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1416 Ninth Street, Room 1320
Sacramento, CA 95814
(916) 653-4899
www.fgc.ca.gov

Fish and Game Commission

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Wildlife Heritage and Conservation
Since 1870

August 1, 2017

This is to provide you with a copy of the notice of proposed regulatory action relative to adding Section 42, and subsection (a)(2) of Section 703, and amend subsection (c) of Section 43 and subsection (a) of Section 651, Title 14, California Code of Regulations, relating to commercial use and possession of native rattlesnakes for biomedical and therapeutic purposes, which will be published in the California Regulatory Notice Register on August 4, 2017.

Please note the date of the public hearing related to this matter and associated deadlines for receipt of written comments.

Additional information and all associated documents may be found on the Fish and Game Commission website at <http://www.fgc.ca.gov/regulations/2017/index.aspx>.

Laura Patterson, Senior Environmental Scientist Specialist, Department of Fish and Wildlife, (916) 445-6456, has been designated to respond to questions on the substance of the proposed regulations.

Sincerely,

Sheri Tiemann

Associate Governmental Program Analyst

Attachment

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 Section 5061 of the Fish and Game Code, Section 597 of the Penal Code, Sections 11503 and 11506 of the Government Code and to implement, interpret or make specific Sections 5060 and 5061 of the Fish and Game Code, Section 597, of the Penal Code, Sections 11503 and 11506 of the Government Code, proposes to add Section 42 and subsection (a)(2) of Section 703, and amend subsection (c) of Section 43 and subsection (a) of Section 651, relating to Commercial Use and Possession of Native Rattlesnakes for Biomedical and Therapeutic Purposes

Informative Digest/Policy Statement Overview

The Fish and Game Commission (Commission) received a petition in 2015 to amend existing regulations or adopt new regulations that would allow for the commercial use of native rattlesnakes to develop antivenom, vaccines, and other therapeutic agents. The Commission approved the petition request at its February 11, 2016 meeting in Sacramento and forwarded it to the Department of Fish and Wildlife (Department) for evaluation. Department staff met with the petitioners during 2016 to gather additional information. The petitioners had initially proposed using "nuisance" snakes collected by rattlesnake removal businesses for this purpose, as well as raising the possession limit on native rattlesnakes for aversion trainers. However, those proposals would have required additional public outreach and scoping of affected businesses that would have greatly delayed the development of the new regulations. Therefore, with the petitioners' consent, the Department narrowed the scope of the regulatory proposal to address only commercialized use of native rattlesnakes for venom extraction in conjunction with research and development of biomedical and therapeutic agents. In addition, the Department added propagation of native rattlesnakes at the request of the petitioners.

The Commission has the statutory authority to adopt regulations for the commercial use of native reptiles pursuant to Fish and Game Code Section 5061. Currently, there are only two authorized commercial activities in California: captive propagation and sale of three species of snakes, which is allowed under Section 43, and wild collection and sale of native reptiles by Biological Supply Houses, which is allowed under Section 651.

Venom from rattlesnakes differs by species, and in some cases by location within the species. For example, Southern Pacific Rattlesnake (*Crotalus oreganus helleri*) venom has unique properties that differ across its range. Antivenom and vaccines that are derived from different species of rattlesnakes than the species that inflicted the bite are less effective, and sometimes not effective at all, in treatment of the bite. Currently, the only way antivenom, vaccines, and therapeutic agents can be derived from native rattlesnakes in California is through non-commercial research and development through a valid Scientific Collecting Permit pursuant to Section 650. However, Biological Supply Houses can collect native rattlesnakes and sell them to out-of-state scientific and

educational facilities that develop and sell these products.

Existing Regulations

The text of Section 42 was repealed in January 2002, but the title and note are still listed in Title 14, Code of Regulations (CCR). Section 43 contains regulations for the captive propagation of native reptiles and sale of three species of native snakes. Section 651 regulations specify the wild collection and sale of native reptiles by Biological Supply Houses.

Proposed Regulations

The proposed Section 42 regulation will allow California businesses to develop and sell regionally specific antivenom, vaccines, and therapeutic agents derived from native rattlesnake venom that would benefit human, pet, and livestock health. The new permit is structured to allow for:

1. Businesses which seek to maintain live native rattlesnake species for venom extraction and develop and sell therapeutic products from the native rattlesnake venom, or
2. Businesses which only intend to develop and sell therapeutic products from the native rattlesnake venom.

In addition, it is necessary to make minor amendments to Sections 43, 651, and 703 to provide consistency and clarity with the proposed Section 42.

Subsection (a) of Section 42 details the activities that the activities that allowed with a commercial native rattlesnake permit issued by the Department.

Subsection (b) of Section 42 specifies that this regulation does not supersede any other federal, state, or local laws regulating or prohibiting possession of native rattlesnakes or the activities authorized under a commercial native rattlesnake permit.

Subsection (c) of Section 42 lists the species of native rattlesnakes that may be used under this regulation.

Subsection (d) of Section 42 specifies regulations for the permit application, fees, duration of permit, and qualification requirements, such as minimum qualifications, letter of reference, statement of purpose, an emergency action plan, an initial inspection and minimum age. A separate permit is proposed for each facility housing native rattlesnake species or creating products from venom extracted from native rattlesnake species. The proposed regulation establishes a new 2018 Commercial Native Rattlesnake Permit Application (Form DFW 1044 (New 4/2017)), which is incorporated by reference herein.

Subsection (e) of Section 42 describes the general conditions associated with possessing a permit pursuant to this section, including agreeing to random inspections, ability to transfer or exchange rattlesnakes among permittees, prohibition of release into the wild, and conditions under which applications will be denied or permits will be revoked.

Subsection (f) of Section 42 describes the humane care and treatment that permittees must provide to native rattlesnakes possessed under this regulation. It includes requirements on enclosure size, substrate, and cleanliness; appropriate food and water; pest control; and observation and handling.

Subsection (g) of Section 42 describes the requirement for each facility to maintain an Emergency Action Plan and the minimum contents of that plan in the event of a bite, escape, or emergency evacuation.

Subsection (h) of Section 42 describes the records a permittee must maintain while operating under a permit pursuant to this section and the duration the records must be kept and made available to the department. The proposed regulation establishes a new Commercial Native Rattlesnake Permit Record (Form DFW 1044A (New 4/2017)), which is incorporated by reference herein.

Subsection (i) of Section 42 describes the annual reporting requirements under the regulation.

Subsection (j) of Section 42 describes the terms of shipping live native rattlesnakes under the authority of this regulation and clarifies that this regulation does not supersede any federal, state, local, or shipping entity's rules regarding shipment of live rattlesnakes.

Subsection (c) of Section 43 restricts the sale, possession, transportation, importation, exportation, and propagation of native reptiles for commercial purposes except as provided in subsection 40(f) and the species identified within Section 43. To ensure consistency with the new regulation, this amendment adds an exception for entities permitted through Section 42.

Subsection (a) of Section 651 limits the sale of native reptiles and amphibians to scientific or educational institutions to biological supply houses that operate under a permit issued by the Department. This proposed amendment states that persons who hold a valid commercial native rattlesnake permit issued by the department and commercial developers of biomedical or therapeutic agents shall be considered scientific and educational institutions for the purposes of this section.

Subsection (a)(2) of Section 703 specifies the forms and fees associated with the Commercial Native Rattlesnake Permit.

FORMS INCORPORATED BY REFERENCE

2018 Commercial Native Rattlesnake Permit Application
Form DFW 1044 (New 4.2017)

Commercial Native Rattlesnake Permit Record
Form DFW 1044A (New 4/2017)

BENEFITS OF THE REGULATIONS

Allowing for limited collection and possession of native rattlesnakes as described in Section 42 is expected to result in more effective and cheaper antivenom and vaccines as well as other therapeutic agents.

CONSISTENCY WITH STATE AND FEDERAL REGULATIONS

Article IV, Section 20 of the State Constitution specifies that the Legislature may delegate to the Fish and Game Commission such powers relating to the protection and propagation of fish and game as the Legislature sees fit. The Legislature has delegated to the Commission the power to regulate commercial take of native reptiles (Fish & Game Code, §5061). The Commission has reviewed its own regulations and finds that the proposed regulations are neither inconsistent nor incompatible with existing state regulations. The Commission has searched the California Code of Regulations and finds no other state agency regulations pertaining to native rattlesnakes. Further, the Commission has determined that the proposed regulations are neither incompatible nor inconsistent with existing federal regulations.

NOTICE IS ALSO GIVEN that any person interested may present statements, orally or in writing, relevant to this action at a hearing to be held at the SpringHill Suites by Marriott, 900 El Camino Real, Atascadero, California, on Wednesday, October 11, 2017, 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 5:00 p.m. on September 28, 2017 at the address given below, or by email to FGC@fgc.ca.gov. Written comments mailed, or emailed to the Commission office, must be received before 12:00 noon on October 6, 2017. All comments must be received no later than October 11, 2017, at the hearing. If you would like copies of any modifications to this

Availability of Documents

The Initial Statement of Reasons, text of the regulations, as well as all related documents upon which the proposal is based (rulemaking file), are on file and available for public review from the agency representative, Valerie Termini, 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 Valerie Termini or Sheri

Tiemann at the preceding address or phone number. **Laura Patterson, Department of Fish and Wildlife, has been designated to respond to questions on the substance of the proposed regulations. Ms. Patterson can be reached at (916) 341-6981 or Laura.Patterson@wildlife.ca.gov.** Copies of the Notice of Proposed Action, the Initial Statement of Reasons, and the text of the regulation in underline and strikeout can be accessed through our 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. 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 Assessment

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. It establishes the ability for California companies to compete with out-of-state companies in the development and sale of pharmaceutical products derived from native rattlesnakes.

- (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:

The Commission does not anticipate significant impacts on the creation or elimination of jobs, the creation of new business, the elimination of existing businesses or the expansion of businesses in California due to the limited number of anticipated permit applications.

The Commission anticipates benefits to the health and welfare of California residents through the development of improved therapeutic agents to treat rattlesnake bites in pets and domestic livestock. The Commission does not anticipate any non-monetary benefits to worker safety.

(c) Cost Impacts on a Representative Private Person or Business:

The Commission estimates that a representative private person or business would necessarily incur \$815 in permitting and inspection costs in the first year and \$113 in annual costs in reasonable compliance with the proposed action.

(d) Costs or Savings to State Agencies or Costs/Savings in Federal Funding to the State:

The Commission anticipates revenue to recover the Department's administrative costs from initial inspections and permit fees for the first year from each business and annual renewal fees thereafter. The proposed action will not affect any other State Agency.

(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: July 18, 2017

Valerie Termini
Executive Director