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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
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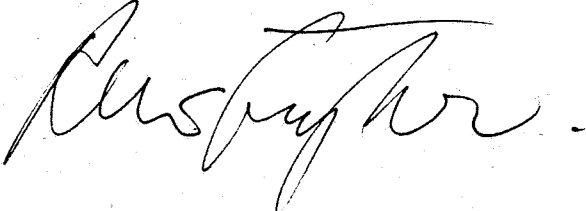
OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

Subject: Dose Selection for a 1-Year Dog Study on Trifluralin

To: Lois Rossi, Chief
Re-Registration Branch
SRRD

From: Reto Engler, Chief
SACB
HED



DowElanco has submitted a protocol for a 1-year dog study for review. This review is not assessing the adequacy of the study protocol per se, since the protocol for such a study is clearly presented in Section F of the EPA Testing Guidelines. This review instead focuses on the dose selection for the dog study as it might relate to the establishment of an RfD for Trifluralin.

The present RfD is based on a NOEL of 0.75 mg/kg/day in a chronic dog study; the LEL in that study was 3.75 mg/kg/day. Another critical study in the Trifluralin data base is a 90-day rat study with a NOEL of 2.5 mg/kg/day and a LEL of 10 mg/kg/day, this study was specially conducted to shed additional light on the adverse effects of trifluralin on the kidney.

The registrant now proposes to carry out a chronic dog study with doses of 0, 0.75, 2.4, and 40 mg/kg/day, presumably with the expectation to establish a NOEL of 2.4 mg/kg/day and thus an RfD which is about three (3) times higher than the present one.

Conclusion:

With respect to the safety evaluation of Trifluralin we conclude that the proposed dog study is entirely unnecessary, and in fact may be in conflict with the Agency's policy and concern about animal welfare and EPA's continued efforts to reduce the impacts and suffering on animals based on its testing requirements. At present the TMRC based on tolerances only uses about 10% of the RfD; even in case the tolerances should in the future approach 100% of the RfD a more realistic evaluation of the

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actual residue levels would be more appropriate than to repeat the dog study. Moreover, at present trifluralin is regulated as a carcinogen and the RfD is not appropriate for a risk assessment.

We would welcome the opportunity to discuss our conclusion with DowElanco at the meeting they are requesting.