



BIOTECHNOLOGY
INDUSTRY
ORGANIZATION

**Statement of the Biotechnology Industry Organization on
HCR 270/HR180 “Urging the State to Establish Advisory Boards
Regarding Genetically Modified Organisms”**

*Submitted to the Hawaii House Committees
on Environment and Agriculture*

April 7, 2004

Please accept this statement on behalf of the Biotechnology Industry Organization (BIO) and its member companies regarding HCR270/HR180, which urges the state to establish advisory boards regarding “genetically modified organisms.” BIO is the national trade organization, based in Washington, DC, representing more than 1,000 biotechnology companies, academic institutions and biotechnology centers in all 50 states and 33 countries. BIO members are involved in the research and development of health care, agricultural and environmental biotechnology products. BIO has concerns that the proposed resolution could adversely impact the state’s reputation as a center of excellence for biotech research and development.

BIO supports science-based regulation and suggests that this oversight remain at the federal level rather than create an inconsistent patchwork of county-by-county (or state-by-state) guidance as this resolution suggests.

The use of biotechnology as a tool to improve crop and food production—from making cheese and bread, brewing beer, and protecting crops from pests and disease—is a well-established practice. For nearly 20 years, the federal government has exerted a rigorous, science-based approach to regulating biotech crops and food products. BIO supports this federal regulation, which is currently provided through a coordinated framework of three government agencies, including the U.S. Department of Agriculture (USDA), U.S. Environmental Protection Agency

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(EPA), and the Food and Drug Administration (FDA). Companies and research entities spend, on average, between two and ten years and \$4 million and \$8 million to meet the full spectrum of safety and environmental testing and evaluation necessary for government approval and commercialization.

However, there is always room for improvement to keep pace with the changing technology. In the Pew Initiative on Food and Biotechnology's (PIFB) recent report "Issues in the Regulation of Genetically Engineered Plants and Animals," authors acknowledge that genetically modified crops grown by farmers today have been appropriately regulated within the existing coordinated framework. However, improvements need to be made for the next generation of biotech products, such as transgenic animals and plant-made pharmaceuticals.

The U.S. model, which has become the international gold standard for regulation, is built on three principles: 1) that all regulations are science-based; 2) that regulations focus on properties of the transferred gene; and 3) that the corresponding regulations are based on the level of risk to public health, informed by our experience and familiarity with the regulated article. BIO and other stakeholders are working aggressively with federal agencies, specifically the USDA Animal & Plant Health Inspection Services (APHIS) and the FDA Center for Food Safety and Nutrition (CFSAN), as they modify regulations to oversee "next generation" agricultural technologies.

USDA and FDA are much better equipped to regulate these technologies than are state or county governments. Piecemeal regulation is costly and would require the allocation of significant state and local resources. The biotech industry is working to ensure that the federal regulatory agencies have adequate resources for a thorough, scientific analysis of biotechnology foods and drugs. We have a vested interest in their ability to understand and evaluate these products to certify that they are safe for human consumption and the environment.

County-level board guidance could conflict with federal and state statutes governing the regulation of ag biotech.

The Plant Protection Act expressly grants jurisdiction of the regulation of crops developed through biotechnology to the USDA [see 7 U.S.C. § 7756(b)]. Under this statute, state regulations must be consistent with the USDA's treatment of the product. And if the state can demonstrate need to USDA's satisfaction, its regulations may go beyond USDA's extensive requirements. With this resolution, one possible scenario is that county board decides to make biotech test plot locations public. Not only would the release of this type of information make research locations vulnerable to eco-terrorism, industrial espionage, or compromise food security, but it would also violate state privacy protection laws found in the Uniform Trade Secrets Act, codified at Chapter 482B of the *Hawaii Revised Statutes*. If county guidance conflicts with existing federal and state statutes, the efforts of the board proposed in this resolution may do little more than create confusion for the public and research community.

BIO supports policies that foster research and development that have made the United States the world's leader in biotechnology advancements.

More than 40 states have provisions to foster research and development and biotech clusters. Hawaii is proactively pursuing biotech researchers to the state and is invested in being a leader in biotech industry. Please consider the following:

- Hawaii's academic institutions, according to the "State Government Initiatives in Biotechnology 2001" report, spend approximately \$60 million on life sciences research and development (R&D) annually. This investment continues to grow each year and has increased about 60 percent over the last ten years. *(The report was compiled by Battelle Memorial Institute and the State Science and Technology Institute)*
- On Oahu, the University of Hawaii is building a new, state-of-the-art medical facility at Kaka'ako. The state legislature allotted \$150 million of tobacco settlement funds for revenue bonds to finance the

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first phase, which will be occupied in 2005. Once completed, this facility will include a 216,000-square-foot research facility and an additional 138,000-square-foot for an education and administration building. This undertaking is projected to generate \$80 million to \$100 million in annual revenues and create 1,000 new jobs in the state.

- Hawaii's Department of Business, Economic Development & Tourism identified the biotech industry as a strategic growth industry. In 1999, it released "Biotechnology in Hawaii: A Blueprint for Growth," which outlines several strategies for promoting an indigenous biotech industry in the state. This document identifies several strategies for the state to undertake, include the following initiatives: expanding venture capital for the biotechnology sector; implementing a tax structure that provides incentives for high technology product development companies; improving the transfer of university developed technologies; and developing a bio-age curriculum.

Many of these strategies have been made a reality. For example, in exchange for equity, the Hawaii Strategic Development Corporation (HSDC) leverages public funds with those from the federal government and private sources to provide investment capital in biotech and other industries. In addition, existing tax policy includes a high-technology business investment tax credit, a tax credit for increased research activities, net operating loss carryover, ability to exclude high-tech royalties from gross income, as well as a tax exemption on stock options from qualified high tech businesses.

The creation of county advisory boards seem to ignore the rigorous regulations in place and may send a signal that is contrary to the economic objectives of the state.

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Please feel free to contact me at 202-962-9513 or kmcgrath@bio.org if you have follow up questions or would like additional information on this issue. Thank you for your consideration of the biotech industry's concerns about HCR270/HR180.

Respectfully submitted by:

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