

# Implementing the Pesticide Registration Improvement Act - Fiscal Year 2013

## Tenth Annual Report



*March 1, 2014*

## **Maintenance Fees**

### **Expedited Processing (FIFRA Section 3(c)(3)(B))**

Under Section 33(k)(2)(A)(iv), the agency is to report the number of applications completed for identical or substantially similar applications under section 3(c)(3)(B), including the number of such applications completed within 90 days pursuant to that section. There are two types of identical or substantially similar applications – new products and label amendments that require no data review. The former have been called in the past “Fast Track New Products,” while the label amendments are still called “Fast Track Amendments”.

Identical or substantially similar new products (formerly “Fast Track New Products”) are subject to registration service fees and have mandated decision review time frames under PRIA, and processing costs are also supported by maintenance fees. Identical or substantially similar products, or Fast Track New Products, are subdivided into separate fee categories, all of which have time frames greater than three months. With the passage of PRIA 3, the decision review timeframes for identical or substantially similar product categories (R300, A530, B660 and B710) were increased from 3 months (in PRIA 2) to 4 months (in PRIA 3). The number of identical or substantially similar products (A530, B660, B710, and R300) completed in FY’13 was 227, of which 104 were completed within 90 days; 112 were completed within their PRIA time frames; 8 were completed within their extended due date timeframes and 3 were completed late. The number completed in FY’13 was less than that in FY’12 (227 versus 306).

An additional 90 identical or similar new products in categories (A531, A532 and R301) were completed (80 within the PRIA statutory time frame and 10 within their due date extension timeframes). The number completed in FY’13 was greater than in FY’12 (90 versus 58).

The time frame for “Fast Track Amendments,” label amendments that required no data review, remained 90 days. These amendments are not subject to registration service fees. In FY’13, the agency completed 2,194 fast track amendment decisions (antimicrobial 872, biopesticide 130, and conventional 1,192), which was fewer than in FY’12 (2,555), FY’11 (2899) and FY’10 (3384).