April 14, 2016

Ms. Michelle Arsenault
National Organic Standards Board
USDA-AMS-NOP
1400 Independence Avenue, SW
Room 2648-So., Ag Stop 0268
Washington, DC 20250-0268

Docket: AMS-NOP-15-0085

RE: Materials Subcommittee – Excluded Methods Terminology (Proposal)

Dear Ms. Arsenault:

Thank you for this opportunity to provide comment on the Materials Subcommittee's Proposal on Excluded Methods Terminology.

The Organic Trade Association (OTA) is the membership-based business association for organic agriculture and products in North America. OTA is the leading voice for the organic trade in the United States, representing organic businesses across 50 states. Its members include growers, shippers, processors, certifiers, farmers' associations, distributors, importers, exporters, consultants, retailers and others. OTA's Board of Directors is democratically elected by its members. OTA's mission is to promote and protect organic with a unifying voice that serves and engages its diverse members from farm to marketplace.

The Materials Subcommittee is requesting comments from organic stakeholders on its proposal to update the NOP regulatory definition of "excluded methods" through guidance. OTA recognizes that the definition of "excluded methods" was based on the efforts of NOSB in 1995, and is now outdated. Organic producers and handlers as well as Accredited Certifying Agencies (ACAs) and USDA's National Organic Program (NOP) must have clear and up-to-date definitions to make consistent and concrete determinations regarding compliance with the prohibition of GMOs. For this reason, we continue to be supportive of the work being done to move forward a recommendation to NOP.

Summary of OTA's Position
In summary, OTA continues to support a process-based approach to evaluating the use of excluded methods. We believe that the proposed definitions will be useful, and with some revisions, they will be "proposal ready." The "terminology chart" and the "criteria and principles," however, need a considerable more amount of time and attention. OTA recommends taking the entire proposal back to subcommittee for further work with the goal of releasing a final proposal prior to the Fall 2016 NOSB meeting. We also recommend separating out the 'definitions' from the rest of the proposal, and moving the definitions section forward as an independent recommendation.

- **Definitions:** We support the proposed definition for "Modern Biotechnology" but request that NOSB reference Codex Alimentarius rather than the Cartegena Protocol since Codex is recognized by the U.S. and referenced by the World Trade Organization (WTO).

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As explained in our detailed comments below, we suggest revisions for "**Genetically Modified Organism**" and "**Non-GMO**" and we suggest removing the definition for **"Genetic Engineering."** We generally support the definition of "**Synthetic Biology"** but we are concerned about its "working draft" status. Finally, we encourage NOSB to define "traditional" or "classical" plant breeding and its varying techniques.

- **Terminology Chart**: OTA continues to support the creation of a terminology chart. We believe it would be appropriate to move forward with a chart in the Fall of 2016 (or when it is ready) provided it is more definitive and includes existing terminology from the "excluded methods" definition. The chart should also include a disclaimer (attached to the chart itself) that it is not an exhaustive or closed list (that is, it will be updated over time).

- **Principles and Criteria**: This section needs more work and more public input before it will be ready to move forward. The short 30-day public comment period did not allow time for public commenters to give it the full attention needed to work through the complex information presented. In fact, several OTA members expressed the need for more time. If there is general agreement from public commenters that this section needs more work, OTA would be willing to form a task force and prepare comments in advance of the Fall meeting.

We offer the following more detailed comments:
OTA supports several parts of the proposal as written. We are encouraged by the progress being made, but we believe further refinement is needed before a recommendation is finalized. There is a great risk of moving too quickly and creating a situation where long-standing traditional or classical breeding methods could be challenged as prohibited under the NOP regulations. The expert panel scheduled to present at the meeting will also offer important additional information that can help shape a final proposal for consideration at the fall 2016 meeting.

DEFINITIONS
OTA favors referencing Codex Alimentarius over the Cartagena Protocol on Biosafety to the Convention on Biological Diversity.[1] Codex is recognized internationally, recognized by the U.S. and referenced by the World Trade Organization (WTO). It is also referenced by many U.S. agencies such as FDA, USDA APHIS and EPA. Adopting definitions that are used by Codex should help support U.S. trade and interagency coordination. The United States is not, however, a member of the Convention on Biodiversity (CBD), and therefore does not recognize it.

OTA **supports** the following definitions:

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

[1] The *Cartagena Protocol on Biosafety to the Convention on Biological Diversity* is an international agreement which aims to ensure the safe handling, transport and use of living modified organisms (LMOs) resulting from modern biotechnology that may have adverse effects on biological diversity, taking also into account risks to human health. It was adopted on 29 January 2000 and entered into force on 11 September 2003.

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used in conventional breeding and selection. (From Codex Alimentarius)

> **OTA comment:** The reference to Codex Alimentarius rather than the Cartegena Protocol is important distinction. The definition is the same, however, under Cartegena, a living organism is expressly defined as containing three essential elements: 1) it must be a living organism; 2) it must possess a novel combination of genetic material; and 3) such genetic material must have been obtained through the use of modern biotechnology. This opens up the debate on what a "novel combination of genetic material" means. The Codex definition doesn't include this element. Instead, it simply states that an rDNA plant is a plant produced using modern biotechnology. Thus, the Codex definition of "modern biotechnology" would cover virtually all of the new gene editing techniques, e.g., CRISPR Cas9, TALEN, zinc finger nucleases, RNA-dependent DNA methylation, etc. as well as RNAi and gene drives.

Synthetic Biology – A further development and new dimension of modern biotechnology that combines science, technology and engineering to facilitate and accelerate the understanding, design, redesign, manufacture and/or modification of genetic materials, living organisms and biological systems. (Operational Definition developed by the Ad Hoc Technical Expert Group on Synthetic Biology of the UN Convention on Biological Diversity)

> **OTA comment:** It should be noted that the definition of "synthetic biology" is a working definition under the CBD Ad Hoc Technical Expert Group on Synthetic Biology. It may be advantageous to not use this definition until the Expert Group has completed its work.

OTA **requests revisions** to the following definitions:

1. Genetic Engineering
The subcommittee is proposing the following definition for genetic engineering:

> **Genetic engineering (GE)** – A set of techniques from molecular biology (such as recombinant DNA and RNA) by which the genetic material of plants, animals, micro-organisms, cells and other biological units are altered and recombined (first sentence modified from IFOAM Position).

OTA suggests eliminating this definition because it is too broad and could encompass many methods traditionally used in plant breeding. Given the definition of Modern Biotechnology, we do not think this is needed.

2. Genetically Modified Organism (GMO)
The subcommittee is proposing the following definition for genetically modified organism:

> **Genetically Modified Organism (GMO)** - A plant, animal, or microorganism that is transformed by genetic engineering as defined here. This term also applies to products and derivatives from genetically engineered sources (first sentence from IFOAM Position cited above, second sentence modified from their definition).

OTA suggests the word "organism" be used instead of "microorganism" so that the definition includes fungi. This may be important in anticipation of new GMOs that may be developed in the future.

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Additionally, the word "transformed" relates to a specific technology. We propose the board consider "modified" or "created." In general, clarification is needed to emphasize the distinction between modification of the genome through genetic engineering and any modification that occurs through conventional plant breeding methods.

3. Non-GMO

The inclusion of a "non-GMO" definition comes at a critical time, given the final FDA guidance on voluntary GE labeling, and the various state and federal initiatives to require labeling of genetically engineered foods. The term "non-GMO" is also commonly used throughout the organic sector on labels and marketing materials to mean that the product was produced and handled without the use of excluded methods, as required by the organic regulations. Unlike the term "GMO free", the term "non-GMO" does not necessarily mean a product is 100% free of GMOs. Securing a definition of "non-GMO" in NOP guidance will help support the consistent use and interpretation of this frequently used term.

The subcommittee is proposing the following definition, which they say is based on the comments OTA submitted in April 2015 (**See Appendix A**).

> **Non-GMO** – The term that is used to describe or label a product that was produced without any of the excluded methods defined here. It is consistent with the NOP process-based standard that does not imply freedom from GMOs but does indicate that processes to prevent GMO contamination have been used (from the public comment by the Organic Trade Association, April 2015[7])

Unfortunately, the subcommittee's proposed definition captures **some but not all** of our comments.

OTA requests that the subcommittee revise the definition as follows:

> *In track-change mode:*
> **Non-GMO** – The term that is used to describe or label a product that was produced without any of the excluded methods defined in the organic regulations and corresponding NOP policy. The term "non-GMO" is consistent with the NOP process-based standard ~~that~~ and does not imply a product is 100% free of "GMOs." Instead, "non-GMO" communicates that the organic operation has not used excluded methods and has taken the required steps to avoid contact with the products of excluded methods as detailed in their approved organic system plan ~~freedom from GMOs but does indicate that processes to prevent GMO contamination have been used~~ (from the public comment by the Organic Trade Association, April 2015[7])
>
> *Changes accepted:*
> **Non-GMO** – The term that is used to describe or label a product that was produced without any of the excluded methods defined in the organic regulations and corresponding NOP policy. The term "non-GMO" is consistent with the NOP process-based standard and does not imply a product is 100% free of "GMOs." Instead, "non-GMO" communicates that the organic operation has not used excluded methods, and has taken the required steps to avoid contact with the products of excluded methods as detailed in their approved organic system plan.

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And finally, OTA strongly encourages the subcommittee to define "traditional" or "classical" plant breeding and its varying techniques to help support the reference to "traditional breeding" in the current definition of excluded methods.

OTA would like to see all of the above definitions included in NOP's existing Policy on GMOs (11-3). Our suggested course of action is for NOSB to draft a stand-alone proposal on definitions with a request to include an additional "Issue & Reply" in the Policy addressing GMO terminology.

The "Issue & Reply" would include the terms and definitions above, and would clarify that: 1) they fall under the definition of excluded methods at 7 CFR 205.2 (Terms Defined) and are therefore prohibited in organic production and handling; and 2) they may be used for the labeling and marketing of organic products.

TERMINOLOGY CHART

OTA continues to support the creation of a terminology chart that would be added to NOP Guidance. The chart would help clarify the specific techniques that fall under NOP's definition of excluded methods.

An example of where this chart would be helpful is 'gene editing.' The existing NOP definition of 'excluded methods' does not specifically list gene editing. The definition references "methods or means that are not possible under natural conditions or processes that are not compatible with organic production" and it includes gene deletion, gene doubling, introducing a foreign gene, and changing the position of genes as examples of recombinant DNA technology. To the best of our understanding, the list of examples in the definition is not a "closed-list" and gene editing would also fall under NOP's definition of 'excluded methods.'

However, there is a debate in the agricultural sector over whether 'gene editing' should trigger regulatory oversight by USDA APHIS. Some contend that gene editing occurs in traditional breeding, and therefore doesn't meet the Cartagena Protocol definition of 'Modern Biotechnology.' There have been at least eight instances in which USDA APHIS has deemed gene editing outside its regulatory authority.

This creates confusion and uncertainty. A terminology chart could be used to remedy this confusion and uncertainty.

An existing debate in the agricultural sector is whether 'gene editing' should be a trigger for regulatory oversight by USDA's APHIS. Some are making the case that it occurs in traditional breeding and therefore doesn't meet the Cartagena definition of Modern Biotechnology. There have been at least eight cases where USDA's APHIS has deemed it outside its regulations.

To the best of our knowledge, gene editing falls under NOP's definition of 'excluded method.' Although the definition of 'excluded methods' doesn't specifically include gene editing as an example, it references "methods or means that are not possible under natural conditions or processes that are not compatible with organic production." Gene deletion, gene doubling, introducing a foreign gene and changing the position of genes are all included as examples.

Under the organic regulations, we maintain a process-based approach with emphasis on genetic modifications (techniques) that are handled outside the organism (in vitro) by people. Gene editing is

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targeted genetic modification and would therefore be viewed as an excluded method. However, the absence of its specific inclusion in the definition creates uncertainty. A terminology chart could be used to remedy this kind of situation.

The chart presented in the subcommittee's proposal is a good start but it needs significant work. For example, some of the listed items are naturally occurring (transposons, for example) and others (induced mutations, embryo rescue, double haploids) are widely used in many crops and include numerous techniques within each category that need to be examined more specifically to identify what aspect is actually excluded.

We believe it would be best to move forward with a chart once organic stakeholders have had more time to discuss and comment on it. Once completed, we also recommend that NOSB include a disclaimer that it is not an exhaustive or closed list.

PRINCIPLES AND CRITERIA

This section still needs more work and more public input before it will be ready to move forward. The short 30-day public comment period did not allow time for public commenters to give it the full attention needed to work through the complex information presented. In fact, several OTA members expressed the need for more time. If there is general agreement from public commenters that this section needs more work, OTA would be willing to form a task force and prepare comments in advance of the Fall meeting.

Conclusion

The Organic Trade Association (OTA) continues to be extremely supportive of moving recommendations forward to NOP that will not only improve the practices used to keep GMOs out of organic seed, feed and crops, but will also clarify the standards and terminology used for making clear and consistent compliance determinations.

On behalf of our members across the supply chain and the country, OTA thanks the National Organic Standards Board for the opportunity to comment, and for your commitment to furthering organic agriculture.

Respectfully submitted,

Gwendolyn Wyard
Senior Director of Regulatory and Technical Affairs
Organic Trade Association

cc: Laura Batcha
Executive Director/CEO
Organic Trade Association

Appendix A: OTA's April 7, 2015 comments on Excluded Method Terminology

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SINCE 1985 Organic trade association

April 7, 2015

Ms. Michelle Arsenault
National Organic Standards Board
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Docket: AMS-NOP-15-0002

RE: Materials/GMO Subcommittee: Discussion Document on Excluded Methods Terminology

Dear Ms. Arsenault:

Thank you for this additional opportunity to provide comment on the Materials/GMO Subcommittee Discussion Document entitled "Discussion Document on Excluded Methods Terminology."

The Organic Trade Association (OTA[1]) supports the continued discussion and work on updating and clarifying "excluded methods" terminology. The National Organic Standards Board's (NOSB) continued work on the topic of GMOs is paramount. OTA continues to be very supportive of moving recommendations forward to NOP that will not only improve the practices used to keep GMOs out of organic seed, feed and crops, but will also clarify the standards and terminology used for making clear and consistent compliance determinations.

In the last fall 2014 round of comments, OTA submitted comments in support of a process-based approach. We also weighed in on the usefulness of a chart containing a list of GE and non-GE terms, and requested that the chart be included in NOP Guidance maintained in the NOP Handbook that is publicly available on the NOP website. Our position remains unchanged. We are re-submitting the same comments for the record once again, but with an additional suggestion for the list of terms included in Appendix 1. Specifically, we are requesting that the phrase "Genetically Modified Organism" along with its commonly used acronym "GMO" be included in the Appendix. We are also requesting that the acronym "GE" be used alongside of "Genetic Engineering." The inclusion of this common terminology will support and secure the language most commonly used on organic packaging, in our day-to-day communications, and with the various state and federal labeling initiatives to require labeling of GE foods.

[1] OTA is the membership-based business association for organic agriculture and products in North America. OTA is the leading voice for the organic trade in the United States, representing organic businesses across 50 states. Its members include growers, shippers, processors, certifiers, farmers' associations, distributors, importers, exporters, consultants, retailers and others. OTA's Board of Directors is democratically elected by its members. OTA's mission is to promote and protect the growth of organic trade to benefit the environment, farmers, the public and the economy.

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We offer the following more detailed comments:

Terminology

OTA is requesting that the phrase "Genetically Modified Organism" along with its commonly used acronym "GMO" be expressly included in Appendix 1. We're also requesting that the acronym "GE" be included alongside with "Genetic Engineering." Both would appear in Appendix 1 as follows:

- Genetically Modified Organisms or "GMO"
- Genetic Engineering or "GE"

The phrase "genetically modified organism" is included in the first sentence of the NOP definition of "Excluded Methods" (7 CFR 205.2[2]) but for some reason it was not included in Appendix 1. The inclusion of GMO comes at a critical time considering the policies and guidance in progress under the U.S. Food and Drug Administration (FDA) and the various state and federal initiatives to require labeling of genetically engineered foods.

The term "GMO" is frequently used as a synonymous term to describe the "excluded methods" prohibited under the organic regulations. All communications regarding genetic engineering from NOP since 2000 refer to "GMOs." This includes USDA policy statements, instructions to certifiers and certified operations, and USDA fact sheets/educational materials for the public, all of which are available on the NOP website. In fact, this subcommittee refers to itself as the Materials/GMO Subcommittee. It's critical to recognize that the organic sector has grown familiar through a decade of common usage of the acronyms "GMO" and "GM" and "GE" to be shorthand for "not produced using genetic engineering." For the reasons explained further in detail below, OTA is requesting that these terms and their associated shorthand acronyms be expressly recognized and included in any proposal sent to NOP.

Why is this important?

In January 2001, FDA released for public comment draft guidance on "voluntary labeling indicating whether foods have or have not been developed using bioengineering." That draft guidance explains that consumer focus group data indicate that consumers do not understand the acronyms "GMO" and "GM" and prefer label statements referring to **bioengineering**. The draft guidance also indicates uneasiness with a label representing that a product is free of GMOs – and a preference for a label representing that the process is free of GMOs. The public comment period lasted until March 2001, although the docket has remained open since then. After no additional public comment period or other outreach to stakeholders, FDA has indicated that it intends to finalize guidance on voluntary labeling in 2015[3].

[2] *Excluded methods.* A variety of methods used to genetically modify organisms or influence their growth and development by means that are not possible under natural conditions or processes and are not considered compatible with organic production. Such methods include cell fusion, microencapsulation and macroencapsulation, and recombinant DNA technology (including gene deletion, gene doubling, introducing a foreign gene, and changing the positions of genes when achieved by recombinant DNA technology). Such methods do not include the use of traditional breeding, conjugation, fermentation, hybridization, in vitro fertilization, or tissue culture.

[3] Upon FDA's notice that they would be releasing final guidance, OTA submitted comments in support of "GMO" and "Non-GMO" terminology. **See Appendix A**.

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FDA's Draft Guidance encourages manufactures to avoid the phrase "not genetically modified" and acronyms utilizing "GM" and "GMO." This guidance is outdated, will confuse consumers, and will conflict with existing organic labeling practices. As stated earlier, all communications from NOP since 2000 refer to "GMOs." Industry and consumers also use the terms "GMO," "GM" or "GE" to refer to bioengineering. Since 1997, the organic industry has grown from $3 billion to over $31 billion with the acceptance of "non-GMO" as the common use terminology. This term is used to express that a product is produced without the use of GMOs. Any change would be extremely disruptive to years of organic product and market development. A change from this historical use would cause consumers to question whether the organic standards concerning GMO have changed. For this reason, it is critical that the discussion on excluded methods terminology include the terms that are most commonly used when referring to "excluded methods" – Genetically Modified Organisms (GMO) and Genetic Engineering (GE).

Non-GMO is consistent with the NOP standards and prohibition on Excluded Methods
OTA recommends that NOSB include the term "Genetically Modified Organism" and its acronym "GMO" and clarify its use in a "non-GMO" statement. FDA's draft guidance states (and we agree that any final guidance should retain) that NOP certification provides for adequate segregation throughout distribution to assure that non-organic foods do not become mixed with organic foods. Accordingly, the practices that substantiate the "certified organic" statement are sufficient to substantiate a claim that a certified organic food was not produced using bioengineering.

OTA recommends that NOSB emphasize that the term "non-GMO" is consistent with NOP process-based standards, and therefore with FDA's desire to create a process-driven label. The phrase "non-GMO," when used on NOP certified product labels, is understood to mean that the product was produced without the use of bioengineering/genetic engineering (excluded methods). "Non-GMO" is an accurate statement because it declares a product is produced without the use of excluded methods. Unlike the term "GMO-free," the term "non-GMO" does not necessarily mean the product is 100% free of GMOs.

OTA recognizes that the discussion document largely focuses on definitions, techniques and methods. However, all three are inherently attached to terminology and we believe it would be a huge oversight to not include the term Genetically Modified Organism (GMO) in addition to Genetically Engineered (GE). The term "GMO" is used extensively throughout the document because "GMO" (as well as Genetic Engineering (GE)) has become the most common shorthand way to discuss and refer to excluded methods. Accordingly, we ask that they both be clearly recognized as the common terms that are used to describe any and all of the methods and techniques that are considered "excluded methods" under the organic regulations.

Process-based Approach
As stated in our comments submitted in fall 2014, OTA supports continuing a process-based approach. We remain unchanged in our position that a processed-based standard can and should be intertwined with quantitative tools that can be used to assess the validity of a process-based approach.

This relationship between a "process-based" standard and "product" evaluation is codified in the Organic Foods Production Act and the USDA organic regulations under the Periodic Testing Rule (§ 205.670). ACAs are required to conduct periodic residue testing of organically produced agricultural products annually on at least 5% of their certified operations. Testing of residues is not limited to pesticides. Under

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the existing regulations, certifying agents have the flexibility to test for a range of prohibited materials and excluded methods, including, but not limited to, pesticides, hormones, antibiotics, and **GMOs**.

Testing is one of the most definite and effective tools ACAs can use to evaluate whether an organic operation has adequate measures in place to prevent commingling with or contact with GMOs. Testing is used to determine whether the "processes" and methods being used to avoid prohibited substances (including GMOs) are effective.

Conclusion

OTA recognizes that the definition of excluded methods was based on the efforts of NOSB in 1995 and is now outdated. Organic producers and handlers as well as Accredited Certifying Agencies (ACAs) and USDA's NOP must have clear and updated definitions in order to make consistent and concrete determinations.

OTA encourages the Materials/GMO Subcommittee to continue this discussion and its work on clarifying and updating the definition of excluded methods. The prohibition on excluded methods (GMOs) must remain in the regulations. We strongly suggest working with NOP to incorporate clarification on terminology **into guidance**, so that terms and definitions can be more easily updated and stay current with evolving technologies and products.

Again, on behalf of our members across the supply chain and the country, OTA thanks NOSB for the opportunity to comment and for your commitment to furthering organic agriculture.

Respectfully submitted,

Gwendolyn Wyard
Senior Director of Regulatory and Technical Affairs
Organic Trade Association

cc: Laura Batcha
Executive Director / CEO
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Appendix A: OTA comments to FDA titled "Draft Guidance for Industry: Voluntary Labeling Indicating Whether Foods Have or Have Not Been Developed Using Bioengineering" – April 21, 2014

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April 21, 2014

Dockets Management Branch (HFA-305)
U. S. Food and Drug Administration
5360 Fishers Lane, Room 1061
Rockville, MD 20852

RE: Draft Guidance for Industry: Voluntary Labeling Indicating Whether Foods Have or Have Not Been Developed Using Bioengineering

Docket No. 00D-1598

To Whom It May Concern:

Thank you for the opportunity to provide comments on the Food and Drug Administration's ("FDA") Draft Guidance for Industry on "Voluntary Labeling Indicating Whether Foods Have or Have Not Been Developed Using Bioengineering" ("Draft Guidance").

OTA is the membership-based business association for organic agriculture and products in North America. OTA is the leading voice for the organic trade in the United States, representing over 6,500 organic businesses across 49 states. Its members include growers, shippers, processors, certifiers, farmers' associations, distributors, importers, exporters, consultants, retailers and others. OTA's mission is to promote and protect the growth of organic trade to benefit the environment, farmers, the public and the economy.

One of the hallmarks of being certified by the U.S. Department of Agriculture's ("USDA's") National Organic Program ("NOP") is that certified products may not be produced using genetically modified organisms ("GMOs"). Because of this, OTA has actively and successfully advocated for the right of organic food processors to label their products as made without the use of GMOs, to reinforce the consumer understanding that to be certified organic means – among other things – to be non-GMO. OTA also believes that consumers have the right and desire to know more about their food in general. To that end, we strongly support mandatory labeling of all genetically modified foods.

These comments address three specific topics. First, OTA urges that the final guidance endorse the term "GMO," which organic consumers are very familiar with and accustomed to seeing on their products. Second, the final guidance should recognize "non-GMO" or other similar phrases as acceptable shorthand term for "not produced using genetic engineering/bioengineering." Third, for the substantiation of a "non-GMO" label claim, the final guidance should continue to state that third-party certification under the USDA NOP as "100 percent organic," "organic," or "made with organic (specified ingredients or food groups)," is sufficient to substantiate a claim that a food was not produced using genetic engineering.

Background

On January 18, 2001, FDA released draft guidance on "voluntary labeling indicating whether foods have or have not been developed using bioengineering." The public comment period closed March 19, 2001, but to date FDA has not issued a final version of the guidance. On September 5, 2013, FDA's Center for Food

Safety and Applied Nutrition ("CFSAN") issued its "Plan for Program Priorities, 2013-2014," in which it included, as Objective 4.1.11, "Publish final guidance to help manufacturers who wish to voluntarily label their foods as being made with or without the use of bioengineered ingredients." In addition, in testimony before Congress in late March of this year, FDA Commissioner Margaret Hamburg indicated that she intended to finalize this guidance "soon."

As CFSAN returns, after so many years, to develop final guidance, OTA believes it is important and timely to comment on the draft guidance. In the past 13 years since the draft guidance was published, the organic food industry in the United States has grown in annual sales from $3 billion in 2001 to $31 billion today. At the same time, the public has become increasingly aware of GMOs in the overall food supply. The final guidance that CFSAN issues must reflect the significant changes that have taken place over the past 13 years with regard to public perception of organic foods in general and GMOs in particular.

In addition, OTA requests that because over 13 years have passed since the draft guidance was published, the FDA publish revised guidance for a new round of public comment before it issues the guidance as final.

1. The term "GMO" should be endorsed.

Over the past 13 years, USDA's NOP has developed an extensive body of federal regulations relating to GMOs. The NOP regulations prohibit the use of "excluded methods," including "Genetically Modified Organisms (GMOs)," during the production or handling of organic products [7 CFR 205.105(e)]. This prohibition on the use of GMOs extends to all NOP certified label categories ("100% Organic," "Organic," and "Made with Organic") and all ingredients contained within each category (organic and non-organic ingredients and processing aids). Compliance is verified through the robust and auditable NOP certification process that includes periodic testing for prohibited substances such as pesticides, heavy metals and GMOs.

Organic consumers are highly familiar with the acronyms "GMO" and "GM." All communications regarding genetic engineering from NOP since 2000 refer to "GMOs." This includes USDA policy statements, instructions to certifiers and certified operations, and USDA fact sheets/educational materials for the public, all of which are available on the NOP website (see Appendices A-C for examples).

The 2001 draft guidance cites a consumer focus group study from 2000 indicating that consumers did not understand "the acronyms 'GMO' and 'GM' and preferred instead "label statements with spelled out words that mean bioengineering." However, while this perception may have been accurate in 2000, it does not hold true today. Consumers in 2014, after being exposed to so much information about organic foods and GMOs, have an increased understanding of the terms "GMO" and "GM."

In a 2014 survey conducted by OTA and Kiwi Magazine[1], parents were asked to characterize their knowledge of a set of acronyms used to refer to genetically engineered foods. This study revealed a higher

[1] *US Families' Organic Attitudes and Beliefs study in 2014*. The target audience consists of KIWI Magazine's Parents' Advisory Board (PAB), supplemented with a national online panel of U.S. households. Panelists were invited to participate in a web survey via e-mail. All respondents were screened to be 18 and over with at least one child under the age of 18 in the household and to have sole or shared responsibility for household grocery store purchases. Data collection took place between February 25, 2014, and March 3, 2014. A total of 1,209 usable surveys were completed, including 600 KIWI PAB panelists and 609 national panelists. Data from both panels were combined and weighted to reflect the demographics of U.S. households online. The total sample of 1,209 reflects the target population of U.S. households online at a confidence interval of +/- 3% at the 95% confidence level.

level of knowledge in the acronym "GMO" (82% have some kind of knowledge of what it means) than the acronyms "GM" or "GE." Of the three acronyms, "GMO" was the only acronym that yielded a majority saying they "know exactly what it means." Non-organic buyers, on the other hand, are significantly less familiar with any of the three acronyms (only 14% know what "GMO" means, 12% know what "GM" means, and 8% know what "GE" means). **See Appendix D.**

Data also reveal that when shopping for organic products, parents are most likely to look for the term "organic" (63%) on packaging labels. The next two terms most identified by organic consumers were "Non GMO" (34%) and "Produced without GMOs" (34%). Organic buyers are least familiar with "produced without biotechnology" (20%) followed by "Non-GE" (19%). **See Appendix E.**

This data not only confirm the familiarity of the term "GMO," but demonstrate that organic buyers are much more knowledgeable about GMO acronyms in general compared to non-organic buyers. Consumers today, particularly organic consumers, have an increased understanding of the terms "GMO" and "GM" because the GMO term is an integral part of the organic regulations and has been used commonly on USDA's NOP certified product labels and marketing materials for over a decade.

Therefore, OTA believes that the draft guidance must clarify "GMO" as an acceptable term for "genetically engineered" foods when used on organic products.

2. NOP Regulations, Industry Practice, and Consumers All Recognize "Non-GMO" as Standing for "Not Produced Using Bioengineering."

OTA agrees with the draft guidance that labeling a food as "free" of bioengineered material can be potentially inaccurate.

This illustrates the crucial distinction between products labeled as "GMO-free" and those labeled "non-GMO" or "made without the use of GMOs." The USDA organic label certifies that a product has been made through a ***process*** in which all organic production standards (such as soil fertility requirements, pest management practices, and contamination prevention measures) have been followed. This includes not using "excluded methods," including GMOs. The term that has come to be associated with the USDA organic label ***process*** claim is "non-GMO" or "made without the use of GMOs" because the organic regulations require that no GMOs may be used in the production of organic agricultural products. The USDA organic standard does not mean that the products themselves have been tested and found to be "GMO free."

Since 1997, the organic industry has grown from $3 billion to over $31 billion. This growth has been accompanied by the acceptance of the term "non-GMO" on an organic product as shorthand for "not produced using bioengineering." Results from *OTA's 2014 Organic Families Tracking Study* show that eight in ten organic buyers identify "buying organic products in order to avoid genetic modification" as an "extremely important or very important reason" to buy organic products" (86% among organic buyers total). **See Appendix F**.

If the final guidance were to discourage the use of "non-GMO," this would cause extensive disruption and economic hardship within the organic industry.
The final guidance must recognize that the term "non-GMO" has become established in the regulations of NOP, among companies in the industry, and among consumers, as a *process* claim associated with NOP organic certification. For this reason, the final guidance should allow the term "non-GMO" and other similar phrases as suitable shorthand for "not produced using genetic engineering (or bioengineering)." Examples of similar phrases include "produced without GMO ingredients," "made without the use of GMOs" and "contains non-GMO ingredients only."

3. FDA Should Continue to Recognize Organic certification as sufficient substantiation for non-GMO labeling claims.

The draft guidance states in its concluding paragraph that NOP certification provides for adequate segregation throughout distribution to assure that non-organic foods do not become mixed with organic foods. The guidance further states that the practices and recordkeeping that operations perform in order to be "certified organic" would therefore "be sufficient to substantiate a claim that a food was not produced using bioengineering."

OTA appreciates FDA's acknowledgement of these facts, and strongly agrees with their inclusion in any final guidance. This was a valid conclusion when FDA made it in 2001, and it is even more valid today, now that USDA's NOP has existed for over 11 years and has steadily broadened and intensified its third-party certification, compliance efforts, and enforcement process.

Accordingly, OTA urges FDA to reaffirm and emphasize in any guidance that the practices that substantiate the "certified organic" claim are sufficient to substantiate a claim that a certified organic food is "non-GMO," and allow certified organic operators to indicate this on their label in well-accepted terms employed by USDA, *i.e.,* the "non-GMO" claim.

Conclusion
OTA appreciates FDA's efforts to provide final guidance on this critical issue. However, in consideration of the 13 years that have passed since the first public comment period, we respectfully request that once the FDA has updated its 2001 draft guidance, it should publish new proposed guidance for another round of public comment.

OTA further requests that final guidance clearly recognize the use of the term "non-GMO" on organic products as acceptable shorthand for "not produced using genetic engineering."

And finally, for the substantiation of a "non-GMO" label claim, the final guidance should reaffirm and emphasize that certification under USDA's NOP as "100 percent organic," "organic" or "made with organic (specified ingredients or food groups)" is sufficient to substantiate a claim that a food was not produced using genetic engineering.

Once again, on behalf of our members across the supply chain and the country, OTA thanks FDA for the opportunity to comment on its Draft Guidance.

Respectfully submitted,

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Appendix A: NOP Policy Memorandum: Clarification of Existing Regulations Regarding the Use of Genetically Modified Organisms in Organic Production and Handling

Appendix B: Organic 101: Can GMOs Be Used in Organic Products?

Appendix C: NOP Fact Sheet: Can GMOs Be Used in Organic Products

Appendix D-F: *2014 OTA U.S. Organic Families Tracking Study:*

Appendix D: Knowledge of GMO acronyms

Appendix E: Parents use of terms when shopping of organic products

Appendix F: Buying organics to avoid GMOs