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

MEMORANDUM **Date: 05/14/09**

SUBJECT: **Response to registrant Comments on Combined Fipronil (129121) Ecological Risk Assessment (Terrestrial Wildlife Issues) DP353647**

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The Environmental Fate and Effects Division has reviewed and prepared the following responses to issues and comments presented to the Agency in MRID 47438301. This response document deals with the terrestrial wildlife effects and exposure issues and is intended to be a companion with the previous response to comments on Aquatic issues dated 11/19/08.

Terrestrial Effects Assessment

Body Size Scaling and appropriate Endpoint for Passerines
Registrant Comment: The registrant disagrees with the Agency risk assessment approach and the use of body weight scaling for birds. The registrant believes that the chemicals used as a basis for body weight scaling relationships from published sources are not representative of the mode of action of fipronil. The registrant believes that available test data for fipronil suggests that passerines are not more sensitive than other larger birds so body weight scaling is not supportable for this compound. The registrant believes that the passerine test submitted should be used to represent 20g birds.

EFED Comment: EFED's overview document is clear in that the most sensitive species tested forms the basis of the screening risk assessment; this is not the passerine species data for this chemical. It is unclear how the mechanism of action of fipronil has been demonstrated to be influential in scaling of any kind and it has been and continues to be the position of EFED that there are insufficient data to make definitive declarative statements regarding the relative sensitivity of Passeriformes and other bird taxa. Nevertheless, the registrant's comment is suggestive of a degree of uncertainty associated with the EFED risk conclusion. It is possible, though not proven by the amount of data provided to the Agency that body weight scaling utilized in EFED models does not represent the toxicological reality of fipronil in birds.

The avian risk assessment does not limit 20g birds as to represent songbirds exclusively. This was made clear to the registrants during the rebuttal to the very first risk assessment for fire ant use of fipronil. To date nothing has changed relative to EFED policy in this regard.

LD50/ft^2

Registrant Comment: The LD50/ft^2 quotient is not a risk quotient and there is no way to relate pesticide load available to pesticide intake of individuals and no basis for concluding that 0.1, 1, 10, 100 or any other number represents a threshold between minimal and high risk. No conclusions can or should be made about the magnitude of risk on the basis of this metric.

EFED Comment: The Agency has presented the assessment method to the scientific community during evaluation of corn cluster pesticides in 1996. That peer review did not result in a policy change in the use of this metric. Of course other lines of evidence may be used to illuminate possible significance of specific routes of exposure and to this end some of the information provided by the registrant in comments is useful for selected exposure route evaluation.

Calculation of the Number of Granules Required Achieving LD50

Registrant Comment: calculations on the number of granules necessary for consumption of by a small bird to reach an LD50 is presented and indicates that it is highly unlikely that birds or mammals would incidentally pick up such large numbers of granules.

EFED Comment: EFED concurs that the information presented by the registrant (even when adjusted by EFED to use the policy-required lowest acute oral dose value from all tested birds for the 20 g bird provides other lines of evidence that incidental ingestion of fipronil treated granules is not likely to be a significant source of exposure. This information, combined with past risk assessment analysis for invertebrates based on fugacity approaches suggest that dietary exposure may not be a significant contribution to avian or mammalian risk for fipronil.