

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

SUMMARY: The Food Safety and Inspection Service (FSIS) is proposing 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. Meat and poultry carcasses and parts would not be permitted to contain water resulting from post-evisceration processing unless the establishment demonstrates that water retention is necessary to meet applicable food safety requirements. In addition, the establishment would be required to disclose on the label the maximum percentage of retained water in the product. The proposed labeling statement would provide information to consumers of raw meat and poultry products that would help them to make purchasing decisions. Establishments having data demonstrating that there is no retained water in their 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.

FSIS is also proposing to revise 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: Comments must be received on or before December 10, 1998.

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 97-054P in your comments. All comments submitted in response to this proposal, as well as 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.

FOR FURTHER INFORMATION CONTACT: 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 in interstate and foreign commerce are wholesome, not adulterated, and properly marked, labeled, and packaged. The Agency maintains continuous inspection oversight of operations in meat and poultry slaughtering and processing establishments and in egg product processing plants. Among the requirements enforced by the Agency are those having to do with the post-evisceration handling and storage of carcasses and parts.

Meat and poultry carcasses are handled in a manner intended to yield wholesome, unadulterated products. After evisceration, raw meat and poultry carcasses are subject to various processes, including washing and chilling, to preserve the safety of the products. The Agency is concerned about the potential for water absorption and retention in the stages of processing after livestock and poultry carcasses are eviscerated and trimmed. Because an eviscerated carcass is open and exposed to water through the washing, chilling, and spraying processes, it is likely to absorb and retain water under the skin and in muscle tissue. There is a potential for product adulteration due to excess water absorption and retention.

In livestock slaughtering establishments, carcasses undergo a final wash after slaughter and dressing to remove any adhering foreign matter before being placed in the cooler. Historically, meat carcasses have been air-chilled. Since the late 1970's, FSIS has permitted air chilling in combination with a water spray to minimize carcass shrinkage and promote rapid heat loss.

Air chilling results in 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 retain water, and consequently, weight, which would have been lost as a result of air chilling. Water spray systems must be operated in a manner that does not result in a shift's production of meat carcasses from weighing, on average, more than their pre-chilled weight. (FSIS Directive 6330.1) This directive 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.

Although livestock slaughter establishments are not prohibited from using water immersion chilling methods, federally inspected establishments in the United States do not use immersion chilling for livestock carcasses. Immersion chilling is impractical because of the size of livestock carcasses and the associated costs of equipment and other resources.

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. Tripe is bleached and scalded 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 livestock establishments, 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 degrees F. or less within 4 to 8 hours after slaughter, depending on the size of the carcass (9 CFR 381.66(b)).

Water-immersion chilling is the preferred poultry chilling method in the United States for several reasons. First, water is the most effective and efficient conducting medium for removing animal heat.

Before the 1960's, poultry was chilled in layers of ice or immersed in small tanks of ice water. The poultry was chilled using these methods for a sufficient amount of time to reduce the temperature of the poultry to 40 degrees F. or below, after which the tanks were emptied. The use of small individual single-use tanks required significant resources, including space, employees, and water or ice. Because of these disadvantages, continuous immersion chillers were developed. Continuous immersion chillers consist of one or more large tanks where chilled water is continually replenished and poultry carcasses continuously enter and exit. Modern chillers are equipped with refrigeration units and systems for controlling water volume, direction, and agitation. They are efficient, rapid, and economical.

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 in poultry products be minimized. FSIS is mandated to prevent the distribution in commerce of meat and poultry products that are adulterated or misbranded. A product is adulterated if, among other circumstances, "a substance has been added to or mixed with the product to increase its bulk or weight or make it appear of greater value than it is." (21 U.S.C. 601(m)(8), 453(g)(8)). Thus, a product containing excessive water may be considered adulterated. Likewise, a product containing excessive water may be considered misbranded. A product is misbranded if, among other circumstances, its label is false or misleading in any particular. (21 U.S.C. 601(n)(1), 453(h)(1)). Immersion chilling of poultry could result in a product's becoming misbranded or economically adulterated through the retention of absorbed water. However, because immersion chilling is the most 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.

FSIS has limited water retention to amounts that are considered unavoidable while achieving applicable food safety requirements. The regulations generally require water absorption and retention in poultry products to be minimized (9 CFR 381.66(d)(1)). FSIS promulgated

regulations defining maximum water retention levels for classes of poultry in 1959, 1960, and 1971 (24 FR 9566 (12/1/59); 26 FR 6471 (7/19/61); and 35 FR 739 (10/7/70)). Poultry products containing water in excess of the regulatory limits are considered adulterated.

To ensure that poultry products do not exceed maximum water retention levels, inspectors sample carcasses each day from each chilling system at a point before the poultry is washed and again shortly after the poultry exits the chiller. If the water limits are exceeded, the poultry is retained until enough water has drained to bring the poultry into compliance with the limits. As a practical matter, establishments maintain overall water absorption averages below the maximum limitation to consistently comply with the regulatory limits. However, some firms equip and operate their processing lines in a manner that will enable them to control retained water to a level as close as possible to the regulatory limits. Sometimes the regulatory limits are exceeded. The poultry may then be held at the plant for a longer time to permit excess water to drain, or it may be diverted to operations, such as boning and cut-up, or other processing operations in which excess water is lost.

Concerns About Differences Between the Meat and the Poultry Regulations

Early in 1996, FSIS received a petition from several national livestock industry associations concerning perceived inequities between the meat and poultry regulations. The petitioners argued that the restriction on water absorption in meat carcasses is inequitable in comparison to the absorption allowance for poultry and that, moreover, poultry carcasses with weight added through water absorption are economically adulterated. The petitioners requested that FSIS prohibit the retention of any water absorbed by poultry carcasses during immersion chilling. This request was among those the petitioners reiterated in a February 7, 1997, letter to the Department. FSIS plans to address elements of the petitioners' requests other than the absorbed-water issue in future rulemaking documents.

In 1994, a group of poultry consumers and red meat producers brought an action against the Department in the United States District Court for the Southern District of Iowa challenging several differences in the regulatory requirements for meat and poultry, including the contaminant removal methods, standards of identity, and water-retention. (*Kenney, et al. v. Glickman*.)

Plaintiffs alleged that poultry products containing absorbed water were both economically adulterated and misbranded within the meaning of the PPIA. They also alleged that the regulations establishing maximum levels for water retention violated the Administrative Procedure Act because they were arbitrary and capricious when compared to the regulatory prohibition on absorbed water in meat carcasses. The Court found that poultry containing absorbed water was not economically adulterated or misbranded under the PPIA. However, the Court also 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 (9 CFR 381.66(d)(2)) was arbitrary and capricious because the Secretary did not explain in the rulemaking record how he determined the particular water retention levels, why water retention cannot be reduced below current levels, or why meat and poultry should be treated differently.

The Court left in place the general requirement at 9 CFR 381.66(d)(1) for establishments to minimize water absorption and retention in poultry at the time of packaging. The Court also left standing the regulations at 9 CFR 381.66(d)(3)-(6) controlling the amount of retained water in chickens and turkeys that are to be cut up or ice-packed.

The American Meat Institute (AMI), a trade association representing meat and poultry slaughtering and processing establishments, petitioned the Department on October 2, 1997, to amend the regulations governing water absorption and retention in certain raw meat and poultry products. This petitioner requested five specific changes:

- Repealing regulations requiring poultry carcasses to be chilled below 40 °F within a specified time
- Requiring water retention in meat and poultry products to have been minimized at the time of packaging
- Allowing meat and poultry carcasses to absorb and retain water that is incidental and unavoidable in chilling practices designed to improve food protection
- Measuring weight gain from water retention as the difference between the hot carcass weight and the weight of packaged, finished products
- Requiring labeling of raw meat and poultry with retained water above certain minimum absorption and retention levels FSIS considered the petitioner's requests in developing this proposal.

Purpose for New Regulation

In proposing new regulations governing water retention in raw meat and poultry products, FSIS intends: (1) to provide consumers with additional information to help them in making purchasing decisions; (2) to eliminate certain differences between the meat and the poultry inspection regulations; (3) to establish regulations that are consistent with the objectives of regulatory reform and with the Agency's "Pathogen Reduction; Hazard Analysis and Critical Control Points Systems (PR/HACCP)" regulations (61 FR 38806; July 25, 1996); and (4) to streamline the regulations.

This proposal would respond to the District Court's findings that the regulations the Court set aside were "arbitrary and capricious" by providing: (1) that any water retention limits be established on the basis of sound data; (2) that such limits be as low as technically feasible in meeting food safety requirements; and (3) that, to the extent possible, the same criteria for establishing water retention limits apply both to meat and to poultry products.

FSIS currently lacks information on which to base any water retention limit, or to determine whether any limit currently in use can be further reduced. The proposal would be intended, in part, to ensure the availability of data demonstrating that water retention in affected products is unavoidable and that any water retention limits the Agency sets are the minimum feasible. The soundness of the data would be ensured in large measure by its having been collected under protocols approved by FSIS (see below).

This proposal would respond, at least in part, to four of the five requests in AMI's petition. It concerns water absorbed and retained in product as a result of post-evisceration processing and, hence, the difference between "hot carcass" and finished product weight. It would require that water retention be minimized, that the processing that resulted in water absorption have a food-safety purpose, and that the amount of water retained be indicated on labels of affected products.

This proposal does not address the time and temperature requirements for chilling poultry carcasses. FSIS intends to undertake a separate rulemaking on this subject.

Proposed Provisions To Limit Retained Water in Meat and Poultry

FSIS is proposing new requirements in new Part 441 to address water retention in single-ingredient raw meat and ready-to-cook poultry products as a

result of post-evisceration processing. The proposed requirements would replace those set forth in 9 CFR § 381.66(d)(3)-(8) as well as those in § 381.66(d)(2). The intention is to restrict, as much as feasible, the amount of water absorbed and retained in meat and poultry products. The Agency would also require product labels to state the maximum percentage of retained water the products may contain.

Some quantitative limit or measure is necessary to determine whether water retention has been minimized. Until the decision in *Kenney v. Glickman*, FSIS used the limits specified in § 381.66(d)(2) to determine whether poultry establishments were meeting the requirement to minimize water absorption and retention in whole birds.

The only currently available quantitative limit for determining whether water retention in raw products has been minimized (other than the limits for cut-up or ice-pack poultry in 9 CFR 381.66(d)(3)-(6)) is zero percent. 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. FSIS is therefore proposing 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 expects 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 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 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 assumed or specified in the protocol used to justify the limit.

FSIS requests comment on the advisability of accepting, during the comment period on this proposed rule, protocols for gathering data that would justify industry-wide or process-specific water retention limits. FSIS also requests comment on whether the Agency should accept protocols submitted by industry groups for individual establishments.

In a recent **Federal Register** notice (62 FR 64767; December 9, 1997), FSIS requested comments on specifications for protocols to be used for collecting data on chilled, ready-to-cook poultry products. The suggested specifications for such a protocol included: a statement of purpose; the type of washing or chilling system; a description of the chiller system process, components, equipment, modifications, and steps in the chilling process; the number of chillers in a series and arrangements of components; the number of evisceration lines feeding into a chiller; any pre-chilling steps; anti-microbial treatments, if any; the length and velocity of dripping lines; any special apparatus or procedure for removing excess water from birds; and a description of chilling system factors affecting water absorption and retention, such as the time of the birds in the chiller, the water temperature, and the amount of chill water agitation.

To date, FSIS has received two comments on the notice. Three livestock producer associations submitted a comment stating that they were not in a position to provide information regarding protocols or specifications for protocols to collect water retention data. They maintained that the poultry industry would be supplying most, if not all, the data needed to support any added-water limitations. They also expressed the suspicion that data collected by the poultry industry would reflect a "push" in the direction of maximum retention rather than the true capability of technology and processing procedures to minimize water retention.

The other comment was submitted by a trade association representing turkey and other poultry producers and processors. The association listed two principles and attendant considerations that, in its view, should be observed in developing protocols. The first principle was food safety: Considerations in achieving safety were rapid chilling of carcasses and the efficiency of immersion chilling. The second principle was product wholesomeness and quality. Attendant considerations were restricting water absorption to the amount necessary to achieve food safety, calculating water absorption from the point of entry of carcasses into

the chilling medium, and recognizing that it is a documented fact that water absorption is unavoidable in all poultry species. Additional considerations presented in the comment were that water absorption is not a food safety issue, and that water loss occurs during further processing of carcasses.

FSIS has considered these comments and will be interested in further discussion of water-data protocols in the context of this proposal. Regarding the livestock producer associations' comment on possible bias in data submitted by the poultry industry, FSIS notes that any data submitted would have to have been collected under scientifically designed protocols approved by the Agency. FSIS now expects protocols it will approve to be composed of the elements listed in Appendix A of this document. Further, any water retention in a single-ingredient, raw meat or poultry product would have to be reflected on the product label. The discipline of the marketplace as well as FSIS regulatory oversight would help ensure the accuracy of label statements.

Under proposed § 441.10(a), meat or poultry products would 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 would reflect the maximum percentage of water that may be retained in the product. Alternatively, the label could 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 would not have to label the products and could include a no-retained-water claim on the product label. The labels would be generically approved pursuant to 9 CFR 317.5(b)(2) or 381.133(b)(2).

This proposed 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 anti-misbranding provisions of the FMIA and the PPIA (especially 21 U.S.C. 601(n)(1), (6); 453(h)(1), (6)). It would ensure that the product labeling is not misleading with respect to water retention in the product. The placement of the required information on the label would ensure that the information would be likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

The information to be required would be analogous to the information conveyed to consumers on the labels of "ham—water added" or fruit beverages labeled to indicate the actual percentage of juice in the product. As a result, consumers would be able to determine before they buy packaged raw meat or poultry products whether or not the value of products with retained water was commensurate with prices of alternatives in the meat case. The market will provide significant incentives to plants to adopt new cost-effective technologies for reducing retained water. FSIS requests comment on the usefulness to consumers of the proposed labeling requirement.

The proposed requirements would affect only single-ingredient, raw, whole, cut-up, or ground meat and poultry carcasses and parts, including edible organs and other edible meat and poultry byproducts. It would 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 proposal also would not cover cooked and cured pork products, such as those currently subject to protein-fat-free requirements (9 CFR 318.19(a)(5), 319.104–.105, 327.23).

FSIS personnel would verify an establishment's control of water retention by checking the establishment records or by conducting in-plant or in-distribution tests of products by methods that the Agency would develop. FSIS would also conduct independent tests of the establishment's absorbed-water control as part of investigations if a problem were suspected or in the course of special studies.

Proposed Changes in Poultry Chilling Regulations

FSIS is proposing to amend the chilling requirements for poultry. Various prescriptive requirements and specifications, such as the minimum amount of fresh water intake by continuous chillers for each poultry carcass, would be removed. Establishments would be given the flexibility to take advantage of the latest technologies and procedures.

This proposal would amend 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 proposal would eliminate 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 will be unnecessary when HACCP plans are implemented because each HACCP plan will specify the measures to be taken to protect poultry products from physical, chemical, or biological contamination. The requirements in current paragraphs (a) and (c) of 9 CFR 381.65 would be retained as paragraphs (a) and (b) because they set out general principles of good sanitation and commercial practice that all establishments must observe.

The requirements in paragraphs (h) and (j) of 9 CFR 381.65, relating to poultry thawing and dressing techniques, would be replaced with two performance standards. The first would require simply that establishments use thawing procedures that will prevent adulteration of, or net weight gain by, the product. The second would require that water used in thawing be permitted to drain freely from the carcass. Proposed paragraph (c)(1), which would replace paragraph (h), would require 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 current thawing regulation 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. The current 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 analysis. Establishments must be given the responsibility and flexibility to choose thawing measures that are effective and do not create food safety hazards.

Proposed paragraph (c)(2) would replace the current 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.

Current paragraph (d), which contains a requirement to remove kidneys from mature chickens and turkeys, would be 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, current paragraph (d) is redundant with the HACCP regulations. The requirement to remove kidneys is referenced in the definition of "ready-to-cook poultry" at § 381.1(b)(44). Therefore, the Agency is proposing to amend that definition. Commenters on this proposal may wish to address the need for regulatory food safety performance standards to control heavy metal residues in organ meats, given the fact that establishments will be operating HACCP systems.

Current paragraph (i), which specifies how poultry carcasses are to be cut open for evisceration, would be removed. The regulation is outdated, prescriptive, and may be an obstacle to improved product safety. The current 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 by the postmortem inspector.

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 the 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 current 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. The new technologies can potentially improve efficiency and product wholesomeness but are not likely to be implemented unless the regulation is amended. The Agency believes that establishments should have the flexibility to innovate and to implement promising new technologies, consistent with their HACCP plans.

The requirement in current paragraph (k) to adequately drain ready-to-cook poultry after chilling to remove ice and water before packaging would be retained and the paragraph would be redesignated as paragraph (d).

Current paragraphs (l) through (p) would be 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 to be addressed by establishments in their HACCP plans.

Finally, current paragraph (q), concerning the harvesting of detached ova for human food, would be redesignated as paragraph (e) and would be slightly revised to eliminate a command-and-control requirement that the ova be identified past the point of inspection. The requirement that ova may leave the official establishment only for shipment to an egg products processing plant would remain.

In 9 CFR 381.66, paragraph (a) would be revised. This paragraph requires that poultry 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 current paragraph, a command-and-control requirement to file a description of the chilling or freezing procedures with the inspector in charge, would be removed.

The general chilling requirements for poultry, paragraph (b), would remain the same. FSIS regards 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) would be removed. For example, proposed paragraph (c)(2)(i) does not specify chilling media temperatures and the use of recording thermometers, as does the current paragraph (c)(2)(i). Proposed paragraph (c)(1) would continue to require the use of potable water, and proposed paragraph (c)(2)(i) would continue to require sufficient water for a continuous overflow from chilling system sections. 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, would be removed.

Current paragraph (c)(2)(iv) would be redesignated as (c)(2)(ii). This paragraph, which concerns the chilling of major portions of poultry carcasses, is the subject of a final rule (proposed at 62 FR 31017; June 6, 1997) that appears elsewhere in this issue of the **Federal Register**.

Current 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, would be removed. Establishments subject to the poultry products 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, would be removed, and in paragraph (c)(5), the highly specific requirements concerning the use of continuous chillers to chill giblets would be 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 would remain.

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

FSIS is proposing to remove current 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 address any food safety hazards associated with containers in their HACCP plans.

The Agency is likewise proposing to remove paragraph (d)(11), which requires establishments to prevent free water from being included in giblet packages. Among other things, the current regulation 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 proposal would give establishments greater responsibility and flexibility in choosing appropriate giblet packaging materials. By complying with the proposed retained-water limitation requirements (discussed below) and by appropriately labeling product, establishments would be ensuring that water absorption is controlled and that consumers are informed.

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

The removal of the current poultry chilling regulations would eliminate prescriptive, command-and-control procedures for determining product compliance and would encourage processors to use the most efficient and effective methods of controlling microorganisms.

Executive Order 12866 and Regulatory Flexibility Act

This proposed rule has been determined to be economically significant and was reviewed by the Office of Management and Budget under Executive Order 12866. The full text of the PRIA is published as Appendix B of this document.

Summary: Preliminary Regulatory Impact Analysis

The proposed rule resulted from an analysis of six alternative regulatory approaches for addressing retained water in raw meat and poultry products. The six alternatives include: (1) no limit on retained water but mandatory labeling that identifies the percentage of retained water in the product; (2) a requirement that all establishments meet a water limit based on best available technology, with mandatory labeling to indicate any retained water; (3) a moisture limit based on best performance with existing equipment, with mandatory labeling to show any retained water; (4) a standard of zero retained moisture; (5) a requirement that no retained water could be included in net weight; and (6) 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. For all alternatives where a limit on retained water is established, the analysis assumed that the limits would be established by the regulated industry associations or other groups.

FSIS chose the last alternative. The selected option would not allow retained water in an affected product unless it is an inevitable consequence of the process or processes used to meet applicable food-safety requirements. Levels of unavoidable retained water would be established by inspected establishments, associations, or other groups, using acceptable protocols. Also, the maximum amount of retained water that could be present would have to be indicated on the product label. FSIS found that this option provides more benefits and fewer costs than other options allowing retained water. By "inevitable consequence" the Agency means an unavoidable and irreducible side effect. A food-safety requirement could be a regulatory prescription, such as the temperature to which a product must be chilled and held. It could also be a preventive measure taken at a CCP or a critical limit in the establishment's HACCP plan. Given a food-safety requirement, an establishment must choose a method for satisfying the requirement.

FSIS understands that the choice of method is based on a judgment of technical and economic feasibility. FSIS understands that product quality and product acceptability to the consumer are also important factors. The Agency requests comment on these matters.

The method selected for meeting food safety requirements could have side effects that cannot be eliminated. A side effect of an antimicrobial treatment of carcasses or a carcass chilling method could be an increase in the water content of carcasses and parts. FSIS is proposing to require that the amount of water that might be retained in carcasses and parts as a result of using such an antimicrobial or chilling method be an unavoidable and irreducible side 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 an FSIS-approved protocol. The proposal would allow a protocol to be developed and data-generating studies following the protocol to be carried out by an individual establishment, an industry trade association, or other group using the same or similar processing techniques and equipment. 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 indicate the presence of retained water in the products.

This requirement would not appear to have a significant impact on the meat industry because the meat industry is already achieving zero-percent retained water. This proposal would, however, provide an alternative for establishments that are having or will have trouble meeting the *Salmonella* performance standards. These establishments could use a full range of antimicrobial rinses or hot-water rinses without having to worry about meeting zero-percent retained water. If they can demonstrate that they need a non-zero limit to meet the *Salmonella* standards, they can use the flexibility provided by the proposed rule and establish a new water limit as long as they state the maximum percentage of water absorbed and retained on product labels.

Immersion chilling is the process used by most poultry establishments to meet the existing chilling requirements for poultry, e.g., 9 CFR 381.66(b)(2) requires that poultry carcasses under 4 pounds shall be chilled to 40 °F within 4 hours following evisceration. It follows 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. FSIS recognizes that this "minimum" must be established within practical limits for operating parameters such as drip time and chiller water temperature. The Agency believes that the industry already has information concerning the chiller variable settings that minimize water retention. FSIS, therefore, believes the poultry industry can establish water retention limits for various chiller systems with minimal costs. FSIS also recognizes that some poultry establishments may require higher levels of retained water to meet the *Salmonella* standards than they do to meet the existing chilling requirements.

The proposal does not provide specific guidance on options available for poultry processors that are already operating far below the existing standards for *Salmonella*, such as by permitting higher retained water levels

if data showed further pathogen reductions would be achieved.

The analysis estimates a range of costs the industry will incur to meet this new regulatory requirement. If establishments are able to demonstrate that current levels of retained water are necessary to achieve applicable food safety standards, establishments would not incur 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. This estimate is based on each establishment's 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 if all raw, single-ingredient poultry continues to retain water.

To the extent that establishments cannot demonstrate that current retained water levels are necessary for achieving applicable food safety standards, significant costs could be incurred as establishments modify processes to minimize retained water levels. Reducing retained water could entail a wide range of processing modifications, depending on the type of chilling equipment currently used and amount of retained water that would have to be removed. The PRIA estimates that the cost of removing a substantial portion of the existing retained water could easily approach \$100 million. The PRIA 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.

The proposed 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, based on the Small Business Administration criterion of more than 500 employees. There are from 50 to 60 establishments that 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 proposal are the firms operating immersion chillers in a manner so as to target the maximum allowable retained water.

Because of the Court's decision, FSIS needs to develop new regulatory requirements to carry out its responsibilities for protecting the public

from economic adulteration. Preventing economic adulteration provides a consumer benefit. Consumers would also benefit from the additional information that would be provided by the labeling requirement. The information on retained water should lead to more informed purchasing decisions. The proposal would 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 proposal would eliminate some recordkeeping and reporting burdens, provide for increased flexibility and reduce the costs of HACCP implementation.

Executive Order 12988

This proposed 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 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, or, in the case of imported articles, which are not at such an establishment, after their entry into the United States.

This proposed 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 proposed rule. However, the administrative procedures specified in 9 CFR 381.35 must be exhausted prior to any judicial challenge of the application of the provisions of this proposed 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 proposed rule on environmental and

health conditions in low-income and minority communities.

This proposed rule would 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 above, the proposed regulations should generally benefit consumers of meat and poultry products. The proposed regulations would 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 proposed rule would 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.

Paperwork Requirements

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

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

Abstract: Changes to product labels would be generically approved. The paperwork and recordkeeping associated with such label approval is approved under OMB control number 0583-0092. 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 FSIS-approved protocols.

This proposed rule would require an estimated 210,000 hours to develop the data to support retained water levels above zero. All 300 federally inspected poultry establishments would need to conduct studies to establish minimum retained water levels. The PRIA assumed that the average establishment would conduct studies for two product categories. The PRIA 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 PRIA assumes 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).

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, Cotton Annex Building, Room 107, 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 the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology. Comments may be sent to Lee Puricelli, Paperwork Specialist, see address above, and Desk Officer for Agriculture, Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20253.

Comments are requested by December 10, 1998. To be most effective, comments should be sent to OMB within 30 days of the publication date of this proposed rule.

List of Subjects

9 CFR Part 381

Food labeling, Poultry and poultry products.

9 CFR Part 441

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

For the reasons discussed in the preamble, FSIS is proposing to amend 9 CFR Chapter III, as follows:

PART 381—POULTRY PRODUCTS INSPECTION REGULATIONS

1. The authority citation for part 381 would continue 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)(44) of § 381.1 would be revised 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, vestigial feathers (hair or down), and from which the head, feet, crop, oil gland, trachea, esophagus, feet, crop, oil gland, reproductive organs, and lungs have been removed, and mature poultry from which the kidneys 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 would be 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 shall be strictly in accord with clean and sanitary practices and shall be conducted in such a manner that will result in sanitary processing, proper inspection, and the production of poultry and poultry products that are not adulterated.

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

(c)(1) When thawing frozen ready-to-cook poultry in water, the establishment shall use methods that prevent adulteration of, or net weight gain by, the poultry.

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

(d) Ready-to-cook poultry shall be adequately drained after chilling, to remove ice and water before the poultry is packaged or packed for shipping.

(e)(1) Detached ova may be collected for human food in the official establishment provided the collection is sanitary. Ova from condemned carcasses shall be condemned and treated as required in § 381.95. Ova for human food must be cooled, packaged, and handled so as to be fit for human food.

(2) Detached ova harvested for human food may leave the official establishment only for movement to an egg products processing plant for processing as allowed in § 59.440 of the regulations (7 CFR 59.440) under the Egg Products Inspection Act, and when moved from the official establishment shall bear labeling which indicates that the ova were harvested under sanitary supervision of the Inspection Service.

4. Section 381.66 would be 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 which are necessary for chilling and freezing ready-to-cook poultry, including all edible portions thereof, shall be in accordance with operating procedures which ensure the prompt removal of the animal heat and will preserve the condition and wholesomeness of the poultry and assure that the products are not adulterated.

(b) * * *

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

(2)(i) Chillers must contain sufficient water or ice, or both, to keep the chilling media clean and provide a continuous overflow from each section of the chilling system. If there is no loss of water between sections, multiple section chilling systems may be connected so the overflow from subsequent sections serves as water intake for the first section.

(ii) Partial trimming and salvage of parts of poultry carcasses often result in parts of major size, either front or rear portions, wherein the major portion of

the poultry carcass remains intact. These portions may be chilled in water and ice, including chilling in continuous chillers. Individual parts from salvage operations, including but not limited to drumsticks, thighs, split carcasses, and split breasts, shall not be cooled in water and ice but may be cooled in the air, or ice, or under a spray of water with continuous drainage.

(3) Previously chilled poultry carcasses and major portions shall be maintained constantly at 40 °F. or below until 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 shall 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 shall 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 shall 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 shall be such as will minimize water absorption and retention at time of packaging.

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

* * * * *

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

PART 441—CONSUMER PROTECTION STANDARDS: RAW PRODUCTS

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

§ 441.10 Retained water.

Raw meat and poultry carcasses and parts shall not contain water resulting from post-evisceration processing unless the establishment preparing them demonstrates to the Administrator, with data collected in accordance with an FSIS-approved protocol, that any water retained is an inevitable consequence of the process used to meet applicable food safety requirements. Raw meat and poultry carcasses and parts that retain water must bear a statement on the label in prominent letters and contiguous to the product name indicating the maximum percentage of water that may be retained. Raw meat and poultry

carcasses and parts that retain no water may bear a statement indicating that no water is retained.

Done at Washington, DC on September 3, 1998.

Thomas J. Billy,
Administrator.

Appendix A—Expected Elements of a Protocol for Gathering Water Retention Data

Purpose statement. The primary purpose of the protocol should be to determine the amount or percentage of water absorption and retention that is inevitable 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.

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 product 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.

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.

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.

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.

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, commenters are free to suggest a practicable standard 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.

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.

Reporting of data 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.

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

Appendix B—Preliminary Regulatory Impact Analysis—Retained Water in Meat and Poultry Products

August 1998—U.S. Department of Agriculture, Food Safety and Inspection Service

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Executive Summary

This analysis was conducted to meet the requirements of Executive Order 12866 and

the Regulatory Flexibility Act. The proposed rule has been designated economically significant because there is a potential impact of \$100 million or more. This Preliminary Regulatory Impact Analysis (PRIA) shows that the rule could lead to a substantial reduction in the amount of retained water in poultry which could have a significant economic impact on the poultry industry. Under the proposed rule, raw, single-ingredient meat and poultry products would not be permitted to contain water resulting from post-evisceration processing unless the establishment demonstrates that water retention is an inevitable consequence of the process or processes used to meet applicable food safety requirements. There are three types of costs associated with this proposed rule. There are costs for conducting the tests necessary to establish retained water levels. There are also costs associated with reducing retained water to such levels. Finally, there are costs for revising product labels to indicate the presence of retained water. Product labels would indicate the percentage of net weight represented by retained water. This information could be used by consumers in making product choices. The market could provide incentives to firms to invest in new technologies that would reduce retained water.

Most of the cost of this proposed rule would be experienced by the poultry industry. Most, if not all, raw poultry products now contain retained water whereas only a few meat byproducts or organ meats may now contain retained water. Most costs experienced by the meat industry would be associated with voluntary decisions to use new or different processes to meet food safety requirements that would result in some level of unavoidable retained water.

This analysis estimates a range of costs the poultry industry would incur to meet this new regulatory requirement. If establishments are able to demonstrate that current levels of retained water levels are an inevitable consequence of the processes used to meet applicable food safety standards, establishments would not incur costs for reducing retained water. These establishments would incur costs for justifying existing retained water levels and costs for revising product labels. The costs of establishing limits for the poultry industry are estimated to be \$1.5 million. Label revision costs are estimated to be \$18.4 million if all raw, single-ingredient poultry continues to contain retained water.

To the extent that poultry establishments cannot demonstrate that current retained water levels are necessary for achieving applicable food safety standards, significant costs could be incurred as establishments modify processes to reduce retained water levels. Reducing retained water could entail a wide range of processing modifications, depending on the type of chilling equipment currently used and the amount of retained water that would have to be removed. The analysis estimates that the average retained water for chicken as a percentage of net weight is probably in the 5.0 to 6.5 percent range. The average retained water for turkey as a percentage of net weight is probably in the 4.0 to 4.5 percent range.

If this proposed rule would require removing a substantial portion of the existing retained water, then the costs to the poultry industry could exceed \$100 million. FSIS' retained water tests on whole broilers show that retained water varies considerably from establishment to establishment. For 13 establishments operating under the 8 percent regulatory limit for whole broilers, the average retained water at the end of the drip line ranged from 4.72 to 7.32 percent. FSIS believes that the establishments operating at the higher end of this spectrum are targeting the regulatory limit and establishments operating at the lower end of this spectrum are, most likely, operating at or near the minimum necessary to meet existing chilling requirements which are food safety standards. For this reason, FSIS does not expect to see costs approaching the \$100 million level. However, FSIS also recognizes that the retained water levels at the lower end of the spectrum could be tied to purchase specifications or other factors and may not be true minimum levels. Therefore, this analysis has estimated the cost of removing a substantial portion of the current levels of retained water from all poultry establishments.

This PRIA estimates that using additional drain time to reduce retained water in poultry by 4 to 5 percentage points in all establishments could cost up to \$94 million in one-time fixed costs. Annual recurring costs are estimated at \$10 million. These cost estimates are based on situations where inspected establishments were required to drain retained water that exceeded regulatory limits. FSIS program personnel do not believe it is feasible to eliminate all retained water from immersion-chilled poultry. Thus, if establishments must eliminate a substantial portion of retained water, they would incur the costs of minimizing the water plus the costs of establishing the minimum or minimums and labeling costs. The costs of the proposed rule, however, are highly dependent on the level of retained water that is necessary to meet existing food safety requirements. That level will remain unknown until established by well-designed studies. However, as discussed above, FSIS predicts that only those poultry establishments operating at the higher end of the retained water spectrum would have to substantially reduce their retained water levels. This prediction is based on data showing that establishments can control retained water and data showing that some are controlling retained water so as to be at or near the applicable regulatory limit.

This proposal fills a regulatory void created by the U.S. District Court decision to set aside the water retention limits for whole birds. The regulatory limits that the Court set aside were not based on adequate analytical support. Regulatory limits are necessary to protect the public from economic adulteration. Preventing economic adulteration provides a consumer benefit. Consumers would also benefit from the additional information that would be provided by the labeling requirement. The information on retained water should lead to more informed purchasing decisions.

The proposal would also provide affected establishments with the flexibility they need

to choose the most appropriate means for implementing HACCP plans for assuring the safety of raw product. For example, under the proposed rule, both meat and poultry carcasses would be allowed to retain absorbed water if data showed that such water was unavoidable in order to assure compliance with the pathogen reduction performance standards for *Salmonella*. In addition, by replacing certain existing command-and-control requirements with HACCP-consistent performance standards, the proposal would allow increased flexibility which should reduce the costs for HACCP implementation. This analysis does not attempt to quantify the benefits of the increased flexibility that results from eliminating command-and-control requirements. The proposal would also remove certain recordkeeping and reporting requirements.

In terms of aggregate market effects, the analysis concludes that, when compared to the present situation, the proposed rule could result in higher prices for both poultry and meat, with less poultry consumed and more meat consumed. However, when estimated costs are compared with aggregate consumer expenditures, the analysis shows that costs are very small compared with current expenditures. Maximum first year cost estimates for the poultry industry represent 0.36 percent of aggregate consumer expenditures on poultry. Recurring costs to the poultry industry represent only 0.03 percent of consumer expenditures and 0.04 cents per pound.

I. Introduction

FSIS is proposing regulations limiting the amount of retained water raw meat and poultry products may contain. The proposed rulemaking would, among other things, amend the meat and poultry inspection regulations governing water retained by carcasses and parts of carcasses as a result of post-evisceration washing and chilling necessary to ensure product safety and wholesomeness. The amended regulations would apply the same retained-water standard to both red meat and poultry. Meat and poultry carcasses and parts would not be permitted to contain water resulting from post-evisceration processing unless the establishment demonstrates that water retention is an unavoidable consequence of the processing used to meet existing food safety requirements. Under the proposal, raw meat and poultry products that retain water would have to be labeled indicating the maximum amount of retained water that may be present as a percentage of product weight.

In addition to revising the regulations controlling retained water, FSIS is also proposing to revise the poultry regulations covering thawing procedures, water use and reconditioning, and certain other operating procedures. These other regulations are being revised 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. By replacing command-and-control requirements with

HACCP-consistent performance standards, the proposal would allow increased flexibility and should reduce costs for HACCP implementation. Removing some command-and-control regulations would also eliminate some existing recordkeeping and reporting burdens. This analysis does not attempt to quantify the benefits of the increased flexibility that results from eliminating command-and-control requirements.

II. Need for Regulatory Action

Respond to Court Decision

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 interpreted as minimizing 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 Court case referred to below, the maximum retained water for most whole chickens (those 4.25 pounds or under) was 8 percent. The maximum retained water for chicken that will be ice-packed or subsequently cut up into parts is 12 percent. The 12 percent limit is based on the premise that chicken parts from whole birds with water levels between 8 and 12 percent will reach the 8 percent level by the time the parts are packaged. The analogous limits for turkey are similar but include unique limits for 12 different carcass weight categories. The maximum retained water limits for whole turkey range from 4.3 to 8.0 percent depending on weight. The corresponding limits for cut-up turkey range from 5.3 to 9.0 percent. The maximum retained water for whole ducks, geese and guineas was 6 percent, the same limit that applied to chickens over 4.25 pounds.

The U.S. District Court, in the matter of *Kennedy v. Glickman*, set aside the water retention limits for whole birds. The Court found that the analytical support for the existing limits was insufficient. Thus, there are currently no regulatory criteria to determine whether retained water has been minimized in chilled or frozen whole birds. FSIS is mandated to prevent the distribution in commerce of meat or poultry products that are adulterated or misbranded. Under the meat and poultry statutes, a product is adulterated if, among other circumstances, a substance has been added to or mixed with the product to increase its bulk or weight or make it appear of greater value than it is. Thus, if water has not been minimized, the product may be considered adulterated. Such product may also be considered misbranded. Without limits on retained water, FSIS cannot adequately protect consumers from adulteration and misbranding due to excessive retained water in whole birds.

Eliminate Inconsistency

In addition to the situation created by the July 1997 Court decision, FSIS sees additional need for regulatory action. With respect to the regulation of retained water, there are differences or inconsistencies both between the livestock and poultry industries and within the existing regulatory framework for poultry. FSIS allows poultry to retain water absorbed during processing as an unavoidable result of traditional chilling practices. There is no comparable allowance for meat. The regulatory definitions for economic adulteration "by substances added so as to increase bulk or weight or make a product appear better or of greater value than it is" are identical for meat and poultry. Although the Secretary of Agriculture has the authority to apply the adulteration provisions differently, FSIS believes there can be more consistency between the livestock and poultry industries in how the adulteration provisions are applied to retained water in raw products. The traditional differences in chilling practices have led to a situation where the weight of a meat carcass usually decreases during chilling while the weight of a poultry carcass increases.

The Department promulgated regulations limiting water absorption in poultry in 1959, 1961, and 1970 (December 1, 1959, 24 FR 9566; July 19, 1961, 26 FR 6471; October 7, 1970, 35 FR 739). The existing regulations contain a standard of performance that calls for minimization and maximum retained water limits for poultry carcasses based on carcass weight and intended use. Under the existing regulatory enforcement framework, a poultry establishment is "minimizing" retained water when it is operating within the existing limits. FSIS is aware that not all establishments are really minimizing retained water. Data analyzed for this PRIA show that some poultry establishments have been controlling their processes to retain the maximum allowed 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.

III. Background

There are no existing meat regulations that address retained water in raw meat products. Without any regulatory limits, FSIS has enforced the adulteration provision of the FMIA to mean that any level of retained water is adulteration. FSIS has allowed cold water spray chilling systems as a supplement to air chilling of beef and hog carcasses under the conditions outlined in FSIS Directive

6330.1. That document requires that establishments develop quality control systems and inspectors monitor these quality control programs to make sure that the total weight of a group of spray-chilled carcasses is not greater than the total pre-wash weight of the same carcasses. Thus, while an individual carcass may show a weight gain, FSIS enforces a standard of zero-retained water for groups of beef or pork carcasses for spray chilling systems. In contrast, FSIS has not required establishments to closely monitor water when using pathogen reduction methods on the kill floor, such as pre-evisceration carcass sprays or steam vacuum processes.

FSIS implements an extensive program to assure compliance with existing limits for retained water in poultry. Retained water can result from both carcass washing and carcass chilling, i.e., the post-evisceration washing and chilling processes. The existing procedures for conducting retained water tests for poultry are outlined in Part 10 of the Meat and Poultry Inspection Manual. The standard procedures instruct the inspector to tag and weigh a sample of 10 birds from the eviscerating line before the final carcass wash. The final carcass wash occurs before birds enter the chiller. The same 10 birds are then weighed after the chiller at a point specified in the establishment's water control procedures as outlined on FSIS Form 528. The most common point is the end of the drip line or the last accessible point on the drip line. The test procedures are the same regardless of whether the whole bird or cut-up limits apply.

Under standard procedures, inspectors conduct one test each shift. Today, many establishments are tested once each week based on history of compliance. The standard procedures state that test birds must not be allowed extra draining, i.e., they must reflect the production lot. The standard water procedures may specify that the test birds are drained for a specific time if production is all drained for the same time. For example, one establishment specifies that test birds are to be drained four (4) hours before being weighed. When water limits are exceeded, product is retained.

Violations do occasionally occur and appear to be a function of how close to the regulatory limit an establishment is operating. Existing data indicate that some establishments control their process way below the limits and never come close to a violation. Based on the data reviewed for this analysis, most establishments do not have water violations or rarely exceed existing limits. A few, however, appear to target the limit and frequently experience retained product as an extra operating expense. In the data examined for this analysis, retained product required additional drain times ranging from 3 minutes to 12 hours.

FSIS' existing retained water control program is a relatively resource intensive effort. In a poultry establishment with two shifts and two chiller systems, FSIS may be conducting four 10-bird tests each day. Each test takes from 40 to 60 minutes for selecting, tagging, and weighing birds and then recording results and making necessary calculations. Even with reduced testing in

many establishments, it appears reasonable to estimate that FSIS conducts between 300 and 400 retained water tests each day. Assuming a 260-day work year, FSIS conducts from 78,000 to 104,000 tests annually. At 40 to 60 minutes each, the annual testing represents from 25 to 50 staff years of 2,080 hours each. The Agency also expends an estimated 560 staff-hours each year reviewing changes in establishment washing, chilling, and draining procedures. These estimates do not include the cost of addressing violations.

FSIS intends to pursue a new water control program that can incorporate wholesale or retail sampling to identify establishments that may be exceeding water limits and then target resources to conduct follow-up testing to confirm compliance or noncompliance. FSIS is aware of a retail testing method that has been developed and used in European Union member States. The method involves measuring drippage from sampled products against what is considered the natural water content of the product.

In its 1980 net weight proposal, FSIS considered a "building-block" approach to net weight compliance that was then being reviewed by the Codex Alimentarius Commission. This approach, as described in the 1980 notice, "would be modeled on a statistical limits of variance technique developed by Switzerland for application to imported, prepackaged foods. Inspectors would make limited inspections for compliance at retail. If the sampling technique indicates a noncompliance problem, additional inspection of the same product would be made at retail and further back in the marketing chain, including at processing plants. If the problem continues following notification of the producers, a more precise enforcement test would be applied." An alternative that lends itself to this type of approach will rate high on the criterion for an efficient, equitable enforcement system.

IV. Description of Proposed Rule

The proposed rule would establish a single retained water standard for all raw, single ingredient meat and poultry products. This standard would allow retained water only if that water was an inevitable consequence of the process or processes used to assure compliance with existing food safety requirements. The presence of any retained water would, however, have to be identified on product labeling.

The proposed requirements would affect only single-ingredient, raw, whole, cut-up, or ground meat and poultry carcasses and parts, including edible organs and other edible meat and poultry byproducts. It would not affect raw products with labeling that includes a list of ingredients or nutrition labeling, such as pre-basted frozen turkeys or individually quick frozen (IQF) poultry parts labeled to indicate the addition of basting solutions.

The proposal would also modify other existing regulations related to water use and chilling requirements. For example, the proposal would remove a requirement that establishments must file a description of chilling and freezing procedures with the

inspector-in-charge (IIC). At the same time, the proposal would remove the requirements that the establishment submit written notice of any adjustments to washing, chilling, and draining methods before any changes are made and provide FSIS data showing the adjustments are effective in meeting existing water limits. These modifications would reduce recordkeeping and reporting burdens.

The proposal would also remove specific requirements concerning the amount of fresh water intake required in the first section of a continuous chilling system. The existing regulations require a minimum of one-half gallon per frying chicken and proportionately more for other classes of poultry, including not less than one gallon per turkey. The potential for lowering water costs is unknown. The general requirements for using potable water and continuous overflow from one section of the chiller to the next will remain. The requirement for continuous overflow would appear to limit the opportunity for reduced water usage.

The regulations concerning water intake were established at a time when FSIS assumed responsibility for controlling pathogen levels and frequently did so with design requirements. In 1978, the Department published a proposal (43 FR 14043, April 4, 1978) that would reduce water intake requirements by 50 percent when chlorine levels in the incoming water were at least 20 parts per million. The proposal was subsequently withdrawn. Of concern during the rulemaking were studies by USDA and the Virginia Polytechnic Institute and State University (VPI) that showed that bacteria levels increased as intake water was reduced. While the relationship of water intake and pathogen levels remains a public health concern, FSIS is no longer attempting to design protection using command and control regulations. Under the Pathogen Reduction/HACCP final rule, establishments are required to meet pathogen reduction performance standards. This current proposal is a performance-based standard that will lead to retained water levels that are necessary to meet pathogen reduction requirements and other food safety standards. The current proposal is consistent with FSIS objectives of setting performance standards and moving away from design requirements, such as the minimum of one-half gallon of fresh water intake per chicken. It is now industry's responsibility to establish how water intake relates to both retained water and pathogen levels.

The proposal would also remove prescriptive requirements for water reconditioning systems for poultry chillers. This change would not have an impact because reconditioning systems have not proven feasible in commercial operations.

FSIS intends to retain the existing requirements mandating that the internal temperature of poultry carcasses be lowered to 40 °F. or less within a specified time. The Agency also will continue to require that each establishment provide scales, weights, identification devices, and other supplies necessary to conduct water tests. While the Agency envisions a compliance-sampling program using the deviation from an expected level of total water content as a

screening system, the Agency will still use the existing sampling system to confirm potential compliance problems.

The poultry regulations discussed above concerning water use, chilling requirements and water retention are all contained in 9 CFR 381.66 (Temperatures and chilling and freezing procedures). This proposal would also remove several existing regulations from 9 CFR 381.65 that now address general operating procedures, many of which are not related to water use or chilling procedures. Operating procedure requirements that would be removed or revised under this proposal include the following:

- Specific requirements that prescribe the nature of opening cuts for evisceration,
- The requirement to remove kidneys from mature poultry,
- Requirements pertaining to the handling and storage of materials that could adulterate product,
- Requirements for containers, packaging, and covering materials,
- Requirements on removing offal from establishments,
- Requirements prescribing how to thaw frozen poultry and drain ready-to-cook poultry,
- Requirements on how establishments can chill parts of carcasses, and
- Requirements related to harvesting detached ova.

The regulations that would be eliminated are either regulations that are overly prescriptive command and control regulations, such as those defining opening cuts or regulations that are now redundant with HACCP, e.g., the removal of kidneys. The reason for removing the kidneys of mature chickens and turkeys is that they are a source of cadmium, which can accumulate in the human liver and kidneys and cause acute or chronic health problems. This is a "food safety hazard reasonably likely to occur" that establishments will identify in their hazard analyses and control through their HACCP systems. Thus, a regulatory requirement for their removal would be redundant with the HACCP regulations.

V. Analysis of Existing Data on Retained Water

As discussed above, most raw, single-ingredient meat products are not currently allowed to contain any retained water. This analysis assumes that these meat products will continue to be produced without retained water. Products that are packed in water or may retain water are already labeled to indicate such information. Chitterlings (swine intestines) are washed and chilled before shipment and are packaged with water. Certain organ meats and meat from ears and tails are also washed and chilled using 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. The Agency does not have data on the volume of meat products with retained water or data on the current levels of retained water. These products do not, however,

represent a major portion of the meat industry.

In order to estimate the current level of retained water, in early 1997, the Agency's headquarters staff informally requested field offices to forward readily available water data from poultry plants. The material assembled varied from region-to-region and plant-to-plant. The field offices did not use a standard method to summarize available data. In some cases, the individual establishments were identified; in other instances, all plant identification was removed. The allowable water, i.e., the applicable regulatory limit, was not always readily discernible. The data covered the period of January through May 1997. Most of the data was included on the Daily Moisture Records (FSIS Form 549 or its replacement Form 6310-1). These records record the pre-wash and post-chill weight of each individual bird for each 10-bird test. Five 10-bird tests are recorded on each record.

While the data assembled was not systematically collected, it has a degree of randomness and provides a preliminary estimate of the amount of water currently absorbed and retained during the washing and chilling process as measured by existing FSIS water test procedures. An analysis was conducted using all the data that met the following criteria for establishments slaughtering young chickens.

- Minimum of twenty 10-bird tests (200 birds).
- Existing regulatory limit available.
- All available test data collected under a single applicable limit.
- All results clearly legible.
- Establishment identified (to connect water data with production).

The data from 33 establishments slaughtering young chickens met the above criteria. These 33 establishments represented 17.5 percent of FY 1996 production. Within the 33, 19 establishments were operating under the 12 percent water limit that was applicable to cut-up and ice-pack poultry. These 19 establishments accounted for 9.11 percent of the total FY 1996 production and 52 percent of the production within the 33 establishments.

Thirteen establishments were operating under an 8 percent water absorption limit during the period the data was collected. The 8 percent limit applies to whole carcass pack chickens or frozen chickens that are 4.25 pounds or less. The 13 establishments represented 7.95 percent of FY 1996 production. One establishment was operating under the 6 percent limit for whole chickens over 4.25 pounds.

Among the 33 establishments, 48 percent of the young chickens were being processed under the water limits for whole birds. Today, the National Broiler Council estimates that only 10 percent of broilers are "marketed" as whole birds. Two factors explain this difference. First, if any birds in a production shift are to be shipped whole, the entire shift is subject to the whole bird limit. Second, some birds are shipped whole and then cut up in a second establishment conducting further processing. The 10 percent "marketed" as whole birds refers to retail and food service destinations.

The 13 establishments operating under the 8 percent limit had an average absorbed water level of 5.81 percent and a production based weighted average of 5.68 percent. Individual establishment averages ranged from 4.72 to 7.32 percent. These percentages

represent percentage gain relative to the carcass weight prior to the final carcass wash. The individual plant averages were calculated by combining all available water tests from all shifts and all washer/chiller systems. Averaging all water test results in this manner assumes that each test represents an equal amount of production. Many plants have more than one chiller system and multiple shifts. Production may not be equally distributed across all shift-chiller combinations.

The 19 establishments operating under the 12 percent limit had an average absorbed water level of 9.11 and a weighted average of 9.02 percent. As above, these percentages represent percentage gain relative to the carcass weight prior to the final carcass wash. While 18 of these establishments had absorbed water levels close to 8 percent or above, one establishment had an average water level of 5.37 based on sixty 10-bird tests (600 birds) conducted from January through April 1997. The establishment operates two systems, one averaged 5.61 percent, the other 5.14. All the daily records were checked to indicate the establishment was producing cut-up poultry.

In addition to the data analyzed above (33 establishments), the 1997 data included water tests from three young chicken establishments that processed both whole birds under the 8 percent limit and cut-up chickens under the 12 percent limit. For these 3 plants, there were at least 20 tests at each level.

The results are shown in the following table:

Establishment	8 percent limit	12 percent Limit	Difference
A	6.42	7.67	1.25
B	5.26	6.15	0.89
C	5.94	7.30	1.36

An analysis of variance procedure indicated that, after accounting for variability between plants, there is a statistically significant difference (confidence greater than 99%) between the percentages of water gain at the two regulatory limits. It follows that these establishments are not really minimizing retained water when operating under the 12 percent limit because they have lower retained water when processing whole birds. The difference does not, however, approach 4 percent.

Because there are 12 different water limits for different sizes of turkeys, the approach to analyzing existing data had to be different. It's common to see three different water limits for a five-test series recorded on the Daily Moisture Records. The data from turkey establishments was sorted using the following two criteria:

- Minimum of ten 10-bird tests conducted under limits applicable to turkeys packaged as whole birds.
- Establishment identified.

A review of the existing data identified six establishments that were operating under the

limits for whole carcass packing procedures. These six establishments represented 12.7 percent of federally inspected turkeys in FY 1966. An estimated 40 percent of all turkeys are marketed as whole birds. Because of the 12 different limits for whole turkeys depending on weight, this analysis did not attempt to estimate absorbed water for different sizes of birds.

The six turkey plants had an average absorbed water level of 4.39 percent and a weighted average of 4.74 percent. Individual plant averages ranged from 1.91 to 5.53 percent. This analysis did not attempt to estimate water levels for cut-up or ice-packed turkeys.

The review of Daily Moisture Records identified a couple of potential issues that should be addressed by comments. First, some of the highest water results occurred when line speeds were running too slow for the established water control procedures. Since slowing line speeds may be a response to higher pathogen levels there is some indication that water pick up and pathogen levels may be inversely related under some

conditions. In one case, a company conceded that it could not pass the 8 percent whole bird water limits at certain lower speeds and agreed to divert birds to cut-up operations when the line speed dropped to a certain level. By diverting the birds to cut-up, the establishment avoided the process of conducting a 50-bird test to establish the necessary drain time to meet the 8 percent limit. Another plant noted that slower speeds resulted in insufficient numbers of birds for proper travel through their chiller system with rocker arms.

As a second issue, the data indicate that more problems arise with very small birds, i.e., broilers in the 2½ to 3-pound range. Individual birds would show water pick-up in the 20 to 24 percent ranges. FSIS staff notes that eviscerating equipment sometimes causes extra large openings on small carcasses that lead to pockets of water under the skin. These birds are informally referred to as "water bags." The water test is rather meaningless for these birds if they are headed to cut-up operations because the water in

these pockets drains quickly and easily at the cut-up operation.

VI. Retained Water in Net Weight

The proposed rule would require that product labels indicate the percentage of net weight represented by retained water. All the data presented in the previous section refers to retained water as a percentage gain from the carcass weight prior to the final carcass wash. The same volume of retained water expressed as a percentage of net weight will be somewhat lower because net weight includes the pre-wash carcass weight plus any absorbed water.

A second difference occurs because FSIS water tests normally occur at the end of the drip line. The exact relationship between the volume of retained water as recorded by FSIS tests and the volume of retained water in finished packaged product is unknown. Retained water in finished packaged product will be lower for several reasons. First, an establishment's handling procedures will lead to some water loss before the product is packaged and weighed. Today, only 10 percent of broilers are "marketed" as whole birds. Thus, a lot of broilers produced under whole bird limits are being cut up in the originating establishment or in a subsequent establishment before being packed as finished product. Second, any product that exceeds existing limits is required to drain for a specific time as determined by program personnel. Third, the establishment may implement draining procedures to meet a customer's purchase specifications. In these cases, the retained water included in net weight could be far less than the retained water measured by FSIS tests.

It is also difficult to compare the water data for whole birds with the data on cut-up poultry. As discussed above, available data showed whole young chickens to average 5.68 percent while cut-up young chickens averaged 9.02 percent on a production-based weighted average. The 12 percent limit on cut-up chickens was based on a premise that if poultry for cut-up averages less than 12 percent at the time of water test, it would drain to less than 8 percent during the remaining handling prior to final packaging. This does not mean that poultry destined for cut-up will drain 4 percent. It seems reasonable to assume, however, that the level of 9.02 percent will approach the whole bird level of 5.68 percent, probably ending up somewhere between 6.0 and 7.0 percent.

Allowing for some drain in the whole bird packaging process and considering the conversion to percentage of net weight, it seems likely that the average retained water for chicken as a percentage of net weight is probably in the 5.0 to 6.5 percent range. This estimate is consistent with findings published in a study¹ conducted in 1979 by the Economics, Statistics, and Cooperatives Service (ESCS (now ERS)). That study, hereafter referred to as the 1979 ERS study, estimated that average water pickup for six processors at the time of packaging was 5 to

6 percent. Because some product undergoes further cut-up and packaging in other establishments, the average water level leaving originating establishments is not the same as the level in customer packages.

The whole bird data on turkeys, i.e., 4.74 percent retained water, is a better estimate for packaged turkey since 40 percent are marketed as whole birds. One would expect some additional drainage before the birds are packaged. The average retained water level for turkey as a percentage of net weight is probably somewhere in the range of 4 to 4.5 percent.

VII. Economic Analysis of Retained Water in Meat and Poultry

This chapter examines the economic issues associated with retained water in poultry. For analytical purposes, this chapter assumes that the average retained water for all chicken is 5 percent of net weight and the average for turkeys is 4 percent of net weight. The analysis in Sections 4 and 5 concluded that the averaged retained water for chicken is probably between 5.0 and 6.5 percent and the average retained water for turkey is probably between 4.0 and 4.5 percent.

In FY 96, there were 7.67 billion chickens slaughtered under Federal inspection. Based on an estimated average carcass weight of 3.36 pounds, the total weight of ready-to-cook chicken was 25.8 billion pounds. If the average retained water was 5 percent, then one can view the total as 24.5 billion pounds of chicken and 1.3 billion pounds of retained water. Since the wholesale price of whole broilers was \$.6124 per pound,² the chicken had an estimated whole bird, wholesale value of \$15.8 billion.

In FY 96, there were 289.6 million turkeys slaughtered under Federal inspection. Using an average carcass weight of 17.9 pounds, the production was 5.18 billion pounds. The average FY 1996 wholesale price was \$.665 per pound resulting in a total wholesale value of \$3.4 billion. Using an estimated average retained water level of 4 percent, one could view the production as 4.97 billion pounds of turkey and 0.21 billion pounds of retained water.

There are two ways of looking at the current situation. One is the perspective that customers are paying \$15.0 billion for the chicken and \$789.4 million for the retained water and \$3.3 billion for turkey and \$136 million for retained water. The other is that the water has no effect on the value of the poultry. In this case, the value of the chicken is \$15.8 billion and the value of the turkey is \$3.4 billion. The customer is simply not being informed that the true wholesale price of the chicken on a "zero added water" basis is \$.6446 per pound and not \$.6124. Similarly, the customer is not being informed that the true wholesale value of turkey is \$.684 per pound and not \$.665.

While the 1979 ERS study was focused on analyzing alternative net weight regulations, the study addressed essentially the same issue as retained water when it considered drained weight labeling. The ERS study used an "added water in chicken" example to

illustrate the retail price effects of dry tare versus drained weight labeling of packaged chicken. The example was a package of chicken breasts selling for \$1.20 per pound with a labeled weight of 3 pounds using a dry tare system. The tare is the weight of any container, or wrapper, or other material not included in the stated weight of a package. This package would cost the consumer \$3.60. If this package undergoes a water loss of 4 percent, and assuming the net weight was exact under the dry tare system, the consumer selecting this package would be receiving 2.88 pounds of drained weight chicken and the real price per pound of chicken is \$1.25 (\$3.60÷2.88 pounds).

Under a drained weight system, assuming exact measurements, the package would show a net weight of 2.88 pounds and a price per pound of \$1.25. The cost of the package would remain \$3.60. The ERS study used this example to illustrate that changing net weight methodology, by itself, only changes the information a consumer receives but not the real cost of the product. After analyzing the "water in chicken" issue, the 1979 ERS study concluded:

Whether consumers pay chicken prices for water is not clear simply because a dry tare labeling weight is allowed. If \$3.60 is the competitive cost for a package of chicken breasts of that quality, then the consumer is not paying \$1.20/lb. for 0.12 lb. of water and juices. The consumer is simply not being informed that the true price of chicken at the retail level on a drained weight basis is \$1.25/lb. not \$1.20. Consumers may well be paying more for chicken or other meat and poultry products than can be justified. But to verify such an assertion would require an extensive study of the industrial organization of the industry and data on firm costs, revenues, and profits. Answering that question is beyond the scope of this study.

The economic issue raised by the retained water issue is whether labels reflecting the price of poultry on a "green weight" basis would have enough of an effect on the demand for poultry that consumers would purchase less poultry and more product that competes with poultry. This analysis, like the earlier ERS study, has not attempted to predict the shifts in supply and demand that might occur if product labels included the "true" price of poultry. The marketplace issues are more complex than just pounds and cents. Discussions with retail industry personnel indicate that they believe many consumers object to free liquid in packages and that "dry" looking packages would have a positive impact on demand. They also noted that labeling of water is not necessarily a detraction. They point to the rapidly growing market for Individually Quick Frozen (IQF) Ice-Glazed poultry. This product sometimes includes labeling indicating the addition of basting solutions to enhance flavor and juiciness. IQF Ice-Glazed and marinated products are marketed based on convenience.

VIII. Options Identified

FSIS identified six options for regulating retained water in raw meat and poultry products. These six options are:

¹ Assessment of Proposed Net Weight Labeling Regulations, Staff Report, Prepared by the Economics, Statistics, and Cooperatives Service for the Food Safety and Quality Service, USDA, August 1979.

² Livestock, Dairy and Poultry Situation and Outlook, LDP-M-44, ERS, USDA, August 15, 1997.

- No limits on retained water as long as the product label indicated the amount of retained water.
- A standard requiring zero retained water for all raw, single-ingredient products.
- A requirement that there could be no retained water in the stated weight of the product.
- A standard that would set limits for retained water based on best available technology within traditional production practices. This option would also require that retained water be identified on product labels.
- A standard that would set limits for retained water based on optimum use of existing equipment. This option would also require that retained water be identified on product labels.
- A standard that would require an establishment to demonstrate that any retained water is an inevitable consequence of the process used to meet applicable food safety requirements. This option would also require that retained water be identified on product labels.

IX. Analysis of Options

This section provides an assessment of the six regulatory options identified. The six options fit into three categories. The first category is represented by Option 1 and can be characterized as the option where there would be no limits on retained water for any raw product as long as the label indicated the presence of that water. The second category covers options where no retained water would be allowed. This analysis discusses two variations, one (Option 2) where no retained water would be allowed in the product and another (Option 3) where no retained water could be included in the product weight. Options 4, 5, and 6 are all similar in that they would permit limited water retention and they would require that any retained water be identified on product labels. These last three options differ in the basis for establishing the limits for water retention. The three options consider limits based on best available technology, limits based on best performance with existing equipment, and limits based on the retained water necessary to meet existing food safety requirements. Setting new limits based on any of these three criteria would have to meet the Court's requirement that the rulemaking record explain how particular water retention levels are set.

All six options provide consumers with improved information on the "true" price of poultry. Improved information results from either labeling the level of retained water, eliminating all retained water, or a combination of labeling and limiting the amount of retained water. Improved information provides a consumer benefit in that it allows consumers to make more informed purchasing decisions. The analysis that follows does not quantify the consumer benefits of each option. FSIS recognizes that removing all retained water informs consumers of the "true" price of poultry; no further calculation balancing water content and label price would be necessary. A combination of labeling with a limit on retained water may have greater consumer

benefits than labeling alone because the labeled product price would provide improved information to those consumers that would not use the retained water information.

Option 1—Labeling of Percentage Retained Water

Under this option, there would be no limit on retained water as long as the amount, i.e., percentage of product weight, was indicated on the product label. The same requirement would apply to both meat and poultry products. To assure prominent notification, the product name on the labeling of an affected product would be accompanied by a statement, such as "may contain up to ___ percent retained water" or "contains ___ percent retained water."

After identifying this option, the department concluded that this regulatory option would not be consistent with the existing adulteration provisions discussed earlier. In other words, unlimited retained water would constitute economic adulteration, even if identified through labeling. While this conclusion eliminates this option, this analysis uses the option as a vehicle to discuss the costs and benefits of using labels to inform consumers about retained water.

The cost analysis presented later in Section X concludes that all poultry labels could be revised at a cost of \$18.4 million. This cost would be an up-front, nonrecurring cost. The label revision costs of \$18.4 million are an estimate for the cost of revising labels for raw poultry shipped from federally inspected poultry establishments that both slaughter and further process raw poultry. The estimate of \$18.4 million does not include potential label revision costs for product that is produced in one of the slaughter/processing establishments and then further processed in a second inspected establishment that does not slaughter poultry. To illustrate, there are inspected establishments that purchase whole birds and further process these carcasses into parts of carcasses and other establishments that purchase parts of carcasses and further process these parts. The inspected establishments purchasing product that has "percentage retained water labeling" would have to label their further processed, single-ingredient, raw products unless they had data showing that the further processing they conduct removes all the retained water. Presumably, the percentage of retained water would decrease during further processing. The further processing establishments would have to label their products to indicate the presence of any remaining retained water. FSIS does not have information on the number of establishments or labels that could potentially be affected.

There are two other situations where revised labels could be required. While most raw poultry sold in retail stores is packaged and labeled in federally inspected establishments, some raw product is repackaged and labeled at the retail level. Retail stores would have to label their single-ingredient, raw products unless they had data showing that the processing and repackaging they conduct removes all retained water. Thus, there would be some

cost for labeling retained water at the retail level. Finally, there may also be a few meat labels that need to be revised since some byproducts and organ meats are now washed in water before being shipped.

There would also be the cost of establishing the level of retained water. As discussed earlier, FSIS now employs from 25 to 50 staff years measuring retained water. Inspected establishments could utilize FSIS test results or conduct their own retained water tests. If such tests are conducted by Quality Control (QC) technicians making \$35,000 annually, the cost of 25 to 50 staff years represents from \$875,000 to \$1.75 million, annually. This option would not require any reduction in the current levels of retained water. Thus, there would be no costs for modifying production practices. The cost analysis in Section X addresses the cost of establishing a minimum which is a different task than establishing the level.

The labeling of product to identify retained water benefits consumers. The information provided has value because it allows consumers to make better decisions. In the terminology of the 1979 ERS study, the labeling of retained water would help consumers establish the "true" price of poultry.

The extent of the labeling benefit, i.e., the value of labeling information to consumers, is affected by several factors. These include the type of label that will eventually be required, the number of different labels present in the marketplace and the variation in retained water within a specific production lot. The first factor affecting the value of the labeling information is the type of label statement. If the label statement indicates "up to ___ percent retained water," the consumer cannot use the information to calculate a true price per pound because the label would not specify the actual amount of retained water. The "up to ___ percent" type of label would provide consumers with general information indicating that some level of added water was present. This type of label does not provide the same incentive to minimize added water as a label indicating a specific percentage, i.e., "contains ___ percent added water."

The second factor affecting the value of labeling is the number of different labels present in the marketplace. If different establishments have different labels for different levels of retained water, consumers could be faced with a multitude of different labels making price comparisons very difficult. It is not unusual for a large supermarket to stock raw poultry from more than 10 different federally inspected establishments. While it appears reasonable to assume that a company or an establishment would prefer to use a single retained water statement for all raw product labels, it is possible that some establishments would develop alternative labels for each product, each indicating a different level of retained water. Added water content could be established on a day-to-day or production-shift basis.

A third factor affecting the value of labeling is the variation in retained water within a specific production lot. Natural

variation is a component of all food attribute labeling. Variation does appear, however, to present a greater than usual concern with retained water. Based on the 10-bird tests conducted by FSIS, the package-to-package variation could be relatively high for whole birds. In a randomly selected 10-bird test for whole broilers (average "green weight", i.e., carcass weight prior to any water absorption, was 3.6 pounds), the average retained water was 6.57 percent. The range was from less than 1.0 percent (0.95) to 14.6 percent. Only five birds were within ± 2.0 percent of the average 6.57 percent. Two individual birds exceeded the 8.0 percent limit. In a second 10-bird test of 3.2-pound broilers averaging 6.92 percent retained water, 6 of 10 were within ± 2.0 percent. Three individual birds exceeded the 8.0 percent limit. This data raises an issue concerning how a percentage labeling option would be implemented, i.e., what level would be required to appear on product labels? Would it be the average or would it be a level that included 90 or 95 percent of the individual birds?

The amount of retained water appears to vary less for turkeys. In one randomly selected 10-bird test of smaller turkeys (regulatory limit of 6.0 percent), 9 of 10 were within ± 1.0 percent of an average retained water level of 5.45 percent. In a 10-bird test of larger birds (regulatory limit 5.3 percent), 7 of 10 were within ± 1.0 percent. One bird exceeded the regulatory limit.

While the variation rate affects the value of the labeling benefit, it does not eliminate the benefit. For an individual purchase, purchasing a product labeled "2% retained water" does not guarantee more useable product than purchasing a product labeled "4% retained water." When averaged over several purchases, however, the product labeled to indicate less retained water should result in more useable product. In addition, a large portion of raw poultry is now marketed as packages of thighs, wings, breast quarters, leg quarters, and boneless, skinless breast meat, etc. For these types of packages, the bird-to-bird variation is less of a concern.

Option 2—Zero Retained Water

The Agency could establish a standard of zero retained water for all raw, single-ingredient meat and poultry products. In theory, given sufficient drip time or drain time or drying time, all raw, single-ingredient products can be returned to a "green weight." However, available data suggests that returning immersion-chilled poultry to "green weight" may not be feasible. The 1979 ERS study included data that supports the conclusion that water retained during washing and chilling does not completely drain from poultry by the time the product reaches the consumer. For the study, ERS, in conjunction with ten local weights and measures agencies, measured the percent drain in 297 retail packages of chicken from five poultry processors. All packages were whole cut-up chicken packed at establishments using immersion chilling. All brands had an average water pickup of 5 to 6 percent at the time of packaging. For the 297 packages the average drain was a percentage of labeled net weight was 3.42 percent. Assuming the product started at an

average of 5.5 percent, the product was still retaining approximately 2.0 percent absorbed water when sampled at retail. The study did not indicate how many days the product had been in distribution. One processor was shipping to retail stores on both the east and west coast. Thus, in some cases, there was considerable transportation time involved.

There was a second³ study that showed that the water loss that occurs in the plant from the time the poultry is placed in the package to the time it leaves the plant is substantially less than total retained water. During the development of the 1989 Net Weight Proposal (54 FR 9370, March 6, 1989), FSIS, in cooperation with the National Broiler Council and the National Conference on Weights and Measures, conducted a study on water loss. Data collected from ten chicken processors showed that the average water loss occurring in the plant after packaging was 1.8 percent. The study did not, however, include data on the length of time the product stayed in the plant after initial packing.

FSIS technical personnel believe that a zero standard would require the poultry industry to abandon immersion chilling because attaining zero-retained water with immersion chilling is not technically feasible. Installing air chilling or air chilling/spray systems would require major reconstruction costs for the poultry industry. There is also a potential cost associated with possible increases in pathogen levels. Studies have shown that immersion chilling reduces overall pathogen levels on poultry. If this option would force the poultry industry to abandon immersion chilling and pathogen levels increased, then there could be additional social costs associated with increases in foodborne illness. With this option there would be no need to revise product labels.

Under this option, consumers would benefit by being fully informed as to the "true" price of both meat and poultry products. No balancing of water content and label price would be necessary. However, because the benefits of better informed consumers from a zero-retained water standard are unlikely to surpass the costs, this option was eliminated.

Option 3—"Green Weight" Labeling

A variation on the concept of zero-retained water is the option where there could be no retained water in the stated weight of the product. Establishments would be required to establish a retained water level for each "lot" or shift. Scales would then have to be adjusted to account for retained water. The weight indicated on product labels would be an estimate of the "green weight" prior to the final carcass wash.

The only direct cost is the cost of establishing the amount of retained water in order to adjust scales. There would be no need to revise product labels or modify chilling practices. The major impact would be a reduction in the labeled volume of poultry production by an estimated 1.5

billion pounds. To maintain the current level of sales in dollars, the poultry industry would have to raise the wholesale price per pound by an average of 5.1 percent. Retail prices would also increase. Consumers would, most likely, perceive an increase in poultry prices. As the 1979 ERS study noted, however, changing net weight methodology, by itself, only changes that information a consumer receives but not the real cost of the product. Consumers would, however, be fully informed as to the "true" price of poultry.

A disadvantage of this option would be that the labeled weight would only be an estimate of the "green weight." The package-to-package variation would now be an issue for the accuracy of the net weight statement rather than the accuracy of a qualifying statement. There could also be considerable differences between labeled weight and packaged weight. This option would require the Agency to revise the overall system for regulating net weight accuracy.

If this option were selected, FSIS would have to reopen the net weight regulations. In 1990, after four proposals and almost two decades, FSIS published final rules for net weight labeling of meat and poultry products (55 FR 49826, November 30, 1990). In the final net weight rule, FSIS established a regulatory framework that for all compliance testing in federally inspected establishments, the net weight of raw chicken would be established using a dry tare system. In a dry tare system, both free liquid and liquid absorbed by packaging material would be included in the net weight of the product. At the same time, the rule recognized that a few State and local weights and measures authorities still prefer to conduct wet-tare compliance testing. Under a wet-tare system, the free liquid and liquid absorbed by packaging material are not counted in measuring the product weight. The final rule established a 3 percent "gray area" where if fresh poultry minus any liquids (free liquid plus liquid absorbed by any packaging material) is within 3 percent of the labeled weight, further information is sought before any determination is made. The 3 percent "gray area" applies only in localities using wet-tare testing. The task force that recommended the 3 percent gray area for raw poultry noted⁴ that the recommended level would require over pack by manufacturers supplying wet-tare localities to compensate for water lost.

Enforcement of net weight requirements is an area where Federal, State, and local authorities share responsibility and must cooperate. The enforcement procedures, 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." FSIS' net weight regulations incorporate Handbook 133 by reference. The National Institute of Standards and Technology (NIST) has a statutory responsibility for "cooperation with the

³ U.S. Department of Commerce, National Institute of Standards and Technology (NIST), Report of the 73rd National Conference on Weights and Measures, NIST Special Publication 750, 1988.

⁴ U.S. Department of Commerce, National Institute of Standards and Technology (NIST), Report of the 73rd National Conference on Weights and Measures, NIST Special Publication 750, 1988.

States in securing uniformity of weights and measures laws and methods of inspection." At the same time, the FMIA and PPIA do not allow State and local jurisdictions to impose any standards that differ from those published by FSIS. In publishing the final net weight regulations in 1990, FSIS stated that the "rule is designed to enhance the ability of Federal, State, and local agencies to enhance the industry-wide use of strict net weight standards at the packing, warehouse and retail level." Although this option would enable FSIS to address economic adulteration, it was eliminated because (1) the benefits in the form of consumer information do not appear to outweigh the costs of adjusting scales and labels to show green weight, and (2) because of the need to maintain uniformity in weights and measures laws and methods of inspection.

Option 4—Retained Water Limits Based on Best Available Technology Within Traditional Production Practices

Under this option, FSIS would require all establishments to meet water limits based on the lowest levels that are currently being achieved by those establishments using the best available water-immersion chilling technology. The limit for retained water in carcass beef, pork, lamb, and goat would remain at zero. There might be some costs associated with establishing limits for the byproducts and organ meats that are now processed separately from carcasses.

FSIS recognizes that, for the poultry industry, the concept of a "minimum" cannot be separated from some definition of standard manufacturing practices that would include a reasonable drip or drain time and some reasonable minimum temperature for chiller water. Longer drip lines and lower chiller water temperatures are both factors that would increase the cost of chilling poultry.

Under this option, it is envisioned that the new limits would be established based on data from the establishments using the best technology. There would be costs for collecting and analyzing the data and costs from modifying processes to reduce water retention. This option could impose considerable costs on those establishments that do not currently have the best available technology.

The maximum allowed water level could actually be a series of levels for different types and weights of meat and poultry products. Under this option, products could not contain more than the established limits and all products containing retained water would have to be labeled indicating the presence of retained water. The costs of labeling the percentage retained water would be similar to those described under Option 1. The factors affecting the value of labeling information would still exist, but there should be fewer different labels because the range of permissible retained water levels would be reduced.

Operating the best technology so as to minimize retained water may not be consistent with minimizing pathogens. Thus, there is a potential cost associated with increased pathogen levels and increased foodborne illness.

This option would enable FSIS to effectively address economic adulteration and would provide consumers information. However, because the costs to industry to acquire the best available technology would be large and would outweigh consumer benefits, this option was eliminated. Furthermore, the option has the effect of a design standard.

Option 5—Water Limits Based on Existing Equipment

This option would require all establishments to operate their existing equipment so as to minimize retained water. As discussed in the previous option, minimums would have to be based on some reasonable limits for operating parameters. The retained water requirement for carcass meat would remain at zero since meat establishments are already operating at zero.

As with the previous option, new retained water limits are required for this option. Data would have to be collected and analyzed to establish minimum water levels for different types of equipment. There would be costs for collecting and analyzing this data, most likely greater than for the previous option. However, no establishment would have to replace equipment, as all minimums would be based on existing equipment. This option would presumably lead to a larger number of retained water requirements. FSIS technical staffs believe retained water is related to variables such as type of chiller, water temperature, time in chiller and type and level of agitation.

Retained water would have to be identified on product labels. The costs of labeling retained water would be similar to those under Options 1 and 4. The factors affecting the value of labeling would still exist. Having different minimums for different equipment would probably lead to a greater number of labeling variations.

Minimizing retained water may not be consistent with processes that minimize pathogens. Thus, there is a potential cost associated with increased pathogen levels and increased foodborne illness.

Option 5 is superior to Option 4 in that no establishment would have to replace existing equipment or processes. This factor outweighs the potentially higher cost of establishing limits and the potential decrease in the value of labeling information due to a greater number of labeling variations. Option 5 is deemed inferior to the preferred option which follows because it does not provide flexibility to the meat industry and does not integrate food safety requirements. Options 4 and 5 may lead to increased pathogen levels and increased costs of foodborne illness.

Option 6—Retained Water Limits Established by Processes Necessary To Meet Food Safety Requirements

Under this option, all establishments would be expected to meet a zero-retained water standard (i.e., Option 2) unless data demonstrate that another level is necessary to meet existing food safety standards using existing washing, chilling, and draining systems (i.e., by introducing food safety objectives to Options 4 and 5). FSIS envisions that such data could be established

on an industry-wide basis, for a specific industry sector using similar processes, or on an establishment-by-establishment basis. The data could be collected and analyzed by individual establishments or by trade associations or other groups.

There would be costs for collecting and analyzing data. For the previous option, the data would be collected to establish a minimum. For this option, the data would be collected to establish a minimum while still meeting the existing chilling requirements. Thus, the poultry industry costs for establishing the limits should be essentially the same as the costs for the previous option. The meat industry would establish limits for retained water only if they viewed it as a new lower cost option for meeting pathogen reduction performance standards. Any retained water would have to be identified on product labels. The limits on retained water would, most likely, be a series of levels for different types and weights of meat and poultry products. The costs of labeling retained water would be similar to those under Options 1, 4 and 5. The value or usefulness of the labeling will depend on the number of different limits and whether those limits are established on an industry-wide basis or on an establishment-by-establishment basis.

The actual retained water limits for this option would be based on the inevitable consequence of meeting food safety requirements with existing processes. The necessity of meeting food safety requirements would lead to equal or higher retained water levels than those based on best available technology (Option 4) or best use of existing equipment (Option 5). Since the costs of modifying production processes decrease as the level of allowed retained water increases, costs are the same or lower for this option than those for Options 4 and 5. The costs for establishing the retained water limits should be similar to those for Options 4 and 5. The labeling costs are essentially the same. For this option, there are no potential costs associated with increases in pathogen levels and foodborne illness. Thus, since the labeling benefits are essentially the same, this option is expected to have the greatest net benefits of the three options that permit limited retained water. This option was selected as the proposed rule.

X. Cost of Proposed Rule

The purpose of this section is to estimate the costs of proposed rule. The proposed rule would create three types of costs: (1) the costs for establishing water levels necessary to meet food safety requirements, (2) the costs associated with reducing retained water to such levels, and (3) the costs of revising product labels to indicate the presence of retained water. Most of the potential cost impact falls on the poultry establishments using water-immersion chiller systems. There are approximately 300 federally inspected and an estimated 65 State-inspected poultry slaughter establishments. There will also be some impact on livestock slaughter establishments and on retail stores that re-pack and re-label raw, single ingredient meat and poultry products.

Cost of Establishing Water Limits

The proposed rule would prohibit retained water in raw meat and poultry products unless the water is an inevitable consequence of the process or processes used to meet applicable food safety requirements. To establish a non-zero retained water limit, an inspected establishment or trade association or other group would have to generate supporting data. The proposal would allow such data generating studies to be conducted for an individual establishment or for an industry sector using the same or similar processing techniques and equipment.

This requirement would not appear to have a significant impact on the meat industry because the meat industry is already achieving zero retained water. This proposal would, however, provide an alternative for establishments that are having or will have trouble meeting the *Salmonella* performance standards. These establishments could utilize a full range of approved antimicrobial rinses or hot water rinses without having to worry about achieving zero retained water. If establishments can demonstrate that they need a non-zero limit to meet the *Salmonella* standards, they can utilize the flexibility provided by this rule and establish a new retained water limit as long as they indicate the presence of retained water on product labels.

It is assumed that 500 meat establishments (10% of the 5,000 affected meat establishments) would conclude that they cannot meet the new pathogen reduction standards without using a process that results in some level of retained water. The 10% estimate is from the Final RIA published with the final PR/HACCP rule (see **Federal Register** Vol. 61, No. 144, July 25, 1966, pages 38976–38977). In that analysis, FSIS referred to historical data showing control problems in from 5 to 10 percent of inspected establishments. The estimated 500 establishments having difficulty meeting pathogen reduction standards would be required to conduct water tests to establish unavoidable levels and possibly some additional *Salmonella* tests. The analysis assumes 200 hours per establishment for water tests and 100 hours to collect a sample set for *Salmonella*. The total cost would be 150,000 hours or \$3.75 million for labor and another \$1.2 million for 35,000 sample analyses. These estimates are based on cost factors from the FRIA for the PR/HACCP rule, i.e., \$25 an hour for a quality control manager and \$34 for a laboratory analysis for *Salmonella*. The average sample set for meat is approximately 70 samples considering 82 for steer or heifer carcasses and 55 for swine carcasses. The total cost for the meat establishments would be an estimated \$5 million. The costs for *Salmonella* testing and the costs of using alternative processes such as carcass washing systems have already been addressed in the FRIA for the PR/HACCP rule in the discussion of compliance costs for meeting the *Salmonella* standards (Federal Register reference noted above). The cost of establishing water limits (100,000 hours or \$2.5 million) would be additional costs. In return, this rule provides an alternative that doesn't currently exist.

FSIS does not consider air chilling an economically feasible alternative for chilling

poultry. Thus, it seems reasonable to assume that the poultry industry would conclude that immersion chilling is necessary to meet the existing chilling requirements for poultry, e.g., 9 CFR 381.66(b)(2) requires that poultry carcasses under 4 pounds shall be chilled to 40° F. within 4 hours following evisceration. It follows that the retained water necessary to meet food safety requirements is the minimum level that can be reached with existing equipment and still be in compliance with chilling requirements. There is also the possibility that the retained water necessary to meet the pathogen reduction performance standards for *Salmonella* would be higher than the level necessary to meet chilling requirements. The following discussion, however, assumes that the unavoidable retained water levels are driven by the chilling requirements.

The Agency believes that the industry already has considerable information concerning the chiller variable settings that minimize water retention. The variables of concern are chiller water temperature, water intake, total time in chiller and level of agitation. FSIS, therefore, believes the poultry industry can establish water limits for various chiller systems with minimal costs. Under current regulations (9 CFR 381.66(d)), establishments must conduct a 50-bird test to demonstrate that any change in chilling procedures does not affect compliance with existing requirements. This analysis assumes that poultry establishments could establish minimum retained water levels by conducting four 10-bird tests at ten different chiller settings for each product category. It is assumed that the average establishments would have two product categories, e.g., light hens versus heavy toms. Each test would take an estimated 2.5 hours to select birds, tag and weigh birds, and reweigh birds after chilling. (The FSIS 10-bird test takes from 40 to 60 minutes.) Time required between tests would not be considered a cost. Thus, testing would cost each plant 200 hours or \$5,000 using a quality control manager making \$25 per hour. The cost to 300 inspected establishments would be 60,000 hours or \$1.5 million. Some smaller federally inspected establishments and presumably more State inspected establishments do not use immersion chilling. They chill using ice and slush on processing tables/counters and have retained water levels below 2 percent. In the data collected from the field, two chicken establishments with annual production under 200,000 birds had retained water levels of 1.58% and 1.7%. It is assumed these smaller establishments are at a minimum level and would incur no additional cost to establish a minimum. These establishments do not appear to have any variables that could be studied during a water test.

The proposal doesn't provide specific guidance on options available for poultry processors that are already operating far below the existing standards for *Salmonella*. As an illustrative example, consider what options are available for a broiler slaughter establishment that has an unavoidable retained water level of 5 percent (due to immersion chilling for time/temperature) and

is consistently achieving *Salmonella* positive levels of around 10 percent, well below the existing standard of 20 percent. Should this establishment be able to operate at a higher retained water level if data showed that the establishment could then achieve an even lower level of *Salmonella*? Should the Agency's food safety objectives lead to a solution where any level of water would be allowed if data demonstrated a reduction in pathogens? While the current proposal does not allow such flexibility, the Agency is requesting comment on this aspect of the proposal. Under the current proposal, if FSIS lowers the pathogen reduction standards as stated in the preamble to the PR/HACCP rule, inspected establishments would have the option of increasing retained water if appropriate tests showed that such increases were unavoidable in meeting revised food safety standards.

Costs of Reducing Retained Water

If establishments are able to demonstrate that current levels of retained water are necessary to meet food safety standards, establishments would not incur costs for reducing retained water. However, to the extent that establishments cannot demonstrate that current retained water levels are necessary for meeting applicable food safety standards, significant costs could be incurred as establishments modify processes to minimize retained water levels. Reducing retained water could entail a wide range of processing modifications, depending on the type of chilling equipment currently used and amount of retained water that would have to be removed.

The Economic Research Service (ERS) conducted some preliminary analyses to begin to establish estimates of what it might cost to significantly reduce the amount of retained water in raw poultry. There are three ways to reduce retained water. The first involves holding poultry in refrigerated rooms until excess water has drained off the birds. The second involves making adjustments in the chilling process to reduce water absorption. The third involves a change in the chilling system, i.e., a move to air chilling or air chilling in combination with a water spray. As noted elsewhere in this PRIA, FSIS does not consider requirements that would mandate air chilling to be economically feasible. The existing regulations for air chilling (9 CFR 381.66(e)) require the internal temperature of the carcass to be reduced to 40 °F or less within 16 hours. There are limited data on costs of air chilling. Both reconstruction costs and operating costs would be high. The 1979 ERS study included an estimate from an industry source that air chilling uses more energy and costs about 4 cents per pound more than immersion chilling. The ERS study noted that there was only one major U.S. poultry processor using air chilling in 1979. A draft Impact Analysis Statement conducted for the 1978 proposal to reduce water use requirements for chilling stated that retail prices for air chilled birds were running approximately 20 percent higher than water chilled birds. That analysis attributed the higher retail prices to the higher capital cost and higher operating expenses.

The simplest way of viewing the cost of reducing retained water is to consider the incremental operating costs under the conditions, e.g., chiller temperature, that established the minimum unavoidable water. Such conditions could also involve optimizing water temperature and flow through the chillers, reducing the amount of agitation of the chilling medium, and reducing the "dwell time" of poultry in the chillers. If, as some believe, lower water temperature reduces water absorption, the response to tighter retained water requirements will be the installation of new or heavier compressors to lower the temperature in the chiller units. An installed additional compressor would cost an estimated \$150,000 per establishment, or an estimated \$45 million for all 300 federally inspected establishments.

FSIS does not have a method for estimating a cost for operating at conditions that establish a non-zero level of retained water necessary to meet food safety requirements. As an alternative, this PRIA estimates the cost of removing a substantial portion of the existing water using an extended draining or dripping process. One can view the estimated draining costs as an upper bound on the cost of removing water. An establishment would only use draining under conditions where the cost of draining was less than the incremental operating costs.

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:

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

With the above factors in mind, one can address the questions of: "What are the fixed costs of draining a substantial amount of absorbed water from poultry?"

The Daily Moisture Records sometime include a record of the additional drain time required. The time varies considerably probably depending on the initial water level, the drain configuration, and the location of the excess water, i.e., under skin versus between muscle tissue or within muscle tissue. The available data, for cases where young chickens were more than 1 percent over the limit, indicates that it can take from 1/2 to 3 1/2 hours to drain one percent. In two cases where broilers exceeded the 12 percent regulatory limit by more than 4 percent, the required drain time was approximately 12 hours. Program personnel estimate that the drain time per

percent increases as the birds approach "green weight," i.e., it takes longer to drain from 8 to 4 percent than it does from 12 to 8 percent. Thus, it seems reasonable to conclude that a 12-hour drain would be the minimum time required to remove most of the retained water from chickens.

Most of the drain times for turkeys ranged from 1/2 to 1 hour on an "hour per percentage reduction" basis. However, two cases showed drain times in the 10 to 11 hours per percentage reduction range. 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 existing limits.

The existing data from water control efforts indicates that it could take at least 12 hours to remove a substantial portion of the retained water in chickens. The 12-hour estimate is based on starting at a relatively high percentage and lowering the level by 4 to 5 percentage points. Thus, a 12-hour drain would reduce the existing level from 5 to 6.5 percent by an amount less than 4 to 5 percentage points. To drain chickens for 12 hours is somewhat equivalent to saying the industry would need to add the 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; 354,120 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.

Similarly, half a day's production for turkeys is 557,000 birds requiring 5,570 vats at a cost of \$5.57 million and cooler space at a cost of \$8.36 million. Assuming that the largest 70 turkey establishments would require an additional forklift at a total cost of \$1.68 million, the total fixed costs for draining all turkeys for 12 hours would be \$15.6 million. Thus, total fixed costs for a 12-hour drain for chickens and turkeys are estimated at \$94.3 million.

One can argue that large plants already have the capacity to store a shift's production. This occurs today when limits are exceeded. The MPI Manual provides, as an alternative to calculated drain time, a 24-hour continuous drain at 40° F. or below before shipping. The data reviewed for this analysis included two such cases. Today's excess capacity can also be viewed as a contingency capacity that would still be required over and above any additional capacity needed to achieve an overall water reduction.

This analysis has not attempted to estimate the complete variable costs of holding poultry to drain. Variable costs would include increased labor costs, increased utility costs, increased overhead, and the cost of carrying additional inventory. Holding half a day's production is equivalent to continually storing a wholesale value of \$37 million in poultry (\$19.2 billion divided by 520 shifts). At a 10 percent interest rate, the

annual cost of draining poultry for 12 hours would be \$3.7 million.

It would also seem reasonable to assume a minimum average of one additional employee per establishment. Three hundred employees at \$21,500 per year (average wage in chicken slaughter establishments of \$10.34 per hour) would result in an annual operating cost of \$6.4 million. Thus, FSIS estimates the minimum variable costs at \$10.1 million (\$3.7 million plus \$6.4 million) per year if the response is to drain poultry.

The above analysis has provided an estimate of the cost of reducing retained water by a "substantial" amount, i.e., an amount that can be equaled to a 12-hour drain. Available data indicates that a 12-hour drain could reduce overall water by an amount somewhat less than 4 to 5 percentage points at an estimated first year cost of \$104.3 million (\$94.2 plus \$10.1 million) and recurring annual costs of at least \$10.1 million.

Cost of Revising Labels

The cost of revising labels is a relatively easy cost to quantify. For previous rulemakings, FSIS has collected survey data on the costs of label revisions. Labeling changes have been the subject of several rulemakings in recent years.

The proposed rule would entail a one-time change in affected raw meat and poultry product labels to add a statement of the percentage of retained water in the product next to the product name. Establishments would have to prepare or order new product labels to comply with this requirement. FSIS would allow establishments to run out their stocks of existing product labels before the proposed labeling requirements would take effect. The establishments would, therefore, not incur costs of discarding existing label inventories.

The cost of revising a label varies widely depending on the type of label, the number of colors affected, and the printing process used. Adding a water content statement is the lowest cost type of modification because it involves single color printing and no graphic art. The cost of revising labels is an up-front, nonrecurring cost. This analysis uses an average cost of \$1,000 for each product label that must be modified. The cost can vary widely, however. Discussions with turkey industry personnel indicate that it can cost from \$1,500 to \$2,000 to change a label for one of the opaque plastic bags used to package whole turkeys. In contrast, a 1992 survey conducted in conjunction with nutrition labeling regulations found that many small firms use simplified labels that can be revised for less than \$200 per label.

The primary impact will be on the approximately 300 federally inspected and 65 State inspected establishments that slaughter and pack raw poultry. Currently, 135 of the federally inspected establishments are considered large entities, according to Small Business Administration (SBA) criteria (establishments having more than 500 employees). The cost to these "large" establishments of changing labels is estimated at approximately \$12.5 million. There are another 168 federally inspected poultry establishments that slaughter and

pack raw poultry. The estimated labeling cost for these establishments is \$5.9 million. The method for estimating these costs is illustrated in Table 2.

TABLE 2.—COSTS OF REVISING PRODUCT LABELS FOR POULTRY ESTABLISHMENTS

Establishment category	Number of establishments	Average number of labels	Cost at \$1,000 per label (\$000)
Large Chicken	115	^a 100	\$11,500
Large Turkey	20	50	1,000
Small Poultry	168	35	5,880
Total	303	18,380

^a Available information indicates large chicken plants have more unique labels, but many are modified by changing a retail chain specific sticker on a base label. A single modification to a base label in effect revises many labels.

There may be some labeling costs to the meat industry. Some edible meat byproducts and organ meats are washed and cleaned before being shipped in commerce and may be chilled or packed in water to preserve their safety and wholesomeness. Tripe, for example, is bleached and scalded before being shipped. Some organ meats, such as chitterlings (swine intestines), are chilled and packed in water. The Agency does not have any data to estimate the number of establishments or number of labels affected. Similarly, the analysis has not accounted for separate packaging of poultry giblets. Poultry giblets, including livers, hearts, and gizzards (and necks, though strictly speaking, necks are not giblets) are washed and chilled in water before being packaged and shipped.

There will also be some labeling cost to retail stores that repack raw products. They would have to apply some form of label, most likely a sticker, to store packaged product that has retained water. Today, most raw poultry sold from retail meat counters is packaged under Federal inspection. Thus, the overall retail impact should be minimal. Many large supermarkets also prepare fried chicken or rotisserie chicken that is marketed through their deli departments. Obviously, if they prepare the product as ready-to-eat product, it would no longer have to be labeled. The same would be true for products that are marinated or otherwise seasoned and marketed as convenience ready-to-cook products.

XI. Benefits of Proposed Rule

The proposed rule provides FSIS with the necessary regulatory limits to prevent economic adulteration and misbranding due to excessive retained water. Preventing economic adulteration provides a consumer benefit. Quantifying that benefit is beyond the scope of this analysis. Another consumer benefit results from the additional labeling information that would be available to household consumers and other customers to help them in their purchasing decisions. As noted in Section VII, customers are currently not being informed as to the true price of poultry. Customers would benefit from having improved knowledge of product quality, in terms of meat or poultry meat content.

The proposed rule would provide the meat industry with additional flexibility for meeting pathogen reduction performance

standards. Meat processors would be able to utilize pathogen reduction techniques without having to be concerned about meeting the existing zero retained water requirement.

This proposed rule would also 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 proposal could reduce HACCP implementation costs.

As discussed in the background section, this proposal would eliminate many requirements, including the following:

- The requirement that poultry establishments must provide FSIS with a description of all chilling and freezing procedures.
- The requirement that poultry establishments must notify FSIS before any changes in chilling procedures are implemented and provide FSIS with test results demonstrating the effectiveness of any such changes.
- The existing requirements that meat carcasses cannot show any weight gain resulting from the use of carcass spray systems.
- The existing water intake requirements.

Retail stores could benefit from reduced water. While discussions with retailers indicate a primary concern with packaging that doesn't leak, reduced water should help prevent leakage which leads to costs of cleaning retail counters.

XII. Effect on Product Quality

FSIS is aware that a substantial change in retained water could have an effect on product quality and performance. Certainly, consumers have become accustomed to purchasing fresh poultry that is very moist and presumably could have a lot less retained water and still have a moist surface. FSIS is not aware of any studies concerning how water level affects cooking properties, flavor, shelf life, or visual attributes. Discussions with officials in the retail industry indicate that they do frequently hear consumer complaints concerning excess water in packages. FSIS is interested in comments providing any information as to

whether poultry without retained water would be too dry after cooking or whether consumers would select packages if the product appeared less moist or if lower water would be perceived as being less fresh. Since most meat products do not currently have retained water, FSIS assumes that industry would conduct marketing studies that would demonstrate the viability of product with added water before any production practices were changed.

XIII. Aggregate Market Effects

Comparative statics analysis provides insight into the qualitative impacts of the proposed rule on the poultry and meat markets. Focusing first on the unambiguous effects on costs of production it is assumed that for the moment the rule has no direct effect on consumer demand. The analysis also assumes that there will be no direct effect on the meat market. The rule will increase the cost of production for poultry. At a minimum there will be cost increases resulting from developing and conducting the protocols and from adding information on water levels to the product label. Costs of production will increase more if poultry plants have to undertake steps to reduce water by adding new equipment, constructing facilities to drain poultry or operating existing equipment at higher costs. In a comparative statics analysis, higher costs of production would be represented by a decrease in the supply of poultry. The result in the poultry market would be a new equilibrium price that would be higher and a new equilibrium quantity that would be lower. There would be an effect on the meat market because meat is a substitute for poultry. Higher poultry prices would lead to an increased demand for meat with the result that both the new equilibrium price and equilibrium quantity consumed of meat would be higher. Thus, compared to the present situation, the proposed rule would result in higher prices for both poultry and meat, with less poultry consumed and more meat consumed.

Consider now the direct effect of the proposed rule on demand for poultry. There are two effects which may affect demand for poultry. First, the rule is expected to result in drier poultry being sold, that is, on average, the retained water in poultry will be lower. Second, labels on retail packages of poultry will inform consumers as to the

maximum retained water permitted in the plant from which the poultry in a retail package was shipped. If consumers consider drier poultry a desirable product quality, this would increase the demand for poultry. This would lead to a higher equilibrium price for poultry. However, the new equilibrium quantity consumed would be indeterminate because of the simultaneous decrease in supply described earlier. Again, the expected higher equilibrium price for poultry will lead to new higher equilibrium price and quantity consumed in the meat market.

The effect of label information on consumer demand for poultry is unclear. Consumers could react to label information showing the percentage retained water by reducing demand for poultry. The reasoning being that consumers will perceive the product as less desirable. If this is the consumer reaction, it would work against the demand increasing effect of drier poultry. In such cases comparative statics analysis cannot predict unambiguously the new equilibrium price and quantity consumed of poultry nor the effect on the meat market. However, consumers might react to label information by increasing poultry demand. An argument for this reaction is that consumers have greater assurance that the package of poultry they purchase is of an acceptable water level. Currently, unless consumers are aware of FSIS water regulations, they have no objective measure of the amount of retained water. For example, consumers who perceived poultry as high in water say, 12 percent, might react favorably

to label information reporting a 6 percent maximum and increase demand for poultry. It seems likely that consumers will use label information to select among poultry supplied from plants with different water limits.

The analysis of costs considered the possibility that some meat plants would not be able to meet the new pathogen reduction standards without using a process that results in some level of retained water. A comparative statics analysis of the meat market would parallel what has been presented for poultry.

Comparative statics analysis can provide insights into the qualitative effects of changes that affect supply and demand. Insights into the magnitude of these effects would require quantitative specifications of supply and demand relationships that incorporate the variables of interest. FSIS is not aware of empirical specifications that would be applicable to analyzing this rule.

Data on the aggregate supply and use can provide additional insight into the effects of this rule on the poultry and meat markets. It was estimated that the cost of the proposed rule for poultry was \$1.5 million for establishing water limits, \$104.3 million if plants had to reduce water, and \$18.4 million for revising labels. Total first year cost could be as high as \$124.2 million. This compares to an estimated \$34.5 billion spent by U.S. consumers on poultry in 1997. In percentage terms, first year costs would represent 0.36 percent of aggregate consumer expenditures on poultry or about one half cent per pound of retail weight. In subsequent years,

recurring costs are \$10.1 million, corresponding to 0.03 percent of consumer expenditures and 0.04 cents per pound.

Estimated costs of the rule for meat were \$2.5 million for establishing water levels. No quantitative estimates are provided for reducing water or for labeling but these are expected to be quite small. Aggregate consumer expenditures on meat are estimated at \$80.3 billion dollars in 1997. The quantity consumed on a retail weight basis was about 30.8 billion pounds.

The proposal is not expected to have significant impacts on international trade. Like consumers, trading partners would benefit from additional information that would facilitate purchasing decisions. Countries exporting poultry to the United States would have to have equivalent systems. Currently, annual poultry imports are about 5 million pounds. Any imports containing retained water would have to have product labeling indicating the presence of that water.

Foreign buyers can develop their own purchase specifications in the area of retained water. FSIS is aware that one large domestic customer requires that product weight be adjusted downward based on the results of a 48 hour drain. In other words, if a sample of birds drains "x" percent in 48 hours, the product weight must be reduced by "x" percent.

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