



BIOTECHNOLOGY
INDUSTRY
ORGANIZATION

April 5, 2004

The Honorable A.G. Kawamura
Secretary of Agriculture
California Department of Food and Agriculture
1220 N Street, P.O. Box 942871
Sacramento, California 94271-0001

Dear Mr. Secretary:

On behalf of the Biotechnology Industry Organization (BIO), BayBio, and BIOCOM, we are writing to express strong support for your authorization of a protocol approved by the California Rice Commission on March 29, 2004. This protocol, which was developed in a series of public meetings over the last 12 months, allows rice containing lactoferrin and lysozyme proteins to be grown in certain areas of California that are outside the state's major rice growing regions. It seems appropriate that California, with its historically strong support of the biotechnology industry, would be the site for this important work. As you know, California is the birthplace of the modern biotechnology industry. The state has more biotechnology companies than any other state, or for that matter, any other country in the world.

These rice varieties, being researched by Ventria Bioscience, represent a class of products called plant-made pharmaceuticals (PMPs) and result from a breakthrough application of biotechnology to enable plants to produce therapeutic proteins to combat life-threatening illnesses. In this process, plants themselves become "factories" that manufacture therapeutic proteins. These proteins are then extracted, refined and formulated into products to enhance human health. Using plants to produce these products could deliver on the promise of affordable medicines to combat disease in the US as well as diseases afflicting the developing world.

Biotechnology industry researchers continue to develop new products to address infectious disease, arthritis, cancer, obesity and many other human ailments. Many of these products will come from California biotech companies, like Amgen and Genentech. However, many patients will not have access to these new products without new systems of production that can economically meet demand without placing a significant economic burden on the health care system. Plant-made pharmaceuticals offer an exciting approach to scalable, economically attractive biopharmaceutical manufacturing, providing broad access to exciting new health products to address many of the most prevalent human diseases. This protocol is a very important step in the continued development of new biotech products for human health.

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Plant-made pharmaceuticals are regulated by the United States Department of Agriculture (USDA) through issuance of permits prior to planting. USDA permits issued in California must be approved by the California Department of Food and Agriculture (CDFA). Strict regulatory guidelines have been put in place to ensure that these products adhere to mandatory standard operating procedures for the safe planting, harvesting, storage and transportation of these materials. Included in the permitting process is an environmental assessment and multiple USDA inspections during the growing season. Ventry Bioscience, the company applying for the permit, has been conducting research in California under USDA and CDFA approved permits since 1997.

We urge you to approve this protocol. We appreciate your thoughtful consideration. If you have any questions please contact Kay McGrath, BIO's Director of State Government Relations, at 202.962.9513 or via e-mail at kmcgrath@bio.org.



Patrick M. Kelly
Vice President,
Biotechnology Industry
Organization

Sincerely,



Matt Gardner
President
BayBIO



Joseph Panetta
President
BIOCOM

cc: Governor Arnold Schwarzenegger

The Biotechnology Industry Organization (BIO) represents more than 1000 biotechnology companies, academic institutions, state biotechnology centers and related organizations in all 50 U.S. states and 33 other nations. BIO members are involved in the research and development of health care, agricultural, industrial and environmental biotechnology products. For more information on BIO, visit our website at www.bio.org

BayBio is Northern California's bioscience association. It support the regional bioscience community through networking, advocacy, group purchasing, and communicating the impact of our industry on the community. Members of the 14-year-old association include organizations engaged in or supportive of research, development, and commercialization of products derived from living organisms. For more information on BayBio, visit our website at www.baybio.org

BIOCOM is a premiere life science industry association, based in San Diego, representing more than 450 member companies. The association focuses on initiatives that positively influence the growth of the life science industry, including capital formation, public policy, workforce development, and scientific discovery and development. For more information on BIOCOM, visit our website at www.biocom.org