DEPARTMENT OF FOOD AND AGRICULTURE
ANIMAL BLOOD BANKS
FINAL STATEMENT OF REASONS

Hearing Date

No hearing was scheduled by the Department of Food and Agriculture (Department) or requested by the public regarding this proposal.

Update of Initial Statement of Reasons

The Department published an initial 15-day notice of modified text and documents added to the rulemaking file which included an Addendum to the Initial Statement of Reasons to provide further justification and clarification of the modified text and the documents added to the rulemaking file. A subsequent second 15-day notice of modified text was published to further modify the text. The initial and second modifications to the text are described below.

Extension to the 45-Day Public Comment Period

The Department received a request to extend the 45-day public comment period ending March 18, 2024, to April 1, 2024. The Department accepted the comment and published a notice of the extension to the comment period.

The text was modified and noticed to the public along with documents added to the rulemaking file for a 15-day comment period beginning June 6, 2024, and ending June 20, 2024:

Section 1303(i)(2) struck the phrase “or caregiver” from the definition of “community sourced animal” because of concerns regarding a person other than the owner bringing the animal blood donor to the blood bank.

Section 1304.1(c) struck the subsection to reduce the record keeping burden. Obtaining the “name and address of the person(s) who oversee properties, establishments, or institutions that keep, house, or maintain animal blood donors used by the closed-colony blood bank” is not necessary as the closed-colony blood bank licensee is responsible for the care of animal blood donors.

Section 1304.1(e) revised the text to specify the “addresses of properties, establishments, or institutions that keep, house, or maintain animal blood donors used by the closed-colony blood bank” instead of “a full description of properties, establishments, or institutions that keep, house, or maintain animal blood donors used by the closed-colony blood bank”. This change is in response to a stakeholder comment that obtaining and submitting a full description for all vendors would be overly burdensome.

Section 1304.2(d) struck the entire section to avoid any confusion on when the Department will discontinue the closed-colony licensing program.

Section 1304.3 struck the entire section due to stakeholder concerns regarding additional facility licensing and because it is unnecessary since section 1306.1 specifies the Department will inspect all commercial blood banks with products registered with the Department. This removal requires renumbering of the remaining sections in Article 2.

Section 1305.1(a)(2) struck the entire subsection regarding quarterly reporting because the proposal to include additional products in quarterly reports specified in section 1304.2(d)(1)-(4) has been revised. Removal of this subsection requires renumbering of the remaining subsections in 1305.1(a).

Section 1305.1(c) struck "the animal left the blood donor program for any reason including" and "natural death" from the definition of "disposition". Added "or other purpose" to have the definition of "disposition" have the same meaning as defined in Food and Agricultural Code Section 9253(d).

Section 1305.1(c)(4) added a new subsection to specify that disposition records shall include the date of the animal's disposition. This ensures that the Department has information vital to animal welfare investigations.

Section 1306.4(a) is updated to reflect the February 2024 California Consumer Price Index values. The following formula was used in this calculation:

California (All Urban Consumers) February 2022 Index Value: 311.048
California (All Urban Consumers) February 2024 Index Value: 338.496
338.496 / 311.048 = 1.088
1.088 * $1000 = $1088

Section 1306.4(b) is updated to reflect the February 2024 California Consumer Price Index values. The following formula was used in this calculation:

California (All Urban Consumers) February 2022 Index Value: 311.048
California (All Urban Consumers) February 2024 Index Value: 338.496
338.496 / 311.048 = 1.088
1.088 * $500 = $544

<u>Documents added to the rulemaking file and noticed to the public for a 15-day comment period beginning June 6, 2024, and ending June 20, 2024:</u>

February 2024 California Consumer Price Index (CPI): The fees in the proposed regulatory text were based on a prior year's calculations. Therefore, the Department added the February 2024 CPI to the rulemaking file as a basis for the increased fee amounts. The CPI is the most widely used measure of inflation, closely followed by policymakers, financial markets, businesses, and consumers.

Animal Blood Bank Program Expenses and Revenue 2024/25: The Department also updated its expenses and revenue data calculations based on the February 2024 CPI. The Department is ensuring that the program is funded by licensees and registrants and to ensure compliance with statutes and regulations.

Economic and Fiscal Impact Statement (STD 399): The Department is updating and clarifying the fiscal data to reflect initial and ongoing costs to businesses, and update the total number of businesses affected by this proposal at this time. At the time that the initial form was filled out there were only 2 commercial blood banks registered with the Department. There have been an additional 3 registered blood banks. The Department anticipates that there will be 4 commercial blood banks selling blood and blood component products in California in FY 2024/25. The Department plans on collecting fees one quarter after the approval of the regulation. The earliest would be Q1 of FY 2024/25 but most likely it will be Q2 of FY 2024/25.

The text was modified and noticed to the public for a second 15-day comment period beginning July 1, 2024, and ending July 15, 2024:

Section 1304.1(d)-(g) re-lettered to correct typos in the first modified proposed text.

Section 1306.3, struck “licensed” and added “with products registered” to clarify that all blood banks with product registered with the Department shall pay the proposed fee.

Section 1306.4, corrected the Food and “Agriculture” Code to read Food and “Agricultural” Code as that is the correct title of the Code.

Section 1306.4(a) struck “fifty-four” and added “eighty-eight” to have the text correctly reflect the listed numerical value for the fee.

Section 1306.4(b) struck “twenty-seven” and added “forty-four” to have the text correctly reflect the listed numerical value for the fee.

The text was modified and noticed to the public for a second 15-day comment period beginning December 20, 2024, and ending January 6, 2025:

§ 1303 (c) added definition for “best clinical practice” to provide clarity to the use of the term.

§ 1303 (d-m) re-lettered because of the addition of § 1303 (c).

§ 1303(h) amended definition of “commercial blood banks for animals” to clarify what types of facilities are included in the definition.

§ 1303 (n) added definition for “standards of care” to provide clarity to the use of the term.

§ 1304.1 (e)(6) revised to specify the sections of the Code of Federal regulations that contain husbandry standards for dogs and cats.

§ 1305.2 revised to include the specific mailing address and e-mail address for submitting quarterly reports.

Article 4 amended title to clarify that this article only provides information on inspections.

§ 1306.1 struck “the product safety standards and” from the section for clarity. Compliance with protocols required by Section 9244(a) of the Food and Agricultural Code will ensure product safety standards.

§ 1306.5 renumbered to 1306.3 and amended to provide clarity on when the Department will investigate commercial blood banks.

Article 5 added and titled to specify the contents of the article.

§ 1306.3 moved to Article 5 and renumbered to 1307.1. Title and text amended to provide clarity on the type of fee being paid. Specified that the fee shall be adjusted annually for inflation.

§ 1306.4 moved to Article 5 and renumbered to 1307.2. Revised and added subsections to specify how annual inflation adjustments will be calculated.

Extension to the 15-Day Public Comment Period

The Department received a request to extend the 15-day public comment period ending January 6, 2025, to January 16, 2025. The Department accepted the comment and published a notice of the extension to the comment period.

Nonsubstantive changes were made to the regulation text following the close of third 15-day notice comment period ending January 16, 2025:

§ 1303 (h) amended the definition for “commercial blood bank for animals” in response to stakeholder feedback. The updated definition is now consistent with the meaning established in Food and Agricultural Code Section 9201(g).

§ 1304.1, 1304.2, and 1305.1, capitalized the word “Secretary” for accuracy purposes to mean the Secretary of the Department.

§ 1307.1, Spelled out the numerical amount for consistency purposes of five cents, added parenthesis and the word ‘milliliters’ was corrected to ‘milliliter’.

Mandate on Local Agencies or School Districts

The Department has determined that the proposed regulatory action would not impose a mandate on local agencies or school districts.

Economic Impact on Small Businesses

The Department has received a proposed alternative from the public which would lessen any adverse economic impact to small businesses. The Department published a 15-day notice of modified text and documents added to the rulemaking file which addressed record keeping and licensing requirements to lessen burdens to small businesses.

Summary and Response to Written Comments Received During the 45-Day Public Comment period ending March 18, 2024.

Comment Number 1

The California Veterinary Medical Association (CVMA), through its Director of Regulatory Affairs, Grant Miller, DVM, offered the following comments summarized as follows:

Comment 1.1: Submitter writes in support of "Alternative 1" for the trigger that will initiate the discontinuation of closed-colony blood bank license issuance by CDFA.

Response: The Department thanks the CVMA for their support of proposed Alternative 1 for determining the trigger that will initiate the discontinuation of closed-colony blood bank license issuance by CDFA.

Comment 1.2: Submitter writes in support of "Alternative 1" for fees to support Department oversight of blood products registered with the Department and believes that "Alternative 2" would be unattainable and likely pose a deterrent to veterinary practices that wish to enter the animal blood banking industry.

Response: The Department thanks the CVMA for their support of proposed Alternative 1 for fees to support Department oversight of blood products registered with the Department.

Comment Number 2

The San Francisco Society for the Prevention of Cruelty to Animals (SF SPCA), through their Animal Welfare Advocacy Counsel Representative, Barbara Schmitz, offered the following comments summarized as follows:

Comment 2.1: Submitter proposes that under new Section 1305.1 relating to closed-colony blood bank quarterly reporting, adding a new subsection (4) to subsection (c) to also require that disposition records include the date of disposition of the colony animal.

Response: The Department has considered and accepted this comment. Subsection (4) was added to subsection (c) of section 1305.1 of the proposed regulation. The Department agrees that disposition records should include the date of disposition of the donor animal and specifying this in the proposed regulations clarifies this requirement.

Comment 2.2: The submitter writes "The SF SPCA appreciates the thorough and detailed proposed regulations. We are hopeful that with the adoption of these regulations, California will be in a good position to achieve the goals of the Act and end the use of closed-colony blood banks for veterinary transfusion medicine."

Response: The Department thanks the SF SPCA for their support of the proposed regulations.

Comment Number 3

Jeremy A. Meier of Greenberg Traurig, LLP, counsel to Animal Blood Bank Inc. (ABB), made the following comment summarized as follows:

Submitter requests the Department extend the public comment period for an additional 14 days.

Response: The Department considered this comment and granted this request by extending the initial 45-day comment period by an additional 14 days. The Department published a Notice of Extension of the Public Comment Period.

Summary and Response to Written Comments Received during the 14-day extension to the original comment period ending April 1, 2024.

Comment Number 4

Jeremy A. Meier of Greenberg Traurig, LLP, counsel to Animal Blood Bank Inc. (ABB), made the following comments summarized as follows:

Comment 4.1: Creation of a New License Category for Animal Blood "Processing, Distribution, and Resale" Facilities Exceeds the Act's Requirements.

The submitter writes "The Department lacks authority to create a newly defined and licensable category of blood bank, especially when the Legislature has declined to do so. Section 1303(g) of the proposed regulations defines a "commercial blood bank for animals" to include "facilities that obtain blood or blood component products for additional processing, distribution, and resale." In combination with section 1304.3, the proposed regulations purport to require such "processing, distribution, and resale" facilities to obtain a license from the Department. To do so would exceed the Department's statutory authority. A.B. 1282 codifies the definition of a "commercial blood bank for animals," and nowhere in that definition is there any mention of facilities that process, distribute, or resell animal blood or blood component product. The Department's regulations should not allow licensing of this new category of processors, distributors, or resellers of animal blood or blood component products."

The submitter also writes "Note too that section 9212.5(c) allows/requires closed-colony blood banks to convert to community blood banks if they continue operations after the statutory trigger is met. It makes no sense that CDFA would license a "processor" now and then that processor would have to convert to a community-based license later." Additionally, the submitter writes "And section 9212.5(b) imposes a moratorium on CDFA issuing of any new licenses for commercial blood banks for animals that produce canine blood or blood component products sourced from closed-colony dogs. So, it is entirely inconsistent for the Department to create a new category of licensees (as the proposed regulation does) while it has no authority to issue new canine blood bank licenses at all. There is no authority in the Act for this new category of licensee, it will not work in practice, and it is inconsistent with existing law. CDFA has no authority to create a new license category. The Act speaks only about closed-colony (for banks that rely on closed-colony animals for production) and community (for banks that rely on community-based animals) blood bank licenses. Closed-colony licenses are issued by CDFA under the Act while community licenses are issued by the Veterinary Medical Board ("VMB") under the Business and Professions Code. This is also inconsistent with section 9212.5(c) (regarding a "producer license").

The Submitter recommends the Department modify section 1303(g) of the proposed regulations to state that "'Commercial blood bank for animals' means an establishment that produces animal blood or blood component products from closed-colony or community-sourced animals to market and sell for use in the cure, mitigation, treatment, or prevention of injury or disease in animals."

Response: The Department has considered this comment and partially accepted and incorporated it into the proposed regulations. Struck section 1304.3 "Additional Facility Licensing" from the proposed regulation due to stakeholder concerns and to avoid confusion in the marketplace. Section 1303(g) definition of "commercial blood bank for animals" remains unchanged. As stated in the initial statement of reasons, it is important to specify that facilities that obtain blood or blood components for additional processing, distribution, and resale are considered "commercial blood banks" as they are engaging in the "production" of blood or blood component products, as defined in proposed regulation section 1303(k), Food and Agricultural Code (FAC) section 9201(j), and BPC 4920(h). By

specifying that they are considered commercial blood banks, it clarifies that they need to register the blood and blood component products that they intend to sell.

Comment 4.2: The proposed regulations are inconsistent with California law and require applicants for license to submit information not contemplated by AB 1282.

Comment 4.2.1: The submitter writes "A.B. 1282 amended Food & Agriculture Code section 9221, which governs the application requirements for establishments producing animal blood and blood component products from a closed-colony blood bank. It describes the specific pieces of information that such establishments must provide to obtain a license. Cal. Food & Agric. Code § 9221(a)–(f). The proposed licensing regulations purport to modify those application requirements in ways never contemplated by the Legislature. The Department should withdraw them and make any licensing requirements consistent with A.B. 1282. Section 1304.1(c) of the proposed regulations purports to require applicants to submit "The name and address of the person(s) who oversee properties, establishments, or institutions that keep, house, or maintain animal blood donors used by the closed-colony blood bank." This is a substantial departure from the statute: the analogous provision in A.B. 1282 requires an applicant to submit only "The name and address of the person who shall oversee the production of animal blood and blood component products." Cal. Food & Agric. Code § 9221(b). As applied to ABB, A.B. 1282 therefore requires that ABB's license application include the name and address of its owner. By contrast, the proposed regulations would require ABB to submit a much broader array of information. Specifically, they would require ABB to provide the names and addresses of every person who oversees any of ABB's vendors. The Legislature has been consistent in the last 25 years regarding required licensee information and not from vendors.

Response: The Department has considered and accepted this comment. Struck subsection 1304.1(c) to reduce record keeping burden. Obtaining the "name and address of the person(s) who oversee properties, establishments, or institutions that keep, house, or maintain animal blood donors used by the closed-colony blood bank" is not necessary as the closed-colony blood bank licensee is ultimately responsible for the care of animal blood donors.

Comment 4.2.2:

The submitter writes "Even more significantly, subsection (e) of the same proposed regulation would require ABB to submit "A full description of the building, including its address, facilities, equipment, and apparatus, to be used in the production of animal blood and blood component products. This shall include full descriptions of properties, establishments, or institutions that keep, house, or maintain animal blood donors used by the closed-colony blood bank." In essence, the proposed regulations would require ABB to turn over complete schematics of every vendor with which ABB does business. There is no statutory provision requiring such intrusive disclosures. The regulations must provide for maintenance of owners' and donors' confidentiality as required by the California Information Privacy Act (California Civil Code §§ 1798-1798.78) which expands State Constitutional privacy guarantees. The Department cannot collect information it does not need, including personal information. The Department's only argument is that such disclosure "will help the Department ensure all closed-colony blood donors are being adequately cared for and treated humanely." But there is no evidence that this is a problem that needs remedying. ABB and its vendors are already subject to extensive compliance requirements to ensure animal husbandry and product quality. The licensing information application regulations would impose a significant regulatory burden on ABB out of all proportion to the purported benefits the Department hopes to achieve."

Response: The Department has considered and partially accepted this comment. Subsection 1304.1(e) revised text to specify that the "addresses of properties, establishments, or institutions that keep, house, or maintain animal blood donors used by the closed-colony blood bank" instead of "a

full description of properties, establishments, or institutions that keep, house, or maintain animal blood donors used by the closed-colony blood bank". Having the addresses where animal blood donors are housed is important in fulfilling the Departments oversight of animal blood banks and is not overly burdensome to licensees.

Comment 4.2.3: The submitter writes that the proposed regulations would alter and expand quarterly reporting requirements in section 1305.1(a)(2)-(4) and 1305.1(c).

The submitter writes "These quarterly reporting regulations would require providing information including disposition, names and addresses and numbers inconsistent with and not called for under A.B. 1282. The intent of 1282 was to expand the blood supply by allowing for the licensing of community blood banks by the VMB while continuing CDFA licensing of colony blood banks. And the Legislature took care to protect the privacy of both colony and community bank information to ensure their privacy under the PRA. The additional information that is being required in these regulations undermines that legislative intent. The recent PRA litigation findings in Sacramento Superior Court supports continued protections and limits on disclosure of vendor and other non-licensee information. And as seen with the demise of the other blood bank, these reporting requirements will only add another layer of unnecessary burden on the only remaining blood bank.

Response: No changes have been made in response to this comment. Section 1305.1(a)(2) has been struck because the proposal to include additional products in quarterly reports specified in section 1304.2(d)(1)-(4) has been revised (see response to comment 4.5)

FAC section 9253(b)(2) requires that closed-colony blood banks licensed by the Department submit quarterly reports that include "the number of animals kept, housed, or maintained at the closed-colony blood bank, by species of animal". This clearly indicates the legislature felt it important that closed-colony blood banks report on the number of animals donating blood. Section 1305.1(a)(3) of the proposed regulation clarifies that each facility that houses animal blood donors must be included in quarterly reports as this is necessary for monitoring the source of animal blood and blood component products.

FAC section 9253(b)(3) requires that closed-colony blood banks licensed by the Department submit quarterly reports that include "The disposition records of any animals and the total number of animals released for adoption". This clearly indicates that the legislature felt it important that closed-colony blood banks provide disposition records for animals donating blood. Section 1305.1(a)(4) of the proposed regulation clarifies that each facility that houses animal blood donors must be included in quarterly reports as this is necessary to monitor the outcomes of blood donor animals, which is vital to assessing donor health and welfare.

Comment 4.3: The Department Cannot Lawfully Modify the Statutory Definition of "Disposition."

The submitter writes "section 1305.1(c) of the proposed regulations redefines that term to include instances when "the animal left the blood donor program for any reason," as well as the animal's "natural death." Here, again, the proposed regulation exceeds the Department's statutory authorization. The Department should modify the proposed regulation to make the regulatory definition consistent with the statute.

The submitter also writes "It is unclear why this departure from the statutory text is necessary, as the Department's Initial Statement of Reasons provides no policy justification. It states only that this provision "is proposed to clarify that disposition includes natural death and removal from the donor pool for any reason, in addition to the criteria listed in Food & Ag. Code section 9253(d)." Not so. This regulation does not "clarify" the statutory definition at all, rather it wholly rewrites it to encompass

new activities referenced nowhere in A.B. 1282. Particularly in the absence of any cognizable policy basis, there is no reason to do so."

Response: The Department has considered and accepted this comment. struck "the animal left the blood donor program for any reason including" and "natural death" from the definition of "disposition". Added "or other purpose" to have the definition of "disposition" have the same meaning as defined in FAC Section 9253(d).

Comment 4.4: Modification of the statutory definition of "Community Sourced" Animal is Improper.

The submitter writes "Business and Professions Code section 4920(f) defines a "community blood bank" to mean a commercial blood bank for animals that produces animal blood or blood component products solely from "community-sourced animals" whose owners voluntarily consent to the donation. In turn, subsection (g) contains a three-part definition of a "community sourced" animal. Relevant here, subsection (g)(2) requires that a "community sourced" animal must be "[b]rought by its owner to a community blood bank for animals to have its blood collected." Cal. Bus & Prof. Code § 4920(g)(2) (emphasis added). Section 1303(i)(2) purports to broaden that definition by permitting a "caregiver" to bring the animal to a community blood bank, a word that is not defined nor even appears anywhere in the Food and Agriculture Code. This proposed regulation is improper because the power to alter statutory provisions rests with the Legislature, not the Department.

The Department's Initial Statement of Reasons does not identify any legal authority for modifying the statutory definition of "community sourced" in this manner. The Department's justification is entirely prudential, noting merely that "It is common in the pet industry for someone other than the owner to bring an animal to a veterinary premises." Perhaps, but the Department is not permitted to override the plain statutory text simply because that text is contrary to the supposed prevailing practice in the industry.

There are also sound policy reasons for adhering to the Legislature's definition of a "community sourced" animal. These animals are brought to blood banks to have blood drawn, a procedure which necessarily carries some risk of complications. If the animal suffers an adverse event or requires further medical treatment, any onsite veterinarian will need the owner's permission to perform those procedures. See, Cal. Food & Agric. Code § 9201(a); Cal. Bus. & Prof. Code §4920(a) et seq. If the owner is absent and unable to provide informed consent, the animal's life may at risk due to the veterinarian's inability to provide treatment.

Response: The Department has considered and accepted this comment. The definition for "community sourced animal" was amended by striking **"**or caregiver" from section 1303(i)2 of the proposed regulations.

Comment 4.5: The proposed modification to the statutory formula for Calculating "Canine Blood" production is inconsistent with the act.

The submitter writes "The Legislature defined "canine blood" to mean "whole blood, packed red blood cells, and fresh frozen plasma." The proposed regulations reject that definition and instead assert that "canine blood" calculations may also include "additional blood component products." The Legislature did not delegate authority to the Department to modify this definition. Accordingly, this proposed regulation should be modified to adhere to the statutory text.

The Legislature built specific benchmarks into A.B. 1282 to ensure a sufficient supply of animal blood supplies. Before discontinuing its licensing program for commercial blood banks for animals that produce canine blood and blood component products sourced from closed-colony dogs, the

Secretary must first find that "community blood banks sold an annual amount of canine blood in California that equals or exceeds the annual amount closed-colony blood banks sold in four consecutive quarters[.]" Cal. Food & Agric. Code § 9212.5(a)(1)(B) (emphasis added).

As noted above, "canine blood" means "whole blood, packed red blood cells, and fresh frozen plasma." It does not include other products, such as platelet concentrate, cryoprecipitate, cryosupernatant, and albumin. Some (though not all) of these products fall within the definition of "blood and blood component products," a separate defined term appearing elsewhere in A.B. 1282. See Cal. Bus. & Prof. Code § 4920(b).

The Legislature elected to measure the adequacy of the state's animal blood supply with respect to "canine blood." If it had intended to include a wider array of products in that measurement, it would have used a different term. The policy-based arguments offered in the Department's Initial Statement of Reasons may be well-meaning, but it is not the province of the Department to substitute its own judgment for that of the Legislature.

The Department should strike section 1304.2(d) of the proposed regulations and issue new regulations that adhere to the statutory methodology for calculating canine blood found in Food & Agriculture Code section 9212.5(a)."

Response: The Department has considered and accepted this comment by striking section 1304.2(d) of the proposed regulation. Removal of the section will avoid any confusion as to when the Department will discontinue the closed-colony licensing program. With this revision, section 1305.1(a)(2) is no longer applicable and was struck from the proposed regulation.

Comment 4.6: ABB agrees with the Department's proposed Alternative 1 regarding the trigger language.

Response: The Department thanks the ABB for their support of proposed Alternative 1 for determining the trigger that will initiate the discontinuation of closed-colony blood bank license issuance by CDFA.

Summary and Response to Written Comments Received During the initial 15-Day Public Comment period ending June 20, 2024.

The modified text and documents added to the rulemaking file were made available to the public for comment from June 6, 2024 to June 20, 2024. A total of one e-mail was received during the comment period.

Comment Number 5

Jeremy A. Meier of Greenberg Traurig, LLP, counsel to Animal Blood Bank Inc. (ABB), made the following comments summarized as follows:

ABB remains concerned that the requirements under Section 1304.1 (Closed-Colony Facility Licensing") remain overbroad and unduly burdensome. The Department is still requiring a "full description of the building, including its address, facilities, equipment, and apparatus, to be used in the production of animal blood and blood component products" in the first sentence in 1304.1(e). And while the second sentence of 1304.1(e) has been modified to delete the requirement for disclosing "full descriptions" of properties, establishments, or institutions that keep, house, or maintain animal blood donors used by the closed-colony blood bank to instead now require

disclosure of “the addresses” of properties, establishments, or institutions that keep, house, or maintain animal blood donors used by the closed-colony blood bank, this section remains unduly burdensome and overly intrusive.

Further, the “address[es]” disclosure requirement added to 1304.1(e) is inconsistent with Assembly Bill 1282 (Chapter 752. Statutes of 2021) otherwise known as the California Pet Blood Bank Modernization Act (the “Act’). The Department’s modification in 1304.1(e) goes beyond the requirements of the Act and is inconsistent with the judicial rulings in the recent 2023 Sacramento County Superior Court Public Records Act litigation involving ABB and the CDFA (in particular, concerning the confidentiality of information related to third-party vendors’ facilities).

There is no authority for the Department to add the language cited in 1304.1(e). ABB looks forward to final proposed language consistent with the law and its Comments.

Response: No changes have been made in response to this comment. Food and Agricultural Code Section 9221(d) requires applicants submit “A full description of the building, including it’s address, facilities, equipment, and apparatus, to be used in the production of animal blood and blood component products.” Section 1304.1(e) of the proposed regulation clarifies that this must include the addresses of properties, establishments, or institutions that keep, house, or maintain animal blood donors used by the closed-colony blood bank. Having these addresses is necessary for the Department to carry out inspections required by Food and Agricultural Code Section 9266. Additionally, this information is vital to ensuring that closed-colony blood donors are being adequately cared for and treated humanely.

Summary and Response to Written Comments Received During the second 15-Day Public Comment period ending July 15, 2024.

The second modified text was made available to the public for comment from July 1, 2024 to July 15, 2024. No comments were received regarding the second modified text.

Summary and Response to Written Comments Received During the third 15-Day Public Comment period ending January 6, 2025.

The third modified text was made available to the public for comment from December 20, 2024 to January 6, 2025. A total of four letters, telephone calls, or e-mails were received during the comment period.

Comment Number 6

The California Veterinary Medical Association (CVMA), through its Director of Regulatory Affairs, Grant Miller, DVM made the following comment summarized as follows:

Submitter requests the Department extend the public comment period for an additional 10 days.

Response: The Department considered this comment and granted this request by extending the initial 15-day comment period by an additional 10 days. The Department published a Notice of Extension of the Public Comment Period.

Comment Number 7

Steve Epstein, Director of the Blood Bank and Transfusion Medicine Service at the University of California, Davis School of Veterinary Medicine, made the following comments summarized as follows:

Comment 7.1: In the new text, under section 1307.1 it states that with this modification we would not be paying an additional registration fee of $0.05 per milliliter. There is no justification listed for why this change occurred. I think it would be much easier to just increase the registration fee than add this per milliliter tax paid quarterly.

Response: The Department directed the commentor to the initial statement of reasons, which provide justification for the fee and discussion of alternatives that were considered, which included increasing the registration fee.

The commentor followed up an additional comment.

Comment 7.2: Thanks for sending this. I would definitely rather pay 5 cents/ milliliter rather than a $5,000 per product license fee if those are the two options.

Response: The Department thanks the commentor for their support of the proposed fee structure.

Comment 8

Jeremy A. Meier of Greenberg Traurig, LLP, legal counsel for Animal Blood Bank Inc. (ABB), made the following comments summarized as follows:

How does the Department intend to apply its added new definitional language in revised 1303(h) to Colony Blood Banks and, specifically, to Animal Blood Bank? The language as it stands could be interpreted to reflect that contract facilities and organizations providing blood or blood products, for further processing, to Animal Blood Bank would now be required to be independently licensed by the Department.

Response: The Department considered this comment and has revised Section 1303(h). The updated definition is now consistent with the meaning established in Food and Agricultural Code Section 9201(g).

Summary and Response to Written Comments Received during the 10-day extension to the original comment period ending January 16, 2025.

Comment Number 9

Jeremy A. Meier of Greenberg Traurig, LLP, legal counsel for Animal Blood Bank Inc. (ABB), made the following comments summarized as follows:

Comment 9.1: The creation of a new license category under the definition of "commercial blood banks" in modified Section 1303(h) exceeds the requirements of the Act. The Department has overstepped its authority under the Administrative Procedure Act (APA) and introduced an unclear definition in subsection 1303(h). If the modified language in 1303(h) is intended to apply to colony blood banks (ABB), such an application cannot stand. To address this issue and provide clarity, the Department should either strike the added second sentence in 1303(h) entirely or, at a minimum, modify it to specify that it applies only to community blood banks.

Response: The Department considered this comment and has revised Section 1303(h). The updated definition is now consistent with the meaning established in Food and Agricultural Code

Section 9201(g).

Comment 9.2.1: The new language regarding “standards of care” guidelines in section 1303(n) is impermissibly vague and unnecessary, particularly the second sentence, which references guidelines published by entities such as the American Veterinary Medical Association, the American College of Veterinary Internal Medicine, the California Veterinary Medical Association, AVMA-accredited veterinary colleges, and government organizations.

There is no authority for including these guidelines, as they conflict with existing statutory language. Furthermore, the listed organizations lack familiarity with the relevant industry and have not adopted standards appropriate for it. This delegation of regulatory authority is improper, as these organizations could change their guidelines without adhering to the Administrative Procedure Act (APA), and the inclusion of “including but not limited to” opens the door to unspecified outside entities.

The Department cannot delegate authority to named or unnamed entities to issue rules with the force of law when no such authority exists. This improper delegation embraces future guidelines from listed and unlisted entities without complying with the APA, creating potential conflicts between these guidelines and the Food & Agriculture Code, with no mechanism to reconcile discrepancies. By bypassing the APA, the Department risks adopting uncertain and unsound regulations. The organizations in question lack clear guidelines, are not industry experts, and have no history with the industry. Moreover, ABB is not subject to the rules of the named third-party organizations. The Legislature has already rejected similar “guideline” language in the legislative process for A.B. 1282, demonstrating a clear precedent against such delegation.

Rather than outsourcing vague standards, the Department should initiate a stakeholder process to gather necessary background information and propose sound, informed regulations. This approach would facilitate an educated forum to discuss and develop specific regulations if truly needed. Additionally, the standard of care is already addressed in the Food & Agriculture Code, and the Act does not provide authority to promulgate further specific standards.

Accordingly, all of section 1303(n) should be stricken or, at minimum, the second sentence in 1303(n) must be stricken.

Comment 9.2.2: The language in section 1303(c) regarding “best clinical practice” and referencing “guidelines and publications by various non-governmental entities” is vague, unauthorized, and unnecessary. The term “best clinical practice” is specifically defined in Food & Agriculture Code section 9221(e)(8) to relate to testing for bloodborne pathogens, and while it is more broadly used in Business & Professions Code section 4920.2 for community blood banks, there is no legal basis to extend its application or impose vague requirements based on third-party guidelines. This language is inconsistent with the established legal definitions and conflicts with the Food & Agriculture Code.

Furthermore, the proposed regulations in section 1303(c) are not applicable to ABB, as they are intended for veterinary clinics, which do not apply to commercial blood banks like ABB. Therefore, the language should be clarified to indicate that these provisions are not relevant to commercial blood banks that do not operate veterinary clinics. In light of these issues, subsection 1303(c) should either be completely stricken or, at the very least, modified to specify that it only pertains to community blood banks.

Response: No changes have been made in response to this comment. The terms “best clinical practice” and “standard(s) of care” are explicitly referenced in Food and Agricultural Code Sections 9221(e)(8), 9221(e), and 9253(b)(5), all of which apply to closed-colony blood banks. Since these terms are statutory but not specifically defined in the Food and Agricultural Code or the Veterinary

Medicine Practice Act, the Department is providing definitions narrowly focused on animal blood banking to offer necessary guidance to the regulated public.

The proposed definitions strike a balance between offering clear guidance to the regulated community and maintaining the flexibility needed to accommodate advancements in veterinary medicine and evolving industry standards. They serve as a foundation for consistent regulatory enforcement while ensuring continued relevance and feasibility in diverse circumstances.

References to guidelines and publications from organizations such as the Association of Veterinary Hematology and Transfusion Medicine, the American College of Veterinary Internal Medicine, and others are included to provide transparency about where regulated entities can find resources to help achieve compliance. These references are offered as non-exclusive examples, not mandates, and do not constitute a delegation of regulatory authority.

The regulation is designed to establish a foundation for consistent enforcement while maintaining adaptability to advancements in veterinary science and industry needs. By defining “best clinical practice” and “standards of care” in this manner, the Department ensures that these standards remain relevant, achievable, and grounded in current veterinary medicine.

Furthermore, the proposed language in Section 1303(c) does not impose requirements that conflict with the statutory framework. Instead, it clarifies and supports existing statutory obligations under the Food and Agricultural Code.

The Department acknowledges the importance of ensuring these definitions remain appropriate and effective. As part of this commitment, the Department will further review these definitions and collaborate with stakeholders to assess any necessary refinements. Any future edits to these definitions will be considered in a subsequent rulemaking package.

Comment Number 10

The California Veterinary Medical Association (CVMA), through its Director of Regulatory Affairs, Grant Miller, DVM made the following comments summarized as follows:

Comment 10.1: The CVMA is opposed to adding definitions for “best clinical practice” and “standard(s) of care” and requests that those definitions be stricken and that all references to those terms in the previous version of the proposed regulation be removed. The CVMA believes that the regulations can achieve compliance with statute without these definitions or associated references.

Defining and requiring “best clinical practice” in the proposed regulation places veterinarians in an excessively burdensome position of having to achieve nothing less than a “gold standard” to meet legal requirements. In addition, “best clinical practice” is a continually evolving concept that is fundamentally ill-equipped to serve as a dependable or predictable enforcement-related baseline. In addition, administrative law regulations should reflect minimum standards rather than gold standards.

“Standard of care” is intentionally not defined in the California Veterinary Medicine Practice Act because, like “best clinical practice,” it constantly changes and varies, sometimes even on a case-by-case basis. Indeed, multiple evolving factors influence “standard of care,” creating different acceptable levels of such care based on the specific facts and circumstances at issue. Client decisions and financial constraints, new medical scientific findings and advancements, geographical considerations, and other factors (consider the COVID pandemic, for instance) contribute to a constantly changing standard of care. Attempting to define “standard of care” in regulations will inevitably do more to hinder compliance and enforcement than it will to facilitate those aims.

The CVMA included a tracked-changes version of the proposed regulation with suggested edits in red bold for consideration. CVMA stated the proposed amendments still achieve the intent of the statute without creating unintended issues.

Response: The Department appreciates the CVMA's feedback and has reviewed the tracked changes provided. However, no changes have been made to the proposed regulation in response to this comment.

The terms "best clinical practice" and "standard(s) of care" are explicitly referenced in Food and Agricultural Code Sections 9221(e)(8), 9221(e), and 9253(b)(5). Since these terms are statutory but not specifically defined in the Food and Agricultural Code or the Veterinary Medicine Practice Act, the Department is providing definitions narrowly focused on animal blood banking to offer necessary guidance to the regulated public.

The proposed definitions strike a balance between offering clear guidance to the regulated community and maintaining the flexibility needed to accommodate advancements in veterinary medicine and evolving industry standards. These definitions are intended to establish a practical and adaptable framework rather than impose an inflexible or "gold standard" requirement. They serve as a foundation for consistent regulatory enforcement while ensuring continued relevance and feasibility in diverse circumstances.

The Department acknowledges the importance of ensuring these definitions remain appropriate and effective. As part of this commitment, the Department will further review these definitions and collaborate with stakeholders to assess any necessary refinements. Any future edits to these definitions will be considered in a subsequent rulemaking package.

Comment 10.2: CVMA, in their track changes document, suggested amending section 1303(h) to:

"Commercial blood bank for animals" means an establishment that produces animal blood or blood component products from captive closed-colony or community-sourced animals to market and sell for use in the cure, mitigation, treatment, or prevention of injury or disease in animals. Facilities that do not collect blood but obtain blood or blood component products for additional preparation, testing, processing, storage, or distribution to market and sell for the purpose of transfusion are considered commercial blood banks for animals."

Response: The Department considered this comment and has revised Section 1303(h). The updated definition is now consistent with the meaning established in Food and Agricultural Code Section 9201(g).

ALTERNATIVES THAT WOULD LESSEN THE ADVERSE ECONOMIC IMPACT ON SMALL BUSINESSES

No alternative proposed to the Department that would lessen any adverse economic impact on small businesses were rejected by the Department.

ALTERNATIVES DETERMINATION

The Department determined that no alternative it considered or that was otherwise identified and brought to its attention 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 adopted regulation, or would be more cost effective to affected private persons and equally effective in

implementing the statutory policy or other provision of law.

The amendments adopted by the Department are the only regulatory provisions identified by the Department that accomplish the goal of creating clear license, registration, reporting, and fee procedures to ensure that animal blood and blood component products are not only safe and efficacious, but also produced in a humane manner. The amendments will facilitate a smooth transition from closed-colony blood banks to community-based blood banks. The final regulation reflects an alternative licensing proposal as discussed in response to comment 4.1 above. The final regulation reflects a reduced record keeping burden alternative proposed as discussed in response to comments 4.2.1 and 4.2.2 above. The final regulation reflects alternative proposed definitions of “disposition” and “community sourced” as discussed in response to comments 4.3 and 4.4 above. The final regulation reflects modifications to the formula for calculating canine blood production as discussed in repones to comment 4.5. Except as set forth and discussed in the summary and response to comments, no other alternatives were proposed or otherwise brought to the Department’s attention.