



Bioengineered Food Disclosure Updates

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Where do things stand?

- Compliance date = Jan. 1, 2022
 - AMS has rejected the industry requests for an extension
- AMS has finalized its testing guidance
- Now we wait (patiently/impatiently) for information and testing records from suppliers in order to make disclosure decisions



Agenda

- Review of the regulation
- New guidance on detectability testing and validation of refining processes
- Managing upcoming compliance dates

Scope of standard

What foods are covered?

- Law covers:
 - Products subject to labeling requirements under the FFDCA
 - Meat, poultry, and egg products subject to labeling requirements of the FMIA, PPIA, and EPIA **only if**:
 - the most predominant ingredient would be subject to FFDCA; OR
 - if the most predominant ingredient is broth, stock, water, or a similar solution, and the second most predominant ingredient is subject to the FFDCA
- All other meat, poultry, and egg products are excluded
- AMS defines “predominance” as the order of ingredients on the label by weight
 - “Predominant ingredients are those most abundant by weight in the product”



BE Food Defined

- *Bioengineered food* means—
 - A food that **contains 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**; *provided that*
 - **Such a food does not contain modified genetic material if the genetic material is not detectable** pursuant to § 66.9.

Where to Start: Bioengineered foods list

- Alfalfa
- Apple (Arctic™ varieties)
- Canola
- Corn
- Cotton
- Eggplant (BARI Bt Begun varieties)
- Papaya (ringspot virus-resistant varieties)
- Pineapple (pink flesh)
- Potato
- Salmon (AquAdvantage®)
- Soybean
- Squash (summer), and
- Sugar beet



Bioengineered foods list

- Non-exhaustive!
- The list is just a starting point – a “tool” to help regulated entities – also must disclose if “**actual knowledge that a food is bioengineered**”
 - AMS example: “enzymes, yeasts, and other similar foods produced in controlled environments”
 - Simply because a crop or food is on the list does not necessarily mean it requires disclosure; if, for example, the regulated entity maintains records that they are using a non-bioengineered version of the food or the food does not contain
- AMS will maintain more detailed information on its website about each food/crop on the list to help determine whether disclosure is required

Treatment of refined ingredients

- For refined foods or ingredients that are derived from BE sources (e.g., corn syrup derived from BE corn), no disclosure is required if the food does not contain detectable modified genetic material
- Final rule sets out how to demonstrate that modified DNA is undetectable
 1. Records verifying the food is from a non-BE source
 2. Records showing the food has been subject to a refinement process “validated” to render modified genetic material undetectable
 - Once process is validated, additional testing not needed, provided no significant changes to process
 3. COAs or other testing records appropriate to the specific food tested that confirm the absence of modified genetic material
- Rule includes standards of performance for testing
- AMS states that if testing methodologies evolve so that the modified DNA in a food becomes detectable in the future, the food would be subject to disclosure

Exemptions

1. Food served in a restaurant or similar retail food establishment
2. Very small food manufacturers
 - (Less than \$2.5M in annual receipts)



Exemptions, continued

3. A food derived from animals is not considered a BE food solely because the animal consumed feed produced from, containing, or consisting of a BE substance
- Milk, meat, eggs would not be considered “bioengineered” solely because the cow, animal, or chicken consumed BE feed
 - Insects are considered animals, so honey is exempt
 - Rennet and other enzymes derived from animals are also exempt (but microbial rennet and enzymes are not categorically exempt)



Exemptions, continued – organic foods

4. Foods certified under the National Organic Program
 - Covers all NOP certified label categories (“100% Organic,” “Organic,” and “Made with Organic _____”)
 - Does not cover products with less than 70% organic ingredients



Exemptions, continued – threshold

5. Foods with less than a designated amount of BE substances due to inadvertent presence
 - Statute directs AMS to determine the amounts of a “BE substance” that may be present in order for a food to be considered a BE food
 - “BE substance” = substance that contains modified genetic material
 - e.g., BE soy in wheat flour would be a “BE substance”
 - Final rule establishes a threshold for the inadvertent or technically unavoidable presence of BE substances of **up to 5% for each ingredient**, provided that no ingredients are intentionally used in the food that contain a BE substance
 - No threshold for intentionally added BE ingredients unless the ingredient qualifies as an incidental additive

Threshold

- As an example, we interpret the final rule as not requiring disclosure for a food that contains wheat flour as an ingredient, when the wheat flour contains no more than 5% of BE soy and BE corn due to cross contact
- Only customary business records required:
 - “AMS will look to the records to determine whether a regulated entity intended to purchase non-BE ingredients and the documentation they have from their suppliers indicating as much”



“Factors or Conditions” (Exemptions)

Do “other factors or conditions” affect the foods BE status?

- The final rule establishes a process for submitting a request or petition to limit the scope of the definition of bioengineered food, based on other “factors or conditions”
- AMS also listed one “factor or condition” in the final rule:
 - **Incidental additives** – i.e., those that are present in food at an insignificant level and that do not have any technical or functional effect in the food – are not considered BE foods.

Mechanics of disclosure

Mandatory Disclosure Options

1. A text disclosure

- “Bioengineered Food”
- “Contains a bioengineered food ingredient”

2. Symbol



- ## 3. A text message a [command word] to [number] for more bioengineered food information”

4. An electronic or digital link (can’t use URL)

On-pack:

- “Scan here for more food information” directly above or below the link
- “Call 1-800-555-1111 for more food information” in “close proximity” to link
- May combine these two : “Scan here for more food information or call [number]”

Disclosure accessed by link

- Link must provide the disclosure (text or symbol) on the first screen to appear on the device after the link is accessed
- Page must exclude marketing and promotional material

Voluntary disclosure

Voluntary disclosure - scope

- The rule is prescriptive with regard to the foods that qualify for the voluntary disclosure
- The following foods clearly qualify for the voluntary disclosure
 - Foods sold by very small food manufacturers (must use same disclosure as BE foods)
 - Foods sold by restaurants and similar institutions (must use same disclosure as BE foods)
 - Foods that contain a refined ingredient derived from a listed BE crop but do not contain detectable DNA (must use voluntary disclosure options with distinct language)
- The rule does not authorize a voluntary disclosure for:
 - Incidental additives that are bioengineered
 - Inadvertent BE substances at no more than 5% per ingredient
 - An animal product derived from an animal that consumed BE feed
 - Being derived from a bioengineered food not on the bioengineered food list
 - Certified organic foods
- AMS states that an FSIS-regulated food that does not fall within the scope of the standard may not bear the voluntary disclosure regardless of the other ingredients in the product

Voluntary disclosure

- Final rule allows voluntary disclosures that a food is derived from a bioengineered source, including when modified genetic material is not detectable in the food (e.g., refined ingredients)
- Using one of same methods as for mandatory disclosure but using different language
 - **Text:** “derived from bioengineering” or “ingredient(s) derived from a bioengineered source” or “corn syrup derived from a bioengineered source”
 - **Symbol:** AMS has established a unique symbol that can be used on foods derived from BE
 - **Electronic or Digital Link** and phone number
 - **Text Message** must use above language or symbol, as appropriate



Recordkeeping and enforcement

Enforcement

- Law prohibits:
 - Knowingly failing to disclose that a food is bioengineered as required by the standard and USDA’s regulations
 - Declaring that a food is bioengineered except in compliance with the federal standard
- Companies must maintain and make available any records required under USDA regulations to establish compliance with the standard
- USDA authorized to conduct audits of records to demonstrate compliance with the standard
- AMS does not have recall authority based on compliance with disclosure standard
- “AMS does not intend to test final food products to determine compliance with the rule”

Recordkeeping

- Must keep “customary or reasonable” records to demonstrate compliance
 - For example: Supply chain records, bills of lading, invoices, supplier attestations, labels, contracts, brokers’ statements, third party certifications, laboratory testing results, validated process verifications, and other records generated or maintained by the regulated entity in the normal course of business
- Records must contain sufficient detail as to be readily understood and audited
- If a food is on the BE foods list, must keep records regarding the food or ingredient
- If a food bears a disclosure based on actual knowledge and is not on the list, must maintain records for such food or ingredient
- If records demonstrate that a product originates from a country where BE food is not commercially grown, those records are sufficient to justify lack of disclosure and demonstrate compliance with the NBFDS

Recordkeeping

- May be in paper or electronic form
- May be maintained at a central location
- Must maintain records at least 2 years after the date the food is sold or distributed for retail sale
- Must provide to AMS within 5 days upon request, unless AMS extends the deadline
- AMS would provide at least 3 days notice if the agency needs to access records at the entity's place of business



Audits

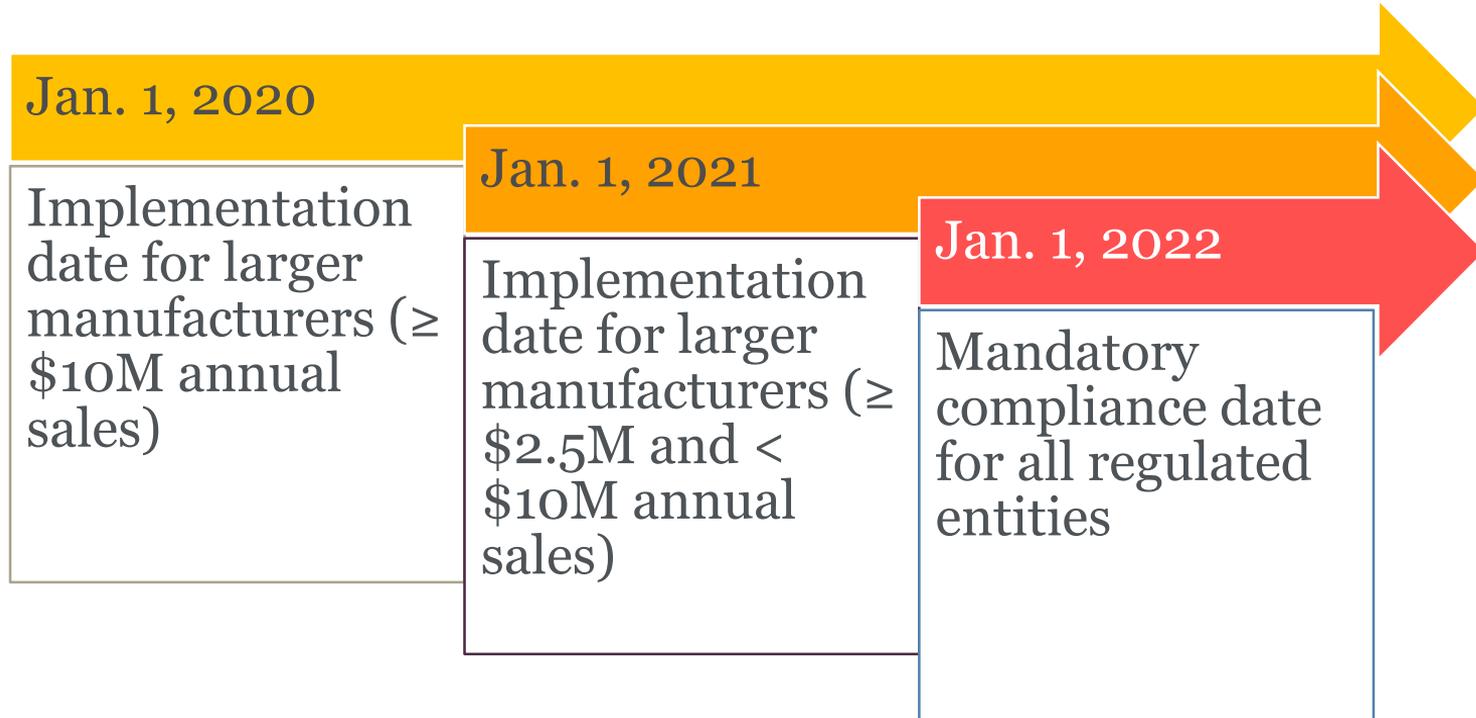
- Any interested person may file a written statement or complaint with the agency about a possible violation of the disclosure standard
- If AMS determines that reasonable grounds exist for an investigation of the complaint, it may conduct an audit or examination of the records of the entity responsible for the disclosure
 - After completing the audit or examination, AMS would make its findings available to the entity audited
 - The entity could then request a hearing objecting to the AMS finding
 - After the conclusion of the hearing, or after 30 days from the entity's receipt of the finding, if the entity does not request a hearing, AMS would make public a summary of the final results of the audit or examination

A note on “non-GMO”

- No specific exemption for products certified by third parties as “non-GMO”
- Records created through third-party certification programs could be used to support a decision not to disclose, to the extent the records align with the rule
- Statute and final rule do not address “non-GMO” claims, other than:
 - Certified organic foods may bear a non-GMO claim
 - Simply because a food does not require the mandatory disclosure does not mean it automatically qualifies as non-GMO



BE Food Disclosure Compliance Date



Summary: Key BE Rule Provisions

1. Mandatory compliance date = **Jan. 1, 2022**
2. Refined ingredients/foods not subject to mandatory disclosure, provided they contain no detectable levels of rDNA
3. Undetectable modified DNA may be demonstrated by:
 - Records verifying the food is from a non-BE source
 - Records showing the food has been subject to a refinement process “validated” to render rDNA undetectable
 - Once process is validated, additional testing not needed, provided no significant changes to process
 - COAs or other testing records appropriate to the specific food tested that confirm the absence of rDNA
4. Threshold = no disclosure required where the food contains **no more than 5% per ingredient** of inadvertent/technically unavoidable presence of BE substances (No threshold for intentionally added BE ingredients)
5. Incidental additives exempt; certified organic foods exempt
6. Records: Flexibility in the specific type of record used to establish compliance, but if food is on the BE foods list or BE based on actual knowledge, must keep records
7. Voluntary disclosure permitted for refined ingredients/foods using specific text (“derived from bioengineering”) or symbol, but narrow in scope

Recently finalized guidance documents

AMS Final Guidance on Testing Methods

- Test method must be “fit for purpose”
- No specific limit of detection identified; AMS states that entities should use their best discretion when selecting a test method to ensure appropriate sensitivity
- PCR is the most widely used and commercially accepted test method
 - No longer states a preference for quantitative PCR testing over qualitative PCR testing
 - In some matrices, broad-spectrum PCR may not be capable of detecting BE events and/or may be subject to false positives, in which case event-specific or construct-specific PCR tests may be necessary
 - Labs must ensure that the method is validated for the specific matrix and adequately extracts DNA for each ingredient/matrix and should monitor PCR inhibition
 - AMS states that highly refined foods may contain lipids that interfere with a PCR reaction, and regulated entities must follow appropriate procedures or acceptable methods to remove PCR inhibiting compounds in the sample extraction process
- Limited guidance on appropriate sample size

AMS Final Guidance on Testing Methods

- AMS identifies the following as examples of customary or reasonable records that entities could use to demonstrate compliance with the disclosure requirements as they relate to detectability testing:
 - supply chain records, supplier attestations, third-party certifications, laboratory testing results, validated process verifications, and other records generated in the normal course of business
 - certificates of analysis or other records of testing that confirm the absence of modified genetic material
- Records should include information to assess whether a test method is fit for purpose

AMS Final Guidance on Process Validation for Refined Ingredients

- Need to determine which processing step(s) are key in rendering rDNA undetectable, and assemble validation information to demonstrate that the key step consistently and effectively renders rDNA undetectable
 - Can include testing, validation studies, experimental data, applied data
 - Need to monitor the parameters in the key steps (typically existing monitoring procedures will suffice)
 - May need to revalidate if significant changes made to process
- Meaning of “undetectable”: no de minimus level defined for rDNA
- A process validated in compliance with the guidance is not subject to the “moving target” associated with the emergence of more sensitive testing capabilities

Practical considerations and outstanding issues

Practical Considerations

- Question: If my product contains [HFCS, refined oils, etc. from BE crops] do I need to collect records showing no detectable rDNA, or could I just make a disclosure
- Validation of a refining process is not required; it is simply one of several potential ways to demonstrate that modified genetic material is non-detectable
- AMS states, “If regulated entities do not have [such records] and do not want to create them, they must make a bioengineered food disclosure.”
 - Pros and cons of this approach

Practical Considerations

- What to do while we wait for suppliers to conduct testing to confirm rDNA is not detectable?
- For compliance, marketer of finished food must have documentation from supplier that rDNA is not detectable when food ingredient is on BE list or there is actual knowledge that it is BE
- Ingredient suppliers have been justifiably reluctant to conduct testing before final guidance was issued
- Categorize ingredients from BE sources into 3 categories
 1. Expected to have non-detectable rDNA or be exempt (refined oils, refined sugars, fermentation products) . . . PATIENTLY WAIT for documentation
 2. Questionable as to whether rDNA is detectable (starches, lecithin, others) IMPATIENTLY WAIT (urge suppliers to make these a priority)
 3. Expected to contain detectable rDNA

Outstanding Issues

- Clarification that GE microorganism and substrates in fermentation products are not subject to labeling
- What happens if supplier of a refined ingredient refuses or can't provide any testing data?
- What flexibility is there to communicate GMO inputs when the product does not qualify for the voluntary disclosure (e.g., milk from cows that consume GMO feed)?

Questions?



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