

DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

9 CFR Part 381

[Docket No. 94-022F]

RIN 0583-AB86

Use of the Term "Fresh" on the Labeling of Raw Poultry Products

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Final rule.

SUMMARY: The Food Safety and Inspection Service (FSIS) is amending the Federal poultry products inspection regulations to prohibit the use of the term "fresh" on the labeling of raw poultry products whose internal temperature has ever been below 26° F. This final rule requires that raw poultry products whose internal temperature has ever been below 26° F, but above 0° F, must be labeled with the descriptive term "hard chilled." The word "previously" may be used with the term "hard chilled" on an optional basis. The rule also provides for the relabeling of raw poultry products. This action will help ensure that raw poultry products distributed to consumers are not labeled in a false or misleading manner.

EFFECTIVE DATE: August 26, 1996.

FOR FURTHER INFORMATION CONTACT: Charles R. Edwards, Director, Product Assessment Division, Regulatory Programs, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC 20250, (202) 254-2565.

SUPPLEMENTARY INFORMATION:

Background

The current poultry products inspection regulations prescribe freezing procedures for poultry products and the labeling of products that are rapidly changed from a non-frozen state to a frozen state. The regulations (9 CFR 381.66(f)(2)) state that "ready-to-cook poultry shall be frozen in a manner so as to bring the internal temperature of the birds at the center of the package to 0° F or below within 72 hours from the time of entering the freezer." Under the poultry products labeling regulations (9 CFR 381.129(b)(3)), poultry that is not quick-frozen according to certain permitted procedures may be labeled "frozen" only if it has undergone prescribed 0° F or below freezing procedures.

On January 11, 1989, FSIS issued Policy Memo No. 022C that allowed raw poultry to be labeled as "fresh" if its internal temperature is above 0° F and

below 40° F, and it has not been previously frozen at or below 0° F. The policy memorandum states that "it is not practical, under existing marketing strategies and distribution patterns, to define 'fresh' in terms of internal temperature beyond the scope of current regulations, nor is it practical to define consumer expectations for poultry products labeled as 'fresh.'" In establishing this policy in 1989, FSIS concluded that the consumer is the best judge of preference in chilling temperatures for raw poultry products labeled as "fresh," and that the marketplace is best suited for making these distinctions.

The State of California enacted a law (Section 26661 of the California Food and Agriculture Code) on September 27, 1993, restricting the use of the term "fresh" on the labels of poultry products. Section 26661 prohibited, among other things, poultry wholesalers from labeling or otherwise marketing as "fresh" any poultry product whose internal temperature ever has been equal to or below 25° F or that ever has been stored in the aggregate for 24 hours or more at an average ambient temperature of 25° F or below, regardless of the temperature of the product itself. That law was to have taken effect January 1, 1994. However, three trade associations filed suit in the U.S. District Court for the Eastern District of California to prevent enforcement of the California statute, claiming that it was preempted by the Poultry Products Inspection Act (PPIA) (*National Broiler Council, et al. v. Voss* (E.D. Cal. Civil No. CV-S-93-1882 DFL/JFM)). At the request of the Court, USDA filed a brief on February 14, 1994, as *amicus curiae*, on the question of whether the California law was preempted by Federal law. In its decision of April 8, 1994, a U.S. District Judge held that the PPIA preempts state labeling requirements that are "in addition to, or different than" Federal requirements and declared that the labeling provision of the California law was preempted by Federal law.¹

California appealed this decision to the U.S. Court of Appeals for the Ninth Circuit, and USDA filed an *amicus* brief. On June 16, 1994, the State of California amended its statute by removing the reference to the "ambient temperature"

of the poultry and prohibiting use of the term "fresh" on the labeling of any poultry or poultry meat whose internal temperature has been below 26° F. On December 14, 1994, the Court of Appeals for the Ninth Circuit upheld the District Court's judgment that the labeling provision of the California statute was pre-empted by the PPIA, but ruled that other portions of the amended statute, such as those governing the advertising of "fresh" poultry, could stand.²

Reassessment of FSIS' Policy on "Fresh"

Because of the issues raised by the California law, the Secretary of Agriculture on February 10, 1994, directed FSIS to reexamine its policy on the use of the term "fresh" on the labeling of raw poultry products. The Secretary stated that this reexamination of policy was necessary to ensure that the policy "is reasonable and meets today's consumer expectations." The Secretary directed FSIS to "make sure that any policy change does not open the door to problems like the growth of bacteria that could cause foodborne illness."

On June 16, 1994, two subcommittees of the U.S. House of Representatives Committee on Government Operations held a joint hearing on the issue of "fresh" labeling of poultry products. Representatives from USDA, the poultry industry, and consumer groups presented their views on the "fresh" labeling issue. Subsequently, on July 27, 1994, Senator Barbara Boxer of California, together with Congressman Gary Condit of California, introduced H.R. 4839, the Truth in Poultry Labeling Act of 1994. This bill would have prohibited use of the term "fresh" on labeling of poultry that has ever been frozen below 26° F.

In response to the Secretary's direction and the events described above, FSIS initiated the following action. On August 26, 1994, it published a notice in the **Federal Register** (59 FR 44089) announcing three public hearings on the use of the term "fresh" on the labeling of raw poultry products. The hearings were held during September 1994 in Modesto, CA, Atlanta, GA, and Washington, DC. The hearings focused on issues relating to current industry practices and controls and consumer expectations and perceptions regarding the term "fresh" on the labeling of raw poultry products. Also in September 1994, FSIS conducted an informal survey of callers

¹ The District Court's Memorandum of Decision and Order as well as other documents and pleadings related to the lawsuit are available for public inspection under Docket Number 94-022F at the office of the FSIS Docket Clerk, Room 4352, South Building, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC 20250, from 8:30 a.m. to 1:00 p.m., and from 2:00 p.m. to 4:30 p.m., Monday through Friday.

² The Ninth Circuit's ruling is also on file at the office of the FSIS Docket Clerk.

to the USDA Meat and Poultry Hotline to determine their attitudes, perceptions, and expectations regarding poultry that is to be labeled as "fresh." FSIS also reviewed the scientific literature to determine and resolve any scientific or technical time- and temperature-related issues concerning the safety of poultry products during shipment and storage. Transcripts of the public hearings and copies of information submitted during the hearings, a copy of the informal survey entitled "Consumer Views on Fresh Chicken—Results of a Hotline Survey," and a copy of the literature review entitled "Effects of Temperature on the Microbiological Profile and Quality Characteristics of Raw Poultry" were made available for review at the office of the FSIS Docket Clerk.

FSIS also requested USDA's Agricultural Research Service (ARS) to conduct research studies on sensory, chemical, and microbial properties of raw poultry products that have been exposed to and held at temperatures from 0° F to 40° F for different storage periods. The ARS report entitled "Characteristics of Chilled Poultry," dated December 20, 1994, was subsequently placed on file in the office of the FSIS Docket Clerk. The ARS report found that there was no clear-cut pattern of change in the sensory characteristics of cooked, deboned chicken breasts over the temperature range tested (40° F, 32° F, 26° F, 10° F, and 0° F). Slight changes that were noted were sample dependent, and it is unlikely that the average consumer would detect the differences found by the highly trained taste panel. All shear values were in a range that would be translated as "tender." Near infrared reflectance spectroscopy (NIR) can be used for the determination of temperature, drip loss, and to classify storage temperature of deboned chicken breasts. However, classification of the 26° F storage temperature is not, at present, sufficiently accurate to permit NIR to be used as a regulatory enforcement tool to detect if a product was chilled to temperatures in the mid 20-Fahrenheit range. ARS also reported that microorganisms were not killed or significantly reduced by exposure to temperatures as low as 0° F; however, *Salmonella* and other enterobacteriaceae do not grow below 40° F. Spoilage type bacteria can grow at temperatures as low as 26° F but will not grow at 10° F or 0° F.

The Proposal

After reviewing the information provided at the public hearings, the results of the Meat and Poultry Hotline

survey, the literature review, the U.S. District Court proceedings in California on "fresh," and other information, FSIS issued in the **Federal Register** on January 17, 1995 (60 FR 3454), a proposed rule to amend the Federal poultry products inspection regulations to establish the conditions that would govern the use of the term "fresh" on the labeling of raw poultry products and the language that would apprise consumers when such products do not meet FSIS' proposed criteria for "fresh." FSIS stated that the current policy on the use of the term "fresh" on the labeling of raw poultry products has considerable potential to mislead consumers about the products they seek to buy as "fresh," and that the potential for economic deception is great when a product offered for sale as "fresh" is not the product the consumer expects to purchase. FSIS also stated that there should be no increased microbiological safety risks associated with raw poultry that is maintained at 40° F or below.

FSIS proposed that raw poultry products whose internal temperature has ever been below 26° F, but above 0° F, may not bear a label declaration of "fresh" and must be labeled with the descriptive term "previously frozen." The term "previously frozen" was chosen because FSIS believed that this term would be the most readily understood by consumers based upon comments from the public hearings. FSIS also proposed that raw poultry products whose internal temperature has ever been at or below 0° F may not bear a label declaration of "fresh" and must be labeled with either the descriptive term "frozen" or "previously frozen," except when such labeling duplicates or conflicts with the products' special handling labeling instructions, e.g., "keep frozen" or "shipped/stored and handled frozen for your protection," as required by 9 CFR 381.125. FSIS stated that it would continue to permit use of terms such as "fresh frozen" and "frozen fresh," as currently provided by 9 CFR 381.129(b)(3), to describe products that are frozen rapidly to an internal temperature of 0° F or below in accordance with the provisions of 9 CFR 381.66(f)(1).

FSIS also identified several additional issues regarding the use of the term "fresh" on the labeling of raw poultry products and solicited comments on whether these issues should also be addressed in the final rule. While FSIS proposed the use of the descriptive term "previously frozen," it invited comments on alternate descriptive terms. FSIS indicated that it would consider alternate terms if information

submitted during the comment period demonstrated greater consumer understanding and acceptability. In addition, FSIS discussed the advantages and disadvantages, which it identified, of the terms "previously frozen," "previously held at _____° F," "thawed for your convenience," "freshly frozen," and "previously freshly frozen." FSIS invited comments regarding procedures for monitoring compliance with the fresh labeling requirements. FSIS also sought comments on its position that the term "fresh" can be used in brand names, company names, sensory modifiers, etc., on the labeling of raw poultry product in a manner that does not cause the purchaser to assume the product itself is unprocessed and, consequently, not "fresh." FSIS described its labeling policy expressed in Policy Memo No. 022C that the term "fresh" may not be used on the labeling of any cured, canned, hermetically sealed shelf stable, dried, or chemically preserved poultry product and invited comments on whether it would be useful and desirable to initiate rulemaking to establish regulatory requirements for all uses of the term "fresh" on the labeling of poultry products.

Extension of Comment Period; Solicitation of Comments

During the comment period on the proposed rule, FSIS received two requests from trade associations to extend the comment period in order to allow the public time to obtain and review the findings of the ARS evaluation on chilled poultry. The ARS report was not available for public review in the FSIS Docket Clerk's office at the time the proposed rule was published. Previously, FSIS had stated its intention to seek comment from the National Advisory Committee on Microbiological Criteria for Foods on FSIS' conclusion stated in the preamble to the proposed rule that "there should be no increased microbiological safety risks associated with the growth of pathogenic microorganisms" by changing the labeling definition for "fresh" poultry. At that time, the next meeting of the Committee was scheduled to begin April 17, 1995. FSIS also received a comment noting the conflict between the proposed use of the term "previously frozen" and the existing regulatory definition of "frozen." In order to allow adequate time for public comment on the ARS report, allow the National Advisory Committee on Microbiological Criteria for Foods the opportunity to comment on FSIS's conclusion that product safety is not an issue should FSIS change the

definition of "fresh" from 0° F to a value less than 28° F, and solicit public comments on options for reconciling dual use of the term "frozen." FSIS announced in the **Federal Register** on March 20, 1995 (60 FR 14668), that it was extending the comment period for an additional 60 days until May 19, 1995.

In the notice of extension of comment period and solicitation of comments, FSIS discussed three possible options to resolve the inconsistency between the proposed use of the term "previously frozen" and the preexisting regulatory definition of "frozen." The first option on which FSIS solicited comments involved using descriptive terms that do not include the word "frozen" or the unqualified word "frozen," e.g., "previously semi-frozen," "held semi-frozen," "previously partially frozen," "previously chilled to a semi-solid state," "shipped/stored/handled semi-frozen (insert optional statement, e.g., to preserve quality)," or "previously frosted." The second option was to eliminate the requirement that poultry products labeled as "frozen" be brought to an internal temperature of 0° F or below and to require use of the term "frozen" to identify all poultry products whose internal temperature has ever been below 26° F. The third option described would use the proposed term "previously frozen" on labeling of products with internal temperatures between 0° F and 26° F and would create an additional qualifier for products with an internal temperature of 0° F or below, such as "frozen for long-term preservation," in order to differentiate between these two types of products.

Discussion of Comments

FSIS received 26,208 comments in response to the January 17, 1995 proposed rule and the March 20, 1995 solicitation of comments. The comments were from a range of sources as follows: 25,530 from individuals; 611 from poultry processors and growers; 23 from trade associations; 12 from state government agencies; 6 from academia; 6 from consumer organizations; 5 from congressional members; 3 from chefs; 2 from Federal government agencies; 2 from professional associations; 2 from food consultants; 2 from food retailers; and 4 from other sources. Many of the individual commenters who identified themselves as consumers also indicated that they were employed by the poultry industry. Some of the comments included issues beyond the scope of the proposed rule. For example, some commenters raised questions about the difference in meaning of the term

"fresh" as proposed for poultry products and its meaning for red meat and fish products. In addition, 7 other comments addressed only issues outside the proposal, e.g., water uptake during the chilling process. Since these issues do not come within the scope of the proposed regulation, they are not addressed in this final rule. FSIS also received 3,990 letters in support of the proposal, which carried typed signature blocks but were unsigned. A summary of the comments submitted with respect to the proposed rule and FSIS' response to the comments follows.

Use of the Term "Fresh"

Numerous commenters agreed that the proposed rule is necessary to provide consumers with information they need to make informed purchasing decisions. Many commenters indicated that they often freeze poultry at home for later use and that they want to avoid inadvertently refreezing poultry that has been previously frozen and thawed out. Many expressed surprise that the practice of marketing thawed poultry existed and was allowed under Federal regulations. Some of these commenters suggested that a twice-frozen, twice-thawed product might be dry and tough, more likely to spoil, or be unsafe. Most supporting commenters expressed the opinion that the issue is one of labeling a product for what it is, that "fresh" is the opposite of "frozen," and that, to consumers, "frozen" means a product was rock hard or previously in that condition. While some of these commenters associated the term "fresh" with other factors in addition to temperature history, such as recent slaughter or age, freedom from bacteria, and superior flavor, texture, and juiciness, they insisted that "fresh" and "frozen" are, nonetheless, mutually exclusive.

In contrast, a large number of commenters who opposed the proposed rule contended that it is based on perceptions and that selection of a temperature threshold level of 26° F below which a product could not be labeled as "fresh" was arbitrary and lacked a scientific foundation. Large poultry processors stated that they had received no or extremely few complaints from consumers that made any reference to temperature as it relates to freshness of the product. They interpreted the lack of complaints to mean that the "fresh" versus "frozen" issue is a very minor consumer concern. Others commenters suggested that consumers have demonstrated their satisfaction with broiler meat through an unparalleled increase in per capita consumption in the last 50 years.

Opponents of the proposal further argued that consumers demand a product that does not require thawing, but, instead, is ready-to-cook, and that most consumers know that the colder the temperature, the higher the quality of the product. With respect to concerns about refreezing thawed poultry, one processor noted that, since this has been the general practice for years, there are obviously no problems.

Many of the commenters who objected to the proposed rule suggested that temperature alone is not a reasonable basis for labeling poultry products as "fresh" because freshness diminishes with time, e.g., a product kept at 26° F and held for 3 months is not "fresh." These commenters argued that "fresh" means "wholesome" and that "fresh" is not the opposite of "frozen" because fresh poultry is characterized by a variety of factors, including appearance, smell, taste, texture, whether the product will spoil relatively quickly, among others. Some opponents charged that FSIS attempted to define "fresh" by default, thereby creating a currently non-existent product category, which FSIS proposed to call "previously frozen," and which was not requested by either consumers or industry. These commenters expressed the opinion that consumer expectations do not include changing current free enterprise markets by creating non-market-demanded new product categories that affect both labeling and current practices concerning handling statements.

Quality Issues

A number of the commenters, including chefs, who wrote in support of the proposal, stated that frozen poultry can taste good but that fresh poultry has a better taste and texture. Many consumers remarked that they do not mind paying a premium price for a fresh product, which they perceive to be of high quality; however, they do mind paying a premium price for a product labeled as "fresh" that has been frozen for shipment and then thawed for sale. Opponents of the proposal argued that there is no clear and easily discernable quality difference between products brought to different temperature levels. They pointed to the conclusion of the ARS study where an expert taste panel found "that there was no clear-cut pattern of change in the sensory characteristics over the temperatures tested" and that "all shear values were in the 'tender' range." The temperatures tested ranged from 0° F to 40° F and included refrozen product. These opponents interpreted the ARS results to show that "fresh" cannot be based on,

or solely defined by, a single temperature threshold. In contrast, supporters of the proposal suggested that it would be premature to draw conclusions about the ARS sensory results without further evaluation and peer review of the findings.

Opponents of the proposal were very concerned that it would jeopardize product wholesomeness. They stated that appropriate temperature control is a good manufacturing practice designed to maximize shelf life and minimize growth of microorganisms to ensure consistent high quality and freshness to the consumer. The commenters believed that the proposed rule would not provide for an improved product, but would cause consumers to purchase a product of lesser quality or to pay more for poultry without any change in product quality.

Trade Issues

Numerous opponents, including congressional members, expressed the opinion that the proposed rule would inhibit the interstate shipment of poultry. Many stated that the "fresh" issue is not a consumer issue but, rather, a marketing issue in which FSIS should not be involved. They believed that the proposed rule would certainly mean higher prices for local products through a forced reduction in competition and deny free trade in those states enforcing the regulation. On the other hand, supporting commenters believed that it is wrong for producers who compete against truly fresh products to call frozen and thawed poultry "fresh," and characterized such a merchandizing practice as fraudulent. Several commenters asserted that national processors shipping interstate would not be precluded from any markets, and, if they wanted to sell fresh poultry, they could do so successfully. One commenter noted that most of the perishable food consumed in the U.S. is the subject of interstate commerce and that poultry is no more or less perishable than many other items in the American market-basket.

Other opponents argued that the proposed rule was inequitable. For example, a trade association contended that the Food and Drug Administration (FDA) permits the term "fresh" to be used so long as "the term does not suggest or imply that the product is unprocessed or unpreserved," as described in the introductory paragraph to 21 CFR 101.95. They suggested that poultry products would be "fresh" under FDA's definition because poultry products kept at temperatures below 26° F (i.e., 23° F or 24° F) are not preserved because they will spoil.

Similarly, they questioned why poultry chilled below 26° F could not be thawed and sold as "fresh" when fresh milk has been pasteurized, fresh bread has been baked, and fresh crab has been cooked and picked.

Many poultry producers and growers were concerned with the potential effect of the proposal on the poultry industry. Some were concerned that it could open the door to opportunism by creating an adverse relationship between the manufacturer and the customer who might claim a product to be "frozen" and expect a price adjustment of the bill of lading. Others contended that the proposal could adversely affect small companies or create loss of sales, shortages of product, possible loss of jobs, and decrease the demand for poultry. A number of opponents considered the task of monitoring the proposed rule throughout distribution channels to be monumental. They stated that enforcement would require the expenditure of substantial resources, which is not justified because no food safety issue exists.

FSIS Response

The large volume of comments expressed widely diverse opinions about the meaning of the term "fresh" as applied to poultry. FSIS agrees that there can be numerous perceptions associated with the term "fresh," including one of higher quality. However, the comments and information gathered at the public hearings held last summer on the "fresh" issue show that neither consumers' expectations about fresh products nor their willingness to pay more for such products is affected by whatever quality differences may exist between poultry products subjected to different temperatures.

FSIS has concluded that the "fresh" labeling issue is an important consumer protection issue about false and misleading labeling. FSIS has the authority to regulate the labeling of poultry products based upon the statutory provisions concerning misbranding in the PPIA (21 U.S.C. 453(h)(1)) in order to prevent the distribution of misbranded products in commerce. Under these statutory provisions, an article is misbranded if its labeling is false or misleading in any particular. Because the "fresh" issue is a labeling issue, it is not relevant to this rulemaking whether or not the "fresh" issue is also a trade or marketing issue as many commenters suggested. Generally, the commenters' concerns about loss of trade opportunities and markets appear to be driven by factors that relate to how products will have to

be labeled under the regulations and how FSIS will enforce these regulations. FSIS has addressed these concerns in the sections of this document that pertain to descriptive labeling and compliance procedures.

After evaluating all of the comments and other data in the rulemaking record, FSIS has concluded that consumers equate the term "fresh" with a product that has never been chilled until it is hard-to-the-touch. Rather than simply refrigerated, consumers consider such a hard-to-the-touch product to be frozen. Based on the comments, FSIS concludes that use of the term "fresh" on the labeling of products that have been chilled to the point where they appear to consumers to be frozen but are presented for sale in a thawed condition without revealing the fact that they had been chilled to a hard-to-the-touch state, is misleading. In addition, the available information suggests that many consumers want to know the history of the poultry product they buy, as related to temperature, so that they can handle the product accordingly if they choose to do so, e.g., with respect to refreezing. FSIS does not believe that "frozen" and "fresh" are synonymous or that a product which has been chilled until it is hard-to-the-touch is the same as a product which has not been so chilled. A product that has been chilled until it is hard has been processed for purposes of preservation regardless of whether or not all of the water in the product is in a frozen state.

FSIS does not agree with the argument that it defined "fresh" by default and created a new product category. The category of product that has been chilled until the product is hard-to-the-touch but not frozen to an internal temperature of 0° F or below has been in existence for many years, during which time it was often labeled as "fresh," when, in fact, it was chilled for preservation. FSIS does not consider fresh milk, fresh bread, or fresh crab to be analogous to fresh poultry because the use of the term "fresh" in this context is generally not misleading. On the other hand, the comments and other information in the rulemaking record show that there is confusion among consumers with respect to poultry labeling, and that consumers were not aware that poultry products sold as "fresh," and pliable at retail display, may have once been hard and then thawed. Moreover, an unprocessed, unpreserved form of poultry, which has never been chilled to render the product hard-to-the-touch, is available in the marketplace.

Safety Issues

In its proposed rule, FSIS explained that it does not believe that imposing a temperature requirement for use of the term "fresh" on the labeling of poultry products will increase microbiological safety risks as long as the product is held at 40° F or lower. The National Advisory Committee on Microbiological Criteria for Foods was asked to review and comment on this matter. The Committee discussed the issue and concluded that: "The available scientific data on the microbial characteristics of poultry products and growth of bacterial foodborne pathogens below 40° F were considered in our evaluation. This information leads us to conclude that changing the temperature that defines labeling of poultry as 'fresh' from 0° F to a value less than 28° F should not cause any increased risks to public health. This issue is related to labeling and quality rather than microbiological safety." FSIS agrees with the determination of the Committee on this issue.

Accordingly, for the reasons stated above, FSIS concludes that a temperature-related requirement for use of the term "fresh" is necessary to preclude misleading consumers about the nature of the poultry products they purchase.

Temperature Threshold

The vast majority of the commenters writing in support of the proposed rule agreed that the minimum temperature for fresh poultry should be set at the proposed temperature of 26° F. Some of these commenters expressed the opinion that 26° F is not an arbitrary number but a temperature below which poultry is hard-to-the-touch and appears frozen to the consumer. Other commenters stated that, since most ice crystal formation occurs within a narrow temperature range between 27° F and 25° F, it makes sense to use 26° F as the dividing line between "fresh" and "frozen" poultry. A few commenters recommended 32° F or 33° F as the cutoff threshold because 32° F is the freezing point of water. One commenter suggested that any product stored for prolonged periods at or below 32° F will become hard-to-the-touch and, thus, in the customer's view, would be a frozen product.

Many opponents of the proposed rule argued that there was no scientific evidence that poultry products freeze at 26° F. They noted that the freezing of food is a process involving a change in the product's moisture from a liquid to a solid state over a wide temperature range, generally from 28° F to -4° F.

Given this range, they argued that the selection of a single temperature cannot be justified. A few commenters requested additional research to determine the freezing point of poultry. Some members of the turkey industry argued that the proposal's analysis of the "fresh" versus "frozen" issue focused on chicken. They suggested that more research be conducted before the proposal is applied to turkeys, which might possibly freeze at a lower temperature. Some commenters suggested that an attempt to define complex processes by an oversimplified and arbitrary temperature is scientifically unsound and may actually have a negative impact on the application of new technologies, improvement of product quality, and purchasing options for consumers.

Need for a Lower Temperature

Numerous commenters from industry called for a lower and more reasonable temperature than 26° F as the definition for "fresh" because colder temperatures provide for a higher quality, better tasting, and safer product. Congressional members also noted that there are other temperatures below 26° F that preserve the "fresh" characteristics consumers seek while giving poultry products the longer shelf life necessary for transportation over long distances. Many poultry processors indicated that the proposed limit would force them to process and ship their products at higher temperatures in order to ensure that product labeled as "fresh" does not fall below 26° F in order to avoid costly relabeling procedures. They believed that a practice of using higher temperatures would shorten shelf life, increase incidence of spoilage, and adversely affect product quality and/or safety. Industry also expressed the belief that temperatures colder than 26° F provide a safety margin in the distribution chain. In addition, commenters argued that a temperature of 26° F would create extensive operational problems in order to control temperatures, e.g., ensuring that small packages do not go below 26° F while ensuring that large packages receive adequate protection, or achieving a consistent 26° F temperature in very thick products like turkey carcasses.

With respect to lower temperatures, a number of commenters stated that existing research shows that growth of psychrophilic bacteria normally associated with product spoilage begins to approach a state of inactivity at a temperature close to 14° F or 15° F. They argued that a temperature of 14° F or 15° F would recognize that at least part of the distinction between "fresh"

and "frozen" is the difference between continuous bacterial degradation of the product and product in which it has been halted. On the other hand, some supporters of the proposal challenged this suggestion that the point at which spoilage bacteria cease to grow be considered as the dividing line between "fresh" and "frozen" because spoilage bacteria do not cause foodborne illness.

Industry commenters stated that there is no indication that any consumer defined "fresh" as being tied to 26° F, and that they would support 20° F as a practical temperature that would not disrupt commercial practices, which have proven themselves over 25 years of use. One commenter urged FSIS to determine whether there exists any distinguishable palpability or quality differential between poultry chilled at 20° F and that chilled at 26° F, and, if not, requested FSIS to change its temperature standard to 20° F so as to impose the least burden on the regulated community. Other commenters contended that "fresh" could easily be product that is 22° F or above, as well as the proposed level of 26° F, considering that FSIS terminology for "frozen" is 0° F. Yet others supported a temperature of 23° F, which has been considered by some researchers to be the freezing point of poultry. Commenters also noted that it has been shown that keeping product as low as even 24° F will reduce bacterial growth, thus enhancing the quality of the product. In addition, a few commenters asked whether the upper end temperature limitation of 40° F would be voided should the proposed regulation replace Policy Memo No. 022C.

FSIS Response

FSIS believes there is adequate information on which to limit the use of the term "fresh" on the labeling of raw poultry products to product whose internal temperature has never been below 26° F. The effect of various temperatures on the physical and shelf life properties of poultry has been studied extensively since the 1920's. Many reference books on the preservation of foods by freezing and engineering textbooks, such as the 1994 ASHRAE Handbook on Refrigeration, I-P Edition, Chapter 12, Poultry Products, published by the American Society of Heating, Refrigerating, and Air-Conditioning Engineers, Inc., Atlanta, GA, state that 27° F is the highest temperature at which poultry

begins to freeze.³ At 27° F, ice crystals begin to form in poultry flesh. Below 26° F, poultry products become hard-to-the-touch because much of the free water is changing to ice. At 25° F, the literature suggests that approximately half of the water in the poultry is frozen. By 23° F, approximately 80 to 85 percent of the free water in the product is frozen, and the product appears to be frozen solid. FSIS notes that one commenter stated that it is very difficult to insert a temperature probe by hand into a product at 22° F.

Pliability of Product

At 26° F, the product is still pliable in that it yields to the thumb. This characteristic is described by various commenters on the proposed rule and participants at the public hearings and last year's court proceedings. A temperature of 26° F as the threshold for product to be labeled as "fresh" is also supported by the National Institute of Standards and Technology (NIST). NIST's Handbook 133, "Checking the Contents of Packaged Goods," Supplement 3, October 1992, states in part: "Fresh Poultry.—For net weight determinations only, fresh poultry is defined as poultry above 26° F. This is product that yields or gives when pushed with a person's thumb."⁴ While NIST defines fresh poultry for the purpose of net weight determinations only, FSIS believes that it is pertinent to this issue that another Federal agency recognizes that poultry is pliable down to a temperature of 26° F. FSIS does not believe that consumers would consider a product to be frozen or in some other state as opposed to "fresh" when it is pliable, i.e., when it is not hard-to-the-touch. The recognition by NIST that poultry is pliable down to 26° F lends further support to the selection of 26° F as the temperature threshold for an FSIS labeling definition for "fresh" poultry products.

Based on the scientific evidence that most of the free water in raw poultry products freezes over a 4-degree temperature range between 27° F and 23° F, FSIS believes that the selection of 26° F as the lower limit for a product to be called "fresh" is reasonable. The selection of 26° F is also supported by the comments and other information and documents in the rulemaking record, as discussed above. A product that has not been held below 26° F should meet consumer expectations that

"fresh" products have not been chilled until they are hard. Accordingly, FSIS is adopting 26° F as the temperature at or above which a poultry product must have been continually held in order to be labeled as "fresh." FSIS does not believe that it is necessary to incorporate an upper limit of 40° F into the labeling provision because the 40° F internal temperature pertains to chilling and holding requirements as described in 9 CFR 318.66 (b), (c), and (d).

Product Coverage

With respect to comments that turkey should not be covered by this final rule because it might have a different freezing point than chicken, FSIS disagrees that turkey should be exempted while more research is conducted to determine its freezing point. There is an abundance of information on the freezing of turkey products—from reference books on the freezing preservation of foods and engineering textbooks, including the 1994 ASHRAE Handbook on Refrigeration—which shows that turkey freezes over the same temperature range as chicken. In addition, references to scientific studies on the freezing of turkey are cited in FSIS' literature review entitled "Effects of Temperature on the Microbiological Profile and Quality Characteristics of Raw Poultry," which was discussed in its proposed rule, and in the paper entitled "Superchilling of Poultry Meat" by W. J. Stadelman.⁵

In FSIS' view, the various studies do not show significant differences between turkey and chicken with respect to the effects of freezing on the products. FSIS notes that the ASHRAE Handbook on Refrigeration refers to 27° F as the point at which poultry starts to freeze. This temperature is not restricted to chicken but, rather, refers to all poultry, including turkey. Moreover, FSIS has not been presented with any evidence from the public hearings, the U.S. District Court proceedings, or comments on its proposed rule that suggests the effect of various temperatures on the physical and shelf life properties of turkey differs from chicken to an extent sufficient to warrant a temperature threshold other than 26° F as an appropriate threshold for the labeling of "fresh" turkey. With respect to pliability, FSIS notes that the NIST Handbook 133 refers to "fresh poultry," rather than specifically to "fresh chicken," when defining poultry products for the purpose of net weight determinations as those that are pliable

down to 26° F. Therefore, for these reasons, FSIS will not exempt turkey from the requirements of this final rule.

Descriptive Labeling

Those commenters who favored regulating use of the term "fresh" on the labeling of poultry products generally supported requiring use of a descriptive term on the labeling of products whose internal temperature has ever been below the 26° F minimum temperature defining "fresh." These commenters also contended that if the labeling says nothing, many consumers will likely assume product in a retail case is "fresh," i.e., has never been frozen, because it is soft-to-the-touch. They argued that consumers should not be subjected to either the affirmative, deceptive verbal representation that a product is "fresh" when it has been frozen or the deception implied by the unfrozen condition of a product presented for retail sale that it is "fresh" when, in fact, it has been frozen and thawed.

In contrast, many poultry processors and trade associations asserted that industry should not be required to use any descriptive term for product that is not declared to be either "fresh" or "frozen." These commenters believed that a regulation governing the use of the term "fresh" should be handled in the same manner as other affirmative marketing claims such as nutrient content claims. Specifically, they suggested that FSIS should establish the criteria for the use of the term and allow all manufacturers the option to make the claim or not as they see fit. At the minimum, the commenters stated that descriptive labeling for product between 0° F and 26° F should be optional.

The Term "Previously Frozen"

A large majority of commenters who supported use of descriptive labeling to describe the nature of the product favored the term "previously frozen," which FSIS proposed to require. They expressed the opinion that the simple phrase "previously frozen" was adequate because, in general, consumers only want to distinguish between fresh and thawed poultry. A trade association submitted results of a national telephone survey of consumers, conducted in November 1994, which consisted of a minimum of 1,000 interviews. Results showed that 87 percent of those interviewed said they want a properly descriptive label on poultry that was frozen and then thawed. When the respondents who wanted a descriptive label were asked to rate seven terms on the basis of accuracy to describe such product, the

³ A copy of Chapter 12 from the 1994 ASHRAE Handbook is available for public inspection in the FSIS Docket Clerk's office.

⁴ A copy of the page from the NIST Handbook 133 containing this entry is available for public viewing in the FSIS Docket Clerk's office.

⁵ These documents are available for public inspection in the office of the FSIS Docket Clerk.

percentages of those surveyed rating the terms as "most accurate" were as follows: 49.7 percent for "do not refreeze"; 48.4 percent for "previously frozen"; 35.5 percent for "previously frozen for your convenience"; 26.9 percent for "thawed"; 21.6 percent for "previously thawed for your convenience"; 18.3 percent for "fresh"; and 10.2 percent for "chill-pack." The commenter interpreted these results as showing that "previously frozen" was a preferred choice for a descriptive label.

Without exception, opponents of the proposed rule voiced strong objection to use of the proposed term "previously frozen" on the labeling of poultry products brought to temperatures between 0° F and 26° F. They stated that products that have experienced temperatures below 26° F cannot be characterized accurately as "previously frozen." These commenters noted that the proposal was internally inconsistent because it would require products to be identified as "previously frozen" when they could never be labeled legally as "frozen" based on FSIS' regulations (9 CFR 381.66(f)(2)), which provide that poultry may only be labeled as "frozen" if it reaches a temperature of 0° F or below. They argued that, because the shelf life of raw poultry products held below 26° F is not the same as for those held at 0° F or below, the labeling would be very misleading and confusing to the consuming public who have an expectation that frozen product should not spoil and has a long shelf life. These commenters also argued that requiring use of the term "previously frozen" would be confusing to facets of the industry because they would handle product labeled as "previously frozen" in the same manner as they would handle fresh frozen or frozen product, thereby resulting in increased product mishandling.

Additionally, numerous opponents of the term "previously frozen" considered it to be a negative or punitive description that connotes undesirable handling and implies that the products are inferior, although they consider the products to be superior from a shelf life and microbiology standpoint. They expressed concern that the proposed labeling would make it harder to market poultry because consumers would not want to buy a previously frozen product. These commenters contended that the proposal establishes a double standard which could cause consumers to discriminate against certain products. For example, the proposal would require that product reaching temperatures below 26° F be labeled as "previously frozen," while products that are frozen rapidly (within 48 hours

after initial chilling) may be labeled as "fresh frozen" or "frozen fresh," in accordance with 9 CFR 381.66(f)(1). In their opinion, use of "previously frozen" on labeling suggests the product is not "fresh" when, in all likelihood, it could be fresher than a fresh frozen product.

Some supporters of the term "previously frozen" did not agree that the term might be confusing. They stated that the designation of "frozen" for poultry below 0° F is not in conflict with the designation of "previously frozen" for product in the temperature range between 0° F and 26° F because the latter is a labeling designation that accurately reflects consumers' perceptions that hard-to-the-touch poultry is frozen poultry. They noted that the freezing regulations describe a process for handling poultry products that allows them to remain in good condition for an extended period of time. They suggested that labeling thawed poultry as "previously frozen" would not impede or contradict that important processing requirement, but would alert consumers that the poultry they are buying was once in a short-term frozen state and should not be refrozen at home.

Because the regulatory definition of "frozen" describes a condition of the product which makes it suitable for long-term storage and subsequent use and/or for consumer education purposes, some commenters who favored use of the term "previously frozen" suggested that the term could be clarified in the regulations to alleviate any possible confusion. For example, one commenter suggested that the term "previously frozen" be defined as "defrosted or thawed raw poultry products which have been chilled (internal temperature has ever been below 26° F) or frozen (internal temperature of 0° F or below)." Similarly, another commenter suggested that terms could be numerically defined in the regulations such as "frozen (0° F or below)"; "previously frozen (1° F to 25° F)"; and "fresh (26° F to 40° F)."

Alternate Terms

FSIS reviewed numerous comments on the four possible alternate terms discussed in the proposed rule, i.e., "previously held at _____° F," "thawed for your convenience," "freshly frozen," and "previously freshly frozen." FSIS also received numerous comments on the use of a phrase which either does not include the word "frozen" or does not include the unqualified word "frozen," as discussed in the notice soliciting comments to reconcile dual use of the word "frozen." Some

commenters stated that all the terms convey basically the same information and clearly alert the consumer that the product has not been kept at fresh temperatures. These commenters argued that individual processors should be permitted to select from a group of terms that accurately depict the product in order to accommodate different marketing approaches. A number of commenters who supported descriptive labeling recognized the difficulty of identifying the best terminology.

A few supporters disliked the phrase "previously held at _____° F" on the basis that it might not give consumers the information they need because many might not know that poultry freezes below 26° F. A commenter also stated that this particular phrase, if used, should specify a time period in days or weeks, i.e., "previously held at _____° F for less than (insert time period)."

Some supporters of descriptive labeling opposed the term "thawed for your convenience" on the basis that the product is frozen for the convenience of the producer and/or retailer rather than the consumer, or that it is an unnecessarily confusing way of saying "previously frozen." Similarly, some commenters opposed use of the phrase "previously frozen for your protection" on the basis that freezing does not make the product safer but, rather, extends its shelf life. Other commenters preferred the phrase "previously frozen and thawed for your convenience," while yet others preferred the simple word "thawed." To avoid confusion over dual use of the word "frozen," a consumer organization also suggested "thawed," but was concerned that some consumers might not understand that the product had been held in a frozen state.

Concerning terms using the word "freshly," some supporters contended that "freshly frozen" implies that the poultry is still in the frozen state, which would not likely be the case, and that it might be confused with the term "fresh frozen," which is used for certain poultry frozen to 0° F or below. Others expressed opposition to any language that permits manufacturers to market a product as "freshly frozen" or "previously freshly frozen" on the basis that "fresh" and "frozen" are diametrically opposed terms. Some commenters considered the phrase "previously freshly frozen" to be little different than "previously frozen," except that it adds an unnecessary word. Generally, commenters indicated that terms that avoided the word "frozen," e.g., "previously chilled to a semi-solid state," or that avoided the unqualified word "frozen," e.g., "previously semi-frozen," were

awkward and would be disregarded by consumers.

Industry commenters and trade associations who objected to the term "previously frozen" also objected to the alternative terms discussed in the proposed rule and the notice. They stated that all the alternatives, like "previously frozen," are based on the dichotomy that if a product is not fresh, it must be frozen. The commenters argued further that requiring wholesome product to be labeled with terms such as "previously partially frozen" and "previously chilled to a semi-solid state," which FSIS acknowledged will be viewed negatively by consumers, is unprecedented and wholly unnecessary. They alleged that such terms are awkward, unclear, impractical or inaccurate.

In its notice seeking further comments to reconcile the existing definition of "frozen" and the proposed use of the term "previously frozen" (60 FR 14668), FSIS discussed an option to eliminate the current requirement that poultry products labeled as "frozen" must be brought to an internal temperature of 0° F or below and to require use of the term "frozen" to identify all products whose internal temperature has ever been below 26° F. This option found no support among commenters whether or not they supported or opposed the intent of the proposal. Commenters stated that, not only would the option require more work for the industry and local governments, it would simply shift the confusion from "fresh" to those who understand and rely on the meaning of "frozen." Some noted that the temperature range from above 0° F to 26° F is not ideal for freezing poultry for storage and suggested that time limits should be set on this type of storage.

In the same notice, FSIS also discussed an option to create an additional qualifier for products frozen to 0° F or below, specifically, "frozen for long-term preservation," to distinguish them from chill pack products whose temperatures are often between 20° F and 26° F. This option also found virtually no support among any of the commenters. They stated that the phrases "frozen for long-term preservation" or, similarly, "frozen for long-term storage" imply a difference between the current labeling for "frozen" and proposed labeling for "long term" when there is no difference. Others saw no need for "frozen for long-term . . ." and did not understand what additional benefit to the consumer this term could provide compared to the current labeling requirement of "keep frozen." As with the preceding options, the commenters contended that

requiring such terms only serves to create confusion for existing products and implies the existence of a new product when there has been no change in product quality and safety.

Other Suggested Terms

Some supporting commenters offered other terms to reconcile the definitions of "frozen" and the proposed term "previously frozen." Those who found "previously frozen" to be confusing suggested that "defrosted for your convenience" and "defrosted" would be acceptable because, like "thawed for your convenience" and "thawed," they have been used on seafood and accepted by grocery store customers. A trade association suggested that use of the term "fresh, previously frozen" would sufficiently harmonize the labeling of the products. Poultry processors and other trade associations believed that manufacturers should be able to use any number of optional, meaningful terms such as "chilled," "very chilled," "iced," or "frosted," which, they suggested, meet the physical characteristics of poultry in the semi-frozen state that the consumer could understand. A number of these commenters suggested "deep chilled" or a similar term to suggest to the consumer more than adequate chilling analogous to "deep frozen" as a method of freezing that was more than adequate. Likewise, a number of these commenters stated that "hard chilled" would be an appropriate designation analogous to "hard frozen." In support of such terminology, a poultry farmer submitted a copy of descriptive terms from a 1937 publication, *Marketing Poultry Products*, 3rd. ed., E. Benjamin and H. Pierce, John Wiley & Sons, Inc., New York.⁶ The commenter suggested that what we do today has already been done and the terms and accepted practices now under discussion were standard in the past. The chilling descriptions from the publication are: Fresh, dressed—poultry that is cooled but has not been hard chilled or frozen; fresh, hard chilled—fresh, dressed poultry that has been frozen only hard enough to allow it to be carried in good condition to market; and frozen—poultry that has been frozen solid.

FSIS Response

After carefully considering the many comments on the proposed requirement that poultry products whose temperature has ever been below 26° F, but above 0° F, be labeled with a

descriptive term, FSIS continues to believe that such a requirement is necessary to prevent consumers from being misled about the nature of the products they purchase. Without such labeling, there is no way for a consumer to know that a product was at some time in a hard condition because once that product has been thawed for presentation in the fresh retail case it may be commingled with product that has never been below 26° F, which may, or may not bear a designation of "fresh." As stated previously, FSIS believes that consumers do not equate poultry products that have been chilled to the point where they are hard-to-the-touch with fresh poultry products. Therefore, to present such chilled products to consumers in a thawed state, without alerting them to the fact that the product was at some time in a partly frozen state, misleads those consumers into assuming that the product was always in an unfrozen condition and is a fresh product.

However, after thorough consideration of the volume of comments that expressed concerns with the negative aspects of the proposed term "previously frozen" and concerns about confusing consumers into assuming that chill pack products are identical to deep frozen products, i.e., products frozen to internal temperatures of 0° F or below, with which they are long familiar, as well as other information in the rulemaking record, FSIS has decided not to use the proposed descriptive term "previously frozen." FSIS has been persuaded that the proposed term "previously frozen" is not the most appropriate term to convey the accurate message about the chill pack products to consumers considering the different qualities that partially and completely frozen products possess across the freezing range. FSIS recognizes that consumers might confuse chill pack products with deep frozen products, i.e., those whose internal temperature has been brought to 0° F or below, and vice versa, under the proposed labeling scheme. Instead, FSIS will require that poultry product whose internal temperature has ever been below 26° F, but above 0° F, be labeled with the descriptive term "hard chilled."

Based on information provided in the comments on the proposed rule, the public hearings, the U.S. District Court proceedings, and other information in the rulemaking record, FSIS has concluded that there are differences in poultry products at different internal temperatures. The chill pack products that are brought to the lower 20-degree Fahrenheit range will spoil in a matter

⁶A copy of the page from the publication containing the descriptive terms is available for review in the office of the FSIS Docket Clerk.

of weeks. A product chilled to 14° F to 15° F, where most of the free water is in a frozen state and where bacterial growth has stopped, will develop off-flavors due to chemical oxidation after several months. A product frozen to 0° F or below, where almost all of the free water is in a frozen state, has an expected shelf life of a year or more depending on packaging and storage temperature. Thus, while products with internal temperatures in the lower 20-degree Fahrenheit range and those at about 15° F and at 0° F or below have the same hard physical appearance, they do not have the same attributes in terms of stability for preservation. According to the available information, some poultry processors bring certain products to internal temperatures in the range of 15° F to 20° F, but most do not take product below 20° F due to the cost of refrigeration, unless they take the product to 0° F or below for long-term preservation.

The objective of the labeling requirements adopted in this final rule is to apprise consumers whether certain poultry products may have been partly frozen to a hard-to-the-touch state at some time. FSIS believes that such descriptive labeling should not conflict with the long-established regulatory definition for "frozen," nor should it disparage the high quality, wholesome products that consumers have been purchasing for many years. Having clearly stated the objective of the descriptive labeling and qualifying conditions, FSIS could choose not to require use of any one specific term or terms on an industry-wide basis. Rather, FSIS could require that individual processors select terms or phrases that meet the objective of descriptive labeling. However, the disadvantage of this approach is that not all potential terms convey the message equally well. Use of multiple terms to communicate an identical message could be a source of confusion for consumers. FSIS believes that consumers would be better served by use of a single term that promotes name recognition of the type of chilling process to which the bulk of the products in question have been subjected and their resulting physical condition.

Assessment of Terms

FSIS has reviewed and considered the comments regarding the various descriptive terms to determine how well each conveys the fact that products had at one time been brought to a very hard physical state. FSIS believes that the terms containing the word "frozen" pose potential conflicts with the regulatory definition of "frozen" and

may well imply that products are of a lesser quality or that they had been in a frozen condition for some length of time, e.g., months, after slaughter. In fact, poultry products are typically of high quality and recently slaughtered, e.g., usually within one or two weeks, when presented for sale. Similarly, phrases that use terms like "semi-frozen," "semi-solid," and "partially frozen" may be awkward and confusing to consumers and may also imply that the products have been mishandled or are inferior. FSIS considers the terms "chilled," "very chilled," "chilled pack," "iced," and "frosted" to convey only ordinary refrigeration, packaging in ice above 26° F, or an ice crust on the surface. The phrase "previously held at _____° F" might convey a hard condition because most consumers know that water freezes at 32° F and would assume temperatures in the lower 20-degree Fahrenheit range are freezing temperatures for foods; however, consumers might also assume the products are frozen solid. The terms "thawed" and "defrosted" are also commonly understood words that convey the message that products were frozen, but FSIS believes that these terms also pose potential conflicts with the Agency's existing definition of "frozen."

The Term "Hard Chilled"

FSIS carefully considered the term "deep chilled" because it might convey the notion of exceptional coldness extending to the interior of the product or excessive coldness such as is suggested by terms like "deep frozen" or "deep freeze." In addition, according to some commenters, the term "deep chilled" is one often used by processors as a trade term to describe poultry that is processed by the chill pack cooling system. FSIS believes that one of the central issues in this rulemaking is selection of a descriptive term that will convey that the subject products had at one time been brought to a very hard physical state, which consumers equate with products that are frozen. FSIS does not believe that the term "deep chilled" adequately conveys such information. FSIS does believe, however, that the term "hard chilled" is a reasonably precise and understandable term that conveys accurate information about both the physical condition of a product and the chilling process to which it has been subjected. Thus, FSIS has concluded that the term "hard chilled" is superior to "deep chilled," and will achieve the objective of accurate, descriptive labeling for use by consumers and industry. FSIS has also determined that the term "hard chilled"

will promote name recognition of the type of chilling process to which the bulk of the products in question have been subjected and their resulting physical condition.

While FSIS will not require qualification of the term "hard chilled" with the word "previously" on the labeling of poultry products whose internal temperature has ever been between 0° F and 26° F when that product reaches an internal temperature of 26° F or above prior to sale or during display for sale, this labeling option will be permitted under this final rule. A commenter, who identified himself as a meat cutter for a grocery chain, informed FSIS that, in the commenter's particular situation, the retail walk-in box is maintained typically at about 32° F, while the retail fresh meat case is maintained at about 35° F. These approximate temperatures for retail situations are substantiated by information provided by other commenters and by participants at the public hearings. Because the temperatures of the retail cases are above 27° F, which, as FSIS has previously discussed, is the point at which poultry begins to freeze, FSIS has concluded that most poultry offered for sale in a retail setting will be pliable to the touch.

FSIS does not believe that consumers would be confused by a product labeled as "hard chilled" that is no longer hard-to-the-touch. The term "hard chilled" simply conveys that the product has been subjected to a cooling process that lowered its temperature below 26° F and became hard-to-the-touch. The term "hard chilled" could imply that poultry is still in a hard state, even though the product may no longer be hard when it is offered for sale in a retail setting. Because FSIS does not believe that consumers would be confused by a product labeled as "hard chilled" that is no longer hard-to-the-touch, this final rule does not make a regulatory distinction between the terms "hard chilled" and "previously hard chilled" because both terms describe the cooling process to which the product was subjected. Therefore, FSIS is providing in this final rule that the word "previously" may be used on poultry labeling contiguous to the term "hard chilled" on an optional basis. This added flexibility allows processors and retailers the option to select either "hard chilled" or "previously hard chilled."

Based on all the considerations set forth in the preceding discussion, FSIS is revising its proposed provision at 9 CFR 381.129(b)(6)(i). FSIS is providing in this final rule that raw poultry product whose internal temperature has

ever been below 26° F, but above 0° F, must be labeled with the descriptive term "hard chilled" or in order to inform consumers and other end users that the product was subjected to a chilling process sufficient to render the product hard-to-the-touch. This final rule also provides for use of the word "previously" with the term "hard chilled" on an optional basis.

Products Frozen to 0° F

FSIS does not believe that requiring descriptive labeling in the form of "hard chilled" on poultry products whose temperature has ever been below 26° F, but above 0° F, conflicts with the long-established regulatory definition of "frozen." Therefore, FSIS has decided that it is not necessary to require an additional qualifier, e.g., "frozen for long-term preservation," for products frozen to 0° F or below. FSIS also agrees with commenters that an additional qualifier on products frozen to 0° F might confuse consumers about the existing products and lead them to believe they are in some way different when, in fact, they are not. In addition, FSIS no longer believes that it is necessary to require use of the term "previously frozen" for the same reasons discussed above with respect to use of the word "previously" in conjunction with the term "hard chilled." However, FSIS will allow the use of the word "previously" with the term "frozen" on an optional basis. Accordingly, FSIS is revising the requirement in its proposal by adding a provision that the word "previously" may be used contiguous to the term "frozen" on an optional basis, and is adopting the requirement that raw poultry product whose internal temperature has ever been at or below 0° F must be labeled with the descriptive term "frozen," except when such labeling duplicates or conflicts with special handling labeling requirements in 9 CFR 381.125.

The requirement to identify that the product is or was "frozen" is not negated under any circumstance. Even if the product is frozen to an internal temperature at or below 0° F and thawed by the processor before distribution, the fact that the product was frozen at one time must be revealed by use of the descriptive term "frozen" or by appropriate handling statements prescribed in 9 CFR 381.125. The term "frozen" may always be qualified with appropriate statements, e.g., "frozen, thawed for your convenience," at the manufacturer's discretion, when frozen product is destined to be thawed prior to sale or during display for sale. However, the product may not be

labeled solely with a handling statement of "keep refrigerated," which would not suffice to reveal that the product was once frozen to a temperature at or below 0° F.

Optional Statements

With respect to optional statements used in conjunction with descriptive labeling, FSIS will continue to allow the use of phrases such as "for your convenience" or "to preserve quality."

Compliance Procedures

In the proposed rule, FSIS stated its belief that processors, transporters, wholesalers, and retailers would establish appropriate controls to ensure that their poultry products comply with FSIS' proposed labeling requirements in designing and following good manufacturing practices. Therefore, FSIS did not believe that it was necessary to propose detailed procedures to be followed by the Agency in monitoring compliance with the rule governing the use of the term "fresh" on raw poultry products. FSIS did, however, invite comments regarding such procedures.

Many commenters sought clarification about the procedures for measuring compliance with "fresh" labeling requirements. Others requested that specific conditions be incorporated into FSIS compliance instructions. A number of commenters from industry stated that flexibility needs to be provided in enforcement because of the inherent practical problems in maintaining product temperature adequate to ensure its quality. These commenters cited situations where variations in equipment, product, and other factors might cause products unavoidably to fall below 26° F, including the following: (a) typical commercial and retail refrigeration units experience operating variances of 2° F and 4° F, respectively; (b) refrigerated trailers experience fluctuations from 3° F to 10° F from front-to-back and/or top-to-bottom; (c) brief mechanical stops and product spills in a blast chiller can result in product temperatures below 26° F even if the blast is set correctly; (d) temperature variances occur during chilling operations and storage between large and small products due to density, e.g., breasts versus wings or whole birds versus small trays; (e) physical position in a refrigeration unit causes temperature variation, e.g., product closest to the air circulation fans will be measurably colder than product in the middle or on the far side of a pallet; and (f) variation in product temperature occurs during storage due to insertion of product with higher or lower

temperature than ambient cooler temperature, relative humidity, or the act of opening and closing a cooler or truck compartment to gain access to product. Many commenters also contended that typical thermometers are only accurate to 2° F.

A trade association, which supported the proposal, countered the arguments that there are difficulties in maintaining a steady temperature in refrigerated trucks. The commenter expressed the opinion that, if poultry is loaded into the cargo cooler at 26° F, air temperature inside the cooler would have to be kept much lower than 26° F for a very long period of time for it to have an effect on the internal temperature of the poultry itself. The commenter further contended that it is not difficult to maintain a steady temperature in a refrigerated truck because thermostats can control temperatures within a range of 1.5 to 2 degrees.

Temperature Tolerances

Numerous commenters called for a temperature tolerance, noting that FSIS has established tolerances in other areas such as net weight determinations. They argued that a tolerance should reflect recognition of the physical realities and limitations of product processing and distribution and represent good manufacturing practices. Some poultry processors suggested that they be permitted to target a 2° F window, i.e., a temperature range of 24° F to 26° F, as opposed to a single temperature of 26° F. Many suggested that product temperature be regulated to allow a 3° F variance on any given check unless there is a consistent pattern of abuse. Other commenters asserted that it would be reasonable to accept a cumulative effective variance of 4° F assuming the more salient variances to be represented by commercial refrigeration units and temperature measuring devices. Still other processors stated that, since neither food safety nor product quality is at risk, a tolerance of 5° F would be practical in commercial operations as long as it can be proven that the raw poultry did reach its optimum temperature for its state, e.g., a fresh condition, before being shipped. In addition, a trade association suggested that the regulatory option which FSIS discussed in the preamble to its proposed rule be used as an alternative compliance system, i.e., a two-step process control system in which temperatures between 23° F and 26° F would be attributed to normal effective variances in refrigeration units and temperature measuring devices; temperatures between 20° F and 23° F would require process control

adjustments; and temperatures below 20° F would require product relabeling. The commenters further suggested that the first step be set at 22° F in recognition of the 4° F cumulative effective variance mentioned previously.

Commenters supporting the proposed rule were divided as to whether FSIS should modify compliance procedures to provide for a temperature tolerance. Some of these commenters contended that FSIS should provide for a minimal range of flexibility throughout processing, storage, and transportation. On the other hand, some supporters of the proposal argued against a rule providing for a tolerance because they saw this as undercutting the proposed rule to establish the 26° F temperature as the most appropriate standard.

Testing and Sampling Procedures

Some commenters said that the proposal did not address the issue regarding which location within a package or container, e.g., the perimeter or center, a sample for testing would be drawn. Commenters also wanted to know at what anatomical location of the product the temperature would be measured. Several commenters stated that products such as chicken wings, which are less dense than other products, should be excluded from temperature measurements. Also, commenters requested that sampling procedures should be more precisely defined to provide for a representative sample. One trade association requested that the intended sampling scheme be modified to monitor the warmest area of a designated "lot," rather than the overall lot average, because products most at risk, i.e., those products furthest away from the cooling elements of a refrigerated chamber, could be plus 4° F higher than the target temperature, i.e., over 30° F.

A professional organization, which agreed that the proposed action would meet consumer expectations, expressed concern about temperature abuse in light of the prevalence of *Salmonella* in broilers and turkeys. The commenter stated that the present practice of chilling poultry to temperatures between 0° F and 26° F provides a greater margin of safety, as compared to poultry transported and stored at temperatures above 26° F, because temperature abuse during storage or transportation might raise the temperature of the poultry to dangerous levels above 40° F. The commenter suggested that, until HACCP systems are implemented throughout the transportation, retail, and food service industries, temperature sensing and

indicating devices should be used on poultry packaging that will alert retailers, food service workers, and consumers if temperature abuse has occurred.

Concerns About Responsibility for Compliance

Generally, commenters opposed to the proposed rule objected to the fact that the rule was too narrowly focused on the original processor because the proposed requirements would apply to products in all stages of commerce. Many processors expressed concern that products in compliance at the time of processing could subsequently become misbranded through no fault of their own. Some supporters of the proposal, including congressional members, commented that the vast majority of poultry processors do their own packaging, storing, and shipping, and, therefore, would not lose a "fresh" designation through no fault of their own. They contended that one company is responsible for maintaining the temperature of the product at all points. In contrast, a number of processors reported that they shipped on non-company carriers. They stated that the processor, as the producer of the product, assumes liability for that product, yet is unable to ensure against potentially varying product conditions during distribution and sale that would be deemed non-compliant under the proposal. Other processors insisted that once the product is sold and title passes it should be the responsibility of that party (distributor, wholesaler, or retailer), and not the original processor, to ensure proper temperature or, if the product's temperature moves out of compliance, to relabel it. Some commenters suggested that, in order not to disrupt marketing and distribution of products, whether a product is in compliance should be determined at time of shipment.

Relabeling of Product

Trade associations and processors contended that poultry is packaged such that it would be impossible to change labels on a particular product that may inadvertently fall below the temperature designated as "fresh." They stated that, if products are chilled to a temperature below 26° F while in distribution and are deemed "misbranded" and unable to proceed in commerce until relabeled, the distributors are not equipped to relabel product. They asserted that under existing regulatory requirements, it would be unlawful to affix new labels different from the labeling affixed at the inspected establishment.

A number of commenters argued that there needs to be an opportunity for relabeling of product at the retail level if a product accurately labeled at the point of packaging has been abused during shipment, storage, and handling after leaving the plant. Others expressed concern that relabeling could result in food safety problems due to the additional handling that would occur. One processor suggested use of a tag on product originating as "fresh" which has a tear off that can be removed if product falls below 26° F. Some commenters noted that wholesalers or retailers may freeze product labeled as "fresh" due to excessive inventory and would need to repackage and relabel or apply appropriate stickers to products with FSIS-approved labels. These commenters encouraged FSIS not to require prior label approval of such stickers.

FSIS Response

FSIS is confident that processors, transporters, wholesalers, and retailers will be able to maintain the appropriate controls to ensure that their poultry products comply with the requirements of this final rule. FSIS does not intend, therefore, to adopt a temperature tolerance below 26° F, such as 24° F, as was suggested by many commenters. FSIS believes that such a tolerance would allow a significant percentage of poultry products which had fallen below 26° F, and thus rendered hard-to-the-touch, to nevertheless be labeled as "fresh," thereby misleading consumers.

FSIS acknowledges that there may be instances where poultry product labeled as "fresh" may fall below the minimum temperature that defines "fresh" despite the efforts of manufacturers, distributors, retailers, and others to keep the product in a "fresh" condition. FSIS, therefore, intends to design a practical compliance policy that will maintain the integrity of the 26° F standard while providing the flexibility to deal with the problems that occur despite the adoption of good manufacturing practices.

FSIS expects that the primary focus of its compliance efforts will be on products labeled as "fresh" or bearing no descriptive term. FSIS resources will be focused on ensuring that such products meet the requirements of this regulation when they leave the FSIS-inspected plant. The policy will also seek to avoid condemnation or relabeling of entire lots of product if only a small number of units within the lot have fallen below the standard. FSIS expects that its compliance policy will take into account the good manufacturing practices that producers

have adopted to maintain compliance with the requirements of this rule. FSIS intends to avoid the prescriptive command-and-control approach as to how companies achieve the performance standards in this final rule.

FSIS shares the concerns of the many commenters about the need for clarification of product testing and sampling procedures and about the need for practical compliance procedures throughout processing, storage, and distribution. To provide instructions to FSIS employees and to assist producers in complying with this rule, FSIS intends to issue an FSIS Directive explaining the compliance policy, including product testing and sampling procedures, as soon as possible. Because of the complexity of the testing and sampling issue, FSIS intends to obtain further public input on this matter prior to issuing the Directive so that its procedures will be both practical and reasonable while ensuring the integrity of the standards contained in this final rule. FSIS is also interested in obtaining input on other aspects of the compliance policy, including the allocation of Agency and industry resources.

Obviously, product in the possession of or under the control of an official establishment remains the responsibility of the establishment. Establishments must, therefore, take reasonable precautions to ensure that their product is maintained in accord with these regulations, even when it is in a transport vehicle or otherwise not physically at the establishment. Generally, the establishment's responsibility for compliance ends when ownership passes; compliance then becomes the responsibility of the buyer. However, any person or firm who causes a product to become misbranded can be held responsible for causing it to become misbranded whether or not they owned the product at that time.

Moreover, any person or entity that produces product or handles product in commerce is responsible for ensuring that products remain properly labeled. If a producer, handler or commercial buyer determines that products covered by these regulations and labeled as "fresh," or bearing no descriptive term, have been chilled to an internal temperature below 26° F, that person will be responsible for ensuring that the product is brought into compliance. Such a producer, handler, or buyer must report the fact to FSIS to ensure that remedial action is taken.

If an Agency official discovers product which is not in compliance with these regulations, the product will be retained or detained. The product

would be required to be relabeled or, if not relabeled, the product would be condemned. The Agency would take such additional compliance or enforcement measures as are warranted under the facts and circumstances of each case.

Labeling procedures for product found to require relabeling before it leaves the official establishment are covered under subpart N of the poultry products inspection regulations. Also, existing regulations (9 CFR 381.140) specify procedures for the relabeling of products in commerce found to require relabeling. Generally, such products are relabeled under the supervision of an inspector and FSIS is reimbursed for the cost of that supervision. However, under the "fresh" regulations, such an enforcement approach would place a demand on scarce FSIS resources and cause delays in bringing product into compliance. This area is one of considerable concern to many commenters. FSIS anticipates that the circumstances requiring relabeling to correct misbranding where the temperature of the product labeled as "fresh" or bearing no descriptive term has dropped below 26° F after leaving the official establishment will be relatively infrequent. Therefore, this final rule will permit an alternative and simple relabeling procedure.

Relabeling Options

The relabeling procedures established by this final rule provide flexibility for relabeling inspected and passed product that was heretofore unavailable under the poultry products inspection regulations when product became misbranded after leaving a federally inspected establishment. Owners of product will now have the option of notifying the Area Office of the FSIS Compliance Program that the product outside an establishment has become misbranded under this rule. The Compliance Program will authorize the movement of the product to an official establishment for relabeling or to a retail entity where it can be relabeled without an inspector's supervision, or to another end user. Relabeling may be accomplished by prominently applying stickers disclosing that the product has been "hard chilled" or "frozen" to the packages, provided any claim such as "fresh" is obliterated, covered or removed. Removal could be accomplished by removal of a hang tag or a tear off from such a tag as suggested by one commenter. At retail, relabeling may also be accomplished by completely removing the inspected establishments's label and applying the retail store's label. The Compliance

Program will monitor such product movement and relabeling. The issue of who bears the cost of such relabeling is a contractual matter between buyers and sellers of the product.

Accordingly, FSIS is adding a paragraph at 9 CFR 381.129(b)(6)(iii) to incorporate procedures for the handling and relabeling of products as described above. FSIS is also adding a provision at 9 CFR (b)(6) (i) and (ii) to specify that, if additional labeling containing a descriptive term required under paragraph (b)(6) (i) or (ii) of this section, as appropriate, is used, it shall be prominently affixed thereon with such conspicuousness (as compared with other words, statements, designs or devices in the labeling) as to render it likely to be read and understood by the ordinary person under customary conditions of purchase and use. FSIS has concluded that it would not be possible for such additional labeling to be placed in such fashion to be read and understood by the ordinary person unless the false claim is obliterated, covered or removed.

FSIS also agrees with the commenter who stated that appropriate stickers for relabeling of product that has become misbranded should not require prior label approval. Because these regulations prescribe the exact language of descriptive labeling, this final rule provides that the processor may apply the descriptive labeling, or that the authorized retail entity or other end user may apply the descriptive labeling to approved labels. Furthermore, this rule provides that the descriptive labeling may be approved under the provisions for generic label approval. Such action will minimize loss of product shelf life by eliminating any delay involved in securing prior label approvals. Accordingly, FSIS is adding a paragraph at 9 CFR 381.134 to this effect.

Brand Names

While some commenters stated that FSIS should maintain its current stance of non-restrictive use of the term "fresh" in trademarked names, company names, fanciful names, logos, and sensory modifiers, others contended that the proposed rule contained a loophole with respect to such uses. They stated that companies should not be allowed to incorporate the word "fresh" within a brand name, etc., on the labeling of frozen poultry products because the term would be inherently misleading. The commenters alleged that producers will continue to use and may even change their brand names so as to indirectly represent their products as "fresh." They noted that FDA's fresh labeling policy does not permit such

allowances for brand names, sensory modifiers, etc., and urged FSIS not to create an inconsistency between the two agencies' labeling regulations without some compelling reason. One commenter stated that if use of the word "fresh" is permitted in brand names and sensory modifiers, FSIS should require a specific disclaimer of equal size to the effect that the product had been frozen below 26° F.

FSIS does not agree that use of the word "fresh" as part of a brand name, etc., or in sensory modifiers on the labeling of a raw poultry product necessarily suggests or implies that the product has not been processed or preserved. FSIS believes that it should evaluate use of the term "fresh" within the context of the entire product labeling to determine if it is used to imply that a product has not been subjected to a chilling or freezing process, i.e., used in a false or misleading manner. If such an implication is made, the product would have to comply with the FSIS definition of "fresh." This final rule on use of the term "fresh" on the labeling of poultry products provides for clear descriptive labeling, i.e., "hard chilled" or "frozen" to alert consumers about the nature of products that have ever been brought to internal temperatures below 26° F. FSIS believes that such labeling will prevent consumers from being misled about whether a product has been processed or preserved.

This policy is consistent with FDA's policy with respect to use of the term "fresh" in a brand name or use as a sensory modifier. In the preamble to its final rule entitled "Food Labeling: Nutrient Content Claims, General Principles, Petitions, Definition of Terms; Definitions of Nutrient Content Claims for the Fat, Fatty Acid, and Cholesterol Content of Food" published in the **Federal Register** on January 6, 1993 (58 FR 2302), FDA states at 58 FR 2405 that "[i]f, however, a use of the term "fresh" as part of a brand name does not imply or suggest that the food is unprocessed, and the use is not otherwise false and misleading, there is nothing in this final rule that would prevent this use of the term." For these reasons, FSIS has not adopted specific regulatory language that governs use of the term "fresh" as part of a brand name or as a sensory modifier.

In response to the comment that, if use of the word "fresh" is permitted in brand names and sensory modifiers, FSIS should require a specific disclaimer of equal type size to the effect that the product had been frozen below 26° F, FSIS does not agree that a type size requirement is warranted. The

special handling statements required at 9 CFR 381.125(a), e.g., "keep refrigerated" or "keep frozen," do not have specific type size requirements although they must be prominently displayed on the principal display panel of the label. After many years of use, FSIS has no information that the requirements for special handling statements are not adequate to inform consumers about the products. Therefore, FSIS rejects the suggestion to add a type size requirement for descriptive labeling. However, in order to ensure that the descriptive labeling is clearly visible on packages, FSIS is revising proposed 9 CFR 381.129(b)(6)(i) to provide that the information shall be prominently displayed on the principal display panel of the label. This requirement is consistent with the treatment of special handling label statements for frozen products as provided in 9 CFR 381.125(a).

Economic Impact

Several commenters suggested that FSIS, in assessing the costs and benefits of the proposed rule, should have quantified the benefits of appropriate labeling. In making its cost estimate, FSIS assumed that a price difference might develop between affected chill pack products and "fresh" products so that the chill pack products might decrease in price in an amount totaling between \$60 to \$140 million annually. The commenters asserted that, considering the projected potential cost impact for some producers, there is likely to be a corresponding benefit of the same magnitude or larger to consumers who save money or get better value for their poultry purchases. Another commenter noted that FSIS listed as an unquantified consumer benefit the fact that consumers "would be assured that the poultry products they purchase would not be labeled in a false or misleading manner." The commenter suggested that, because the proposed rule removes no products from the market, requires no changes in products, and leaves the choice among products to consumers, the estimated \$60 to \$140 million is a "cost" neither to the seller nor the buyer, but is a measure of the potential benefit to the consumer should all consumers who previously purchased thawed product shift their preference to fresh product. Additional amounts voluntarily paid by consumers place a monetary value on the exercise of informed choice. The commenter further asserted that the loss of opportunity to commit unlawful business acts such as fraud, deception, and misleading representation should

not be accounted for as a cost of regulation.

FSIS believes the latter commenter assumes that the \$60 to \$140 million cost estimate reflects an increase in the price of fresh product. In making this particular cost estimate, FSIS assumed that the price of fresh product under the proposed rule would remain constant while the affected product, specifically 1.4 billion pounds of long-distance-shipment chill pack product, would be priced down. FSIS made this assumption based on information presented at the public hearings and in the U.S. District Court proceedings which indicated that consumers generally would expect products bearing labeling with terms such as "frozen" or "previously frozen" to be lower priced. In this case, the theoretical "cost" represents loss of current revenues for producers who did not act in an unlawful manner, but in accordance with existing Federal policy. FSIS agrees that a price saving, which could be quantified, would be conferred to consumers who continue to buy the lower priced product as FSIS noted in its discussion of the benefits of the proposed rule.

Some opponents of the proposal suggested that FSIS did not fully address the economic impact on product that may fall between "fresh" and "frozen" and for which there would not be a premium market. Many contended that the proposed rule, as written, could be devastating to the poultry industry and, especially, to tray pack operations. Some stated that labor costs for applying pressure sensitive stickers, redesigning permanent labels, costs for reapproval of labels, etc., will also have an economic impact. A few commenters asserted that there is a cost factor associated with decreased shelf life of poultry, which could result in increased product waste and/or more frequent deliveries for poultry retailers.

FSIS has fully considered these comments on the economic impact, but, considering the difficulty of predicting future dollar values of future sales, FSIS continues to believe that it has made the most reasonable cost analysis possible with the information available, as is discussed under Executive Order 12866. The commenters provided no data or further information to aid FSIS in a reassessment of the costs and benefits of the rulemaking than were available at the time FSIS developed its proposal. FSIS weighed all commenters' expressed concerns about the economic impact of a final rule and has attempted to mitigate those concerns by providing flexibility through compliance procedures and descriptive labeling.

FSIS believes that changing the requirement for what was perceived as very negative labeling in the form of the term "previously frozen" to the term "hard chilled" will enable processors to develop marketing strategies that promote the high quality of their products without misleading consumers about the products' history.

FSIS also received a comment regarding the impact of the proposed rule on small entities. The commenter disagreed with FSIS' certification that the proposal would not have a significant impact on a substantial number of small entities. The commenter noted that FSIS stated that most smaller poultry processors use ice or dry ice packs to chill poultry to temperatures between 32° F to 35° F so that the proposed rule will not apply to most small processors. However, the commenter insisted that this assumption ignores about 1,000 small poultry wholesalers and retailers. The commenter contended that, hypothetically, if a poultry shipment leaves the processing plant in a "fresh" state, but temperatures subsequently drop below 26° F during shipment, the wholesaler or retailer has several choices as follows: (1) Accept the delivery and risk the sanctions for selling misbranded poultry, (2) accept the delivery and relabel each branded package with a generic label and sell the product at a loss because a brand name commands a higher price, or (3) refuse the shipment and send customers to other retail establishments to purchase poultry.

FSIS disagrees that this rulemaking will have an impact on a substantial number of small wholesalers and retailers. The commenter provided no data to support such an argument but, rather, speculated about possible adverse impacts on this constituent group. Under its discussion on compliance procedures, FSIS has provided guidance and flexibility regarding actions wholesalers and retailers may take in the event that product labeled as "fresh" is found upon receipt to be below the minimum temperature defining "fresh." FSIS believes that its guidance and provisions for practical relabeling options for wholesalers and retailers are sufficient to prevent disruption at the wholesale or retail level. In addition, and as noted in response to the preceding comments, the terminology that FSIS is providing in the form of the term "hard chilled" for the products in question should minimize potential lost revenues.

Other Issues

1. Cured and Processed Poultry Products

FSIS received only two responses to its request for comments on whether it would be useful and desirable to initiate rulemaking to establish regulatory requirements for all uses of the term "fresh" on the labeling of poultry products. One commenter expressed the opinion that it would make sense to incorporate in the regulations the prohibition on use of the term "fresh" on the labeling of cured, canned, hermetically sealed shelf stable, dried, or chemically preserved poultry, as described in Policy Memo No. 022C. The commenter contended that the policy is not controversial, and it would be desirable to make the regulatory requirements for use of the term "fresh" as comprehensive as possible. Another commenter stated, without further elaboration, that it is not appropriate for FSIS to initiate rulemaking to establish regulatory requirements for all uses of the term "fresh" on the labeling of poultry products.

FSIS has concluded that it is not necessary to establish regulatory requirements for all uses of the term "fresh" on the labeling of poultry products. FSIS continues to believe that Policy Memo No. 022C and the current poultry products inspection regulations (9 CFR 381.129) are sufficient to preclude the false and misleading use of the term "fresh" on poultry products that are processed or preserved by methods other than freezing. For clarity, FSIS is restating its policy on other uses of "fresh" on the labeling of poultry products as follows. The term "fresh" may not be used on the labeling of poultry products which are cured, canned, hermetically sealed shelf stable, dried, or chemically preserved because such use would be inappropriate and misleading. Chemical treatments include, but are not limited to, use of antioxidants, antimicrobial agents, or preservatives that introduce chemically active substances that remain in or on the product. FSIS notes that, with regard to raw poultry or poultry parts, no substances are permitted to be added by the poultry products inspection regulations for the purpose of shelf life extension.

FSIS will allow raw poultry products to be labeled as "fresh" that had been treated with ionizing radiation at an absorbed pasteurization dose of 1.5 to 3.0 kiloGrays as provided for in 9 CFR 381.147(f)(4). The treatment of raw poultry products with low dose irradiation causes no changes in the products that FSIS believes would affect

consumer perceptions that they are raw and unprocessed (55 FR 18538, May 2, 1990). In addition, the products are required to be labeled with a unique logo and the statement "treated with radiation" or "treated by irradiation" in accordance with 9 CFR 381.135, which distinguishes them from non-irradiated products.

Because the term "fresh" has acquired acceptance when used to identify further processed products, i.e., products whose chemical composition has been changed by processes such as heating or by the addition of functional ingredients, that are sold in the refrigerated state, FSIS permits the term "fresh" to be used on the labeling of such products. Examples of such products are poultry nuggets and dinners sold in the refrigerated state even when they are made from components that are processed by procedures such as curing, canning, etc. as described above. In these instances, the term "fresh" is used to describe the final products, i.e., the nuggets and dinners, and to identify that they are refrigerated products. When used in this manner, the term does not imply that the components or ingredients in the final products, e.g., the poultry meat, are themselves unprocessed. Another example of this category of refrigerated product that may be labeled as "fresh" while containing ingredients that could not be labeled as "fresh" is a poultry salad sold in the refrigerated section of a grocery store. The salad might contain cured or previously frozen chicken or turkey meats but the term "fresh," when used on such products, suggests a freshly made salad and does not imply that the ingredients are unprocessed.

FSIS does not preclude further processed poultry products from bearing the term "fresh" on their labeling when they are in sealed packages or containers, which are designed to assure freshness, but are not shelf stable, and which are sold in the refrigerated state. Examples include vacuum packed products, products packaged in modified atmosphere packaging, and products packaged in thermoformed oxygen barrier multi-layer films. Further processed poultry products which themselves do not qualify to be labeled as "fresh," but which are made with fresh ingredients (including non-meat and non-poultry ingredients), may also bear label statements stating this fact provided such statements clearly refer to the ingredients and do not imply that the products themselves are unprocessed. An example is canned gravy made with fresh mushrooms. With respect to ground poultry products sold in the fresh retail case that have

been made from frozen and thawed hand deboned or mechanically deboned poultry, FSIS does not believe that such ground products should bear the term "fresh" on their labeling. However, FSIS does not see any need for the labeling of such products to disclose the fact that the products were made from meats that were at one time frozen. FSIS would not object if such products were labeled with the statement "freshly ground" when the products had, in fact, been recently ground.

As with products subjected to freezing processes, FSIS believes the word "fresh," when used as part of trademarked names, company names, fanciful names, logos, and sensory modifiers on the labeling of poultry products that are cured, canned, hermetically sealed shelf stable, dried, chemically preserved, or are refrigerated further processed products of the type previously described, does not necessarily suggest or imply that the products have not been processed or preserved. FSIS believes that it should evaluate the term within the context of the entire labeling to determine if it is used to imply that the product has not been subjected to such processes, i.e., used in a false or misleading manner.

2. Other Products

FSIS also received comments on several issues beyond the scope of the proposed rule. Some commenters raised questions about the difference in the meaning of the term "fresh" as proposed for poultry products and its meaning for other products. Some commenters asserted that the proposed policy for poultry products highlights a lack of uniformity between the regulations for poultry and those for red meat, and that it would provide a marketing advantage to the red meat industry. Commenters also raised concerns about the apparent inconsistencies the proposed rule would leave between poultry and fish because FDA does not define a specific temperature at which a fish product would be deemed to be frozen. Commenters argued that the "fresh" labeling rules for poultry products should also be applied to these other products. Since these issues do not come within the scope of the proposed regulations, they are not addressed in this final rule.

In contrast to the poultry industry's marketing practices addressed by this rule, whole cuts of red meat are not frozen, thawed, and marketed as "fresh." The term "fresh" has typically been used to identify those red meat products that are uncured and uncooked or otherwise not thermally processed or made shelf stable. The use of the term

"fresh" on the labeling of red meat products has not caused consumer confusion. The labeling of fish and fish products is an issue within FDA's jurisdiction and cannot be addressed in this docket.

3. Implementation Date

FSIS did not receive any comments on its proposed rule concerning an effective date or implementation period. However, the provisions of this final rule will require the relabeling of those products currently on the market whose manufacturers elect to chill, store, and ship at internal temperatures below 26° F, but above 0° F. Based on its review of the comments, FSIS realizes that the provisions may cause some processors to make operational changes so they can continue to supply "fresh" poultry. Such changes might include alternate methods of chilling dedicated to small trays, close adjustments of temperature controls in coolers and transport vehicles, modification in or purchase of new equipment to more precisely control temperatures, and development of contingency plans for products that fall below 26° F after leaving the processing establishment.

Therefore, FSIS has decided that sufficient time should be allotted for processors and handlers to make any changes necessary to comply with this rule. FSIS believes that processors may need to establish new policies and procedures, formulate methods for compliance, and exhaust label inventories to the extent possible. A survey of meat and poultry companies for FSIS' final rule on nutrition labeling indicated that firms carry an average label inventory of 5 to 6 months. While FSIS will permit use of stickers with descriptive labeling, many firms will likely not want to use that avenue because of the added step of applying the stickers and the chance that they may become dislodged. Therefore, many firms may want to redesign their permanent labels. Providing adequate time to accomplish the operational activities described above and to prevent inventory losses will minimize the impact of the final rule on affected parties. After considering the factors mentioned above and recognizing that product safety is not a concern, FSIS has determined that this final rule will be implemented 12 months from the date of its promulgation.

Executive Order 12866

FSIS has determined that this final rule is significant within the meaning of Executive Order 12866. The final rule requires all poultry processors and handlers to maintain the internal

temperature of raw poultry at 26° F or above if the term "fresh" is used on the labeling of such products. In addition, the final rule requires that poultry products whose internal temperature has ever been below 26° F be labeled with a descriptive term reflecting this fact.

Regulatory Options

FSIS could have chosen to prohibit the use of the term "fresh" on the labeling of raw poultry products whose internal temperature has ever been below 20° F. Many commenters on the proposed rule stated that they would support 20° F as a practical temperature that would not disrupt commercial practices and suggested that temperatures in the lower 20-degree Fahrenheit range were best for the preparation and distribution of the highest quality product. Others favored a two-step process control system in which temperatures between 23° F and 26° F would be attributed to normal effective variances from refrigeration units and temperature measuring devices; temperatures between 20° F and 23° F would require process control adjustments; and temperatures below 20° F would require product relabeling. If FSIS had chosen 20° F as the temperature at or above which product could be labeled as "fresh," the impact on the poultry industry would be minimal because few processors chill products below that temperature due to the cost of refrigeration unless they take the product to 0° F or below for long-term storage. However, poultry is very solid and very hard at 20° F, because much of the free water in the product is in a frozen state. Consumers perceive such products to be frozen rather than fresh, and their expectations for the products would not be met.

Impacts of the Final Rule

In the preamble to its proposed rule, FSIS examined possible sources of market price changes which could result in transferring economic value from producers to consumers if it adopts the proposed rule as a final rule. FSIS stated that Americans consumed approximately 17.9 billion pounds of chicken (retail weight) in 1993, of which approximately 8.9 billion pounds were purchased at retail. Based on a survey of broiler marketing practices, FSIS reported that 27 percent of chicken destined for the retail market was shipped in containers filled with shaved or crushed ice (ice pack) or solid carbon dioxide (dry ice pack); 57 percent was shipped using the chill-pack method of refrigeration; 3 percent was frozen (i.e.,

below 0° F); and 13 percent was marketed in miscellaneous forms.

Because the internal temperature of poultry products that are refrigerated by ice pack or dry ice pack methods ranges from about 32° F to 35° F, FSIS assumed that the final rule will not affect this portion of the market. Also, most smaller processors use ice or dry ice packs because they do not have the production volume or chilling equipment to store and ship poultry products using the chill-pack cooling system. For this reason, the economic impact of a final rule on small poultry processors should be minimal. FSIS believes that the final rule will not affect the 3 percent of chicken that is marketed at retail as frozen (i.e., below 0° F). The final rule might have an economic impact on the 13 percent of chicken that is marketed in miscellaneous refrigerated forms, but FSIS has no information on what such an impact might be.

In its proposed rule, FSIS stated that most turkey is prepared and shipped as product that is frozen to 0° F or below, and, thus, most turkey will be unaffected by the proposal. However, FSIS received a number of comments from the turkey industry indicating that many of their products, e.g., boneless tray-pack turkey products, would be affected by the rule. FSIS also recognizes that, under this final rule, "whole bagged" turkeys that are frozen at or below an internal temperature of 0° F can no longer be thawed at the establishment before distribution and be labeled solely with a handling statement of "keep refrigerated." Rather, the labeling on these products must reveal that the products were at one time in a frozen condition by use of an appropriate statement such as "frozen, thawed for your convenience." Therefore, FSIS has examined the market share of turkey compared to chicken as shown by production and per capita consumption data contained in USDA's Agricultural Statistics 1994 published by the U.S. Government Printing Office. Based on that information, FSIS concludes that incorporation of cost estimates for turkey would raise the potential cost estimate for this final rule by approximately 25 percent.

FSIS continues to believe that the final rule could potentially affect a portion of the 57 percent (5.1 billion pounds) of the 8.9 billion pounds of chicken marketed domestically at retail as chill pack product, specifically, chill pack products with internal temperatures ranging from 20° F to 25° F that are destined to be transported long distances. FSIS examined interstate

shipping distances for ready-to-cook chicken and estimated that about 72 percent of chill pack products are shipped 800 miles or less. Such trips do not take more than two days. FSIS believes that products shipped 800 miles or less with proper refrigerated transportation could be labeled as "fresh." FSIS does not believe that poultry processors using the chill-pack cooling system would change current procedures for products shipped long distances of over 800 miles. It may well be desirable to chill and ship poultry on long-distance hauls at temperatures in the lower 20-degree Fahrenheit range. FSIS estimates that 28 percent (1.4 billion pounds) of the 5.1 billion pounds of chill pack product sold at retail falls into the long-distance-shipment category and might be affected by this final rule because it could not be labeled as "fresh."

Based on information presented at the public hearings and in the U.S. District Court proceedings, and confirmed by commenters on the proposed rule, consumers generally expect frozen products to be lower priced than fresh products. Using a conservative estimate of price difference at 4 cents per pound (based on a difference in price between fresh and frozen turkey) and a less conservative estimate of price difference at 10 cents per pound, FSIS calculated a potential economic transfer of about \$60 million to \$140 million from producers to consumers. Adding the impacts for potentially affected turkey products to these amounts, the potential economic transfer becomes about \$75 million to \$175 million. This impact assumes affected product would decrease in price and, as such, this impact represents an extreme scenario.

FSIS is convinced that the extreme scenario presented will not actually develop considering the modifications it has made in this final rule in response to expressed concerns from commenters on the proposal. This final rule provides processors with an appropriate descriptive term in the form of "hard chilled" that does not disparage the products, while the term conveys to consumers the temperature history of the products, i.e., relates information about the cooling process to which the products were subjected, as well as their physical state after undergoing that process. Furthermore, FSIS is firmly committed to providing a practical and reasonable compliance strategy. FSIS has also provided for viable options for relabeling of product should that become necessary and for generic approval of such labeling. In addition, FSIS has provided adequate time for

processors to come into compliance with the final rule.

Most of the poultry products affected by this rule are branded products that consumers have come to recognize for their high quality. FSIS does not believe that all customers will turn away from the products they have been buying because the quality of the products will remain unchanged. Thus, there is no reason for the products to be priced down to the extent in the extreme scenario.

It can also be argued that, under this rule, producers of fresh product could command even higher prices than they do now or a larger share of the market, which would represent a cost to the buyer. FSIS considers this to be quite speculative and subject to supply and demand and market forces. Such a situation may occur in certain areas, but, in general, there is no basis to assume that all consumers will pay more or are even willing to pay more than they do now for truly fresh product or would choose fresh products over those affected by this final rule.

Under this final rule, affected products will also require relabeling with an appropriate descriptive term. About half of all labels submitted to FSIS each year for approval are for label changes on existing products. Thus, relabeling costs for printed labels arising from the final rule would decrease as companies incorporate the mandated changes with regularly scheduled label redesigns. The average costs of redesigning and printing new labels and inventory losses fall significantly as the implementation period increases. FSIS has provided for a 12 month implementation period so that relabeling costs for printed labels may approach zero taking into consideration that stickers may also be used as needed and generic approval of descriptive labeling is authorized. Stickers could always be used in those cases where label inventory stocks exceed a 1-year supply.

As stated in the proposed rule, FSIS believes relabeling costs can be minimized considerably by use of pressure sensitive stickers until firms make routine label changes for existing products or exhaust label inventories. While this feature may not be of particular interest to processors on a routine basis, it is of interest to processors and retailers when relabeling of product becomes necessary, e.g., when product labeled as "fresh" or bearing no descriptive term falls below 26° F in commerce. FSIS estimates the cost of pressure sensitive stickers to be about \$0.01 each. Assuming the potentially affected 1.4 billion pounds

of chill pack product were packaged in 2-pound packages, and all required relabeling, FSIS estimates that use of the stickers to bring such product into compliance, whether applied at the plant or retail level, would cost about \$7 million, excluding the cost for labor, during any one year period.

Consumers will benefit from the final rule because they would be assured that the poultry products they purchase would not be labeled in a false or misleading manner. Information from the public hearings held by FSIS, the informal survey conducted by the FSIS Meat and Poultry Hotline staff, and many comments on the proposed rule indicate that consumers place considerable value on knowing how poultry products were handled prior to being offered for sale. The quality of the products offered for sale would not be changed because their shelf life would not be adversely affected. However, consumers would not be led to pay a higher price for products that have been chilled to temperatures below 26° F because the informative labeling would advise them of that fact. Any price decreases that might occur for products that were so chilled would result in a savings for consumers who purchase those products. Thus, if a price differential results in an impact on the industry of \$75 to \$175 million, as discussed under the impact estimate, it is viewed as a transfer to consumers from producers.

If products chilled below 26° F do not suffer a loss in price or market share, it is possible that "fresh" products could command increased prices and revenues for producers of fresh poultry, who will be benefitted as a result of the final rule. Consumers would benefit because they expressed a willingness to pay more for truly fresh poultry that was accurately labeled as "fresh." With or without an increased price for fresh products, consumers would be assured that products they buy would meet their expectations even if they elect to exercise their choice by paying more for the products. Truthful labeling information about the nature of poultry products would improve consumer knowledge about the products and aid them in purchasing decisions. FSIS believes that the benefits of labeling that is not false or misleading would be greater than actual costs associated with the final rule considering the reality of the marketplace. The labeling strategy then offers consumers a true purchasing option that accurately reflects their expressed expectations.

Executive Order 12778

This final rule has been reviewed under Executive Order 12778, Civil Justice Reform. States and local jurisdictions are preempted under section 23 of the Poultry Products Inspection Act (PPIA) (21 U.S.C. 467E) from imposing any marking, labeling, packaging, or ingredient requirements on federally inspected poultry products that are in addition to, or different than, those imposed under the PPIA. States and local jurisdictions may, however, consistent with requirements of the PPIA, exercise concurrent jurisdiction over poultry products that are outside official establishments for the purpose of preventing the distribution of poultry products that are misbranded or adulterated under the PPIA, or, in the case of imported articles, which are not at such an establishment, after their entry into the United States. Under the PPIA, states that maintain poultry inspection programs must impose requirements that are at least equal to those required under the PPIA. The states may, however, impose more stringent requirements on such state inspected products and establishments.

No retroactive effect will be given to this rule. The administrative procedures specified in 9 CFR 381.35 must be exhausted prior to any judicial challenge of the application of the provisions of this final rule, if the challenge involves any decision of an inspector relating to inspection services provided under the PPIA. The administrative procedures specified in 9 CFR part 381, subpart W, must be exhausted prior to any judicial challenge of the application of the provisions of this final rule with respect to labeling decisions.

Effect on Small Entities

The Administrator has determined that this final rule will not have a significant effect on small entities, as defined by the Regulatory Flexibility Act (5 U.S.C. 601). The small entities that could be affected by the final rule would be small processors of raw poultry. However, the economic impact of the final rule on such poultry processors (small plants operating single-inspector processing lines) should be minimal because such processors currently ship poultry in ice pack or dry ice pack containers. The internal temperature of products refrigerated by these methods does not fall below 26° F, and products handled in this manner could be labeled as "fresh" according to the regulatory requirements. FSIS is aware that there are approximately 1,000 small

wholesalers and retailers who potentially could be affected by this final rule. However, FSIS does not believe they will be impacted because this final rule provides realistic relabeling options for this group as discussed in the section of this document dealing with compliance procedures.

Paperwork Requirements

The final rule specifies the regulations permitting the use of the term "fresh" on the labeling of raw poultry products. The final rule requires many manufacturers to revise their labeling and submit such labeling to FSIS for approval. However, this final rule also provides that descriptive labeling may be approved under the provisions for generic label approval so as to minimize paperwork requirements. Paperwork requirements contained in this final rule were approved by the Office of Management and Budget under control number 0583-0102.

List of Subjects in 9 CFR Part 381

Food labeling, Poultry and poultry products.

Final Rule

For the reasons set forth in the preamble, FSIS is amending 9 CFR part 381 as follows:

PART 381—POULTRY PRODUCTS INSPECTION REGULATIONS

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

Authority: 7 U.S.C. 138f; 7 U.S.C. 450; 21 U.S.C. 451-470; 7 CFR 2.17, 2.55.

2. Section 381.66 is amended by adding a sentence at the end of paragraph (f)(2) to read as follows:

§ 381.66 Temperatures and chilling and freezing procedures.

* * * * *

(f) * * *

(2) * * * Such procedures shall not apply to raw poultry product described in § 381.129(b)(6)(i) of this subchapter.

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

§ 381.129 False or misleading labeling or containers.

* * * * *

(b) * * *

(6)(i) Raw poultry product whose internal temperature has ever been below 26° F, but above 0° F, may not bear a label declaration of "fresh" and must be labeled with the descriptive term "hard chilled." The word "previously" may be used contiguous to the term "hard chilled" on an optional

basis. The descriptive term shall be prominently displayed on the principal display panel of the label. If additional labeling containing the descriptive term is affixed to the label, it shall be prominently affixed thereon with such conspicuousness (as compared with other words, statements, designs or devices in the labeling) as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use. Product as described in this paragraph is not subject to the freezing procedures required in § 381.66(f)(2) of this subchapter.

(ii) Raw poultry product whose internal temperature has ever been at or below 0° F may not bear a label declaration of "fresh" and must be labeled with the descriptive term "frozen" except when such labeling duplicates or conflicts with the labeling requirements in § 381.125 of this subchapter. The word "previously" may be used contiguous to the term "frozen" on an optional basis. The descriptive term shall be prominently displayed on the principal display panel of the label. If additional labeling containing the descriptive term is affixed to the label, it shall be prominently affixed thereon with such conspicuousness (as compared with other words, statements, designs or devices in the labeling) as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use. Product as described in this paragraph is subject to the freezing procedures required in § 381.66(f)(2) of this subchapter.

(iii) Handling and relabeling of products. (A) Except as provided under paragraph (b)(6)(iii)(C) of this section,

when any inspected and passed product has become misbranded under this subpart after it has been transported from an official establishment, such product may be transported in commerce to an official establishment after oral permission is obtained from the Area Supervisor of the area in which that official establishment is located. The transportation of the product may be to the official establishment from which it had been transported or to another official establishment designated by the person desiring to handle the product. The transportation shall be authorized only for the purpose of the relabeling of the product. The Area Supervisor shall record the authorization and other information necessary to identify the product and shall provide a copy of the record to the inspector at the establishment receiving the product. The shipper shall be furnished a copy of the authorization record upon request.

(B) Upon the arrival of the shipment at the official establishment, a careful inspection shall be made of the product by the inspector, and if it is found that the product is not adulterated, it may be received into the establishment; but if the product is found to be adulterated, it shall at once be condemned and disposed of in accordance with § 381.95 of this subchapter. Wholesome product will be relabeled in accordance with paragraph (b)(6) (i) or (ii) of this section, as appropriate.

(C) When any inspected and passed product has become misbranded under this subpart after it has been transported from an official establishment, the owner may transport the product in commerce to a retail entity for relabeling in accordance with paragraph (b)(6) (i)

or (ii) of this section, as appropriate, or to other end users, such as hotels, restaurants or similar institutions; or, relabel the product in accordance with paragraph (b)(6) (i) or (ii) of this section, as appropriate if the product is already at a retail entity. A hotel, restaurant or similar institution is not required to relabel product misbranded under this subpart; *Provided*, That the product is prepared in meals or as entrees only for sale or service directly to individual consumers at such institutions, and that the mark of inspection is removed or obliterated. Oral permission shall be obtained from the Area Officer-in-Charge of the Compliance Program for the area in which the product is located prior to such transportation or relabeling. The Area Officer-in-Charge shall record the authorization and other information necessary to identify the product, and shall furnish a copy of the authorization record upon request. Before being offered for sale at a retail entity, such product shall be relabeled.

4. Section 381.134 is amended by adding a new paragraph (b)(15) to read as follows:

§ 381.134 Generically approved labeling.

* * * * *

(b) * * *

(15) The addition of a descriptive term as required by § 381.129(b)(6) of this subchapter.

* * * * *

Done at Washington, DC, on: August 21, 1995.

Michael R. Taylor,

Acting Under Secretary for Food Safety.

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