FINAL STATEMENT OF REASONS Pet Food Regulations Title 17, California Code of Regulations (CCR) Division 1. Chapter 5, Subchapter 2 Group 2, Definitions and Standards Article 16, Processed Pet Food Regulations

Update of the Initial Statement of Reasons

The information contained in the Initial Statement of Reasons at the time of Public Notice remains unchanged with the exception of the following modifications. As authorized by Government Code Section 11346.9(d), the California Department of Public Health (Department) incorporates by reference the Initial Statement of Reasons prepared for this rulemaking.

In the Initial Statement of Reasons on page 3, the Department indicated that one of the benefits of this regulation was the continued protection of the public health and safety. On Page 15 of the Initial Statement of Reasons, the Department included a typo where it was stated the proposed regulations will have no effect on the health and welfare of California residents. To clarify, the Department is confirming the proposed regulations will have an effect on the health and welfare of California residents.

Section 19025: the Department will not incorporate by reference Chapter X (ten) of the AAFCO Pet Food and Specialty Pet Food Labeling Guide (revised May 2016). At the time of the first comment period, the 2024 version of the AAFCO Official Publication and Pet Food Labeling Guide had not been published, The AAFCO Official Publication has since been published on February 19, 2024.

Section 19025(g): was modified to delete the term "fit for human food," "fit for human consumption," or any similar terms that are prohibited on the labels or in advertisements of processed pet food. As this language could lead to confusion for regulated parties and inconsistency in enforcement.

Section 19025(g): was also modified to include the reference to the Health and Safety Code section 110105 to specify the meaning of "good manufacturing practices", which were no longer proposed amendments to subsection (g) and (q).

Section 19025(g): was also modified to delete reference to subsection (t) which is no longer incorporated in the text.

Section 19025(q): was modified to include the reference to the Health and Safety Code section 110105 to specify the meaning of "good manufacturing practices", which were no longer proposed amendments to subsection (g) and (q).

Section 19025(q): was also modified to delete reference to subsection (t) which is no longer incorporated in the text.

Section 19025(r): delete this subsection after feedback from the first formal comment period. The Department received a comment conveying that AAFCO is in the process of updating its publications for 2024. Thus, the version the Department had proposed to incorporate by reference may soon be obsolete.

Section 19025(s): delete this subsection because it is duplicative with statute at Health and Safety Code section 113120, which states that "[t]his chapter shall be administered by the department in accordance with Part 5 (commencing with Section 109875)."

Section 19025(t): delete this subsection because it is duplicative with statute at Health and Safety Code section 110105, which states that "[a]II good manufacturing practices regulation...and any amendments...adopted pursuant to the federal act...are the good manufacturing practices regulations of this state". During the first comment period, the Department had proposed the adoption of this subsection to place processors and consumers on notice as to the definition of good manufacturing practices used in this section. However, adding this subsection is not necessary to achieve that, as the requirements are already in statute.

The regulation text was made available for initial public comment for at least 45 days, from August 25, 2023, through October 10, 2023. There were five comments received. The second comment period was available for at least 45 days from February 23, 2024, to April 9, 2024. One comment was received during the second comment period. There was no request for a Public Hearing.

Local Mandate Determination:

The Department has determined that the regulations do not impose a mandate on local agencies or school districts, nor are there any costs for which reimbursement is required by Part 7 (commencing with Section 17500) of Division 4 of the Government Code, nor are there any other non-discretionary costs imposed.

Impact on Business:

The Department has determined that the regulations would not have a significant statewide adverse economic impact directly affecting business, including the ability of California businesses to compete with businesses in other states.

Alternatives Determination:

In accordance with Government Code Section 11346.5(a)(13), no reasonable alternative considered by the Department 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 determined no reasonable alternative considered or otherwise 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 regulated individuals than the proposed regulatory action, or would be more cost-effective to regulated individuals.

The Department considered various alternatives. One such alternative that was suggested during the public comment period was to incorporate by reference the upcoming 2024 AAFCO Model Regulations for Pet Food and Specialty Food. However, the Department determined this alternative was unreasonable because this reference was not released at the time regulations were drafted and would be much larger in scope and thus more burdensome than what CDPH proposes. Another alternative suggested during the public comment was to delay the effective date by 1 to 2 years regarding allowing manufacturers to update labels and packaging to comply with the changes. However, though the Department considered this alternative, the Department determined this delay would be less effective, as this alternative would unreasonably restrict product availability during that period.

Technical, Theoretical, or Empirical Study, Reports or Documents Relied Upon
Please note we clarified that only Chapter X was included for the AAFCO Association of
American Feed Control Officials-AAFCO Pet Food and Specialty Pet Food Labeling
Guide.

The following were used by the Department in development of these regulations:

- AAFCO Association of American Feed Control Officials, 2020 Official Publication (2020)
- AAFCO Association of American Feed Control Officials, AAFCO Pet Food and Specialty Pet Food Labeling Guide Chapter X (Revised May 2016)
- Memorandum of Understanding Between the United States Food and Drug Administration and the Association of American Feed Control Officials, MOU 225-07-7001 (7/9/2019)

 a. AAFCO Association of American Feed Control Officials-AAFCO Pet Food and Specialty Pet Food Labeling Guide Chapter X

Authority Cited and References:

The Department proposes this amendment under the authority provided in Sections 113115, 131000, 131050, 131051, 131052, and 131200 of the Health and Safety Code. The proposed regulations implement, interpret, and make specific Sections 113060, 113065, 113095, 113100, 113105, 113110, 113115, of the Health and Safety Code.

Public Comment Period

Responses to Comments Received During the Initial Comment Period From August 25, 2023, through October 10, 2023

Comment	Response
Consumers, and those subject to the proposed regulations, cannot access Chapter 10 of the Association of American Feed Control Officials (AAFCO) Pet Food and Specialty Food Labeling Guide incorporated by reference for free.	The California Department of Public Health (CDPH) is unable to publish Chapter 10 of the AAFCO Pet Food and Specialty Food Labeling Guide due to copyright restrictions. Anyone who wishes to review these materials for free may arrange to review a physical copy of the materials by contacting FDBcomments@cdph.ca.gov.

Comment	Response	
For the terms "natural" and "human grade," the department is incorporating by reference an outdated AAFCO Official Publication (OP). The department should consider using the more current 2022 AAFCO OP.	CDPH developed labeling language based on guidelines from the 2020 AAFCO OP regarding claims for "human grade" and "natural". While CDPH labeling requirements for "natural" matches the 2020 AAFCO OP guidelines, the labeling requirements for "human grade" are different. CDPH allows pet food manufacturers to label their pet food products as a whole, as "human grade". This is in-line with the 2020 guidelines; however, CDPH also allows the manufacturers to identify specific ingredients as "human grade". If not all of the ingredients are "human grade" a manufacturer is not allowed to indicate that the product as a whole is "human grade". Allowing pet food manufactures to identify ingredients as "human grade" will expand opportunities for manufacturers to incorporate this claim onto their products. CDPH is aware the 2022 AAFCO OP has updated the labeling guideline for "human grade" and "natural" claims and understand the proposed regulatory language for meeting human grade and natural claims will be different than those required by AAFCO. Maintaining CDPH's proposed regulatory language would address current restrictions on "human grade" labeling and alleviate enforcement actions taken against processed pet food manufacturers labeling pet foods as "human grade" and allow these products to be available to consumers. In addition, the proposed regulation would provide an initial framework for processed pet food manufacturers for the use of "natural" claims where previously there were none. CDPH disagrees that the proposed regulation needs to incorporate by reference the AAFCO OP 2022. However, CDPH will consider reviewing changes in the AAFCO OP 2024 once released and make any changes if necessary.	

Comment	Response
The department is incorporating by reference the 2016 AAFCO Pet Food Labeling Guide. Instead, the department should incorporate by reference the upcoming 2024 AAFCO Model Regulations for Pet Food and Specialty Food.	CDPH proposed to incorporate by reference Chapter X of the 2016 AAFCO Pet Food Labeling Guide to increase clarity on the requirements for "human grade" and "natural claims". The Department agrees the 2016 AAFCO Pet Food Labeling Guide is a guidance document that is no longer up to date with AAFCO's most up to date OP. Therefore, CDPH will not incorporate by reference the 2016 AAFCO Pet Food Labeling Guide at this time to prevent inconsistencies among our proposed language, AAFCO's most up to date OP, and the labeling guide. CDPH will consider reviewing changes in the AAFCO OP 2024 once released and make any changes if required.
The proposed language, mainly around the use of "natural," will require some pet food manufacturers to change their current labeling/packaging. It is requested that the department delay the effective date of these changes for at least one year, preferably two years, to allow time for manufacturers to comply. It would be unfair to both manufacturers and consumers to restrict the availability of products while labeling changes are being made.	Currently, the processed pet food regulations either prohibit the use of or does not provide a regulatory framework for human grade and natural claims. The proposed regulations would give the manufacturer the opportunity to label pet foods as human grade or natural if requirements are met but is not required to label pet foods as such. Therefore, CDPH disagrees with the statement that the department must delay the effective date 1-2 years because it will restrict the availability of products during that time period while the labeling changes are made.

Comment	Response
The proposed regulations do not incorporate the recent revisions to the AAFCO Model Regulations for Pet Food and Specialty Pet Food	CDPH is aware the proposed regulations do not incorporate recent revisions to AAFCO's Model Regulations for Pet Food and Specialty Pet Food. However, maintaining CDPH's proposed regulatory language would address current restrictions on "human grade" labeling and alleviate enforcement actions taken against processed pet food manufacturers labeling pet food as "human grade" and allow these products to be available to consumers. Although CDPH understands the importance of harmony and consistency of regulations across the states for the manufacture and distribution of processed foods, at this time CDPH does not have adequate information on the feasibility of adopting all the AAFCO guidelines for the use of the term "human grade", therefore no changes will be made at this time for "human grade" claims. CDPH will consider reviewing the updated AAFCO OP 2024 and evaluate its impact for future regulations.

List of commenters who submitted written comment via email, electronic form, or postal mail.

COMMENTOR NO.	COMMENTOR INFO	DATE RECEIVED
001	Susan Thixton, Pet Food Consumer Advocate TruthaboutPetFood.com	8/29/2023
002	Dana Brooks, President & CEO Pet Food Institute	10/9/2023
003	Louise Calderwood, Director of Regulatory Affairs American Feed Industry Association	10/10/2023
004	Scott Young, Vice President Animal Policy Group	10/10/2023
005	Austin Therrell, Executive Director Association of American Feed Control Officials	10/11/2023

Response to comment received during the second 45-day comment period held from February 23, 2024, through April 9, 2024.

Comment	Response
For the terms "human grade," the department is using an outdated AAFCO Official Publication (OP). The department should consider using the more current 2024 AAFCO OP to develop regulations for both the revised human grade guidelines as well as the new model regulations for pet and specialty pet food.	CDPH developed labeling language based on guidelines from the 2020 AAFCO OP regarding claims for "human grade" and "natural". While CDPH labeling requirements for "natural" match the 2020 AAFCO OP guidelines, the labeling requirements for "human grade" does not. CDPH's intent is to meet the demands of consumers for pet food products labeled and eliminate the current restrictions imposed on pet food manufacturers due to the California Code of Regulations for Processed Pet Foods which prohibits the use of, or similar words which may elude the product to be, "for human consumption".
	The proposed regulation will allow pet food manufacturers to label their pet food products, as a whole, as "human grade". This is in-line with the 2020 guidelines. In addition, the proposed regulation will also allow the manufacturers to identify specific ingredients as "human grade" even if the pet food as whole is not "human grade". Allowing pet food manufacturers to identify ingredients as "human grade" will expand opportunities for manufacturers to incorporate this claim onto their products. CDPH is aware the 2024 AAFCO OP has made significant changes to the labeling guideline for "human grade" and "natural" claims and understand the proposed regulatory language for meeting human grade and natural claims will be different than those currently required by AAFCO. However, maintaining CDPH's proposed regulatory language would address current restrictions on "human grade" labeling and alleviate enforcement actions taken against processed pet food manufacturers labeling pet foods as "human grade" and allow these products to be available to consumers. Although CDPH understands the importance of harmony and consistency of regulations across the states for the manufacture and distribution of processed pet foods, at this time CDPH does not have adequate information on the feasibility of adopting all AAFCO guidelines for the use of the term "human grade", therefore no changes will be made at this time for "human grade" claims. CDPH will consider reviewing the updated AAFCO OP

Commenter who submitted written comment via email

COMMENTOR NO.	COMMENTOR INFO	DATE RECEIVED
001	Dana Brooks, President & CEO Pet Food Institute	4/9/2024