10-3-85

DATA EVALUATION RECORD

1. Chemical: Methamidophos

2. Test Material: Monitor 4®; 40% ai; viscous liquid

3. Study Type: Pen Study: Bobwhite Quail

4. Study ID: Mobay Chemical Corporation. (1985) Simulated Field Study of Monitor 4® Toxicity to Bobwhite Quail. Submitted by Mobay Chemical Corporation, Stilwell, KS. EPA Registration No. 239-2452. EPA Accession No. 258108, reference 4.

5. Reviewed by: Margaret Rostker
EEB/HED
Signature: Margaret Rostker
Date: 3 Oct. 1985

6. Approved by: Harry Craven
EEB/HED
Signature: H. T Craven
Date: 10/3/85

7. Conclusions:

The study does not fulfill guideline requirements, nor can the results be used in a hazard assessment.

8. Recommendations:

N/A

9. Background:

Required under Registration Standard.

10. Discussion of Individual Tests:

N/A

11. Materials and Methods:

a. Test Animals: Bobwhite Quail (Colinus virginianus) from Sand Prairie Quail Farm, Mequoketa, Iowa. Age at study initiation: 18 weeks; male weight: 171 to 220 g; female weight: 170 to 233 g.

Test System: Ten test pens, ten control pens; each housing 2 quail. Pen size: 4 x 5 x 3 feet high, open bottom, staked to ground. Total treated test area = 12- x 70-foot area.

b. Dose: Monitor 4® applied on days 0, 14, and 28 at rate of 1.0 lb ai/A, using a tractor-mounted boom.

c. Design: Twenty birds exposed to Monitor 4®; 20 birds as control.

d. Statistics: One-way analysis of variance; 2 x 2 contingency test; Fisher's exact test. SAS software.

12. Reported Results:

The study reported that treated birds gained less weight than did controls, but the difference was statistically significant only in males. Clinical signs not observed; no gross lesions seen at necropsy. Whole blood cholinesterase activity significantly decreased in all posttreatment samples in both sexes. Brain cholinesterase activity significantly decreased at end of study in both sexes relative to controls.

13. Study Authors' Conclusions/QA Measures:

Monitor 4®, applied in a manner similar to normal field use at 1.0 lb (454 g) ai/A, the maximum recommended rate, did not cause mortality, signs of intoxication, or gross lesions in adult bobwhite quail. Monitor 4® did cause a mild decrease in body weight gain and significant blood and brain cholinesterase depression. Recovery began within 2 days after application.

Quality Assurance Statement provided in report.

14. Reviewer's Discussion and Interpretation of Study:

a. Test Procedures: Protocol for a small pen study is given in the 1978 guidelines. The study here reviewed was required under the Methamidophos Registration Standard, published on September 30, 1982. In October 1982, new guidelines were issued which deleted use of small pen

studies to support registration of a pesticide presumed to cause hazard to birds. The decision to delete small pen testing from tier testing requirements was partially based on Agency findings that such small pen tests failed to yield sound, useful data relevant to hazard assessment. There is a general consensus that in most cases small pen studies cannot adequately simulate actual field applications of the pesticide nor nontarget organism exposure and/or response.

EEB evaluated the methamidophos study under the 1978 protocol guidelines because those were operative when the study was initially required. EEB also evaluated the study in general terms of its usefulness and validity in understanding avian risk from use of methamidophos. Under both sets of evaluation criteria this study was found insufficient, incomplete, and not capable of scientifically documenting avian safety from use of methamidophos.

The following details the more serious problems with the study as evaluated by the 1978 guidelines and specific instructions published in the Registration Standard:

1. The Agency specified the test was to be conducted with the end-use formulation Monitor 6 Spray. The study used Monitor 4 instead. Monitor 6 Spray contains 60 percent ai; Monitor 4, 40 percent ai; hence, the formulation with the highest concentration of methamidophos was not tested.

2. When the test was required, the major uses of methamidophos were on:

   cotton, potatoes, cabbage and other cole crops.

   Tolerances had been established for:

   broccoli, brussels sprouts, cabbage, cauliflower, cottonseed, cucumber, eggplant, lettuce, melons, peppers, potatoes, sugar beet roots and tops, and tomatoes.

   The Registration Standard, while not specifying a crop to be tested, noted a 1980 bird kill in cabbage and listed cotton, potatoes, and vegetable crops as crops of concern. Because no crop was specified the study was to be conducted on any currently registered crop. Beans were not registered at that time and thus are an invalid test crop.

3. From the guidelines regarding test procedures: "Pens and shelters are to be placed in position and birds introduced prior to application of the pesticide."

   The study reports that this was not done, and instead, "Birds and cages were temporarily removed from the treated area during spraying."

4. From the guidelines regarding test procedures: "... preceding the pesticide application, place waterers and food in one-half of the total test and control pens used. The remaining test and control pens are to be left without feed and water for 12 hours after the pesticide application, at which time feed and water is to be introduced to these pens ...."

   The study reports "One hundred grams of Purina Game Bird Layena was scattered on the ground daily in each pen. Water was available ad libitum."

   EEB also evaluated the present study for general utility in hazard assessment and concluded that the study did not simulate a field application to a crop frequented by birds. The pen was reportedly placed in a bean crop, but the kind of bean is not specified, nor is the height, age, etc. of the crop detailed. The ground surface is not described. EEB finds the lack of habitat description a serious omission but notes that submission of this information will not override the design flaws listed above.

   In summary, this study used the wrong end-product, the wrong crop, and failed to follow basic guideline protocols. The study is not a sound test and cannot be used by EEB to assess avian hazard from methamidophos. The study cannot be repaired by submission of test design because the basic test features are unacceptable.

b. Statistical Analysis: No part of the statistical analysis was checked because the test design rendered the study invalid.

c. Discussion/Results: There are no valid results.

d. Adequacy of Study:

   1. Classification: Invalid
   2. Rationale: Refer to 14.a.
   3. Repairability: not repairable

15. Completion of One-liner for Study:

N/A

16. CBI Appendix:

N/A