

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 2011 was 298, of which 220 were completed within 90 days; 280 were completed within their three month PRIA time frame; and the remainder had due date extensions. While the number completed was less in FY 2011 than in FY 2010 (346 versus 298), it is close to the number completed in FY 2009 (299). The percentage of three month time frame decisions completed within three months was 94%, which was more than in previous fiscal years under PRIA 2 (FY 2010, 85%, FY 2009 92.6% and FY 2008 92.4%).

An additional 74 identical or similar new products with time frames of greater than three months (A531, A532 and R301) were completed (49 within the PRIA statutory time frame and 25 with due date extensions). The number of these actions completed in FY 2011 is the same as the number completed in FY 2009 (74) and more than in FY 2010 (63) or 2008 (37).

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 2011, the Agency completed 2899 fast track amendment decisions or actions (unaudited results - antimicrobial 983, biopesticide 140, and conventional 1776), which was fewer than in FY 2010 (3384) and more than in FY 2009 (2640). Most of the difference among these three fiscal years was due to the difference in the number of antimicrobial decisions (983, 1385, and 864 for FY 2011, 2010 and 2009 respectively). These “decisions” represented 3551 submissions (1,008, 198, and 2345, respectively). Each decision can have a number of submissions, each with a time frame of 90 days. Of these submissions, 3276 were completed within 90 days (994, 137, and 2145, respectively).