Role of the Institutional Biosafety Committee in Recombinant DNA Research

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Of the recently developed biotechnologies, none holds greater promise for agriculture, industry, and medicine than recombinant DNA. DNA, short for deoxyribonucleic acid, contains the genetic information necessary for life. Even a "simple" form of living cell such as a bacterium has more than 2,000 genes in its DNA; plant and animal DNAs are much more complex. Recombinant DNA techniques allow small pieces of DNA from one source to be inserted into the DNA of another using enzymes derived from bacteria. Because the DNA is manipulated in a test tube, most biological barriers to genetic recombination are avoided. If the recombinant DNA is then transferred into a living cell, usually a bacterium, the newly introduced DNA may confer a useful property such as insulin production.

At the time they were first used in the early 1970s, recombinant DNA methods seemed to make possible limitless genetic recombinations--some of which could be harmful to health or the environment. Leading scientists in the field met and recommended that the National Institutes of Health (NIH) develop guidelines for working with potentially hazardous recombinant DNA molecules. The first NIH Guidelines for Research Involving Recombinant DNA Molecules appeared in 1976 after months of development by both scientists and public representatives. Originally intended to apply to all NIH-funded research, the Guidelines have since been adopted by all federal agencies, including the USDA.

In the years since they were first promulgated, the Guidelines have been revised as perceived fears have been shown to be unjustified. To the credit of the Guidelines and the scientific community, no person has ever been harmed by recombinant DNA. Because of their success, there is little doubt that the Guidelines will remain in effect for years to come, although appropriate changes will be made when warranted.

A key component of the regulatory process is the Institutional Biosafety Committee (IBC). Every institution conducting recombinant DNA research supported by federal funds is required to maintain an IBC. Over the years, supervision of recombinant DNA experiments has become increasingly decentralized so that, now, local IBCs have virtually all oversight responsibilities.

In 1983, the late President L.D. Loftsgard established a "local" IBC to serve North Dakota State University and the USDA Metabolism and Radiation Research Laboratory on campus; the IBC received NIH recognition in early 1986. The NDSU IBC has 10 members with a variety of highly useful professional backgrounds. Among its membership are experts in recombinant DNA methodology, human and veterinary medicine, plant pathology, and radiation safety. Two of the members, a local physician and a communicable diseases specialist for the North Dakota Health Department, are not affiliated with NDSU.

NDSU is typical of institutions across the country in that the vast majority of recombinant DNA experiments are exempt from the requirements of the Guidelines because the organisms and procedures pose no significant risk to health or the environment. In these cases, the IBC recommends that Biosafety Level 1 (BL1) conditions be observed by the researchers. BL1 conditions are laboratory practices that minimize risks to workers and confine viable organisms to well-defined areas. There have been two cases at NDSU where IBC approval was necessary to continue experimentation, but these involved activities having the least stringent regulation. In both cases, BL1 conditions were required by the IBC.

The IBC at NDSU will become more highly visible in the future as requests for field testing of organisms modified by recombinant DNA techniques are made. The trend has begun--the first deliberate releases of such organisms have occurred within the United States in the past year or so, following more than six years of scrutiny and litigation. Early indications are favorable for additional releases because no adverse consequences have been observed thus far. It will be important for the IBC to assure that field testing involving recombinant DNA be absolutely safe and environmentally sound so that the potential benefits of recombinant DNA research to agriculture can be realized.

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