Modification of Study Designs to Meet Changing Regulatory Requirements and Specific Compound Requirements

To bring a new agrochemical to market we need to deliver a series of regulatory studies covering environmental fate, toxicology, residues and metabolism. Many of these studies are detailed in specific guidelines and we work to meet the requirements of these guidelines. Occasionally we will see a fundamental change in regulatory expectations as recently happened in Europe and we also see more gradual changes. We need to be focussed on these and respond with modified study designs.

In addition, we have to adapt to the specific needs of each chemical we develop. This means we have to adapt standard approaches to meet particular compound requirements and still meet the expectations of the regulators. We also have to change or develop study designs when we start to work with a new test system for which limited or no guidance exists.

This broad ranging presentation will look at recent regulatory changes and discuss how we have adapted our standard study designs and developed new capabilities. The presentation will look at examples from metabolism (NOR studies), environmental fate, field trials and residues analysis. It will also look at how different guideline interpretations can lead to significantly different study designs.

The nature of a new active substance will dictate changes to standard study design and in the second half of this presentation we will examine how we deal with issues like volatility, high and low application rates, instability and persistence. Finally we will look at how we adapt to specific test systems, for example estuarine and marine sediment and GM crops.