DPH-18-016 July 27, 2022

INFORMATIVE DIGEST

Summary of Proposal

This proposal would amend the Labeling and Licensing Requirements of Sections 19025 and 19041 (respectively) of the regulations set forth in Title 17, of the California Code of Regulations (CCR) which relate to the Pure Pet Food Act of 1969 (Act). Regarding labeling, the amendment would permit pet food producers who meet the requirements set forth in Section 19025 to use the terms "human grade" and "natural" in describing their processed pet food products, delete unclear and non-specific language related to the term human grade, and incorporate labeling guidelines from the Association of American Feed Control Officials (AAFCO) Pet Food and Specialty Pet Food Labeling Guide (Labeling Guide). Regarding licensing, the amendment to Section 19041 would align the fees and licensing period noted in the regulations with the fees and licensing period set forth in the Health and Safety Code. Finally, non-substantive changes are also proposed.

Background and Summary of Existing Laws and Regulations

Background: A processed pet food manufacturer is required to have a valid license (if manufacturing in-state) or a valid registration certificate (if manufacturing out-of-state for import into California), issued by the California Department of Public Health (Department), Food and Drug Branch. An individual or company seeking a license or registration certificate submits an application along with a representative label from the product, and a license or registration certificate fee. The Department reviews the submitted documents and, if necessary, conducts a pre-licensing inspection of the applicant's facilities. The Department will then issue a license or registration certificate or deny the application. The reasons for a denial include, but are not limited to, a label that does not comply with regulations set forth in Article 16, Title 17 of the CCR, which were promulgated pursuant to the Act.

The Department received a formal petition from a processed pet food producer regarding the labeling guidelines set forth in Section 19025 (hereinafter processed pet food producers will be generically referred to as "producers" or a "producer"). The petition stated the petitioner is in compliance with the Association of American Feed Control Officials, Inc. Official Publication (AAFCO OP) on the use of the term "natural" on the label and asked for clarification of Department regulations. The petitioner was sued for deceptive and misleading labeling as it had labeled its pet food as "natural." Existing regulations set forth in Section 19025 do not address the use of "natural" on a processed pet food label.

Also, during the comment period on the petition, the Department received a request from a different producer regarding Section 19025, subsection (g), which prohibits producers from using the "terms 'fit for human food,' 'fit for human consumption,' or any similar terms" on their labels. The commenter previously applied for a license to the Department. The application included a representative label from the products it wished

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to sell in California, which included the term human grade. The Department denied the application under subsection (g)'s prohibition of the terms "fit for human food," "fit for human consumption," or "any similar terms" (emphasis added) because "human grade" was a similar enough term to deny the application. The producer noted the AAFCO OP permits use of the term human grade on pet food labels, which appears to be inconsistent with this subsection of the regulations. In addition to this comment from the producer, the Department received several correspondences from consumers asking that producers be permitted to offer "human grade" pet food in California.

Considering the changing pet food market, the Department agrees amendments are necessary to provide clarity and consistency for the nationwide industry and California consumers while continuing to ensure the quality and safety of processed pet food. Additionally, an amendment to the licensing section would align with language in the CCRs and the Act.

Existing Laws and Regulations: The Department evaluated this proposal and determined, if adopted, it will not be incompatible or duplicative with existing state or federal regulations. No statute or regulation conflicts with this proposed regulatory update. No other State regulation addresses the same subject matter, and this proposal is not inconsistent or incompatible with other state regulations.

Policy Statement Overview

Problem Statement: The Department recognizes the pet food market has changed from when these regulations were originally adopted. Today, both producers and customers desire to sell and have access to a wider variety of options. Therefore, the Department proposes adding guidelines to the regulations permitting producers to use the terms human grade and natural. This Amendment is necessary to keep current with the changing pet food market, to provide clarity and consistency for the industry and consumers, and to ensure the quality and safety of processed pet food. The Department proposes incorporation by reference of a chapter in the AAFCO Labeling Guide which provides producers and consumers further guidance on labeling. In addition to the labeling sections noted above, existing regulations include unclear language related to a prohibition on labeling processed pet food; specifically, the existing regulations include the ambiguous phrase "or any similar terms" as related to the prohibited terms "fit for human food" or "fit for human consumption." The Department does not intend to permit a producer to state or imply processed pet food is "human edible;" however, it proposes deleting this section's prohibitions on use of "fit for human food," "fit for human consumption," and "any similar terms" to harmonize it with the addition of the human grade labeling language. Of note, the proposed amendment permitting using of the term human grade includes limitations and prohibitions, which would prohibit a producer from stating or implying its food is anything other than pet food.

Finally, during the process of reviewing and updating the regulations, the Department found one additional area that would benefit from clarification. Specifically, the licensing

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regulations express the licensing fees differently than the Health and Safety Code.

Objectives: Broad objectives of this proposed regulatory action are to:

- Incorporate labeling guidelines based upon those from the AAFCO OP to increase consistency for producers and consumers.
- Incorporate by reference the Labeling Guide to increase clarity for producers and California consumers.
- Clarify ambiguous language in the existing regulations.
- · Clarify licensing fees for producers.

Benefits: Anticipated benefits from this proposed regulatory action are:

- Increases clarity of terms regulated producers can use to describe processed pet food, providing consumers with a better understanding of what they are purchasing for their pets.
- Increased clarity in permissible language regulated producers can print on a processed pet food label to protect consumers from confusion as to the proper use of the processed pet food.
- Increased consistency for producers selling in more than one state.
- Updated labeling guidelines for increased consistency with industry standards.
- Continued protection of the public health and safety.
- Enhances the public's wellbeing through protection of the health of their pets.
- Updated, clear, and consistent regulations.

<u>Evaluation as to Whether the Regulations Are Inconsistent or Incompatible with</u> <u>Existing State Regulations</u>

The Department has determined these regulations are neither inconsistent nor incompatible with other state regulations.

<u>Substantial Difference from Federal Regulation or Statute</u>

The Department has determined these regulations are not substantially different from either a federal regulation or statute.

Incorporation by Reference

The Department is proposing to incorporate by reference Chapter X¹ (ten) of the AAFCO Pet Food and Specialty Food Labeling Guide: AAFCO Association of American Feed Control Officials, AAFCO Pet Food and Specialty Pet Food Labeling Guide (Revised May 2016).

<u>Information Required for Notice of Proposed Action (NOPA)</u>

Public Hearing

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¹ The AAFCO Pet Food and Specialty Pet Food Labeling Guide designates chapters with Roman numerals.

The Department has not yet scheduled a public hearing on this package.

Public Comment

The Department has not yet scheduled a public comment period for this package.

Authority and Reference

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, and 113115, of the Health and Safety Code.

Mandated by Federal Law or Regulations

The Department determined these regulations are not identical to previously adopted or amended federal regulations.

Other Statutory Requirements

The Department has determined there are no other statutory requirements

Local Mandate

The Department has determined this regulatory action would 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.

Technical, Theoretical, or Empirical Study, Reports or Documents Relied Upon

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 (Revised May 2016)
- Memorandum of Understanding (MOU) Between the U. S. Food and Drug Administration and the Association of American Feed Control Officials, MOU 225-07-7001 (7/9/2019)

Fiscal Impact Statement

- Cost or Savings to Any Local Agency or School District: None.
- Cost or Savings to Any State Agency: None.
- Other Nondiscretionary Cost or Savings Imposed on Local Agencies: None.
- Cost or Savings in Federal Funding to the State: None.

Housing Costs

The Department has determined this regulatory action will not have any significant

effect on housing costs.

Significant Statewide Adverse Economic Impact

The proposed regulations will not have any significant statewide adverse economic impact directly affecting business or the ability of California businesses to compete with businesses in other states.

Statement of the Results of the Economic Impact Assessment

The Department has determined that the proposed regulations would not affect the following:

- A. The creation or elimination of jobs within the state.
- B. The creation of new businesses or the elimination of existing businesses within the state.
- C. The expansion of businesses currently doing business within the state.

Anticipated Benefits:

The Department anticipates a benefit to the health and welfare of California residents by the enhancement of the public's wellbeing through protection of the general health and diet of their pets, and a continued protection of the public health and safety. There are no anticipated benefits to worker safety or the state's environment.

Cost Impacts on Representative Person or Business

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.

Effect on Small Business

As this regulatory action permits a business to choose whether or not to produce or sell pet food under the new labeling guidelines it permissive and not mandatory. The new regulations would affect all business including small businesses if they chose to label products based on the labeling guidelines.

Alternatives Statement

The Department must determine that 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 (to align 17 CCR with 40 C.F.R. § 745.65 as required by 40 C.F.R. § 745.325(e)(1)), 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 intent of 17 CCR section 35035 or other provision of law.