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NOTE TO: Mike Mendelson

SUBJECT: Old and new ecological effects data

As pointed out in the original Registration Standard on Bacillus thuringiensis (B.t.), the data in hand prior to 1986 is sketchy and are insufficient to perform a complete risk assessment on the ecological effects of B.t. I will summarize these studies.

Avian testing.

1. Avian Oral Pathogenicity Test (B. t. var. kurstaki) using the chicken. The results showed an LC50 of 80,000 mg/Kg. This test was considered to only partially fulfill the requirement because the chicken is not a recommended test species and the potency of the material tested was not supplied.

2. Avian Oral Pathogenicity Test (B. t. var. israelensis using the mallard duck. The results showed an LC50 of greater than 3179 mg/Kg for a test material containing 8000 I.U./mg. This test was considered to be core, fulfilling the guideline requirement.

3. Avian Injection Pathogenicity Test (B. t. var. israelensis. This test showed an LC50 of greater than 318 mg/Kg for a test material containing 8000 I.U./mg. This test was considered core and fulfilled the data requirement.

4. Avian Field Study (B. t. var. kurstaki. This study showed no effect on the cowbird, crossbill, towhee, sparrow, finch or junco. The study was not considered to fulfill the guideline requirement because the potency of the test material was not known.

Aquatic species

1. There were two studies each on the bluegill sunfish and rainbow trout performed using B. t. var. israelensis. In the first, the LC50 was found to be greater than .656 ppm for each species. This test did not fulfill the guideline requirement because the maximum dose tested was too low (less than 100 ppm). In the second test, the LC50 was found to be greater than 600 ppm for the bluegill and greater than 370 ppm for the rainbow trout. These tests were judged not to fulfill guideline requirements because the potency of the test material was not indicated.

2. There were two studies on freshwater aquatic invertebrates (B. t. var. israelensis - one on Daphnia magna and one on Dugesia tigrina. The former showed an LC50 of greater than .656 ppm and was considered not to fulfill the guideline requirement because the highest tested dosage was too low. The second test revealed an LC50 of greater than 318 ppm. This test did not fulfill the guidelines requirement because the potency of the test material was not indicated.

3. A study using a variety of marine and estuarine organisms was performed using B. t. var. kurstaki. The results showed an LC50 of greater than 400 ppm for the oyster, mussel, periwinkle, and Anguilla. Artemia had an LC50 of 85 ppm. All were treated with a formulated product containing 16,000 I.U./mg. This study was found not to fulfill the guideline requirement because of the lack of raw data and substantial deviations from recommended test procedures.

Nontarget plants

1. A study using B t. var. israelensis was submitted. The study showed no detectable effects on sixteen varieties of plants (grasses and vegetables). The study did not fulfill the guideline requirement because the potency of the test material was not submitted.

These studies cannot, at this time, be used to develop an ecological risk assessment. It is unclear as to whether the B.t. strains used in these studies are identical, or substantially similar to the strains in current use. Hence, identification data, including the history of the isolate, is necessary before any determination of the applicability of these data can be made.

Recently (since 1986), Tier I studies have been performed and show nontarget toxicity by random strains of B. thuringiensis. The toxic component(s) have not been identified. The species affected include mammals, birds, freshwater fish and aquatic invertebrates, plants tested with OF and end use products, and rare beneficial insects.

More specifically, mouse inhalation and injection studies, but not acute feeding studies, show significant mortality. Bird studies show an LD50 of 178 ppm and a no-effect level (NOEL) of 1 ppm by interperitoneal injection. The level of toxicity to other species has not yet been determined. This toxicity, shown by some B. t. strains, minimizes the ability to bridge data between nonidentical B. t. products. Therefore, it is essential that identification data, along with history of the isolate, be submitted so that an

ecological risk assessment may be made.

Risk to federally listed endangered species cannot be determined at this time. Although the ranges of endangered insects is fairly well known, the effect of various varieties of B. t. containing different toxins cannot be assessed until the data required under this registration standard are submitted.

Bob Pilsucki