

the label or in the labeling of foods regulated by FDA. The requirements of the section also pertain to use of the term "fresh" in a brand name and use as a sensory modifier, for example, "fresh tasting." According to the provision at 21 CFR 101.95(a), the term "fresh," when used on the label or in labeling of a food in a manner that suggests or implies that the food is unprocessed, means that the food, including refrigerated food, is in its raw state and has not been frozen or subjected to thermal processing or other methods of preservation, with certain exceptions, for example, surface treatments such as waxing of produce. Thus, fish that is caught, cleaned, and displayed for sale under refrigeration may be labeled "fresh." If the fish was frozen aboard a fishing vessel, then thawed and prepared for sale in a central facility, it could not be labeled as "fresh" because it has been processed by freezing. However, FDA does not specify a precise temperature at which the product would be deemed to be frozen. FDA also permits use of the term "fresh" as a descriptor on foods if use of the term does not suggest or imply that a product is unprocessed or unpreserved, as described in the introduction to 21 CFR 101.95. For example, use of the term "fresh" as a descriptor for crabmeat that is traditionally cooked and picked is acceptable to distinguish it from pasteurized crabmeat that has a lower price and requires special handling.

At the international level, the Codex Alimentarius Commission of the Food and Agriculture Organization of the United Nations (FAO)/World Health Organization, in its Draft Code on Hygienic Practice for Fresh Meat, defines "fresh meat" (including poultry) as a product that has not been treated by any other means than by modified atmosphere packaging or vacuum packaging to ensure its preservation, except that if it has been subjected only to refrigeration it continues to be considered "fresh" for the purpose of the code. (Codex Alimentarius Commission, FAO, 20th Session, Geneva, Switzerland, 28 June–7 July 1993; Alinorm 93/16A: Report of the 7th Session of the Codex Committee on Meat Hygiene, Rome, 29 March–2 April 1993.)

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. 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, among other things, that it was preempted by the PPIA. 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. 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 Appeals Court 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.

Current Policies on Use of the Term "Fresh Frozen"

Both FSIS and FDA have regulations governing the use of the term "fresh frozen." The FSIS poultry products inspection regulations at 9 CFR 381.129(b)(3) specify that the terms "fresh frozen," "quick frozen," "frozen fresh," and terms of similar import apply only to ready-to-cook poultry (raw poultry) processed in accordance with the freezing regulations described at 9 CFR 381.66(f)(1). These freezing regulations specify that these labeling terms imply a rapid change from a fresh state to a frozen state, and that any product to be labeled with such descriptive terms shall be placed into a freezer within 48 hours after initial chilling in accordance with 381.66(b). During this period, if such poultry is not immediately placed into a freezer after chilling and packaging, it shall be held at 36° F or lower. Under FDA's regulations at 21 CFR 101.95(b), the

terms "fresh frozen" and "frozen fresh" may be used to describe a food that was quickly frozen while still fresh, for example, recently harvested, by a freezing system such as blast-freezing (sub-zero Fahrenheit temperature with fast moving air directed at the food). The process should ensure that the food is frozen quickly, even to the center of the food, and that virtually no deterioration has taken place. Blanching of food such as vegetables before blast-freezing does not preclude use of the terms.

Reassessment of FSIS' Policy on "Fresh"

Because of the issues raised by the California law and the litigation that arose in its wake, 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 also 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. As a result of newspaper articles and the publicity surrounding the hearings, FSIS received 7,500 letters from consumers asking the Agency to reevaluate its policy on "fresh" labeling.

Subsequent to the hearing, Senator Barbara Boxer of California, together with Congressman Gary Condit of California, introduced H.R. 4839, the Truth in Poultry Labeling Act of 1994, on July 27, 1994. This bill would prohibit use of the term "fresh" on labeling of poultry that has been frozen, or previously frozen below 26° F.

FSIS is committed to achieving the Secretary's objectives by considering both the scientific bases for the labeling policy and consumer expectations regarding the use of the term "fresh" as it is applied to raw poultry. In response to the Secretary's direction and the significant events described above, FSIS pursued the following courses of action: (1) On August 26, 1994, FSIS 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;