ASSESSING THE RISKS ASSOCIATED WITH BIOTECHNOLOGY: THE REGULATORY PROBLEM

Janis C. Kurtz

Dynamic Corporation
11140 Rockville Pike
Rockville, MD 20852

ABSTRACT

In examining the regulatory problem posed by biotechnology, three areas must be considered: 1) the potential benefits to mankind, 2) the generation of profits to industry, and 3) the mitigation of risk presented to human health and the environment. Environmental risk assessments involving exposure and effects assessments must consider the potential for establishment in the environment, the potential for altering ecosystem processes and the potential for unexpected events as they relate to biotechnology applications. Predictive and analytical tools must be developed and used by regulators to ensure that the rewards of genetic engineering to both mankind and industry are realized with minimal consequence.

KEY WORDS: Biotechnology, Regulation, Genetic Engineering, Risk, Risk Assessment, Environmental Release, Microcosm, Differential Light Scattering.

ASSESSING THE RISKS ASSOCIATED WITH BIOTECHNOLOGY: THE REGULATORY PROBLEM

Biotechnology presents us with the possibility for solutions to many of mankind's problems and presents industry with unique opportunities for new markets, yet is perceived to present novel risks also - defining a regulatory problem. My objective is to further explore this problem, examining the sources of risk and the techniques that can help to predict and mitigate it.

The genetic engineering of microorganisms involves the introduction of new genetic sequences into existing microorganisms to enhance their capabilities to perform a function. One method of engineering is DNA recombination. Figure 1 presents a simplistic representation of DNA recombination. A selected characteristic present in the donor DNA molecule is removed using restriction enzymes and inserted or recombined into plasmid DNA. The recombinant DNA is then cloned into a bacterial host where the desired function can be expressed. The application of genetic engineering technology by recombinant DNA and other methods has come to be known as biotechnology (OTA, 1981).