

Amendments to the AAFCO Feed Term Definition and Guidelines
for "Human Grade" Claims on Pet Food Labels

A proposal to the AAFCO Pet Food Committee

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Proposed amendments

The proposed amendment to the Official Feed Terms is as follows:

Human Grade: Every ingredient and the resulting product are stored, handled, processed and transported in a manner that is consistent and compliant with regulations for current good manufacturing practices (cGMPs) for human **edible** foods as specified in 21 CFR Part 117.

The proposed amendment to the Guidelines for "Human Grade" Claims is as follows:

Guidelines for "Human Grade" Claims

AAFCO recommends and supports the following guidelines for the use of the term "human grade" in the labeling of pet foods and specialty pet foods.

- (1) In the AAFCO-defined feed term "human grade," the use of the term "human grade" is only acceptable in reference to the product as a whole. The feed term specifies that every ingredient and the resulting product must be stored, handled, processed, and transported in a manner that is consistent and compliant with regulations for current good manufacturing practices (cGMPs) for human **edible** foods as specified in 21 CFR part 117.*
- (2) In the definition, the term "human grade" is false and misleading if the product as a whole is not fit for human consumption under the applicable laws and regulations edible. "Human grade" claims may not be made for individual ingredients in a finished product that does not fully adhere to manufacturing and ingredient specifications identified above.*
- (3) In order to substantiate that a "human grade" claim is truthful and not misleading, a manufacturer making one or more "human grade" claims must have documentation that:
 - A. Each of the individual ingredient suppliers has verified that the individual ingredients supplied to the manufacturer are fit for human consumption. For meat and poultry ingredients subject to the Federal Meat Inspection Act or the Poultry Products Inspection Act, verification of fitness for human consumption shall include documentation that the ingredient, prior to the manufacturing of the final pet food product, is edible as per 9 CFR § 301.2 (for meat) or § 381.1(b) (for poultry), and for eggs subject to the Egg Products Inspection Act, that the ingredient, prior to the manufacturing of the final pet food product, is not inedible as per 9 CFR § 590.5.**

*B. Every ingredient and the resulting product are stored, handled, processed, and transported in a manner that is consistent and compliant with regulations for cGMPs for human **edible** foods as specified in 21 CFR part 117.*

*C. The manufacturing facility is licensed to produce human food by the appropriate authority (which varies by jurisdiction). Such evidence may include, but is not limited to, facility licenses or permits for operation of **edible human** food manufacturing facilities or results of most recent inspections issued by local, country, or state public health authorities.*

(4) A pet food or specialty pet food product with "human grade" claims must be clearly labeled for its intended use as animal food, such as "dog food" or "cat treats," and follow all other pet food or specialty food labeling requirements. The following also applies to labeling:

A. Statements of quality or grade may not appear in the ingredient statement [PF5(d)(3)].

B. 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).

C. A claim of "human grade ingredients" is only acceptable if the product complies with all parts of this guideline.

D. In order to use the term "human grade" on labeling (brochures, point of sale materials, websites, etc.), the statement of intended use must also be included. All uses of the words "human grade" on labeling can be no larger than the statement of intended use.

Purpose of the amendments

The purpose of the proposed amendments is to provide a structure for orderly commerce by resolving the confusion in applicable laws and regulations as they relate to "human grade" ingredients and products, and to clarify for both state feed control officials and the regulated industry the ingredient and product requirements for making a "human grade" claim on pet food labels.

Problems with existing definition and guidelines

The intent of the AAFCO definition and guidelines is to ensure that ingredients and products bearing the claim are compliant with FDA laws and regulations for human food. Unfortunately, use of the term "edible" in the definition and guideline has caused confusion as to the appropriate authority in this matter. "Edible" as defined by USDA-FSIS for both meat and poultry products are simply those articles "intended for use as human food." However, as the term is applied elsewhere in the USDA regulations, there are USDA-specific processing and inspection requirements that must be in place for that

term to be applicable. For a meat or poultry product under USDA jurisdiction to be edible, it must wholly conform to the applicable requirements set forth in 9 CFR, including the need for continuous USDA inspection. Because pet food products are not subject to mandatory USDA inspection, by definition they are not "edible." USDA does not define "edible" in the case of eggs intended for human food, though in its definition of "inedible," it notes the defects in eggs that would render them unfit for human consumption.

FDA, on the other hand, does not define "edible" similarly to USDA, nor is use of the term in FDA regulations generally in the same context. Rather, FDA's uses of the word "edible" in regulations primarily relate to the use of drugs or other substances in food-producing animals, e.g., reference to residues of compounds in the "edible tissues" of animals. In other uses of the word in FDA regulations, "edible" may be interpreted simply as "fit to be eaten," without specific regard to the intended species. FDA uses the term in its few references in its regulations to substances such as "edible oils" or "edible yeasts" as they apply to both human and animal foods. In other words, all foods under FDA jurisdiction, regardless of intended species, need to be edible (i.e., safe and suitable for consumption) even though they may not necessarily be "edible" by USDA standards. Where FDA does make specific reference to human food, it does not use the term "edible." For example, the title of 21 CFR 117 is "Current Good Manufacturing Practice, Hazard Analysis, And Risk-Based Preventive Controls For Human Food," not "For Human Edible Food."

Problems with interpretation and application of the AAFCO definition and guidance for "human grade" primary stem from inappropriate use of the term "edible." Because meat and poultry products for pet consumption that are subject to the "human grade" definition and guidelines are not required to be inspected by USDA, they simply aren't "edible," notwithstanding the fact that they are required to be wholly fit for human consumption by FDA standards. For example, to meet the AAFCO definition of "human grade," ingredients and products must be "compliant with regulations for current good manufacturing practices (cGMPs) for human edible foods." While the products under this guidance would be edible in the broad sense of the term and certainly suitable for human consumption under FDA laws and regulations, they would not necessarily be "edible" by USDA's definition, in that they do not meet all the processing and inspection requirements of USDA.

The simplest fix is simply to remove the word "edible" from the definition and guidelines where used to describe ingredients and products to which the USDA definition is not intended to apply. For example, "compliant with regulations...for human foods" in the definition is sufficient on its own to describe the fitness of a product for human consumption under FDA laws and regulations. The term "edible" becomes superfluous at best, and at worst can only serve to confuse the matter. Persons unfamiliar with AAFCO's intent could interpret that phrase as meaning that in addition to any FDA standards that must be met, the pet food product also must necessarily be in full compliance with USDA requirements as "edible."

On the other hand, it is equally important to make clear that individual ingredients that are subject to USDA authority when intended for human consumption are in full compliance with applicable USDA laws and regulations before they are incorporated into the pet food product. Because USDA has primary authority over meat, poultry and egg products intended for human consumption, some ingredients in a "human grade" pet food product may not be under FDA authority prior to inclusion in the product. Regardless, "human grade" pet food products demand that all ingredients be fit for human consumption by the appropriate authority. The only meat, poultry and egg ingredients that fit the bill are those that were under USDA inspection authority prior to inclusion in the final pet food. AAFCO guidance must be amended to clarify that point. .

Benefits of the proposed amendments

The proposed amendments would be of benefit to the pet food and specialty pet food industries, as well as to state feed control officials, in that it would eliminate the confusion as to the applicability of laws and regulations to a given ingredient or product subject to the "human grade" definition and guidelines. The proposals do not change AAFCO's intent in any way, nor do they mitigate the requirement that the product as a whole be fit for human consumption as per FDA laws and regulations. Rather, the amendments clarify that all meat and poultry ingredients used in a pet product designated as "human grade" must be "edible," i.e., subject to all processing and inspection requirements as dictated and enforced by USDA prior to its inclusion in the final pet food product. In the same vein, any egg ingredients may not be "inedible" as determined by USDA. However, all other ingredients, as well as the pet food or specialty pet food itself, must be fit for human food (i.e., conform to FDA laws and regulations), although not necessarily "edible" by the USDA meaning of the term.

Conclusion

For the definition and guidelines to be effective and enforceable, both state feed control officials and the regulated industry must have a clear understanding as to the applicable laws and regulations for both "human grade" pet food products and the different ingredients of which such products are comprised. These amendments clarify which laws and regulations apply to which.