

## Registration Review

### Background

Pesticide products must be registered by the Environmental Protection Agency (EPA) before they are marketed. To decide if a pesticide and its uses are acceptable for registration, EPA examines a tremendous amount of data from studies on potential health and environmental risks.

Amendments to the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) in 1988 required EPA to determine the reregistration eligibility of every pesticide product registered before November 1984. Subsequent amendments tied that process to tolerance reassessment under the Food Quality Protection Act of 1996 (FQPA) and reset the deadline to August 2008. EPA has conducted risk assessments utilizing the most up-to-date data available and has substantially met that reregistration deadline.

FQPA also directed the Agency to set up a Registration Review program to review all pesticide products on a 15-year rotating basis, following completion of reregistration and tolerance reassessment. In August 2006, EPA issued a rule to implement this program, which was developed with input from a wide range of stakeholders. In the fall of 2006, EPA began opening dockets for specific pesticides according to an established schedule to commence Registration Review. The Agency is now opening some 70 dockets per year in order to meet a 2022 deadline for completing the first round of Registration Review.

Under the program, EPA will update risk assessments conducted under the reregistration program, taking into account the most recent data available and any changes to regulatory requirements.

In Registration Review, EPA intends to incorporate results of the Endocrine Disruptor Screening Program (EDSP), which was mandated by FQPA but is still under development. The program is intended to determine if synthetic substances, such as

pesticides and other chemicals, have the potential to interact with hormonal systems in humans.

A "positive" result in EDSP screening tests (Tier 1) would indicate a molecular affinity between a chemical and the hormonal systems in test species; *it would not determine or quantify any effects*. Subsequent more complex testing (Tier 2) would be required to determine if effects could occur. EPA must consider available information on endocrine effects in humans when establishing tolerances for pesticide residues in foods, but FQPA does not otherwise specify the Agency's regulatory action in response to "positive" data from either Tier 1 or Tier 2 studies.

EPA has also decided to conduct required endangered species risk assessments in the course of Registration Review. A regulation promulgated by the Fish and Wildlife Service (FWS) in 2006 intended to streamline endangered species consultations with EPA was challenged in federal court and partially invalidated. Another regulation promulgated by FWS in late 2008 would clarify how EPA conducts its endangered species risk assessments and consults with the Services, however it has been subject to legal challenge also. Other lawsuits challenging a broad range of pesticides in relation to numerous endangered species further complicate the regulatory picture and the Agency's intentions for the Registration Review program.

### Position

- CropLife America supports the registration review program prescribed by the FQPA.
- The EDSP program will produce new and novel data requiring further advances in risk assessment methodology.
- Endangered species risk assessments will require cooperation between EPA and FWS to further develop the science of ecological risk assessment.