Mérieux NutriSciences

Better Food. Better Health. Better World.

Where's the BEef: Commercial and Technical Challenges of Complying with the National Bioengineered Food Disclosure Standard

James S. Haudenshield

Presented to: AEIC Semiannual Meeting (virtual). 7 April 2022.

About us

- Silliker, Inc. founded in 1967 by John H. Silliker (1922–2015), in Chicago, as a food testing laboratory.

- Merged several years ago with Institut Mérieux (est. 1897), an independent, family-owned French group with worldwide laboratories. Silliker, Inc is now DBA Mérieux NutriSciences.

- The 71,000 ft^2 Crete, Illinois facility houses an Analytical Laboratory, and the Food Science Center. Broad range of retail analyte tests from pesticides to fats & fibers to allergens and vitamins, to all manner of microbes.

- Retail testing of samples for GMO, and other PCR-based analyses (e.g., allergen, meats, etc.) Facilitate compliance, transparency, stewardship, trade, manufacture.

- Our company also provides auditing, labeling, and other services.

Mérieux NutriSciences

The National Bioengineered Foods Disclosure Standard (7 CFR Chapter 1, Part 66)

- Covers food for human consumption (not animal feed or pet food).
- BE Labeling of foods containing any ingredient on "**The List**" unless proven non-BE.
- BE Labeling of foods containing an off-list ingredient* known to the producer to be of BE origin.
- Exceptions: Incidental additives. National Organic Program. Unintentional (inadvertent or technically unavoidable) — with threshold of 5% per "single ingredient".

*only food ingredients subject to labeling requirements of FDCA, and not the FAAA (alcohol), FMIA (meat), PPIA (poultry), or EPIA (egg).

“The List”:

If the ingredient is on the List of Bioengineered Foods, or is produced from a food on the List, it is presumed to contain detectable modified genetic material unless a regulated entity has records that show one of the statements below is applicable.

The ingredient may not contain detectable modified genetic material if your records show:

1. You have specifically sourced a non-bioengineered ingredient;
2. The ingredient is sourced from an area that does not allow production of bioengineered foods;
3. The ingredient has been subjected to a validated refining process that renders modified genetic material undetectable;
4. The ingredient has been tested to verify that modified genetic material is not detectable.

§ 66.6 List of Bioengineered Foods.

The List of Bioengineered Foods consists of the following: 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), and sugarbeet.

“The List” and events outlined on AMS site:

Corn [forty-one events, plus 5 NC]

Soybean [eighteen events, plus 2 NC]

Canola [ten events, plus 9 NC]

Sugarbeet [H7-1, plus 2 NC]

Cotton [thirty events, plus 3 NC]

Potato [thirty-seven events]

Alfalfa [J101, J163, KK179]

Summer Squash [ZW20, CZW3]

Apple (Arctic™) [GD743, GS784, NF872]

Salmon (AquAdvantage™) [EO-1α]

Pineapple (pink flesh) [EF2-114]

Papaya [55-1, Huanong No.1]

Eggplant (Bari Bt Begun) [EE1]

Compliance Challenges

- Marketing challenges & questions from producers:

- Technical hurdles:

Compliance Challenges

- Marketing challenges & questions from producers:
  - "What do we have to test for?" — NBFDS depends on ingredients ("The List"), etc. Anything known to be present? Marketing intent? Export?
  - Ambiguities: Does the 5% threshold apply to the "single ingredient" corn starch? Or to corn starch + corn meal + corn fiber?

- Technical hurdles:

Compliance Challenges

- Marketing challenges & questions from producers:
  - "What do we have to test for?" — NBFDS depends on ingredients ("The List"), etc. Marketing intent? Export?
  - Ambiguities: Does the 5% threshold apply to the "single ingredient" corn starch? Or to corn starch + corn meal + corn fiber?

- Technical hurdles:
  - CRM or other Reference Material?
    - Crucial for test onboarding (LOD and spike for LOQ)
    - Needed as a calibrant/PC and/or Process Control Sample (quant)
  - Test method availability? Interlaboratory validation?

Compliance Challenges

- CRM or other Reference Material?
  - Crucial for test onboarding (LOD and spike for LOQ)
  - Needed as a calibrant/PC and/or Process Control Sample (quant)
- Test method availability?
  Interlaboratory validation?

(c) *Standards of performance for detectability testing.* Analytical testing for purposes of detecting the presence of modified genetic material in refined foods pursuant to paragraph (a) of this section shall meet the following standard:

(1) Laboratory quality assurance must ensure the validity and reliability of test results;

(2) Analytical method selection, validation, and verification must ensure that the testing method used is appropriate (fit for purpose) and that the laboratory can successfully perform the testing;

(3) The demonstration of testing validity must ensure consistent accurate analytical performance; and

(4) Method performance specifications must ensure analytical tests are sufficiently sensitive for the purposes of the detectability requirements of this part.

“The List” and events outlined on AMS site:

Are reference materials available?

- ✓ **Corn** [forty-one events, plus 5 NC]
- ✓ **Soybean** [eighteen events, plus 2 NC]
- ✓ **Canola** [ten events, plus 9 NC]
- ✓ **Sugarbeet** [H7-1, plus 2 NC]

“The List” and events outlined on AMS site:

Are reference materials available?

- ✓ **Corn** [forty-one events, plus 5 NC]
- ✓ **Soybean** [eighteen events, plus 2 NC]
- ✓ **Canola** [ten events, plus 9 NC]
- ✓ **Sugarbeet** [H7-1, plus 2 NC]

- ➔ **Cotton** [thirty events, plus 3 NC]
- ➔ **Potato** [thirty-seven events]

"The List" and events outlined on AMS site:

Are reference materials available?

- ✓ **Corn** [forty-one events, plus 5 NC]
- ✓ **Soybean** [eighteen events, plus 2 NC]
- ✓ **Canola** [ten events, plus 9 NC]
- ✓ **Sugarbeet** [H7-1, plus 2 NC]

- ➔ **Cotton** [thirty events, plus 3 NC]
- ➔ **Potato** [thirty-seven events]

- ✘ **Alfalfa** [J101, J163, KK179]
- ✘ **Summer Squash** [ZW20, CZW3]
- ✘ **Apple** (Arctic™) [GD743, GS784, NF872]
- ✘ **Salmon** (AquAdvantage™) [EO-1α]
- ✘ **Pineapple** (pink flesh) [EF2-114]
- ✘ **Papaya** [55-1, Huanong No.1]
- ✘ **Eggplant** (Bari Bt Begun) [EE1]

Are testing methods available?

- ✓ **Corn** [forty-one events, plus 5 NC]
- ✓ **Soybean** [eighteen events, plus 2 NC]
- ✓ **Canola** [ten events, plus 9 NC]
- ✓ **Sugarbeet** [H7-1, plus 2 NC]
- ➔ **Cotton** [thirty events, plus 3 NC]
- ➔ **Potato** [thirty-seven events]

- ✘ **Alfalfa** [J101, J163, KK179]
- ✘ **Summer Squash** [ZW20, CZW3]
- ✘ **Apple** (Arctic™) [GD743, GS784, NF872]
- ✘ **Salmon** (AquAdvantage™) [EO-1α]
- ✘ **Pineapple** (pink flesh) [EF2-114]
- ✘ **Papaya** [55-1, Huanong No.1]
- ✘ **Eggplant** (Bari Bt Begun) [EE1]

Are testing methods available?

- ✓ **Corn** [forty-one events, plus 5 NC] **15/41**
- ✓ **Soybean** [eighteen events, plus 2 NC] **15/18✓**
- ✓ **Canola** [ten events, plus 9 NC] **11/10 ✓**
- ✓ **Sugarbeet** [H7-1, plus 2 NC] **1/1 ✓**

- ➔ **Cotton** [thirty events, plus 3 NC] **14/30**
- ➔ **Potato** [thirty-seven events] **1/37 ✗**

- ✗ **Alfalfa** [J101, J163, KK179] **0/3** (3/3 lit)
- ✗ **Summer Squash** [ZW20, CZW3] **0/2 ✗**
- ✗ **Apple** (Arctic™) [GD743, GS784, NF872] **0/3 ✗**
- ✗ **Salmon** (AquAdvantage™) [EO-1α] **0/1** (1/1 lit)
- ✗ **Pineapple** (pink flesh) [EF2-114] **0/1 ✗**
- ✗ **Papaya** [55-1, Huanong No.1] **1/2**
- ✗ **Eggplant** (Bari Bt Begun) [EE1] **0/1 ✗**

A challenge to testing labs:

(c) *Standards of performance for detectability testing.* Analytical testing for purposes of detecting the presence of modified genetic material in refined foods pursuant to paragraph (a) of this section shall meet the following standard:

(1) Laboratory quality assurance must ensure the validity and reliability of test results;

(2) Analytical method selection, validation, and verification must ensure that the testing method used is appropriate (fit for purpose) and that the laboratory can successfully perform the testing;

(3) The demonstration of testing validity must ensure consistent accurate analytical performance; and

(4) Method performance specifications must ensure analytical tests are sufficiently sensitive for the purposes of the detectability requirements of this part.

What about “Non-List” GMOs?
The NBFDS is not limited to 13 crops!

Even if a food is not on the List, regulated entities that have actual knowledge that a food they are selling is bioengineered, as defined in § 66.1, must make appropriate disclosure of that food.

What about “Non-List” GMOs?
The NBFDS is not limited to 13 crops!

➔**Flaxseed** [“Triffid” plus seven events] **1/8**

➔**Rice** [BT63; Golden Rice; LL62/601] **3/3**

What about “Non-List” GMOs?
The NBFDS is not limited to 13 crops!

➔**Flaxseed** [“Triffid” plus seven events] **1/8**

➔**Rice** [BT63; Golden Rice; LL62/601] **3/3**

✖ **Wheat** [fifteen events] **1/15** ✖

✖ **Cassava** [seventeen events] **0/17** ✖

✖ **Sugarcane** [thirteen events] **0/13** ✖

✖ **Safflower** [five events] **0/5** ✖

✖ **Cowpea** [three events] **0/3** ✖

✖ **Tomato** [eight events] **0/8** ✖

✖ **Common bean** [two events] **0/2** ✖

What about “Non-List” GMOs?
The NBFDS is not limited to 13 crops!

➔**Flaxseed** [“Triffid” plus seven events] **1/8**

➔**Rice** [BT63; Golden Rice; LL62/601] **3/3**

✘ **Wheat** [fifteen events] **1/15** ✘

✘ **Cassava** [seventeen events] **0/17** ✘

✘ **Sugarcane** [thirteen events] **0/13** ✘

✘ **Safflower** [five events] **0/5** ✘

✘ **Cowpea** [three events] **0/3** ✘

✘ **Tomato** [eight events] **0/8** ✘

✘ **Common bean** [two events] **0/2** ✘

✘ **Barley** [twelve events] **0/12** ✘

✘ **Bananas** [four events] **0/12** ✘

✘ **Okra** [one event] **0/1** ✘

✘ **Chicory** [four events] **0/4** ✘

✘ **Cantaloupe** [two events] **0/2** ✘

✘ **White Birch, Eucalyptus, Rubber trees, Aspens, Poplars, Chestnut** **0** ✘

✘ **Carnations, Orchids, Roses** **0** ✘

✘ **Mosquitos, Olive fly, GloFish** **0** ✘

What about “Non-List” GMOs?
The NBFDS is not limited to 13 crops!

- ➔ **Flaxseed** [“Triffid” plus seven events] **1/8**
- ➔ **Rice** [BT63; Golden Rice; LL62/601] **3/3**
- ✘ **Wheat** [fifteen events] **1/15** ✘
- ✘ **Cassava** [seventeen events] **0/17** ✘
- ✘ **Sugarcane** [thirteen events] **0/13** ✘
- ✘ **Safflower** [five events] **0/5** ✘
- ✘ **Cowpea** [three events] **0/3** ✘
- ✘ **Tomato** [eight events] **0/8** ✘
- ✘ **Common bean** [two events] **0/2** ✘
- ✘ **Barley** [twelve events] **0/12** ✘
- ✘ **Bananas** [four events] **0/12** ✘
- ✘ **Okra** [one event] **0/1** ✘
- ✘ **Chicory** [four events] **0/4** ✘
- ✘ **Cantaloupe** [two events] **0/2** ✘
- ✘ **White Birch, Eucalyptus, Rubber trees, Aspens, Poplars, Chestnut 0** ✘
- ✘ **Carnations, Orchids, Roses 0** ✘
- ✘ **Mosquitos, Olive fly, GloFish 0** ✘
- ✘ **Tobacco & *Arabidopsis* 0/millions** ✘

Scads of important food BE modifications.

Few reference materials.

Few test methods.

Makes for difficult compliance.

Offers little transparency.

Suggests poor stewardship.

Raises barriers to trade

Reduces incentive to invent.

Can we at least cover “The List”?

- ✓ **Corn** [forty-one events, plus 5 NC] **15/41**
- ✓ **Soybean** [eighteen events, plus 2 NC] **15/18✓**
- ✓ **Canola** [ten events, plus 9 NC] **11/10 ✓**
- ✓ **Sugarbeet** [H7-1, plus 2 NC] **1/1 ✓**

- ➔ **Cotton** [thirty events, plus 3 NC] **14/30**
- ➔ **Potato** [thirty-seven events] **1/37 ×**

- × **Alfalfa** [J101, J163, KK179] **0/3** (3/3 lit)
- × **Summer Squash** [ZW20, CZW3] **0/2 ×**
- × **Apple** (Arctic™) [GD743, GS784, NF872] **0/3 ×**
- × **Salmon** (AquAdvantage™) [EO-1α] **0/1** (1/1 lit)
- × **Pineapple** (pink flesh) [EF2-114] **0/1 ×**
- × **Papaya** [55-1, Huanong No.1] **1/2**
- × **Eggplant** (Bari Bt Begun) [EE1] **0/1 ×**

Compliance Challenges

- Marketing challenges & questions from producers:
  - "What do we have to test for?" — NBFDS depends on ingredients ("The List"), etc. Marketing intent? Export?
  - Ambiguities: Does the 5% threshold apply to the "single ingredient" corn starch? Or to corn starch + corn meal + corn fiber?

- Technical hurdles:
  - CRM or other Reference Material?
    - Crucial for test onboarding (LOD and spike for LOQ)
    - Needed as a calibrant/PC and/or Process Control Sample (quant)
  - Test method availability? Interlaboratory validation?
    - Pay-walls
    - Access control

Where's the BEef: Commercial and Technical Challenges of Complying with the National Bioengineered Food Disclosure Standard

Where indeed.

Mérieux NutriSciences

Better Food. Better Health. Better World.

Thank you

Compliance. Transparency. Stewardship. Trade. Manufacture.