FSIS Guideline for Retained Water

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This guideline clarifies how establishments are required to collect and use data to demonstrate the amount of retained water in the product covered by its retained water protocol (RWP). Specific topics include:

- Protocol development, how to calculate retained water;
- o Process control; and
- Labeling retained water products.

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Preface

This is a revised version of the *FSIS Compliance Guideline for Retained Water*. It has been updated from the previous version and renamed. It clarifies how establishments can meet requirements to collect and use data to demonstrate the amount of retained water in the product covered by the retained water protocol (RWP) and how to accurately label product to reflect the amount of water retained. In addition, the guideline has been revised to include new updates based on the latest scientific information. The guideline also includes changes to improve its readability.

This guideline represents FSIS' current thinking on these topics and should be considered usable as of its issuance. The information in this guideline is provided to assist meat and poultry establishments in meeting the regulatory requirements of <u>9 CFR 441.10</u>. The contents of this document do not have the force and effect of law and are not meant to bind the public in any way. This document is intended only to provide clarity to industry regarding existing requirements under the regulations. Under the regulations, meat and poultry establishments may choose to implement different procedures than those outlined in this guideline, but they would need to support how those procedures result in truthful labeling.

This guideline is focused on small and very small establishments in support of the Small Business Administration's initiative to provide small businesses with compliance assistance under the Small Business Regulatory Enforcement Fairness Act (SBREFA). However, all meat and poultry establishments may apply the recommendations in this guideline. It is important that small and very small establishments have access to a full range of scientific and technical support, and the assistance needed to establish safe and effective Hazard Analysis and Critical Control Points (HACCP) systems. Although large establishments can benefit from the information, focusing the guideline on the needs of small and very small establishments provides them with assistance that may be otherwise unavailable to them.

Purpose of this Guideline

This guideline contains information to assist meat and poultry establishments in producing products that comply with the requirements in <u>9 CFR 441.10</u>. This guideline includes information on:

- How establishments are to collect and use data to determine the amount of retained water in their product.
- How establishments are to have good process control to ensure, on a continuing basis that the product labels accurately state the amount of retained water (<u>9 CFR 441.10(b)</u>).
- How establishments are to label products that retain water including, multi-ingredient product, religious dietary product, air-chilled product, and giblet product.

Reason for Reissuing the Guideline

In accordance with The Retained Water In Raw Meat And Poultry Products (January 9, 2001) final rule (<u>https://www.govinfo.gov/content/pkg/FR-2001-01-09/html/01-460.htm</u>), establishments are

required to label the products with the amount of water retained. Establishments must maintain on file a written data-collection RWP. Currently, RWPs are reviewed and approved by the Office of Policy and Program Development (OPPD)/Risk Management and Innovations Staff (RMIS). FSIS has announced that establishments need to submit updated RWPs, if necessary, to RMIS by March 3, 2025, and beginning October 2025, inspection program personnel (IPP) in the Office of Field Operations (OFO) will review required RWPs instead of RMIS (<u>9 CFR 441.10(c)(2)</u>). FSIS is revising this guideline in response to comments received on the March 2024 version and additional questions received from establishments during protocol review.

Changes from the Previous Version of the Guideline

FSIS made the following changes to this guideline to clarify what is needed in an RWP.

This version incorporates the following changes:

- Updated explanation of what is needed when an establishment develops a new RWP or revises an existing RWP, including:
 - Further guidance on Protocol development.
 - Recommends that the protocol state the specific product covered (e.g., carcasses, giblets);
 - Recommends that a flow chart of the establishment's process be included with the RWP;
 - Removes outdated regulatory pathogen reduction performance standards for Salmonella (<u>9 CFR 310.25(b)</u> and <u>9 CFR 381.94(b)</u>);
 - Recommends protocol include information on all antimicrobial treatments, not just the chiller;
 - Provides guidance on water retention when using dips or sprays as interventions applied to beef trim, pork cuts, or poultry parts;
 - Provides guidance for information on retained water testing methods to be employed, such as the number of poultry carcasses tested, the specific poultry carcass type, weight of poultry carcass tested at each point tested, time period tested, the number of sets tested, and frequency of how often retained water is verified for labeling purposes; and
 - Provides guidance on how to calculate retained water, particularly for laboratory analysis determinations.
 - Further guidance on Water Retention <u>Process Control</u>.
 - Further guidance on:
 - <u>Labeling Retained Water Products</u>.
 - Multi-Ingredient Product;
 - <u>Religious Dietary Product Labeling</u>;; and
 - <u>Giblet Labeling</u>.
 - Removes references to variables affecting retained water that occur pre-evisceration.
 - Removes outdated information about chiller settings.
 - Includes a list of processes and products subject to <u>9 CFR 441.10</u>.
 - Corrects example information.
 - Adds the moisture content formula for dry basis in a format that matches the wet basis formula.

How to Effectively Use the Guideline

This guideline is organized to provide users with the current science and recommendations. To use this guideline, FSIS recommends that readers use the navigation headings to move efficiently through the document sections of interest. Hyperlinks, where provided, will quickly take you to the correct place in the document electronically and are also provided to other complementary documents.

The reference list at the end of the document provides resource material used in the development and revision of this guidance (<u>References</u>).

Questions Regarding Topics in this Guideline

If after reading this guideline you still have questions, FSIS recommends searching the publicly posted Knowledge Articles ("Public Q&As") in the <u>askFSIS</u> database. If after searching the database, you still have questions, refer them to the Office of Policy and Program Development through <u>askFSIS</u> and select **Sampling** as the Inquiry Type or by telephone at 1-800-233-3935.

Documenting these questions helps FSIS improve and refine present and future versions of the guideline and associated issuances.

Background

In the 2001 final rule, "Retained Water in Raw Meat and Poultry Products; Poultry Chilling Requirements" (<u>66 FR 1750</u>, January 9, 2001), FSIS issued regulations that provide that raw livestock, poultry, and fish carcasses and parts will not be permitted to retain water resulting from post-evisceration processing unless the establishment preparing those carcasses and parts demonstrates to FSIS, with data collected in accordance with a written protocol, that any water retained is from addressing food safety requirements (<u>9 CFR 441.10(a)</u>) and that the retained water is declared on the label per <u>9 CFR 441.10(b</u>). The focus of the guideline is "retained water" as described in <u>9 CFR 441.10</u>. This guideline does not address adding water to products as an ingredient or as an added solution. If the product has added solutions, then that product must be labeled in accordance with <u>9 CFR 317.2(e)(2)</u> for meat and <u>9 CFR 381.117(h)</u> for poultry.

Federally inspected meat and poultry products with retained water, must bear a statement on the label in prominent letters and contiguous to the product name or elsewhere on the principal display panel of the label stating the maximum percentage of water that may be retained (e.g., "up to X% retained water," "less than X% retained water," "up to X% water added from processing"). The percent water statement does not need to accompany the product name on other parts of the label. If the written data-collection protocol supports that there is no retained water, then establishments can choose to not have a retained water statement or use a claim of no retained water (<u>9 CFR 441.10(b)</u>).

Applicable Processes and Products

Post-evisceration processes that are subject to <u>9 CFR 441.10</u> include:

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

The following processes are not subject to <u>9 CFR 441.10</u>.

- 1. Scalding or flushing gastrointestinal organs to remove digestive tract contents.
- 2. Flushing beef heads to remove digestive tract contents.
- 3. Washing parts to remove excess blood.

Products that meet all inspection requirements and bear the mark of inspection are subject to the retained water regulations (<u>9 CFR 441.10(b)</u>). This includes, but is not limited to:

1. Kosher products. Koshering is the process of soaking and salting product. Although Kosher products are labeled as "soaked and salted," they are not considered multi-ingredient products. Any water absorbed from koshering is not declared as retained water;

and koshering steps are not included in the written RWP. However, IPP are to verify that any water retained before or after koshering, such as chilling, is declared;

- 2. Further processed product when the source material retained water;
 - a. Ground product made with source materials that retained water during processing must also declare the retained water, unless the establishment has data to support that the product has a net loss of retained water.
 - b. Product made with multiple source materials, each with a different retained water amount, must declare the highest retained water percentage found in the source materials.
- 3. Giblets packaged separately or with a whole single-ingredient poultry carcass. A whole carcass with giblets is a single-ingredient product. If the giblets retain a different amount of water than the rest of the carcass, then the establishment may label for the highest amount or label for each individual product within the package;
- 4. Ritually slaughtered product that bears the mark of inspection;
- 5. Product chilled in saltwater containing 70 pounds or less of salt per 10,000 gallons of water;
- 6. Chitterlings packaged without purge; and
- 7. Ice-glazed poultry.

Products that are not subject to <u>9 CFR 441.10</u> include:

- 1. Multi-ingredient products.
 - a. Raw meat or poultry products used as ingredients in multi-ingredient products, e.g., raw or cooked sausage, deli meats.
 - b. Basted, marinated, injected, or tumbled products, including giblets in a basted carcass. Aqueous solutions from these processes are declared in the ingredients statement.
 - c. Product chilled in saltwater containing more than 70 and up to 700 pounds of salt per 10,000 gallons of water (the water and salt must be declared on the label as ingredients).
- 2. Religious exempt product that does not bear the mark of inspection.
- 3. Chitterlings packaged with no more than 20 percent purge.

Protocol Development

If the product does not retain water from the applicable post-evisceration processes, the establishment must document support that the products do not retain water. The establishment needs to make supporting documentation available to IPP but does not need to prepare and maintain an RWP on file. Products that do not retain water are not required to have a retained water label. If the product does retain water over 0.49%, the establishment must maintain a written RWP on file and make the RWP available for IPP review. IPP will review the RWPs based on the nine

expected elements of an RWP, which are listed below. Examples of expected content are noted for each element. This guideline uses the term "chilling" throughout to refer to chilling and cooling processes.

• Purpose Statement. (<u>9 CFR 441.10(d)(1)</u>)

State the primary purpose of the RWP and provide clarification that the RWP is specific to the product being produced (e.g., livestock carcasses, fish carcasses, poultry parts, poultry giblets). The primary purpose of the RWP is to determine the amount or percentage of retained water and to verify the amount of retained water in products for labeling purposes. Additional purposes could be to evaluate product quality and to determine chilling system efficiency.

NOTE: FSIS recommends that the establishment describes the verification frequency of its RWP to ensure that its product is not mislabeled.

FSIS recommends the establishment ensures that its RWP:

- Provides a product-specific flow chart that documents the production process of the product from slaughter through evisceration, chilling, further processing, and final packaging.
 - Example:
 - The primary purpose of this RWP is to determine the amount of water absorption and retention by poultry carcasses for labeling purposes.
 - If a revised protocol, describe changes made in the post-evisceration process.
 - State the time/temperature chilling parameters.

• Type of washing and chilling system used by the establishment. (<u>9 CFR 441.10(d)(2)</u>)

Describe any post-evisceration washing or chilling processes that affect the water retention levels and microbial loads on raw products. For poultry establishments, describe the main immersion chiller types (e.g., the drag-through, the screw type, or the rocker-arm type) to identify the mechanism used in transporting the poultry carcasses through the chiller or to agitate the water in the chiller. For fish (Siluriformes fish) establishments, describe the chilling processes (e.g., chiller, combo bins, or barrels). For livestock establishments, describe the type of coolers (e.g., blast freezers, refrigeration systems, or hot boxes).

• Configuration and any modifications of the chiller system components. (9 CFR 441.10(d)(3))

Describe the chiller system configurations and modifications, including the number and type of chillers/coolers in a series and arrangements of chilling system components, and the number of evisceration/kill lines feeding into a chiller system. Accurately describe the purpose and type of equipment used if there is a pre-chilling step in the process. Describe any mechanical or design changes to the chilling equipment.

• Special features in the chilling process. (9 CFR 441.10(d)(4))

Describe any special features in the chilling process, including antimicrobial treatments, length and velocity of the dripping line, and total time allowed for dripping. Explain any special apparatus, such as a mechanism for removing excessive water from meat or poultry products.

Although not required, FSIS recommends that the establishment include information on all the antimicrobial treatments used in the specific production process as well as information on the chiller/cooler system in use. This documentation provides IPP tasked with verification of RWPs with needed information and is part of the establishment's supporting documentation of the efficacy of its RWP.

Description of variable factors in the chilling system. (<u>9 CFR 441.10(d)(5)</u>)

Below are variables that can affect retained water. The establishment may consider these variables when preparing its RWP. FSIS recommends that the establishment describe the variables in its system that will be tested and repeat the data collection if any of these variables change from the time of the last data collection.

In poultry processing, such factors include:

- Carcass temperature.
 - The average carcass temperature before the antimicrobial dip prior to chilling, after the dip but before entering the pre-chiller, chiller, and then at the end of the chiller process.
 - Warmer carcasses could require more time to chill, additional chill time in an immersion chiller, and could increase water retention.
- Carcass and parts size.
 - Smaller carcasses and parts have a larger ratio of surface area to volume, thus increasing retained water percentage compared to larger carcasses and parts.
- Water temperature of pre-chiller and chiller.
 - This information is helpful to ensure that the temperature in the pre-chiller and chiller is adequate to ensure food safety and assist in the chilling process.
 - Water is often picked up in the carcass in the pre-chiller because of the slightly higher temperature of the water, compared to the chiller. The pores in the skin are still open and that allows water to enter. Generally, the warmer the water temperature during pre-chilling, the higher the water pick-up in the skin of the carcass.
- Agitation, including air agitation, if used.
 - Most chiller systems have air agitation systems that force air into the chiller from the bottom, thereby keeping the carcasses floating and moving to reduce stacking of carcasses throughout the chiller.
 - The higher water agitation leads to higher water absorption by the carcasses.
- Time in the chiller water.
 - \circ The time the carcasses are submerged in water increases water absorption.

In meat processing, such factors include:

- Carcass and parts size.
 - Smaller carcasses and parts have a larger ratio of surface area to volume, thus increasing retained water percentage compared to larger carcasses and parts.
- Number, types, and amounts of water applications (e.g., antimicrobial solution or water sprays, rinses or dips).
- Time in coolers.
- Standards to be met by the chilling system. (9 CFR 441.10(d)(6))

Based on these regulations, establishments are required to state the outcomes to be met by the chilling system. Specifically, state the time and temperature parameters to be achieved for meat and poultry, such as chilling carcasses to 44°F within 16 hours, chilling giblets within four hours. The establishment is also required to describe how they measure the process control. Doing so demonstrates that it is preventing contamination of carcasses and parts by enteric pathogens throughout the entire process, especially post-evisceration. These process control measures for controlling contamination must be included into their HACCP plans, Sanitation Standard Operating Procedures (Sanitation SOPs), or other prerequisite programs.

• Testing methods to be employed. (<u>9 CFR 441.10(d)(7)</u>)

The objective of the testing methods is to ensure that products are properly labeled with the retained water percentage. The method for calculating water absorption and retention must be reproducible and statistically verifiable. FSIS recommends that the establishment describes the verification activity to evaluate process control, including the number of samples, type of samples, sampling time period, type of testing or measurement, frequency of testing (for ensuring accuracy of labeling), and the test results.

FSIS recommends that the establishment provides detailed information on the testing methods to be employed. This may include, but is not limited to:

- Sample size
 - FSIS recommends that the sample size provides reproducible and statistically verifiable results.
 - FSIS recommends the sample size demonstrates an appropriate statistical confidence (e.g., 95 percent) that a given package in a lot retains no more water than what is declared on the label, within a 20 percent margin of error. Establishments may use the one-sided or two-sided test option in sample size calculators. FSIS used a one-sided test for its examples.
 - Establishing the sample size needed to determine retained water depends on the characteristics of the process, such as average retained water and the standard deviation. For instance, an establishment with a 6 percent mean water retention rate and a standard deviation of 2.2 percent (in decimals, 0.06 and 0.022) would require 42 samples to be 95 percent confident that the value for retained water will be within 20 percent (i.e., no more than 7.2

percent retained water). A small pilot study from as few as 10 product samples can provide the estimates of mean water retention and its standard deviation to determine the appropriate full sample size.

NOTE: Establishments may consider using sample size calculators provided by universities. FSIS does not require or endorse university sample size calculators but recognizes that it may be beneficial for the establishment to consider one that meets its production process.

For example, below is a link to a sample size calculator from the University of British Columbia, Canada. This sample size calculator compares the difference in two means. Concerning the establishment's production process, consider the average percent water retained to be plugged in for mu (μ) in the calculator, and the standard deviation of the process used for sigma in the calculator. Take for example, a process where the calculated average retained water is 0.0534 (5.34 percent) with a standard deviation of 0.016 (1.6 percent) (sigma). Suppose the establishment chooses to label the product as "up to 6 percent retained water." The input to the calculator would then be 0.06 for μ_1 , 0.072 for μ_2 (0.06 + 20 percent of 0.06), and 0.016 for 'sigma.' This results in a calculated sample size of 11.

Link to sample size calculator from the University of British Columbia, Canada: <u>https://www.stat.ubc.ca/~rollin/stats/ssize/n2.html.</u>

• Frequency of determining the retained water to ensure the labels accurately reflect the amount of retained water in the product.

NOTE: FSIS recommends that establishments determine the retained water to ensure the labels accurately reflect the amount of retained water in the product when there is a change in their post-evisceration process, or any changes in the variables in the process that would affect the amount of retained water.

- Specific carcass type (e.g., chicken, beef, pork, fish).
- The weights of the products or carcasses tested (at each point tested), and duration of the test.
- Methods used to determine the amount of retained water in the product being produced.
 - The establishment typically collects data, then uses one of two different calculation approaches to determine the amount of retained water in its product. Different mathematical calculations are performed based on the method used.

Note: Under the regulations, the retained water labeling statement is required to provide the maximum percentage of water that may be retained (*e.g.*, "**up to** X% retained water," "**less than** X% retained water," "**up to** X% water added from processing")." Therefore,

establishments are in compliance if their product contains less water than what is stated on the label.

Calculating Retained Water

As previously stated, the method used for calculating water absorption and retention must be reproducible and statistically verifiable (<u>9 CFR 441.10(d)(7)</u>). The following examples are provided as acceptable methods for calculating retained water. Further, the methods provided in this guideline cover safe harbors and also provide common errors or unsupportable approaches. Establishments may decide to develop alternative methods for calculating retained water. If so, establishments must ensure that their alternative methods are properly validated.

One approach is the <u>wet weight method</u>, which involves weighing the same sample units before and after the chilling and intervention processes to determine the weight gain of the samples. Establishments using this <u>wet weight method</u> can correctly determine the percentages of retained water in their production processes. This method, which is commonly used for <u>whole poultry and livestock carcasses</u>, is straightforward and directly represents the mathematic definition of percent retained water. It is typically not used for determining the retained water percent in parts because the whole carcasses are cut up into parts after the intervention/chilling processes. Whole poultry carcasses are removed from the line post-evisceration before any water is added, and then they are weighed ("post-evisceration weight"). Carcasses are tagged for identification and returned to the line. After the carcasses go through all the washing and chilling processes, including any antimicrobial interventions, the same carcasses are weighed again to determine the "pre-pack weight."

Calculate the retained water using the following formula:

Pre-pack carcass weight – postevisceration carcass weight

100 = Percentage Water Retained

Post-evisceration carcass weight

- The pre-pack carcass weight is weight of the post-chill carcass.
- The post-evisceration carcass weight is the weight of carcass post-evisceration prior to the chilling and washing process.
- The post-evisceration carcass weight is also referred to as the "green" weight.

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The second approach is the **<u>laboratory method</u>**, which involves taking samples from different steps of the production line, determining moisture contents of the samples, and then calculating the retained water percentage. This method can be used for <u>whole carcasses</u> and <u>parts</u>. FSIS is providing two examples of calculations that can be used to accurately calculate the retained water using moisture content.

The establishment may use alternate calculations, but it would need to provide scientific support that the calculation provides accurate results. FSIS would not consider subtraction of the moisture percentages to be supportable. FSIS included an example of why subtraction of moisture percentages undercalculates the true retained water amount in <u>Appendix 1</u>.

In <u>Appendix 2</u>, FSIS provides an example of the step-by-step process to ascertain the dry basis formula by relating moisture percentages to their respective weights as well as the standard formula for converting dry matter into a wet matter basis, which provides the wet basis formula. A side-by-side comparison of both approaches illustrates that all formulas provide the same end result (see <u>Appendix 1</u> for the side-by-side comparison using the wet basis formula).

Many laboratory methods and techniques are available for the determination of the moisture content in food products (e.g., convection oven, infrared heating, halogen oven, microwave oven). Generally, moisture content can be described in two ways: **on a wet basis** or **on a dry basis**.

1. **Wet basis moisture content** is the ratio of the moisture weight to the total weight of the sample described as a percentage:

M_w = weight of water/total weight of the product

The <u>FSIS CLG-MOI.04</u> Moisture Determination laboratory method or similar accredited method may be used to determine the wet basis moisture content. For this method, laboratory determination of the wet basis moisture contents of both post-evisceration and pre-pack samples is determined to calculate the retained water percentage. For the post-evisceration sample, whole poultry carcasses are typically removed from the line post-evisceration before any subsequent waterbased intervention. For the pre-pack sample moisture content in whole poultry carcasses, the carcasses are removed from the line after the chilling process and any other pre-pack water-based interventions. To calculate the pre-pack moisture content in parts, the parts are removed after all water-based interventions. Samples of the poultry carcasses or parts are weighed, dried, and reweighed according to the accredited method and the moisture content is determined using the following formula:

$$M_{w} = \frac{100\%^{*}(B-C)}{A}$$

A = sample weight prior to drying B = weight of dish + sample prior to drying C = weight of dish + sample after drying

 M_w = moisture content (wet basis)

NOTE: If the establishment's data supports that the product has no retained water (\leq 0.49 percent), then it is not required to have a retained water label statement.

After laboratory determination of the wet basis moisture contents of both postevisceration and pre-pack samples, establishments would use the following formula to determine the retained water percentage.

Percentage Retained Water = (M_{pre-pack} – M_{post-evisceration}) / (100% - M_{pre-pack})

Example:

The laboratory determined that the **wet basis moisture contents** of post-evisceration and pre-pack carcasses are 66.0 percent and 67.6 percent, respectively.

2. **Dry basis moisture content** is the ratio of the moisture weight to the total weight of the sample described as a percentage:

Md= weight of water/weight of the dry matter

$$M_{d} = \frac{100\%(B - C)}{D}$$

B = weight of dish + sample prior to drying
C = weight of dish + sample after drying
D = sample weight after drying (dry weight)
M_d = moisture content (dry basis)

When the laboratory analysis provides moisture content on a dry basis, the establishment would use the following formula to determine the retained water percentage.

Percentage Retained Water = (M_{pre-pack} – M_{post-evisceration}) / (100% + M_{post-evisceration})

Example:

The laboratory determined that the **dry basis moisture contents** of postevisceration and pre-pack carcasses are 194 percent and 209 percent, respectively.

Percentage Retained Water = (M_{pre-pack} – M_{post-evisceration}) / (100% + M_{post-evisceration})

= (209.0% - 194.0%) / (100% + 194.0%) = 5.0 %

NOTE: Regardless of whether the moisture content is reported on a **wet basis** or a **dry basis**, it is not appropriate to subtract the post-evisceration moisture content from the pre-pack moisture content. Different sample units represent the respective pre-pack and post-evisceration moisture contents. The post-evisceration sample is represented by the natural moisture and the dry matter of the product. However, the pre-pack sample is represented by the natural moisture and the natural moisture, the dry matter of the product, and the retained water.

NOTE: The typical wet basis moisture content for whole chicken is 66% according to the FSIS website: <u>https://www.fsis.usda.gov/wps/portal/fsis/topics/food-safety-education/get-answers/food-safety-fact-sheets/meat-preparation/water-in-meat-and-poultry/ct_index.</u>

Reporting of data and evaluation of results. (<u>9 CFR 441.10(d)(8)</u>)

Under these regulations, establishments should explain the criteria for evaluating the results and the basis for conclusions to be drawn. FSIS recommends that this explanation include:

- Sufficient detail to explain how data collected are to be reported and summarized.
- The verified statistical design and analysis.
- Information about how the calculated retained water percentages are used to determine appropriate retained water labeling. For example, establishments may calculate a 95 percent confidence interval and label products with the upper bound of that 95 percent confidence interval. By using the upper bound of a 95 percent confidence interval, most of the individual products will have a retained water of less than or equal to that labeled amount, with a small fraction of products that exceeds the labeled amount but does not exceed the allowed 20 percent variance (67 FR 1280, Jan. 10, 2002). However, the 20 percent allowed variance only relates if it applies a retained water statement to the product label. If the establishment's data supports that the product has no retained water, then it is not required to have a retained water. If any product exceeds the 0.49 percent, then the product must have a retained water statement on the label.

Conclusions. (<u>9 CFR 441.10(d)(9)</u>)

Provide a statement of what the data demonstrates, and the conclusions reached. FSIS recommends the conclusion statement includes what will be on the label and how the establishment came to that conclusion, such as a certain standard deviation above the average. For example, "the poultry carcasses retained on average 5.3% water, with a

standard deviation of 1.6%. The product will be labeled as 8% retained water (1.5 standard deviations, rounded down to the nearest ½ percent)."

Water Retention Process Control

Water retention process control refers to the establishment's continuous ability to keep the retained water amount from exceeding 20 percent above the declared label amount (<u>9 CFR 441.10(b)</u>). There is a loss of process control if packages exceed more than 20 percent above the declared label amount.

Some variability may be inherent to the sampling, especially when using the oven-drying approach. Because oven-drying is a destructive sampling method comparing results across samples (rather than within a single sample like the wet method), having consistent samples for comparison postevisceration and pre-pack is critical to accurate results. Variability between paired samples before processing (e.g. variation in natural moisture across two parts that will be compared) increases the variability of the results when they are compared.

If the individual sample variability is high, then comparison using the oven-drying method may not provide reliable results, because the before and after measurements are not comparing "like" data points. The table below illustrates how variability between paired samples introduces potential error into the retained water calculation when using moisture percentages from oven-drying. There are 5 samples in this example for each post evisceration location and pre-pack location. Since the samples are destructive, a new sample is collected for the pre-pack location. Each sample number with the same number is a "paired" sample. This shows that there is variability in water retention, but also post evisceration moisture percentage variability. The overall calculated retained water percentage is impacted by both variabilities.

Sample	Post Evisceration Moisture Percentage		Pre-Pack Moisture Percentage	Calculation	Retained Water
1	67	Destructive sample	-	(69.67)/67	3.12%
1	66.5		68	(68-67)/67	3.12%
2	68.8	Destructive sample	-	(68.5-68.8)/68.8	-0.95%
2	67.5		68.5	(00.5-00.0)/00.0	-0.95%
3	67.2	Destructive sample	-	(71-67.2)/67.2	13.1%
3	69		71	(71-07.2)/07.2	13.170
4	68.8	Destructive sample	-	(69.2-68.8)/68.8	1.3%
4	67.4		69.2	(09.2-00.0)/00.0	1.370
5	69.2	Destructive sample	-	(69.5-69.2)/69.2	0.98%
5	68.3		69.5		0.90%

Establishments may account for the layered variability by calculating the standard deviation of the difference of two random variables. An example of this approach is described here:

https://study.com/skill/learn/how-to-calculate-the-standard-deviation-of-the-difference-of-two-random-variables-explanation.html

In addition, performing the wet method by weighing parts post-evisceration and pre-pack may provide more usable data, even when performed off-line using the same operational parameters as the online process.

Labeling Retained Water Products

Establishments are required to include a retained water statement on labeling of meat and poultry products that retain water during post-evisceration processing, e.g., water and ice chilling, thawing, antimicrobial processing aid interventions (≥ 0.5 percent). Retained water is not regarded as intentionally added or as a product ingredient. However, the labeling of products with retained water must bear a prominent statement disclosing the maximum amount of water that may be retained, e.g., "contains up to X% retained water," or "with X% absorbed water" (9 CFR 441.10(b)). These products include single-ingredient cut-up, ground, and mechanically separated products which meet the retained water regulations, as provided in the <u>Applicable Processes and Products</u> section. The retained water statement must be prominently located on the principal display panel of the label and could be contiguous to the name of the product. Refer to <u>Retained Water – Example Labels</u> section for further information. When meat or poultry products with different retained water levels are packaged together, the labeling would bear a statement reflecting the highest range, e.g., "less than 4% retained water" or "contains up to 3% retained water."

Meat and poultry products shipped for further processing only are not exempt from the declaration of retained water and must be properly labeled with a retained water statement prior to shipment. Establishments are required to maintain data that accounts for water retained (9 CFR 441.10(c)(1)), if any, and to label the product accordingly (9 CFR 441.10(b)). If the establishment's data demonstrates that source material that is further fabricated has a net loss of retained water, then the product may bear a lower or no retained water statement.

An establishment that has data or information to demonstrate that its products do not contain retained water will not be required to label products with such a statement. However, the establishment is required to maintain records that demonstrate through data or information that its product does not gain water as a result of the production process (9 CFR 441.10(c)(1)). These establishments can include a "no retained water" claim on the label.

Rounding Methods and Considerations

It is recommended that retained water amounts determined through testing be rounded and declared by the nearest half percent, with exception to the 20 percent variation restrictions. For example, 0.7 percent retained water is rounded up to 1 percent and 1.2 percent is rounded down to 1 percent. Retained water amounts determined by ongoing in-plant verification is permitted a 20 percent variation from the declaration on labeling. When the retained water declaration exceeds the 20 percent of the label declaration, establishments have two options. One option is to accurately relabel the product. Processors can modify existing labels by use of pressure sensitive stickers or indelible ink rubber stamps bearing the percent-retained water statement or a "no retained water" claim. This type of label change is possible under the generic label approval regulations. The other option would be to allow the product to drain so that the retained water statement is truthful. This may involve re-packaging the product unless the product is ice pack poultry in drainable containers. However, the 20 percent variation permitted for the retained water statement would not apply when a "no retained water" claim is made on labeling. Rounding rules apply. Thus, the product cannot retain more than 0.49 percent water such that the rounded amount of water is 0 percent. (Refer to the text box below for further clarification regarding the rounding rules for the 20 percent variation from declaration on the label.)

Rounding Rules for 20 Percent Variation from Declaration on Label

Retained water amounts determined by ongoing in plant verification is permitted a 20 percent variation from the declaration on labeling.

For establishments that are rounding down and maintaining no more than 20 percent variability from the labeled amount, most times, this is not an issue for labels with greater than or equal to 3 percent declared retained water. FSIS does not object to the over declaration of retained water, as the consumer is not misled by this practice. In cases where the rounding rule permits the retained water declaration to be rounded down, but the retained water determination results in an excess of the 20 percent variation rule, establishments are advised that it may be prudent to over declare the retained water to the next highest percent to provide a safe margin for error and avoid noncompliance.

For example, under normal numeric rounding rules, an establishment with a retained water determination between 1.21 percent and 1.49 percent, may wish to round and label its product as containing up to 1 percent retained water. However, under the 20 percent maximum allowable variation from the labeled retained water declaration, the product would only be allowed to have up to 1.2 percent retained water. Therefore, a retained water determination on labeling yielding 1.21 percent or greater would NOT be acceptable.

An establishment with a 2.49 percent retained water determination may not label its product with "up to 2 percent" declared retained water. This is because the "up to 2 percent" declared retained water is only allowed up to 2.4 percent retained water in the product to comply with the 20 percent maximum. Therefore, a retained water determination yielding 2.0 to 2.4 percent would be acceptable for the "up to 2 percent" label, but not for a 2.41 to 2.49 percent retained water determination. In this case, while not required by the rounding rule, it would be prudent for an establishment to over declare its retained water statement as "up to 3 percent" retained water verification results.

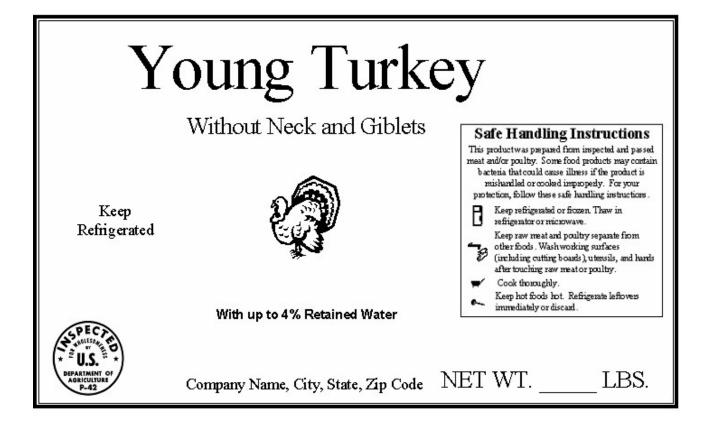
As a third example, consider an establishment with a 3.49 percent retained water determination. It may label its product "up to 3 percent" declared retained water and be allowed to have up to 3.6 percent retained water under the 20 percent maximum allowable variation. Therefore, a retained water determination yielding 3.49 percent would be acceptable.

Exported Products

Some countries restrict how much retained water certain products can retain. 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 match that of other countries, including Canada and countries in the European Union.

Retained Water - Example Labels









Example Situations for When Product Must or Must Not Declare Retained Water

Products that do not declare retained water

Example 1

Beef and Turkey Italian Sausage contains starting material that is labeled as "turkey containing 3 percent retained water." The ingredient declaration would not identify the retained water in the turkey because the retained water is not an ingredient. The post-evisceration retained water in the turkey would not affect the 3 percent added water limit for the finished product that is established by the standard of identity or composition. Water added to facilitate mixing to dissolve ingredients is an ingredient and is permitted up to 3 percent in raw sausage.

Products that must declare retained water

Example 2

When beef trimmings that have been sprayed with chilled water so that they contain 5 percent retained water are used to make a single-ingredient raw ground product, like ground beef or hamburger, the resulting product must be labeled to declare any retained water above naturally occurring water. Also, single-ingredient ground poultry produced from poultry containing retained water would be required to be labeled to declare any retained water above naturally occurring water. The retained water would not affect compliance with the standard, i.e., no added water, because retained water is not an ingredient. If the products were subsequently cooked, the retained water would have no effect on the finished product or it's labeling.

NOTE: Examples are applicable to all meat and poultry products, regardless of species or kind.

References

[FSIS] Food Safety and Inspection Service. 2018. Chemistry Laboratory Guidebook, Food Chemistry, CLG-MOI.04, Moisture Determination. Retrieved from: <u>CLG-MOI.04 Moisture</u> <u>Determination (usda.gov)</u>.

[FSIS] Food Safety and Inspection Service. 2001. Final Rule: Retained Water in Raw Meat and Poultry Products; Poultry Chilling Requirements (66 FRN 1749). Retrieved from: https://www.govinfo.gov/content/pkg/FR-2001-01-09/html/01-460.htm.

[FSIS] Food Safety and Inspection Service. 2002. Final Rule; Suspension of regulation: Retained Water in Raw Meat and Poultry Products (67 FRN 1277). Retrieved from: <u>Federal Register, Volume</u> 67 Issue 7 (Thursday, January 10, 2002) (govinfo.gov).

Resources

- Websites
 - Sample size calculator. University of British Columbia, Canada: <u>https://www.stat.ubc.ca/~rollin/stats/ssize/n2.html</u>
 - Statistical Power and Why It Matters | A Simple Introduction. Pritha Bhandari, 2021 (Revised 2022).
 Statistical Power and Why It Matters | A Simple Introduction (scribbr.com)
 - Water content of meat and poultry. Food Safety and Inspection Service: Water in Meat & Poultry | Food Safety and Inspection Service (usda.gov)

Appendix 1 - Comparing Moisture Percentages

A common error in retained water protocols reviewed by FSIS is the use of subtraction to compare moisture percentages from two points in the process. This approach results in an underreporting of retained water because the two moisture percentages have different bases, or denominators. The post-evisceration product is comprised of the dry weight and the natural moisture. However, the prepack product is comprised of the dry weight, the natural moisture, and the retained water.

The example below demonstrates a single hypothetical product in both the wet weight method and the laboratory method; note that either method is valid, and both will result in the same finding when used correctly. The first (blue) box shows the retained water calculation using wet weights. The second (yellow) box shows the retained water calculation for the same carcass using the laboratory method to calculate moisture percentages. The red box shows the common error for comparison, including demonstrating the mismatched denominators.

A) RETAINED WATER USING WET WEIGHT METHOD:					
Post-evisceration, pre-interventions bird weight (green weight)	10	pounds			
=> goes through chiller		pounds retained water			
Prepack bird weight	10.5	pounds			
Using weight to calculate retained water		(10.5-10) / 10* 100%	5%		
B) RETAINED WATER USING LABORATORY METHOD (e.g. The CLG method for determining % moisture in each sample, in which A = sample weight B = weight of dish + sample before drying C = weight of dish + sample after drying D = D = A = DOP A = TOPY A		:			
B.1) LABORATORY METHOD CARCASS EXAMPLE: CLG moisture percentage of green weight sample= 70%	10	pounds bird =	10 * 0.7	7	pounds water
=> goes through chiller	0.5	pounds water			•
Pre-pack water weight	10.5	pounds bird =	7 + .5	7.5	pounds water
Final moisture percentage		= 7.5 / 10.5	71.4%		
Using subtraction of moisture percentage to calculate retained water 7.5 pounds water 3 pounds dry matter, 7 pounds natural moisture, .5 pounds retained water).	(71.4% - 70%) 7 pounds water 3 pounds dry matter, 7 pounds na	1.4% tural moisture	X	(common error: notice mismatched denominators)
Using guideline formula for wet weight moisture percentage (71.4% - 70%) / (100% - 71.4%) 5.00% (pre-pack moisture percentage - post-evisceration moisture percentage) / (100% - pre-pack moisture percentage) (100% - or evisceration moisture percentage)					
B2) LABORATORY METHOD PARTS EXAMPLE: (same approach as above; the CLG method measures the % moisture, which can be used to calculate retained water using the same approach as in Example B1) Using a 10lbs starting sample of mixed parts that weighs 10.5lbs at pre-pack: 1) If the before (post-evisceration / pre-interventions parts percentage) measures 70% moisture via the CLG method 2) and the final sample (after interventions / pre-pack moisture percentage) measures 71.4% moisture via the CLG method Simply use your before and after values from the laboratory method in the same approach to properly calculate: Using guideline formula for wet weight moisture percentage (71.4% - 70%) / (100% - 71.4%)					
(pre-pack moisture percentage - post-evisceration moisture percentage				\checkmark	output as weight method)

This comparison makes it clear that subtracting moisture percentages results in a retained water calculation that is different from the retained water calculated using the weight of the carcass, even though it is the same product. Once the differences in "bases" is accounted for – through dividing that difference by the difference of pre-pack percentage from the whole – the retained water calculation from the laboratory method now matches the retained water calculated using the wet weight method.

Appendix 2 – Process to Determine Retained Water Formula Using Moisture Percentages

Arithmetic Example illustrating the formula for calculating retained water using moisture percentages by relating the moisture percentages to their respective weights on a dry basis.

M _{post-evisceration} is the moisture content of the post-evisceration sample, which is mathematically represented in weights as:

M post-evisceration = <u>Weight natural moisture</u> Weight dry matter

M _{pre-pack} is the moisture content of the post-evisceration sample, which is mathematically represented in weights as:

M pre-pack = Weight natural moisture + Weight retained water Weight dry matter

R is the retained water, which is mathematically represented in weights as:

This is the same formula used to calculate retained water using weights:

Where the Weight pre-pack – Weight post-evisceration equates to the Weight retained water; and the postevisceration weight is represented by the Weight natural moisture and the Weight dry matter.

To get R expressed in the terms of moisture percentage, 2 mathematical statements are used to arrive at expressing R in terms of M. These formulas are:

1) M pre-pack – M post-evisceration

Express this formula in terms of weights, using the mathematical definitions above.

Weight natural moisture + Weight retained water	Weight natural moisture		Weight retained water	
Weight dry matter	 Weight dry matter		Weight dry matter	

Consolidate the entire formula.

The reciprocal of this equation is:

2) M pre-pack

M post-evisceration

Express this formula in terms of weights, using the mathematical definitions above.

Weight natural moisture + Weight retained water	Weight natural moisture + Weight retained water		Weight dry matter
Weight dry matter	Weight dry matter	X	Weight natural moisture
Weight natural moisture Weight dry matter	(For division within a division, multiply inverse of the denominator. The Weig		

Consolidate the formula.

Weight natural moisture + Weight retained water Weight natural moisture

In the next step, separate out the numerator into two separate fractions.

=> Weight natural moisture Weight natural moisture + Weight natural moisture

When a numerator and denominator match, it becomes 1.

Consolidate the entire formula.

Subtract 1 from each side.

Remember that a matching numerator and denominator equals 1. Vice versa, the 1 can be replaced with a matching numerator and denominator, in this case $M_{post-evisceration}$ to match the denominator in the first fraction.

Combine both fractions, since they have the same denominator.

Then inverse the formula.

Use 2 mathematical formulas to express R in terms of M.

Express R using the mathematical definition from above.

Inverse this formula.

Separate out the fraction.

Recognize that each fraction matches 1) and 2) from above. Restate the formula using color-coding to correlate with the formulas from above.

$$\frac{1}{R} = \frac{\text{Weight natural moisture}}{\text{Weight retained water}} + \frac{\text{Weight dry matter}}{\text{Weight retained water}}$$

Replace each color-coded fraction for their respective M values.

Combining both fractions, since they have the same denominator.

$$\frac{1}{R} = \frac{M_{\text{post-evisceration}} + 1}{M_{\text{pre-pack}} - M_{\text{post-evisceration}}}$$

Finally, the inverse:

$$R = \frac{M_{\text{pre-pack}} - M_{\text{post-evisceration}}}{M_{\text{post-evisceration}} + 1}$$

This formula matches what is in the guideline for dry basis. While this has 1 instead of 100%, that is the difference between using decimals for M _{post-evisceration} (correlating to the 1) versus using percentages for M _{post-evisceration} (correlating to the 100% in the guideline).

The dry basis moisture content can also relate back to a wet basis moisture content with the following formula (<u>https://engineering.purdue.edu/~abe305/moisture/html/page10.htm</u>, with using 1 (meaning wet and dry moisture contents would be in decimal versus percentage format) in lieu of 100 (which would be applicable when moisture contents are in percentage format).

Dry =
$$\frac{\text{Wet}}{1 - \text{Wet}}$$

Where Dry is the dry basis moisture content and Wet is the wet basis moisture content.

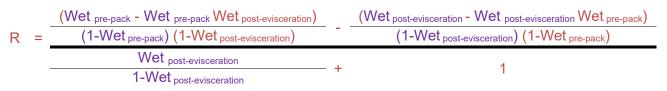
Use the dry basis formula for R above and replace the dry basis moisture content with the conversion formula.

Cross-multiply the two fractions in the numerator to get the same denominator.

R =
$$\frac{\frac{\text{Wet}_{\text{pre-pack}} * (1-\text{Wet}_{\text{post-evisceration}})}{(1-\text{Wet}_{\text{pre-pack}})(1-\text{Wet}_{\text{post-}}} - \frac{\text{Wet}_{\text{post-evisceration}} * (1-\text{Wet}_{\text{pre-pack}})}{(1-\text{Wet}_{\text{post-evisceration}})(1-\text{Wet}_{\text{pre-pack}})}$$

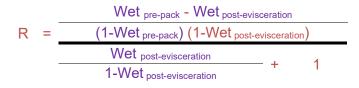
$$\frac{\text{Wet}_{\text{post-evisceration}}}{1-\text{Wet}_{\text{post-evisceration}}} + 1$$

Multiply the purple in the numerator of the two fractions with the orange.



Combine the two fractions. Note that there is a minus sign in front of the second fraction. When the two fractions are combined to remove the parenthesis, it will make the minus in the second fraction a plus.

At this point, the Wet pre-pack Wet post-evisceration cancels itself out (a negative with a positive).



Switch to working on the denominator. Turn the 1 into a fraction.

$$R = \frac{(1-Wet_{pre-pack} - Wet_{post-evisceration})}{Wet_{post-evisceration}} + \frac{1-Wet_{post-evisceration}}{1-Wet_{post-evisceration}}$$

Combine the two fractions in the denominator since they have the same denominator.



The Wet post-evisceration cancels out with the Wet post-evisceration.

To get rid of the division within a division, multiply the numerator by the inverse of the denominator.

The (1-Wet post-evisceration) from denominator in the first fraction cancels out with the numerator in the second fraction. For illustrative purposes, the 1 is brought over to the denominator of the first fraction, but it will go away because 1 multiplied anything is the same answer.

$$R = \frac{\text{Wet }_{\text{pre-pack}} - \text{Wet }_{\text{post-evisceration}}}{(1 - \text{Wet }_{\text{pre-pack}}) \times 1}$$

This gives the same formula in the guideline for wet basis, where the Wet would equal the M in wet basis. Change the 1 to 100% if M is expressed as percentages instead of decimals.

$$R = \frac{M_{pre-pack} - M_{post-evisceration}}{(1-M_{pre-pack})}$$





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