

PART 9

ENVIRONMENTAL TOXICOLOGY

DACO:

9.2.4.3

Title:

Hive study (field)

Details:

The EAD has identified a potential chronic risk to bees. In order to refine this risk, fate and toxicity data are required.

During the original review of the seed treatment use of Clothianidin (REG2004-06_revision), the EAD had identified data gaps linked with the potential of toxic exposure of non-target pollinators to residues of Clothianidin from the pollen and nectar of treated seeds. This triggered a requirement for field testing (DACO 9.2.4.3) to evaluate the possible chronic exposure to honey bee larvae and queen. The study submitted to fulfill this data requirement was deemed unacceptable.

This data is also required for the assessment of the spray application uses proposed for Clothianidin, as it is expected that such uses will also lead to the translocation of Clothianidin residues into pollen and nectar.

To date, no valid Hive studies have been submitted to the PMRA. This represents a critical data gap in the risk assessment of Clothianidin. A new study is required to address the toxicity of Clothianidin to bees. This study must be designed to characterise the fate of Clothianidin under field conditions, as well as chronic toxicity of Clothianidin to bees. The applicant is required to discuss the protocol with the PMRA before starting of the study.