RISK ASSESSMENT OF DELIBERATE RELEASE OF GENETICALLY-ENGINEERED

MICROORGANISMS

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ABSTRACT

Hazard identification and evaluation of dose response and exposure, the standard approach to risk assessment, take on a new meaning when one evaluates the risks associated with deliberate release of genetically-engineered microorganisms (GEMs). Hazard identification of GEMs may be quite complex since one must consider not only their potential toxic effects on humans and animals, but also disruptions that the introduction of novel GEMs may cause in the ecological equilibrium. Initially, these changes might not be as obvious as direct toxic effects. Unlike with chemicals, for which the risk assessment scheme was initially developed, exposure to GEMs does not necessarily decrease with time due to dilution and degradation. This paper will describe conceptual models of risk assessment applicable to deliberate release of GEMs.

KEY WORDS: Risk assessment, genetic engineering, microorganisms, deliberate release

INTRODUCTION

New genetically-engineered microorganisms (GEMs) promise a great benefit to humanity, yet their use may pose a risk to public health or cause ecological damage. Thus, the potential adverse effects need to be reviewed and evaluated.

Application of genetic engineering results in three categories of products:

(1) Macroscopic plants and animals with altered genes, presumably improved from the original species; for example, more pest- and drought resistant plants, "super" cows, and "super" sheep.

(2) Products made by GEMs, such as insulin, growth hormone, interferon, various polypeptides, and vitamins.

(3) A GEM is itself a product designed to perform a specific task, and may be deliberately released into the environment for the following purposes: