Report to the Legislature
November 1, 2000
Budget Item 3980-001-0001

Office of Environmental Health Hazard Assessment
Genetically Modified Organisms

Background

This report provides information about: 1) workload information for the office's toxicologists since 1990 in consulting and reviewing federal permit applications, and 2) the need for statutory direction and additional resources to undertake the evaluation and tracking of potential human and environmental hazards associated with the development, manufacture, use, or consumption of genetically modified organisms (GMOs).

Part 1: Workload information for the office's toxicologists since 1990 in consulting and reviewing federal permit applications related to genetically modified organisms (GMOs).

The California Department of Food and Agriculture and the Department of Pesticide Regulation are the state agencies responsible for regulating genetically modified organisms related to agricultural products and bioengineered pesticides, respectively. The Department of Health Services' Food and Drug Branch has mandates regarding food-labeling requirements. The Office of Environmental Health Hazard Assessment (OEHHA) has no specific oversight authority for reviewing federal permit applications related to GMOs. However, in the mid-1990s, OEHHA's staff toxicologists (0.1 person year equivalent) assisted the lead agencies and were involved in reviewing permit conditions for a limited number of GMOs (for example, Rhizobium) for controlled release in California and for the marketing and sale of the "Flavr Savr" tomato. In addition, one of our toxicologists (0.1 person year equivalent) has worked with the U.S. Environmental Protection Agency's (U.S. EPA) Office of Pesticides, Pollution Prevention and Toxic Substances since 1992 in helping to develop the California Environmental Protection Agency's capabilities in this area and in fostering state and federal interactions.

Part 2: Recommendations regarding the office's needs for statutory direction and/or additional resources to undertake the evaluation and tracking of potential human and environmental hazards associated with the development, manufacture, use, or consumption of GMOs.

At the federal level, U.S. EPA has developed in-house capability to provide hazard evaluations for genetically modified microorganisms and plants under the *Toxic*

Substances Control Act and the *Federal Insecticide, Fungicide, and Rodenticide Act.* Other federal agencies such as the U.S. Department of Agriculture and the Food and Drug Administration, have oversight roles in the development and use of bioengineered products.

For California, the Governor in September 2000 signed SB 2065 (Costa, Chapter 569, Statutes of 2000), which creates a state Food Biotechnology Task Force to oversee a two-year study of biotechnology issues. The bill initially appropriated $125,000 for the first year study. Additional appropriations by the Legislature will be needed to complete the study. The study will include a review of the scientific literature on biotechnology and an evaluation of the potential benefits and impacts to human health, the state's economy and the environment accruing from food biotechnology. While not named in the law, OEHHA, if asked, could assist the task force in reviewing the scientific literature and assessing potential impacts. This law took effect on January 1, 2001. The study must be submitted to the Governor and the Legislature by January 1, 2003.

OEHHA is not specifically mandated to evaluate or track the potential human health or environmental hazards associated with the development, manufacture, use, or consumption of genetically modified plants or food. OEHHA has no specific oversight authority to ensure thesafety of genetically modified foods, has not carried out any special investigations or environmental assessments of potential associated health or environmental hazards, and has not developed health exposure standards for genetically modified organisms.

It appears that some of public perception is that the industry is under-regulated, and that there is the potential for catastrophic environmental and public health hazards. However, there is no documentation of actual risks to humans or the environment from the products in question, nor has there been adequate evaluation of the risks.

OEHHA develops guidelines for risk assessment and evaluates health hazards associated with contaminants in food and other consumer products, air, drinking water, fish, and sediments. It conducts health risk assessment of hazards in the workplace, in residences, and in public places from pesticide and other chemical exposures. OEHHA provides public health oversight and technical support in the regulation of chemicals found in air, water, food, and hazardous waste to other departments and boards in California government. Therefore, OEHHA has the expertise to assist the Task Force in establishing a system to evaluate and track potential human and environmental hazards associated with the development, manufacture, use or consumption of GMOs should be considered by the Task Force.

Because of the ongoing advancements in the methodology for developing genetically modified plants and products, many new plant products will be introduced into commerce in the coming years, greatly affecting the state economy. Public pressure in Europe and in Mexico has already led to restrictions on the distribution and use of such

new products. A similar public pressure can be expected, which may affect the use of these products in California. Similarly, if the safety of GMOs is disputed, California's multi-billion dollar biogenomics industry may be adversely affected.

Like all new inventions, potential problems and unforeseen consequences might arise with the use of GMOs. Genes do not work in isolation, and the characteristics displayed by a GMO are greatly influenced by both its natural heritage, and by the environment. For example, specific genes and their protein products introduced into two different plants may cause different patterns of chemical changes in the plants. An enzyme may produce other products besides the intended chemical, depending on substrate availability. In addition, foreign protein may introduce some toxicity or allergenicity not normally associated with that food, such as the introduction of a Brazil nut allergic protein to soybeans in an attempt to improve their content of sulfur-containing amino adds. A gene, which confers some survival benefits, such as herbicide or pest resistance, may also be carried over by normal interbreeding (cross-pollination) into related weed species. Thus, genetic transfers must be examined in a larger context, including what else it does in the plant, its effects when consumed by other organisms, and its potential for environmental consequences. There are already several examples of each of these problems despite the relatively short time period GMO methods have been used. Therefore, OEHHA suggests that the Task Force, as part of its broad mandate under SB 2065 to evaluate potential impacts to human health and the environment accruing from food biotechnology, establish a database and guidelines for conducting risk assessments for GMOs. This would include:

- A mechanism for coordinated tracking, review, and research of the production and use of GMOs in California.
- A database for the eventual evaluation of the potential human health hazards and environmental impacts of GMOs and their products.
- Guidelines for conducting risk assessment of the GMOs and food products derived from GMOs.
- Resources or depository of information to assist the public in understanding the nature and scope of use of GMOs, to clarify any misconceptions of the public concerning GMOs, and to identify concerns that are founded on the best science and public policy

The SB 2065 task force study does not provide for these activities, but may consider such needs. OEHHA could assist the Task Force with this work.