

**DEPARTMENT OF FOOD AND AGRICULTURE  
PROPOSED REGULATORY TEXT – ANIMAL BLOOD BANKS**

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The Department of Food and Agriculture, Animal Blood Banks Program, proposes to update its Animal Blood Banking administrative penalties, as specified below:

1) Adopt new Section 1308 of new Article 6 of Chapter 8 of Division 2 of Title 3 of the California Code of Regulations, to read as follows:

Article 6. Enforcement Procedures

Section 1308. Administrative Penalties for Animal Blood Banking

(a) Failure to comply with the provisions of the statutes relating to animal blood banking under Chapter 1.5 (commencing with Section 9201) of Division 5 of the Food and Agricultural Code, and any regulations adopted pursuant to them, constitutes a violation punishable by a fine of not less than one hundred dollars (\$100) and not more than one thousand dollars (\$1,000) for each violation, as authorized by Section 9166 of the Food and Agricultural Code.

(b) The Department shall use the provisions of this Section to determine the violation class, severity of the violation, and amount of the penalty. One instance of conduct may result in multiple violations.

(c) For purposes of this Section, violations are classified as “serious,” “moderate,” or “minor”. Repeat violations may result in an escalation of violation class and/or penalty. Escalation of penalties will apply for a revolving three-year period from the date of each unique Section code violation.

(d) Table “A” Administrative Violation Classification Schedule shall be used by the Department and provides the level of severity of a particular violation, and the corresponding penalty range for “serious,” “moderate,” and “minor” violation classes, for violations pursuant to Subsection (a) of this Section.

(1) “Serious” violations are those committed recklessly or negligently, or those that present a significant risk of spreading animal disease, causing undue pain or distress to animal blood donors, contaminating animal blood or blood component

products, or otherwise compromising animal or public health, ~~the environment, or the economy~~. This includes, but is not limited to, violations that have resulted in, or reasonably could result in, the introduction or spread of an animal disease, or that interfere with the Department's ability to prevent, trace, or respond to such risks. It also includes failures in blood and blood component product traceability as well as ~~improper collection, handling, storage, or distribution~~ practices that undermine product integrity or biosecurity. Serious violations are punishable by an administrative penalty ranging from five hundred one dollars (\$501) to one thousand dollars (\$1,000).

(2) "Moderate" violations are those where there is potential for spreading animal disease, causing undue pain or distress to animal blood donors, contaminating animal blood or blood component products, or otherwise compromising animal or public health, ~~the environment, or the economy~~. This includes violations that may contribute to the introduction or spread of animal disease or hinder the Department's efforts to prevent, trace, or respond to such risks. It also encompasses deficiencies ~~in traceability, collection, handling, storage, or distribution~~ that could affect product integrity or biosecurity. Moderate violations are punishable by an administrative penalty ranging from three hundred one dollars (\$301) to five hundred dollars (\$500).

(3) "Minor" violations are those that are unintentional and pose minimal risk of spreading animal disease, causing undue pain or distress to animal blood donors, contaminating animal blood or blood component products, or otherwise compromising animal or public health, ~~the environment, or the economy~~. These violations have minimal potential to result in the introduction or spread of animal disease or to interfere with the Department's oversight functions. They may involve minor lapses in ~~traceability, collection, handling, storage, or distribution~~ protocols that do not significantly affect product integrity or biosecurity. Minor violations are punishable by an administrative penalty ranging from one hundred dollars (\$100) to three hundred dollars (\$300).

(e) When determining the penalty for any violation of Chapter 1.5 (commencing with Section 9201) of Division 5 of the Food and Agricultural Code and any regulations adopted pursuant to them, the Department shall consider any aggravating or mitigating factors. The penalty assessed shall represent a totality of the circumstances: the greater risk or recalcitrance of the violator will place the assessed penalty progressively higher within the range. Cooperation, risk mitigation, and severity of the violation will be considered and will place the penalty at the lower end of the range. The Department shall assess each violation using the following risk categories:

(1) Risk to donor animal health and welfare: A low risk to donor animal health is one where there is a minimal risk to animal blood donor health or welfare from blood

banking activities. A high risk to donor animal health is one where the event or occurrence poses a significant risk of harm to donor animal health or welfare, or the violator acted recklessly.

(2) Risk to recipient animal health: A low risk to recipient animal health is one where there is minimal risk and only under irregular conditions could there be any possibility of transmission of an illness or contamination of the blood products, and all reasonable precautions have been taken. A high risk to recipient animal health is one where the event or occurrence poses a significant risk of harm, has occurred or is likely to occur, or the violator knew or should have known that the event or activity would result in risk to the recipient of the blood product, or the violator acted recklessly.

(3) Risk to animal blood supply: A low risk to the animal blood supply is one where the event or occurrence poses minimal risk and only under irregular conditions could there be any possibility of loss of efficacy of the product or transmission of an illness. A high risk to the animal blood supply is one where the event or occurrence poses significant risk of harm, has occurred or is likely to occur, and the violator knew or should have known that the event or activity would result in decreased efficacy of the product or transmission of an illness, or the violator acted recklessly.

(4) Cooperation of the violator: The Department shall consider whether the violator has been non-responsive, recalcitrant, or deceptive. The violation can be mitigated by compliance and subsequent remedial measures.

(f) Administrative penalties must be paid within 30 days from the date of receipt of the order of assessment.

(g) A respondent, or his or her duly authorized representative, may contest a notice of violation by requesting an informal hearing as outlined in Article 1 of Chapter 9 of Division 2 of Title 3 of the California Code of Regulations.

<b>Table "A" Administrative Violation Classification Schedule</b>					
<b><i>Food and Agricultural Code</i></b>	<b><i>Title 3 California Code of Regulations</i></b>	<b><i>Description of Violation</i></b>	<b><i>Minor \$100 - \$300</i></b>	<b><i>Moderate \$301 - \$500</i></b>	<b><i>Serious \$501 - \$1000</i></b>
9210		No person shall engage in the production of animal blood or blood component			Any violation

		<p>products for retail sale <del>or</del> <b>and</b> distribution except in commercial licensed blood bank for animals licensed by the secretary or in accordance with Article 7 (commencing with Section 4920) of Chapter 11 of Division 2 of the Business and Professions Code</p>			
9222		<p>Discriminating against California veterinarians in the sale of animal blood or blood component products</p>	1 <sup>st</sup> violation	2 <sup>nd</sup> violation	3 <sup>rd</sup> violation & subsequent
9221(e)	1304.1(fe)	<p>Failure of a closed-colony blood bank to <del>follow</del> adhere to written protocols approved by submitted to the Department</p>		1 <sup>st</sup> violation	2 <sup>nd</sup> violation & subsequent

9221	1304.1(g)	<u>Failure of a closed-colony blood bank to notify the Department of any changes to the information provided in its license application within 30 days of the change</u>	1 <sup>st</sup> violation	2 <sup>nd</sup> violation	3 <sup>rd</sup> violation & subsequent
9241		<u>No person shall offer for sale or use any blood or blood component product unless it is produced in an establishment licensed by the secretary or in accordance with Article 7 (commencing with Section 4920) of Chapter 11 of Division 2 of the Business and Professions Code, or imported into the state pursuant to Section 9252 and registered</u>			Any violation

		<u>with the department in accordance with Section 9244 registered by the Department</u>			
<u>9244</u>	<u>1304.3</u>	Failure of a blood bank to notify the Department of any changes to the information provided in its product registration application within 30 days of the change	1 <sup>st</sup> violation	2 <sup>nd</sup> violation	3 <sup>rd</sup> violation & subsequent
9244(a)(5)		Failure of a blood bank to <del>follow Department approved</del> <b><u>adhere to operate in accordance with the production protocols included in the application for registration submitted to on file with the Department for blood or</u></b>		1 <sup>st</sup> violation	2 <sup>nd</sup> violation & subsequent

		<b><u>blood component products, as required by FAC section 9244, and any subsequent changes reported to the Department pursuant to 3 CCR section 1304.3</u></b>			
9244(a)(6)		Failure <b><u>of a blood bank</u></b> to use <del>approved</del> labels consistent with <u>samples included in the application for registration on file with submitted to</u> the Department for blood or blood component products, as required by FAC section 9244, and any subsequent changes reported to the Department pursuant to 3 CCR section 1304.3.	1 <sup>st</sup> violation	2 <sup>nd</sup> violation	3 <sup>rd</sup> violation & subsequent

9252, 9253, BPC 4920.6	1305.1, 1305.2, 1307. <b>31</b>	Failure to submit quarterly reports and associated fees as specified	1 <sup>st</sup> violation	2 <sup>nd</sup> violation	3 <sup>rd</sup> violation & subsequent
9266	<del>1304.1</del> 1306.1 1306.2 1306.3	Failure to comply with inspections			Any violation

Note: Authority cited: Sections 407, 9166, 9245, 9251 of Food and Agricultural Code.

Reference: Sections 9210, 9221, 9222, 9241, 9244, 9252, 9253, 9266 of Food and Agricultural Code. Section 4920.6 of Business and Professions Code. **Article 1 of Chapter 9 of Division 2 of Title 3 of the California Code of Regulations.**

Section 1309. Suspension and Revocation

(a) The Department may suspend or revoke any facility license or product registration issued under Chapter 1.5 (commencing with Section 9201) of Division 5 of the Food and Agricultural Code. In making its determination, the Department shall consider any aggravating or mitigating factors and may take such action based on any of the following grounds:

(1) ~~Repeated~~ Two or more “serious” violations, whether the same violation committed multiple times or multiple distinct violations, as defined in Section 1308(d)(1), by the registrant or licensee of any provision of Chapter 1.5 (commencing with Section 9201) of Division 5 of the Food and Agricultural Code and any regulations adopted pursuant to it or Chapter 8 of Division 2 of Title 3 of the California Code of Regulations.

(2) ~~Aiding, abetting, or permitting the any “serious” violation, or repeated violations, of any provision of Chapter 1.5 (commencing with Section 9201) of Division 5 of the Food and Agricultural Code and any regulations adopted pursuant to it or Chapter 8 of~~ Division 2 of Title 3 of the California Code of Regulations.

(3) Misrepresentation of any information provided in connection with an application for a facility license or product registration.

(4) Material alteration of records required to be maintained, or quarterly reports required to be submitted, under Chapter 1.5 of Division 5 of the Food and Agricultural Code, Article 7 of Chapter 11 of Division 2 of Business and Professions Code, or Chapter 8 of Division 2 of Title 3 of the California Code of Regulations, with the intent to deceive.

(5) Any act or omission that would have constituted grounds for the denial of a facility license or product registration application.

(6) Willful or repeated failure to pay any administrative penalties assessed by the Department.

(b) Proceedings for the suspension or revocation of a license or product registration shall be conducted as a formal hearing in accordance with the provisions of Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of Title 2 of the Government Code.

(c) The Department shall send written notice of a proposed suspension or revocation of a facility license or product registration. This notice shall include:

(1) The date the proposed suspension or revocation is issued;

(2) The reasons for the proposed suspension or revocation;

(3) The effective date of the proposed suspension or revocation;

(4) The impact of a suspension or revocation on future eligibility for registration including conditions for reinstatement, which shall be determined by the Department based on the demonstrated pattern of violations described in subsections (a)(1) through (a)(5) of this section; and

(5) The right to request a formal hearing within 30 calendar days of the date the proposed suspension or revocation was issued.

(A) A request for a formal hearing shall be submitted in writing to the California Department of Food and Agriculture, Legal Office of Hearings and Appeals, 1220 N Street, Suite 315, Sacramento, California 95814.

(d) The notice of adverse determination shall remain in effect pending the outcome of a formal hearing.

Note: Authority cited: Sections 407, 9166, 9245, 9251 of Food and Agricultural Code.

Reference: Sections 9210, 9221, 9222, 9241, 9244, 9252, 9253, 9266 of Food and Agricultural Code. Section 4920.6 of Business and Professions Code. **Sections 11500 – 11529 of Chapter 5 (commencing with Section 11500)** of Part 1 of Division 3 of Title 2 of the Government Code.

2) Amend Section 839 of Article 14, Chapter 2, Division 2, of Title 3 of the California Code of Regulations, to read as follows:

**Section 839. Administrative Penalty Schedules.**

(a) ...

<b>Table "A" Administrative Violation Classification Schedule</b>					
<b>Food &amp; Agricultural Code</b>	<b>Title 3 California Code of Regulations</b>	<b>Description of Violation</b>	<b>Minor \$100-\$300</b>	<b>Moderate \$301-\$500</b>	<b>Serious \$501-\$1000</b>
9101	[No change]	[No change]	[No change]	[No change]	[No change]
[...]	[...]	[...]	[...]	[...]	[...]
9210		No person shall engage in the production of animal blood or blood component products for retail sale or distribution except in commercial licensed blood bank for animals licensed by the secretary			Any violation
<del>9241</del> <b>9241</b>		<u>No person shall offer for sale or use any biologic unless it is manufactured pursuant to the terms of a valid license or permit issued by the US Department of Agriculture;</u> No person shall offer for sale or use any biologic unless it is manufactured pursuant to the terms of a valid license or permit issued by the US Department of Agriculture; or blood or blood component product unless it is produced in an establishment licensed by the secretary			<u>Any violation</u> Any violation
9351	[No change]	[No change]	[No change]	[No change]	[No change]
[...]	[...]	[...]	[...]	[...]	[...]

**Table "B" Administrative Violation Schedule**

<b><i>Food &amp; Agricultural Code</i></b>	<b><i>Title 3 California Code of Regulations</i></b>	<b><i>Description of Violation</i></b>	<b><i>Penalty</i></b>
10781	[No change]	[No change]	[No change]
[...]	[...]	[...]	[...]

Authority cited: Sections 9166 and 10786, Food and Agricultural Code.

Reference: Sections 9101, 9161, 9164, 9210, 9241, 9351, 9352, 9561, 9563, 9570, 9641.5(a)(1), 9641.5(a)(2), 9694, 9695, 9696, 9697, 9698, 9699, 9702, 10325, 10326, 10327, 10351, 10352, 10610, 10951, 18727 and 10781, Food and Agricultural Code.