THE VOICE OF FOOD RETAIL

Feeding Families Enriching Lives

July 3, 2018

Submitted Electronically via www.regulations.gov

Agricultural Marketing Service
U.S. Department of Agriculture
Docket Clerk
1400 Independence Ave. SW
Room 4543-South
Washington, DC 20250;

Re: Proposed Rule: National Bioengineered Food Disclosure Standard; Docket ID: AMS-TM-17-0050

On behalf of the retail and wholesale members of the Food Marketing Institute (FMI), we appreciate the United States Department of Agriculture (USDA) Agricultural Marketing Service's (AMS) consideration of our comments regarding the National Bioengineered Food Disclosure Standard (NBFDS) proposed rule. FMI is proud to participate in the Coalition for Safe, Affordable Food ("Coalition") and to be associated with the comments submitted by the Coalition; however, we submit these comments to further clarify some of the most significant issues from the retail and wholesale perspective. We appreciate the opportunity to comment on the proposed rule and look forward to working with AMS, and encourage the Administration to continue to act prudently but expeditiously to promulgate a final rule. Additionally, as noted in our comments, economic impact studies and consumer feedback confirm that a single national standard is far preferable to a state-by-state approach both in the eyes of our customers as well as to achieve much-needed supply chain efficiencies.

The Food Marketing Institute proudly advocates on behalf of the food retail industry, which employs nearly 5 million workers and represents a combined annual sales volume of almost $800 billion. FMI member companies operate nearly 33,000 retail food stores and 12,000 pharmacies. FMI membership includes the entire spectrum of food retail venues; single owner grocery stores, large multi-store supermarket chains, pharmacies, online, and mixed retail stores. Through programs in public affairs, food safety, research, education, health and wellness and industry relations, FMI offers resources and provides valuable benefits to almost 1,000 food retail and wholesale member companies and serves 85 international retail member companies. In addition, FMI has almost 500 associate member companies that provide products and services to the food retail industry. For more information, visit www.fmi.org and for information regarding the FMI Foundation, visit www.fmifoundation.org.

The following associations and companies support the comments below.

Alex Lee, Inc.
C & S Wholesale Grocers
The Kroger Co.
Associated Food & Petroleum Dealers
California Grocers Association
Georgia Food Industry Association
Idaho Retailers Association
Illinois Food Retailers Association
Louisiana Retailers Association
Massachusetts Food Association
Michigan Retailers Association
Minnesota Grocers Association
Missouri Retailers Association
Northwestern Pennsylvania Food Council
Ohio Council of Retail Merchants
Pennsylvania Food Merchants Association
Tennessee Grocers & Convenience Store Association
Washington Food Industry Association

Background

FMI members are fully committed to providing their customers with the wealth of information they increasingly request and are considered a trusted resource regarding the foods they sell. To better understand the trends and evolving preferences of our member companies' customers, FMI undertakes a significant amount of research on an annual basis to remain current on all aspects of the food retail industry, with much of the research focused on the varying preferences of consumers. Last year, FMI's research explored in more depth the growing consumer desire for transparency in the food supply. The research signals that in this evolving marketplace, U.S. grocery shoppers want to be more deeply connected to the way their food is produced. We recently released a comprehensive consumer study, *FMI U.S. Grocery Shopper Trends 2017*, completed jointly with the Hartman Group. This report tracks trends among U.S. grocery shoppers and, for the last four decades, FMI has traced such critical issues as where they shop, how they shop and what concerns them most when it comes to the food they buy for themselves and their families.

In developing our findings, we heard directly from customers and the feedback was consistent with our experiences in stores – that there is an increasing number of grocery customers who want more information about their food, and with regard to biotechnology specifically, they support disclosure of whether their food contains or is derived from bioengineered crops. Importantly, this desire for information is not related to food safety or nutrition concerns, but merely because customers "just want to know exactly what goes into the food I eat" (48%). Our research also shows that customers are increasingly interested in a large number of other attributes about where their food comes from and how it was grown. Toward this end, retailers are working diligently to provide as much information as possible in a format that is easily accessible to customers and also provides retailers the opportunity to communicate additional information or context that might be of interest to customers. FMI members are fully committed to this goal and will continue to provide the information their customers demand in the most accessible and convenient way possible. We note that as customers ask for more information about certain attributes in their foods, and as we experience continued advances in technology, the method by which this information is most effectively communicated may evolve. We therefore urge AMS to take advances in new technology into consideration in the final rulemaking.

I. Overarching Philosophy to be Applied to the Rule

FMI agrees that the focus of the final rule should be to establish a workable marketing standard for the disclosure of foods produced or derived from bioengineered (BE) ingredients. FMI also supports preserving the ability of food companies to voluntarily disclose information above and beyond that required by the federal standard where the information is consistent with applicable federal law. FMI believes a large number of FMI members will choose to do so. FMI further agrees that the NBFDS should be a uniform national standard sufficient to ensure that federal preemption is maintained in accordance with USDA-AMS's statutory mandate and that customers will receive consistent information about products regardless of where they are manufactured or purchased.

As noted above, FMI supports the comments submitted by the Coalition for Safe, Affordable Foods Coalition; however, the comments below focus on areas of critical importance to FMI members, including the types of foods subject to the mandatory disclosure along with some of the unique challenges grocery stores may face with respect to the variety of foods sold in a retail establishment. We note that many of our members already provide information to their customers on whether a food was produced with bioengineered ingredients and would like to continue to do so following publication of the final rule, regardless of whether they are subject to mandatory disclosure.

II. Voluntary Disclosure

In order to preserve the ability for food manufacturers and retailers to disclose information above and beyond that is required under the NBFDS, FMI supports a rigorous voluntary disclosure option linked to the BE Source List. Specifically, for products that do not meet the definition of "bioengineered food" but that contain an ingredient derived from the BE Source List, manufacturers and retailers should be permitted to make voluntary disclosures using phraseology that is distinctly different from the mandatory disclosure language, provided that any such claims are truthful, not misleading, and otherwise consistent with applicable federal law, as noted in proposed Section 66.118. Any such voluntary disclosures must be otherwise consistent with the Act.

As an example of such a voluntary claim, a manufacturer should be allowed to disclose the presence of a refined ingredient that has been placed on the Excluded Ingredients List, but which was derived from a BE crop. For purposes of clarity, FMI requests including the following non-exclusive examples of such voluntary truthful and non-misleading claims in the text of the final regulation:

- Bioengineered crops used in the production of this food;
- Ingredients sourced from bioengineered crops;
- Products derived from a bioengineered source;
- Products produced from a bioengineered source; and
- Products sourced from bioengineered crops but do not contain any bioengineered substances.

In addition to a robust framework for voluntarily providing information on whether a particular food is derived from bioengineered ingredients, FMI supports the voluntary disclosure options under Section 66.116 for foods that are otherwise exempt from the Act. FMI believes preserving the option to voluntarily provide information on foods that are otherwise exempt will strike the desirable balance between providing customers with the information they desire without being overly burdensome for retailers who sell foods that are unpackaged or prepared and processed in a retail-owned or operated establishment.

III. FMI Supports the Definition of Similar Retail Food Establishment

Under the Act, Congress unequivocally determined that the law shall not apply to foods served in restaurants and similar retail food establishments. FMI appreciates AMS's recognition of the need for certain establishments to be exempt from the rule given the very unique nature of the food retail business. FMI also supports the Agency's proposed definition of "similar retail food establishment" in Section 66.1, which USDA-AMS has indicated is based on 7 C.F.R. § 60.107 and 7 C.F.R. § 65.140, with minor modifications. The exemption establishes consistency with the Act, the Senate Report, regulatory frameworks administered by FDA,[1] and the National Organic Program, as the Agency notes in the preamble to the Proposed Rule. FMI respectfully asks that USDA-AMS maintain this important definition in the final rule. In particular, it reads as follows:

> *Similar retail food establishment* means a cafeteria, lunch room, food stand, saloon, tavern, bar, lounge, other similar establishment operated as an enterprise engaged in the business of selling prepared food to the public, or salad bars, delicatessens, and other food enterprises located within retail establishments that provide ready-to-eat foods that are consumed either on or outside of the retailer's premises.

As explained in more detail below, there are significant differences between foods prepared in a grocery store setting and those produced and packaged by a manufacturer. Importantly, grocery stores offer a large variety of products, from large national brands of manufactured foods to unique local and seasonal offerings that differ from location to location. Additionally, although grocery stores fully support providing customers with the transparency they desire, the manufacturers and suppliers of the foods retailers sell are generally better positioned to provide information regarding the individual food items and ingredients used. AMS's proposed definition of a similar retail food establishment will significantly reduce the burden of disclosures for those fresh, prepared foods that are made and sold within a grocery store while ensuring the majority of foods sold in a grocery store are still subject to the regulation.

We agree that this language adequately covers the grocery store setting, and **ask that the Agency maintain this important definition in its final rule**.

IV. AMS Should Further Clarify the Scope of Foods Not Subject to the Proposed Rule

Although USDA-AMS has included in the proposed rule language stating that "[t]his part shall not apply to . . . [f]ood served in a restaurant or similar retail food establishment," it is not entirely clear the foods within those establishments to which this exemption is meant to apply. Consistent with the exemption provided for in the Act, **FMI urges AMS to clearly define the foods served in a restaurant or retail establishment that are not subject to the rule.**

[1] For example, restaurants and retail food establishments are not required to register with the Food and Drug Administration under the Bioterrorism Act because they are selling foods directly to consumers.

As described above, grocery stores offer a large variety of products, ranging from large national brands of manufactured foods to unique local and seasonal offerings. Some are traditional grocery items. Others are offered for sale in diverse ways and in varying packaging formats, including, for example, made-to-order sandwiches packed by a store clerk in food-grade paper, customer-assembled salads eaten on site in a reusable bowl or clam shell, pasta salad sold by weight and packed by the retailer into a plastic container, unpackaged loose sweet corn sourced from a farm down the road that may be partially shucked and wrapped in store for customer convenience, among many others. Accordingly, grocery stores occupy a unique position with respect to implementation of the NBFDS, particularly given that manufacturers and suppliers of the foods sold by grocery stores are in many instances best positioned to provide information regarding individual food items and ingredients used. As such, it is important that FMI provide USDA-AMS with our feedback regarding food covered by the similar retail establishment exemption.

While USDA-AMS has confirmed the Act's exemption from the NBFDS of "[f]ood served in a restaurant or similar retail food establishment," FMI requests that USDA-AMS provide three additional clarifications regarding the specific foods served in a restaurant or similar retail establishment that USDA-AMS intends to exempt from disclosure. This clarification is particularly important to ensure the rule is not applied in a way that limits the availability of fresh, prepared foods in a grocery store. As described in more detail below, retailers are increasingly expanding the variety and types of foods produced and prepared in their stores and they want to continue to do so, both to limit food waste and to provide healthy, convenient, ready-to-eat food options similar to those served in traditional restaurants. AMS should not impose a burdensome disclosure framework that would ultimately limit the availability of these foods sold within a grocery store. In order to ensure the NBFDS is not overly burdensome when applied to these unique food choices, FMI requests that USDA-AMS provide three additional clarifications regarding the specific foods served in a restaurant or similar retail establishment that USDA-AMS intends to exempt from disclosure.

First, FMI asks that USDA-AMS clarify in the final rule that all foods prepared, processed, or packaged in the retail food establishment are exempt from the disclosure requirement and that USDA-AMS define the term "packaged" using the definition established in 21 C.F.R. § 1.20, FDA's general food labeling requirements. Doing so will provide additional clarity regarding to whom the obligation to disclose applies and will provide consistency with FDA's regulations, ensuring the NBFDS is easy to understand and implement and leading to reduced compliance costs. This is also consistent with the Senate Report, which stated that "[u]npackaged foods and *food processed or prepared in a restaurant or similar retail food establishment* are also excluded from the scope of the disclosure requirement."[2] In particular, Section 1.20 defines "packaged" as follows:

> "In the regulations specified in §1.1(c) of this chapter, the term package means any container or wrapping in which any food, drug, device, or cosmetic is enclosed for use in the delivery or display of such commodities to retail purchasers, but does not include:

[2] Senate Report at 5.

> a. Shipping containers or wrappings used solely for the transportation of any such commodity in bulk or in quantity to manufacturers, packers, processors, or wholesale or retail distributors;
> b. Shipping containers or outer wrappings used by retailers to ship or deliver any such commodity to retail customers if such containers and wrappings bear no printed matter pertaining to any particular commodity; or
> c. Containers subject to the provisions of the Act of August 3, 1912 (37 Stat. 250, as amended; 15 U.S.C. 231-233), the Act of March 4, 1915 (38 Stat. 1186, as amended; 15 U.S.C. 234-236), the Act of August 31, 1916 (39 Stat. 673, as amended; 15 U.S.C. 251-256), or the Act of May 21, 1928 (45 Stat. 635, as amended; 15 U.S.C. 257-257i).
> d. Containers used for tray pack displays in retail establishments.
> e. Transparent wrappers or containers which do not bear written, printed, or graphic matter obscuring the label information required by this part."[3]

Foods considered to be "packaged in the retail food establishment" should also include foods packaged in retailer owned or operated facilities. In particular, grocery stores often utilize a central kitchen or commissary location for the preparation of certain prepared foods. These facilities range significantly across the FMI membership, from a kitchen located across the parking lot at a two-store chain, to those serving a number of stores. These centralized locations allow grocery stores to develop efficient preparation processes, while ensuring the same strict food safety protocols utilized in-store are followed. In particular, offsite kitchens allow stores to focus employee efforts and training solely on food preparation, such that sufficient quantities of various ready-to-eat foods can be safely prepared and distributed to stores. Clarifying that foods packaged in retailer-owned or -operated facilities are treated the same as those packaged in the retail food establishment under the NBFDS will help minimize the burden and preserve the use of these offsite facilities as a safe and efficient option for food retailers.

Additionally, finished products in grocery stores may be partially prepared in these kitchens and partially prepared in-store. For example, a store-owned facility might provide a particular store with 25 turkey sandwiches a day. If these sell out, the grocery store itself may prepare additional sandwiches to meet demand. Because these sandwiches are identical to the end-customer, it is important that those prepared in-store be treated the same as those prepared in the store-owned facility under the NBFDS to eliminate potential consumer confusion. Similarly, a store-owned central kitchen may prepare a bakery item, but leave the final baking or decorating to be done in the retail store to maximize freshness and personalization for items like pizzas or cakes.

Second, FMI asks that USDA-AMS clarify in the final rule that unpackaged foods are generally exempt from disclosure, an exemption also contemplated in the Senate Report. In particular, as noted above, the Senate Report specifically states that "[u]npackaged foods and *food processed*

[3] 21 C.F.R. § 1.20

or prepared in a restaurant or similar retail food establishment are also excluded from the scope of the disclosure requirement."[4]

Third, FMI asks that USDA-AMS recognize the impracticality of labeling certain food categories and establish an exemption from the NBFDS in the final rule for those foods that are exempt from FDA's traditional nutrition facts panel (NFP) labeling under 21 C.F.R. § 101.9 ("Nutrition labeling of food"), including but not limited to the exemption in 21 C.F.R. § 101.9(j)(10) for raw fruits and vegetables subject to section 403(q)(4) of the Federal Food, Drug, and Cosmetic Act (FFDCA). Incorporating these exemptions into USDA-AMS's rule would be in keeping with Congress's instruction that the rule implementing the Act be consistent with "other federal requirements."[5] Additionally, BE disclosure of foods such as raw fruits and vegetables would be particularly burdensome and challenging for retailers, as these items are often mixed together in large bins even when sourced from different suppliers. For example, sweet corn or summer squash of the same variety may be sourced from numerous suppliers to fully meet supply demands; however, because space is limited and the products are the same, stores generally do not segregate these products by supplier source. As such, requiring BE disclosure for unpackaged foods would be difficult, and is likely to lead to over labeling and consumer confusion. In particular, because these items would generally be sold by weight rather than by a specific barcode, it is unlikely that stores would be able to fully track when BE versus non-BE inventory was fully used from the bin, and may need to continuously retain BE labeling on the display to err on the side of caution.

As noted above, prepared foods are a large part of retailers' offerings and retail executives expect additional investments in these key areas of success, especially fresh and prepared foods. The intense and varied competition, along with the ever-growing number of options in foodservice, is spurring constant in-store innovation for grocery operators. These fresh, healthy items offered in a grocery store increasingly appeal to consumers as a less expensive, much healthier alternative to standardized restaurant items. FMI strongly urges AMS to acknowledge the unintended consequences and costs associated with grocery retailer compliance under a framework intended for manufactured food products.

V. Retailer Responsibility

FMI appreciates USDA-AMS's work in proposing a rule that seeks to clarify the entities responsible for disclosure under the NBFDS. FMI has concerns with the proposed rule as it relates to food retailers and shares below our recommendations for ensuring that implementation of the Act is as efficient and cost-effective as possible. One of these concerns relates to imported products. Under the proposed rule, AMS states that the responsibility for disclosure lies with the manufacturer, importer or retailer in the case of retail packaged foods. AMS further indicates in the preamble to the proposed rule that "[i]f a food is packaged prior to receipt by a retailer, either the food manufacturer or the importer would be responsible for ensuring that the food label bears a BE food disclosure in accordance with this part." FMI agrees with this clarification; however, since the importer of record is responsible for necessary labeling in certain other regulatory frameworks, we ask that USDA-AMS clarify this in the final rule.

[4] Senate Report at 5.
[5] Senate Report at 6.

VI. Flexibility in Disclosure Methods

As discussed above, clearly it is the intent of the Law to ensure the manufacturer of a packaged food product, and not the retailer selling the food product, is the entity responsible for compliance with the disclosure regulations. Despite this intent, the proposed rule suggests there may be scenarios under which the retailer is responsible for BE disclosure. FMI believes it is important to understand the difference in labeling capabilities between the retailer and the manufacturer before finalizing the rule in this regard. While the manufacturer may have plentiful resources and options[6] for labeling their products, retailers have only what is available in-store. This generally includes only limited store personnel, and even more limited printing equipment and labeling methods. As such, it is important critical that retailers be given flexibility in scenarios where they are responsible for disclosure.

The proposed rule briefly discusses retailer options for disclosure of information with regard to bulk foods. In particular, USDA-AMS states that "[t]he disclosure would be required to appear on signage or other materials (stickers, bindings, etc.) on or near the bulk item." Additionally, the Regulatory Impact Analysis (RIA) for the proposed rule discusses signage for use in the produce section. Although we do not agree that unpackaged products like bulk foods and fresh produce should be covered by the rule, we agree that signage is a more reasonable method of disclosure. As such, we ask that USDA-AMS allow signage as an option for any scenario under which the retailer is responsible for disclosure in the final rule. Additionally, FMI believes the final rule should permit signage near the item, such as a single sign in the produce section listing all BE foods in that section.[7] A single sign approach will provide retailers with the necessary flexibility to disclose in the least costly and least burdensome way possible and will allow FMI to help achieve consistency for customers. As noted in the RIA, this will help keep costs as low as possible for retailers and will provide consistency for customers.

VII. Disclosure of Information to Retailers

USDA-AMS suggests in the proposed rule there may be scenarios under which the retailer is responsible for BE disclosure. As we have noted, although grocery stores fully support providing customers with this information, food manufacturers and suppliers are generally better positioned to provide information regarding individual food items and their ingredients. Manufacturers may frequently shift ingredient suppliers, depending on prices, availability, and many other factors. As drafted, however, the proposed rule would place NBFDS responsibility

[6] Manufacturers will have access to any available labeling format, including printing technology, adhesives, etc., and often utilize companies specializing in these services to label their products.

[7] For example, USDA's Country of Origin Labeling regulations provide that "[a] bulk container (*e.g.*, display case, shipper, bin, carton, and barrel) used at the retail level to present product to consumers, may contain a covered commodity from more than one country of origin provided all possible origins are listed." 7 C.F.R. § 65.400(d) (applicable to lamb, chicken and other agricultural commodities); *see also* 7 C.F.R. § 60.300(d) (similar provision for fish and shellfish).

solely with the retailer in certain circumstances.[8] Placing the burden on retailers to interface with manufacturers or modify commercial contracts requiring manufacturers to notify retailers regarding formulation or other product changes relevant to BE disclosure is time consuming and costly. Accordingly, FMI asks that USDA-AMS clarify in the final rule that manufacturers are responsible for disclosing to the retailer that a food contains BE ingredients or is otherwise subject to the NBFDS in situations where the retailer is responsible for final disclosure to the customer.

VIII. AMS should Provide Additional Flexibility for Small Retailers

FMI notes that USDA-AMS has proposed additional disclosure flexibility for small food manufacturers and has proposed to exempt very small food manufacturers from the rule altogether. Given the particular challenges faced by food retailers with respect to disclosure, FMI asks that USDA-AMS promulgate a final rule that extends the flexibility provided to small and very small food manufacturers to small retailers by establishing a threshold for "small retailers," using the standard incorporated into FDA's Menu Labeling rule, thereby exempting such retailers from the NBFDS. In particular, the menu labeling rule applies to "restaurants and similar retail food establishments that are part of a chain with 20 or more locations doing business under the same name (regardless of the type of ownership of the locations) and offering for sale substantially the same menu items."[9]

IX. Appearance and Placement of Disclosure

FMI's associate members include the supplier partners of its retail and wholesale members, including private label manufacturers who are subject to the NBFDS. Many retailers operate private label brands that are positioned as lower cost alternatives to regional, national or international brands. FMI commends USDA-AMS on its proposal with respect to the placement of the disclosure and options for type, text, and size. In contrast to more prescriptive approaches proposed under separate regulatory frameworks, the Agency's proposal is workable and provides significant flexibility to regulated entities, thereby enabling continued work toward sustainable packaging, other packaging innovation, and lower packaging costs generally. FMI urges the Agency to maintain this flexibility in the final rule.

X. Text Disclosure

FMI appreciates USDA-AMS's efforts to develop a simple, workable standard for on-pack text disclosure for use with the NBFDS, including USDA-AMS's proposal to distinguish between foods comprised solely of BE foods and foods that are comprised of both BE foods (or BE substances) and non-BE foods. FMI supports use of the term "bioengineered food" for foods that are entirely a product of bioengineering, but suggests the Agency establish in the final rule the term "Includes (a) bioengineered food ingredient(s)" for foods that are a mix of BE and non-

[8] The proposed rule suggests, for example, that retailers should disclose BE ingredients for bulk foods. Although we do not agree that bulk foods should be covered by the rule, this serves as an example where retailers [often may] not have adequate information to provide such disclosure.

[9] 21 U.S.C. 343(q)(5)(H)(i); 21 C.F.R. § 101.11(a).

BE ingredients, rather than the proposed rule's language, which states "Contains (a) bioengineered food ingredient(s)." FMI is concerned that use of the term "Contains" may suggest to consumers that the statement is a safety or health warning, rather than a marketing statement. For example, FDA requires use of the phrase "CONTAINS PHENYLALANINE" as an indication to individuals with phenylketonuria (i.e. PKU), a disorder that causes the amino acid phenylalanine to build up in the body. Given this potential association, and the fact that Congress prohibited disclosures under the NBFDS from suggesting that a covered food is "not as safe as" a counterpart food not covered by the NBFDS,[10] FMI urges USDA-AMS to use the term "includes" rather than "contains."

As noted previously, FMI supports the Coalition's proposed alternative which we believe is a workable alternative approach consisting of a single BE Source List. Should USDA-AMS proceed with a single list like the one proposed above, the Coalition supports use by regulated entities of phrases such as "May be bioengineered food" or "May include (a) bioengineered ingredient(s)" for those foods or ingredients that are not excluded under the Excluded Ingredients List. Such language will provide flexibility for regulated entities unable to consistently source food or food ingredients throughout the year without significantly increasing their costs.

XI. Symbol Disclosure

Regarding the options for disclosure by symbol proposed by the Agency, FMI recommends USDA-AMS adopt in the final rule the symbols listed under Alternative 2-A, rather than the symbols under 2-B and 2-C.

In addition, FMI commends USDA-AMS for the flexibility it has proposed related to placement of the disclosure and the use of color or black and white, should a regulated entity opt to comply with the NBFDS using the symbol. Relevant to USDA-AMS's requests for comment on the economic impacts of the proposed rule, FMI notes that color printing can involve as few as one color ink (which may not be black), such as a simple sticker label printed in a dark blue, and emphasizes the importance of providing flexibility for color options as well. FMI further notes that adding additional colors to the printing process solely for BE symbol disclosure will increase printing costs or disrupt product design in other ways. Additionally, it is important that the symbol be conspicuous on the package, regardless of the color of the package, including where the background color of the package closely matches the colors suggested in the proposed rule. For all these reasons, FMI emphasizes the importance of providing regulated entities with flexibility with respect to color options. Ensuring maximum flexibility and including additional color options in the final rule would best place regulated entities in a position to ensure the symbol is clear and readable without having to change the overall color design for the product, which often may be subject to "trade dress" protection. FMI members believe maintaining the black and white option and providing similar flexibility for color symbols would limit disruptions to the printing process, help keep costs down, and allow clear communication of the BE food disclosure to consumers.

[10] Section 293(b)(3), 7 U.S.C. § 1639b(b)(3); *see also* Senate Report at 2, 4.

XII. Electronic or Digital Link Disclosure

FMI appreciates that USDA-AMS has provided additional detail regarding the electronic or digital link disclosure option established in the Act. The Coalition supports the fact that the proposal provides regulated entities with flexibility in determining the placement of digital links on the physical package, as set forth in Section 66.100(d), and for flexibility with the call to action in light of potentially changing disclosure technologies. FMI urges USDA-AMS to retain these provisions in the final rule.

However, FMI has concerns with other aspects of USDA-AMS's proposal related to the electronic or digital link disclosure.

First, FMI has significant concerns with the Agency's requirement in proposed Section 66.106 that the electronic or digital link disclosure "be accompanied by a telephone number that will provide the bioengineered food disclosure to the consumer, regardless of the time of day." The Act provides that the NBFDS "require that the form of a food disclosure … be text, a symbol, or electronic or digital link … with the disclosure option to be selected by the food manufacturer."[11] The Act also provides that the NBFDS "ensure that … (4) the electronic or digital link disclosure also includes a telephone number that provides access to the bioengineering disclosure…."[12] Although those Act provisions do not require that the telephone number be provided on pack, USDA-AMS's proposal would require that the digital or electronic link disclosure be accompanied on-pack with a telephone disclosure and call to action "in close proximity." In effect, these provisions require a regulated entity to comply with two different modes of disclosure simultaneously, making compliance with the digital or electronic link disclosure option significantly more onerous in terms of label space, thereby increasing compliance costs. These outcomes and increased costs of compliance are in direct contravention with the Act, which intended regulated entities to have the option of choosing a single disclosure method from the three, equally valid disclosure options described in the Act.

Second, FMI is concerned that USDA-AMS's on-pack telephone number proposal will require regulated entities to unnecessarily duplicate existing telephone food information disclosures. FMI notes it is already common practice for manufacturers to list a toll-free customer hotline on food packages. In fact, customer service representatives increasingly use digital transparency programs such as SmartLabel® to answer consumer questions about a food. Accordingly, FMI asks that USDA-AMS promulgate a final rule that permits regulated entities choosing the digital or electronic link disclosure option to provide the BE disclosure using existing telephone hotlines and to retain the same placement and call to action for those numbers, much like USDA-AMS has proposed for telephone disclosures used for very small packages as set forth in Section 66.112(d). Without this flexibility, consumers may face two competing phone lines on a single package, which would cause confusion, while regulated entities are faced either with the cost and burden of establishing and maintaining two separate food information hotlines or shrinking the

[11] Section 293(b)(2)(D), 7 U.S.C. § 7 U.S.C. § 1639b(b)(2)(D).
[12] Section 293(d)(4), 7 U.S.C. § 1639b(d)(4).

amount of food information available to consumers by replacing its existing hot line with the NBFDS-compliant telephone disclosure.

Third, FMI has concerns regarding the requirement that the telephone disclosure be available "regardless of the time of day," effectively mandating that a regulated entity choosing the digital or electronic link disclosure option be required establish and maintain a 24-hour a day, 7-day a week hotline, a significant and unnecessary expense at odds with the intent of the Act. FMI has found that shoppers generally only access consumer information phone lines during normal shopping hours. The requirement for 24/7 availability is unnecessarily burdensome and will increase the costs of compliance, as manufacturers currently do not maintain 24/7 telephone lines.

FMI also notes the on-pack telephone disclosure requirements are firmly at odds with the Act's requirement that USDA-AMS undertake a study regarding the availability of access to the disclosure via digital or electronic methods. No such study would have been necessary had Congress intended that the telephone disclosure accompany the digital or electronic link *on pack*. In light of these tensions with the Act and Congress' intent, FMI asks that USDA-AMS revise the telephone disclosure provisions in the final rule to ensure parity between the three disclosure options and to provide maximum flexibility and efficiency to regulated entities.

Finally, FMI has concerns with USDA-AMS's proposal in Section 66.107(b)(1) that the "product information page be the first screen to appear on an electronic or digital device after the link is accessed as directed." The Act requires a regulated entity to "provide access to the bioengineering disclosure located, in a consistent and conspicuous manner, on the first product information page,"[13] but does not require the complete disclosure itself to appear on the first product information page. FMI asks that USDA-AMS provide additional flexibility in the final rule on the required location of disclosure after a consumer has accessed a digital link, consistent with the statutory language, and to provide a mock-up or examples of compliant disclosures.

XIII. Study on a Digital or Electronic Link Disclosure Option or a Text Message Disclosure Option

FMI also appreciates USDA-AMS's efforts to comply with the Act's requirement that the Secretary conduct a study to identify potential technological challenges that may affect whether consumers would have access to the bioengineering disclosure through electronic or digital disclosure methods. The Act requires the study consider five factors: (i) the availability of wireless internet or cellular networks; (ii) the availability of landline telephones in stores; (iii) challenges facing small retailers and rural retailers; (iv) the efforts that retailers and other entities have taken to address potential technology and infrastructure challenges; and (v) the costs and benefits of installing in retail stores electronic or digital link scanners or other evolving technologies that provide bioengineering disclosure information. The Act also requires the

[13] Section 293(d)(2), 7 U.S.C. § 1639b(d)(2) (emphasis added).

Secretary, after consultation with food retailers and manufacturers, to provide additional and comparable options to access the bioengineering disclosure, should the Secretary determine that consumers, while shopping, would not have sufficient access to the bioengineering disclosure through electronic or digital disclosure methods.

Specifically, FMI appreciates USDA-AMS's work in conducting and analyzing the results of the study. In response to the draft study, FMI also conducted a survey of our members[14] and found, consistent with the Agency's findings, that overall customers have overwhelming access to WiFi while shopping. As technology evolves and retailers continue to expand their in-store WiFi offerings, the Coalition, which represents the entire American food and agriculture value chain, anticipates this access to increase significantly in the coming years. These studies also found that:

- The majority of Americans own a smartphone (77%) and ownership rates are trending upward. The adoption of smartphones will continue to rise in all age groups.
- 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. FMI's study found this number to be increasing. Customers may also access information by utilizing cellular data if WiFi is unavailable.
- Consumers may recognize digital links, but lack familiarity with scanning. As digital links become more ubiquitous we expect consumers' understanding regarding the technology to grow. For example, FMI and Grocery Manufacturers Association (GMA) are undertaking a comprehensive educational campaign through multiple media outlets to help inform consumers about SmartLabel. The initial consumer education campaign was launched in June 2018 and has already achieved significant outreach in less than one month. Additionally, during Q1 2017, SmartLabel received more than 1,300,000 visits across participating brands. More than 50% of those visits were via smartphone. SmartLabel has seen a greater than 80% growth in QR scans since September 2017. Further, 30,000 products are already labeled with a SmartLabel digital link – a number that grows each day and will continue to grow following publication of a final rule. Based on current trends, FMI and GMA expect SmartLabel adoption to reach 40,000 product pages by the end of 2018.
- As consumers become more comfortable with technology, including the ability to access digital information related to whether a food is produced with BE foods, the concern related to access will diminish significantly.

Although FMI views the digital or electronic link disclosure option as sufficiently accessible to support its reliable use for BE disclosure, FMI also supports USDA-AMS's proposed text

[14] FMI surveyed its member companies using a brief online survey to assess the degree to which WiFi (wireless internet) service is currently available to customers in store. A total of 43 companies representing more than 16,000 stores responded to the survey, comprising roughly 50% of the retail food industry in the United States. The companies responding range from independent operators with less than ten stores (31) to some of the largest chains in the country.

message disclosure, and finds it to be another effective method of delivering BE information to consumers.

As proposed, the text message option would operate similarly to the electronic or digital disclosure under proposed § 66.106, but it would not rely on broadband access and would not require consumers to have smart phones in order to access the disclosure. Regulated entities choosing this option would be required to include a statement on the package that instructs consumers to ''Text [number] for more food information,'' where the number would be a phone number or short code. Specifically FMI requests that because text messaging could be a useful tool for providing consumers with other information regarding their food, any final rule provisions enabling use of text message disclosure be sufficiently flexible so as not to restrict the disclosure so that BE information is the only information that could be provided to consumers through that method. As noted above, consumers are increasingly demanding a variety of types of information about the foods they eat and AMS should allow for additional information to be provided should a manufacturer decide to comply with the regulation via the text message option.

FMI also recommends that as technologies continue to evolve, the Agency consider providing additional disclosure options that may be appropriate for consumers depending on their evolving preferences. For example, artificial intelligence technologies may provide additional opportunities for innovation with respect to food disclosure, and USDA-AMS should ensure the final rule enables the Agency to accommodate advances in these new and evolving technologies as they evolve.

XIV. Small Food Manufacturers

FMI supports additional clarification from USDA-AMS with respect to the definition of a "small food manufacturer" and supports the additional telephone and internet website disclosure options proposed for manufacturers meeting the definition of a small food manufacturer. For reasons stated above, FMI opposes USDA-AMS's proposal that the telephone BE food disclosure be available "regardless of the time of day."

FMI supports the Coalition's suggestion that USDA-AMS adopt a definition of "small food manufacturer" in the final rule based on the number of employees, rather than on annual receipts. A definition based on number of employees would establish consistency with the definition for "small business" under the Small Business Administration regulations,[15] therefore easing compliance burdens by establishing a more stable, durable metric.

XV. Recordkeeping Requirements

FMI generally supports USDA-AMS's proposal related to recordkeeping to demonstrate compliance with the NBFDS, including provisions enabling persons required to keep records to

[15] 13 C.F.R. § 121.201.

rely on existing records that are customary, reasonable, and regularly kept and maintained in the ordinary course of business, and FMI urges the Agency to retain these principles in the final rule.

More specifically, FMI supports the twelve (12) categories of documentation identified by the Agency as appropriate to verify that foods are not BE and/or not subject to disclosure. FMI urges the Agency not to limit regulated entities to those categories. The final rule should make clear that recordkeeping entities should be allowed to retain any documentation relating to BE foods, or foods containing BE ingredients, provided such documentation is sufficient to verify the foods are not subject to mandatory disclosure.

FMI also appreciates that the proposed rule provides flexibility by enabling the use of multiple documentation sources and asks that the examples of appropriate records be incorporated into the text of the final rule. FMI notes that USDA-AMS has suggested in the preamble to the rule that regulated entities opting not to disclose under the rule may choose to rely on "supplier attestations." The Coalition and FMI reiterates that the phrase "supplier attestations" is intended to refer to contractual documents, confirmations or other certifications entered into or provided by suppliers, and does not provide an obligation by the buyer to engage in supplier verification programs for a marketing, rather than food safety standards, and which would impose significant costs and regulatory burdens.

FMI also supports USDA-AMS's proposal that recordkeeping entities maintain records for two years after a food product is manufactured. AMS should clarify that record maintenance is tied to the date a product enters interstate commerce rather than the date a product is sold by the retailer. From a practical standpoint, there is no way to track the date on which a product is sold by the retailer.

FMI has concerns with the proposal to provide only five business days for an entity to provide records to AMS, and asks that the final rule provide recordkeeping entities with between four and six weeks to provide records to AMS, thereby establishing consistency with FDA's Menu Labeling requirements.[16] It is also consistent with the fact that the NBFDS is a marketing standard and does not require the haste of a health and safety concern. FMI supports a notice period of at least three days for an on-site visit by USDA-AMS, but asks that the final rule permit the recordkeeping entity to determine the location of the audit at the recordkeeper's discretion to more accurately reflect the location of the records thereby making the audit more productive for both parties. The Coalition and FMI reiterate their opposition, as described in the Response to the Proposed Rule Questions Under Consideration, to any provisions requiring that a recordkeeping entity be required to provide access to confidential business information, including but not limited to product formulation information or recipes, in connection with the NBFDS.

[16] 21 C.F.R. § 101.11(c)(3) "A covered entity must provide to FDA, within a reasonable period of time upon request, information substantiating nutrient values including the method and data used to derive these nutrient values." *See also* FDA, Menu Labeling: Supplemental Guidance for Industry (May 2018), Q&A 7.3 (on pages 36-37), available at https://www.fda.gov/downloads/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/UCM583492.pdf ("We consider a reasonable period of time to be about 4-6 weeks after the request is made.")

XVI. Enforcement

Regarding enforcement, FMI appreciates the Agency's acknowledgment that the Act does not authorize USDA-AMS to recall any food subject to the NBFDS "on the basis of whether the food bears a disclosure that the food is bioengineered" or to impose civil penalties for violations and asks that those limitations of authority be included within the text of the final rule. The Coalition and FMI otherwise support USDA-AMS's proposal with respect to enforcement.

XVII. Compliance Date

FMI appreciates USDA-AMS's proposal to harmonize compliance dates for the NBFDS with FDA's new nutrition labeling rules. Such harmonization would significantly alleviate the expense of making two sets of changes to food labels in a short period of time. However, given the timing of USDA-AMS's proposal and anticipated timing for the final rule, which appears destined to extend well beyond July 2018, FMI is concerned that a compliance date of January 1, 2020 for the NBFDS would provide inadequate time for regulated entities to comply with the new standard, even accounting for the flexibility AMS proposed to allow regulated entities to exhaust existing label inventory until January 1, 2022. Instead, FMI requests that USDA-AMS establish in the final rule a compliance date of two years (24 months) after the effective date of the final rule, and that the Agency retain in the final rule the provision providing regulated entities additional flexibility to exhaust existing label inventory.

FMI also urges the Agency to specify that the compliance date only applies with respect to the date that products are shipped into interstate commerce. This will ensure continued marketability for products previously labeled, held in storage, in shipment or offered for sale at the retail establishment.

Further, FMI urges USDA-AMS to include in the final rule provisions allowing regulated entities flexibility as to the means of applying NBFDS-compliant text, symbols or electronic or digital link disclosures. Although most labels will need to be redesigned and printed to comply with the standard, FMI asks that the Agency permit compliance through the traditional printing of food labels or, alternatively, through application of stickers or ink-jet printing to an existing label.

Ensuring an adequate and orderly compliance timeline is critical to preventing dramatically increased compliance costs and will ensure that regulated entities have sufficient time to manage costs associated with supplier verification of BE ingredients, as well as to assess and manage changes to ingredients or formulations, and design, print, and apply the label to products subject to the NBFDS. The typical retailer carries approximately 40,000 or more different stock keeping units (SKUs). Without adequate time to revise the label, every packaged food label required to bear the disclosure will have to be revised in a short time frame adding excessive and avoidable costs for retailers. These higher costs are likely to be passed down the supply chain to consumers in the form of higher prices at retail. The private brand industry is unique and strives to provide consumers with quality products at a significant savings. Unlike national brands, private brand manufacturers do not invest considerable resources in advertising and label modifications, which gives them the ability to provide lower priced products on which some consumers rely. Infrequent label changes permit private brand manufacturers to purchase packaging in bulk to minimize costs. To ensure labeling capacity for the entire food supply-chain, reduce significant

waste and minimize disruption, FMI believes AMS should provide an initial two-year compliance date for label revisions. Consumers rely on private label alternatives as a viable money-saving option and FMI believes a compressed compliance time frame will result in higher prices and significant waste of current packaging inventories, which is in conflict with a number of government and food industry initiatives to reduce food waste.

FMI appreciates USDA-AMS's recognition in the proposed NBFDS that regulated entities using food labels should have an opportunity to use up their current food labels for a period of time. In particular, we agree with USDA-AMS that using up inventory is important to reduce costs and burdens, and to limit food waste. It is also particularly important for our member stores' private brands which, as discussed in more detail above, rely on limited labeling modifications to keep costs low. USDA-AMS has proposed in Section 66.120 that "[p]roducts that are manufactured, labeled, and entered into the stream of commerce prior to January 1, 2022, or until regulated entities use up remaining label inventories as of the initial compliance date, whichever date comes first, may be sold using their existing food labels."

As noted above, FMI urges USDA-AMS to establish in the final rule a compliance date of two years (24 months) after the effective date of the final rule. In addition, FMI asks that USDA-AMS retain in the final rule the provision providing regulated entities additional flexibility to exhaust existing label inventory until two years after the compliance date. Providing a necessary timeframe for using up existing inventory will help reduce costs and prevent unnecessary waste in the food supply.

XVIII. Economic Analysis

FMI appreciates the in-depth and detailed economic analysis contained within the Agency's Regulatory Impact Analysis (RIA). FMI agrees that the costs of compliance with the Act and the final rule must be viewed in the context of the significant costs food manufacturers and retailers faced related to compliance with state labeling requirements enacted and effective in Vermont, and additional labeling initiatives that would have taken effect in other states should a national preemptive standard not be in place under the Act. As the Agency notes in its RIA, "[t]he benefits of the proposed NBFDS would be the elimination of costly inefficiencies arising from a state-level approach to BE disclosure."[17] Elimination of these inefficiencies, as well as customer confusion and significant costs, justifies the costs to consumers, manufacturers, and producers that this regulation would impose.

FMI developed additional data based on the RIA undertaken by USDA-AMS to test the RIA's conclusion that a federal labeling standard is the most cost-effective method for providing the information consumers seek while minimizing inefficiencies resulting from inconsistent standards. The data[18] was developed by John Dunham and Associates (JDA), a firm that has previously completed economic impact studies for a number of the farm and food sectors as well

[17] RIA at 1.

[18] John Dunham and Associates, National Bioengineered Food Disclosure Standard: A Review of the United States Department of Agriculture's Regulatory Impact Analysis (Brooklyn, NY: June 2018).

as the farm to fork, "Feeding the Economy" analysis. FMI is submitting the JDA study along with our comments. The JDA study states that:

- Multiple disclosure and/or labeling systems requiring significant design costs and higher reformulation costs bring the initial cost of complying with 20 separate and distinct state rules to $19.5 billion and the overall discounted 20-year cost to $97.3 billion.

- Costs are higher if different labeling provisions are adopted in 51 different states. The potential benefit of the proposed rule is as high as $129.7 billion discounted over 20-years, with $35.5 billion of that being initial labeling, reformulation and recordkeeping costs.

Conclusion

FMI appreciates the opportunity to comment on the proposed rule and believes that with an expeditious but thoughtful approach, the final rule will both ensure customers are provided the information they demand without being overly burdensome on the food industry. By providing consumers with the information they seek in a way that minimizes inefficiencies and decreases the regulatory burden on those tasked with compliance, USDA is conforming to Congress' direction in the Senate Report that the Agency "take every effort to minimize the impacts on growers, handlers, processors, manufacturers, distributors, retailers, and consumers."[19]

Following publication of a final rule, FMI encourages USDA to adopt a robust consumer education campaign to inform consumers about the new disclosure standard and how best to understand it. Important elements of the campaign would include education around the change in terminology from "Genetically Modified Organism" (GMO) to "Bioengineered" (BE) as well as the use of the phrase "may be" bioengineered. In addition, USDA should ensure consumers are aware of and understand the symbol option, just as the Department did for the introduction of the Organic seal. Furthermore, we encourage the Department to review and/or conduct relevant research to better understand consumer comprehension of this terminology, the symbols, and effective messaging for this education campaign. FMI would be pleased to be a partner in these efforts.

Sincerely,

Leslie G. Sarasin
President and
Chief Executive Officer

[19] Senate Report at 7.

National Bioengineered Food Disclosure Standard

A Review of the United States Department of Agriculture's Regulatory Impact Analysis

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June 28, 2018

Executive Summary

The United States Department of Agriculture (USDA) has proposed a rule, the *National Bioengineered Food Disclosure Standard* (NBFDS), aimed at ensuring mandatory, uniform disclosure of bioengineered (BE) food products.[1] The stated objectives of the rule are twofold: (1) to provide consumer-demanded information on food sources, and (2) to prevent costly state or local disclosure inefficiencies with a uniform national standard.

With respect to food, "bioengineering" (BE) refers to food that *contains genetic material that has been modified through in vitro recombinant deoxyribonucleic acid (DNA) techniques, for which the modification could not otherwise be obtained through conventional breeding or found in nature*.[2] The rule would apply to the following products either as foods or as food and supplement ingredients: Canola, field corn, cotton, soybean, sugar beet, apple, sweet corn, papaya, potato, and certain summer squash varieties.

Regulatory actions that are "likely to impose costs, benefits, or transfers of $100 million or more" in a given year or likely to "adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities" require an extensive Regulatory Impact Analysis (RIA).[3] The RIA is a way to develop and present the benefits and costs of a proposed rule, and to provide an evaluation of the proposed rule on small businesses, and an analysis of practical alternatives to the regulatory need for the rule.

The proposed NBFDS rule was deemed to have met this requirement and an extensive Regulatory Impact Analysis was conducted and submitted by the USDA in May 2018.[4] The following research consists of an extensive critique of the USDA's RIA regarding the NBFDS, as well as its alternatives. In all, four scenarios are considered – adoption of the NBFDS standard, a baseline where no national standard is adopted, a baseline in which Vermont's previously adopted BE standard is adopted nationally, and a baseline free-for-all system wherein each state determines its own standards.

The following analysis agrees, in large part, with the results yielded through the USDA's RIA. A federal disclosure standard is the most cost-effective method to address the twin goals of information provision and minimizing inefficiencies resulting from inconsistent standards.

Based on the RIA and models constructed by JDA using publicly available sources, the cost of implementing the proposed rule is between $2.7 and $4.0 billion depending on whether the USDA's assumptions or those of JDA are used. The discounted present cost (NPV) of the rule is between $9.2 and $17.4 billion depending on the model. Table 1 presents a full breakdown of these cost calculations.

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1 US Department of Agriculture, Agricultural Marketing Service, Proposed Rule, 7 CFR Part 66, *National Bioengineered Food Disclosure Standard*, Federal Register, May 4, 2018, page 19860.

2 7 U.S.C. 1639(1).

3 Federal Register, Vol. 58, No. 190, *Executive Order 12866 of September 30, 1993*, Monday, October 4, 1993, at: https://www.archives.gov/federal/executive-orders/pdf/12866.pdf and Federal Register, Vol. 76, No. 14, *Executive Order 13563, Improving Regulation and Regulatory Review*, Friday, January 21, 2011, at: https://www.gpo.gov/fdsys/pkg/FR-2011-01-21/pdf/2011-1385.pdf

4 US Department of Agriculture, Agricultural Marketing Service, *Regulatory Impact Analysis, Proposed National Bioengineered Food Disclosure Standard Public Law 114-216 with amendments to the Agricultural Marketing Act of 1946 Subtitles E and F*, April 30, 2018

It should be noted that the future costs of the rule are somewhat speculative in that they are highly dependent on the number of products that manufacturers decide to reformulate using non-BE ingredients, and the reaction of the agricultural market to these demands. Currently, it is estimated that non-BE products would cost about 11.7 percent more than their BE alternatives. The level of production of non-BE corn and soy is also way too small to meet much in the way of increased demand. Were prices to rise considerably, the future costs could be much higher. On the other hand, increased demand for non-BE crops could lead to increased production and a leveling of prices over time.

Table 1
Estimated Cost of Proposed Rule Based on Two Different Models

	RIA	JDA
Administrative (RIA includes Design)	$ 1,657,029,000	$ 105,193,209
Recordkeeping	$ 54,908,000	$ 54,908,000
Labeling	$ 290,000,000	$ 2,269,148,065
Reformulation	$ 619,000,000	$ 1,335,051,079
Retail	$ 103,716,230	$ 195,486,165
Distribution	$ -	$ -
Total	$ 2,724,653,230	$ 3,959,786,518
NPV (7%)	$ 6,509,570,391	$ 13,426,219,104
Total 20 Year	$ 9,234,223,621	$ 17,386,005,622

Based on this uncertainty, the RIA based its cost-benefit calculation on the initial costs and benefits of the rule.

The RIA stated that there were no consumer or social benefits that would result from increased disclosure. Rather, Congress made clear in the National Bioengineered Food Disclosure Law (the federal disclosure statute), requiring the promulgation of a NBFDS, that the benefit of a national standard is to preempt a patchwork of state and local disclosure and/or labeling statutes including a BE labeling rule already enacted and set to go into effect in the state of Vermont. The RIA calculated the initial cost of the preempted Vermont rule at about $4.4 billion and the 20-year cost at about $10.6 billion. JDA calculates the initial cost of the Vermont rule at about $9.0 billion with the 20-year cost at just under $14.0 billion.

Table 2
Estimated Benefit of Proposed Rule (Cost of Preempted Vermont Rule)

	RIA	JDA
Administrative (RIA includes Design)	$ 1,228,500,000	$ 84,168,782
Recordkeeping	$ 54,908,000	$ 54,908,000
Labeling	$ 2,550,000,000	$ 8,401,570,738
Reformulation	$ 583,500,000	$ -
Retail	$ -	$ -
Distribution	$ -	$ 458,083,837
Total	$ 4,416,908,000	$ 8,998,731,357
NPV (7%)	$ 6,166,660,456	$ 4,955,211,205
Total 20 Year	$ 10,583,568,456	$ 13,953,942,561

The higher initial benefit of preempting the Vermont rule is likely large enough (no matter what assumptions are used) to justify the costs of the federal disclosure statute and the mandated NBFDS; however, the rule is not justified if the long-term costs of either reformulating products, or maintaining a separate distribution system, are accurately estimated. Table 3 below shows the cost-benefit ratio of the proposed rule based on the preemption of the Vermont statute alone.

Table 3
Cost Benefit of Proposed Rule Compared to Baseline

	RIA	JDA
Cost of NBFDS		
Initial Costs	$ 2,724,653,230	$ 3,959,786,518
Discounted 20 Year Cost	$ 6,509,570,391	$ 13,426,219,104
Total Cost	$ 9,234,223,621	$ 17,386,005,622
Benefit from Preemption of Vermont Rule		
Initial Costs	$ 4,416,908,000	$ 8,998,731,357
Discounted 20 Year Cost	$ 6,166,660,456	$ 4,955,211,205
Total Cost	$ 10,583,568,456	$ 13,953,942,561
Benefit-Cost Ratio		
Initial Costs	1.62	2.27
Discounted 20 Year Cost	0.95	0.37
Total Cost	1.15	0.80

As the table shows, based on the RIA, both initially and over a 20-year period, the NBFDS has a positive net social benefit. The initial benefit is substantial, though the benefits in the out-years are less certain as the cost of switching from BE to non-BE ingredients can be substantial. Based on JDA's assumptions, the initial benefit is much higher than that estimated in the RIA; however, the long-term costs of reformulation swamp the savings that would result from not having to maintain a separate distribution system in Vermont.

Moreover, the largest potential benefit of the federal disclosure statute and the mandated NBFDS is the preemptive effect over all other overlapping and potentially inconsistent state disclosure and/or labeling initiatives. According to the RIA there are currently 20 states that have either passed or are seriously considering a BE disclosure and/or labeling law. Were this to spread to all 50 states, the costs to businesses (and eventually to consumers) would be dramatic. Table 4 on the following page outlines these costs.

The RIA did not calculate this possibility as it found that simply preempting the Vermont rule would in and of itself provide for a net benefit. JDA calculated these estimates in order to provide a worst-case scenario.[5] Based on the worst-case scenario, the potential initial costs could be as high as $35.5 billion if all of the states were to adopt laws similar in nature to Vermont's but with different labeling and content requirements. The long-term (20-year) cost would reach $129.7 billion. As Table 5 on the following page shows, the benefit-cost ratio of the NBFDS would be as high as 7.46 were it to lead to the

[5] An analysis looking at just the 20 states identified in the RIA as having or potentially having BE disclosure and/or labeling provisions in the near term was also performed.

preemption of different BE labeling rules in all 50 states. Under this scenario, it would be expected that every company would (as much as possible) shift to non-BE ingredients because the cost of maintaining 51 different distribution systems would be prohibitive.

Table 4
Estimated Cost of 51 Different State BE Labeling Requirements

	RIA	JDA
Administrative	$ -	$ 963,435,403
Recordkeeping	$ -	$ 2,800,308,000
Labeling	$ -	$ 24,775,687,794
Reformulation	$ -	$ 6,954,980,381
Retail	$ -	$ -
Distribution	$ -	$ -
Total	$ -	$ 35,494,411,578
NPV (7%)	$ -	$ 94,230,572,135
Total 20 Year	$ -	$ 129,724,983,713

This suggests that, based on a number of different assumptions and potential outcomes, the preemptive effect of the federal disclosure statute and mandated NBFDS provides a substantial benefit to the economy, businesses, consumers and society in general. This benefit would likely outweigh any costs imposed by the proposed NBFDS rule. Depending on how companies react to the disclosure rules by either sticking with their existing products formulations or shifting to non-BE ingredients, the benefits could be significantly higher or lower.

Table 5
Cost Benefit of Proposed Rule Compared to 51 Different BE Disclosure Requirements

	RIA	JDA
Cost of NBFDS		
Initial Costs	$ 2,724,653,230	$ 3,959,786,518
Discounted 20 Year Cost	$ 6,509,570,391	$ 13,426,219,104
Total Cost	$ 9,234,223,621	$ 17,386,005,622
Benefit from Preemption of 51 State Rules		
Initial Costs	Not Calculated	$ 35,494,411,578
Discounted 20 Year Cost	Not Calculated	$ 94,230,572,135
Total Cost	Not Calculated	$ 129,724,983,713
Benefit-Cost Ratio		
Initial Costs		8.96
Discounted 20 Year Cost		7.02
Total Cost		7.46

The major model assumptions were taken from an earlier analysis of the Vermont labeling rule conducted in 2016. Due to timing considerations this model was adapted to the current analysis. If industry input-

output data for the food processing industry has changed considerably over the past two-years, the results in the JDA analysis may either under- or over-estimate the actual costs.

Any errors, omissions, or misstatements of fact are the responsibility of John Dunham & Associates.

Introduction and Background

The United States Department of Agriculture (USDA) is comprised of twenty-nine agencies tasked primarily with oversight of the nation's agriculture supply, food safety, and land management. The Agricultural Marketing Service (AMS) deals specifically in the domestic and international marketing of U.S. agricultural products.

Congress required the USDA to create a system for identifying and disclosing information on BE foods.[6]

Since the enactment of the proposed rule would have a substantial impact on business, consumers and the economy, it is what the Office of Management and Budget defines as a "significant" regulation.[7] This means that the USDA is required to perform a regulatory impact analysis (RIA) under the guidelines set out under Executive Order 12866,[8] Executive Order 13563,[9] the Regulatory Flexibility Act (5 U.S.C. 601-612),[10] and the Unfunded Mandates Reform Act of 1995 (Public Law 104-4).[11] Under these provisions, the USDA must not only determine if the regulation is necessary but must assess all costs and benefits of available regulatory alternatives to select approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). It also requires the USDA to, among other things, analyze regulatory options that would minimize any significant impact of a rule on small entities.

The Proposed Rule

The proposed rule under question establishes the National Bioengineered Food Disclosure Standard (NBFDS), which requires disclosure of BE foods or BE foods ingredients. Food manufacturers and any other business that manufacture food for retail sale would be responsible for disclosing information about BE foods or BE food ingredients.

The objectives of the proposed rule are to provide consumer-demanded information on food sources, and to prevent costly state or local disclosure inefficiencies with a uniform national standard. It is important to note that the proposed rule does not attempt to make any claims about the health effects nor any other benefits or drawbacks of BE foods vis-à-vis non-BE food.

Definitions

In order to proceed, a number of terms should be defined as explicitly as possible.
"Bioengineering" is defined as a food "that contains genetic material that has been modified through in vitro recombinant deoxyribonucleic acid (DNA) techniques; and for which the modification could not otherwise be obtained through conventional breeding or found in nature."

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6 Public Law No: 114-216, *An Act To reauthorize and amend the National Sea Grant College Program Act, and for other purposes, Section 1, National Bioengineered Food Disclosure Standard*, July 29, 2016.

7 ''Significant regulatory action'' means among other things any regulatory action that is likely to result in a rule that may have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities. See: *Executive Order 12866 of September 30, 1993*, at: www.reginfo.gov/public/jsp/Utilities/EO_12866.pdf.

8 *Executive Order 12866 of September 30, 1993*, at: www.reginfo.gov/public/jsp/Utilities/EO_12866.pdf.

9 *Executive Order 13563 of January 18, 2011*, at: www.gpo.gov/fdsys/pkg/FR-2011-01-21/pdf/2011-1385.pdf.

10 *5 U.S. Code Chapter 6 - The Analysis Of Regulatory Functions*, at: http://www.law.cornell.edu/uscode/text/5/part-I/chapter-6.

11 *Public Law 104 - 4 - Unfunded Mandates Reform Act Of 1995*, at: http://www.gpo.gov/fdsys/pkg/PLAW-104publ4/content-detail.html.

"Conventional breeding" may need to be defined as well. The USDA offers a number of potential definitions:

a. "traditional breeding techniques, including, but not limited to, marker assisted breeding and chemical or radiation-based mutagenesis, as well as tissue culture and protoplast, cell, or embryo fusion."
b. "traditional methods of breeding or crossing plants, animals, or microbes with certain desired characteristics for the purpose of generating offspring that express those characteristics."
c. "the creation of progeny through either: The union of gametes, e.g., syngamy, brought together through processes such as pollination, including bridging crosses between plants and wide crosses, or vegetative reproduction. It does not include any of the following technologies: Recombinant DNA; other techniques wherein the genetic material is extracted from an organism and introduced into the genome of the recipient plant through, for example, micro-injection, macro-injection, micro-encapsulation; or cell fusion."

Regulatory Impact Analysis Requirements

According to the Office of Management and Budget, there are 16 key elements that every Regulatory Impact Analysis needs to address.[12] The OMB provides agencies with a detailed Primer on how to conduct a RIA in accordance with its guidelines and the underlying Executive Orders.[13] Additional requirements from the various laws governing RIAs, such as the Unfunded Mandates Reform Act and the Regulatory Flexibility Act, also need to be met by the FDA.

The nine key elements that the OMB suggests that each agency include are:

1. A reasonably detailed description of the need for the regulatory action;
2. An explanation of how the proposed regulatory action will meet that need;
3. An appropriate baseline assessment of how the world would look in the absence of the proposed action;
4. An assessment of potentially effective and reasonably feasible alternatives to the proposed regulatory action;
5. An explanation of why the planned regulatory action is preferable to the potential alternatives;
6. An uncertainty analysis;
7. A description and discussion of the distributive impacts of the potential alternatives;
8. A clear, plain-language executive summary including an accounting statement that summarizes the benefit and costs for the regulatory action;
9. A clear and transparent table presenting anticipated benefits and costs.

In addition, the OMB states that each regulatory impact analysis:

1. Use the best reasonably obtainable scientific, technical economic information and present it in a clear, complete and unbiased manner;
2. Provide the data, sources and methods used in the RIA to the public via the internet;
3. Quantify and monetize the anticipated benefits from the regulatory action to the extent feasible;
4. Quantify and monetize the anticipated costs from the regulatory action to the extent feasible;

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[12] Office of Management and Budget, *Agency Checklist: Regulatory Impact Analysis*, www.whitehouse.gov/sites/default/files/omb/inforeg/regpol/RIA_Checklist.pdf.

[13] Office of Management and Budget, *Regulatory Impact Analysis: A Primer*, at: www.whitehouse.gov/sites/default/files/omb/inforeg/regpol/circular-a-4_regulatory-impact-analysis-a-primer.pdf.

5. Explain and support how the benefits of the intended regulation justify its costs;
6. Ensure that the preferred option has the highest net benefits unless the law requires a different approach;
7. Use appropriate discount rates for benefits and costs expected to occur in the future;

In addition to these 16 items, a proper RIA must examine a number of additional impacts including international effects and the effects on small businesses.

Critique of the USDA Regulatory Impact Analysis

The RIA prepared by the USDA for the proposed rule is fairly rigorous. Of the sixteen requirements, eleven are satisfied. The following section offers point-by-point review.

A reasonably detailed description of the need for the regulatory action

Detailed in the RIA, the proposed rule is a means to address the recent amendment to the Agricultural Marketing Act of 1946 that mandates disclosure of BE food and BE food ingredients. **The USDA's RIA addresses this objective in several instances.** Additionally, the USDA takes the extra step to clearly state this proposed rule is not a means of relaying any health or safety information.

Congress specifically required the USDA to promulgate a rule setting out a NBFDS in Public Law 114-216, an amendment to the Agricultural Marketing Act, which directs the Secretary of Agriculture "to establish the National Bioengineered Food Disclosure Standard (NBFDS)" and "to establish requirements and procedures necessary to carry out the new standard."

An explanation of how the proposed regulatory action will meet that need

The USDA's Regulatory Impact Analysis does explain how the NBFDS rule will meet the stated goals. The proposed regulation mandates uniform disclosure of bioengineered food and food ingredients. All food items would be subject to the same regulation, which fulfills the first objective of supplying marketing information of BE foods to those consumers who are interested. Second, the preemptive effect of the federal disclosure statute and mandated NBFDS prevents a potentially costly patchwork state or even local regulations, whereby certain states follow one set of standards while other states follow another, and so on. In the extreme, there could potentially exist fifty-one distinct sets of BE disclosure and/or labeling standards – one for each of the states (including the District of Columbia).[14] A manufacturer would have to ensure its food product is disclosed correctly in each environment and would have to potentially maintain as many different types of disclosure, as each might register its own disclosure guidelines. There are a number of reasons numerous disclosure standards could be confusing and costly; the USDA's RIA addresses several.

According to the USDA, since non-BE disclosure is often preferred by a subset of consumers, a preponderance of products is already labeled as such. It could be argued that consumers might infer products that are bioengineered or contain BE products through the absence of such voluntary non-BE labeling. However, there are a number of reasons this would be insufficient for meeting consumer demand: (1) the number of foods labeled non-BE is very small, (2) the non-BE labeled foods often live in a separate aisle or section of the store than the non-labeled, and (3) a number of products contain BE ingredients for which there are limited alternatives. By enforcing a single standard, consumers are able to compare items directly, at any aisle in the store.

[14] Not to mention the possibility of certain states allowing localities to pass their own standards.

There are currently three states (Connecticut, Maine, and Vermont) that have passed mandatory labeling proposals, prior to the NBFDS. In addition, there are four states (California, Colorado, Oregon, and Washington) for which a mandatory labeling proposal failed prior to the NBFDS. Finally, there are thirteen states (Alaska, Arizona, Iowa, Illinois, Massachusetts, Minnesota, Missouri, New Jersey, New York, Ohio, Oklahoma, Rhode Island, and Tennessee) that had pending mandatory labeling proposals at the time NBFDS became law. If a single national standard is not adopted that can be problematic for a couple of reasons: (1) Cost to manufacturers in "deciphering diverse and often contradictory requirements" could be prohibitively high, and (2) supply-chain disruptions and reconfigurations would be numerous, including the generation of "parallel" SKUs for the same product labeled differently for different states. By mandating one standard disclosure practice nationally, some of this uncertainty is expelled and significant inefficiencies would be removed from the manufacturing and distributing process.

An appropriate baseline assessment of how the world would look in the absence of the proposed action

The USDA Regulatory Impact Analysis contains a baseline analysis. While the RIA develops a number of potential baselines – including a null alternative where no disclosure requirements are enforced. The statute requiring the USDA to develop the NBFDS (PL 114-216) preempted states from enacting any BE disclosure standards leading to the preemption of the Vermont labeling requirement. The USDA used the benefits of the preemption of the Vermont law as its baseline it the development of the RIA.

An assessment of potentially effective and reasonably feasible alternatives to the proposed regulatory action

The USDA's Regulatory Impact Analysis very carefully considers numerous alternatives. Three alternatives are presented, whereby certain products might be exempted. For each alternative, the agency calculates different costs based on small manufacturers, exemptions, different compliance periods, and different thresholds for acceptable levels of biologically engineered material.

Specifically, Scope 1 allows for no exemptions, Scope 2 exempts sugars and oils, and Scope 3 exempts foods that have undetectable levels of rDNA. Alternative considerations for small businesses include businesses with annual receipts below $500,000, below $2.5 million, or below $5 million.

The Null Alternative would be the enactment of the Vermont guidelines. True market based or voluntary alternatives are therefore not practical since they would be overridden by the Vermont guidelines, which effectively reach out to every state through their enforcement mechanisms.

An explanation of why the planned regulatory action is preferable to the potential alternatives

The RIA finds that the proposed NBFDS rule is preferable to either a nationally adopted Vermont standard or a multitude of state-by-state standards. There are three alternative versions of the NBFDS, each with numerous options. The RIA examines each of these *scopes* and finds the same costs for Scope 1 (no food/ingredient exemptions) and Scope 2 (oils and sugars exempted) since most foods contain more than one ingredient. If products are not required to disclose due to the presence of sugar, for example, that does not mean that the product itself does not need a disclosure if it contains other covered ingredients. Additionally, there are potential cost increases that may exist under Scope 2. If there are no exemptions, the instant one ingredient is determined to be BE, disclosure is necessary, whereas if sugars and oils are exempted each and every ingredient must be searched and declared BE or non-BE.

Scope 3 exempts certain products based on whether detectable genetic material makes it through processing. This alternative has a slightly lower initial costs at the lower bound of the agency's estimates: $578 million, compared to $598 million under Scope 1. However, Scope 3 is more-costly at the upper bound: $3.8 billion, compared to $3.5 billion. **Therefore, the analysis does determine that the proposed rule is the least costly alternative and therefore the most preferred of the alternatives.**

An uncertainty analysis

According to the OMB, once the plausible scenarios are described, the RIA should include a formal uncertainty analysis in which it characterizes the distribution of benefits, costs, and net benefits. In this RIA, there are many references to uncertainty in the estimates, and often upper and lower estimates are presented to account for some level of uncertainty. However, **no formal uncertainty analysis is performed in the RIA.**

A description and discussion of the distributive impacts of the potential alternatives

In the case that the regulatory action has significant distributive effects, an accounting of those effects and those of the alternatives should be provided to the extent possible. Examples of distributional effects include "health benefits that accrue principally to low-income groups," "regulatory costs that are imposed principally on low-income groups," "reduction in sales by one business that are matched by increases in sales by another," and "reductions in well-being for some consumers that are matched by increases for others."

There are a number of foreseeable distributive issues, yet no description or discussion is presented in the USDA's RIA. For instance, it is conceivable that the additional costs associated with disclosure compliance push food prices up. Rising food prices would tend to be regressive, affecting households with low incomes to a higher extent than middle- and high-income households. Additionally, it is possible that the regulation adversely affects businesses that sell BE foods or products containing BE ingredients, while those that pass the definition of non-BE might see additional sales. Neither of these, nor any additional distributional impact is included in the analysis.

A clear, plain-language executive summary including an accounting statement that summarizes the benefit and costs for the regulatory action

A concise executive summary is presented at the beginning of the USDA's Regulatory Impact Analysis. It clearly summarizes the NBFDS rule proposal. It states the range of benefits and costs, assuming stated discount rates.

A clear and transparent table presenting anticipated benefits and costs

The proposed analysis leads to 54 possible interpretations of the NBFDS, when considering the three scopes, three small business definitions, two compliance period alternatives, and three tolerance thresholds. There are a number of tables detailing the anticipated costs of *some* of the alternatives.

There are assumed to be no direct benefits to disclosure, one way or another. That is, the benefit of consumer demand for disclosure of BE products is not quantified or monetized anywhere in the study, as the agency finds that there is no clear basis on which to estimate the size of this benefit since consumer surveys, experimental studies and market outcomes suggest different valuations. The benefits of the NBFDS alternatives are entirely based on the foregone cost of the baseline scenario which would be the enactment of the Vermont BE labeling guidelines.

The USDA RIA contains numerous tables outlining costs and benefits of the proposed NBFDS rule, **however such tables are not comprehensive and are scattered throughout the analysis.**

Use the best reasonably obtainable scientific, technical economic information and present it in a clear, complete and unbiased manner

For the most part, the USDA's Regulatory Impact Analysis is based on quality data. The analysis does rely somewhat heavily on RTI modeling, without supporting documentation. [15]

Provide the data, sources, and methods used in the RIA to the public via the internet

The USDA extensively cites sources throughout the study. There are 35 sources cited in the RIA's reference section, however, only eight of the cited references are hyperlinked

Quantify and monetize the anticipated benefits from the regulatory action to the extent feasible

The USDA RIA of the proposed NBFDS rule contains a thorough accounting of the benefits of the regulatory action. Benefits of the federal disclosure statute and mandated NBFDS are assumed to be the foregone costs associated with the preemption of the Vermont disclosure law. There are no quantifiable benefits identified from the disclosure of whether an item is BE or not.

Quantify and monetize the anticipated costs from the regulatory action to the extent feasible

The USDA RIA of the NBFDS rule contains thorough accounting of the costs of regulatory action, as well as the alternatives.

Explain and support how the benefits of the intended regulation justify its costs

The USDA's Regulatory Impact Analysis explains how benefits of the NBFDS justify its costs. In the case of the Vermont standard applied nationally as a baseline, adoption of the NBFDS is able to achieve a similar consumer information objective at a much smaller cost. Based on the analysis presented in both the Agency RIA, as well as JDA's own modeling, the initial costs of the preempted Vermont legislation in and of themselves provide a sufficient benefit to offset the costs of the NBFDS. Over the long-term, the net benefits would be highly variable depending on how ingredient suppliers react to changes in demand for non-BE products.

Ensure that the preferred option has the highest net benefits unless the law requires a different approach

The RIA presents the costs of numerous scopes and alternatives within the NBFDS framework. Additionally, it indicates that Scope 1 and Scope 2 bear nearly identical costs, and that Scope 3 is likely to bear significantly higher initial and ongoing costs. **Therefore, based on the assumptions used, a no-exemption or sugar and oil exemption version of the proposed NBFDS rule is preferred to exemptions allowed based on whether or not foods retained genetic information.** It might be noted that Scope 3 has a slightly lower initial cost at the lower bound than Scope 1.

Use appropriate discount rates for benefits and costs expected to occur in the future

[15] Muth, M., Ball, M., Coglaiti, M., & Karns, S., *FDA labeling cost model*, U.S. Food and Drug Administration, Center for Food Safety and Applied Nutrition, 2011. The model is somewhat outdated and is not available to the public.

The USDA discounts its cost estimates using discount rates of three percent and seven percent. These are applied individually as separate analyses and appear to have been randomly selected. They are not equal to the current discount rate of 0.2 percent required by the OMB. **The discounting performed by the RIA is, therefore, not properly conducted.**

Cost Analysis (Agency Results)

The RIA presented by the USDA included five specific cost categories. These are:

- Administrative costs, which includes the cost of testing products for potential BE ingredients;
- Recordkeeping costs, including all administrative costs associated with complying with the rule;
- Disclosure costs, including printing of new compliant labels and spoilage of existing non-compliant ones;
- Reformulation costs, which would be the difference in the cost of non-BE and BE products like corn, soy or papaya;
- Retailer costs, including administrative and signage costs for non-packaged products, typically produce.

The agency does a good job explaining the different cost categories and includes a number of small adjustments. It also presents a low cost and a high cost estimate for each category. Averaging the low and high values together and using the general assumptions from the RIA related to the number of SKUs that would need to be disclosed or tested, and the USDA's assumptions about how many products might be reformulated using non-BE ingredients, provides the average estimated cost of the proposed rule as outlined in Table 6 below. Based on our reading of the RIA, the initial cost of complying with the proposed rule would be about $2.7 billion, with recurring costs equal to $8.2 billion using the RIAs assumed discount rate of 7 percent.[16] The agency does not present an overall 20-year cost figure, but rather an annualized cost.

Table 6
RIA Cost Calculations USDA v. JDA

	RIA	JDA
Administrative (RIA includes Design)	$ 1,657,029,000	$ 105,193,209
Recordkeeping	$ 54,908,000	$ 54,908,000
Labeling	$ 290,000,000	$ 2,269,148,065
Reformulation	$ 619,000,000	$ 1,335,051,079
Retail	$ 103,716,230	$ 195,486,165
Distribution	$ -	$ -
Total	$ 2,724,653,230	$ 3,959,786,518
NPV (7%)	$ 8,243,086,088	$ 17,001,656,523
Total 20 Year	$ 10,967,739,318	$ 20,961,443,041

Based on our analysis, the proposed rule would cost businesses just under $11.0 billion to implement and comply with over a 20-year period.

[16] This discount rate is much higher than suggested by the OMB and is also higher than the discount rate that JDA would suggest (4.35 percent) which is the current effective yield of BBB rated corporate bonds. The use of the lower discount rates would increase the on-going costs of the rule but would also lead to increases in long-term benefits.

Cost Analysis (JDA)

JDA developed a similar model to estimate the cost of the proposed rule using slightly different assumptions that are based on publicly available data sources. The analysis evaluates the costs across a range of 41 different food and beverage production categories (Table 7). Data on the production function for each of these categories was obtained from the IMPLAN input-output model for each state and the District of Columbia.[17]

Table 7
Food and Beverage Categories Examined in Analysis

Code	Industry Category	Code	Industry Category
65	Dog and cat food manufacturing	88	Ice cream and frozen dessert manufacturing
66	Other animal food manufacturing	89	Animal, except poultry, slaughtering
67	Flour milling	90	Meat processed from carcasses
68	Rice milling	91	Rendering and meat byproduct processing
69	Malt manufacturing	92	Poultry processing
70	Wet corn milling	93	Seafood product preparation and packaging
71	Soybean and other oilseed processing	94	Bread and bakery product, except frozen, manufacturing
72	Fats and oils refining and blending	95	Frozen cakes and other pastries manufacturing
73	Breakfast cereal manufacturing	96	Cookie and cracker manufacturing
74	Beet sugar manufacturing	97	Dry pasta, mixes, and dough manufacturing
75	Sugar cane mills and refining	98	Tortilla manufacturing
76	Nonchocolate confectionery manufacturing	99	Roasted nuts and peanut butter manufacturing
77	Chocolate and confectionery manufacturing from cacao beans	100	Other snack food manufacturing
78	Confectionery manufacturing from purchased chocolate	101	Coffee and tea manufacturing
79	Frozen fruits, juices and vegetables manufacturing	102	Flavoring syrup and concentrate manufacturing
80	Frozen specialties manufacturing	103	Mayonnaise, dressing, and sauce manufacturing
81	Canned fruits and vegetables manufacturing	104	Spice and extract manufacturing
82	Canned specialties	105	All other food manufacturing
83	Dehydrated food products manufacturing	106	Bottled and canned soft drinks & water
84	Fluid milk manufacturing	107	Manufactured ice
85	Creamery butter manufacturing	108	Breweries
86	Cheese manufacturing	109	Wineries
87	Dry, condensed, and evaporated dairy product manufacturing	110	Distilleries

The categories listed in Table 7 are aggregated food industry product manufacturers with similar production processes as derived from the Input-Output accounts. Each of these industries requires a large number of supplier goods and services from other industries, some of which are related to administrative functions like testing and developing products, some of which provide ingredients, some of which are related to the development and printing of labels, and some of which are involved in the wholesale distribution of food. In addition, each of the industries produces a range of products outside of their core categories (for example: Canned fruit and vegetable manufacturers also produce a small amount of soft drinks).

It is impossible to know exactly how a manufacturer will respond to the disclosure requirements. However, it is possible to model the costs based on the USDAs assumptions, as well as the costs for complying with different BE disclosure requirements. This model is based on the assumption that manufacturers would react to the different possible scenarios by either reformulating their products or disclosing and ensuring that

[17] The IMPLAN model adopts an accounting framework through which the relationships between different inputs and outputs across industries and sectors are computed. It is based on the national income accounts generated by the US Department of Commerce, Bureau of Economic Analysis (BEA). The BEA model, RIMS II is a product developed by the U.S. Department of Commerce, Bureau of Economic Analysis as a policy and economic decision analysis tool. IMPLAN was originally developed by the US Forest Service, the Federal Emergency Management Agency and the Bureau of Land Management. It was converted to a user-friendly model by the Minnesota IMPLAN Group in 1993. Data in this model come from the 2014 IMPLAN accounts, IMPLAN Group LLC.

products with proper disclosures were distributed to each jurisdiction based on their individual disclosure and testing requirements.

The model starts with the IMPLAN data for each state and each industry. First, the categories of production for each industry are examined and the percentage of total sales from the primary category is calculated. For example, only the percentage of dollar sales of canned fruit and vegetables in the canned fruit and vegetables sector is used in the analysis. This eliminates any double counting in situations which one manufacturing sector produces products that are sold by another. This is denoted as matrix (B) in the model.

Next, the various inputs into the production process are detailed for each industry. These are calculated as a percentage of each dollar of manufacturer sales. From this, and input/output matrix is generated for each of the 41 categories in each state in which they are produced. This is the food and beverage industry production matrix (A).

As previously noted, some categories of food and beverage production are not fully subject to the law. For example, there are exemptions for meat products and organic products. Because of the proposed rule's exemptions, however the study removes these 13 product categories from the analysis leaving a total of 28 covered production categories for use in the analysis. This likely underestimates the overall cost of the proposed rule but is more conforming to the baseline Vermont rule.

Next, a code was assigned to each of the 536 input industry categories in the IMPLAN model. These codes were used to assign an input to either labeling, testing and certification, distribution or potential BE-containing commodities. These input industries and their assignments are denoted as (B) in the model. These were multiplied by an estimate of the percentage of BE in the product line. For example, about 92 percent of the corn grown in the US uses bioengineered seed, as does 90 percent of canola.[18] In the case of product lines where no reliable data is available on the actual percentage of BE product (for example nearly all mangoes are BEs; however, data on the total amount of fruit that is BE is not reported), a proxy of 5 percent has been used.[19] These data are included in matrix (D) in the model.

Based on these data, it is possible to determine the percentage of sales value (or in this case economic output which is used as a proxy for sales) for each of the 28 product categories that are due to disclosure, testing, distribution, and commodities that could potentially contain BE ingredients. These percentages are then multiplied by total output of the core product line in each of the categories. The result is the total amount of industry sales (at the level of production or ex-dock) that falls into each of the three cost categories. The full model is therefore denoted as:

$A_{is}*B_s*C_z*D_{cz}*Output_{is}=Cost_{is}$ where:

A_{is} = The industry production matrix for each industry (i) and each state (s)
B_s = The percentage of each Ai production in each state (s)
$C_{z=}$The matrix of each cost component in each category (z) – labeling, BE commodity, testing
D_{cz}=The matrix containing the estimated of BE in each component (c) for each category (z)
$Output_{is}$ = The economic output in each industry (i) and each state (s)
$Cost_{isz}$=The cost to manufacturers for each industry (i) each state (s) and each category (z)

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[18] *See Adoption of Genetically Engineered Crops in the U.S.,* US Department of Agriculture, Economic Research Service, at: http://www.ers.usda.gov/data-products/adoption-of-genetically-engineered-crops-in-the-us.aspx#.UfFqm9LCaM4.

[19] As of April 2014, a total of 165 GE crops in 19 plant species were approved in the United States although not all were being grown commercially. See: *The Potential Impacts of Mandatory Labeling for Genetically Engineered Food in the United States,* Council for Agricultural Science and Technology, Issue Paper 54, April 2014.

In each case the costs occur over a different period of time. For labeling, we estimate the one-time cost as labels are changed to denote BE ingredients. The same is true for testing and the development of reformulated products. The model assumes that administrative, distribution and non-BE substation costs occur on an annual basis.

The cost of reformulating products to remove BE ingredients would occur annually and would be based on the difference between BE and non-BE input costs. In this case the average price differential on futures markets between BE and non-BE corn and soybeans is used as a proxy. This is assumed to equal 11.9 percent for corn and 11.5 percent for soybeans; therefore, 11.7 percent is used in the model.[20] This is higher than the 10 percent used in the USDA RIA which is between 5 and 10 percent.

This same difference is applied to all potential BE inputs as price differentials for papaya or squash (as examples) are not readily available.[21] These costs represent the market costs of traded commodities, not necessarily the cost that manufacturers will pay, which could be slightly higher or lower depending on how they purchase commodities.

A similar analysis is performed for dietary supplements. Dietary supplements are produced under a number of different IMPLAN codes, none of which may be particularly representative of the characteristics of the supplement industry. Therefore; the USDA's assumptions are used, with the ratio between food and supplements being held constant throughout this analysis. In other words, if the disclosure costs in the RIA for supplements were 20 percent higher than for food, this analysis maintains that same ratio.

Since consumers have little information about the benefits or costs of bioengineered crops, many may react by demanding that food companies remove these ingredients from their products. It is certainly possible, given consumers' lack of science-based information on this subject, that 100 percent of all products would eventually be reformulated.[22] This would lead to extreme disruptions in the nation's food supply chain that could take many years to overcome. The 11.5 percent price differential represents the assumed difference in cost of production per unit of output between BE and non-BE crops. Bioengineering allows farmers to plant crops on fields that would not otherwise be economically viable. BE.

The ability to actually reformulate products is therefore an extremely important assumption to this model. It is quite likely that the costs of reformulation could be dramatic - over a time horizon of several years, these

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20 Based on an earlier model of the Vermont BE standards using *National Weekly Non-GE/GMO* Report, United States Department of Agriculture, and Colorado Department of Agriculture, January 27, 2016, at: https://www.ams.usda.gov/mnreports/gl_gr112.txt.

21 This is likely a low estimate. According to The Council for Agricultural Science and Technology, *the prices received by U.S. non-GE corn and soybean producers in recent years have averaged 15% more than the prices received by conventional commodity producers. Likewise, the prices received by U.S. organic corn and soybean growers have at times been more than twice the prices received by the nonorganic growers*, See: *The Potential Impacts of Mandatory Labeling for Genetically Engineered Food in the United States*, Council for Agricultural Science and Technology, Issue Paper 54, April 2014.

22 According to Alston and Sumner, the most likely response by the food processing industry to mandatory labeling *Would be to substitute non-GE ingredients for GE ingredients where possible, either by using certified non-GE (including organic) forms of current ingredients, or reformulating products to use alternative ingredients that are not produced in GE forms. As in Europe, food processors and retailers … will be reluctant to offer for sale food with labels that may (a) frighten or otherwise dissuade some consumers, even though the label is not informative about food safety or the process used to produce it, and (b) provide a target for political action by groups opposed to GE foods, whose stated intention is to take action if such foods are offered for sale.* Alston, Julian and Daniel Sumner, *Proposition 37 – California Food Labeling Initiative: Economic Implications for Farmers and the Food Industry if the Proposed Initiative Were* Adopted, Working Paper, September 3, 2012, http*://www.noprop37.com/wp-content/uploads/2014/09/Alston-Sumner-Prop-37-review.pdf*

costs would be passed on to consumers both through higher prices and lower product quality. It is worth noting that several farm commodities in the U.S. are produced almost exclusively with bioengineered seed, and some substitutes simply are not available in the marketplace. In some cases, substitute commodity inputs for products such as these would not be available for many years as farmers switch from BE to non-BE crops.

Even if only a small percentage of food manufacturers were able to switch to non-BE ingredients, there would be major costs associated with the legislation. Companies would be forced to segregate BE and non-BE grains for example and document them as such, leading to higher distribution costs. Food manufacturers would be required to produce multiple versions of products which would increase overall production costs as run-lengths would decrease. Also, a system with smaller volume sales of more product lines would lead to higher distribution costs as more trucks and equipment would be required to handle the smaller batches. The actual costs of this regulation will depend on the interplay between these higher production and distribution costs relative to higher ingredient costs. In the case of the alternative models, the number of SKUs converted to non-BE ingredients is calculated based on minimizing the overall cost to the manufacturer.

The production cost differentials for each product category across states are calculated as documented above. These are weighed by the actual 2014 output in each state, which provides overall figures on costs to manufacturers. Table 6 on page 12 outlines these costs for each category. It should be noted that the cost categories do not match exactly since the agency included the costs of designing new labels in its Administrative section, while the JDA analysis includes them in Labeling.

The initial cost based on this model would be just under $4.0 billion, or 45.3 percent greater than the costs calculated by the USDA. Much of this is due to higher cost assumptions for labeling. The USDAs numbers come from a 2011 model that was developed by RTI. This is not fully documented in the RIA. The label cost figures in the RIA average just $398 per SKU. This is much lower than JDA's average cost of $8,933 per SKU, which does include design costs that are lumped into the RIA's Administrative section. Even adding both of these cost components together, the JDA model comes up with results that are 21.9 percent higher.

The recordkeeping costs developed by the USDA are assumed to be accurate. It is difficult to accurately calculate administrative costs like these. However, in the case of the RIA, they represent just 2.0 percent of the initial costs, so even a large differential would not impact the analysis to a great extent.

As was mentioned before, reformulation costs are much higher than those assumed by the agency. This is the result of both the higher price differential between BE and non-BE ingredients, but also the fact that the JDA analysis has a higher ingredient component cost than does the USDA model which is based on overall crop production data rather than how the cost of the crop is translated into actual food products (this accounts for about one-sixth of the overall cost differential between the USDA and JDA models).

Finally, the JDA model has slightly higher costs for retailers. USDA estimates that there are 68,835 establishments that potentially sell raw BE products like sweet corn or papayas. These establishments are operated by 44,823 distinct firms. Using data provided by Infogroup, JDA estimates that there are 129,741 establishments that would be subject to the rule including convenience retailers, department stores (like Target or Wal-Mart), grocers, warehouse clubs and specialty fruit and vegetable stores.[23] This higher firm count raises the estimated costs by 88 percent.

[23] Infogroup is the leading provider of business and consumer data for the top search engines and leading in-car navigation systems in North America. Infogroup gathers data from a variety of sources, by sourcing, refining, matching, appending, filtering, and delivering the best quality data. Infogroup verifies its data at the rate of almost 100,000 phone calls per day to ensure absolute accuracy.

In sum, JDA estimates that the proposed rule will cost businesses nearly $4.0 billion up front, with total costs of just under $21.0 billion discounted over 20 years using a 7 percent rate. JDA's overall cost estimates are therefore almost double those presented in the RIA.

Benefits Analysis (RIA)

According to the RIA, the benefits of the federal disclosure statute and mandated NBFDS are the foregone costs associated with the preemption of the recently enacted Vermont BE disclosure law. The Agency suggests that there are no quantifiable benefits identified from the disclosure of whether an item is BE or not; therefore, the benefit analysis consists of a similar cost analysis as outlined above but based on the Vermont law.

Table 8
RIA Benefit Calculations USDA v. JDA

	RIA	JDA
Administrative (RIA includes Design)	$ 1,228,500,000	$ 84,168,782
Recordkeeping	$ 54,908,000	$ 54,908,000
Labeling	$ 2,550,000,000	$ 8,401,570,738
Reformulation	$ 583,500,000	$ -
Retail	$ -	$ -
Distribution	$ -	$ 458,083,837
Total	$ 4,416,908,000	$ 8,998,731,357
NPV (7%)	$ 6,166,660,456	$ 4,955,211,205
Total 20 Year	$ 10,583,568,456	$ 13,953,942,561

As Table 8 shows, using both the assumptions outlined in the RIA and in JDA's alternative model, the initial cost of the preempted Vermont BE labeling regulations are much higher than those of the proposed rule. This is mainly due to the fact that the Vermont law would go into effect immediately, forcing firms to scrap all of their existing labels. Under the proposed rule, only about 7 percent of existing label stock would be scrapped. Based on the higher label production costs in the JDA analysis, and accounting for the fact that the cost structure means that it is likely that products would not be reformulated nationally simply to sell in Vermont, there would be more products to label as containing BE ingredients.

The higher labeling costs are offset by slightly lower administrative costs. The Vermont rule also did not require signage at retail.

In order to determine how firms would react to BE disclosure laws at the state level, JDA developed a model that included state level product distribution costs. These are developed in the same manner as the labeling and administrative costs based on the percentage of warehousing and wholesaling costs to sales for food processors at the state level.[24] Overall, food and supplement manufacturers spend $131.4 billion on distribution related expenses. These would increase were they forced to maintain separate systems across states in order to either meet BE content or disclosure requirements. Firms face a trade-off between the cost of reformulating their products to contain only non-BE ingredients, and the cost of maintaining these separate distribution systems.

The cost of the distribution systems comes from the IMPLAN data as discussed above. The need for a separate system would depend on both the number of states involved and the percentage of BE to non-BE

[24] These data are developed from the IMPLAN tables for food processors. The actual distribution costs will be incurred based on the point of sale rather than of production, however, those data were not readily available; therefore, the state of production is used as a proxy. At the national level the costs would be equal, however, different distributions of production and consumption across states makes the calculation less exact.

products. A company selling 100 percent BE products would need to maintain multiple distribution systems, while one with 100 percent non-BE products would be able to keep a national system. The higher the percentage of non-BE SKUs and the more states involved, the more expensive the system.

The JDA model was set up to calculate the minimum cost of a rule based on these trade-offs. Looking just at Vermont, the cost of maintaining a separate distribution system would be small, just $837 per SKU. This rises to nearly $157,800 per SKU if separate systems had to be maintained to comply with 51 different and distinct state laws. As such, the higher the cost of the system, the more firms would be encouraged to shift to non-BE production.

Looking at just Vermont, the costs would be minimized by not reformulating, and rather keeping a completely separate disclosure and distribution system for the state. This is why the JDA analysis assumes no reformulation costs but adds in higher distribution charges. Based on this model, the benefit that resulted from moving to a national disclosure system was almost $9.0 billion initially, with a 20-year savings of $13.9 billion discounted at 7 percent.

Benefit Analysis Alternative 1 – 20 Different States

While Vermont's labeling law was slated to go into effect in 2016, there were 20 other states that had BE disclosure or labeling laws either already adopted or in consideration.[25] The RIA did not calculate what the potential cost of 20 separate and potentially contradicting rules. Instead, the USDA determined that preempting the Vermont rule alone provided sufficient social benefits to outweigh the costs of the NBFDS. In order to determine the benefits of preventing different laws in the 20 states currently with (or considering) BE labeling requirements, JDA modified the Vermont analysis. In this case, the assumptions made for Vermont were modified as follows:

- Administrative: The cost assumptions remain constant. Growth is due to the increase in the number of products anticipated to be reformulated;
- Recordkeeping: This is equal to the RIA recordkeeping costs multiplied by 20 since each state is presumed to promulgate its own requirements;
- Labeling: Assumptions remain the same. It is assumed (as is the case with Vermont) that labeling changes would be required with no grandfathering.
- Reformulation: Same as the Vermont costs. The model was solved and the lowest cost alternative for firms would be to reformulate all products rather than maintain 20 separate state distribution systems.
- Retail: Same as Vermont – no retail signage requirements.
- Distribution: As with the Vermont analysis, the wholesaling costs for producers in each state were used as a proxy or food and supplement product wholesaling costs in the state. The costs for the 20 states identified in the RIA were used.

As was stated above, product distribution requirements become progressively more expensive as firms are subject to more and more specialized disclosure and/or labeling, formulation and recordkeeping systems. Based on the distribution costs in the 20 states, it is more efficient and cost-effective for all food processors to shift (where ever possible) to non-BE ingredients. This is similar to what has occurred in

[25] According to the RIA as of 2017 Connecticut, Maine and Vermont had adopted labeling provisions. Legislatures in Alaska, Arizona, Iowa, Illinois, Massachusetts, Missouri, New Jersey, New York, Ohio, Oklahoma, Rhode Island and Tennessee were debating provisions. Provisions were also considered in California, Colorado, Oregon and Washington but failed. As these states are among the most progressive in the country it would be likely that legislation would be reintroduced were the NBFDS to not go into effect.

Europe.[26] While the USDA suggests that few manufacturers would change to non-BE ingredient sources as there are few consumer benefits, it also reports that evidence from countries that already have mandatory BE disclosure shows that very few if any BE labeled foods are found on grocery store shelves. If mandatory disclosure is the reason for this, then U.S. markets may also veer sharply away from BE products with the introduction of mandatory disclosure.

Table 9
Calculation of Benefit of Preempting 20 Differing State Requirements (JDA)

	RIA	JDA
Administrative (includes Design)	$ -	$ 963,435,403
Recordkeeping	$ -	$ 1,098,160,000
Labeling	$ -	$ 10,474,054,509
Reformulation	$ -	$ 6,954,980,381
Retail	$ -	$ -
Distribution	$ -	$ -
Total	$ -	$ 19,490,630,293
NPV (7%)	$ -	$ 77,788,784,499
Total 20 Year	$ -	$ 97,279,414,792

JDA's analysis is based exclusively on cost savings. In other words, all benefits are derived from the prevention of a costly, state to state BE disclosure and/or labeling rule. Since the cost of maintaining complex overlapping distribution systems is so high, firms would be encouraged to shift to non-BE production, assuming ingredients are available and that costs do not markedly increase. Multiple disclosure and/or labeling systems requiring significant design costs and higher reformulation costs bring the initial cost of complying with 20 separate and distinct state rules to $19.5 billion and the overall discounted 20-year cost to $97.3 billion.

Benefit Analysis Alternative 2 – 51 Different States

Table 10
Calculation of Benefit of Preempting 51 Differing State Requirements (JDA)

	RIA	JDA
Administrative	$ -	$ 963,435,403
Recordkeeping	$ -	$ 2,800,308,000
Labeling	$ -	$ 24,775,687,794
Reformulation	$ -	$ 6,954,980,381
Retail	$ -	$ -
Distribution	$ -	$ -
Total	$ -	$ 35,494,411,578
NPV (7%)	$ -	$ 94,230,572,135
Total 20 Year	$ -	$ 129,724,983,713

Costs go even higher if different disclosure provisions are adopted in 51 different states, not to mention the potential of stricter local disclosure requirements in states that do not preempt them. Table 10 on the

[26] See RIA page 42.

prior page shows the overall costs if this were to occur and thereby the maximum potential benefit of the proposed NBFDS. Based on JDA's analysis and using the same assumptions as were outlined in the 20-state model, the potential benefit of the proposed rule is as high as $129.7 billion discounted over 20-years, with $35.5 billion of that being initial labeling, reformulation and recordkeeping costs.

Cost-Benefit

Clearly, the potential costs of complying with 51, or even 20 different state disclosure requirements can be substantial, which is why Congress enacted the federal disclosure statute and required the Department of Agriculture to promulgate national rules.

Table 11
Cost Benefit of Proposed Rule Compared to Baseline

	RIA	JDA
Cost of NBFDS		
Initial Costs	$ 2,724,653,230	$ 3,959,786,518
Discounted 20 Year Cost	$ 6,509,570,391	$ 13,426,219,104
Total Cost	$ 9,234,223,621	$ 17,386,005,622
Benefit from Preemption of Vermont Rules		
Initial Costs	$ 4,416,908,000	$ 8,998,731,357
Discounted 20 Year Cost	$ 6,166,660,456	$ 4,955,211,205
Total Cost	$ 10,583,568,456	$ 13,953,942,561
Benefit-Cost Ratio		
Initial Costs	1.62	2.27
Discounted 20 Year Cost	0.95	0.37
Total Cost	1.15	0.80
Benefit from Preemption of 20 State Rules		
Initial Costs	Not Calculated	$ 19,490,630,293
Discounted 20 Year Cost	Not Calculated	$ 77,788,784,499
Total Cost	Not Calculated	$ 97,279,414,792
Benefit-Cost Ratio		
Initial Costs		4.92
Discounted 20 Year Cost		5.79
Total Cost		5.60
Benefit from Preemption of 51 State Rules		
Initial Costs	Not Calculated	$ 35,494,411,578
Discounted 20 Year Cost	Not Calculated	$ 94,230,572,135
Total Cost	Not Calculated	$ 129,724,983,713
Benefit-Cost Ratio		
Initial Costs		8.96
Discounted 20 Year Cost		7.02
Total Cost		7.46

Based on the analysis presented in both the Agency RIA, as well as JDA's own modeling, the initial benefits from PL 114-216 that preempted the Vermont legislation in and of themselves provided a sufficient benefit to offset the costs associated with the federal disclosure statute and mandated NBFDS. Over the long-term, the net benefits would be highly variable depending on how ingredient suppliers react to changes in demand for non-BE products. Table 11 outlines the benefit-cost ratios for the various models considered in this analysis.