



The Procter & Gamble Company  
Mason Business Center  
8700 Mason-Montgomery Road  
Mason, Ohio 45040-9462  
[www.pg.com](http://www.pg.com)

July 17, 2017

[GMOLabeling@ams.usda.gov](mailto:GMOLabeling@ams.usda.gov)

**RE: National Bioengineered Food Disclosure Standard\_ Responses to USDA AMS Questions for Consideration**

Dear USDA Agricultural Marketing Service,

Procter & Gamble appreciates the opportunity to provide responses to 30 questions posed by the USDA Agricultural Marketing Service (AMS) at <https://www.ams.usda.gov/rules-regulations/gmo-questions> regarding Bioengineered Food Disclosure. Per the AMS's request, Procter & Gamble is providing comments on the specific questions outlined.

**Proposed Rule Questions Under Consideration**

***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.***

Procter & Gamble proposes that the terms "genetically modified" and "genetically engineered" should be considered as interchangeable with "bioengineering"/ "bioengineered" since they are consumer recognizable terms and are often used interchangeably by industry, federal agencies, international bodies, and other interested stakeholders. This is also consistent with FDA's perspective regarding interchangeable terms for bioengineering outlined in the November 2015 Guidance for Industry: Voluntary Labeling Indicating Whether Foods Have or Have Not Been Derived from Genetically Engineered Plants.

Procter & Gamble also proposes the term "GMO" should be considered as interchangeable with "bioengineering"/ "bioengineered". "GMO" is one of the most consumer recognizable and utilized terms that is used for a product/ingredient containing genetically engineered material. Even though food products do not contain entire genetically modified organisms (except yogurts that contain microorganisms), consumers, industry, and certification bodies (e.g. Non-GMO Project Verified) still utilize the term. In fact, the FDA has stated that "We do not intend to take enforcement action against a label using the acronym "GMO" in a statement indicating that the product (or an ingredient) was produced through the use of modern biotechnology, as long as the statement was true and the food's labeling is not otherwise false or misleading" (November 2015 Guidance for Industry: *Voluntary Labeling Indicating Whether Foods Have or Have Not Been Derived from Genetically Engineered Plants*).

***2. Which breeding techniques should AMS consider conventional breeding? (Sec. 291(1)(B))***



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**Context:** *AMS is considering what would be defined as modifications that could otherwise be obtained through conventional breeding because these modifications would be exempt from mandatory disclosure.*

Procter & Gamble does not have any comments for this question.

### **3. Which modifications should AMS consider to be found in nature? (Sec. 291(1)(B))**

**Context:** *AMS is considering what would be defined as modifications that could otherwise be found in nature because these modifications would be exempt from mandatory disclosure.*

**Fermentation:** Procter & Gamble proposes that fermentation should be considered as a modification/process found in nature. It is a metabolic process in which an organism naturally converts a carbohydrate, such as starch or a sugar, into an alcohol or an acid. For example, yeast performs fermentation to obtain energy by converting sugar into alcohol. Bacteria perform fermentation, converting carbohydrates into lactic acid. For example, vinegar is the result of fermentation in which bacteria consumes alcohol and produces acetic acid as a byproduct. This is a process that occurs naturally as a result of acetic acid bacteria that are prevalent in the environment. Thus, fermentation should be considered by the AMS as a naturally occurring process.

**Agrobacterium Modifications:** Procter & Gamble also proposes that *agrobacterium* modifications should be considered as being found in nature. Scientists at the International Potato Center in Lima, Peru have shown that *agrobacterium* modifications occur in nature without human intervention (published in the Proceedings of the National Academy of Sciences). *Agrobacterium* is a genus of gram-negative bacteria that has been shown to horizontally transfer segments of its genetic information into sweet potatoes. *Agrobacterium* is ubiquitous in soils all around the world, as demonstrated by the presence of these bacteria in 291 sweet potato varieties, including ones grown in the U.S., Indonesia, China, parts of South America, and Africa. Thus, *agrobacterium* modification is one example of genetic modification that occurs naturally in a commonly consumed crop.

Kyndt T, Quispe D, Zhai H, Jarret R, Ghislain M, Liu Q, Gheysen G, Kreuze J. 2015. The genome of cultivated sweet potatoes contains *Agrobacterium* T-DNAs with expressed genes: An example of a naturally transgenic food crop.

PNAS: [www.pnas.org/cgi/doi/10.1073/pnas.1419685112](http://www.pnas.org/cgi/doi/10.1073/pnas.1419685112)

### **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.*

Consistent with FDA's interpretation of the "bioengineering" definition outlined in the National Bioengineered Food Disclosure Standard Law, Procter & Gamble proposes that disclosure should not be required for highly refined products derived from bioengineered crops (e.g. oil from soy or canola, sugars)



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if there is no detectable genetic trace of the genetically modified crops they were derived from. Thus, the product would not “contain” genetic material that has been modified through in vitro recombinant deoxyribonucleic acid (DNA) techniques. Since the refining processes and analytical methodology are key to determining genetic traceability, Procter & Gamble proposes that AMS outline both the refining processes and analytical methods that can detect 0.1% of GMO material that should be utilized to validate that these products do not contain genetically modified material. The proposed 0.1% quantitation limit is consistent with other GMO standards globally:

- The COSMOS Standard provides the following requirements for GMOs:

**5.1.2 Genetically modified organisms (GMOs)**

*Primary raw materials or ingredients that are GMOs or derivatives of GMOs are forbidden.*

*Contamination of primary raw materials or ingredients with genetically modified material must not be above 0.9% for that primary raw material or ingredient, and may only be above the reliable detection limit of 0.1% if adventitious or technically unavoidable.*

<https://www.soilassociation.org/media/5236/cosmos-standards-october-2013.pdf>

- Regulation EC 619/2011 ([European Commission, 2011](#)) applies only to food/feed and provides details on the sampling and methods of detection for low level presence (LLP) of particular GMOs for which an authorization procedure is pending or the authorization of which has expired. This regulation introduced a minimum required performance limit (MRPL) of 0.1% (relative to mass) as “the lowest amount or concentration of analyte in a sample that has to be reliably detected and confirmed by official laboratories”.

Although some standards (e.g. Non-GMO Project Verified) require analytical methods to detect down to 0.01% GMO material, most laboratories set the limit of quantification ten-fold higher at 0.1% to avoid the problems with precision that occur near the limit of detection. Thus, Procter & Gamble proposes that setting a limit of quantification at 0.1% is a more reliable and practical quantification limit for industry to meet.

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.***

Procter & Gamble does not have any comments for this question.



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**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.

Procter & Gamble proposes that AMS should consider ingredient predominance for bioengineered disclosure (i.e. first and second predominant ingredients require disclosure) for all types of foods, not just for meat, poultry, and egg products. As such, Procter & Gamble proposes that predominance of ingredients should be determined by quantitative weight or volume (e.g. Ingredient X at 100 mg is the more predominant ingredient compared to ingredient Y at 2 mg). This is consistent with 21 CFR 101.4 Designation of Food Ingredients, 21 CFR 102.33 Beverages that contain fruit or vegetable juice, and the FDA Food Labeling Guide, whereby ingredients must be labeled in descending order by quantitative weight/ volume. This is also consistent with the flavor regulation 21 CFR 101.22 Foods; labeling of spices, flavorings, colorings and chemical preservatives, which addresses “characterizing” (i.e. predominance of) flavors.

**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.

Procter & Gamble agrees that regulatory language consistent with the wording in the National Bioengineered Food Disclosure Standard Law should be considered such as:

*A food derived from any animal, including invertebrates (crickets, bee products), should not be considered a bioengineered food solely because the animal consumed feed produced from, containing, or consisting of a bioengineered substance.*

This language would also be consistent with individual state GMO disclosure laws that were eventually preempted by the National Bioengineered Food Disclosure Standard Law (e.g. Vermont Consumer Protection Rule 121).

**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 bioengineered substance that may be present in food in order for the food to be a bioengineered food





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*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.*

Procter & Gamble proposes that a food should not be considered bioengineered if the total weight of the food that was genetically engineered is less than 0.9% of the total weight of the food (excluding water and salt). This is consistent with previous state GMO disclosure laws (e.g. An Act to Protect Maine Food Consumers' Right to Know about Genetically Engineered Food and Seed Stock, Chapter 565 Genetically Engineered Products; Vermont's Consumer Protection Rule 121) that were eventually preempted by the National Bioengineered Food Disclosure Standard Law. This is also consistent with global regulations (e.g. Regulation (EC) No 1829/2003).

**9. Should AMS consider more than one disclosure category? (Sec. 293(b)(2)(D))**

*Context: AMS is considering if it should develop various categories for disclosure and if it should differentiate between those products that a) are bioengineered, b) contain ingredients that are bioengineered, or c) contain ingredients derived from bioengineered crops or animals. Additionally, AMS is considering the creation of a set of disclosures for a category of bioengineered foods for those products that, due to changes in sourcing, include bioengineered ingredients for part of the year, and non-bioengineered ingredients for other parts of the year. AMS is considering the advantages and disadvantages, based on cost, clarity, and other factors, of using a single disclosure category or multiple disclosure categories.*

Procter & Gamble proposes that AMS should consider more than one disclosure category for the disclosures to be truthful and not misleading. Limiting the disclosure categories to 2 would minimize burden on industry and limit consumer confusion. Procter & Gamble proposes the following disclosure categories:

Disclosure Category	Disclosure	Example
1	Bioengineered Product	Corn (on the cob)
2	Product Contains [a] Bioengineered Ingredient[s]	Product contains strawberry flavor (strawberry is a genetically engineered ingredient)

**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*



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*requires disclosure based on the predominance of ingredients (Sec. 292(c), Question 6), among others. The outcomes of these determination requests might be publicly 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.*

Procter & Gamble proposes that it would be helpful to industry and consumers if AMS issued a guidance document that outlines the factors that should be considered when assessing whether a product/ingredient is genetically modified and subject to disclosure. Providing specific examples or case studies in the guidance document would be beneficial as well, as opposed to public disclosure of outcome requests.

Procter & Gamble also proposes that it would be helpful if AMS provided a 1-800 number for industry and consumers to ask questions regarding disclosure.

**11. Could AMS consider whether a type of food is considered a bioengineered food under the determination process? (Sec. 293(b)(2)(C))**

***Context: AMS is considering if AMS could exclude certain food types such as medical food and dietary supplements, among others from requiring disclosure as bioengineered.***

Procter & Gamble proposes that dietary supplements (and hence dietary ingredients) should be excluded from requiring disclosure as bioengineered foods for the following reasons:

- The National Bioengineered Food Disclosure Standard Law passed in 2016 defines “foods” as: “Section 291 Definitions (2) Food- The term “food” means a food (as defined in section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C 321) that is intended for human consumption.”
- Per the FD&C Act (21 U.S.C. 321), foods and dietary supplements are defined under different provisions. Foods are defined under 21 U.S.C. 321(f) as “(1) articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article”. Dietary supplements are separately defined and regulated under the Dietary Supplement and Education Act (21 U.S.C. 321(ff)). In fact, dietary supplements “cannot be represented for use as a conventional food or as a sole item of a meal or the diet (21 U.S.C. (ff)(2)(B))”.
- Dietary supplement labeling is regulated under the Dietary Supplement Health and Education Act, whereas conventional food labeling is not. Dietary supplements and foods are also regulated under different labeling regulations (21 CFR 101.36 and 101.8 respectively). For example, supplements are labeled with a Supplement Facts box and conventional foods are labeled with a Nutrition Facts box. Thus, it was/is the intent of Congress and the FDA/ USDA to regulate these products differently, particularly with respect to labeling.



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- Dietary supplements and conventional foods are regulated under different Good Manufacturing Practices (GMPs). Dietary supplements are regulated under 21 CFR 111, as set forth in the Dietary Supplement Health and Education Act, and foods are regulated under 21 CFR 117.
- Dietary supplements are exempt from certain aspects of the Food Safety Modernization Act (FSMA), while foods are not. For example, FSMA’s preventive controls rule, 21 CFR 117.5(e), exempts finished dietary supplements from the requirements for preventive controls and a supply-chain program if they are in compliance with 21 CFR 111, and with adverse event reporting.
- Although eventually preempted by the National Bioengineered Food Disclosure Standard Law, certain individual state GMO disclosure laws excluded dietary supplements from the scope of disclosure (e.g. Vermont Consumer Protection Rule 121).

Thus, Procter & Gamble proposes that dietary supplements should be excluded from requiring disclosure as bioengineered foods, since dietary supplements are not defined nor regulated as “foods”.

**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.*

Procter & Gamble proposes that standard bioengineered food disclosure text should be required in order to drive consistency across food products. Procter & Gamble also proposes different text categories so that the statements are truthful and not misleading to consumers. The following table outlines 2 disclosure category options for consideration:

Disclosure Category	Disclosure	Example
1	Bioengineered Product	Corn (on the cob)
2	Product Contains [a] Bioengineered Ingredient[s]	Product contains strawberry flavor (strawberry is a genetically engineered ingredient)

Procter & Gamble also proposes that the standard text disclosure language is placed on the Information Panel of the product label below other mandatory labeling text such that it is not considered intervening



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text. Consumers typically review the Nutrition Facts box, ingredients, and allergens to obtain key information regarding the product. Thus, it is reasonable that consumers would expect a bioengineered food text disclosure located in close proximity to other product ingredient information.

**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.***

Procter & Gamble proposes that if a symbol is utilized for bioengineered food disclosure, that it is placed on the Information Panel of the product label below other mandatory labeling text such that it is not considered intervening text. Consumers typically review the Nutrition Facts box, ingredients, and allergens to obtain key information regarding the product. Thus, it is reasonable that consumers would expect a bioengineered food disclosure located in close proximity to other product ingredient information.

Thus, Procter & Gamble proposes a green seal with text such as “USDA GE” or “USDA GE-I” in the center.

*GE = Genetically Engineered (for product); GEI = Genetically Engineered Ingredient(s)*

While Procter & Gamble acknowledges the 9/29/2016 AMS Policy Memorandum *Consistency between Bioengineered Disclosure and the National Organic Program*, Procter & Gamble recommends that this symbol is differentiated from other USDA symbols/seals (e.g. USDA Organic) in order to prevent consumer confusion. Procter & Gamble also proposes that the USDA/AMS provide public awareness materials for consumers so that they understand what the symbol looks like and means.

**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.***

Procter & Gamble proposes similar requirements for electronic or digital link disclosures as outlined in the 2013 FTC guideline [.com Disclosures How to Make Effective Disclosures in Digital Advertising](#). These include (but are not limited to):

- Electronic or digital link disclosures should be clear and conspicuous (i.e. obvious) and of sufficient size in order to be effectively scanned or read by a digital device.
- Electronic or digital link disclosures should be as close as possible to the ingredient information, as long as it does not qualify as intervening text.





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- Electronic or digital link disclosures should take consumers directly to the click-through information page.

**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.*

Procter & Gamble proposes that AMS should not specify a particular type of electronic or digital technology for disclosure of bioengineered food information in regulation, as current electronic or digital technologies will likely be obsolete in the future. Rather, AMS should issue guidance that outlines the permissible electronic or digital technologies for access to information about the bioengineered food. This will allow AMS to update electronic or digital technologies as they become obsolete over time.

**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.*

Procter & Gamble does not have any comments for this 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.*

- 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.*
- FDA also has allowances for packages that have less than 40 square inches of total surface area available to bear labeling.*

Procter & Gamble proposes that AMS should define small or very small packages such that they are consistent with the definitions outlined in the nutrition labeling regulations 21 CFR 101.9(j)(13).



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**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?**

Procter & Gamble agrees that the disclosure requirements for very small or small packages could be met by providing an address or phone number where consumers could obtain the information. Procter & Gamble proposes that if a phone number is utilized for consumers to obtain disclosure information, it should be the same phone number than what is utilized for consumer questions/complaints/adverse events and triaged to direct consumers to the disclosure option.

- 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?**

Procter & Gamble proposes that disclosure requirements for small packages could be met by providing an abbreviated text disclosure where consumers could obtain disclosure information. If abbreviated text disclosure is pursued, it would be beneficial if the specific text disclosure is outlined in regulation. Procter & Gamble proposes that if a seal is utilized with “USDA GE” or “USDA GE-I”, then abbreviated text may not be necessary. If abbreviated text is required, then AMS could consider “GE/GE-I Info” or “Access to GE/GE-I Info”.

Procter & Gamble proposes if a website address is utilized for consumers to obtain disclosure information, then the website link should navigate a consumer directly to the disclosure information (as opposed to a general product website).

**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).**



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

Procter & Gamble does not have any comments for this question, as Procter & Gamble does not qualify as a small food manufacturer per the definitions captured above and in the FSMA regulations.

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.*

Procter & Gamble does not have any comments for this question.

21. *The Law excludes restaurants and similar retail food establishments from disclosure requirements. How should AMS define similar retail food establishment to exclude these establishments from the requirements of the regulation? (Sec. 293(b)(2)(G)(i))*

*Context: AMS is considering how to treat establishments that sell food ready for human consumption, such as institutional food service, delicatessens, or catering businesses. In its regulations for Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments (21 CFR 101.11), FDA defines restaurant or similar retail food establishment and restaurant-type food*

*For FSIS, the FMIA provides for the mandatory inspection of commercial meat and meat products. The FMIA and implementing regulations do, however, provide exemptions from the continuous inspection provisions for retail operations and restaurants (9 CFR 303.1(d)(2)).*

*NOP also defines retail food establishment in its regulations (7 CFR 205.2).*

*AMS is using this information as it considers definitions for restaurants and similar retail establishments, with the understanding that these definitions will be used to determine what types of retail establishments are excluded from the requirements of the Law.*

Procter & Gamble does not have any comments for this question.

22. *How should AMS define very small food manufacturers to exclude these manufacturers from the requirements of the regulation? (Sec. 293(b)(2)(G)(ii))*

*Context: See Question 19. AMS could use definitions similar to how other Federal agencies define very small businesses, and is considering definitions to distinguish small food manufacturers (Question 19) and very small food manufacturers, with understanding that very small food manufacturers would be excluded from the requirements of the Law.*

Procter & Gamble does not have any comments for this question.



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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.*

Procter & Gamble proposes the following language accompanying the electronic or digital disclosure: “Access for More Food Information”. This language would be relevant for various types of electronic or digital disclosure options.

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.*

Procter & Gamble proposes that the bioengineered food/ ingredient information is located on the Information Panel of the product label. In order for the disclosure information to be conspicuous, Procter & Gamble proposes that the text size should be consistent with the Ingredients statement and Name and Place of Business text size (i.e. type size no smaller than 8 point or 1/16 inches minimum height).

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.*

Procter & Gamble proposes that AMS should outline the requirements and specifications for each specific type of electronic or digital disclosure in guidance. This will allow AMS to update this information accordingly as technologies become obsolete over time.

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*





The Procter & Gamble Company  
Mason Business Center  
8700 Mason-Montgomery Road  
Mason, Ohio 45040-9462  
[www.pg.com](http://www.pg.com)

***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.***

Procter & Gamble proposes the following types of records (including electronic records) should be maintained to verify compliance with the disclosure regulations:

- Manufacturing records to demonstrate the product was properly labeled when “distributed” for sale. “Distributed” means sold or transported to a retailer, whether or not the food is offered for retail sale immediately thereafter.
- Records demonstrating the quantitative weight/ volume of the ingredient in question as compared to the total weight/volume of the product (excluding water and salt).
- Records demonstrating certification or verification by an authorized third party (e.g. supplier) that the ingredient(s) in the product are not bioengineered or are not derived from bioengineered ingredients.

Procter & Gamble proposes that manufacturers shall retain records sufficient to demonstrate compliance with the disclosure regulations for a 2-year period from the date the manufacturer sells the food.

***27. How should AMS obtain information related to potential non-compliance with these regulations? Is there information USDA should request prior to conducting an examination of non-compliance? (Sec. 293(g))***

***Context: AMS is considering what tools could be used to identify potential non-compliance and enforce compliance with the regulations. AMS is considering the types of information needed to verify compliance with the Law and the most optimal way to obtain such information.***

Procter & Gamble does not have any comments for this question.

***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.***

Procter & Gamble proposes that the rules of practice for a hearing and an internal adjudication are consistent with the Administrative Procedure Act.



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**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.

Procter & Gamble proposes that AMS should post the results and findings of any examination, audit, or similar activity after the notice and opportunity for a hearing in a database that is publicly available.

This is consistent with FDA's current practices for reporting results and findings of manufacturing/packaging site audits (e.g. FDA Form 483).

**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.

Procter & Gamble proposes that finished products containing bioengineered ingredients that are imported into the US should be subject to the disclosure requirements set forth in the National Bioengineered Food Disclosure Standard Law, as they are sold directly to consumers (for which this disclosure law was enacted for). In contrast, bioengineered ingredients (i.e. raw materials) intended to eventually be utilized in finished food products that are imported into the US and intended to be sold in the US should not be subject to the disclosure requirements set forth in the National Bioengineered Food Disclosure Standard Law. This is because these ingredients/ raw materials are not sold directly to consumers.

Procter & Gamble thanks the AMS for the opportunity to respond to the questions related to bioengineered food disclosure.

Sincerely,

Maria Petrey, MS, RAPS

Regulatory Affairs Manager

The Procter & Gamble Company

(P) 1-513-622-3649

[petrey.me@pg.com](mailto:petrey.me@pg.com)