

reducing the additional holding and storage payments for 2002 reserve raisins intended for use as cattle feed so that such payments will accrue beginning September 13, 2003, rather than August 1, 2003.

This rule imposes no additional reporting or recordkeeping requirements on either small or large raisin handlers. As with all Federal marketing order programs, reports and forms are periodically reviewed to reduce information requirements and duplication by industry and public sector agencies. Finally, USDA has not identified any relevant Federal rules that duplicate, overlap or conflict with this rule.

Further, the RAC's Administrative Issues Subcommittee and RAC meetings on July 2, 2003, where this action was deliberated were both public meetings widely publicized throughout the raisin industry. All interested persons were invited to attend the meetings and participate in the industry's deliberations. Finally, all interested persons are invited to submit information on the regulatory and informational impacts of this action on small businesses.

A small business guide on complying with fruit, vegetable, and specialty crop marketing agreements and orders may be viewed at: <http://www.ams.usda.gov/fv/moab.html>. Any questions about the compliance guide should be sent to Jay Guerber at the previously mentioned address in the **FOR FURTHER INFORMATION CONTACT** section.

A 60-day comment period is invited to allow interested persons to respond to this rule. All written comments timely received will be considered prior to finalization of this rule.

After consideration of all relevant material presented, including the information and recommendation submitted by the RAC and other available information, it is hereby found that this rule, as hereinafter set forth, will tend to effectuate the declared policy of the Act.

Pursuant to 5 U.S.C. 553, it is also found and determined upon good cause that it is impracticable, unnecessary, and contrary to the public interest to give preliminary notice prior to putting this rule into effect, and that good cause exists for not postponing the effective date of this rule until 30 days after publication in the **Federal Register** because: (1) This action needs to be in place by August 1, 2003, so that additional payments regarding reserve raisins held by handlers on August 1, 2003, and intended for cattle feed will be incurred beginning September 13, 2003, rather than August 1 2003; (2)

handlers and producers are aware of this action which was recommended by the RAC at a public meeting; (3) the action was recommended by a unanimous vote of the RAC; and (4) this interim final rule provides a 60-day comment period for written comments and all comments timely received will be considered prior to finalization of this rule.

#### List of Subjects in 7 CFR Part 989

Grapes, Marketing agreements, Raisins, Reporting and recordkeeping requirements.

■ For the reasons set forth in the preamble, 7 CFR part 989 is amended as follows:

#### PART 989—RAISINS PRODUCED FROM GRAPES GROWN IN CALIFORNIA

■ 1. The authority citation for 7 CFR part 989 continues to read as follows:

**Authority:** 7 U.S.C. 601–674.

■ 2. In § 989.401, paragraphs (b) and (c) are revised to read as follows:

#### § 989.401 Payments for services performed with respect to reserve tonnage raisins.

\* \* \* \* \*

(b) *Additional payment for reserve tonnage raisins held beyond the crop year of acquisition.* Additional payment for reserve tonnage raisins held beyond the crop year of acquisition shall be made in accordance with this paragraph. Each handler holding such raisins for the account of the Committee on August 1 shall be compensated for storing, handling, and fumigating such raisins at the rate of \$2.30 per ton per month, or any part thereof, between August 1 and October 31, and at the rate of \$1.18 per ton per month, or any part thereof, between November 1 and July 31: *Provided*, That handlers holding 2002–03 Natural (sun-dried) Seedless reserve raisins on August 1, 2003, that are intended for use as cattle feed shall be compensated for storing, handling, and fumigating such raisins at the rate of \$2.30 per ton per month, or any part thereof, between September 13 and October 31, 2003, and at the rate of \$1.18 per ton per month, or any part thereof, between November 1, 2003, and July 31, 2004. Such services shall be completed so that the Committee is assured that the raisins are maintained in good condition.

(c) *Payment of rental on boxes and bins containing raisins held beyond the crop year of acquisition.* Payment of rental on boxes and bins containing reserve tonnage raisins held beyond the crop year of acquisition shall be made

in accordance with this paragraph. Each handler, producer, dehydrator, and other person who furnishes boxes or bins in which such raisins are held for the account of the Committee on August 1, shall be compensated for the use of such boxes and bins: *Provided*, That persons holding 2002–03 Natural (sun-dried) Seedless reserve raisins on September 13, 2003, that are intended for use as cattle feed shall be compensated for the use of such boxes and bins, and that no compensation shall be accrued for such raisins held between August 1 and September 12, 2003. The rate of compensation shall be: For boxes, two and one-half cents per day, not to exceed a total payment of \$1 per box per year, per average net weight of raisins in a sweatbox, with equivalent rates for raisins in boxes other than sweatboxes; and for bins 20 cents per day per bin, not to exceed a total of \$10 per bin per year. For purposes of this paragraph, *box* means any container with a capacity of less than 1,000 pounds, and *bin* means any container with a capacity of 1,000 pounds or more. The average net weight of raisins in each type of box shall be the industry average as computed by the Committee for the box in which the raisins are so held. No further compensation shall be paid unless the raisins are so held in the boxes on the succeeding August 1.

\* \* \* \* \*

Dated: July 25, 2003.

**A.J. Yates,**

*Administrator, Agricultural Marketing Service.*

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## DEPARTMENT OF AGRICULTURE

### Food Safety and Inspection Service

#### 9 CFR Part 319

[Docket No. 01–018F]

#### Definitions and Standards of Identity or Composition: Elimination of the Pizza with Meat or Sausage Standards

**AGENCY:** Food Safety and Inspection Service, USDA.

**ACTION:** Final rule.

**SUMMARY:** The Food Safety and Inspection Service (FSIS) is rescinding the regulatory standards of identity for “pizza with meat” and “pizza with sausage.” FSIS has determined that the standards no longer serve their original purpose of protecting the public from economic deception. Furthermore, FSIS believes that the standards may be

inhibiting manufacturers of federally inspected pizzas from producing and marketing the styles of pizzas that today's consumers demand. Once this rule becomes effective, products may be identified with a common or usual name that includes the term "pizza;" identifies the meat or poultry component, *e.g.*, "pepperoni;" and declares other components as a feature that distinguishes them from the other pizza product, *e.g.*, "pizza—garlic sauce, tomatoes, reduced-fat cheese, and seasoned beef strips on a crust."

FSIS is also amending the meat and poultry products inspection regulations to require, for a limited time, that the labels of products identified as meat or poultry pizzas in their common or usual names include the percent of meat or poultry in the product in a parenthetical statement that is contiguous to the ingredients statement. This labeling requirement will expire after three years. FSIS is adopting this requirement because, based on comments received in response to the proposed rule, the Agency has concluded that some consumers still rely on the standards to ensure that a product identified as a meat or poultry "pizza" contains a certain amount of meat or poultry. FSIS will allow pizza manufacturers to exhaust their remaining packaging inventory before they will be required to comply with the new labeling requirement. Requiring percent labeling of the meat or poultry content of non-standardized pizzas for a limited time is a transitional step to allow these consumers to understand the nature of the food.

**DATES:** This rule is effective October 22, 2003. Sections 317.8(b)(40) and 381.129(f) shall expire October 24, 2006.

**FOR FURTHER INFORMATION CONTACT:** Robert C. Post, Ph.D., Director, Labeling and Consumer Protection Staff, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC 20250-3700; (202) 205-0279.

**SUPPLEMENTARY INFORMATION:**

**Background**

On November 2, 2001, FSIS published a proposed rule in the **Federal Register** to amend part 319 of the Federal meat inspection regulations to rescind the standards of identity for "pizza with meat" and "pizza with sausage" (66 FR 55601). The proposed rule was in response to a petition submitted on February 4, 1999, by the National Frozen Pizza Institute (NFPI). In support of its petition, NFPI submitted data to demonstrate that the pizza standards are restricting the development of new products by the frozen pizza industry,

including pizzas with reductions in constituents that are of health concern to some people, such as fat and cholesterol. NFPI also presented evidence that, due to product innovation in the food service industry, consumers' expectations of what is meant by the term "pizza" are broader than what is prescribed by the current standards.

Once this final rule becomes effective, products identified as meat or sausage pizzas will no longer be required to contain tomato sauce, cheese, and a bread-based crust, as prescribed by the standards under 9 CFR 319.600. In addition, manufacturers of pizza products will be permitted to reduce the minimum meat content from 12 percent cooked or 15 percent raw to 2 percent cooked or 3 percent raw, the level of meat required for a product to be considered a meat food product subject to USDA jurisdiction.

In the preamble to the proposed rule, FSIS mentioned that although the regulations do not contain a standard of identity for pizza products that contain poultry, FSIS has treated these products as "like products" to pizza with meat or sausage. The Agency's policy has been that these products must contain at least 12 percent cooked poultry meat. Once this final rule becomes effective, the policy that pizzas that contain poultry must have a minimum poultry content will also be revoked.

As discussed in the preamble to the proposed rule, rescinding the meat and sausage pizza standards of identity does not mean that the names for products identified as "pizzas" will be unregulated. Under 9 CFR 317.2(c)(1) and 381.117(a), non-standardized meat and poultry products must be identified by the common or usual name of the product, or if the product has no common or usual name, a truthful, descriptive designation. FSIS has determined that, in the absence of a regulatory standard of identity, the term "pizza" represents the appropriate common or usual name for the class of products that have been traditionally formulated with the components stipulated in the regulatory standard prescribed by 9 CFR 319.600, *i.e.*, tomato sauce, cheese, and meat topping on a bread-based crust. Products that contain these ingredients may be identified by a common or usual name that includes the term "pizza;" identifies the meat or poultry component, *e.g.*, pepperoni; and declares any other components or features that distinguish it from traditional pizzas, *e.g.*, "pizza—garlic sauce, tomatoes, reduced-fat cheese, and seasoned beef strips on a crust."

In the preamble to the proposed rule, FSIS requested comments on whether the product names of non-standardized pizzas should be required to include the percent of meat or poultry. Based on the comments received in response to this question, FSIS has concluded that some consumers still rely on the standards to ensure that a meat or poultry product identified as a "pizza" contains a certain amount of meat or poultry. To prevent these consumers from being misled about the meat or poultry content of non-standardized pizzas, the Agency is requiring that the labeling of products that are identified in their common or usual names as pizzas that contain a meat or poultry component (*e.g.*, "pizza with meat," "sausage, green pepper, and mushroom pizza," "Thai pizza—chicken, peanut sauce, and vegetables on a crust") include a parenthetical statement of the percent of meat or poultry in the product that is contiguous to the ingredients statement. This labeling requirement will be effective for three years to allow consumers to become familiar with variations in the meat or poultry content that will be permitted in pizzas as non-standardized foods. FSIS will allow manufacturers of meat and poultry pizzas to exhaust their remaining packaging inventory before they will be required to comply with the new labeling requirement.

**Comments and Responses**

The comment period for the proposed rule closed on January 2, 2002. However, in response to comments requesting that FSIS extend the comment period, on March 14, 2002, the Agency reopened and extended that comment period for an additional 30 days. Thus, the comment period closed on April 15, 2002.

FSIS received 36 comments in response to the proposed rule from consumers, consumer advocacy organizations, members of the frozen pizza industry, academia, industry consultants, and trade and professional associations representing livestock producers, meat processors, food processors, seasoning manufacturers, soy product producers, and dietitians. Most of the commenters supported eliminating the standards of identity for meat and sausage pizzas. In general, the supporters agreed that the standards are restricting the development of new products by the frozen pizza industry, and that consumers' expectations of what is meant by the term "pizza" are broader than what is prescribed by the current standards. Eight commenters opposed the proposed rule, mainly because they believe that the current

standards still serve their intended purpose of protecting consumers from economic deception, particularly with regard to the meat content of products identified as meat or sausage pizzas. Three commenters, a trade association representing the frozen foods industry, a trade association representing meat processors, and a large company that manufactures a variety of food products, including frozen pizzas, took no position on whether FSIS should eliminate the existing pizza standards but submitted comments on certain aspects of the proposed rule. Summaries of issues raised by commenters and Agency responses follow.

*Comment:* As mentioned above, in the preamble to the proposed rule, FSIS stated that, if it were to rescind the pizza standards, it had tentatively determined that required labeling features, such as the product name, ingredients statement, and nutrition facts panel, will provide adequate information for consumers to make informed choices when purchasing federally inspected pizza products (66 FR 55601, 55602). In particular, the Agency concluded that the product name would become a descriptive feature to convey to the consumer the components of the product. The Agency went on to request comments on whether the product name of non-standardized pizzas should be required to include the percent of meat or poultry in the product. Almost all commenters that supported eliminating the pizza standards opposed this proposed requirement. Following is a summary of the reasons for their opposition.

- The product names of pizzas sold by restaurants and delivery services would not be required to contain the percent of meat or poultry in the product, thereby re-establishing different regulatory treatment for the retail and frozen pizza industries.

- Percentage labeling of a specific ingredient is not required for other products regulated by FSIS or the Food and Drug Administration (FDA).

- If the product name for non-standardized pizzas must include the percent of meat or poultry in the product, then it should also be required to include the percent of other characterizing ingredients, such as mushrooms or seasonings, as well.

- Requiring that the percent of meat or poultry in a non-standardized pizza product be included as part of the product name is not necessary because existing required labeling features, including mandatory ingredient and nutrition information, already provide sufficient information about a product's meat or poultry content.

- Requiring percent labeling of the meat content implies that meat is the most valuable ingredient in the product. The amount of meat topping is not the determining characteristic of the product. Consumers also look at overall cost and quality of ingredients used.

- Unlike some other products, the meat content of a pizza is readily apparent with even a superficial visual exam, which allows consumers to assess the value of the product for the price.

- Such information would have little meaning to consumers and could lead to counterproductive competitive labeling contests, which would not serve consumers' best interests.

- Percent meat content labeling assumes that all meat toppings are equivalent in cost, which is not an accurate assumption.

- Pizzas subject to FDA and FSIS jurisdiction should be marketed and regulated similarly. FDA has no such specific requirement or any standards for pizzas subject to FDA's jurisdiction.

- Few consumers have a working knowledge of the current standards. Therefore, it is not relevant to require the labeling to include the percentage of meat or poultry in the pizza.

- Requiring percent labeling of the meat or poultry content would require manufacturers to disclose proprietary information, including trademark recipes. Manufacturers who wish to provide this information voluntarily could do so if they believed that communicating the percent of meat in the product provided them an advantage.

- Percent ingredient labeling, including a requirement for meat or poultry percent ingredient labeling, is not in keeping with historical U.S. government policy regarding standards that suggest percentage ingredient labeling of foods in international trade. For a number of years, the U.S. delegation to the Codex Committee on Food Labeling opposed a European Union (EU) proposal to require labeling of percent fish core in fish sticks. Importantly, unlike frozen pizza, fish sticks do have one characterizing ingredient.

One commenter, a representative of a consumer advocacy organization, stated that requiring that the product names of non-standardized pizzas include the percent of meat or poultry in the product, although well intentioned, seems clumsy and extreme. A better solution, suggested the commenter, is to identify the percent of meat or poultry in a product somewhere outside the ingredients statement, but not as part of the product name.

Another commenter, a trade association representing meat processors, noted that if the meat and sausage pizza standards are rescinded, it is important that FSIS give consideration to alternative ways to provide truthful information about the meat or sausage component of products identified as "pizza."

*Response:* The Agency was not persuaded by the comments that opposed percent labeling of the meat or poultry content of non-standardized pizzas because many of these comments are misleading or inaccurate. Requiring percent labeling of the meat or poultry content for packaged pizzas will not re-establish different regulatory requirements for retail and frozen pizza industries, as suggested by the comments. Even with the elimination of the pizza standards, restaurant pizzas and packaged pizzas will still be subject to different regulatory requirements. For example, nutrition labeling is required for packaged pizzas but not for restaurant pizzas.

The statement that percent labeling of a specific ingredient is not required for any other products regulated by FSIS and FDA also is not accurate. FDA regulations require that the common or usual name of a food contain the percentage of any characterizing ingredients when the proportion of such ingredients in the food has a material bearing on price or consumer acceptance, or when the labeling or appearance of the food may create the erroneous impression that the ingredient is present in an amount greater than is actually the case (21 CFR 102.5(b)). Thus, contrary to what was suggested in the comments, requiring percent labeling of the meat or poultry component of a meat or poultry pizza with a common or usual name is consistent with FDA regulations.

Although it is true that the meat content of pizza is readily apparent when examining the pizza itself, the meat content is not readily apparent if there is a solid cover on the package. Furthermore, FSIS disagrees that percent meat content labeling promotes unproductive labeling contests. The Agency believes that it could promote consumer choice and fair competition.

Upon further consideration of the issue, FSIS has determined that required labeling features, such as the nutrition facts panel and ingredients statement, do not provide sufficient information about the meat or poultry content of products identified as "pizza." Although ingredients must be listed in order of predominance, there could be such a wide range of ingredients in a pizza that such a listing does not

effectively convey the proportion of meat or poultry in the product. FSIS agrees with the comment that, once the standards are rescinded, the Agency should consider alternative ways to provide truthful information about the meat or poultry content of products identified as "pizza." It also agrees that the percent of meat or poultry in products identified as "pizza" need not appear as part of the product name and can be conveyed somewhere else on the product label.

Therefore, FSIS has decided to require, for three years from the effective date of this final rule, that products that are identified as "pizza" and whose common or usual name identify a meat or poultry component state the percent of meat or poultry in the product in a parenthetical statement contiguous to the ingredients statement. If consumers find this information useful, and believe that it should appear on the product labeling permanently, they may petition the Agency to rescind the expiration date of this part of the regulation.

*Comment:* Most of the commenters who opposed eliminating the meat and sausage pizza standards did so because, as previously mentioned, without the standards a product identified as a "meat pizza" or a "sausage pizza" would be permitted to contain as little as 2 percent cooked or 3 percent raw meat instead of the 12 percent cooked or 15 percent raw meat prescribed by the standards. These commenters noted that meat is the most expensive ingredient in a meat pizza, and that without standards, manufacturers would be able to significantly reduce the meat content of meat pizzas without consumers' knowledge. They also asserted that descriptors of meat or sausage imply that a product contains some minimum amount of these ingredients, and that consumers' expectations are that this amount is greater than two percent. Thus, the commenters argued, removing the meat and sausage pizza standards would lead to economic deception of consumers that purchase non-standardized pizzas.

*Response:* As discussed above, FSIS believes that these comments demonstrate that some consumers rely on the pizza standards of identity to ensure that a product identified as a meat or poultry pizza contains a certain amount of meat. However, the Agency does not believe that retaining the regulatory pizza standards of identity is necessary to address the concerns expressed by these comments. As discussed above, to address concerns that consumers could be misled about the meat content of non-standardized

pizzas, the Agency is requiring temporary supplemental labeling of the meat or poultry content for products that are identified as "pizzas" and whose product name includes a meat or poultry component.

Furthermore, FSIS does not agree that rescinding the meat and sausage pizza standards will lead to economic deception of consumers that purchase non-standardized pizzas. FSIS has determined that over the years consumer expectations, industry creativity, and technological innovation have created new types of pizza products that fall outside the realm of the traditional or standardized pizza of several decades ago. The existing pizza standards inhibit the production and marketing by Federal establishments of new pizza products. Examples of new pizza products found at retail and food service establishments include: "deep dish pizzas" that provide a smaller surface area for toppings, "white pizzas" that do not have a traditional tomato-based sauce, and ethnic-oriented pizzas that often reduce the meat component to permit a greater amount of vegetable toppings. The current standards for meat and sausage pizzas require that the products contain tomato sauce, cheese, and a bread-based crust, in addition to a minimum percentage of meat or poultry. Thus, the current standards impede the development and marketing of these new and innovative products.

*Comment:* Many commenters that opposed the proposed rule stated that eliminating the meat and sausage pizza standards of identity is not necessary for companies to produce pizzas with nutritional profiles more consistent with nutritional guidance (e.g., lower in fat). They stated that nutritionally improved products can and should be achieved by using lower fat ingredients, not less of fat-containing ingredients, such as meat and cheese. One commenter, an individual consumer, stated that even if the pizza standards were eliminated, it would not likely result in more lower-fat frozen meat or sausage pizzas. To support his argument, the commenter noted that of all the restaurant menus that NFPI presented in support of its petition, not one contained a meat or sausage pizza advertised as being a healthier or lower fat product.

Supporters of the proposal felt that the current standards are obstructing producers' ability to create meat pizzas lower in fat, saturated fat, and cholesterol in response to changing consumer tastes. They stated that eliminating the standards will give manufacturers the flexibility to offer pizzas with less meat, sausage, and fat,

and will permit the production of frozen pizzas with reduced-fat cheese or no cheese, provided there is disclosure on the product's label. One commenter noted that it is not always economical to use leaner meats, which are more expensive on a per pound basis, when a manufacturer has to comply with a percentage minimum weight.

*Response:* FSIS does not disagree that once this final rule is effective, many pizza manufacturers will continue to market the traditional pizza products that are available to consumers today. However, these manufacturers will also have greater flexibility to produce meat and poultry pizzas with reductions in constituents that are of health concern to some people, such as calories and fat. While it is true, as noted in some of the comments, that the standards permit the production of pizzas with improved nutritional profiles through the use of lower fat ingredients, removing the standards will give pizza manufacturers additional flexibility to produce and market nutritionally improved packaged pizzas.

Removal of the pizza standards will not only permit greater use of lower fat ingredients in meat pizza products, such as vegetables and soy-based and other reduced-fat cheeses, it will also permit reductions in the amount of fat-containing ingredients, such as meat and cheese, which will result in a wider selection of pizza products that meet nutrient content claims such as "lower fat," "healthy," and "lean." As noted by one commenter, using leaner meats to reduce the fat content of a pizza product that must comply with a minimum meat content is not always economical because leaner meats are more expensive on a per pound basis. Thus, eliminating the standard will permit pizza manufacturers to provide packaged pizza products with improved nutritional profiles at a variety of pricing levels.

*Comments:* Some of the commenters that opposed eliminating the pizza standards asserted that changes in standards should be based on consumer research. They pointed out that, while NFPI presented restaurant menu data to support its petition, it did not provide research to indicate that consumers liked the new styles of pizzas presented on the menus. One commenter noted that neither FSIS nor the petitioner presented strong evidence of consumer confusion or dissatisfaction with the current standards.

A few commenters presented their own consumer research that they contended provides evidence that consumers are satisfied with the pizza standards. Two commenters, trade

associations representing livestock producers, submitted a consumer research report from a consumer focus group study on the meaning of food names and the assumptions underlying them. The report concluded, among other things, that the identities of certain foods, such as bologna and beef stew, are so distinct to consumers, and consumers are so used to the products being labeled as such, that consumers have difficulty grasping the concept of a simulated change to the names or composition of the product. The research report also concluded that changing the composition of a commonly named food product is equivalent to changing the meaning of the name itself. These findings, the commenters asserted, are evidence that consumers rely on product standards to ensure product integrity and prevent economic adulteration.

Another commenter, a manufacturer and distributor of frozen prepared food products that supported removal of the portion of the pizza standards that prescribes the four basic components (meat, cheese, tomato sauce and bread based crust) but opposed elimination of the minimum meat content requirement, submitted a consumer survey that questioned consumers about the meat content of specific meat pizza products produced by the commenter's company. A majority of the consumers surveyed felt that the meat content of each product involved in the survey was "just about right." The commenter stated that these results indicate that consumers are satisfied with the meat content requirements imposed by the current standards and that the standards still "promote honesty and fair dealing in the interest of the consumer."

Another commenter, a multinational manufacturer and marketer of consumer branded meat and food products, submitted the results of a survey conducted after publication of the proposed rule in which the company contacted over 1,000 consumers by telephone. The survey asked consumers how they felt about the U.S. Government's proposal "to change the minimum amount of meat for frozen meat pizza to two percent of the cooked weight or three percent of the raw weight." The commenter's survey found that consumers' were overwhelmingly against the proposed change.

*Response:* The restaurant menu data submitted by NFPI in support of its petition demonstrate that many products identified as "pizza" that are purchased by consumers in restaurants do not meet the Agency's standards. Thus, even without consumer survey data, it is no longer reasonable to

assume that consumer expectations with regard to what constitutes a pizza mirror the standards for FSIS-inspected products. Restaurants would not be offering such a variety of pizza products if consumers were not interested in purchasing such products.

Although FSIS does not dispute the findings of the consumer studies submitted by the commenters, the Agency disagrees that these findings demonstrate a need to retain the meat and sausage pizza standards of identity. The consumer focus group study that examined the meaning of common names for meat products submitted by the two trade associations questioned consumers about their expectations regarding the composition of a variety of products that have regulatory standards of identity, including bacon and bologna. However, it did not question consumers about their expectations regarding the composition of products identified as "pizza."

The data submitted by NFPI in support of its petition indicate that, unlike consumer perceptions of products that were the subject of the consumer focus group studies, such as bacon or bologna, consumer perceptions of what a product identified as a "pizza" is have changed dramatically in recent years to include a wide variety of non-traditional, non-standard versions of pizzas. Thus, it is unlikely that changing the composition of a product identified as a "pizza" will result in consumer confusion as to the characteristics of the product. FSIS does not completely disagree with the commenters' conclusion that the study results support the notion that consumers rely on product standards to ensure product integrity and prevent economic adulteration. However, when a product standard no longer reflects consumer expectations about the composition of the product, the standard is not serving its purpose and should be rescinded.

The survey conducted by the frozen foods manufacturer that found that a majority of the consumers surveyed felt that the meat content of a variety of meat pizza products was "just about right," and the survey conducted by the multinational manufacturer of meat products that asked consumers how they felt about the U.S. Government's proposal "to change the minimum amount of meat for frozen meat pizza to two percent of the cooked weight or three percent of the raw weight," both imply that the sole effect of eliminating the pizza standards would be a reduction in the minimum meat content and that once the standards are rescinded every pizza manufacturer will

reduce the meat content of frozen pizzas to 2 percent cooked or 3 percent raw meat.

Rescinding the pizza standards involves more than permitting a reduction in the minimum meat content requirement for meat food products identified as "pizza." It also involves permitting the use of sauces other than tomato-based sauces, crusts other than bread-based crusts, and components other than standardized cheese and cheese food products in federally inspected pizzas. Thus, in addition to permitting a reduction in the meat content of a meat or sausage pizza, eliminating the pizza standards provides the opportunity for the development and marketing of non-traditional pizza products, such as pizza with no sauce or cheese component. None of the consumer research studies submitted by the commenters questioned consumers on how they felt about this aspect of eliminating the pizza standards.

Furthermore, the fact that consumers state that they are satisfied with the meat content of certain products does not necessarily mean that that meat content must be prescribed by regulation. As discussed above, to allow consumer to become familiar with the variations that will be permitted in the meat content of non-standardized pizzas, the Agency is requiring that products identified as "pizza" that include a meat or poultry component as part of the product name bear temporary supplemental labeling that conveys the percent of meat or poultry in the products. Furthermore, in the absence of a prescribed meat content requirement, companies are likely to continue to manufacture pizzas with an amount of meat that consumers desire because if they do not they will lose their market share to companies that do.

As demonstrated by the studies discussed above, consumer research can be greatly affected by the manner in which questions are posed to consumers. Thus, the results of the consumer surveys submitted in response to the proposed rule have not persuaded FSIS to retain the pizza standards of identity.

*Comment:* One commenter stated that policy interpretations on the regulations made by FSIS over the years provide frozen pizza manufacturers with sufficient flexibility to produce and market "non-traditional" meat pizzas, and therefore, there is no need to eliminate the pizza standards. The commenter cited FSIS's interpretive policies related to the pizza standards, including the policy that permits certain products to be identified as "white

pizza,” the policy that defines “tomato sauce” as any sauce that contains two percent tomatoes, the policy that liberally interprets “bread-based crust” to include most every kind of flour-based component, and the policy that allows for percentage meat labeling on pizza products that do not otherwise comply with the minimum meat content prescribed by the standards.

*Response:* In addition to allowing pizza manufacturers to produce the “non-traditional” products that are currently described in FSIS policy documents, rescinding the standards of identity for meat and sausage pizza will provide pizza manufacturers with the flexibility to create new and novel styles of pizza products without having to approach FSIS for new policy interpretations or regulatory changes.

*Comment:* Several commenters requested that FSIS clarify whether it will permit generic label approval for meat and poultry pizza products once the pizza standards are rescinded.

*Response:* Modifications made to incorporate the percent meat or poultry content declaration prescribed by this final rule into the labels of existing meat or poultry pizza products will be generically approved pursuant to 9 CFR 317.5(b)(1) and 9 CFR 381.133(b)(1). These provisions of the FSIS regulations allow generic approval of the labeling for products that have product standards as specified in the meat and poultry inspection regulations or in the FSIS Standards and Labeling Policy Book (the Policy Book). In addition to those products produced in accordance with the regulatory pizza standards in 9 CFR 319.600, many of the meat and poultry pizza products on the market today qualify for generic label approval because they are produced under informal standards described in the Policy Book.

Although meat and poultry pizza products will not be subject to prescribed product standards once this final rule becomes effective, for labeling approval purposes, FSIS will consider existing meat or poultry pizza products whose labels were generically approved prior to the effective date of this final rule as products that qualify for generic label approval under 9 CFR 317.5(b)(1) and 9 CFR 381.133(b)(1).

New meat and poultry pizza products that are developed and marketed after the effective date of this final rule will not qualify for generic label approval under 9 CFR 317.5(b)(1) and 9 CFR 381.133(b)(1) because these products are not subject to a product standard. Thus, unless they qualify for generic label approval under a provision other than 9 CFR 317.5(b)(1) or 9 CFR 381.133(b)(1),

the labels of such products must be submitted for formal approval from FSIS.

Once the labels of non-standardized pizza products have been approved as sketch labeling, certain modifications made to the final labeling may be generically approved pursuant to 9 CFR 317.5(b)(9) and 381.133(b)(9). For example, under 9 CFR 317.5(b)(9)(vii) and 9 CFR 381.133(b)(9)(vii), changes made to the percent meat or poultry declaration statement may qualify for generic approval if the modification reflects a change in the quantity of the meat or poultry ingredient shown in the formula without a change in the order of predominance shown on the label. Also, once the three-year effective date for the meat or poultry content labeling requirement has expired, the meat or poultry content declaration will become a non-mandatory feature. Deletions of non-mandatory features qualify for generic labeling approval under 9 CFR 317.5(b)(9)(xxiii) and 9 CFR 381.133(b)(9)(xxiii).

*Comment:* Several commenters requested that, in conjunction with this rulemaking, FSIS modify the policies contained in the Food Standards and Labeling Policy book and in the FSIS Policy Memoranda that are associated with the regulatory pizza standards of identity. Most of the requested modifications were to eliminate the references to 9 CFR 319.600 in these policies.

*Response:* Most of the FSIS policies for products identified as “pizza” require that these products comply with the minimum meat content requirement prescribed by 9 CFR 319.600. Once this final rule becomes effective, products with standards specified in the Policy Book will no longer be subject to this requirement. However, like all products identified as “pizza” with a meat or poultry component as part of the product name, the labels of pizza products that had been subject to standards specified in the Policy Book will be required to bear a statement contiguous to the ingredients statement that conveys the percent of meat of poultry in the product.

*Comment:* Several commenters requested that, in the preamble to the final rule, FSIS provide clarification as to what it considers to be appropriate descriptive names for non-standardized pizza products. These commenters agreed with the Agency’s statements in the preamble to the proposed rule that products with the four “traditional” pizza ingredients should be identified by the term “pizza” with a designation of the meat component (e.g. “pizza with sausage”). These commenters also

agreed that the labeling of products that vary in terms of the four traditional components should bear a descriptive qualifier following “pizza” that specifies the principal components (e.g., “pizza with sausage and pesto sauce”). However, the commenters believed that the descriptive qualifier for products with “non-traditional” components should not list the ingredients in order of predominance but in the order that best characterizes the non-traditional product. These commenters also suggested that a description of the crust not be required to be included in the descriptive qualifier unless the crust is different from the traditional dough-based crust.

*Response:* An appropriate descriptive name for a non-standardized pizza product that contains components that differ from those stipulated in the regulatory standard prescribed by 9 CFR 319.600 (i.e., tomato sauce, cheese, and meat topping on a bread-based crust) would be a listing of the components used at levels that characterize the product. Historically, the Agency has considered food and ingredient components used at levels above two percent of product formulation to be “characterizing.” While all characterizing components must be listed in the descriptive product name, they need not be listed in order of predominance. As suggested by the commenter, they may be listed in an order that best characterizes the non-traditional product. The descriptive name should list all characterizing components of the non-standardized pizza product, including crust even if the crust is a traditional dough-based crust. This is consistent with descriptive labeling requirements for other non-standardized products such as stuffed sandwiches or meat fillings wrapped in dough.

*Comment:* One commenter felt that the examples of acceptable descriptive names for products that do not comply with the traditional standards but that purport to be pizzas provided by FSIS in the preamble to the proposed rule are unwieldy, cumbersome, and in direct contradiction to the goals of the proposed rule. The commenter stated that listing names of ingredients in the name of the pizza, as suggested by the Agency, duplicates the information listed in the ingredients statement.

*Response:* The examples of descriptive names for non-standardized pizzas provided by FSIS in the preamble to the proposed rule list all characterizing components of the non-standardized pizza product. This is consistent with descriptive labeling

requirements for other non-standardized meat and poultry products.

*Comment:* One commenter suggested that rather than rescind the pizza standards, FSIS should decline jurisdiction over pizzas made with processed meat products. The commenter felt that inspection of these products is a waste of resources that could be better directed to overseeing the slaughter of animals and preparation of raw meat products. The commenter stated that legally FSIS could declare that food products that contain less than 50 percent cooked meat are not considered "meat food products" and therefore, are not subject to FSIS jurisdiction.

*Response:* Under section 1(j) of the FMIA, the Secretary of Agriculture, and FSIS by delegation, may exempt from the definition of "meat food products" those products that contain meat only in relatively small proportions or that have not been considered by consumers as products of the meat food industry (21 U.S.C. 601(j)). FSIS does not believe that products that consist of up to 49 percent cooked meat contain meat in relatively small proportions as contemplated by the FMIA. Furthermore, FSIS is not aware of any evidence to indicate that consumers do not consider meat pizzas as products of the meat food industry. Therefore, FSIS disagrees that it should decline jurisdiction over meat pizzas and other products that contain less than 50 percent cooked meat.

*Comment:* One commenter suggested that in addition to eliminating the pizza standards, FSIS should examine the wisdom of its remaining regulatory standards. Another commenter stated that standards reform should not be delayed. This commenter felt that continued adherence to the standards by FSIS impedes product innovation to the detriment of consumers and food industry alike. Another commenter stated that rather than eliminating regulatory standards of identity for meat and poultry products, FSIS should implement them in a more harmonious way. The commenter stated that the regulatory standards governing the amount of poultry in processed food products that contain poultry are substantially different from those governing the meat content of similar processed products that contain meat.

*Response:* FSIS and FDA are jointly developing a proposed rule whose goal is to establish "general principles" that outside parties can apply in requesting changes to food standards. The proposed rule, "Food Standards; General Principles and Standards Modernization" (the "General Principles" proposal) will address all

Federal food standards of identity, whether under FSIS jurisdiction or that of the FDA. Following the conclusion of this rulemaking, parties interested in pursuing changes to the regulatory standards of identity may petition the Agency to initiate rulemaking to make the requested changes.

*Comment:* One commenter noted that in the preamble to the proposed rule, FSIS stated that consumers "understand the term "pizza" to mean "an open-faced crust with one or more of a variety of ingredients" (66 FR 55601). The commenter noted that it produces pizza stuffed sandwiches that are required to comply with the pizza standards and requested that FSIS recognize that the term "pizza" is not limited to products with open-faced crusts.

*Response:* Products such as "pizza rolls" or "pizza pockets" are non-standardized products that must be identified by descriptive names. Those products that were required to comply with the minimum meat content prescribed by the standards will no longer be required to do so once the standards are eliminated. However, any product identified as "pizza" product that lists a meat or poultry component as part of the product name, including a product identified as a "meat pizza roll," must comply with the meat or poultry content labeling requirement prescribed by this final rule.

*Comment:* One commenter stated that in the proposed rule's analysis under the Regulatory Flexibility Act, FSIS failed to discuss the impact that elimination of the pizza standards will have on small businesses that make meat toppings for pizzas.

*Response:* The four companies that supply most of the meat toppings, such as pepperoni, sausage, and chopped meat, to both major and contract pizza manufacturers are large businesses. There are some small regional companies that supply meat toppings to regional manufacturers. However, this final rule is not likely to have a significant economic impact on these small businesses. Once the standards are rescinded, FSIS has no information to indicate that in the absence of the minimum meat content requirement prescribed by the standards companies will significantly reduce the amount of meat or poultry in products identified as "pizza". As discussed above, companies are likely to continue to manufacture pizzas with an amount of meat that consumers desire because if they do not they will lose their market share to companies that do. Therefore, FSIS does not believe that this final rule will have an adverse impact on the small

businesses that supply meat toppings for packaged pizza products.

### The Final Rule

As proposed, FSIS is rescinding the regulatory standards of identity for pizza by removing 9 CFR 319.600 from the federal meat inspection regulations. In addition, the Agency is amending 9 CFR 317.8 and 9 CFR 381.129 by adding new paragraphs (b)(40) and (f), respectively, to require that the labeling of meat or poultry products identified as "pizza" that contain a meat or poultry component as part of the product name convey the percent of the meat or poultry in the product in a parenthetical statement contiguous to the ingredients statement. The percentage of meat or poultry in the product must be calculated on the weight of the cooked, dried, or cured meat or poultry in the product (as opposed to the weight of the raw meat or poultry) in relation to all components of the product. This labeling requirement will expire three years after the effective date of this rule. Pizza manufacturers are permitted to exhaust their remaining packaging inventory before they will be required to comply with the new labeling requirement.

### Executive Order 12866 and Unfunded Mandates Reform Act

#### I. Executive Order 12866: Cost-benefit Analysis

This action has been reviewed for compliance with Executive Order (EO) 12866. EO 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when a regulation is necessary, to select the regulatory approach that maximizes net benefits (including potential economic, environmental, public health and safety, and other advantages, distributive impacts, and equity). We have determined that this final rule maximizes net benefits to consumers by removing the standard of identity for "pizza with meat" and "pizza with sausage."

EO 12866 classifies a rule as significant if it meets any one of a number of specified conditions, including: having an annual effect on the economy of \$100 million, adversely affecting a sector of the economy in a material way, adversely affecting competition, or adversely affecting jobs. A regulation is also considered a significant regulatory action if it raises novel legal or policy issues. This final rule has been designated as non-significant as defined by EO 12866 and therefore has not been reviewed by the Office of Management and Budget.

## II. Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (Public Law 104-4), requiring cost-benefit and other analyses, in section 1531 (a) defines a significant rule as "a Federal mandate that may result in the expenditure by State, local, and tribal governments in the aggregate, or by the private sector, of \$100,000,000 (adjusted annually for inflation) in any 1 year." This final rule is not a significant rule under the Unfunded Mandates Reform Act.

## III. Industry Profile

The meat and poultry pizza industry affected by this final rule consists of manufacturers who produce refrigerated pizzas, frozen pizzas, pizza kits, and mixes. Because frozen pizzas are the dominant products of this industry, making up 99 percent of the affected market, FSIS is focusing on this segment of the industry in this analysis.

It is estimated that there are about 155 manufacturers of frozen pizzas<sup>1</sup> (manufacturers of both brand and private label frozen pizzas) and these consist of 6 major manufacturers, 20 private-label manufacturers, and approximately one hundred twenty nine regional contract manufacturers.<sup>2</sup> The major manufacturers produce brand-named frozen pizzas on a national basis and the contract manufacturers produce brand-named frozen pizzas on a regional basis. Some restaurants make pizzas, freeze them, and then sell them to the local grocery stores on a contractual basis. Finally, there are several companies, like chain supermarkets, warehouse clubs, restaurants, and franchises, that contract out the production of frozen meat pizzas to approximately 20 private label manufacturers and regional contract manufacturers.

Four major suppliers to pizza manufacturers supply meat toppings, such as pepperoni, sausage, and chopped meat, to both major and contract pizza manufacturers. There are also some small regional companies that supply meat toppings to regional manufacturers. FSIS has determined that the suppliers of meat pizza toppings will most likely not be adversely affected by the final rule because even though pizza manufacturers may reduce the amount of meat toppings on pizzas, these suppliers can still supply other markets with their meat toppings, e.g. deli, frozen dinners, etc. In addition, these

suppliers offer several product lines of pizza toppings other than meat, and they may experience an increase in demand for these other toppings. The agency believes, however, that as a direct result of the final rule, the overall demand for frozen pizzas will increase, and therefore the total demand for pizzas with meat toppings will also increase.

## IV. Benefits

The final rule removes the standard of identity for meat and sausage pizza and requires that for a 3-year period, the labeling of products identified as pizza that lists a meat or poultry component as part of the product name will bear a statement that conveys the percent of meat or poultry in the product. The percentage statement must appear contiguous to the ingredients statement.

The following sections contain qualitative descriptions of consumer and manufacturer benefits that will ensue from eliminating the meat and sausage pizza standards of identity.

### A. Consumer Benefits

The final rule will allow consumers to choose from a greater variety of meat and poultry pizzas, some of which may have improved nutritional profiles. Consumers will have a greater opportunity to improve their diets, should they desire to do so, because manufacturers will now be able to market meat and poultry pizzas that contain less meat or poultry and may contain non-meat toppings such as soy-based toppings,<sup>3</sup> and other innovative toppings that contain a lesser amount of meat than the amount of meat (12% cooked or 15% raw) that they are currently required to contain.

Consumers may also benefit because they may be able to purchase less costly meat and poultry pizzas. In addition, some consumers may be willing to pay more for some pizzas if they perceive that these meat and poultry pizzas are healthier than other pizzas. In either case, consumers will benefit because both the low and high end of the market can be expanded.

Under the final rule, consumers will also be protected from any misrepresentations of the amount of meat or poultry contained in pizzas. Percentage labeling of meat and poultry in pizzas, which is required for the next three years, will benefit those consumers who have come to expect a

certain amount of meat or poultry on pizzas (*i.e.*, consumers who rely on standards) by allowing them to become familiar with and accustomed to a variation in meat or poultry amount on pizzas. Percentage labeling will also help reduce any confusion consumers may experience when they are comparing the amounts of meat or poultry in pizzas. During the 3-year period, consumers will be able to reduce their search costs when comparing pizzas because when selecting meat or poultry pizzas, they will be able to readily ascertain the amount of meat or poultry in different products. Consumers will be able to make choices consistent with their desire to have more or less meat or poultry on pizzas, and the percentage labeling will help them make accurate selections.

Finally, consumers, who live in areas where there are very few restaurants, or in areas where the restaurants do not sell pizzas, or in areas where pizza delivery is limited, will benefit because they will have access to a greater variety of non-traditional pizzas in their local supermarkets.

### B. Manufacturer Benefits

Manufacturers of pizzas containing meat or poultry will benefit from the final rule because the elimination of the traditional FSIS pizza standards of identity will make them more competitive with non-meat and non-poultry containing pizza producers and retail outlets. Currently, manufacturers of FDA-regulated pizzas and pizzas sold by restaurants and carry out/delivery services, whether frozen or fresh, are able to experiment with innovative recipes and ingredient profiles, in offering consumers new products. These innovative pizzas that are sold in retail stores need not contain cheese or tomato sauce, as FSIS requires.

Manufacturers of non-traditional pizzas will potentially experience an increase in sales and therefore revenues, when they achieve economies of scale while producing a large variety of these pizzas. Since the manufacturers will not be restricted to manufacturing a prescribed recipe pizza, they can become more innovative and create new markets by offering new products and mass producing them. Also, these manufacturers can use less costly ingredients and eliminate or reduce certain ingredients, thereby offering more economically priced meat and poultry pizzas. For some manufacturers, this may increase their market share and revenues.

<sup>1</sup> Final rule affects all meat and poultry pizzas produced in federally inspected establishments.

<sup>2</sup> The exact number of regional contract manufacturers is unknown.

<sup>3</sup> One large manufacturer has begun producing Smart Pizza for the school lunch program. Smart Pizza is the first of its kind to utilize soy protein. By utilizing soy in the pizzas, sodium is reduced by up to 22 percent and total fat is lowered by as much as 35 percent.

V. Costs

A. Pre-printed Package Labels

This final rule does not mandate changes in the way meat or poultry products are produced. However, it does impose a new labeling requirement, for a limited time, on firms that manufacture and market products identified as pizzas that list meat or poultry components as part of the product name. When this rule becomes effective, all companies that produce products identified as pizzas that list a meat or poultry component as part of the product name will be required to modify their product labels by adding a statement contiguous to the ingredients statement that states the percent of meat or poultry in the product. Companies must consequently redesign their product labels by adding the required information to their existing label designs, or by applying a separate sticker with the required information to their existing labels. FSIS will permit companies to use their remaining packaging inventory before they will be required to comply with the new labeling requirement so that they will not have to discard any unused packaging.

Manufacturing of pre-printed packaging is generally contracted out to third-party firms. Costs to redesign product labels or add information to existing label designs are one-time costs and include costs associated with internal administrative activities, assessing the meat or poultry amounts,

altering the graphic design, conducting prepress activities, and changing engraving plates or cylinders.<sup>4</sup>

1. One-Time Costs

FDA's Labeling Cost Model was originally developed by researchers at RTI International for various consumer food products and was adapted for egg products, which are primarily shipped to foodservice and further food manufacturers. RTI adapted the model to determine the cost of the new regulation of placing the statements "keep refrigerated" or "keep frozen" on all egg products that require special handling to maintain their wholesome condition. Additionally such statements had to be printed on the principal display panel of the product. In determining the cost of the proposed egg products rule, the model was used to determine the cost of placing refrigeration labels, the cost of the labels, and the cost of the labeling equipment needed and the average size of the containers requiring the labels. FSIS believes that this is a reasonable and valid model to use to estimate the cost of the final rule for changing the labels on frozen meat and poultry pizzas.

Using the FDA Labeling Cost Model, the following table provides the costs associated with changing labeling information for frozen and refrigerated pizzas packaging using the offset lithography printing method<sup>5</sup> for each universal product code (UPC) that needs to be changed. A UPC is a unique code

assigned to every consumer package good and is read by a scanner when purchased.<sup>6</sup>

TABLE 1.—ONE-TIME COSTS TO CHANGE LABELS FOR FROZEN AND REFRIGERATED PIZZAS, KITS, AND MIXES USING OFF-SET LITHOGRAPHY PRINTING METHOD

Cost Type	Per UPC Costs		
	Low	Medium	High
Administrative .....	\$132	\$308	\$484
Graphic Design ...	330	495	660
Total .....	462	803	1,144

Source: FDA Labeling Cost Model (Muth, Gledhill, and Karns, 2001).  
<sup>1</sup> Estimated for 2001.

It is estimated that the cost per UPC will range from a low of \$462 to a high of \$1,144, with the more likely cost being \$803<sup>7</sup> as depicted in the above table.

In 2001, there were 1,603 UPC's associated with refrigerated and frozen pizzas including a small percentage of pizza kits and mixes, of which 1,042 were from brand name labels and 561 were from private labels. When all these costs are considered, the estimated one-time cost to modify pre-printed pizza packaging labels for 1,603 UPC, as shown in the table below is \$741 thousand (\$462 × 1,603 UPCs) to \$1.8 million (\$1,144 × 1,603 UPC),<sup>8</sup> with the more likely cost being \$1.3 million (\$803 × 1,603 UPCs).

TABLE 2.—ONE-TIME COSTS, FROZEN AND REFRIGERATED PIZZAS, KITS, AND MIXES FOR ESTIMATED 1,603 UPC CHANGES<sup>1</sup>

Cost Type	For Estimated 1,603 UPC Changes		
	Low	Medium	High
Administrative .....	\$211,636	\$493,636	\$775,997
Graphic Design .....	529,089	793,634	1,058,178
Total .....	740,725	1,287,270	1,834,175

Source: FDA Labeling Cost Model (Muth, Gledhill, and Karns, 2001).

<sup>1</sup> Estimated for 2001

<sup>4</sup> In this analysis, there will be no costs associated with assessing the meat or poultry contents of pizzas because companies will be producing meat and poultry pizzas based on a formula. The final rule requires companies to calculate the weight of the meat or poultry toppings in relation to all components of the pizzas, which FSIS believes will result in no new incremental costs. There will not be any prepress activities and changing the engraving plates costs because these costs will be incurred during their normal business cycle.

<sup>5</sup> The FDA Labeling Cost Model assumes that either the offset lithography or flexography printing method will be used. In this analysis the offset lithography printing method is assumed to be used

because of its relative advantages in quality, simplicity, and cost. The complexity of the label change determines the level of effort for artwork, stripping or image assembly, and engraving. It also determines the number of plates or cylinders that must be modified or replaced. Typically, when companies use offset lithography printing, many companies engrave new lettering onto an existing printing plate to save time and resources. Other companies, however, order new printing plates regardless of how minor the line copy change may be.

<sup>6</sup> UPC is a 10 digit code where the first five digits are assigned to the vendor and the last 5 digits are specific to the item.

<sup>7</sup> For each component of cost in this model, RTI obtained a range of estimates for each printing method. The lowest of these estimates is considered the limit of the low range, and the highest of the estimates is considered the limit of the high range. The low and high range of total cost is calculated by adding together all of the low and high range estimates of each component cost, so the low and high range estimates of this model are unlikely.

<sup>8</sup> Source: Muth, M.K., E.C. Gledhill, and S.A. Karns. 2001. "FDA Labeling Cost Model." Prepared for the U.S. Department of Health and Human Services. Research Triangle Park, NC: RTI.

2. Annual Costs

a. Administrative.

The total cost of administrative activities is the dollar value of the

incremental effort expended in order to comply with the final rule. Administrative costs consist of activities such as interpreting the rule in relation to the firm's products, determining the

scope and coverage related to product labels, establishing a corporate position, formulating a method for compliance, and managing the compliance method.

TABLE 3.—TOTAL ANNUAL COSTS OF FROZEN, REFRIGERATED PIZZAS, KITS, AND MIXES <sup>1</sup>

Year	Cost level	Admin cost	Graphic design cost	Total cost	Disc factor 7%	Total disc cost
1 .....	Low	\$211,636	\$529,089	\$740,725	0.93	\$688,874
	Medium	493,816	793,634	1,287,450	.....	1,197,329
	High	775,997	1,058,178	1,834,175	.....	1,705,783

<sup>1</sup> Costs are over a three year period, even though the industry does not incur costs during the second and third year.

FSIS estimates that the administrative costs over the three-year period of compliance for the industry will range between \$212 thousand and \$776 thousand, (\$197 thousand and \$722 thousand, discounted at the 7% rate)<sup>9</sup> as depicted in Table 3, with the mid-point being at \$494 thousand and the per company cost being \$3,186 at the mid-point (\$493,816/155 firms). These administrative costs of changing labels for pre-printed packages will only be incurred in the first year of the rule.

b. Graphic Design

The graphic design costs are being counted as a direct cost of the final rule, range from \$529 thousand to \$1.1

million, with the mid-point being at \$794 thousand, as depicted in Table 3, and the per company cost is \$5,120 at the mid-point (\$793, 634/155 firms). The cost depends upon the type of printing processes used, the complexity of the label change, and the length of the compliance period. The graphic design costs will be incurred in the first year only, and no additional costs are expected because companies will need to print labels regardless of whether this rule is promulgated.

c. Stickers

Companies will also have the option of supplying the required information by applying a separate sticker to existing

product labels. It should be noted that the meat and poultry pizza manufacturers of brand-name and private-label pizzas who regularly use stickers to convey product information already incur these costs. Thus, these costs are not expected to be a direct effect of the final rule for all meat and poultry pizza manufacturers. Table 4 depicts the costs of changing and applying stickers to pizza packages for 2,068 UPC,<sup>10</sup> ranging from a low of \$6.9 million to a high of \$18 million, with the mid-point being at \$12.6 million.

TABLE 4.—TOTAL INDUSTRY COSTS ASSOCIATED WITH USING INDIVIDUAL STICKERS TO MODIFY PRODUCT LABELING<sup>1</sup>

Cost type	Low	Medium	High
Administrative .....	\$273,009	\$637,021	\$1,001,033
Graphic Design .....	\$682,523	\$1,023,784	\$1,365,045
Stickers .....	\$5,926,137	\$10,981,288	\$15,654,141
Total .....	\$6,881,669	\$12,642,093	\$18,020,219

Source: FDA Labeling Cost Model (Muth, Gledhill, and Karns, 2001).

<sup>1</sup> Estimated for 2001.

The use of pre-printed stickers to modify the product labels also has recurring labor costs, assuming that the stickers are manually applied. Estimated sticker application costs range from \$0.014 to \$0.034 per package<sup>11</sup>, which is included in the cost for stickers given in Table 4, ranging from \$6 million to \$16 million, with the mid-point being \$11 million. Stickers' application costs

comprised 87 percent of the total costs for stickers.

In most cases, FSIS believes that it will not be practical for meat and poultry pizza manufacturers to use these stickers to incorporate the required information on the product label because they are small and difficult to apply. Moreover, FSIS believes that the cost of using stickers for longer than six months is unrealistic because the costs associated with stickers are expected to

be higher than the alternative of printing packages. For example, the FDA Labeling Cost Model shows that the total cost of applying stickers to frozen and refrigerated pizzas as depicted in the Table 5 below is over 8 times higher than the costs of changing the labels on packages. The total costs depicted for printing stickers in the table include both labor and the one-time redesign cost.

<sup>9</sup> The discount factor of 7 percent is used to calculate the present worth of a future value at the end of a 3 year period.

<sup>10</sup> The number of UPCs increased from 1,603 for pre-printed packages to 2,068 for stickers because the FDA Labeling Cost Model assumes that the companies which use stickers will have six months to comply. In those six months, the companies will

print the stickers until they are set up to print their packages. Therefore the number of UPCs will increase.

<sup>11</sup> Muth, Gledhill, and Karns, 2001.

TABLE 5.—FROZEN AND REFRIGERATED PIZZAS: COMPARISON OF TOTAL COSTS OF PRINTING STICKERS AND PACKAGES<sup>1</sup>  
[In thousands]

Product category	Packages			Stickers		
	Cost level			Cost level		
	Low	Medium	High	Low	Medium	High
Frozen & refrigerated pizzas .....	740	1,287	1,834	6,880	12,642	17,940

Source: RTI Labeling Cost Model (Muth, Gledhill, and Karns, 2001).

<sup>1</sup> Estimated for 2001.

#### d. Labeling Approval

FSIS will generically approve the necessary modifications made to labels of existing pizza products needed to make these products compliant with the new labeling requirement. Thus, for existing pizza products, there will be no additional costs associated with the submission of labels for approval from FSIS. Also, once the three-year effective date for the labeling requirement has expired, manufacturers will be able to remove the meat or poultry content statement because the statement will be a non-mandatory feature. Therefore, there will be no incremental cost attributed to the final rule.

#### 3. Other Costs

Other costs associated with the rule are voluntary. Companies that chose to develop and market new styles of pizza will incur the normal costs of production, labeling, and marketing as before. Labels for new pizza products may require formal approval from FSIS if they do not qualify for generic approval. Thus, manufacturers of new pizza products may incur costs to obtain formal label approval from FSIS. Companies that chose to identify products with a descriptive name rather than as a "pizza", e.g., "sausage, cheese, and sauce on a crust," will not be subject to the meat or poultry content labeling requirement.

Additionally, when the three-year effective date for the final rule has elapsed, companies that chose to remove the percent meat or poultry statement from their product labels will incur similar administrative and graphic design costs to modify their labels should they choose to remove this statement. However, companies will remove the percent meat or poultry statement from their product labels, if they believe that the benefits exceed the costs of removing the statement. FSIS does not believe that this is a cost of the final rule.

#### 4. Total Costs

The total cost associated with the requirement that the percent of meat or

poultry be conveyed on the labeling of meat or poultry pizzas is estimated at the mid-range point of \$1,287,270 industry-wide or \$8,305 (administrative cost—\$3,185 and graphic design costs—\$5,120) per firm for the three-year period. The actual costs will be lower than the estimated total costs because the analysis included the cost of changing the labels for all pizzas including cheese and vegetable and cheese pizzas that are not affected by the final rule. The final rule will be cost-beneficial because FSIS believes that the non-quantifiable benefits of providing consumers a greater variety of meat pizzas that have varied and potentially improved nutritional profiles and protecting consumers from any potential misrepresentation of the amount of meat and poultry content of pizzas justifies the cost to companies of providing the percent label of meat and poultry content on pizzas.

#### VI. Effect on Small Entities

FSIS has examined the economic implications of the final rule as required by the Regulatory Flexibility Act (5 U.S.C. 601–612). If a rule has a significant economic impact on a substantial number of small entities, the Regulatory Flexibility Act requires that the regulatory options that would lessen the economic effect of the rule on small entities be analyzed. FSIS has determined that the final rule will not have a significant impact on a substantial number of small entities.

FSIS has estimated the annualized cost impact on 149 small entities potentially affected by the final rule. The annualized costs to small meat and poultry pizza manufacturers are estimated to be approximately \$8,640 over three years, or \$2,880 annualized. The annualized cost of this final rule does not exceed \$6,711 which equates to 1 percent of the average small entity annual revenue, and therefore the impact of the final rule is considered not significant.

In addition, the cost of modifying the label is offset by the fact that manufacturers will be permitted to

exhaust their current inventory of pre-printed packages and therefore will not experience any additional cost of retiring unused packages.

#### Executive Order 12988

This final rule has been reviewed under Executive Order 12988, Civil Justice Reform. This final rule: (1) Preempts State and local laws and regulations that are inconsistent with this rule; (2) has no retroactive effect; and (3) does not require administrative proceedings before parties may file suit in court challenging this rule. However, the administrative procedures specified in 9 CFR 306.5, 381.35, and 590.320 through 590.370 must be exhausted before any judicial challenge of the application of the provisions of this rule, if the challenge involves any decision of an FSIS employee relating to inspection services provided under the FMIA or PPIA.

#### Paperwork Requirements

FSIS has reviewed the paperwork and recordkeeping requirements in this final rule in accordance with the Paperwork Reduction Act and has determined that the paperwork requirements have already been accounted for in the Marking, Labeling, and Packaging Material information collection approved by the Office of Management and Budget (OMB). The OMB approval number for the Marking, Labeling, and Packaging Material information collection is 0583–0092.

#### Additional Public Notification

Public awareness of all segments of rulemaking and policy development is important. Consequently, in an effort to better ensure that minorities, women, and persons with disabilities are aware of this final rule, FSIS will announce it and make copies of this **Federal Register** publication available through the FSIS Constituent Update. FSIS provides a weekly Constituent Update, which is communicated via Listserv, a free e-mail subscription service. In addition, the update is available on-line through the FSIS web page located at <http://www.fsis.usda.gov>. The update is

used to provide information regarding FSIS policies, procedures, regulations, Federal Register notices, public meetings, recalls, and any other types of information that could affect or would be of interest to our constituents/ stakeholders. The constituent Listserv consists of industry, trade, and farm groups, consumer interest groups, allied health professionals, scientific professionals, and other individuals that have requested to be included. Through the Listserv and web page, FSIS is able to provide information to a much broader, more diverse audience than would otherwise be possible.

For more information contact the Congressional and Public Affairs Office, at (202) 720-9113. To be added to the free e-mail subscription service (Listserv) go to the "Constituent Update" page on the FSIS Web site at <http://www.fsis.usda.gov/oa/update/update.htm>. Click on the "Subscribe to the Constituent Update Listserv" link, then fill out and submit the form.

List of Subjects

9 CFR Part 317

Food labeling, Meat inspection.

9 CFR Part 319

Food grades and standards, Food labeling, Meat inspection.

9 CFR Part 381

Food labeling, Poultry and poultry products.

For the reasons stated in the preamble, FSIS amends 9 CFR Chapter III as follows:

PART 317—LABELING, MARKING DEVICES, AND CONTAINERS

1. The authority citation for part 317 continues to read as follows:

Authority: 21 U.S.C. 601-695; 7 CFR 2.18, 2.53.

2. Section 317.8 is amended by adding a new paragraph (b)(40) to read as follows:

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

(b) \* \* \*

(40) Products identified as "pizza" that list a meat component as part of the product name must bear a parenthetical statement contiguous to the ingredients statement that conveys the percent of the cooked, cured, or dried meat component in the product. This paragraph shall expire on October 30, 2006.

\* \* \* \* \*

PART 319—DEFINITIONS AND STANDARDS OF IDENTITY OR COMPOSITION

3. The authority citation for part 319 continues to read as follows:

Authority: 7 U.S.C. 450, 1901-1906; 21 U.S.C. 601-695; 7 CFR 2.18, 2.53.

§ 319.600 Removed and Reserved]

4. Section 319.600 is removed and reserved.

PART 381—POULTRY PRODUCTS INSPECTION REGULATIONS

5. The authority citation for part 381 continues to read as follows:

Authority: 7 U.S.C. 138f, 450; 21 U.S.C. 451-470; 7 CFR 2.18, 2.53.

6. Section 381.129 is amended by adding a new paragraph (f) to read as follows:

§ 381.129 False or misleading labeling or containers.

\* \* \* \* \*

(f) Products identified as "pizza" that list a poultry component as part of the product name must bear a parenthetical statement contiguous to the ingredients statement that conveys the percent of the cooked, cured, or dried poultry component in the product. This paragraph shall expire on October 30, 2006.

Done at Washington, DC: July 28, 2003.

Linda Swacina,

Acting Administrator.

[FR Doc. 03-19505 Filed 7-30-03; 8:45 am]

BILLING CODE 3410-DM-P

NUCLEAR REGULATORY COMMISSION

10 CFR Part 110

RIN 3150-AH21

General License for Import of Major Nuclear Reactor Components

AGENCY: Nuclear Regulatory Commission.

ACTION: Direct final rule; confirmation of effective date.

SUMMARY: The Nuclear Regulatory Commission (NRC) is confirming the effective date of August 11, 2003, for the direct final rule that appeared in the Federal Register of May 28, 2003 (68 FR 31587). This direct final rule amended the NRC's regulations to issue a general license for the import of major components of utilization facilities for end-use at NRC-licensed reactors. This document confirms the effective date of the direct final rule.

DATES: The effective date of August 11, 2003, is confirmed for this direct final rule.

ADDRESSES: Documents related to this rulemaking, including comments received, may be examined at the NRC Public Document Room, Room O-1F23, 11555 Rockville Pike, Rockville, MD. These same documents may also be viewed and downloaded electronically via the rulemaking Web site (<http://ruleforum.llnl.gov>). For information about the interactive rulemaking Web site, contact Ms. Carol Gallagher (301) 415-5905; email: [CAG@nrc.gov](mailto:CAG@nrc.gov).

FOR FURTHER INFORMATION CONTACT: Grace H. Kim, Senior Attorney, Office of the General Counsel, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, telephone (301) 415-3605, email [GHK@nrc.gov](mailto:GHK@nrc.gov).

SUPPLEMENTARY INFORMATION: On May 28, 2003 (68 FR 31587), the NRC published in the Federal Register a direct final rule amending its regulations in 10 CFR Part 110 to issue a general license for the import of major components of utilization facilities for end-use at NRC-licensed reactors. The amendment facilitates imports of major components of domestic nuclear reactors in furtherance of protection of public health and safety and reduces unnecessary regulatory burdens related to the maintenance of NRC-licensed reactors. In the direct final rule, NRC stated that if no significant adverse comments were received, the direct final rule would become final on the date noted above. The NRC did not receive any comments that warranted withdrawal of the direct final rule. Therefore, this rule will become effective as scheduled.

Dated at Rockville, Maryland, this 25th day of July, 2003.

For the Nuclear Regulatory Commission.

Betty K. Golden,

Acting Chief, Rules and Directives Branch, Division of Administrative Services, Office of Administration.

[FR Doc. 03-19489 Filed 7-30-03; 8:45 am]

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