



# AAFCO's Human Grade Pet Food Work Group Responses to Questions Submitted regarding the Proposed Guidelines for Human Grade Pet and Specialty Pet Food Claims

December 15, 2021

## Questions pertaining to the Preamble:

**AFIA:** The preamble only addresses process requirements and makes no comments about inspection or validation requirements. The AFIA would appreciate AAFCO members working together to determine acceptable means of validation, for example, affidavits.

**AAFCO:** The workgroup believes that it's the responsibility of each state to determine what documents will be considered acceptable to validate the substantiation of claims. The workgroup believes that affidavits are an acceptable form of validation, but the language must remain broad to cover other documents that states may want to request. AAFCO will work with members to promote uniformity in the documents that are requested for validation.

**PFI:** The current version of the guidelines indicates that the facility producing the Human Grade product should be compliant with 21 CFR part 117 (human food) but subject to inspection under 21 CFR 507. It was suggested that instead of part 507 that part 501 (Animal Food Labeling) should be included since these are products made in a human food facility but labelled (intended for) as an animal (pet) food.

**AAFCO:** The intent of the guidelines is to ensure that products with the voluntary "human grade" claim are manufactured in facilities that are compliant with all applicable human food regulations, such as but not limited to 21 CFR Part 117. Since these products are still intended for animal consumption only, they are still subject to inspection under 21 CFR Part 507. Facilities would need to be registered with FDA as both a human food facility and an animal food facility.

**S Thixton:** We question why the document references two different Current Good Manufacturing Standards. A human grade pet food manufactured in a licensed human food facility would not be subject to 21 CFR part 507. These facilities would only be subject to 21 CFR part 117. We would like an explanation to why the animal food CGMS is referenced.

**AAFCO:** The human grade pet food, although held to a higher manufacturing standard, is still intended solely for animal consumption and is not a human food. Therefore, the products are subject to 21 CFR Part 507 as animal foods, but also must be compliant with the regulations that apply to human food in 21 CFR Part 117.

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## Questions pertaining to Paragraph (2):

**AFIA:** The AFIA proposes the addition of "USDA FSIS" to assure Point 2 aligns with Point 5.

*(2) All facilities that process or package a final "human grade" pet product that are considered ready to eat must be registered both as an FDA human food facility and/or a USDA FSIS inspected establishment and an FDA Feed animal food facility.*

**AAFCO:** Any facility that processes or packages a final "human grade" pet product should be registered with FDA as both a human food facility and an animal food facility. This also applies to a USDA FSIS inspected establishment on top of their USDA requirements. Paragraph (2) has been updated to clarify the language "as both an FDA human food



facility and an FDA animal food facility.”

**S Thixton:** We question why Item (2) of the guideline conflicts with human food standards. Item (2) states: "Alf facilities that process or package a final "human grade" pet food product that is considered ready-to-eat must be registered as both an FDA food facility and an FDA feed facility." We would like an explanation to why a licensed food facility would be required to register as a feed facility. And we ask if anyone has investigated if this is even possible? Such as, has anyone consulted with USDA (who would oversee production in a licensed human food facility with products containing more than 3% meat) if dual registration would be allowed?

**AAFCO:** The licensed human food facility is also required to register as an animal food facility because the product they are producing is intended for animal consumption and not human consumption. Dual jurisdiction is allowed and commonly happens at USDA facilities that also have on-site rendering divisions.

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#### **Questions pertaining to Paragraph (4):**

**AFIA:** The AFIA requests clarity be provided in the guidelines that “*the firm*” means the pet food manufacturer and the use of signed affidavits is sufficient to meet the documentation requirement for “*documentation (e.g., affidavits) sufficient to show...*”

**AAFCO:** The workgroup believes the use of the word firm is most appropriate in that not all facilities taking part in the manufacturing of the human grade pet food are held by the pet food manufacturer. The guidelines have been updated to reflect the request to add “(e.g., affidavits).”

**PFI:** More specifically, PFI members have asked for more clarity on section four of the guideline in which it states that: “In order to substantiate that a “human grade” pet food claim is truthful and not misleading on products under the federal authority of FDA for human food production and subject to 21 CFR Part 117, the firm must maintain and make available upon request, documentation sufficient to show that...” PFI requests that the language be modified to clearly reflect that “the firm” is understood to be the pet food manufacturer and that the use of signed affidavits is sufficient to ensure these documentation requirements.

**AAFCO:** See above

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#### **Questions pertaining to Paragraph (5):**

##### **Section (a. and b.):**

**AFIA:** The AFIA requests clarity in the guidelines that the use of signed affidavits is sufficient to meet the documentation requirement for “*documentation (e.g., affidavits) sufficient to show...*”

**AAFCO:** The guidelines have been updated to reflect this comment.

##### **Section (b. ii.)**

**J Perron:** Section (5)b.ii. of the proposed Guidelines states: “The processing and/or packing of the final product is conducted in an area/room identified within the facilities required HACCP/Food Safety Plan as an area/room dedicated



to the blending, packaging, repackaging and/or labeling of an edible ready-to-eat food; ... ." (Emphasis in original.) The USDA Federal Meat Inspection Act regulations at 9 C.F.R. § 301.2 and the Poultry Products Inspection Act regulations at 9 C.F.R. § 381.1 define "edible" as "[i]ntended for use as human food." USDA considers pet food and ingredients intended for use in pet food to be "inedible". Indeed, the definition of "inedible" in 9 C.F.R. § 301.2 is "[a]dulterated, uninspected, or not intended for use as human food." Accordingly, the language in the proposed Guidelines that states that a final pet food product must be processed and/or packed in "an area/room" within a USDA inspected facility which area/room the facility's HACCP or Food Safety Plan identifies as "dedicated to the blending, packaging, repackaging and/or labeling of an edible ready to eat food" is confusing as phrased. How can an area or room that is "dedicated" to the blending, packaging, repackaging and/or labeling of a ready to eat food "intended for human consumption" (*i.e.*, that is "edible") be used to process and/or pack a final pet food that is, by definition, NOT intended for human consumption (inedible)? Put another way, if the room is "dedicated" to the blending, packaging, repackaging, or labeling of food intended for human consumption, how can it be used to process or pack a food not intended for human consumption? To remedy this issue, I would suggest that the proposed Guidelines replace the words "dedicated to" with the words "that can be used for". As a line edit, I also suggest replacing "facilities" in that same sentence with "facility's."

The revised section would therefore read: "The processing and/or packing of the final product is conducted in an area/room identified within the facilities facility's required HACCP/Food Safety Plan as an area/room dedicated to that can be used for the blending, packaging, repackaging and/or labeling of an edible ready-to-eat food; ... ."

AAFCO: The guidelines have been updated to reflect this comment.

### Section (b. iii.)

**AFIA:** The proposed requirement for processing and/or packing of the final product to be conducted in an area/room identified within the facilities requiring a HACCP/Food Safety Plan as an area/room dedicated to the blending, packaging, repackaging and/or labeling of an edible ready-to-eat food is problematic. Use of the word "edible" in this section creates a contradiction, as by definition (9 C.F.R. § 301.2) pet food is inedible, therefore the room would not qualify for a human grade claim. The AFIA requests use of the same language that is used in the rest of the guidelines, which refers to "Human Food" or use the same language in Part 5 (a).

AAFCO: The guidelines have been updated to reflect this comment.

**PFI:** Part 5 (b) iii of the draft states that "The processing and/or packing of the final product is conducted in an area/room identified within the facilities required HACCP/Food Safety Plan as an area/room dedicated to the blending, packaging, repackaging and/or labeling of an edible ready-to-eat food;" PFI feels the word "edible" in this section creates a contradiction with 9 CFR 301.2 which defines edible food only as intended for human consumption, therefore the room would not qualify for a human grade claim. PFI requests that the working group use the same language that is used in the rest of the guidelines, which refers to "Human Food."

AAFCO: The guidelines have been updated to reflect this comment.

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### Questions pertaining to Paragraph (6):

#### Section (c.)

**AFIA:** The AFIA believes the requirement combining the statement of intended (SOI) use and human-grade claim is too restrictive. This requirement has the potential to impact product naming and claims by requiring the combination of the SOI use and human grade. We think the current human-grade labeling guidelines regarding font size are clear and do



not need additional requirements to include a statement of intended use. The proposed requirement of juxtaposing the SOI in each panel imposes unnecessary restrictions to what currently is established in PF2 (a) 2, which asks for the SOI to be present only in the principal display panel. This rule could impact product naming and claims by requiring the combination of SOI and human grade. The AFIA requests removal of this requirement and to maintain the requirement in current guidelines (all uses of the words “human grade” on the label can be no larger than the statement of intended use required by PF2(a)(2)).

**AAFCO:** The workgroup believes that the language contained in (6) c. mirrors the language found in the “Guidelines for Natural Claims” and is no less restrictive than using the term “natural” on a product label.

**PFI:** Last, there’s some confusion with 6(c) which seems to have changed since the committee last viewed it. It reads that the term human grade must be juxtaposed with the statement of intended use on each panel where it appears. We would like the language to reflect that the intended use statement is not a requirement on every panel for Human Grade pet food. Leaving the language as it currently would impose unnecessary restrictions to what currently is established in PF2 which only requires the statement of intended use to be present in the principal display panel.

**AAFCO:** See above.

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#### **Comments Throughout:**

**AFIA:** The AFIA requests that the word “firm” be replaced with the term “pet food manufacturer” throughout the guidelines.

**AAFCO:** The workgroup believes the use of the word firm is most appropriate in that not all facilities taking part in the manufacturing of the human grade pet food are held by the pet food manufacturer.

**AFIA:** Also, the proper reference to the Food and Drug Administration’s facility registration should be changed from “feed” to “animal food.”

**AAFCO:** The guidelines have been updated to reflect this comment.

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#### **General Comments**

**AFIA:** We understand the guidelines are a stand-alone document and are not tied to the voluntary process verified program (PVP) audit being developed through the U.S. Department of Agriculture’s Agricultural Marketing Service (AMS). From conversations with our members, we understand the PVP is likely the preferred method for many pet food manufacturers to achieve the inspection requirements for a human-grade label claim. Because of the high likelihood that pet food manufacturers will use the AMS PVP, we feel the proposed audit requirements from the AMS should be available for review by pet food manufacturers ahead of the finalization of the human-grade guidelines through the AAFCO review and approval process.

**AFIA:** As currently drafted, the guidelines do not provide specificity for how to substantiate or regulate the human-grade claim allowing the possibility for every state to develop different requirements for how a manufacturer would affirm a human-grade claim. It is possible that the AMS audit that is being developed will address this, giving another reason why the PVP audit requirements should be made available. The phrase “documentation sufficient to show” appears at several locations in the proposed guidelines. While the AFIA appreciates the potential for flexibility for a manufacturer to provide documentation, we are concerned that states will request differing levels of “proof” to meet this burden of “documentation sufficient to show” for compliance. This is the case with the existing guidelines and, as



currently written, the proposed guidelines do not provide relief from this burden. The AFIA would appreciate AAFCO members working together to determine acceptable forms of documentation.