PR NOTICE 72-6

October 6, 1972

CHANGES IN STANDARD FOR EXPRESSING POTENCY OF PRODUCTS CONTAINING BACILLUS TRURINGIENSIS BERLINER

THE NOTICE STATES:

PR Notice 71-6 informed the industry of the adoption of International Units (IU) as the basis for expressing potency (insecticidal efficacy) of B. thuringiensis Berliner for labeling and registration purposes.

This organism was first isolated in 1911. Work prior to 1950 indicated that it and related bacteria were pathogenic to a number of lepidopterous larvae. In January of 1961 products containing it were registered under the provisions of the Federal Insecticide, Fungicide, and Rodenticide Act. At that time dosages and representations of insecticidal efficacy were based upon the number of viable spores per gram of the product. The early work indicated that insecticidal efficacy depended upon adequate dispersal of enough spores to initiate an epidemic in the target species.

In 1953 Hannay suggested that the free diamond-shaped crystals, which he observed in a number of preparations of sporulating cultures, might be connected to the pathogenicity of the bacterium. Subsequently it was demonstrated that these crystals were the primary source of insecticidal toxicity. Presently known as S-endotoxin, this substance has been found to be a high molecular weight protein; no quantitative analytical procedures have yet been developed.

In 1966 participants at the International Colloquium on Insect Pathology and Microbial Control in Wageningen, The Netherlands, passed a resolution recommending that the E-61 formulation of B. thuringiensis from the Institut Pasteur, Paris, France, be adopted as an international standard. The E-61 formulation was assigned a potency of 1000 International Units (IU) per mg. They further recommended that the antilepidopterous (insecticidal) activity of all such products be standardized by bioassay, comparing the LD 50's of these materials with E-61 and expressing their potencies in IU per mg. This standard was adopted as the basis for expressing insecticidal efficacy of B. thuringiensis Berliner products for labeling and registration purposes.

A bioassay has since been developed by Howard T. Dulmage of the ARS-USDA, et al. This procedure designates the HD-1-S-1971 strain with an assigned potency of 18000 IU/mg. as the Primary U.S. Reference Standard for Commercial B. thuringiensis formulations in the United States. This bioassay procedure using the HD-1-S-1971 strain as the standard is hereby adopted as the

official assay procedure for B. thuringiensis formulations. A summary report concerning the adoption of this standard and bioassay procedure is to be published in the Journal of Invertebrate Pathology.

All applications submitted for registration after receipt of this notice will be required to express their potency in terms of International Units (IU) of potency per milligram of product as determined by this bioassay.

This PR Notice supersedes PR Notice 71-6 dated April 9, 1971.

The Order was signed:

Harold G. Alford
Director

Enclosure

Information on Required Ingredient Labeling
for Bacillus Thuringiensis Berliner Products

The potency of Bacillus thuringiensis Berliner products will be expressed in terms of International Units (IU). A product having a potency of 500,000 IU per milligram will be considered to consist of 100% active ingredients and the percent of active ingredients will be calculated on this basis.

The following sample Ingredient Statement will serve as a guide in the preparation of product labels.

Active Ingredients:

Bacillus thuringiensis Berliner Potency of _____ million International Units per mg. (at least _____ Billion viable spores per mg.)* - _____%

Inert Ingredients:
%

*Equivalent to potency of _____ Billion International Units per pound (quart) of this product.