Implementing the Pesticide Registration Improvement Act - Fiscal Year 2014

Eleventh Annual Report

March 1, 2015

Maintenance Fees

Accomplishments

Inert Ingredients

Inert Ingredient Actions under PRIA

FIFRA section 33(k)(2)(F) requires the EPA to report the number of inert ingredients (inerts) pending review by the Agency. Under PRIA 3 all new requests for approval of inert ingredients became subject to registration service fee requirements, and ten new PRIA categories were established specific to inert ingredient approvals. In FY'14, 64 inert ingredient requests were received as covered PRIA 3 applications.

In FY'14, 45 inert ingredient approval requests were completed, including 33 PRIA 3 actions and 12 non-PRIA inert ingredient clearances, which were submitted prior to inert ingredient approvals becoming a covered a pesticide activity under PRIA 3. At the end of FY'14, there were 67 inert ingredient approval requests pending in various stages of review including 51 PRIA 3 inert actions and 16 non-PRIA inert clearances.

Process Improvement in Inert Ingredient Reviews

By FY 2014, it became evident that significant improvements in the quality of inert clearance submissions under PRIA 3 were needed. The number of PRIA 3 inert submissions in FY'14 almost doubled from the previous fiscal year (64 vs 37) while the number of completed inert clearances increased only slightly (45 in FY'14 vs 43 in FY'13). 27% of the FY'14 completed clearances had to have their PRIA due date re-negotiated, and an additional 12% were completed late (after their PRIA due date). Almost all of the inert packages submitted over a two-year period under PRIA 3 were significantly deficient which caused delays and substantial additional work for the inerts staff. With the full support of the PRIA Stakeholders Coalition, an inerts workshop was held in December 2014. More than 80 inert stakeholders were in attendance. The workshop provided (1) an in-depth review of each of the 10 PRIA 3 inert categories and what must be submitted for each, (2) a detailed explanation of the inert ingredient evaluation and approval process for each category including discussion of critical data needs or appropriate data surrogates (i.e., models, structure/activity relationships, analogues), and (3) a two-year retrospective analysis identifying the most common deficiencies in inert package submissions.

Also, continual updates have been made to InertFinder, an online database for searching substances used as inert ingredients in pesticide products. InertFinder, which is searchable by chemical name or CAS Registry Number, provides information on the approval status of substances used as inert ingredients for use in food use and nonfood use pesticides, and as fragrances in pesticide products and is available on the agency's website at http://www.epa.gov/pesticides/inertfinder. Similarly, updates have been made to "The List of Trade Names of Inert Ingredients" http://iaspub.epa.gov/apex/pesticides/f?p=inertfinder:mixtures website to further enhance public access to information related to the EPA approval status of trade name inert ingredients used in pesticide products. Both InertFinder and The List of Trade Names of Inert Ingredients provide useful resources to applicants and have been demonstrated to improve the quality of registration applications submitted to the Agency.