

DEPARTMENT OF FOOD AND AGRICULTURE

INITIAL STATEMENT OF REASONS

ANIMAL BLOOD BANKS

The California Department of Food and Agriculture (the Department) proposes to adopt 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 also proposes to amend 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.

PROBLEM STATEMENT

Pursuant to Government Code Section 11425.50(e), a penalty may not be based on a guideline, criterion, bulletin, manual, instruction, order, or standard of general application unless it has been adopted as a regulation. The Department's Animal Blood Banks program has no specified criteria placed in regulation on how the Department may assess any penalties for violations of its statutes and regulations for animal blood banking following an investigation of the evidence and facts presented in each case.

PURPOSE

This proposal will enhance the ability of the Department to carry out administrative enforcement in a consistent manner by providing a standard and systematic approach to the assessment of administrative penalties. This approach is based on the violation and the potential harm to donor animal health and welfare, recipient animal health and welfare, risk to public health, risk to the animal blood supply, and cooperation of the violator. Therefore, the Department is proposing to adopt regulations specifying violation categories, a range of fines that may be assessed to establish administrative penalty schedules in accordance with Food and Agricultural Code section 9166.

BENEFITS OF THIS REGULATORY PROPOSAL

This proposal benefits commercial blood banks for animals, veterinarians, and the public by ensuring that the Department has effective enforcement mechanisms in place, clearly classifying violation categories and establishing penalty schedules in regulation that apply to penalties imposed for violations of specified statutes and regulations. Monetary benefits could include the potential reduction of violations, as the penalty schedules may deter potential violators of the statutes and regulations governing the operation of a commercial

blood bank for animals, which enables the Department to ensure animal blood and blood component products sold in California are efficacious, safe, and humanely produced. An example of a nonmonetary benefit would be public confidence that animal blood donors are being treated humanely.

SPECIFIC PURPOSE AND RATIONALE FOR EACH SECTION, PER GOVERNMENT CODE 11346.2(b)(1):

Add proposed new Article 6. Enforcement Procedures to specify the contents of the article.

Section 1308. Administrative Penalty Schedules, is the heading that describes the contents of the new section.

Subsection (a) is needed to inform the regulated public that the Department may impose a fine of not less than one hundred dollars (\$100) or more than one thousand dollars (\$1,000) for each violation of statutes and regulations adopted pursuant to Division 5 of the Food and Agricultural Code relating to animal blood banks. This section also lists the Food and Agricultural Code section that authorizes the Department to levy a fine against a person or blood bank if they violate those sections of law, relating to the regulations for animal blood banking. The fine range is consistent with Food and Agricultural Code section 9166.

Subsection (b) provides clarity to the regulated public by explaining how a penalty amount will be determined for the violation categories.

Subsection (c) provides clarity to the regulated public by explaining the terms used to describe categories of violations, explaining that violations range in severity from serious, moderate, to minor. Subsection (c) also explains the escalation of a violation class due to repeat violations and specifies the applicable revolving term period for violations.

Subsection (d) references Table “A”, the Administrative Violation Classification Schedule. The table is included in this regulation section and will be printed in Title 3 of the California Code of Regulations. The table indicates the range of penalties for each of the cited sections from the Food and Agricultural Code and/or Title 3 of the California Code of Regulations. There are no new penalty provisions being adopted into the table. The table simply cites excerpts from specified statutes and regulations, and places them in table format. The penalties range from \$100 to \$1,000. After determination and a review of the facts and evidence presented in each case, a penalty will be assessed to the alleged violators according to the penalty schedule. The penalty schedule provides the public with clear information on how the Department will cite and fine persons and producers, and what it considers to be serious, moderate, or minor offenses, as specified.

Subsections (d)(1), (2) and (3) provide the public with an explanation and definitions of what the Department considers to be serious, moderate, and minor violations of its statutes and regulations. It will depend upon the extent of the threat 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, and the level of potential harm as indicated by the circumstances and facts of each case.

The Department believes that these penalty provisions will enhance its ability to carry out administrative enforcement in a consistent manner by providing a standard and systematic approach to the assessment of administrative penalties.

Section (e) and Subsection (e)(1), (2), (3), (4) provide the public with the factors that the Department uses in determining the penalty amount within the serious, moderate, and minor ranges. The Department will also consider aggravating and mitigating factors. The categories that determine the penalty amount are the following: Risk to Donor Animal Health and Welfare, Risk to Recipient Animal Health, Risk to Animal Blood Supply, and Cooperation of the Violator.

When evaluating a risk to donor animal health and welfare, the Department will take into consideration the degree and magnitude of the activity that negatively impacts donor animals.

When evaluating a risk to recipient animal health, the Department will take into consideration the degree and magnitude of the activity that negatively impacts animals receiving blood or blood component products or leads to the spread of disease.

When evaluating a risk to the animal blood supply, the Department will take into consideration the degree and magnitude of the activity that negatively impacts the blood supply efficacy or leads to illness.

When evaluating the cooperation of the violator, the Department will consider whether the violator is recalcitrant or takes proactive steps to immediately correct the actions that are outside of the law.

The final determination of the penalty will be evaluated using these four categories and judged on a totality of the circumstances.

Section (f) specifies the acceptable time period for payment of assessed penalties.

Section (g) clarifies that respondents may contest a notice of violation.

Section 1309. Suspension and Revocation is the heading that describes the contents of the new section.

Subsection (a) and Subsections (a)(1) – (6) provide the public with factors that the Department uses when making the decision to suspend or revoke a facility license or product registration. The inclusion of these grounds in regulation is essential to ensure the Department can uphold compliance and maintain the integrity of its licensing and registration programs.

Repeated serious violations of applicable laws and regulations demonstrate a pattern of non-compliance that necessitates enforcement action.

Entities that aid, abet, or permit violations contribute to a breakdown in regulatory oversight and must be held accountable.

Misrepresentation of information during the application process undermines the Department's ability to assess whether an applicant meets the required standards.

Altering records or reports with the intent to deceive compromises transparency and obstructs effective oversight. When a licensee or registrant engages in conduct that would have warranted denial of their original application, continued licensure or registration is no longer appropriate.

Failure to pay administrative penalties reflects a lack of accountability and diminishes the enforcement authority of the Department.

Subsection (b) specifies that hearings regarding the suspension or revocation of a license or product registration shall be conducted as a formal hearing.

Section 839, Table "A," is amended to remove the two violations related to animal blood banking and relocate them to Table "A" in newly created Section 1308. This change is intended to improve clarity and ensure regulatory consistency by consolidating all animal blood banking-related violations within a single, dedicated section.

TECHNICAL, THEORETICAL, AND EMPIRICAL STUDY, REPORT, OR SIMILAR DOCUMENT

No technical, theoretical or empirical study, report, or similar document was used in the formulation of this proposal.

SPECIFIC TECHNOLOGIES OR EQUIPMENT

This regulation does not mandate the use of specific technologies or equipment.

ECONOMIC IMPACT ASSESSMENT

Business Impact

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 impact producers or persons involved in animal blood banking 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.

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

The Department is not aware of any cost impacts that a representative, private person or business would necessarily incur in reasonable compliance with the proposed action. Any costs imposed would be incurred by a person who was found to be in violation of specified statutes and regulations, after investigation of the facts presented, and a penalty would be imposed as specified in the penalty schedules included in this proposal. There would also be costs to a person wishing to appeal the penalty and violation imposed by the Department, including travel to the hearing location and legal counsel if they choose to hire representation.

The above-noted determinations are based on the fact that this proposal is necessary to establish procedures for the implementation of administrative penalties against any person found to be in violation of specified statutes and/or regulations relating to animal blood banking in accordance with Food and Agricultural Code Sections 9166.

Persons/Businesses affected by this proposal:

The Department has made an initial determination that this regulatory proposal will only affect producers or persons involved in animal blood banking industries 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.

Anticipated compliance requirements for persons or businesses are as follows:

- This regulation imposes no costs or fees upon the regulated public. Any fees incurred would be upon persons where a penalty was imposed according to the penalty schedules as specified in this proposal. If they wish to appeal the Department's decision, they will bear the burden of their own costs including transportation and legal costs, if any.
- No paperwork, reporting, or record keeping requirements are imposed by this proposal.

Economic Impact Assessment Conclusion

The Department has made an initial determination that the proposed regulatory action will not have any significant, statewide adverse economic impact directly affecting businesses, including the ability of California businesses to compete with businesses in other states by making it more costly to produce goods or services, and that it will not create or eliminate jobs or occupations. The proposal does not affect the creation of new businesses or the elimination of existing businesses within the State of California and does not affect the expansion of businesses currently doing business within the State of California. The proposed regulation benefits donor animal health and welfare, recipient animal health, the animal blood supply, and the veterinary industry by serving to ensure producer compliance with statutes and regulations relating to animal blood banking in California. This proposal is necessary to establish procedures for the implementation of administrative penalties against any person found to be in violation of specified statutes and/or regulations relating to animal blood banking, including the adoption of penalty schedules, in accordance with Section 9166 of the Food and Agricultural Code.

Alternatives Determination

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, or 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. This proposal is necessary to establish procedures for the implementation of administrative penalties against any person found to be in violation of specified statutes and/or regulations relating to commercial animal blood banks.

DUPLICATION OR CONFLICT WITH FEDERAL REGULATIONS

This proposal does not duplicate or conflict with federal regulations.