



# Labeling and Claims Procedures for Food Ingredients: Natural, Allergens, and Nutrition

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# Agenda

- Overview
- Product Labeling
- Claims
- Consumer Perception
- SmartLabel
- Q & A



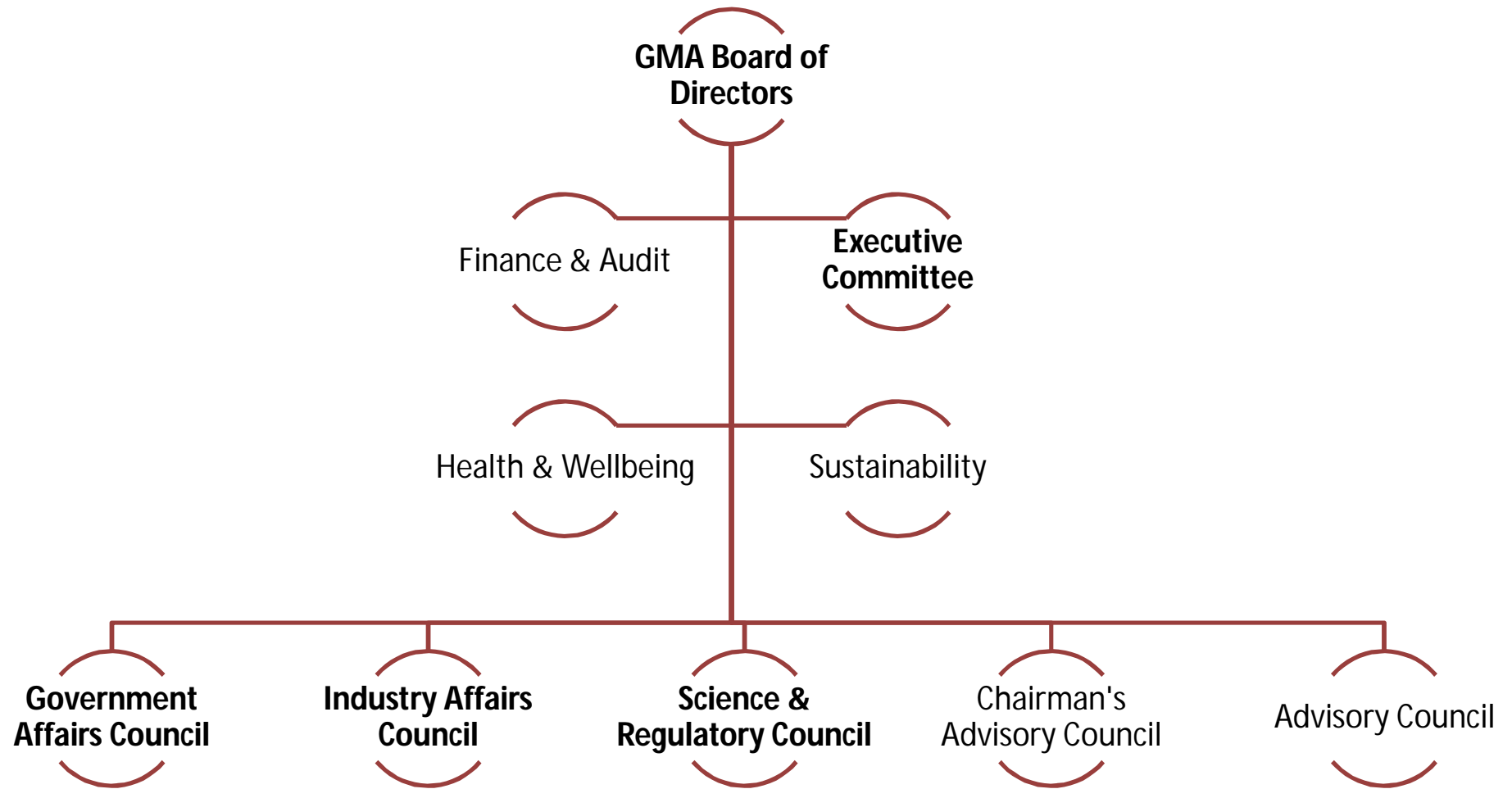
smartlabel™



# The GMA Purpose

*Provide a voice for the CPG industry as we seek to improve the health and wellbeing of consumers and society.*

# Executive Leadership







# Science & Regulatory Affairs

## Mission

Develop and promote science-based solutions that enhance the safety, quality and compliance of GMA member's products in order to build the trust and confidence of consumers.

# What We Do

Provide science-based solutions that help members improve integrity of consumer products to build consumer confidence and trust



**Product Safety & Regulatory Compliance**

- **Policy engagement**
- **Member collaboration**
- **Technical service**

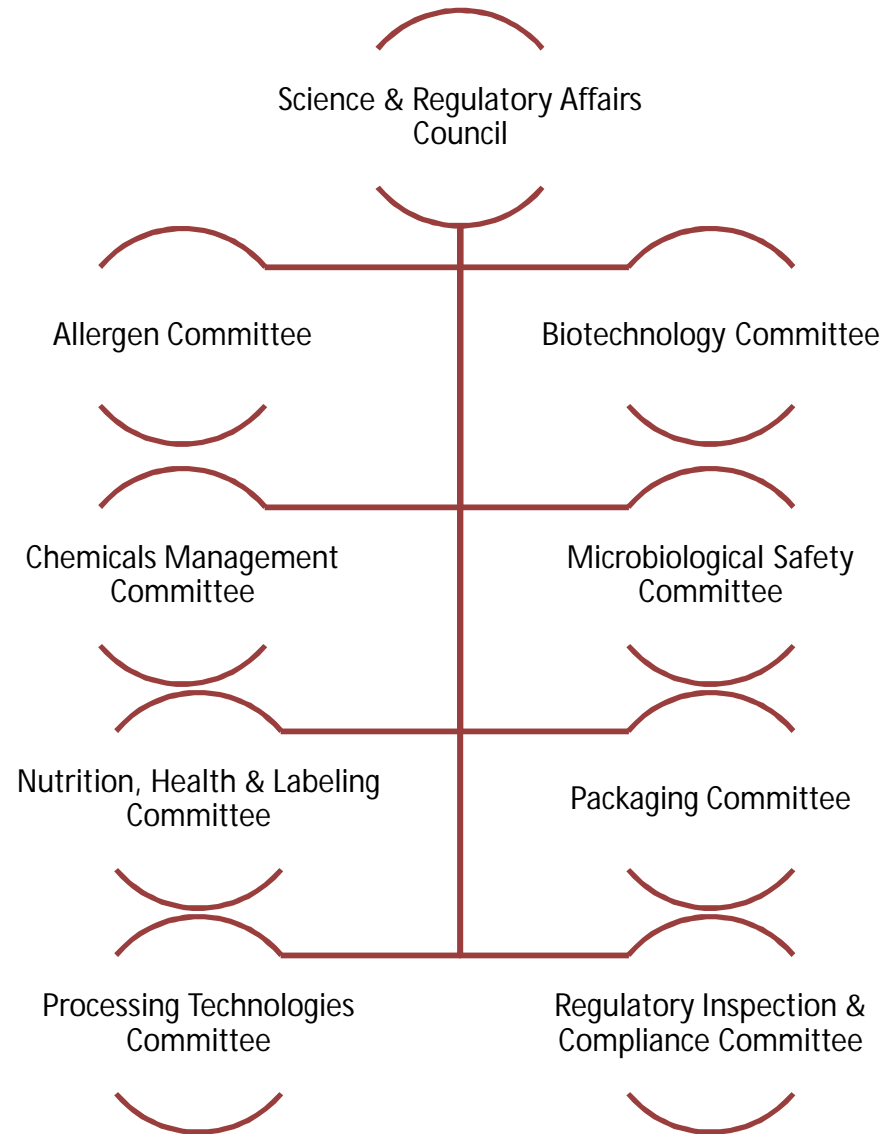


**Consumer Product Information & Transparency**



**Nutrition, Health & Wellbeing**

# Science & Regulatory Affairs



# GMA Participation in Codex

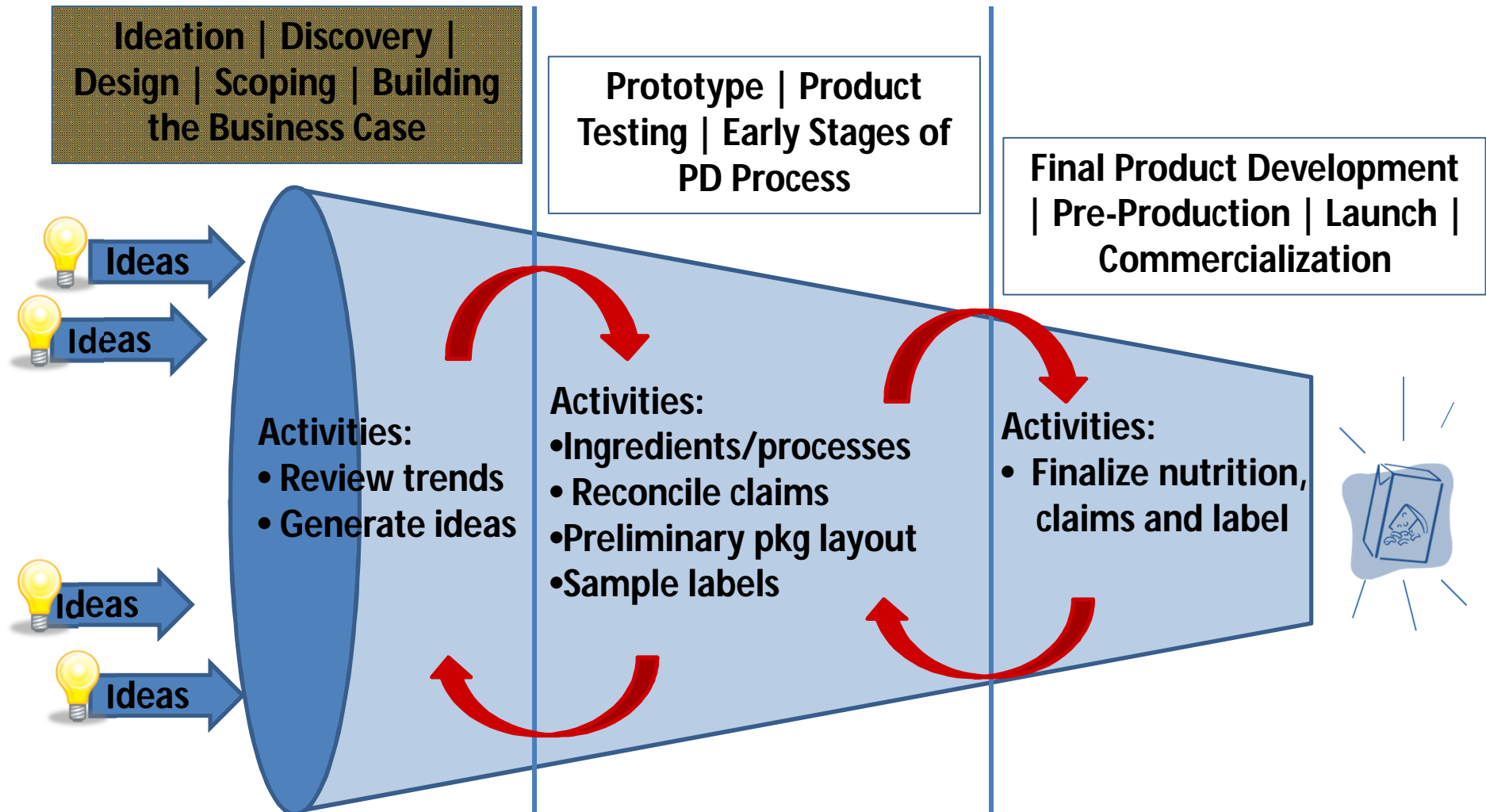


Advance science-based international policy in  
Codex Alimentarius

- Promoting harmonization within Codex standards and policies, and
- Facilitating international trade

ICGMA is accredited as an observer organization  
in Codex

# Product Development & Labeling





# Key Terminology

## Labels and Labeling

1. Labels: Written, printed, graphic matter on immediate container
  - a. Visible at retail sale
2. Labeling: includes labels plus written, printed, graphic matter accompanying product
  - a.e.g., Hang tags, point-of-sale brochures, shelf talkers
3. Websites and social media may be considered labeling
4. Distinct from “Advertising”

# Food Labeling

- ◉ Facebook “Like”
  - FDA has exercised jurisdiction where a company “liked” a Facebook post from a customer who said the product (a dietary supplement) had helped “keep cancer at bay”
- ◉ Other Social Media Activity
  - Comment on a Facebook post
  - Claims on a Twitter page
  - Search terms linked to a company’s website
  - Blog posts linked from a company’s website







# Authority to Regulate Labeling in U.S.

- ◉ Who defines key terminology for food labeling?
- ◉ What is the source of authority to regulate labels and labeling?

## **Legislative Branch**

Congress  
Makes Laws

## **Executive Branch**

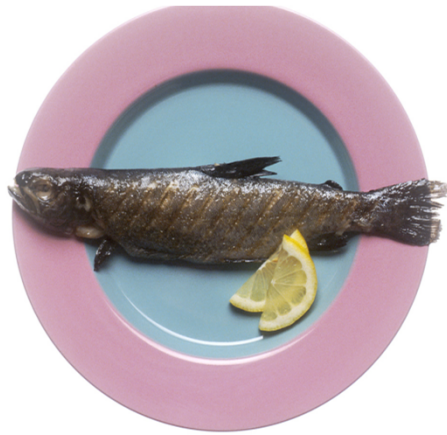
President & Agencies  
Enforce Laws

## **Judicial Branch**

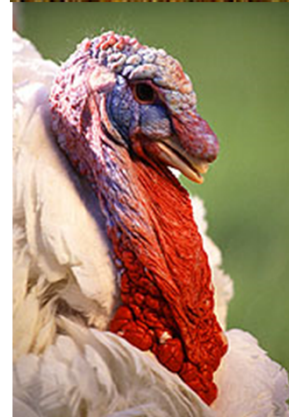
Courts  
Interpret Laws

# Who Regulates Food in U.S.?

FDA



USDA-FSIS





# Food Product Jurisdiction

Who regulates what food?

- ◉ FDA – most food products
  1. 85% of food supply
- ◉ USDA-FSIS – meat and poultry species and derived products, egg products, and now catfish
  1. 15% of food supply
  2. Meat, poultry, egg products subject to continuous/daily inspection are “amenable”
  3. FSIS decides what is amenable. Many game meats are NOT amenable (thus are FDA-regulated)



# FDA Authority

## Law: Federal Food, Drug, and Cosmetic Act (FFDCA)

- \*Food labeling, Section 403 (Misbranding)
- ◉ “Misbranding” Provisions of the Law
  - Truthful and non-misleading labeling
  - Disclosing “material facts”
- ◉ Accurate and substantiated claims
- ◉ Specific National Uniformity – Federal Preemption provisions



# USDA Authority

- ◉ Some Key USDA Agencies:
  1. Agricultural Market Service (AMS) – Grade standards, “Organic,” Country of Origin labeling, Disclosure for bioengineered foods
  2. Food and Nutrition Service (FNS) – School Lunch and School Breakfast Program standards
  3. Food Safety and Inspection Service (FSIS) – meat, poultry, egg product inspection and labeling



# USDA Authority

- ◉ Federal Meat Inspection Act
- ◉ Poultry Products Inspection Act
  1. Any domesticated bird (e.g., chicken, turkey, domestic duck, goose)
  2. Egg Products (whole eggs, yolks, whites, broken from shells and processed)
  3. Catfish\*
  4. Broad Federal Preemption

# Claims: Natural (FDA)

- ◉ “Natural” claims - FDA

100% NATURAL

*All Natural Ingredients*

**ALL NATURAL**

FDA policy expressed:

“not to restrict the use of the term “natural” except for added colors, synthetic substances, and flavors as provided by § 101.22”

58 Fed. Reg. 2407 (January 6, 1993)



# Claims: Natural (USDA-FSIS)



## Food Standards & Labeling Policy Book:

- ◉ Must contain no artificial flavors, no preservatives, no color additives
- ◉ Must be “minimally processed”



# Allergen Labeling

## Food Allergen Labeling and Consumer Protection Act (FALCPA)

- ◉ Legislation enacted by Congress, signed by President, August 2004 (Pub. L. 108-282 Title II)
- ◉ Labeling requirements effective January 1, 2006
- ◉ Applies to all FDA-regulated foods that are not raw agricultural commodities
- ◉ To assist food allergic consumers to identify when a packaged food was made using an ingredient (including a coloring, flavoring, or incidental additive) that contains a “major food allergen” so that they can avoid it

# FALCPA

Where are the FALCPA regulations?

- ◉ No regulations. FALCPA is self-implementing law
- ◉ Labeling requirements set in statutory language
- ◉ FDA has issued interpretive guidance

Labeling Provisions:

- ◉ Defines Major Food Allergens
- ◉ Requires plain language food allergen labeling
- ◉ Removes ingredient labeling exemptions for food allergens in flavors, colors, incidental additives

# FALCPA: Major Food Allergens

- ◉ Peanuts
- ◉ Milk
- ◉ Egg
- ◉ Tree nuts
- ◉ Wheat
- ◉ Soybeans
- ◉ Fish (e.g. bass, flounder, cod)
- ◉ Crustacean shellfish (e.g. shrimp, crab)

## Tree Nuts

- ◉ Almond
- ◉ Beech nut
- ◉ Brazil nut
- ◉ Butternut
- ◉ Cashew
- ◉ Chestnut
- ◉ Chinquapin
- ◉ Coconut
- ◉ Hazelnut
- ◉ Ginko nut

- ◉ Hickory nut
- ◉ Lichee nut
- ◉ Macadamia nut
- ◉ Pecan
- ◉ Pine nut
- ◉ Pili nut
- ◉ Pistachio
- ◉ Sheanut
- ◉ Walnut

# FALCPA: Labeling Products

## **Within the list of ingredients:**

- ◉ The common or usual name of the major food allergen immediately followed parenthetically by the name of the food source. e.g. Whey (milk), Natural flavors (peanut, almond)

## **In a separate summary statement:**

- ◉ The word “contains” followed by the name of the food source from which the major allergen is derived, immediately after or adjacent to the list of ingredients. e.g. Contains: peanuts, wheat, and soy

# Claims: Allergen Free



FDA & USDA claim:

- No regulatory definition
- Must be truthful and non-misleading



# Nutrition & Health Labeling

## Nutrient Content Claims (NCC)

- ◉ Information from the Nutrition Facts Panel included elsewhere on the label is regulated as NCC
- ◉ Nutrient content claims established by:
  - Regulation (petitions may be used)
  - Authoritative statements, through notification (FDAMA claims) – for FDA-regulated foods





# Nutrition Content Claims

- ◉ Nutrient content claims characterize the level of nutrients in foods
- ◉ There are two types of NCCs
  - **Expressed**
  - **Implied**
    - Healthy
- ◉ All the provisions for nutrient content claims apply if the claim is part of the brand name of the food

21 CFR 101.13(a), 21 CFR 101.13(b)



# Serving Size and NCC

- ⦿ For Individual Foods:
  - NCCs are based on the Reference Amount Customarily Consumed (RACC)
  - Some claims also have criteria per labeled serving
- ⦿ For Meals and Main Dishes:
  - NCCs are based on 100 grams servings
  - Foods that qualify as “meals” or “main dishes” (for the purpose of claims) have more generous criteria or special rules for expressing the claim

# Consumer Confusion

## Natural vs. Artificial





# Current Trends

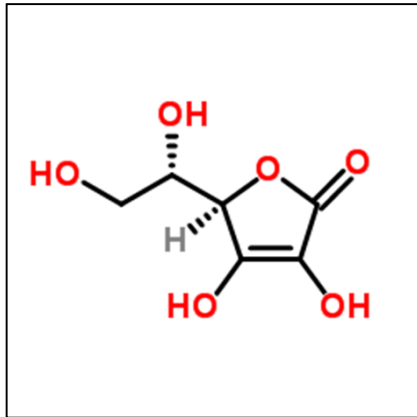
- ◉ Consumers are afraid of ingredients in foods and beverages due to the perception that they are “unnatural,” unnecessary or unhealthy = Chemophobia
- ◉ Consumers now more than ever want to know what’s in their food
- ◉ Consumers are increasingly pushing for “clean” labels
- ◉ However, most consumers have a fundamental misunderstanding of the role of food additives:
  - Do not understand safety evaluations
  - Do not understand benefits
  - Do not understand food additive names

# Misunderstanding Safety



- ◉ “Natural” ingredients and food itself (i.e., grain, meat, vegetables) are “substances” comprised of chemicals
- ◉ Most consumers don’t realize common substances are in fact chemicals (ex., NaCl = salt)
- ◉ Food additives are “substances” too
- ◉ “Natural” ingredients are no more inherently safe than food additives
- ◉ Many natural ingredients can be toxic and harmful:
  - Just because something is “natural” doesn’t mean it is inherently safe
  - Just because something is “synthetic” doesn’t make it inherently unsafe

# Food is Chemicals



Vs.



## AN ALL-NATURAL BANANA



**INGREDIENTS:** WATER (75%), **SUGARS (12%)** (GLUCOSE (48%), FRUCTOSE (40%), SUCROSE (2%), MALTOSE (<1%), STARCH (5%), **FIBRE (3%)** (E460, E461, E462, E464, E466, E467) **AMINO ACIDS** (GLUTAMIC ACID (19%), ASPARTIC ACID (16%), HISTIDINE (11%), LEUCINE (7%), LYSINE (5%), PHENYLALANINE (4%), ARGININE (4%), VALINE (4%), ALANINE (4%), SERINE (4%), GLYCINE (3%), THREONINE (3%), ISOLEUCINE (3%), PROLINE (3%), TRYPTOPHAN (1%), CYSTINE (1%), TYROSINE (1%), METHIONINE (1%)), **FATTY ACIDS (1%)** (PALMITIC ACID (30%), OMEGA-6 FATTY ACID: LINOLEIC ACID (14%), OMEGA-3 FATTY ACID: LINOLENIC ACID (8%), OLEIC ACID (7%), PALMITOLEIC ACID (3%), STEARIC ACID (2%), LAURIC ACID (1%), MYRISTIC ACID (1%), CAPRIC ACID (<1%), ASH (<1%), PHYTOSTEROLS, E515, OXALIC ACID, E300, E306 (TOCOPHEROL), PHYLLOQUINONE, THIAMIN, **COLOURS** (YELLOW-ORANGE E101 (RIBOFLAVIN), YELLOW-BROWN E160a), **FLAVOURS** (ETHYL HEXANOATE, ETHYL BUTANOATE, 3-METHYLBUT-1-YL ETHANOATE, PENTYL ACETATE), E1510, NATURAL RIPENING AGENT (ETHENE GAS).

# “Competitive Advantage” Driver

- ◉ WhiteWave: Carrageenan
- ◉ Chipotle: Non-GMO, and eliminate additives
- ◉ Panera: List of over 150 banned ingredients
- ◉ Pizza Hut & Taco Bell: Artificial colors, and flavors
- ◉ Subway: Artificial flavors, colors, and preservatives
- ◉ General Mills: Artificial flavors and colors







# Regulators and Industry

- ◉ Collaborate on the development of food additive standards and specifications that are based on sound science and globally harmonized.
- ◉ Maintain food additive standards that are based on technological need/function.
- ◉ Educate consumers about the safety of food additives. Go beyond the label
- ◉ Provide simple, clear messages about the role food additives play and their necessity for a safe and stable food supply.
  - [FoodIngredientFacts.org](http://FoodIngredientFacts.org)

# Beyond the Label



**A Proactive** industry solution that **educates**, enhances the lives of, and **builds long-term trust** with, **consumers**.

# Beyond the Label

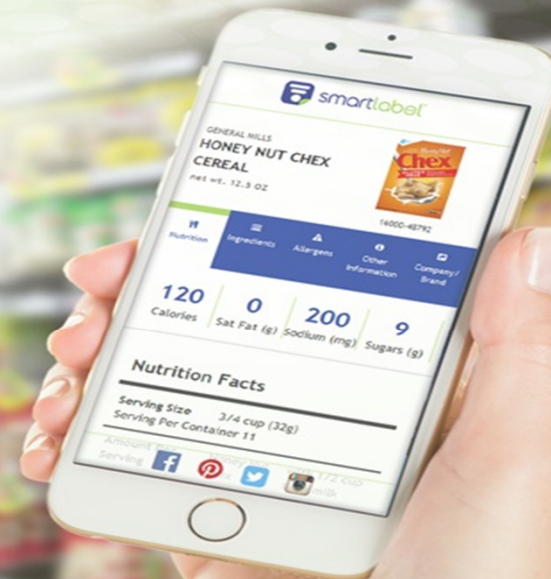
- Consumers are actively expanding their purchase criteria
- They want to know
  - What it is, What it does, Why it is in there, Where it came from
- They place value on a brand's impact on
  - Health, the environment and society



# Beyond Label

## SmartLabel® - Our Promise

- *Easy access to More Information than could ever Fit on a Label*
- Thousands of products
- Compliant digital disclosure of GMOs, Cleaning Product Ingredients



# Beyond Label

SmartLabel.org

Mobile App

Scan QR Code



Sodium	Less than	2,400mg	2,400mg
Total Carbohydrate		300g	375g
Dietary Fiber		25g	30g

INGREDIENTS: MILK CHOCOLATE [CANE SUGAR; MILK; CHOCOLATE; COCOA BUTTER; MILK FAT; LECITHIN (SOY); NATURAL FLAVOR]. © D

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# Beyond Label

smartlabel

Breyers  
**Breyers, Gelato Indulgences, Creamy Vanilla Gelato With A Luscious Caramel Sauce & Gourmet Caramelly Curls, Vanilla Caramel**  
 28.5 fl oz (842 mL)




077567327352

Nutrition	Ingredients	Allergens	Other Information	Company/Brand
180 Calories	4.5 Sat Fat (g)	70 Sodium (mg)	20 Sugars (g)	

**Nutrition Facts**  
 Serving Size 1/2 cup (80 g)  
 Servings Per Container 7

Breyers  
**Breyers, Gelato Indulgences, Creamy Vanilla Gelato With A Luscious Caramel Sauce & Gourmet Caramelly Curls, Vanilla Caramel**  
 28.5 fl oz (842 mL)



077567327352

- Nutrition
- Ingredients
- Allergens
- Other Information
- Company/Brand


Milk >

Sugar >

Corn Syrup >

Cream >

Breyers  
**Breyers, Gelato Indulgences, Creamy Vanilla Gelato With A Luscious Caramel Sauce & Gourmet Caramelly Curls, Vanilla Caramel**  
 28.5 fl oz (842 mL)



077567327352

- Nutrition
- Ingredients
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According to the FDA, the most common food allergens are milk, peanuts, eggs, fish, crustacean shellfish, soy, tree nuts and wheat.

Milk Contains >

Standardized information sharing across





# Thank You

Manojit Basu, PhD

Grocery Manufacturers Associations

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[mbasu4@jhu.edu](mailto:mbasu4@jhu.edu)



The Association of Food, Beverage  
and Consumer Products Companies