

Registration Data Requirements for Antimicrobial Pesticides in the United States

Before pesticides can be marketed and used in the United States, they are thoroughly evaluated to ensure they meet federal safety standards to protect human health and the environment. Pesticides that meet the requirements are granted a license or “registration” that permits their distribution, sale, and use according to specific use directions and requirements identified on the label.

In evaluating an application, EPA’s Office of Pesticide Programs assesses a wide variety of potential human health and environmental effects associated with use of the product. The producer of the pesticide must provide data from tests done according to EPA guidelines. Those guidelines are not always harmonized with international testing guidelines.

These tests evaluate whether a pesticide has the potential to cause harmful effects on humans, wildlife, fish, and plants, including endangered species and non-target organisms, as well as possible contamination of surface water or ground water from leaching, runoff, and spray drift. Potential human risks range from short-term toxicity to long-term effects such as cancer and reproductive system disorders. In addition, efficacy data is required to ensure that the product performs to acceptable standards when used in accordance with its directions for use.

When EPA approves a particular pesticide for registration, the Agency has assessed the chemical and found that, when used according to label directions, it does not pose unreasonable risk to public health and the environment.

Data requirements for registration are intended to generate data and information necessary to address concerns pertaining to the identity, composition, potential adverse effects and environmental fate of each pesticide. EPA’s requirements for data are listed in the Code of Federal Regulations, Chapter 40, Part 158. Detailed tables within that Part give the specifics of data requirements for various proposed use patterns and provide reference to the guidelines on how the tests are to be conducted. The data requirements, which have not been updated since 1988, currently are undergoing extensive revision for conventional pesticides and for biochemical and microbial pesticides; proposed rules for each were issued during 2005 and 2006, with final regulations expected to be issued either in 2007 or 2008.

The data requirements currently identified in 40 CFR Part 158 were established primarily for conventional chemicals used on crops. Both EPA and Congress have recognized that Part 158 was drafted for conventional chemicals, and that separate regulations need to be promulgated for antimicrobials. Congress recognized the different degree and type of review needed for antimicrobials and mandated EPA to propose regulations for antimicrobials within 270 days of the passage of the Food Quality Protection Act (FQPA), P.L. 104-170, which was enacted on August 4, 1996. See FIFRA § 3(h)(3)(ii). However, the separate regulations for antimicrobials still have not been issued. A proposed rule is expected to be published for comment sometime during the second half of 2008. This upcoming rulemaking is expected to have a significant impact on the requirements for registration of antimicrobial pesticides in the United States.

**For further information on this important rulemaking, please contact
Seth Goldberg, partner, at sgoldberg@steptoe.com (Tel: +1 202 429 6213), or
Elizabeth Brown, Ph.D., non-lawyer technical specialist, at eabrown@steptoe.com (Tel: +1 202 419 5166)**