



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

OFFICE OF  
PREVENTION, PESTICIDES AND  
TOXIC SUBSTANCES

**MEMORANDUM**

PC Code: 084301

DPBarcode: D281322

**SUBJECT:** Response to Dow AgroSciences' Comments on EFED RED Chapter for Benfluralin

**FROM:** William P. Eckel, Ph.D., Agronomist

Michael Davy, Agronomist

Environmental Risk Branch II  
Environmental Fate and Effects Division (7507C)

**TO:** Diane Isbell  
Special Review and Reregistration Division (7508C)

**THRU:** Tom Bailey, Branch Chief  
Environmental Risk Branch II / EFED (7507C)

**DATE:** June 4, 2004

Attached are EFED's responses to Dow AgroSciences' report of April 26, 2004 entitled "Dow AgroSciences' Response to the U.S. EPA's Benfluralin; Availability of Risk Assessments (Interim Process) Documents."

Our responses are keyed to the EPA document number (for example, OPP-2003-0381-002) and page number of the registrant's comment document.

We are also sending a revised EFED benfluralin science chapter that incorporates the registrant's comments that we agree with. The changes in the science chapter are in strikeout and redline fonts.

## **Responses to Comments**

### **OPP-2003-0381-002 (p. 8)**

The Agency appreciates the clarification about the formulations and uses of benfluralin. The spelling error will be corrected.

### **OPP-2003-0381-003 (p. 8-9)**

The structures of twelve major degradates are given in Appendix X of the EFED Risk Assessment.. A January 22, 2003 memorandum to the file lists the 26 degradates, the environmental fate studies in which they were found, and the maximum concentration at which each was found. Not all of the degradates have been completely identified (formulas and structures may not be known). This information was derived from the studies submitted by the registrant.

### **OPP-2003-0381-005 (p. 14)**

The Agency appreciates the clarification about the formulations and uses of benfluralin. References to the use of benfluralin as an insecticide will be removed from the ecological risk assessment.

### **OPP-2003-0381-006 (p. 14-18)**

(Risk to Terrestrial Animals)

The registrant asserts that despite the lack of a No-Observed-Adverse-Effect-Concentration (NOAEC) in the chronic toxicity test for bobwhite quail, that the risk assessment is conservative because the exposure assumptions are unrealistic.

First, the registrant asserts that exposure will only be caused by consumption of plants at the edge of the field, where the concentration of benfluralin will be lower than in-field exposures, because the contamination will be due to spray drift alone (estimated at 5% of the application rate). However, the Agency is also concerned about consumption of food items such as insects that occur in-field, and will therefore be contaminated at the levels estimated by the Hoerger-Kenaga nomogram.

Second, the registrant argues that the assumption that a bird or mammal will obtain all of its food in a narrow strip beside a sprayed field for 20 weeks is highly conservative. This is actually not as conservative as the registrant contends, because exposure will be in the treated field, as well as at the edge of the field. Also, there are many birds and mammals with a sufficiently small foraging range, that treatment of only a few adjacent fields would effectively contaminate their entire food supply. It is also possible that the observed chronic effects in birds and mammals are due to short-term exposures, rather than chronic

exposures. Some pesticides (such as carbamates and organophosphates) cause chronic effects from short-term exposures. Since the exposure length needed for benfluralin to produce chronic effects has not been established, the Agency believes it is prudent to assume that a short-term exposure may be sufficient.

Third, the registrant criticizes the chronic exposure calculation used by the Agency to assess risks to birds and mammals from granular applications, by asserting that the proper calculation should be for earthworms in the top 7.5 centimeters, rather than the top 1.0 cm of soil. The Agency notes that the 7.6-cm depth represents incorporated applications (lettuce, clover, alfalfa), and the 1.0-cm depth represents non-incorporated applications of granules to areas such as non-bearing fruit and nut trees and vineyards, Christmas tree farms and non-agricultural areas, and turf. Even so, the registrant acknowledges that the Risk Quotient for the 12 lb/acre application rate exceeds the Agency's Level of Concern ( $RQ = 1$ ) for chronic risk to mammals. The risk is even greater for birds because, as the registrant acknowledges, the NOAEC for one of the surrogate test species (bobwhite quail) has not been established.

Finally, the registrant argues that the granules will not last long enough for chronic exposure to occur. The Agency notes that the ingestion of granules represents only one route of chronic exposure (diet), and that there will also be exposure via bioconcentration in food, direct exposure to contaminated soil (for both burrowing and non-burrowing animals), licking of fur and preening of feathers, and contaminated drinking water (puddles in the field). Thus, the estimation of chronic exposure via consumption of granules alone is an underestimate, and therefore not very conservative.

#### (Risk to Aquatic Organisms)

The registrant argues that exposure of aquatic organisms is over-estimated because benfluralin was assumed to be stable in water bodies, due to the lack of an aerobic aquatic metabolism study. The registrant claims that a study conducted under German guidelines (Knoch and Heim, 2002) yields a total-system DT50 (50% disappearance time) of 1 day. This DT50 is then used in a Tier 1 model (GENEEC) to reduce 60-day environmental exposure concentration (EEC) estimates, which are then used to demonstrate that lowered chronic risk quotients (RQ) would be obtained.

The Agency will consider the new study if it can be submitted and reviewed in time. The Agency notes, however, that available data indicate that benfluralin and its reduced degradates that may be re-oxidized to parent benfluralin, are stable in anaerobic sediment, and partition strongly to sediment (average  $K_{oc} = 10,750$ ). These degradates may be desorbed from the sediments over time and re-oxidized to parent benfluralin. Also, benfluralin is stable to abiotic hydrolysis. Thus, the assumption of stability in aerobic aquatic systems was not unreasonable.

The new study will need to be reviewed for the formation and decline of degradates of concern, thus the total-system DT50 for parent benfluralin cannot be used directly. The effect of any degradation rate in aerobic aquatic systems will then have to be assessed using Tier 2 modeling (PRZM-EXAMS).

The registrant compares monitoring data (95<sup>th</sup> percentile concentration of 0.002 ppb benfluralin) to peak concentrations from PRZM-EXAMS. This is not a valid comparison, as in the absence of information on the time elapsed between chemical application and sampling, the monitoring data are more likely to represent chronic, not peak concentrations. The Agency's risk assessment noted that this was the case.

(Specific page and line comments)

(Chronic Risk to Mammals)

p. 8: The Agency will correct all references to the Mammalian NOEL from 5 mg/kg/day to 7.2 mg/kg/day.

p. 31, Table 16: The Agency will correct the mammalian NOEL to 7.2 mg/kg/day. The Agency notes, however, that even with this change, the chronic risk quotients exceed the Level of Concern.

p. 109: The Agency will correct all references to the Mammalian NOEL from 5 mg/kg/day to 7.2 mg/kg/day.

(Comments on Environmental Fate Assessment)

The Agency will note that soil photolysis and aqueous photolysis have only the one degradate (LY-274766) in common.

(Comments on Drinking Water Assessment)

The registrant argues that human drinking water exposure is over-estimated because benfluralin was assumed to be stable in water bodies, due to the lack of an aerobic aquatic metabolism study. The registrant claims that a study conducted under German guidelines (Knoch and Heim, 2002) yields a total-system DT50 (50% disappearance time) of 1 day.

The Agency will consider the new study if it can be submitted and reviewed in time. The Agency notes, however, that available data indicate that benfluralin and its reduced degradates that may be re-oxidized to parent benfluralin, are stable in anaerobic sediment, and partition strongly to sediment (average K<sub>oc</sub> = 10,750). These degradates may be desorbed from the sediments over time and re-oxidized to parent benfluralin. Also, benfluralin is stable to abiotic hydrolysis. Thus, the assumption of stability in aerobic aquatic systems was not unreasonable.

(Comments on Aquatic Exposure and Risk Assessment)

Table 9: The reference to a 56-day average exposure will be corrected to a 60-day average, which is what was actually used. The registrant's recalculation of the aquatic EECs will be verified upon submission and

review of the referenced study.

(Comments on Appendix II)

The Agency will consider the new study (Knoch and Hein, 2002) if it can be submitted and reviewed in time. The Agency notes, however, that available data indicate that benfluralin and its reduced degradates that may be re-oxidized to parent benfluralin, are stable in anaerobic sediment, and partition strongly to sediment (average  $K_{oc} = 10,750$ ). These degradates may be desorbed from the sediments over time and re-oxidized to parent benfluralin. Also, benfluralin is stable to abiotic hydrolysis. Thus, the assumption of stability in aerobic aquatic systems was not unreasonable.

**OPP-2003-0381-016**

See the Agency's response to the previous comment.