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DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Part 918

[Docket No. AO-162-A6; AMS-FV-88-039]

Fresh Peaches Grown in Georgia; Order Amending the Marketing Agreement and Order; Correction

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Final rule; correction.

SUMMARY: This action corrects the final rule amending the Georgia peach marketing agreement and order by removing duplicate amendatory instructions and provisions relating to the addition of a new paragraph (d) to § 918.81 Termination.

FOR FURTHER INFORMATION CONTACT: George J. Kelhart, Marketing Order Administration Branch, Fruit and Vegetable Division, AMS, USDA, P.O. Box 96456, Room 2525-S, Washington, DC, 20090-6456; telephone: (202) 475-3919.

SUPPLEMENTARY INFORMATION: In Federal Register document 90-903 beginning on page 1379 of the Tuesday, January 16, 1990, issue of the *Federal Register*, the following corrections are necessary to remove erroneous wording:

1. On page 1382, in the first column, amendatory instruction 11 and paragraph (d) of § 918.81 which follows are removed.

2. Amendatory instruction 12 is renumbered as 11.

Dated: February 23, 1990.

Robert C. Keeney,

Deputy Director, Fruit and Vegetable Division.

[FR Doc. 90-4619 Filed 2-28-90; 8:45 am]

BILLING CODE 3410-02-M

Animal and Plant Health Inspection Service

7 CFR Part 354

9 CFR Part 97

[Docket No. 90-020]

Fee Increase for Overtime Services

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Final rule; correction.

SUMMARY: In a document published in the *Federal Register* on January 31, 1990 (55 FR 3197-3198, Docket No. 90-005), we amended the regulations that establish charges for Sunday, holiday, or overtime work performed by inspectors of the Animal and Plant Health Inspection Service (APHIS) of the United States Department of Agriculture at laboratories, border ports, sea ports, and airports. The regulations were amended to: (1) Increase the hourly rates charged a person, firm or corporation having ownership, custody, or control of plants, plant products, animals, animal byproducts, or other commodities or articles subject to certain inspection, laboratory testing, certification, or quarantine and who requires the services of an APHIS employee on a Sunday or holiday or at any other time outside the employee's regular tour of duty; and (2) increase the hourly rates charged an owner or operator of an aircraft requesting inspection or quarantine services at an airport outside of the regularly established hours of service.

In the third sentence of the paragraph explaining the effective date, which begins on page 3197, column 3, the word "signature" should read "publication." The sentence correctly reads "In order to allow for orderly implementation and maximum recovery of costs, the rule will be effective the beginning of the first pay period following publication." The date which appeared in the "EFFECTIVE DATE" line, February 11, 1990, is correct.

FOR FURTHER INFORMATION CONTACT: Paul R. Eggert, Director, Resource Management Support, PPQ, APHIS, USDA, Room 621, Federal Building, 6505 Belcrest Road, Hyattsville, MD 20782, (301) 436-7764; or Louise Rakestraw Lothery, Director, Resource Management Support Staff, VS, APHIS, USDA, Room 740, Federal Building, 6505

Belcrest Road, Hyattsville, Maryland 20782, (301) 436-7517.

Done in Washington, DC, this 23rd day of February 1990.

James W. Glosser,

Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 90-4620 Filed 2-28-90; 8:45 am]

BILLING CODE 3410-34-M

Food Safety and Inspection Service

9 CFR Parts 317 and 381

[Docket No. 86-037F]

Ingredients That May Be Designated as Natural Flavors, Natural Flavorings, Flavors or Flavorings When Used in Meat or Poultry Products

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Final rule.

SUMMARY: The Food Safety and Inspection Service (FSIS) is amending the Federal meat and poultry products inspection regulations to better define and limit the substances which are permitted to be designated only as "spice," "natural flavor," "natural flavoring," "flavor" or "flavoring" in the list of ingredients on labels for meat and poultry products. The final rule addresses the use of substances which are often added to product for purposes such as flavor enhancers, emulsifiers, stabilizers, binders, extenders and as nutrient sources, but are currently only identified as natural flavor, natural flavoring, flavor or flavoring. Most of the substances that will be affected by the final rule are proteinaceous (substances containing protein or nitrogen) materials having nutritional value and which may be considered foods in their own right. The final rule requires that, when used in meat and poultry products, these substances must be identified separately in the list of ingredients on many product labels by their standard, common or usual names, thereby informing consumers of the origin of these substances. In addition, those substances which are of livestock or poultry origin must include the species and animal tissues from which they are derived unless otherwise exempted. The final rule addresses the personal, cultural, and religious concerns of consumers, as well as the allergies or

sensitivities some consumers may have to some of the substances.

EFFECTIVE DATE: August 28, 1990.

FOR FURTHER INFORMATION CONTACT:

Ashland L. Clemons, Director,
Standards and Labeling Division,
Regulatory Programs, Food Safety and
Inspection Service, U.S. Department of
Agriculture, Washington, DC 20250;
Area Code (202) 447-6042.

SUPPLEMENTARY INFORMATION:

Executive Order 12291

The Administrator has determined that this final rule is not a "major rule" within the scope of E.O. 12291. It will not result in an annual effect on the economy of \$100 million or more; a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; or significant adverse effect on competition, employment, investment, productivity, innovation, or the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets.

This final rule requires that, when used in meat and poultry products, certain substances that are now identified as spices or flavorings must be identified separately in the list of ingredients on product labels. This will require the revision of the list of ingredients on many product labels. When the proposal was published in August, 1987, FSIS stated that "While there may be some costs involved in label changes, these costs would be minimized by providing adequate time to use existing label inventories and to include required changes in normal redesigning or repurchasing of labels." Because some comments addressed the issue of labeling revision costs, FSIS conducted some additional studies to provide more detailed information on estimated costs.

As a first step, FSIS asked a group of experienced inspectors to provide an estimate of the average life of an approved label. Out of a group of 20 inspectors, 16 agreed that 2 years was a best estimate. Using this estimate and the data showing 114,000 new labels approved in 1988, FSIS estimates that there are approximately 230,000 labels in use.

Two thousand labels approved during June, 1989, were examined to provide the estimates described in the following analysis. The 2,000 labels were first divided into the categories of cooked sausage labels and "other" labels. When the rule was proposed, FSIS knew that the products affected the most would be cooked sausages with limits on added

water. These are the products for which there is an economic incentive to add nonmeat proteinaceous materials of plant, yeast, or dairy origin. The review of 2,000 labels found that 13.75 percent were labels for cooked sausage. Thus, there are an estimated 32,000 approved labels for cooked sausages in use ($230,000 \times 0.1375 = 31,625$). These products are produced in over 2,500 establishments. Although it is frequently impossible to determine the exact composition of flavors by examining label approval records, the review led to an estimate that possibly 25,000 of the 32,000 cooked sausage labels would be affected. Of the estimated 198,000 labels for other meat and poultry products, it is estimated that approximately 20,000 would be affected. For these products, the leading cause for change is the new requirement that Hydrolyzed Vegetable Protein (HVP) be identified separately in the list of ingredients. The analysis of 2,000 labels has, therefore led to an estimate that approximately 45,000 labels would be affected.

The cost of producing a revised label can vary widely depending on the number of colors involved, the need for graphic redesign, the portion of the label that requires modification and the printing process used. The least costly revision is a change in a single color of text, the type of revision that will be required to comply with this rule. The cost of revising the single-colored text on a label has been estimated to range from \$125 to \$150 per label.

If 25,000 cooked sausage labels had to be revised at \$150 per label, the total cost would be \$3.75 million for 2,500 establishments, or an average of \$1,500 per establishment. The 20,000 other labels would cost another \$3 million. This would be spread over a larger number of establishments including many or most of the cooked sausage producers.

There are at least two factors that should have a considerable affect in reducing these estimates of potential costs. First, FSIS is providing a period of 180 days after publication before the rule becomes effective. This action reduces the impact in two ways. It allows time to use existing label inventories and provides the opportunity to include the required label revisions with any ongoing plans to revise or redesign labels. When the required changes can be included with a planned revision, the incremental costs associated with this rule are essentially zero. Using the average label life estimate of 2 years, FSIS would expect that 25 percent of the 45,000 labels would be revised within 180 days. This would reduce the cost estimate from

\$6.75 million to approximately \$5 million.

The second factor is that establishments may choose to eliminate an ingredient rather than identify it separately on the product label. Removing an ingredient now identified as a flavoring will not lead to a label revision if the order of predominance of the remaining flavorings is not affected. FSIS believes this will be the case for a substantial number of products.

While the revision of existing labels is viewed as the primary impact of this rule, there are other potential impacts. The rule may also increase the total number of approved labels for the affected products. Today, one label may be sufficient for multiple product formulations because various ingredients are lumped together and identified collectively as "flavorings." Establishments can vary formulations and use the same label as long as the order of predominance of the total "flavoring" combination does not change.

FSIS recognizes that certain establishments have benefitted because of the policy to allow certain proteinaceous substances to be identified as flavorings. However, there was also a cost associated with the flexibility to change formulations under a single label. FSIS considers it important that consumers be able to determine, through reading the ingredients statement, when product composition is changed. The flexibility to change spices or true flavorings, without label change, is not affected by this rule.

Effect on Small Entities

The Administrator has determined that this rule will not have a significant economic impact on a substantial number of small entities as defined by the Regulatory Flexibility Act (5 U.S.C. 601). Although a substantial number of small entities will be affected, the economic impact will not be significant for most small entities.

As discussed above, over 2,500 establishments have labels approved for the production of cooked sausages with limits on added water. The majority of these processors would be viewed as small businesses under any reasonable definition of "small business." This rule will affect most of these establishments as they will have to revise the ingredient listing on the label of meat and poultry products affected. The rule will also affect some producers that only produce "other" products. However, based on the Executive Order 12291 discussion above, the Administrator has concluded

that these impacts will not be significant for a substantial number of small entities.

Background

Many meat and poultry products contain proteinaceous (substances containing protein or nitrogen) ingredients obtained from a variety of sources in addition to meat, meat byproducts, mechanically separated (species), or poultry. These proteinaceous ingredients may be of plant, yeast, dairy, egg or fish origin. These ingredients may fulfill many functions, the most significant of which are cost reduction, binding, extending and flavor enhancing. In the last decade, there has been a marked increase in the use of proteinaceous ingredients in meat and poultry products to replace, in part, the meat, meat byproduct or poultry ingredients in these products.

FSIS's labeling regulations require that all ingredients be listed on labels of products fabricated from two or more ingredients by their common or usual names (9 CFR 317.2(c)(2) and 317.2(f)(1), and 381.118 (a) and (c)) unless otherwise exempt. The terms "natural flavor," "natural flavoring," "flavor" or "flavoring" may be used to designate natural spices, essential oils, oleoresins, and other natural spice extractives (9 CFR 317.2(f)(1)(i) and 381.118(c)). FSIS has permitted these terms to include powdered onion, powdered garlic and powdered celery which are added for flavoring purposes and which do not provide a significant nutritional contribution.

In recent years, FSIS granted an exception to the common or usual name rule to proteinaceous materials, including products of livestock, poultry, egg, milk, plant or yeast origin, permitting them to be designated as natural flavor, natural flavoring, flavor or flavoring in meat and poultry products under the incorrect assumption that they were being used for flavoring purposes only and did not provide a significant nutritional contribution.

More recently, however, the levels at which proteinaceous materials are used in products have increased as manufacturers of these substances have promoted them expressly for their nutritional and other functional values, especially as low cost meat replacements. Due to concerns about the perceived improper label designation of these ingredients, FSIS published a proposed rule in the *Federal Register* (52 FR 30922) on August 18, 1987, to amend the Federal meat and poultry products inspection regulations to better define and limit the substances which are permitted to be designated as spice,

natural flavor, natural flavoring, flavor or flavoring on packages of meat and poultry products.

Most of the proteinaceous substances addressed in the proposed rule are not defined as natural flavor or natural flavoring under Food and Drug Administration (FDA) regulations (21 CFR 101.22). FDA ingredient labeling regulations explicitly state that the name of an ingredient shall be a specific name, not a collective or generic name (21 CFR 101.4(b)). Specific exemptions are listed, including exemptions for spices, natural flavors and natural flavorings (21 CFR 101.4(b)(1)). The term "spice" is defined as "any aromatic vegetable substance in the whole, broken, or ground form, except for those substances which have been traditionally regarded as foods, such as onions, garlic and celery; whose significant function in food is seasoning rather than nutritional; that is true to name; and from which no portion of any volatile oil or other flavoring principle has been removed * * *" (21 CFR 101.22(a)(2)).

The term "natural flavor" or "natural flavoring" is defined as "the essential oil, oleoresin, essence or extractive, protein hydrolysate, distillate, or any product of roasting, heating, or enzymolysis, which contains the flavoring constituents derived from a spice, fruit or fruit juice, vegetable or vegetable juice, edible yeast, herb, bark, bud, root, leaf or similar plant material, meat, seafood, poultry, eggs, dairy products, or fermentation products thereof, whose significant function in food is flavoring rather than nutritional * * *" (21 CFR 101.22(a)(3)).

FSIS has become concerned that the policy of allowing proteinaceous substances or ingredients to be declared as natural flavor, natural flavoring, flavor or flavoring has resulted in the terms being inappropriately used to list ingredients that should be identified by their common or usual name because their functions include more than flavoring.

When these ingredients are designated as natural flavor, natural flavoring, flavor or flavoring, there is no method by which consumers can determine the presence of specific components. Many people may want to avoid certain ingredients, for health reasons or because of religious or cultural preferences, but cannot do so unless those ingredients are listed on the product label by their common or usual names.

FSIS's paramount concern is public health. Many individuals suffer allergic reactions from eating certain proteinaceous substances. When such

ingredients are designated on meat or poultry product labels only as natural flavor, natural flavoring, flavor or flavoring, consumers who are sensitive ingest these ingredients without knowledge of their presence, discovering their presence only after suffering an allergic response. For example, FSIS has received several letters from persons afflicted with celiac sprue disease which prevents them from digesting gluten-containing products. Some substances now identified on labels of meat and poultry products as natural flavor, natural flavoring, flavor or flavoring may contain gluten. Consumers are unable, in these cases, to identify and thereby avoid these substances.

FSIS is aware of and concerned about the potential severity of such allergic reactions. Label designation of these proteinaceous ingredients by their common or usual names is essential to reduce the likelihood of consumers ingesting them unknowingly.

Similarly, protein hydrolysates may contain high levels of sodium. Unless hydrolysates are designated by their common or usual names, consumers are not aware of their presence, and those on sodium restricted diets unknowingly may be consuming relatively high levels of sodium.

There are also many consumers who have cultural or religious preferences regarding meat and poultry products who are frustrated by the absence of disclosure of these ingredients. For example, when components of slaughtered animal tissues, even though they may be hydrolysates or extracts (e.g., blood components), are not specifically identified, consumers have no way of determining their presence and exercising dietary preferences.

It should be noted that other substances used mainly to flavor foods, such as salt, sugar and corn syrup (a plant material hydrolysate), are already required by regulation to be identified in the ingredient statement by their common or usual names.

In the August, 1987, proposed rule (52 FR 30922), FSIS stated its intent to amend 9 CFR Part 317 of the Federal meat inspection regulations and 9 CFR Part 381 of the poultry products inspection regulations to require that ingredients, now identified as natural flavor, natural flavoring, flavor or flavoring but also serving other functions, be listed, without exception, in the list of ingredients on meat and poultry product labels by their common or usual name. This included the species of origin and the specific tissue from

which ingredients of slaughtered animal origin are derived.

The proposed regulation specified that only natural spices, essential oils, oleoresins, and other natural spice extractives, and powdered onion, powdered garlic and powdered celery may be listed as flavorings. The term "spices" would be allowed to designate only natural spices. Further, the proposed regulation specified that any other ingredients, including ingredients that contribute to flavor, must be identified by their common or usual name. When these ingredients are blends or mixtures of more than one substance or ingredient, each individual component of that mixture or blend would have to be identified by its common or usual name on the label of the product in which the blend is used as an ingredient, unless the component is a spice or flavoring as specified above.

The proposed rule (52 FR 30922) provided a comment period extending to October 19, 1987. FSIS received several requests to extend the comment period, and re-opened the comment period until December 22, 1987.

Discussion of Comments

FSIS received 80 written comments in response to the proposed rule. Multiple signature comments were treated as a single comment. Comments ranged from simple expressions of opinion to extensive commentary. Approximately 45 of the comments were submitted by employees, local sympathizers, or meat and poultry processors influenced directly by Hercules, Incorporated, a processor of yeast products. These 45 commentaries opposed the proposed rule. Of the remaining 35 comments, 22 supported the proposed rule and 13 opposed it.

Twenty-nine comments were received from individuals. Twenty-eight of those individuals were identified as Hercules, Incorporated employees or Hutchinson, MN (the location of a Hercules, Incorporated facility) residents who opposed the proposed rule. They expressed concern that a change in the regulations would result in reduced usage of yeast products which would result in job losses and increased sausage prices. Many of these commentaries also mentioned the beneficial effects to sausage due to the nutritional value of yeast products and to their binding capacity. One individual supported the proposed rule citing her allergic sensitivity to certain proteins.

Five organizations based in Hutchinson, MN opposed the proposed rule on the premise that jobs would be

lost, revenues would be reduced and the cost of sausage would be increased.

Twenty meat and poultry processors submitted comments concerning the proposed rule. Fifteen opposed the proposal, five supported it. Eleven of the comments were as a form letter opposed to the proposal. These commentaries stated there would be consumer confusion as a result of the changes and that there would be inconsistencies between labeling of flavors when present in FSIS or FDA regulated products. Four of the remaining processors opposed the proposed rule, and five supported it. Opposition to the proposed rule centered on perceived differences with FDA interpretations of flavor labeling and increased cost of sausage products.

Ten suppliers or manufacturers of seasonings and "flavorings" submitted comments. Six opposed the rule, four supported the rule. Those opposing the proposal cited increased cost, consumer misunderstanding, inconsistency with FDA labeling requirements and inconsistency with labeling some plant protein products and animal protein products.

Ten trade associations commented on the proposed rule. Nine of the associations supported the rule provided the final rule is consistent with FDA labeling interpretations. One association expressed opposition to specific label identification of hydrolyzed vegetable protein when used as an ingredient in meat or poultry products.

Six comments were received from other interested parties. Three supported the proposed rule, three opposed it. The objections centered on need for identification of specific flavoring ingredients, economic impact and loss of label flexibility for use of alternate ingredients.

The major concerns of commenters are: (1) definition of what constitutes a natural flavor, natural flavoring, flavor or flavoring, and the need for consistency of labeling between FSIS and FDA regulated products; (2) the need (or lack of) for consumers to know the specific name of some ingredients now designated as natural flavor, natural flavoring, flavor or flavoring and that specific ingredient disclosure would confuse consumers; and, (3) specific label disclosure of these substances would result in increased labeling costs. Comments relating to these specific issues will be examined and evaluated on the specific issue basis.

The labeling issue perceived as a problem by 27 commenters concerned the definition of what ingredients can properly be designated as natural flavor, natural flavoring, flavor or flavoring,

and the need for consistency of labeling such ingredients among FSIS and FDA regulated food products. FSIS agrees that there should be uniformity of labeling between FSIS and FDA regulated products, and the language of the rule has been modified to more closely resemble that found in FDA regulations. The language of the rule has been changed to more closely resemble that in the FDA regulations designating what is a spice and what is designated as natural flavor, natural flavoring, flavor or flavoring, except that spices and powdered onion, garlic and celery may also be designated as natural flavor, natural flavoring, flavor or flavoring. There were no objections to the provisions in the proposed rule to permit spices, powdered onion, powdered garlic and powdered celery to be designated as natural flavor, natural flavoring, flavor or flavoring. This practice has been followed for many years, and the final rule permits such labeling in the future even though this is not consistent with FDA regulations.

Sixteen commenters specifically referred to the significant nutritional benefits and other functional effects of many of the ingredients now being permitted to be declared as natural flavor, natural flavoring, flavor or flavoring on the labels of meat or poultry products. While it is true that ingredients now identified as natural flavor, natural flavoring, flavor or flavoring have significant nutritional benefits, FSIS has concluded that it is reasonable that such ingredients should be designated by their common or usual name because such a requirement is consistent with FDA requirements and will more properly inform consumers of ingredients that are present in a meat or poultry product.

Two commenters objected to the requirement that ingredients of livestock or poultry origin should be designated by names that include the species and livestock and poultry tissue from which the ingredients were derived. This labeling designation requirement is generally applicable to all slaughtered animal products processed under FSIS inspection, except certain mixed rendered animal fats (9 CFR 317.2(f)(1)(iii)) and casings, and will be applied to ingredients of livestock or poultry origin now being designated as natural flavor, natural flavoring, flavor or flavoring. FSIS believes that consumers have the right to know this information for purposes of health, religious or cultural reasons. The final rule does not permit ingredients of livestock or poultry origin to be designated as natural flavor, natural

flavoring, flavor or flavoring on the label of the product unless the ingredient's primary function is flavoring rather than nutritional.

FSIS agrees that there should be as much uniformity as possible between FSIS and FDA in the labeling of all food products. Therefore, the final rule is written in language which is intended to result in uniformity of label declaration. The exception being that the FSIS regulations will permit spices, powdered onion, powdered garlic and powdered celery to be designated as natural flavor, natural flavoring, flavor or flavoring on meat and poultry product labels. Those ingredients whose primary function in food is nutritional must be declared individually by their common or usual name. Most of the proteinaceous substances which have been commented on in this rulemaking procedure contain between 50 and 95 percent protein on a dry basis and, therefore, are considered to have significant nutritional value and do not meet the requirements of those substances which may be designated as natural flavor, natural flavoring, flavor or flavoring.

Fourteen commenters addressed the issue of whether consumers need to know the specific names of ingredients and that such information would confuse them. Several commenters proposed that when flavoring ingredients were added at low levels, e.g., in condimental quantities of less than one percent, then such ingredients should be permitted to be declared as flavorings. While it is agreed that many consumers may not fully understand what all ingredient names mean in terms of ingredient characteristics and functions, this is not a valid argument for not listing ingredients by their common or usual name as currently required by the Federal Meat Inspection Act, the Poultry Products Inspection Act, the Federal meat inspection regulations and the poultry products inspection regulations. Neither do the above-cited authorities provide for distinctions to be made in label disclosure based on quantitative determinations. Therefore, the final rule does not provide relief from specific disclosure of ingredients by their common or usual name depending on the amount present in the product.

Four commenters expressed the view that health, religious, ethnic and personal preferences concerning consumption of some of the ingredients now declared as flavorings was not a problem and consumers were not in need of specific information. Eight other

commenters addressed this issue and supported the need to know for those concerned consumers. The Center for Science in the Public Interest was particularly concerned about the disclosure of the presence of hydrolyzed vegetable protein (HVP) as a flavoring because it contains monosodium glutamate (MSG). They advocated that products containing HVP identify the ingredient as "hydrolyzed vegetable protein (contains MSG)" so that concerned consumers could avoid consumption of products containing MSG. There were 479 petitions from consumers supporting this position attached to that comment. The final rule requires that HVP be declared by its common or usual name on the labels of products in which it is an ingredient. FSIS believes that the "(contains MSG)" is unnecessary as consumers who need to avoid MSG would be aware that HVP contains MSG. The requirement to disclose that HVP contains MSG would also be inconsistent with FDA requirements, as "(contains MSG)" is not required on labels of FDA regulated products containing HVP.

FSIS also believes that products labeled according to the new rule will better enable consumers to exercise their right to know the ingredients contained in meat and poultry products. This will make it easier for consumers to avoid purchase and consumption of products which may contain ingredients to which they may be allergic or which they may want to avoid for personal, ethnic or religious reasons. In addition, the requirement that ingredients which are derived from livestock and poultry tissues be identified by both species and tissue will also help consumers make informed selections for the reasons described above. This requirement does not apply to mixed animal fats or casings.

Fifteen commenters expressed concern that specific disclosure of ingredients would increase costs to processors and consumers due to labeling change requirements. FSIS recognizes that changing the ingredients statement on labels does cost money. Therefore, the effective date of this rule provides for sufficient time to use up existing labels and to coordinate ingredient declaration changes with other normal label changes that are routinely made as to minimize the cost of compliance with this rule.

Three commenters referred to loss of flexibility in changing formulations when specific ingredient identification of ingredients, which are not spices or flavors, is required. Some of the current

flexibility will be lost under this final rule. When product composition is changed, it is essential for consumers to be better able to determine when a product contains an ingredient they may wish to avoid. This determination is made by reading the ingredients statement. Flexibility to change spices or true flavors is not affected by this rule.

The concerns expressed about the cost of label changes due to the impact of the proposed rules is of concern to the FSIS. Therefore, to minimize the cost impact of the required labeling changes, the effective date of 180 days from date of publication will allow processors sufficient time to make any formulation of labeling changes they may desire without unnecessary economic hardship.

Final Rule

After careful consideration of the comments and all other available information, FSIS is amending Parts 317 and 381 of the meat and poultry products inspection regulations to more clearly identify those ingredients that may be designated as "spice," "natural flavor," "natural flavoring," "flavor" or "flavoring" in the list of ingredients on the labels of meat or poultry products as set forth below:

List of Subjects

9 CFR Part 317

Labeling, Marking devices, and Containers.

9 CFR Part 381

Labeling, and Containers.

PART 317—LABELING, MARKING DEVICES, AND CONTAINERS

1. The authority citation for part 317 is revised to read as follows and the authority citations following the sections in part 317 are removed:

Authority: 21 U.S.C. 457, 601-695; CFR 2.17, 2.55.

2. Section 317.2(f)(1)(i) is revised to read as follows:

§ 317.2 Labels: definition; required features.

* * * * *

(f) * * *

(1) * * *

(i) The terms spice, natural flavor, natural flavoring, flavor and flavoring may be used in the following manner:

(A) The term "spice" means any aromatic vegetable substance in the whole, broken, or ground form, with the exceptions of onions, garlic and celery,

whose primary function in food is seasoning rather than nutritional and from which no portion of any volatile oil or other flavoring principle has been removed. Spices include the spices listed in 21 CFR 182.10, and 184.

(B) The term "natural flavor," "natural flavoring," "flavor" or "flavoring" means the essential oil, oleoresin, essence or extractive, protein hydrolysate, distillate, or any product or roasting, heating or enzymolysis, which contains the flavoring constituents derived from a spice, fruit or fruit juice, vegetable or vegetable juice, edible yeast, herb, bark, bud, root, leaf or any other edible portion of a plant, meat, seafood, poultry, eggs, dairy products, or fermentation products thereof, whose primary function in food is flavoring rather than nutritional. Natural flavors include the natural essence or extractives obtained from plants listed in 21 CFR 182.10, 182.20, 182.40, 182.50 and 184, and the substances listed in 21 CFR 172.510. The term natural flavor, natural flavoring, flavor or flavoring may also be used to designate spices, powdered onion, powdered garlic, and powdered celery.

3. Section 317.8(b)(7) is revised to read as follows:

§ 317.8 False or misleading labeling or practices generally; specific prohibitions and requirements for labels and containers.

(b)

(7)(i) No ingredient shall be designated on the label as a spice, flavoring, or coloring unless it is a spice, flavoring, or coloring, as the case may be. An ingredient that is both a spice and a coloring, or both a flavoring and a coloring, shall be designated as "spice and coloring", or "flavoring and coloring", as the case may be, unless such ingredient is designated by its common or usual name.

(ii) Any ingredient not designated in § 317.2(f)(1)(i) of this part whose function is flavoring, either in whole or in part, must be designated by its common or usual name. Those ingredients which are of livestock and poultry origin must be designated by names that include the species and livestock and poultry tissues from which the ingredients are derived.

PART 381—POULTRY PRODUCTS INSPECTION REGULATIONS

4. The authority citation for Part 381 continues to read as follows and the authority citations following the sections in Part 318 are removed:

Authority: 7 U.S.C. 450; 21 U.S.C. 451-470; 601-695; 33 U.S.C. 1254; 7 CFR 2.17, 2.55.

5. Section 381.118(c) is revised to read as follows:

§ 381.118 Ingredients statement.

(c) The terms spice, natural flavor, natural flavoring, flavor or flavoring may be used in the following manner:

(1) The term "spice" means any aromatic vegetable substance in the whole, broken, or ground form, with the exceptions of onions, garlic and celery, whose primary function in food is seasoning rather than nutritional and from which no portion of any volatile oil or other flavoring principle has been removed. Spices include the spices listed in 21 CFR 182.10, and 184.

(2) The term "natural flavor," "natural flavoring," "flavor" or "flavoring" means the essential oil, oleoresin, essence or extractive, protein hydrolysate, distillate, or any product of roasting, heating or enzymolysis, which contains the flavoring constituents derived from a spice, fruit or fruit juice, vegetable or vegetable juice, edible yeast, herb, bark, bud, root, leaf or any other edible portions of a plant, meat, seafood, poultry, eggs, dairy products, or fermentation products thereof, whose primary function in food is flavoring rather than nutritional. Natural flavors include the natural essence or extractives obtained from plants listed in 21 CFR 182.10, 182.20, 182.40, 182.50 and 184, and the substances listed in 21 CFR 172.510. The term natural flavor, natural flavoring, flavor or flavoring may also be used to designate spices, powdered onion, powdered garlic, and powdered celery.

(i) Natural flavor, natural flavoring, flavor or flavoring as described in paragraph (c)(1) and (2) of this section, which are also colors shall be designated as "natural flavor and coloring," "natural flavoring and coloring," "flavor and coloring" or "flavoring and coloring" unless designated by their common or usual name.

(ii) Any ingredient not designated in paragraph (c)(1) of this section whose function is flavoring, either in whole or in part, must be designated by its common or usual name. Those ingredients which are of livestock or poultry origin must be designated by names that include the species and livestock and poultry tissues from which the ingredients are derived.

Done at Washington, DC on: January 28, 1990.

Lester M. Crawford,
Administrator, Food Safety and Inspection Service.

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9 CFR Part 318

[Docket No. 86-038F]

RIN 0583-AA30

Determination of "Added Water" in Cooked Sausages

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Final rule.

SUMMARY: The Food Safety and Inspection Service (FSIS) is amending the Federal meat inspection regulations by (1) defining the kinds of proteins which will be credited as of livestock or poultry origin and those that will not be credited as of livestock or poultry origin when added water is calculated in cooked sausages, and (2) by setting forth the method by which FSIS determines the quantity of added water in cooked sausages. Added water in cooked sausages means any water not attributable to ingredients of slaughtered livestock or poultry origin, except those processed by hydrolysis, extraction, concentrating, or drying; and any water not attributable to one percent of the formula weight of the cooked sausage by ingredients of slaughtered livestock or poultry origin processed by hydrolysis, extraction, concentrating, or drying or by ingredients from any other protein-contributing source. The Federal meat inspection regulations limit the amount of added water in cooked sausages to a maximum percentage of finished product weight. The amount of added water is determined by laboratory analysis and appropriate calculations. Each one percent of protein from sources other than slaughtered livestock or poultry origin or from ingredients of slaughtered livestock or poultry origin which are processed by hydrolysis, extraction, concentrating, or drying, not subtracted from the total protein content results in the addition of 4 percent added water in cooked sausages.

Therefore, FSIS is amending the Federal meat inspection regulations to define the kinds of protein which will be credited the same as protein of slaughtered livestock or poultry origin and those that will not be credited the same as protein of slaughtered livestock

or poultry origin when added water is calculated, and to set forth the method by which the amount of added water will be determined.

EFFECTIVE DATE: August 28, 1990.

FOR FURTHER INFORMATION CONTACT: Ashland L. Clemons, Director, Standards and Labeling Division, Regulatory Programs, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC 20250; Area Code (202) 447-6042.

SUPPLEMENTARY INFORMATION:

Executive Order 12291

The Administrator has determined that this final rule is not a major rule under Executive Order 12291. It will not result in an annual effect on the economy of \$100 million; a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies or geographic regions; or a significant adverse effect on competition, employment, investment, productivity, innovation, or upon the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets.

The final rule defines the kinds of proteins which will be credited the same as protein of slaughtered livestock or poultry origin and those that will not be credited the same as protein of slaughtered livestock or poultry origin when added water is calculated in cooked sausages and sets forth the method by which FSIS will calculate the amount of added water in cooked sausages. This final rule may require some cooked sausage processors to reformulate their product(s). These product reformulations may require some minor labeling changes. Costs to reformulate and/or to modify labels will not result in an annual effect on the economy of \$100 million or more.

Effect on Small Entities

The Administrator, FSIS, has determined that this action will not have a significant economic impact on a substantial number of small entities as defined by the Regulatory Flexibility Act (5 U.S.C. 601). A substantial number of small entities could be affected by this rule but not significantly so. This final rule may require some cooked sausage processors to reformulate their products and make labeling changes to reflect changes in product formulations. However, to minimize any economic impact of this rule, FSIS has modified the rule to permit the addition of ingredients not of slaughtered livestock or poultry origin or of slaughtered

livestock or poultry origin which have been processed by hydrolysis, extraction, concentrating, or drying, in an amount of one percent of the product formulation. Since some of these ingredients are less expensive than slaughtered livestock or poultry ingredients, some savings may be realized. In addition, the rule will not become effective for 180 days after publication to allow affected entities ample time to reformulate products and to use up existing labels.

Background

Many meat and poultry products contain added water. The amount of added water in a product is controlled by food standard regulations (See 9 CFR part 319 and part 381, subpart P) or by label declarations (See 9 CFR part 317 and part 381, subpart N) to ensure that consumers receive products that are not adulterated with excess water in violation of the Federal Meat and Poultry Products Inspection Acts (21 U.S.C. 601(m)(8) and 453(g)(8), respectively). Products containing added water include such widely diverse groups as sausages, cured products, and seasoned fresh products. Methods of control currently employed by FSIS to ensure product compliance with regulatory requirements include formulation control, weight measurement, and laboratory analysis. Laboratory analysis of finished product is used more and more as the preferred method of measurement to ensure product compliance with standards and/or label declarations. Laboratory analysis is the only method used for determining compliance with added water limits for cooked sausages, which are the subject of this final rule.

Cooked sausages are meat food products which have existed as recognized items of commerce for generations. They are commonly known by such names as frankfurters, bologna, liverwurst, and cotto salami (See 9 CFR 319.140, 319.180-319.182). These products are mixtures of tissues of livestock or poultry origin, water, salt, seasonings, and other ingredients. Cooked sausages may be cured or smoked and may contain binders which are added for functional purposes. The amount of added water which may be present in the finished product is limited by regulation (9 CFR 319.140, 319.180-319.182). Added water may be water that is added as such or contained in certain ingredients which are not of slaughtered livestock or poultry origin. Water naturally contained in meat, meat byproducts, mechanically separated (species), or poultry product ingredients

is not considered as added water but as water indigenous to livestock or poultry.

The procedure traditionally employed by FSIS to determine the amount of added water present in a product has been to: (1) calculate the protein attributable to protein ingredients of slaughtered livestock or poultry origin, (2) multiply that figure by four to get the amount of water attributable to the slaughtered livestock or poultry ingredients, and (3) subtract the water attributable to the slaughtered livestock or poultry ingredients from the total water present to get "added water." This calculation is based on the fact that slaughtered livestock or poultry ingredients have a consistent moisture to protein ratio of approximately 4:1 that is utilized for this compliance determination.

Protein content is determined by measuring the amount of nitrogen present in a sample of product and making appropriate calculations. Therefore, when nonmeat proteins or other nitrogenous substances are added to cooked sausages, they must be deducted from total analytical protein to determine the amount of slaughtered livestock or poultry protein present and to determine what proportion of the water present in the product is attributable to these slaughtered livestock or poultry ingredients. This calculation is easily accomplished if the laboratory knows the amount of nonmeat protein or other nitrogenous substances that have been added so that a deduction can be made from the total protein content of the finished product. This information is normally available to, and provided by, the inspector taking the sample at the establishment.

In recent years, proteinaceous materials identified only as "flavorings" have been utilized in increasingly large quantities as ingredients in cooked sausages and have constituted as much as 20 percent or more of the protein in some cooked sausage formulations without being deducted in the added water calculations.

FSIS was petitioned by three trade associations and one company to reassess the situation in which nonmeat proteins have been counted in determining added water in cooked sausages. These petitioners asked FSIS to deduct nonmeat proteins when determining the added water content of cooked sausages and to enforce existing regulatory standards and labeling requirements. FSIS believed that while these proteinaceous additives might serve as flavorings or flavor enhancers, they should be deducted when determining the added water content of

cooked sausages. This rule responds to the above-mentioned petitions.

FSIS had, in response to petitions requesting that nonmeat proteins be included as part of the slaughtered livestock or poultry ingredients when calculating "added water," considered the option of permitting a limited amount of nonmeat proteins and four times that amount of added water to be considered as part of the slaughtered livestock or poultry ingredients when calculating added water in cooked sausages. However, FSIS believed that any such crediting of nonmeat proteins, even a limited amount, would be inconsistent with current FSIS policy as reflected in the Protein Fat Free (PFF) regulations for cured pork products, which do not allow any nonmeat protein contribution to minimum PFF percentages (9 CFR 319.104, 319.105, 318.19 and 327.23). An attempt by FSIS to review nonmeat proteins on a substance-by-substance basis to determine whether or not the protein should be treated the same as protein of slaughtered livestock or poultry origin would be unworkable because so many ingredients are utilized to perform various functions, such as binding, emulsifying and stabilizing.

Consequently, FSIS published a proposed rule in the *Federal Register* (52 FR 30925) to establish procedures by which the "added water" content of cooked sausages would be determined. The proposed rule would ensure that cooked sausages to which nonmeat protein had been added were in compliance with prescribed regulatory standards, guaranteeing that such products would not be considered adulterated, misbranded, or otherwise not in accordance with the requirements of the Federal Meat Inspection Act. The proposed rule, which was consistent with regulations concerning the addition of nonmeat proteinaceous substances to cured pork products, addressed concerns expressed by the three trade associations and proposed to implement the principle that nonmeat protein used for any purpose should not result in the replacement of proteins of slaughtered livestock or poultry origin in cooked sausages.

FSIS proposed to determine the amount of added water in cooked sausages based solely on the amount of protein which was of slaughtered livestock or poultry origin and contributed by meat, meat byproduct, mechanically separated (species), and poultry product ingredients, except ingredients that have been processed by such means as hydrolysis, extraction, concentrating, or drying. The total

protein contributed by proteins of slaughtered livestock or poultry ingredients must be known to ensure compliance with regulatory limits for added water. It was proposed that products such as partially defatted chopped (species), partially defatted (species) fatty tissues, and proteolytic enzyme treated (species) trimmings be credited as part of slaughtered livestock or poultry ingredients, because they are moderately processed ingredients which are used as a nutrient source and not for specific functional purposes, such as binding, emulsifying, stabilizing, flavoring, and similar uses (see 9 CFR 301.2(tt) and 301.2(uu); see also 9 CFR 319.5, 319.15(e), 319.180(g), and 381.1(b)(41)).

To determine the amount of protein from slaughtered livestock or poultry ingredients during added water calculations, FSIS proposed that: (1) all proteinaceous materials which are not of slaughtered livestock or poultry origin be identified as to the amount added to the product formulation, and these proteinaceous materials be deducted from total protein when calculating the amount of added water (such substances would include but would not be limited to plant products, yeast products, milk products, egg products, or their derivatives); (2) proteinaceous materials which were of slaughtered livestock or poultry origin but which are processed by such means as hydrolysis, extraction, concentrating, or drying would not be credited as part of the slaughtered livestock or poultry ingredients. The amount of protein added to the product formulation by ingredients processed by hydrolysis, extraction, concentrating, or drying would be required to be identified for deduction from total protein. (Such proteinaceous materials included, but were not limited to (species or kind) extracts, stocks and broths, hydrolyzed tissues, and tissue extracts.) These materials, while of slaughtered livestock or poultry origin, have been so extensively processed that they have lost their identity as slaughtered livestock or poultry ingredients. These materials have been added as functional ingredients, and the degree of processing used to make these ingredients is such that the natural moisture to protein ratio has been altered.

Accordingly, FSIS proposed that all nonmeat proteins be deducted from total protein present during compliance determinations of added water in cooked sausages. The proposed rule was published on August 18, 1987 (52 FR 30925), and provided for a comment period until October 19, 1987. FSIS

received several requests to extend the comment period, and reopened the comment period until December 22, 1987.

Discussion of Comments

FSIS received 88 comments in response to the proposed rule. Multiple signature comments were counted as a single comment. Comments ranged from simple expressions of opinion to extensive commentary. Approximately 57 of the comments were submitted by employees, local sympathizers, or meat and poultry processors influenced directly by Hercules, Incorporated, a producer of yeast products. These 57 commenters opposed the proposed rule. Of the remaining 31 comments, 24 supported the proposed rule and 7 opposed it.

Thirty-nine comments were received from individuals. All of these individuals were identified as employees of Hercules, Incorporated, or residents of Hutchinson, MN (location of a Hercules, Incorporated, facility) and all opposed the proposed rule. They expressed concern that a change in the regulations would result in reduced usage of yeast products which could result in lost jobs and increased sausage prices.

Five organizations based in Hutchinson, MN opposed the proposed rule on the premise that jobs would be lost, revenues would be reduced, and the cost of sausage would be increased.

Twenty comments were received from meat and poultry processors. Thirteen opposed the proposed rule on the basis that it would require formulation changes and would increase product costs. The seven remaining processors generally supported the concept of limiting the amount of added water in cooked sausage. However, several suggested limiting the amount of nonmeat protein that could be added to cooked sausage formulations and/or permitting limited amounts of nonmeat proteins to be considered the same as proteins of slaughtered livestock or poultry origin when determining "added water."

Ten suppliers or manufacturers of seasonings and flavorings submitted comments. Six generally supported the proposed rule, four opposed it. The opposition centered on increased costs if more than 10 percent "added water" is not permitted in cooked sausages. Those in support of the concept wanted a limited quantity of nonmeat protein to be credited the same as protein of slaughtered livestock or poultry origin when calculating "added water."

Seven trade associations commented in support of the proposed rule. All suggested limiting the amount of nonmeat protein that could be considered the same as protein of slaughtered livestock or poultry origin or limiting the amount of nonmeat protein that could be added as ingredients in cooked sausage.

Seven comments were received from other interested parties. Three opposed the proposal and questioned the economic impact of the proposed rule. Two wanted to change the standards for cooked sausage to require a minimum protein content. Two supported the proposed rule.

The major issues addressed by the commenters were: (1) the inclusion of nonmeat protein when calculating "added water"; (2) the economic impact of limiting the amount of added water in cooked sausage to the level permitted by regulatory standards; and (3) inclusion of all processed proteins of slaughtered livestock or poultry origin when calculating "added water." These issues will be discussed individually.

Many commenters wanted to include some, or all, nonmeat proteins when determining the amount of added water in cooked sausages. Several wanted restrictions on the amount of nonmeat proteins allowed in cooked sausages, and most wanted to include a maximum amount. Three commenters wanted no restrictions on the amount of nonmeat protein which would be permitted and credited the same as protein of slaughtered livestock or poultry origin when calculating "added water."

FSIS has considered these arguments and has determined that it is appropriate to provide for a limited amount of nonmeat proteins to be credited the same as protein of slaughtered livestock or poultry origin when determining "added water." Past practice permitted the inclusion of some nonmeat proteins in calculating added water as described earlier. FSIS has concluded that a reasonable amount would be one percent of the formula weight excluding added water. It is further concluded that the one percent nonmeat protein may be contributed by any proteinaceous ingredient not of slaughtered livestock or poultry origin or any ingredient of slaughtered livestock or poultry origin which has been processed by hydrolysis, extraction, concentrating, or drying. This will include ingredients added for purposes such as binding, extending, flavor enhancement, and other functions.

Crediting one percent of nonmeat proteins the same as protein of slaughtered livestock or poultry origin will not significantly affect the

nutritional character of the cooked sausages. Most cooked sausages contain approximately 11 percent protein from slaughtered livestock or poultry ingredients. The creditable one percent nonmeat protein could therefore constitute approximately nine percent of total protein to be credited in calculating added water.

Some commenters suggested that the nutritional value of the nonmeat proteins be considered when determining whether they should be credited. FSIS recognizes that the nonmeat proteins may be either superior to, or inferior to, proteins of slaughtered livestock or poultry origin, but protein quality is not an issue when determining added water. The issues associated with nutritional equivalency of different kinds of proteins are too numerous and complex to be within the scope of this rulemaking. However, FSIS will entertain petitions for a separate rulemaking on this issue.

The second major issue addressed by the comments was the economic impact. Commenters addressed the scope of the FSIS's Threshold Analysis, the estimate for current production practices, the cost of nonmeat proteins, and the impact on small businesses. The Threshold Analysis is a document prepared by FSIS to facilitate decisionmaking prior to the development of a regulatory response and includes information whereby the Administrator may determine whether Regulatory Flexibility Analysis is required under the Regulatory Flexibility Act. The Threshold Analysis as used by FSIS is not a rulemaking requirement. The comments on economic impact were directed at the analysis conducted by FSIS as part of the Threshold Analysis prepared during the development of the proposal.

Comments submitted by Hercules, Incorporated, state that USDA did not adequately take economic factors into consideration when it calculated only the cost to the regulated industry. The Department is well aware that certain types of regulations have the effect of benefitting one sector of the economy at the expense of the other. In this case, the recent increased use of nonmeat proteins has benefitted the suppliers of these substances at the expense of the producers and suppliers of livestock or poultry ingredients. The regulation, as proposed, would have reversed that trend, but the net gains and losses would have been zero. The important point is that regulatory decisions that affect the choice of ingredients should not be based on who wins and who loses, but rather on a regulatory

objective that is based on the intent of the relevant statute.

FSIS believes that the proposal was consistent with the intent of the existing statutes and regulations. This final rule is also consistent with that intent and, in addition, accommodates practices that are viewed as "traditional" or have evolved over several years. In this case, production practices have evolved over a period of time as the result of a series of policy decisions on specific proteinaceous substances.

The comments by Hercules, Incorporated, also criticized the FSIS analysis for focusing on changes in production cost and not on projected changes in retail prices. FSIS is well aware that the food distribution chain frequently uses standard markups to arrive at wholesale and retail prices. Retail price increases above production cost increases are also accompanied by additional profits at the wholesale or retail level. The net effect of markups is also a transfer or shift in impact with increased costs equaling increased benefits. For this reason, FSIS focused its threshold analysis on changes in production costs.

There is a second issue related to retail price increases. The comments from Hercules, Incorporated, suggest that consumers would be unhappy about any price increase for cooked sausages. FSIS points out that it is not a simple issue of a single product with two prices. This regulation addresses analytical procedures for determining compliance by a standardized meat food product. FSIS believes that consumers expect the protein in these products to come primarily from ingredients of slaughtered livestock or poultry origin. A product with substantial amounts of proteins not of slaughtered livestock or poultry origin is a different product, and it is not clear how fully informed consumers would make their purchasing decisions.

A second area of comment on economic impact concerned the FSIS estimate on the use of nonmeat proteins in cooked sausages. In preparing the Threshold Analysis, FSIS estimated that the average cooked sausage contained approximately 0.83 percent protein from all nonmeat protein sources. Hercules, Incorporated, cited discussions with experts that indicate the average level of use is about 1.25 percent. FSIS believes that 0.83 percent is the best available estimate. Before using this estimate, FSIS examined over 1,200 different formulations. In view of the fact that the final rule allows one percent nonmeat protein to be counted the same as protein of slaughtered

livestock or poultry origin during calculations, the difference in these estimates becomes less important.

Some commenters also claimed that FSIS overestimated the cost of nonmeat proteins. While that may be correct, the nonmeat protein suppliers have not provided any detailed information on the cost of their products. However, because of the changes in the final rule, this issue also becomes less important. Using the Threshold Analysis estimates of 0.83 percent nonmeat protein content and \$2.50 per pound for flavorings, FSIS calculated a production cost change of \$25 million. Using the Hercules, Incorporated, estimates of 1.25 percent for nonmeat protein content and \$1.50 per pound, the final rule would result in a production cost change of \$11.25 million. (This estimate assumes that all producers are currently formulating for 1.25 percent nonmeat protein and would cut back to one percent.)

Comments on economic impact, including comments from the U.S. Small Business Administration, also addressed the impact on small businesses and the possible requirement to conduct a Regulatory Flexibility Analysis. In publishing the proposal, FSIS concluded that the rule may affect a substantial number of small businesses. At the time, FSIS was less certain that the impact on many small processors would not be significant. The changes in the final rule remove any uncertainty. With the allowance of one percent of protein from livestock or poultry origin processed by hydrolysis, extraction, concentrating, or drying, and/or any other protein-contributing source to be credited in the added water calculation, the impact on small businesses would not be significant.

The third major issue addressed in the comments concerned what proteins of slaughtered livestock and poultry origin should be included when calculating added water. Several commenters wanted to include all proteins of slaughtered livestock or poultry origin. Their arguments were based on historic precedence and the character of the protein. FSIS believes that proteinaceous materials which are of slaughtered livestock or poultry origin, but which have been processed by such means as hydrolysis, extraction, concentrating, or drying, have lost their character as ingredients of slaughtered livestock or poultry and should not be considered as such. These proteinaceous materials include, but are not limited to (species or kind), extract, stock and broth, hydrolyzed tissue, and tissue extract. However, as discussed above, the final rule permits these proteins

(livestock or poultry origin processed by hydrolysis, extraction, concentrating or drying) to be used at a level of one percent of the formula weight, and they will be credited as slaughtered livestock or poultry origin when calculating added water.

Final Rule

Several changes have been made to the final rule in response to comments received on the proposal as discussed earlier and for clarification purposes.

First, FSIS has determined that it is appropriate to permit one percent of the formula weight of certain ingredients not considered as proteins of slaughtered livestock or poultry origin to be considered as protein when calculating added water. This means that ingredients of slaughtered livestock or poultry origin which have been processed by hydrolysis, extraction, concentrating, or drying or ingredients from any other protein-contributing source, such as plant products, dairy products, egg products, yeast products, or their derivatives will be credited as proteins at a level of one percent of the formula weight in calculating added water. This determination necessitated further revisions to the rule as discussed below.

Second, as a result of the determination made above, it was necessary to develop and define two categories of proteins. In the proposal, these categories were referred to as meat and nonmeat proteins. With the addition of the one percent allowance, it was necessary to more clearly differentiate between the kinds of proteins that would and would not be credited when calculating added water. The first category is designated "Group 1 protein-contributing ingredients," and this category covers all ingredients of slaughtered livestock or poultry origin from muscle tissue which is skeletal or which is found in the edible organs, with or without the accompanying and overlying fat, and the portions of bone, skin, sinew, nerve, and blood vessels which normally accompany the muscle tissue and which are not separate from it in the process of dressing; meat byproducts; poultry products; and mechanically separated (species), except those ingredients processed by hydrolysis, extraction, concentrating or drying. The second category is designated "Group 2 protein-contributing ingredients" and covers all protein-contributing ingredients of slaughtered livestock or poultry origin which have been processed by hydrolysis, extraction, concentrating, or drying, and any other ingredient which contributes protein, such as plant

products, dairy products, egg products, yeast products, or their derivatives.

These categories (Group 1 and Group 2) were developed without regard to the quality or value of the proteins, but were simply chosen to make clear what kinds of protein are traditionally considered as proteins of slaughtered livestock or poultry origin (Group 1) and those which may be of livestock or poultry origin, but which have been processed to a degree where they have lost their traditional identity and to include nonlivestock or nonpoultry protein substances (Group 2).

Third, FSIS has defined the term cooked sausage by providing a reference to § 319.140 and §§ 319.180-182 of the Federal meat inspection regulations which describe cooked sausages and provide standards of identity for sausage products. Because this rule pertains only to cooked sausages and sets forth the method for determining added water in cooked sausages, it was necessary to include a reference to the products covered by this rule.

Fourth, the description of the method used to calculate added water, set forth in the proposal, has been extensively revised. The revision is a result of the FSIS decision to permit one percent of Group 2 proteins to be credited as livestock or poultry protein. Therefore, it was necessary to revise § 318.22 as originally set forth in the proposal. This rule provides the detailed step-by-step procedure FSIS will use to calculate added water in cooked sausages.

Some processors may wish to reformulate their products as a result of this rule. To minimize any disruption, FSIS is providing an effective date of 180 days from the date of publication.

Final Rule

For reasons set forth in the preamble, part 318 is amended as set forth below:

List of Subjects in 9 CFR Part 318

Meat inspection, Preparation of product, Approval of substances.

PART 318—ENTRY INTO OFFICIAL ESTABLISHMENTS; REINSPECTION AND PREPARATION OF PRODUCTS

1. The authority citation for part 318 is revised to read as follows and the authority citations following the sections in part 318 are removed:

Authority: 7 U.S.C. 450, 1901-1906; 21 U.S.C. 451-470, 601-695; 33 U.S.C. 1254; 7 CFR 2.17, 2.55.

2. Part 318 is amended by adding a new § 318.22 to read as follows:

§ 318.22 Determination of added water in cooked sausages.

(a) For purposes of this section, the following definitions apply.

(1) *Cooked sausage.* Cooked sausage is any product described in § 319.140 and §§ 319.180-319.182 of this chapter.

(2) *Group 1 Protein-Contributing Ingredients.* Ingredients of livestock or poultry origin from muscle tissue which is skeletal or which is found in the edible organs, with or without the accompanying and overlying fat, and the portions of bone, skin, sinew, nerve, and blood vessels which normally accompany the muscle tissue and which are not separated from it in the process of dressing; meat byproducts; mechanically separated (species); and poultry products; except those ingredients processed by hydrolysis, extraction, concentrating or drying.

(3) *Group 2 Protein-Contributing Ingredients.* Ingredients from Group 1 protein-contributing ingredients processed by hydrolysis, extraction, concentrating, or drying, or any other ingredient which contributes protein.

(b) The amount of added water in cooked sausage is calculated by:

(1) Determining by laboratory analysis the total percentage of water contained in the cooked sausage; and

(2) Determining by laboratory analysis the total percentage of protein contained in the cooked sausage; and

(3) Calculating the percentage of protein in the cooked sausage contributed by the Group 2 protein-contributing ingredients; and

(4) Subtracting one percent from the total percentage of protein calculated in (b)(3); and

(5) Subtracting the remaining percentage of protein calculated in (b)(3) from the total protein content determined in (b)(2); and

(6) Calculating the percentage of indigenous water in the cooked sausage by multiplying the percentage of protein determined in (b)(5) by 4. (This amount is the percentage of water attributable to Group 1 protein-contributing ingredients and one percent of Group 2 protein-contributing ingredients in a cooked sausage.); and

(7) Subtracting the percentage of water calculated in (b)(6) from the total percentage of water determined in (b)(1). (This amount is the percentage of added water in a cooked sausage.)¹

¹ The equation for the narrative description of the calculation for added water is as follows: $AW = TW - (TP - (P - 1.0))4$. Where AW = Added Water, TW = Total Water Determined by Laboratory Analysis, TP = Total Protein Determined by Laboratory Analysis, P = Protein Contributed by Group 2 Protein-Contributing Ingredients, 1.0 = Percent Allowance for Group 2 Protein-

Done at Washington, DC, on: January 28, 1990.

Lester M. Crawford,

Administrator, Food Safety and Inspection Service.

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DEPARTMENT OF THE TREASURY**Office of Thrift Supervision****12 CFR Part 563**

[No. 90-163]

Operations; Outside Borrowing and Preferred Stock Authority Delegation Reference Removed

AGENCY: Office of Thrift Supervision, Treasury.

ACTION: Final rule.

SUMMARY: The Office of Thrift Supervision ("Office") is amending its regulations on outside borrowings and preferred stock by deleting the references to delegated authority. The delegation of authority concerning outside borrowings is being expanded to allow a District Director's designee to approve as well as deny any outside borrowings in excess of one year filed by savings associations who do not meet capital requirements. The delegation of authority concerning preferred stock is being expanded to allow the District Director authority to approve or deny any preferred stock applications which present no issues of policy or law. This expansion of authority will shorten the decision chain and enable the Office to respond more quickly and efficiently to outside borrowing notices and preferred stock applications.

EFFECTIVE DATE: March 1, 1990.

FOR FURTHER INFORMATION CONTACT:

John F. Connolly, Associate Deputy Director, Corporate and Securities Division, (202) 906-6465, Office of Thrift Supervision, Department of the Treasury, 1700 G Street NW., Washington, DC 20552, or Robyn Dennis, Financial Analyst, Supervision/Operations, (202) 331-4572, Office of Thrift Supervision, Department of the Treasury, 801 17th Street NW., Washington, DC 20006.

SUPPLEMENTARY INFORMATION: The Director of the Office of Thrift Supervision ("Director") has previously

Contributing Ingredients, 4 = Moisture-Protein Ratio for Cooked Sausage.

delegated significant elements of application and supervisory functions to the District Offices under the direction of the District Directors. The Office of Thrift Supervision, created by the Financial Institutions Reform, Recovery, and Enforcement Act of 1989 ("FIRREA"), Public Law 101-73, 103 Stat. 183, intends to continue the process of delegation as the Director has determined that these and other recent delegations of authority will further improve the effectiveness of the supervisory and application functions.

As part of this continuing process, the Director, upon consideration of a recommendation by its Office of Supervision/Operations ("Supervision/Operations"), has determined that delegation of decisions relating to supervisory and application issues, currently involving Washington staff, can be more efficiently and effectively carried out by relying on the existing expertise at the District Offices, except for those decisions involving significant issues of policy or law upon which the Director has not taken a formal position.

This delegation does not diminish the statutory responsibility of the Director, through Supervision/Operations, to oversee, control, and where necessary improve application and supervisory functions. It will, however, expedite delivery of decisions.

Eventually it is anticipated all delegations currently in the regulations will be transferred to the Delegation Data Base maintained by the Secretariat of the Office. The Delegation Data Base will be published periodically and updated when necessary. This will provide a central repository for all delegations of authority including those currently in the regulations and those granted by Director's orders.

Pursuant to 5 U.S.C. 553 Administrative Procedure Act, the Director finds that, because these amendments relate to rules of the Office's organization, procedure, and practice, notice and public procedure are unnecessary, as is the 30-day delay of the effective date.

Regulatory Flexibility Act

Because no notice of proposed rulemaking is required for this regulation, the provisions of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) do not apply.

Executive Order 12291

This revision of 12 CFR 563.75 and 563.80 does not fall within the scope of