



TRACEGAINS WEBINAR

New Product Development around Nutrition Claims: Understanding the Regulations

September 22, 2022



Meet
Your Moderator



Kristen Goodale
Marketing Coordinator



Slides And Recording Will Be Shared

We want to hear from you! Please type your questions in the chat box.



About TraceGains

Together we do more



Food and Beverage ••• Dietary Supplements ••• Retail ••• Consumer Packaged Goods



TRACEGAINS

Discover the Power of Networked

What Makes TraceGains Different?

On average, companies find that 80% of their suppliers are already on TraceGains Network.



Meet

Your Speakers



Sara Jane Bellocchi
Networked Ingredients Functional
Consultant



Ruben Galbraith
Software Sales Engineer



TRACEGAINS WEBINAR

New Product Development around Nutrition Claims: Understanding the Regulations

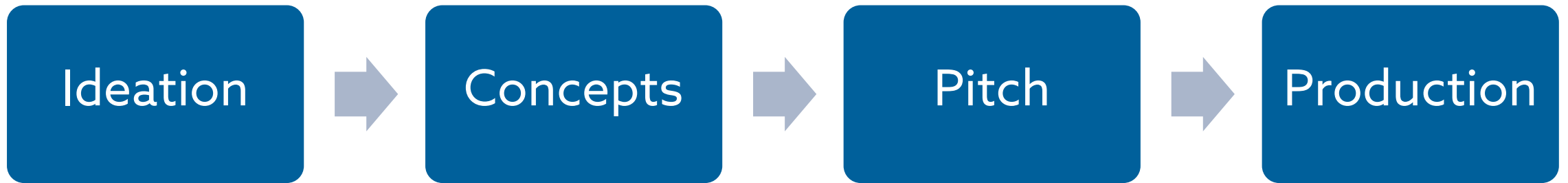
Sara Jane Bellocchi – Networked Ingredients Functional Consultant
September 2022

Disclaimer

This session and discussions arising from this content are not meant as legal advice.

This information is not for diagnosis, treatment, or prevention of any disease. Before making any changes to your lifestyle or diet please consult a physician.

What are we talking about...



Product Claims need to be considered throughout the new product development lifecycle.

What We'll Cover Today

- Applicable CFR's and Overview of Regulatory Landscape
- Definitions
- Nutrition Claims (per FDA)
 - Nutrient Content Claims
 - Health Claims
 - Qualified Health Claims
 - Structure/Function Claims
- Assured Status Claims
- Allergen Claims

We will focus on claims that do not address the safety of products (or the suitability for certain populations) but are meant for a more informed consumer.

Food Law and Regulations in the US

- **Guidance for Industry: Food Labeling Guide**
(September 1994; Revised April 2008; Revised October 2009; Revised January 2013)
- **21 CFR 101 – Food Labeling**
 - 101.9 Nutrition labeling of food
 - Subpart D – Specific Requirements for Nutrient Content Claims
 - Subpart E – Specific Requirements for Health Claims
 - Subpart F – Specific Requirements for Descriptive Claims That Are Neither Nutrient Content Claims nor Health Claims
- **Guidance for Industry: Reference Amounts Customarily Consumed (RACC)**
 - See also - 21 CFR 101.12 Reference amounts customarily consumed per eating occasion
- **21 U.S. Code § 343 - Misbranded food and § 350 - Vitamins and minerals**



**“Laws are like sausages. It's better not to see how they are made.”
Otto Von Bismarck (1815-1898)**

Important Definitions

In relation to Claims

Reference Amounts Customarily Consumed (RACC)

PRODUCT CATEGORY	REFERENCE AMOUNT	LABEL STATEMENT	EXAMPLES OF PRODUCTS ⁴
Brownies	40 g	_ piece(s) (_ g) for distinct pieces; fractional slice (_ g) for bulk	All types of brownies.
Cakes, heavyweight (cheese cake; pineapple upside-down cake; fruit, nut and vegetable cakes with more than or equal to 35 percent of the finished weight as fruit, nuts, or vegetables or any of these combinations) ⁵	125 g	_ piece(s) (_ g) for distinct pieces (e.g., sliced or individually packaged products); _ fractional slice (_ g) for large discrete units	All cheese cakes, pineapple upside-down cake, and all cakes which contain 35 percent or more of fruit, nuts, or vegetables (e.g., Christmas fruit cake). Cakes in this category typically weigh 10 g or more per cubic inch. <u>NOTE:</u> Fruitcake weighs 18 g per cubic inch, which is considered a heavyweight cake. However, the serving size for fruitcake is 1 ½ ounces. See footnote 5 in table 2 of 21 CFR 101.12(b).

21 U.S. Code § 343 - Misbranded food

A food shall be deemed to be misbranded –

(a) False or misleading label

If (1) its labeling is false or misleading in any particular, or (2) in the case of a food to which section 350 of this title applies, its advertising is false or misleading in a material respect or its labeling is in violation of section 350(b)(2) of this title.

Nutrition Claims

- **Nutrient Content Claims**

- Free/Low/Reduced or Less
 - Calories
 - Total Fat
 - Saturated Fat
 - Cholesterol
 - Sodium
 - Sugars
- Relative Claims
 - Light
 - Reduced/Added/Plus/Fortified/Enriched
 - More/Less/Fewer
- Other
 - High/Rich In/Excellent Source of
 - Good Source/Contains/Provides
 - More/Fortified/Enriched/Added/Extra/Plus
 - Modified
 - Fiber
- Implied Claims
 - “Healthy”
 - “Good Source of Oat Bran”

- **Health Claims**

- “Boosts the immune system.”
- “Powerful antioxidants.”
- “Supports skin texture”
- “Helps reduce cholesterol.”

- **Qualified Health Claims**

- Must also have a disclaimer or qualifying language.

- **Structure/Function Claims**

- Not about preventing disease but maintenance of healthy metabolic function.

More details on Nutrient Content Claims

For nutrient content claims your food must contain less than: 13 g Total Fat, 4 g Saturated Fat, 60 mg Cholesterol, and 480 mg Sodium per RACC

Some of the Conditions for the Use of “Healthy”

	Individual Food	Seafood/Game Meat	Meal/Main Dish
Total Fat	3 g or less per RACC (and per 50 g if RACC is small)	< 5 g fat /RACC & /100g	3 g or less per 100 g and not more than 30% of calories from fat
Saturated Fat	1 g or less per RACC and 15% or less of calories from saturated fat	< 2 g sat fat /RACC & /100g	1 g or less per 100g and less than 10% of calories from saturated fat
Sodium	≤ 480 mg /RACC and / l.s.; or /50 g, if RACC is small	≤ 480 mg /RACC and /l.s.; or /50 g, if RACC is small	≤ 600 mg /l.s.
Cholesterol	≤ disclosure level	< 95 mg /RACC & / 100 g	≤ 90 mg /l.s.

Assured Status Claims

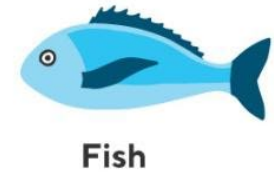
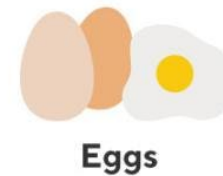
- **Certification or method of production based:** Kosher, Halal, Gluten Free (also an allergen claim though), Non-GMO Project Verified, Organic, GlobalG.A.P. etc.
- **Natural, Antibiotic Free**
- **Genetically Modified Organism (GMO) status**
- **Identity Preserved (IP)**
- **Specifically Trademarked Ingredients:** E.g. Demeter Certified *Biodynamic Sugar*, Crystal Dextrogrape, etc.



Allergen Claims

- Allergens **ALWAYS** need to be labeled.
 - Common or usual name
 - Contains Statement
- If making “No Allergens” or “Free from XX”
 - Supply chain
 - Segregation
 - Product testing

Resource: Food Allergen Labeling And Consumer Protection Act of 2004 Questions and Answers



Key Take-Aways

- **Don't wait to begin evaluating claims.** *It starts with your supply chain.*
- **Have a system and team to review claims and packaging.**
- **You can't know it all.** You just need to know your resources.

“I am a firm believer in the people. If given the truth, they can be depended upon to meet any national crisis. The great point is to bring them the real facts, and beer.”
— Abraham Lincoln

Demo



Live Q&A

Type your questions
into the chat box!

Win a Cup of Coffee...

Take our survey and be
entered to win a \$10 gift
card to your favorite coffee
shop!





 together ²⁰²²

october 19-20 | learn. solve. transform.



Thank You

Together we do more

