UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
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OFFICE OF
PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Classification of Killed Microbial Pesticides

TO: Phillip O. Hutton)(PM-17)
Insecticide/Rodenticide Branch
Registration Division (H7505C)

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The OPP Biotechnology Team met September 8, 1989, to discuss the classification of killed microbial pesticides. Present were Fred Betz, Reto Engler, Tom McClintock, Bob Pilsucki, Bill Schneider, Roy Sjoblad, George Tompkins, and Zig Vaituzis. Using the Mycogen product, a killed Pseudomonas which had been engineered to produce Bacillus thuringiensis delta endotoxin, as an example, the group concluded that there were problems associated with describing it as a microbial pesticide, biochemical, or chemical.

If it were living, it clearly would be a microbial pesticide. In this case, however, the major, most unique, property of microbial pesticides, that of reproduction and multiplication in a favorable environment, is lacking. Once the non-viability of killed products is established, the infectivity portions of the microbial test protocols become unnecessary.

It could be classified as a chemical, but the scientific reviewers do not feel that the chemical testing data requirements are appropriate for this product since it is very similar to the products registered as B. thuringiensis. The active toxin is identical and the killed product will behave much like B. thuringiensis in the environment since B. thuringiensis does not

multiply to lethal levels under normal environmental conditions and, although germination and infection by vegetative cells of B. thuringiensis do contribute to the overall efficacy, they are not essential to its effectiveness.

The possibility of treating killed microbial pesticides as biochemicals was discussed. Although the killed product does not meet all the requirements to be called a biochemical pesticide, it is similar in that the mode of action of the delta endotoxin is reasonably specific and is non toxic to mammalian species. However, since it may require a high exposure use pattern as compared to biochemical pesticides, and is not highly host specific, it was agreed that it should not be classified as a biochemical.

Since this type of product does not fit well into any of the three product classification, the OPP Biotechnology Review Team thought it would be best to uniquely classify this product as a "killed microbial pesticide" and establish a procedure to handle similar products. Since the data requirements and review time for these products, which utilize the B. thuringiensis delta endotoxin, would be similar to living microbial pesticides, we recommend that Registration Division treat them as such for administrative purposes. Their use for small scale field testing should comply with any policies or regulations in force at the time, except that the only data needed for notification purposes would be to confirm that the product was nonviable.