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History

EPA Approves First Use in Environment of Genetically Altered Bacteria

[EPA press release - November 14, 1985]

The U.S. Environmental Protection Agency today approved experimental use permits for small scale field tests of two genetically altered strains of naturally occurring bacteria that could prevent frost damage to plants.

The experimental use permits were granted to Advanced Genetic Sciences (AGS) of Oakland, California.

The natural bacteria, *Pseudonomas syringae* and *Pseudonomas fluorescens*, promote the formation of ice on plants. They produce a protein which serves as a seed for the formation of ice crystals. This process is known as ice nucleation. AGS has deleted genetic material which instructs the ice nucleating active bacteria (INA+) to produce the protein. Because the genetically altered bacteria (INA-) are incapable of producing the protein, ice is less likely to form on plant surfaces colonized by the altered bacteria.

The California company will apply its INA- products to strawberry plants on a test plot in the central coast area of California in order to evaluate the potential of these products for controlling frost damage under actual field conditions. The INA- products will be applied at the onset of blossoming to allow the INA- bacteria to colonize the blossoms before the naturally occurring INA+ bacteria can establish themselves, with the intent of inhibiting frost formation until temperatures drop to below -5 degrees Celsius (23 degrees Fahrenheit). AGS plans to test these products in late December or January.

"I am confident that EPA can safely and efficiently regulate products of this new and burgeoning industry which promises to produce enormous benefits for society," said Dr. Jack Moore, EPA's Assistant Administrator for Pesticides and Toxic Substances. "In the case of the AGS experiment, I need to point out that the majority of naturally occurring bacteria on plants lack the ability to nucleate ice crystals. AGS has developed extensive data to demonstrate that their INA- bacteria do not possess any unique pathogenic or growth characteristics and that the minute numbers of bacteria that will disseminate from the test plot will pose no threat to environment."

AGS notified EPA of its intent to conduct field tests on INA- products in November 1984, shortly after the agency issued its Interim Policy on Small Scale Field Testing of Certain Microbial Pesticides. In February 1985, the agency responded to the AGS notification by indicating than an experimental use permit would be required in order to conduct the proposed field study. The agency also requested additional information at that time.

In July 1985, AGS applied for an experimental use permit to field test the two organisms. As provided for under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), EPA asked for public comments on the experimental use permit applications. Comments were

received from the U.S. Department of Agriculture, National Institutes of Health, Food and Drug Administration, members of the agency's Scientific Advisory Panel, an Intra-Agency Work Group on Biotechnology, and Edward Lee Rogers on behalf of the Foundation on Economic Trends (Jeremy Rifkin, et. al).

After internal review by agency scientists, external peer review, and consideration of public comments on the AGS proposal, the agency determined that AGS has submitted information sufficient to show that small scale use of INA- bacteria will not pose hazards. The key data show:

- that the INA- bacteria will not have a competitive advantage over INA+ bacteria on plants outside the test plot;
- that upward flux, drift and dissemination of the INA- bacteria from the test plot is expected to be very low;
- that the number of INA- bacteria drifting onto plants outside the test area will be much lower than the indigenous INA+ bacteria already present on plants and therefore will not displace the natural bacteria;
- that neither of the genetically altered strains are pathogenic to plants and that a variety of plant species did not even support growth of the INA- bacteria.

"Given the facts in this case," Moore said, "EPA is fully convinced that AGS' small scale field studies will not have any adverse effects outside the test plot."

The two strains of genetically altered bacteria comprising a total of 8×10^{12} cells in a volume of 10.0 liters of water will be applied in a 0.2 acre area, surrounded by a 15 meter wide bare soil buffer zone. A total of 2400 strawberry plants will be included in the test zone. Applicators wearing protective clothing will apply the bacteria using low pressure hand-held sprayers with nozzles adjusted to promote rapid settling of the spray. Numerous monitoring samples will be taken inside and outside the testing plot at the time of the application as well as for up to a year or more after the application. An authorized EPA observer will be present during the experimental application.

In addition to the AGS application, EPA has received an experimental use permit proposal from the Monsanto Chemical Co. of St. Louis to approve use of a genetically altered pesticide organism. The Monsanto proposal is under review.