



exceptions to that prohibition. However, because the list of prohibitions is exclusive in nature, any process of genetic manipulation not expressly prohibited is necessarily allowed under this definition. In a dynamic field in which innovation and the development of new techniques is commonplace, this static definition is ill-equipped to address changed circumstances and new approaches to genetic modification. Second, the current definition arguably limits the scope of transgenic to those individual animals whose DNA was directly altered and thus could be interpreted to exclude the progeny of those modified animals from the definition. If this interpretation were to prevail, 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, merely 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. This would render the entire regulatory program for transgenic animals ineffective. Finally, 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. As with the issue of progeny, if this interpretation were to prevail it would undermine the entire regulatory program by allowing any producer of transgenic animals to evade regulatory control merely by importing, distributing, and selling only those transgenic animals that had been hybridized with other lines of transgenic animals. For these reasons, the Department has concluded that the current definition of transgenic in Section 1.92 does not provide native fish, wildlife, and plants with sufficient protection from the threats posed by transgenic or genetically modified animals.

The regulatory protections of the state from detrimental animals are 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 so doing, seeks to enhance the ability of the Commission and the Department to protect native fish, wildlife, and plants. In developing this revised definition, the Department surveyed the statutes and regulations relating to transgenic and genetically modified animals from all forty-nine other states as well as the federal government. The proposed revision of Section 1.92 begins by 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 general definition is supplemented by four subsections further defining the scope of the definition.

- First, 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” as required by the current definition.
- Second, subsection (a)(2) sets forth a non-exclusive list of examples designed to address some of the most common methods for genetic manipulation. By combining a broad, open-ended definition of transgenic with a non-exclusive list of examples, the revised definition would automatically cover any new or novel technique for genetic manipulation unless the Commission later amends the definition to expressly exclude it.
- Third, 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.”
- Finally, 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 a DNA vaccine are not transgenic.

In Section 1.92 and Section 703, the Department proposes to add a narrowly circumscribed exemption and application procedure to cover certain transgenic aquatic animals (aquarium fish) that will be maintained in closed systems and not placed in the waters of the state and which the Department has determined pose no risk to native fish, wildlife, and plants.

To qualify for this exemption, the person or entity seeking to import, possess, distribute and sell transgenic aquatic animals within California must submit both an application, based on credible science, that complies with the application requirements of subsection 703(a)(3) and an application fee to cover the Department's costs incurred in processing the application. As an integral component of the application, the applicant must provide:

- (1) a detailed description of the methods by which the genome of the species has been altered;
- (2) a detailed analysis of the known or anticipated effects of the modification and of the potential risk to native fish, wildlife, and plants; and
- (3) a detailed description of the applicant's proposed importation, possession, distribution, and sale of the transgenic aquatic animals within the state.

For the exemption to apply, the Department must make a written determination—based on the information provided and any other credible scientific information—that the transgenic aquatic animals in fact pose no reasonably foreseeable risk to native fish, wildlife, or plants. The Department has concluded that the narrow eligibility requirements coupled with meaningful scientific review of the potential for harm to native fish, wildlife, or plants make this proposed exemption a reasonable compromise between the paramount need to protect native species and the reasonable desire of the public to have access to popular and harmless aquarium fish.

Once an applicant receives a written determination from the Department that the transgenic aquatic animal poses no reasonably foreseeable risk to native fish, wildlife, or plants, the applicant may import, possess, distribute, and sell the animal within the State. Wholesalers and retailers may operate under the determination issued to the applicant, provided that they possess a copy of that determination and written documentation to demonstrate they purchased the animal from the applicant. A consumer who purchases a transgenic aquatic animal may possess it without also possessing a copy of the Department's determination provided the animal is kept in a closed system and not placed in the waters of the state.

## **Proposal**

The Department is proposing to amend the current definition of "*transgenic*" in Section 1.92 as follows:

(a) An animal 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.

(1) An animal is transgenic if its chromosomes contain artificially transferred genetic material from any other organism or a laboratory construct, regardless of whether the original source's genetic material was modified prior to insertion, or whether the originally transferred genetic material was inherited through normal reproduction.

(2) Methods of producing transgenic animals may include, but are not limited to, recombinant DNA and RNA techniques, cell fusion, micro- and macro-encapsulation, introduction of a foreign gene, or gene knock-in.

(3) Any 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.

(4) Notwithstanding subsection (a) above, an animal is not transgenic within the meaning of this section if:

(A) It is an aquatic animal produced through breeding, conjugation, fermentation, hybridization, in vitro fertilization, or tissue culture and no transgenic organisms are involved;

(B) It is an aquatic animal produced through whole genome ploidy manipulation; or

(C) The foreign gene or genes in the animal is the result of therapeutic treatment with a DNA vaccine.

(b) Notwithstanding subsection 671(c)(11), a transgenic aquatic animal is not detrimental, and therefore not subject to regulation under Section 671 and subsection 671.1(a)(8), if all of the following apply:

(1) It is a live tropical marine or freshwater animal that will not be utilized for human consumption or bait purposes and will be maintained in a closed system and not placed in waters of the state;

(2) The person or entity seeking to import, possess, distribute, and sell the transgenic aquatic animal in California has submitted to the department the application and fee specified in Section 703; and

(3) The department has determined in writing, based on the information provided pursuant to subsection (b)(2), and any other relevant credible scientific information in the possession of the department or submitted to the department, that the presence of the transgenic aquatic animal, as modified, within California poses no reasonably foreseeable risk to native fish, wildlife, or plants.

In addition, the Department proposes to amend Section 703 by adding a new subsection (a)(3) Determination that a Transgenic Aquatic Animal is not Detrimental, which includes an application procedure and an application fee. The contents of an application are specified and the nonrefundable fee is proposed to be set at \$4,790. The fee was determined to cover the Department's costs to review such applications as provided in FGC 1050.

The amendment in Section 703 also establishes the effect of the Department's determination:

1. Once it receives a determination from the department of 'not detrimental', the applicant may import, possess, distribute, and sell the animal within the state provided that it possesses a copy of the department's determination.
2. Any wholesaler or retailer purchasing a transgenic aquatic animal from the applicant must also possess both a copy of the department's determination and written documentation to demonstrate that the wholesaler or retailer purchased the animal from the applicant.
3. Individuals purchasing a transgenic aquatic animal from the applicant or authorized wholesalers or retailers may possess the animal, without a copy of the department's determination or any other documentation, provided that the animal is maintained in a closed system and not placed in the waters of the state.

(b) Authority and Reference Sections from Fish and Game Code for Regulation:

Section 1.92: Authority cited: Sections 200, 202, 205, 210, 220, and 1050 Fish and Game Code. Reference: 1050 and 2271, Fish and Game Code.

Section 703: Authority cited: Sections 713, 1002, 1050, 1053, 1745, 2118, 2120, 2122, 2150, 2150.2 and 2157, Fish and Game Code. Reference: Sections 395, 396, 398, 713, 1050, 1053, 1745, 2116, 2116.5, 2117, 2118, 2120, 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 Title 50, Code of Federal Regulations, Parts 21.29 and 21.30.

(c) Specific Technology or Equipment Required by Regulatory Change: None.

(d) Identification of Reports or Documents Supporting Regulation Change: None.

(e) Public Discussions of Proposed Regulations Prior to Notice Publication:

No public meetings are scheduled prior to the notice publication. The 45-day public notice comment period provides adequate time for review of the proposed changes.

#### IV. Description of Reasonable Alternatives to Regulatory Action:

(a) Alternatives to Regulation Change:

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 proposed regulation, or would be more cost effective to affected private persons and equally effective in implementing the statutory policy or other provision of law.

#### V. Mitigation Measures Required by Regulatory Action:

The proposed regulatory action will have no negative impact on the environment; therefore, no mitigation measures are needed.

#### VI. 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 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 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 growth rates, as described at <http://www.americanpetproducts.org>, that are projected to 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 regulations.

The requirement of a fee of \$4,790 is calculated to recover associated Department costs, in accordance with Section 1050, Fish and Game Code, is very modest and without significant adverse impact, in comparison to the potential economic opportunity to the applicant.

(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.

## VII. Economic Impact Assessment

The Department is proposing a regulation amending the definition of "*transgenic*," i.e., genetically altered. Generally, transgenic aquatic animals, including genetically altered fish for aquarium use, are prohibited for import into the state under provisions

in sections 671 and 671.1, Title 14, CCR. The purpose of the current limitations is to prevent the introduction of non-native, detrimental species. The new definition incorporates new scientific understanding of transgenic animals. An amendment in Section 703 enables an application to the Department for a finding of 'not detrimental' so that certain transgenic aquatic animals could be imported for aquarium hobbyists.

Although the number of aquarium fish which might be allowed under the new amendment is undetermined, it is only a small fraction of the market for pets, aquarium fish, or other species in the California market. An applicant must submit to the Department credible scientific information which, along with any other available data, will be evaluated by the Department. The Department must make a determination that the presence of the transgenic aquatic animal, as modified, within California poses no reasonably foreseeable risk to native fish, wildlife, or plants in order to label the particular aquatic animal as "not detrimental" and therefore not subject to Section 671 and subsection 671.1(a)(8).

In accordance with Section 1050, Fish and Game Code, the Commission may establish a fee in an amount sufficient to recover all reasonable administrative and implementation costs of the Department and Commission. The following table details the projected cost of a typical application in accordance with the proposed regulation changes.

<b>Cost Description</b>	<b>Hours</b>	<b>Rate<sup>1</sup></b>	<b>Total Costs</b>
<i>Fisheries Branch Costs</i>			
<i>Transgenic Application Review</i>			
Senior Environmental Scientist (Supervisor)	16	\$ 78.95	\$ 1,263
Environmental Program Manager	8	\$ 91.30	\$ 730
CEA - Branch Chief	8	\$ 100.90	\$ 807
OGC - Senior Staff Counsel	8	\$ 93.42	\$ 747
<b><i>Per Application Subtotal</i></b>			\$ 3,548
Overhead		35%	\$ 1,242
<b>Total Costs</b>			\$ 4,790

Notes: <sup>1</sup> Rate includes salary and benefits.

Sources: California Department of Human Resources, California Department of Fish and Wildlife Accounting Branch, Fisheries Branch.

Therefore, the Commission proposes to add a new, nonrefundable application fee to cover the administrative costs of a Department determination in the amount of \$4,790, to Section 703, Title 14, CCR, Miscellaneous Applications, Tags, Seals, Licenses, Permits, and Fees.

Effects of the regulation on the creation or elimination of jobs within the State

The regulation is unlikely to affect the creation or elimination of jobs.

Effects of the regulation on the creation of new businesses or the elimination of existing businesses within the State

The regulation is unlikely to affect the creation or elimination of businesses.

Effects of the regulation on the expansion of businesses currently doing business within the State

Although the amendment will allow the importation, possession, distribution, and sale of aquatic animals determined “not detrimental” and therefore result in profits for participating businesses, the regulation is unlikely to affect the expansion of businesses because any potential increase is likely to be only a small fraction of the current market.

Benefits of the regulation to the health and welfare of California residents

The amendment is unlikely to affect the health and welfare of California residents.

Benefits of the regulation to worker safety

The regulation does not affect worker conditions or safety.

Benefits of the regulation to the State's environment

It is the policy of the State to encourage the conservation, maintenance, and utilization of the living resources under the jurisdiction and influence of the State for the benefit of all the citizens of the State. Current regulations protect these resources of the state by prohibiting the importation of non-native species which may be detrimental to native species. 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.

## 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.