

STATE OF CALIFORNIA
FISH AND GAME COMMISSION
INITIAL STATEMENT OF REASONS FOR REGULATORY ACTION
(Pre-publication of Notice Statement)

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. 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

- III. Description of Regulatory Action:
 - (a) Statement of Specific Purpose of Regulation Change and Factual Basis for Determining that Regulation Change is Reasonably Necessary:

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.

According to the California Poison Control System, over 300 rattlesnake bites are reported in the state each year. According to the National Institutes of Health, approximately 7,000-8,000 people receive venomous bites in the United States and about 5 people die. While exact numbers are unavailable, it has been estimated that well over 100,000 domesticated animals are bitten annually in the United States by venomous snakes, sometimes resulting in death. Rattlesnake bites are known to cause serious tissue, muscle, liver, and neurological damage. The composition of rattlesnake venom 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. The currently available rattlesnake vaccine for domestic animals is derived from Western Diamondback Rattlesnake (*Crotalus atrox*) venom. A study in the American Journal of Veterinary Medicine (Cates et al. 2015) found this vaccine improved survival rate and survival time after envenomation from Western Diamondback Rattlesnakes. However, while it may offer some limited protection against Northern Pacific Rattlesnake (*Crotalus oreganus oreganus*) venom, it did not provide significant protection against Southern Pacific Rattlesnake venom.

Amendments to existing commercially authorized activities pursuant to Sections 43 and 651 are impractical. Section 43 pertains to the production of captive born reptiles for the purpose of selling them in the pet trade and has no application to the commercialization of rattlesnake venom or products derived from venom. Section 651 is restricted to the sale of native reptiles and amphibians collected from the wild to scientific and educational institutions by owners of biological supply houses that have been issued a permit from the Department. Therefore, to advance public and domestic animal health and safety, a new regulation is being proposed (Section 42) to address the need for regionally specific antivenom, vaccines, and other venom-derived therapeutic agents, that are effective against the bites from native rattlesnakes and provide other biomedical benefits. This new regulation would authorize commercial development of these products by California businesses under a permit issued by the Department.

Existing Regulations

The text of Section 42 was repealed in January 2002, but the title and note are still listed in Title 14, California Code of Regulations (CCR). Section 43 contains

regulations for the captive propagation of native reptiles and sale of three species of native snakes for the pet trade. Section 651 regulations specify the wild collection and sale of native reptiles by Biological Supply Houses.

Proposed Regulations

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

1. Businesses to maintain live native rattlesnake species for the purposes of venom extraction and the development and sale of therapeutic products derived from native rattlesnake venom, or
2. Businesses to develop and sell therapeutic products derived from commercially obtained 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.

Section 42

Subsection (a) of Section 42 details the activities allowed under a commercial native rattlesnake permit issued by the Department. This subsection is necessary to provide the context for the purpose of the regulation and to specify the activities that would be authorized under a permit issued pursuant to the regulation.

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. This subsection is necessary to ensure consistency with other laws and to clarify that this regulation does not supplant existing or future restrictions on the possession and use of native rattlesnakes by other jurisdictions.

Subsection (c) of Section 42 lists the species of native rattlesnakes that may be used under this regulation. This subsection is necessary to make it explicit that all currently recognized species of native rattlesnakes, their subspecies and taxonomic successors, are allowed to be used for the purposes of this regulation with the exception of the Red Diamond Rattlesnake (*Crotalus ruber*), which is a California Species of Special Concern.

Subsection (d) of Section 42 specifies requirements for the permit application, fees associated with the application, duration of permit, and qualification requirements. The proposed regulation establishes a new Commercial Native

Rattlesnake Application (Form DFW 1044 (New 4/2017)), which is incorporated by reference herein. A separate permit is proposed for each facility housing native rattlesnake species or creating products from venom extracted from native rattlesnake species. The qualification requirements differ depending on whether the applicant plans to house live native rattlesnakes in their facility as follows:

1. If the applicant proposes to house live native rattlesnake species for the purposes of developing therapeutic products from venom, minimum experience and animal husbandry qualifications are proposed. A resume demonstrating a minimum of 1,000 hours experience with captive husbandry of snakes and 200 hours working directly with captive rattlesnakes or other venomous snakes within five years of the date of application is required. The Department believes these are the minimum amounts of time necessary for individuals to obtain the skills needed to competently, and safely handle native rattlesnakes. In addition, an original, signed letter of reference is required as documentation that the experience requirements have been met. A statement of purpose for maintaining native rattlesnakes and a Written Emergency Action Plan are also required. Proof of minimum age (18 years) is also required.
2. If the applicant proposes only to develop therapeutic products from venom, the animal husbandry and Emergency Action Plan requirements no longer apply. A resume and an original, signed letter of reference documenting the applicant's experience are required. A statement of purpose for the planned use of the venom and proof of minimum age (18 years) are also required.

This subsection is necessary to establish the permitting system under which the activities will be authorized and to inform potential applicants of the application process, minimum qualifications, and fees involved in obtaining and maintaining a permit issued pursuant to this section. The information required in DFW 1044 is consistent with the information required in Form DFW 391b. Personal and business information is necessary for the Department to be able to contact the applicant and to undertake inspections of the facilities. The number of each species of native rattlesnake and how they were acquired are necessary to determine if the proposed plan for commercial use is consistent with the terms of Section 42. Fees were calculated based on presumed staff time necessary to undertake application review, renewal, and issuance, as well as facility inspections. Minimum qualifications for working with native rattlesnakes or their venom are consistent with subsection 671.1(c)(1).

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. The prohibitions and requirements in this subsection are consistent with existing prohibitions and requirements in subsections 40(e), 43(a) and 43(k). This subsection is necessary to inform

potential applicants of the terms and conditions associated with possessing a permit pursuant to this section.

Subsection (f) of Section 42 describes the humane care and treatment that permittees must provide to native rattlesnakes possessed under this regulation. This subsection specifies requirements for enclosure size, substrate, and cleanliness; appropriate food and water; pest control; and observation and handling. This subsection will align the new regulations with the existing requirements in subsection 43(g). This subsection is necessary to ensure native rattlesnakes are properly cared for, reducing suffering and the need to collect from wild populations. This subsection is also necessary to inform applicants of the minimum care and treatment standards required to obtain and maintain a permit pursuant to this regulation and for consistency with the requirements of subsection 43(g).

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 a bite, escape, or emergency evacuation. The requirements in this subsection are similar to those in subsection 671.1(c)(3)(I). This subsection is necessary because permitted facilities may be housing large numbers of venomous snakes which may result in a public health and safety issue. The Emergency Action Plan will prepare the permittee and its employees in responses to accidental escapes and bites and ensure appropriate equipment is stored on site. It will also ensure appropriate agencies are notified in a timely manner of an escape or any serious injury or death of a person bitten by a native rattlesnake possessed under a commercial native rattlesnake permit.

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 requirements in this subsection are consistent with existing reporting requirements in subsections 43(h) and 43(i). This subsection is necessary to ensure that the permittee is complying with the terms of the permit and regulation. The proposed regulation establishes a new Commercial Native Rattlesnake Record (Form DFW 1044A (New 4/2017)), which is incorporated by reference herein. The information required in DFW 1044A is similar to the information required Forms DFW 391c, 391d, 391e.

Subsection (i) of Section 42 describes the annual reporting requirements under the regulation. This subsection is necessary to inform applicants that the records maintained under subsection (h) must be submitted to the Department on an annual basis.

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. This subsection is necessary to ensure proper notification to postal workers, documentation to law enforcement that the native rattlesnakes are being shipped legally under the authority of this regulation, and to ensure this regulation does not conflict with any other jurisdiction's rules or regulations regarding shipping native rattlesnakes.

Subsection (c) of Section 43

Subsection (c) of Section 43 restricts the sale, possession, transportation, importation, exportation, and propagation of native reptiles for commercial purposes to subsection 40(f) and the regulations contained within Section 43. To ensure consistency with the new regulations, this subsection needs to be amended to allow an exception for entities permitted through Section 42.

Subsection (a) of Section 651

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. Confusion regarding whether these institutions can also develop commercial products from the native reptiles and amphibians requires the addition of clarifying language proposed in this amendment. The proposed language explicitly 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

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

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

Authority: Section 5061, Fish and Game Code. Section 597, Penal Code. Sections 11503 and 11506, Government Code.

Reference: Sections 5060 and 5061, Fish and Game Code. Section 597, Penal Code. Sections 11503 and 11506, Government Code.

- (c) Specific Technology or Equipment Required by Regulatory Change:

None.

(d) Identification of Reports or Documents Supporting Regulation Change:

Cates, C.C., E.V. Valore, G.W. Lawson, and J.G. McCabe. 2015. Comparison of the protective effect of a commercially available western diamondback rattlesnake toxoid vaccine for dogs against envenomation of mice with western diamondback rattlesnake (*Crotalus atrox*), northern Pacific rattlesnake (*Crotalus oreganus oreganus*), and southern Pacific rattlesnake (*Crotalus oreganus helleri*) venom. *American Journal of Veterinary Research* 76(3):272-279.

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

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

IV. Description of Reasonable Alternatives to Regulatory Action:

(a) Alternatives to Regulation Change:

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 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 is not expected to have a significant effect 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 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.

VII. Economic Impact Assessment:

- (a) Effects of the Regulation on the Creation or Elimination of Jobs Within the State:

Due to the limited number of expected applicants, the regulation has the potential to create a small number of jobs in the State. The proposed regulation should not eliminate any jobs.

- (b) Effects of the Regulation on the Creation of New Businesses or the Elimination of Existing Businesses Within the State:

The regulation is expected to provide new business opportunities within the State.

- (c) Effects of the Regulation on the Expansion of Businesses Currently Doing Business Within the State:

None.

- (d) Benefits of the Regulation to the Health and Welfare of California Residents:

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.

- (e) Benefits of the Regulation to Worker Safety:

None.

- (f) Benefits of the Regulation to the State's Environment:

None.

- (g) Other Benefits of the Regulation:

None.

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 Commercial Native Rattlesnake 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 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.

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.