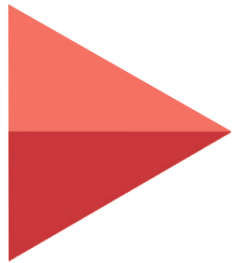




Successfully Navigating Product Claims Organic, Gluten-Free, All Natural, GMO



Organic



Legal and Regulatory History

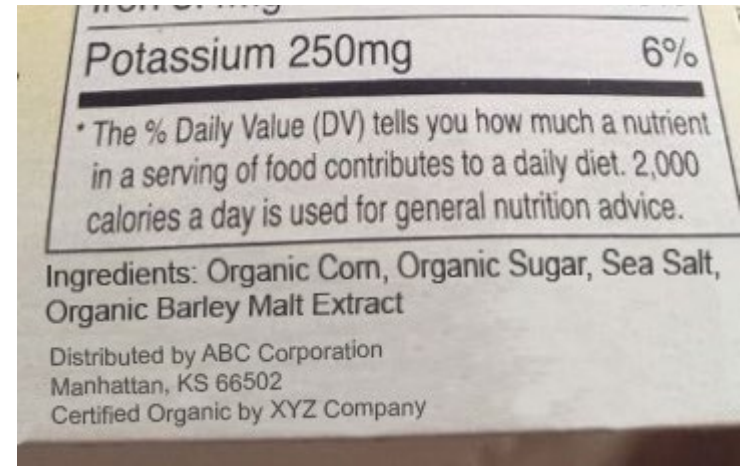
- Organic Foods Production Act of 1990
 - Part of the 1990 Farm Bill
 - USDA/Agricultural Marketing Service (AMS) developed standards
 - Certification program established
 - National Organic Standards Board created
 - Regulations basically cover from “farm to fork”

Becoming a Certified Operation

- Farm or business:
 - Adopts organic practices
 - Selects a USDA-accredited certifying agent
 - Submits application and fees to the certifying agent
- Certifying agent reviews application to verify practices comply
- An inspector conducts an on-site inspection of operation
- Certifying agent reviews inspector's report to determine if the applicant complies
- Certifying agent issues organic certificate

Organic Product Label Declarations

- Certified organic food:
 - Must identify each organic ingredient in ingredient statement
 - Name of certifying agent must appear on information panel below the name/address of manufacturer or distributor (would not apply for less than 70% organic)



100% Organic



- Use only organically produced ingredients except for water and salt
- May display USDA seal
- May display certifying agent seal

95 to 100% Organic Ingredients



- At least 95 percent organically produced ingredients except for water and salt
- May display USDA seal
- May display certifying agent seal

70 to 95% Organic Ingredients

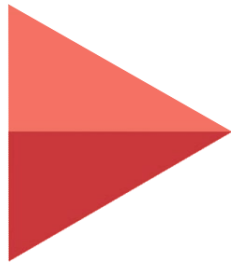


- At least 70% organic ingredients
- List up to 3 of the organic ingredients or food groups on principal display panel
- **Cannot** display USDA seal
- May display % organic
- May display certifying agent seal

Up to 70% Organic Ingredients



- The word “organic” can only be used in the ingredient statement to describe organic ingredients
- Company processes are not required to be certified



Gluten-Free



Gluten Definition

- Proteins that naturally occur in a gluten-containing grain and that may cause adverse health effects in persons with celiac disease

Gluten-Containing Grain Definition

- Any one of the following or their crossbred hybrids:
 - Wheat, including any species belonging to the genus, *Triticum*
 - Rye, including any species belonging to the genus *Secale*
 - Barley, including any species belonging to the genus *Hordeum*

Gluten-Free Definition

- A food bearing this claim in its labeling does not contain any one of the following:
 - An ingredient that is a gluten-containing grain
 - An ingredient that is derived from a gluten-containing grain and that has not been processed to remove gluten
 - An ingredient that is derived from a gluten-containing grain and that has been processed to remove gluten, if the use of that ingredient results in the presence of 20ppm or more gluten in the food
 - 20ppm or more gluten in any food

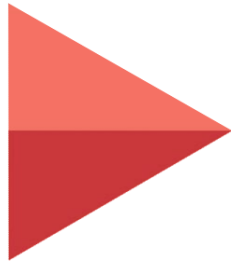
Gluten-Free Terms

- “Gluten-Free”
 - “No Gluten”
 - “Free of Gluten”
 - “Without Gluten”
- All of the above would need to meet the requirements in 21CFR101.91 for “gluten-free”
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Gluten-Free and Wheat

- Food that bears the term “wheat” in the ingredient list (e.g. wheat starch) or in a separate “Contains Wheat” statement and the product bears a “gluten-free” claim:
 - An asterisk will be placed next to the term “wheat” and the following statement placed in close proximity to the ingredient statement:

**The wheat has been processed to allow this food to meet the Food and Drug Administration (FDA) requirements for gluten-free foods.*



Natural



“Natural” in the Food Product’s Labeling

- USDA
 - Labeling Guidance on the Voluntary Claim “Natural”
- FDA
 - No Definition of “Natural”

Natural - USDA

Standards and Labeling Policy Memorandum (Memo) 055, dated November 22, 1982
(Rescinded August 2005)

Food Standards and Labeling Policy Book “Natural Claims”

Natural - USDA

- Meat and Poultry products do not contain any:
 - Artificial flavor
 - Color
 - Chemical preservative
 - Any artificial or synthetic ingredient
- Product and its ingredients are not more than minimally processed

Natural - USDA

- Minimal processing may include:
 - Traditional processes to make food edible, preserve it or to make it safe. Includes smoking, roasting, freezing, drying, and fermenting
 - Physical processes which do not fundamentally alter the raw product and/or only separate a whole, intact food into component parts. Includes grinding meat, separating eggs, and pressing fruits to produce juices

Natural - FDA

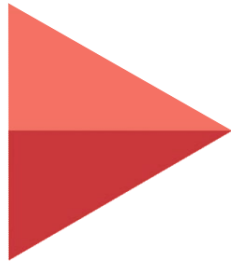
- No Definition for “Natural”
 - 1993 Federal Register Policy Statement
 - Volume 58, No. 3, Page 2407
January 6, 1993

Natural - FDA

- Policy:
 - “nothing artificial or synthetic (including all color additives regardless of source) has been included in, or has been added to, a food that would not normally be expected to be in the food.”

Natural - Things to Watch For

- Enrichments added to flour are mostly synthesized vitamins
 - Simple leavening agents may be synthetically derived
 - Any color additive even if it comes from a natural source
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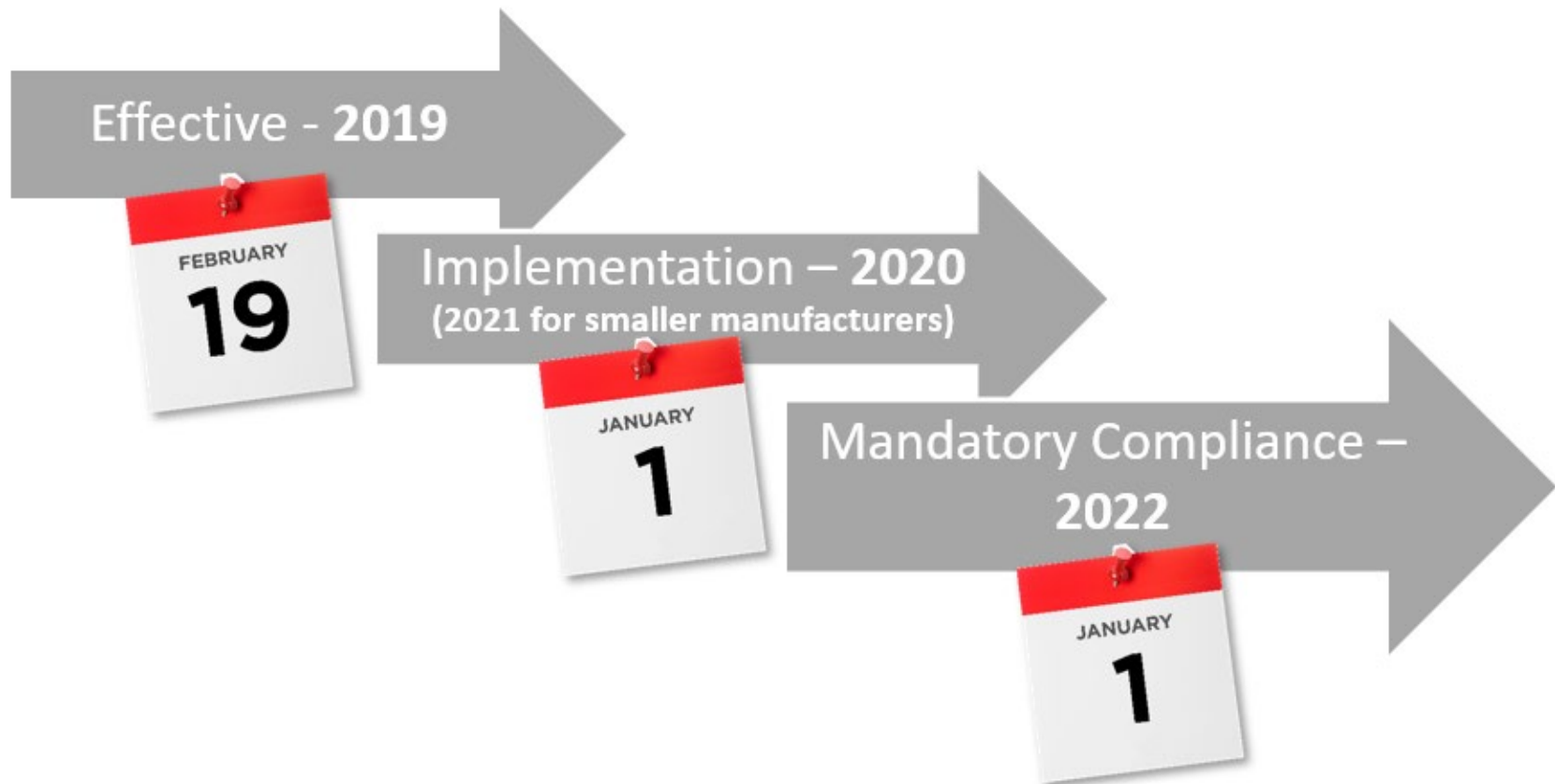
GMO or Bioengineered



National Bioengineered (BE) Food Disclosure Standard

- Foods that are or contain an ingredient on the AMS-maintained list of bioengineered foods commercially available in the US will need to disclose that the food is a BE food, contains a BE ingredient or may contain a BE ingredient.
- Various methods of disclosure – statement, symbol, electronic or digital link, or text message are all options.

Bioengineered Food Disclosure



Bioengineered Foods

A food that

- (A) Contains genetic material that has been modified through in vitro recombinant deoxyribonucleic (DNA) techniques; and
- (B) For which the modification could not otherwise be obtained through conventional breeding or found in nature



Bioengineered Foods

- The following foods and ingredients are not bioengineered foods:
 - Incidental Additives
 - Must meet FDA's definition in 21 CFR 101.100(a)(3)
 - Refined Products
 - BE food is refined to remove the modified genetic material so it is no longer detectable
 - Must be subjected to a validated refinement process or analyzed to confirm absence

List of Bioengineered Foods

- Includes crops and food products globally
- Will be reviewed annually to add new products
- Descriptions and trademark names are included to help manufacturers

List of Bioengineered Foods		
Alfalfa	Eggplant (BARI Bt Begun varieties)	Soybean
Apple (Arctic™ varieties)	Papaya (Ringspot virus-resistant varieties)	Squash (summer)
Canola	Pineapple (pink flesh)	Sugar beet
Corn	Potato	
Cotton	Salmon (AquaAdvantage®)	

List of Bioengineered Foods

- How to use the list
 - Determine if food or food ingredient is on the list
 - If it is on the list:
 - Records show it is BE = Disclosure
 - Records can't confirm = Disclosure
 - Records show not BE = No Disclosure
 - If it is not on the list:
 - No disclosure unless actual knowledge it is a BE food
 - Statements such as “May be bioengineered” are not allowed

Exemptions From Disclosure

- Food served in a restaurant or similar retail establishment
 - Very Small Food Manufacturers – Less than \$2.5 million in annual receipts
 - Inadvertent BE presence under 5% in each ingredient
 - Food derived from animals that are fed a BE crop
 - Organic certified foods – 100%, Organic, and Made with Organic
-

Disclosure Methods

- Appearance
 - Disclosure should be of sufficient size and clarity
- Placement
 - Placed on information panel adjacent to the responsible company
 - Anywhere on the PDP
 - Alternate panel if the PDP and IP have insufficient space

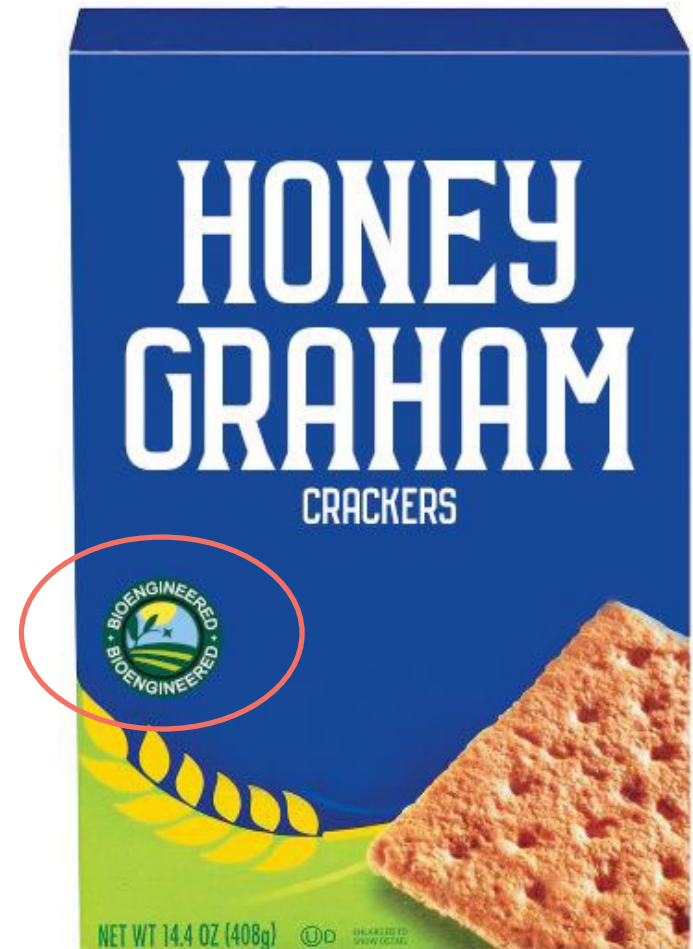
Disclosure Methods

- Text Disclosure
 - “Bioengineered Food”
 - Foods that are bioengineered or multi-ingredient food that has all bioengineered ingredients
 - “Contains a bioengineered food ingredient”
 - Foods that contain one or more ingredients derived from a bioengineered source



Disclosure Methods

- Symbol Disclosure
 - Black and white or color options
 - Same placement requirements



Disclosure Methods

- Electronic or Digital Link
 - Must include directions such as “Scan here for more food information”
 - Must include a telephone number for disclosure
 - Clear instructions included
 - Disclosure accessible 24/7
 - May be pre-recorded



Disclosure Methods

- Text Message Disclosure
 - Clear instructions included “Text XXX-XXX-XXXX for more food information”



Disclosure Methods – Special Requirements

- Small Food Manufacturers
 - Annual receipts between \$2.5 mil and \$10 mil
 - Telephone number
 - Website URL



Disclosure Methods – Special Requirements

- Small Packages
 - 40 square inches or less of available labeling space
 - May use modified disclosure methods:
 - Electronic or digital link – “Scan for info”
 - Text message – “Text XXX-XXX-XXXX for info”
 - Telephone number – “Call XXX-XXX-XXXX for info”



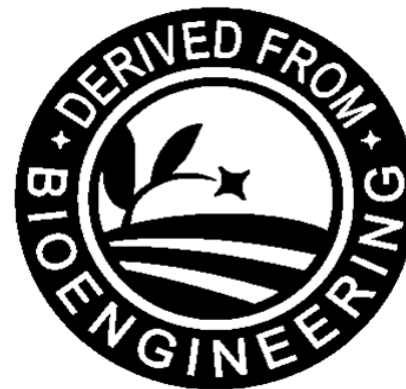
Disclosure Methods – Special Requirements

- Very Small Packages
 - 12 square inches or less of available labeling space
 - May use pre-existing URL or telephone number



Disclosure Methods – Voluntary Disclosure

- If exempt from disclosure because it was refined to remove modified genetic material, may voluntarily make a modified disclosure
 - “Derived from bioengineering”
 - Any of the disclosure methods may be used



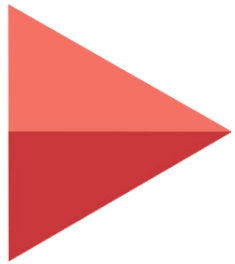
Recordkeeping

- Exact records are not specified but should contain sufficient data
- Must be kept at least 2 years after food is sold or distributed for sale
- Records must be provided to AMS within 5 business days

Absence Claims

- Non-GMO or Not Bioengineered
 - Not prohibited
 - Not defined
 - FDA/FSIS retain authority
 - Organic certification sufficient





Other Claims



Carbohydrate Claims

- “Low Carb” is an undefined nutrient content claim
- More acceptable call outs that companies have trademarked
 - Carb Sense™
 - Carb Counter™
 - Carb Chopper™
 - Carb Balance®

Carbohydrate Claims

- “Net Carb” amounts can be called out if the information about how it is calculated is on the label
e.g.,
$$\text{Net Carbs} = \text{Total Carbohydrate} - \text{Dietary Fiber} - \text{Sugar Alcohols}$$
- However, “Low Net Carb” would again be an undefined nutrient content claim.

Protein Claims

- A statement of the amount of protein outside of the Nutrition Facts, e.g., “5g Protein” is considered a nutrient content claim and is subject to claim requirements
 - General disclosure levels for total fat, saturated fat, cholesterol and sodium
 - Declare % daily value for protein in nutrition panel after correcting protein with the Protein Digestibility Corrected Amino Acid Score (PDCAAS)

Protein Claims

- Many plant proteins have limiting amino acids so the corrected protein amount is often less than the declared amount
- Wheat and corn both are both limited in lysine
- Legumes such as beans, peas, and lentils have lysine that can provide a better balance of amino acids

Questions

