

**QUESTIONS AND ANSWERS ON DESCRIPTIVE DESIGNATION FOR RAW MEAT
AND POULTRY PRODUCTS WITH ADDED SOLUTIONS
FSIS-2010-0012 docket, Final Rule, 9 CFR 317.2(e)(2) and 381.117(h)**

Compliance
Generic Labeling
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Miscellaneous

COMPLIANCE

Q1: Are the effective and applicability dates for the Final Rule: Descriptive Designation for Raw Meat and Poultry Products Containing Added Solutions (FSIS-2010-0012) based on the packaging date or when the product is displayed for sale?

A: The effective and applicability dates are based on when the product is labeled within the establishment. Products labeled prior to the effective and applicability dates that are then held in storage, for example, frozen product, will not have to be relabeled to comply with 9 CFR 317.2(e)(2) and 381.117(h) if they are released for sale after the effective date.

The effective date:

January 1, 2016 - raw red meat products with added solution (excluding raw mechanically tenderized beef) and raw poultry products with added solution must meet all regulatory requirements, except for the requirement that the product name and the descriptive designation appear in print with the lower case letters not smaller than one-third (1/3) size of the largest letter (9CFR 317.2(e)(2)(iv) and 381.117(h)(4)). These products may use 1/4 sizing for lettering instead of 1/3 size.

The applicability date:

January 1, 2018 - all raw meat and poultry products with added solution must meet all labeling requirements, including the 1/3 sizing requirement. As stated in the final rule, "DATES: Effective Date: January 1, 2016. Applicability Date: The regulation that prescribes that the product name appear with the lower case letters not smaller than one-third (1/3) the size of the largest letter in the product name (9 CFR 317.2(e)(2)(iv) and 381.117(h)(4)) will be applicable on January 1, 2018."

NOTE: On May 17, 2016, raw mechanically tenderized beef with added solution products must meet all regulatory labeling requirements in the final rule but must use 1/3 sizing for the mechanically tenderized descriptive designation.

Q2: Does the rule apply to product containing added solution, regardless of the method of incorporating the solution (for example, marinating, basting, injection, vacuum tumbling)?

A: Yes. The rule applies to products where solution has been incorporated into raw meat or poultry through any method, for example, marinating, basting, injection, vacuum tumbling.

Q3: How is the percent solution pickup calculated? Does the establishment need to weigh the meat prior to being marinated/injected and then weigh it after to see how much was absorbed?

A: Determining the percent pick up involves weighing the raw meat or poultry before solution is added, weighing the raw meat or poultry after adding solution, and performing a calculation to determine the percent solution pick up in accordance with 9 CFR 317.2(e)(2)(i) and 9 CFR 381.117(h)(1): "The percentage of added solution (total weight of the solution ingredients divided by the weight of the raw meat without solution or any other added ingredients multiplied by 100)."

Q4: When the percentage of solution is listed (for example, 15%), is that the percentage compared to the meat in the batch/lot or by the individual piece of meat?

A: If all products in the batch or lot are about the same size, the establishment can use the same percent in all products in the lot.

Q5: Do statements, such as "colored with annatto" and "coated with seasonings," need to be in the same type style, height, and color as the rest of the product name?

A: No. Statements that further describe the product name, for example, "colored with annatto" and "coated with seasonings," are not part of the descriptive designation and do not need to comply with the formatting requirements.

Q6: If raw poultry is injected with 2% sodium or potassium lactate solution, does the label need to comply with the final rule for raw meat and poultry products containing added solutions?

A: Yes. The final rule applies to raw meat or poultry products where added solution increases the raw weight of the meat or poultry by any amount, for example, chicken with 2% solution of water and potassium lactate.

Q7: Does fresh raw pork and poultry sausage with sodium lactate or potassium lactate solution added in the formula need to comply with the new rule?

A: No. The rule does not apply to products with a standard of identity, such as, raw sausage per 9 CFR 319.140, where added liquid ingredients are in compliance with the standard.

Q8: If the word "marinated" is used in the product name, can the full descriptive designation be excluded on the label?

A: No. While the descriptive designation may include the word "marinated," this fact does not eliminate the requirement for the percentage of added solution and the identity of the solution ingredients to be included in the descriptive designation. For example, "simply marinated beef with up to 12% solution of water and seasonings" would be acceptable.

Q9: If a boneless pork loin is injected with a sodium phosphate and water solution and will bear a label that reads "contains up to 7%" of said solution, but the establishment's records show that percent solution pick-up is over this amount, for example, 7.3% or 7.4%, at what point is the label non-compliant?

A: The compliance level is 20% of what is stated on the label. For example, if the label claims "containing up to 7% of a solution," the label would be out of compliance if the actual amount was more than 8.4% (7% plus 1.4%). However, the labeling should be corrected to reflect the average amount of solution if the process consistently retains more solution than the percent declared on the label, even if it is within the 20% allowance. The 20% allowance is based on the allowance stated for pumped product in FSIS Directive 7620.3, Processing Inspector's Calculations Handbook, which is available at the FSIS web site.

<http://www.fsis.usda.gov/wps/portal/fsis/topics/regulations/directives/7000-series>

Q10: Does water have to be included in the percentage of added ingredients declared in the descriptive designation per 9 CFR 317.2(e)(2) and 381.117(h) for a marinated raw poultry product?

A: Yes. All ingredients that make up the solution, including water if that is the liquid used in the formula, must be declared in the descriptive designation.

Q11: We produce products for a chain restaurant, a food-service distribution company, and HRI. They will cook the product at their facilities. Does the final rule regarding the descriptive designation per 9 CFR 317.2(e)(2) and 381.117(h) apply to food service labels?

A: Yes. The rule applies to labeling for raw products with added solution going to Food Service, HRI, and retail.

Q12: Is uncooked ham water added and ham with natural juices covered under this rule?

A: No. These products have a standard of identity in 9 CFR 319.104. Therefore, if the product meets the standard requirements, the products are not subject to this rule.

Q13: Can we use "contains x% solution" as an identifier on box end labels on a shipping container that holds fully labeled packages inside the box?

A: The labeling for a shipping container that holds fully labeled immediate containers is not required to bear a product name, but when the container voluntarily bears the product name, the name must be complete to accurately reflect the nature of the product inside. The product name for raw products with added solution subject to this rule must include the solution descriptive designation. However, FSIS has made an exception to allow a shortened version of the descriptive designation on the shipping container. For example, if the retail label inside the shipping container declares "pork with 10% solution of water, salt, and sodium phosphate," the shipping container label may repeat the same information or use an abbreviated format such as "Pork w/10% Solution" or "PRK w/10% SLN". The immediate containers inside the shipping container may not bear a shortened version of the descriptive designation.

Q14: How often does the establishment need to verify the percent solution in raw meat and poultry products?

A: FSIS no longer prescribes specific quality control programs. The manufacturers need to ensure that they monitor the percent solution pick up to verify that product labeling is not false or misleading.

Q15: What level of documentation will be required (if any) to substantiate the accuracy of the descriptive designation required per 9 CFR 317.2(e)(2) and 381.117(h)?

A: The establishment is required to maintain records in accordance with 9 CFR 320.1(b)(11) to verify that labeling is truthful and not misleading. In the past, FSIS relied on Quality Control programs; however, FSIS regulations no longer include specific Quality Control requirements. Each manufacturer is expected to maintain documentation to show that labeling is truthful and not misleading. The frequency and manner of testing will depend on the manufacturer's protocol and not on specific guidance from FSIS.

GENERIC LABELING

Q16: If we find that any of our labels need correcting based on the recently published final rule for raw products with added solutions, can we do this with a generic approval?

A: Yes, provided that the label complies with 9 CFR 412.2. Modifying or adding a descriptive designation is not considered a special claim.

See 9 CFR 412.1 and 412.2 and the guidance for generic label approval at the FSIS web site <http://www.fsis.usda.gov/wps/portal/fsis/topics/regulatory-compliance/labeling>

Q17: Would the following added solution descriptive designations be acceptable?

1. Brined with up to 15% Chicken Broth, Carrageenan and Salt.
2. Contains up to 15% Brine of Chicken Broth, Carrageenan and Salt.
3. Contains up to 15% Pre-Brine Solution of Chicken Broth, Carrageenan and Salt

A: The first 2 statements would be acceptable. However, option 3 would not be acceptable because the solution is brine, and identifying it as a “pre-brine” would be false and misleading to the consumer.

INGREDIENTS STATEMENT

Q18: Will an asterisk still be allowed in the added solution statements to refer to another area or ingredients listing, especially ones that are long?

A: Yes. While an asterisk is not required to direct consumers to the ingredients statement, one may be used if desired provided the product name and descriptive designation are in compliance with 9 CFR 317.2(e)(2) or 381.117(h). For example, “Beef containing 12% solution of water and seasonings,*” and the label has an ingredients statement on the information panel as “*ingredients: beef, water, seasoning (salt, spices).”

Q19: When the added solutions descriptive designation includes all of the ingredients in place of an ingredients statement, may the descriptive designation also include the allowance to list ingredients less than 2 percent in any order in accordance with 9 CFR 317.2(f) and 381.118(2)(i)?

A: Yes. The requirements in 9 CFR 317.2(e) and 381.117(h), which require that the product name include a descriptive designation, do not affect the labeling allowances provided in 9 CFR 317.2(f) or 381.118(2)(i) for an ingredients statement. For example, “pork loin containing up to 15% of a solution of water, soy sauce (soybeans, wheat, salt, alcohol), contains less than 2% of spices, salt, and sodium phosphate” would be acceptable because when the descriptive designation includes all of the added ingredients it serves as both the product name and the ingredients statement.

Q20: Under this final rule, does the ingredients statement need to be on the Principal Display Panel (PDP)?

A: No. The regulations in 9 CFR 317.2(c)(2) and (f) and 381.118 continue to allow the ingredients statement to be placed on the information panel or on the 20% panel for cylinders.

DESCRIPTIVE DESIGNATION

Q21: Does the word “contains” or “containing” have to be in the added solution descriptive designation?

A: No. The descriptive designation may use the word contain or contains, but these words are not required. Other terms that may be used include “added,” “with,” or “up to.”

Q22: Does the word “solution” need to be included in the descriptive designation?

A: No. The word “solution” is not required in the descriptive designation as long as the added ingredients are included.

Q23: Can the word "enhanced" be included in the descriptive designation, for example, "YOUNG TURKEY BREAST MOISTNESS ENHANCED BY UP TO 25% SOLUTION ADDED DEEP INSIDE CONSISTING OF: TURKEY BROTH, SALT, SODIUM PHOSPHATE"?

A: No. The descriptive designation cannot include “enhanced” (9 CFR 317.2(e)(2)(v) and 9 CFR 381.117(h)(5)): “The product name for a raw poultry product that contains added solution and does not meet a standard of identity in this part must contain a descriptive designation that includes:… The word “enhanced” cannot be used in the product name.”

Q24: May the descriptive designation include other words such as “injected,” “flavored,” “added,” or “added deep inside”?

A: Yes. Additional words (other than enhanced), such as, “injected,” “flavored,” “added,” or “added deep inside,” may be included in the descriptive designation provided all the required elements are included in the descriptive designation, for example, “turkey breast injected with 20% solution of turkey broth, salt, and sodium phosphate added deep inside.”

Q25: Does the descriptive designation need to include all of the ingredients that are in the added solution?

A: The statement must 1) include all the ingredients of the solution in descending order of predominance, or 2) include a combination of single and multi-ingredient components of the solution in descending order of predominance in accordance with 9 CFR 317.2(e)(2)(ii) and 9 CFR 381.117(h)(2).

Q26: Does the requirement that the product name and descriptive designation “be printed in a single easy-to-read type style and color” mean that all of the words, for example, “Tender Young Turkey contains up to 9.5% solution of natural turkey broth & seasonings” appear in only one font and one color without shading?

A: The product name and descriptive designation must be in only one easy-to-read type style, in one color, on a single color contrasting background, and with no letter less than 1/3 size (see exception* below) of the largest letter in accordance with 9 CFR 317.2(e)(2)(iv) and 9 CFR 381.117(h)(4). The rule does not prohibit type styles with shading. However, if the type style used has shading, then all of the lettering in the product name and descriptive designation needs to be in the same font style with shading.

*Labels with 1/4 sizing for the product name and added solution descriptive designation can be used until January 1, 2018. After that date, labels must meet the 1/3 size requirement.

Q27: Can an establishment use multiple lines for the product name and descriptive designation with different font sizes?

A: Yes. The product name and descriptive designation may appear on more than one line provided there is no intervening text or graphics. The font sizes may be different provided the 1/3 (or 1/4 size until January 1, 2018) requirement has been met.

Q28: Regarding the 1/3 size requirement for the descriptive designation, is the smallest lower case lettering of the added solutions supposed to be 1/3 height of largest letter in the product name.

A: Yes. The requirement in 9 CFR 317.2(e)(2)(iv) and 9 CFR 381.117(h)(4) means that the smallest letter (whether a lower case letter or a capital letter) may be no smaller than 1/3 the size of the largest letter (whether a lower case letter or a capital letter) across the entire product name and descriptive designation.

Q29: Can the descriptive designation include “may,” for example, “Beef for Fajitas - may contain up to a 20% solution of water, salt, and spices”?

A: No. It is misleading to use the word “may” because the statement is required to convey the percent added solution that the product actually contains.

Q30: Can a label state "contains 18% solution" under the product name but list the solution ingredients in a separate location on the label?

A: No. It is insufficient to only state the percent of added solution. The descriptive designation must include the individual or multi-ingredient components that make up the solution.

Q31: Will the use of the term “marinated” or “basted” have any restrictions when the final rule becomes effective?

A: No. The words “marinated” and “basted” may be used in the descriptive designation without restriction to the level of solution.

Q32: Is it still acceptable to use the verbiage "up to X%" in the added solution statement, for example, "contains up to 12% of a solution of water and salt"?

A: Yes. The added solution descriptive designation may include the words “up to” as used in written discussions in the proposed and final rules.

MULTI-INGREDIENT COMPONENTS

Q33: Please clarify what is considered a “multi-ingredient component.”

A: A multi-ingredient component is an ingredient added to the formula that itself is made up of two or more ingredients, for example, seasoning (salt and spices) or soy sauce (water, soybeans, wheat).

Q34: When listing the multi-ingredient components in the added solutions descriptive designation, is a purchased seasoning blend considered a multi-ingredient component?

A: Yes. A purchased seasoning blend is a multi-ingredient component just as teriyaki sauce is. Product with a seasoning blend could bear the descriptive designation: “Pork Shoulder – Contains up to 20% solution of water, seasonings, natural flavor and sodium phosphate.” The label also must bear an ingredients statement to provide the seasoning ingredients, for example, Ingredients: “Pork Shoulder, Water, Seasoning (Corn Syrup Solids, Salt, Garlic Powder, Onion Powder, and Spices), Natural Flavor, and Sodium Phosphate.”

Q35: If an establishment adds several spices and other ingredients to its formula, can the establishment put them all together and call them “seasoning” in the descriptive designation?

A: Yes. An establishment may make its own seasoning blend by combining ingredients together to make a seasoning blend prior to adding the blend to the product formula.

ADDITIONAL for RETAIL

Q36: Will all products with added solutions sold at retail need to comply with the requirements in 9 CFR 317.2(e)(2) and 381.117(h) by Jan 01, 2016?

A: No. Only raw products subject to the final rule that are labeled in an establishment or at retail will need to be in compliance by the applicable effective date (see Q1).

Q37: Is the scale/price label applied by the retailer required to list the added solution statement or may it be communicated with a point of sale placard or sign?

A: Both the point of sale placard if one is used (which is a form of labeling) and the label that will be placed on the wrapped package will need to be updated to comply with the requirements in 9 CFR 317.2(e)(2) and 381.117(h).

Q38: Will there be a grace period for compliance after Jan 01 2016? We have quite a few marinated items in our meat service case and we are trying to understand how we will be able to accommodate several tags with the descriptive designations.

A: No. FSIS is not considering a grace period. We recommend that you plan accordingly so that labeling will be in compliance by the established effective dates (see Q1).

Q39: What will be the expected best practices for a retailer to support the percent of added solution if questioned?

A: There are no specific labeling record keeping requirements for retailers under 9 CFR 320.1(b)(11) and 381.175(b)(6). However, FSIS recommends keeping accurate records of your product formulas and processing procedures to support that the label applied at retail is truthful and accurate. Records might also include raw weights before added solution, raw weights after solution is added, and a calculation of the percent pickup.

Q40: Is the rule of thumb used in nutritional analysis databases for absorption rates ($\frac{1}{2}$ to 1 tsp marinade per ounce) acceptable to use when calculating % uptake in different marinated items?

A: No. The amount of added solution needs to be based on the weight of the product prior to adding solution and the weight after solution is added (See Q3).

Q41: Does the ruling apply for pour-over marinades where the absorption rate might not be significant? For example, meat and poultry items that are placed in a tray and a marinade is poured over. These items are immediately placed in the service case and available for sale.

A: Yes. Any amount of added solution that can be expressed as a percentage will need to be identified with a descriptive designation. The percent added solution must be accurate for the whole length of time the product is displayed for sale. While you might display the product immediately after pouring on the marinade, if the meat or poultry sits in marinade for several hours before it is sold it will have a higher absorption rate than when the marinade was first poured on.

Q42: Does the marinating process determine whether the label requirements apply? For example, if raw meat and marinade are combined in a plastic lug for

approximately 24 hours but are not injected or vacuum tumbled to force absorption, does this require a descriptive designation with the % of absorption?

A: Yes. The marinating process you describe typically increases the weight of the raw meat or poultry by up to 3% of the green weight. These products do need to include the percentage of solution pick up as part of the product name. The percentage declared will need to be based on your specific formula and processing procedures.

Q43: Our scale labels do not have enough character space to put the percentage of marinade and the ingredients with the product name. Can we use a sticker in addition to the scale label to provide the descriptive designation for added solution?

A: The descriptive designation may be placed next to the product name by use of an additional sticker provided the formatting meets the criteria in the regulations, and there is no intervening text or graphics between the product name and the descriptive designation.

Q44: If we make several different raw products with added solutions that use different formulations and display the unlabeled product in a display case, do all the descriptive designations need to be placed next to the item?

A: Yes. Each product needs to have a product name and descriptive designation that accurately reflects the formulated product in close proximity to the product.

Q45: Are there specific font size requirements for the descriptive designation used on tags used for service case items?

A: Yes. Wherever the product name and added solutions descriptive designation is displayed to the consumer, it needs to comply with the formatting requirements in 9 CFR 317.2(e)(2) or 381.117(h).

Q46: Does FSIS have any guidance for retailers on how to calculate added solution content beyond what is in the final rule? What degree of flexibility do retailers have in determining added solutions content?

A: FSIS does not have specific guidance for determining the percent solution pick up outside of what was provided in the final rule in 9 CFR 317.2(e)(2)(i) and 9 CFR 381.117(h)(1). While products manufactured at the retail store are not produced under FSIS inspection, they are subject to the same misbranding regulations as a federal establishment. In general, it is up to each retail store to determine the average solution pick up for each specific formulation and processing procedure followed. There is no set rule for how much solution is absorbed by meat or poultry. There are many factors that will affect the percent pick up, such as the type or cut of meat or poultry, the size of the pieces of meat or poultry, the formula of the solution, the addition of phosphates, the amount of time the product is marinated, or the amount of solution that is injected or vacuum tumbled.

For compliance, as stated above, FSIS allows a 20% variation from the percentage declared on the label for federal establishments. For example, if the label declares 10% solution, the permitted variation would be not more than 2% above the declared amount; that is, no more than 12% total. FSIS does not object to retail stores following the same 20% variance as allowed for federal establishments.

Q47: May literature studies be used in place of production records to verify the percent of added solution declared in the descriptive designation?

A: Yes. If the product formula and processing procedures match that used in a literature study that documents solution absorption percentages, the study may be used to support the label declaration of added solution.

MISCELLANEOUS

Q48: Is it acceptable to label a fresh pork tenderloin with 25% of a solution of water, sodium phosphates, potassium acetate, potassium lactate, and salt (to improve Juiciness and Tenderness) as "Unseasoned"?

A: No. To claim that the product is "unseasoned" would be false and misleading. All the ingredients in the solution except perhaps the water provide flavor and season the product, even though the solution may also have been added to improve juiciness and tenderness.

Q49: Our product's principal display panel has a product name and descriptive designation in compliance with the final rule. Does a reference to the name on the back of the package (that is, the information panel) also need to include the complete descriptive designation?

A: No. Only the product name on the principal display panel and all alternate display panels are required to include the descriptive designation with the product name. If the product name is repeated on the information panel it does not need to be complete with the descriptive designation.

Q50: If an establishment receives raw meat or poultry with added solutions and cooks it, does it need to include an added solutions descriptive designation?

A: No. The requirements do not apply to cooked product.