Chapter 20

Resistance Management Programs for Transgenic Crops

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The registration of plant-incorporated protectant (PIP) products is authorized under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Federal Food, Drug, and Cosmetics Act (FFDCA), as amended by the Food Quality Protection Act (FQPA). Insect resistance management (IRM) is an integral part of PIPs registration and is justified by the U.S. Environmnetal Protection Agency's (EPA) concerns for abating the predicted rapid evolution of resistance in target insects to PIP toxin, the presumed responsive increase in conventional pesticide application to replace the affected PIP, and the loss of effectiveness in certain Bacillus thuringiensis (Bt) spray products used in organic agriculture. IRM requirements are an unprecedented EPA regulation for insecticidal product registration. The table on the following page presents PIP events developed since 1995.

EPA's insect resistance management strategy for labeling PIPs includes several unique (to insecticide registration) provisions incumbent upon the registrant. These provisions include:

- conduct/sponsor research on resistance evolution and management in target insects, resistance monitoring, resistance mitigation, and other areas relevant to IRM;
- maintain a grower agreement that legally obligates the grower to accomplish IRM provisions related to the PIPs purchased;
- necessitate structured refuges in a manner described on the PIPs label, if required, to provide non-resistant insects to dilute the genes of resistant target insects in the pest population;
- develop and conduct a monitoring program to detect increased tolerance and resistance to each unique PIP before resistance genes become established in the target pest population at a high level;
- develop a remedial action plan for abatement of resistance for each PIP and implement the plan when resistance occurs;
- educate growers and increase communication among producers, researchers, and the public about PIPs regulatory requirements and use; and
- monitor and enforce grower compliance to the IRM refuge requirement.

The Grower Agreement and IRM

Registrants must ensure that growers comply with the IRM requirements of each PIP and must develop and use a growers' agreement that purposefully obligates them to implement specific IRM practices. Non-compliance with IRM terms may result in the grower losing the right to purchase biotech products in the future, from the particular company. The grower agreement contains many stipulations, including IRM provisions, which obligates the grower and serves to educate the user of PIP products.

Requirements for Structured Refuge

Structured refuges are used for PIP cotton and corn to produce non-selected adults of target insects. These insects are intended for mating with resistant allele-carrying moths from the PIP crop. The structured refuge must produce adequate numbers of adult target insects to ensure a high probability that resistant insects from the PIP crop will mate with refuge insects. Synchrony of adults occurring from the refuge and the PIP crop is required for successful mating. The refuge must be close enough to the PIP crop so that adult target insects originating from refuge and PIP plants will find each other.

Bt Cotton

Single-toxin Cry1Ac (Bollgard), dual-toxin Cry1Ac + Cry2Ab (Bollgard II) from Monsanto Company and dual toxin Cry1Ac + Cry1F (Widestrike) from Dow Agrosciences cottons are currently registered in the United States and other parts of the world. Farmers wishing to plant Bollgard, Bollgard II or Widestrike cottons within the United States are legally required to plant one of three refuge options, or a combination of the options. These requirements may change because the EPA periodically reviews label specifications and new research data and alternative refuge options may be developed (e.g., for highly efficacious dual toxin products as opposed to single toxin PIPs). The current requirements for Bollgard, Bollgard II and Widestirke cottons are identical and include: