HOUSE COMMITTEE ON
ENERGY & ENVIRONMENTAL PROTECTION

February 1, 2007

House Bill 1048 Relating to Genetically Modified Crops

Chair Morita and members of the House Committee on Energy & Environmental Protection, I am Rick Tsujimura, representing the Biotechnology Industry Organization (BIO).

BIO is in opposition to House Bill 1048 Relating to Genetically Modified Crops. If passed, this bill would restrict a very promising area of research and potentially harm the state's reputation as a growing center of excellence for technology development, particularly in the field of agriculture.

The potential of plant-based technology is enormous. New advances in biotechnology have made it possible to turn plants into "factories" that produce therapeutic proteins for use in the manufacture of drugs, medicines, and therapies. Plant-made pharmaceuticals (PMPs) are the result of an innovative application of biotechnology to plants to enable them to produce therapeutic proteins that could ultimately be used by the medical community to combat life-threatening illnesses. Traditional methods of producing pharmaceuticals are time and capital intensive. It can take up to 15 years and more than $1 billion to research and develop a single new drug product. In many cases, plant-based techniques offer a more expedient and economical way to mass-produce these proteins. Deriving medicines from plants would allow researchers to increase supply and reduce production costs. In addition, plant-made production of pharmaceuticals holds distinct advantages over current production methods. Most proteins cannot be chemically synthesized, therefore previous production options are limited to mammalian or microbial cell cultures, which are time consuming and expensive to develop.

Stringent USDA and Food and Drug Administration (FDA) requirements already exist to regulate the production of plant-based proteins. USDA established its Biotechnology Regulatory Services (BRS) division in 2002 to place increased emphasis on the agency's regulatory responsibilities for biotechnology. Prior to that time, plant products of biotechnology were regulated under the general authority of USDA's Animal and Plant Health Inspection Services (APHIS). APHIS has a long

history of regulating agricultural biotechnology products, overseeing the safe conduct of more than 10,000 field tests of plants produced through biotechnology.

Since 2002, BRS has been consistently reviewing and strengthening the requirements for PMP field trial permits, as well as the rigor of the division's oversight of permit compliance. These modifications to the PMP permitting requirements are based on the experience that BRS personnel have developed over years of dealing with these types of field trials. It is anticipated that PMP permit requirements will continue to be strengthened over the next several planting seasons. Doing so at the federal level promotes needed uniformity and a level regulatory playing field across the entire United States.

These regulations are comprehensive, rigorous, and national in scope. BIO feels that researchers and consumers are best served by a strong, uniform regulatory system — not a patchwork of inconsistent guidelines that can vary widely from state to state, as well as put any individual state at an advantage or disadvantage.

Additionally, BRS announced in 2004 that it was undertaking substantial revisions to its regulations for all plants developed through biotechnology, including PMPs. These regulations will reflect new authority that USDA was granted under the Plant Protection Act of 2000 and, according to public statements made by BRS, will fundamentally alter certain aspects of the current permitting system, including that used for PMP permits. The promulgation of these new regulations is being accompanied by the preparation of a Programmatic Environmental Impact Statement (PEIS), which will examine the potential environmental impacts of this rule-making. The PEIS process includes the opportunity for public comment. Additionally, the rulemaking itself will be subject to public notice and comment. We understand that BRS currently anticipates publication of the draft PEIS prior to the 2007 growing season.

In the interests of regulatory economy, the state would be best served by directing its resources towards participating in the ongoing federal policy revisions and rulemaking processes, rather than moving ahead prematurely with a policy that would unnecessarily stifle new and valuable technology. Until the federal government issues new guidelines and permit requirements, adopting policies at the state level may well prove an unnecessary expenditure of time, effort, and financial resources.

BIO and its members are committed to protecting human health and the environment by ensuring the safety of PMPs during all stages of development and production. This can best be accomplished by committing to a close working relationship with state and federal regulatory authorities to assure that applicable requirements are both rigorous and enforceable.

Commodity crops are a natural choice for protein production due to extensive knowledge and familiarity with growing these plants. The evolution of production agriculture has enabled scientists to develop significant knowledge of plant genetics, agronomics, and environmental impact of many of the food crops we grow

today. With this in-depth knowledge, scientists understand what is required for the successful development, confinement, and extraction of proteins from a variety of plants.

Current federal regulatory guidelines dictate that pharmaceutical protein-producing plants be grown and processed separately from food and feed crops. After harvest, the plant material is processed to separate and purify the proteins, which are then delivered to manufacturers. In addition, the seeds to grown protein-producing plants are available only to those with an appropriate U.S. Department of Agriculture (USDA) growing permit, and cannot be purchased off-the-shelf at a local seed store.

House Bill 1048 will only serve to create confusion about a promising area of research and impede the state's effort to grow its life science industries. This legislation is reactionary and would only serve to harm the state's reputation as a center of excellence for technology development — a reputation that has attracted, grown, and retained so many outstanding research organizations. BIO applauds the commitment the state of Hawaii has shown to new technologies and research through initiatives such as the Hawaii Life Sciences Roadmap. Hawaii is a leading state in the United States for plant biotechnology research, and has led the country in the number of permitted agricultural biotech field tests. House Bill 1048 could significantly undermine the state's leadership position in this field.

We appreciate the Committee's consideration of our concerns and encourage committee members to oppose House Bill 1048.

*The **Biotechnology Industry Organization (BIO)** is a national trade organization, based in Washington, D.C., representing more than 1,100 biotechnology companies, academic institutions, state biotechnology centers, and related organizations across the United States and 31 other nations. BIO members are involved in the research and development of healthcare, agricultural, industrial and environmental biotechnology products.*