

WHITEPAPER

How to Efficiently Comply with Bioengineered Food Disclosure per NBFDS



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NBFDS: A Brief History

INTRODUCTION

The USDA's new National Bioengineered Food Disclosure Standard's [NBFDS] mandatory compliance date of January 1, 2022, is less than a year away. The Standard is complex and as new bioengineered crops become commercially available, products will be subject to further review. This whitepaper explores the challenges to comply with the standard and presents solutions to achieving and staying in compliance.

THE NATIONAL BIOENGINEERED FOOD DISCLOSURE STANDARD

Currently, the food industry is seeing an acceleration in consumers' desire for healthier foods. This desire for transparency into the food supply chain initially drove demand for voluntary disclosure standards such as Non-GMO Project Verification, USDA Organic Certification, and Certified Humane.

The past decade has seen increasing consumer concern regarding the foods they eat, but the COVID-19 global pandemic has further amplified this trend. For example, according to the Organic Trade Association, the pandemic has had dramatic consequences for the organic sector in 2020.

According to Laura Batcha, CEO and executive director of the Organic Trade Association, "Our 2020 survey looks at organic sales in 2019 before the coronavirus outbreak, and it shows that consumers were increasingly seeking out the Organic label to feed their families the healthiest food possible. The pandemic has only increased our desire for clean, healthy food."

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- Laura Batcha, CEO & Executive Director, Organic Trade Association

NBFDS: A Brief History

One of the aspects of organic and other voluntary certifications is that they draw on consumers' desire to know their food origins and production methods. This preference for transparency has increased the pressure on food manufacturers to disclose more than just their food's nutritional aspects.

In response, the United States government is now taking a more assertive approach to meeting public outcry for greater transparency. In 2016, Congress amended the Agricultural Marketing Act of 1946 with the National Bioengineered Food Disclosure Law. It directed the USDA to establish a standard requiring food manufacturers, importers, and individual retailers to ensure bioengineered foods are appropriately disclosed.





The National Bioengineered Food Disclosure Standard [NBFDS] was declared on December 20, 2018, by U.S. Secretary of Agriculture Sonny Perdue and a mandatory compliance date was set for January 1, 2022. Regulated entities can voluntarily comply with the Standard until December 31, 2021.



Steps to Compliance

The Standard involves many nuances and exceptions and products are subject to further review as new bioengineered crops become commercially available. As such, companies have the daunting task of understanding which ingredients pose a BE risk, reviewing them against the standard, and determining which elements apply to their formulation.

They must then determine whether their products are required to make a BE disclosure. If companies want to provide safe food products to consumers that do not contain bioengineered ingredients, they need to determine relevant compliance pathways. These may include not marketing products that require disclosure, reformulation, alternate sourcing, or DNA detectability testing.





STEP ONE: Determining who and what is regulated

First, there is the question of who must regulate. Regulated entities include food manufacturers, importers, and retailers that package and label food for retail sale or sell bulk food items. However, this does not include restaurants and similar retail food establishments or very small food manufacturers (<\$2,500,000 annual receipts).

If you are to comply with the new Standard, you will have to determine which foods/ingredients are subject to the mandate. According to the USDA, a bioengineered food is one that "contains genetic material that has been modified through in vitro rDNA techniques and for which the modification could not otherwise be obtained through conventional breeding or found in nature."

Bear in mind that foods in which the modified genetic material is not detectable are not bioengineered foods.

Steps to Compliance

STEP TWO: Review against the Standard

This then introduces the challenge of determining which elements of a product represent one of the 13 currently listed bioengineered foods (and these are subject to updates):

- 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)
- Sugar beet





STEP THREE: Understand what parts of the rule apply to your formulation

Detection requires extensive testing, supply chain insight, and documentation. Any of these high-risk crops previously noted can be translated into thousands of products and ingredients sourced from numerous global suppliers.

Products may require disclosure based on those various ingredients. For example, if the first ingredient on the label is subject to FMIA, PPIA, or EPIA, it is not subject to the Standard. However, if other components appear first on the label, it may be.

Steps to Compliance

Hence, detectability becomes a critical element of determining compliance.

According to the USDA, modified genetic material is not detectable if:

- Records verify the product is made with non-bioengineered food; such records may include:
 - Organic certification
 - Documentation that the ingredient is sourced from a country that does not allow that specific ingredient in a bioengineered form
- Records verify that the food is refined using a process validated to render the modified genetic material undetectable; such documents may include:
 - Records indicating that a specific process is used to refine an ingredient, using the analytical testing that meets the NBFDS's performance standards, to render any modified genetic material undetectable.
- Testing records for the specific food confirm the absence of detectable modified genetic material.

STEP FOUR: Correctly choose the relevant pathway for compliance

Once the need for compliance is determined, disclosure must be addressed per the Standard. Requirements for small food manufacturers – defined as \$2,500,000 - \$10,000,000 in annual receipts – include a telephone number or website. Small and tiny packages may disclose with shortened electronic or digital statements, URL, text message, or phone number.

Electronic or digital disclosure must include the instructions to "Scan here for more food information," or similar language that reflects a change in technology, such as "Scan anywhere on the package for more food information."

Additional requirements apply for telephone, text, and URL disclosures.

On-package disclosures include "Bioengineered food," "Contains a bioengineered food ingredient," or "Contains bioengineered food ingredients." Two new disclosure symbols are also available.



Prospective Solutions

1. DO THE ENTIRE THING YOURSELF

Considering exceptions and gray areas, the logistics become complicated and time-consuming for even the most seasoned regulatory and quality professionals.

2. OUTSOURCE SOME OF IT

For some manufacturers, this may be an option. However, it will still require a significant amount of human resources and paperwork.

3. OUTSOURCE ALL OF IT

For mid-to large-scale manufacturers with multiple product lines and complex supply chains, this is the best option. FoodChain ID has found that many companies do not have the internal technical expertise, resources, or time required to do this – particularly in light of the supply chain disruptions caused by the global pandemic.





AN OUTSOURCING OPTION TO CONSIDER

As one of the world's leading group of companies specializing in food safety, quality, and sustainability solutions, FoodChain ID is uniquely positioned to assist brand manufacturers in navigating this new mandate - especially if they're currently using FoodChain ID's existing solutions to manage global regulatory requirements and certifications.

FoodChain ID specializes in GMO detection, developing proprietary DNA extraction techniques as part of the first commercial laboratory for GMO food identification. We also created the first Non-GMO Certification scheme and became the founding technical administrator for the Non-GMO Project.

Prospective Solutions

Leveraging this expertise, FoodChain ID's NBFDS compliance service identifies products containing BE ingredients at a level of sensitivity required to achieve compliance and provides recordkeeping and supply chain management through our existing Supply-Trak® compliance database.

SupplyTrak is a cloud-based multi-assessment compliance database that maps customer's supply chains, sharing data between programs (Non-GMO-Project Verification/USDA Organic/BE

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Compliance). It enables clients to manage, track, and comply with them all efficiently, reducing the time and complexity of the BE evaluation and yearly program renewals.

This technology addresses several needs, including a leaner document management process. SupplyTrak organizes and stores program documents for re-use and management over time and keeps supply chain data easily accessible.

SupplyTrak's ability to auto-fill forms streamlines the process of data input. Further, it integrates program supply chain data across assessments to be shared and used to pre-populate forms, simplify data entry, and decrease time spent on certifications and renewals.

If disclosure is deemed necessary, FoodChain ID will recommend appropriate disclosure per NBFDS' requirements. FoodChain ID's advisory services also offers options on how customers can avoid using bioengineered substances if necessary.

Of the many lessons learned by our company in dealing with the global food supply chain, one of the most critical is that leaner teams mean a renewed focus on operational effectiveness. Our BE Compliance service is a crucial tool that food manufacturers and brand owners can leverage to quickly and efficiently meet the new NBFDS deadlines.



Meet your NBFDS Compliance needs with FoodChain ID. Contact a specialist today.





Expertise in GMO Avoidance

FoodChain ID was the first commercial laboratory in the United States that tested for GMO's and was the founding technical administrator for the Non-GMO Project Verification program – where we have verified more products than all other technical administrators combined.

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