



August 25, 2004

Mr. Jim Kellogg, President
California Fish and Game Commission
1416 Ninth Street
Sacramento, CA 95814
Email: fgc@dfg.ca.gov

RE: Comments regarding August 26, 2004 Meeting of California Fish and Game Commission, Agenda Item 3

Dear Mr. Kellogg:

On behalf of BayBIO, BIOCUM, and the Biotechnology Industry Organization (BIO), we would like to express concern to the Commission regarding the implementation and potential impacts of the permitting system adopted last year for the importation and possession of transgenic aquatic animals.

In promulgating Section 671 of Title 14, California Code of Regulations, the Commission banned the importation or possession of all transgenic aquatic animals without a permit.¹ The Commission then established permit conditions that allow for research to be conducted, but are so restrictive that they appear to effectively prohibit the commercial or recreational use of these animals regardless of their safety.² For example, one requirement would prohibit non-permitted movement of live transgenic aquatic animals from facilities. Another condition would restrict access to facilities containing transgenic aquatic animals.

In addition to being overly restrictive on their face, we believe that the Commission's establishment of the ban and permit regulations is overly broad and may have exceeded the applicable statutory authority by covering all transgenic aquatic animals without meeting the required evidentiary standard. Specifically, Section 2118 of the California

¹ Cal. Code Regs. tit. 14, § 671(c)(11).

² Cal. Code Regs. tit. 14, § 671.1.

Fish and Game Code authorizes the Commission to ban certain taxonomic categories of animals without a permit under specified conditions.³ “Transgenic aquatic animals” are neither a recognized taxonomic category of animals nor a category of animals for which there is any credible scientific evidence to demonstrate a threat cognizable by the Commission.

The regulatory language adopted by the Commission appears to criminalize the process of transgenesis for these animals, and erroneously assumes that all transgenic aquatic animals, regardless of taxonomic category, habitation or feeding habits inherently “pose a threat to native wildlife, the agriculture interests of the state or to public health or safety.”⁴ Under California law, such a regulatory finding must be based on “substantial evidence.”⁵ It is unclear to what extent, if any, the Commission’s promulgation of this regulation was based on sufficient evidence to establish that all transgenic aquatic animals, regardless of phenotype, *or even existence*, pose the type or magnitude of risk that would be required by statute to justify this ban.

Our members fully support science-based regulation, including regulation for products of biotechnology such as transgenic aquatic animals. However, we are deeply concerned by a regulatory action that appears not to have been the result of a thoughtful review of the relevant law and science, and not to have been taken in accordance with statutory requirements.

In their present form, the Commission’s regulations effectively ban the commercial or recreational use and possession of transgenic aquatic animals within the State. Our members feel strongly that a science-based review process will establish that transgenic aquatic animals can be responsibly used for commercial or recreational purposes, and would welcome the opportunity to work with the Commission to suggest ways in which this could be done, while preserving the health, welfare and environment of the State. At a minimum, the harm caused by the Commission’s action in adopting the transgenic aquatic animal regulations in their current form must be undone. Because the Commission’s action rests on the false assumptions that transgenic aquatic animals are a taxonomic category and that this category of animals is inherently dangerous, the resultant regulations are seriously flawed, unworkable and legally vulnerable.

³ The Commission’s authority can only be exercised with respect to a “class, order, family, genus, or species” of wild animal. Cal. Fish and Game Code § 2118.

⁴ Cal. Code Regs. tit. 14, § 671(b).

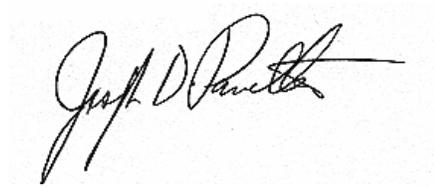
⁵ Cal. Gov’t Code § 11349(a).

We appreciate the opportunity to provide comment on this important issue and respectfully urge the Commission to attach the highest priority to addressing the concerns raised by our members. If you have any questions or need additional information, please do not hesitate to contact Barbara Glenn, Ph.D., BIO's Director of Animal Biotechnology, at 202.962.6697 [phone] or bglenn@bio.org [e-mail]. Thank you for your consideration.

Sincerely,



Matt Gardner, President
BayBIO



Joe Panetta, President
BIOCOM – San Diego



Mike Phillips, Vice President, Food and Agriculture,
Science and Regulatory Policy
Biotechnology Industry Organization

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