Creating Opportunities for American Farmers and Businesses

Overview of the National Bioengineered Food Disclosure Standard

May 29, 2018

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Creating Opportunities for American Farmers and Businesses

Presentation Overview

- Introduction and Background
- II. Applicability
- III. Disclosure
- IV. Administrative Provisions
- V. Regulatory Flexibility Analysis, Regulatory Impact Analysis

Public Law 114-216

The Law amended the Agricultural Marketing Act of 1946 and was signed on July 29, 2016.

The Law directs the Secretary to establish the National Bioengineered Food Disclosure Standard for disclosing bioengineered food and food that may be bioengineered.

Applicability

What foods are subject to the NBFDS?

- 1. Federal Food, Drug, and Cosmetic Act
- 2. Federal Meat Inspection Act
- 3. Poultry Products Inspection Act
- 4. Egg Products Inspection Act

Applicability Meat, Poultry and Egg Products







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Applicability

The term **bioengineering**, and any similar term, as determined by the Secretary, with respect to a food, refers to a food:

- (A) that **contains genetic material** that has been modified through in vitro recombinant deoxyribonucleic acid (DNA) techniques; and
- (B) for which the modification could not otherwise be obtained through **conventional breeding** or **found in nature**.

Applicability

Commercially Available BE Foods

Highly Adopted

Canola - 90%

Corn, Field – 92%

Cotton - 93%

Soybean - 94%

Sugar Beet - 100%

Not Highly Adopted

Apple, Non-browning cultivars

Corn, Sweet

Papaya

Potato

Squash, Summer varieties

Applicability Factors and Conditions

Petition/request for determination of factor or condition.



AMS reviews petition/request using standards for consideration



If petition/request satisfies the standards for consideration, AMS would initiate rulemaking

II. Applicability Factors and Conditions

- 1. Whether incidental additives present in food should be considered "bioengineered food"
- 2. Whether the modified genetic material in a food may be detected.

Applicability Exemptions

- 1. Food served in a restaurant or similar retail food establishment
- 2. Very small food manufacturers
- 3. Threshold
- 4. Animals fed with bioengineered feed and their products
- 5. Food certified under the National Organic Program

Disclosure

Who would make disclosures?

- 1. Food manufacturers
- 2. Importers
- 3. Retailers who:
 - a) Package and label foods for retail sale
 - b) Display and sell bulk food items

Imports and Mutual Recognition Arrangements

As proposed, by mutual agreement, the bioengineered food labeling laws of a trading partner could be recognized as sufficient to meet NBFDS requirements and vice versa.

Lists of bioengineered foods commercially available in the United States

- Highly adopted 85% or more of US plantings of these crops are bioengineered: Canola, field corn, cotton, soybean and sugarbeet.
- Non-highly adopted Less than 85% of US plantings of these crops are bioengineered: Nonbrowning apple cultivars, sweet corn, papaya, potato, summer squash

Bioengineered foods on either list would be subject to disclosure.

Disclosure Options Written Text

"Bioengineered food" or "Contains a bioengineered food ingredient"

(For foods on either list of commercially available bioengineered food)

"May be bioengineered food" or "May contain a bioengineered food ingredient"

(Only for foods on the list of non-highly adopted bioengineered food)

Disclosure Options Symbols

The proposed rule offers three alternatives for comment

Symbols may be full color or black and white







Disclosure Options Electronic or Digital Disclosures

- QR codes
- Digital watermarks
- To be accompanied by instructions to "Scan here for more food information" or "Scan anywhere on package for more food information"

Electronic Disclosure Study

- Mandated by Congress
- Completed and published September 2017
- Evaluates nationwide consumer access to electronic and digital disclosures
- Secretary will determine whether it would be appropriate to offer a fourth disclosure option
- AMS has proposed text messages as a possible fourth option
- Consumer would be able to type in a numeric code and receive food information in response via text messaging

Additional Disclosure Flexibilities

Small food manufacturers (annual receipts \$2.5 to \$10 million)

Telephone number to call for food information

Internet website to access for food information

<u>Small food packages = less than 40 square inches surface area</u>

Would be able to use modified standard disclosures

Very small food packages = less than 12 square inches surface area

Would be able to use modified standard disclosures or preexisting phone numbers and URLs to provide food information

Foods Sold in Bulk Containers

- Retailers would be responsible for disclosure
- Would be able to use any of the standard disclosure options
- Disclosures would be placed on signage or other materials on or near the bulk food items

Voluntary Disclosure

- Requested by commenters
- Food meets proposed definition of bioengineered food, but would be exempt from disclosure (For example, a very small food manufacturer not required to make a disclosure)
- If making a voluntary disclosure is desired, any of the standard disclosure options may be used
- Voluntary disclosures would be required to comply with requirements applicable to standard disclosure options

Recordkeeping Requirements

- Everyone subject to mandatory bioengineered food disclosure would be required to keep sufficient records to establish compliance with the standard
- Customary and usual records would be generated in the course of normal business – no new records or forms are proposed
- Individuals would determine which records to maintain provided they are sufficient to demonstrate compliance
- Records may be in any format (hard copy or electronic)
- Records may be stored at any business location

Types of Records to Maintain

Individuals would be able determine what business records to maintain provided that they demonstrate compliance with the disclosure standard.

Examples of possible records to keep include

Invoices

Bills of lading

Inventory records

Supply chain records

Process verifications

Organic certifications

Laboratory test results

How Recordkeeping Applies to Disclosure

- For non-disclosure of foods on either list of commercially available bioengineered foods, records would need to verify that the food is not bioengineered
- For positive disclosure of foods on either list, records would simply identify the food (e.g. "Cornmeal")
- For "may" claims on foods from the non-highly adopted bioengineered food list, records would simply identify the food (e.g. "Papaya")

More on "May" Claims

 Would be limited to use for foods on the list of commercially available, but not highly adopted, bioengineered foods

 Would be made using any of the disclosure options (written text, symbol, electronic, text message, phone number, or website), as appropriate

More on Recordkeeping

- Records would be required to be maintained for two years after the food is offered for retail sale
- Some records, such as process verifications, may be required to be retained longer, as necessary to demonstrate compliance with disclosure requirements
- When requested by USDA, records would be required to be produced within five business days, unless an extension is granted by USDA
- When on-site access to records is required by USDA, three days' notice would be provided by USDA, unless an extension is granted

Enforcement

- Failure to make a bioengineered food disclosure as required by the NBFDS is prohibited
- Complaints about possible violations of the NBFDS would be made to AMS
- AMS would determine whether further investigation is warranted
- AMS would conduct a records audit
- The regulated entity would be notified about the results of the audit or investigation

Enforcement (continued)

- Regulated entities would be able to appeal the results of an audit or investigation
- Following an appeals hearing, AMS would notify the regulated entity of its final determination in the matter
- The results of the audit or investigation would be posted to AMS's website

Proposed Effective and Compliance Dates

- The final rule would become effective 60 days after publication in the Federal Register
- Proposed initial compliance date of January 1, 2020, is intended to align with proposed extended compliance dates for FDA labeling and serving size rules
- A delayed compliance date of January 1, 2021, is proposed for small food manufacturers
- Entities with existing label inventories would be allowed to use them up or until January 1, 2022, whichever comes first

Impact on Small Businesses

- Description of Businesses Directly and Indirectly Covered by the Proposal
- Statutory Provisions Related to Mitigating Impact on Small Business
- Evaluating Impact Using Cost to Revenue Ratio

Businesses Covered

- Proposal would apply directly to food manufacturers, dietary supplement manufacturers, and retailers who sell products in bulk
- Number of firms potentially impacted (by size category)

	Very Small	Small Food Manufacturer	Small Businesses	Large Businesses	Total
Food Manufacturers	18,000	3,000	3,000	1,000	25,000
Dietary Supplement Manufacturers	180	70	120	20	390
Retailers	N/A	N/A	N/A	N/A	142,000

 Approximately 40,000 firms indirectly affected (96 percent of which are small)

Reducing Impact on Small Business

Statute exempts "very small food manufacturers"

- Proposal defines food and dietary supplement manufacturers with annual revenues below \$2,500,000 as very small
- Exempts 74 percent of food manufacturers and 45 percent of supplement manufacturers. Maintains coverage of 96 percent and 98 percent of products respectively

Statute provides additional year to comply for "small food manufacturers"

- Proposal defines food and dietary supplement manufacturers with annual revenues below \$10,000,000 as small consistent with FDA labeling standards
- 86 percent of food manufacturers and 64 percent of dietary supplement manufacturers meet this definition

Potential Impact to Food Manufacturers

Compared upper bound annualized cost to firm revenues at a seven percent discount rate

ENTERPRISE RECEIPT SIZE	NUMBER	ANNUAL	ESTIMATED	Percent of	Percent of	Annualized	Cost/Revenue Ratio
	OF FIRMS	PAYROLL (\$1,000)	RECEIPTS (\$1,000)	Firms	Receipts	Cost (\$1,000)	
Fotal Control of the	24,874	59,447,985	787,095,654	100%	100%	410000	0.05%
<100,000	4,962	71,910	49,521	20%	0%	496	1.00%
100,000-499,999	6,143	453,230	1,744,160	25%	0%	3126	0.18%
500,000-999,999	3,425	540,554	2,399,048	14%	0%	3728	0.16%
1,000,000-2,499,999	3,821	1,143,176	5,923,937	15%	1%	7884	0.13%
2,500,000-4,999,999	1,854	1,128,772	6,323,360	7%	1%	7785	0.12%
5,000,000-7,499,999	794	798,934	4,636,029	3%	1%	5510	0.12%
7,500,000-9,999,999	486	645,847	4,025,187	2%	1%	4454	0.11%
10,000,000-14,999,999	669	1,175,626	7,634,675	3%	1%	8108	0.11%
15,000,000-19,999,999	355	770,707	5,734,325	1%	1%	5315	0.09%
20,000,000-24,999,999	283	811,275	5,984,273	1%	1%	5595	0.09%
25,000,000-29,999,999	202	688,622	5,205,359	1%	1%	4749	0.09%
30,000,000-34,999,999	156	597,983	4,664,275	1%	1%	4124	0.09%
35,000,000-39,999,999	122	554,643	4,142,321	0%	1%	3825	0.09%
40,000,000-49,999,999	178	864,342	7,031,428	1%	1%	5961	0.08%
50,000,000-74,999,999	319	1,941,093	17,424,495	1%	2%	13387	0.08%
75,000,000-99,999,999	175	1,513,479	13,428,642	1%	2%	10438	0.08%
100,000,000+	930	45,747,792	690,744,619	4%	88%	315513	0.05%

Potential Impact to Dietary Supplement Manufacturers

NTERPRISE RECEIPT SIZE	NUMBER OF FIRMS	ANNUAL PAYROLL	ESTIMATED RECEIPTS (\$1,000)	Percent of Firms	Percent of Receipts	Annualized Cost (\$1,000)	Cost/Revenue Ratio
		(\$1,000)					
otal	394	2,461,491	13,358,607	100%	100%	31360	0.23%
100,000	29	426	0	7%	0%	5	No Reported Revenue
00,000-499,999	37	2,407	13,912	9%	0%	31	0.22%
600,000-999,999	37	5,394	29,000	9%	0%	69	0.24%
000,000-2,499,999	75	29,696	126,057	19%	1%	378	0.30%
,500,000-4,999,999	55	42,409	182,218	14%	1%	540	0.30%
5,000,000-7,499,999	12	13,959	70,272	3%	1%	178	0.25%
,500,000-9,999,999	7	14,304	63,036	2%	0%	182	0.29%
0,000,000-14,999,999	21	45,749	251,402	5%	2%	583	0.23%
5,000,000-19,999,999	14	53,192	231,082	4%	2%	678	0.29%
0,000,000-24,999,999	12	56,803	235,221	3%	2%	724	0.31%
5,000,000-29,999,999	8	31,496	167,216	2%	1%	401	0.24%
0,000,000-34,999,999	6	25,279	137,924	2%	1%	322	0.23%
5,000,000-39,999,999	5	26,429	179,352	1%	1%	337	0.19%
0,000,000-49,999,999	6	0	0	2%	0%	0	No Reported Revenue
0,000,000-74,999,999	18	179,233	975,448	5%	7%	2283	0.23%
5,000,000-99,999,999	1	0	0	0%	0%	0	No Reported Revenue
0,000,000+	51	1,878,179	10,356,257	13%	78%	23928	0.23%

28,060

12.901

4.422

1,988

1,849

796

408

249

187

127

188

218

123

779

1,000,000-2,499,999

2,500,000-4,999,999

5,000,000-7,499,999

7,500,000-9,999,999

10,000,000-14,999,999

15,000,000-19,999,999

20.000.000-24.999.999

25,000,000-29,999,999

30,000,000-34,999,999

35,000,000-39,999,999

40.000,000-49.999,999

50,000,000-74,999,999

75,000,000-99,999,999

100,000,000+

Potential Impact to Retailers

0.00%

0.00%

0.00%

0.00%

0.00%

0.00%

0.00%

0.00%

0.00%

0.00%

0.00%

0.00%

0.00%

0.00%

Table 35: Cost to Revenue Ratios for Food and Dietary Supplement Retailers by Revenue Classification							
Enterprise Receipt Size	Number of Firms	Annual Payroll (\$1,000)	Estimated Receipts (\$1,000)	Percent of Firms	Percent of Receipts	Annualized Cost (\$1,000)	Cost/Revenue Ratio
Total	142,346	89,356,338	874,354,889	100%	100%	21160	0.00%
<100,000	13,249	148,773	707,959	9%	0%	35	0.00%
100,000-499,999	47,884	1,729,902	13,442,071	34%	2%	410	0.00%
500,000-999,999	28,918	2,215,996	20,625,343	20%	2%	525	0.00%

43,955,174

44,677,197

26.256.212

16,513,423

20,949,064

12,435,957

7.878.198

5.616.010

4.980.920

3,386,627

6,671,626

9,449,270

6,132,813

630,453,005

20%

9%

3%

1%

1%

1%

0%

0%

0%

0%

0%

0%

0%

1%

5%

5%

3%

2%

3%

2%

1%

1%

1%

0%

1%

1%

1%

69%

1144

1147

677

433

561

330

208

158

130

89

167

266

173

14699

4,830,013

4,845,133

2.859.141

1,829,506

2,367,964

1,392,853

877.529

668.356

548.687

375,793

703,781

1,121,868

729,491

62,071,005

Potential Impact on Small Businesses

Based on the analysis, it does not appear likely that this rule would have a significant impact on a substantial number of small businesses

Economic Impact Analysis

Table 1: Total Costs Scope 1 - No exempted foods*		
(Very small manufacturer<\$2.5 million annual revenue; compliance period	d includes label use up)
	Lower bound (\$million)	Upper bound (\$million)
Initial costs		
Administrative – Food manufacturers	317	2,509
Administrative – Supplement manufacturers	39	303
Administrative – Retail	17	138
Printing – Food manufacturers	92	260
Printing – Supplement manufacturers	48	145
Signage – Retail	4	41
BE replacement – Food and supplement manufacturers (administrative plus segregation costs)	213	1,010
BE replacement – Retail (administrative plus segregation costs)	11	36
Adjustment to administrative, printing and signage costs to account for percentage of market that goes non-BE	-145	-929
USDA costs for administering the rule	2	2
Total initial costs	598	3,515
Ongoing costs		
BE replacement – Food and supplement manufacturers (recordkeeping plus segregation costs)	103	210
BE replacement – Retail (recordkeeping plus segregation costs)	9	13
USDA costs for administering the rule	2	2
Total ongoing costs	114	225
Annualizations		
20 years		
Annualized at 3 percent (3%)	154	461
Annualized at 7 percent (7%)	170	557
Perpetuity Perpetuity	170	337
Annualized at 3 percent (3%)	132	330
Annualized at 7 percent (7%)	156	471
	130	7/1

Top 50 Ingredients Subject to the NBFDS

Table 5: Top 50 ingredients triggering disclosure for food products under Scope 1 (and the proportion
of labels listing the ingredient)

Ingredients 1-25	Ingredients 26-50
Sugars (39%)	Artificial Flavor (6%)
Natural Flavor (25%)	Sodium Citrates (4%)
Citric Acid (24%)	Yeast Extract (4%)
Spice (15%)	Flavor (4%)
Lecithin (soy) (15%)	Malt Flour (Barley) (4%)
Riboflavin (Vitamin B2) (15%)	Soybean (4%)
Soy Bean Oil (13%)	Molasses (4%)
Corn Syrup (12%)	Brown Sugar (4%)
Enzyme (11%)	Distilled Vinegar (4%)
Dextrose (11%)	Chocolate (3%)
Xanthan Gum (10%)	Sodium Carboxymethylcellulose (3%)
Natural and Artificial Flavor (10%)	Cheese (cheddar) (3%)
Corn Starch (9%)	MSG (3%)
Canola Oil (9%)	Corn Syrup Solids (3%)
Mono and Diglycerides of Fatty Acids (9%)	Vanilla (3%)
Modified Starch (Corn) (8%)	Malic Acid (3%)
Maltodextrin (8%)	Partially Hydrogenated Soy Oil (3%)
High Fructose Corn Syrup (8%)	Rice Flour (3%)
Vitamin C (7%)	Corn (3%)
Cheese Culture (7%)	Corn Oil (2%)
Yeast (6%)	Potatoes (2%)
Vegetable Oil (6%)	Corn Flour (2%)
Modified Food Starch (6%)	Soy Flour (2%)
Vinegar (6%)	Potato Starch (2%)
Flour (6%)	Cheese (parmesean) (2%)

Administrative Cost, Physical Labeling Cost, and BE Replacement Cost

Table 1: Total Costs		
Scope 1 - No exempted foods*	من امطاما مماسات المشاهم	
(Very small manufacturer<\$2.5 million annual revenue; compliance p	eriod includes label us	e up)
	Lower bound (\$million)	Upper bound (\$million)
Initial costs		
Administrative – Food manufacturers	317	2,509
Administrative – Supplement manufacturers	39	303
Administrative – Retail	17	138
Printing – Food manufacturers	92	260
Printing – Supplement manufacturers	48	145
Signage – Retail	4	41
BE replacement – Food and supplement manufacturers (administrative plus segregation costs) BE replacement – Retail	213	1,010
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Adjustment to administrative, printing and signage costs to account for percentage of market that goes non-BE	-145	-929
USDA costs for administering the rule	2	2
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Ongoing costs		
BE replacement – Food and supplement manufacturers (recordkeeping plus segregation costs)	103	210
BE replacement – Retail		
(recordkeeping plus segregation costs)	9	13
USDA costs for administering the rule	2	2
Total ongoing costs	114	225
Annualizations		
20 years		
Annualized at 3 percent (3%)	154	461
Annualized at 7 percent (7%)	170	557
Perpetuity		
Annualized at 3 percent (3%)	132	330
Annualized at 7 percent (7%)	156	471

Administrative Costs

Table 8b: Scope 1 Manufacturers' administrative costs, very small cutoff at less than \$2.5 million annual
receipts (in 2017 dollars)

ГСССІР	105 (111 2017 dollars)	_		
		Number of UPCs	\$Cost/ UPC	Total \$million
Row	Food			
1	Very small manufacturer exemption			
		30,000		
2	Organic or non-BE certified	80,000	0	0
3	Meat	55,000	341-2,971	19-163
4	No BE ingredients	125,000	376-3,084	47-386
	Products with disclosure:			
5	low cost analysis	330,000	376-3,084	124-1,018
6	medium cost analysis	110,000	811-6,106	89-672
7	high cost analysis	35,000	1,074-7,745	38-271
8	Total Food	760,000	N/A	317-2,509
	Dietary Supplements			
9	Very small manufacturer exemption			
		1,000		
10	Organic or non-BE certified	3,000	0	0
11	No BE ingredients	10,000	376-3,084	4-30
	Products with disclosure:			
12	low cost analysis	13,000	376-3,084	5-40
13	medium cost analysis	38,000	811-6,106	31-232
14	Total Dietary Supplements	64,000	N/A	39-303

Physical Labeling Costs

Table 11: Scope 1 physical printing costs for food manufacturers with and without the label use-up provision (2017 dollars)

	Compliance Alternative		
Very small definition	No Label Use Up	Label Use Up	
	(\$million)	(\$million)	
Receipts less than \$500,000	1180-2970	92-260	
Receipts less than \$2,500,000	1170-2940	92-260	
Receipts less than \$5,000,000	1160-2930	92-260	

Table 11a: Scope 1 physical printing costs for dietary supplement manufacturers with and without the label use-up provision (2017 dollars)

	Compliance Alternative		
Very small definition	No Label Use Up	Label Use Up	
	(\$million)	(\$million)	
Receipts less than \$500,000	128-277	49-146	
Receipts less than \$2,500,000	126-273	48-145	
Receipts less than \$5,000,000	125-271	48-145	

Retail Administrative and Signage Costs

Table 12: Retail administrative and signage costs					
	Firms	Establishments	Total		
	44,823	68,835			
Administrative Costs	(\$376-\$3084/firm) \$17 mil -\$138 mil	N/A	\$17 mil -\$138 mil		
Signage Costs	N/A	(\$60-\$600/establishment) \$4 mil - \$41 mil	\$4 mil - \$41 mil		
Total	\$17 mil -\$138 mil	\$4 mil - \$41 mil	\$21 mil-\$179 mil		

BE Replacement Costs

ing oct vice				
Table 1: Total Costs				
Scope 1 - No exempted foods*				
(Very small manufacturer<\$2.5 million annual revenue; compliance period includes label use up)				
	Lower bound	Upper bound		
	(\$million)	(\$million)		
Initial costs				
Administrative – Food manufacturers	317	2,509		
Administrative – Supplement manufacturers	39	303		
Administrative – Retail	17	138		
Printing – Food manufacturers	92	260		
Printing – Supplement manufacturers	48	145		
Signage – Retail	4	41		
BE replacement – Food and supplement manufacturers				
(administrative plus segregation costs)	213	1,010		
BE replacement – Retail				
(administrative plus segregation costs)	11	36		
Adjustment to administrative, printing and signage costs to				
account for percentage of market that goes non-BE	-145	-929		
USDA costs for administering the rule	2	2		
Total initial costs	598	3,515		
Ongoing costs				
BE replacement – Food and supplement manufacturers				
(recordkeeping plus segregation costs)	103	210		
BE replacement – Retail				
(recordkeeping plus segregation costs)	9	13		
USDA costs for administering the rule	2	2		
Total ongoing costs	114	225		
Annualizations				
20 years				
Annualized at 3 percent (3%)	154	461		
Annualized at 7 percent (7%)	170	557		
Perpetuity				

132

156

330

471

Annualized at 3 percent (3%)

Annualized at 7 percent (7%)

Scenario: Sugar and Oil are Exempted

Table 1: Total Costs				
Scope 1 - No exempted foods* AND Scope 2 – Sugar and oils exempted (Very small manufacturer<\$2.5 million annual revenue; compliance period includes label use up)				
	(\$million)	(\$million)		
Initial costs				
Administrative – Food manufacturers	317	2,509		
Administrative – Supplement manufacturers	39	303		
Administrative – Retail	17	138		
Printing – Food manufacturers	92	260		
Printing – Supplement manufacturers	48	145		
Signage – Retail	4	41		
BE replacement – Food and supplement manufacturers				
(administrative plus segregation costs)	213	1,010		
BE replacement – Retail				
(administrative plus segregation costs)	11	36		
Adjustment to administrative, printing and signage costs to				
account for percentage of market that goes non-BE	-145	-929		
USDA costs for administering the rule	2	2		
Total initial costs	598	3,515		
Ongoing costs				
BE replacement – Food and supplement manufacturers				
(recordkeeping plus segregation costs)	103	210		
BE replacement – Retail				
(recordkeeping plus segregation costs)	9	13		
USDA costs for administering the rule	2	2		
Total ongoing costs	114	225		
Annualizations				
20 years				
Annualized at 3 percent (3%)	154	461		
Annualized at 7 percent (7%)	170	557		
Perpetuity				
Annualized at 3 percent (3%)	132	330		
Annualized at 7 percent (7%)	156	471		

Scenario: No Detectable Genetic Material

Table 2: Total Costs		
Scope 3 - No detectable genetic material		
(Very small manufacturer<\$2.5 million annual revenue; comp	•	
	Lower bound	Upper bound
	(\$million)	(\$million)
Initial costs		
Testing costs – Food and dietary supplement manufacturers	0 (0.046)	25
Administrative – Food manufacturers	392	3010
Administrative – Dietary supplement manufacturers	29	227
Administrative – Retail	17	138
Printing – Food manufacturers	69	200
Printing – Dietary supplement manufacturers	16	47
Signage – Retail	4	41
BE replacement – Food and supplement manufacturers		
(administrative plus segregation costs)	149	707
BE replacement – Retail		
(administrative plus segregation costs)	11	36
Adjustment to administrative, printing and signage costs to		
account for percentage of market that goes non-BE	-101	-650
USDA costs for administering the rule	2	2
Total initial costs	<i>578</i>	3783
Ongoing costs		
Testing costs – Food and dietary supplement manufacturers	0 (.046)	25
BE replacement – Food and supplement manufacturers		
(recordkeeping plus segregation costs)	103	210
BE replacement – Retail		
(recordkeeping plus segregation costs)	9	13
USDA costs for administering the rule	2	2
Total ongoing costs	114	250
Annualizations		
20 years:		
Annualized at 3 percent (3%)	153	504
Annualized at 7 percent (7%)	169	607
Perpetuity		
Annualized at 3 percent (3%)	132	363
Annualized at 7 percent (7%)	155	515

Vermont Standard Baseline

	Lower bound	Upper bound
	(\$million)	(\$million)
Initial costs		
Administrative – Food manufacturers	472	3,230
Printing – Food manufacturers	1,200	2,880
BE replacement – Food and supplement manufacturers		
(administrative plus segregation costs)	162	771
Adjustment to administrative, printing and signage costs to		
account for percentage of market that goes non-BE	-240	-1,087
Total initial costs	1,594	5,794
Ongoing costs		
BE replacement – Food and supplement manufacturers		
(recordkeeping plus segregation costs)	78	159
Total ongoing costs	78	159
Annualizations		
20 years		
Annualized at 3 percent (3%)	185	548
Annualized at 7 percent (7%)	228	706
Perpetuity		
Annualized at 3 percent (3%)	126	333
Annualized at 7 percent (7%)	190	565

Thank You!

Please submit comments to www.regulations.gov by July 3, 2018

For additional information, please visit the AMS webpage at www.ams.usda.gov/be