

Implementing the Pesticide Registration Improvement Act - Fiscal Year 2012

Ninth Annual Report



March 1, 2013

Maintenance Fees

Accomplishments

Inert Ingredients

Pending Inert Ingredient Reviews at the End of FY 2012

FIFRA section 33(k)(2)(F) requires the EPA to report the number of inert ingredients (inerts) pending review by the Agency. In FY 2012, 20 new petitions for food use inert ingredients were received as non-PRIA 2 actions. When PRIA was reauthorized by PRIA 2, a request to approve an inert submitted with an application to register a conventional new product became subject to registration service fee requirements.

In FY 2012, 15 final inert ingredient tolerance rules were published in the *Federal Register* and one inert ingredient tolerance petition was withdrawn. At the end of FY 2012, there were 30 petitions in various stages of review. Inert ingredient tolerance petitions are reviewed in the order received. The agency estimates that the average review time is 3-6 months for a polymer exemption petition and approximately 12 months (including data review, science assessment, decision document, and final rule) for a new inert petition. All new petitions are screened for deficiencies before being scheduled for review, and the EPA works with petitioners to discuss the reliability and adequacy of the data to meet the FQPA (Food Quality Protection Act) safety finding. In FY 2012, an additional 10 nonfood use inert approval requests were granted and 11 nonfood use inert requests were withdrawn or denied. Seventeen nonfood inert requests were pending at the end of FY 2012.

The Inert Ingredient Assessment Branch (IIAB), consisting of nine employees at the end of FY 2012, reviews inert ingredient actions. When needed, IIAB staff is supplemented with other OPP staff particularly as related to the review of inert ingredients associated with biopesticide and antimicrobial products. In addition to inert ingredient reviews the branch is also responsible for the review of minor conventional formulation amendments, and in FY 2012 330 reviews of minor formulation amendments were completed.

Process Improvement in Inert Ingredient Reviews

In 2012, as reported in the FY 2011 PRIA Annual Report, IIAB published updates to several [guidance documents](#) on the Web, including guidance for submitting food use tolerance petitions and non-food use requests, guidance for polymer exemption submissions, and updated the inert ingredient frequently asked questions. These documents help individuals develop and submit inert ingredient approval requests as demonstrated by the continued improvements in the quality of submissions. These improvements reduced the time spent by the IIAB staff working with the registrants to make necessary corrections and decreased overall submission review time. Additionally, IIAB has continued to update [InertFinder](#), an online database for searching substances used as inert ingredients in pesticide products. InertFinder is searchable by chemical name or CAS Registry Number and provides information on the approval status of substances used as inert ingredients for use in food use, nonfood use, and fragrance use pesticide products available on the agency's website at <http://www.epa.gov/pesticides/inertfinder>. In 2012 a new database “The List of Trade Names of Inert Ingredients” has also been added to the Agency’s website to enhance public access to information related to the EPA approval status of trade name inert ingredients used in pesticide products.