An assessment of the fate and potential effects of plant incorporated protectants (PIPs) is an integral component of the ecological risk assessment. An early step in the ecological assessment of PIPs is to characterize the spectrum of insecticidal activity and the environmental fate. Monsanto is developing a biotechnology-derived insect-protected corn product that confers resistance to corn rootworm (Diabrotica spp.) via RNA-based gene regulation. An overview of a hypothesis-based approach for characterizing the spectrum of insecticidal activity for this PIP will be presented. This approach is designed with the goal of defining selectivity and specificity to help define the scope of Tier 1 non-target organism hazard testing that is required for a robust non-target organism assessment. Additionally, the approach and general methodology for characterizing the environmental fate of dsRNA in soil will be presented. These approaches, for characterizing environmental fate and potential non-target organism effects, are consistent with the existing framework for ecological risk assessment of PIPs and provide a high level of certainty in the conclusions of the ecological risk assessment for a PIP that operates by RNA-based gene regulation.

Keywords: RNAi, non-target organism, activity spectrum, environmental fate