

NOTICE PUBLICATION/REGULATIONS SUBMISSION

REGULAR

(See instructions on reverse)

For use by Secretary of State only

STD. 400 (REV. 01-2013)

OAL FILE NUMBERS	NOTICE FILE NUMBER Z-2015-0811-07	REGULATORY ACTION NUMBER 2015-1027-025	EMERGENCY NUMBER
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For use by Office of Administrative Law (OAL) only

<p>NOTICE</p>	<p>REGULATIONS</p>
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ENDORSED - FILED
in the office of the Secretary of State
of the State of California

DEC 10 2015

2:10 PM

2015 OCT 27 P 1:49
OFFICE OF ADMINISTRATIVE LAW

AGENCY WITH RULEMAKING AUTHORITY Fish and Game Commission	AGENCY FILE NUMBER (If any)
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A. PUBLICATION OF NOTICE (Complete for publication in Notice Register)

1. SUBJECT OF NOTICE Transgenic Definition; Application and Fee	TITLE(S) 14	FIRST SECTION AFFECTED 1.92	2. REQUESTED PUBLICATION DATE August 21, 2015
3. NOTICE TYPE <input checked="" type="checkbox"/> Notice re Proposed Regulatory Action <input type="checkbox"/> Other	4. AGENCY CONTACT PERSON Jon Snellstrom	TELEPHONE NUMBER (916) 653-4899	FAX NUMBER (Optional) (916) 653-5040
OAL USE ONLY	ACTION ON PROPOSED NOTICE <input type="checkbox"/> Approved as Submitted <input type="checkbox"/> Approved as Modified <input type="checkbox"/> Disapproved/Withdrawn	NOTICE REGISTER NUMBER 2015, 34.2	PUBLICATION DATE 8/21/2015

B. SUBMISSION OF REGULATIONS (Complete when submitting regulations)

1a. SUBJECT OF REGULATION(S) Transgenic Definition; Application and Fee	1b. ALL PREVIOUS RELATED OAL REGULATORY ACTION NUMBER(S)
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2. SPECIFY CALIFORNIA CODE OF REGULATIONS TITLE(S) AND SECTION(S) (Including title 26, if toxics related)

SECTION(S) AFFECTED (List all section number(s) individually. Attach additional sheet if needed.)	ADOPT
	AMEND 1.92, 703
	REPEAL
TITLE(S) 14	

3. TYPE OF FILING

<input checked="" type="checkbox"/> Regular Rulemaking (Gov. Code §11346)	<input type="checkbox"/> Certificate of Compliance: The agency officer named below certifies that this agency complied with the provisions of Gov. Code §§11346.2-11347.3 either before the emergency regulation was adopted or within the time period required by statute.	<input type="checkbox"/> Emergency Readopt (Gov. Code, §11346.1(h))	<input type="checkbox"/> Changes Without Regulatory Effect (Cal. Code Regs., title 1, §100)
<input type="checkbox"/> Resubmittal of disapproved or withdrawn nonemergency filing (Gov. Code §511349.3, 11349.4)	<input type="checkbox"/> Resubmittal of disapproved or withdrawn emergency filing (Gov. Code, §11346.1)	<input type="checkbox"/> File & Print	<input type="checkbox"/> Print Only
<input type="checkbox"/> Emergency (Gov. Code, §11346.1(b))		<input type="checkbox"/> Other (Specify) _____	

4. ALL BEGINNING AND ENDING DATES OF AVAILABILITY OF MODIFIED REGULATIONS AND/OR MATERIAL ADDED TO THE RULEMAKING FILE (Cal. Code Regs. title 1, §44 and Gov. Code §11347.1)

9/22/15 - 10/8/15 DM per agency request 12/9/15

5. EFFECTIVE DATE OF CHANGES (Gov. Code, §§ 11343.4, 11346.1(d); Cal. Code Regs., title 1, §100)

<input type="checkbox"/> Effective January 1, April 1, July 1, or October 1 (Gov. Code §11343.4(a))	<input type="checkbox"/> Effective on filing with Secretary of State	<input type="checkbox"/> \$100 Changes Without Regulatory Effect	<input checked="" type="checkbox"/> Effective other (Specify) Jan. 1, 2016 per 11343.4(b)(3)
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6. CHECK IF THESE REGULATIONS REQUIRE NOTICE TO, OR REVIEW, CONSULTATION, APPROVAL OR CONCURRENCE BY, ANOTHER AGENCY OR ENTITY

<input type="checkbox"/> Department of Finance (Form STD. 399) (SAM §6660)	<input type="checkbox"/> Fair Political Practices Commission	<input type="checkbox"/> State Fire Marshal
<input type="checkbox"/> Other (Specify) _____		

7. CONTACT PERSON Jon Snellstrom	TELEPHONE NUMBER 916 653-4899	FAX NUMBER (Optional)	E-MAIL ADDRESS (Optional) Jon.Snellstrom@fgc.ca.gov
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8. I certify that the attached copy of the regulation(s) is a true and correct copy of the regulation(s) identified on this form, that the information specified on this form is true and correct, and that I am the head of the agency taking this action, or a designee of the head of the agency, and am authorized to make this certification.

SIGNATURE OF AGENCY HEAD OR DESIGNEE <i>Melissa Miller-Henson</i>	DATE 10/27/15
TYPED NAME AND TITLE OF SIGNATORY Melissa Miller-Henson, Staff Services Manager	

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ENDORSED APPROVED

DEC 10 2015

Office of Administrative Law

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 altered, modified or engineered 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 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 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.

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 alteration, modification or engineering 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 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 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 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 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 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 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 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 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.