L5 Current Challenges in the US Regarding PRIA 3 and Registration of a New Active Ingredient
－米国 PRIA 3 と新規有効成分の登録における最近の課題－

Ms. Lisa Setliff (LANDIS INTERNATIONAL, INC., USA)

Abstract:
On October 1, 2012 EPA initiated PRIA 3, the Pesticide Registration Improvement Renewal Extension Act of 2012. PRIA establishes a fee schedule and a timeframe for pesticide registration. The PRIA 3 timeframe for registration of a conventional new active ingredient is 24 months.

Timeframes under PRIA 3 begin 21 days after the EPA receives an application and fee. During the first 21 days, the EPA conducts an initial screen to determine if the application is complete and formatted properly. The applicant must resolve any problems within the 21-day period or the EPA will reject the application. If the EPA rejects the application during the 21-day screening, they will keep 25% of the PRIA fee (approximately $150,000 for a new active ingredient). Next, EPA performs a 45/90 day preliminary technical screen to determine whether the data and information submitted is accurate and complete. If the EPA finds any deficiencies during the 45/90 day screen, the applicant is given 10 days to correct the deficiencies (to include submission of required studies). If the application fails the technical screen, and the deficiencies cannot be corrected by the applicant within 10 business days after receipt of the Agency's notification of the failure, the Agency will reject the application. Refunds for applications withdrawn after the first 60 days of the decision review period will be proportional to the work remaining at the time the action is withdrawn.

Once an application proceeds through the technical screening, an in-depth review is completed. If deficiencies are noted during the in-depth review period, the EPA will issue the applicant a 75-day deficiency letter, allowing the applicant 75 days to correct the deficiencies. Due to the constantly changing requirements for data; it is essential to be in constant contact with the Agency regarding the new studies that will be required otherwise an applicant can easily be faced with an application that will be rejected due to lack of data. During this seminar, we will discuss some of the studies that have caused applicants to receive deficiency letters from the EPA.