# US Foods Exclusive Brands Regulatory Food Labeling Manual



# Statement of Purpose:

US Foods Exclusive Brand (EB) labels are integral to the success of US Foods. This Manual detrails the current regulatory (federal and state) and US Foods requirements for labeling.

# Introduction:

Suppliers are ultimately responsible for ensuring that all printed labeling material is compliant with current regulatory (federal and state) requirements and meeting other US Foods requirements where applicable. Where there is a disagreement between the supplier and US Foods a formal agreement will be reached and acknowledged by both parties.

All printed labeling material is reviewed by a group of internal and external approvers which includes, but is not limited to the Supplier, Regulatory, members of the Project team, the Printer, and Packaging (3<sup>rd</sup> party graphics on-site). Each team member looks at specific aspects of the labels. All members of the team must approve before a label can be printed.

Each section contains basic information. Since it is not possible to examine every detail of labeling in a manual, the individual performing this function must be familiar with all applicable regulations. Always refer to applicable regulations for clarification. Questions regarding which regulations apply should be directed to US Foods-Regulatory.

If product is intended, or expected to be, exported, contact US foods Regulatory for additional labeling requirements for non-US use.

# Label Processing:

EB food labels are processed primarily through a database system known as US Foods Packaging Artwork eManagement System owned and operated by Trident, a strategic partner to US Foods. Several Trident employees are housed at US Foods. Trident can grant access to the database system and provide all necessary training to operate comfortably within their system.

Occasionally labels will be routed to approvers outside of the Trident system, via email. This alternate process, while discouraged, is occasionally necessary.

# **US Foods Retail Labeling**

US Foods preference is for labels, at all levels, to be set up for retail sale requirements, as spelled out in this policy. This allows for product to be broken <del>up</del> and sold as individual units or on the case level for both retail and food service.

# **US Foods Sample Labeling:**

All samples shall be fully labeled as required by the appropriate regulations and US Foods policies and SOPs.

Labeling includes:

- "Sample- Not for Retail Sale" in large bold letters
- Product's Name and Product Code
- Ingredient Statement
- Any allergens listed on the label in the "Contains:" statement
- Address line: "Distributed by US Foods, Inc., Rosemont, IL 60018"
- Cooking or Preparation Instructions, if appropriate
- Brand
- USDA inspection legend, if appropriate
- Storage Statement
- Lot code

# LABELING

## Principal Display Panel: 21CFR101.1, 9CFR 317.2(d), 9CFR381.116

- The Principal Display Panel (PDP) is the part of a label most likely to be displayed, presented, shown, or examined under customary conditions of display for retail sale.
- Alternate PDP If the PDP is repeated, all required features on the PDP are required to be repeated.

### Information Panel: 21CFR101.2, 9CFR317.2(d), 9CFR381.116(C)(2)

- The Information Panel is the first usable panel to the right of the Principal Display Panel. This is usually a side panel, but if not large enough to accommodate the features, the back panel can be used (which would be the next usable panel).
- The required features included on the information panel must be contiguous and may not be separated by non required features (Example: nutrition panel, ingredient statement, and distributed by statement cannot be separated by the preparation instructions.)

#### Required Features that <u>Must</u> Appear on PDP:

- Product Name/Identity
- Quantity/Net Weight statement/Pack Size
- USDA inspection legend (meat, poultry)
- Handling Statement (meat, poultry, eggs)

#### Required Features that <u>can</u> appear on an Information Panel but may exist on the PDP

- Distributed By Statement (Address Line)
- Ingredient Statement (including allergen statement)
- Nutrition Facts Panel
- Safe Handling Statement (meat, poultry)
- Handling Statement (FDA)

#### Other Features that can exist anywhere on the label:

- Country of Origin
- Preparation Instructions
- Claims / Marketing Copy
- Brand
- UPC
- Product Code
- Artwork

## Languages: 21 CFR 101.15(c)(1)-(2)

- It is US Foods preference for labels to be bilingual including both English and Spanish.
- If any labeling features are stated in a second language, all must be so stated in a second language. Note that Logos do not fall under this requirement.
- Example: "Espanol Al Lado Opuesto" is used on English side of the package, it must be mirrored by "English on the Opposite Side" on the Spanish side.

# **Artwork / Graphics**

- Do not use artwork that hides or detracts from the prominence and visibility of required label statements or that misrepresents the food. For example, strawberry jam cannot have a vignette that includes apples and oranges.
- Graphics including additional products (pan sprays showing a pan with vegetables) must include the phrase "serving suggestion" next to the photo.

### True Product Name: 21CFR101.3, 9CFR317.2(c), 9CFR381.117

- Every product must contain only one true product name.
- If the product meets a standard, then the standardized name is the true product name. Note: the product must meet the regulatory standards in order to use a standardized name. Standard of Identity can be found at 21 CFR 130-169 and 21 CFR 102 for FDA products and 9 CFR 319 as well as the "Foods Standards and Labeling Policy Book" for USDA products.
- If the product is unstandardized, a Fanciful Name (Coined Name) may be used, but must include a descriptive name that accurately depicts the product by listing the major components in order of predominance. The descriptive name in this case is the true product name.
- The true product name must describe the form of the food in the package if there are optional forms such as sliced and unsliced.
- The true product name must appear on the PDP and be prominent relative to the largest print on the PDP (no less than 1/16") in lines generally parallel to the base of the package when displayed.
- The lettering may appear in lower and upper case letters, with the difference between the smallest and largest letter be no more than 1/3 in the size.

# Meat / Poultry Labeling:

- Product name qualifiers must appear contiguous to the product name and can be in any order. They must be at least ¼ the size of the largest letter in the product name.
- Caramel Color is considered an artificial color. When included in the product or on the surface and imparts a color on the meat product, a caramel color product name qualifier is required. Options include statements such as "Caramel Color

Added" or "Caramel Colored" or may be apart of the "Coated with" or "Rubbed with name qualifier (see below).

Coated with" and "Rubbed with" statements are required product name qualifiers. They do not have to be repeated in the ingredients – unless a class name such as "seasoning" is used which must be individually listed (According to 9CFR317.2(f)(iv)).

Example - Does <u>not</u> need to be included in ingredient statement: Fully Cooked Roast Beef Rubbed with Cracked Black Pepper Ingredients: Beef, Water, Sea Salt

Example - Does need to be included in ingredient statement: Fully Cooked Roast Beef Rubbed with Seasonings Ingredients: Beef, Water, Sea Salt. Rubbed with Salt, Sugar, Garlic, Spices.

- Smoked vs Smoke Flavor
  - Naturally smoked product using burning wood, saw dust, corn cob or other requires "Smoked" or "Naturally Smoked" to be in the product name.
  - Liquid smoke flavor that is used to coat the product and has been transformed into a true gaseous state or vaporized can be called "Smoked" (cannot use the term "Naturally Smoked") in the product name. The smoke flavoring does not have to appear in the ingredient statement.
  - Liquid smoke flavor added into the product and/or not atomized must use a product name qualifier to show the addition, such as "Smoke Flavoring Added."
- Solution Statements: % Solutions Statements are required when products include additional solution ingredients above green weight of the meat (unless included in the product standard). The percent solution statement requirements differ if they are raw or fully cooked as well as red meat vs poultry.
  - RAW MEAT AND POULTRY % SOLUTION REQUIREMENTS
    - The raw product solution statement is part of the product name. It is not a product name qualifier; therefore, the solution statement/descriptive designation must be before any product name qualifiers.
    - Print may appear in upper and lower case letters the smallest letter not being less a 1/3 the size of the largest letter to the product name.
    - Can be located above, below, or next to the product name

- Must appear in easy to read type style and color on a single color contrasting background,
- The solution must list the percentage above green weight levels and state, "Contains up to X% added solution of:
  - include all the ingredients of the solution in descending order of predominance
  - or 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)
- Cannot use the word "enhanced" or "may"

#### • FULLY COOKED RED MEAT - % SOLUTION PRODUCTS (Policy 84A)

- For cooked product, the solution statement is considered a qualifier equal to caramel color added or coated with seasonings. Product name qualifiers can be listed in any order.
- The statement must be no less than 1/4 the size of the largest letter in the true product name and state, "Contains up to X% added ingredients".
- Note: it is not required to list all the ingredients in order of predominance.
- FULLY COOKED POULTRY DOES NOT REQUIRE A % SOLUTION STATEMENT.

#### • FULLY COOKED RED MEAT RETURNS TO GREEN WEIGHT

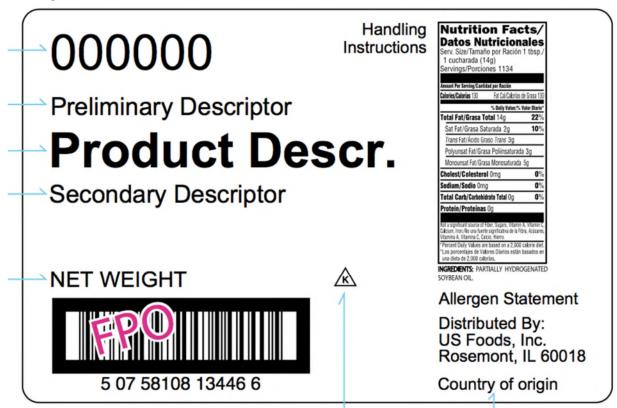
- Include the term "Flavored" or "Seasoned" at no less than 1/3 the size
- **UNCURED PRODUCTS** all products that include the requirement of being cured may be without curing (ie without direct addition of sodium nitrite or sodium nitrate). The following requirements are then required:
  - "Uncured" as part of the product name in the same size and style of lettering of the product name
  - "No Nitrate or Nitrite Added" must be adjacent to the product name in easily readable style at least ½ the size of the smallest letter in the product name
  - "Except those naturally occurring in the X Ingredient" If naturally occurring nitrite disclaimer must be made on the same panel and connected to (with "\*" or similar) "No Nitrate or Nitrite Added" statement.

 O "Not Preserved. Keep Refrigerated Below 40°F At All Times" – must be adjacent to product name in easily readable style in at least ½ the size of the smallest letter in the product name

# **US Foods Product Name Guidelines:**

- A maximum of four lines for naming should be available. Every word should count and avoid redundancy. Names should not be misleading.
- Line # 1 (Preliminary Descriptor): This is an optional line with no expectation for use unless it offers to differentiate brand/quality/state of product (such as sliced).
- Line # 2 (Product Description): Use for Fanciful Name for unstandardized name or True Product Name for standardized products
- Line #3 4 (Secondary Descriptor): Use for descriptive name for unstandardized products or qualifying statements for standardized names as necessary. Marketing can use to call out key ingredients, attributes, size / count, etc. as long as such items are not false or misleading.

Example:



## Net Weight Statements: 21CFR101.105, 9 CFR317.2(h), 9CFR381.121

■ The net weight statement is an accurate statement of net quantity of food product in the package and is required on all packages weighing greater than ½ oz.

- The net weight statement must be placed in the bottom 30 percent of the principal display panel, in lines generally parallel with the base of the container.
- The lettering must not exceed three times as high as it is wide.
- The net weight statement may use more than one line.
- The minimum height sizing of the smallest letter in the net weight statement (if lower and upper case letters are used, the lower case letter "o" must meet the minimum sizing) is based on the PDP area as below:

PDP Size (are in square inches)	Minimum Height of Net Weight Lettering (inches)
<u> </u>	1/16'' = 0.0625''
$> 5 \text{ to} \le 25$	1/8" = 0.125"
$> 25 \text{ to} \le 100$	3/16" = 0.1875"
$> 100 \text{ to} \le 400$	$\frac{1}{4}$ = 0.25"
> 400	$\frac{1}{2}$ = 0.5"

- The net weight statement must be separated by a buffer zone free of writing or designs of two times the width of the letter "N" for left and right of the statement and the height of the letter "N" top and bottom.
- Food labels must show the net contents in both U.S. Customary (ounces, pounds, fluid ounces) and metric (grams, kilograms, milliliters, liters) units.
- On a multi unit retail package (a package containing two or more individually packaged units of the same commodity and same quantity- other than butter or margarine) a statement of the quantity of contents shall appear on the outside of the package and shall include the number of individual units along with the total, such as: "6-16 oz bottles (96 fl oz)" or "3-16 oz cans (net wt. 48 oz)".
- Drained weight "DR WT" is required for certain products whose weight are based as such, ex. canned olives, mushrooms, tuna, etc.

# **US FOODS NET WEIGHT STATEMENT RULES**

- Apply weight statement at every level of packaging
- It is US Foods preference to label shipping and institutional containers in retail format. If labeled only as a shipping or institutional only container, however, it is unnecessary to follow size spacing rules. Exceptions must be approved in advance by Regulatory.

#### **ROUNDING:**

- Use normal rounding rules: 0-4 round down, 5-9 round up
- Always round down on the converted metric equivalent units (reference: NIST Handbook 130 (6.13) (page 68-69).
- Grams, and Milliliters to nearest one's place (unless more places are needed on very small items).
- Kilograms and Liters to the nearest 100<sup>th</sup>'s place
- Generally do not use more than 2 decimal places except when required by a very small package
- Only declare to the non-zero level (ex. Net 10 kg not Net Weight 10.00 kg).

- Do not show decimal places of pounds instead show the number of whole pounds and ounces.
- Show grams when value is less than a kilogram.

#### **CONVERSION FACTORS FOR NET WEIGHT:**

By Weight

- 1 lb = 16 oz
- 1 oz = 28.35 g
- 1 kg = 1000g
- By Volume
  - 1 fl oz = 29.574 mL
  - 32 fl oz = 1 quart
  - 1 gallon = 4 quarts
  - 1 gallon = 3.785 L

Dairy

- half pint = 237mL
- 1 pint = 473mL
- 1 quart = 946mL
- 1 gal = 3.78 L

#### FORMATING:

- Period on abbreviations of "WT" and units are optional.
- Must follow the guidelines as spelled below:

#### Sold by Weight:

Less than 1 Pound: express in oz and g

ex. NET WT. 4 OZ. (113 g) ex. NET WT 0.18 OZ (5.1 g)

Between 1 and 4 Pounds: express in oz, lb, and g or kg (Reminder: Do not show decimal places of pounds – instead show the number of whole pounds and ounces)

> ex. NET WT. 20 OZ (1 LB 4 OZ) 567 g ex. NET WT. 48 OZ (3 LB) 1.36 kg

 4 Pounds and Greater : express in lb and kg (Reminder: Do not show decimal places of pounds – instead show the number of whole pounds and ounces)

> ex. NET WT. 4 LB 2.5 OZ (1.88 kg) ex. NET WT 7 LB (3.17 kg)

#### Sold by Volume:

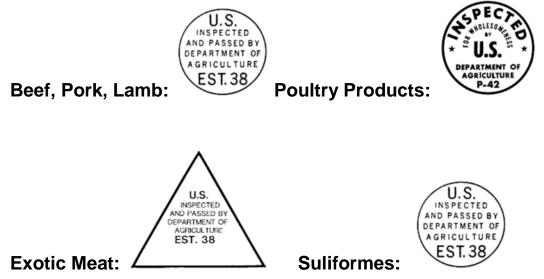
- Less than 1 Pint: express in fl oz and mL ex. NET 12 FL OZ (354 ML)
- Between 1 and 2 Pints: express in fl oz and mL ex. NET 16.9 FL OZ (1.05 PT) 499 ML
- Between 1 and 4 Quarts express in fl oz, qt, and L ex. NET 96 FL. OZ. (3 QT.) 2.83 L ex. NET 33 FL OZ (1.03 QT.) 1L
- 1 Gallon and Greater expressed in gal and L ex. NET 2 GAL. (7.57 L) ex. NET 3.5 GAL. (13.25 L)

#### Dairy Only – by Volume:

- Half Pint: express in pints and mL ex. NET HALF PINT (236 ML)
- Pint: express in pints and mL ex. NET 1 PINT (473 ML)
- Quart: express in quarts and mL ex. NET 1 QUART (946 ML)
- Half Gallon expressed in gal and L ex. NET HALF GAL (1.89 L)
- Gallons expressed in gal and L ex. NET 1 GAL (3.78 L)

#### USDA Inspection Legend (Bug) 9CFR317.2(c)(5) and 9CFR381.96, 9 CFR 352.7(exotic meat), 9 CFR 530 (catfish)

- The meat inspection legend must appear on the PDP (and alternate PDP) of any meat or poultry product.
- For red meat, the "U.S." and "EST. XXX" must be at least twice as high and twice as bold as the rest of the lettering in the circle.
- The circle must be clear and separate from the background color.
- The establishment number may be left blank within the seal as long as it is else where on the packaging, and the label states where the number can be found, and the number is preceded with "EST".
- Examples of the legends are:



## Handling Statement 9CFR 317.2(k) and 9CFR381.125(a)

- Any product that is not shelf stable must bear a handling statement, which indicates where the product needs to be stored in order to keep wholesome condition.
- To comply with California Health and Safety Code 110700, we require all refrigerated statements to include the word "Perishable" such as, "Perishable Keep Refrigerated." (Keep Frozen statements are exempt from this requirement). To remove "Perishable" from the "Keep Refrigerated" Statement – the following three step process must be followed:
  - 1. Regulatory approves the removal Challenge study documentation is provided that proves that refrigeration is needed for quality and not food safety.
  - 2. Category Management approves the removal.
  - 3. Specification should also state product is refrigerated for quality not food safety

- USDA products: If any type of refrigeration is required at point of purchase, statement must be on the PDP at no less than 1/16".
  - 1. Examples of acceptable handling statements include:
    - Perishable Keep Refrigerated
    - Keep Frozen
  - 2. For USDA products that are distributed frozen but sold refrigerated:
    - Previously Handled Frozen for your Protection, Keep Refrigerated or Refreeze (red meat)
    - Shipped/Stored and Handled Frozen for Your Protection, Keep Refrigerated or Refreeze (poultry)
- For FDA products, it is US Foods preference to include a handling statement of "Perishable - Keep Refrigerated" or "Keep Frozen" to be located on the PDP at no less than 1/16" (if required for wholesomeness).
  - 1. If refrigeration is needed only after opening, statement can be on the information panel, examples:
    - Refrigerate After Opening
    - Store in a Cool Dry Place
- Shell Eggs:
  - 1. "Keep Refrigerated" must appear on the PDP or information Panel
  - 2. A safe handling instruction must appear on the label set off in a hairline (very thin) rule box: "SAFE HANDLING INSTRUCTIONS: To prevent illness from bacteria: Keep eggs refrigerated, cook eggs until yolks are firm, and cook foods containing eggs thoroughly."

# Safe Handling Statement – Raw Meat and Poultry 9CFR317.2(I) and 21CFR381.125(b)

- Safe handling statements are required for all raw (non ready-to-eat) meat and poultry products
- Must be enclosed within a hairline (very thin) rule box or freeform shape.
- Title must be "Safe Handling Instructions" in larger type.
- Icons must depict a refrigerator, soapy hands under a faucet, a skillet, and a thermometer.
- Wording is as example:

# Safe Handling Instructions

This product was prepared from inspected and passed meat and/or poultry. Some food products may contain bacteria that could cause illness if the product is mishandled or cooked improperly. For your protection, follow these safe handling instructions.



Keep refrigerated or frozen. Thaw in refrigerator or microwave.

Keep raw meat and poultry separate from other foods. Wash working surfaces (including cutting boards), utensils, and hands after touching raw meat or poultry.



Cook thoroughly.

Keep hot foods hot. Refrigerate leftovers immediately or discard.

# **US Foods Required Country of Origin (COOL) Statement**

- US Foods policy is to include COOL statement on <u>every product</u> indicating the product's source or location of final processing (last substantial transformation).
- A country of origin statement is required to be included on the label. Location of statement may vary as such:
  - FDA Imported Products must be located contiguous to the address line in no less than 1/16" in height.
  - USDA Imported Products must be located contiguous to the legal name at no less than 1/3 the size of the largest letter of the legal name but no less tan 1/16" in height
  - US sourced items can be located anywhere on package at no less than 1/16"

#### ■ USDA / AMS PRODUCTS REQUIRED COOL STATEMENTS

 The USDA/AMS (7 CFR 60 and 65) is responsible for COOL labeling of covered commodities i.e., muscle cut and ground meats: venison, lamb, goat, and chicken; wild and farm-raised fish and shellfish; fresh and frozen fruits and vegetables; peanuts, pecans, and macadamia nuts; and ginseng. Must follow regulations as pertain to each.

- A process is needed to qualify as a substantial transformation requiring COOL labeling. Packaging alone does not qualify as a substantial transformation.
- Must be legible and at least 1/16" in height
- The following regulated COOL statements should be used:

Condition	Regulation	COO	Labeling
Meat Cuts - Must have been born, raised, and slaughtered in USA	7 CFR 65.260 (a) (1)	USA	"Born, Raised, and Slaughtered in the U.S.A."
Muscle Cuts – born in Country X, Raised and Slaughtered in USA	7 CFR 65.300 (e)	Imported animal but raised and slaughtered in USA	"Born in Country X, Raised and Slaughtered in the USA"
Muscle Cuts – born and raised in Country X, Slaughtered in USA	7 CFR 65.300 (e)	Imported animal but slaughtered in USA	"Born and Raised in Country X, Slaughtered in USA"
Muscle Cuts - imported	7 CFR 65.300 (f) (2)	Imported product	Product of Country X
Ground Meat	7 CFR 65.300 (h)	USA or Imported	Label shall list all countries contained therein or may be contained therein "Product of USA" "Product of Country X and USA"

#### Venison, Veal, Lamb, Goat, Chicken:

#### FISH AND SHELLFISH – wild and farmed\*:

Condition	Regulation	COO	Labeling
Hatched, raised, harvested (or just harvested), & processed in the U.S. and No substantial transformation outside the USA	7 CFR 60.128 (c) and (d)	USA	"Product of USA"
Have NOT gone through substantial transformation in US	7 CFR 60.200 (f)	Imported	"Product of Country X"
HAVE gone through substantial Transformation in USA	7 CFR 60.200 (g)	Imported	"From Country X, Processed in the USA" Or "Product of Country X and USA"
Contains multiple countries of origin	7 CFR 60.200 (h) (1) and (2)	Comingled – imported and product of USA	"Product of Country X and USA"

\*Fish and Shellfish require both country of origin and method of production. Acceptable Method of Productions include: • Farm-Raised • Farmed • Wild-Caught • Wild

omseng.			
Condition	Regulation	C00	Labeling
Produced in the USA	7 CFR 65.260 (b)	USA	"Product of USA" "Produce of USA"
Imported (no substantial transformation in USA)	7 CFR 65.300 (f)	Imported	"Product of Country X"
Comingled	7 CFR 65.300 (g)	Comingled – imported and product of USA	"Product of Country X and USA"

# Fresh Fruits and Vegetables, Peanuts, Pecans, Macadamia Nuts, Ginseng:

#### **USF COO Statements – non regulated products**

**Product of USA** – This is the desired statement for all product categories except for produce and disposables. Statement applies if product is 100% domestic – does not contain any foreign materials and was produced and packaged in the USA.

**Made in USA** – Statement applies if product is 100% domestic – does not contain any foreign materials and was produced and packaged in the USA.

**Processed in USA** – Statement applies if product/produce contains any imported materials but substantial transformation shall have occurred in the USA.

**Bottled in USA** – Statement applies if beverage concentrate is from an imported source.

**Packaged in USA** – Statement applies if product had substantial transformation occur outside the USA and/or has both domestic and imported sources, but is always packaged in the USA.

#### Canned in USA – not acceptable

**Processed in USA with Imported ingredients** – Acceptable alternative statement applies if product contains any imported ingredients.

**Processed in USA with Domestic and Imported ingredients** – Acceptable alternative statement applies if product contains any imported ingredients.

**Product of "Country Name"** – Statement applies when products are manufactured/ sourced from a foreign country and all substantial transformation occurred in such foreign country.

**Product of Country Name and USA** – statement when product is comingled from different countries including the USA.

# US Foods Distributed By Statement (Address Line): 21CFR101.5, 9CFR317.2(g)(1) and 9CFR318.122

- Must be present on both inner packages and outer shippers.
- Must be at least 1/16" in height.
- May be a single line or stacked
- US Foods does not allow manufacturers' identities to be printed on the labels.
- Must use one of the following formats:





DISTRIBUTED BY US FOODS, INC. Rosemont, IL 60018

www.usfoods.com

DISTRIBUTED BY US FOODS, INC. ROSEMONT, IL 60018 www.usfoods.com

**Ingredient statements:** 21CFR101.4 and 101.22, 9 CFR317.2(c)(2), 9CFR381.118

- An ingredient statement is required on any product made up of two or more ingredients.
  - There is no height requirement but must be legible (generally 1/16" is considered acceptable). Type that is too small or too cramped to read is unacceptable.
  - The ingredient listing may be included as part of the legal name. However, if listed as a stand alone statement must begin with "Ingredients:" (An exception is cured pork products which may begin with "Cured with...)
  - Ingredients shall be listed by common or usual name in descending order of predominance by weight using the mixing bowl values (before any processing has occurred).
  - Minor ingredients may be listed in any order at the end of the ingredient statement if preceded by "Contains 2% or less of the following:"
- Must follow any applicable ingredient listing regulations.

# US Foods Allergen warnings: FALCPA

 US Foods requires an allergen statement on all labels of products that contain allergens.

- Place under the ingredient statement after skipping a line.
- The allergen statement should read "Contains: allergen".
- Allergens include the following FALCPA'S Big 8 ALLERGENS:
  - Wheat
  - Soy
  - Milk
  - Eggs
  - Fish (use the word "Fish" followed by species. "Contains: Fish (Cod)"
  - Shellfish (use the word "Shellfish" followed by species.
    - "Contains: Shellfish (Shrimp)"
  - Peanuts
  - Tree Nuts (must call out the name of the tree nut [walnut, pecan, coconut] not the word "Tree nut")
- The allergenic ingredient must also be included in the ingredient list. If it is not obvious that the ingredient contains an allergen, it must be spelled out, such as, "natural flavor (milk)"
- Molluscan shellfish are not allergenic and are not included in the allergen statement (examples include oysters, scallops, and clams)
- Never include food colors, dies, sulfites, sesame seeds, etc as an allergen
- A "May Contain" statement is not allowed in ingredients or on allergen warning. Suppliers may add a separate notice such as "Produced in a facility that handles peanuts", but not as part of ingredients or allergen warning.
- Do not include highly refined oils in the allergen statement. Highly refined oils are non-allergenic as their proteins which could cause an allergic reaction have been removed.
- Pink peppercorns are in the same botanical family as cashews and pistachios. If pink peppercorns are used, must include the disclaimer, "Pink peppercorn are related to cashews and pistachios, may contain nut allergens" under the allergen contains statement.

#### US Foods Nutrition Facts Panel (NFP): 21CFR101.9, 9CFR 317.3-317.400 and 9CFR381.400-381.500

- Every label shall include an NFP whenever possible.
- A minimum of one NFP is required on every product.
- All FDA labels need to follow the final rule titled "Revision to the Nutrition and Supplemental Facts Labels" by January 20, 2020. Any new FDA labels need to follow this format.
- FDA NFP format must follow Trident / US Foods NLEA Government Initiative Revision of the Nutrition and Supplemental Facts Labels Bilingual Master document.

- USDA (meat and poultry) products to follow NFP regulations 9CFR 317.3-317.400 and 9CFR381.400-381.500
- USDA products may follow FDA NFP format until FSIS final rule is released; however, if any changes are made in the final rule, labels must then be updated to comply with regulations.
- Serving Size Guidance:
  - Serving size needs to be shown in a household measure closest to RACC and the gram or ml equivalent (see regulations for specifics by product type).
  - Required conversion factors for NFP:
     Must use these not decimal fractions of each
    - 1 tsp = 5 mL
    - 1 Tablespoon = 15mL
    - 1 cup = 240 mL
    - 1 fl oz = 30 mL
    - 1 oz = 28 g
  - Normal rounding rules should be used (>5 round up and 0-4 round down)
  - Single Serve Containers need only list 1 unit (metric equivalents are not required)
  - If serving size is 200 300% of RACC must show 2 columns one for closest to RACC serving and one for total package. Note: this does not apply to raw fruits, vegetables, or fish.

#### ■ Number of Servings Guidance:

- 2 5 servings must be rounded to the nearest .5 serving.
- >5 servings are rounded to the nearest 1 using normal rounding rules
- Rounding must be indicated by using the word "about" (ie "about 5 servings")
- Random weight products use the word "varied."

#### ■ New NFP - Vitamins and Minerals -

- Vitamin D, Calcium, Iron, and Potassium are required to be listed (in that order) in the new NFP and/or be included in a footnote if insignificant.
- Additional vitamins and minerals are required to be listed if needed to confirm a claim (example: "good source of 8 vitamins and minerals").
- If no claim is made on the additional vitamins and minerals, the business must agree with their inclusion in the NFP.
- Table lists order that the nutrients must appear in NFP, along with unit of measure, and RDI value used to determine %DV.
- The %DV must be rounded as follows: <2% = 0; 2-10 = nearest 2%;</li>
   >10% 50% = nearest 5%, >50% = nearest 10%
- The values of vitamins and minerals may be rounded as per column labeled "Quantitative Rounding" but may give the exact values without rounding as decided by manufacturer.

Nutrient	Unit of measure	RDI	Quantitative
			Rounding*
Vitamin D	Micrograms (mcg)	20	Nearest .1 mcg
Calcium	Milligrams (mg)	1,300	Nearest 10 mg
Iron	Milligrams (mg)	18	Nearest .1 mg
Potassium	Milligrams (mg)	4,700	Nearest 10 mg
Vitamin A	Micrograms RAE (mcg)	900	Nearest 10 mcg
Vitamin C	Milligrams (mg)	90	Nearest 1 mg
Vitamin E	Milligrams (mg)	15	Nearest .1 mg
Vitamin K	Micrograms (mcg)	120	Nearest 1 mcg
Thiamin	Milligrams (mg)	1.2	Nearest .1 mcg
Riboflavin	Milligrams (mg)	1.3	Nearest .1 mg
Niacin	Milligrams NE (mg)	16	Nearest .1 mg
Vitamin B6	Milligrams (mg)	1.7	Nearest .1 mg
Folate <sup>6</sup>	Micrograms DFE (mcg)	400	Nearest 5 mcg
Vitamin B12	Micrograms (mcg)	2.4	Nearest .1 mcg
Biotin	Micrograms (mcg)	30	Nearest 1 mcg
Pantothenic acid	Milligrams (mg)	5	Nearest .1 mg
Phosphorus	Milligrams (mg)	1,250	Nearest 10 mg
Iodine	Micrograms (mcg)	150	Nearest 1 mcg
Magnesium	Milligrams (mg)	420	Nearest 5 mg
Zinc	Milligrams (mg)	11	Nearest .1 mg
Selenium	Micrograms (mcg)	55	Nearest 1 mcg
Copper	Milligrams (mg)	0.9	Nearest .1 mg
Manganese	Milligrams (mg)	2.3	Nearest .1 mg
Chromium	Micrograms (mcg)	35	Nearest 1 mcg
Molybdenum	Micrograms (mcg)	45	Nearest 1 mcg
Chloride	Milligrams (mg)	2,300	Nearest 10 mg
Choline	Milligrams (mg)	550	Nearest 10 mg

\*The quantitative amount may be declared to the nearest hundredth or thousandth of a mg or mcg when that level of specificity is necessary to attain a value that is at least 2% DV in a serving of food.

Nutrients with less than 2%DV may declare the values by any of the following:

- 0
- by use of an asterisk to bottom footnote that says, "Contains <2% of the Daily Value of this (these) nutrient(s)" or by use of footnote only
- Footnote only, "Not a Significant source of\_\_\_\_\_".

# Specific Product Labeling and Claims Associated to Each

## Milk Labeling:

- Homogenized Milk MUST be so labeled on PDP.
- Grade A /Pasteurized Milk MUST be so labeled on PDP.
- Ultra-Pasteurized MUST be so labeled on PDP and all panels where name is declared.
- If vitamins are added to the milk, MUST be so labeled on PDP and all panels where name is declared.
- Kosher Dairy symbol MUST be present on the label/inner carton/case (if applicable).
- The statement: "Processed at Plant #...." MUST be present on label/inner carton/case.
- In the cases when packaging will be shared by more than one manufacturing facility, the statement: "Processed at Plant # see above" MUST be present on the label/inner carton/case. In those cases the plant # will be embossed or ink jetted by the suppliers.
- If product is Reduced Fat Milk a comparative statement explaining the reduction MUST be on the label.
  - Example: 2% Reduced Fat. "37% Less Fat than Whole Milk/Fat Reduced from 8g to 5g per Serving.
  - Reduced Fat or Low Fat milk claims will be verified by a 3<sup>rd</sup> party lab analysis or vendor's nutrition software

# From Cows Not Treated with rBST Claim:

- Claim "From cows not treated with the growth hormone rBST" MUST include a disclaimer, "No significant difference has been shown between milk derived from rBST and non-rBST treated cows". The disclaimer may be on the PDP or the information panel if there is no room on the PDP.
- The vendor MUST provide a letter from the officer of the company verifying the product is rBST free in order to validate the claim.

# Grade Standards:

The USDA grade shields, official seals and labels are reputable symbols of the quality and integrity of American agricultural products that follow the official grade standards and process standards developed, maintained and interpreted by USDA's Agricultural Marketing Service. All Grade Standards must have gone through and been properly graded before being included on labeling. Use the following link to requirements for each: <u>https://www.ams.usda.gov/grades-standards</u>

# California Egg Labeling:

To meet California Department of Agriculture (CDFA) Code 1350, all producers and egg handlers that sell eggs in California MUST label eggs with the following statement: "California Shell Egg Food Safety Compliant"

• Exempt are laying hens who shell eggs are pasteurized or otherwise processed to reduce the risk of *Salmonella enteritidis*.

# Cage-Free Eggs Claim:

- A "Cage-Free\*" or "From Freely Roaming Hens" are laid by hens that are allowed to roam in a room or open area, which is typically a barn or poultry house.
- The vendor will provide a letter from an officer of the company certifying product is Cage-Free as well as, a third party certification audit from American Humane.

## Label Approval: (USDA Meat/Poultry/Catfish/Processed Egg products)

- Products without claims can be generically approved.
- The following claims need to be submitted to FSIS for approval:
  - Animal Raising Claims
  - Certified Claims
  - Gluten Free Claims
  - Health Claims
  - Pathogen Disclaimers
  - Natural Claims
  - Negative and Free Claims
  - Undefined Nutrition Claims
  - Organic Claims
  - Omega 3 Fatty Acid Claims
  - Serving Sizes in NFP not following guidance
  - Whole Grain Claims
  - Nutrition Front of Pack Statements

# CLAIMS

# USDA CLAIMS

## **Natural Claim:**

- USDA Products are defined as natural if they contain no artificial ingredient and are not more than minimally processed. Note: Raw meat is considered natural.
- Claims allowed are "Natural", "All Natural", "All Natural Ingredients"
- Must include a disclaimer in close proximity to claim tied with an asterisk to the natural claim "No Artificial Ingredients, Minimally Processed"
  - Example:

Natural\* Pork \*No Artificial Ingredients. Minimally Processed.

- Claim requires submission to the FSIS for label approval.
- No documentation other than submission with formulation and processing information is required.

#### NOTE: NATURAL FDA PRODUCTS NOT ALLOWED BY US FOODS

- FDA has not defined the claim; therefore, US Foods will not use the claim until fully defined.
- Exceptions to this policy must be approved by the Director of Regulatory Compliance and leadership.

# **Free Range Claim**

- This indicates that the flock was provided shelter in a building, room, or area with unlimited access to food, fresh water, and continuous access to the outdoors during their production cycle. The outdoor area may or may not be fenced and/or covered with netting-like material.
- The vendor will provide a letter from the officer of the company certifying the flock are Free Range and allowed access to the outside
- Claim requires submission to the FSIS for label approval.

# Grass Fed Claim:

- USDA defines "grass fed" as Grass and forage shall be the feed source consumed for the lifetime of the ruminant animal, with the exception of milk consumed prior to weaning. The diet shall be derived solely from forage consisting of grass (annual and perennial), forbs (e.g., legumes, *Brassica*), browse, or cereal grain crops in the vegetative (pre-grain) state.
- Grass must meet at least 80% or more of the animal's energy source throughout its life.

- Animals cannot be fed grain or grain byproducts and must have continuous access to pasture during the growing season. Hay, haylage, baleage, silage, crop residue without grain, and other roughage sources may also be included as acceptable feed sources. Routine mineral and vitamin supplementation may also be included in the feeding regimen. If incidental supplementation occurs due to inadvertent exposure to non-forage feedstuffs or to ensure the animal's well being at all times during adverse environmental or physical conditions, the producer must fully document (e.g., receipts, ingredients, and tear tags) the supplementation that occurs including the amount, the frequency, and the supplements provided.
- The vendor will provide a letter from the officer of the company certifying product is Grass Fed.
- Claim requires submission to the FSIS for label approval.

### **Pasture-Raised Claim:**

• USDA has not defined "pasture raised" therefore we will not use this claim.

## **Certified Humanely Raised Claim:**

- Multiple labeling programs make claims that animals were treated humanely during the production cycle, but the verification of these claims varies widely.
- These labeling programs are not regulated under a single USDA definition.
- US Foods requires a 3<sup>rd</sup> party audit and certification.
- Claim requires a definition on pack along with claim spelling out ownership (who is making the claim) and specific definition of claim. Example, "US Foods defines Humanely Raised as..."
- Claim requires submission to the FSIS for label approval.

#### **Raised without Added Hormones Claim:**

- Added Hormones are only allowed in Beef. US Foods requires a third party audit in order to use the claim for beef.
- A disclaimer is required for all other species, "Federal Regulations prohibit the use of hormones in *species*". No other documentation is needed to make the claim.
- Claim requires submission to the FSIS for label approval.

## **Raised without Antibiotics Claim:**

 Claim product can have no antibiotics administered from birth to harvest, includes raising and feed.

- Does allow for cocciciostats (including ionophors) to be used for parasite control only.
- US Foods requires a third party audit in order to make the claim.
- Claim requires submission to the FSIS for label approval

# **Raised without Growth Promotants Claim:**

- Claim product can have no growth promotants (examples: Paylean or Ractopamine) administered from birth to harvest, includes raising and feed.
- Note a general claim is allowed, but it is not acceptable to list the promotant on the label (for example: "Raised without Paylean" is not allowed).
- US Foods requires a third party audit in order to make the claim.
- Claim requires submission to the FSIS for label approval

## No Animal By-Products Claim:

- Mammalian and avian byproducts are not allowed in the feed.
- Fish by-products and vitamin and mineral supplementation of animal origin are permitted (Examples: gelatin, Vitamin D3 derived from Lanolin made from lambs wool).
- US Foods requires a third party audit in order to make the claim.
- Claim requires submission to the FSIS for label approval

## Grain Fed / Vegetable Grain Fed Claims:

- Raised Using Vegetarian Feeds This means all vegetable feeds and no animal products (e.g., whey) are fed to the animal.
- Raised Using Vegetarian Feeds with a disclaimer to clarify animal products are fed to the animal for a certain period of time. Examples of such disclaimers may be "except for dairy products fed from birth to eight weeks," or "after 8 weeks". This disclaimer is so that it is not false and misleading to the consumer if dairy (e.g., milk or whey), egg, or any other animal product is fed under the claim of an all vegetarian diet.
- Grain Fed / Vegetable Grain Fed the animal is fed grains at least 50% of its rations and meets no animal by-products claim.
- Requires a feed attestation letter describing the feed breakdown.
- US Foods requires a third party audit in order to make the claim.
- Claim requires submission to the FSIS for label approval

# **GENERAL PRODUCT CLAIMS:**

## Nutrient Content Claims 21CFR101.13,

- 1- Size of Nutrient content claim can be no larger than twice the size of the legal product name.
- 2- Claims must meet standard as described below in table.
- 3- Value Nutrient that claim is made for must be included in and supported by values in NFP and must state per serving.

Example: "Contains 0g Trans Fat per Serving"

- 4- FDA does not require a specific method of analysis for Nutrition Facts, but the agency does require label values to be accurate and within the (<u>+</u>20%) tolerances as specified in the Code of Federal Regulations (CFR).
- 5- Ongoing product testing must occur by the FSQA manager
- 6- Disclaimer Statement for any fat, saturated fat, trans fat, cholesterol, sodium, or fiber claims:
  - A disclaimer statement of, "See nutrition information for \_\_\_\_\_ content" is required when values exceed per RACC or per serving (or per 50g when RACC is less than 30g or 2T or less) values:
    - Single Food contains more than: 13g fat, 4 g saturated fat, 60mg cholesterol or 480mg sodium
    - Meal contains more than: 26 fat, 8 g saturated fat, 120mg cholesterol or 960mg sodium
  - The disclaimer must be in easily legible boldface print or type no less than half the size of the claim but no smaller than 1/16". (if greater than 2X the size of the net weight can be the same size of the net weight).
  - The disclaimer must be adjacent to the nutrient content claim and have no intervening material.
  - When multiple claims are made on a single panel, a single disclaimer can be made by the most prominent claim.
  - When claim is made on multiple panels, the disclaimer must appear on all panels – except if claim is made on same panel as the NFP.

#### TABLE OF CLAIM REQUIREMENTS FOR INDIVIDUAL FOODS

Nutrient	DRV	High In Excellent Source* Per %DV / RACC	Good Source* Per %DV / RACC	Free Per RACC and Per Serving	Low Per RACC	Reduced** Less* Per RACC	Notes
Calories	NA	NA	NA	<5 calories	40 or less	At least 25% less	21 CFR 101.60 Reference food cannot be Low Calorie
Total Fat	178g	NA	NA	<0.5g	3g or less	At least 25% less	21 CFR 101.62 Reference food cannot be Low Fat
Saturated Fat	120g	NA	NA	<0.5g	1g or less	At least 25% less	21 CFR 101.62 Reference food cannot be Low Sat Fat
Trans Fat	NA	NA	NA	NA	NA	NA	Claims will be written as "0g trans fat per serving". Mono and poly fats need to be listed in the NLEA for trans fat claims
Cholesterol	300mg	NA	NA	<2mg	<20mg	At least 25% less	21 CFR 101.62 Claims only allowed when sat fat is less than 2g per RACC
Sodium	2300mg	NA	NA	<5mg	140mg (35mg very low sodium)	At least 25% less	21 CFR 101.61 Reference food cannot be Low Sodium
Total Carbohydrate	1275g	NA	NA	NA	NA	NA	NA
Sugar	150g	NA	NA	<0.5g*	NA	At least 25% less	*disclaimers required: "adds a trivial amount of sugar" "not a low calorie food"
Fiber	128g	>20%	10 – 19%	NA	NA	NA	Check total fat content. The food product cannot be low in total fat
Protein	150g	>20%	10 – 19%	NA	NA	NA	Protein claims will be written as "X g per serving". Need to provide %DV of 46% and put in footnote under fiber 50g/65g in columns
Vitamins and Minerals	See vitamin section of NFP	>20%	10 – 19%	NA	NA	NA	Per %DV/RACC

(\*) High In or Excellent Source: 20% of RDI or DRV per RACC. Only can make a claim on nutrients with RDI or DRV.

(\*\*) Good Source: 10-19% of RDI or DRV per RACC. Only can make a claim on nutrients with RDI or DRV.

(\*\*\*) Reduced/Less/Fewer Claims: Has to have the statement regarding the % or fraction reduced, the reference food of category (see below), and amount of nutrient. Example: "Reduced Fat 44% Less Fat than our regular cream cheese. Fat content has been reduced from 9g to 5g per serving". The % or fraction is to be immediately adjacent to the claim. The amount of nutrient is to be adjacent to the claim or on the same panel as the NLEA. All comparative claims must be reviewed periodically to ensure continued accuracy (e.g., confirm that underlying products have not changed causing the claim to shift to being misleading. If you no longer sell the regular product, this claim cannot continue to be used unless made against another appropriate product).

"A Low X Food" Claim: Can be made to describe the absence of a nutrient or low in a nutrient when the food has not been specially processed, altered, formulated, reformulated to lower the amount.

NOTE: "Trans fat free" and "no artificial trans fat added" claims are not defined by the FDA or USDA therefore US Foods will only use the claim "0g trans fat per serving" on EB products.

#### Healthy Claim 9CFR317.363, 9CFR381.463, 21CFR101.65(d)(2)

- A Healthy claim may use the words "Healthy" or "Good for You" and/or be implied with the use of a check mark or other symbol in combination of another nutrient content claim.
- A check mark or other symbol in combination of another nutrient content claim <u>must meet the definition of healthy</u>.

• The food must meet the following conditions:

Nutrient	Individual Food	Seafood / Game Meat (single ingredient meat)	Meal / Main Dish
Total Fat	Low Fat (<3 g / RACC and serving )	≤5 g / RACC and 100g	Low Fat ( <u>&lt;</u> 3g / 100g and not more than 30% of the calories from fat)
Saturated Fat	Low Sat Fat (≤1g / RACC and Serving)	<u>&lt;</u> 2 g / RACC and 100 g	Low Sat Fat ( $\leq$ 2 g / 100g and not more than 10% calories from sat fat)
Sodium	≤ 480 mg / RACC and serving or 50g if RACC is ≤ 30g / 2 Tbsp	≤ 480 mg / RACC and serving or 50g if RACC is ≤ 30g / 2 Tbsp	≤ 600 mg / serving size
Cholesterol	≤ 60 mg / RACC and serving	< 95 mg / RACC and 100g	< 90 mg / serving size
Nutrients	Contain at least 10% DV / RACC for Vit A, Vit C, calcium, iron, protein, or fiber. Vegetables and Fruits cannot have addition of ingredients that change nutrient profile. Enriched cereal-grain products must conform to standard of identity	Contain at least 10% DV / RACC for Vit A, Vit C, calcium, iron, protein, or fiber	Contain at least 10% DV / RACC for 2 Nutrients for Main dish and 3 for Meal products of: Vit A, Vit C, calcium, iron, protein, or fiber

# Light or Lite Claim

- A Light or Lite Claim is a nutrient content claim that relates to calories or fat.
- Must accompany a disclaimer statement in immediate proximity to Light Claim in no less than ½ the size of the claim stating the reference food and the percent or fraction the food has been reduced.
  - Example:. "Light Cheesecake 1/3 fewer calories and 50% less fat than our regular cheesecake".

- Qualification Data:
  - Light claims can be made without qualification if:
    - If fat is reduced by at least 50% of the reference food or
    - If calories <50% calories from fat and calories must be a 1/3 less per RACC
  - Otherwise qualification data must be included comparing the reference levels of fat and calories that it replaces is declared adjacent to the most prominent claim or to the NFP (if NFP is on the information panel – qualification data may be anywhere on the information panel)
  - All comparative claims must be reviewed periodically to ensure continued accuracy (e.g., confirm that underlying products have not changed causing the claim to shift to being misleading. If you no longer sell the regular product, this claim cannot continue to be used unless made against another appropriate product).
- Reference food cannot be low calorie or low fat.
- Light as reference to color is also allowed such as "Light brown sugar".

## No Added MSG Claim:

- Claim must read "No Added MSG" or "No MSG Added".
- If MSG is present in the product, it is required to be called out in the ingredient statement. NO MSG can be present in the product.
- This claim can be made regardless of free glutamic acid that may be naturally available in the product through ingredients and processing.
- If an ingredient contains free glutamic acid that may be naturally available in the product or through processing, the following disclaimer must be used on the same panel of the claim, "\*except for that naturally occurring in X Ingredient(s)".

# **Negative Claims (Without):**

- Claim must be true and not misleading.
- The claim must be verified from the ingredients.
- Examples of claims allowed are (there are more allowed than are listed):
  - No Artificial Colors (Note: product cannot contain natural items that color the products – such as caramel color – as they are artificially coloring the product)
  - No Artificial Flavors
  - No High Fructose Corn Syrup
  - No Salt Added
  - No Sugar Added

## "Vegetarian" or "Vegan" Claim:

- FDA has not defined a vegetarian or vegan claims; however, the statement has to be truthful and not misleading.
- Since there are different types of vegetarians, it is best to use a clarifying statement such as "\*This product is suitable for lacto-ovo vegetarians."

- The product must not have any ingredients that are from animal origin including milk, eggs, honey, and gelatin.
- The claim must be verified by the ingredients within the specifiation.

# US Foods / Marketing Board / Certified Programs:

- All US Foods defined claims must be reviewed and approved by Regulatory and US Foods Legal Counsel.
- Must have a written program and must meet the requirements including any fees, third party audits (as necessary), and approvals required.
- Certified Claims require the approval of the certifying body.
- US Foods requires the following claims to be certified:
  - o **Halal**
  - o Kosher
  - o Fair Trade
  - Non GMO (see below)
  - Gluten Free (see below)
- US Foods Serve Good- Go to Serve Good Policy. All products intended to bear the Serve Good mark must be approved by Regulatory and US Foods Legal counsel.

## **Child Nutrition Programs:**

- Must include calculation for the USDA Meal Pattern Requirements Contribution.
- Must be approved by FSIS for use on label.

## **Prop 65 – Regulated Chemicals:**

- Meat and Poultry are under federal exemption and do not fall under this rule.
- FDA products must ensure compliance.

## Fresh Claim:

#### FDA PRODUCTS 21 CFR 101.95

- "Fresh" means that the food is in a raw state and has not been frozen or subjected to any form of thermal processing or preservation except for those listed below.
- "Fresh Frozen" or "Frozen Fresh" means the product was quickly frozen while in its fresh state.
- The following processes are allowed and still use the claim:
  - o Blanching
  - Addition of waxes or coatings
  - Post harvest use of approved pesticides
  - Application of mild chlorine wash or mild acid wash on produce
  - Post harvest use of ionizing radiation not to exceed the maximum dosage of 1 Kilogray.

#### USDA PRODUCTS

- "Fresh" may not be used to describe:
  - Any cured product
  - Any canned, hermetically sealed shelf stable, dried, or chemically preserved product.
  - Any raw poultry, any injected, basted or marinated poultry product or other poultry product (including cooked poultry) whose internal temperature has ever been below 26F.
  - Any uncured red meat product permitted to be treated with a substance that delays discoloration – such as ascorbic acid, erythorbic acid, or citric acid.
  - Any product treated with an antimicrobial substance or irradiated.
- "Never Frozen" is not permitted on any poultry product where the temperature has been below 0F or on any red meat product that has ever been frozen.

#### Gluten-Free Claims: 21CFR101.91

- Acceptable Claims are "Gluten-Free", "Gluten Free", "Free of Gluten", or "Without Gluten".
- Gluten is the presence of proteins which may cause adverse health effects to a person with Celiac disease; includes proteins from wheat, rye, triticale, and barley.
- Compliance verification by FDA/USDA will test for the rejection limit of 20ppm. No third party audit is required unless using the claim "Certified Gluten-Free".
- US Foods requires a third party audited program with a rejection limit of 10ppm.
- US Foods uses the following labeling scenarios:

<ol> <li>Certified Gluten Free – i.e. meets USF requirements as listed above with testing at less than 10ppm gluten. Product and facility will be certified by a 3<sup>rd</sup> party auditor.</li> </ol>	This will be labeled "Gluten Free" along with the statement, "US Foods' Gluten Free products contain less than 10 parts per million of gluten and are produced in certified "gluten free" facilities." The certifying body may also be included on the labeling.
<ol> <li>Never contained gluten (inherently/naturally gluten free). Non-formulated product (ex: produce, darry, non-processed meats)</li> </ol>	Will not use the claim "Gluten Free".
<ol> <li>Products manufactured in non- gluten free certified facilities with</li> </ol>	Claim allowed:. "Made with Gluten Free Ingredients"

multiple ingredients that normally
could be made with gluten
(formulated product). The product
will be verified by the ingredients
within the spec by FSQA (ex:
bakery, pasta)

Exceptions to this policy must be approved by Regulatory and FSQA Leadership. Example: USDA facility with no gluten containing products may not need certification to make "Gluten Free" claim.

#### Whole Grain Claim: 21 CFR 102.5 (b)

- US Foods requires 100% whole grain to include Whole Grain as part of the true product name.
- US Foods allows whole grain in a secondary descriptor along with the % of whole grain and amount per serving such as "Made With 53% Whole Grains - 16g per serving"
  - Note: The % is the amount of whole grain in the entire product, not whole grain versus refined flour
     For example, if a product weighs 4 oz, and it contains 1 ounce of refined flour
    - and 1 ounce of whole grain, the % would be 25%, not 50%
- US Foods requires the Whole Grain Council Stamp in order to use the claim.
- Three stamps are available:
  - 100% Stamp all grain is whole, minimum 16g per serving
  - 50%+ Stamp some refined grain is OK, at least half of grain is whole grain, minimum 8g per serving
  - Basic Stamp some refined grain is ok, less than half of grain is whole, minimum
     8g per serving
- The product will be verified by the ingredients within the spec by FSQA and the vendor sending calculations page
- Whole Grain Council Certificate of approval is also required.

# Non-GMO Claim:

- An accurate statement about whether a food (or specific ingredient) was not produced using bioengineering must provide information in a context that clearly refers to bioengineering technology.
- Any reference to genetic modifications will not be included as part of the product name.
- Claims not allowed include: "GMO free," "GE free," "does not contain GMOs," "non-GMO,"
- Examples of allowable claims include (and similar):
  - "Not genetically modified through the use of modern biotechnology." (\*US Foods preferred statement)
  - "This product does not include ingredients sourced from genetically engineered (GE) crops, commonly known as GMO's."
  - o "Food not derived from genetically engineered plants"
  - o "We do not use ingredients that were produced using modern biotechnology."

- The PDP will show the NONGMO Project Verified logo.
- US Foods will only make a non-bio-engineered claim if verified by a 3<sup>rd</sup> party.

# **Organic Claim:**

- The FDA has not defined "Organic" and uses the USDA definition which is defined by the "National Organic Program."
- There are four different USDA organic categories on raw, fresh and processed products:
  - 100% Organic may use the USDA organic seal
  - 95% Organic may use the USDA organic seal
  - Made with Organic Ingredients may not use the USDA organic seal but can use the claim on pack
  - Less than 70% Organic Ingredients organic ingredients denoted in ingredient list only.
  - Overseen and certified by a 3<sup>rd</sup> party USDA National Organic Program- authorized certifying agent following all USDA organic regulations.
  - Products need to have the certifying body on the label under the distributed by statement or COO stating "Certified Organic by (name)"

## Marketing Materials / Terms:

- Marketing materials must follow the same requirements of labeling claims, must not be misleading, and must be truthful. The terms must meet what the consuming public would expect.
- Examples of Marketing terms where there is no regulation for the term:
  - o "Artisan"
  - o "Ancient"
  - o "Premium"
  - o "Highest Quality Ingredients"
  - o "Clean Label"
  - o "Hand Crafted"
  - o Heirloom