

**COMMENTING ON THE NATIONAL  
BIOENGINEERED FOOD  
DISCLOSURE STANDARD  
A WEBINAR FOR BRANDS AND  
RETAILERS**

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June 20, 2018

# BACKGROUND

- In late July 2016, a law was enacted directing the USDA to establish a National Bioengineered Food Disclosure Standard (NBFDS, Public Law 114-216); deadline for implementation was 2 years (July 29, 2018)
- Passage of this law followed two decades of Americans demanding GMO labeling, which had culminated in states starting to pass their own labeling laws; this federal law (NBFDS) pre-empted all state laws, making them illegal
- The USDA held an initial public comment period in July 2017
- On May 3, 2018, it published the long-awaited draft standard, which is meant to outline the actual rules for GMO labeling
- Comments on the draft are being accepted through July 3, 2018

# NON-GMO PROJECT POSITION

- The Non-GMO Project is a non-profit organization that believes that everyone has a right to know what's in their food, and deserves access to non-GMO choices
- As such, the Non-GMO Project has always been a supporter of meaningful mandatory labeling and played an active part in raising awareness about the various state efforts to label GMOs
- The NBFDS is about labeling foods that DO contain GMOs; it does not have any guidelines about non-GMO labeling, and non-GMO labels like the Non-GMO Project Butterfly are outside the scope of this law and standard
- Our intention in commenting, and encouraging others to comment, is to leverage our unique 11.5 years of experience with consumer communication and non-GMO supply chains to help this law be as meaningful as it can be
- There is no doubt that the rigor of the Non-GMO Project Standard will vastly exceed that of the NBFDS, and the Butterfly will remain the go to symbol for the 46% of shoppers actively seeking to avoid GMOs

# OVERVIEW OF DRAFT NBFDS

- The draft rule consists of 84 pages of background and questions, followed by 20 pages of an actual standard
- The draft standard does not provide a clear indication of how the final rule will treat a number of important topics
- Where a strong direction is indicated, there is cause for concern in numerous areas
- Our focus in this presentation is on the parts of the rule that we believe to be of greatest significance when it comes to giving Americans a GMO labeling standard that is as meaningful, clear, and accessible as possible

# KEY ISSUES

- INCLUSION/MEANINGFULNESS
  - Detectability
  - Definitions
  - Thresholds
  - Testing Methodology
  - Lists of “Bioengineered” Food
- CLEAR LABELING
  - Text claim language
  - Symbols
- ACCESSABILITY (Disclosure Method)
  - QR codes & Text messages
- REASONABLE OPPORTUNITY TO COMMENT FURTHER

# INCLUSION: DETECTABILITY

- The Standard should include ALL GMOs, regardless of whether or not they have detectable transgenic DNA in the finished product
  - Most refined, processed food cannot be tested for GMO content due to the limits of current testing methodology
  - Likewise, new GMOs like those produced through various gene editing techniques (e.g. CRISPR, RNAi) are not yet commercially testable
- This is the number one issue from our perspective, as if the rule contains an exemption for products in which “the modified genetic material cannot be detected,” the majority of GMO foods would be exempt from disclosure

# INCLUSION: DEFINITIONS

- The NBFDS should use the definition put forth in the Codex Alimentarius; this is arguably the most authoritative international definition of genetic engineering, as it is what the World Trade Organization looks to in resolving trade disputes. (This is one reason the Non-GMO Project has aligned our definition of Biotechnology with Codex.)

- The Codex definition is as follows:

*Modern Biotechnology – the application of:*

- a. in vitro nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and the direct injection of nucleic acid into cells or organelles; or*
  - b. fusion of cells beyond the taxonomic family that overcome natural physiological, reproductive, or recombination barriers and that are not techniques used in traditional breeding and selection.*
- Rather than inventing a new definition, the NBFDS should align with the definition that is both the most authoritative internationally and which also forms the basis for the United States' most established non-GMO program (the Non-GMO Project).

# INCLUSION: THRESHOLDS

- The draft standard lays out three options for threshold:
  - #1: Food in which an ingredient contains a bioengineered substance that is inadvertent or technically unavoidable, and accounts for no more than five percent (5%) by weight of the specific ingredient OR
  - #2: Food in which an ingredient contains a bioengineered substance that is inadvertent or technically unavoidable, and accounts for no more than nine-tenths percent (0.9 %) by weight of the specific ingredient; OR
  - #3: Food in which the ingredient or ingredients that contain a bioengineered substance account for no more than five percent (5%) of the total weight of the food in final form.
- Option 2 is by far the strongest, aligning most closely with the 0.9% threshold used by the Non-GMO Project and used in the E.U.; however it does have some technical errors that should be corrected to ensure correct interpretation:
  - Food in which any ingredient contains a bioengineered substance that is inadvertent or technically unavoidable, and accounts for no more than nine-tenths percent (0.9 %) ~~by weight~~ of the specific ingredient



# INCLUSION: TESTING METHODOLOGY

- While the draft makes several references to testing records, there is no detail in the document about what constitutes valid content in a testing record. The following points are critical to ensuring meaningful testing (and therefore a meaningful rule):
  - Testing to determine GMO content should be conducted using Real-Time or Digital PCR method; testing should be conducted by an ISO 17025 accredited laboratory
  - The testing to establish GMO content must be conducted on a sample where appropriate laboratory controls indicate that the DNA of the input is sufficiently intact to allow for valid quantitative analysis using PCR; a non-detect result based on a test of a highly refined ingredient is not an adequate basis for exemption
  - Records must show that a valid and meaningful sampling plan was employed in accordance with industry standards (e.g. GIPSA)
  - Tests must demonstrate GMO content of less than 0.9% for all ingredients in order for a product to be exempt from labeling

# INCLUSION: THRESHOLDS & TESTING (CONT)

- One final but important note on thresholds and testing is that these considerations don't work for the new GMOs that are not yet commercially testable (e.g. products of CRISPR, RNAi, etc.)
- It is therefore critical that the NBFDS include an Affidavit requirement for ingredients that may have been sourced from untestable GMO crops (this would be in addition to testing records when appropriate)
  - For example, currently there are both testable and untestable varieties of genetically engineered canola on the market; sufficient records should include BOTH documentation of compliant testing (as described on the previous slide) AND an affidavit stating that the canola was not developed using oligonucleotide directed mutagenesis (ODM), which is not yet testable

# INCLUSION: LISTS OF “BIOENGINEERED FOOD”

- The draft contains two “Lists of Bioengineered Foods”
  - **Commercially Available – Highly Adopted** (proposed adoption threshold of 85%) – requires a “Contains Bioengineered Ingredients” disclosure
  - **Commercially Available** (no adoption threshold proposed) – requires a “May contain...” disclosure
- Steps are laid out proposing how the list would be updated annually
- The Non-GMO Project uses a 14-point matrix to assess risk level, and a 10% adoption rate is one of the criteria; we employ a full-time research analyst to track changes to risk and our Standard Revision Terms of Reference allow for real-time changes to our risk lists as needed
- Accordingly, we propose that:
  - A 50% adoption rate be applied for the “Highly Adopted” list
  - A 10% threshold be applied for the “Commercially Available” list
  - The final rule should include a mechanism for no less than QUARTERLY updates to the lists

# CLEAR LABELING: TEXT CLAIM LANGUAGE

- The only term allowed for text claims in the rule is “Bioengineered” – this is a medical term that is not recognized by consumers and has no meaning in the food industry
- The rule MUST allow for disclosure using plain English terms that people understand; the most well-established term is “genetically engineered;” for example, this is the term used in the Whole Foods Market GMO Labeling Transparency Policy established in 2013, and which thousands of brands have already changed packaging to comply with; it is also the language used in various state labeling efforts and voluntarily adopted by large CPGs like Campbells
- Restricting text claims to an unrecognized single term (“Bioengineered”) would be burdensome and expensive for food companies and misleading to consumers
- Ultimately, the law is only meaningful if consumers understand what the label says

# CLEAR LABELING: SYMBOLS

- Again, the rule MUST allow for disclosure using plain English terms that people understand; the acronym “BE” is newly invented and has no meaning to the public
- As such it is inherently misleading
- The only acceptable acronyms should be “GMO” or “GE”
- Further, the symbols proposed convey a stylistic bias not present in other AMS logos



VS



Existing AMS logos are aesthetically neutral

Proposed NBFDS logos clearly convey a positive bias

# ACCESSIBILITY: QR CODES & TEXT MESSAGES

- The draft rule proposes allowing QR codes for disclosure; this requires a smartphone and broadband connection, two criteria that discriminate against more than 100 million Americans—especially many in rural, low-income, minority and elderly populations; the USDA's own 2017 study confirms this
- The draft also proposes a text message option, which for many people would impose additional costs for each message sent and received
- Both of these options are time consuming and unrealistic; they impede rather than promote the disclosure the law is meant to support
- **The only acceptable disclosure is plain English terms that are well-established and well understood by the general public; e.g. GMO, GE, genetically engineered, genetically modified**

# REASONABLE OPPORTUNITY TO COMMENT FURTHER

- The draft NBFDS published on May 3 is not a complete draft; it leaves many significant questions unanswered
- Because of the technical complexity of the issue, there are critical dependencies within the rule that are impossible to adequately comment on without seeing a fully developed draft that indicates clear direction
- **The public should have another opportunity to comment once a fully developed standard has been drafted**

# KEY ISSUE RECAP

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# STEPS FOR ACTION

- Reminder: Comments are due by July 3, 2018
- Submit comments via the Federal eRulemaking portal at <https://www.regulations.gov/comment?D=AMS-TM-17-0050-0004>
- All comments should include:
  - Header:
    - Date
    - U.S. Department of Agriculture
    - Agricultural Marketing Service
    - Docket No: AMS-TM-17-0050
    - RE: Comments on proposed regulations to implement the National Bioengineered Food Disclosure Standard
  - Background about your organization, with a focus on why your perspective on this is valuable
  - Your comments on the rule
- **A downloadable template is available on the Non-GMO Project website**