



WEBINAR



How to Comply with the Bioengineered Food Disclosure Law

Presented by **ESHA Research**

Wednesday, February 26, 2020

11:00 AM PDT | 1:00 PM CDT | 2:00 PM EDT



ESHA Research

ESHA Research was established in 1981 as one of the very first nutrition software solutions. Today, ESHA's suite of nutritional software products, services, and databases are recognized as the industry's top choice for food and supplement formulation, recipe development, labeling, nutritional analysis, and regulatory compliance.

ESHA Solutions

- Genesis R&D[®] Food Formulation
- Genesis R&D[®] Supplement Formulation
- Food Processor[®] Nutrition & Diet Analysis
- Consulting Services

Our mission is to help remove the complexity of product development and regulatory compliance for the food, beverage, and supplement industries through software, services, and nutritional databases.



Genesis R&D Foods

Genesis R&D Foods, first released in 1991, is designed to help users manage processes, overcome industry challenges, and meet federal requirements. Industry professionals use Genesis R&D for quick and accurate nutrient evaluation, virtual product development, nutrition labeling, and regulatory compliance.

- Product Development
- Formulation Analysis
- Menu Analysis
- Reporting
- Regulatory Compliance





Upcoming Webinars

March 18, 2020 | FAQ: Nutrition Facts Label Settings in Genesis R&D Foods

Creating a government-compliant Nutrition Facts label in Genesis R&D is simple. One click and you're done. However, creating *your* label, one that conforms to your exact design, layout, nutrient display, and other specifications, can take a little more fine-tuning. Luckily, Genesis R&D offers a host of modification options to let you get your label just the way you want it, and making these changes is easier than you think. During this webinar, we will answer the most frequently asked "How do I ...?" questions that come up about basic formatting, nutrient display, and more involved configurations.

April 15, 2020 | Genesis R&D Foods Nutrition Reports Overview

The Genesis R&D Foods program offers a variety of reports to help you analyze your formulas and recipes. During this webinar, we review the different nutrition analysis reports, report options, customizations, printing, and exporting.

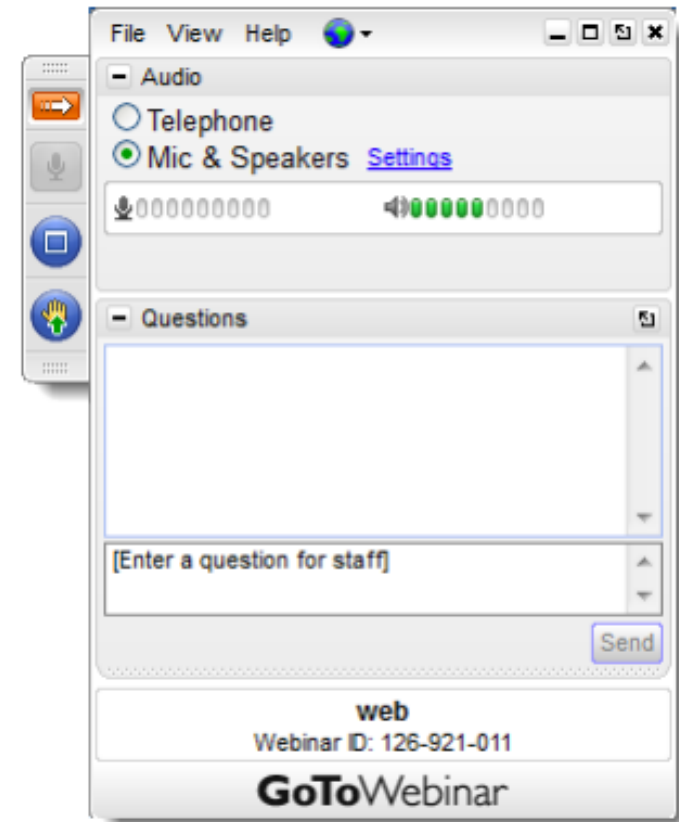
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- ✓ All webinars available on our website
- ✓ Submit your questions in the GoToWebinar control panel
- ✓ We'll email a copy of the recording and the slides following the webinar

WEBINAR



What we'll cover today

- Implementation and compliance dates
- What is considered a bioengineered food and what is not
- Labeling and disclosure options
- Record keeping
- Attributes feature in Genesis R&D
- Q&A



National Bioengineered Food Disclosure Standard (NBFDS)



Definition

- Bioengineered foods are *“those that contain detectable genetic material that has been modified through in vitro recombinant deoxyribonucleic acid (rDNA) techniques and for which the modification could not otherwise be obtained through conventional breeding or found in nature.”*
- “Bioengineered Foods” is the term to use for *this* Standard
 - Previous related discussions center around “GMO”, “non-GMO”

USDA Agricultural Marketing Service

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





Implementation & Compliance Dates

January 1, 2020: Implementation Date (Voluntary Compliance)

- During this period, manufacturers should prepare to comply with the BE Disclosure Standard
 - Review foods and formulas and identify the foods that must bear BE disclosure
 - Gather documentation to support BE declarations and exemptions
- Companies may declare BE on products during the implementation period

Note: For small food manufacturers (\$2.5M to <\$10M annual sales) there is an extended implementation date of January 1, 2021.

January 1, 2022: Mandatory Compliance Date

- Foods entering into commerce *must* be labeled to comply with BE Disclosure Standard
- The date that the food is labeled (label applied to the packaging)



Who Must Declare?



- Food manufacturers
- Dietary Supplements manufacturers
- Retailers of packaged and bulk foods
- Importers



Exemptions for BE Disclosure

- Food served in restaurants or similar food establishments
- Very small food manufacturers (<\$2.5 million annual receipts)
- Foods certified 100% organic under National Organic Program
- Food derived from an animal is not considered BE solely because it was fed BE substance
- Food that contains up to 5% inadvertent or technically unavoidable BE substance per ingredient
- Certain foods containing meat, poultry, or eggs
- Foods where broth, stock, water, or similar is the first ingredient and meat, poultry, or eggs is the second ingredient

Similar Retail Food Establishments



“Similar retail food establishments” is defined as:

- Cafeterias, lunchrooms
- Food stands, food trucks
- Transportation carriers (such as a trains or airplanes)
- Bars, taverns, lounges, saloons
- Other similar establishments operated as an enterprise engaged in the business of selling prepared food to the public
- Salad bars, delicatessens, and other food enterprises located within retail establishments that provide ready-to-eat foods that are consumed either on or outside the retailer’s premises





Refined Products

Highly refined products (made from bioengineered ingredients) that no longer contain detectable modified genetic material are exempt from the Standard disclosure.

Some refining processes have been validated to show that, when followed, no detectable modified genetic material remains in the resulting product ingredient. If an ingredient is subjected to such a validated refining process, this demonstrates that the food or ingredient does not contain bioengineered material.



Allowed Threshold and Unavoidable Presence

Threshold

- Recognizes the realities of the supply chain and acknowledges that BE and non-BE food and ingredients are often grown, harvested, transported, and processed in close proximity to one another. There may be a trace amount of a BE substance that remains on shared equipment.
- Exempts food in which no ingredient intentionally contains a bioengineered substance and allows for the inadvertent or technically unavoidable presence of a BE substance – up to 5% in each ingredient.

Inadvertent or technically unavoidable presence of a BE substance

- Occurs unintentionally when reasonable and customary practices are implemented to separate BE and non-BE ingredients.
- Example: a small amount of BE corn that remains in a combine after a reasonable effort to remove all BE corn before harvesting non-BE corn, if the BE materials are present in an amount of up to 5%.
- *Not* technically unavoidable example: a food manufacturer was producing a non-BE product, ran out of one non-BE ingredient, and replaced it with a BE version of that ingredient, would be considered an *intentional* use and require a BE food disclosure.



Exemptions: Meat, Poultry, Eggs, and Catfish

- If the first ingredient is subject to the Federal Meat Inspection Act (FMIA), the Poultry Products Inspection Act (PPIA), or Eggs Product Inspection Act (EPIA)
- or -
- If the first ingredient is broth, stock, water, or similar solution, and the second ingredient is subject to FMIA, PPIA, or EPIA

Reviewing Ingredients



BE Labeling Status	Ingredient Statement	Why?
Exempt , Does Not Require BE Declaration	Ingredients: Chicken breast, wheat flour, water, sugar, corn starch, spices, salt, soybean oil.	First ingredient: poultry
Exempt , Does Not Require BE Declaration	Ingredients: Vegetable broth, chicken, onion, red bell pepper, corn, black beans, corn flour, salt, chicken fat, spices, modified food starch.	First ingredient: broth Second ingredient: chicken
Not Exempt , Requires BE Declaration	Ingredients: Vegetable broth, potatoes, chicken, peas, carrots, modified food starch, soybean oil.	First ingredient: broth Second ingredient: <i>not</i> meat, poultry, eggs, etc.
Not Exempt , Requires BE Declaration	Ingredients: Potatoes, milk, butter (cream, salt), sodium benzoate (preservative), soybean oil, spices.	First ingredient: potatoes



USDA AMS List of Bioengineered Foods

“The Agricultural Marketing Service (AMS) developed the List of Bioengineered Foods to identify the crops or foods that are available in a bioengineered form throughout the world and for which regulated entities must maintain records. These records will inform regulated entities about whether they must make a bioengineered food disclosure. The list includes any BE crops or foods that are to capture any BE crops or foods that are currently in legal production somewhere in the world. New BE products continue to be developed. Even if a food is not included on the List, regulated entities whose records show that a food they are selling is bioengineered must make appropriate disclosure of that food. AMS will review the List annually and, if necessary, make updates through the federal rulemaking process.”

For foods on the list, regulated entities are required to keep customary and reasonable business records regarding the food.

- 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

<https://www.ams.usda.gov/rules-regulations/be/bioengineered-foods-list>

Product Specific Info from the BE List - Canola



BE Canola Crop Summary

BE Canola Events in the Food Supply

BE Event	Trait	Producing Countries	Comments	FDA Review
HCN92	Herbicide Tolerance	Australia, Canada, United States	Trade Name: Liberty Link™ Innovator™	BNF-023
23	High Laurate	Australia, Canada, United States	Trade Name: Laurical™	BNF-025
GT73	Herbicide Tolerance	Australia, Canada, United States	Trade Name: Roundup Ready™	BNF-020
MS1	Pollination	Australia, Canada,	Trade Name:	BNF-032

“BE Canola Production BE canola is commercially produced in three countries: Australia, Canada and the United States. Canola from these three countries should be presumed to be canola.”

In 2017, 30% of all global canola production was BE canola (Statistica, 2018). Note that in the ISAAA database, canola is listed in two separate categories: Argentine and Polish. These are historic terms that refer to Brassica napus and B. rapa, respectively. No B. rapa BE canola has ever been commercialized...”



Record Keeping

- Companies are required to keep records of a food's bioengineered status for two years beyond the date that the food is sold or distributed.
 - Records can be kept in paper or electronic form.
 - Entities must be able to produce records within five days of any request.
- A variety of records maintained in the *normal course of business* may be used to verify the BE status of a food or ingredient (*e.g. supply chain documents, bills of lading, invoices, supplier or broker statements, third-party certifications, laboratory testing results, validated process verifications, and others.*)
- Record keeping might indicate a known BE source, such as use of ingredients from the AMS List of Bioengineered Foods.
- Or, record keeping might show that an ingredient or food is sourced from a non-bioengineered crop. Such as ingredients or foods that are organic certified or records that show a non-BE crop variety was used.

BE Disclosure

Disclosure Options

- **Text Disclosure:** “Bioengineered food” or “Contains a bioengineered food ingredient”
- **Graphic Disclosure:** USDA approved symbol
- **Electronic or Digital Disclosure:** “Scan here for more food information” accompanied by a phone number and statement “Call...for more food information”
- **Text Message Disclosure:** “Text [command word] to [number] for bioengineered food information” – sends immediate disclosure to consumer’s phone

Special Cases

- **Additional options for small entities:** Using telephone or internet address to disclose information
- **Small packages:** Abbreviated statements, like “Scan for info” or “Call for info”
- **Very small packages:** Can use existing phone # or website



USDA approved symbols



Where to Disclose BE

- Information panel adjacent to the manufacturer or distributor information
- or -
- Principal display panel (PDP)
- *if there is insufficient space on the information panel or PDP, then BE disclosure can be placed on any other part of the packaging that is likely to be seen by the consumer under typical shopping conditions*

Don't Forget!

- BE disclosure should use sufficient size and clarity to be conspicuous on the product packaging
- For bulk foods, signage or outer packaging on or near the bulk containers may be used



PDP

Information Panel



Which BE Declaration to Use

“Bioengineered food”

Used for single ingredient item or food that contains all bioengineered ingredients

“Contains a bioengineered food ingredient” or “Contains bioengineered food ingredients”

Used for foods that contain combination of bioengineered and non-bioengineered ingredients

“Derived from bioengineering”

Used only with voluntary disclosure on foods derived from BE ingredients but the food has non-detectable amounts of genetic material, e.g. highly refined products





Attributes in Genesis R&D

- Categorize and document properties or characteristics of foods
- Assign to Ingredients and Recipes
- Ingredient Attributes carry forward to Recipes
- Attach documentation to support the Attribute

Ingredient	Attributes		
	Property	Qualifies	Documentation
Nutrients	Bioengineered ⓘ	<input checked="" type="checkbox"/> <input type="checkbox"/> ??	<input checked="" type="checkbox"/> Biogenereed-report.docx
Yields/Measures	No Artificial Flavor	<input checked="" type="checkbox"/> <input type="checkbox"/> ??	<input type="checkbox"/> ⊕
Cost			
Groups			
Attributes			
Ingredient Statement			
Allergens			
Attachments			

⊕ [Add an attribute](#)



Attributes Indicators



= yes, attribute applies



= no, attribute does not apply



= undetermined

Recipe Information

Recipe

Nutrients

Measures

Brix Calculation

Cost

Groups

Attributes

Compare To

Preparation Method

Reference Amount

Nutrient Content Claims

Notes

HACCP

Attachments

Attributes

Qualifies	Property	Override		Documentation
✓	Bioengineered ⓘ	✓	⊘	clear
✓	No Artificial Flavor	✓	⊘	clear

+ [Add an attribute](#)

OK Cancel



Attributes Rules

Attributes in Genesis R&D adhere to one of two rules:

- “All items in the food must have the attribute”

- or -

- “At least one item in the food must have the attribute”

Bioengineered Rule: if one ingredient meets the determination of bioengineered, then the Recipe *could* be considered bioengineered



Genesis R&D Training

Genesis R&D Training | April 28-30, 2020 | Oak Brook, IL

Professional *and/or* Advanced training session. The first two days cover the fundamentals of the Genesis R&D Food program: creating ingredients, building recipes/formulas, nutrition analysis and reporting, labeling, and best practices. In addition, you can attend a third day of Advanced instruction, or just attend the Advanced session as a single day. Advanced training presents more complex scenarios and more comprehensive regulatory issues.

Genesis R&D Training: [Menu Labeling](#) | May 14-15, 2020 | Oak Brook, IL

Instruction covers the fundamentals of the Genesis R&D Food program: creating ingredients, building recipes/formulas, nutrition analysis and reporting, labeling, and best practices. In addition, the class includes direction and discussion on the 2018 Menu Labeling requirements and Menu Label features in Genesis R&D.

Genesis R&D Training: [Canadian Labeling](#) | June 16-17, 2020 | Oak Brook, IL

Professional training session with Canadian labeling. This two-day class cover the fundamentals of the Genesis R&D Food program: creating ingredients, building recipes/formulas, nutrition analysis and reporting, labeling, and best practices. In addition, the labeling instruction focuses on Canadian labeling regulation and creation.

See the Full 2020 Schedule: <https://www.esha.com/news-events/training-schedule/>

QUESTIONS?



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