

Attachment A.
Responses to Public Comments on Proposed Regulations to
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, CCR
Received by the Fish and Game Commission Between August 4 and October 11, 2017

Commenter Name, Date, Format		Comment #		Response #	
1	Karin Lease, 8/11/17, email	A.	Why did the Department not want to conduct additional public outreach and scoping that would have been necessary to move forward with the proposals in the original petition? What is the rush?	A.	The Department, Commission, and Petitioners determined that the benefits to the public, including health and safety benefits, that are expected as a result of allowing commercial use of native rattlesnakes to develop regionally-specific pharmaceutical products warranted moving forward on a more limited scope than what was requested in the initial petition and without additional public outreach or scoping.
		B.	Also, how is cruelty in handling of the snakes prevented, and what laws prevent their abuse?	B.	The Department requires that any applicant for this new permit that will be working with native rattlesnakes must meet minimum age and experience qualifications detailed in subsection (d)(4) of Section 42. Humane care and treatment requirements are detailed in subsection (f) of Section 42. Under subsection (e) of Section 42, the Department may enter permitted facilities at any reasonable hour to inspect animals and their enclosures and may suspend or revoke a permit at any time if a permittee is convicted of violating Fish and Game Code, Title 14 regulations, or any other state or federal statute or regulation pertaining to wildlife or animal cruelty.

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2.	Brian Hinds, 8/18/17, email	A.	Do the regulations limit the amount of the total take or the amount of rattlesnakes allowed to be taken from one area?	A.	The proposed regulation does not allow collection of native rattlesnakes from the wild under the new permit that would be issued pursuant to Section 42. Therefore, no limits on take were included in the rulemaking package. Collection of wild native rattlesnakes for development and sale of biomedical and pharmaceutical products requires a Biological Supply House permit pursuant to Section 651.

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1	James McCabe CEO, ZooToxins LLC 6/26/2018 Letter	A.	Application 2_DFW1044_New_4-2018 ; Page 2, Paragraph 2 "Note: Permittees who are not renewing...or WITH 30 days of the business closure" There appears to be a typo and WITH should be WITHIN.	A.	Correction made.
		B.	42regs2 : Page 2, subsection (d).(4).(A).1. "1. A resume that provides the dates and description of an applicant's or their employee's experience researching and creating products from venom extracted from rattlesnake species or similar experience and working with venomous snakes..." <u>Comment:</u> (a) The standard here is too strict. First, requiring <i>both</i> handling experience with snakes <i>and</i> developing products from venom is exorbitant. Some applicants may want to produce venom, but not develop a product, or vice versa. (b) Second, the standard of experience "researching and creating products from venom extracted from rattlesnake species" is extremely specific. Perhaps there are people with experience developing vaccines or antivenoms, but not necessarily from rattlesnake venom. Of course, there should be a standard with which the Department can evaluate people who will not house rattlesnakes, but handle venom to develop and sell therapeutic products.] (c) For applicants who want to develop products from venom, but not house rattlesnakes, the resume should show they are capable of handling venom in	B.	(a) 42(d)(A) specifically applies to businesses that are proposing to house rattlesnakes for the purpose of extracting their venom and creating pharmaceutical products. Therefore, the business needs to have people working there that have experience with handling venomous snakes and manufacturing pharmaceutical products. A business can have people who specialize in husbandry, venom extraction, and/or creating pharmaceutical products. Not every person working there must have experience in all facets of the operation, but for a business to be permitted it must have staff that are qualified to carry out the proposed work. (b) The regulation does not require that the person possess experience creating pharmaceutical products from rattlesnake venom. The Department and Commission recognized that this would be nearly impossible, which is why "or similar experience" was included.

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		<p>accordance with pharmaceutical manufacturing industrial standards. The requirement for the resume could state that applicants disclose, 'experience in handling biological materials in a way that ensures their quality for use in the development of therapeutic products.' This way, applicable experience in sterile technique, work in biochemical laboratories, or other related manufacturing experience would be applicable.</p> <p>C. 42regs2: Page 2, subsection (d).(4).(A).3. "3. A statement of purpose describing in detail the planned uses for the species native rattlesnakes, including approximate desired maximum quantities of each species being housed at the facility, and their venom."</p> <p><u>Comment:</u> We cannot determine the need for describing the 'approximate maximum quantity of venom' housed at the facility and would like the phrase, "and their venom" to be removed. First, there is no standard for what a permit applicant should report. Does the permittee report the desired volume of whole liquid venom or fractions of venom? The desired mass of dried venom or dried fractions of venom? Should they report all of these quantities individually or holistically? With what units should they report them? Is there a standard for a desired quantity that is <i>too high</i>, and what is that</p>	<p>(c) 42(d)(B) applies to businesses that are not going to house native rattlesnakes but are only going to make pharmaceutical products from their venom. The requirement for this type of business is that staff working with the venom have experience making pharmaceutical products from rattlesnake venom or similar experience. Experience in handling (non-venom) biological materials in a way that ensures their quality for use in the development of therapeutic products would be considered "similar experience."</p> <p>C. The regulation does not require the maximum desired amount of venom to be disclosed. The maximum quantities refers only to the rattlesnakes being housed. Only the planned uses of the venom are required in the statement of purpose.</p> <p>The Commission has revised the sentence (see below) to ensure the purpose is clear.</p> <p>"A statement of purpose describing in detail the planned uses for the native rattlesnakes and their venom, including the approximate desired maximum quantities of each species being housed at the facility."</p>
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		<p>standard? Second, we do not keep extracted venom in our snake facility, so does this mean that we do not need to report our desired maximum amount? Third, it is impossible to estimate how much venom any facility is capable of producing in a given year, so there is no justification for asking about the <i>desired maximum quantities</i>. The amount produced relies on a range of factors not limited to, the number of snakes in the colony, the number of extractions performed in the year, the health status of each animal at each extraction, etc. Thinking about what ZooToxins would report to meet this standard, we would likely put down a ridiculous number such as 100L of liquid venom or fractions thereof and 100kg of dried venom or fractions thereof. It would seem easier to just strike the request for this information as it informs nothing about the capacity of the facility to maintain rattlesnakes and is hard to enforce for personnel assessing applications or renewal information.</p> <p>D. Amended Initial Statement of Reasons for Regulatory Action, 42isor2, page 4, paragraph 3:</p> <p>“Subsection (d) of Section 42 specifies requirements...A separate permit is proposed for each facility housing native rattlesnake species or creating products from venom extracted from native rattlesnake species because the Department must evaluate facility-level specifics such as whether the proposed use plan is consistent with the regulation, staff working there meet the minimum qualifications, and the facility itself appears capable of housing the proposed numbers of rattlesnakes and is reasonably</p>	<p>D. The minimum enclosure requirements in 42(f)(1) will be used to determine whether a facility has the spatial capacity to house the approximate maximum number of each species. The Department and Commission do not agree that a modification to the regulatory language is necessary.</p>
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			<p>secure.”</p> <p>This statement is used to justify the requirement to report the number of snakes (see 42_DFW1044A-2018). 42isor2, page 4, final paragraph on the page, goes on to say:</p> <p>“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.”</p> <p><u>Comment:</u> As written, this justification is fraught—it states that reporting the number of animals will be used to inform permitting, but there is no description of a standard for evaluation in Section 42. Why report this information if there is no correlation to proper housing practices? What makes us uncomfortable is that it seems that the department could walk into our facility, decide it is 'not capable of housing the proposed numbers of rattlesnakes' and arbitrarily deny or retract permitting. If this reporting requirement is to remain in the applications and renewal materials, there should be a clear standard included in subsection (f) of Section 42, related to the humane care and treatment of rattlesnakes. Otherwise, the requirement to report such specific information should be removed and the applications adjusted. The individual snake housing requirements described in subsection (f) <i>should</i> be a sufficient standard to evaluate if "the facility itself appears capable of housing the proposed numbers of rattlesnakes and is reasonably secure." That is, if the facility can handle enough caging to fulfill the</p>		
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		<p>individual housing requirements and there is evidence that the number of animal care staff and their schedule keeps these animals properly maintained, then the absolute number of animals is irrelevant.</p> <p>We understand that this information may also help determine if a permit holder has become an animal dealer, but the justification is written to ensure quality care of the animals, not to help police the sale of these animals. Thus, there should be clear definitions on how this standard is evaluated by the Department to protect permit holders from arbitrary or subjective permitting decisions and to make it easy for the Department to enforce this policy.</p> <p>We feel that a comprehensive solution to this fraught justification requires changes to permit applications and to section 42. We know that this is a lot to request; however, it was not apparent that this reporting requirement would be problematic until drafts of the actual forms were finally released in April 2018.</p>		
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