



United States Department of Agriculture  
Food Safety and Inspection Service  
Office of Policy and Program Development  
Washington, D.C. 20250-3700

# Labeling and Consumer Protection

## Proprietary Mixture Suppliers and Manufacturers Questions and Answers

**March 17, 1995**

To: Proprietary Mixture Suppliers and Manufacturers

This letter is intended to supplement the previous letter to the Proprietary Mixture Suppliers and Manufacturers (dated November 1, 1990), and FSIS Directive 7237.1 (Rev. 1), by conveying a compilation of updated questions and answers (Enclosure) pertaining to ingredient review, use, and labeling. The questions and answers are those frequently posed regarding current Agency issuance's on ingredient policies, e.g., proprietary mixes and reaction flavors, and are updated to reflect rule changes promulgated on January 6, 1993, by the Food and Drug Administration on ingredient labeling.

Questions regarding ingredient mix formulation review, use, and labeling may continue to be sent to the Labeling and Additives Policy Division (LAPD) at the following address:

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1400 Independence Avenue, SW, Room 602 - Annex Building  
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As always, proprietary ingredient mix formulations that are submitted by companies to the Agency for review in order to respond to questions are exempt from mandatory disclosure under the Freedom of Information Act, 5 U.S.C. 552 (b) (4), and will only be used to determine proper listing of the ingredients on meat and/or poultry product labels.

Sincerely,

Robert C. Post, Ph. D., Director  
Labeling and Additives Policy Division

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QUESTIONS AND ANSWERS RELATING TO USE AND LABELING OF INGREDIENTS,  
INCLUDING FLAVORINGS, PROPRIETARY INGREDIENT MIXES, INGREDIENTS IN  
STANDARDIZED AND NON-STANDARDIZED FOODS, AND PROTEIN  
HYDROLYSATES

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### I. LABELING OF FLAVORINGS

1. **Question:** What commonly used ingredient may be designated as "flavors," "flavorings," "flavoring," or "flavor?"

**Answer:** Spices, spice extractives, essential oils, oleoresins, onion powder, garlic powder, celery powder, onion juice, and garlic juice. Spices, oleoresin, essential oils, and spice extractives are listed in 21 CFR 172.510, 182.10, 182.20, 182.40, 182.50, and 184.

2. **Question:** What commonly used ingredients, which have been designated as "flavors" prior to March 1990, must be designated by their common or usual name?

**Answer:** Hydrolyzed (source) proteins (e.g., hydrolyzed corn gluten, hydrolyzed casein, hydrolyzed wheat protein, and hydrolyzed milk protein), gelatin, hydrolyzed meat and meat by-products (i.e., "hydrolyzed [species and tissue of origin]"), autolyzed yeast, and autolyzed yeast extract are some examples.

3. **Question:** Can dry meat or poultry stocks, dried broth, extracts, and dried beef plasma be designated as "flavors?"

**Answer:** No, because dried stocks, dried broths and extracts, and blood fractions are of animal origin, they must be designated as dried (species) stock, dried (species) broth, (species) extract, or dried (species) plasma.

4. **Question:** Can commonly used organic acids be designated as flavors?

**Answer:** No, because they have restricted uses and use levels, commonly used acids must be designated by their specific name (e.g., ascorbic, citric, lactic, phosphoric, etc.).

5. **Question:** Can fruit (or vegetable) juices, purees, powders, and similar ingredients be designated as "flavors?"

**Answer:** No, with very few exceptions, these ingredients are foods that have nutritional value and may not be designated as "flavor" and must be listed by their common or usual name, e.g., tomato powder and lemon juice. However, powdered onion, powdered garlic and powdered celery, as specifically cited in the regulations (9 CFR 317.2 (f) (1) (i) and 381.118 (c) (2)), may be labeled as "flavor," "natural flavors," or similar terms. Onion juice and garlic juice, according to FDA, may also be termed "flavor," etc.

6. **Question:** Must specific ingredients that meet the definition of "flavor," e.g., rosemary, and are not proteinaceous, be identified on the label application form?

**Answer:** No. Spices, oleoresins, essential oils, and spice extractives may be grouped together and listed as "spices" or "flavor" or similar terms without specific names. If color is imparted, they must be designated as, for example, "spice and coloring" or by their specific name(s), e.g., turmeric.

7. **Question:** Can the use of mustard as part of the ingredient mix be designated in the label application as "spice?"

**Answer:** Yes, mustard may be listed in the ingredient statement on the label of a meat or poultry product as "mustard," "spice," or "flavoring" (see 9 CFR 317.2 (f) (1) (i)).

8. **Question:** Can "deflavored" or "decharacterized" mustard (or other spices) be used as an ingredient in meat or poultry products? If so, how should it be designated in the ingredient statement?

**Answer:** Deflavored (or decharacterized) mustard is an acceptable ingredient in the preparation of meat or poultry products, under the conditions of use that are acceptable for spices or flavorings,

including level of use. When used in a meat or poultry product, deflavored mustard may be designated as "deflavored mustard," "deheated mustard," or "deactivated mustard." According to FDA, deflavored mustard, however, may not be designated as "mustard," "spice," or "flavoring." The same would hold true for other spices.

9. **Question:** If the processor declares spice(s) or spice extractive(s) on the meat or poultry product label, is it necessary to identify the specific spice(s) and spice extractive(s) on the label application form?

**Answer:** Generally, the processor need not identify each spice or spice extractive and the quantity of each on the label application form. As always, the total quantity of all spices versus all spice extractives will need to be indicated on the label application form to determine order of predominance for the different terms, i.e., spice(s) and spice extractive(s). In addition, if the label is submitted by an establishment in a foreign country, each spice and spice extractive must be identified on the label application form by name because of differences between countries in regulations for these ingredients.

10. **Question:** Can paprika, saffron, and turmeric be designated as "spice" or "flavoring" on meat and poultry product labels?

**Answer:** No. Paprika, saffron, turmeric, and extractives of these, according to FDA, are both spices and coloring, or flavoring and coloring and should be declared as "spice and coloring" or "flavoring and coloring" unless the specific spice or spice extractive is named in the ingredients statement.

- **Question:** Can annatto be designated as "spice" or "flavoring" on meat and poultry product labels?

**Answer:** No. Annatto may be called either "annatto" or "artificial color" or "artificial coloring" but may not be labeled as spice or flavoring.

12. **Question:** Does each constituent of ingredients designated, as "artificial flavor(s)" have to be identified on the label application form?

**Answer:** No. It is not necessary to identify the specific components of artificial flavors when the substances meet the definition in 21 CFR 172.515 and 182.60.

13. **Question:** Do ingredients that are designated as "spice(s)," "flavor," etc., in FDA-regulated foods that are used as components in meat and poultry products need to be identified on the label application form as to the specific spices or flavors used?

**Answer:** No, foods produced under FDA jurisdiction (e.g., sauces, vegetable mixes, baked beans) that are purchased and used as components of meat or poultry products need not identify the flavors on the label application. The ingredients listed on the label of the FDA regulated product may be listed as such on the label of the meat or poultry product because it is expected they will be in conformance with FDA ingredient labeling rules.

14. **Question:** When does a processor need to provide specific "flavor" component information on purchased products?

**Answer:** Specific information need only be provided if the product is a seasoning ingredient or if there is reason to suspect that the purchased product contains ingredients that are inappropriately designated as "flavor," etc.

15. **Question:** Does the Agency recognize a de minimis (minimal) level below, which a flavoring ingredient need not be declared?

**Answer:** No, there is no de minimis level at which a flavoring ingredient need no be declared by its common or usual name.

16. **Question:** How much information must suppliers of natural flavors, such as "tomato flavor" or "egg flavor," provide?

**Answer:** Suppliers of these types of ingredients must supply FSIS, at the time of label approval, with the identification of all constituents (ingredients) of that flavor.

17. **Question:** Can natural smoke flavoring be listed as natural flavor?

**Answer:** No, the labeling of natural smoke flavorings is covered by 9 CFR 317.2 (j) (3) and 381.119 (a) and by Policy Memo 117, "Smoke Flavoring." Natural smoke flavoring may not be listed as "natural flavor" or "flavor" in the ingredients statement. It may be declared as "natural smoke flavoring" or "smoke flavoring." Artificial smoke flavoring must be labeled as such.

18. **Question:** Would a distillate of acid, alcohol, or food be considered "flavor?"

**Answer:** Yes, distillates from acid, alcohol, or food that are the result of a distillation process, can be designated as "flavor," if they contain solely the flavoring constituents that are not of nutritional consequence. That is to say, no components of the substrate are present – only the chemical constituents that provide flavor, e.g., aldehydes, ketones, etc.

19. **Question:** Can cultured, fermented, or enzyme-modified products be designated as "flavorings?"

**Answer:** No. According to FDA, these ingredients must be designated by their common or usual name, e.g., "cultured whey" and "enzyme modified cheddar cheese (sublisted ingredients)."

20. **Question:** Can flavoring compounds which are separated from fermented products be designated as "flavors" (e.g., aldehydes, ketones, diacetyl, etc.)?

**Answer:** Yes, provided the mixture contains only the flavoring compounds and does not contain the substrate from which the flavoring compounds were removed.

21. **Question:** How would the "natural" versus "artificial" status of a flavoring compound be verified and by whom?

**Answer:** FSIS regulations do not provide criteria for differentiating between "natural" and "artificial" flavoring compounds (e.g., "natural" diacetyl). Determination for proper nomenclature can be obtained from the FDA.

22. **Question:** Can sandalwood extract or yellow sandalwood may be designated as "flavor" on labels of meat and poultry products?

**Answer:** White sandalwood extract or yellow sandalwood may be designated as "flavor" in the ingredients statement. FDA does not permit the use of red sandalwood extract in food, with the exception of alcoholic beverages.

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## II. PROPRIETARY INGREDIENT MIXTURES AND INGREDIENTS IN STANDARDIZED AND NON-STANDARDIZED FOODS

1. **Question:** Does a proprietary ingredient mix formula have to be reviewed approved by FSIS, LAPD, before it can be used in meat or poultry products?

**Answer:** No. Prior review and approval of proprietary ingredient mixes intended for use in meat or poultry products have never been required by the Agency. A letter of guaranty and a complete bulk label that lists all ingredients of the mix in descending order by common or usual name have always been a means of confirming the identity of ingredient mixes and assuring compliance with FDA ingredient rules and the rules of this Agency. Percentages of individual constituents of a mix may appear on bulk labels depending on whether the ingredient is restricted in meat or poultry products and/or the meat or poultry manufacturer intends to use a composite approach to listing ingredients on the meat and poultry product label.

2. **Question:** Can processors submit their proprietary ingredient mix formulas to FSIS, LAPD, to be kept in confidential files for reference before or during the label approval process?

**Answer:** Yes. Processors may submit the proprietary ingredient mix formulas to FSIS. The formulas will remain I confidential files, as in the past, and will be used for the purpose of verifying the ingredients statements on labels for meat and poultry products.

3. **Question:** What proprietary mix formulas can be submitted to FSIS?

**Answer:** The formulas for mixtures of non-meat and/or non-poultry ingredients, e.g., breeding mixes, seasonings, spices, marinades, flavorings, cures, and antioxidants, may be voluntarily submitted.

4. **Question:** Is there a prescribed format required for submission of proprietary mix formulas?

**Answer:** The suggested format for submission is a list of the following: (1) date of submission, (2) company name and mailing address, (3) technical contact person, (4) telephone number, (5) name of proprietary mixture (brand name, code, or other designation under which ingredient mix is marketed), (6) intended use and level of use, (7) statement of composition (list of the quantitative formula with percentages of each ingredient in descending order of predominance – provide a sublisting of any ingredients used to formulate another ingredient), (8) a description of the manufacturing process used to formulate the ingredient mix, including temperatures and time, (9) the proposed labeling of the mix in the meat/poultry ingredients statement, and (10) certification by a company representative (including name, signature, title, and date) that the description of the mix is accurate and complete, and that it is in accordance with FSIS guidelines and rules.

5. **Question:** Does FSIS provide advisory letters to manufacturers who voluntarily submit their ingredient mix formulas?

**Answer:** FSIS will issue letters conveying labeling advice when specifically requested.

6. **Question:** When spices, such as rosemary and thyme, are listed on a proprietary mix label, must they be listed separately on the meat or poultry product label or can they be termed as spices or flavorings?

**Answer:** Ingredients that are spices can be listed by their names, e.g., rosemary and thyme, or as "spices," "flavorings," or similar terms, regardless of the wording on the ingredient mix bulk label.

7. **Question:** If an ingredient mix is to be used in a product such as "Italian sausage," which must contain the spices, pepper and anise or fennel, as required by 9 CFR 319.145, should the label application list the total amount of spices and sublist each with its percentage?

**Answer:** While it is not necessary to list separately or provide the percentage of each spice on the label submittal form nor to sublist each spice by common or usual name on the proprietary mix label, it would be useful to identify the required spices by name on the label application or on the ingredient mix label because labels for an "Italian sausage" in which the mix is used will not be approved unless the label application shows the mix contains the required spices.

8. **Question:** Is it necessary to disclose the individual percentage of each proteinaceous ingredient in a mix on the label?

**Answer:** No, while each percentage disclosure for ingredient mixes that are allowed in moisture controlled products has been a practice in the past, we have reconsidered this requirement since publication of the "flavoring" and "added water" regulations (9 CFR 317.2 (f) (1) (i), 318.22, and 381.118) (c) (2)) in March 1990.

9. **Question:** When are ingredients considered incidental additives?

**Answer:** Ingredients that are present in a meat or poultry product in an insignificant amount and have no functional or technical effects in the finished meat or poultry product may be considered incidental additives. The definition of incidental additives provided by FDA (21 CFR 101.100 (a) (3)) is applied to meat or poultry products. Compliance with these conditions is determined by the Agency (LAPD/FSIS) on a case-by-case basis by considering the use of the proposed incidental additive and the specific meat or poultry product formulation to which it is added.

10. **Question:** Are incidental additives declared in the ingredient statement?

**Answer:** No, incidental additives are not required to be listed in the ingredients statement of meat and poultry product labels. Anticaking substances, as defined by FDA, such as silicon dioxide (used at less than 2 percent of a spice and seasoning blend), are examples of incidental additives frequently used in spices and seasoning blends. When meat and poultry processors use such spices in their products, they are not required to list the anticaking agent in the ingredients statement because it is present in insignificant amounts and because it no longer serves an anticaking function.

11. **Question:** What are "carriers?"

**Answer:** Carriers are substances that are, in and of themselves, non-functional (i.e., inert) but which are used to carry and distribute functional additives added to meat and poultry product.

Functional additives which are frequently added to formulations through the use of carriers are flavorings, antioxidants, and other substances which are used in very small quantities. The use of carriers assists in accurate quantitative measurement and in uniform distribution of the functional additive.

12. **Question:** Are carriers considered incidental additives? If not, how should carriers be labeled on meat and poultry labels?

**Answer:** A carrier may be required to be designated in the ingredients statement of the product to which it is added unless it is determined to be an incidental additive. If the carrier is determined to be an incidental additive, it need not be designated on the finished product label. There is no precise level at which the carrier becomes an incidental additive and the issue is handled on a case-by-case basis.

13. **Question:** Under what circumstances is the listing of carriers on the meat or poultry product ingredients statement required?

**Answer:** In cases where the carrier performs a functional role in the product, the carrier is not an incidental additive and must be declared on the label of the finished meat or poultry product in accordance with labeling rules. However, when lactose, salt, and proteinaceous substances are used as carriers, they are not considered to be incidental additives and must be designated by their specific common or usual names on the meat or poultry product label.

14. **Question:** When is dextrose or sugar considered a carrier of spices?

**Answer:** Dextrose and/or sugar are commonly used as carriers for spice extracts and resins of spices. The carrier must be declared in the ingredients statement of the meat or poultry product, except in those cases where a sweetening agent is used separately in formulating the meat or poultry product and the use of the spice mixture will not result in the quantity of the carrier being more than 0.75 percent of the product. When a determination cannot be made from the information on a label application, declaration is required.

15. **Question:** Are there any situations when the label declaration of monosodium glutamate (MSG) as an added ingredient is not required?

**Answer:** No, there is no established limit, below which, monosodium glutamate does not need to be declared on the label of a product to which it is added. Therefore, when monosodium glutamate is used as an ingredient it must be identified on the finished product label regardless of the amount used.

16. **Question:** Do FDA certified color additives and their lakes have to be individually declared in the ingredients statement?

**Answer:** Yes. According to FDA rules (21 CFR 101.22 (K) (1), certified color additives and their lakes are distinct ingredients and, thus, must be declared individually, e.g., "FD&C Red #40" or "Red 40," in the ingredients statement and not by a grouped term such as "coloring."

17. **Question:** Do FDA certified color additives and their lakes have to be individually declared when added to the casings for sausage products and the casings are removed but the surface color effect remains?

**Answer:** Yes. Certified colors must be declared whenever used. In situations where colored casings on sausage products impart a color to the product, the manufacturer must continue to apply



the product name qualifier "Casing Colored," and may either include the name of the certified color in the qualifier (e.g., "Artificially Colored with FD&C Red #40," or may include it in the ingredients statement of the sausage product.

18. **Question:** Does an FD&C color, e.g., Red #3 or Red #40, have to be declared in the ingredients statements of meat and poultry products when it is added to cure mixes as a tint to distinguish nitrite from salt?

**Answer:** No. The policy has always been that since the color does not function as a color additive in the meat or poultry product, it is considered to be incidental and does not require declaration.

19. **Question:** How are non-certified color additives identified?

**Answer:** Color additives not subject to certification may continue to be declared as "artificial color," "artificial color added," or "color added." Alternatively, such color additives may be declared as "colored with , " or "\_color," with the blank space filled in with the name of the color additive listed in 21 CFR 73, e.g., "colored with annatto," or "caramel color."

20. **Question:** When used as ingredients in meat or poultry products, do the common or usual names of ingredients of standardized FDA-foods and ingredients have to be listed?

**Answer:** Yes. According to FDA rules (21 CFR 130.11), the ingredients of standardized foods must be (1) declared parenthetically following the name of the standardized ingredient (i.e., "component" labeling), e.g., "cheddar cheese (milk, enzymes, salt)" or (2) declared by dispersing each ingredient in its order of predominance in the ingredients statement of the product in which it is used without naming the standardized food specifically (i.e., "composite" labeling).

21. **Question:** When used as ingredients in meat or poultry products, do the ingredients of non-standardized FDA-foods and ingredients have to be listed?

**Answer:** Yes. FDA has always required the ingredients in non-standardized FDA-foods, e.g., egg products and Ricotta cheese, to be listed when used as ingredients in other foods. In the past, FSIS has allowed limited exceptions to the rule, however, after August 8, 1995, all meat and poultry products containing FDA components as ingredients must list all ingredients in those components.

22. **Question:** What non-standardized foods will require full declaration of ingredients after August 8, 1995?

**Answer:** Soy sauce and Worcestershire sauce are examples of the non-standardized items used as ingredients in meat and poultry products that will need full disclosure of ingredients.

23. **Question:** What is the policy for declaring ingredients in cured meat products that are used as ingredients in other meat and poultry items?

**Answer:** Consistent with the recent FDA rule changes requiring the declaration of ingredients in all foods, FSIS is changing its policy on the use of cured meat products as ingredients to require the declaration of ingredients regardless of the use level.

24. **Question:** How would vegetable oils be listed in an ingredients statement in regard to source material?

**Answer:** FDA regulations require that the source of specific fats or oils be identified. This provision is different with regard to Federal meat inspection regulations which permit the use of a general term such as "vegetable oil" (9 CFR 317.2 (f) (1) (iii), 317.8 (b) (21), 319. 701). Therefore, "vegetable oil" is acceptable as an ingredient declaration and will continue to be acceptable until

the meat and poultry products inspection regulations are amended accordingly.

25. **Question:** What is the acceptable designation of vegetable starches and starchy vegetable flours?

**Answer:** In some cases, USDA regulations (e.g., the Tables of Approved Substances) require a specific source disclosure, e.g., "pea flour." In many cases, however, the regulations use general terms, e.g., "vegetable starches" and "starchy vegetable flour." Unless specified in FDA regulations, source labeling of starches is not required by FDA and, therefore, is not required by FSIS. Thus, terms like "modified food starch" are acceptable.

26. **Question:** Is it acceptable to use an "and/or" (or "may contain") approach to declare the ingredients of a FDA-foods or ingredient, e.g., ketchup, that is purchased from different manufacturers?

**Answer:** The use of "and/or" labeling will be permitted for the declaration of ingredients in purchased FDA-foods and ingredients in accordance with FDA's regulations, only if they are listed as components in the ingredients statements of meat and poultry products in which they are used.

27. **Question:** Can the use of "and/or" (or "may contain") labeling be applied to minor ingredients, i.e., those present at 2 percent or less, of products such as cured meat or poultry products or such products that are further processed (i.e., sliced, diced, etc.) and packaged?

**Answer:** The use of "and/or" labeling will be permitted for minor ingredients of a component of meat or poultry products in accordance with Policy Memo 072, "Composite Ingredient Labeling." Thus, the use of "and/or" labeling will be permitted for cured meat components, such as bacon ends and pieces, and ham, as well as for non-meat components, such as soy sauce. Additionally, cured meat poultry items, e.g., ham, with variations in minor ingredients in their formulations, can be sliced, diced, etc., and bear a label containing an "and/or" or "may contain" statement in the ingredients listing.

28. **Question:** Is the term "seasoning" an acceptable ingredient designation on meat and poultry product labels?

**Answer:** No. "Seasoning" is not established by FDA as a common or usual name. Because it is a very general term, whenever "seasoning" is used in the ingredients statement, its components must be identified as a sublisting.

29. **Question:** Can approved phosphates be collectively designated as "sodium phosphates" or "potassium phosphates," as the case may be?

**Answer:** Yes. As a convenience to meat and poultry processors, we are continuing to allow these substances to be declared on labels of meat and poultry products simply as "sodium phosphates" or "potassium phosphates." However, if the processor chooses to use a more specific name, the phosphates can be declared by their accepted chemical names.

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### III. LABELING OF REACTION FLAVORS

1. **Question:** What are "reaction flavors?"

**Answer:** During the heating process, chemical reactions occur between reducing sugars and amino acids or proteins. This process conforms to what is commonly understood in chemistry to be the "Maillard reaction." End products of Maillard reactions are referred to as Maillard reaction flavors, "processed flavors," or as "reaction flavors."

2. **Question:** What processing procedures must be used for reaction flavors?

**Answer:** Presently, reaction flavor products must be processed by heating the reactant mixes at not less than 100° C for not less than 15 minutes.

3. **Question:** Are reaction flavors "flavoring?"

**Answer:** Yes. According to FDA's advisory opinion, the reaction mixture of free amino acid(s) (e.g., cysteine) and reducing sugar(s) (e.g., xylose) in a Maillard reaction system may be termed "flavor," etc.

4. **Question:** If other substances are added to make a reaction flavor, when should the reactants in a reaction system be listed in the ingredients statement?

**Answer:** The following label guidelines apply to ingredients that are part of a reaction system:

- a. All ingredients that are of animal origin must be identified by species and tissue, if appropriate, e.g., beef fat, chicken broth, gelatin, and must be listed in descending order of predominance.
- b. Complex carbohydrates, e.g., modified food starch and maltodextrin, must always be declared because they are not totally consumed (i.e., used up) under most reaction conditions.
- c. All non-animal proteinaceous substances, e.g., autolyzed yeast extract, hydrolyzed (source) protein, monosodium glutamate, soy sauce, whether totally consumed or not, must be declared.
- d. All ingredients that are of seafood origin, e.g., Bonito fish extract and shrimp must be listed.
- e. All ingredients that are foods, meat food products or poultry products, e.g., fruit or vegetable juice, cheddar cheese, beef extract or broth, pepperoni, and bacon must be declared by their standardized names.
- f. Thiamine hydrochloride, phosphates, salt, and vegetable oil must always be listed because they are not consumed in reaction process.

- g. Reducing sugar(s) and amino acid(s) that produce a flavor when treated with heat for at least 15 minutes at 100° C may be grouped together and labeled as "flavors."

5. **Question:** Is there a standard of composition or identity for reaction flavor?

**Answer:** No, there is no standard of composition or identity for reaction flavor products; they are merely required to bear non-misleading descriptive names that comply with the established labeling guidelines.

6. **Question:** How would a reaction flavor be labeled?

**Answer:** The Agency has established specific guidelines for labeling of reaction flavors.

**Example:**

- a. If 40 percent water, 40 percent chicken meat, 10 percent hydrolyzed soy protein, 5 percent chicken broth, and 5 percent sugar were reacted with sufficient time and heat for a reaction to take place (100° C and 15 minutes), the product name would be Chicken Flavor (contains hydrolyzed soy protein and chicken broth).
- b. If 30 percent water, 30 percent beef extract, 20 percent xylose, 10 percent cysteine, 5 percent thiamine, and 5 percent salt were reacted with sufficient time and heat, the product would be labeled Beef Flavor (contains beef extract, thiamine, and salt).
- c. If a chicken "type" flavor was produced from a reaction without chicken as a substrate, using 40 percent water, 20 percent beef extract, 20 percent bacon fat, 10 percent dextrose, 5 pepperoni and 5 percent cysteine, the resulting product would be called Chicken Type Flavor (contains beef extract, bacon fat, and pepperoni).
- d. If the substrate is 90 percent chicken meat and 10 percent sugar, under the prescribed reaction conditions, the label would state "Chicken Meat and Chicken Flavor," unless it can be shown that the chicken meat is broken down in the reaction to yield only amino acids. In this case, the label would state "chicken flavor" or "flavor (contains chicken)."
- e. If the substrate is 50 percent pork trimmings, 30 percent xylose, 10 percent cysteine hydrochloride, 5 percent onion powder, 3 percent clove oil, and 2 percent rosemary extract, the label would state "pork flavor" or "flavor (contains pork)."

7. **Question:** Are the labeling guidelines for reaction flavors intended to encompass ingredients with a separate identity as a meat food product or poultry product, e.g., dried beef plasma or pork stock?

**Answer:** No.

8. **Question:** Can reaction flavors be labeled as "natural flavor?"

**Answer:** No. The reaction mixture does not come from a natural source, as such, but is carefully formulated in specific proportions to ensure a product mixture of desired flavor characteristics.

9. **Question:** Do processors have to declare water as an ingredient in a reaction flavor?

**Answer:** No. Water that is needed in order for the Maillard reaction to take place does not have to be declared.

10. **Question:** Can ingredients that are precluded by regulations from use in any meat or poultry product, e.g., sorbates, be used in the preparation of a reaction flavor?

**Answer:** No.

11. **Question:** What is the appropriate labeling for a reaction mix that is not heat processed?

**Answer:** The labeling guidelines for reaction flavors are not applicable to a mix of reactants (e.g., amino acids and reducing sugars) where heat has not been applied. Each ingredient, including amino acid(s) and reducing sugar(s), in the mix must be individually identified just as ingredients are listed in a seasoning or spice blend.

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#### IV. LABELING OF PROTEIN HYDROLYSATES

1. **Question:** Can protein hydrolysates be grouped in the ingredients statement, e.g., "hydrolyzed vegetable protein (corn, soy, wheat)"?

**Answer:** No, "hydrolyzed vegetable protein" is not established by FDA as a common or usual name, nor is it established as an appropriate collective name for a variety of different protein hydrolysates. The common or usual name of a protein hydrolysate should be specific to the ingredient and shall include the identity of the source from which the protein was derived. Hydrolyzed soy protein, hydrolyzed corn gluten, and hydrolyzed casein is examples of acceptable names. The acceptable FDA designation is hydrolyzed corn protein, hydrolyzed soy protein, and hydrolyzed wheat protein.

• **Question:** What is the rule of thumb when the identity and function of a hydrolyzed substance is in question?

**Answer:** According to FDA, appropriate standards exist to allow a distinction between commercially available "highly" hydrolyzed protein hydrolysates and those variously termed "partially," "mildly," or "lightly" hydrolyzed that are not used for flavor-related purpose.

According to the FDA, "highly" hydrolyzed proteins are declared as "hydrolyzed (source protein)"

and can be defined as those whose ratio of alpha-amino nitrogen (AN) to total nitrogen (TN) is greater than 0.62 (AN:TN > 0.62). Proteins that are not highly hydrolyzed would have AN:TN of less than 0.62 (AN:TN < 0.62) and may be declared by using such terms as "partially," "mildly," or "lightly," e.g., "partially hydrolyzed (source protein)."

When a problem arises regarding whether a hydrolyzed substance used in the formulation of a meat or poultry product is accurately identified and serving the primary function of flavoring, we consider these definitions and the level of use of the substance in question. In our experience, substances that have AN:TN > 0.62 would be used at less than 2 percent of the meat or poultry product formulation when used for the primary purpose of flavoring.

3. **Question:** What is the proper nomenclature of hydrolyzed protein derived from an animal source when utilized as an ingredient in meat or poultry products?

**Answer:** The hydrolyzed protein of slaughtered animal species and tissue of origin, other than gelatin, must be indicated, e.g., "hydrolyzed beef plasma," "hydrolyzed pork stock," and "hydrolyzed pork skin."

4. **Question:** What are the acceptable declarations for protein hydrolysates that are made of blends of proteins, i.e., the proteins from different sources are hydrolyzed together or individually?

**Answer:** According to FDA rules, for proteins that are blended prior to being hydrolyzed, an appropriate name for the hydrolyzed protein must be sufficiently descriptive of the product and must include all of the various proteins that were used to make the hydrolyzed protein. For example, a hydrolyzed protein made from a blend of corn protein, soy, protein, and wheat gluten would be "hydrolyzed corn, soy, and wheat gluten protein."

If proteins are hydrolyzed individually prior to blending, then the common or usual name of each protein hydrolysate must be indicated, e.g., "hydrolyzed corn protein, hydrolyzed soy protein, and hydrolyzed wheat gluten."

5. **Question:** Is "hydrolyzed gelatin" an acceptable common or usual name?

**Answer:** No. According to a FDA decision, "hydrolyzed gelatin" falls within the standard for Type B gelatin and, therefore, would be declared as "gelatin."

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