Prepared by the North Dakota Legislative Council staff for the Agriculture Committee
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GENETICALLY MODIFIED ORGANISMS - BACKGROUND MEMORANDUM

Section 1 of 2001 House Bill No. 1338 (attached as an appendix) directed the Legislative Council to study issues related to genetic modification, including impacts on health, the environment, the food supply, and product labeling; actions by other jurisdictions regarding experimental medicine and research; and the promulgation of accurate information regarding genetic modification efforts that exist or are expected to exist in the near future. The Legislative Council approved the study but directed that it be limited to the genetic modification of agricultural products.

INTRODUCTION

Genetically modified organisms (GMOs) are the culmination of thousands of years worth of natural and human intervention in the food production process. Virtually since time immemorial, yeasts, molds, and bacteria have been used to make fermented foods and to preserve foods. One example of this is the turning of milk into cheese. Occurrences which were not capable of being sufficiently explained in the past have now given rise to a whole range of new disciplines. Plant, animal, and microbial biology, biochemistry, molecular biology, genetics, chemical engineering, and computer science have been linked in the new field of biotechnology. Independently and together, the disciplines promise new opportunities and challenges. These opportunities and challenges include the prevention of plant and animal diseases, the control of insects without the use of chemical pesticides, increased livestock productivity, enhanced food quality, reduced environmental degradation, and a host of other outcomes that have not even been conceived.

All technological developments have a societal context. Technological developments are introduced to meet certain needs or to afford certain opportunities. In turn, the developments cause a modification of life in that society. Professor David Atkinson, Vice Principal of Research and Education, Scottish Agricultural College, has stated:

> It is a matter of some debate as to how far these are truly shared as public needs given that most technology emerges from scientific discoveries. Since science is becoming more specialised [sic] and complex, and thus more remote from the majority of the population, society is now frequently surprised by discovery and finds it hard to judge their probable impact upon individuals or the broader implications of developments. At the level of the individual, some technological developments may have little noticeable result but others are more pervasive in their effect. Genetic engineering appears to be such a technology, both because of the scale and impact of its probable effects, and because using the ability to manipulate heritability, and the genetic code, comes close to altering core elements of life.

The ongoing debate regarding the merits of GMOs is lengthy, colorful, and filled with both optimism and cynicism. This memorandum will attempt to highlight the myriad of issues inherent in the genetic modification of organisms.

WHAT IS GENETIC ENGINEERING?

Plants and animals are made up of millions of cells, each of which has a nucleus. Inside each nucleus are strings of deoxyribonucleic acid (DNA). The DNA molecules, which are made up of units called genes, contain all the information needed by the cells in creating the organism. Put another way, the characteristics of any organism are determined by the information in its DNA.

In the breeding of plants and animals, variety is achieved by having the breeder select from the genetic traits that already exist within a species' gene pool. Creativity is, however, limited by nature. One type of rose can cross with a different kind of rose. However, a rose will never naturally cross with a mouse.

When the creativity is governed by the possibilities of science, limitations are less defined. Using genetic engineering, genes from one species can be inserted into another species. One example which generated a considerable amount of debate involved selecting a gene from an arctic fish such as the flounder and splicing it into a tomato or into a strawberry to make the fruit frost-resistant.

Transferring DNA is accomplished by several methods, including the direct injection of cells with DNA using a special gun or inserting the DNA into specially modified bacteria or viruses that carry it into the cells they infect. Regardless of the method used, the process of transferring DNA from one organism to another is that of genetic engineering. Any plant or animal that has been modified to contain DNA from an external source is called transgenic.

It can be argued that mankind has been modifying the genes of plants and animals for thousands of years and that consequently, genetic engineering is no more than an extension of traditional breeding practices. While it is true that the food crops eaten today bear

little resemblance to the wild plants from which they originated, it is also true that through this new technology organisms are being manipulated in a fundamentally different way.

Today, unlike even a few short years ago, products have been genetically engineered through the modification of their DNA. Each day the number of such products increases. Genetic engineering has resulted in drugs such as insulin for diabetics and tissue plasminogen activators for heart attack victims. Animal drugs like the growth hormones bovine or porcine somatotropin are being produced by bacteria that have received the appropriate human, cow, or pig gene.

Through genetic engineering, we have been able to identify and replace genes that are missing or not functioning properly. This has enabled us to treat immune system defects such as adenine deaminase (ADA) deficiencies in children. Blood cells with normal ADA genes were injected into the patients' bodies. This prompted the production of enough normal cells to improve the patients' immune systems. Gene therapy is already at the clinical trial stage with respect to the treatment of malignant brain tumors, cystic fibrosis, and HIV.

Genetic engineering has already produced transgenic plants that are tolerant of herbicides, that are resistant to insects and viruses, and that can produce modified fruits or flowers. Today, corn plants can resist European corn borers because the plants produce an insecticidal protein and tomatoes can be ripened longer on the vine before they have to be harvested and shipped. Transgenic animals are being developed and raised to help researchers diagnose and treat human diseases. Because companies have designed and are testing transgenic mammals, products such as insulin, growth hormone, and tissue plasminogen activators that are currently produced by the fermentation of transgenic bacteria will soon be available from the milk of transgenic cows, sheep, and goats.

NEED FOR GENETICALLY MODIFIED FOODS

Traditional agricultural technologies have allowed the survival of the current world population using a finite land base. However, with the expected increases in the world's population, it is believed that the use of traditional technologies will not meet the demands of the future world population for food. Through genetic engineering, the potential exists to not only increase food production but also to enable food production in regions that right now have only marginal food production capabilities.

ENVIRONMENTAL CONCERNS

Through genetic engineering, the ability exists to develop crops that have an increased resistance to weeds, pests, or diseases. The ability exists to increase crop yields dramatically. This combination of factors would appear to reduce the need for a variety of chemical applications. This same combination of factors may also carry with it potential risks. Will genetically engineered plants become weeds or will genes introduced into certain plants, through natural processes, be transferred to related species? Questions still exist regarding biodiversity--the balance of plant species in natural communities with the balance of wildlife.

REGULATION

Like all new technologies, genetic engineering raises questions regarding the morality of the activity, the balance of benefits and risks, and the appropriate level of public accountability. Presently, genetically engineered products are regulated by a number of federal agencies. Products that are food are governed by the Food and Drug Administration under the Food, Drug, and Cosmetic Act; products that are pesticides are regulated by the Environmental Protection Agency under the Federal Insecticide, Fungicide and Rodenticide Act; and plant pests are regulated by the United States Department of Agriculture under the Plant Pest Act and the Plant Quarantine Act. Internationally, the United States is working on several fronts to bring about the harmonization of regulatory approaches for these products. These efforts include bilateral environmental consultations with the Commission of the European Union and the establishment of a permanent technical working group on biotechnology and the environment. There are also informal meetings with representatives of the Commission of the European Union and key trading partners.

CONCERNS AND ISSUES

Despite assurances from the scientific community and the government regulators, concerns about the safety of genetically engineered foods continue to be articulated. Those concerns tend to fall into the categories of choice, health, ethics, politics, profit, and the environment. They involve:

- The lack of ability to practically segregate and label foods that have been genetically engineered and the resultant lack of consumer choice regarding the purchase and use of such foods;
- An unwillingness to replace familiar foods with those that have undergone genetic engineering, on the basis of governmental assurances that the products are substantially similar or that there is no evidence of harm;
- The relationship between humans and nature and a belief that genetic engineering of foods is neither natural nor necessary;

- The ramifications of free trade agreements, the power of commercial interests, and the ability of those interests to influence governments;
- The domination of genetically engineered foods and products by a handful of multinational corporations such as Monsanto, Novartis, Zeneca, Aventis, and DuPont; and
- Risks to the ecosystems, the potential threat to biodiversity, and questions regarding the long-term effects on sustainable agriculture.

While the above concerns are fairly broad in nature, there are also specific legal issues that await continued discussion and action by various governmental entities and the courts. These issues include patent and intellectual property claims, the enforcement of seed contracts, labeling, segregation, the enforcement of international agreements, biosafety protocols, genetic pollution and drift, and genetic expression control or seed sterilization.

> Clearly, while the issues will be debated and possibly resolved on an international level, the signals they send both socially and economically will be felt on farms and in grocery aisles, as well as in laboratories and boardrooms. The result may be that all of these issues will in some way impact the actions of American farmers and shape the food choices for the world's consumers . . . . Because the products or technologies are used in the production of foods destined for eventual human consumption, the public's attitude, understanding, and acceptance of biotechnology will be critical in influencing the ultimate economic reality. Neil D. Hamilton, *Legal Issues Shaping Society's Acceptance of Biotechnology and Genetically Modified Organisms*, 6 Drake J. Agr. L. 81, 110 (2001).

ATTACH:1