

## **TITLE 14. Fish and Game Commission Notice of Proposed Changes in Regulations**

**NOTICE IS HEREBY GIVEN** that the Fish and Game Commission (Commission), pursuant to the authority vested by Sections 200, 202, 205, 210, 220, 395, 396, 398, 713, 1002, 1050, 1053, 1745, 2116, 2116.5, 2117, 2118, 2120, 2122, 2125, 2150, 2150.2, 2150.4, 2151, 2157, 2190, 2193, 2271, 3005.5, 3007, 3503, 3503.5, 3511, 3513, 3950, 10500, 12000 and 12002, Fish and Game Code and to implement, interpret or make specific Sections 1050 and 2271, of said Code; and Title 50, Code of Federal Regulations, Parts 21.29 and 21.30, proposes to amend Sections 1.92 and 703, Title 14, California Code of Regulations, relating to Transgenic Definition; Application and Fee Regulations.

### **Informative Digest/Policy Statement Overview**

Current law provides for a definition of “transgenic” as:

“Genetically altered by introducing DNA (1) from another species or (2) through engineered endogenous constructs by means such as but not limited to recombinant DNA and RNA techniques to produce, gene addition, deletion, and doubling, or changing the position of the gene. This definition excludes DNA vaccines, individuals produced by the techniques of whole genome ploidy manipulation, and hybridization between closely related species, as in traditional hybridization.” – Section 1.92, Title 14, CCR

The Department’s review of the current definition of transgenic in Section 1.92 has revealed several vulnerabilities that could prevent the Commission and the Department from adequately protecting native fish, wildlife, and plants from the threat of predation by, competition with, or hybridization with potentially threatening transgenic animals. First, the definition is structured around a finite list of prohibited methods of genetic manipulation coupled with a finite list of exceptions to that prohibition.

A producer of transgenic animals could evade the protections set forth in Title 14, sections 671 and 671.1 (relating to restricted species permits), which incorporate the transgenic definition in Section 1.92, by withholding the first generation of animals subject to direct genetic manipulation and by importing, distributing, and selling only the progeny of that first generation.

Also, as currently written, the definition excludes “hybridization between closely related species” but does not expressly indicate that to qualify for the exemption such hybridization cannot involve transgenic animals. If this interpretation were to prevail it would undermine the entire regulatory program by allowing any producer of transgenic animals to evade regulatory protections merely by importing, distributing, and selling only those transgenic animals that had been hybridized with other lines of transgenic animals.

Current law also provides for regulatory protections of the state from detrimental animals as set forth in Title 14, Section 671:

*671(a): "It shall be unlawful to import, transport, or possess live animals restricted in subsection (c) below except under permit issued by the department."*

*671(b): "...Those species listed because they pose a threat to native wildlife, the agriculture interests of the state or to public health or safety are termed "detrimental animals" and are designated by the letter "D"..."*

*671(c)(11): "Transgenic Aquatic Animals.  
Includes freshwater and marine fishes, invertebrates, amphibians, and reptiles (D).*

*Note: Unpermitted transgenic aquatic animals are determined to be detrimental to native wildlife, therefore the exemption provided for in Fish and Game Code Section 2150(e) is not applicable."*

*Fish and Game Code, §2150(e) "Any university, college, governmental research agency, or other bona fide scientific institution, as defined in regulations adopted by the commission, engaging in scientific or public health research is exempt from any permit requirement pursuant to this chapter except for animals whose importation, transportation, or possession is determined by the department, in cooperation with the Department of Food and Agriculture, to be detrimental or cause damage to agriculture, native wildlife, or the public health or safety."*

The Department's proposed revision to the definition of transgenic addresses each of these vulnerabilities and, in doing so, seeks to enhance the ability of the Commission and the Department to protect native fish, wildlife, and plants.

It also includes an exemption process for a determination to be made by the Department to render a decision to label a particular transgenic aquatic animal (aquarium fish) as "not detrimental" and therefore not subject to Section 671 and subsection 671.1(a)(8), Title 14, CCR.

The Department is proposing the following regulatory changes:

- Delete the present definition of transgenic in Section 1.92.
- Add a new subsection (a) to Section 1.92 defining transgenic to include all animals "whose genome has been deliberately altered, modified, or engineered through means not possible under natural conditions, by insertion of a foreign gene or genes using genetic engineering methods." This definition is supplemented by four subsections further defining the scope of the definition, which include the following:
  - Subsection (a)(1) clarifies that an animal is transgenic if it contains any artificially transferred genetic material, even if that material is not directly

- “from another species.”
- Subsection (a)(2) includes a non-exclusive list of examples designed to address some of the most common methods for genetic manipulation.
  - Subsection (a)(3) includes an explicit statement that the “progeny of a transgenic animal or any animal that is the result of breeding involving transgenic animals is transgenic within the meaning of this section.”
  - Subsection (a)(4) reiterates and refines provisions in the existing definition that indicate that animals subject to standard breeding and hybridization practices commonly used by fish hatcheries (when no transgenic animals are involved), whole genome ploidy manipulation, and therapeutic treatment with DNA vaccine are not transgenic.
- Add a new subsection (b) to Section 1.92 which includes a narrowly circumscribed exemption to cover certain transgenic aquarium animals subject to the following restrictions:
    - The transgenic animals will be maintained in closed systems and not placed in the waters of the state; and
    - the Department has determined the transgenic animals are “not detrimental” and pose no risk to native fish, wildlife, or plants; and
    - to qualify for this exemption, the person or entity seeking to import, possess, distribute and sell transgenic aquatic animals within California must submit a letter of application, based on credible science; and
    - to qualify for this exemption, the person or entity seeking to import, possess, distribute, and sell individual transgenic aquatic animals within California must pay a nonrefundable application fee.
  - Amend Section 703 by adding a new subsection 703(a)(3) which describes the application process, requirements, and nonrefundable fee of \$4,790 to cover the Department’s costs incurred in processing the application, and the Department’s findings.

## **Benefits of the Proposed Regulations**

The proposed revisions to the definition of transgenic will improve the protection of the environment and the state’s fish, wildlife, and plant resources by providing a modern definition that accounts for future changes in genetic methods and eliminates potential loop holes associated with the progeny of transgenic animals or animals resulting from hybridization with transgenic animals. The new application and approval process for certain transgenic aquatic animals will allow the Department to thoroughly review relevant scientific data to determine there is no reasonably foreseeable risk to native fish, wildlife, or plants. If supported by credible scientific evidence, the Department may make a determination that the animal is not detrimental and therefore not subject to Section 671 and subsection 671.1(a)(8).

## **Evaluation of Incompatibility with Existing Regulations**

The proposed regulations are neither inconsistent nor incompatible with existing State regulations. The Legislature has delegated authority to the Commission to adopt regulations for ornamental marine or freshwater plants and animals that are not utilized for human consumption or bait purposes and are maintained in closed systems for personal, pet industry, or hobby purposes (Fish and Game Code, Section 2271). The proposed regulations are consistent with current restricted species regulations in Section 671, Title 14, CCR. Commission staff has searched the California Code of Regulations and has found no other State regulations related to the use of transgenic species.

**NOTICE IS GIVEN** that any person interested may present statements, orally or in writing, relevant to this action at a hearing to be held at Embassy Suites – LAX North, 9801 Airport Boulevard, Los Angeles, California, on Thursday, October 8, 2015, at 8:00 a.m., or as soon thereafter as the matter may be heard. It is requested, but not required, that written comments be submitted on or before October 6, 2015, at the address given below, or by e-mail to [FGC@fgc.ca.gov](mailto:FGC@fgc.ca.gov). Written comments mailed or e-mailed to the Commission office, must be received before 5 p.m. on October 5, 2015. All comments must be received no later than October 8, 2015, at the hearing in Los Angeles, California. If you would like copies of any modifications to this proposal, please include your name and mailing address.

The regulations as proposed in strikeout-underline format, as well as an initial statement of reasons, including environmental considerations and all information upon which the proposal is based (rulemaking file), are on file and available for public review from the agency representative, Sonke Mastrup, Executive Director, Fish and Game Commission, 1416 Ninth Street, Box 944209, Sacramento, California 94244-2090, phone (916) 653-4899. Please direct requests for the above mentioned documents and inquiries concerning the regulatory process to Sonke Mastrup or Jon Snellstrom at the preceding address or phone number. **Roger Bloom, Department of Fish and Wildlife, phone 916-445-3777, has been designated to respond to questions on the substance of the proposed regulations.** Copies of the Initial Statement of Reasons, including the regulatory language, may be obtained from the address above. Notice of the proposed action shall be posted on the Fish and Game Commission website at <http://www.fgc.ca.gov>.

#### Availability of Modified Text

If the regulations adopted by the Commission differ from but are sufficiently related to the action proposed, they will be available to the public for at least 15 days prior to the date of adoption. Circumstances beyond the control of the Commission (e.g., timing of Federal regulation adoption, timing of resource data collection, timelines do not allow, etc.) or changes made to be responsive to public recommendation and comments during the regulatory process may preclude full compliance with the 15-day comment period and the Commission will exercise its powers under Section 202 of the Fish and Game Code. Regulations adopted pursuant to this section are not subject to the time

periods for adoption, amendment or repeal of regulations prescribed in Sections 11343.4, 11346.4 and 11346.8 of the Government Code. Any person interested may obtain a copy of said regulations prior to the date of adoption by contacting the agency representative named herein.

If the regulatory proposal is adopted, the final statement of reasons may be obtained from the address above when it has been received from the agency program staff.

### **Impact of Regulatory Action/Results of the Economic Impact Analysis**

The potential for significant statewide adverse economic impacts that might result from the proposed regulatory action has been assessed, and the following initial determinations relative to the required statutory categories have been made:

- (a) Significant Statewide Adverse Economic Impact Directly Affecting Businesses, Including the Ability of California Businesses to Compete with Businesses in Other States:  
The proposed action will not have a significant statewide adverse economic impact directly affecting business, including the ability of California businesses to compete with businesses in other states. The proposed regulation is likely to have a positive effect on hobby and pet aquarium businesses within the State.
- (b) Impact on the Creation or Elimination of Jobs Within the State, the Creation of New Businesses or the Elimination of Existing Businesses, or the Expansion of Businesses in California: The regulation is unlikely to affect jobs or businesses. Benefits of the Regulation to the Health and Welfare of California Residents, Worker Safety: The amendment is unlikely to affect resident's health and welfare or worker safety. Benefits of the Regulation to the State's Environment: The proposed amendment allows for a scientific determination to be made by the Department that qualifying transgenic aquatic animals pose no reasonably foreseeable risk to native fish, wildlife, or plants.
- (c) Cost Impacts on a Representative Private Person or Business:  
The agency is not aware of any cost impacts that a representative private person or business would necessarily incur in reasonable compliance with the proposed action.
- (d) Costs or Savings to State Agencies or Costs/Savings in Federal Funding to the State: None.
- (e) Nondiscretionary Costs/Savings to Local Agencies: None.
- (f) Programs Mandated on Local Agencies or School Districts: None.
- (g) Costs Imposed on Any Local Agency or School District that is Required to be

Reimbursed Under Part 7 (commencing with Section 17500) of Division 4,  
Government Code: None.

(h) Effect on Housing Costs: None.

**Effect on Small Business**

It has been determined that the adoption of these regulations may affect small business. The Commission has drafted the regulations in Plain English pursuant to Government Code Sections 11342.580 and 11346.2(a)(1).

**Consideration of Alternatives**

The Commission must determine that no reasonable alternative considered by the Commission, or that has otherwise been identified and brought to the attention of the Commission, would be more effective in carrying out the purpose for which the action is proposed, would be as effective and less burdensome to affected private persons than the proposed action, or would be more cost effective to affected private persons and equally effective in implementing the statutory policy or other provision of law.

FISH AND GAME COMMISSION

Dated:

Sonke Mastrup  
Executive Director