



Rebuilding Labels to Ensure Compliance

December 9, 2021

Megan Murphy

Labeling & Regulatory Specialist, ESHA

Kevin McCaffrey
Account Executive, TraceGains

Meet Your Moderator



Mercedes Howard

Webinar Specialist



TRACEGAINS

Meet Your Speakers



Megan Murphy

Labeling & Regulatory Specialist



Kevin McCaffrey

Account Executive



REBUILDING LABELS TO ENSURE COMPLIANCE

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What We'll Cover Today



- FDA Food Labeling
 - Mandatory Nutrients/Checks
 - Dietary Fiber
 - Calorie and Carbohydrate Calculation
 - Added Sugars
 - RACC
 - Claims
 - Sesame
 - Sulfites
 - Processing Adjustments
 - International Labels
- BE Disclosure
- USDA COOL
- Recalls and Class Actions
- Documentation
- Q&A





MISSING MANDATORY NUTRIENTS

Nutrition Facts	
About 3 servings per container	
Serving size	2/3 Cup
Amount per serving	
Calories	190
	% Daily Value*
Total Fat 10g	13%
Saturated Fat 6g	30%
Cholesterol 30mg	10%
Sodium 65mg	3%
Total Carbohydrate 25g	9%
Dietary Fiber --g	--%
Total Sugars 22g	
Includes 15g Added Sugars	30%
Protein 3g	
Vitamin D 0mcg	0%
Calcium 96mg	8%
Iron 1mg	6%
Potassium 220mg	4%
*The % Daily Value tells you how much a nutrient in a serving of food contributes to a daily diet. 2000 calories a day is used for general nutrition advice.	
Calories per gram: Fat 9 • Carbohydrate 4 • Protein 4	

Missing Mandatory Nutrients are displayed here with a dashed line – NOT COMPLIANT

NOTE:

- If only 1 out of 9 of your ingredients contain the required dietary fiber information, only that one ingredient's dietary fiber nutrients **will appear** on the label. This can potentially show inaccurate results on the Nutrition Facts Label
- The Spreadsheet report in Genesis R&D will need to look like this for the dashes to appear next to the nutrient on the label:

Cals (kcal)	Prot (g)	Carb (g)	Fib(16) (g)	Sugar (g)	SugAdd (g)	Fat (g)	SatFat (g)	TransFat (g)	Chol (mg)	Vit D-mcg (mcg)	Calc (mg)	Iron (mg)	Pot (mg)	Sod (mg)
55.17	0.08	2.25	ERROR	2.22	2.17	5.18	0.81	0.01	2.91	0.01	0.74	0.03	3.21	44.04
47.04	0.07	0.04	ERROR	0.04	0	5.18	0.81	0.01	2.91	0.01	0.55	0.01	1.38	43.93
8.03	0.01	2.18	ERROR	2.17	2.17	0	0	0	0	0	0.16	0.01	1.37	0.11
0.10	0.00	0.03	ERROR	0.01	0	0.00	0.00	0	0	0	0.03	0.00	0.45	0.00
55.17	0.08	2.25	ERROR	2.22	2.17	5.18	0.81	0.01	2.91	0.01	0.74	0.03	3.21	44.04

SUPPLIER MANDATORY INFORMATION FOR EACH INGREDIENT



- Date of Specification
- Nutrition on a 100-gram basis
- All Mandatory Nutrients should be populated with a value, even if the value is 0
- Sulfites must be declared for each ingredient. Presence of sulfites must be declared if the recipe exceeds 10 ppm
- Water/Moisture and Ash are needed to ensure total weight and moisture loss for processing
- Ingredient Statement - Full ingredient statement that includes any sub-ingredients
- Range Formulas for ingredients or nutrients should be discouraged
- Allergen Declaration even if it says “No Allergens Present”

ESHA Research

ESHA Consulting Services

The following are items required to create a compliant food label. Please provide the nutrients on a 100 gram unrounded basis, a complete list of all ingredients and sub-ingredients as well as any allergens.

<input checked="" type="checkbox"/>	NUTRIENT	MEASURE
<input type="checkbox"/>	Added Sugars	grams
<input type="checkbox"/>	Ash (Needed for total weight)	grams
<input type="checkbox"/>	Calcium	milligrams
<input type="checkbox"/>	Calories	
<input type="checkbox"/>	Cholesterol	milligrams
<input type="checkbox"/>	Dietary Fiber (Beneficial soluble and insoluble)	grams
<input type="checkbox"/>	Iron	milligrams
<input type="checkbox"/>	Potassium	milligrams
<input type="checkbox"/>	Protein	grams
<input type="checkbox"/>	Saturated Fat	grams
<input type="checkbox"/>	Sodium	milligrams
<input type="checkbox"/>	Total Carbohydrates	grams
<input type="checkbox"/>	Total Fat	grams
<input type="checkbox"/>	Total Sugars	grams
<input type="checkbox"/>	Trans Fat	grams
<input type="checkbox"/>	Vitamin D	micrograms
<input type="checkbox"/>	Sulfites or sulfiting agent (§130.9)	ppm (parts per million)
<input type="checkbox"/>	Sesame	
<input type="checkbox"/>	<i>Mark any component, ingredient, flavoring or spice that is sourced from Sesame</i>	
<input type="checkbox"/>	Water/Moisture (Needed for total weight)	grams
<input type="checkbox"/>	TOTAL WEIGHT	
<input type="checkbox"/>	Ash + Protein + Total Carbohydrates + Total Fat + Water/Moisture (+ Alcohol)	100 grams

INGREDIENTS (Must list all ingredients and/or sub-ingredients.)

<input checked="" type="checkbox"/>	ALLERGENS (Must declare if any of the 9 allergens are present)
<input type="checkbox"/>	Milk
<input type="checkbox"/>	Peanuts
<input type="checkbox"/>	Eggs
<input type="checkbox"/>	Tree nuts (must identify type such as almonds, cashews, walnuts)
<input type="checkbox"/>	Fish (must identify type such as bass, cod, flounder)
<input type="checkbox"/>	Shellfish (must identify type such as crab, lobster, shrimp)
<input type="checkbox"/>	Soy
<input type="checkbox"/>	Wheat
<input type="checkbox"/>	Sesame

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Nutrition Facts	
servings per container	
Serving size	(14g)
Amount per serving	
Calories	35
% Daily Value*	
Total Fat 0g	0%
Saturated Fat 0g	0%
Trans Fat 0g	
Cholesterol 0mg	0%
Sodium 0mg	0%
Total Carbohydrate 11g	4%
Dietary Fiber 7g	25%
Total Sugars 0g	
Includes 0g Added Sugars	0%
Protein 1g	
Vitamin D 0mcg	0%
Calcium 140mg	10%
Iron 1mg	6%
Potassium 60mg	2%
*The % Daily Value tells you how much a nutrient in a serving of food contributes to a daily diet. 2,000 calories a day is used for general nutrition advice.	

NUTRIENT COMPARISON

14 g vs. 100 g



Nutrition Facts	
servings per container	
Serving size	(100g)
Amount per serving	
Calories	250
% Daily Value*	
Total Fat 1g	1%
Saturated Fat 0g	0%
Trans Fat 0g	
Cholesterol 0mg	0%
Sodium 10mg	0%
Total Carbohydrate 81g	29%
Dietary Fiber 53g	189%
Total Sugars 2g	
Includes 0g Added Sugars	0%
Protein 4g	
Vitamin D 0mcg	0%
Calcium 1002mg	80%
Iron 8mg	45%
Potassium 431mg	10%
*The % Daily Value tells you how much a nutrient in a serving of food contributes to a daily diet. 2,000 calories a day is used for general nutrition advice.	

cheat sheet

DIETARY FIBER

noun | di·e·tary fi·ber | \ 'dī-ə-, ter-ē 'fī-bər\

: a statement of the number of grams of dietary fiber in one serving of a food



ON THE LABEL

Dietary fiber is indented and rounded to the nearest gram.

- If a serving contains less than 1 gram, declaration is not required, but you may choose to use one of the following:
 - <1g
 - Contains <1g
 - Contains less than 1 g
 - Less than 1g
- If the serving contains less than 0.5 gram, the content may be expressed as zero.

Nutrition Facts

4 servings per container	
Serving size	1 cup (140g)
Amount per serving	
Calories	160
% Daily Value*	
Total Fat 7g	9%
Saturated Fat 3g	15%
Trans Fat 0g	
Cholesterol 0mg	0%
Sodium 60mg	3%
Total Carbohydrate 20g	7%
Dietary Fiber 10g	36%
Total Sugars 5g	
Includes 2g Added Sugars	4%
Protein 5g	
Vitamin D 5mcg	25%
Calcium 20mg	2%
Iron 1mg	6%
Potassium 230mg	4%

*The % Daily Value tells you how much a nutrient in a serving of food contributes to a daily diet. 2,000 calories a day is used for general nutrition advice.

DV CHANGE
28g up from 25g

NEW FIBER DEFINITION

Naturally occurring fibers that are “intrinsic and intact” in plants (vegetables, whole grains, fruits, cereal bran, flaked cereal and flours), and added isolated or synthetic non-digestible soluble and insoluble carbohydrates that the FDA has determined to have beneficial physiological effects to human health.

Note: Manufacturers are required to make and keep records verifying the declared amount of dietary fiber.

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4747 Skyline Rd #100
Salem, OR 97306 USA
www.esharesearch.com
info@esharesearch.com
503-585-6242

beneficial dietary fibers

ADDED, NON-DIGESTIBLE ISOLATED OR SYNTHETIC FIBERS:

Alginate
 Arabinoxylan
 Beta-glucan
 Cellulose
 Cross-linked phosphorylated starch (RS4)
 Galactooligosaccharide (GOS)
 Glucomannan
 Guar gum

NON -DIGESTIBLE CARBOHYDRATES

Ingredients, such as gum acacia, that do not meet the definition of dietary fiber are not included in the dietary fiber total on the label. They still will be included in the Total Carbohydrate number.

High amylose starch
 (resistant starch 2)
 Hydroxypropylmethylcellulose
 Inulin and inulin-type fructans
 Locust bean gum
 Mixed plant cell wall fibers
 Pectin
 Polydextrose
 Psyllium husk
 Resistant maltodextrin/dextrin

5g BENEFICIAL Soluble Fiber (oats)
+5g BENEFICIAL Insoluble Fiber (cellulose)
0g NON-DIGESTIBLE Soluble Carbohydrates
+5g NON-DIGESTIBLE Insoluble Carbohydrates (gum acacia is not 'beneficial')
10g TOTAL DIETARY FIBER (only 'beneficial' fiber used to calculate total)

NEW CALCULATION

Based on the new definition, a sample bar with oats, cellulose and gum acacia would have 10g of Total Dietary Fiber. The 5g of non-digestible carbohydrates that comes from gum acacia are not used in calculating Total Dietary Fiber, but ARE used in calculating Total Carbs.

“BENEFICIAL” FIBERS (DIETARY FIBER 2016)



- Alginate*
- Arabinoxylan*
- Beta-Glucan
- Cellulose
- Cross Linked Phosphorylated RS4**
- Galactooligosaccharide (GOS)*
- Glucomannan***
- Guar Gum
- High Amylose Starch (Resistant Starch 2)*
- Hydroxypropylmethylcellulose
- Inulin and Inulin-type Fructans*
- Locust Bean Gum
- Mixed Plant Cell Wall Fibers*
- Pectin
- Polydextrose*
- Psyllium Husk
- Resistant Maltodextrin/Dextrin*

*** Added January 10, 2020

** Added on March 27, 2019

* Added on June 14, 2018

Source: <https://www.fda.gov/food/food-labeling-nutrition/questions-and-answers-dietary-fiber> 10

7 “NON-BENEFICIAL” FIBERS (NON-DIGESTIBLE CARBOHYDRATES)



- CARBOXYMETHYLCELLULOSE
- GUM ACACIA
- KARAYA GUM
- PULLULAN
- RETROGRADED CORN STARCH RS3
- XANTHAN GUM
- XYLOOLIGOSACCHARIDES

<https://www.fda.gov/food/food-labeling-nutrition/questions-and-answers-dietary-fiber>

CITIZEN PETITION TO FDA WITHOUT RESPONSE



If a manufacturer has submitted a citizen petition, but FDA has not yet responded, can the manufacturer include the amount of the added isolated or synthetic carbohydrate that is the subject of the petition in the "dietary fiber" declaration in the meantime?

If the applicable Nutrition Facts label compliance date has not yet occurred and the manufacturer has not updated its product labels to reflect the updated Nutrition Facts label and Supplement Facts label requirements, then these carbohydrates can remain included in the dietary fiber declaration. However, once the compliance date has passed, then a manufacturer cannot include isolated or synthetic non-digestible carbohydrates that are the subject of pending petitions in the declaration of "dietary fiber." However, the added carbohydrate must be included in the declaration for total carbohydrate.

Source: <https://www.fda.gov/food/food-labeling-nutrition/questions-and-answers-dietary-fiber>

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CALORIE CALCULATION COUNTRY SPECIFIC



METHOD	U.S.	CANADA	EU	MEXICO
4-4-9	X			X
4-4-9 Minus Soluble Fiber	X			
4-4-9-7		X		
4-4-9-7 Adjusted for Fibre		X		
Atwater	X	X		
Bomb Calorimetry	X			
Calculation of Proteins				X
Estimates			X	
General Factors Caloric Values Sugar Alcohols	X			
General Factors for Caloric Value of Sugar Alcohols, Glycerol & Polydextrose		X		
Known Data			X	
Specific Food Factors	X			
Total Value			X	

CARBOHYDRATE CALCULATION COUNTRY SPECIFIC



METHOD	U.S.	CANADA	EU	MEXICO
Carbohydrate by Subtraction (Total Gram Weight - Protein, Fat, Alcohol Water & Ash)	X	X		
Available Carbohydrate (Carbohydrates + Sugars + Starches - Fiber)			X	X

ADDED SUGARS 2016

CONSIDERED ADDED

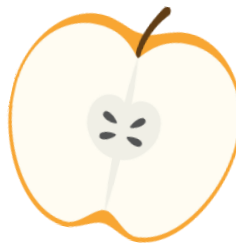
- Molasses*
- Corn Sweetener
- Pure Maple Syrup*
- Honey*
- Sugar
- Agave*
- Syrup



NOT CONSIDERED ADDED

Naturally occurring sugars in:

- Dairy products
- Vegetables
- Fruits
- Grains



Nutrition Facts	
2 servings per container	
Serving size	1 cup (140g)
Amount per serving	
Calories	170
	% Daily Value*
Total Fat 8g	10%
Saturated Fat 3g	15%
Trans Fat 0g	
Cholesterol 0mg	0%
Sodium 60mg	3%
Total Carbohydrate 27g	9%
Dietary Fiber 0g	11%
Total Sugars 25g	
Includes 23g Added Sugars	54%
Protein 3g	
Vitamin D 5mcg	25%
Calcium 20mg	2%
Iron 1mg	6%
Potassium 230mg	4%

*The % Daily Value tells you how much a nutrient in a serving of food contributes to a daily diet. 2000 calories a day is used for general nutrition advice.

Nutrition Facts	
8 servings per container	
Serving size	1 tbsp (21g)
Amount per serving	
Calories	60
	% Daily Value*
Total Fat 0g	0%
Saturated Fat 0g	0%
Trans Fat 0g	
Cholesterol 0mg	0%
Sodium	0%
Total Carbohydrate 17g	6%
Dietary Fiber 0g	0%
Total Sugars 17g	34%†
Protein 0g	
Vitamin D 0mcg	0%
Calcium 0mg	0%
Iron 0mg	0%
Potassium 0mg	0%

*The % Daily Value tells you how much a nutrient in a serving of food contributes to a daily diet. 2,000 calories a day is used for general nutrition advice.

†One serving adds 17g of sugar to your diet and represents 34% of the Daily Value for Added Sugars.



NEW MANDATORY NUTRIENT

DV: 50g

The FDA recommends that your added sugar intake does not exceed 10% of total calories.

These items require special consideration

- Juice concentrates
- Purees/Pastes, Sugars after fermenting, Corn syrup solids
- Dried cranberries and cranberry juices**

*Single Ingredient Sugar Products are no longer required to bear “includes Xg Added Sugars”

**May use symbol and explanatory text.

- Added Sugars Indented
- Single Ingredient Sugar Product only %DV + footnote
- Rounding Rules
 - “< 1g” or “less than 1g” declaration not required with insignificant footnote
 - < .5g may be expressed as 0 or declaration not required

ROUNDING RULES



Contains Nonbinding Recommendations

**Nutrition and Supplement Facts Labels:
Questions and Answers Related to the
Compliance Date, Added Sugars, and
Declaration of Quantitative Amounts of
Vitamins and Minerals: Guidance for
Industry**

*Additional copies are available from:
Office of Nutrition and Food Labeling
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5001 Campus Drive
College Park, MD 20740
240-402-1450
<https://www.fda.gov/FoodGuidances>*

You may submit electronic or written comments regarding this guidance at any time. Submit electronic comments to <https://www.regulations.gov>. Submit written comments on the guidance to the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number FDA-2016-D-4414.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Food Safety and Applied Nutrition

Issued November 2018
Revised December 2019

cheat sheet

ROUNDING RULES FOR LABEL NUTRIENTS (U.S.)

: the FDA's recommendations for the declaration of quantitative amounts of vitamins and minerals using incremental rounding

Nutrient	Unit of Measure	RDI for Adults and Children ≥ 4 years	Recommended Increment
Vitamin A	Micrograms RAE (mcg)	900	Nearest 10 mcg
Vitamin C	Milligrams (mg)	90	Nearest mg
Calcium	Milligrams (mg)	1,300	Nearest 10 mg
Iron	Milligrams (mg)	18	Nearest .1 mg
Vitamin D	Micrograms (mcg)	20	Nearest .1 mcg
Vitamin E	Milligrams (mg)	15	Nearest .1 mg
Vitamin K	Micrograms (mcg)	120	Nearest mcg
Thiamin	Milligrams (mg)	1.2	Nearest .01 mg
Riboflavin	Milligrams (mg)	1.3	Nearest .01 mg
Niacin	Milligrams NE (mg)	16	Nearest .1 mg
Vitamin B6	Milligrams (mg)	1.7	Nearest .01 mg
Folate	Micrograms DFE (mcg)	400	Nearest 5 mcg
Vitamin B12	Micrograms (mcg)	2.4	Nearest .01 mcg
Biotin	Micrograms (mcg)	30	Nearest .1 mcg
Pantothenic Acid	Milligrams (mg)	5	Nearest .1 mg
Phosphorus	Milligrams (mg)	1250	Nearest 10 mg
Iodine	Micrograms (mcg)	150	Nearest mcg
Magnesium	Milligrams (mg)	420	Nearest 5 mg
Zinc	Milligrams (mg)	11	Nearest .1 mg
Selenium	Micrograms (mcg)	55	Nearest mcg
Copper	Milligrams (mg)	0.9	Nearest .01 mg
Manganese	Milligrams (mg)	2.3	Nearest .01 mg
Chromium	Micrograms (mcg)	35	Nearest .1 mcg
Molybdenum	Micrograms (mcg)	45	Nearest .1 mcg
Chloride	Milligrams (mg)	2300	Nearest 10 mg
Potassium	Milligrams (mg)	4700	Nearest 10 mg
Choline	Milligrams (mg)	550	Nearest 10 mg

Note: This chart shows only the RDIs that have been established for adults and children 4 years of age and older. The recommended increments, however, can be applied to RDIs for infants through 12 months, children 1 through 3 years, and pregnant and lactating women as well, which can be found in 21 CFR 101.9(c)(8)(iv).

4747 Skyline Rd #100, Salem, OR 97306 USA | www.esha.com | info@esha.com | 503-585-6242

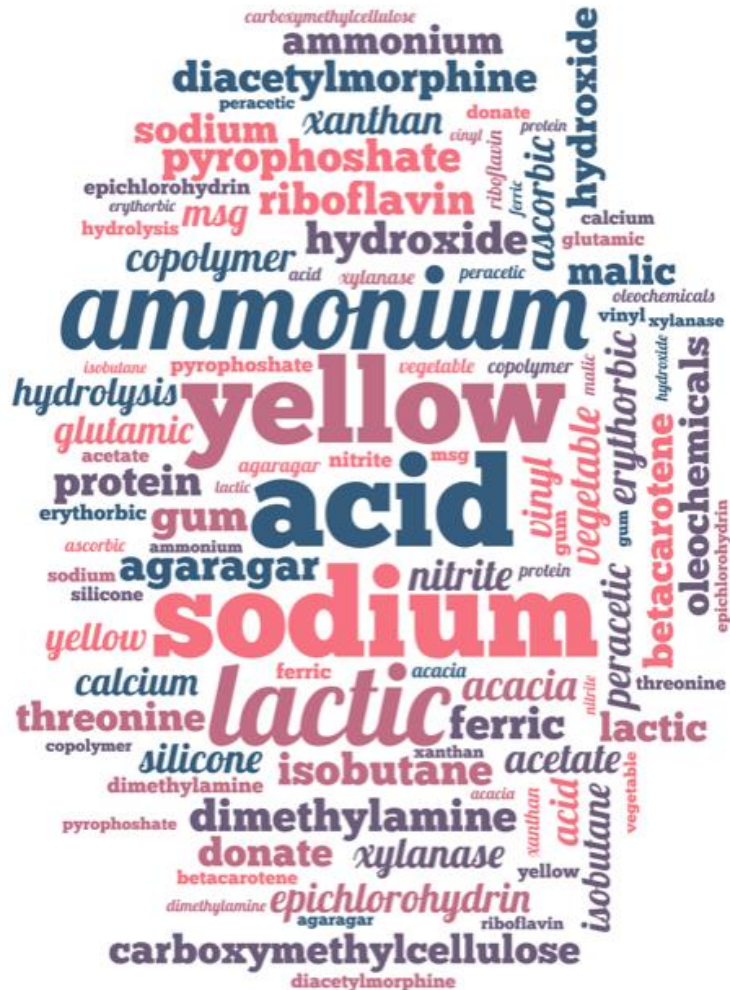
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INCIDENTAL ADDITIVES

21 CFR 101.100(a)(3)



- No technical or functional effect but are present because it was incorporated into the food as an ingredient of another food
- Processing aids
- Substances migrating from equipment or packaging



RACC

noun | racc | \ˈrɑk\

: reference amounts customarily consumed

DEFINITION

Serving sizes of foods that can be reasonably consumed at one eating occasion. These have recently been updated to reflect real-world consumption. A RACC table can be found in the Code of Federal Regulations, 21CFR101.12.

Nutrition Facts

2 Servings Per Container

Serving size **12 fl oz (360 mL)**

	per serving		per container	
	150		300	
	% Daily Value*		% Daily Value*	
Calories				
Total Fat	1g	1%	2g	3%
Saturated Fat	0g	0%	0g	0%
Trans Fat	0g		0g	
Cholesterol	0mg	0%	0mg	0%
Sodium	10mg	0%	20mg	1%
Total Carbohydrate	38g	14%	76g	28%
Dietary Fiber	0g	0%	0g	0%
Total Sugars	37g		73g	
Includes Added Sugars	35g	70%	70g	140%
Protein	0g		0g	
Vitamin D	0mcg	0%	0mcg	0%
Calcium	4mg	0%	7mg	0%
Iron	0mg	0%	0mg	0%
Potassium	18mg	0%	37mg	0%

*The % Daily Value tells you how much a nutrient in a serving of food contributes to a daily diet. 2,000 calories a day is used for general nutrition advice.

updated in 2016

formula

Recipe weight / RACC = XX

XX multiplied by 100 = XX%

FOODS WITH CHANGED RACCs

40g



MOST BREAKFAST CEREALS

8 sq inch*




PIE CRUST, PASTRY SHEETS

50g




FRUITS USED AS INGREDIENTS

360 mL




CARBONATED, NON CARBONATED BEVERAGES

15g/15 mL



HARD CANDIES/LIQUID CANDIES

360 mL



COFFEE OR TEA

8g



SUGAR

170g



YOGURT

240 mL



MILK BEVERAGES, FRUIT JUICES

2 TBSP



CAKE FROSTINGS, ICINGS

85g



CANNED FISH, SHELLFISH, GAME MEAT

2/3 c



ICE CREAM, FROZEN YOGURT



USING RACC TO DETERMINE DUAL COLUMN USAGE

With the new rules, containers that hold between 2 and 3 servings of a food may now need to show a Dual Column label to show nutrition information for a single serving and per the whole container. To determine this, check the determined serving size for your product. If your package weighs at least 200 percent and up to and including 300 percent of the applicable reference amount, you need to use the Dual Column label.

YOGURT RACC CHANGE EXAMPLE



1990

225 g RACC & Serving Size

Nutrition Facts	
Serving Size 1 Container (225g)	
Amount Per Serving	
Calories 170	Calories from Fat 10
% Daily Value*	
Total Fat 1g	2%
Saturated Fat 0g	0%
Trans Fat 0g	
Cholesterol 10mg	3%
Sodium 75mg	3%
Total Carbohydrate 23g	8%
Dietary Fiber 1g	4%
Sugars 21g	
Protein 19g	
Vitamin A 0%	• Vitamin C 0%
Calcium 20%	• Iron 0%
*Percent Daily values are based on a 2,000 calorie diet. Your daily values may be higher or lower depending on your calorie needs:	
	Calories: 2,000 2,500
Total Fat	Less than 65g 80g
Saturated Fat	Less than 20g 25g
Cholesterol	Less than 300mg 300mg
Sodium	Less than 2,400mg 2,400mg
Total Carbohydrate	300g 375g
Dietary Fiber	25g 30g
Calories per gram:	
Fat 9 • Carbohydrate 4 • Protein 4	

Excellent Source of Calcium

2016

170 g RACC & Serving Size

Nutrition Facts	
Serving size 1 Container (170g)	
Amount per serving	
Calories	130
% Daily Value*	
Total Fat 0.5g	1%
Saturated Fat 0g	0%
Trans Fat 0g	
Cholesterol 5mg	2%
Sodium 60mg	3%
Total Carbohydrate 17g	6%
Dietary Fiber 1g	4%
Total Sugars 16g	
Includes 10g Added Sugars	20%
Protein 14g	14%
Vitamin D 0mcg	0%
Calcium 155mg	10%
Iron 0mg	0%
Potassium 210mg	4%
*The % Daily Value tells you how much a nutrient in a serving of food contributes to a daily diet. 2000 calories a day is used for general nutrition advice.	
Calories per gram:	
Fat 9 • Carbohydrate 4 • Protein 4	

Good Source of Calcium

- RACC changes may affect Nutrient Content Claims
- Be sure to evaluate your entire package when updating labels with RACC changes

CLAIMS – 21 CFR 101.13



Nutrient Content Claims

Calories	21 CFR 101.60(b)
Total Fat	21 CFR 101.62 (b)
Saturated Fat	21 CFR 101.62(c)
Cholesterol	21 CFR 101.62 (d)
Sodium	21 CFR 101.61
Sugars	21 CFR 101.60 (c)

Relative Claims

Light: A food representative of the type of food bearing the claim and a similar food

Reduced and Added: An established regular product or average and similar food

More and Less: An established regular product or average and a dissimilar food in same product category which may be generally substituted

SESAME AS AN ALLERGEN

FASTER Act of 2021

S. 578



Food Allergy Safety, Treatment, Education, and Research Act of 2021

- Signed into Law April 23, 2021
- Compliance Required by January 1, 2023
- Sesame is the 9th Major Allergen under the Food Allergen Labeling and Consumer Protection Act (FALCPA)
- New framework established for review of how additional potential allergens are to be considered and reviewed

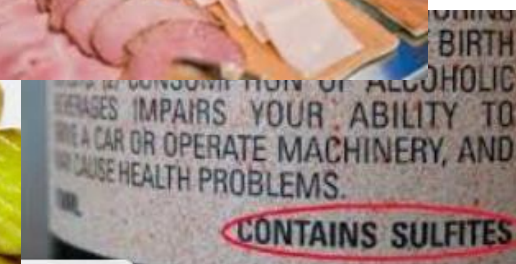
9 Major U.S. Allergens

Milk, Eggs, Fish, Crustacean Shellfish, Tree Nuts, Peanuts, Wheat, Soy and Sesame.



SULFITES §101.100 (a)(4) & §130.9

- Found naturally in some foods
- Commonly used as an additive to maintain color or prevent spoilage
- FDA requires declaration on food labels ≥ 10 ppm
 - Both naturally and/or added is detectable in finished food
- Specific name of additive (e.g. sodium bisulfite) must be declared when added to food
 - Sulfur dioxide
 - Sodium sulfite
 - Sodium bisulfite
 - Potassium bisulfite
 - Sodium metabisulfite
 - Potassium metabisulfite



<https://www.ecfr.gov/current/title-21/chapter-I/subchapter-B/part-130/subpart-A/section-130.9>



PROCESSING ADJUSTMENTS



Be sure to account for any processing loss by documenting the product weight before and after cooking



Frying items could lose moisture as well as add additional fat



Vitamin degradation is likely during cooking and storage



Lab Analysis from an accredited lab may be required for oil absorption and vitamin degradation



FOOD LABELS BY COUNTRY

- One label cannot be used across multiple countries
- Ingredient and recipe specific requirements
- Formatting requirements
- Language
- Spelling
- Allergens
- Claims
- Front of Pack/Stoplights



National Bioengineered Food Disclosure Standard (NBFDS)



- **Implementation Date:** Jan. 1, 2020
- **Mandatory Compliance Date:** Jan. 1, 2022

The Standard requires food manufacturers, importers, and certain retailers to ensure bioengineered foods are appropriately disclosed.



BIOENGINEERED

- Alfalfa
- Apple (Arctic™ Varieties)
- Canola
- Corn
- Cotton
- Eggplant (BARI Bt Begun Varieties)
- Papaya (Ringspot Virus-Resistant Varieties)
- Pineapple (Pink Flesh Varieties)
- Potato
- Salmon (AquAdvantage®)
- Soybean
- Squash (Summer)
- Sugarbeet

BE Alfalfa Crop Summary

BE Alfalfa Events in the Food Supply

BE Event	Trait	Producing Countries	Comments	FDA Review
J101	Herbicide Tolerance	Canada, Mexico, United States		BNF-084
J163	Herbicide Tolerance	Canada, Mexico, United States		BNF-084
KK179	low lignin	Canada, United States	Trade name: HarvXtra™	BNF-138

BE Alfalfa Production

BE alfalfa is commercially produced in Canada and the United States. BE alfalfa is also approved for commercial cultivation in Mexico and Japan; however, no BE alfalfa is currently produced in these two countries. Producers of alfalfa sprouts should maintain records to demonstrate that they sourced non-BE alfalfa seed.

About 13% of the 2013 alfalfa harvest in the United States was BE alfalfa (USDA-ERS, 2016). ISAAA (2017) estimated that there was 1.22M ha of BE alfalfa in the United States in 2017.

BE Alfalfa Food Safety Reviews

FDA biotechnology consultations were completed for events J101 and J163 in 2004, and for event KK179 in 2013 (FDA, 2018). Health Canada completed food safety reviews for events J101 and J163 in 2005 (Health Canada, 2005) and for event KK179 in 2015 (Health Canada, 2015).

References

FDA (2018) Biotechnology Consultations on Food from GE Plant Varieties
https://www.accessdata.fda.gov/drugsatfda_docs/nda/2018/213077Orig1s001.pdf

Health Canada (2005) Novel Food Information – Glyphosate Tolerant Alfalfa Events J101 and J163

Health Canada (2015) Novel Food Information – Reduced Lignin Alfalfa KK179

ISAAA (2017) Global Status of Commercialized Biotech-GM Crops - 2017

USDA-ERS (2016) The Adoption of Genetically Engineered Alfalfa, Canola and Sugarbeets in the United States.

USDA COOL – Country of Origin

Country of Origin Labeling (COOL) is a USDA labeling law that requires declaration of the source of certain foods:

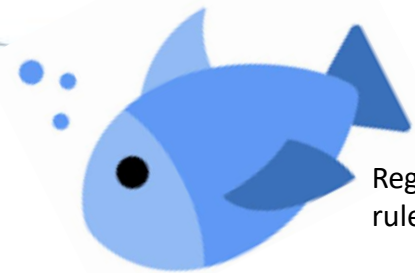
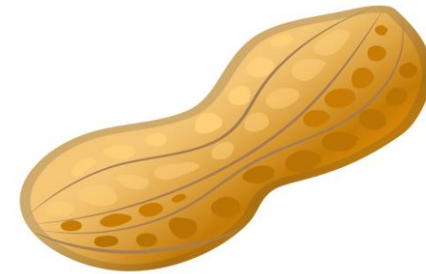
- 1) Muscle Cut and Ground Meats (Lamb, Goat, & Chicken)
- 2) Wild and Farm-Raised Fish and Shellfish;
- 3) Fresh and Frozen Fruits and Vegetables;
- 4) Peanuts, Pecans, and Macadamia Nuts; and Ginseng.

Exemptions

- Regulations pertain to raw commodities only, processed items are exempt.

Regulations for fish and shellfish covered commodities (7 CFR Part 60) became effective in 2005. The final rule for all covered commodities (7 CFR Part 60 and 7 CFR Part 65) went into effect on March 16, 2009

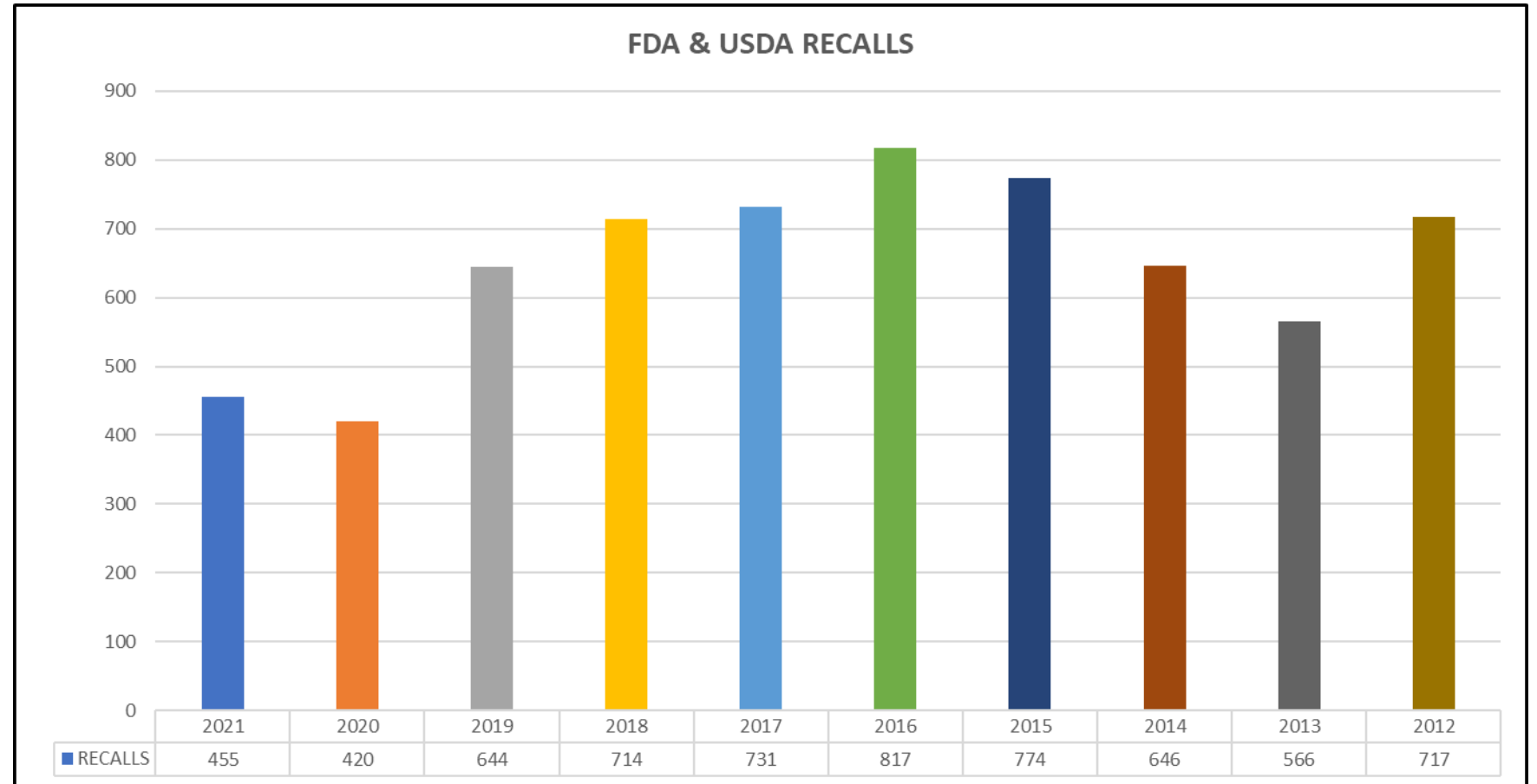
Source: <https://www.ams.usda.gov/rules-regulations/cool>





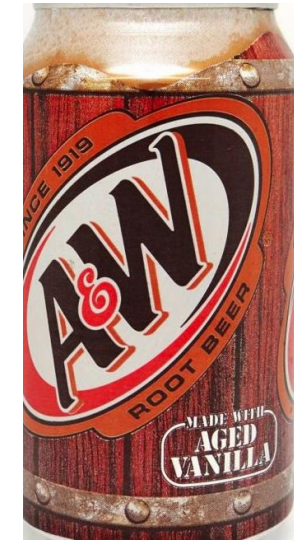
FDA AND USDA RECALLS

- 3,257 Recalls due to undeclared allergens
- 780 Recalls due to failure to declare dyes, flavors or preservatives
- 349 Recalls due to Sulfites
- 112 Recalls due to undeclared ingredient
- 73 Recalls due to undeclared Sesame (ingredient/allergen)



CLASS ACTION

- Heavy Metals
- Ingredient Representations
 - Vanilla/Vanilla Extract
 - Pure
 - Ice Cream
- Absence “No Preservatives”
- Artificial Flavors/Sweeteners/Sugar
- Origins (Olive Oil, Macadamia Nuts)
- Extra Virgin



CHECKLIST



- ✓ Create a new supplier protocol
- ✓ Create a process for any existing supplier changes
- ✓ Confirm RACC sizes
- ✓ Review ingredient statements and standard of identities
- ✓ Review allergens
- ✓ Ensure all ingredients have all mandatory nutrients
- ✓ Confirm Claims



cheat sheet
NUTRITION FACTS LABEL COMPLIANCE CHECKLIST

noun | lab•el com•pli•ance check•list | \ˈlā-bəl kəm-ˈplī-ən(t)s ˈchek- list
: a checklist to help you make sure your labels comply with the latest regulations

▶ HOW TO USE

Nutrition facts label regulations change from time to time. Use this checklist to help you follow the necessary steps for compliance.

checklist items

- Request updated spec sheets from your suppliers**
Update any ingredient data that has changed.
- Verify that you have displayed any allergens in your ingredients**
The nine required allergens are: milk, wheat, sesame, tree nuts, soy, fish, shellfish, and peanuts.
- Verify sulfite content in your ingredients**
The presence of sulfites must be declared on your food packaging.
- Review Added Sugars and Total Sugars definitions and label requirements**
Update Added Sugars label amounts and %DVs to reflect the latest regulations.
- Gather nutrient information for newly mandated nutrients (Added Sugars, Vitamin D, Potassium)**
These nutrients are mandatory. Make sure you have the analysis data for these nutrients.
- Double-check the nutrient information for dietary fiber**
Dietary fiber was defined more rigidly after 2016 and includes beneficial fibers, but not non-beneficial, non-digestible carbs. Learn more: <https://www.esha.com/dietary-fiber-nutrition-facts-label/>
- Make sure you are using the correct nutrient values and units of measure**
Nutrients are occasionally updated with new units. Use the Calculate Nutrients feature in Genesis R&D to double-check that your values and units of measure are correct.
- Check RACC and serving size for your food category to see if it's changed**
The RACCs were extensively updated in 2016 to more accurately reflect real-world eating patterns. Please see the Electronic Code of Federal Regulations for the latest RACCs: <http://bit.ly/2ssM1aw>
- Verify that your Nutrient Content Claims are valid**
Your claims should reflect the latest %DVs and the latest established RACC values. Genesis R&D can help you determine what claims your food is eligible for.
- Check to see if your package size requires Dual Column labeling**
If your food requires further preparation or is in a container that holds between 2 and 3 servings, check to see if you are required to use a Dual Column label.
- Review layout specifications**
Make sure the label sizes, layouts, fonts and placement are correctly communicated to your design team.
- Document! Keep meticulous records of your process to show proof of good-faith effort.**

4747 Skyline Rd #100, Salem, OR 97306 USA | www.esha.com | info@esha.com | 503-585-8242  ©2021 ESHA Research



DOCUMENTATION

The FDA requires manufacturers to maintain documents for up to 2 years.

- Document how you arrived at your nutritional information.
- Keep copies of critical documents:
 - Supplier Spec Sheets
 - Analyses of Nutrient Databases
 - Recipes or Formulations
 - Batch Records
 - Any other records that contain the required information

QUESTIONS?



CONTACT US

Phone: 503-585-6242

Sales: sales@esha.com

Support: support@esha.com

Consulting Services: cs@esha.com

Training: training@esha.com



HELPFUL RESOURCES

LinkedIn: [linkedin.com/company/esha-research/](https://www.linkedin.com/company/esha-research/)

eLearning Center: esha.com/resources/esha-elearning-center/

Blog: esha.com/blog

eNewsletter: esha.com/esha-newsletter

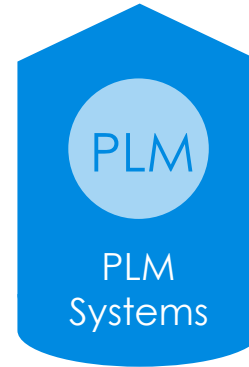
Label Compliance Can Be Overwhelming



- ✓ Change Management
- ✓ Claims Substantiation
- ✓ Product Criteria
- ✓ Raw Material Costs
- ✓ Regulatory Requirements
- ✓ Research
- ✓ Supply Chain Fluctuations
- ✓ Version Control
- ✓ Testing

Data Needed for Label Compliance is Siloed

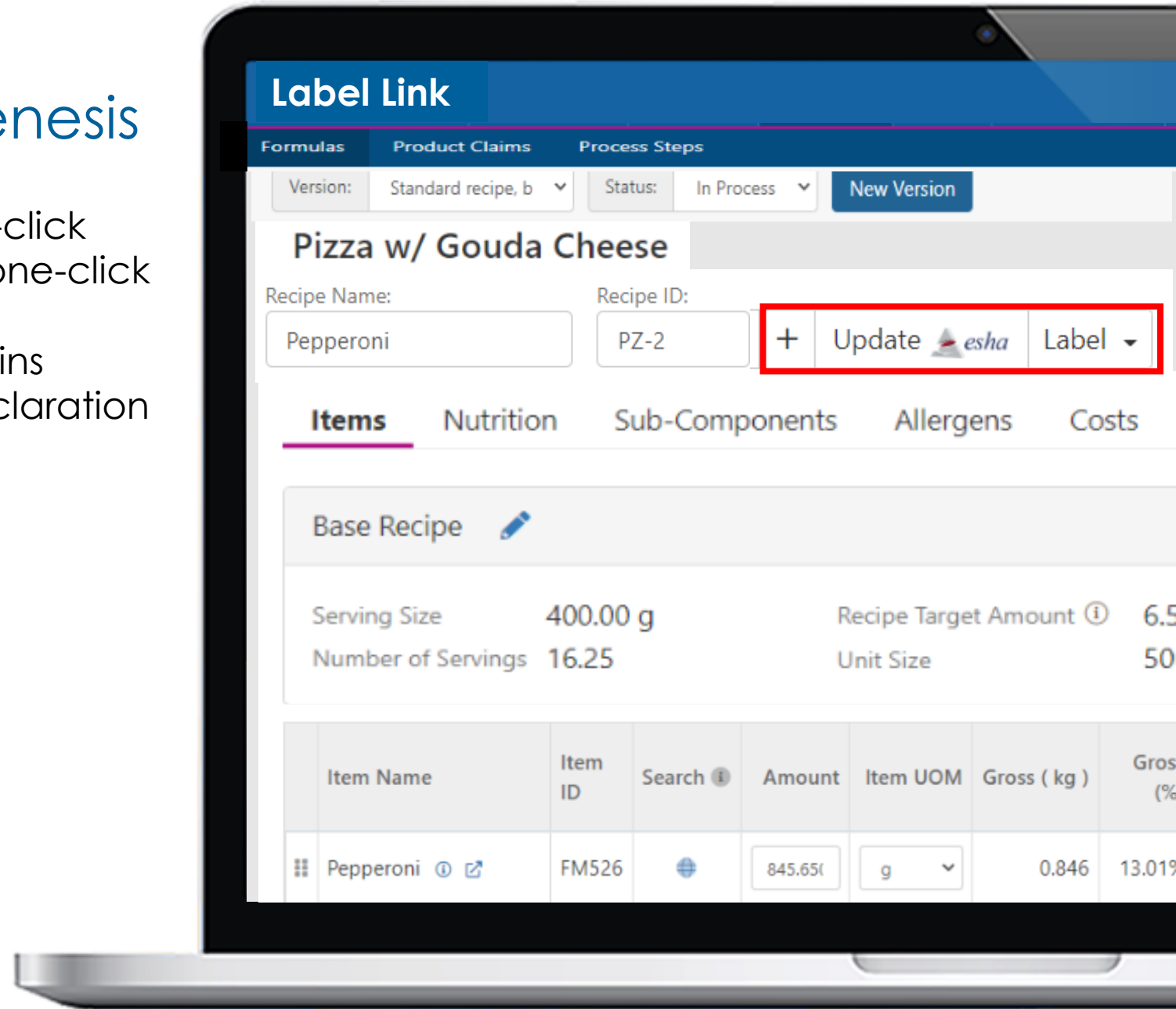
Data is Scattered
Across Departments
and Facilities



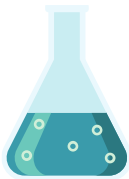
As much as 75% of your
supply chain data lives
with your suppliers

TraceGains Label Link for Genesis

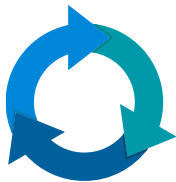
- Create new items in Genesis with one-click
- Update existing items in Genesis with one-click
- Eliminates duplicate data entry
- Returns compliant labels into TraceGains
- Use the formatted Fact Panel and Declaration as images to use in Specs



Networked Product Development Platform



Rapid Formula
Innovation & Iteration



End-to-End
Digital Thread



Collaboration &
Automation



ERP
Integration



TraceGains
Network

The only solution connected to a **Network** so you can accelerate NPD at every stage.

30K+

SUPPLIER LOCATIONS

305K+

ITEMS

2.5M+

SUPPLIER & ITEM DOCS

120+

Supplier Countries

TraceGains Network Powers Digital Transformation for Innovation



TraceGains
Network

Live Q&A



Thank You
Plug In. Go Faster.