



nonrefundable fee apply to each 'species' inclusive of its progeny (lineage) for which a non-detrimental determination is being sought.

- Subsection 703(a)(3)(B)2.c.: The addition of the words “to native fish, wildlife, or plants” clarifies what shall not be harmed.
- Subsections 703(a)(3)(C): The addition of the words “its authorized agent” clarifies that an agent of the applicant may also import, possess, distribute, and sell the transgenic aquatic animal within the state.
- Subsections 703(a)(3)(C)1.: The deletion of the words “it possesses on the premises or within the vehicle, if in transit” and the addition of the words “both the applicant and its authorized agent possess and provide within three business days, upon request by the department” removes the requirement that the applicant and its authorized agent must have the documentation in their immediate possession and allows for the documentation to be provided within a reasonable amount of time.
- Subsection 703(a)(3)(C)2.: The addition of the word “import” clarifies that a wholesaler or retailer may legally import the approved transgenic aquatic animal in addition to possess, distribute, and sell the animal. The deletion of the words “it possesses on the premises or within the vehicle, if in transit” and the addition of the words “the wholesaler or retailer possesses and provides within three business days, upon request by the department” removes the requirement that the wholesaler or retailer must have the department’s determination and written documentation in their immediate possession and allows for the documentation to be provided within a reasonable amount of time. This provision (and the following subparagraph 3.) is also changed to clarify that the subject animal has actually been “originated” from the applicant.
- Subsection 703(a)(3)(C)3.: For editorial purpose the lengthy reference to the subsection numbering is deleted and changed to simply “this section” as all requirements must be met by the applicant and its agents, etc., as set forth in the regulation.

The Fish and Game Commission adopted the proposed regulations which were noticed on August 21, 2015 and re-noticed on September 22, 2015, without any additional changes at its October 8, 2015 meeting.

VI. Summary of Primary Considerations Raised in Support of or Opposition to the Proposed Actions and Reasons for Rejecting Those Considerations:

No comments, written or oral, were received during the public comment period of the Notice of August 21, 2015, or the 15-Day Notice of September 22, 2015, to the adoption hearing of October 8, 2015.

VII. Location and Index of Rulemaking File:

A rulemaking file with attached file index is maintained at:  
California Fish and Game Commission  
1416 Ninth Street  
Sacramento, California 95814

VIII. Location of Department Files:

Department of Fish and Wildlife  
1416 Ninth Street  
Sacramento, California 95814

IX. Description of Reasonable Alternatives to Regulatory Action:

(a) Alternatives to Regulatory Action:

No alternatives were identified.

(b) No Change Alternative:

The no change alternative would leave existing regulations in place.

(c) Consideration of Alternatives:

In view of information currently possessed, no reasonable alternative considered would be more effective in carrying out the purpose for which the regulation is proposed, would be as effective and less burdensome to affected private persons than the adopted regulation, or would be more cost effective to affected private persons and equally effective in implementing the statutory policy or other provision of law.

X. Impact of Regulatory Action:

The potential for significant statewide adverse economic impacts that might result from the proposed regulatory action has been assessed, and the following 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 improves the definition of transgenic animals, to a current standard. Transgenic animals are currently unlawful to import or

possess in California. The changes to the definition will not affect any other animal currently permitted; there is therefore no adverse impact to existing businesses. Adverse impacts due to this rulemaking are unlikely in an industry with significant growth rates, as described by the website [www.americanpetproducts.org](http://www.americanpetproducts.org), that are projected be 4.39% from 2014-15, and IBISWorld reports the live-fish and some small animal segment at about 5.6 percent of total industry revenue.

As set forth in Part VII below, there is a growing interest by the pet fish industry to provide certain transgenic aquarium fish to hobbyists. Such animals are presently permitted for sale throughout the United States, but not in California because of the prohibitions set forth in Section 671. The proposed action provides an opportunity for any business in California, or out of state, to demonstrate through the specified application process that certain transgenic aquarium fish will not have a detrimental effect on California wildlife. If an application were disapproved, with a finding of potential impact on wildlife, the business would not be impacted because the animal is already prohibited under the current definition and as proposed in this rulemaking.

- (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; Benefits of the Regulation to the Health and Welfare of California Residents, Worker Safety, and the State's Environment: None.
- (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.

## Updated Informative Digest/Policy Statement Overview

The Department's review of the current definition of "*transgenic*" in Section 1.92, Title 14, California Code of Regulations (CCR) 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 species. 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.

## **UPDATE**

**On September 21, 2015, the Department of Fish and Wildlife submitted a Pre-adoption Statement of Reasons to the Commission recommending changes to the original regulatory language. In accordance with Government Code §11346.8, the following changes to the regulatory language are sufficiently related to the original text that the public was adequately placed on notice that the changes could have resulted from the originally proposed regulatory action. The full text of the resulting amendments to Section 1.92 and Section 703 with the changes clearly indicated was made available to interested and affected parties, as well as the general public for at least 15 days before the adoption hearing.**

**Subsection 1.92(b)(1): The addition of the words “research purposes” clarifies that this is not a purpose for which an application can be made and is subject to regulation under Section 671.**

**Subsection 1.92(b)(2): The addition of the words “applicant, which may be a” clarifies that a person or entity may be an applicant.**

**Subsection 703(a)(3)(A)4.: The addition of the words “separate” and “per species of transgenic aquatic animal” clarifies that the application and nonrefundable fee apply to each ‘species’ inclusive of its progeny (lineage) for which a non-detrimental determination is being sought.**

**Subsection 703(a)(3)(B)2.c.: The addition of the words “to native fish, wildlife, or plants” clarifies what shall not be harmed.**

**Subsections 703(a)(3)(C): The addition of the words “its authorized agent” clarifies that an agent of the applicant may also import, possess, distribute, and sell the transgenic aquatic animal within the state.**

**Subsections 703(a)(3)(C)1.: The deletion of the words “it possesses on the premises or within the vehicle, if in transit” and the addition of the words “both the applicant and its authorized agent possess and provide within three business days, upon request by the department” removes the requirement that the applicant and its authorized agent must have the documentation in their immediate possession and allows for the documentation to be provided within a reasonable amount of time.**

**Subsection 703(a)(3)(C)2.: The addition of the word “import” clarifies that a wholesaler or retailer may legally import the approved transgenic aquatic animal in addition to possess, distribute, and sell the animal. The deletion of the words “it possesses on the premises or within the vehicle, if in transit” and the addition**

**of the words “the wholesaler or retailer possesses and provides within three business days, upon request by the department” removes the requirement that the wholesaler or retailer must have the department’s determination and written documentation in their immediate possession and allows for the documentation to be provided within a reasonable amount of time. This provision (and the following subparagraph 3.) is also changed to clarify that the subject animal has actually been “originated” from the applicant.**

**Subsection 703(a)(3)(C)3.: For editorial purpose the lengthy reference to the subsection numbering is deleted and changed to simply “this section” as all requirements must be met by the applicant and its agents, etc., as set forth in the regulation.**

**There have been no changes in applicable laws or to the effect of the proposed regulations from the laws and effects described in the Notice of Proposed Action.**

**The Fish and Game Commission adopted the proposed regulations which were noticed on August 21, 2015 and re-noticed on September 22, 2015, without any additional changes at its October 8, 2015 meeting.**