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## Fish and Game Commission



*Wildlife Heritage and Conservation*  
*Since 1870*

### 15 Day Notice of California Notice Register 2015, No.34-Z, Z-2015-0811-07

#### Re: Transgenic Definition; Application and Fee

September 22, 2015

This is to provide you with a 15 day continuation notice of proposed regulatory action relative to amending sections 1.92 "Transgenic" and 703 "Miscellaneous Applications, Tags, Seals, Licenses, Permits, and Fees," Title 14, California Code of Regulations, relating to the proposed regulations for "Transgenic Definition; Application and Fee," which was published in the California Regulatory Notice Register on August 21, 2015, Register 2015, No. 34-Z; OAL Notice File No. Z-2015-0811-07. The proposed additional language, shown in double underline/strikeout underline is for clarification of originally noticed language and is sufficiently related to the originally proposed text.

The date of the public hearing related to this matter, and associated deadlines for receipt of oral or written comments at the meeting to be held on October 8, 2015 in Los Angeles has not changed from the original notice.

Additional information and all associated documents may be found on the Fish and Game Commission website at [http://www.fgc.ca.gov/regulations/2015/index.aspx#1\\_92](http://www.fgc.ca.gov/regulations/2015/index.aspx#1_92).

**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.**

Sincerely,

Jon D. Snellstrom  
Associate Governmental Program Analyst

Attachment

## REGULATORY TEXT

Section 1.92, Title 14, CCR is amended as follows:

### **§1.92. Transgenic.**

~~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.~~

(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 species produced through breeding, conjugation, fermentation, hybridization, in vitro fertilization, or tissue culture and no transgenic organisms are involved;

(B) It is an aquatic animal species 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 **research purposes**, human consumption, or bait purposes and will be maintained in a closed system and not placed in waters of the state;

(2) The **applicant, which may be a** person or entity, seeking to import, distribute, possess, and sell the transgenic aquatic animal in California has submitted to the department the application and fee specified in Section 703.

(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.

Note: Authority cited: Sections 200, 202, 205, ~~210~~, and 220, and 1050 Fish and Game Code. Reference: Sections ~~200-202, 205, 206, 210 and 220.~~ 1050 and 2271, Fish and Game Code.

## REGULATORY TEXT

Section 703, Title 14, CCR is amended as follows:

### **§703. Miscellaneous Applications, Tags, Seals, Licenses, Permits, and Fees.**

(a). Applications, Forms and Fees for January 1 through December 31 (Calendar Year).

. . . *[No changes to subsections 703(a)(1) through (2)]*

#### (3) Determination that a Transgenic Aquatic Animal is not Detrimental

(A) The applicant shall apply in the form of a letter, on letterhead if an entity, for a department determination that a transgenic aquatic animal is not detrimental in accordance with Section 1.92 and shall include all of the following:

1. The name, mailing address, telephone number(s), and e-mail address of the person seeking to import, possess, distribute, and sell the transgenic aquatic animal or of the principal contact person if an entity seeks to import, possess, distribute, and sell the transgenic aquatic animal.

2. A detailed analysis based on credible science containing:

a. The common and scientific names of the species for which an exemption is sought.

b. A description of the life history of the species.

c. A description of the method(s) by which the genome of the species has been deliberately altered, modified, or engineered.

d. The known or anticipated effects of the genetic modification of the species.

e. An analysis of the potential risk to native fish, wildlife, or plants posed by the presence of the transgenic aquatic animal, as modified, within California.

f. A description of the applicant's proposed importation, possession, distribution, and sale of the transgenic aquatic animal within California.

3. Certification in the following language: I certify that the information submitted in this application is complete and accurate to the best of my knowledge and belief. I understand that any false statement herein may subject the application to rejection, or the department determination to revocation, and to civil and criminal penalties under the laws of the State of California.

a. The original signature of the person, or principal contact person if an entity, seeking the determination.

4. The applicant shall submit a **separate nonrefundable** application **and nonrefundable** fee of \$4,790 **per species of transgenic aquatic animal.**

5. The applicant shall submit one paper copy, and an electronic copy (via email or other device as directed by department staff) containing all application materials, and the application fee, to the Fisheries Branch Chief at 830 S Street, Sacramento, CA 95811.

#### (B) Contents of the Department Determination

1. The department shall issue a determination in writing, based on the information provided by the applicant, and any other relevant credible scientific information in the

possession of the department or submitted to the department.

2. The determination shall state whether:

a. The presence of the transgenic aquatic animal, as modified, within California is detrimental and subject to regulation under Section 671 and subsection 671.1(a)(8); or,

b. The presence of the transgenic aquatic animal, as modified, within California is not detrimental and poses no reasonably foreseeable risk to native fish, wildlife, or plants and is not subject to regulation under Section 671 and subsection 671.1(a)(8).

c. In making its determination, the department may impose reasonable conditions to ensure the proposed importation, possession, distribution, and sale of the transgenic aquatic animal within California is not detrimental **to native fish, wildlife, or plants.**

d. The department may revoke or change its determination at any time upon newly-obtained information or circumstances involving said animal's detrimental impacts.

3. If the department identifies deficiencies in the application, requiring additional time or further review, the department shall reject the application and provide written notification of the identified deficiencies in the application to the applicant. No additional fee is required if the application, with required information, is resubmitted within one year of receipt of the original application.

(C) Effect of Department Determination

1. Once it receives a determination from the department that the transgenic aquatic animal poses no reasonably foreseeable risk to native fish, wildlife, or plants, the applicant **or its authorized agent** may import, possess, distribute, and sell the animal within the state provided that **it possesses on the premises or within the vehicle, if in transit, both the applicant and its authorized agent possess and provide within three business days, upon request by the department,** a copy of the department's determination.

2. Any wholesaler or retailer purchasing a transgenic aquatic animal from the applicant **or its authorized agent** may **import,** possess, distribute, and sell the animal provided that **it possesses on the premises or within the vehicle, if in transit, the wholesaler or retailer possesses and provides within three business days, upon request by the department,** both a copy of the department's determination and written documentation to demonstrate that **the animal that** the wholesaler or retailer purchased **the animal originated** from the applicant **or its authorized agent.**

3. Individuals purchasing a transgenic aquatic animal **that originated** from the applicant, **its authorized agent,** or wholesalers or retailers **as authorized by this section pursuant to subsection 2 of section 703(a)(3)(C)** 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.

*[No changes to subsections 703(b) and 703(c)]*

Note: 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.