

STATE OF CALIFORNIA
FISH AND GAME COMMISSION
FINAL STATEMENT OF REASONS FOR REGULATORY ACTION

Add 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
Re: Commercial Use and Possession of Native Rattlesnakes
for Biomedical and Therapeutic Purposes

- I. Date of Initial Statement of Reasons: April 12, 2017
- II. Date of Amended Initial Statement of Reasons: May 25, 2018
- III. Date of Final Statement of Reasons: October 18, 2018
- IV. Dates and Locations of Scheduled Hearings:
 - (a) Notice Hearing: Date: June 21, 2017
Location: Smith River
 - (b) Discussion and Adoption Hearing: Date: October 11, 2017
Location: Atascadero
- V. Update:

At its October 11, 2017, meeting, the Fish and Game Commission (Commission) adopted the proposed regulations as described in Notice Z2017-0725-12, without changes.

On June 11, 2018, the Commission issued a 15-day notice of the revised proposed regulatory language described in the Amended Initial Statement of Reasons for Regulatory Action, dated May 25, 2018.

Based on public comment, subsection 42(d)(4)(A)3. was revised to clarify that the quantity of venom is not required to be included in the statement of purpose, which was always the intent of the Commission, and not a change in the effect of subsection 42(d)(4)(A)3.

Changes were made to Section 651 for grammatical and consistency purposes.

Authority and reference citations for Section 43 were corrected to match existing citations.

Sections 1053 and 1745, Fish and Game Code, were removed from the list of authority citations, and Section 1745, Fish and Game Code, was removed from the list of reference citations for Section 703. Section 1053 of the Fish and Game Code was repealed in 2015 statutes. Section 1745 of the Fish and Game Code addresses Department of Fish and Wildlife lands and is not applicable to Section 703, Title 14.

A minor editorial change was made to DFW 1044 to identify the acronym “FGC” to mean “Fish and Game Code” and a typographical error, changing “with 30 days” to “within 30 days”, was corrected in the instructions for this form.

Form DFW 1044 has been updated to the 2019 calendar year since the regulations, including the forms, will not go into effect in 2018.

Speckled rattlesnake (*Crotalus mitchellii*)” is changed to “Southwestern speckled rattlesnake (*Crotalus pyrrhus*)” in subsection 42(c)(4). The Committee on Standard English and Scientific Names (Brian I. Crother, Committee Chair) published the 8th Edition of “Scientific and Standard English Names of Amphibians and Reptiles of North America North of Mexico, with Comments Regarding Confidence in our Understanding” in 2017. In it, the committee adopted new taxonomic nomenclature based on a recently published genetics study, which recommended elevating three subspecies of the Speckled Rattlesnake (*Crotalus mitchellii*) to full species. As a result, *C. mitchellii*, as it is currently recognized, no longer occurs in California and has been replaced with the Southwestern Speckled Rattlesnake (*Crotalus pyrrhus*).

At its October 17, 2018 meeting, the Commission considered the public comments received on the 15-day notice and adopted the regulations described in the Amended Initial Statement of Reasons dated May 2, 2018 with the changes described above.

There have been no other changes in applicable laws or to the effect of the adopted regulations from the laws and effects described in the June 11, 2018 15-day notice.

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

A summary and response to comments received between August 4 and October 11, 2017 is provided in Attachment A.

A summary and response to comments received between June 11 and June 26, 2018 is provided in Attachment B.

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:

The Department evaluated amending Section 43 “Captive Propagation and Commercialization of Native Reptiles” to include native rattlesnakes in subsection (c). This alternative was rejected due to the desire to maintain a narrow scope on the allowable commercial use of native rattlesnakes in the new regulation (i.e., solely for the development and sale of therapeutic products). Because the original purpose of Section 43 was to authorize propagation of select species for the pet trade, it is necessary to keep commercial use of native rattlesnakes in a separate section to avoid confusion and the unintended creation of a commercial market for native rattlesnakes.

(b) No Change Alternative:

Under the no change alternative, no commercial production of antivenom, vaccines, or other biomedical and therapeutic agents derived from native rattlesnakes could legally occur in California.

(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 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.

Nondiscretionary Costs/Savings to Local Agencies: None.

Programs Mandated on Local Agencies or School Districts: None.

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.

Effect on Housing Costs: None.

Updated 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. Section 703 contains the applications, forms and fees associated with Department-issued permits for restricted species, non-detrimental transgenic aquatic animals and falconry.

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,

2. Businesses which only intend to develop and sell therapeutic products from the native rattlesnake venom, and
3. Businesses to purchase native rattlesnakes from a biological supply house for the purpose of developing and selling biomedical and therapeutic products.

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 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 Commercial Native Rattlesnake Permit Application (Form DFW 1044 (New 4/2018)), which is incorporated by reference herein.

Subsection (e) of Section 42 describes the general permit conditions to maintain qualified staff at each facility whenever rattlesnakes are handled or their venom processed, the prohibition of sale of rattlesnakes with allowance of transfer or exchange of rattlesnakes among permittees, prohibition of release of rattlesnakes into the wild, the inspection requirements, and the conditions under which permits will be suspended, denied, or 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 Record (Form DFW 1044A (New 4/2018)), 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 natural persons who hold a valid Commercial Native Rattlesnake Permit issued by the department and out-of-state 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. The forms are incorporated by reference because it would be cumbersome, unduly expensive, and otherwise impractical to publish them in Title 14, CCR. These forms are identified by title, form number, and date of publication.

Benefits of the regulations

Allowing for possession and propagation 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 and Game Code, Section 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.

Update

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