years.

The intervening basic pesticide registrants, including Syngenta Crop Protection, Inc., Dow Agrosciences LLC, BASF Corp., Bayer Cropscience LP, E.I. du Pont de Nemours and Co., and Monsanto Co., agreed with CPDA that, in enacting FIFRA, Congress intended to encourage innovation, remove entry barriers and streamline the registration process. However, the intervening basic registrants contended that these objectives were limited to the granting of federal registration, without any concern for registration requirements that states might enact. They also argued that Section 12811.5 actually promotes Congress's objectives, rather than frustrates them, by protecting innovators' proprietary interest in their test data and by providing an avenue for generic registrants to avoid having to duplicate data.

The Court recognized that there is a presumption against preemption of state laws by federal laws, and explained that preemption will only be found if there is a clear conflict between the two. The Court determined that Section 12811.5 does not present a conflict requiring preemption, as the evidence did not establish that Section 12811.5 had stifled innovation or decreased competition on a large scale. Thus, an actual conflict was not demonstrated. The Court wrote, "there is nothing even approaching a nationwide conflict between FIFRA and the states" and "moreover, even in California the purported conflict...falls far short of thwarting FIFRA."

This decision means that follow-on registrants will require letters of authorization in order to rely upon certain types of data submitted to DPR by previous registrants. If it is not overturned on appeal, the decision represents a substantial victory for DPR and basic registrants.

The Court's ruling comes at a time when California's government is looking at ways to streamline the registration process in an effort to save money, in the face of massive deficits. One of the options offered in the most recent draft of the [DPR Pesticide Product Registration Reform initiative](#) is the repeal of Section 12811.5, which officials believe would dramatically accelerate registration decisions. As a result, activity on this issue also will move into the California political arena.