

DEPARTMENT OF AGRICULTURE**Food Safety and Inspection Service****9 CFR Parts 381 and 441****[Docket No. 97-054F]****RIN 0583-AC26****Retained Water in Raw Meat and Poultry Products; Poultry Chilling Requirements****AGENCY:** Food Safety and Inspection Service, USDA.**ACTION:** Final rule.

SUMMARY: The Food Safety and Inspection Service (FSIS) is issuing regulations to limit the amount of water retained by raw, single-ingredient, meat and poultry products as a result of post-evisceration processing, such as carcass washing and chilling. Raw livestock and poultry carcasses and parts will not be permitted to retain water resulting from post-evisceration processing unless the establishment preparing those carcasses and parts demonstrates to FSIS, with data collected in accordance with a written protocol, that any water retained in the carcasses and parts is an inevitable consequence of the process used to meet applicable food safety requirements. In addition, the establishment will be required to disclose on the labeling of the meat or poultry products the maximum percentage of retained water in the raw product. The required labeling statement will help consumers of raw meat and poultry products to make informed purchasing decisions. Establishments having data demonstrating that there is no retained water in their products can choose not to label the products with the retained-water statement or to make a no-retained-water claim on the product label.

FSIS is also revising the poultry chilling regulations to improve consistency with the Pathogen Reduction/Hazard Analysis and Critical Control Points (PR/HACCP) regulations, eliminate "command-and-control" features, and reflect current technological capabilities and good manufacturing practices.

DATES: *Effective Date:* This rule is effective on January 9, 2002. Establishments wishing to implement the provisions of this final rule prior to the effective date should contact the appropriate FSIS District Office. FSIS will provide instructions to its inspection program personnel for facilitating early implementation.

Comments: Comments on the guidance material published in Appendix A should be received by April 9, 2001. Comments responding to information requested in the preamble to this final rule should be received by FSIS by April 9, 2001.

ADDRESSES: Submit one original and two copies of written comments to Docket Clerk, U.S. Department of Agriculture, Food Safety and Inspection Service, Room 102, 300 12th Street, SW., Washington, DC 20250-3700. Please refer to docket number 97-054F in your comments. All comments submitted on this rule, as well as the research and background information used by FSIS in developing this document, will be available for public inspection in the Docket Clerk's Office between 8:30 a.m. and 4:30 p.m., Monday through Friday. The final regulatory impact analysis referred to in this document and summarized in the section discussing the Agency's compliance with Executive Order 12866 is available for viewing on the Agency's Internet homepage located at "<http://www.fsis.usda.gov>".

FOR FURTHER INFORMATION CONTACT: Ms. Patricia F. Stolfa, Assistant Deputy Administrator, Office of Policy, Program Development and Evaluation, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC 20250-3700; (202) 205-0699.

SUPPLEMENTARY INFORMATION:**Background**

FSIS carries out the mandates of the Federal Meat Inspection Act (FMIA; 21 U.S.C. 601 *et seq.*), the Poultry Products Inspection Act (PPIA; 21 U.S.C. 451 *et seq.*), and the Egg Products Inspection Act (21 U.S.C. 1031 to 1056) to ensure that meat, meat food, poultry, and egg products prepared for distribution in commerce are wholesome, not adulterated, and properly marked, labeled, and packaged. The FMIA and PPIA prohibit anyone from selling, transporting, offering for sale or transportation, or receiving for transportation in commerce, of any adulterated or misbranded meat or poultry product (21 U.S.C. 610, 458).

Under the Acts (21 U.S.C. 601(m)(8); 453(g)(8)), a product is adulterated if, among other circumstances in which it might be adulterated, "any substance has been added thereto or mixed or packed therewith so as to increase its bulk or weight, or reduce its quality or strength, or make it appear better or of greater value than it is." Under the same Acts (21 U.S.C. 601(n)(1), (12) and 21 U.S.C. 453(h)(1), (12)) a product is misbranded if, among other

circumstances in which it might be misbranded, "its labeling is false or misleading in any particular."

FSIS provides continuous inspection in meat and poultry slaughtering and processing establishments and in egg product processing plants to ensure that the establishments sell in commerce only products that are not adulterated or misbranded. At meat and poultry slaughtering establishments, FSIS enforces requirements intended to prevent the adulteration of carcasses and parts during post-evisceration processing, handling, and storage. Some of these requirements concern the washing and chilling of the carcasses and parts.

After evisceration, raw livestock and poultry carcasses are subject to various processes, including washing and chilling, to ensure the safety of the products. In livestock slaughtering establishments, air chilling causes carcass weight loss from evaporation of the natural water in the carcass during evaporative cooling. Spraying water on livestock carcasses during air chilling either replaces the water that would have evaporated during air chilling or prevents the water in the carcass from evaporating. The result is that livestock carcasses subjected to a water spray do not lose weight through evaporation. Establishments should operate water spray systems in a manner that does not result in an increase in the average weight of a group of livestock carcasses produced during a scheduled period of operations over the carcasses' pre-chilled weight. FSIS Directive 6330.1, which describes the Agency's policies on the spray-chilling of carcasses, recognizes that it is technologically feasible and commercially practical to chill livestock carcasses in a manner that, on average, does not result in an increase in the carcass weight above the pre-chilled weight.

However, the processing and chilling methods used for some edible meat byproducts and organ meats may result in water retention. For example, cheek meat, meat from ears and tails, and organ meats are washed, cleaned, and chilled to preserve safety and wholesomeness before being shipped. Chitterlings (swine intestines) are washed and chilled before shipment and are packaged with water. A few establishments chill beef cheek meats in water, a process that may result in the absorption of water. The product is labeled to indicate the maximum percentage added water it may contain to alert buyers to the fact that the product may weigh more because of the chilling process.

Unlike meat packers, poultry processors have traditionally chilled poultry using the water-immersion chilling method. Although air chilling is permitted, immersion chilling is more rapid and cost efficient. The use of water immersion chilling is limited to whole poultry carcasses or major carcass portions. Poultry establishments are required to reduce the internal temperature of water-chilled poultry carcasses to 40 °F or less within 4 to 8 hours after slaughter, depending on the size of the carcass (9 CFR 381.66(b)).

Chilling poultry carcasses in water-immersion chillers always results in some absorption and retention of water, primarily in the skin and the tissue immediately under the skin. Also, some water becomes bound to the muscle tissue.

FSIS has consistently required that the retention of water in meat and poultry products be minimized. FSIS is mandated to prevent the distribution in commerce of meat, meat food and poultry products that are adulterated or misbranded.

Immersion chilling of poultry could result in a product becoming misbranded or economically adulterated through the retention of absorbed water. Nonetheless, since immersion chilling is an efficient way to control bacterial growth in poultry products and to ensure that establishments consistently meet applicable chilling time and temperature requirements, FSIS has permitted the retention of some water in poultry products. The Agency requires, however, that retained water amounts be minimized (9 CFR 381.66(d)(1)) and has set limits on the amount of water a poultry product may retain (9 CFR 381.66(d)(2)–(4)).

The Agency promulgated regulations limiting water absorption and retention in poultry products in 1959, 1961, and 1970 (24 FR 9566, December 1, 1959; 26 FR 6471, July 19, 1961; 35 FR 15739, October 7, 1970). The retained-water limits were based on carcass weight and intended use of the product. For example, higher limits were provided for birds that were to be cut-up than for those to be sold as whole birds because, when the birds are cut up, water retained at or near those higher limits declines below the regulatory limits for whole birds. If water has not been minimized, the product may be considered adulterated. Such product may also be considered misbranded if its labeling does not disclose the presence of retained water at levels higher than the required limits. Until a Federal court set aside the regulatory limits on retained water in poultry products, public knowledge of the limits

obviated the need for a requirement for retained water to be disclosed on a product label. Without published limits on retained water, FSIS cannot adequately protect consumers from adulteration and misbranding due to excessive retained water in whole birds.

FSIS, however, lacks information on which to decide what level, if any, of retained water would not constitute adulteration, or to determine whether the limits that are in use do not result in adulteration.

Provisions To Limit Retained Water in Raw Meat and Poultry Products

On September 11, 1998, FSIS proposed regulations that would limit the amount of water retained by raw carcasses and parts of livestock and poultry as a result of post-evisceration processing, such as carcass washing and chilling. Under the proposal, meat and poultry carcasses and parts could not retain water from such processing unless the establishment preparing the carcasses and parts demonstrated that water retention is an unavoidable consequence of procedures necessary to meet applicable food safety requirements. FSIS also proposed to require that the establishment disclose on the product labeling the maximum percentage of retained water in the product. The labeling statement would provide information that would be helpful to consumers in making purchasing decisions. An establishment having data demonstrating that there is no retained water in the products could choose not to label the products with the retained-water statement or to make a no-retained-water claim on the product label. The proposed requirements were intended to replace those set forth in 9 CFR 381.66(d)(2)–(8). The purpose of the proposed requirements was to restrict, as much as feasible, the amount of water absorbed and retained in raw meat and poultry products.

The proposed rule was prompted by longstanding industry petitions and by the Agency's need to reform its regulations to make them more consistent with its Pathogen Reduction/Hazard Analysis and Critical Control Point System (PR/HACCP) regulations, in accordance with its regulatory reform agenda. The rulemaking gained further impetus in the wake of a July 23, 1997, Federal court decision in *Kenney v. Glickman* vacating the regulations in 9 CFR 381.66(d)(2) that contain the water-retention tables for poultry.

As explained above, FSIS has consistently required that the retention of water in meat and poultry be minimized and has considered product

with too much retained water to be adulterated. FSIS used the retained water limits specified in § 381.66(d)(2) to determine whether poultry establishments were meeting the requirement to minimize water absorption and absorption and retention in whole birds. The decision in *Kenney v. Glickman*, however, removed this regulation because its basis was inadequate, and left the Agency without a regulatory limit, greater than zero percent, at or below which it could consider retained water in whole poultry to have been minimized. The limits for cut-up or ice-pack poultry in 9 CFR 381.66(d)(3)–(6)) were unaffected by the Court decision. This final rule replaces retained water limits that have been set out in the regulations with a requirement that products not retain water unless establishments demonstrate that the retained water is an unavoidable consequence of meeting food safety requirements.

FSIS is aware that it may be difficult to eliminate water retention for poultry and some meat products while continuing to meet applicable food safety requirements. Even in operations that yield raw product with zero-percent retained water, there is a certain amount of process variability. FSIS therefore proposed an alternative to a zero-percent retained-water requirement. Establishments would be required to collect data, in accordance with a protocol approved by FSIS, and demonstrate that water retention is an unavoidable consequence of the process used to meet a food safety requirement, such as the *Salmonella* performance standards or time/temperature chilling requirements. FSIS expected that, to determine that any unavoidable water retention is the minimum feasible, the protocol would provide for testing the process under alternative equipment settings or other variables.

FSIS said in the proposal that it would accept data generated from an approved protocol to support water retention levels for multiple establishments using similar post-evisceration processing techniques and equipment. Depending on the design of the protocol and the adequacy of the data collected under it, the Agency stated that the data could be used to justify an industry-wide water-retention limit, a limit applying to poultry products processed by several establishments, or a limit applying only to a single establishment's product. Establishments using an industry-wide or multi-establishment limit would have to be able to demonstrate that the conditions under which their products

are processed match those specified in the protocol used to justify the limit.

Comments

FSIS received 252 letters commenting on the proposed rule. Most were from members of the regulated industry. Sixty-one were from companies, company officials, or other individuals associated with the meat industry, or trade associations representing the industry, including both producers and packers. One hundred and sixty-nine were from companies, company officials or other individuals associated with the poultry industry, or from trade associations representing the industry, including both producers and processors. The rest were sent in by consumer-advocacy groups and other consumer-oriented organizations (3), individual consumers (7), weights and measures officials (7), a trade association not exclusively concerned with meat and poultry (1), technology firms (3), and the European Union. Consumers, consumer groups, and commenters representing livestock producer and meat packing interests tended to favor the proposal or to criticize it for not going far enough in restricting water retention. Poultry interests tended to oppose the proposal or to favor extensive modifications. Technology firms were divided on the merits of the proposal and on processes for improving food safety.

Comment summaries (each termed "Comment") by topic and Agency responses follow:

Alleged Inequitable Regulatory Treatment

Comment: Meat industry groups said that FSIS must eliminate the substantial inequity in the regulatory treatment of meat, compared with the treatment of poultry. They said that requirements for chilling meat and poultry products must be the same. The "equity" issue, they said, remains unresolved by the proposal, and that FSIS is maintaining the *status quo* without offering compelling food safety reasons for doing so. Poultry chilling, they said, should be subject to the same "rigorous requirements" as those that apply to the chilling of meat. The rule should be science-based, equitable, and HACCP-consistent.

On the other side, poultry groups said that the proposal does not treat poultry equitably with meat. They said that the meat industry uses spray chilling and does not have to adhere to chilling time/temperature requirements as does the poultry industry. Moreover, they said, organ meats are chilled in water without regulatory limitation.

Poultry groups also suggested that the proposed regulations may not apply equally to livestock and poultry parts. They said that "parts" in the meat regulations has a connotation different from that of "parts" in the poultry regulations. They asserted that there are few proposed changes that would affect the chilling and labeling of meats.

Response: FSIS disagrees that it is not resolving the "equity" issue. This rulemaking clearly applies to both meat and poultry products. Both meat and poultry establishments must abide by the retained-water minimization requirements of this final rule. Also, the retained-water labeling requirement will make both meat and poultry product establishments accountable to consumers for water retention.

The point of the poultry industry commenters with respect to the spray chilling of meat carcasses is well taken, and it is true that meat carcasses do not have to meet chilling time/temperature requirements as do poultry carcasses.

FSIS acknowledges the need to address the issue involving the chilling time and temperature requirements for poultry that were raised in both the American Meat Institute's 1997 petition and industry comments on this rulemaking. However, as the Agency indicated in the preamble to the proposed rule (63 FR 48963, 48965), FSIS did not intend to address this issue in this but in a future rulemaking.

FSIS does not agree with the poultry industry statement about the meaning of "parts" in the meat and poultry regulations, nor does the Agency see the relevance of the point to this rule. Raw, single-ingredient meat and poultry products, including parts of either meat or poultry carcasses, are covered. Some products of the meat industry that previously have not been covered by a retained-water regulation, *e.g.* livestock organs and offal, are now covered by this rule—a fact to which members of the meat industry have objected.

If applying "the same rigorous requirements" to poultry as to meat means requiring the poultry industry to adopt non-immersion-chilling methods, this final rule will not accomplish that objective. The food safety rationale for mandating the use of a particular technology has not been demonstrated.

Comment: FSIS is biased in favor of the poultry industry when it states that immersion chilling reduces overall pathogen levels. There are other ways to reduce pathogens. The Agency is particularly biased in stating that installing air chilling or air-spray systems in the poultry industry would be economically infeasible.

Response: FSIS acknowledges that pre-chill treatments can be advantageous in controlling bacteria and in achieving the objectives of the rulemaking. FSIS has never suggested, however, that the purpose of immersion chilling is to *remove* pathogens, but has stated that chilling reduces the temperature of the carcass and thus inhibits the growth of pathogens and other bacteria. FSIS stated in the Preliminary Regulatory Impact Analysis (PRIA) that requiring the poultry industry to install air chilling or air-spray chilling systems would entail major construction costs (63 FR 48976). FSIS does not consider this conclusion of its analysis to be evidence of bias.

Comment: Poultry has been immersion-chilled for decades. The poultry and meat industries are different and should be regulated differently.

Response: Different technologies may be needed to produce safe products from different species. FSIS is not banning or discouraging the use of immersion-chilling technologies to produce safe poultry products. The Agency is obligated, however, to take the same regulatory approach to meat as to poultry products, unless it finds, based on the available record, that different approaches are necessary.

Technology of Chilling and Bacterial Control

Comment: FSIS should encourage investment in technology adjustments that prevent water retention in poultry. The meat industry uses steam vacuum and steam-and-hot-water pasteurization without adding water weight via water retention in carcasses.

Response: By requiring establishments to justify unavoidable retained water in food safety terms and to apply retained-water labeling to their products, the final rule will provide an incentive for technological adjustments that minimize water retention in carcasses.

Comment: Consumer groups and meat industry commenters asserted that FSIS has failed to consider the most recent information on the effectiveness of chilling technologies other than immersion chilling. They said FSIS seemed to dismiss air chilling because it could result in product discoloration. Some noted that European processors use air chilling, which does not have the cross-contamination risks of chiller baths.

Response: In framing the proposed regulation, FSIS did not assume that immersion chilling will be the technology of choice for either the meat or the poultry product industry.

FSIS has taken no position on the safety or quality of air-chilled product but has limited data on the effectiveness of air chilling, especially in large-scale operations of the kind that supply most of the poultry products sold in the United States.

Comment: Immersion chilling is the best way to prevent potential food safety problems. Using chilled water is the most efficient, effective way to remove carcass heat and is the best way to achieve the purposes of HACCP. One company reported data on post-chill compared with pre-chill carcasses that show a 73-percent reduction in pathogenic organisms and an 85-percent reduction in generic *E. coli*. After a trisodium phosphate (TSP) carcass-rinse treatment, the incidence of *Salmonella* and *E. coli* is 0 percent. (Carcasses not rinsed with TSP show 96 percent and 30 percent, respectively. *Campylobacter* was found in 78 percent of untreated carcasses, and in 46 percent after TSP treatment.) The company maintained that air-chilling methods are not so effective, but that immersion chilling is an effective and economical way to meet the USDA time/temperature requirement.

Response: FSIS appreciates the food safety accomplishments of firms using any post-evisceration processes, but consumer protections other than food safety must also be ensured. Although immersion chilling can be effective in controlling microbial growth, products exposed to the process will retain water. This final rule is intended to address this problem.

Comment: A poultry processor who uses air chilling stated that air chilling is economically feasible. Analysis of retail prices shows air-chilled poultry yields 7 to 8 percent more poultry meat to the consumer than does water-chilled poultry.

Response: FSIS is not endorsing the use by the regulated industry of a particular technology.

Comment: Consumer groups cited recent studies, including a 1987 conference paper by C.J. Thomas, *et al.*, and a 1997 paper by M. Ristic, as evidence of the advantages of air-chilling technology.

Response: The paper by C.J. Thomas *et al.* refers only in passing, in a question-and-answer section, to an increasing use of air-chilling processes. The paper is not really about air chilling.

The Ristic (1997) paper cited by the commenters and other studies by the same author have consistently shown air-spray chilling to have certain advantages over other methods. The studies do not compare the feasibility of

air-spray chilling with that of other chilling technologies in an industry with a production volume as high as that in the United States, nor do they provide a basis for regulatory action with respect to one or another technology.

Comment: A European Union official asked if there are scientific studies that support immersion chilling, rather than air-spray chilling, of livestock carcasses.

Response: FSIS is not aware of any peer-reviewed study on the water-immersion chilling of whole livestock carcasses. Among studies on the efficacy of livestock-carcass spray chilling, including systems using anti-microbial solutions, are:

Gill, C.O., and T. Jones, 1992. Assessment of the hygienic efficiencies of two commercial processes for cooling pig carcasses. *Food Microbiology* 9(4):335-343.

Gill, C.O., and J. Bryant, 1997. Assessment of the hygienic performances of two beef carcass cooling processes from product temperature history data or enumeration of bacteria on carcass surfaces, 1997. *Food Microbiology* 14(6):593-602.

Gill, C.O., and T. Jones, 1997. Assessment of the hygienic performance of an air-cooling process for lamb carcasses and a spray-cooling process for pig carcasses. *International Journal of Food Microbiology*, 38(2/3):85-93.

Grier, G.G., and B.D. Dills, 1988. Bacteriology and retail case life of spray-chilled pork. *Canadian Institute of Food Science and Technology journal* 21:295-299.

Hamby, P.L., J.W. Savell, G.R. Acuff, C. Vanderzant, and H.R. Cross, 1987. Spray-chilling and carcass decontamination systems using lactic and acetic acid. *Meat Science* 21:1-14.

Jericho, K.W.F., G. O'Laney, and G.C. Kozub, 1998. Verification of the hygienic adequacy of beef carcass cooling processes by microbiological culture and the temperature-function integration technique. *Journal of Food Protection* 61(10):1347-1351.

Stevenson, K.E., R.A. Merkel, and H.C. Lee, 1978. Effects of chilling rate, carcass fatness, and chlorine spray on microbiological quality and case-life of beef. *Journal of Food Science* 43:849-852.

Comment: The ozonation process achieves significant *E. coli* reductions on carcasses sampled at post-chill. Any rule permitting immersion chillers to use ozonation should be supported.

Response: If it is true that ozonation reduces generic *E. coli* populations, establishments may find the process useful in meeting requirements of the PR/HACCP regulations. The FSIS

regulations do not prohibit use of ozonation equipment with immersion chillers. However, the Food and Drug Administration must approve the use of ozone for food processing purposes before FSIS can allow it.

Time/Temperature Chilling Requirement for Poultry

Comment: Some commenters disputed the FSIS statement that "for most poultry establishments, the inevitable retained-water amount is the 'minimum' level that can be reached with existing immersion chiller equipment while still meeting the chilling requirement (for poultry to reach a temperature 40 °F or below within a specified number of hours)." They stated that the poultry chilling requirement (9 CFR 381.66(b)(2)) is a command-and-control regulation that the final rule should eliminate. Commenters favoring both the meat-industry and the poultry-industry sides of the water-retention issue argued for immediate repeal of the poultry chilling requirement. Some even thought the proposal was premature and should be withdrawn because it did not address this matter.

Response: FSIS views the poultry time/temperature 40 °F chilling requirement as a food safety performance-standard issue that would best be addressed in a separate notice-and-comment rulemaking, which the Agency plans to conduct. The Agency believes that any performance standard that might replace the 40 °F requirement should be science-based, HACCP-consistent, and applicable to all species subject to mandatory inspection. The Agency is continuing to study this matter and hopes to be able to propose regulatory amendments in the coming months. In the meantime, FSIS will permit establishments to vary the parameters of their chilling or other processing operations as necessary to meet the objectives of their data collection protocols.

Product Quality Argument "Arbitrary and Capricious"

Comment: The product-quality-based water-weight allowance is arbitrary and capricious, claimed the plaintiffs in the *Kenney* case. Quality is no problem in Europe, where poultry is air-chilled or air-spray-chilled. Adding water is adding an ingredient to make a multi-ingredient product. The product should be labeled to show the amount of retained water that is necessary for food safety purposes and the amount that is necessary for food-quality purposes.

Response: The commenters' criticism is unwarranted. This rule is primarily

intended to limit water retention resulting from processing to the amount that is unavoidable to achieve a food safety objective. However, FSIS has stated that, in their data collection protocols, establishments may specify determining product quality as a secondary or tertiary purpose of the data collection activity. This rulemaking does not provide for an additional retained-water amount that an establishment may consider necessary to maintain product quality.

Ready-to-cook poultry in Europe is dryer than ready-to-cook poultry in the United States. Whether United States consumers will eventually demand poultry that is similar to the European product is a question that can be answered by the market.

FSIS does not agree with the statement that water should be considered an ingredient in immersion-chilled poultry products. Water is not added to the products being chilled to create new products.

Zero Retained Water

Comment: Various commenters supported a zero-retained-water standard for both meat and poultry products. They said FSIS was wrong to reject, as a reason for a zero-retained-water standard, the argument that the information benefit to consumers is unlikely to exceed costs.

Consumer groups commented that FSIS's own figures show consumers pay almost \$1 billion/year for retained water in poultry. They said FSIS should be proposing zero retained water, and that neither meat nor poultry products should be allowed to gain water. The proposal falls well short of what is needed, they said, strongly preferring Option 2 (zero retained water) in the regulatory analysis to Option 6 (retained water limits established by processes necessary to meet food safety requirements—the selected option). They said FSIS should reconsider Options 2 and 4 (retained water limits based on best available technology within traditional production practices).

Response: Mandating zero water retention for the poultry industry would be tantamount to requiring the re-tooling of the industry on an economically prohibitive scale. FSIS calculated that the resulting benefit to consumers, an informational benefit, would be slight in comparison to the impact on the national economy. The Agency calculated that consumers could receive a desirable informational benefit at a lower cost to society.

The proposal did not specify any acceptable amount of retained water, only that any amount that is retained be

no greater than the unavoidable amount resulting from post-evisceration processing to achieve regulatory food safety requirements.

In the PRIA, FSIS suggested that the value of poultry production could be viewed as the production of poultry and the production of water. The Agency also said that another view was that the water has no effect on the price of poultry meat, but that the consumer is simply not being informed of the wholesale-price of poultry or turkey on a zero-added-water basis. The Agency's concern in much of the PRIA was the effect of full disclosure of retained water on consumer purchasing. The Agency concluded that this effect was unclear, though beneficial. The Agency did not take the position that water is literally being sold at poultry prices.

In the FRIA, the Agency has not attempted to quantify the overall benefits of the rule. However, FSIS rejected Option 2 and Option 4 because the costs to industry would be substantially disproportionate to consumer benefits.

This rule will ensure that water retention is limited to the amount unavoidable for food safety reasons, and that consumers are informed about this water retention. In establishing zero water retention as the default requirement, the rule compels the industry to justify scientifically any amount of water retention in raw, single-ingredient, meat or poultry product. Water in excess of the amount that is scientifically justified will adulterate the product.

Comment: Individual commenters generally supported the proposal on the ground that consumers would not purchase meat containing too much water. Some even thought the Agency should permit zero-percent retained water. Commenters said they do not know the exact water weight of poultry product because it is not labeled. Some said that added water in curing or other processing is a consumer rip-off. One commenter said immersion-chilling water is a "fecal soup" in which poultry are marinated.

Response: FSIS appreciates commenters' support for the general direction of this rulemaking. The Agency disagrees with the characterization of poultry chillers because the chillers efficiently reduce carcass temperatures and slow microbial growth. FSIS also disagrees that this rule should impose an unconditional limit of zero-percent retained water in raw meat and poultry products. Regarding added water in cured products, curing is outside the scope of the rulemaking. In any event, if a

product that contains a curing solution weighs more than it did in the untreated state, that fact must be reflected on the product label.

Comment: A commenter with a veterinary background claimed that continuous chillers are insanitary common baths to which there are economically feasible alternatives. These alternatives—chilling tunnels, chill-spray conveyor lines, immersion-chilled vacuum-packaged product—should be explored, said the commenter. Other alternatives are unsatisfactory. Radiation treatments are not wholly effective.

The commenter stated that irradiation at doses lower than those resulting in off-odors yields spore formers like *C. botulinum* Type C. Irradiation kills spoilage bacteria that can be indicators of unwholesomeness.

As for antimicrobial interventions used with immersion chillers, chlorination of chiller water is not entirely effective and forms toxic organochlorine compounds that have environmental impacts. Phosphates used in post-chill dips facilitate water retention.

Eliminating retained water in poultry would "correct a consumer fraud and [an] advantage poultry has over other parts of the food industry." The result of imposing regulatory limits on water retention after continuous chillers were introduced was to allow the poultry industry to sell "legally adulterated product."

Response: Studies do not bear out the feasibility of using technologies other than immersion chilling that would achieve the same food safety benefit on the same scale. FSIS is not aware of any technology other than food irradiation that is 100-percent effective in eliminating pathogens on raw meat or poultry products. Irradiated product generally is not shelf-stable. Through proper control, sufficient numbers of spoilage organisms remain to successfully compete against outgrowth of *C. botulinum*.

Regarding chlorination, FSIS agrees that organochloride compounds form in chlorinated poultry chill water. Nevertheless, FSIS considers the potential food safety benefits of chlorination to outweigh the risks.

The adulteration hazard of phosphates (extra water pick-up) that are used on raw products is exaggerated for two reasons. First, some phosphate compounds, such as orthophosphate dips, have been approved for use on raw products but are not in general use. Second, the treatment of raw products with such anti-microbial phosphate solutions as TSP should not be equated

with the addition of phosphate compounds to pickle-cured meat products to reduce the amount of cooked out juices. Such food additives become components of the products and do cause the products to hold water.

On the charge that regulatory water retention limits constitute legalized adulteration and a fraud, the Agency points out that the water retention that it is allowing would have to be disclosed on the label. Therefore, there would be no fraud. The Agency also believes that in appropriate circumstances, it could determine that some water retention is necessary, is unavoidable, and would not need to be disclosed. However, those circumstances have not been established in this rulemaking.

Data-Collection Protocol Requirement

Comment: Requiring an establishment-generated data-collection protocol for determining minimum unavoidable retained moisture would be arbitrary and capricious. FSIS has failed to articulate uniform criteria for such a protocol or a process for review of protocols.

Response: FSIS does not have the data necessary to set a regulatory limit on the amount of moisture a raw, single-ingredient product may retain. FSIS has put the burden of developing data to justify a level of retained water other than zero on official establishments because they are in the best position to determine what they have to do simultaneously to meet food safety requirements and to minimize retained water in their products. FSIS published suggested protocol specifications for comment on December 9, 1997 (62 FR 64767), and a list of expected elements of protocols with the proposed rule. The Agency received few comments on the expected protocol elements. These elements of protocol design give industry flexibility in collecting data that will be useful in determining water-retention limits on an establishment-by-establishment or industry-wide basis.

Regarding protocol review procedures, as discussed below, in response to comments, the Agency has decided not to pre-approve the data collection protocols establishments will use because to do so would contradict its regulatory policy which is opposed to command-and-control regulation.

Comment: The proposal, with its requirement for data-collection protocols to be pre-approved by FSIS, represents a return to command-and-control regulation.

Response: FSIS proposed that it review the data-collection protocols because of the need to ensure a degree

of uniformity in and scientific validity of data-collection procedures for establishing the amount of unavoidable water retention. FSIS agrees with the commenter, however, that the proposed pre-approval of protocols would be a command-and-control requirement. The Agency, therefore, will not be pre-approving such protocols. FSIS is requiring, however, that an establishment notify the Agency as soon as the protocol is available for review. FSIS will then have 30 days in which it may object to or require changes in the protocol.

Comment: A poultry industry association opposed "pre-clearance of retained water after pre-clearance of data protocols."

Response: As stated in the preamble of the proposal (at 63 FR 48964), the labels with the retained-water statements will be generically approved pursuant to 9 CFR 317.5(b)(2) and 381.133(b)(2). Generically approved labels may be used without being submitted to the Agency for approval provided that they show all mandatory features and are not false or misleading. FSIS samples generically approved labels at establishments to determine their compliance with labeling requirements. With respect to labels with retained-water statements, the Agency may, from time to time, examine the data collected by establishments to ensure that the basis for label statements is sound. The Agency, however, will not pre-approve either the data or the water-retention limits the data are purported to justify.

Protocol Approval Process

Comment: A European Union official suggested that FSIS clarify the protocol approval process: Would the establishment, after it is recognized as eligible, have to "submit systematically a dossier" on final treatment of livestock and poultry carcasses and parts?

Response: Foreign establishments recognized as eligible to export to the United States will not have to submit a dossier to FSIS on water retention. However, they will have to maintain a file containing data that demonstrate either that the product they ship contains no retained water, or that it contains no more than the amount that is stated on the product label and that such amount is no greater than the amount that is unavoidable in achieving food safety objectives. The data must be collected under a protocol that is acceptable to the foreign government.

Process for Determining Amount of Unavoidable Retained Water

Comment: FSIS should more fully describe the process for demonstrating that retained water is unavoidable.

Response: FSIS is not prescribing a method for determining the unavoidable amount of retained water. Each establishment should be able to choose the method that is most appropriate for its processing situation. However, a slaughtering establishment should consider varying its process in whatever manner seems most likely to reduce carcass microbial counts and maintain them at a low level. The establishment should then measure the water retention amounts corresponding to the respective microbial reductions. A series of trials to achieve pathogen reduction by running chilling equipment at different settings, making other process changes, and plotting the microbial and water-retention data, should show what the retained water levels in the product were when any observed increase or decrease in microbial counts occurred.

The establishment might consider plotting available *E. coli* process-control data, or *Salmonella* or other microbial data that it has collected, on a time chart with water-retention data collected on the same product on the same dates. It should then be possible to observe the retained-water levels corresponding to microbial counts on the same products. From this information, an establishment should be able to determine what is the unavoidable level of retained water that corresponds to the lowest microbial counts.

FSIS is not prescribing any particular method for establishments to use to determine the amount of retained water in their products. A number of chemical and physical methods are available for determining the amount of moisture in foods, such as the method described in Appendix A of this document.

Retained-Water Limits

Comment: There is no connection between water retention and HACCP.

Response: Although this rulemaking is intended to establish a basis for controlling retained water in raw meat and poultry products, it is understood that retained water is an unavoidable consequence of certain processes commonly used to achieve food safety objectives, such as immersing chickens as a means of lowering the temperature of carcasses while limiting the opportunity for pathogen growth. This objective derives from the need to meet the pathogen reduction performance standard, a food safety requirement that must be met (63 FR 48963). While the

Agency does not prescribe the critical control points or critical limits that establishments must include in their HACCP plans, the failure by an establishment to meet the pathogen-reduction performance standards constitutes failure to maintain an adequate HACCP plan (9 CFR 310.25(b)(3)(iii), 381.94(b)(3)(iii)). Thus, there is a relationship between this rule and HACCP.

Comment: It is difficult to predict with precision the amount of water that may be retained. It would be difficult for the industry to devise protocols and guidelines necessary to comply with the proposed rule. Changes in systems would require changes in protocols, which would have to be resubmitted for approval to the Agency. This requirement would be burdensome to the industry and the Agency.

Response: Under this final rule, FSIS may review, but will not pre-approve, data-collection protocols developed by establishments. FSIS does not expect the development and use of a data-collection protocol for determining unavoidable water retention to be continuous. In most cases, protocol development will be largely a one-time-only expense. FSIS is taking a flexible approach toward the data-collection protocols. FSIS understands that there are many factors that determine water retention. If variables in the model used in a protocol changed, FSIS would not necessarily expect a whole new protocol to be developed. The Agency is mainly interested in knowing that the protocols are scientifically valid, that the data collected under them will reflect water-retention amounts that are unavoidable, and that the data support the water-retention statements on product labeling. For this reason, FSIS is requiring that an establishment make its new or revised protocol available for review by the Agency, but FSIS will not be pre-approving the protocol.

Comment: The proposed requirements for limiting water retention and labeling the amount of retained water are redundant. If there is a labeling requirement, there should be no requirement for industry to limit water retention. If there is a water-retention requirement, there is no need for a labeling requirement.

Response: The retained water minimization and labeling requirements are not redundant but address two different legal prohibitions—adulteration and misbranding. This rule is intended to prevent adulteration and misbranding of raw meat and poultry products by ensuring that water retention in the products is minimized and by improving the availability of

information on water retention. The retained-water minimization requirement stems from the Agency's long-held view that excessive water retention is a form of product adulteration. The labeling requirement is intended to help prevent misbranding. It is intended to help prevent potential buyers from being misled about a characteristic of the product—retained water—by providing them with information about the characteristic. Product labeling is one of the most useful ways to provide such information. The labeling requirement is especially necessary in the wake of the U.S. Court decision in *Kenney* which, by setting aside the regulations that prescribed limits for water retention in ready-to-cook whole poultry, left consumers without any information that retained water was being held below a certain maximum percentage.

Simply imposing a regulation that limited water retention would not inform consumers of the retained water content of products unless specific water retention limits were clearly presented in the regulation. For reasons discussed elsewhere in this document, FSIS has found that it is not in a position to impose such a regulation. On the other hand, simply requiring labeling would not be consistent with the adulteration provisions of the FMIA and PPIA. Unlimited retained water would constitute economic adulteration even if identified through labeling.

If an outcome of this rule were that no raw, single-ingredient meat or poultry product retained any water from processing, a labeling requirement might eventually be unnecessary.

Comment: A weights and measures official said, regarding FSIS's view that "excessive" water retention may constitute adulteration, that the proposal did not limit water in raw, single-ingredient products but only required a more technical justification.

Response: The final rule clearly does limit water retention. The rule does not flatly mandate zero-percent water retention, but requires a demonstration that any water retention is unavoidable. Any retained-water percentage greater than zero percent will be considered excessive unless the percentage is justified by data collected under a valid protocol.

Food Safety Requirements

Comment: FSIS must identify the food safety requirements to be met in the post-evisceration or chilling process.

Response: In the PR/HACCP regulations, FSIS has identified process-control criteria and pathogen-reduction performance standards that

establishments must meet. In the expected elements published with the proposed rule on retained water, FSIS stated its preference concerning the purpose of a data-collection protocol: To determine the amount or percentage of moisture absorption and retention that is unavoidable using a particular chilling system while achieving the pathogen-reduction performance standard for *Salmonella*. In conducting hazard analyses and developing their HACCP plans, establishments may identify additional or other food safety objectives. It has been unnecessary in this rulemaking to set out further food safety requirements.

Retained-Water Labeling

Comment: Poultry industry commenters suggested that the retained-water labeling requirement was a punishment for using the most effective techniques. Some thought the retained-water labeling provision might decrease consumer demand for the labeled products.

Response: FSIS has an obligation to balance the interests in any situation. While it is true that any water that will be declared on the label will be the unavoidable result of an effective process, it is also true that the misbranding and economic adulteration provisions of the FMIA and PPIA make clear the obligation of producers raw meat or poultry products not to mislead consumers. FSIS thinks that if they market as meat or poultry a product that contains something other than meat or poultry, that fact should be disclosed. Comments received in response to the proposal are inconclusive on how consumers will regard product with labeled retained-water amounts, although consumer advocacy groups and some individual commenters favored the labeling proposal.

Comment: Plaintiffs in *Kenney* opposed the proposed labeling provision, saying it would only be sanctioning the reporting of illegal water retention.

Response: FSIS disagrees. The Court in the *Kenney* case held that, under the PPIA, the Secretary of Agriculture had the authority to require labeling of the amount of retained water in and to define a poultry product. (*Kenney v. Glickman*, No. 4-94-CV-10402 (S.D. Iowa, Jul. 23, 1997) (order granting plaintiff and respondent motions for summary judgment) at pp.12, 13.)

Comment: A turkey processor said that the proposal would create a bag-printing headache for the poultry industry because turkey processors ship many products under private-label brands.

Response: FSIS does not foresee a problem in this regard. The purchasing specifications provided by firms for which processed birds are prepared cannot be lower than the minimum water retention of which the processor's technology is capable. The processor should be able to order or produce bags labeled with a retained-water statement that routinely complies with the regulation.

Comment: Industry groups suggested that if labeling is needed, a percent-retained-water statement could be either in the product name or in the ingredient statement, or the retained moisture could be reflected in nutrition labeling of the product.

Response: Placing the retained-water statement in an ingredient statement would imply that the product is fabricated of more than one ingredient. This implication would be misleading, because the water that would be listed in the ingredient statement is retained from processing and not literally added to the product to create a new meat or poultry product.

FSIS also does not agree that nutrition labeling can be used. First, assuming that retained water could be regarded as part of the product, and that the nutrition labeling were accurate, few consumers would notice changes in the percentages of protein, fat, or other nutrients resulting from a change in the percentage of retained water in the product. Also, a retained water statement in a nutrition facts panel would not be as conspicuous as one on the principal display panel. Moreover, because nutrition labeling of single-ingredient products is still voluntary, relatively few consumers of such products would have the advantage of even the limited amount of information on water retention that nutrition labels could convey.

Comment: A local weights and measures agency stated that percent-retained-water labeling should be standardized and placed in a uniform location on the package.

Response: FSIS wants to be as flexible as possible, consistent with the objective of informing the consumer of the amount and presence of retained water in affected product. The Agency is requiring that the retained water statement be contiguous to the product name or elsewhere on the principal display panel of the label.

Comment: Several companies and groups wrote that if FSIS insists on a labeling requirement, it should apply only to processor-packaged product intended for sale to consumers at retail. The final rule should exempt from the labeling requirement products intended

for export, products shipped in bulk for further processing, and product to be sold to institutions and food-service operations.

Response: The commenters appear to be alluding to exemptions in the FSIS nutrition labeling regulations for products intended for further processing, certain products that are not for sale to consumers, products intended for export, certain products sold at retail stores, and items on restaurant menus (9 CFR 317.400(a)(2), (3), (6), (7); 381.500(a)(2), (3), (6), (7)). Those regulations were intended to be consistent with the aim of the Nutrition Labeling and Education Act and regulations implemented by the Food and Drug Administration, to assist consumers in maintaining healthy dietary practices. The preamble to the FSIS nutrition labeling final rule states the Agency's goal of providing consumers with more accurate and complete nutritional information (58 FR 635; January 3, 1993). In response to comments on its nutrition labeling proposed rule, FSIS did provide exemptions in the final rule of the sort the commenter refers to, on the ground that there was little value in requiring nutrition information where the consumer will not see it (58 FR 639).

However, unlike the nutrition labeling regulations, this final rule is intended to provide information directly both to household consumers and to large purchasers of meat and poultry products. Product shipped in bulk should be labeled accurately to ensure accurate formulation of further-processed products. Also, product shipped to institutions and food-service operations should be labeled with the same accuracy as product shipped to household consumers.

On the matter of exported product, the industry does not produce, and FSIS does not regulate, a separate class of raw, single-ingredient, meat or poultry product for export to which this rule would not appropriately be applicable. Thus, FSIS disagrees that export product should be subject to retained-water labeling requirements different from those to which product for domestic sale is subject.

Comment: The proposed retained-water labeling requirement should be adopted immediately.

Response: FSIS appreciates the support for the labeling provision of the proposal. The Agency, however, is setting the effective date of the final rule at 1 year following publication of the rule in the **Federal Register** to mitigate the effects of the rule on establishments—particularly those that are considered small businesses under

Small Business Administration criteria—that may have to consider changing or updating their chilling processes and equipment.

This 1-year pre-implementation period will enable FSIS to prepare sampling, testing, and document review procedures; train Agency personnel in the new procedures; and develop a new national reference database on the natural moisture content of raw products in the various meat and poultry product classes. However, establishments can voluntarily implement the provisions of this rule in advance of the effective date.

Comment: A local weights and measures official commented that the labeled water retention amount on poultry products should not be based on an average but should be applicable to 95 percent of individual birds.

Response: FSIS notes that this comment was based on the analysis in the PRIA of rulemaking Option 1—to allow any percentage of retained water so long as the percentage amount is on the product label. FSIS will expect establishment data collection protocols (see § 441.10(d)) to include the sampling and testing methods for determining that food safety requirements (pathogen reductions) are being met and the testing methods for determining water retention. FSIS will also expect the protocols to explain how water retention data are to be reported and evaluated. The data collected by the establishment should show with reasonable confidence—*i.e.*, 95-percent statistical confidence—that a given package retains no more water than is unavoidable, and no more than the label states.

Labeling Format

Comment: Rather than the statement “up to X% retained water” or “less than X% retained water,” the label of affected products should state, “contains X% added water.” The “up to X%” statement prevents the consumer from calculating the true price per pound without added water weight. A “contains X%” statement would be consistent with the ban on qualifying terms in the Fair Packaging and Labeling Act.

Response: Current production practices yield product with varying levels of water retention. It is therefore difficult for an establishment to target an exact water-retention percentage for all its products of a certain class. FSIS has taken this fact into consideration and has framed the labeling requirements of this final rule in a way that will minimize inadvertent industry noncompliance.

It is true that a consumer may not be able to compute the exact percentage of retained water in a product labeled "with up to X% retained water." The establishment that prepared the product, however, will have had to determine a water-retention range based on the data used to determine the amount of retained water that is unavoidable in the product. The establishment will be free to label its product with the water-retention amount that reliably represents the amount that is in the packaged product.

Consumers of the product will have available more information on water retention than they have had in the past.

Retained-Water Labeling and Product Tare

Comment: If FSIS insists on a labeling requirement, product tare should be addressed. For example, if product labeled as having 4-percent retained water that loses 2 percent of the water is sold in a wet-tare jurisdiction, how would the product be labeled? How would the regulation be applied?

Response: Compliance with net-weight regulations is determined by following the wet-tare and dry-tare procedures in National Institute of Standards and Technology (NIST) Handbook 133, which is incorporated by reference in the FSIS regulations at 9 CFR 317.19 and 381.121b. The actual net weight of the product, as determined on a lot-average basis by these procedures, is compared with the labeled net weight of the product.

The commenter did not say whether the 2-percent moisture loss was additional to or part of the 4-percent retained-water amount represented on the label. FSIS assumes that the 2-percent loss is from the 4-percent amount. Thus, in the example presented by the commenter, the retained-water statement should reflect that the product contains at least 2 percent or as much as 4 percent water from processing.

Using the 3-pound dry-tare chicken example presented in the PRIA and FRIA, the product net weight in a wet-tare jurisdiction would be as much as 2.94 lb. or as little as 2.88 lb. The labeled net weight corresponding to a "2-percent" retained-water statement would be 2.94 lb. The loss to the product, labeled with this net weight, of an additional 2 percent in water weight would raise the issue of short weighting. The actual net weight of the package would enter the "gray area" provided in the NIST Handbook 133 procedures for determining net-weight compliance in wet-tare jurisdictions. FSIS and local weights and measures authorities would

then follow the procedures provided for gray-area product. Depending on the wording of the retained-water statement, this loss of additional moisture could mean that the statement is inaccurate, and the product misbranded for that reason.

If a company has had difficulty in determining the unavoidable amount of retained water in the product, the company should recheck the data on which its determination of "unavoidable" is based, its data-collection protocol, and its processing procedures.

If the company knows that the product will lose 2 percent of net weight because of water loss while in distribution channels, the company should adjust the retained-water statement to account for the fact. If the company knows that a retained-water product will continue to retain a certain percentage when it is sold in the wet-tare jurisdiction, the retained water statement must account for that percentage of water retention.

National Standard for Retained Water

Comment: Several commenters said that if FSIS proceeds with the rulemaking, the Agency should develop national standards for "unavoidable moisture retention." Products should be able to exceed the national standard if labeled. Some argued that, based on information in the PRIA at 63 FR 48978, water retention could be held to 2–5% with appropriate technology. Others suggested that the Agency could simply justify scientifically the water retention limits in the regulations that were set aside.

Response: To be valid, a national standard such as envisioned by the commenters would have to be applicable to homogeneous products produced under similar conditions.

The currently available data on water retention provide an inadequate basis for setting any retained-water standard because the data that could be applied to the industry are based on industry practices that conformed to the regulations that the U.S. District Court set aside in *Kenney v. Glickman*. The Court set the regulations aside, in part, because USDA had not adequately explained how the particular water retention limits in the regulations were determined or why water retention could not be reduced below those levels.

FSIS would have to have new data, collected under new protocols and criteria that meet the concerns expressed in the Court decision in *Kenney* to be able to revive the previous regulations, including updated tables

listing the water retention limits for poultry. In other words, the Agency would have to be able adequately to explain how the particular water retention limits were determined and why they could not be further reduced. Moreover, the Agency would have to be able to explain adequately how such regulations would apply to meat and poultry. Commenters did not state how this could be done.

FSIS agrees with the commenter who cited the analysis in the PRIA of available water retention data. This analysis indicates that water retention can be held at substantially below the regulatory limits that were set aside by the United States District Court in *Kenney v. Glickman*. It thus seems unlikely that new data would support the limits in the regulations that were set aside.

Comment: Even with supporting data, an industry-wide water-retention standard could still be "arbitrary and capricious."

Response: Depending on the design of the protocol and the adequacy of the data collected, a limit applying to the products of one or more establishments could be scientifically justified and not be arbitrary and capricious.

Costs of Rule

Comment: Compliance to ensure labeling accuracy should not result in added costs.

Response: The data-collection and labeling requirements will be minimal for meat establishments whose products do not gain water. Poultry establishments will have to collect data to determine the minimum water-retention levels in their products and will have to be able to verify on a continuing basis the accuracy of their product labels. Establishments will not necessarily have to conduct more tests or collect more data than they have been collecting under the regulations that this rule replaces. Thus, day-to-day costs of complying with the requirements for labeling accuracy will not be greater than past costs of complying with water-retention requirements.

Measuring Retained Water

Comment: The water retention amount should be measured as the difference between the "hot carcass weight" and finished package weight of the product. The second amount should be measured at the point of packaging.

Response: Establishments may use in-plant methods, such as weighing carcasses before and after washing or chilling procedures, as a means of controlling water retention. However, FSIS emphasizes that compliance with

this final rule will primarily depend on whether the retained-water amount of the product in distribution channels, *i.e.* the retained water weight of the product at the time it enters commerce, is no greater than the amount that is demonstrably unavoidable. FSIS intends to subject product samples collected in-distribution to an oven-drying test (described in Appendix A of this document) to determine the amount of water in the samples. Those amounts will be compared with the amount of naturally occurring water in the products to determine compliance with labeling and the retained-water-minimization provisions of the final rule. FSIS will, however, conduct in-plant verification of establishment process controls, and this verification may occasionally involve comparing hot carcasses weights with the weights of carcasses after spray chilling.

Compliance, Oversight and Control

Comment: FSIS must explain how compliance with the regulation is to be determined. A European Union official requested information on methods currently used to detect water content. One company suggested that moisture gain be determined at the last possible point before consumer packaging. Another observed that the poultry industry views retained water as the amount in the product to be lost over time as the product is en route to the consumer.

Response: Until now, FSIS and official establishments have measured water content by sampling and weighing carcasses before the carcass wash and after chilling. In poultry slaughtering establishments, carcasses are sampled and weighed before and after immersion chilling. In livestock slaughtering establishments, sampled carcasses are weighed after slaughter before and after being subject to spray-chilling processes. These traditional in-plant methods for determining the effectiveness of retained water controls continue to be available to the Agency and industry.

Under this final rule, though, FSIS will be verifying compliance with the retained-water limitation and labeling requirements primarily by reviewing establishment water-retention data collected under the required data-collection protocol. The Agency also plans to conduct in-plant and in-distribution tests of the moisture content of products using the oven-drying method described in the Agency's Chemistry Laboratory Guidebook and in Appendix A of this document. FSIS will not be dictating to

industry the in-plant sites for measuring and controlling retained water.

Establishments must be aware that the Agency will be most concerned with the amount of retained water in product that has entered commerce.

Comment: The proposed rule has no provision for compliance oversight in distribution channels and at retail or food-service operations.

Response: The regulation clearly applies to products in distribution channels, although it does not specify how the Agency will enforce regulatory requirements outside official establishments. Official slaughtering establishments will be primarily responsible for minimizing water retention, subject to meeting the food safety objectives of their HACCP plans and of the PR/HACCP and other regulations. FSIS will conduct in-plant and in-distribution activities to verify labeling accuracy and retained-water minimization.

Comment: Correction of the water-adulteration problem at retail would trigger costly recalls and reduce consumer confidence in regulatory bodies.

Response: If a recall is necessary to prevent the sale of adulterated product, the Agency will expect the industry to take the necessary action.

Weights and Measures Checks

Comment: "Weights and Measures officials generally inspect prepackaged meat and poultry at the retail level. Any changes * * * should either have no effect on point-of-sale package weight inspection procedures or, even better, simplify them."

Response: Net-weight compliance procedures will be largely unaffected by this rulemaking. FSIS will be following NIST Handbook 133 procedures for determining whether or not product is misbranded with respect to net weight. These procedures are used by State and local weights and measures officials, so there will be no difference between the procedures followed by the Federal Government and the States with respect to net weight.

Offal Products

Comment: From companies and associations representing the meat industry: Offal products should be exempt from the rule because they are not considered meat products. Moreover, FSIS Standards and Labeling Division policy covers "purge" from organ products.

Response: In the interests of equitable regulation, offal products and other products of the meat industry and any poultry products with which there is a

water-retention issue are subject to the present rule. This final rule supersedes current policy notices and directives affecting water retention; as appropriate, the Agency will revise or cancel those documents.

FSIS Priorities

Comment: The proposal is a misapplication of FSIS resources, which should be focused on food safety concerns. Consumers are more interested in knowing about product safety than retained water.

Response: While the Agency's primary concern is food safety, the FMA and PPIA provide other consumer protections as well, including that consumers have the right to be apprised of what they are buying.

Consumer Situation

Comment: Some commenters asserted that FSIS offered no data showing consumers are misled about retained water in poultry products.

Response: It is true that FSIS has not gathered survey data showing that consumers are being misled about retained water, but from inquiries it has received over the years, the Agency is aware of consumer concerns about water in packaged poultry. Although consumers did not petition the Agency for a retained-water-labeling requirement, a number of individuals and consumer advocates who commented on the proposal regarded informing consumers about retained water as an important purpose of the rule. Some requested immediate implementation of the labeling requirement.

Comment: The proposed rule could adversely affect industry and consumers. Product quality could be adversely affected. The proposal itself (at 63 FR 48980) suggests that retained-water labeling, by inducing a reduction in retained water in raw products, would actually be harmful to consumers who may prefer a moist product.

Response: The information on consumer receptiveness to poultry products that might be less moist is inconclusive. The Agency acknowledged in the PRIA, to which the commenter refers, that consumers in the United States have become accustomed to purchasing fresh poultry that is very moist. FSIS requested comment on whether consumers would be more or less likely to purchase a package of meat or poultry that appeared less moist but received little information on this matter in response.

FSIS Response to Kenney Case Decision

Comment: The proposal is not justified by the limited scope of the decision in *Kenney*. FSIS misinterpreted the decision, in which the Court found poultry with retained water not to be adulterated and recommended science-based limits.

Also, the decision in the *Kenney* case does not require the Agency to mandate retained-water labeling.

Response: The Agency does not agree with the commenter's view that the Agency misinterpreted the District Court decision in the *Kenney* case, nor does the Agency infer from the decision that it is not warranted to proceed with this rulemaking. The Court affirmed the Agency's right to define a poultry product to include poultry product with retained water. Although the Court did not specifically instruct the Agency to revise the retained water regulations that the Court set aside, the Court clearly affirmed the Agency's authority to regulate the amount of retained water in poultry products. This final rule will limit the amount of retained water in raw meat and poultry products and FSIS believes the retained water limitation will be scientifically based.

Regarding the labeling requirement in the final rule, it will prevent misbranding of products subject to the rule.

Comment: Poultry industry commenters argued that FSIS is responding to competitive, not consumer, concerns and to lobbying by the meat industry. The Agency is responding to "perceived inequity" rather than to food safety concerns.

Response: FSIS took seriously the determination by the Court that the basis for its regulation of retained water in poultry was inadequate. As a result of the decision, the Agency believed it was necessary to re-examine the basis for regulation and determine the most appropriate, science-based approach for regulating retained water in poultry. The Agency's response on this issue was grounded in its obligation to ensure that consumers are protected from adulterated and misbranded product.

Comment: According to some poultry industry commenters, the rule is arbitrary and capricious in that it makes unjustified sweeping changes to the Agency's long-established policy of not requiring that meat or poultry be labeled to show retained-water content. The rule could be invalidated under the "arbitrary and capricious" standard applied by the Supreme Court (in *Automobile Manufacturers Assn. v. State Farm*) to the Department of Transportation's rescission of a rule

requiring the installation of passive restraints in new cars. Simply requiring that meat and poultry establishments justify retained water in their products would fully satisfy the mandate of the U.S. District Court in *Kenney v. Glickman*.

Response: FSIS disagrees that, in requiring labeling of raw, single-ingredient meat and poultry products to state the retained-water content of the products, it is making "arbitrary and capricious" sweeping policy changes. Rather, FSIS is attempting to carry out its statutory obligation to prevent the distribution of products that are adulterated or misbranded under circumstances in which a regulation intended to prevent adulteration or misbranding of poultry products has been invalidated.

With respect to the labeling issue, FSIS thinks that the *State Farm* case is inapposite. FSIS is willing to concede that it had a policy not to require labeling of poultry products for retained water. However, the *Kenney* decision represents a change in circumstances that requires that the Agency rethink its policies and change them if it is unable to justify them within the legal context established by the Court's decision. The case has left the Agency without a published, regulatory limit on retained water to prevent adulteration. Because there is no longer such a limit, the case has also left the public without access to information about the characteristics of poultry products. In the absence of a specific level of retained water that is unavoidable in the production of a safe product, FSIS finds that the level of retained water is a fact that is material in that the product is being represented as meat or poultry. Failure to disclose this fact would misbrand the product.

Therefore, FSIS is requiring that meat and poultry products be labeled to show the maximum amount of water they may retain. In the absence of data, the Agency is taking the most logical and reasonable course of action available to it.

Regarding the U.S. District Court decision in the *Kenney* case, the Court agreed with the Department's contention that the PPIA (21 U.S.C. 457(b)(2)) gives the Secretary the authority to determine that the composition of a poultry product includes a limited amount of water retained from processing. The Court also stated that, given the deference that must be shown the Secretary on this matter, "the Secretary did not abuse his discretion or act contrary to law by failing to conclude that a label that does not disclose the retained water in a poultry product was false or

misleading." The Court further held that, notwithstanding the quantity-of-contents labeling provisions of the PPIA, the Secretary was within his discretion in not finding poultry with retained water to be misbranded.

However, the Court found that the Secretary acted arbitrarily and capriciously in not adequately explaining the reasons for the water retention limits for poultry products and in not explaining why water retention could not be further reduced. In other words, the Secretary did not provide a basis for determining whether and what amount of water retention should be permitted or could be considered non-adulterative, or what amount of water retention is unavoidable in a poultry product. Put another way, the Secretary did not provide a basis for distinguishing a poultry product with permissible retained water from such a product adulterated by excessive retained water. The Court also found the Secretary to have acted arbitrarily and capriciously in not according the same regulatory treatment to meat and to poultry. The Court therefore set aside the regulation that provided the water retention limits for poultry products (9 CFR 381.66(d)(2)).

Thus, this situation is distinguishable from that in *State Farm*. FSIS is not simply abandoning a long-held, well-justified position. When asked to justify its position on retained water in poultry, the Agency could find no basis for it in the record compiled when the position was adopted. Thus, the Court in *Kenney* found that FSIS water retention levels for poultry were not sustainable. When FSIS sought a reliable basis for arriving at a new level, it could find no evidence that would justify any water retention in poultry. In view of this, and the Agency's obligation, in the absence of evidence that justifies a contrary approach, to treat meat and poultry products the same way in its regulations, FSIS is left with little choice but to insist that meat and poultry products contain no retained water unless there is a substantial justification for permitting some water retention.

FSIS is not stating in this final rule what the justification for retained water should be beyond stating that it must be an unavoidable consequence of processing to meet food safety requirements. This is the only justification FSIS can find for the presence of retained water in a livestock or poultry carcass.

As stated previously in this document, the Agency has consistently required that establishments minimize retained water in meat and poultry

products, but the Agency no longer has a quantitative limit or measure other than zero-percent retained water by which to determine that retained water has been minimized. For this reason, and because the Court found that the Agency did not have a basis for determining unavoidable retained water in a product, the Agency must insist that, in addition to justifying the presence of retained water, establishments also substantiate the amount of retained water that is unavoidable.

In order to determine whether or not a poultry product is economically adulterated by retained water, the Agency must have available to it data that show what the amount of unavoidable retained water is and the amount that the product retains. Hence, the requirement that establishments collect such data according to written protocols.

Effect on Pathogens

Comment: Increasing water retention in achieving non-required *Salmonella* levels (*i.e.*, reducing *Salmonella* levels below the pathogen reduction performance standards) would defeat the purpose and goal of the rule.

Response: FSIS encourages establishment efforts to improve the safety of meat and poultry products by reducing the incidence of *Salmonella* below the prescribed performance standards. We recognize that achieving such results may cause the product to have increased retained water that would be required to be labeled on the package. However, we feel that the requirement to label a product to indicate the maximum amount of water that may be retained in the product is necessary to reflect the material fact that water has been retained.

Comment: The proposal (at 63 FR 48977) suggested the possibility that pathogens on product could increase with decreased retained water, and that efforts to reduce the retained-water level would harm consumers.

Response: The commenter misinterpreted the proposal. The commenter took out of context a step in the Agency's reasoning on the potential costs of a rejected option: that of establishing retained water limits based solely on the capabilities of existing equipment. In fact, this rule is based on the chosen option of limiting water retention to the amount that is unavoidable in meeting food safety requirements.

Comment: A consumer group commented that FSIS has paid insufficient attention to Lillard (1990), who reports a significant increase in the

incidence of *Salmonella* on post-chill poultry carcasses.

Response: The Lillard (1990) paper cited by the commenter did indeed show that *Salmonella* incidence increased on post-chill as compared with pre-chill poultry. The study identified immersion chilling as the most significant point of cross contamination in modern commercial poultry processing. However, the study also confirmed that the immersion chilling process has a washing effect, and that even though *Salmonella* incidence may have increased on the birds, the microbiological quality of the poultry carcasses, as determined by enumeration of aerobic bacteria and *Enterobacteriaceae*, improved. In other words, though bacteria might be spread from bird to bird during the process, the overall level of bacteria on the birds decreased.

Comment: A consumer group said that FSIS should determine the pathogen levels in poultry package liquid and the relationship between these levels and the risk of cross-contamination in the kitchen. FSIS should compare the benefits in lower social and medical costs from contaminated poultry, compared with increased costs to the poultry industry and consumers from eliminating all retained water.

Response: As explained in the FRIA, FSIS has assumed as an indirect benefit of the final rule the possible health effects from reducing retained water. However, to determine the relationship between pathogen levels in poultry and the risk of cross contamination in the consumer's home, and to compare the increased costs to the poultry industry of this rule with the possible health benefits to society from reducing retained water, would require a lengthy study. If such a study were a prerequisite for this final rule, the rule and its beneficial effects would be delayed.

Apparent Inconsistency in Proposed Rule

Comment: There is, apparently, an inconsistency between the preamble use of the term "raw, single-ingredient, meat, meat products, and poultry products" and the term "carcasses and parts" in the proposed regulation concerning products to be covered by the labeling requirement.

Response: "Raw, single-ingredient meat, meat products and poultry products" are broadly comprised of "carcasses and parts," whether of livestock or of poultry. The term "carcass" in the FSIS regulations denotes "all parts, including viscera, of

any slaughtered livestock" (9 CFR 301.2(p)) and in the poultry products regulations "all parts, including viscera, of any slaughtered poultry" (9 CFR 381.1(b)(9)). By the term "carcasses and parts," FSIS means a class of product included in the terms "meat and meat food product" and "poultry product," namely, raw, single-ingredient products that have been subject to no more than minimal processing, such as cutting or grinding, before being sold in commerce. The current regulatory definitions for "meat food product" and for "poultry product" include product made partly or wholly from carcasses and parts of livestock or poultry for use as human food. Thus, FSIS finds no inconsistency between the use of terms in the preamble of the proposed rule and the proposed regulatory text.

Time and Flexibility for Final Rule Implementation

Comment: If FSIS proceeds to a final rule, the Agency should give industry time and flexibility to minimize cost impacts. The industry should have flexibility similar to that provided in the sausage casings notice (FSIS Docket No. 96-020N: 61 FR 39853; July 31, 1996).

Response: FSIS believes that the commenter is referring to the labeling options that would be available to establishments subject to the proposed rule on sausage casings, "Labeling of Natural or Regenerated Collagen Sausage Casings" (FSIS Docket No. 96-020N: 62 FR 38220; July 17, 1997). Under that proposal, the labels of sausages in natural casings made from livestock or poultry viscera or regenerated collagen casings would have to identify the type of livestock or poultry from which the casings are derived, if different from the livestock or poultry meat component of the sausage. The casing identification could be on the principal display panel or in the ingredient statement. Establishments producing, manufacturing, or using natural or regenerated collagen casings would have to keep records on the livestock or poultry source of the casings.

FSIS is trying to minimize the cost impacts of the labeling requirements of this final rule by providing ample time for implementation and allowing the industry to use existing stocks of labels until they are exhausted. FSIS also is providing a degree of flexibility by permitting establishments to place the required retained water statement either contiguous to the product name or elsewhere on the principal display panel of the label.

Recommendations for Various Technical Changes

Comment: The qualifier "mature" should be restored to the term "reproductive organs" in § 381.1(b)(44).

Response: As discussed in the proposal, FSIS is revising the definition of "ready-to-cook poultry" to account for the elimination of the requirement to remove kidneys from mature birds. The qualifier "mature" was inadvertently dropped from the term "mature reproductive organs" in the proposed regulatory text and is restored in this final rule. The verb phrase expressing the action taken with respect to mature reproductive organs and kidneys is changed from "have been removed" to "may have been removed" (in § 381.1(b)(44)) to reflect the fact that the decision to remove these organs is HACCP-based. Some establishments, in operating their HACCP systems, have shown that they can determine when poultry kidneys constitute a hazard (e.g., when they contain cadmium) and when they do not.

Comment: The phrase "feet, crop and oil glands" appears twice in proposed § 381.1(b)(44).

Response: FSIS is correcting this typographical error.

Comment: Remove § 381.65(a) and (b). These are covered by HACCP or Sanitation SOP.

Response: FSIS agrees that sanitary handling and processing of poultry and the protection of poultry products from adulterants ought to be covered by establishment Sanitation SOP's and HACCP plans. FSIS is removing paragraph (b) of 9 CFR 381.65 for that reason, as proposed, but retaining paragraph (a). The paragraph requires establishments to conduct operations and procedures in a manner that will ensure sanitary processing, proper inspection, and products that are not adulterated. These are basic performance objectives for any official establishment. The requirement to ensure proper inspection is especially pertinent to poultry processing and is not duplicated by the SSOP and HACCP regulations. Paragraph (c) is being re-designated as paragraph (b). FSIS will review the requirements in these and other paragraphs for further streamlining.

Comment: Remove § 381.65(d) because it is redundant with proposed § 441.10.

Response: Proposed § 381.65(d) is a re-designation of § 381.65(k), which requires ready-to-cook poultry to be adequately drained after chilling to remove ice and free water before packaging or packing. FSIS agrees that

it is redundant with the new 9 CFR 441.10 and is removing it.

Comment: Paragraph (d)(8) in § 381.66 requiring the plant to notify the inspector of changes in washing, chilling, and draining procedures should be removed.

Response: FSIS is removing 9 CFR 381.66(d)(8) as proposed.

Comment: Proposed § 381.66(c)(2)(i), restricting how plants operate chillers, should be revised to eliminate prescriptive requirements for the continuous overflow of water between chiller sections and references to the design of multi-section chillers. The paragraph should only require that the chiller be operated in a manner consistent with meeting pathogen reduction performance standards.

Response: FSIS agrees in principle with the suggested change and is revising the paragraph. The Agency is removing the prescriptive design requirements for chillers and replacing them with a performance standard requirement that is consistent with the PR/HACCP regulations.

Comment: Proposed § 381.66(c)(2)(ii) should be revised to refer to split carcasses as defined in § 381.170(b)(22). FSIS should revise the second sentence, the chilling method to be applied to individual poultry parts, because it is not consistent with HACCP.

Response: FSIS agrees that the wording of proposed § 381.66(c)(2)(ii) should be modified as suggested by the commenter.

FSIS is removing the second sentence of the paragraph, which prohibits the chilling in water and ice of individual parts from salvage operations. While the purpose of this prohibition, to prevent the marketing of parts that retain too much water, coincides with some of the objectives of this final rule, it is a command-and-control requirement that is inconsistent both with HACCP and with the basic thrust of this final rule. FSIS published the retained-water proposal in the same issue of the **Federal Register** as the final rule permitting the continuous chilling of transversely split carcasses (63 FR 48957; September 11, 1998). The split-carcass-chilling final rule left unchanged the prohibition against the chilling in water and ice of individual parts.

This final rule, however, applies to transversely split carcasses and other portions and parts of poultry. It applies to all raw, single-ingredient, poultry products. This final rule makes redundant the requirements concerning the specific chilling method applied to these parts or portions of poultry.

Therefore, the Agency is removing these requirements.

Comment: Delete the proposed § 381.66(d)(1) and (2) as redundant with § 441.10.

Response: While 9 CFR 381.66(d)(1), which requires that poultry washing, chilling, and draining practices minimize water absorption and retention, may appear to some to be redundant with 9 CFR 441.10, it articulates a general principle with which the Agency agrees irrespective of the present rulemaking: Retained water should be minimized. 9 CFR 381.66(d)(1) does not, however, present a measurable criterion for judging minimization, as 9 CFR 441.10 does. Therefore, FSIS finds it appropriate to adopt both provisions.

FSIS finds that the proposed 9 CFR 381.66(d)(2), requiring the establishment to supply measuring devices or scales for use in measuring retained water, should be retained to ensure that both the establishment and the Agency can conduct in-plant checks for compliance with this final rule.

Comment: Delete 9 CFR 381.66(f)(3), a prior-approval requirement for FSIS approval for off-premises freezing of ready-to-cook poultry. This prescriptive requirement is inconsistent with HACCP.

Response: The commenter's suggestion is beyond the scope of the present rulemaking. FSIS regards the procedures for freezing poultry as encompassing a separate set of issues that are peripheral to the concerns of this rulemaking, which are focused on the chilling of poultry.

Effect on International Trade

Comment: The proposal could distort international trade because the only establishments that will be considered eligible to export to the United States will be those that are able to demonstrate that "residual water content is due to the final decontamination of the products and not to the chilling process."

Response: The final rule does not identify any specific post-evisceration process that an establishment must use for any purpose. Further, the rule is not expected to have significant impacts on international trade. Any imports containing retained water will have to be appropriately labeled, and poultry products are likely to be more affected than meats. Only six countries, however, Canada, France, Great Britain, Hong Kong, Israel, and Mexico, are listed as eligible to ship poultry products to the United States. Currently, about 5 million pounds of poultry imports enter the United States

annually. This is a relatively small amount of trade.

Provisions of the Final Rule

Under § 441.10(a), raw livestock and poultry carcasses and parts may not retain any amount of water resulting from post-evisceration processing, absent a demonstration, with data, by the establishment preparing them that such water is the unavoidable consequence of a process used to meet applicable food safety requirements. The data must have been collected according to a written protocol.

Under § 441.10(c)(1), the establishment must keep this protocol on file and available to FSIS personnel. The protocol must explain how the data will be collected and used in making the required demonstration for the product the protocol covers. Under § 441.10(c)(2), the establishment must notify FSIS as soon as its data-collection protocol—whether new or revised—is available to the Agency. Within 30 days after receipt of this notification, FSIS may object to or require the establishment to make specified changes in the protocol. FSIS will take this action if it determines that the protocol is not valid, or that the data collected under it will not be sufficient to demonstrate that the amount of water retained in the product is an unavoidable consequence of the process used to meet applicable food safety requirements.

FSIS is including in § 441.10(d) the expected elements of a protocol for gathering water retention data. These protocol elements were published for comment as Appendix A of the September 11, 1998, proposal.

Under § 441.10(b), meat or poultry products will have to bear a label statement of the maximum percentage of water absorbed and retained as a result of post-evisceration processes. A qualifying statement accompanying the product name could read, "may contain up to ___ percent absorbed water." The percentage must reflect the maximum percentage of water that may be retained in the product. Alternatively, the label may simply bear an accurate statement of the percentage of retained water in the product. Establishments having data or information to demonstrate that their products do not contain retained water will not have to label the products and could include a no retained water claim on the product label. The labels will be generically approved pursuant to 9 CFR 317.5(b)(2) or 381.133(b)(2).

This requirement, which is responsive, in part, to the AMI petition discussed above, would ensure that accurate information concerning the

product is conveyed to the consumer in accordance with the misbranding provisions of the FMIA and the PPIA (especially 21 U.S.C. 601(n)(1), (6); 453(h)(1), (6)). It will ensure that the product labeling is not misleading with respect to water retained by the product.

FSIS had proposed that the retained-water statement be contiguous to the product name on the product label. In response to comments, the Agency is providing some flexibility in this matter by also permitting the statement to appear either contiguous to the product name or elsewhere on the principal display panel of the label. The placement of the required information on the label will ensure that the information will be likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

With the required labeling information, consumers will be in a better position to compare packaged raw meat or poultry products containing retained water with alternatives in the meat case. The market will provide incentives to plants to adopt new, cost-effective technologies for reducing retained water. The rule will not affect raw products that now bear complete labeling or nutrition labeling, such as pre-basted frozen turkeys, or further processed products, such as deli meats. This final rule also will not cover cooked and cured pork products, such as those subject to protein-fat-free requirements (9 CFR 318.19(a)(5), 319.104–105, 327.23).

As stated elsewhere in this document, the Agency's concern in this rule is to ensure that products in commerce will not be adulterated or misbranded. To alleviate some confusion on this point that was expressed in a number of the comments received, the labeling provision in new § 441.10(b) has been more precisely phrased than in the proposal.

Changes in Poultry Chilling Regulations

FSIS is amending the chilling requirements for poultry by removing various prescriptive requirements and specifications, such as the minimum amount of fresh water intake by continuous chillers for each poultry carcass. The removal of those requirements should encourage processors to use the most efficient and effective methods of controlling microorganisms. Establishments will have the flexibility to take advantage of the latest technologies and procedures.

This final rule amends 9 CFR 381.65, which concerns general operating procedures, by removing provisions that are redundant, excessively detailed, or

inconsistent with the PR/HACCP final rule. The final rule eliminates current paragraph (b), the prohibition on handling and storing materials that could cause adulteration of poultry products in any room where poultry products are processed, handled, or stored. This provision is unnecessary because HACCP plans have been implemented in every affected establishment and because each HACCP plan must specify the measures to be taken to protect poultry products from physical, chemical, or biological contamination. The requirements in paragraphs (a) and (c) of 9 CFR 381.65 will be retained as paragraph (a) and (b) because they set out general principles of sanitation and commercial practice to which all establishments must adhere.

The requirements in paragraphs (h) and (j) of 9 CFR 381.65, relating to poultry thawing and dressing techniques, are being replaced with two performance standards. The first requires simply that establishments use thawing procedures that will prevent adulteration of, or net weight gain by, the product. The second requires that water used in washing ready-to-cook poultry be permitted to drain freely from the carcass. A new paragraph (c), which replaces paragraph (h), requires that frozen poultry be thawed for further processing in a manner that will prevent product adulteration but would not require that any specific thawing method be used.

The thawing regulation that is being replaced does not prevent practices that may constitute hazards to food safety. For example, it does not prevent re-exposure of thawed, or partially thawed, product to a thawing medium that may have become contaminated by previous use and that may be too warm to prevent microbial growth. Paragraph (h)(1)(i) specifies a maximum permitted thawing medium temperature of 70 °F, which is too high to prevent microbial growth in product that is re-exposed to or held in the medium. The regulation conflicts with HACCP because establishments should assess thawing processes when conducting their hazard analyses. Establishments must be given the responsibility and flexibility to choose thawing measures that are effective and that do not create food safety hazards.

A new paragraph (d) replaces paragraph (j), which specifies the manner in which carcass wash water is to be drained, with a performance standard requiring simply that the wash water be permitted to drain freely from the carcass.

Paragraph (d), which contains a requirement to remove kidneys from

mature chickens and turkeys, is being eliminated. The kidneys of mature chickens and turkeys are a source of cadmium, which can accumulate in the human liver and kidneys and cause acute or chronic health problems. Kidneys with excess cadmium are a "food safety hazard reasonably likely to occur" that establishments will identify in their hazard analyses and control through their HACCP systems. Thus, paragraph (d) is redundant with the HACCP regulations. The requirement to remove kidneys is referenced in the definition of "ready-to-cook poultry" at 9 CFR 381.1(b)(44). Therefore, the Agency is amending that definition.

Paragraph (i), which specifies how poultry carcasses are to be cut open for evisceration, is being removed. The regulation is outdated and prescriptive and may be an obstacle to improved product safety. The regulation is intended to ensure that opening cuts are made without cutting the intestinal tract and without contaminating the carcass. Unnecessary cuts are prohibited because they may result in carcass contamination during evisceration or excessive water absorption during chilling. The regulation is also intended to maximize the viewing of the interior and viscera of the carcass during the postmortem inspection.

In recent years, the poultry industry has developed new methods of poultry evisceration that do not result in adulteration. For example, ultrasound techniques are available for use as a diagnostic aid to detect malformities or other defects before carcasses are opened. Also, equipment is available that can remove the viscera intact, using vacuum suction, without breakage or spillage of intestinal contents, and other available evisceration systems require that the carcass be opened by a longitudinal cut. The regulation generally limits the opening cut to the area around the vent (cloaca) to prevent birds from carrying excess water under the skin that could cause water-control test failures. Because of this limitation, the new technologies, which can improve efficiency and product wholesomeness, are not likely to be implemented. Establishments, however, should have the flexibility to innovate and to implement promising new technologies, consistent with their HACCP plans.

Paragraph (k), a requirement to adequately drain ready-to-cook poultry after chilling to remove ice and water before packaging, is redundant because of new part 441, and FSIS is removing it.

Paragraphs (l) through (p) are also being removed. These paragraphs

include requirements concerning the chilling of poultry parts, the removal from establishments of offal resulting from evisceration, the cleanliness of containers, the sturdiness of packaging materials, and the use of protective coverings. These are all matters that are to be addressed by establishments in their Sanitation SOP's and HACCP plan.

Finally, paragraph (q), concerning the harvesting of detached ova for human food, is being re-designated as paragraph (e) and revised to reduce duplication with requirements in § 590.440 for handling ova and to eliminate a command-and-control requirement to identify the ova past the point of inspection. Also, the reference to a section of the egg products inspection regulations has been amended to account for the recent redesignation (63 FR 72353) of those regulations to Title 9, CFR.

In 9 CFR 381.66, paragraph (a) is being revised. This paragraph requires poultry to be chilled or frozen in a manner that promptly removes animal heat from the carcasses and does not adulterate the product. The second sentence of the paragraph, a command-and-control requirement to file a description of the chilling or freezing procedures with the inspector in charge, is being removed.

The general chilling requirements for poultry, paragraph (b), remain the same. FSIS has long regarded the chilling of poultry to a safe internal temperature within a minimum number of hours as a useful food safety precaution. However, as mentioned above, the Agency intends to undertake rulemaking on this matter. The table of maximum times and temperatures in paragraph (b) is based on the duration of the lag phase of bacterial growth on the surfaces of dressed, ready-to-cook poultry carcasses under plant conditions. Although interested persons are encouraged to submit data that would justify a change in this provision, amending the paragraph is outside the scope of the present rulemaking.

The numerous detailed, prescriptive, command-and-control requirements in paragraph (c) are being removed. For example, the amended paragraph (c)(2)(i) does not specify chilling media temperatures or the use of recording thermometers. New paragraph (c)(1) requires that potable water be used, and new paragraph (c)(2)(i) requires that sufficient water be used to maintain the sanitation of chilling media. However, specific requirements (paragraphs (c)(2)(ii)-(iii) and (c)(2)(v)) concerning the operation of continuous chilling systems, including the minimum

amount of fresh water intake per bird, are being removed.

Paragraph (c)(2)(iv) is being re-designated as (c)(2)(ii) and revised as discussed above in the response to comments. This paragraph, which concerns the chilling of major portions of poultry carcasses, was the subject of a September 18, 1999, final rule (63 FR 48958; proposed at 62 FR 31017; June 6, 1997).

Paragraph (c)(2)(vi), the highly detailed and prescriptive requirements concerning water-reconditioning systems for poultry chillers, including the requirement for prior approval of such systems by FSIS, is being removed. Establishments subject to the poultry product inspection regulations are not using these systems because none have proven feasible in commercial operations.

The requirements in paragraphs (c)(4)(i) and (c)(4)(ii), concerning the holding of poultry in chilling tanks, are being removed, and in paragraph (c)(5), the highly specific requirements concerning the use of continuous chillers to chill giblets are also being removed. Establishments will address the food safety hazards associated with these procedures in their HACCP plans. However, the requirement to chill giblets to less than 40 °F in under 2 hours will remain at this time.

Paragraph (d) of § 381.66 is being completely revised. The general requirement to minimize water absorption by raw poultry, and the requirement to furnish equipment necessary for water tests, will remain. The tables setting water absorption and retention limits for the various kinds and weight classes of poultry are being eliminated, as are the requirements for daily water testing by FSIS inspectors. The requirement to notify FSIS of any adjustments in washing, chilling, and draining methods is also being removed.

FSIS is removing paragraph (d)(10), which specifies how poultry may be ice-packed in barrels and requires FSIS approval for the use of alternative types of containers. Establishments will ordinarily have procedures for determining appropriate containers for a product. If, in their hazard analyses, they determine that there are food safety hazards reasonably likely to occur that are associated with containers, they will address these hazards in their HACCP plans.

The Agency is likewise removing paragraph (d)(11), which requires establishments to prevent free water from being included in giblet packages. Among other things, paragraph (d)(11) requires use of a specific type of giblet wrapping material and incorporates by

reference the testing standards that must be met in evaluating the material. This kind of detailed specification is no longer necessary under the Agency's new regulatory approach. Also, establishments must comply with the regulations on net quantity of contents and net weight (9 CFR 317.18-19, 381.121-121b). This provision will give establishments flexibility in choosing giblet packaging materials, but also the responsibility to ensure that their choice is suitable, as well as safe, for this use. By complying with the retained-water limitation requirements (discussed below) and by appropriately labeling product, establishments will be ensuring that water absorption is controlled as well as ensuring that consumers are appropriately informed.

Finally, paragraph (e), on air chilling, and paragraph (f), governing the freezing of poultry, are being retained substantially in their present form. Paragraph (f)(6), concerning immersion or spray freezing compounds and equipment, will be removed because it is a prior-approval requirement inconsistent with the HACCP regulations and is duplicative of other inspection regulations.

Implementation of the Final Rule

FSIS foresees little difficulty in implementing the revised poultry chilling regulations, which relieve poultry establishments of certain burdens without raising misbranding or adulteration issues. FSIS will ensure compliance with the revised regulations through normal inspection.

To implement the retained-water provisions of this final rule, on the other hand, both the Agency and the regulated industry will have to adopt new procedures. FSIS personnel will verify an establishment's control of water retention by checking establishment records or by conducting in-plant or in-distribution tests of sampled products. FSIS intends to sample product in distribution channels and in official establishments, using the oven-drying method described in Appendix A to determine the amount of moisture in product samples. At poultry processing establishments, the traditional method of weighing birds before and after chilling to determine moisture pick-up will continue to be available to both the Agency and the establishments as a process control check.

FSIS also will conduct independent tests of the establishment's retained-water control as part of investigations of suspected problems or in the course of special studies. The overall focus of the Agency's activities will be to ensure that raw products that enter commerce do

not contain water in excess of the amount that is unavoidable in achieving food safety objectives.

FSIS is providing a full year from the publication date for implementation of this final rule to mitigate the effects of the rule on establishments that may have to consider changing or updating their chilling processes and equipment. The extended implementation period should be especially helpful to establishments that meet the small-business-entity size criteria defined by the Small Business Administration.

During the period before the effective date, FSIS will provide its field inspection personnel with the instructions they will need to carry out their review of protocols and verify that establishment data demonstrate the amount of water retention that is unavoidable and support product labeling statements. The Agency will prepare sampling, testing, and document review procedures for Agency use; train Agency personnel in the new procedures; and develop a new national reference database on the natural moisture content of raw products in the various meat and poultry product classes with which this rule is concerned.

To develop this national database on natural moisture content, FSIS will test product samples drawn at official establishments. The Agency will use a common, analogous point of reference in livestock carcass and poultry product preparation at which to determine the naturally occurring percentage of moisture in meat products and poultry products, namely, the point at which the calculated yield weight is determined. (Calculated yield weight of a carcass is its predicted "green weight"—the weight of the carcass after dressing and before any additional in-plant processing.) In poultry plants, this point is at the re-hanging operation (after de-feathering and hock removal). The analogous point in livestock slaughtering establishments is before the pre-evisceration carcass wash. FSIS has chosen these common reference points to reduce the possibility of measurement errors caused by various carcass-washing procedures.

To determine the moisture content of a product sample, the Agency plans to rely on the oven-drying method described in its Chemistry Laboratory Guidebook and in Appendix A of this document. This method involves weighing, before and after drying, a dish containing a homogenized meat or poultry product sample. The method can be applied to products at any point in processing or distribution. Similar oven-drying methods for determining

the amount of moisture in meat, meat products, and poultry products are described in the Official Analytical Methods of the Association of Official Analytical Chemists and in ISO 1442, published by the International Organization for Standardization.

After developing sufficient information on the natural water content of raw meat or poultry products, FSIS will be in a better position to verify that the establishment is complying with the requirement to minimize retained-water amounts when the final rule becomes effective. To determine whether an establishment is complying with the regulations, the Agency will verify the establishment's protocol documentation and the data collected under the protocol, including data on retained-water minimization and pathogen reduction. FSIS also will verify compliance with the requirement that product labels display retained-water amounts, and that the actual retained water in the products corresponds to the labeled amount.

Usually, the verification will consist only of a document check. However, the Agency will occasionally test products for moisture content to verify the establishment's findings.

FSIS will randomly sample raw meat and poultry products both in-plant and in-distribution and will test the products for retained water content. FSIS will collect and run tests on product samples and statistically analyze the results of the tests.

The Agency will directly measure the moisture content of the raw products sampled in-plant at pre-shipment using its oven-drying method. The Agency will compare the results of these tests with the naturally occurring amounts of water in the national reference database and with the retained-water statements on the product labels to determine whether the products are in compliance with the requirement to minimize retained water, and whether they are correctly labeled with a retained-water statement.

To measure the amount of retained water and determine compliance with the final rule in in-plant situations when using the weighing method, FSIS will compare product weights taken after chilling, but before the product leaves the establishment, to the pre-final-wash weight or (in poultry plants) the calculated yield weight. In livestock slaughtering plants, the Agency expects to be comparing pre-final wash or "hot" carcass weights with the "cold weights" taken after spray chilling in establishments using the spray-chill process.

The Agency does not expect to use calculated yield weight data as a basis for comparing hot and cold livestock carcass weights because such data are not available for most livestock establishments. The great majority of such establishments do not weigh carcasses after de-hiding or de-hairing and before the pre-evisceration wash. FSIS is aware that there may be a slight, measurable gain in carcass weight immediately after the pre-evisceration wash. However, this gain is usually more than offset by moisture loss on the kill floor. Thus, the "hot" carcass weight does not include a moisture gain resulting from the pre-evisceration wash.

FSIS is not prescribing any particular method that official establishments must use to measure the amount of retained water in their products. Establishments are free to use any scientifically valid method for this purpose. Establishments may want to use the food chemistry method described in Appendix A and used by FSIS to determine the moisture content of their products. Because of the destructive nature of the method and the delay in getting results, establishments may find it more convenient on a day-to-day basis to compare the weights of carcasses and parts before and after they are exposed to washes, sprays, or immersion chilling. The data from such checks would have to be available to FSIS to verify. As mentioned, poultry establishments will continue to be able to use the traditional method involving the weighing of birds before and after chilling as a check on water retention controls.

FSIS also will conduct surveys of products in plants and in distribution channels to obtain an overview of national compliance with the regulations and to update the national reference database on the moisture content of meat and poultry products. The Agency will compare the results of these surveys with the information in its database to determine whether any adjustments in its enforcement of the regulations are necessary. Comments are requested on sampling and survey methods that the Agency should consider using both for initially building the national reference database and for the on-going compliance overview.

FSIS will continue to verify that products are in compliance with the net-weight requirements for meat and poultry products. As stated elsewhere in this document, neither the net-weight requirements nor the obligation of an

establishment to comply with them is affected by this final rule.

FSIS expects there to be requests for adding water solutions to meat and poultry manufacturing trimmings in an effort to reduce the pathogen levels on product. Such applications may or may not result in retained water, as well as chemical residues. FSIS expects such applications to adhere to the same criteria as other applications resulting in retained water. FSIS will allow establishments to implement the provisions of this final rule in advance of the effective date provided the establishment informs the appropriate District Office in order that inspection program personnel are provided with the necessary instructional materials. FSIS expects to provide instructions regarding early implementation of the final rule.

Executive Order 12866 and Regulatory Flexibility Act

Current Practices in the Poultry Industry

The regulations controlling retained water in poultry carcasses have consisted of three major components: (1) A performance standard requiring washing, chilling, and draining practices that will minimize water absorption and retention at time of packaging; (2) limits for maximum retained water in birds that will be packaged as whole carcasses; and (3) limits for maximum retained water in birds that will be ice-packed or cut up prior to packaging. The performance standard is to minimize the water that is absorbed and subsequently retained, *i.e.*, it is not interpreted as requiring minimization of both water absorption and water retention. In implementing the standard, FSIS concludes that the performance standard is met when retained water is under the maximum limits.

Until the *Kenney* case, argued in U.S. District Court and referred to earlier in this document, various limits on maximum retained water applied to the various weight classes of whole chickens and turkeys. For example, the maximum retained water for most whole chickens weighing 4.25 pounds or less was 8 percent. The maximum retained water for chicken that is ice-packed or subsequently cut up into parts has been 12 percent. In its July 1997 decision, the U.S. District Court found that the regulation specifying water absorption and retention limits for ready-to-cook poultry that is to be frozen, cooked, or consumer-packaged as whole poultry was arbitrary and capricious because the Secretary of Agriculture did not explain in the

rulemaking record how he determined the particular water retention levels, why water retention cannot be reduced below those levels, or why meat and poultry should be treated differently with respect to water retention. The Court therefore set aside the water retention limits for poultry to be consumer packaged, frozen, or cooked as whole poultry. In the wake of the decision, there have been no regulatory criteria by which to determine whether retained water has been minimized in chilled or frozen whole birds.

As discussed previously, FSIS is mandated by the FMIA and PPIA to prevent the distribution in commerce of meat or poultry products that are adulterated or misbranded. Without limits on retained water, FSIS cannot adequately protect consumers from adulteration and misbranding due to excessive retained water in whole birds. Hence, the Agency is establishing a new regulatory basis for minimizing retained water.

FSIS is replacing the regulations under which poultry establishment was considered to be "minimizing" retained water when it was operating within the regulatory limits. FSIS is aware that not all establishments have really been minimizing retained water. Data analyzed for this FRIA show that some poultry establishments have been controlling their processes to retain the maximum allowed amount of water. While this is considered acceptable in the sense that product is not adulterated, it is not consistent with a regulatory intent to minimize. However, it may be consistent with food safety objectives to reduce pathogens.

The existence of the 12-percent limit for cut-up chicken is in itself inconsistent with the concept of minimization. Many establishments pack both whole-and cut-up chicken. In meeting the 8-percent limit for whole birds, they demonstrate that their minimum is below 8 percent. The 12 percent limit serves as an opportunity to maintain water levels in cut-up poultry. The 12-percent limit is also available as default when the 8-percent limit is not achieved. An establishment can divert birds to cut-up operations when they fail the whole bird limit.

With this final rule, FSIS also is addressing the issue of inconsistent treatment of meat and poultry in its regulations because, under the final rule, both meat and poultry products will be subject to the same requirements.

Need for the Rule

The FMIA and PPIA, which the Agency administers, make clear the

obligation of producers of raw meat or poultry products not to mislead consumers. FSIS thinks that if they market as meat or poultry a product that contains something other than meat or poultry, that fact should be disclosed. It has been the consistent policy of FSIS to ensure that information that accurately discloses the contents of meat or poultry products is made available to consumers of those products.

As noted earlier in this document, a 1997 U.S. District Court decision set aside the regulatory limits on retained water in poultry products. The District Court found that the Agency had not presented the basis for its retained water levels, why water retention could not be reduced below those levels, or why meat and poultry should be regulated differently with respect to water retention.

The District Court ruling left FSIS without regulatory criteria for determining whether retained water had been minimized or what levels constituted adulteration. The Agency also no longer had available published retained water limits that it could enforce in an effort to protect consumers from misbranded product.

Analysis of Alternatives

This rule resulted from an analysis of six alternative regulatory approaches for addressing retained water in raw meat and poultry products. The six alternatives are as follows:

1. No limit on retained water but mandatory labeling that identifies the percentage of retained water in the product. FSIS did not recommend this alternative for adoption because it would not reduce retained water so that economic adulteration would continue to persist. It would, however, be advantageous to consumers because it would enable them to compare alternative packages of poultry with varying quantities of retained water and prices and select the package to suit their budgets.

2. A requirement that all establishments meet a water limit based on best available technology, with mandatory labeling to indicate any retained water. FSIS did not propose this option because the adoption of the best available technology would be a step backward into a regime of command and control. It would also impose considerable costs on plants that are currently not employing such a technology without a corresponding improvement in food safety. For example, if the best available technology is determined to be the continuous chillers, there are several small and medium size plants that do not employ this technology. The economic impact of such an option would be significant on these plants. In the current environment of regulatory reform, FSIS is moving away from command and control to incentive-based performance standards. Such standards permit plants to

reduce their retained water levels irrespective of the technology they employ. A moisture limit based on the best performance achievable with existing equipment, with mandatory labeling to show any retained water. FSIS did not adopt this option because, beyond stating that water retention should be minimized consistent with maximizing the safety of the product, it would be difficult, if not impossible, for FSIS to define the best performance achievable. This option would also encourage establishments to continue to use existing equipment, perhaps beyond the economic life of the equipment.

3. A standard of zero retained moisture. FSIS did not recommend this option because the costs of this option might exceed the benefits. Finally, some minimum amount of retained water might be necessary for reducing pathogens.

4. A requirement that no retained water could be included in net weight. FSIS did not recommend this option for adoption because it would require establishments to adjust their scales to account for retained water. The costs of adjusting these scales could be excessive. Moreover, enforcement of net weight requirements is an area where Federal, State and local authorities share responsibility and must cooperate. The enforcement procedure, as adopted by the National Conference on Weights and Measures, are published in NIST Handbook 133, Third Edition, Supplement, "Checking the Net Contents of Packaged Goods". The National Institute of Standards and Technology (NIST) has a statutory responsibility for "cooperation with the states in securing uniformity of weights and measures laws and methods of inspection.

5. A requirement of zero retained water unless the water retention is unavoidable in processes necessary to meet food safety requirements, e.g., to reduce pathogens, with product labeling to indicate the presence of retained moisture, where applicable. FSIS recommended this option because it prioritizes food safety above retained water. It also includes the provision of labeling the retained water to help consumers decide amongst alternative packages with different levels of retained water and prices.

FSIS chose the last alternative. The selected option does not allow retained water in an affected product unless it is an unavoidable consequence of the process or processes used to meet applicable food safety requirements. By "unavoidable consequence" the Agency means an unavoidable and irreducible side effect. Under this option, inspected establishments, associations, or other groups, using acceptable protocols must establish levels of unavoidable retained water. Also, the maximum amount of retained water that can be present must be stated on the product label. FSIS has found that this option is likely to provide greater benefits than other options because it is more flexible and likely to prove less costly than some of the proposed alternatives. A food safety requirement can be a regulatory

prescription, such as the temperature to which a product must be chilled and held. It can also be a preventive measure taken at a CCP or a critical limit in the establishment's HACCP plan. For example, the proposed rule might increase human handling for transferring products from the chillers to the freezer, thereby increasing cross contamination. A critical control point at such handling could reduce, if not eliminate, cross contamination. Given a food safety requirement, an establishment must choose a method for satisfying the requirement.

The method selected for meeting food safety requirements may have unintended consequences that cannot be eliminated. A consequence of an antimicrobial treatment of carcasses or a carcass chilling method may be an increase in the water content of carcasses and parts. FSIS is requiring that the amount of water that might be retained in carcasses and parts as a result of using such an anti-microbial or chilling method be an unavoidable and irreducible effect of using that method.

To be applicable to the raw products of an inspected establishment, a non-zero retained-water limit would have to be based on supporting data collected in accordance with a written protocol that has been subject to review by FSIS. This final rule will allow an individual establishment or industry trade association or other group using the same or similar processing techniques to develop a protocol and carry out data-generating studies according to the protocol. Depending on the design of the protocol, the data gathered could justify water-retention limits for a single establishment, a group of establishments with similar equipment processing similar classes of raw product, or all such establishments in an industry. To establish a non-zero retained water limit, an inspected establishment, industry trade association, or other group would have to generate the necessary supporting data. The labels of products would have to state the presence of retained water in the products.

Cost Estimates

The analysis estimates a range of costs the poultry industry will incur to meet this new regulatory requirement. If establishments are able to demonstrate that current levels of retained water are unavoidable in achieving applicable food safety standards, establishments will not incur additional costs for reducing retained water. These establishments would only incur costs for establishing limits and costs for labeling the product. The costs of

establishing limits for the poultry industry are estimated to be \$1.5 million (in 1998 dollars). This estimate is based on each establishment conducting its own tests. The cost should be lower if associations or other groups establish limits for different types of chiller systems. Labeling costs are estimated to be \$18.4 million (in 1998 dollars) if all raw, single-ingredient poultry continues to retain water.

To the extent that establishments cannot demonstrate that current retained water levels are unavoidable in achieving applicable food safety standards, significant costs could be incurred as establishments modify processes to minimize retained water levels. FSIS estimates that the average retained water for chicken, as a percentage of net weight is currently in the 5.0 to 6.5 percent range. The corresponding level for turkey is 4.0 to 4.5 percent. Reducing retained water could entail a wide range of process modifications, depending on the type of chilling equipment currently used and amount of retained water that would have to be removed. FSIS estimates that, if extensive modifications to chilling systems were needed throughout the industry, the fixed costs associated with removing a substantial portion of the existing retained water could run to well over \$100 million. The substantial portion was defined in the PRIA, viz., that it would take 12 hours to drain substantial portion of the retained water in chickens. The 12-hour drain would reduce the existing level range from 5–6.5 percent, by 4 to 5 percentage points, i.e., to 1–1.5 percentage range, or by about 80 percent. The fixed costs estimates of these extensive modifications were taken from USDA/ERS study, discussed in the PRIA, and are summarized below.

The drip-dry process for chicken requires production workers to remove chickens from a production line, place the chickens in vats, place the vats in a cool room for 12 hours, and return the chickens to the poultry line. Besides labor, this process requires cooling space, stainless steel vats that hold up to 500 chickens, and a forklift to transfer chickens from a production line to a storage room and then back to the line after the drip-dry process is complete.

To extend draining or dripping time, many establishments would have to add refrigerated facilities, purchase vats for storing birds being drained, hire additional personnel, and purchase additional stock handling equipment. There would be inventory costs due to holding birds off the market for a longer time before shipment. Holding birds at inspected establishments would also

reduce the corresponding retail shelf life.

The ERS staff developed some cost estimates for holding poultry based on the following industry input:

1. One common method of draining uses stainless steel vats at a cost of \$1,000 each.
2. Vats hold approximately 500 chickens or 100 turkeys.
3. Cooler space costs \$125 per square foot.
4. Vats can be stacked two high.
5. Stacked vats with aisles require 12 square feet of space per vat.
6. Forklifts to move vats cost \$24,000 each.

The Daily Moisture Records sometimes include a record of the additional drain time required. The time varies with the initial water level, the drain configuration and the location of the excess water, i.e., under skin versus between muscle tissues or within muscle tissues. Based on the violations data, it was determined that a 12-hour drain would be the minimum time required to remove most of the retained water from chickens.

Most of the drain time for turkeys ranged from ½ to 1 hour on an “hour per percentage reduction” basis. All of the turkey violations noted were less than 1 percent above the existing limit whereas some of the chickens started at water levels 4 to 5 percentage points above the existing limits.

To drain chickens for 12 hours is equivalent to saying the industry would need to add extra capacity to drain half a day’s production, since most chicken is processed in establishments running two shifts.

Since average chicken production is 29.5 million birds per day (assuming a 260-day work year), half a day’s production is 14.75 million birds. Using the above factors, this would require 29,510 vats at \$29.5 million; 354.12 square feet of cooler space at \$44.3 million and \$4.8 million of forklifts assuming the largest 200 chicken establishments would each require an additional forklift. In this 12-hour case, the total fixed costs would be \$78.6 million (\$29.5 + 44.3 + 4.8).

In addition, half a day’s turkey production at 557,000 birds requiring 5,570 vats would cost \$5.57 million and cooler space would cost \$8.36 million. Assuming that the largest 70 turkey establishments would require an additional forklift at a cost of \$1.68 million, the total fixed costs for draining all turkeys for 12 hours would be \$15.61 million (\$5.57 + 8.36 + 1.68).

In short, the total fixed costs for a 12-hour draining of chickens and turkeys would be \$94.2 million (\$78.6 +

\$15.61). Since these costs were estimated in 1997, updating them with to the year 2000 would amount to about \$100 million.

Variable costs of holding poultry to drain would include increased labor costs, higher utility costs, increased overheads, and the cost of carrying additional inventory. Holding half a day’s production is equivalent to continually storing a wholesale value of \$37 million poultry (\$19.2 billion divided by 520 shifts/year). At a 5 percent interest rate, the annual cost of draining poultry for 12 hours would be \$1.85 million.

It would be conservative to assume a minimum average of one additional employee per establishment. Since there are 300 establishments, the cost at \$21,500 per employee per year would result in an annual labor cost of \$6.4 million (\$21,500 x 300). The total variable costs of \$8.25 million (\$1.85 + \$6.4) would increase to about \$10 million in the year 2000 when updated by an increase in Employment Cost Index.

To sum up, the first year costs of draining poultry would amount to \$110 million (\$100 m + \$10 m). These are the costs of reducing retained water in the range of 1–1½ percent. Since the retained water is not reduced to zero, these are merely the lower bounds. The upper bound costs would be the costs of reducing retained water to zero percent.

However, if extensive modifications were not needed, the industry would only incur the costs of establishing retained water limits and meeting the labeling requirements of the final rule.

Benefits of Final Rule

Because of longstanding industry petitions and the decision in the *Kenney* case, FSIS has had to develop new regulatory requirements to carry out its responsibilities for protecting the public from economic adulteration. Prevention of economic adulteration is a consumer benefit. Consumers also will benefit from the additional information on retained water that will be provided as a result of the labeling requirement. The information on retained water should contribute to a sounder basis for purchasing decisions. Consumers are currently not being informed about the amount of retained water. Consumers will benefit from having improved knowledge of product quantity in terms of meat or poultry meat content.

The final rule will provide the meat industry with additional flexibility for meeting the pathogen reduction performance standards. Meat processors will be able to use pathogen reduction techniques without having to be

concerned about meeting the existing zero retained water requirement. Of course, if their single-ingredient raw products retain water, the products will have to be labeled to indicate how much water may be retained.

This final rule also will provide affected establishments with increased flexibility to choose the most appropriate means for implementing HACCP plans for protecting the safety of raw product while minimizing the potential for economic adulteration. By removing certain command-and-control requirements and providing increased flexibility for HACCP implementation, this final rule may reduce the costs of HACCP implementation.

As discussed in the preamble, this final rule eliminates many requirements, including the following:

1. The requirement that poultry establishments provide FSIS with a description of all chilling and freezing procedures.

2. The requirement that poultry establishments notify FSIS before any changes in chilling procedures are implemented and provide FSIS with test results demonstrating the effectiveness of the changes.

3. The requirements that meat carcasses cannot show any weight gain resulting from the use of carcass spray systems.

4. Elimination of minimum water intake requirements for immersion chillers.

Finally, the rule will also provide all affected establishments with the flexibility and market incentives to implement new procedures for meeting pathogen reduction performance standards. In addition, by replacing command-and-control requirements with HACCP-consistent performance standards, the final rule will eliminate some recordkeeping and reporting burdens, provide for increased flexibility, and reduce the costs of HACCP implementation.

Impact on Small Entities

The final rule should not have a significant impact on a large number of small businesses. Almost half of all federally inspected poultry slaughter establishments are large business entities, based on the Small Business Administration size criterion of more than 500 employees.

These establishments, and indeed most poultry establishments, use immersion chilling to meet the existing chilling requirements for poultry, e.g., 9 CFR 381.66(b)(2) requires that poultry carcasses under 4 pounds must be chilled to 40 °F within 4 hours following evisceration. It follows that,

for most poultry establishments, the unavoidable retained water amount is the minimum level that can be reached with existing immersion chiller equipment while still meeting the chilling requirement. FSIS recognizes that this minimum must be established within practical limits for operating parameters such as drip time and chiller water temperature. The industry already has information concerning the chiller variable settings that minimize water retention. Therefore, the poultry industry can establish water retention limits for various chiller systems with minimal costs. FSIS also recognizes the possibility that some poultry establishments may have to use anti-microbial interventions that result in higher levels of retained water to meet the *Salmonella* standards than they do to meet the existing chilling requirements.

Fifty to 60 poultry slaughter establishments process under a million birds annually. Many of these smaller operations do not use continuous immersion chillers. They use ice or slush to meet the existing chilling requirements. Few, if any, would have to reduce the current level of retained water. The establishments most affected by this final rule are the firms operating immersion chillers in a manner that targets the maximum allowable retained water.

This final rule should not have a significant impact on the meat industry because that industry is already achieving zero-percent retained water. This final rule, however, provides an alternative for establishments that are having or will have trouble meeting the *Salmonella* performance standards. These establishments could use a full range of anti-microbial rinses or hot-water rinses without having to worry about meeting a zero-percent retained-water limit. If they can demonstrate that they need a non-zero limit to meet the *Salmonella* standards, they can use the flexibility provided by the final rule and establish a new water limit as long as they state the maximum percentage of water absorbed and retained on product labels. Of the meat products affected by this final rule, edible organs prepared in slaughtering plants are most likely to retain water. Of the 1,200 establishments that prepare these products, about 85 percent are small. Most of these establishments will have to label their products to indicate the maximum retained-water percentage in the products.

Executive Order 12988

This final rule has been reviewed under Executive Order 12988, Civil

Justice Reform. States and local jurisdictions are preempted by the Federal Meat Inspection Act (FMIA) and the Poultry Products Inspection Act (PPIA) from imposing any marking or packaging requirements on federally inspected meat and meat products or poultry products that are in addition to, or different than, those imposed under the FMIA and PPIA. States and local jurisdictions may, however, exercise concurrent jurisdiction over meat and poultry products that are outside official establishments for the purpose of preventing the distribution of meat or poultry products that are misbranded or adulterated under the FMIA or PPIA. States and local jurisdictions also may exercise concurrent jurisdiction, for the same purpose, over imported meat and poultry products that are not at an official establishment after the entry of such imported articles into the United States.

This final rule is not intended to have retroactive effect.

There are no applicable administrative procedures that must be exhausted prior to any judicial challenge to the provisions of this final rule. However, the administrative procedures specified in 9 CFR 306.5 and 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 FSIS employee relating to inspection services provided under the FMIA or PPIA.

Executive Order 12898

Pursuant to Executive Order 12898 (59 FR 7629; February 16, 1994), "Federal Actions to Address Environmental Justice in Minority and Low-Income Populations," FSIS has considered potential impacts of this final rule on environmental and health conditions in low-income and minority communities.

This final rule will provide new, uniform regulations limiting the amount of water retained by raw, single-ingredient, meat and poultry products as a result of post-evisceration processing, such as carcass chilling, considered necessary to minimize pathogen growth on the products. As explained in the economic impact analysis, the regulations should generally benefit consumers of meat, meat products, and poultry products. The regulations will not require or compel meat or poultry establishments to relocate or alter their operations in ways that could adversely affect the public health or environment in low-income and minority communities. Further, this final rule will not exclude

any persons or populations from participation in FSIS programs, deny any persons or populations the benefits of FSIS programs, or subject any persons or populations to discrimination because of their race, color, or national origin.

FSIS estimates that as many as 4 percent of meat and poultry establishments under Federal and State inspection are owned by women or members of non-white minority groups. Therefore, of the establishments affected by this rule, as many as 4 percent of the establishments may be under female or minority ownership. FSIS has no reason for supposing, however, that the effects of this rule, whether adverse or beneficial, on such establishments would be disproportionate.

Additional Public Notification

Public awareness of all stages of rulemaking and policy development is important. Consequently, in an effort to better ensure that minorities, women, and persons with disabilities are aware of this final rule, FSIS will announce it and provide copies of this **Federal Register** publication of this final rule in the weekly FSIS Constituent Update. The FSIS Constituent Update is communicated via fax to over 300 organizations and individuals. In addition, the update is available on line through the FSIS web page located at "http://www.fsis.usda.gov". The update is used to provide information regarding FSIS policies, procedures, regulations, **Federal Register** notices, FSIS public meetings, recalls, and any other types of information that could affect or would be of interest to the Agency's constituents/stakeholders. The constituent fax list consists of industry, trade, and farm groups, consumer interest groups, allied health professionals, scientific professionals, and other individuals who have requested to be included. Through these various channels, FSIS is able to provide information to a much broader, more diverse audience. For more information and to be added to the constituent fax list, readers of this document may fax their requests to the Congressional and Public Affairs Office, at (202) 720-5704.

Paperwork Requirements

Title: Retained Water in Raw Meat and Poultry Products; Poultry Chilling.

Type of Collection: Labels and labeling records; data or information supporting labeling statements.

Abstract: Slaughtering establishments would have to have data to support percent-absorbed-water statements on product labels and to demonstrate that

the amount of absorbed water in the product is unavoidable under the establishments' HACCP plans. The data would have to have been collected under written protocols.

This final rule will require an estimated 210,000 hours to develop the data to support retained water levels above zero. All 300 federally inspected poultry establishments will need to conduct studies to establish minimum retained water levels. The FRIA assumed that the average establishment would conduct studies for two product categories. The FRIA assumed that a reasonable study would examine 10 alternative chiller settings with four 50-bird water tests conducted for each setting. Each test would require 2.5 hours. Thus, it would take an estimated 200 hours for each of 300 poultry establishments, or more than 30,000 hours.

The FRIA assumed that at most 500 meat establishments need to develop non-zero water levels to meet the existing pathogen-reduction performance standards. With larger carcasses, the recording time is doubled to 200 hours per establishment. These 500 meat establishments would also require 100 hours to collect microbial samples. Thus, the information collection would be 300 hours for each of 500 establishments, or 150,000 hours. All 800 establishments with non-zero levels would also have to develop new, generically approved labels.

Estimate of Burden: Protocols for determining minimum feasible water retention in product classes (3,000 hours); data supporting absorbed-water label statements or the lack thereof (210,000 hours). Changes to product labels would be generically approved and, therefore, establishments would not incur a burden from label submission.

Respondents: Meat and poultry product establishments or trade associations.

Estimated Number of Respondents: 800.

Estimated Number of Responses per Respondent: 1.

Estimated Total Annual Burden on Respondents: 213,000 hours.

Copies of this information collection assessment can be obtained from Lee Puricelli, Paperwork Specialist, Food Safety and Inspection Service, USDA, 112 Annex, 300 12th SW., Washington DC 20250.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the Agency, including whether the information will have practical utility; (b) the accuracy of

the Agency's estimate of the burden of the proposed collection of information including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Specifically, FSIS is interested in comments regarding the label requirements. Some commenters expressed concern about the usefulness, or "practical utility," of the information on the maximum percentage of retained water that must be disclosed on the label. FSIS welcomes any information and data to support this requirement or that presents alternatives. FSIS will fully address any comments in its information collection request that it will submit to the Office of Management Budget 60 days after publication of this rule.

Comments may be sent to Lee Puricelli, see address above, and the Desk Officer for Agriculture, Office of Information and Regulatory Affairs, Office of Management and Budget, Washington DC 20253.

Comments are requested by March 12, 2001. To be most effective, comments should be sent to OMB within 30 days of the publication date.

List of Subjects

9 CFR Part 381

Food labeling, Poultry and poultry products.

9 CFR Part 441

Consumer protection standards, Meat and meat products, Poultry products.

For the reasons discussed in the preamble, FSIS is amending 9 CFR Chapter III, 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 2.18, 2.53.

2. Paragraph (b) of § 381.1 is amended by revising the definition of *Ready-to-cook poultry* to read as follows:

§ 381.1 Definitions.

* * * * *

(b) * * *

(44) *Ready-to-cook poultry*. "Ready-to-cook poultry" means any slaughtered

poultry free from protruding pinfeathers and vestigial feathers (hair or down), from which the head, feet, crop, oil gland, trachea, esophagus, entrails, and lungs have been removed, and from which the mature reproductive organs and kidneys may have been removed, and with or without the giblets, and which is suitable for cooking without need of further processing. Ready-to-cook poultry also means any cut-up or disjointed portion of poultry or other parts of poultry, such as reproductive organs, head, or feet that are suitable for cooking without need of further processing.

* * * * *

3. Section 381.65 is revised to read as follows:

§ 381.65 Operations and procedures, generally.

(a) Operations and procedures involving the processing, other handling, or storing of any poultry product must be strictly in accord with clean and sanitary practices and must be conducted in a manner that will result in sanitary processing, proper inspection, and the production of poultry and poultry products that are not adulterated.

(b) Poultry must be slaughtered in accordance with good commercial practices in a manner that will result in thorough bleeding of the carcasses and ensure that breathing has stopped prior to scalding. Blood from the killing operation must be confined to a relatively small area.

(c) When thawing frozen ready-to-cook poultry in water, the establishment must use methods that prevent adulteration of, or net weight gain by, the poultry.

(d) The water used in washing the poultry must be permitted to drain freely from the body cavity.

(e) Detached ova may be collected for human food and handled only in accordance with 9 CFR 590.440 and may leave the establishment only to be moved to an official egg product processing plant for processing. Ova from condemned carcasses must be condemned and treated as required in § 381.95.

4. Section 381.66 is amended by revising paragraphs (a), (c), and (d) and removing paragraph (f)(6), to read as follows:

§ 381.66 Temperatures and chilling and freezing procedures.

(a) *General.* Temperatures and procedures that are necessary for chilling and freezing ready-to-cook poultry, including all edible portions thereof, must be in accordance with

operating procedures that ensure the prompt removal of the animal heat, preserve the condition and wholesomeness of the poultry, and assure that the products are not adulterated.

* * * * *

(c) *Ice and water chilling.* (1) Only ice produced from potable water may be used for ice and water chilling. The ice must be handled and stored in a sanitary manner.

(2)(i) Poultry chilling equipment must be operated in a manner consistent with meeting the applicable pathogen reduction performance standards for raw poultry products as set forth in § 381.94 and the provisions of the establishment's HACCP plan.

(ii) Major portions of poultry carcasses, as defined in § 381.170(b)(22), may be chilled in water and ice.

(3) Previously chilled poultry carcasses and major portions must be maintained constantly at 40 °F or below until removed from the vats or tanks for immediate packaging. Such products may be removed from the vats or tanks prior to being cooled to 40 °F or below, for freezing or cooling in the official establishment. Such products must not be packed until after they have been chilled to 40 °F or below, except when the packaging will be followed immediately by freezing at the official establishment.

(4) Giblets must be chilled to 40 °F or below within 2 hours from the time they are removed from the inedible viscera, except that when they are cooled with the carcass, the requirements of paragraph (b)(2) of this section must apply. Any of the acceptable methods of chilling the poultry carcass may be followed in cooling giblets.

(d) *Water absorption and retention.*

(1) Poultry washing, chilling, and draining practices and procedures must be such as will minimize water absorption and retention at time of packaging.

(2) The establishment must provide scales, weights, identification devices, and other supplies necessary to conduct water tests.

* * * * *

(f) * * *

(6) [Removed]

5. A new Part 441 is added to subchapter E to read as follows:

PART 441—CONSUMER PROTECTION STANDARDS: RAW PRODUCTS

Authority: 21 U.S.C. 451–470, 601–695; 7 U.S.C. 450, 1901–1906; 7 CFR 2.18, 2.53.

§ 441.10 Retained water.

(a) Raw livestock and poultry carcasses and parts will not be permitted to retain water resulting from post-evisceration processing unless the establishment preparing those carcasses and parts demonstrates to FSIS, with data collected in accordance with a written protocol, that any water retained in the carcasses or parts is an unavoidable consequence of the process used to meet applicable food safety requirements.

(b) Raw livestock and poultry carcasses and parts that retain water from post-evisceration processing and that are sold, transported, offered for sale or transportation, or received for transportation, in commerce, must bear a statement on the label in prominent letters and contiguous to the product name or elsewhere on the principal display panel of the label stating the maximum percentage of water that may be retained (e.g., “up to X% retained water,” “less than X% retained water,” “up to X% water added from processing”). The percent water statement need not accompany the product name on other parts of the label. Raw livestock and poultry carcasses and parts that retain no water may bear a statement that no water is retained.

(c)(1) An establishment subject to paragraph (a) of this section must maintain on file and available to FSIS its written data-collection protocol. The protocol must explain how data will be collected and used to demonstrate the amount of retained water in the product covered by the protocol that is an unavoidable consequence of the process used to meet specified food safety requirements.

(2) The establishment must notify FSIS as soon as it has a new or revised protocol available for review by the Agency. Within 30 days after receipt of this notification, FSIS may object to or require the establishment to make changes in the protocol.

(d) Expected elements of a protocol for gathering water retention data:

(1) *Purpose statement.* The primary purpose of the protocol should be to determine the amount or percentage of water absorption and retention that is unavoidable using a particular chilling system while achieving the regulatory pathogen reduction performance standard for *Salmonella* as set forth in the PR/HACCP regulations (9 CFR 310.25(b), 381.94(b)) and the time/temperature requirements set forth in 9 CFR 381.66. Additional purposes that could be included are determining chilling system efficiency and evaluating product quality.

(2) *Type of washing and chilling system used by the establishment.* Any post-evisceration washing or chilling processes that affect water retention levels in and microbial loads on raw products should be described. For poultry establishments, the main chiller types, identified by the mechanism used to transport the birds through the chiller or to agitate the water in the chiller, are the drag-through, the screw type, and the rocker-arm type.

(3) *Configuration and any modifications of the chiller system components.* A description of chiller-system configurations and modifications should be provided. The description should include the number and type of chillers in a series and arrangements of chilling system components, and the number of evisceration lines feeding into a chiller system. If there is a pre-chilling step in the process, its purpose and the type of equipment used should be accurately described. Any mechanical or design changes made to the chilling equipment should be described.

(4) *Special features in the chilling process.* Any special features in the chilling process, such as antimicrobial treatments, should be described. Also, the length and velocity of the dripping line should be described, as well as the total time allowed for dripping. Any special apparatus, such as a mechanism for squeezing excessive water from chilled birds, should be explained.

(5) *Description of variable factors in the chilling system.* The protocol should describe variable factors that affect water absorption and retention. In poultry processing, such factors are typically considered to be the time in chiller water, the water temperature, and agitation. The protocol should consider air agitation, where applicable. Additional factors that may affect water absorption and retention are scalding temperature and the pressure or amount of buffeting applied to birds by feather removal machinery, and the resultant loosening of the skin. Another factor that should be considered is the method used to open the bird for evisceration.

(6) *Standards to be met by the chilling system.* For example, the chilling system may be designed simply to achieve a reduction in temperature of ready-to-cook poultry to less than 40 °F within the time limit specified by the regulations, or in less time. As to the

standard for pathogen minimization, the *Salmonella* pathogen reduction standards, as set forth in the PR/HACCP final rule, have been suggested. Although there is not yet an applicable *Salmonella* standard for turkeys, establishments are free to adopt practicable criteria for use in gathering data on turkeys under the protocols here suggested. Additional microbiological targets, such as *E. coli* or *Campylobacter* levels, or reductions in numbers of other microorganisms, may also be used.

(7) *Testing methods to be employed.* The protocol should detail the testing methods to be used both for measuring water absorption and retention and for sampling and testing product for pathogen reductions. The protocol should call for water retention and pathogen reduction tests at various chilling equipment settings and chilling time-and-temperature combinations. The method to be used in calculating water absorption and retention should be reproducible and statistically verifiable. With respect to the pathogen-reduction aspect of the testing, FSIS recommends the methods used for *E. coli* and *Salmonella* testing under the PR/HACCP regulations. The number of samples, the type of samples, the sampling time period, and the type of testing or measurement should be included in the protocol.

(8) *Reporting of data and evaluation of results.* The protocol should explain how data obtained are to be reported and summarized. The criteria for evaluating the results and the basis for conclusions to be drawn should be explained.

(9) *Conclusions.* The protocol should provide for a statement of what the data obtained demonstrate and what conclusions were reached.

Done at Washington, DC: January 3, 2001.
Thomas J. Billy,
Administrator.

Note: Appendix A will not be codified in Title 9 of the Code of Federal Regulations.

Appendix A—Method for Determining Moisture in Meat and Meat Products and Poultry Products

A. Introduction

Theory: In this determination, a weighed sample is heated, cooled, and then reweighed. The loss in weight is calculated as moisture content.

B. Equipment

- Apparatus:
- Covered aluminum dish. At least 50 mm. diameter and not greater than 40 mm. deep, containing a paddle.
 - Mechanical convection oven, preferably one equipped with a booster heater.
 - Food chopper with plate openings $\leq \frac{1}{8}$ " (3 mm.), or Robot Coupe or equivalent food processor.

C. [Reserved.]

D. [Reserved.]

E. Sample Preparation Procedure for Fresh Meat or Poultry

For accurate and reliable measurement, the raw meat or poultry sample should be finely ground to a homogeneous consistency.

F. Analytical Procedure

- Accurately weigh sample (representing approximately 2 g. of dry material) into an aluminum dish.
 - Weigh the sample as rapidly as possible to minimize loss of moisture.
 - The weight of the pan should include the paddle, which is used in spreading the sample across the bottom of the pan, thereby presenting a greater sample surface area, which is beneficial to moisture removal.
 - If the sample is relatively dry when received, a small quantity of distilled water may be added to the pan only after the sample weight is obtained. This quantity of water will be helpful in spreading the sample across the bottom of the pan, and will introduce no error since it will be evaporated when the sample is oven-dried.
- Dry, with cover removed, for 16–18 hours at 100–102 °C, or for 4 hours at 125 °C in mechanical convection oven.

Do not overload the drying oven or sample may be insufficiently dried and give low results. Drying time will start when the original temperature has been reached. Use the oven's booster heater, if the oven is so equipped, to minimize this recovery time.

G. Calculations

1. Procedure

$$\text{Percent} = \frac{100(B - C)}{A}$$

A = sample weight

B = weight of dish + sample before drying

C = weight of dish + sample after drying

Note: If laboratory is not air-conditioned, and humidity is high, dishes should be desiccated before the initial and final weighings.

Reference: Official Methods of Analysis of the Association of Official Analytical Chemists, 16th Edition, 950.46.

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