THE 80's WERE ROUGH

BRIGHT FUTURE FOR GEMs?

NOTTINGHAM, U.K.— "Living genetically engineered microorganisms (GEMs) will find their place as a legitimate range of products servicing small but important markets." That conclusion from William Harris of Aberdeen University in the U.K. reflected the somewhat subdued mood of the Second International Conference on the Release of Genetically Engineered Microorganisms (REGEM 2) held here recently.

At the time of REGEM 1, three years ago, both the regulation of and commercial prospects for GEMs were a source of considerable optimism. Since then, progress with the commercial development of GEMs has been slower than anticipated. The contributory factors discussed at REGEM 2 included the continuing risk debate, regulatory uncertainty, poor international information exchange, and the absence of a "model" GEM product.

While Harris believed GEMs had potential as animal and human vaccines, he was pessimistic about some other uses. He cited predictions which indicated that, even by 1995, proprietary microbial cultures would represent only a $60 million fragment of the $1.4 billion total U.S. pollution control and bioremediation market. Similarly, GEMs' current share of the pesticides market is currently less than 0.2%, only $30 million out of a $21.6 billion market.

There are few GEM products in advanced development, moreover. To date, over 200 field tests of genetically manipulated organisms have been performed in the U.S. and just under 200 in member states of the European Organization for Economic Cooperation and Development (OECD, Paris). However, the vast majority of these tests have involved plants. The U.S. Environmental Protection Agency (EPA, Washington, DC) has approved Mycogen's (San Diego, CA) M-Trak and MVP biocontrol agents. These are recombinant organisms but significantly, perhaps, they are killed recombinant organisms. A live modified yeast for the baking industry has been approved but only in the U.K.

Despite the number of field tests, there is still a climate of uncertainty surrounding the regulation of genetically engineered organisms, particularly in Europe. The European Commission directives on contained use and deliberate release will not be implemented in European member states by the due date of October 23 for a variety of reasons. The most recent delay was caused when member states failed to agree on what documentation on proposed releases should be included in the summary notification information format, the document that alerts all the national regulatory bodies of new-release proposals.

Hans Kornberg, chairman of the U.K. Advisory Committee for Genetic Modification, was concerned about information exchanges. He suggested that the international exchange of information on the results of releases and monitoring had been inadequate. That was now changing with the OECD's information programs on releases. He welcomed, too, the development of the information resource for the release of organisms, an electronic network linking existing databases worldwide.

A number of participants at REGEM 2 felt that a "model" GEM product was needed to convince both regulators and the public of the benefits and acceptabilty of the products. One suggested model was a product known as "No-Gall."

The product is a genetically engineered strain of *Agrobacterium radiobacter* marketed in New South Wales, Australia, for biocontrol. Naturally occurring *A. radiobacter* has been used to protect stone-fruit and other crops from crown gall. It secretes a powerful plasmid-encoded agrocin which inhibits the growth of the causative organism, *Agrobacterium tumefaciens*. Over time, however, plasmid transfer to the pathogen makes natural *A. radiobacter* less effective. To combat this, Alan Kerr of the Waite Agricultural Research Institute in South Australia, deleted genes encoding the *A. radiobacter* plasmid-transfer mechanism.

Several properties of "No-Gall" qualify it as a model GEM. It is relatively uncontentious from a regulatory viewpoint, since it involves a deletion—rather than the more controversial insertion of new DNA—and a well-characterized organism. It also has significant commercial potential and obvious markets. And the product is likely to be acceptable to the public, since its economic benefits are demonstrable and may outweigh perceived risks to the environment. More such products will be needed to restore the optimism of the 1980s. **—Shirley Lanning**

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