

INITIAL STATEMENT OF REASONS

TITLE 17, California Code of Regulations
Division 1, Chapter 5, Subchapter 2
Group 2, Definitions and Standards
Article 16, Processed Pet Food Regulations

Summary of the Proposed Regulatory Action

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). In regard to 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; incorporate labeling language from the Association of American Feed Control Officials (AAFCO) Pet Food and Specialty Pet Food Labeling Guide (Labeling Guide); clarify which section of the Sherman Food, Drug, and Cosmetic Law applies; and incorporate the California definition of good manufacturing practices. In regard to licensing, the amendment to Section 19041 would align the fees and license period noted in the regulations with the fees and license period set forth in the Health and Safety Code. Finally, non-substantive changes are also proposed.

Background and Summary of Existing Law and Regulations

Background: A valid Pet Food Processor License (if manufacturing in-state) or Registration Certificate (if manufacturing out-of-state for import into California), issued by the California Department of Public Health (Department) Food and Drug Branch, is required to manufacture or sell processed pet food in California. An individual or company seeking a license or registration certificate submits an application, a representative label from the product, and a license or registration certificate fee.

The Department received a formal petition from a processed pet food producer regarding the labeling requirements set forth in Section 19025 (hereinafter processed pet food producers will be generically referred to as “producers” or a “producer”). The petitioner was sued for deceptive and misleading labeling as it had labeled its pet food as “natural.” 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. 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 submitted an application for a

license to the Department. The application included a representative label from the products it wished 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 a number of 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 amendment is 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, amendment to the licensing section would align language in the CCR 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 amending the regulations to permit producers to use the terms human grade and "natural." Amendment is necessary to keep in step 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 of the AAFCO Labeling Guide to which the Department can direct producers and consumers seeking 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 meant to be eaten by a human; 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 regulations express the licensing fees differently than the Health and Safety Code.

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

- Incorporate labeling language based upon guidelines 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:

- Increased clarity of terms regulated producers are permitted to use to describe processed pet food providing consumers with a more complete 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 language for increased consistency with industry standards.
- Continued protection of the public health and safety.
- Protection of the public's wellbeing through protection of the health of their pets.
- Updated, clear, and consistent regulations.

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, 113115, of the Health and Safety Code.

Detailed Discussion of Each Regulation

The specific purpose of each adoption or amendment, the problem the Department intends to address, the rationale for the determination each adoption or amendment is reasonably necessary to carry out, and the problem for which each adoption or amendment is proposed to address is as follows:

Amend Section 19025 Labeling and Restrictions.

Subsections (a)-(d); (f); (h)-(p). No changes are proposed to these subsections.

Subsection (e). The Department proposes amending this section to update repealed sections of the Health and Safety Code with the current relevant sections. Specifically,

repealed Sections 27031, 27032, 27033, and 27034 of the Health and Safety Code will be updated to Sections 113095, 113100, 113105, and 113110.

Subsections (g) and (q). The Department proposes amendment of these sections using the language from the AAFCO OP as a framework. There are no federal or state regulations of the same subject matter as these proposed regulations. Rather, instead of mandating requirements, the U.S. Food and Drug Administration (FDA) (the federal entity responsible for the regulation and monitoring of pet food) has worked with AAFCO to develop the Animal Feed Regulatory Program Standards, in order to “establish a uniform foundation for the design and management of states’ programs responsible for the regulation of animal feed.”¹ California and 22 other states are members of the AAFCO program.²

AAFCO is a voluntary membership association of local, state, and federal agencies, whose members regulate the sale and distribution of animal feeds and drug remedies in their home jurisdictions.³ The FDA is a member of AAFCO and serves in a non-voting advisory role on the AAFCO board.⁴ According to the FDA’s website, the “purpose of AAFCO is to provide a mechanism for developing and implementing uniform and equitable laws, regulations, standards, definitions, and enforcement policies for the manufacturing, labeling, and sale of animal feeds and ingredients.”⁵

Regarding the regulation of labeling, the FDA assures “food for both people and animals is safe, properly manufactured, and properly labeled.”⁶ AAFCO works to “safeguard the health of animals and people; ensure consumer protection; and provide a level playing field of orderly commerce for the animal feed industry.”⁷ Throughout the FDA’s numerous websites discussing pet food and the labeling thereof, it identifies the AAFCO OP as a resource for both producers and consumers.

Based upon the FDA’s citation to AAFCO, in conjunction with the fact multiple states are members of and have adopted at least some portion of the AAFCO guidelines, the Department has determined use of AAFCO’s publications, specifically its model labeling guidelines in the AAFCO OP and the explanations in the Labeling Guide, would provide the most consistency for regulated individuals, align the regulations with industry standards, and increase protection of the health and safety of California residents’ pets.

As noted above, the petition received by the Department and at least one comment in support of that petition, requested adoption of the guidelines. To increase consistency in

¹ <https://www.fda.gov/federal-state-local-tribal-and-territorial-officials/regulatory-program-standards/animal-feed-regulatory-program-standards-afrps>

² <https://www.fda.gov/federal-state-local-tribal-and-territorial-officials/regulatory-program-standards/animal-feed-regulatory-program-standards-afrps#AF2>

³ <https://www.aafco.org>

⁴ <https://www.fda.gov/about-fda/domestic-mous/mou-225-07-7001>

⁵ *Ibid.*

⁶ <https://www.fda.gov/animal-veterinary/animal-health-literacy/fdas-regulation-pet-food>

⁷ *Ibid.*

the national pet food market, the Department agrees with the petitioners that adoption of labeling language similar to guidelines in the AAFCO OP is a reasonable approach.

As an alternative, the Department considered incorporating by reference the model language from the AAFCO OP. However, a verbatim adoption of the labeling guidelines would not be workable in the California regulatory scheme. This is due to language such as “AAFCO Pet Food Committee supports and recommends” as well as regulation of areas outside the Departments’ purview.

Amend Subsection (g). The Department proposes amendment of this section to permit producers, with certain limitations, to use the term human grade on pet food labels. Previously, this section did not permit use of “fit for human food, fit for human consumption, or any similar terms.” This language would be deleted and replaced by language permitting the use of the specific phrase human grade. The Department proposes these amendments in recognition of the change in the pet food market as both producers and customers contacted the Department to express their desire to sell and purchase pet food products labeled as human grade.

Subsection (g) would permit a producer to use this term in reference to the product as a whole, if all ingredients, as well as the finished pet food product, are “stored, handled, processed, and transported in a manner and consistent and compliant with regulations for good manufacturing practices for human food as defined by subsection (t) below.” The proposed language for this section is taken directly from the AAFCO OP guidelines for use of the term human grade, which, as a national organization, reflects the term as it is commonly understood and applied by processors. Permitting processors to use this term, and basing it on the AAFCO OP, will increase consistency in the market for all producers who wish to sell human grade pet food in multiple states. Further, the regulation would consist of a clear definition, which would provide California pet owners who wish to feed a household pet human grade food the ability to know what standards must be met to use the term. Finally, as discussed below, reference to subsection (t) is proposed to increase the clarity of section 19025 by providing a definition of “good manufacturing practices,” which is used in the proposed amendments to subsection (g) and (q).

This amendment also proposes deleting the original language of this subdivision, which prohibited use of the terms “fit for human food,” “fit for human consumption,” and the phrase “or any similar terms” as keeping that language in the regulation while permitting producers to use the term human grade could lead to confusion for regulated parties and inconsistency in enforcement. As an alternative, subsection (g)(2) discussed below, sets forth the labeling requirements, which specify the product must be labeled with its intended use as pet food.

Subsections (g)(1), (g)(1)(A), and (g)(1)(B). This subsection and its two subparts set forth when it is acceptable to use the term human grade in reference to a product as a whole. Subsection (g)(1)(A) requires that, if a producer wishes to use the human grade

term to refer to the processed pet food product as a whole, then every ingredient and component of the ingredient must meet the definition of human grade in Subsection (g). Subsection (g)(1)(B) requires that the finished product must also be stored, handled, processed, and transported in a manner consistent and compliant with the definition in Subsection (g). This amendment, and its requirements that every ingredient, component, and the product itself has to be treated as human grade, would avoid misleading consumers who are purchasing a product they believe, based upon the labeling, is entirely human grade food.

Subsections (g)(2), (g)(2)(A) and (g)(2)(B). These subsections outline the limitations placed upon producers who opt to make human grade claims on their labels or in advertisements. The focus of these sections is to emphasize that regardless of whether or not it could arguably be consumed by a human, the product must be unambiguously labeled as pet food. Subsection (g)(2) sets forth the main thrust of these sections, specifically, that the food must be labeled for its intended use as a pet food. This is included so the phrase human grade does not result in confusion of consumers or ambiguity in the intended use of the food.

Subsection (g)(2)(A). This proposed subsection would prohibit inclusion of the term human grade, or any statement of quality or grade, in the ingredient list on the product label. Not only does this keep the list clear and uncluttered with adjectives but it aligns with the recommendation of the FDA regarding the ingredient labeling of both human and pet food. The FDA's guidance on pet food labels specifies the ingredients must be listed in order of predominance by weight and by their "common or usual" name.⁸ The examples provided are "corn" and "meat."⁹ The Department has chosen to follow the FDA's recommendation to increase and encourage consistency within the national market.

Subsection (g)(2)(B). This proposed section of the regulations would require a producer to include a statement of the product's intended use as pet food in conjunction with each and every printing of the term human grade on either the label or in advertising. Additionally, it specifies human grade cannot be printed larger than the statement of intended use as a pet food. The Department does not want to risk confusion of the term human grade as meaning the food is meant for humans.

Subsection (g)(3). This proposed section of the regulations relates to the use of the term human grade in reference only to a specific ingredient in a processed pet food. This section of the regulations diverges from the AAFCO OP. The AAFCO OP model language only permits use of human grade when the product in its entirety has been "stored, handled, processed, and transported in a manner that is consistent and compliant with regulations for good manufacturing practices." The AAFCO OP permits use of the term natural (discussed in subsection (q) below) to be used to refer either to

⁸ <https://www.fda.gov/animal-veterinary/animal-health-literacy/pet-food-labels-general#Ingredient>

⁹ *Ibid.*

the product as a whole or a specific ingredient. The rationale for this choice is discussed below.

As an alternative, the Department considered adopting the labeling guide model language as written; however, the Department was unable to justify why the term human grade should be treated any differently than the term natural. This is especially true in light of the fact the Department does not approve consumption of processed pet food by humans; therefore, if a producer wishes to make a product that contains only, for example, “human grade bananas,” the Department could not justify denying it that option. The following subsections are the elements a producer must meet in order to use the term human grade in reference to less than the product as a whole.

Subsection (g)(3)(A). This proposed section would require an ingredient referred to as human grade to meet the definition of human grade set forth in subsection (g). This language is the same as the requirements to use the term in reference to a product as a whole. The Department decided use of identical language was necessary to maintain consistency throughout these regulations.

Subsection (g)(3)(B). This proposed section would only permit use of the term human grade in reference to an ingredient if that use does not imply the product as a whole, is human grade. The Department proposes this language because it does not want a producer to attempt to circumvent the requirements set forth above by using the term in a way which would imply it applies to the entire product.

Subsection (g)(3)(C). This proposed section of the regulations would require a producer to include a statement of the product’s intended use as a pet food in conjunction with each and every printing of the term human grade on either the label or in advertising. Additionally, it specifies human grade cannot be printed larger than the statement of intended use. The Department does not want to risk confusion of the term human grade as meaning a food meant for humans.

Subsection (g)(3)(D). This proposed language would prohibit inclusion of the term human grade, or any statement of quality or grade, in the ingredient list on the product label. Not only does this keep the list clear and uncluttered with adjectives but it aligns with the recommendation of the FDA regarding the labeling of both human and pet food. The FDA’s guidance on pet food labels specifies the ingredients must be listed in order of predominance by weight and by their “common or usual” name.¹⁰ The examples provided are “corn” and “meat.”¹¹ The Department has chosen to follow the FDA’s recommendation to increase and encourage consistency within the national market as well as maintain clarity and ease of reading for consumers.

Subsection (q). The Department proposes adoption of this section to permit producers, with certain limitations, to use the term natural on processed pet food labels. The

¹⁰ <https://www.fda.gov/animal-veterinary/animal-health-literacy/pet-food-labels-general#Ingredient>

¹¹ *Ibid.*

majority of the proposed language in this section is taken directly from the AAFCO OP model language for use of the term natural. The model language was not incorporated by reference due to the fact it contains language directly referencing AAFCO and regulates areas outside of the Department's purview. This adoption is to address the potential lack of consistency between the labeling requirements of the national market by using the publication cited to by the FDA. In addition to creating consistency, addition of the language from this section of the AAFCO OP will clearly lay out what claims producers can and cannot include on their labels or in advertisements, which will increase consistency and clarity for California consumers. The added consistency will also reduce the costs of regulation by the Department by providing a framework for producers to follow.

This proposed section provides a definition of the term natural, which is directly from the AAFCO OP. While much of the model language was not adopted verbatim, this definition was adopted verbatim for consistency, which is necessary as there is no universally accepted definition of natural when used in reference to a pet food, or even human food. Additionally, while it may have a colloquial meaning, in these regulations it is technical in nature and therefore the definition is necessary for clarity. Inclusion of this definition will increase consistency and uniformity in regulations between the various states, and clarity and consistency for both producers and consumers.

As an alternative, the Department considered creating its own definition of natural. However, this alternative was rejected as it would risk inconsistency between the states. Also, the definition of natural in the AAFCO OP is in step with how the Department would define it and therefore it is unnecessary to create a new definition from scratch. Finally, the FDA and AAFCO have entered into a memorandum of understanding, in which AAFCO has agreed to maintain the definitions of various ingredients and terms.¹² Therefore, use of the AAFCO definition for the term natural is a reasonable way to achieve the Department's goal of consistency and clarity.

Subsection (q)(1). This proposed language would provide that when a processor wishes to use the term natural in reference to the product as a whole, then all of the ingredients must meet the definition of natural as defined by Subsection (q). This is to provide clarity as to what is required if a processor wishes to have an entire product referred to as natural or in the alternative, prefers to only have a single natural ingredient.

Subsection (q)(2). This proposed language would provide that when the term natural on a processed pet food label or advertisement is used in reference to the product as a whole, it will be considered to be false or misleading if any chemically synthesized ingredients are present in the product. An exception is made in the limited case of chemically synthesized vitamins, minerals, or other trace minerals. A producer is permitted to include chemically synthesized vitamins, minerals, and other trace minerals

¹² <https://www.fda.gov/about-fda/domestic-mous/mou-225-07-7001>

so long as the label includes a disclaimer, which complies with subsections (q)(2)(A) through (q)(2)(F).

The language in this subsection, including the exception, is from the AAFCO OP. The Department has chosen to incorporate it because a balanced and complete diet is difficult to achieve for pets using only whole, natural foods. Additionally, the exception permitting synthesized vitamins or minerals is permissible under the guidelines in the AAFCO OP; therefore, its inclusion is necessary to increase regulatory consistency between states. As long as the producer meets the requirements below, permitting natural pet food to include chemically synthesized vitamins and minerals is the reasonable way to provide sufficient nutrients to be a complete and balanced diet while meeting consumers' desire for natural pet food, and increasing consistency for producers selling their product in more than one state.

Subsection (q)(2)(A). This proposed subsection would require the disclaimer described in (q)(2) to be included with every use of the term natural. The Department is proposing inclusion of this requirement as it would increase clarity for consumers by preventing a producer from printing a single disclaimer on one, perhaps less obvious part of the label, while printing natural on multiple other areas of the label. The specifications found in subsections (q)(2)(A) through (q)(2)(F) are the same as those in the AAFCO OP; however, they have been formatted to better conform stylistically with the California regulations. Inclusion of these subsections will increase both conformity for producers with a market presence in more than one state and predictability for consumers.

Subsection (q)(2)(B). This proposed subsection sets forth the printing requirements for the disclaimer in (q)(2) on processed pet food labels. Specifically, it must be the same style and color as the word natural and the font must be no less than one half the size of the term natural. Again, the Department proposes inclusion of this subsection as it would increase clarity for consumers by preventing a producer from printing the disclaimer in a style or color that is harder to read than the word natural or printing the disclaimer in a very small, difficult to read font. The specifications found in subsections (q)(2)(A) through (q)(2)(F) are the same as those in the AAFCO OP; however, they have been formatted to better conform stylistically with the California regulations. Inclusion of these subsections will increase both conformity for producers with a market presence in more than one state and predictability for consumers.

Subsection (q)(2)(C). This proposed subsection sets forth the printing requirements for the disclaimer in (q)(2) in processed pet food advertisements. Specifically, it must be the same style and color as the word natural and the font must be no less than one half the size of the term natural. Again, the Department proposes inclusion of this subsection as it would increase clarity for consumers by preventing a producer from printing the disclaimer on an advertisement in a style or color that is harder to read than the word natural or printing the disclaimer in a very small, difficult to read font. The specifications found in subsections (q)(2)(A) through (q)(2)(F) are the same as those in the AAFCO OP; however, they have been formatted to better conform stylistically with the California

regulations. Inclusion of these subsections will increase both conformity for producers with a market presence in more than one state and predictability for consumers.

Subsection (q)(2)(D). This proposed language would permit a producer to use the disclaimer outlined in this section in generic terms as long as there is no guarantee made regarding the presence of a specific vitamin or mineral. The Department proposes this language because notification of the presence of the vitamins and minerals necessary to render the food complete and balanced is sufficient notice to the consumers that the food contains non-natural ingredients. Additionally, as noted below, while it would be false or misleading if a producer was marketing its product based upon the specific presence of a vitamin or mineral, here no marketing claims are made and therefore, generic terms are permissible. The specifications found in subsections (q)(2)(A) through (q)(2)(F) are the same as those in the AAFCO OP; however, they have been formatted to better conform stylistically with the California regulations. Inclusion of these subsections will increase both conformity for producers with a market presence in more than one state and predictability for consumers.

Subsection (q)(2)(E). This proposed language would require a producer with a disclaimer referencing a specific ingredient to also include a guarantee on its label as to that specific ingredient. So, for example, if a producer labeled its food “Natural dog food with added calcium” it would need to include a guarantee as to the presence of calcium in the food. In this circumstance the guarantee is necessary to prevent false or misleading claims as to the nutritional value of the pet food. The Department also proposes this language so if a specific nutrient is important to consumers a producer would not be permitted to make false or misleading claims as to the presence of that nutrient in an effort to cash in on consumers’ interest. The specifications found in subsections (q)(2)(A) through (q)(2)(F) are the same as those in the AAFCO OP; however, they have been formatted to better conform stylistically with the California regulations. Inclusion of these subsections will increase both conformity for producers with a market presence in more than one state and predictability for consumers.

Subsection (q)(2)(F). The final proposed language related to the disclaimer if required, such as when used in reference to the product as a whole, is that all other ingredients in the product must meet the definition of natural. While this may appear self-evident, the Department proposes this language so there is no attempt to use a disclaimer to circumvent requirements set forth by this section. The specifications found in subsections (q)(2)(A) through (q)(2)(F) are the same as those in the AAFCO OP; however, they have been formatted to better conform stylistically with the California regulations. Inclusion of these subsections will increase both conformity for producers with a market presence in more than one state and predictability for consumers.

Subsection (q)(3). This proposed subsection would permit a producer to use the term natural in reference to a single ingredient as opposed to the whole product. The language in this section is similar to the AAFCO OP; however, for clarity and conformity with California regulations it was separated into its component parts, as found in

(q)(3)(A) and (q)(3)(B) discussed below. Of note, the AAFCO OP permits use of the term natural in reference to a single ingredient but does not permit use of the term human grade in the same way. As explained in our discussion of human grade in section (g), the Department decided to permit producers to use both terms in reference to a single ingredient.

The Department proposes inclusion of this subsection so a producer wishing to market a pet food product based upon inclusion of a single natural ingredient may do so without having to meet the requirements for the entire product. Additionally, this would provide clarity to consumers who would be informed that only the ingredient noted as natural meets that definition. This specific labeling approach is discussed in the labeling guide incorporated by reference in subsection (r) below. However, as an example, a producer could label a product as “Dog Treats with Natural Broccoli,” which would mean the dog treat as a whole may or may not meet the definition of natural; however, the broccoli does.

Subsection (q)(3)(A). This proposed subsection would require that any ingredient referred to as natural meets the definition in subsection (q). The Department proposes this language for continuity with the rest of this section. Specifically, inclusion will prevent a producer from using this term in reference to a single ingredient solely as a marketing term if that ingredient does not also meet the definition of natural.

Subsection (q)(3)(B). This proposed language would prohibit a producer from using the term natural in a way which would imply the entire product is natural if the term only applies to a single ingredient. The Department proposes this subsection to protect consumers by preventing a pet food producer from using the term natural in a way which would be false or misleading.

Subsection (r). This subsection is proposed to be amended to incorporate by reference Chapter X¹³ (ten) of the AAFCO Pet Food and Specialty Pet Food Labeling Guide (revised May 2016), which was created by AAFCO to clarify the AAFCO OP labeling guidelines and provide examples for producers. The Department proposes incorporating by reference this chapter of the Labeling Guide as it discusses and provides examples of labels that use the terms natural and human grade. Incorporation of this section will increase clarity and consistency for regulated parties and will facilitate enforcement by the Department by providing examples of compliant labels.

Subsection (s). The Department proposes the adoption of this section to place processors and the public on notice as to the fact this Article is subject to the California Sherman Food, Drug, and Cosmetic Law (“Sherman Act”). Health and Safety Code section 113120 specifies the Pure Pet Food Act shall be administered in accordance with the Sherman Act. Additionally, the Sherman Act, specifies it applies to the sale, exhibition, or manufacture “of any food, drug, device, or cosmetic.” (Health and Safety

¹³ The AAFCO Pet Food and Specialty Pet Food Labeling Guide uses Roman numerals as chapter designations.

Code § 110030.) Under the Sherman Act “food” is defined as “any article used or intended for use for food, drink, confection, condiment, or chewing gum by man or other animal.” (Health and Safety Code § 109935, subd. (a) (emphasis added).)

The Pure Pet Food Act is codified in Part 6 of Division 104 of the Health and Safety Code. Part 6 primarily relates to Wholesale Food and includes its own regulatory and administrative provisions. The Sherman Act, and the sections of the Health and Safety Code it applies to, are codified in Part 5. Therefore, this subsection of these regulations is necessary as individuals generally familiar with the structure of the Health and Safety Code may be unaware Part 5’s Sherman Act applies to Part 6’s Pure Pet Food Act.

Subsection (t). The Department proposes the adoption of this section to place processors and consumers on notice as to the definition of good manufacturing practices used in this section. Health and Safety Code section 110105 states, “all good manufacturing practices regulations ... and any amendments ... adopted pursuant to the federal act...are the good manufacturing practices regulations of this state.” (Health and Safety Code § 110105.) The federal act incorporated by the Health and Safety Code sets forth good manufacturing practices pertaining to the processing, handling, storage, and transporting of human foods and animal foods (including pet foods), both of which would apply if a producer chooses to make a human grade claim. (Title 21 Code of Federal Regulations Parts 117 and 507.) Good manufacturing practices is a term of art. The Department does not want to assume anyone reading this section would know the term. Therefore, inclusion of a citation to Health and Safety Code section 110105, is necessary to increase clarity of this section as it provides the public and Producers with an explanation as to what the Department means by “good manufacturing practices.”

Amend Section 19041 Pet Food Licenses and Certificates

Subsection (a). The Department proposes amendment of this section, which currently provides for a license or certificate fee of \$200 every other year. The proposal would align the language with Health and Safety Code sections 113060 and 113065, which specifies that licenses and certificates are good for one calendar year and non-transferable. This proposed amendment would increase clarity in the regulations as it brings it into alignment with the statute by stating the license lasts from one year, while also providing the additional information of when that calendar year starts, which is at the date of issue.

Additionally, deletion of the section stating “The fee for the license or certificate is \$200.00” would increase clarity for consumers. Health and Safety Code section 100425, provides in part that any fees specified in 113060 and 113065 “shall be adjusted annually by the percentage change printed in the Budget Act...” Additionally, subsection (b) of 100425 states the state department will publish a list of the fees annually and subsection (c) exempts the fee increases from the Administrative Procedure Act. Deletion of this section is necessary to increase clarity because, while the fees started

at the amount specified in statute, they have, and will continue to, fluctuate based upon revenue and operational costs. Producers are able to obtain the current amount of fees from the State Department.

Subsections (b) – (d). No changes proposed to these subsections.

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 Between the United States Food and Drug Administration and the Association of American Feed Control Officials, MOU 225-07-7001 (7/9/2019)

Consideration of Reasonable Alternatives

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.

STATEMENT OF DETERMINATIONS

Business Reporting Requirement

The Department determined this regulatory action may have some minor positive effect on businesses, including small businesses and specifically producers, as they will have the option of including the terms natural and human grade on their processed pet food labels. However, as the labels are not required, if a producer chooses not to use the new terms, there would be no additional costs or burdens associated with that part of this proposed amendment. Finally, the change to the licensing fee in order to align it with the language in the statute would not change the actual cost for producers.

Economic Impact Assessment

The Department made an initial determination these regulations would not have a significant statewide adverse economic impact directly affecting businesses, and/or individual consumers, including the ability of California businesses to compete with companies in other states. The Department determined the proposed regulations will affect the following as described:

The creation or elimination of jobs within the state: The Department determined this proposal will not result in any increase or elimination of jobs within California.

The creation of new businesses or the elimination of existing businesses within the state: The Department determined this proposal will not have any impact on the elimination of new businesses within the state of California. However, this proposal may have some minor effect on the creation of new businesses as a company desiring to produce processed pet food with labels that include the terms natural or human grade would be permitted.

The expansion of businesses currently doing business within the state: The Department determined these proposed regulations may have a minor effect on the expansion of producers currently doing business within the state as they may choose to add new pet food product lines which are labeled with the terms natural or human grade.

The benefits of the regulation to the health and welfare of California residents, worker safety, and the environment: The Department determined the proposed regulations will have no effect on the health and welfare of California residents, worker safety, and/or the environment.

Significant Statewide Adverse Economic Impact Directly Affecting Business

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.

Local Mandate Determination

The Department determined the proposed regulations do not impose a mandate on local agencies or school districts that require state reimbursement.

Housing Costs

The Department determined the regulations will have no impact on housing costs.

Specific Technologies or Equipment

These regulations do not mandate the use of specific technologies or equipment.