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Office of Chemical Safety
and Pollution Prevention

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MEMORANDUM

SUBJECT: Reclassification of MRID 46907801/46907802 Data Package 336888 for Clothianidin, PC Code 044309

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The purpose of this memorandum is to transmit the Environmental Fate and Effects Division's (EFED's) final Data Evaluation Record (DER) for the study entitled, "An Investigation of the Potential Long-Term Impact of Clothianidin Seed Treated Canola on Honey Bees, *Apis mellifera* L." (MRID 46907801/46907802) and provide a brief history of activities related to the reclassification of this study.

This field study was originally reviewed by EFED in November 2007 and classified as "Acceptable". A subsequent re-review of the study was conducted in November 2010 as part of a new use assessment for clothianidin seed treatment on mustard seed and cotton. EFED scientists routinely reevaluate studies to determine whether the information submitted is valid and if it is relevant or useful to the regulatory matter in question. In the case of the clothianidin honeybee field study, the study was reconsidered based on an increased understanding and awareness of the potential uncertainties normally encountered in field studies with honeybees. Based on the initial re-review, which occurred on November 2, 2010, the study was thought to be "Invalid"; however, it was later reclassified, on December 3, 2010, as "Supplemental". The study was initially reclassified as "Invalid" based on clothianidin contamination of controls.

Further consideration of the entire study revealed that there was useful information in the study addendum that could be used to qualitatively describe hive survival following exposure to clothianidin at levels described in the study. These results showed that the majority of hives monitored, including those exposed to clothianidin during the previous season, survived the overwintering period. The overwintering results cannot be used quantitatively because cross-contamination of clothianidin in the control hives prevents a comparison between the control hives and the treated hives as they relate to whole hive parameters. Therefore, the final classification for the clothianidin honeybee field study is "Supplemental".

In this field study, control and treated plots were each 1 hectare in size and paired, so that 4 sites were established with a formulation control plot paired with a clothianidin-treated plot. These plots were separated by a minimum of 250 m. The major source of uncertainty is the ability of this study to discriminate treatment-related effects because clothianidin residues were detected in nectar from formulation control colonies. In addition, no negative control was reported to determine if there were statistically significant effects due to the formulation (actives plus inerts minus clothianidin). The presence of clothianidin residues in albeit a limited number of control hive nectar samples at concentrations similar to those detected in nectar from colonies placed in treated fields suggests that at least some workers from control colonies foraged on clothianidin-treated canola. According to the study authors, the minimum distance between the treated and control fields was 250 m and was likely insufficient to prevent cross-foraging of bees between treated and control fields. In addition to the close proximity of treated and control fields, control bees may have foraged in clothianidin-treated fields because the forage in some of the control fields was of lower quality due to insect damage and reduced emergence of canola. Likewise, the extent to which bees in treated fields may have availed themselves to untreated canola is uncertain given the close proximity of the control fields. Additionally, the study did not adequately evaluate the exposure bees to canola via pollen identification analysis. Additional confounding factors associated with overall colony health included the loss of queens from 11 colonies, including three colonies that were classified as "dead" part way through the study and not included in "some" of the statistical analysis. Finally, raw data were not provided in the study to conduct a statistical reanalysis of the study results

Based on the confounding factors associated with potential clothianidin cross-contamination of nectar from control hives and the lack of a negative control, the results of the investigation of the potential long-term impact of clothianidin seed-treated canola on honeybees are not adequate for use in risk assessment. Under the conditions tested, the study indicates that clothianidin residues were brought back to the bee colonies in nectar and pollen and were found in comb honey as well; residues were not detected in comb wax though. The study addendum on the assessment of overwintering colonies provides useful information on the subsequent effects of bee colonies in the year following exposure at measured residue concentrations. In summary, this field toxicity study with honeybees (OPP Gdln. No. 141-5; OPPTS 850.3040) is classified as "supplemental".

Table 1. Ecological data requirements for clothianidin.			
MRID	**Guideline**	**Study Classification[1]**	**Remarks**
469078-01 469078-02 (addendum)	850.3040	Supplemental	This study and associated addendum assessed the toxicity of clothianidin to pollinators using whole hive parameters under field conditions. The study does not satisfy the 850.3040 guideline.

[1]**OPPIN Classifications:**
Acceptable/Guideline; Acceptable/Non-Guideline; Cited; Confirmatory; Decision Deferred; Extraneous submission; In Review; No Decision; Partially Acceptable; Supplemental; Unacceptable/Guideline; Unacceptable/Non-Guideline; Upgradeable.