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OPI: RP/SLD

QUESTIONS AND ANSWERS RELATING TO INGREDIENTS THAT MAY BE DESIGNATED AS FLAVORS, FLAVORINGS, NATURAL FLAVORS OR NATURAL FLAVORINGS IN THE INGREDIENTS STATEMENTS ON THE LABELS OF MEAT AND POULTRY PRODUCTS

I. PURPOSE

The attachment to this directive provides a list of commonly asked questions and answers in response to the final rule titled "Ingredients That May be Designated as Flavors, Flavorings, Natural Flavors or Natural Flavorings When Used in Meat and Poultry Products" which was published in the Federal Register on March 1, 1990. The final rule is effective on March 1, 1991. This is the first set of questions and answers on this subject. Additional sets will follow as needed.

II. RESERVED

III. RESERVED

IV. REFERENCES

Sections 317.2, 317.4, 317.5, 317.8, 317.14, 319.145, 319.180 of the Federal Meat Inspection regulations;
Sections 381.118, 381.119, 381.132, 381.134 and 381.141 of the Poultry Products Inspection regulations
FDA regulations, 21 CFR 172.510, 182.10, 182.20, 182.40, 182.50, and Part 184

V. POLICY

It is FSIS's policy to provide additional information as needed whenever a significant, complex and/or far-reaching regulation is published. The form of the information will vary, however, it is believed that providing a list of commonly asked questions and answers can be an effective means of disseminating information to affected entities and other interested parties.

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Administrator

FSIS DIRECTIVE 7140.1
ATTACHMENT

QUESTIONS AND ANSWERS RELATING TO INGREDIENTS THAT MAY BE DESIGNATED AS FLAVORS, NATURAL FLAVORS, FLAVORINGS OR NATURAL FLAVORINGS

IN THE INGREDIENTS STATEMENTS ON THE LABELS OF MEAT AND POULTRY PRODUCTS

QUESTIONS REGARDING THE ROLE OF THE USDA INSPECTOR

1. QUESTION: What is the role of the FSIS inspector in helping to implement the new regulation?

   ANSWER: Although the inspected establishment is responsible for identifying which labels must be resubmitted for approval, the inspector will provide consultation and assistance in this effort. In addition, inspectors in charge (IIC) of establishments will continue to perform IIC approvals and play a role in generic approvals of labeling when such approvals are based on SLD-approved sketches or labels (See 9 CFR 317.4(e), 317.5, 381.132(c), and 381.134). When the inspected establishment identifies which labels must be resubmitted, the previously approved labels that do not comply with the new regulation should be rescinded by the establishment by the effective date of the new rule, and the IIC should transmit the rescinded label to SLD. (See 9 CFR 317.14 and 381.141). The inspector will not permit use of labels not in compliance with the new regulation after the effective date.

2. QUESTION: May IIC's approve labels which contain ingredients designated as flavors?

   ANSWER: No. IIC's may not approve labels which designate ingredients as flavors unless the plant has an approved sketch for that label, and the sketch was approved no earlier than March 1, 1990.

3. QUESTION: Can the IIC make the determination as to whether a label does not need to be resubmitted because it already complies with the new regulation?

   ANSWER: Aside from those labels which list "spices," "spice extractives," "powdered celery," "powdered onion," "powdered garlic," "oleoresins," or "essential oils" as the only ingredients designated as flavorings, the IIC is not authorized to determine whether a label complies with the new regulation. As the Agency is able to inform IIC's about the complex determinations regarding what may be designated as flavorings, the IIC's role in this regard will expand. When this happens, the industry will be notified. In addition, if the company receives a certification letter from SLD stating that the old label complies with the new regulation, the IIC will receive a copy of the certification letter, and will permit continued use of the old label. These two situations are discussed more fully under "QUESTIONS REGARDING LABELING OF FLAVORINGS." (See Questions B10 and B11.)

B. QUESTIONS REGARDING LABELING OF FLAVORINGS

1. QUESTION: What commonly used ingredients may be designated as flavors?

   ANSWER: Spices, spice extractives, onion powder, garlic powder, celery powder. Spices are listed in 21 CFR 182.10.

2. QUESTION: What commonly used ingredients, which have been designated as flavors, must now be designated by their common or usual name?

   ANSWER: Hydrolyzed vegetable protein, hydrolyzed plant protein, hydrolyzed milk protein, hydrolyzed meat and meat byproducts, autolyzed yeast, and autolyzed yeast extract are some examples.

3. QUESTION: Can dried stocks, dried broths, and extracts be designated as flavors?

   ANSWER: No, dried stocks, dried broths, and extracts must be designated as dried (species) stock, dried (species) broth and (species) extract.

4. QUESTION: Can commonly used acids be designated as flavors?

   ANSWER: No, commonly used acids must be designated by their specific name (e.g., the specific amino acid, ascorbic, citric, lactic, phosphoric, etc.).

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

   ANSWER: No, these ingredients are foods that have nutritional value and may not be designated as flavors. Some examples of these ingredients which have been designated as flavors in the past but now must be listed by their common or usual name are tomato powder and lemon juice. However, powdered onion, powdered garlic and powdered celery, as specifically cited in the regulation, may be labeled as flavors.

6. QUESTION: Are letters from the Proprietary Mix Committee (PMC) acceptable for use in determining ingredients that may be designated as flavors?

   ANSWER: Yes, such letters are acceptable provided they are dated later than March 1, 1990, or they do not stipulate that any of the ingredients in the mix may be labeled as flavorings. For example, some PMC letters have been used for curing mixtures that contain no flavoring ingredients other than salt (which has always been required to be declared as "salt").

7. QUESTION: If the processor has a PMC letter, must specific flavor ingredients be identified on the label submittal form?

   ANSWER: No, the processor need only identify the ingredients of the flavor mix as specified by the PMC letter. The label approval can be handled more efficiently if a copy of the PMC letter is enclosed with the label application, but this is not required.

8. QUESTION: If the processor does not have a PMC letter, must flavors be identified on the label submittal form?

   ANSWER: Yes, if the processor does not have a PMC letter, the submittal form must list each flavor compound by its specific name and the percentage of each compound (e.g., hydrolyzed vegetable protein, powdered onion, garlic powder). However, spices, oleoresins, essential oils, and spice extractives may be declared as such, without a breakdown of the specific spices, oleoresins, etc.

9. QUESTION: If the processor declares spices or spice extractives on the product label, is it necessary to identify the specific spices and spice extractives 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 submittal form. The total quantity of all spices versus all spice extractives will need to be indicated on the label submittal form to determine order of predominance for the different terms. However, the use of mustard must always be broken out on label submittal forms for moisture controlled products. 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 submittal form by name because of differences between countries in regulations for these ingredients.

10. QUESTION: What approved labels which designate ingredients as flavors must be resubmitted for a new approval by the plant?

    ANSWER: Almost all labels that designate an ingredient as a flavor must be resubmitted for reapproval by SLD. There are two kinds of exceptions: (1) if the existing approved label and accompanying submittal form listed "spices," "spice extractives," "powdered celery," "powdered onion," or "powdered garlic" as the only ingredients that have been designated on the label as flavoring; or (2) if the label is certified as valid by a letter from the Standards and Labeling Division (see next question).

11. QUESTION: How is a certifying letter obtained from SLD?
    ANSWER: If a processor believes that his/her current labeling already complies with the new flavoring rule, the processor may make a

written request to the Director, Standards and Labeling Division, for a certifying letter. The request must include one photocopy of each previously approved label and the accompanying transmittal form. Based on this information, a certifica- tion letter will be issued that will stipulate whether the label complies with the new regulation or whether it must be submitted to SLD for approval. If the letter stipulates that the label must be resubmitted, the need for this may be prompted either by a requirement for a change in the label or because of insufficient information to render a judgment. A copy of the certification letter will be sent to the IIC for information and control purposes. Use of certification letters will require less paperwork because only one copy of each label and submittal form will be sent to SLD, and will be more efficient than regular label approval because only one aspect of the label will need to be reviewed.

12. QUESTION: Is the intent of the new rule to distinguish "natural" flavors from artificial flavors?

    ANSWER: No, the intent is to identify those that may be designated as "natural flavorings," "natural flavors," "flavorings," and "flavors."

13. QUESTION: Do approved labels that have artificial flavor designated on the label have to be resubmitted for approval?

    ANSWER: No, the designation of artificial flavor does not by itself trigger a need to resubmit labels. If a purchased product bearing a label that designates an ingredient as an artificial flavor or if the label of a purchased artificial flavor bears information that raises questions about the legitimacy of this term on the meat or poultry product label, it is best to contact SLD for instructions or resubmit the label. Inspectors' questions to SLD must be made through official channels.

14. QUESTION: Does each constituent of ingredients designated as artificial flavors have to be identified on the label submittal form?

    ANSWER: No, it is not necessary to identify the specific components of artificial flavors.

15. QUESTION: Do ingredients that are designated as flavors in FDA-regulated foods that are used as components in meat and poultry products need to be identified on the submittal form as to the specific flavors used?

    ANSWER: No, foods produced under FDA jurisdiction (e.g., sauces, vegetable mixes, beans) need not identify the flavors on the label submittal. 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.

16. QUESTION: After the effective date, do ingredients that are designated as flavors in meat or poultry ingredients purchased from an inspected processor need to be identified on the label submittal form of the processor who uses the purchased product as an ingredient (e.g., pizza, dinner, burrito, omelet, etc.)?

    ANSWER: Yes, although the flavoring ingredients from a purchased meat or poultry ingredient could be identified on the label submittal form, this is not the only option. If the processor is assured by the supplier that the label for the purchased ingredient complies with the new regulations, the processor should obtain the FSIS label approval number for the purchased ingredient and note the number on the label submittal form for the secondary product. The secondary product label should indicate the use of the flavoring ingredients as designated on the label of the purchased product. If the meat or poultry ingredient supplier's label does not yet comply with the new regulation, a temporary approval will be granted for the secondary product label.

17. QUESTION: When does a processor need to provide specific component flavor 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. Batter and breading mixes are examples of purchased products that tend to contain many seasoning ingredients.

18. QUESTION: Will the Agency recognize some de minimus (minimal) level below which a flavoring ingredient need not be declared?

    ANSWER: No, there is no de minimus level at which an ingredient need not be declared.

19. QUESTION: How much information must suppliers of natural flavors such as tomato flavor or orange flavor provide?

    ANSWER: Suppliers of these types of ingredients must supply FSIS with the identification of all ingredients of that flavor.

20. QUESTION: How long can processors continue to use the flavor mix they currently have on hand before they must obtain a new PMC letter from their supplier?

    ANSWER: The flavor mix may continue to be used without a new PMC letter until the effective date of the regulation, August 28, 1990.

21. QUESTION: Can the use of mustard be indicated on the label submittal form as "spice"?

ANSWER: Generally, mustard can be indicated as spice, but its presence and use level must be broken out on label submittal forms for moisture controlled products. This is required because the protein contribution from spices is credited as 10 percent whereas the protein contribution from mustard is credited as 35 percent. For all products, the label declaration for mustard may be as "spice" or "flavoring."

C. QUESTIONS REGARDING PROPRIETARY FLAVORING MIXTURES

1. QUESTION: How long is the turnaround time for a PMC advisory letter?

ANSWER: The target turnaround time is approximately 4 weeks. It will vary with the complexity of the mixture and simpler products may be reviewed in less time. However, a large increase in the volume of requests could result in a longer turnaround time. It is advisable to submit requests as soon as possible.

2. QUESTION: Do all proprietary mixes have to be resubmitted for approval?

ANSWER: No, only proprietary mixes that stipulate labeling as "flavorings" need to be resubmitted. For example, textured vegetable protein (TVP) has always been required to be listed by its common or usual name and a mixture containing TVP without "flavorings" need not be resubmitted to the PMC.

3. QUESTION: If a company has multiple proprietary mixes of identical formulation and the mixes bear different product codes identifying differences in sizes, shapes, or densities, must the company submit multiple applications?

ANSWER: No, one application may be submitted for all the product codes. One PMC letter will be issued and all of the product codes will be listed in the letter. However, if a new code is added to the product line, the company will have to apply for the new product code and request to have either a separate letter issued or the previous letter revised.

4. QUESTION: Can a proprietary flavoring mix be prohibited from entering a meat or poultry establishment because it has a PMC letter dated before March 1, 1990?

ANSWER: No, PMC letters should not be used as the basis for allowing or disallowing proprietary mixes to enter an establishment. A letter of guarantee will continue to be used as the basis for allowing nonmeat ingredients to enter a meat or poultry establishment. The PMC letter only stipulates how use of the mix in a product should be indicated on the meat or poultry product label.

5. 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, rosemary and thyme, or as "spices" or as "flavorings" regardless of the wording on the mix label or in the PMC letter concerning the ingredient statement on the food product label. Usually these wording options are identified in the PMC letter.

6. QUESTION: If a proprietary mix is to be used in a product such as Italian sausage which must contain the spices pepper and anise or fennel (which may be declared as spices or flavorings) as required by 9 CFR 319.145, should the application to the PMC for the mix list the total amount of spices and sublist each with its percentage?

   ANSWER: The application letter to the PMC should include the total percentage of the spices. With the exception of mustard (see next question), it is not necessary to list separately or provide the percentages of each spice on the application nor to sublist each spice by common or usual name on the proprietary mix label. However, it would be useful to identify the required spices by name in the PMC application or on the mix label because labels for an Italian sausage in which the mix is used will not be approved unless the label application or the PMC application shows that the mix contains the required spices.

7. QUESTION: Can the use of mustard as part of the PMC mix be designated in the application as spice?

   ANSWER: No, when mustard is included as part of a PMC mix the percent of mustard must be broken out from the general listing of spices. This is required because the protein contribution from spices is credited as 10 percent whereas the protein contribution from mustard is credited as 35 percent in performing calculations for added water or protein on a fat free basis. The separation of mustard content from spice content is needed for the PMC letter to accurately stipulate the protein content of the mix (See next question).

8. QUESTION: FSIS Notice 6-90 states on page 4 that the PMC advisory letter will specify the percentage of each proteinaceous ingredient. Is it really necessary to disclose this information to the meat or poultry processor?

   ANSWER: No, while such percentage disclosure for mixtures that are allowed in moisture controlled products had been a practice in the past, we have reconsidered this requirement since publication of the Notice. We believe that information stating the protein content of the total proprietary mixture by certification and/or declaration on the label is more useful for protein-fat-free and "added water"

determinations. The protein content (total nitrogen X 6.25) of the mix on a wet weight basis will be included in the PMC letter when the mix contains proteinaceous ingredients. Lack of information on protein content in a PMC letter does not negate the responsibility of the meat or poultry processor to provide the USDA inspector in charge with the amount of nonmeat protein used in moisture controlled products. 9.
QUESTION: Are natural smoke flavorings affected by the regulation?

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.

10. QUESTION: Can a company holding a PMC letter dated prior to March 1, 1990, which contains information that will remain the same under the revised regulation, provide only the name of the mix as opposed to sending an entirely new PMC submittal?

ANSWER: No, if the company wants a new letter, it must submit a new application. However, it may review the previous submission to determine if it is unchanged and contains all of the information requested in the suggested format shown in the March 23, 1990, letter to suppliers and manufacturers (copies may be obtained from the Director, Food Ingredient Assessment Division, Food Safety and Inspection Service, Room 303 Annex Building, Washington, DC 20250). If these conditions are true, it may send a copy of the previous submission with a letter certifying that "the composition, manufacturing process, and ingredient labeling statement of (name) remain the same as previously stated on the submission of (date of previous submission)."