July 13, 2017

The Honorable Sonny Perdue
Secretary of Agriculture
U.S. Department of Agriculture
1400 Independence Ave., SW
Washington, DC 20250

Re: Responses to Proposed Rule Questions Under Consideration (Pub. L. 114-216)
https://www.ams.usda.gov/rules-regulations/gmo-questions

Dear Secretary Perdue,

Few issues have garnered the same level of public attention and support as the labeling of genetically engineered (GE) foods and foods derived from genetically modified organisms (GMOs). Polls consistently demonstrate that roughly 90 percent of Americans support the on-package disclosure of GE foods.[1] In response to this public support, three states – Connecticut, Maine and Vermont – passed mandatory disclosure laws and dozens of other states have considered mandatory disclosure laws over the years.

On July 29, 2016, Congress passed the National Bioengineered Food Disclosure Standard (Pub. L. 114-216) – a law amending the Agricultural Marketing Act of 1946 to require the Secretary of Agriculture establish a mandatory, national disclosure standard for GE foods. Under the law, food manufacturers will be required to disclose GMO foods using either on-package text, a USDA-regulated symbol or an electronic or digital link (e.g., QR code), pursuant to rules.

We thank the USDA Agricultural Marketing Service for allowing the public to provide input on the 30 questions under consideration for the proposed rule. Environmental Working Group has provided detailed responses to these questions under consideration below. Overall, we urge the Department to focus on these key areas:

Definition and scope – Consumers will expect the mandatory GMO disclosure standard to apply to all foods produced with or derived from genetic engineering, including foods which contain ingredients like highly refined sugars and oils, as well as foods produced with new forms of genetic engineering like CRISPR and RNAi. Consumers are not merely interested in whether GMO traits can be detected but how their food was produced, including what methods were used to genetically engineer the plants and animals used to produce food. In a July 1, 2016, letter, USDA General Counsel Jeffrey Prieto clarified that the law provides USDA with the legal authority to label foods produced with all methods of genetic engineering. The GMO disclosure standard should be consistent with international standards set by Codex Alimentarius, and should

[1] *See* Just Label It! Right to Know Center, http://www.justlabelit.org/right-to-know-center/polls-surveys/ (last visited July 11, 2017)

require that GMO disclosures be consistent with those of our international trading partners and provide ingredient-level information.

The regulation of electronic or digital disclosure methods – USDA should establish rules governing the use of electronic or digital disclosure methods, like QR codes, as well as the GMO disclosure itself. Companies that decide to use the electronic or digital disclosure method should be subject to strict rules to ensure that consumers can reliably scan products to access the GMO disclosure, and ensure that retailers provide comparable options for consumers who don't have smartphones or have unreliable cellular service.

Small business exemptions – In exempting very small food manufacturers from having to comply with the labeling requirements of Pub. L. 114-216, Congress intended to only exempt very small businesses such as "cottage food" businesses. In providing additional considerations for small food manufacturers, Congress intended to only include those small businesses that would need additional time to comply with the disclosure requirements or those companies that manufacture most of their food products on a limited or seasonal basis.

Avoid conflict with the organic standards – The use of "excluded methods," which includes the use of GMOs, is strictly prohibited in organic production and handling. As described in section 299 (f)(2) of Pub. L. 114-216 and further clarified through USDA's Policy Memorandum on "Consistency with the AMS National Organic Program," USDA should ensure that any proposed rules for bioengineered food disclosure will not require any modifications be made to the USDA organic regulations.

Implementation date – The law directs the USDA to establish the mandatory disclosure standard, and any requirements and procedures needed to carry out the standard, within two years. Many companies are already labeling their products that contain GMOs and USDA should meet the deadlines set in the statute.

Responses to Proposed Rule Questions Under Consideration

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

In deciding what terms AMS should consider interchangeable with "bioengineering," AMS should look at the legislative intent of the law, relevant state and federal policy, international labeling policies, and what terms would meet reasonable consumer expectations. AMS should consider the terms "genetic engineering," "genetic modification," and "biotechnology" as interchangeable with "bioengineering" because of their contemporaneous use in state and federal policy, as well as in international standards and guidelines developed by Codex Alimentarius.

Prior to passage of Pub. L. 114-216, three states – Connecticut, Maine and Vermont – passed mandatory disclosure laws for genetically engineered foods. Each of these laws used the term "genetic engineering" to describe the process of bioengineering referred to in Section 291(1). In addition to state laws, federal policy has long used the terms "genetic modification" and "genetic

engineering"[2] to describe this process, as do USDA's own regulations of plants produced using bioengineering.[3]

The standards and guidelines[4] adopted by Codex Alimentarius are recognized by the World Trade Organization as the authoritative standard for purposes of settling international trade disputes and therefore should be a guidepost for USDA. The following definition comes from the *Principles for Risk Analysis of Foods Derived from Modern Biotechnology* adopted by the Codex Alimentarius Commission in 2003.[5]

> **Modern biotechnology**:
>
> (i) in vitro nucleic acid techniques, including recombinant DNA and direct injection of nucleic acid into cells or organelles, or
> (ii) fusion of cells beyond the taxonomic family, that overcomes natural, physiological reproductive or recombination barriers, and that are not techniques used in traditional breeding and selection.

At its 39th session held in 2011, the Codex Committee on Food Labeling adopted labeling standards for genetically modified foods and specifically stated in draft language that:

> Different approaches regarding labelling of foods derived from modern biotechnology are used. Any approach implemented by Codex members should be consistent with already adopted Codex provisions. This document is not intended to suggest or imply that foods derived from modern biotechnology are necessarily different from other foods simply due to their method of production.[6]

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

In establishing the mandatory disclosure standard, USDA should broadly interpret the definition of "bioengineering" in Pub. L. 114-216 to ensure that a wide range of products, which include ingredients derived from bioengineering, are subject to the disclosure requirement. An impermissibly narrow interpretation would exclude a significant portion of the market from disclosure requirements, undermining clear legislative intent, contradicting USDA General

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[2] *See* Office of Science and Technology Policy, Executive Office of the President, *Coordinated Framework for Regulation of Biotechnology*, 51 FR 23302 (1986) https://www.aphis.usda.gov/brs/fedregister/coordinated_framework.pdf

[3] 7 CFR § 340.1

[4] *See* Food and Agriculture Organization of the United Nations, Codex Alimentarius, http://www.fao.org/fao-who-codexalimentarius/about-codex/en/ (last visited Oct. 28, 2016).

[5] Food and Agriculture Organization of the United Nations, Codex Alimentarius Commission. 2003. Principles for the Risk Analysis of Foods Derived from Modern Biotechnology (CAC/GL 44-2003). Available online at: www.fao.org/input/download/standards/10007/CXG_044e.pdf

[6] *See* World Health Organization, Food and Agriculture Organization, *Codex Alimentarius, Report of the Thirty Ninth Session of the Codex Committee on Food Labelling*, U.N. Doc. Rep. 11/FL (2011), http://www.fsis.usda.gov/wps/portal/fsis/topics/international-affairs/us-codex-alimentarius/recent-delegation-reports/delegate-report-39th-session-ccfl/ct_index

Counsel Jeffrey Prieto's legal interpretation, and contradicting the international standards developed by Codex.

In crafting the definition of "bioengineering" in Pub. L. 114-216, Congress provided authority to the Secretary to apply the definition broadly to include genetic engineering technologies other than rDNA, like CRISPR, gene editing or RNA interference (RNAi).

In a colloquy on July 12, 2016, Ranking Member of the Senate Agriculture Committee Senator Debbie Stabenow (D-Mich.) reiterated the broad authority of the USDA to include a wide range of ingredients, including highly refined and gene-edited ingredients, under this definition. She stated that "This bill gives USDA broad authority to determine . . . which foods will be subject to this bill's mandatory disclosure standard, including highly refined products derived from GMO crops and products developed using gene editing techniques."[7]

An impermissibly narrow interpretation would fail to account for potential future advances in biotechnology. That means if the industry shifts away from rDNA in the future, some ingredients initially subject to disclosure may become exempt in the future, even if they are still produced with genetic engineering. This could render the disclosure requirements developed under Pub. L. 114-216 obsolete and would once again leave consumers in the dark.

In her colloquy, Senator Stabenow also stated that "the bill gives USDA broad authority to periodically amend its labeling regulations to ensure that there are no new scientific biotechnology methods that may escape any overly prescriptive statutory definition of biotechnology."[8] USDA should establish a clear mechanism under the disclosure standard that requires the inclusion of new genetic engineering techniques, as they are developed, to ensure that companies and consumers understand the full scope of the disclosure standard.

USDA's own General Counsel Jeffrey M. Prieto in 2016 stated that it is well within USDA's authority under Pub. L. 114-216 to broadly interpret the definition of bioengineering. In a letter to Ranking Member Stabenow on July 1, 2016, Prieto wrote:

> Section 291(1) of the Senate bill provides authority to include food in the national disclosure program, including products of certain gene editing techniques. This would include novel gene editing techniques such as CRISPR when they are used to produce plants or seeds with traits that could not be created with conventional breeding techniques. In addition, the definition provides authority to include RNAi techniques that have been used on products such as the non-browning apple and potato.[9]

In addition to the clear legislative intent provided by the Congressional Record, other definitions of biotechnology promulgated by the federal government have included newer forms of genetic engineering. The definition of "biotechnology product" put forward in a 2015 memorandum

[7] *See* 162 Cong. Rec. S4994 (daily ed. July 12, 2016).
[8] 162 Cong. Rec. S4994 (daily ed., July 12, 2016)
[9] 162 Cong. Rec. S4994 (daily ed. July 12, 2016).

issued by the Executive Office of the President includes all of the newer technologies used in biotechnology, such as those of gene editing or gene silencing.[10] In addition, the USDA's National Organic Standards Board recently voted to include such forms of genetic engineering in the definition of biotechnology for purposes of the organic standard.

In addition, we point AMS to the definition of "modern biotechnology" adopted by the Codex Alimentarius Commission in 2003 (see response to Question 2), which covers all modern forms of genetic engineering, such as gene editing or gene silencing.

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

As we state in our response to Question 2, we encourage interpretation consistent with the clear Congressional intent that the scope of the disclosure requirement includes all GMO foods and ingredients produced with or derived from genetic engineering, including foods produced using new genetic engineering techniques. This interpretation is consistent with USDA General Counsel Prieto's legal analysis and the standards established by Codex Alimentarius.

We note that Merriam-Webster defines the term "nature" as "the physical world and everything in it (such as plants, animals, mountains, oceans, stars, etc.) that is not made by people."[11] Thus, none of the modifications produced through genetic engineering could be "found in nature," as the term is defined above. Since none of these modifications could be "found in nature," they must be a food produced through bioengineering for the purposes of this statute.

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))

In a colloquy on July 12, 2016, Ranking Member of the Senate Agriculture Committee Senator Debbie Stabenow (D-Mich.) reiterated the broad authority of the USDA to include a wide range of ingredients, including highly refined and gene-edited ingredients, under this definition. She stated that "This bill gives USDA broad authority to determine . . . which foods will be subject to this bill's mandatory disclosure standard, including highly refined products derived from GMO crops and products developed using gene editing techniques."[12] More specifically she clarified that "this bill does not prohibit the labeling of highly refined products derived from GMO crops including soybean oil made from GMO soybeans, high fructose corn syrup made from GMO corn, and sugar made from GMO sugar beets."[13]

In numerous press releases, postings on social media and public statements, Ranking Member Stabenow stated that Pub. L. 114-216 would require 25,000 more products be subject to a

[10] Memorandum for Heads of Food and Drug Administration, Environmental Protection Agency, and Department of Agriculture Regarding Modernizing the Regulatory System for Biotechnology Products, Executive Office of the President, July 2, 2015 (July 2015 EOP Memorandum) (online at: https://www.epa.gov/sites/production/files/2016-12/documents/modernizing_the_reg_system_for_biotech_products_memo_final.pdf).
[11] "Nature." Merriam-Webster.com. Accessed July 10, 2017. https://www.merriam-webster.com/dictionary/nature.
[12] *See* 162 Cong. Rec. S4994 (daily ed. July 12, 2016).
[13] *Id.*

mandatory disclosure requirement as compared to Vermont Act 120 and other state disclosure requirements.

In a July 7, 2016, statement made on the Senate floor, Ranking Member Stabenow said:

> [I]n Vermont and at the State level, meat, eggs, cheese, and dairy are exempt—totally exempt. So someone called it the Vermont meat loophole. So we said: You know what. That is not acceptable. So we added 25,000 more food products under this law that we would be voting on tonight. On this bill, 25,000 more food products will be labeled for people to know whether they are getting GMO ingredients. [14]

Nationwide, Mandatory GMO Labeling Bill is a Win for Families and Consumers

	Mandatory Labeling Bill	*DARK Act*
First National, mandatory GMO Labeling requirement.	✓	
25,000 More Food Products will be Labeled Compared to Vermont + other State Laws.	✓	
Protects and Strengthens Organic Label.	✓	
Preserves Critical State and Federal Consumer Laws.	✓	
Prevents a Patchwork of 50 state Labeling Laws.	✓	✓

[Image posted online by Office of Ranking Member Debbie Stabenow, U.S. Senate Committee on Agriculture, Nutrition and Forestry]

The clear intent of Congress was to require that more GMO food products be subject to the disclosure requirements of Pub. L. 114-216 than what was required under Vermont Act 120. To understand what effect the law would have on the number of products that are required to carry a GMO disclosure, EWG analyzed ingredient-level information for more than 148,000 food products housed in EWG's online database Food Scores. Based on this analysis, we believe that it would not be possible for 25,000 more products to be subject to mandatory GMO disclosure requirements unless USDA included highly refined GMO ingredients like sugar and oils in the scope of its mandatory disclosure standard.

In total, roughly 88,440 food products in the database contain at least one ingredient that is produced with genetic engineering. Out of that total, as many as 63,664 food products – or 70 percent – contain highly refined GMO ingredients like beet sugar or soybean oil. That means that

[14] 162 Cong. Rec. S4906 (daily ed. July 7, 2016).

if the Secretary implements the law using an overly narrow interpretation of the term "biotechnology" that excludes highly refined GMOs, well over twice the number of products could be excluded from the mandatory disclosure requirement than Congress intended to include.[15]

Further, the USDA's own General Counsel Jeffrey M. Prieto has stated that it is well within USDA's authority under Pub. L. 114-216 to broadly interpret the definition of bioengineering. In a letter to Ranking Member Stabenow on July 1, 2016, Prieto wrote:

> Section 291(1) of the Senate bill provides authority to include food in the national disclosure program, including products which may or may not contain highly refined oils, sugars, or high fructose corn syrup that have been produced or developed from genetic modification techniques. As a practical matter of implementation, the Department would look not only at the definition in Section 291(1) regarding the genetically modified crops used to produce the refined or extracted materials, but also consider authority provided under Section 293(b)(2)(B) and Section 293(b)(2)(C) with respect to the amount of a bioengineered substance present and other factors and considerations which might deem the product to be considered bioengineered food.[16]

Using the Codex standard as a guidepost, USDA should require that all food ingredients derived from genetic engineering be labeled, including foods which contain ingredients like highly refined sugars and oils, as well as foods produced with new forms of genetic engineering like CRISPR and RNAi. This scope would comport well with the standards established by many of our largest trading partners, including the member countries of the European Union, the United Kingdom, China and Brazil.

Based on our review of USDA FAS documents, at least 38 of the 64 countries identified as having mandatory labeling policies require that GMO oils and sugars be labeled, even if the transgenic material may not be detectable.[17] This includes the member countries of the European Union as well as Russia, China and Brazil. These countries also have established broad policies with regard to the type of genetic engineering technique used in the production of the specific GE product or ingredient.

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))

[15] Food Scores is available at www.ewg.org/foodscores
[16] 162 Cong. Rec. S4994 (daily ed. July 12, 2016).
[17] To assess the labeling policies of various countries, EWG reviewed materials prepared by Center for Food Safety (*supra* http://www.centerforfoodsafety.org/ge-map/), relevant international governmental reports and regulations, and reports *from USDA's* Global Agriculture Information Network, where applicable.

The definition of "biotechnology product" put forward in a 2015 memorandum issued by the Executive Office of the President includes all of the newer technologies used in biotechnology, such as those of gene editing or gene silencing.[18] Broadly interpreting the definition of bioengineering for purposes of the disclosure standard, as was the clear intent of Congress, would alleviate this confusion. Doing so would similarly alleviate any potentially trade distorting impacts of a disclosure standard that conflicts with Codex and our major trading partners.

USDA's revised regulations at 7 CFR § 340.1, regarding the importation, interstate movement, and environmental release of certain genetically engineered organisms could create the potential for confusion if APHIS, through its Biotechnology Regulatory Service program, determines that a certain GE plant or organism does not meet the definition of a regulated article under the regulations, but the GE plant or organism may still meet the disclosure requirements under Pub. L. 114-216.

BRS derives its authority to write regulations and regulate certain GMOs from provisions of the *Plant Protection Act*.[19] Under that authority, APHIS currently narrowly regulates certain GMOs if they may present a plant health risk either because it is found to be a plant pest or noxious weed. If a GE crop or GMO meets the definition of a regulated article, the producer must apply for authorization (permit or notification) before proceeding with import, interstate movement or release into the environment. If the GE crop or GMO does not meet the definition of a regulated article,[20] it may fall outside the regulatory purview of BRS and therefore potentially not require a regulatory determination before it enters interstate commerce or is released in the environment. In other cases, after going through a permit or notification process USDA may determine that a regulated GE crop or GMO does not pose more of a plant pest risk than an equivalent non-GE organism and is therefore considered deregulated for purposes of import, interstate movement or environmental release.

Unlike the clear Congressional intent of disclosure requirements of Pub. L. 114-216 to include all foods produced with or derived from genetic engineering, BRS does not currently regulate GE crops or GMOs based on the methods or processes by which GMO products are created, but rather the characteristics of the products (e.g., plant pest risk). AMS should clarify in its rulemaking that a disclosure determination for a GMO food or food ingredient derived from genetic engineering will be made separate from the regulatory status of the particular GE crop or

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[18] Memorandum for Heads of Food and Drug Administration, Environmental Protection Agency, and Department of Agriculture Regarding Modernizing the Regulatory System for Biotechnology Products, Executive Office of the President, July 2, 2015 (July 2015 EOP Memorandum) (online at: https://www.epa.gov/sites/production/files/2016-12/documents/modernizing_the_reg_system_for_biotech_products_memo_final.pdf).

[19] 7 U.S.C. 7701 et seq

[20] *See* Regulated article. Any organism which has been altered or produced through genetic engineering, if the donor organism, recipient organism, or vector or vector agent belongs to any genera or taxa designated in §340.2 and meets the definition of plant pest, or is an unclassified organism and/or an organism whose classification is unknown, or any product which contains such an organism, or any other organism or product altered or produced through genetic engineering which the Administrator, determines is a plant pest or has reason to believe is a plant pest. Excluded are recipient microorganisms which are not plant pests and which have resulted from the addition of genetic material from a donor organism where the material is well characterized and contains only non-coding regulatory regions. [7 CFR § 340.1]

GMO, and whether or not that GMO plant or organisms falls under the regulatory purview of the APHIS part 340 rules.

Finally, it is critical that the language addressing consistency with certain laws, found in section 299 (f)(2), is clearly interpreted and translated through rulemaking in such a way that will protect the definitions and practices that are currently established under the NOP organic regulations and any USDA NOP rulemaking or guidance in process.

Section 299 (f)(2) of Pub. L. 114-216 states:

> "the Secretary shall consider establishing consistency between the national bioengineered food disclosure standard established under this section and the Organic Foods Production Act of 1990 (7 U.S.C. 6501 et seq.) and any rules or regulations implementing that Act."

This provision should not require revisions to organic regulations in order to bring consistency with the standards established under Pub. L. 114-216. As clarified through USDA's Policy Memorandum on "Consistency with the AMS National Organic Program," this is not the intent of this provision and should not be interpreted as such.

The AMS policy was written to ensure that any new proposed regulations or specifications of Pub. L. 114-216 complies with its policy. Central to avoiding conflict and protecting the organic standards, the policy states:

> When proposing standards for national bioengineered food disclosure program, AMS' policy will be as follows:
> - No certified organic products will require disclosure as bioengineered; and
> - No proposed rules for bioengineered food disclosure will require that modifications be made to the USDA organic regulations.

The definition and prohibition on excluded methods is well established in the regulations of NOP. In order to avoid extensive disruption and economic hardship within the organic industry, it is critical that USDA ensures that the rules for mandatory GMO food disclosure will not require any modifications be made to the USDA organic regulations.

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))

For determining the predominance of ingredients, AMS should follow FDA's regulations for food labeling, which directs food manufacturers to label ingredients in descending order of predominance by weight, meaning that the ingredient that weighs the most is listed first, and the ingredient that weighs the least is listed last.[21]

[21] 21 CFR 101.4(a)

While Pub. L. 114-216 excludes foods if the most predominant ingredient in the food is meat, eggs or poultry, or the second most predominant ingredient in the food is meat, eggs or poultry in a case where the most predominant ingredient in the food is broth, stock or water, the intent of the law was not to exempt animals, and any products derived from such animals, that have been genetically engineered themselves. It is critical that AMS include this distinction in its proposed rule. We believe AMS should base its regulatory distinction on FDA's draft revised Guidance for Industry (GFI) #187, "Regulation of Intentionally Altered Genomic DNA in Animals."[22]

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))

Based on EWG's assessment of the 64 countries that currently require the disclosure of GMO foods, no country requires disclosure for such food products solely because the products were derived from animals which were fed GE feed.

We refer AMS to the following European Commission language, specifically exempting animal products from mandatory GMO labeling requirements:

> Thus, products obtained from animals fed with genetically modified feed or treated with genetically modified medicinal products will be subject neither to the authorisation requirements nor to the labelling requirements referred to in this Regulation.[23]

As noted in our response to Question 7, the intent of the law was not to exempt animals, and any products derived from such animals, that have been genetically engineered themselves. It is critical that AMS include this distinction in its proposed rule. We believe AMS should base its regulatory distinction on FDA's draft revised Guidance for Industry (GFI) #187, "Regulation of Intentionally Altered Genomic DNA in Animals."[24]

Additionally, AMS should make clear that just because a food – such as food derived from animals consuming GMO feed – may not be considered "non-GMO" solely because the food is not required to bear a GMO disclosure, as stated in Section 294 (c) of Pub. L. 114-216.

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[22] *See*, Draft Revised Guidance for Industry #187, "Regulation of Intentionally Altered Genomic DNA in Animals." Available at: https://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/ucm113903.pdf

[23] *See Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed (2003*), https://www.food.gov.uk/sites/default/files/multimedia/pdfs/gmguidancent.pdf

[24] *See*, Draft Revised Guidance for Industry #187, "Regulation of Intentionally Altered Genomic DNA in Animals." Available at: https://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/ucm113903.pdf

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))

An important consideration for maintaining consistency with international standards and trading partners is the establishment of a consistent threshold – the amount of GE content above which triggers the mandatory disclosure requirement. We urge AMS to adopt the most common international standard and current industry standard for mandatory disclosure, which is 0.9 percent by individual GE ingredient. The European Commission standard has a lower, 0.5 percent threshold, which applies to unapproved GMO traits that have received a "favourable safety assessment" from an EC scientific committee.[25] Over half of the 64 countries that require GMO labeling have a GMO threshold level of at minimum 0.9 percent.[26] This threshold is also consistent with the Non-GMO Project standard, the leading voluntary GE-free certification standard in the U.S.[27]

However, as we have noted earlier, the ability to detect the presence of GE content alone should not serve as the basis for the GMO disclosure. The use of genetic engineering methods to produce a desired trait should also serve as the basis for the disclosure when the it is difficult to detect the GE material in the finished product. As we have noted, consumers are not merely interested in the presence of GMOs but are also interested in the processes by which GMO traits are produced.

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

We believe that AMS should establish in its proposed rule a requirement that GMO disclosures, made via text disclosure option or on the product information page via the electronic or digital disclosure option, be a presence or derived from claim, not a "may contain" claim, and provide ingredient-level information.

As AMS considers whether or not to establish more than one disclosure category for GMO foods, it may choose to align its proposed rule with Article 13 of the (EC) Regulation No 1829/2003 on genetically modified food and feed referenced in our response to Question 8, which describes the specific food labeling requirements of the EC disclosure standard.[28]

The specific requirements of Article 13 of the (EC) Regulation No 1829/2003 are:

- Where a food contains more than one ingredient, the following indication must be given: "genetically modified" or "produced from genetically modified [name of ingredient]";
- Where a food is designated by the name of a category e.g., "Emulsifiers," the following must appear in the list of ingredients: "contains genetically modified (name of organism)" or "contains (name of ingredient) produced from (name of organism)";

[25] *See supra note 23.*
[26] *See supra* note 17 for methodology.
[27] *See* The Non-GMO Project, The Standard, http://www.nongmoproject.org/product-verification/the-standard/ (last visited Oct. 31, 2016).
[28] *See supra* note 34.

- If there is normally no list of ingredients given on a specific product the following must appear clearly on the labelling: "produced from genetically modified (name of organism)."

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

We support the development of a process to help stakeholders determine whether a food is subject to disclosure. Such a process should include a rubric to help stakeholders, food manufacturers and the public understand how disclosure requirements are triggered, as well as a publically available and searchable online database that includes the full list of determinations, with information provided as to the reason(s) for why a food product does or does not meet the disclosure requirement under the standard. In addition, as we stated in our response to Question 2, we believe USDA should establish a clear mechanism under the disclosure standard that requires the inclusion of new genetic engineering techniques, as they are developed, to ensure that companies and consumers understand the full scope of the disclosure standard.

USDA should also establish a clear mechanism under the disclosure standard that requires the inclusion of new genetic engineering techniques, as they are developed, to ensure that companies and consumers understand the full scope of the disclosure standard.

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

The authorities provided to AMS under Pub. L. 114-216 do not allow AMS to exclude a type of food as genetically engineered under the determination process, only whether or not such foods meet the disclosure requirements of the standard. This means that just because a type of food – such as a medical food or dietary supplement – does not fall under the disclosure requirements of the proposed rule or meet the applicability requirements established in Section 292, the food or type of food could very well still be genetically engineered or produced with genetic engineering.

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))

Consumers are not merely interested in whether or not GMO traits can be detected, but whether or not certain food ingredients are genetically engineered or derived from genetic engineering. Any text disclosure must sufficiently meet consumer expectation and accurately convey to a consumer that the food is genetically engineered, was derived from genetic engineering or contains certain genetically engineered ingredients. We believe that AMS should establish in its proposed rule a requirement that GMO disclosures be a "presence" or "derived from" claim, not a "may contain" claim, and provide ingredient-level 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))

Any symbol disclosure must sufficiently meet consumer expectation and accurately convey to a consumer that the food product is genetically engineered, was produced with genetic engineering or contains certain genetically engineered ingredients. Consumers readily recognize the acronym "GMO" as synonymous with genetic engineering or bioengineering. We recommend that AMS incorporate the term GMO into the symbol design.

AMS should develop criteria for placement such that the symbol is placed near other required disclosures, is prominently sized, and is formatted in a manner that is easily recognizable and seen by a consumer. AMS should consider consumer focus groups as a means of better understanding what symbols could be easily recognized by consumers.

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))

The use of electronic disclosures, like Quick Response (QR) codes, present a number of technological, regulatory and access-related challenges that may impede the ability of a consumer to access a GE disclosure. As USDA is aware, many Americans do not have smartphones to scan electronic disclosures, and many more could potentially suffer from technical or connectivity challenges in retail stores.[29] In addition, without proper regulation and oversight, the use of electronic or digital disclosures could exacerbate consumer confusion or fail to provide consumers with meaningful information about the use of genetic engineering in food products. The proposed rule will need to address these challenges by establishing strong regulations that govern the use of electronic or digital disclosures, and in particular the use of QR codes which currently appear to be the preferred method of electronic or digital disclosure.

> *USDA should establish rules governing disclosures made using electronic or digital methods.*

In addition to ensuring the performance and reliability of an electronic or digital link (see response to Question 25), USDA must take steps to protect consumer privacy, prevent further consumer confusion and ensure that consumers are able to easily access the GMO disclosure information when establishing the mandatory GMO disclosure standard. To address these concerns, the proposed rule should include the following:

1. **A strict prohibition on the use of multiple QR codes on a package.** If a company or food manufacturer opts to disclose the presence of GMOs or ingredients derived from genetic engineering using the electronic or digital disclosure method, there should be a

[29] *See* Jacob Poushter, *Smartphone Ownership and Internet Usage Continues to Climb in Emerging Economies*, Pew Research Center (Feb. 22, 2016), http://www.pewglobal.org/2016/02/22/smartphone-ownership-and-internet-usage-continues-to-climb-in-emerging-economies/.

strict prohibition on the use of additional QR codes on the package that could be used for marketing or promotional purposes because that would be misleading to a consumer.

This is consistent with FDA's existing guidance on labeling. FDA regulations require disclosure statements when a nutrient content claim (NCC) is made and the food contains nutrients that exceed recommended levels.[30] However, to conserve package space and limit consumer confusion, when multiple claims are made on a package, only one disclosure is required.[31] QR codes are likely to take up much more space than a NCC disclosure statement and multiple codes may be confusing to consumers. By limiting the use of multiple QR codes, the USDA regulations will be consistent with other FDA labeling guidance and will limit consumer confusion.

2. **The electronic GMO disclosure must be prominent, as well as omit any marketing and promotional materials.** Sec. 293 of the law clearly states:

> the electronic or digital link will provide access to the bioengineering disclosure located, in a consistent 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.

Therefore, USDA must set strict rules that require that the GMO disclosure be the first thing a consumer sees on the product information page after scanning a digital disclosure using their smartphone, tablet or any other type of electronic scanner. The disclosure should be prominent on that product information page and it should be consistent across all product types. The product information page must omit any marketing or promotional information, and any such information must also be omitted from any clearinghouse information pages.

3. **The GMO disclosure should be a presence disclosure and provide ingredient-level information.** USDA should require that the disclosure on the product information page be a presence or derived from statement, not a may contain claim. The clear majority of the 64 countries that require the mandatory disclosure of GMO foods do not allow the use of a may contain statement to meet their disclosure requirements.[32] The presence or derived from disclosure should denote the specific ingredients that were produced with biotechnology just as required in many countries around the world, including all the EU member countries, Australia and New Zealand.

4. **The product information page must be a mobile enabled or optimized landing page so that consumers using their smartphones to access the GMO disclosure are able to**

[30] 21 C.F.R. § 101.13(h)(1). *See also* U.S. Food & Drug Admin., *Labeling & Nutrition: Guidance for Industry: A Food Labeling Guide (8. Claims)* (2013), http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/LabelingNutrition/ucm064908.htm.
[31] 21 C.F.R. § 101.13(h)(4)(iii).
[32] *See supra* note 18.

view it in real time.

5. **USDA must ensure that the text and toll-free phone number are prominently displayed near the electronic or digital disclosure on a food package.** The law clearly directs USDA to require that any electronic or digital link must be accompanied by text stating "Scan for more food information" as well as a toll-free phone number. This statement and corresponding phone number should be located in a consistent and conspicuous manner. When consumers call that number, they should be able to get the same presence or derived from claim about the product, including ingredient-level information, that could be found on the product information page if they scanned the code.

6. **USDA should require that companies using an electronic or digital disclosure method have a privacy policy in place and prominently displayed on the product information page to ensure consumer privacy is protected.** The law clearly prohibits the electronic link or digital link disclosure from collecting, analyzing, or selling any personally identifiable information about consumers or the devices of consumers. The law further clarified that if any such information must be collected to carry out the purposes of the disclosure, that the information be deleted immediately and not used for any other purpose. If a company chooses to disclose the presence of GMO ingredients or ingredients derived from genetic engineering through an electronic or digital link, it must have a privacy policy in place, ensure its privacy policy is prominently displayed on the product information page and participate in regular audits enforced by USDA.

See response to Question 25 for more information regarding performance standards and requirements for QR code design.

Additional and comparable options for consumers who don't own smartphones

Sec. 293 directs the Secretary to provide additional and comparable options so that consumers who don't have smartphones or who live in parts of the country without reliable cellular service can access the GMO disclosure, if the Secretary determines that such consumers will not have sufficient access to the GMO disclosure through electronic or digital methods.

While the specific "additional and comparable" options will likely be based on the findings of the study on electronic or digital disclosure methods, USDA should ensure that any comparable options be just as convenient as it is for someone to take out their phone and scan a product. For instance, USDA may want to consider requiring that retailers make Wi-Fi internet available to customers if reliable cellular service in their stores is a problem. Another way this condition could be met would be a requirement that retailers place scanners in grocery store aisles. A survey of 2D barcode image scanners on the website www.amazon.com found that scanners could be purchased for as little as $39.99.

This would not be the first time that a government has required that retailers place scanners in stores. State and local governments have required in-store scanners to provide pricing information to consumers. The Massachusetts Grocery Pricing Law (G.L. c. 94, §§184B-184E)

requires food stores and retailers with food departments to either individually place a price tag on all food and grocery items or provide electronic scanners in stores for consumer use to find a product's price.[33] Suffolk County, N.Y. has a similar law.[34]

USDA could tailor such a requirement to make an exception for any retailer that elects to make it a requirement that any product sold in their store that would be subject to the GMO disclosure requirement under the law use either the text or symbol disclosure options.

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))

As AMS recognizes, a QR code is not the only 2D code that companies could use to meet the electronic or digital disclosure requirements of the law. Other coding systems like SnapTag®, Data Matrix, MaxiCode and Aztec Code may be appropriate, however each may also present unique technological challenges or hurdles that could jeopardize the ability of a consumer to access a GMO disclosure.[35] In addition to 2D codes, manufacturers could conceivably use radio-frequency identification (RFID) data chips to meet the electronic or digital disclosure requirements if smartphones could reliably scan such data.

Therefore, USDA must ensure that the regulations of electronic or digital disclosures apply to all types of disclosures and are updated on a regular basis in keeping with changes in disclosure technology, and to reflect changes in consumer technology to ensure that consumers are provided the information they deserve in an easy-to-use manner. AMS should prohibit or place limitations on the use of certain types of electronic or digital disclosures if they would unreliably or fail to adequately provide consumers with bioengineering disclosures.

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))

AMS should require that any GMO food that would not normally be purchased from a grocery store shelf, such as food for sale in bulk or fresh seafood at a fish counter, be accompanied by text disclosure, similar to FDA's regulations for nutrition labeling.

FDA exempts the following foods from compliance with the requirements of section 403(i)(2) of the act 403(i)(2) of the FFDCA based on certain conditions.[36]

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[33] Mass. Gen. Laws ch. 94, § 184E (2014).
[34] Suffolk County Local Law, 37-2008, ch. 542, § 1-19.
[35] *See* Tec-IT, Overview 2D Barcode Symbologies, http://www.tec-it.com/en/support/knowbase/barcode-overview/2d-barcodes/Default.aspx (last visited Oct. 31, 2016).
[36] 21 CFR 101.1(a)(2)

(2) A food having been received in bulk containers at a retail establishment, if displayed to the purchaser with either:

(i) The labeling of the bulk container plainly in view, provided ingredient information appears prominently and conspicuously in lettering of not less than one-fourth of an inch in height; or

(ii) A counter card, sign, or other appropriate device bearing prominently and conspicuously, but in no case with lettering of less than one-fourth of an inch in height, the information required to be stated on the label pursuant to section 403(i)(2) of the Federal Food, Drug, and Cosmetic Act (the act).

In addition, as stated in our response to Question 15, AMS should prohibit or place certain requirements or limitations on the use of certain types of electronic or digital disclosures, such as QR codes, if they would unreliably or fail to adequately provide consumers with bioengineered disclosures. For instance, AMS should consider requiring that any GMO food sold online using an electronic or digital disclosure also include a direct Internet website Uniform Resource Locators that would direct the consumer to the electronic or digital disclosure, with care given to ensuring that the consumer privacy provisions of Pub. L. 114-216 are enforced.

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

Small and very small packages – and small display panels – are well defined in FDA and USDA rules. In particular, FDA rules permit the creation an "acceptable alternative"[37] for disclosure when the display panel is too small to accommodate the required disclosure. USDA rules also create an exemption for packages with small display panels, but require companies to include telephone numbers for additional information. When display panels are too small to accommodate the required GMO disclosure, we propose the use of the symbol in combination with a toll-free number that permits the consumers to get more information.

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

Pub. L. 144-216 creates certain allowances for small food manufacturers to help them more easily comply with the law. This is separate from the exemption for very small food manufactures from the disclosure requirements.

Under section 293, small food manufacturers have an extra year to implement disclosure requirements and are also given additional on-package disclosure options like telephone numbers and Internet websites. However, the bill does not define what qualifies as a small food manufacturer or very small food manufacturer.

[37] 21 C.F.R. § 101.2

UDSA should follow precedent set by existing relevant FDA definitions. AMS could utilize the definition of "very small business", promulgated by FDA under the Food Safety Modernization Act (FSMA) preventative controls rule, which it defines as "a business (including any subsidiaries and affiliates) averaging less than $1,000,000, adjusted for inflation, per year, during the 3-year period preceding the applicable calendar year in sales of human food plus the market value of human food manufactured, processed, packed, or held without sale (e.g., held for a fee)."[38]

Compliance with the disclosure requirements under Pub. L. 144-216, particularly if a business elects to make an on-package disclosure, will likely be much less onerous than the requirements under the preventative controls rule or rules for animal feeds and mitigating food adulteration. By FDA's estimates in 2014, businesses with less than $1,000,000 annual sales produce less than two percent of all food produced in the United States.[39]

For farms, small businesses are defined in FSMA regulations as farms with an average annual monetary value of produce sold during the previous three-year period of no more than $500,000. For farms that are very small businesses, the limit is $250,000.[40]

AMS may want to look to FDA's regulations for nutrition labeling, where it exempts small food manufacturers as defined as companies that sell directly to consumers, such as retailers, that average less than $500,000 in gross annual sales.[41] However, this definition may be more appropriate for AMS to consider as it is considering how to exempt very small food manufacturers and cottage food businesses.

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))

AMS should consider whether or not small food manufacturers would be at an economic disadvantage if they were required to provide ingredient-level disclosures for GMO foods. If AMS feels that small food manufacturers would be hindered by this level of disclosure, either because of seasonal changes in production or paperwork requirements, it should require those companies use the following disclosure based on one of the disclosure options allowed under Vermont's mandatory GMO labeling law: "May Be Produced with Genetic Engineering. Call 1-800-XXX-XXXX for additional information."

[38] 21 C.F.R. § 117.3
[39] *See* Food & Drug Admin., Food Safety Modernization Act Preliminary Regulatory Impact Analysis, http://www.fda.gov/downloads/Food/GuidanceRegulation/FSMA/UCM334117.pdf (last accessed Nov. 1, 2016).
[40] 21 C.FR. § 112.3
[41] 21 CFR § 101.9(j)(1)

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))

AMS should define restaurants and similar retail food establishments in the same manner that FDA defines similar retail food establishments in its regulations for Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments:[42]

> Restaurant or similar retail food establishment means a retail establishment that offers for sale restaurant-type food, except if it is a school as defined by 7 CFR 210.2 or 220.2. Restaurant-type food means food that is:
>
> (i) Usually eaten on the premises, while walking away, or soon after arriving at another location; and
>
> (ii) Either:
>
> (A) Served in restaurants or other establishments in which food is served for immediate human consumption or which is sold for sale or use in such establishments; or
>
> (B) Processed and prepared primarily in a retail establishment, ready for human consumption, of the type described in paragraph (ii)(A) of this definition, and offered for sale to consumers but not for immediate human consumption in such establishment and which is not offered for sale outside such establishment.

Where possible, AMS should also incorporate the National Organic Program's definition of "retail food establishment":[43]

> A restaurant; delicatessen; bakery; grocery store; or any retail outlet with an in-store restaurant, delicatessen, bakery, salad bar, or other eat-in or carry-out service of processed or prepared raw and ready-to-eat-food.

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))

In exempting very small food manufacturers from having to comply with the labeling requirements of Pub. L. 114-216, Congress intended to only exempt "cottage foods" and very small food manufacturers. In order to differentiate the exemption for very small food manufacturers from the additional time requirements for small food manufacturers (see Question 19), AMS should utilize FDA's regulations for small businesses that sell directly to consumers for how it should define very small food manufacturers to exclude these manufacturers from the requirements of the regulation. FDA's nutrition labeling regulations include specific language exempting or providing special considerations for small businesses that sell directly to consumers, such as retailers, which FDA defines as a business that has annual gross sales made or business done in sales to consumers that is not more than $500,000, or has annual gross sales

[42] 21 CFR 101.11
[43] 7 CFR 205.2

made or business done in sales of food to consumers of not more than $50,000.[44] Such an exemption would meet the clear intent of Congress to exempt "cottage foods" while not creating an overly broad exemption.

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))

To satisfy the intent of the statute, AMS should use language that alerts the consumers than scanning the QR code would provide GMO information, not merely more food information, such as "Scan for GMO Information." To reduce consumer confusion, however, AMS should use consistent on-package language to accompany an electronic or digital disclosure.

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))

Sec. 293 of the law clearly states:

> the electronic or digital link will provide access to the bioengineering disclosure located, in a consistent 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.

USDA should establish through regulations a requirement that the GMO disclosure be the first thing a consumer sees on the product information page after scanning an electronic or digital disclosure using their smartphone, tablet or any other type of electronic scanner. The disclosure should be prominent on the product information page and it should be consistent across all product types. The product information page must omit any marketing or promotional information, and any such information must also be omitted from any clearinghouse information pages.

With regard to the specific GMO disclosure that appears on the product information page, we believe that AMS should establish in its proposed rule a requirement that GMO disclosures made on the product information page via the electronic or digital disclosure option be a presence or derived from claim, not a may contain claim, and provide ingredient-level information. The clear majority of the 64 countries that require the mandatory disclosure of GMO foods do not allow the use of a may contain statement to meet their disclosure requirements.[45] The presence or derived from claim should denote the specific ingredients that were produced with biotechnology, just as required by many countries around the world, including all the EU member countries, Australia and New Zealand.

[44] 21 C.FR. § 101.9(j)(1)
[45] *See supra* note 17.

See responses to Question 9 and Question 12 for more information.

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))

USDA will need to establish rules governing QR code design and performance

A QR code is a type of two-dimensional electronic barcode that can be scanned using a smartphone or electronic scanning device. Traditional barcodes use a single linear dimension to code for simple information, like price or a product's identification number, using varying widths of vertical lines and spaces. The more complicated the data one wishes to code for, the longer the barcode needs to be. By comparison, a QR code uses varying widths, lengths and shapes on both vertical and horizontal dimensions to code for information, thereby allowing companies to embed more complicated data like a URL or web link into the code. This level of complexity can streamline the communication of information by allowing a consumer to connect directly to a web link or URL; however, it also presents a number of challenges that can negatively impact performance and thereby jeopardize the effectiveness of QR codes as a means of disclosure for purposes of the law.[46]

Size

The first challenge in designing an effective QR code is size. The size of a QR code is important for two reasons: camera focus and lighting. The smaller the QR code, the more difficult it is for a smartphone or electronic scanner to read the detail of the code. While newer smartphones may have cameras that allow them to scan smaller QR codes, older models may lag quite significantly in their ability to scan QR codes of a certain size. Lighting can also negatively impact performance. Under ideal conditions, a smartphone may be able to read a QR code that is smaller than industry standard, but under low light conditions, in which smartphones typically struggle, it may not be able to do so.[47]

According to analysis by the company TapWalk, QR codes are most effective for scanning between 1.5-2.5 inches in size.[48] Between 1-1.5 inches, QR codes were difficult to scan in low lighting scenarios which can be quite common in grocery store aisles. QR codes below 0.75 inches in size resulted in a number of smartphones not being able to scan products in low light. The company qrd°by asserts that companies should abide by a 10:1 ratio of QR code size to scanning distance, meaning that if you are scanning a product that is 10 inches away, the QR code should be 1 square inch in size.[49] The company Customer Rush states that a QR code that is

[46] *See* Electronic Imaging Materials, Inc., 2D Barcodes, http://barcode-labels.com/technical-support/barcode-white-papers/2d-barcodes/ (last visited Oct. 31, 2016).
[47] *See* Simon Crisp, *Why Aperture Matters on Your Smartphone Camera*, New Atlas, (March 31, 2016), http://newatlas.com/smartphone-camera-aperture/42524/.
[48] *See* TapWalk, Minimum Practical Size of a QR Code, http://tapwalk.com/minimum-practical-size-of-a-qr-code/ (last updated Sept. 24, 2016).
[49] *See* Peter Hlavac, *Minimum Size of a QR Code*, QRD (July 15, 2014), https://blog.qrd.by/2014/07/15/minimum-size-qr-code/.

1.25 square inches is the minimum size to guarantee that all smartphones are able to successfully scan the code.[50]

Sec. 293 clearly directs the Secretary to require that the "electronic or digital link disclosure is of sufficient size to be easily and effectively scanned or read by a digital device." To ensure that all QR codes used on packages to fulfill the mandatory disclosure requirement are large enough to consistently be scanned by all types of electronic disclosure readers, including smartphones, handheld scanners and mounted retail scanners, USDA should establish a minimum 1.25 square inch size requirement for QR codes.

Formatting the QR code image

The second type of challenge in designing an effective QR code has to do with formatting and the design itself. The type of digital format that is used to render the design in quite important. Depending on the format of a QR code design, the image could become blurry or distorted if the size is expanded or decreased beyond the original size design. For example, if the same food product is produced at differing sizes, changes in the product packaging could result in a QR code that cannot be consistently scanned or scanned at all. Experts suggest using vector format.[51]

Color, contrast and "quiet zone"

In addition to the formatting of the QR code, USDA will need to establish rules pertaining to the design of the QR code itself to ensure reliable performance. For guidance, USDA should look to standard setting bodies like ISO/IEC[52] and GS1.[53] Specific consideration should be given to the colors and contrast of the code. A recent white paper found that QR codes performed best when they were designed with dark codes on light backgrounds and when there was a high level of contrast between the code and the background.[54]

In addition to color and contrast, QR codes require a "quiet zone" to serve as a buffer around all four sides of the code itself, where no information (i.e., text, symbols or extraneous design) could be captured or interpreted by a smartphone camera or electronic scanner that might otherwise interfere with their ability to consistently scan a QR code. The quiet zone requirements are in addition to the size requirements of the QR code because they are intended to prevent

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[50] *See* CK Wilde, *3 Mistakes That Make Your QR Codes Worthless*, Customer Rush (Aug. 21, 2014), https://blog.qrd.by/2014/07/15/minimum-size-qr-code/.

[51] *See* Peter Hlavac, *Tips for QR Code Printing*, QRD (Feb. 15, 2016), https://blog.qrd.by/2016/02/15/tips-for-qr-code-printing/.

[52] *See* International Organization for Standardization[ISO], *International Electrotechnical Commission [IEC], QR Code Bar Code Symbology Specification, ISO/IEC JTC 1/SC 31 (3rd ed. 2015),* https://www.iso.org/obp/ui/#iso:std:iso-iec:18004:ed-3:v1:en.

[53] *See* GS1-US, *GS1 General Specifications, Release 16.0* (Jan. 2016), http://www.gs1us.org/DesktopModules/Bring2mind/DMX/Download.aspx?Command=Core_Download&EntryId=618.

[54] Kevin Berisso, *Designer QR Codes; Ensuring the "Beep"* (2013), https://dspace.sunyconnect.suny.edu/bitstream/handle/1951/61465/Berisso_Designer-QR-Code-White-Paper_2013.pdf?sequence=1&isAllowed=y.

interference, not provide information. Experts recommend a minimum quiet zone be equivalent to the size of 4 units or modules based on the size of the QR code itself.[55,56,57]

Considerations for packaging material and shape

Another challenge in designing an effective QR code has to do with the shape of the product package and the packaging material itself. QR codes perform optimally when used on a flat surface. While it is possible to optimize QR codes for curved surfaces,[58] USDA must establish strict rules for companies who would choose to use a QR code on such surfaces like cans to ensure that they can be consistently scanned, and in circumstances where the shape of a package negatively impacts performance or prohibit their use.

Similarly, the type and style of packaging material can negatively impact the performance of a QR code. While a cardboard box may work just fine, packaging like foil wrappers or plastic bags that do not have flat surfaces may not be suitable. Furthermore, a package with a white or black background may be optimal whereas a clear or opaque package may interfere with the ability of a QR code to be scanned effectively. Finally, glossy or reflective coatings on food packages can also interfere with the ability to effectively scan a package. The proposed rule should make clear that QR codes used on non-flat food packages must be able to be effectively scanned under all scenarios, and it should prohibit the use of QR codes as a means of disclosure where the package shape or material does not permit their use.

26 through 29.

AMS has well-established rules to ensure compliance with other claims and standards (e.g., 7 CFR 205.103 and 7 CFR 600.400) and these rules should serve as the basis for compliance with GMO disclosure regulations. AMS should have unlimited and immediate access to documents verifying compliance with these rules, companies should be required to maintain these records for two years, and companies should be required to provide these documents immediately upon request or during a routine inspection by USDA, FDA, or state officials. Any enforcement action, including audits, should be made immediately available to the public through the USDA website.

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[55] *See* GS1-US, *GS1 General Specifications, Release* 16.0 331 (Jan. 2016). http://www.gs1us.org/DesktopModules/Bring2mind/DMX/Download.aspx?Command=Core_Download&EntryId=618.

[56] *See* European Commission, traceability and labelling, http://ec.europa.eu/food/plant/gmo/traceability_labelling/index_en.htm (last visited Oct. 28, 2016).

[57] *See* International Organization for Standardization[ISO], *International Electrotechnical Commission [IEC], QR Code Bar Code Symbology Specification, ISO/IEC JTC 1/SC 31 (3rd ed. 2015),* https://www.iso.org/obp/ui/#iso:std:iso-iec:18004:ed-3:v1:en

[58] *See* Patrick Scheibe, *QR Codes, Viewpoint and Curved Surfaces*, 2D-code (June 10, 2013), http://2d-code.co.uk/qr-codes-on-curved-surfaces/.

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

All products offered for sale in the U.S. should be required to meet the requirements of the new GMO disclosure law. As noted earlier in this response, many of our largest trading partners require an ingredient-by-ingredient disclosure as a condition of sale, including the European Union, the United Kingdom, China and Russia.

1436 U Street NW, Suite 100, Washington, DC 20009
p. 202.667.6982 | f. 202.232.2592