

Implementing the Pesticide Registration Improvement Act - Fiscal Year 2016

Thirteenth Annual Report



March 1, 2017

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. Their processing costs are 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 (A530, B660, B710 and R300) 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’16 was 153, of which 54 were completed within 90 days and 99 were completed within their PRIA time frames. The number completed in FY’16 was slightly less than in FY’15 (153 versus 178).

An additional 89 identical or similar new products in categories (A531, A532 and R301) were completed (82 within the PRIA statutory timeframe and 7 within their due date extension timeframes). The number completed in FY’16 was greater than in FY’15 (89 versus 82).

“Fast Track Amendments,” label amendments that required no data review, are not subject to registration service fees. In FY’16, the agency completed 2,180 fast track amendment decisions (antimicrobial – 592, biopesticide - 260, and conventional – 1,328), which was greater than in FY’15 (2,180 versus 1,963).