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To: AMS - GMO Labeling
Subject: Pub. L. 114-216 comments

July 17, 2017

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

Re: Implementation of the National Bioengineered Food Disclosure Standard (Pub. L. 114-216)

Dear Secretary Perdue,

We thank USDA for recognizing the importance of soliciting stakeholder comments during the process of implementing Pub. L. 114-216, the National Bioengineered Disclosure Standard. Very few food issues have earned as much public attention and support as labeling genetically engineered (GE) foods.

PCC Natural Markets has a unique role and responsibility to comment on the National Bioengineered Disclosure Standard. We are the nation's largest consumer-owned grocery chain and have heard consumer demands for GE label transparency since rBGH hit the dairy industry. On behalf of our 56,000+ active member-owner households, we are pleased for the opportunity to comment.

We respectfully submit the following comments on Pub. L. 114-216 and urge USDA staff to focus on these areas:

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

AMS should consider the terms "genetic engineering," "genetic modification," and "biotechnology" as interchangeable with "bioengineering" because of their current use in state and federal policy, as well as international standards and guidelines in Codex Alimentarius, the internationally recognized standards, codes of practice, and guidelines developed by the World Health Organization for a globally harmonized food code.

The Codex Alimentarius uses the following definitions (*Guidelines for the Production, Processing, Marketing and Labelling of Organically Produced Foods* 7 (2001), <ftp://ftp.fao.org/docrep/fao/005/Y2772E/Y2772e.pdf>):

Genetically engineered/modified organisms. The following provisional definition is provided for genetically/modified organisms. Genetically engineered/modified organisms, and products thereof, are produced through techniques in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination.

Techniques of genetic engineering/modification include, but are not limited to: recombinant DNA, cell fusion, micro and macro injection, encapsulation, gene deletion and doubling. Genetically engineered organisms will not include organisms resulting from techniques such as conjugation, transduction and hybridization.

The Codex definition also says GE techniques “include, but are not limited to” the methods listed in its definition, leaving room for interpretation and new technologies. It focuses on modifications that do not occur through natural mating or recombination, emphasizing the mixing of genetic traits that would not occur naturally. Codex explicitly includes gene deletion, which includes gene editing technologies such as CRISPR.

We urge USDA to interpret the definition broadly to include the scope of existing terms under the globally recognized regulatory body of Codex. This would prevent confusion and contradictions in interpretation and execution. Codex is the definition already referenced by the U.S. Food and Drug Administration in discussion of genetic engineering.

USDA General Counsel Jeffrey Prieto stated in a July 1, 2016 letter to the Ranking Member of the Senate Agriculture Committee, Debbie Stabenow (D-Mich.), that the law gives USDA broad legal authority to adopt a broad and flexible definition that would meet this global standard (162 Cong. Rec. S4994 [daily ed. July 12, 2016]).

USDA General Counsel Prieto wrote specifically that it is well within USDA’s authority to include ingredients derived from “novel gene editing techniques such as CRISPR” and TALEN, and “RNAi technologies” (RNA interference).

Synthetic biology also is an emerging “novel gene editing technique” referenced by Prieto. It’s recognized as genetic engineering and should be included in USDA’s scope and definition.

Congress provided authority and flexibility to the Secretary for such a broad and comprehensive definition by omitting terms in Pub. L. 114-216 that would have required USDA to stay within the parameters of subpart (A) in the definition:

- (A) That [the food] contains genetic material that has been modified through in vitro recombinant deoxyribonucleic acid (DNA) techniques;

USDA General Counsel Prieto’s letter to Stabenow clarifies that the presence of GE material in a finished product is **not** required for it to be within the scope of Pub. L. 114-216.

Prieto clarifies that it is well within USDA’s authority to include products that “have been produced or developed from genetic modification techniques” including “highly refined oils, sugars, or high fructose corn syrup.”

USDA should establish a mechanism and language that requires including disclosure of new GE techniques as they develop. Keeping up with the rapid emergence of products developed with “novel gene editing techniques” would ensure disclosures are meaningful over time.

2. What modifications should AMS consider to be “found in nature?” (Sec. 291(1)(B))

As above, Congress provided authority and flexibility to the Secretary for a broad and comprehensive definition by omitting terms in Pub. L. 114-216 that would have required USDA to stay within the parameters of subpart (B) in the definition:

- (B) For which the modification could not otherwise be obtained through conventional breeding or found in nature.

Prieto’s letter — and the omission of restrictive terms by Congress — mean that determining if a modification is “found in nature” should focus on whether the process — not the genetic trait — is found in nature.

In a July 12, 2016 colloquy, Sen. Stabenow also stated “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.” This was key to the bill’s passage and consumers are counting on this interpretation in the rule.

3. 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 his July 1 letter, Prieto clarified that USDA has authority to include foods that no longer “contain” genetic material in the final product but “contains” ingredients derived from bioengineering.

Specifically, he said USDA has authority to disclose products that contain “highly refined oils, sugars, or high fructose corn syrup that have been produced or developed from genetic modification techniques.”

Stabenow also stated in her July 12 colloquy, “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.”

She concludes, “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.”

In press releases, postings on social media, and public statements, Stabenow also stated Pub. L. 114-216 would require 25,000 *more* products are subject to a mandatory disclosure requirement than Vermont’s Act 120 labeling law and other state disclosure requirements. In a July 7, 2016 statement on the Senate floor, Stabenow said:

“[I]n Vermont and at the State level, meat, eggs, cheese, and dairy are exempt—totally exempt. 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.”

The Environmental Working Group analyzed ingredients of more than 148,000 foods and found it would not be possible for 25,000 more products to be subject to GE labeling if USDA’s scope did *not* include highly refined GE ingredients, such as sugar and oils.

The clear intent of Congress was to require more GE foods would be subject to disclosure than under Vermont’s law. That means including highly refined products derived from bioengineering.

Any narrower interpretation would contradict the legislative intent and exclude the majority of GE foods on grocery shelves.

4. Although the Law states 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 other 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))

USDA organic standards have prohibited genetic engineering as an “excluded method” of production or handling since 2002. As described in section 299 (f)(2) of Pub. L. 114-216 and clarified in USDA’s Policy Memorandum on “Consistency with the AMS National Organic Program (NOP),” USDA must ensure proposed rules for bioengineered food disclosure will not require any modifications in USDA organic regulations.

USDA’s NOP has developed an extensive body of federal regulations regarding genetic engineering. This includes USDA policy statements, instructions to certifiers and certified operations, and USDA fact sheets for the public. The federal advisory board that advises the Secretary of Agriculture in setting organic standards also just completed three years of work through a public process and unanimously passed a recommendation to NOP on “excluded methods” terminology to further clarify GE methods prohibited by USDA organic regulations.

USDA's definition of "bioengineering" in Pub. L. 114-216 also must conform with the existing global definition under Codex Alimentarius. USDA's definition of bioengineering must be harmonized with Codex and the U.S. Food and Drug Administration's (FDA) view. FDA acknowledges and references the definition of genetic engineering in Codex.

The standards and guidelines adopted by Codex also are recognized by the World Trade Organization as the authoritative standard for settling international trade disputes and, therefore, should be a guideline for USDA.

Harmonizing the definition with the Codex definition would make U.S. standards compatible with our largest trading partners, including China, Russia, Mexico, the European Union, and the United Kingdom.

The Codex definition explicitly includes gene editing technologies, such as CRISPR and TALEN, RNAi technology, direct injection and cell fusion, and says genetic engineering techniques "include, but are not limited to" the methods listed in its definition.

USDA consistency with Codex definitions is vital to alleviate confusion in the export market.

5. How should AMS craft language in the regulations acknowledging that the Law prohibits animal products from being considered bioengineered solely because the animal consumed feed products from, containing, or consisting of a bioengineered substance? (Sec. 293(b)(2)(A))

While Pub. L. 114-216 prohibits labeling meat, poultry, seafood, eggs and dairy as GE if the animals were raised on GE feed, the Secretary's broad authority for rule-making would allow such products to be labeled another way — without contradicting the law.

The prohibition in Sec. 293(b)(2)(A) appears intended to make clear that raising animals on GE feed does not make the animals themselves into a genetically modified organism (GMO).

At the same time, exempting products of animals raised on bioengineered feed from disclosure very likely would mislead consumers into concluding the animals were fed "non-GMO" feed.

To prevent misunderstanding in the marketplace, we propose USDA use its authority to label animal products not as GE — but as **"A product of animals raised on GE feed."**

There are many data points, including the USDA organic program, and the rapid adoption and spread of the Non-GMO Project, that show the market is very sensitive to the fact that GE feed is part of the livestock industry. Consumers demand to know how their food was produced, and it would be an enormous shortcoming not to require transparency in meat, poultry, seafood, eggs and dairy sector.

Through our participation in the Non-GMO Project, we have seen a dramatic surge in consumer demand for animal-derived products from animals raised on non-GMO feed and, subsequently, significant industry investment in the non-GE supply chain over the past five years.

Not addressing meat, poultry, seafood, eggs and dairy with an alternative label, as proposed above, would be misleading and deceptive to consumers. We learned during the Washington state GE labeling campaign (2012-2013) that not addressing animal feed caused the loss of some voters' support.

USDA has the broad authority to label animal products as "A product of animals raised on GE feed" and we urge USDA staff to adopt it as part of this disclosure standard.

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

As above, we urge USDA to exercise its authority and label animal products raised on GE feed as a distinct disclosure category.

As noted in #5 above, exempting products of animals raised on bioengineered feed from disclosure very likely will mislead consumers into concluding the animals were fed “non-GMO” feed.

A simple solution is to provide for a separate disclosure category for such foods, stating they are “A product of animals raised on GE feed.”

We urge USDA staff to adopt this solution to prevent confusion, as part of this disclosure standard.

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

The threshold that triggers label disclosure should be consistent with the “action thresholds” of the Non-GMO Project, the dominant certifier for GE food transparency in the United States.

The Non-GMO Project (NGP) has verified more than 43,000 products with more than \$25 billion in annual sales for thousands of companies. It has a deep understanding of brand and consumer expectations for GE transparency and is well established among large conventional companies doing business domestically and abroad.

To avoid confusion in the U.S. marketplace, we urge USDA to adopt the existing Non-GMO Project standards for thresholds that trigger GE disclosure. These standards have been developed by farmers, manufacturers, processors, distributors, retailers, and consumers, based on real world conditions.

Under the NGP standard, the action thresholds are:

- Seeds: 0.25%.
- Inputs to human food, ingredients, supplements, personal care products, and other products that are ingested or applied directly to skin, and pet food: 0.9%
- Livestock feed and supplements, including those used for animal-derived inputs to human food products: 5%.
- Inputs to packaging, cleaning products, textiles and other products that are not ingested or applied directly to skin: 1.5%.

The Non-GMO Project Standard is a consensus-based document, crafted with the insight and expertise of stakeholders reflecting a diverse range of perspectives throughout the supply chain.

It also is compatible with the standards of our trading partners.

We urge USDA to adopt the Non-GMO Project thresholds for all parts of the supply chain, from seeds and animal feed, to finished foods for human consumption or use.

8. 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 expect GE disclosures to be declared ingredient-by-ingredient. E.g. “genetically engineered sugar beet,” “genetically engineered canola oil,” or “genetically engineered soy protein,” etc. This is the method that the Hershey Company currently uses in labeling its products for export to the EU.

Alternatives are “corn syrup (genetically engineered),” “maltodextrin (genetically engineered)” or “cornstarch (genetically engineered).” This is the method that the Betty Crocker currently uses in labeling its products for export to Australia.

9. 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))

A DNA spiral should be the symbol indicating the DNA of a traditional food was altered.

It is the only symbol we can imagine that would be both fitting and appropriate.

10. 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))

PCC Natural Markets is opposed to companies resorting to electronic or digital links for disclosure because they cannot be accessed equally by all shoppers, notably the elderly, low-income, and rural people.

But if or when electronic or digital links — such as QR codes or websites — are used for GE disclosure, USDA must ensure equal access to the information by ALL shoppers, regardless of age, income or where they live. There is ample research from the PEW and others showing consistently that more than half of America’s seniors and roughly a third of low-income people do not have **smartphones to access electronic or digital links**.

It must be assumed that companies that resort to off-package disclosures (via electronic or digital links) are trying to hide the GE status of their foods and make it as difficult as possible to see. Therefore, it is USDA’s responsibility to ensure equal access to GE disclosures, just as FDA requires “uniform, on-package” ingredient disclosure to ensure uniform, equal access.

This means USDA should require companies resorting to electronic or digital links to pay for the cost of convenient scanners, at the point of sale in retail stores, to ensure equal access to GE information. Companies could be assessed based on the annual sales of their GE foods, paying into a dedicated fund that pays for retail scanners. It also could be a cost-share program, where companies directly rebate retailers that install scanners to read the electronic or digital links on their products.

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

As the nation’s largest consumer-owned retailer, we believe a DNA spiral symbol, with a phone number or website added, is the best and most reasonable disclosure option for small or very small packages.

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

UDSA should follow precedent set by other relevant FDA definitions of “small” and “very small” businesses.

The Food Safety Modernization Act, for instance, already defines “very small business” as averaging less than \$1,000,000 per year over a three-year period. FDA estimated in 2014 that such businesses with less than \$1,000,000 in annual sales account for less than two percent of all food produced in the United States. Exempting very small businesses from this regulation would have limited impact on transparency for consumers.

Among farms, “small” farms are defined as having an average annual value of produce sold during the previous 3-year period as no more than \$500,000.

“Very small” farms have an average annual value during a three-year period of \$250,000.

13. 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))

Yes. USDA should require electronic or digital disclosures should be accompanied with a reference to use of GE ingredients in the product.

Electronic and digital disclosures should be accompanied with a statement, “Scan here for more information on the GE ingredients in this product.”

14. 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))

Bioengineered food information should be disclosed ingredient-by-ingredient, preferably in an ingredient list through electronic and digital disclosures.

15. 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))

To keep costs low, AMS should not require USDA agents to conduct any surveillance of foods labeled for retail sale.

An action to enjoin a violation of Pub. L. 114-216 should be brought to any court of competent jurisdiction by a person in the public interest, but only if the complaint is issued more than 60 days after giving notice of the alleged violation to AMS/USDA, the attorney general, and the alleged violator. This model had broad support among the U.S. states that passed, or floated, GE labeling initiatives – 26 states in all.

In its investigations, AMS/USDA should request a company’s record of strip tests or PCR testing of the seeds or stock cultivated, in accordance with industry-established Non-GMO Project Standards.

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

AMS should post the results, findings and summaries of any examination, audit or similar activity after notice and opportunity for a hearing (per Sec. 293(g)(3)(B)) on its website, under a dedicated and easy to find section on “GE food labeling.”

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

Disclosure requirements for imported products must meet all the labeling requirements for U.S. foods and be displayed on wholesale packaging and finished products for sale to the public.

We have no comments at this time on the remaining questions posed by USDA.

Respectfully submitted,

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