



DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

[Docket No. **FSIS-2022-0014**]

**Availability of Revised Guideline for Controlling Retained
Water in Raw Meat and Poultry**

AGENCY: Food Safety and Inspection Service (FSIS), U.S.
Department of Agriculture (USDA).

ACTION: Notice of availability; response to comments.

SUMMARY: FSIS is announcing updates to and responding to comments on its guideline to assist meat (including Siluriformes fish and fish products) and poultry establishments in meeting the regulatory requirements for calculating the correct retained water percentage in raw livestock, poultry, and Siluriformes fish carcasses and parts resulting from post-evisceration processing. FSIS is providing clarification based on arithmetic errors commonly encountered in protocol reviews.

DATES: Establishments will have until March 3, 2025, to submit their revised protocols to the Risk Management and Innovations Staff (RMIS) via askFSIS for review.

Establishments will have until January 1, 2026, to make any necessary label changes.

The Office of Field Operations will start reviewing establishments' retained water protocols on October 1, 2025.

ADDRESSES: A downloadable version of the guideline is available at <https://www.fsis.usda.gov/policy/fsis-guidelines>.

FOR FURTHER INFORMATION CONTACT: Rachel A. Edelstein, Assistant Administrator, Office of Policy and Program Development, FSIS; USDA, Telephone: (202) 205-0495.

SUPPLEMENTARY INFORMATION:

Background

On April 1, 2024, FSIS published a revised guideline to assist meat and poultry establishments in meeting the regulatory requirements found in the final rule "Retained Water in Raw Meat and Poultry Products; Poultry Chilling Requirements" (66 FR 1750), which set limits for water retained by raw, single-ingredient, meat and poultry products from post-evisceration processing, such as carcass washing and chilling. Under 9 CFR 441.10, raw livestock, poultry, and Siluriformes fish carcasses and parts (hereinafter, "meat and poultry products") are not permitted to retain water from post-evisceration processing unless the establishment preparing those carcasses and parts demonstrates to FSIS, with data collected in accordance with a written Retained Water Protocol (RWP) that any water retained is from addressing food safety requirements. In addition, the establishment is required to disclose on the product's label the maximum percentage of retained water in the raw product (9 CFR 441.10(b)). The

required labeling statement is intended to help consumers make informed purchasing decisions.

In the **Federal Register** notice announcing the availability of the revised guideline (89 FR 22331), FSIS explained that it revised its guidance because it conducted a review of older RWPs and found that establishments were not correctly applying formulas when determining changes in total moisture percentage in products after water spray or immersion processing. For example, many establishments subtract the pre-pack moisture percentages from the post-evisceration moisture percentages to calculate the retained water. However, these percentages are represented by different bases (or denominators).

After review and consideration of all comments, FSIS has made changes to and clarified certain aspects of the guideline. The revisions to the guideline are summarized below in FSIS' responses to comments. The updated guideline is available on the FSIS guidance web page at:

<https://www.fsis.usda.gov/policy/fsis-guidelines>. Although comments on this guideline will no longer be accepted through www.regulations.gov, FSIS will continue to update this document as necessary.

The updated guideline represents the Agency's current thinking on retained water requirements. FSIS is encouraging establishments that have been using the previous version of the guideline to update their RWPs

following the recommendations in the new guideline to ensure their data are reproducible and statistically verifiable.

Summary of Comments and Responses

The Agency received three comments on the guideline from organizations representing the meat and poultry industry and one comment from an individual. The individual supported FSIS' retained water regulations but did not specifically comment on the revised guideline.

Use of Guidance to Clarify Retained Water Policy

Comment: Two organizations representing the poultry industry stated that the changes included in the revised guideline are significant, and that the Agency should undertake rulemaking to propose the changes. One commenter stated that the revised guideline will impose new and additional requirements for establishments to calculate retained water amounts in products that substantively differ from FSIS' previous requirements. The commenter further stated that the Agency should provide specific direction on how establishments may satisfy existing regulatory requirements other than by using the formulas for calculating retained water provided in the revised guideline.

Response: As stated in the preface to the revised guideline, the document clarifies how establishments can meet requirements to collect and use data to demonstrate

the amount of retained water in the product covered by the RWP and how to accurately label product to reflect the amount of water retained. The guidance also provides information on how to correctly apply formulas to calculated retained water. The contents of the document, as with all Agency guidance, do not have the force and effect of law and are not meant to bind the public in any way. The document is intended only to provide clarity to industry regarding existing requirements under the regulations in 9 CFR 441.10.

The revised guideline provides examples of acceptable methods for calculating retained water, including discussion of safe harbors and common errors or unsupportable approaches. As stated in the revised guideline, establishments may decide to develop alternative methods for calculating retained water to demonstrate that they meet the regulatory requirements in 9 CFR 441.10.

Scope of Products and Processes Subject to Retained Water Labeling Requirements

Comment: Three commenters representing the meat and poultry industry stated that additional information from FSIS is needed to clarify which meat and poultry products and production processes may be subject to retained water labeling changes based on the revised guideline. For example, two of these commenters stated that in the 2001

retained water final rule, FSIS stated that the requirements in 9 CFR 441.10 apply to all amenable products, including offal (66 FR 1750,1759). However, the commenters noted, the Agency later clarified through guidance that certain products are not subject to the requirements under 9 CFR 441.10 and, therefore, do not need to be covered by an RWP.

Response: The 2001 final rule (66 FR 1750) addresses which products are subject to 9 CFR 441.10. However, FSIS does note that the 2001 final rule does not cover which processes are subject to 9 CFR 441.10, and that FSIS *Directive 6700.1* is the only source of that information. As such, FSIS is clarifying in this **Federal Register** notice and the guideline that the following processes are subject to 9 CFR 441.10:

- Carcass washing with or without an antimicrobial;
- Spray chilling carcasses, parts, trimmings, byproducts, bones, or other edible parts with or without an antimicrobial;
- Water or ice chilling with or without an antimicrobial;
- Post-chill spraying with or without an antimicrobial;
- and
- Application of any aqueous antimicrobial or processing aid.

FSIS further clarifies that the following processes are not subject to 9 CFR 441.10:

- Scalding or flushing gastrointestinal organs to remove digestive tract contents;
- Flushing beef heads to remove digestive tract contents; and
- Washing parts to remove excess blood.

FSIS updated the guideline with this information.

Comment: One commenter representing the meat industry recommended including the Agency's longstanding position that product containing retained water at ≤ 0.49 percent is not required to have a retained water label statement earlier in the guideline.

Response: FSIS agrees and moved the statement up in the document.

Agency Support for Revised Formula to Calculate Retained Water Percentages

Comment: Three organizations representing the meat and poultry industry stated that, before implementing the revised guideline, FSIS should more sufficiently explain the reasoning behind its determination that the mathematical formula for calculating retained water percentages for the purposes of the regulatory requirements under 9 CFR 441.10 is incorrect. Two commenters stated that standard industry practice, when using moisture percentages instead of weights, is to subtract the moisture content of

the post-evisceration sample from the moisture content of the pre-packaging sample to determine the difference and, therefore, the added moisture. The commenters noted that the Agency approved retained water protocols using this method for more than 20 years.

One organization representing the poultry industry noted that the Agency stated in the revised guideline that the changes to the prior version of the guideline are based on the latest scientific information. However, the commenter stated, FSIS failed to explain that science to industry and, instead, only provided the revised formula. The commenter concluded that, for industry to adequately submit comments on the revised guideline, FSIS should explain what the new science is and why the new science supports the determination that the existing Agency guidance needed to be revised.

Response: The updated guideline explains basic math. A difference in moisture percentages does not equal the amount of retained water as a percentage of the product weight, as defined in the 2001 **Federal Register** final rule (66 FR 1750). The side-by-side comparison in the Appendix of the guideline clearly demonstrates that subtraction grossly underrepresents the percentage of retained water in a product when compared to the uncontested formula used to calculate retained water from product weights. The formula provided in the guideline demonstrates that it provides the

same retained water percentage as when using product weights. FSIS has provided an attachment in the guideline that goes through the math step-by-step.

Differences Between Existing and Revised Retained Water Calculations

Comment: Three organizations representing the meat and poultry industry stated that the new mathematical formula discussed in the revised guideline will result in significantly different calculated results in retained water percentages than the formula used in the Agency's existing guidance. Commenters stated that these different results will cause confusion and concern for customers and industry, as the same product may be labeled with different retained water declarations before and after implementation of the revised guideline. One organization representing the poultry industry stated that this confusion could lead to consumer distrust in both industry and FSIS.

One organization representing the poultry industry specifically stated that the new formulas will result in different retained water calculations for a variety of reasons unrelated to the calculation methodology including, but not limited to dwell time, antimicrobial used, pH of the chiller, amount of time from the chiller to point of pack, temperature in second processing, and type of chicken part. The commenter stated that some of the percentages

resulting from following the revised guideline represent water retention that is physically impossible to achieve.

Response: FSIS provided a formula that allows establishments to compare moisture percentages and still provide the same result as if they were using product weights. FSIS disagrees that the results would be physically impossible to achieve. If the establishment used product weights instead of moisture percentages, they would get the same results as when using the formula in the guideline. There is nothing new for consumers to understand. FSIS is still requiring establishments to provide the maximum amount of retained water as a percentage of the product weight. If the retained water amounts are different, before and after implementation of the revised guideline, the establishment previously used incorrect math to calculate their products' retained water. Correcting this miscalculation is important so that consumers receive truthful and accurate information on product labels.

Comment: Two organizations representing the meat and poultry industry stated that the dry and wet methods will return different results. One organization representing the poultry industry stated that industry findings demonstrate that using the revised guideline results in values that increase the retained moisture percentage from 50% to over 400%, even though products were manufactured at the same

facility using the same production process and contain a substantially similar amount of retained water. The commenter stated that the only change which accounts for the difference is the revised guideline formula, which consists of an additional step on top of the existing guideline.

Response: Members of industry may have been underrepresenting their retained water percentages for as long as they have been using subtraction to calculate differences in moisture percentages, rather than the amount of retained water as a percentage of the product weight. FSIS published this guideline to help members of industry ensure that they are not underreporting retained water in the future.

Comment: One organization representing the poultry industry noted that, in the revised guideline, FSIS distinguishes between the calculation of moisture percentage for products with water added incidentally due to processing and for products with solutions, including water, added purposefully to change the nature of the product.

Response: When adding an aqueous solution as an ingredient, the weight of the added solution is known. However, with retained water, the amount that is added is an unknown. Therefore, the formulas to calculate added solutions as ingredients versus retained water are

different. The guideline makes clear that it only applies to the retained water regulations and does not apply to the added solution regulations. If the product has added solutions, then that product must be labeled in accordance with 9 CFR 317.2(e)(2) for meat and 9 CFR 381.117(h) for poultry.

Comment: A member of the meat industry stated that if the establishment's data supports that the product has no retained water (≤ 0.49 percent), then it is not required to have a retained water label statement. The commenter said that it would be more useful for this information to be provided early in the guideline when outlining the scope of the document instead of almost halfway through as a note.

Response: FSIS made the requested change. The Agency clarified when protocols are not needed earlier in the guideline.

Comment: During a RWP review, a member of the poultry industry requested that FSIS change the format of its moisture content formula for dry basis to match the format of the wet basis formula.

Response: FSIS made the requested change to improve readability.

Validation of New Retained Water Formulas

Comment: One organization representing the meat industry stated that studies should be conducted to validate that the calculations provided in the revised

guideline will produce the same retained water percentage as the traditional wet weight method used under existing Agency guidance. The commenter stated that the revised guideline should be withdrawn to allow for such validation studies to be conducted. The commenter offered to partner with FSIS to conduct the studies and provide additional training and support to industry depending on the results.

Response: FSIS disagrees that the guidance requires additional validation by FSIS. The guidance explains basic math. The math doesn't change through repetitions of side-by-side comparisons. FSIS provided the side-by-side comparison in the Appendix of the guideline that clearly demonstrates that subtraction grossly underrepresents the percentage of retained water in a product when compared to the uncontested formula used to calculate retained water from product weights. The formula provided in the guideline demonstrates that it provides the same retained water percentage as when using product weights. However, FSIS encourages any additional industry validation of guidance or support that would facilitate accurate labeling.

Comment: One commenter stated that, prior to implementing the revised guideline on water retention, FSIS should engage with consumers to fully understand how they interpret retained water statements and what those statements mean to end users.

Response: Current retained water regulations went through rulemaking and provided opportunity for consumer comment. As explained above, the guideline explains basic math. FSIS requested comments on the updated guideline and met with industry groups after it announced the updated guideline. The clarifications provided in the revised guideline will ensure that establishments label their products with accurate, supportable retained water statements.

Sample Size Calculation Disparity in Revised Guideline

Comment: One organization representing the poultry industry stated that, when it used the sample size calculator provided on page 10 of the revised guideline, the organization produced a different sample size than reported in the guideline. Specifically, the commenter stated that, in the provided examples with a 6% mean water retention and a standard deviation of 3.1 percent, the calculator indicates that establishments would need a sample size of 105, as compared to the 40 samples reported in the revised guideline.

Response: FSIS acknowledges that the revised guideline did not include sufficient information regarding the provided calculator for establishments to enter the values and replicate the tool. The Agency updated the revised guideline to clarify the examples.

Deadline to Submit Revised RWPs to FSIS and Compliance Date for Labeling Changes

Comment: A few organizations representing the meat and poultry industry stated that the Agency's announced September 30, 2024, deadline for establishments to submit to FSIS for approval any revised RWPs did not provide them enough time to develop and submit revised RWPs.

Three organizations representing the meat and poultry industry also stated that the Agency's announced April 1, 2025, timeline for companies to make label changes in response to the revised guideline is inadequate. The commenters stated that, at a minimum, FSIS should follow the Agency's uniform compliance date for labeling, under which companies would have until January 1, 2026, to make any necessary label changes.

Response: FSIS announced in the August 30, 2024, *Constituent Update* that the Agency has extended the deadlines. The deadline for establishments to submit retained water protocols to the Agency has been moved to March 3, 2025. OFO will start reviewing RWPs on October 1, 2025. Meanwhile, the deadline for establishments to make any labeling changes will be the Uniform Compliance Date, which is January 1, 2026.

Trade Considerations

Comment: One organization representing the poultry industry stated that the revised guideline could impact trade and the ability of domestic producers to export poultry products from the United States.

Response: Some countries restrict how much retained water certain products can retain. However, the changes in this guideline do not affect foreign countries' regulations. FSIS is providing clarification based on arithmetic errors commonly encountered in protocol reviews. In addition, the formula FSIS uses for retained water using product weights matches that of other countries, including Canada and countries in the European Union.

Additional Public Notification

Public awareness of all segments of rulemaking and policy development is important. Consequently, FSIS will announce this notice online through the FSIS webpage located at:

<https://www.fsis.usda.gov/wps/portal/fsis/topics/regulations/federal-register>.

FSIS also will make copies of this **Federal Register** publication available through the FSIS *Constituent Update*, which is used to provide information regarding FSIS policies, procedures, regulations, **Federal Register** notices, FSIS public meetings, and other types of information that could affect or would be of interest to our constituents and stakeholders. The *Constituent Update*

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