Agricultural Marketing Service

Webinar Transcript

Overview of the National Bioengineered Food Disclosure Standard

The May 29, 2018 webinar by the USDA, Agricultural Marketing Service

is available under Resources at

www.ams.usda.gov/BE

Slide 1

Hello, we would like to welcome you to today's webinar on the Proposed National Bioengineered Food Disclosure Standard. You can download a copy of the webinar slides from the USDA Bioengineered Food Disclosure Labeling Standard website at www.ams.usda.gov/be. The material we are going to cover is complex. The goal of this webinar is to provide a detailed overview of the proposed labeling standard and the expected costs and impacts to affected parties. As we move through the presentation, please keep in mind that we are very interested in your feedback and suggestions on the proposed standard. The best way for you to provide us with this feedback is by submitting a formal comment through the rulemaking portal at regulations.gov. The exact link is on our BE labeling website. Comments must be submitted through regulations.gov by July 3. Comments submitted by email to befooddisclosure@ams.usda.gov will not be considered. We will rely on your feedback to develop the final bioengineered food labeling standard. Let's begin - -

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On May 4, 2018, the United States Department of Agriculture published a Notice of Proposed Rulemaking in the Federal Register to establish a national mandatory bioengineered food disclosure standard. The purpose of this webinar is to provide an overview of the proposal. The proposal is divided into three major sections: (1) applicability, (2) disclosure and (3) administrative provisions. We will

discuss each of these sections in turn. We will also provide an overview of the Regulatory Flexibility Analysis and the Regulatory Impact Analysis.

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On July 29, 2016, Public Law 114-216 amended the Agricultural Marketing Act of 1946. The amended Act directs the Secretary to establish the National Bioengineered Food Disclosure Standard for disclosing bioengineered, or BE, food and food that may be bioengineered nationwide. We will refer to the National Bioengineered Food Disclosure Standard as the Standard or NBFDS throughout this webinar. We will now describe the proposed Standard, including the requirements and procedures. We will start with the applicability section of the proposed rule.

Slide 4 and Slide 5

What foods would be subject to the disclosure under the proposed Standard? Foods subject to the labeling requirements of the Federal Food, Drug, and Cosmetic Act, or the FDCA, are subject to the proposed rule. In addition, foods subject to the Federal Meat Inspection Act, the Poultry Products Inspection Act or the Egg Products Inspection Act are subject to the proposed rule, with certain conditions. As set forth in the amended Act, foods subject to the labeling requirements of the Federal Meat Inspection Act, the Poultry Products Inspection Act or the Egg Products Inspection Act are subject to the proposed rule if the most predominant ingredient of the food would independently be subject to the labeling requirements under the FDCA; or if the most predominant ingredient of the food is broth, stock, water, or a similar solution and the second-most predominant ingredient of the food would independently be subject to the labeling requirements under the FDCA. As the preamble describes, we are proposing to use the same methods the Food and Drug Administration, or FDA, uses to identify predominance at 21 CFR 101.4(a)(1).

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The amended Agricultural Marketing Act defines the word “bioengineering” with respect to a food. That same definition was used for the proposed rule and incorporates the amended Act’s language into the regulatory definition of “bioengineered food.” The proposed rule requests comment on two viewpoints regarding the interpretation of the definition of “bioengineered food.” Position 1 maintains that food is bioengineered only if it contains detectable modified genetic material. Proponents of this position would contend that refined products do not contain modified genetic material and therefore do not

meet the definition of "bioengineering." Position 2 would require disclosure for foods and ingredients produced from bioengineered crops, even if the modified genetic material is not detectable. For example, with respect to refined sugar produced from bioengineered sugar beets – proponents of Position 2 would contend that even if the final product – the refined sugar – does not contain detectable modified genetic material that would not definitively mean that there was no such modified genetic material. Proponents of this position would maintain that refined products should be presumed to meet the definition of "bioengineering" because they were produced from bioengineered crops. The definition of "bioengineered food" would also state that "the modification could not otherwise be obtained through conventional breeding or found in nature." As to the definition's component terms, the proposed rule seeks comment on whether "conventional breeding" and "found in nature" should be defined and if so, what those definitions should be.

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In an attempt to make it easier and less burdensome for consumers and regulated entities to understand what products may need to be disclosed under the proposal, AMS has proposed two lists: first, a proposed list of BE foods that are commercially available in the United States with a high adoption rate, and second, a proposed list of BE foods that are commercially available in the United States that are not highly adopted. Only foods or products on either of those lists or made from foods on either of the lists would be subject to disclosure under the NBFDS. The first list includes: canola, field corn, cotton, soybean and sugar beet. Proposed § 66.1 would define this first list as one maintained by AMS and consists of commercially available BE foods that have an adoption rate of eighty-five percent (85%) or more in the United States, as determined by the Economic Research Service or any successor agency. The second list includes: non-browning apple cultivars, sweet corn, papaya, potato and summer squash varieties. The second list consists of commercially available BE foods with an adoption rate of less than eighty-five percent (85%) in the United States.

To compile the proposed lists, AMS considered data reported by USDA's Economic Research Service, data published by the International Service for the Acquisition of Agri-biotech Applications (ISAAA), and FDA's list of Biotechnology Consultations on Food from GE Plant Varieties. The foods on the proposed initial lists are (1) included in FDA's list of Biotechnology Consultations on Food from GE Plant Varieties, (2) produced anywhere in the world, and (3) commercially available for retail sale in the United States.

AMS proposes to have the lists reviewed and revised on an annual basis through Federal Register notices. Interested parties would be invited to recommend additions to and subtractions from the two lists and to provide data supporting those recommendations. Comments would be solicited on those recommendations and AMS would then determine whether revisions to the list would be appropriate. The proposal includes an 18-month grace period to allow regulated entities time to revise food labels appropriately following revisions to the two lists of commercially available BE foods in the United States.

As to specific technologies, the proposed process for establishing and amending the BE foods list would provide a vehicle for AMS to evaluate whether a particular crop meets the definition of "bioengineering."

Slide 8 and Slide 9 (Factors and Conditions)

The proposal also establishes a process for requesting and granting a determination by the Secretary regarding other factors and conditions under which a food is considered a bioengineered food. In order for a request to be considered, a person would have to submit a request or petition to the Secretary's designee, the AMS Administrator. For purposes of transparency, the proposal includes standards for consideration by which the AMS Administrator would evaluate the request or petition. Those standards include: first, whether the requested factor or condition is within the scope of the definition of bioengineering within the amended act; second, the cost of implementation and compliance related to the factor or condition; and third, other relevant information, such as the requested factor or condition's compatibility with food labeling requirements of other Federal agencies or foreign governments.

If the Administrator then determines that the request or petition satisfies the standards for consideration, AMS would initiate rulemaking that seeks to amend the definition of "bioengineered food" in proposed § 66.1 to include the factor or condition.

The proposed rule explores two requests for factors and conditions that AMS has determined meet the proposed standards for consideration. First, whether incidental additives present in food should be considered "bioengineered food" and labeled accordingly. Second, whether the modified genetic material in a food may be detected. Earlier in the webinar, we described two viewpoints on the interpretation of the definition of "bioengineered food." If AMS ultimately decides to proceed with

Position 2 which includes refined ingredients within the definition of "bioengineered food," this factor or condition would be a means to potentially exclude products where modified genetic material cannot be detected.

The proposed definition of "bioengineered food" includes the first requested factor or condition (incidental additives), but does not include the second (detection). AMS seeks comment on whether the final rule should incorporate one or both of them into the definition of "bioengineered food." The impact of adopting these factors or conditions would be to limit the scope of the definition of "bioengineered food," thus potentially excluding certain products from disclosure.

Slide 10 (Exemptions)

The proposed rule also includes several exemptions to the disclosure requirement. First, food served in a restaurant or similar retail food establishment would be exempt. Second, very small food manufacturers-both domestic and foreign -- would also be exempt. The proposed rule defines very small food manufacturer as "any food manufacturer with annual receipts of less than $2,500,000."

The amended Agricultural Marketing Act directs the Secretary to establish a threshold level for the amount of bioengineered substance for determining whether a food must bear a BE disclosure. A food in which the bioengineered substance is below the threshold would not be required to have a BE disclosure. The proposed rule includes three alternative thresholds which are: 1) food in which an ingredient contains a BE substance that is inadvertent or technically unavoidable, and accounts for no more than five percent by weight of the specific ingredient; 2) food in which an ingredient contains a BE substance that is inadvertent or technically unavoidable, and accounts for no more than nine-tenths percent by weight of the specific ingredient; and 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.

Further, the proposed rule also incorporates the amended Act's exemption, prohibiting a food derived from an animal from being considered a bioengineered food solely because the animal consumed feed produced from, containing or consisting of a bioengineered substance. As it relates to the National Organic Program, the proposed rule also exempts certified organic foods from the bioengineered food disclosure.

DISCLOSURE

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Now we will cover who would be required to disclose, what the disclosure would look like and how the disclosure should occur. Generally, if you are a food manufacturer, food importer or food retailer (in certain situations), you would be responsible for disclosing the presence of bioengineered food or bioengineered food ingredients in the food you process and/or sell. The amended Act requires that the disclosures be made using text, a symbol or through certain electronic means.

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Please note, if you import food into the United States you would also be subject to the same disclosure and compliance requirements as domestic entities. We are interested in the impact of these types of requirements on importers and would consider implementation of a "mutual recognition" type of arrangement as a way to better streamline trade. We are specifically requesting comments on these types of mutual recognition agreements.

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As we mentioned earlier, to help clarify whether or not a whole food or ingredient should be disclosed, we are proposing a list of bioengineered foods that are highly adopted, meaning that over the last few years, bioengineered crops have been used in more than 85% of the plantings of theses crops in the United States. Again, highly adopted commercially available bioengineered foods would include canola, field corn, cotton, soybean, and sugarbeet. Since bioengineered versions of the foods on this list are highly adopted in the marketplace we assume that a food from this list would likely be bioengineered. We have also proposed a list of bioengineered foods that are not highly adopted, meaning that bioengineered crops have been used in less than 85% of the planted acreage of those crops in the United States. Commercially available bioengineered foods that are not highly adopted would include non-browning cultivars of apples, sweet corn, papaya, potato, and summer squash.

As a reminder, the purpose of these lists is to provide a straightforward means of determining whether or not a particular food might require disclosure. Basically, if a food or food ingredient is on either of these lists or made from a food on these lists, regulated entities would need to make a disclosure consistent with the standard, or no disclosure, depending on whether the food is bioengineered. For foods or food ingredients on the high adoption list, regulated entities would be required to label the food with the terms "bioengineered food" or "contains a bioengineered food ingredient." They could

also use the symbol or an electronic disclosure depending on the form of disclosure that best meets customer expectations. Foods on the non-highly adopted list would also be able to bear the "may be bioengineered food" disclosure.

In developing these disclosure requirements, USDA has tried to balance flexibility for regulated entities with ensuring that consumers have a clear understanding of the bioengineered content of food they are buying.

For this reason, we are proposing to require labels to be of sufficient size and clarity and to appear prominently on food packages. This way, it is more likely to be read and understood by the consumer under ordinary shopping conditions. The placement of the disclosure on the food packaging should be in a place where consumers who are interested in additional food information typically look for information about their food. Generally this information is found on the information panel or the principal display panel. These are the places on food packaging where manufacturers include the ingredient list, the manufacturer name and address, and if applicable, the country of origin. These are the places to also require disclosure for bioengineered food or bioengineered food ingredients.

Slide 14

Back to the lists - - For foods on the non-highly adoption list, we are actually proposing several disclosure options. For BE foods commercially available, but not highly adopted in the United States, the disclosure would be made using one of the following statements "bioengineered food," "may be bioengineered food," "contains a bioengineered food ingredient," or "may contain a bioengineered food ingredient." We are particularly interested in your input on these topics. Please provide us with your comments on the use of the term "may" and on how bioengineered foods on either of the lists should be required to be disclosed.

Slide 15

A symbol is another way to disclose the presence of bioengineered food or bioengineered food ingredients. We have proposed three alternative symbols. There are several options included in the proposed rule, all three of which include some variation of the letters B and E, short for "bioengineered." We seek comment on the alternatives and the variations of the symbols.

Slide 16

We have also proposed another disclosure option that would allow the use of an electronic or digital link printed on food packaging to provide consumers with information on bioengineered food ingredients. Currently there is technology available including quick response codes or QR codes, and digital watermark technology. We are proposing that food packages must provide clear instructions to consumers, for example, "scan anywhere on package for more food information," or "scan icon for more food information."

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In compliance with the amended Act, USDA completed a study to identify potential technological challenges that may impact whether consumers would have access to the bioengineering disclosure through electronic or digital disclosure methods.

This study considered five factors:

- The availability of wireless Internet or cellular networks;
- The availability of landline telephones in stores;
- Challenges facing small and rural retailers;
- The efforts that retailers and other entities have taken to address potential technology and infrastructure challenges; and
- The costs and benefits of installing in retail stores electronic or digital link scanners, or other evolving technology that provide bioengineering disclosure information

The study found:

- The majority of Americans own a smartphone (77%) and ownership rates are trending upward
- Most Americans live in areas with sufficient broadband access (93.6%) to scan a digital link to access bioengineering food disclosure information
- All national chain stores and most regional chain stores (97%) provide WiFi in store
- Of small retailers, 37 percent already provide WiFi to consumers in store
- Consumers may recognize digital links but lack familiarity with scanning

- Many consumers (85%) experienced technical challenges using certain mobile software applications ("apps") for scanning digital links
- Scanning digital links requires access to the internet; therefore, some retailers may need to install WiFi networks for consumers without access to cellular data or local WiFi networks

The study is under review and the Secretary has not yet made a determination regarding whether consumers, while shopping, would not have sufficient access to the bioengineering disclosure through electronic or digital disclosure methods. We are proposing disclosure through a text message that would operate similarly to the electronic or digital disclosure, in the event that the Secretary makes such a determination. Text message would be a means for consumers that do not have access to broadband Internet or a smart phone to access the disclosure.

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We have worked to provide flexible electronic disclosure options that reflect constantly changing technology. The proposed rule also includes flexibilities for small food manufacturers. Small food manufacturers are defined in the proposed rule as any food manufacturer with less than $10 million in annual receipts but more than $2.5 million in annual receipts. This is similar to the FDA definition of small food manufacturer.

The proposed rule includes the option for small food manufacturers to provide disclosures through a telephone number or Internet website that consumers can call or access for additional food information. Additionally, the standard proposes flexible disclosure options for food contained in small or very small packages.

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Similarly, we have proposed additional flexibilities for food sold in bulk containers. These are foods such as corn meal, or dried fruits that are sold in a bulk bin in a grocery store. For these foods, the proposed rule allows for disclosure using any of the options for on package disclosure, including text, symbol, or electronic or digital link, or text message, if applicable. The disclosure would be required to appear on signage or other materials such as stickers on or near the bulk items. This would allow the consumer to easily identify and understand the bioengineered status of the food.

Slide 20

Finally, we would permit voluntary disclosure of the presence of bioengineered food or food ingredients. Entities who are responsible for disclosure would have the option to disclose bioengineering information for foods that may not be subject to mandatory disclosure. To ensure that any business that wants to provide disclosure has the option to disclose bioengineering information regarding foods that may not be subject to mandatory disclosure, the proposed rule allows voluntary labeling of food that meets the definition of bioengineered food.

Slide 21

We will now shift gears and discuss certain administrative provisions including record keeping and enforcement. This section is intended for all regulated entities. Keep in mind that regulated entities are subject to enforcement actions, including USDA audit. The Amended Act prohibits failure to disclose a BE food or BE food ingredient. If the results of an audit find that certain food ingredients or products were not properly disclosed, the results of such information would be made publicly available.

As to record keeping, the Amended Act requires each entity (food manufacturers, importers, and retailers subject to bioengineered food disclosure) to maintain customary and reasonable business records to demonstrate compliance with bioengineered food disclosure requirements. Our intent is to minimize compliance costs to food companies as much as possible and we are proposing flexibility for regulated entities to decide for themselves what these typical and customary records are. As well, regulated entities would be able choose what format to use for the records they maintain and where to store them. Pertinent records would need to be maintained for two years beyond the date the food product is offered for retail sale.

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We believe that for the most part, manufacturers and retailers already maintain similar and consistent records, for example, purchase orders, invoices, bills of lading, organic certifications, process verifications, testing records, etc. These are the types of records that describe the origin of food and food ingredients, and the types of records that would denote whether a food is bioengineered.

Slide 23

Keep in mind, we are proposing certain record keeping requirements depending on the food that regulated entities process and/or sell. If you sell a food that is either on the high adoption or non-high

adoption list of bio-engineered foods, but do not disclose, you would be required to maintain documentation to verify that the food in question is, in fact, not bioengineered.

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If you are selling a food or food product on either the "highly adopted" or "non-highly adopted" list and you choose to disclose the presence of bioengineering, you would only need to maintain records to show that the food or food ingredient is on one of the lists. Similarly, if using a "may" claim, you would only need to demonstrate that the food is on the non-highly adopted list. Other examples of when a "may" claim could be used is when a manufacturer sources bio-engineered and non-bioengineered versions of the same food ingredient, or when a manufacturer switches sources for a certain ingredient, but does not want to modify their labels.

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Records would be required to be maintained for at least two years after the foods are distributed for retail sale. If alerted by USDA that an audit will be conducted of your records, you would have five business days to produce certain records. If USDA should require access to your records at your place of business, we would provide at least three days' notice. As with other provisions in this proposed rule, we are requesting your input on the record keeping requirements previously described.

Slide 26 and 27

As a reminder, failure to make a bioengineered food disclosure as required by the NBFDS is prohibited. Complaints about possible violations of the NBFDS would submitted to AMS will be promptly addressed. Once we determine whether an investigation is warranted, we would conduct a records audit. Following the audit, the impacted company would be notified and informed of the results. Regulated entities would be able to appeal the results of an audit or investigation, after which, AMS would notify the regulated entity of its final determination in the matter. The results of the audit or investigation would then be posted to AMS's website

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We also wanted to take this opportunity to discuss the proposed effective dates for compliance with this Rule. We intend that any final rule resulting from this action will be effective 60 days after the date of publication in the Federal Register.

We are proposing a compliance date of January 1, 2020, with a delayed compliance date for small food manufacturers of January 1, 2021. These compliance dates would be aligned with certain proposed FDA requirements regarding changes to the nutrition facts and supplement facts label. We want to ensure that regulated entities have adequate time to analyze products and understand new requirements, make necessary changes to their labels, and have the chance to review and update their records and record keeping systems. We are also proposing that entities that have previously printed labels for food packages would be allowed to use up existing supplies until January 1, 2022. Again, we are interested in your input, and invite your comments on this approach.

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Now, we will shift the discussion to the projected impacts on small businesses and the results of the preliminary economic analysis.

We evaluated the potential impact of the proposed rule specifically on small businesses as required by the Regulatory Flexibility Act.

Over the next few slides we will describe the types of small businesses that would be affected by the proposal, should it be finalized in its current form; we will discuss some of the provisions of the statute that we propose to use to reduce adverse impacts on small businesses covered by the proposal; and we will discuss how we evaluated whether the rule would have a significant adverse effect on any group of businesses (large or small).

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The proposed rule sets requirements that would apply directly to food manufacturers, dietary supplement manufacturers and certain retailers.

Food and supplement manufacturers are those that are responsible for packaging food for sale to the public. The manufacturer of a can of soup or a jar of multivitamins is responsible for making sure that product is labeled correctly. Sales between vendors, not intended for direct sale to the public, for example tomato sauce sold to a manufacturer of spaghetti sauce, would not be covered under the proposed rule.

Retailers that separate the product from its label (or who sell product that was never labeled) would be required to provide information on the BE status of that product at the point of sale. For example, if a retailer is selling zucchini loose in the produce section, they would be required to post information on

the BE status of the zucchini in question. However, if the same retailer were selling apples that were bagged by the supplier, the supplier would be responsible for the disclosure.

For purposes of this analysis we assume that all manufacturers and retailers would incur costs as a result of the rule.

Manufacturing businesses are divided into four categories by revenue. Very small manufacturers– those with revenues below $2.5 million per year. Small manufacturers – those with revenues below $10 million per year. Small businesses that meet the Small Business Administration definition of small business would not be considered small manufacturers for purposes of this rule. And large businesses which are businesses that do not meet any of the definitions of small or very small.

The statute provides exemptions and extensions for very small manufacturers and small manufacturers. We do not estimate the number of retailers that would fit into these categories. However, retailers that meet the SBA definition of small account for almost 99 percent of all retailers.

In addition to the firms directly regulated in this program there are additional firms in other industries – particularly wholesalers – that may face consumer driven costs associated with increased demand for BE information on intermediate ingredients or other supplies. While we do not attempt to estimate the level of these costs (we assume they are included in the costs to manufacturers), we do note that there are approximately 40,000 firms in these indirectly affected industry sectors and roughly 96 percent of them meet the SBA definition of small.

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The statute provides specific relief for certain classes of small businesses.

The statute exempts very small food manufacturers. As mentioned, the proposal defines this to be any food manufacturer (including dietary supplements) with receipts of less than $2.5 million per year.

Under this exemption, 74 percent of food manufacturers and 45 percent of dietary supplement manufacturers would be exempt from the rule. Like most industries, however, production is concentrated among the firms at the larger end of the sector. So, 96 percent of food products would still be covered even with 74 percent of the firms exempt. 98 percent of dietary supplement products would be covered.

The statute also provides additional compliance time for “small food manufacturers.” Small food manufacturers have an additional year to label their products. This extension can significantly reduce

the cost of printing and applying labels because it gives manufacturers time to use up existing label stock, reducing waste. However, the extension does not reduce administrative costs of compliance.

The proposed rule uses the FDA Labeling Standard definition of small manufacturers (receipts less than $10 million per year) since the businesses covered by both rules overlap. This helps us synchronize schedules with the FDA further reducing wastage of labels.

An additional 12 percent of food manufacturers (over and above those fully exempt) and 19 percent of dietary supplement manufacturers will receive this additional time under the proposed rule.

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We evaluated whether the rule was likely to have a significant adverse effect on small businesses (or any other business size) by looking at the ratio of costs to revenue for the affected industries.

To ensure that we did not miss any potential adverse effect, we used the upper bound annualized cost, and a seven percent discount rate (which results in higher annualized cost estimates than the three percent rate). We compared the cost for an individual revenue category to the total revenue of all firms in that category to obtain a ratio of cost to revenue.

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While there is no single revenue to cost ratio that can be considered acceptable across all industries, we discussed this with SBA and decided to use one percent and three percent as indicating increasing levels of concern.

As indicated on this and the following slides, costs never exceed one percent of revenue for any size class of firm. Costs do reach one percent of revenue for food manufacturers with receipts of less than $500,000, but such firms would not be covered by the rule due to the very small food manufacturer exemption.

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For retailers, the cost to revenue ratios are all reported as zeros. What this means is that the costs of the rule are less than 0.005 percent of revenues.

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Because the cost of revenue ratio never cross the 1% threshold, it is safe to assume that the proposed rule would not have a significant impact on a substantial number of small businesses.

Please note that while the regulatory impact analysis for their proposed rule correctly states this conclusion. The Notice of Proposed Rulemaking incorrectly states the opposite at 83 FR19881 and 19884 by inadvertently dropping the word, not, in the statements on those pages.

We will publish a correction in the Federal Register explaining the inconsistency and noting the correct conclusion for the initial regulatory flexibility analysis.

Again, our preliminary conclusion is that the proposed rule would not have a significant impact on a substantial number of small businesses.

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Now, we will discuss the preliminary economic impact analysis.

USDA estimates that the cost of the proposed NBFDS would range from $600 million to $3.5 billion for the initial year, with ongoing annual costs of between $114 million and $225 million. The annualized costs would be $132 million to $330 million at a three percent (3%) discount rate and $156 million to $471 million at a seven percent (7%) discount rate (Table 1).

This estimate incorporates a definition of “small manufacturer” of less than $10 million annual revenue (small manufacturers have extra year to comply) and a definition of “very small manufacturer” of less than $2.5 million annual revenue (very small manufacturers are exempt from the law).

This estimate is for the case where no foods are exempted from the NBFDS – though it should be noted that none of the cost estimates in this RIA examine the BE status or potential cost of disclosure of those incidental additives that do not have to be listed on food labels since USDA had no information on which to assess the inclusion and BE content of such ingredients.

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Even leaving aside incidental additives, the proposed rule still has potential to cover a larger number of products. USDA analyzed product labels using the LabelInsight data to find that approximately 75 percent of products for sale in the United States contain one or more ingredients, as shown in table 5,

that could potentially be BE (a similar table in the RIA shows the top 20 ingredients for dietary supplements).

However, not all of the 75 percent of products with a potential BE ingredient will generate any costs under the proposed rule. Zero-cost products include organic products, which are exempt from mandatory disclosure under the statute; non-GMO certified products, which are assumed to already meet the requirements of the proposed rule; and products for which the primary ingredient is meat since these products are not covered by FDA labeling regulations. The remaining 65 percent of food products and 80 percent of dietary supplements contain ingredients that could trigger disclosure and therefore generate costs under the proposed rule.

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Now that we've established coverage of the rule, let's take a closer look at what is driving its high costs.

As outlined in Table 1, the cost estimate is composed of three elements: administrative costs, physical labeling costs, and BE replacement costs.

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The first set of costs, administrative costs, are the costs to manufacturers and retailers for analyzing the rule to figure out if they need to label any of their products. Administrative costs vary depending on how difficult it is to figure out which ingredients are potentially BE and would need to be disclosed. The USDA BE lists will help to contain these costs by providing clear information to manufacturers and retailers about those BE foods subject to disclosure. Thanks to the lists, a grocer selling tomatoes, for example, would not have to investigate whether or not BE tomatoes are currently marketed in the United States. He or she would simply need to consult the USDA BE lists to learn that his/her tomatoes are not subject to disclosure.

The lists to do not, however, lower costs so dramatically for all ingredients. For example, while manufacturers of pasta sauce could consult the USDA BE lists to easily determine that tomatoes do not trigger disclosure, they would have a harder time determining whether the citric acid and spices in the sauce need disclosure. These types of ingredient would entail higher administrative costs.

As shown in table 8b, USDA included three levels of administrative costs to account for the difficulty of determining whether the ingredients in a product triggers disclosure. All in all, the admin costs account for well over half (almost ¾) of initial, first year costs of the proposed rule.

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The second type of costs, physical labeling costs, are those related to designing, printing and applying the physical label to those products that require labeling.

These costs are highly sensitive to the compliance period - the amount of time manufacturers have to comply with the rule. The shorter the compliance period, the greater the amount of existing label stock that manufacturers cannot use. This raises the cost of compliance.

Under the proposed rule, USDA seeks to minimize physical labeling costs by including a label use-up allowance that allows manufacturers to use up any existing labels printed before publication of the final NBFDS rule, with the requirement that all labels printed after January of 2020 contain the required BE disclosure. For the purposes of calculating printing costs, this is the practical equivalent of a 39 month compliance period, while ensuring disclosure occurs as expeditiously as practical within those 39 months.

An alternative compliance period of 15 months with no label use up resulted in substantially higher labeling costs. Tables 11 and 11a show large reductions in cost from the label use up option, with savings ranging from $1 billion to almost $3 billion for food manufacturers across the three definitions of very small and from $77million to $131 million for dietary supplement manufacturers.

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In addition to manufacturers, retailers would also incur direct costs associated with the rule. Most of the products sold by retailers will already be labeled by the manufacturer or processor in packaging. However items such as produce are often sold intact and without packaging. If these products are not already labeled by suppliers, the retailer would be responsible for labeling the items or providing information through other point-of-sale materials.

The first costs retailers would incur are the administrative analysis costs related to determining the applicability of the law. USDA assumed that firms with multiple establishments would centralize these costs at the headquarters level (firm level) so that administrative costs are incurred only at that level. As shown in Table 12, total administrative costs would be $17 million - $138 million.

The second set of costs to retailers is the signage costs to provide consumers information about the BE status of the product. These costs would be incurred at each establishment (not just at headquarters) and for each potentially BE product. Of the produce on the USDA list of commercially available BE

foods, only three types are currently offered for bulk, unpackaged and undifferentiated sale: sweet corn, zucchini (summer squash) and papaya. The non-browning BE potatoes currently on the market are sold in bags with QR codes and are segregated from non-BE varieties. Likewise, non-browning BE apples are trademarked and sold as bagged slices. Grocers would not have to take extra steps to provide signage for these products since they are packaged.

USDA therefore assumed three signs per establishment (for sweet corn, zucchini and papaya) for a total cost of between $4 million and $41 million.

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The third type of costs included in USDA's cost estimates are the BE replacement costs. To avoid potential negative consumer reaction to products labeled BE, some manufacturers and retailers might choose to reformulate away from BE ingredients or replace BE ingredients with non-BE counterparts to avoid having to put the BE disclosure on their products.

How many manufacturers decide to do this – and for how many products—depends on their prediction of how consumers will react to the BE labels. Market observations, hypothetical market experiments and surveys of consumer attitudes provide mixed evidence as to probable consumer reaction and market outcomes. The lack of unambiguous predictors has resulted in a wide range of predicted impacts.

For its analysis, USDA assumed that potential consumer reaction to BE labeling will drive manufacturers to avoid labeling 20 percent (20%) of their products as BE. In other words, USDA assumed that manufacturers and retailers would convert 20% of products to verified non-BE product.

The marketing decision to replace BE ingredients with their non-BE counterparts entails higher costs stretching back to the farm. The extra cost to farmers of supplying non-BE commodities and crops include the costs of sourcing non-BE seeds; avoiding cross contamination with BE varieties during planting, harvesting and transporting; driving to an elevator or handler that is farther away than the nearest bulk elevator; and foregoing the benefits of BE production.

To maintain the integrity of the non-BE commodity or crop once it leaves the farm, grain handlers and distributors will need to ensure that non-BE varieties are not mixed or cross contaminated with BE varieties. This can be achieved by either adjusting existing systems to accommodate handling both BE and non-BE varieties or converting some facilities and systems into specialized non-BE systems. For non-

dedicated systems, BE segregation will require thorough cleaning of facilities, storage bins, trucks and hoppers before handling BE varieties. In some cases, handlers may have to invest in additional containers that can be securely sealed to prevent cross contamination.

USDA estimates that total non-BE segregation costs would add up to between $100 million for a purity threshold of 5 percent to $198 million with a more stringent purity level of 0.9% percent. Since manufacturers of dietary supplements use food grade inputs, these segregations costs include costs to these manufacturers as well.

Assuming that 20 percent (20%) of retailers also decide to pursue a non-BE strategy (equaling 20 percent of retail sales), their segregation costs would equal $8 million annually, with no variation in cost due to purity threshold.

In total, USDA estimates initial administrative plus segregation costs at between 213 million and $1,010 million for food and dietary supplement manufacturers and between $11 million and $36 million for retailers. USDA estimates ongoing segregation costs associated with sourcing non-BE varieties between $103 million and $210 million (record keeping plus segregation) annually for food and dietary supplement manufacturers and at $9 to $13 million annually for retailers.

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Up to now, we've discussed the scenario where no foods are exempted from the NBFDS, which is denoted as scope 1. For the RIA, USDA examined two alternative assumptions about the scope of the proposed rule.

First, USDA examined a scenario where sugars and oils are exempted, called scope 2. Surprisingly, exempting oil or sugar (or both) from disclosure does not usually mean that the product is no longer subject to disclosure. This is because most processed food products contain ingredients other than oils and sugars that trigger disclosure. Exempting the sugar in a can of pasta sauce, for example, does not eliminate the need to label if the product also contains spices, modified food starch, xanthan gum and citric acid.

Due to the large number of multiple ingredient products, exempting sugar and oil doesn't reduce the number of labeled products by enough to affect the bottom line: there would be no noticeable difference in the number of labeled products resulting from a categorical exemption of oils and sugars. This is true for both food and dietary supplement manufacturers.

Interestingly, there is also a slight increase in the modeled administrative cost of scope 2 relative to scope 1 due to a phenomenon USDA calls shielding. Shielding results from the fact that disclosure is a binary decision (you label or you don't). As such, the costs of deciding whether and how to label will be capped by the lowest administrative cost ingredient on a particular label. In other words, if you have BE corn flour, you will label the product before you need to worry about tracking down the BE status of your xanthan gum. To the extent that some of the oils and sugars are on the low administrative cost end of the spectrum, the administrative cost for an individual product could actually increase if the lower administrative cost ingredients are exempted.

For scope 2, USDA assumes that the moderate increase in administrative cost will be roughly equivalent to the moderate decrease in printing cost. As a result, for purposes of this RIA the cost is presumed to be roughly the same under scopes 1 and 2.

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The second alternative scope USDA examined is one that exempts from disclosure foods with undetectable recombinant DNA, called scope 3. As described in the proposed rule under Factors and Conditions, under this alternative assumption, those foods where the modified genetic material cannot be detected would be excluded from the NBFDS. To demonstrate that modified genetic material cannot be detected, regulated entities would need to maintain records showing that food subjected to a specific process has been tested for the purpose by a laboratory accredited under ISO/ICE 17025:2017 standards, using methodology validated according to Codex Alimentarius guidelines.

This alternative results in lower printing costs, but higher administrative costs and the addition of testing costs. The lower printing costs are due to a smaller number of products needing to be labeled.

The higher administrative costs are due to two observations: First, administrative costs are incurred by manufacturers whether they eventually label or not. Second, the shielding effect discussed in the evaluation of scope 2 plays a bigger role in scope 3. Scope 3 presumes that all ingredients except those very closely tied to the BE crop (for example, flours, raw crops, unprocessed oils) and ingredients where the ingredient list is uninformative as to BE status (for example, spice, natural flavors) would be able to test out of the disclosure requirement. The remaining list of ingredients that could trigger disclosure, include few "obvious" ingredients that would short circuit the manufacturer's assessment process and

thereby reduce administrative costs. As a result, USDA estimates slightly higher administrative costs for scope 3 than scope 1 and 2.

An additional cost that increases the total cost of scope 3 is testing costs. Scope 3 allows manufacturers to demonstrate through evidence – including testing – that the ingredients in their product do not contain any rDNA. Using the bioengineered ingredient testing cost in the FDA Label Cost Model, USDA estimates testing costs ranging from less than $1 million to $25 million annually depending on purity threshold.

USDA assumed that as with scope 1, food and dietary manufacturers would go non-BE for 20 percent (20%) of products subject for disclosure. However, since the universe of products subject to disclosure under scope 3 is smaller than that for scope 1, the costs of non-BE sourcing for 20 percent (20%) of products will also be smaller. For retailers, the cost of replacing BE with non-BE product would be exactly the same as in scope 1 since the amount of potentially affect product is the same as in scope 1.

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Benefits:

The proposed NBFDS is not expected to have any benefits to human health or the environment. As noted previously, in its 2016 review of the safety of BE plants, the U.S. National Academies of Sciences, Engineering and Medicine concluded that "no differences have been found that implicate a higher risk to human health safety from these GE foods than from their non-GE counterparts". As a result, even if the new BE labels changed the ratio of BE to non-BE food purchases, there would be no impacts on human health or the environment.

Instead, the primary potential benefit of the proposed rule is the elimination of costly inefficiencies of a state-level approach to BE disclosure. Prior to the NBFDS, seven states had voted on mandatory BE food labeling initiatives and thirteen had pending initiatives. Vermont was the only state to successfully pass mandatory labeling legislation that was not conditioned on the passage of legislation in other states.

In order to gauge the benefits of eliminating the inefficiencies of a state-level approach to BE disclosure, it is necessary to consider the regulatory baseline against which this proposed rule is being assessed. OMB Circular A-4 states that the "baseline should be the best assessment of the way the world would look absent the proposed action…. When more than one baseline is reasonable and the choice of

baseline will significantly affect estimated benefits and costs, you should consider measuring benefits and costs against alternatives baselines."

This proposed rule is one for which assessment against multiple baselines would be informative for purposes of compliance with EO 12866 and Circular A-4. USDA therefore examined three possible baselines. In this webinar, we present the analysis of one of these baselines: namely, the baseline in which the Vermont labeling law is enacted. In this case, the benefits of the proposed rule would be the avoided costs of the Vermont BE labeling law.

The Vermont BE labeling rule required labeling of foods offered for sale in Vermont after July 1, 2016 if they were produced with genetic engineering. Foods exempted from the Vermont rule included meat, milk, cheese and foods certified as organic under USDA's National Organic Program. The Vermont standard required segregation, certifications, and documentation of supply chain management to document compliance. The rule required that transportation and storage systems be designed to segregate BE and non-BE foods.

Though Vermont is a small state, with less than 0.2 percent (0.2%) of U.S. population and 0.17 percent (0.17%) of U.S. GDP, industry leaders and analysts projected widespread application of its GE labeling standard. There are three primary reasons for this conclusion. First, even manufacturers that do not sell to Vermont could not ensure that their unlabeled products would be kept out of the state. For example, a Vermont grocer could directly import unlabeled canned peaches (with BE sugar as an ingredient) from a wholesaler in New Hampshire. Second, the Vermont law held manufacturers liable, with significant monetary penalties ($1000 per day per product), for a mislabeled product in the state even if the manufacturer did not sell its products into the market. As a result, the manufacturer, not the importing grocery, would have been liable for mislabeled canned peaches from New Hampshire. Third, the production of different products for the Vermont market and for the rest of the county could create costly supply-chain and manufacturing inefficiencies. These would be compounded if more states enacted separate BE labeling laws.

For this baseline estimate, USDA assumed that manufacturers would comply with the Vermont BE labeling law for products sold in the Northeast region of the United States, but not for products sold only in other regions of the country. Using this assumption, USDA finds that the cost of the Vermont BE labeling law overall would be slightly higher than the costs of the proposed national BE labeling law. This result is driven by three observations.

First, all manufacturers in the country will incur some administrative costs in figuring out if the Vermont BE law applies to them.

Second, those manufacturers that need to comply with the Vermont law would face more expensive administrative costs than with the national BE law. The Vermont standard had four levels of compliance that were tied to the relative weight of ingredients in the final product. This complexity would make it harder for manufacturers to determine how to comply with the law.

Third, the Vermont standard only allowed twelve months to comply, meaning that manufacturers would have difficulties synching printing and applying the new labels with regularly scheduled labeling changes. This dramatically increases the cost of labeling. Manufacturers that pulled product from the Vermont market (for good) or to synch up with regularly scheduled labeling changes would incur the cost of lost profits.

In total, including costs for retailers and non-BE sourcing, USDA estimates that the total cost for the Vermont BE labeling law applied to products sold in the Northeast would be $126 million to $333 million at a three percent (3%) discount rate and $190 million to $565 million at a seven percent (7%) discount rate.

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This concludes the webinar. As noted earlier in the webinar, comments on the proposed rule must be submitted by July 3. Please submit any comments through the rulemaking portal at regulations.gov. And please remember that comments submitted to befooddisclosure@ams.usda.gov will not be considered. Thank you.

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