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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

4/10/03

Subject: Addendum referring to EFED's Risk Assessment on Clothianidin Use as a seed Treatment on Corn and Canola (PC Code 044309;)

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EFED is including an addendum to the risk assessment for the clothianidin registration on canola and corn seed treatment (DP Barcode: D278110) that includes a revised endangered species and label statement. Our risk assessment showed that the ingestion of treated seeds may result in chronic toxic risk to non-endangered and endangered small/medium size birds (e.g., songbirds), as well as acute/chronic toxicity risk to non-endangered and endangered mammals (e.g., voles and other rodents). Since this compound is persistent (field dissipation $\frac{1}{2}$ life = 277 - 1,386 days), toxic to honey bees, and has the potential for expression in pollen and nectar of flowering crops, EFED also concluded that there was a potential for long term toxicity to these pollinators. The possibility of toxic chronic exposure to nontarget pollinators through the translocation of clothianidin residues in nectar and pollen has prompted EFED to require field testing (141-5) that can help in evaluating this uncertainty. In order to fully evaluate the possibility of this long term toxic effect, a complete worker bee life cycle study must be conducted, as well as an evaluation of exposure and effects to the queen. Because of this concern, EFED suggested that the following honey bee label statement be included:



This compound is toxic to honey bees. The persistence of residues and the expression of clothianidin in nectar and pollen suggests the possibility of chronic toxic risk to honey bee larvae and the eventual stability of the hive.

However, after further consideration, EFED would like to suggest that the registrant be given a conditional registration that is contingent on their conducting the chronic honey bee study that evaluates the sublethal effects of clothianidin to the hive over time. EFED will therefore defer the requirement for this bee labeling statement until after the chronic study has been reviewed. In order to cover poignant endpoints and objectives, the honey bee study should evaluate the effects of clothianidin to the hive over time and should include but not necessarily be limited to the following criteria: a) an evaluation of two complete life cycles (~130 days) including egg, larvae, adult stages, and mortality of the honey bee colony; b) an evaluation of the exposure and effects to the queen during these life cycles; c) provide clothianidin residue analysis of the stored nectar, honey, and pollen at the beginning of the study, at periodic time intervals during the study and at the end of the study; and d) the study must include replicated data with statistical comparison to controls. The registrant must submit a protocol and complete the study that addresses these concerns according to the following generalized time line:

Start (April/May 2003)	Conditional Registration of Clothianidin 600 FS
60 days (June/July 2003)	Registrant submission of draft protocol
120 days (August/September 2003)	EPA response with proposed changes to draft protocol
180 days (October/November 2003)	Registrant submission of final protocol for approval
210 days (December 2003/January 2004)	EPA and registrant concur on study
540 days (1.5 yrs.) (December 2004)	Final completed study submitted to EPA for review

The concern for terrestrial animals, birds and mammals, should also be addressed in a label statement. However the statement proposed by the registrant is a little weak:

"Seeds are treated with clothianidin as an insecticide. Treated seeds exposed on soil surface may be hazardous to wildlife. Cover or collect treated seeds spilled during loading."

However, after referring to : <http://www.epa.gov/oppfead1/labeling/lrm/chap-09.htm> **Label Review Manual Chapter 9: Environmental Hazards**, EFED notes that "some Environmental Hazards statements are prepared specifically for certain chemicals (a.i.'s)". Clothianidin is a compound that has the potential for chronic effects to birds and mammals. Therefore, we suggest that the Agency require the following labeling statement for clothianidin:

"This compound is toxic to birds and mammals. Treated clothianidin seeds exposed on soil surface may be hazardous to birds and mammals. Cover or collect clothianidin seeds spilled during loading."

..or if a pesticide product contains directions for use in treating seed, the Environmental Hazards section can include the following statements:

"Exposed treated seed may be hazardous to birds and other wildlife. Dispose of all excess treated seed and seed packaging by burial away from bodies of water."

Endangered Species

The Agency's level of concern for endangered and threatened birds and mammals is exceeded for the proposed use of clothianidin as seed treatment for corn and canola. Exceedence of the endangered species criteria is interpreted as a warning flag to potential problems and an indicator that further analysis is warranted, but exceedences alone are insufficient evidence to conclude that impacts to listed species will occur. EFED has based their concerns to endangered /threatened mammals and birds after evaluating chronic endpoints such as reproductive and developmental effects. Specifically, EFED is concerned with acute and chronic exposure to endangered/threatened seed eating mammals in the 0.015 - 0.035 kg size range (e.g., shrews and other rodents), as well as avian granivorous species of passerines (e.g., songbirds). Since fields can provide forage and grit for birds and mammals, this feeding strategy, raises a concern at a chronic level because only a few seeds may be necessary to cause reproductive and/or developmental effects (e.g., 8 - 42 corn seeds for small birds). The number of seeds (corn) necessary for an acute effect on small and medium size mammals is about 4.7 - 10, while the number that may cause a chronic effect is about 2 seeds. Expanding this evaluation will require an understanding of species specific habitat and range, as well as life history information that defines specific foraging habits for species of concern. The following considerations can narrow the field of potential endangered species that may be exposed to clothianidin treated seeds:

- 1) Species (granivores) of concern should have a tendency to forage or frequent open fields that are void of cover;
- 2) The exposure window of concern is approximately 2 weeks in the spring (April for canola planting and March to April for corn). Species of concern can include those species whose movements, migratory patterns and/or reproductive cycle coincide with this time period;
- 3) EFED is assuming a 1% unincorporation of seeds. If the registrant has field data that could identify a range of values pertaining to the amount of seeds that are usually not incorporated at planting, this could help to refine the assessment.
- 4) Registrant could identify endangered/threatened species of concern. The information will be used by the OPP Endangered Species Protection Program to develop recommendations to avoid adverse effects to listed species.
- 5) A refined assessment could also address actual clothianidin residues on seeds in the field.

6) Define the dynamics of the endangered/threatened species population in question. What is the sensitivity of the population to mortality. Risk to a highly unstable population could be captured by looking at an extreme in sensitivity distribution (5th percentile) while risk to those from a more stable population could be assessed by evaluating the least sensitive distribution (95th percentile).