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Submitted Electronically via GMOLabeling@ams.usda.gov

Re: **AMS Questions on Bioengineered Food Disclosure Law**

Dear Sir/Madam:

Unilever United States Inc. (Unilever) appreciates the opportunity to submit comments to the U.S. Department of Agriculture's (USDA's) Agricultural Marketing Service (AMS) regarding the National Bioengineered Food Disclosure Standard.

Unilever is one of the world's largest consumer product companies with \$70 billion in global sales. Our foods, home and personal care brands have been trusted the world over since 1890. Our food and beverage products include many leading brands in the United States, such as Hellmann's® mayonnaise; Ben & Jerry's®, Breyers® and Klondike® ice cream; I Can't Believe It's Not Butter®, Promise® and Country Crock® spreads; Lipton® tea and Knorr® savory foods.

Unilever strongly supports the establishment of a uniform national standard for the disclosure of bioengineered foods. We thank AMS for seeking early input from stakeholders as the agency engages in the development of the standard via rulemaking. The responses below address questions posed by AMS regarding the scope of the standard, the required disclosures and other questions related to recordkeeping and imported food.

Question 1. What terms should AMS consider interchangeable with 'bioengineering'? (Sec. 291(1))

Context: The disclosure standard would be a mechanism to inform consumers about their food. AMS is considering the advantages and disadvantages of allowing the use of other terms to provide for disclosure.

Unilever Response:

The term "bioengineering" should be the sole term for purposes of section 291(1) as this is the term that was specifically defined by Congress, whereas other terms were not. However, Unilever believes that

other terms could be used in consumer facing disclosure statements (e.g., “bioengineering”, “biotechnology”, “biotech”, “genetic engineering”, or “GMO”). While we recognize the Food and Drug Administration uses the terms “genetic engineering” and “bioengineering” to describe the use of modern biotechnology¹ and does not recommend use of the terms “genetically modified” or “genetically modified organism” (GMO), the term GMO is the term most widely used and recognized by consumers in the U.S. Regardless, AMS should establish a single and consistent term for use in statements that will be uniformly applied across all food and beverage products to disclose the presence of bioengineered ingredients. The term used in the phrase should not be disparaging to biotechnology² and should characterize the origin of ingredients such as “includes ingredients sourced from biotech crops”.

Question 4. Will AMS require disclosure for food that contains highly refined products, such as oils or sugars derived from bioengineered crops? (Sec. 291(1)(A))

Context: Many processed foods may contain ingredients derived from bioengineered crops, such as highly refined oils or sugars that contain undetectable levels of bioengineered genetic material such that they are indistinguishable from their non-engineered counterparts. AMS is considering whether to require disclosure for foods containing those derived ingredients that may be undetectable as bioengineered.

Unilever Response:

Unilever supports the inclusion of highly refined ingredients and foods, such as oils and sugars derived from bioengineered crops, within the mandatory disclosure standard. This is consistent with our position that bioengineering disclosure should be based primarily on traceability of ingredients through the supply chain back to a crop. We do not believe disclosure should rely on detection of genetic material in the food or food ingredient and, as such, disclosure should not rely simply on specific test methods such as PCR (Polymerase Chain Reaction) testing. This is consistent with the Food and Drug Administration’s guidance to manufacturers on *Voluntary Labeling Indicating Whether Foods Have or Have Not Been Derived from Genetically Engineered Plants*¹ focus on whether the food is derived from a bioengineered plant and not on whether it contains rDNA.

In the U.S., farmers widely use bioengineered seeds to produce five major agricultural crops (corn, soy, canola, cottonseed and sugar beet) that are commonly used to produce foods and food ingredients. Consumers expect foods and beverages that contain highly refined ingredients derived from bioengineered crops to contain a disclosure. Our support for mandatory highly refined ingredient disclosure is grounded in our commitment to transparency and to building consumer trust in the use of bioengineered ingredients and foods. Consumers are seeking more information about the food, beverage and consumer products they consume and use and our company is committed to providing our consumers with the information they need to make informed choices about these products. To this end, Unilever

¹ See Guidance for Industry - Voluntary Labeling Indicating Whether Foods Have or Have Not Been Derived from Genetically Engineered Plants found at <https://www.fda.gov/RegulatoryInformation/Guidances/ucm059098.htm> accessed July 5, 2017.

² Section 293(b)(3) requires that “food disclosures” established by regulations shall not treat a bioengineered food as not as safe as a non-bioengineered food. Therefore, the disclosure term and statement must not mislead consumers that the bioengineered food is unsafe.

discloses the use of highly refined ingredients produced from bioengineered crops in products via SmartLabel™ (i.e., “this product includes ingredients sourced from genetically engineered (GE) crops, commonly known as GMOs”).

Labelling of foods and food ingredients produced from bioengineered crops is mandatory in about 60 countries around the world, including the European Union, Russia, Turkey, Australia and Brazil. In the European Union, products containing highly refined ingredients, such as oils from bioengineered canola, corn and soy and sugar from bioengineered sugar beet require mandatory disclosure even if there is no detectable genetic material in the end product.

A determination that highly refined ingredients are considered as bioengineered foods would be consistent with reasonable consumer expectations. This is further fueled by Non-GMO certification schemes such as Non-GMO Project Verified and True North which consider highly refined ingredients derived from bioengineering subject to GMO disclosure (i.e., if a formulated finished food or beverage product were to contain a highly refined ingredient from a bioengineered source it would not be considered as “non-GMO” under these voluntary labeling schemes).

Consumer interest in bioengineered foods is based on a desire to understand how a crop or ingredient is grown, not whether the food contains rDNA. Furthermore, Section 293(b)(3) specifically requires that a bioengineered food shall not be treated as not as safe as its non-bioengineered counterpart. A narrow focus on the presence of genetic material creates a differentiation based on rDNA that some could use to imply a safety issue with the rDNA. This narrow focus may lead to consumer belief that somehow foods and food ingredients containing genetic material are different for which consumers need to be informed.

Question 5. Although the Law states that the definition of bioengineering shall not affect any other definition, program, rule, or regulation of the Federal government, could there be potential areas of confusion between the definition of bioengineering as used in the Law and others similar terms used by the Federal government? If so, what are the potential remedies that could be added to this regulation to alleviate any confusion between this definition and others by the Federal government? (Sec. 292(b))

Context: AMS recognizes that other Federal agencies have different terms to describe organisms created through recombinant DNA techniques. AMS is considering areas of potential overlap or confusion over terms, as well as potential language to add to this regulation to ensure the term bioengineering does not affect any other definition, program, rule, or regulation.

Unilever Response:

The statute directs AMS to consider establishing consistency between the National Bioengineered Food Disclosure Standard and the Organic Foods Production Act of 1990 and its implementing regulations. Unilever supports consistency, where appropriate, to help reduce consumer confusion. The bioengineered food disclosure statute does not, and future regulations should not, impact the authorities or obligations under the Organic Foods Production Act and no modifications should be made to the USDA Organic rules solely as a result of bioengineered food disclosure rulemaking.

Consistent with USDA's September 19, 2016 Policy Memo³³, no certified organic products should require disclosure as a bioengineered food. Unilever supports that foods certified under the National Organic Program are considered sufficient to continue making claims about the absence and exclusion of biotechnology as outlined in the statute.

Question 6. Meat, poultry, and egg products are only subject to a bioengineered disclosure if the most predominant ingredient, or the second most predominant ingredient if the first is broth, stock, water, or similar solution, is subject to the labeling requirements under FFDCA. How will AMS determine the predominance of ingredients? (Sec. 292 (c))

Context: AMS is considering how to evaluate predominance to determine how the Law will apply to multi-ingredient food products.

Unilever Response:

AMS should rely on the ingredient declaration on the product label to evaluate predominance of ingredients to determine how the law will apply to multi-ingredient food products. As described in 21 CFR 101.4(a), 9 CFR 317.2(f)(1) and 9 CFR 381.118(a), the ingredients are required to be declared on the label of a food by common or usual name in descending order of predominance by weight.

Question 7. How should AMS craft language in the regulations acknowledging that animals consuming bioengineered feed are exempt from the disclosure requirements as bioengineered solely because they fed on bioengineered feed? (Sec. 293(b)(2)(A))

Context: AMS is considering regulatory language similar to the wording in the Law and if the Agency should provide clarity that food derived from any animal, including invertebrates such as crickets or bee products, would not require disclosure as a bioengineered food solely because their nutrition came from food with bioengineered ingredients.

Unilever Response:

Language similar to, but more specific than that used in the Law is recommended. Such language to exclude food and food ingredients from animals may read as follows: "Foods or food ingredients that are derived from animals, insects, or microorganisms which grow or feed on a bioengineered crop or ingredient directly derived from such a crop are exempted from disclosure". Examples include milk, whey protein, eggs, egg lecithin, honey, alcohol, and fermentation-derived ingredients such as amino acids, citric acid, vitamins and vinegar. Similarly, ingredients from animals that have been treated with recombinant drugs and pharmaceuticals (e.g., rBST) should be exempted from disclosure.

Question 8. What is the amount of a bioengineered substance present in a food that should make it be considered bioengineered? (Sec. 293 (b) (2) (B))

Context: The Law authorizes the Secretary to determine the amount of a bioengineered substance present in food in order for the food to be disclosed as a bioengineered food. The amounts of a

³³ Memorandum from Elanor Stamer, AMS Administrator to AMS Deputy Administrators re: Consistency between Bioengineered Disclosure and National Organic Program, September 19, 2016.

bioengineered substance that may be present in food in order for the food to be a bioengineered food might be determined in a variety of ways: if a bioengineered substance is near the top of the list of ingredients, by determining the percentage of bioengineered ingredients in a food product, or by listing any ingredient that was produced through bioengineering, among others. AMS is considering how to determine the amount of bioengineered food or ingredient needed for a product to require a bioengineered disclosure, as well as the advantages and disadvantages of various methods.

Unilever Response:

Many foods and beverages contain varying levels of ingredients that may be subject to bioengineered disclosure. These ingredients often contain sub-components including incidental ingredients / additives, processing aids and secondary direct food additives. Unilever believes that incidental ingredients / additives, processing aides and secondary direct food additives should be excluded from bioengineering disclosure and threshold considerations. This is aligned to FDA's ingredient labeling regulations which provide an exemption for declaring ingredients present in "incidental" amounts in a finished food when the ingredient is present at an insignificant level and has no functional or technical effect in the finished product. Furthermore, ingredients produced from fermentation should also be excluded from bioengineering disclosure simply because the microorganism was grown using a bioengineered substrate (see response to Question 10).

Unilever recognizes that various thresholds are used throughout the world for bioengineering disclosure purpose. We recommend that AMS consider a threshold appropriate to the supply chain situation in the U.S.; i.e., one with well-established use of bioengineered seed to produce food and food ingredients. Unilever prefers a numerical threshold for mandatory disclosure, namely one that incorporates the sum of disclosable ingredients. Disclosable ingredients are those based primarily on traceability through the supply chain to the original bioengineered crop.

Unilever suggests AMS consider the approach taken in Vermont's Consumer Protection Rule 121 where foods and beverages required disclosure if the aggregate weight of the bioengineered ingredients was more than 0.9 percent of the total weight of the food/beverage. This calculation should take into consideration other exclusions and exemptions that can be applied.

Question 10. What other factors or conditions should AMS consider under which a food is considered a bioengineered food? (Sec. 293(b)(2) (C))

Context: AMS must develop a process to help stakeholders determine whether a food is subject to bioengineered disclosure. AMS anticipates the process would include considering factors such as these: whether a food contains a substance that has been modified using recombinant in vitro DNA techniques (Sec. 291(1)(A)), and for which the modification could not be obtained through conventional breeding or found in nature (Sec. 291(1)(B); Question 2 and 3),, and whether a food requires disclosure based on the predominance of ingredients (Sec. 292(c), Question 6), among others. The outcomes of these determination requests might be publically posted on a Web site. The process to implement Sec. 293(b) (2)(C) is not intended to be an investigation or enforcement process (see Questions 26-29); instead, the implementation would likely be framed for manufacturers or developers of bioengineered food or ingredients who have a question on whether their food is subject to disclosure. AMS is considering the factors to be considered, the way to inform the public about the outcome of the requests, and ideas regarding the process to be used to make the determination.

Unilever Response:

As discussed above under our response to question 4, AMS should determine via the rulemaking process that highly refined ingredients derived from bioengineered crops are subject to the disclosure standard. AMS has the authority to require disclosure of foods containing these ingredients as bioengineered foods under section 293(b)(2)(C) of the law.

In addition, a food should not be considered a bioengineered food solely because it contains or is:

- A processing aid, incidental ingredient/additive, or secondary direct food additive that may be from a bioengineered source material. Examples include carriers and encapsulates for flavors and other components that may have a functional role in the ingredient but no function in the final product. Exclusion from mandatory bioengineered disclosure is aligned to FDA's ingredient labeling regulations which provide an exemption for declaring ingredients present in "incidental" amounts in a finished food when the ingredient is present at an insignificant level and has no functional or technical effect in the finished product.
- An ingredient derived from a fermentation process such as a vitamin, amino acid, organic acid, or other product produced by fermentation such as ethanol and vinegar. Some of these fermentation-produced ingredients will use a non-genetically engineered microorganism but will utilize growth media substrates (e.g., corn syrup, soy protein) from bioengineered crops.
- An ingredient currently authorized for use in certified organic foods, including those on the National List of Allowed Substances to assure consistency with the National Organic Program.

Unilever also requests AMS address other fermentation-produced ingredients derived from a genetically engineered microorganism in which the microorganism is not present in the isolated and purified product. Under the statute, AMS has the authority to make a determination that these fermentation-produced ingredients should be excluded from bioengineering disclosure when included in finished food products.

Question 12. If a manufacturer chooses to use text to disclose a bioengineered food, what text should AMS require for a text disclosure? (Sec. 293(b)(2)(D))

Context: Currently, some food manufacturers use language compliant with the Consumer Protection Rule 121 from the State of Vermont to identify their food products as bioengineered ("Produced with Genetic Engineering," "Partially Produced with Genetic Engineering," or "May be Produced with Genetic Engineering"). AMS is considering whether to allow manufacturers to continue using these disclosures under the new national bioengineered disclosure standard and if their language is appropriate. Further, AMS is considering what phrases could be used as a text disclosure for bioengineered food that consumers would find informative, truthful, and not misleading.

AMS is also considering whether there should be one standard text disclosure language, or whether manufacturers should be allowed flexibility to choose from more than one acceptable phrase and where the bioengineered food disclosure should be placed on food packages.

Unilever Response:

There are various terms and statements used today to disclose that a food is bioengineered. For on-pack text disclosure, and to avoid consumer confusion, AMS should consider developing a single and consistent statement that will be uniformly applied across all food and beverage products to disclose the presence

of bioengineered ingredients. The term in the phrase should not be disparaging² to biotechnology and should characterize the origin of ingredients such as “includes ingredients sourced from biotech crops.”

Furthermore, AMS should provide food and beverage companies the option to provide additional details on a voluntary basis (i.e., details in addition to the single, uniform statement) to further enhance consumer understanding. AMS should also allow sufficient time for companies using existing disclosure statements (such as those made following the Vermont labeling law) to conform to the disclosure statement required under Federal law.

Question 13. If a manufacturer chooses to use a symbol to disclose a bioengineered food, what symbol should AMS require for disclosure? (Sec. 293(b)(2)(D))

Context: AMS needs to ensure that the symbol designed for the bioengineered disclosure is not disparaging toward bioengineering. As with the text disclosure, AMS must develop criteria for placement of the symbol to ensure consumers can readily locate the symbol, the symbol is scalable for different sized packages, and the symbol is a meaningful representation of bioengineered foods. AMS is considering what the symbol should look like and guidance on its use.

Unilever Response:

Unilever recommends a common standalone positive image or symbol (such as symbols used to designate Kosher status) be used for on-pack disclosure in order to avoid disparaging perceptions regarding biotechnology. We also recommend that AMS avoid any type of symbol that may be viewed as a type of warning. Furthermore, AMS should provide flexibility to use either a black and white, or color version of the symbol, as is permitted for the USA organic seal.

While text should not accompany the image, there will be a need for consumer education to explain the image. AMS should also consider consumer testing the proposed symbol to understand consumer perceptions.

Question 14. If a manufacturer chooses to use an electronic or digital link to disclose a bioengineered food, what requirements should AMS implement for an electronic or digital link disclosure? (Sec. 293 (b)(2)(D))

Context: See Questions 23-25.

Unilever Response:

AMS should not identify specific electronic or digital disclosure methods by regulation as technologies rapidly become obsolete. Instead, AMS should establish a set of criteria for the disclosure method, including requirements for a digital link and a carrier based on the following principles:

1. The digital link (such as a Uniform Resource Locator or URL) should provide accessibility to consumers via either an app or other technology available on a smart device (such as a mobile phone or tablet). The app or other technology must be widely available to consumers. Smart devices must have the capability to read the URL (or other link) in the carrier either through manufacturer provided utilities or an app available as a free download.

2. Consumers must be able to recognize that the carrier (such as a barcode or other technology) can be read by a smart device and the words “Scan this logo/icon/image for more information” must accompany the carrier.
3. Consumers must be able to scan the carrier with their smart device and the smart device must be able to read the URL (or other link) in the carrier and bring consumers to a webpage containing the required disclosure statement and other voluntary disclosure information.

With respect to specific language used for the disclosure provided via the electronic or digital link, AMS should consider consistency between the disclosure language for used for the electronic or digital link and the on-pack disclosure text (refer to response to Q12 above), including allowance to use additional information to supplement the disclosure text to further enhance consumer understanding.

Question 15. Should AMS specify in the regulations the type of electronic or digital disclosure manufacturers, e.g. QR code, can use to disclose bioengineered food? What steps should AMS take if an electronic or digital disclosure method becomes obsolete? (Sec. 293 (b) (2) (D))

Context: AMS recognizes that disclosure technologies may quickly surpass regulations. AMS is considering what terms will ensure the regulations keep pace with technological changes and how AMS can notify stakeholders about changes in technology as they occur. AMS is also considering what the most appropriate electronic or digital disclosure technologies are currently and how to deal with obsolete technologies.

Unilever Response:

AMS should not identify a specific technology to ensure that regulations do not become obsolete as technologies advance faster than regulations. AMS should provide the principle that electronic or digital disclosure should be made via a digital link in an on-package carrier and not attempt to identify the specific technologies via rulemaking.

Question 16. What kind of text, symbol, or electronic or digital disclosure should AMS require for bioengineered food that is not purchased from a grocery store shelf, such as food for sale in bulk (such as fresh produce in a bin or fresh seafood at a fish counter), in a vending machine, or online? (Sec. 293 (b)(2)(D))

Context: In some situations, disclosures may not be easily located when such products are on display for sale. AMS is considering disclosure practices for these and other non-conventional purchasing or packaging scenarios.

Unilever Response:

The statute does not require that consumers be provided with access to the disclosure information prior to purchase. As such, the information provided on the packaged food label itself should be considered sufficient disclosure to meet the requirements of the law. AMS should not require separate signage / statements for vending machines or for foods sold online. This would ensure that packaged foods are subject to one single set of labeling requirements.

For food sold in bulk, AMS should consider provisions similar to Food and Drug Administration’s approach to voluntary nutrition labeling or such items in 21 CFR 101.45; i.e., require bioengineering disclosure on bins, leaflets, posters, brochures, shelf-labels, etc. AMS should also permit the disclosure to be provided through digital disclosure, similar to the requirements for packaged foods.

Question 17. The Law offers special provisions for disclosure on small or very small packages. How should AMS define very small or small packages? (Sec. 293 (b)(2)(E))

Context: AMS is considering if it should mirror FDA’s treatment of very small and small packages for nutrition labeling.

- a) In 21 CFR 101.9(j)(13)(i)(B), FDA defines small packages as those with less than 12 square inches in total surface area available to bear labeling.
- b) FDA also has allowances for packages that have less than 40 square inches of total surface area available to bear labeling.

Unilever Response:

We recommend AMS consider alignment to the small package definition currently defined by FDA in 21 CFR 101.9(j)(13)(i)(A) for nutrition labeling of foods; i.e., “foods in small packages that have a total surface area available to bear labeling of less than 12 square inches” We believe AMS can use this definition for both small and very small packages.

Question 18. What are the reasonable disclosure options AMS should provide for food contained in very small or small packages? (Sec. 293(b)(2)(E))

Context: AMS is considering the disclosure standards for very small or small packages. FDA regulates nutrition labeling on very small or small packages differently. For example:

- a) Could disclosure requirements for very small packages be met by providing an address or phone number where consumers could obtain the information?
- b) Could disclosure requirements for small packages be met by providing abbreviated text disclosure or a Web site address where consumers could obtain disclosure information?

Unilever Response:

In addition to the standard disclosure options (i.e., text disclosure, electronic or digital link, or symbol), it would be appropriate for AMS to allow products in small and very small packages to meet the disclosure requirements using an alternate method. Such alternate method could be similar to FDA’s approach to nutrition disclosure provision provided in 21 CFR 101.9(j)(13)(i)(A) for small packages. To this end, AMS should consider a bioengineering disclosure option for both small and very small packages in the form of an address, telephone number or website address that a consumer may use to obtain required information.

AMS should also consider provisions for reduced minimum type size, abbreviated text or alternative placement options to provide flexibility to fit the disclosure within the available space of small and very small packages.

Question 19. How should AMS define small food manufacturers? (Sec. 293(b)(2)(F))

Context: AMS is considering using regulatory language similar to that of other Federal government agencies that already define small businesses. For example:

- a) FSIS considers small businesses to be those with 500 or fewer employees and that produces 100,000 pounds or less of annual production of a single product, including single forms of meat such as sausage, bulk, patties, links, consumer product, etc., when determining exemptions from nutrition facts labeling (9 CFR 317.400 (a)(1)(ii)).
- b) FDA has several small business definitions with respect to food labeling rules, such as: i) retailers with total annual gross sales of \$500,000 or less, 21 CFR 101.9(j)(1) and (18); ii) food and dietary retailers with annual gross sales of foods or dietary supplement products of \$50,000 or less, 21 CFR 101.9(j)(1) and 101.36(h)(1); and iii) businesses that employ fewer than 100 full-time workers businesses that produce a product that sells fewer than 100,000 units throughout the United States in a 12-month period, 21 CFR 101.9(j)(18) and 101.36(h)(2).

AMS is considering the advantages or disadvantages of these definitions of small food manufacturers for the bioengineered food disclosure regulations.

Unilever Response:

AMS should consider the definition of a small food manufacturer based on annual sales volume and not on the basis of full-time equivalents. To this end, AMS should align the small business definition to that used by FDA in 21 CFR 101.9(j)(1)(i); i.e., “food offered for sale by a person who makes direct sales to consumers (e.g., a retailer) who has annual gross sales made or business done in sales to consumers that is not more than \$500,000 or has annual gross sales made or business done in sales of food to consumers of not more than \$50,000”.

Question 20. For disclosures by small food manufacturers, what is the appropriate language indicating that a phone number provides access to additional information? (Sec. 293(b)(2)(F)(ii)(I))

Context: AMS is considering using language in Sec. 293(d)(1)(B) of the Law.

Unilever Response:

AMS could consider language similar to that used in 21 CFR 101.9(j)(13)(i)(A) for the small package exemption to nutrition facts labeling (e.g., “For nutrition information, call 1-800-123-4567”). In this manner a small business manufacturer that qualifies for and uses the nutrition facts labeling exemption and bioengineering disclosure option could use language such as “For nutrition and other information, call 1-800-123-4567.”

Question 23. Is there other equivalent on-package language that AMS should consider to accompany an electronic or digital disclosure besides “Scan here for more food information”? (Sec. 293(d)(1)(A))

Context: The word ‘scan’ may or may not be relevant for each type of electronic or digital disclosure in the present or in the future. AMS is considering if it should issue guidance to identify equivalent language as technology changes and what that equivalent language would be.

Unilever Response:

The on-package language to accompany the electronic or digital disclosure should read “Scan [appropriate term] for more information”. “Scan” is likely to remain a ubiquitous call-to-action verb for a long time; thus, it is an appropriate and relevant term to accompany the electronic or digital disclosure.

Manufacturers should be provided with additional flexibility to identify the appropriate reference link to ensure the call-to-action statement is clear to consumers on how to access the disclosure. Therefore, the term “Scan here...” could be replaced with terms such as “Scan this icon...”, “Scan this logo...”, or “Scan this image....” AMS should not prescribe the use of the term “here” in on-package language to accompany electronic or digital disclosures. Also, we do not believe the word “food” is required in the call-to-action statement as there may be other information in the digital disclosure (such as social compliance and sustainability information).

Finally, if a new technology becomes available and it is readily apparent that the term “Scan [appropriate term] is no longer an appropriate action to describe how a consumer may access the information, then AMS should provide the option to use a different verb that better reflects how the new technology provides access to the disclosure.

Question 24. How should AMS ensure that bioengineered food information is located in a consistent and conspicuous manner when consumers use an electronic or digital disclosure? (Sec. 293(d)(2))

Context: AMS is considering requiring the same information associated with the text disclosure as the requirement language for an electronic or digital disclosure (See Question 12). Further, AMS is trying to determine how various disclosure options affect the amount and type of information available to consumers. AMS is also determining if there should be requirements or guidance on what size text would ensure the information is conspicuous to ensure the food information is located in a consistent and conspicuous manner when electronic or digital disclosure is accessed.

Unilever Response:

The required language used in the text disclosure and that used in the information associated with the electronic or digital disclosure should be the same (see response to question 12 for specific recommendations).

With respect to ensuring that the disclosure information is located in a consistent and conspicuous manner when consumers use an electronic or digital disclosure, the statute states the following: “the electronic or digital link will provide access to the bioengineering disclosure located, in a clear and conspicuous manner, on the first product information page that appears for the product on a mobile device, internet website, or other landing page, which shall exclude marketing and promotional information.”

Consistent with the statutory language, consumers must be able to locate the bioengineered food disclosure from the landing page in one click or less. AMS should also accommodate the use of a carrier that requires an additional “click” to initially reach the landing page – for a total of two clicks or less after scanning. This is to accommodate certain codes that prompt the user upon scanning to respond to a question such as “Do you want to open up this URL?” before the user reaches the landing page. Once a

user agrees to proceed, he/she should be able to reach the landing page or product information page to access the bioengineered food disclosure. We ask AMS to accommodate systems with “two clicks or less” – i.e., one click to reach the landing page and one click from the landing page to reach the disclosure – so that the standard is both consistent with the statutory language and provides for multiple types of disclosures.

Question 25. How should AMS ensure that an electronic or digital disclosure can be easily and effectively scanned or read by a device? (Sec. 293(d)(5))

Context: AMS is aware that electronic or digital disclosures need to be effective, that requirements will vary for each specific type of electronic or digital disclosure, and that the technology for electronic or digital disclosure may change faster than AMS will be able to update its regulations. AMS is determining how to address these issues given the variety of electronic or digital disclosures currently available in the marketplace, along with the specifications for these disclosures to be used effectively in a retail setting.

Unilever Response:

With respect to ensuring that the electronic or digital disclosure can be easily and effectively scanned, the language in the statute is sufficient: “The electronic or digital link disclosure is of sufficient size to be easily and effectively scanned or read by a digital device.” This language provides flexibility while still ensuring the disclosure can be easily and effectively accessed. In addition, there are existing industry standards to ensuring the electronic or digital link is effectively scanned; i.e., specifications exist to drive effective and consistent use of bar and QR codes throughout the supply chain.

AMS should address the issue of ease and effectiveness via principles similar to those in Q14 (e.g., the carrier must be broadly read by consumer devices and consumers must easily identify that the carrier is to be scanned by their smart device).

Question 26. What types of records should AMS require to be maintained to establish compliance with the regulations? (Sec. 293(g)(2))

Context: Each person or entity subject to the mandatory disclosure requirement would be required to maintain and make available to the Secretary records that establish compliance with the Law. Typically, record keeping requirements include those for the records required to be kept, the place of maintenance of such records, the record retention period, and what it means for AMS to have adequate access to and inspection of such records.

Under current FSIS regulations, records must be maintained at a place where business is conducted, except that if business is conducted at multiple places of business, then records may be maintained at a headquarters office. When the business is not in operation, records should be kept in accordance with good commercial practices. For FSIS, records are required to be maintained for a 2-year period. The maintenance time for FDA records vary from 6 months through up to 2 years.

AMS is considering what recordkeeping requirements for persons subject to the Law would be most appropriate.

Unilever Response:

The recordkeeping requirements should be tailored to the definition of the term “bioengineered food.” For foods or ingredients derived from crops that are overwhelmingly produced using bioengineering in the country where they are grown, such as corn, canola, soy, and sugar beets grown in the U.S., AMS should apply a presumption that the ingredient is sourced from a bioengineered crop and is a bioengineered food, unless the manufacturer has documentation showing that that is not the case, such as documentation showing the ingredient is certified organic, its identity preserved or can be traced back to the original (non-bioengineered) crop. AMS should also establish recordkeeping provisions related to the threshold of a bioengineered substance established under section 293(b)(2)(B) of the Law and should make clear in the regulation that manufacturers are not required to disclose proprietary information such as recipes or formulations.

As required by the statutory language stating that the records that must be kept are limited to those that are “customary or reasonable in the food industry,” the recordkeeping provisions should not require manufacturers to keep additional records beyond those records customarily maintained.

AMS should recognize it is appropriate to store the required records off-site, such as at a central location or headquarters office, as long as the manufacturer provides the records within a reasonable period of time upon the request of AMS.

With regards to record retention period, AMS should consider that records be kept for two years after introduction or delivery for introduction of the food into interstate commerce. This would be consistent with the retention period that is required in the Food and Drug Administration’s nutrition labeling regulations for records supporting nutrient declarations (21 CFR 101.9(g)(11)) and the Bioterrorism Act (21 USC 350c(b)).

28. What are the rules of practice for a hearing? (Sec. 293(g)(3)(B))

Context: AMS is considering the appropriate procedures for audits and other compliance actions, including opportunities for hearing. AMS is considering this aspect for the rules of practice and other options regarding a prospective hearing and internal adjudication process.

Unilever Response:

It would be appropriate for AMS to follow the general hearing procedures outlined in 7 CFR Part 1, Subpart H, which apply to administrative hearings under the Organic Foods Production Act as well as other AMS-enforced laws and regulations as AMS has experience holding hearings under these procedures.

Question 29. How should AMS make public the summary of any examination, audit, or similar activity? (Sec. 293(g)(3)(C))

Context: AMS is considering if the results and findings of any examination, audit, or similar activity should be posted after the notice and opportunity for a hearing described under Sec. 293(g)(3)(B). AMS is also considering how it should make summaries of the examination, audit, or similar activity public.

Unilever Response:

Sec. 293(g)(3)(C) of the law requires that a summary of any examination, audit, or similar activity be made public after the notice and opportunity for hearing. AMS should use the same approach as for posting other labeling violations such as warning letters, or for posting information related to compliance with the National Organic Program. AMS should ensure that any trade secrets or confidential commercial information is redacted before posting the summary information, as required under Freedom of Information Act.

Question 30. What should the requirements for imports into the United States of products covered by the Law/regulation be? (Sec. 294(a))

Context: AMS considering how the disclosure requirements should be applied to imported products.

Unilever Response:

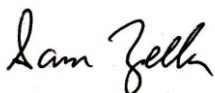
Imported products should be required to follow the same disclosure requirements as products manufactured in the United States. The disclosure requirements should be applied to both domestically produced and imported products in a nondiscriminatory way that is consistent with U.S. obligations under the World Trade Organizations and other international trade agreements.

In conclusion, Unilever strongly supports the establishment of a uniform national standard for the disclosure of bioengineered foods. We thank AMS for seeking stakeholder input as the agency works to implement the standard via rulemaking.

Sincerely,



Patrizia Barone, Ph.D.
Regional Regulatory Affairs Vice President,
Global Foods & Refreshment and North American Region



Samuel Zeller, Ph.D.
Head of Regional Regulatory Affairs