

Antimicrobials Division Issues REDS or PRAs to Meet FY 2004 Targets

In a flurry of activity during the last six weeks of its fiscal year, the Antimicrobials Division (AD) issued a number of Preliminary Risk Assessments (PRAs). These documents were issued using truncated procedures which dramatically reduced the time for public comment and Agency evaluation of those comments. The PRAs provide some insights into AD's methods that are likely to be applied to other compounds in the future, such as the application of an additional 10X safety factor, conducting risk assessments which ignore PPE in certain circumstances, and imposing new data requirements, such as a requirement for chronic studies for all antimicrobials used to preserve metal working fluids.

Recognizing that it was in jeopardy of missing its reregistration targets for fiscal 2004, which ended on September 30, AD applied an abbreviated procedure to issue a number of PRAs in an effort to meet its goal for issuing Reregistration Eligibility Documents (REDs) during fiscal 2004. AD counts the PRAs as if they were REDs, although final RED documents will not be published until sometime in fiscal 2005. Although it has published extensive procedures for six step (<http://www.epa.gov/opsrrd1/public.htm#6phase>) and four step (<http://www.epa.gov/opsrrd1/public.htm#4phase>) reregistration procedures, AD shortened the time frames set forth in these procedures to meet its productivity goals. The Agency's shortened process evoked criticism from environmental groups, which commented that they could not provide input within the very short time periods allowed by EPA. Nevertheless, AD proceeded, and issued a group of draft PRAs before the end of its fiscal year. The compounds addressed by EPA include benzisothiazolin-3-one (BIT), Pine Oil, Halohydantoin, Polyhydrochloride (PHMB), Phenol/Sodium Phenate and Zinc Pyrithione. In addition, PRAs for the wood preservative active ingredients arsenic acid, coal tar creosote and pentachlorophenol were issued in fiscal 2004.

Several of the draft PRAs were withdrawn from EPA's public web site shortly after issuance. Reportedly, the PRAs that have been withdrawn, and others that remain available in draft form, including BIT and the wood preservative active ingredients, will not be counted as completed REDs for fiscal 2004. These actives are now scheduled for REDs in fiscal 2005, although the process that AD intends to use with the revised draft PRAs is unclear. The remaining available PRAs can be accessed in the bar at the right of this page: <http://www.epa.gov/oppad001/#Reregistration>

Based upon a review of the PRAs issued by AD, several trends are apparent:

- First, it appears that AD is applying an additional 10x safety factor in situations under which, according to the Agency's own guidance, the FQPA 10x factor does not apply.
- Risk assessments for occupational scenarios are being conducted both with and without PPE, regardless of label directions. For residential uses, AD is conducting risk assessments assuming all applicators do not use any PPE regardless of label directions. Apparently, AD regards requirements on labels for residential uses to be unenforceable and not followed in the real world.

- Additional toxicology data requirements are being imposed as “confirmatory” data. These include relatively expensive studies such as oncogenicity and repeat dose inhalation, and appear to be focused on certain uses EPA believes are high exposure, such as preservatives for metal working fluids. EPA also is requiring applicator exposure studies as a confirmatory data requirements

Although the draft PRAs have been published, EPA officials have explained that the data requirements will not become final until the agency actually issues data call-ins with the final RED documents. As noted, these may be some time off, and the Agency may reconsider its requirements during the interim period.