

DEPARTMENT OF FOOD AND AGRICULTURE
TITLE 3. CALIFORNIA CODE OF REGULATIONS
NOTICE OF PROPOSED ACTION
ANIMAL BLOOD BANKS - ADMINISTRATIVE PENALTY SCHEDULES

NOTICE IS HEREBY GIVEN that the Department of Food and Agriculture (herein after referred to as the Department) proposes to adopt the regulations described below in the Informative Digest/Policy Statement Overview after considering all comments, objections, and recommendations regarding this proposal. Publication of this notice commences a 45-day public comment period.

PUBLIC HEARING

The Department has not scheduled a public hearing for this proposal. However, a public hearing will be held if the department receives a written request for a public hearing from any interested person, or his or her authorized representative, no later than 15 days before the close of the comment period.

WRITTEN COMMENT PERIOD

Any interested person, or his or her authorized representative, may submit written comments relevant to the proposed regulatory action to the Department. Comments can be submitted via email to sean.brady@cdfa.ca.gov, or mailed to the address listed below. The written comment period begins on **September 5, 2025** and closes on **October 20, 2025**. The Department is not required to respond to comments that are outside the scope of this Notice or comments that are not received or postmarked during the written comment period.

WRITTEN COMMENTS AND REQUEST FOR PUBLIC HEARING

All written comments and any request for a public hearing should be directed to the following person:

Sean Brady, DVM
Department of Food and Agriculture
Animal Health and Food Safety Services
Animal Blood Banks
1220 N Street, Sacramento, CA 95814
Telephone (916) 208-0500
Email: sean.brady@cdfa.ca.gov

AUTHORITY AND REFERENCE

Food and Agricultural Code (FAC) Section 14 authorizes the Department to adopt rules and regulations in accordance with the Administrative Procedure Act. Additional authority vested in FAC grants the Department Secretary the authority to amend or repeal rules and regulations.

FAC Section 407 authorizes the Secretary of the Department to adopt such regulations as are reasonably necessary to carry out the provisions of the FAC which the Secretary is directed or authorized to administer or enforce.

FAC Section 9166 authorizes any person who violates any provision of Division 5 (commencing with Section 9101) of the Food and Agricultural Code, and any regulations adopted pursuant to Division 5, is subject to an administrative penalty of not less than one hundred dollars (\$100) or more than one thousand dollars (\$1,000) for each violation. Each violation during any day constitutes a separate offense. Any money that is recovered under this section shall be paid into the State Treasury and shall be credited to the Department of Food and Agriculture Fund.

FAC Section 9245 authorizes the Secretary of the Department impose such conditions on the production or use of blood or blood component products as he or she deems necessary to accomplish the purposes FAC Division 5, Part 1, Chapter 1.5.

FAC Section 9251 authorizes the Secretary of the Department to adopt reasonably necessary rules and regulations for the administration and enforcement of requirements relating to commercial blood banks for animals.

INFORMATIVE DIGEST/POLICY STATEMENT OVERVIEW

The proposed regulation specifies penalty schedules for any person found to be in violation of specified statutes and regulations, following an investigation and consideration of the facts presented in each case.

Summary of Existing Laws and Effect of the Proposed Action

In 2021, Governor Gavin Newsom signed AB 1282 (Stats. 2021, Ch. 725), the California Pet Blood Bank Modernization Act (Act) into law. The goal of the Act is to address the shortage of animal blood available for veterinary transfusion medicine in California and transition the state from closed colony blood banks to community blood banks. The Act directs the Department to adopt reasonably necessary rules and regulations for administration and enforcement of these changes. On March 10, 2025, the Department adopted California Code of Regulations sections 1303-1307 to interpret and make specific the requirements for operating a commercial blood bank in California.

Objectives and Anticipated Benefits of the Proposal

The Department is proposing the adoption of Section 1308 under Article 6, of Chapter 8, Division 2, Title 3 of the California Code of Regulations, to specify penalty schedules for any person found to be in violation of specified statutes and regulations, following an investigation and consideration of the facts presented in each case. The Department is also proposing the amendment of Section 839 of Article 14, of Chapter 2, of Division 2, of Title 3 of the California code of regulations to remove previously created animal blood bank penalties from this section and place them in newly created Section 1308.

This proposal benefits the animal blood bank industry by serving to ensure that the Department has effective enforcement mechanisms in place by clearly classifying violation categories and establishing penalty schedules in regulation that applies to penalties that may be imposed for violations of specified statutes and regulations. Monetary benefits could include the potential reduction of violations as the penalty schedules may be a deterrent to potential violators of the statutes and regulations affecting the interstate and intrastate movement of animal blood and blood component products, product registration, facility licensing, infectious disease testing, quarterly reporting, all of which enable the Department to ensure animal blood products sold in California are effective, safe, and humanely produced.

Evaluation of Inconsistency/Incompatibility with Existing State Regulations

The Department has evaluated this proposal and has concluded that it is not inconsistent or incompatible with existing regulations. After conducting a review for any regulations that would relate to or affect this area, the Department has concluded that these are the only regulations concerning administrative penalties for commercial animal blood banks in California.

DISCLOSURES REGARDING THE PROPOSED ACTION

The Department has made the following initial determinations:

Mandate on local agencies and school districts: None.

Costs or savings to any state agency: None.

Costs to any local agency or school district which must be reimbursed in accordance with Government Code sections 17500 through 17630: None.

Other nondiscretionary costs/savings to local agencies: None.

Cost or savings in federal funding to the state: None.

Cost impacts on representative private persons or businesses: The Department is not aware of any cost impacts on private persons or businesses complying with the proposed

action. Any costs would result from penalties imposed following verified violations or from costs associated with appealing those penalties, including travel or legal representation.

Business Impact: The Department has determined that this proposal will not significantly impact the creation or elimination of jobs or businesses in California. It is also not expected to adversely affect the ability of California businesses to compete with those in other states. However, this regulation will affect businesses or individuals in the animal blood banking industry found in violation of applicable law or regulation.

The Anticipated Compliance Requirements as a Result of this Proposal: The proposal contains no specific record keeping, paperwork or reporting requirements. It provides clarity to the regulated public on how the Department assesses penalties for violations.

Effect on Housing Costs: None.

Small business determination: The Department's proposal may affect small businesses if an animal blood bank is found, after investigation of the facts presented in the case, to be in violation of specified statutes or regulations, and that person may also be a small business owner as defined in Government Code section 11342.610.

RESULTS OF ECONOMIC IMPACT ASSESSMENT

Impact on Jobs/New Businesses: The Department has determined that this regulatory proposal will not have any impact on the creation of jobs or businesses or the elimination of jobs or existing businesses or the expansion of businesses in California.

Persons/Businesses affected by this proposal: The Department has made an initial determination that this regulatory proposal will only affect animal blood banks or persons involved in the animal blood banking industry in California who are found, after investigation of the facts and evidence presented in each case, to have violated specified sections of the Food and Agricultural Code and any regulations implementing those Codes.

Benefits of the regulation to the health and welfare of California residents, worker safety, and the State's environment: The Department is not aware of any specific benefits this proposal will have on worker safety.

Benefits of the Proposed Action: The proposed regulation benefits donor animal health and welfare, recipient animal health, the animal blood supply, and the veterinary industry by serving to ensure violations of specified statutes and regulations will be handled according to the penalty schedules specified in this proposal. This proposal serves to ensure that any violations of existing statutes and regulations as specified in this proposal, are handled quickly and in a cost-effective manner to all parties involved, as authorized by FAC Section 9166.

Occupations/Businesses Impacted: The Department has determined that this regulatory proposal will not have any impact on the creation of jobs or businesses or the elimination of jobs or existing businesses or the expansion of businesses in California. The Department has made an initial determination that the proposed regulatory action will have no significant, statewide adverse economic impact directly affecting California businesses including the ability of California businesses to compete with businesses in other states. The Department has made an initial determination that this regulatory proposal will only impact persons or businesses involved in the animal blood banking industry in California who are found, after investigation of the facts and evidence presented in each case, to have violated specified sections of the Food and Agricultural Code and any regulations implementing those Codes.

Business Reporting Requirement: There are no new reporting requirements as a result of this proposal.

Comparable Federal Regulations: This proposal does not duplicate or conflict with federal regulations.

CONSIDERATION OF ALTERNATIVES

The Department must determine that no reasonable alternative considered, or that has otherwise been identified and brought to the attention of the Department, 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.

The Department Invites interested persons to present statements or arguments with respect to alternatives to the proposed regulations at the scheduled public hearing or during the written comment period. This proposal is necessary to establish procedures implementing administrative penalties against any person found to be in violation of specified statutes and/or regulations relating to animal blood banking.

AVAILABILITY OF INITIAL STATEMENT OF REASONS AND INFORMATION AND TEXT OF THE PROPOSAL

Copies of the exact language of the proposed regulations, and the Initial Statement of Reasons, as well as all the information upon which the proposal is based, may be obtained by contacting the persons named below or by accessing the Department's website as indicated below in this Notice. The Department will have the rulemaking file available for inspection and copying throughout the rulemaking process at its office located at 1220 N Street, Sacramento, CA 95814. As of the date this notice is published in the California Regulatory Notice Register, the rulemaking file consists of this Notice, the Proposed Text,

and the Initial Statement of Reasons. Copies may be obtained by contacting Dr. Sean Brady at the address or phone number listed below.

AVAILABILITY AND LOCATION OF THE FINAL STATEMENT OF REASONS AND RULEMAKING FILE

Upon its completion, copies of the Final Statement of Reasons may be obtained by contacting the persons named below.

AVAILABILITY OF CHANGED OR MODIFIED TEXT

After considering all timely and relevant comments received, the Department may amend the proposed regulations substantially as described in this Notice. If the Department makes modifications that are sufficiently related to the originally proposed text, it will make the modified text (with changes clearly indicated) available to the public for at least 15 days before the Department adopts the regulations as modified. Please send requests for copies of any modified regulations to the attention of Dr. Sean Brady at the address listed below. The Department will accept written comments on the modified regulations for 15 days after the date on which they are made available.

AVAILABILITY OF DOCUMENTS ON THE INTERNET

Copies of the Notice of Proposed Action, the Initial Statement of Reasons, and the text of the proposed regulations shown in strikethrough and underline format, can be accessed through the Department's website at: <http://www.cdfa.ca.gov/ahfss/regulations.html>, or by contacting the person named below in this Notice.

CONTACT PERSONS

Inquiries and any written comments concerning this proposal are to be addressed to the following:

Sean Brady, DVM
Department of Food and Agriculture
Animal Health and Food Safety Services
Animal Blood Banks
1220 N Street, Sacramento, CA 95814
Telephone (916) 208-0500
E-mail: sean.brady@cdfa.ca.gov

The backup contact person is:

Andrew Halbert
Department of Food and Agriculture

Animal Health & Food Safety Services
1220 N Street, Sacramento, CA 95814
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E-mail: andrew.halbert@cdfa.ca.gov