DEPARTMENT OF FOOD AND AGRICULTURE ANIMAL BLOOD BANK PROGRAM ADDENDUM TO THE INITIAL STATEMENT OF REASONS

In response to a written comment received from the public, the Department made technical, clarifying changes to the text. The Department is also updating the fiscal information and adding the updated documents to the rulemaking file.

The changes are summarized as follows:

Modified Text

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 due to the Department's lack of authority to grant these types of licenses 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

Documents added to the Rulemaking File

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 this could be would be Q1 of FY 2024/25 but most likely it will be Q2 of FY 2024/25.