



BIOTECHNOLOGY
INDUSTRY
ORGANIZATION

February 25, 2005

The Honorable Mike Reilly
Sonoma County Board of Supervisors
575 Administration Drive, Suite 100A
Santa Rosa, CA 95403

Dear Supervisor Reilly:

On behalf of the Biotechnology Industry Organization (BIO), please accept this letter outlining several serious concerns relating to the proposed Sonoma County Ordinance to Prevent Agricultural and Environmental Contamination from Genetically Engineered (Transgenic) Organisms. If this measure were to be enacted in its current form, it could have serious implications on biomedical companies and academic research facilities in Sonoma County. It could also severely limit access to many biological medicines.

BIO is the national trade association representing the many facets of the life sciences industry. BIO represents 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.

Specifically, our concerns are directed towards the following areas:

Prohibition for Sale and Definition of Transgenic Organisms – The prohibition on the sale or distribution of, and the subsequent definition of “transgenic organisms” is so overly broad, that it could be interpreted to ban valuable therapies and pharmaceuticals currently available for human and animal use. A significant amount of medical research and manufacturing involves the use of organisms that would be deemed “transgenic” under the

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initiative's language. Accordingly, the ban on the sale of transgenic organisms will impede such research and manufacturing activities in Sonoma County.

There are in excess of 200 biopharmaceuticals for sale worldwide with more than 400 in late-stage research. While not all of them would fall under the initiative's definition of a "transgenic organism," several products, including genetically recombinant vaccines used for Hepatitis B and genetically engineered proteins used to assist in the production of red blood cells for dialysis patients would technically be banned in the county.

In the animal health arena, approximately 12 commercially available transgenic vaccines protecting horses from West Nile Virus, cats from feline leukemia, and dogs from distemper, parvovirus and parainfluenza would be also be outlawed in Sonoma County.

Research and Manufacturing of Transgenic Organisms – The requirement that research and manufacturing take place in a facility meeting Bio-Security Level 3 Ag (BSL-3) containment guidelines is scientifically unjustifiable and wholly inappropriate. Federal guidelines dictate that the vast majority of transgenic research and manufacturing occurs in BSL level 1 or 2 facilities. The exact level of containment is in correlation to the potential harm presented by the organism in question to either human health or the environment and is prescribed by federal agencies such as the National Institute of Health, Center for Disease Control, Food and Drug Administration, and United States Department of Agriculture.

Instead of an "exemption" as it is presented in the initiative, the BSL-3 Ag requirement will result in a de-facto ban on transgenic research and manufacturing. None of California's thousands of biotechnology companies would be welcome in the Sonoma County.

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Specific impacts of the BSL-3 Ag requirement include:

Medical Research and Manufacturing – Much of the current research and manufacturing underway in California involving medical products such as

insulin, blood clotting factor, cancer vaccines and treatments for stroke, heart attack and anemia patients includes the use of transgenic organisms. Some stem cell research itself utilizes transgenic organisms. None of this research is required to take place in BSL 3 facilities anywhere else in the United States.

Science Education – Biology and other life science education taking place in California's public high schools, community colleges, and universities often utilizes transgenic organisms. A majority of which occurs in BSL-1 facilities. The costs associated with a BSL-3 facility are well beyond the reach of most public education institutions and would eliminate such from occurring in Sonoma County.

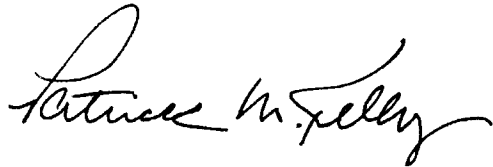
Economic Development – The biotechnology industry is becoming a leading economic engine in the United States. Almost every state in the nation is actively recruiting biotechnology companies and/or investing significant resources in building bioscience research facilities.

California leads the nation in the number of biotechnology companies headquartered in the state. In fact, there are more biotechnology companies in California than in any other country in the world. Because these are environmentally clean companies that create high-skill, high-wage jobs, there is significant competition among states and between counties and municipalities to attract bioscience facilities. The BSL-3 mandate in the proposed initiative, and the expense associated with it, will steer companies away from Sonoma County.

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This initiative proposes solutions to problems that do not exist in the county. It is unnecessary, extremely costly and sends a signal to technology-based life science companies that Sonoma County is not open for business. We strongly encourage you to oppose this initiative.

Sincerely,

A handwritten signature in black ink, reading "Patrick M. Kelly". The signature is written in a cursive style with a large initial "P" and a long, sweeping underline.

Patrick M. Kelly
Vice President
Biotechnology Industry Organization

cc: Members, Sonoma County Board of Supervisors