

Implementing the Pesticide Registration Improvement Act - Fiscal Year 2012

Ninth Annual Report



March 1, 2013

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. With the passage of PRIA 2, identical or substantially similar products, or Fast Track New Products, were further subdivided into additional fee categories, some of which have time frames greater than three months. The number of identical or substantially similar products with a three month time frame (A530, B660, B710, and R300) completed in FY 2012 was 306, of which 204 were completed within 90 days; 282 were completed within their three month PRIA time frame; and the remainder had due date extensions. The number completed in FY 2012 was greater than that in FY 2011 (306 versus 298). The percentage of three month time frame decisions completed within three months in FY 2012 was 92%, which is comparable to previous fiscal years under PRIA 2 (FY 2011, 94%; FY 2010, 85%; FY 2009, 92.6% and FY 2008, 92.4%).

An additional 58 identical or similar new products with time frames of greater than three months (A531, A532 and R301) were completed (45 within the PRIA statutory time frame and 13 with due date extensions). Fewer of these actions were completed in FY 2012 (58) than the number completed in FY 2011 (74) and in FY 2010 (63).

The time frame for “Fast Track Amendments,” label amendments that required no data review, remained 90 days under PRIA 2; these amendments are not subject to registration service fees. In FY 2012, the agency completed 2555 fast track amendment decisions (antimicrobial 880, biopesticide 112, and conventional 1563), which was fewer than in FY 2011 (2899), FY 2010 (3384) and FY 2009 (2640).