Pesticide Registration Branch Report

Impacts of AB 1011 on Pesticide Registration Functions

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Executive Summary

This report constitutes a preliminary analysis of changes in the registration process from 2005 to 2006, one year before and one year after the implementation of Assembly Bill 1011 (Matthews), Chapter 612, Statutes of 2005 (AB 1011). AB 1011 was enacted to close a loophole in the collection of the pesticide mill assessment, and streamline the pesticide product registration process by eliminating the letter of authorization requirement. AB 1011 also directed the Department of Pesticide Regulation (DPR) to accept applications for registration of products containing new active ingredients concurrently with submission to the United States Environmental Protection Agency (U.S. EPA).

To determine the impact of AB 1011 on the business functions of the Pesticide Registration Branch (PRB), staff analyzed the number of submissions and the time required to process these submissions in each year. In the first year of implementation, there was a 7 percent increase in regular submissions and a 56 percent increase in new active ingredient submissions. PRB experienced an overall 29 percent decrease in the number of submissions requiring scientific evaluation and a consistent pattern of decrease in the total number of submissions into each evaluation station. Thus, following implementation of AB 1011, there were fewer submissions going into evaluation, and those that entered evaluation were routed to fewer evaluation stations. It is also apparent from the analysis that changes in the registration process resulted in an overall decrease of 15 percent in the processing time from receipt of submissions to final action for regular submissions. For new active ingredient submissions, there was a decrease in overall processing time of 43 percent from receipt of submission to first posting. This report does not address the consequences of data cost-sharing or possible changes in the volume of “high hazard pesticides” sold in California. These will be addressed in a report to the legislature due by December 31, 2008.

Background

This report examines the impacts of Assembly Bill 1011 (Matthews, Chapter 612, Statutes of 2005) on the Department of Pesticide Regulation's (DPR's) pesticide registration process after one year of implementation. The amendments to Food and Agricultural Code section 12811.5 and 12836.5 pertaining to pesticide registration became effective on January 1, 2006. These amendments resulted in significant changes to DPR's pesticide registration process including: 1) eliminating the need for DPR to obtain a letter of authorization (LOA) before using one company's data to support the registration of another company's product (repeal of section 12404); 2) authorizing DPR to use "previous evaluations" to support new and amended product registrations (new section 12811.5); and 3) requiring DPR to accept all applications for registration of pesticide products containing new active ingredients concurrently with the applicant's submission of an application to the U.S. Environmental Protection Agency (U.S. EPA) for federal registration (new section 12836.5).

FAC section 12811.5 authorizes DPR to rely upon the evaluations of previously submitted data to carry out its registration duties regardless of ownership of the data. Under AB 1011, DPR no longer needs to expend resources reviewing duplicative data submitted to support the registration of new pesticide products that are similar to other currently registered pesticide products or tracking and maintaining letters of authorization. The bill allows DPR to concentrate its limited resources on: (1) reviewing new pesticide products containing new active ingredients; and (2) major new uses not currently registered in California.

The purpose of this report is to analyze the impact of AB 1011 on the business functions of the Pesticide Registration Branch (PRB). The registration process in 2005 (one year before the implementation of AB 1011) is compared with 2006 (the first year after implementation). This preliminary report provides an overview of changes after one year, but does not include a detailed assessment of all data.

Methods

The PRB Tracking System was developed in the early 1990s to enable staff to locate any submission and determine its status and history. Each submission is assigned a unique tracking ID number. The tracking system retains records of all "transactions" made with a submission, with a date/time stamp for each transaction. These data are available for statistical analyses. For this report, the data are sorted by calendar year of submission to compare changes before and after implementation of AB 1011.

If a submission contains active ingredient(s) currently registered in California, that submission is considered a regular submission. From the intake station, submissions are routed to either library indexing (if data are submitted) or the registration specialist (if no data are submitted). After indexing, the package is given to the registration specialist. The registration specialist determines if DPR has previous evaluations that support the product registration or amendment, or if the product requires formal scientific evaluation.

If scientific evaluation is required, the registration specialist determines which discipline(s) need to see the submission. If an application for registration of a new product or an amendment to a currently registered product requires scientific evaluation, the submission is routed sequentially from one scientific evaluation station to the next.

One of the provisions of AB 1011 provides that DPR may rely upon any evaluations of previously submitted data to support any other registration or amendment to a product registration. Registration specialists determine if there are any previously approved pesticide products containing the same active ingredient(s), with the same or similar label claims, including applications rates, pests, and sites, as are on the new product label. If the registration specialist finds a match, then no additional scientific evaluation is conducted. If the specialist finds that only some of the claims on a new or amended product label were previously approved, the new product or amendment may require scientific evaluation, but for only the new (not previously approved) claims.

Technical support staff facilitate transfer of submissions from one station to another, and record the recommendations of the scientists in the tracking system. If no formal evaluation is required, the specialist approves the product labeling, prepares the appropriate documentation, and notifies the registrant that the product is being registered for sale and use in California. Once the product is licensed, a product file is prepared in DPR's Label Resource Center for reference purposes. Discussion of time to action for regular submissions includes the entire time between receipt and final disposition of the submission, regardless of what that final disposition may be.

PRB defines a new active ingredient as any active ingredient for which there is not at least one product actively registered in California at the time of submission. Submissions containing new active ingredients are handled somewhat differently in that PRB routes these submissions simultaneously to all appropriate evaluation stations. The simultaneous evaluation of new active ingredient submissions allows for a more timely scientific review. Discussion of time to posting for new active ingredient submissions includes the time between receipt and first publication for public comment in the PRB Weekly Notices of Decisions, indicating completion of the scientific evaluation process. A pesticide product containing a new active ingredient that is submitted concurrently to DPR and U.S. EPA cannot be registered in California until DPR receives proof of federal registration, a copy of the U.S. EPA stamped accepted label, and accepts the final printed label.

Results and Discussion

The number of regular submissions that PRB received in 2006 increased by 300 over 2005 (4175 submissions received in 2005 and 4479 in 2006) for an overall increase of 7% (Fig.1). For 2006, overall processing time from receipt to final action decreased by 13.6 days from 92.8 days for 2005 to 79.2 days for 2006 for an overall decrease of 15% (Fig.2).

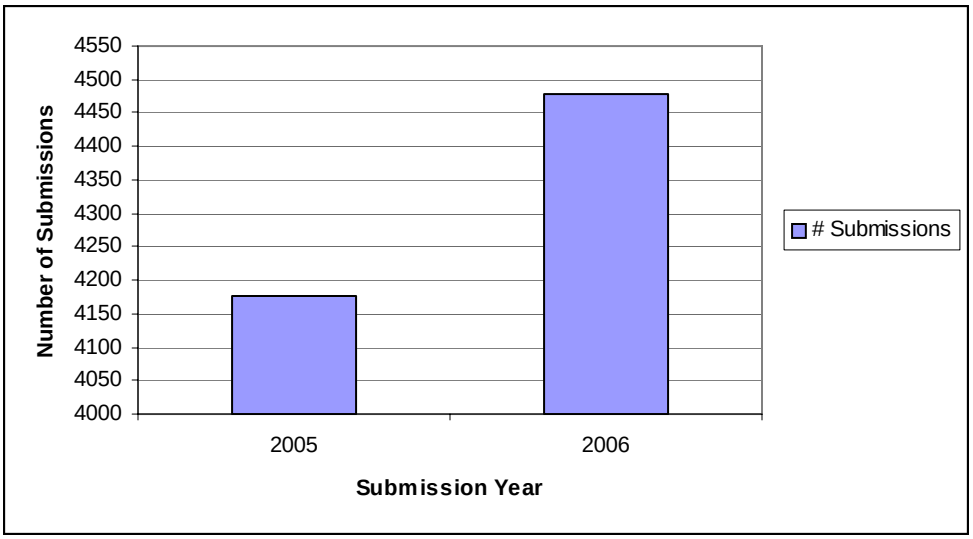

Fig.1. Number of regular submissions received in 2005 and 2006.

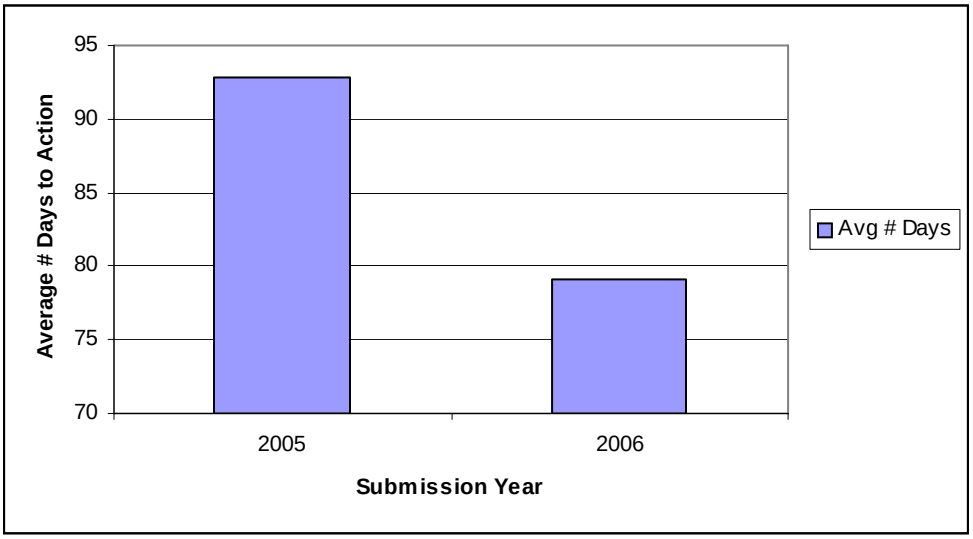

Fig. 2. Average number of days to action for regular submissions received in 2005 and 2006.

The number of new active ingredient submissions submitted in 2006 increased by 26 submissions over 2005, from 46 to 72 for an overall increase of 56% (Fig. 3). Processing time for new active ingredient submissions decreased by 114 days, from 271 days in 2005 to 157 days in 2006, for an overall decrease of 43% (Fig. 4).

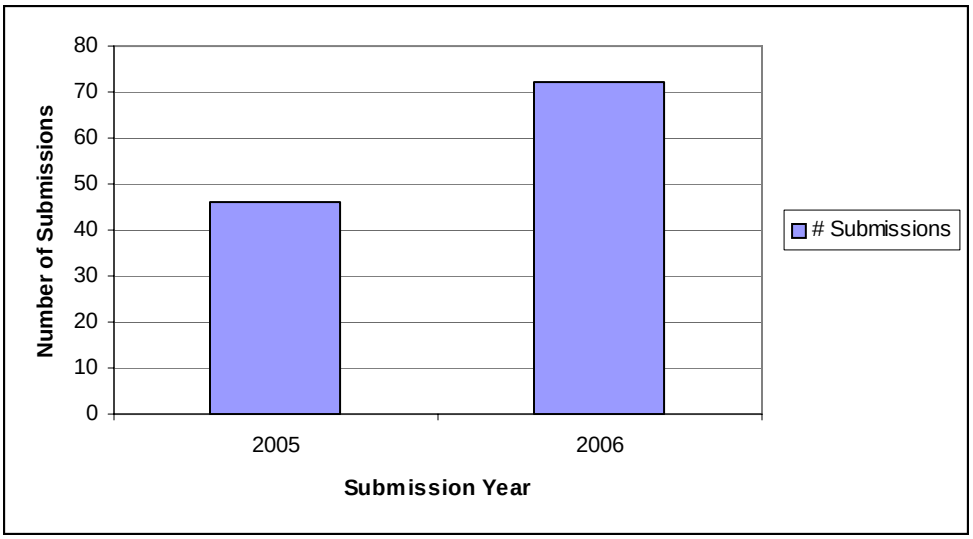

Fig. 3. Number of new active ingredient submissions in 2005 and 2006.

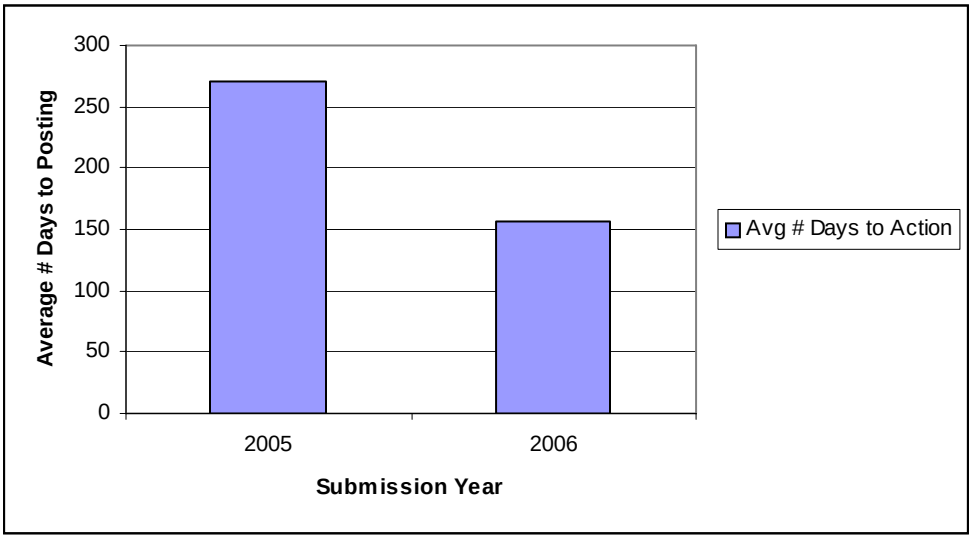

Fig. 4. Average number of days from receipt to first posting for new active ingredient submissions received in 2005 and 2006.

The total number of submissions of all products requiring scientific evaluation dropped from 1,427 submissions requiring scientific evaluation in 2005 to 1,011 submissions requiring scientific evaluation in 2006. This constituted a decrease of 416 evaluation submissions, a 29% decline from the previous year (Fig. 5).

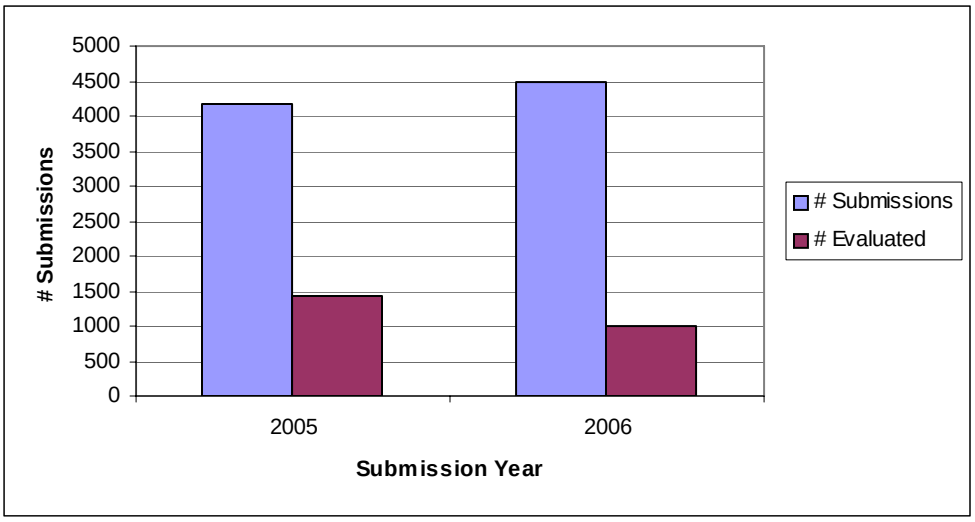

Fig. 5. The number of all submissions, and those submissions entering scientific evaluation in 2005 and 2006.

In addition to a decrease in the total number of submissions requiring any scientific evaluation, we considered whether there was a decrease in the total number of packages submitted to each scientific evaluation station between 2005 and 2006. From 2005 to 2006, the number of submissions routed to chemistry, fish and wildlife, microbiology, pest and disease protection (efficacy), plant physiology (phytotoxicity and efficacy) evaluation stations and the Medical Toxicology and Pesticide Enforcement Branches decreased by 431, an overall average decline of 30.5% (Fig. 6).

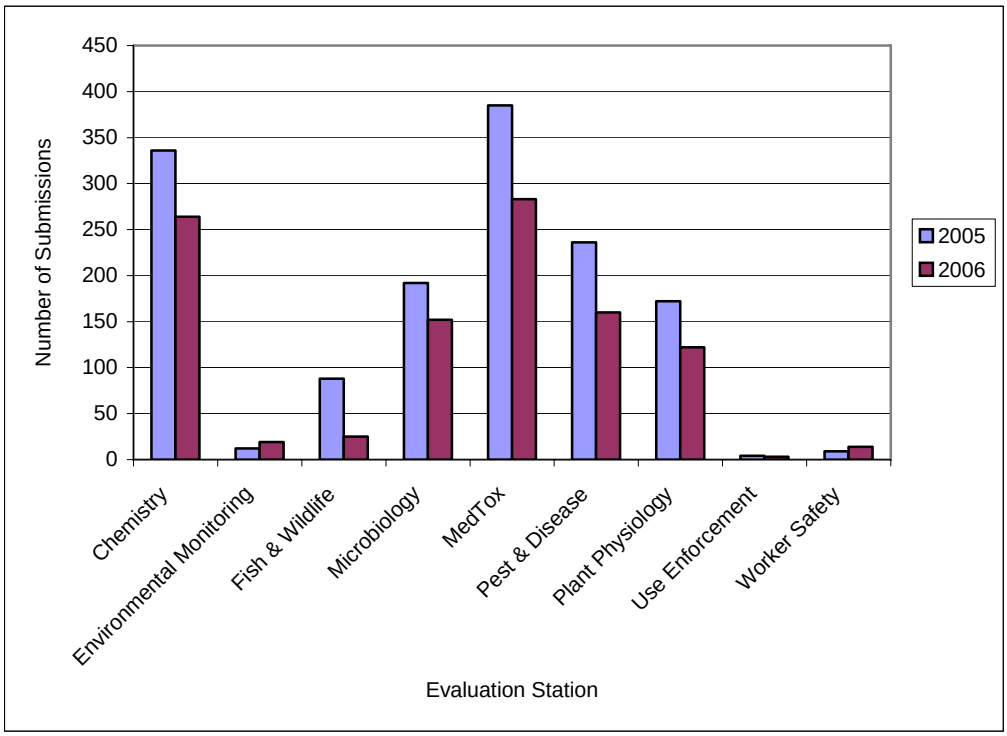

Fig. 6. Number of submissions routed to each evaluation station, by year of submission.

Conclusions

In its first year of implementation, AB 1011's impact on the pesticide registration process included a 7 percent increase in regular submissions and a 56 percent increase in new active ingredient submissions. PRB experienced an overall 29 percent decrease in the number of submissions requiring scientific evaluation, and a consistent pattern of decrease in the total number of submissions into each evaluation station. Thus, following implementation of AB 1011, there were fewer submissions going into evaluation and those that entered evaluation were routed to fewer stations. It is also apparent from the analysis that changes in the registration process resulted in an overall decrease of 15 percent in the processing time from receipt of submissions to final action for regular submissions. For new active ingredient submissions, there was a decrease in overall processing time of 43 percent from receipt of submission to first posting.

This report constitutes a preliminary analysis of changes in the registration process a year before and after the implementation of AB 1011. Ongoing statistical analyses of tracking system data will allow DPR to gain further insight into registration process changes resulting from the passage of this legislation. PRB expects to perform similar analyses of 2007 submissions beginning in January 2008.