

The National Biological Impact Assessment Program

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Accepted for publication 31 October 1990 (submitted for electronic processing).

The responsibilities of science are a contradiction. On the one hand, the scientist must explore the unknown to gain new knowledge. On the other hand, there is a public responsibility to make sure that what is done is safe and in the public's best interest. During past decades, the public has pretty much left science alone to follow opportunities and establish its own practices. There is, however, the public attitude toward science and technology is changing. The public is asking for more accountability and assurance. This has taken the form of federal, state, and local legislation regulating certain research activities and matters such as radiation safety, protection of research subjects, and assurances of the safety of biotechnology research ("biosafety"). Inasmuch as science is to serve the best interests of the public, compliance with these regulations becomes a necessary obligation for researchers.

Biosafety regulation at the federal level is proceeding case by case, or experiment by experiment, under the Federal Coordinated Framework for the Regulation of Biotechnology. The Coordinated Framework provides biosafety assurance (i.e., protection of the environment and public health) by using existing federal statutes and focusing on regulating the products and not the process of biotechnology research. Field trials are an important step in the sequence of agricultural research leading to eventual application. But field trials, by their very nature, require a planned introduction. This aspect of field trial research requires federal agencies to comply with the National Environmental Policy Act through the preparation of an Environmental Assessment (EA). Through earlier precedence and case law, EAs have now become detailed technical documents that require considerable effort in preparation by the responsible federal agency. Consequently, individuals making applications for a permit to conduct a field test are required to submit sufficient information to allow the federal agency to prepare an EA. This has come to be seen by many as an enormous burden. In some cases it may be a deterrent to those who would otherwise conduct a field test.

To address this type of constraint, the U.S. Department of Agriculture has created the National Biological Impact Assessment Program (NBIAP). Its mission is to facilitate safe field testing of genetically modified organisms. It is doing so through three interconnected activities: maintaining a data base, fostering biological monitoring, and supporting biosafety research.

The first NBIAP activity is the exchange of information through a network of data bases accessed through an electronic bulletin board (EBB). The EBB-database system is hosted by the Virginia Polytechnic Institute and State University, at Blacksburg. The EBB is updated every 30 days with information pertinent to biotechnology, biosafety, and field testing. There are currently 13 data bases, which provide information ranging from Institutional Biosafety Committee contacts to current patents in biotechnology, descriptions of research sites, bibliographic information, directories to other sources of information, and similar resources. The system is available toll-free at 800-NBIAPBD.

Other collaborators at the Pennsylvania State University and Louisiana State University are developing a knowledge base to assist scientists in making applications for a permit. The knowledge base is made up of a set of expert systems that allow principal investigators to explore the requirements of the Federal Coordinated Framework, a three-dimensional "hypertext" of pertinent biosafety information, and an intelligent form generator, which drafts an application for a field test permit appropriate to the requirements of the regulating federal authority.

Version 1.0 of the knowledge base addresses nine organism groups, chosen because they are on the leading edge of plant, animal, and microbe biotechnology. Other organism groups will soon be developed and added to the knowledge base as funds become available to support the expert panels that assist in the design of the various components.

A second aspect of the NBIAP is a project to foster biological monitoring. Biological monitoring is particularly critical to providing the assurance that safe confinement practices are in accordance with expectations and that genetically modified organisms, once placed outside of containment, have not escaped. The NBIAP proposes a national information reporting system to collect and publicly share the biosafety experiences of scientists who have completed field tests with genetically modified organisms.

The third aspect of the NBIAP is support for biosafety research in and of itself. Heretofore, much of our accumulated scientific knowledge in biosafety methodology was developed as part of the research process. There is, however, a strong need to begin to develop methods, procedures, and protocols appropriate to broad types of experimentation and to make that know-how available to the individual investigator. The intention of fostering biosafety research is to accelerate safe field testing by developing specifically designed biosafety procedures. Although broad interest in this approach has been expressed by the scientific community, limited funding for this type of research has been a constraint. However, given the strong interests of several non-governmental organizations interested in protecting the environment and the growing awareness of need by several federal agencies responsible for biotechnology research, the prospects now look good for support for research programs in biosafety.

Of course there can be no absolute assurances that any experiment will be completely safe. There is, however, an enormous body of knowledge that can be used to make sound judgments on expectations for existing methodology and to provide scientific assurance for the public. A proper balance is needed between the restraint to assure safety and the freedom to allow discovery. How this balance will be maintained for biotechnology research in agriculture is not yet clear.

What is clear is the need for the scientific community to accept the growing public expectation for biosafety assurances. But, to do this, the scientific community must be provided with assistance to facilitate that compliance. This is the purpose of the NBIAP of the U.S. Department of Agriculture.