SINCE 1985 Organic trade association

April 7, 2015

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-15-0002

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
Organic Trade Association

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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Organic trade association

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,

Gwendolyn Wyard
Regulatory Director of Organic Standards and Food Safety
Organic Trade Association (OTA)

CC: Laura Batcha
Executive Director
Organic Trade Association (OTA)

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

United States Department of Agriculture
Agricultural Marketing Service
National Organic Program

1400 Independence Avenue SW.
Room 2646-South Building
Washington, DC 20250

Policy Memorandum

To: Stakeholders and interested parties

From: Miles McEvoy, Deputy Administrator

Subject: Clarification of Existing Regulations Regarding the Use of Genetically Modified Organisms in Organic Production and Handling

Date: April 15, 2011

The National Organic Program (NOP) has recently received questions concerning the use of genetically modified organisms (GMOs) under the U.S. National Organic Standards. This policy memorandum addresses frequently asked questions concerning GMOs and reiterates the statements made in a 2004 letter from USDA Undersecretary Bill Hawks to the National Association of State Departments of Agriculture.

Compliance with the organic standards entails that operations have verifiable practices in place to avoid contact with GMOs. Since organic certification is process-based, presence of detectable GMO residues alone does not necessarily constitute a violation of the regulation. The NOP relies on organic certifiers and producers to determine preventative practices that most effectively avoid contact with GMOs on an organic operation.

The use of GMOs is prohibited in organic production and handling. The NOP regulations prohibit the use of GMOs as "excluded methods" under 7 CFR § 205.105, "Allowed and prohibited substances, methods, and ingredients in organic production and handling." Excluded methods are defined as:

> A variety of methods 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. (7 CFR § 205.2-Terms defined)

This policy memo reiterates that the use of GMOs is prohibited under the NOP regulations and answers questions that have been raised concerning GMOs and organic production and handling.

Issue: If a producer adheres to all aspects of the NOP regulations, including never utilizing genetically modified seeds, but a certifying agent tests and detects the presence of genetically modified material in the crop, is that crop's status determined to be no longer certified organic?

Reply: Organic certification is process based. That is, certifying agents attest to the ability of organic operations to follow a set of production standards and practices which meet the requirements of the Organic Foods Production Act of 1990 and the NOP regulations. The NOP regulations prohibit the use of excluded methods (i.e., "GMOs") in organic operations. If all aspects of the organic production or handling process were followed correctly, then the presence of a detectable residue from a genetically modified organism alone does not constitute a violation of this regulation. This policy was established at the promulgation of the NOP Regulation in the Preamble to the Final Rule (FR Vol. 65, No. 246, p. 80556), December 21, 2000. The Preamble stated that:

> As long as an organic operation has not used excluded methods and takes reasonable steps to avoid contact with the products of excluded methods as detailed in their approved organic system plan, the unintentional presence of the products of excluded methods should not affect the status of the organic operation or its organic products.

Issue: Is the inadvertent presence of GMOs in organic seeds a violation of the NOP regulations? Can organic producers use seeds that contain the inadvertent presence of GMOs?

Reply: 7 CFR § 205.105 of the NOP regulations prohibits the use of GMOs as excluded methods in organic production and handling. The use of excluded methods, such as planting genetically modified seeds, would require a specific intent, and would render any product ineligible for organic certification. However, the inadvertent presence of GMOs in organic seeds does not constitute a use because there was no intent on the part of the certified operation to use excluded methods. The presence of detectable GMO residues alone in an organic seed does not constitute a violation of the NOP regulations.

Issue: How do organic producers avoid contact with GMOs?

Reply: Organic producers utilize a variety of methods to avoid contact or the unintentional presence of GMOs including testing seed sources for GMO presence, delayed or early planting to get different flowering times for organic and GMO crops, cooperative agreements with neighbors to avoid planting GMO crops adjacent to organic crops, cutting or mowing alfalfa prior to flowering, posting signs to notify neighboring farmers of the location of organic fields, and thorough cleaning of farm equipment that has been used in non-organic crop production.

Issue: What are organic producers required to do in order to avoid the presence of GMOs in their products?

Reply: In order to become a certified organic operation, a producer must submit an organic system plan to a NOP accredited certifying agent for approval. The producer's organic system

plan must include a description of management practices and physical barriers established to prevent contact of organic crops with prohibited substances. Certifying agents evaluate the preventative practices and buffer zones to determine if the producer has taken reasonable steps to avoid contact with GMOs.

Issue: Could a farm's organic certification status be threatened if sufficient buffers and barriers are not established and inadvertent contact with GMO material occurs?

Reply: Organic producers that implement preventive measures to avoid contact with GMOs will not have their certification threatened from the inadvertent presence of the products of excluded methods (GMOs). Crops grown on certified organic operation may be sold, labeled and represented as organic, even with the inadvertent presence of GMOs, provided that all organic requirements under 7 CFR Part 205 have been followed.

Issue: Is there a working definition of the word "contamination" within the NOP?

Reply: There is no definition in the NOP regulations for the word "contamination," even though it is mentioned frequently in the standards. The use of excluded methods in organic production is prohibited, as cited in 7 CFR § 205.105.

Issue: What actions are authorized or required when organic crops or products are found to contain unintended or inadvertent genetically modified substances?

Reply: The inadvertent presence of genetically modified material does not affect the status of the certified operation and does not result in loss of organic status for the organic product, provided it was produced in accordance with all of the organic requirements under 7 CFR Part 205. Certifying agents are responsible for working with organic producers to identify the source of the inadvertent GMOs and to implement reasonable steps to avoid contact with GMOs in the future.

Issue: Are organic products tested for genetically modified substances?

Reply: Under 7 CFR § 205.670(b) certifying agents may test organic products when there is reason to believe that excluded methods were used in the production or handling of an organic agricultural product. Certifying agents may also collect and test organic products from organic handlers to ensure that practices are in place to prevent commingling or contamination during handling and processing.

Issue: Are organic products free of GMO contaminants?

Reply: Organic standards are process based. The NOP regulations prohibit the use of genetically modified organisms, prohibit commingling or contamination during processing and handling, and require preventative practices to avoid contact with GMOs. Organic agricultural products should have minimal if any GMO contaminants; however, organic food products do not have a zero tolerance for the presence of GMO material.

Issue: Has a tolerance level (e.g. 5%) been established for the presence of GMOs in organic agricultural products?

Reply: The NOP regulations do not establish GMO tolerance levels. The NOP regulations establish a tolerance for the presence of pesticides registered by the U.S. Environmental Protection Agency (EPA) that is set at 5% of the EPA tolerance level for the specific residue detected. No federal agency, including EPA or USDA has established tolerance levels for the inadvertent presence of the products of excluded methods (GMOs).

Issue: Processed foods sold as "organic" must contain at least 95% organic ingredients. Are GMOs allowed in the remaining 5% of ingredients? Likewise, processed foods sold as "made with organic (specified ingredients or food group(s))" must contain at least 70% organic ingredients. Are GMOs allowed in the remaining 30% of ingredients for these products?

Reply: The use of GMOs is prohibited in all ingredients in "organic" and "made with organic (specified ingredients or food groups(s))." There is no provision within the NOP regulations that allows the use of excluded methods (GMOs) in ingredients or processing aids under the "organic" or "made with organic (specified ingredients or food group(s))" label categories.

Organic 101: Can GMOs Be Used in Organic Products?

http://blogs.usda.gov/2013/05/17/organic-101-can-gmos-be-used-in-organic-products/

Posted by Miles McEvoy, National Organic Program Deputy Administrator, on May 17, 2013 at 1:20 PM

This is the thirteenth installment of the Organic 101 series that explores different aspects of the USDA organic regulations.

The use of genetic engineering, or genetically modified organisms (GMOs), is prohibited in organic products. This means an organic farmer can't plant GMO seeds, an organic cow can't eat GMO alfalfa or corn, and an organic soup producer can't use any GMO ingredients. To meet the USDA organic regulations, farmers and processors must show they aren't using GMOs and that they are protecting their products from contact with prohibited substances, such as GMOs, from farm to table.

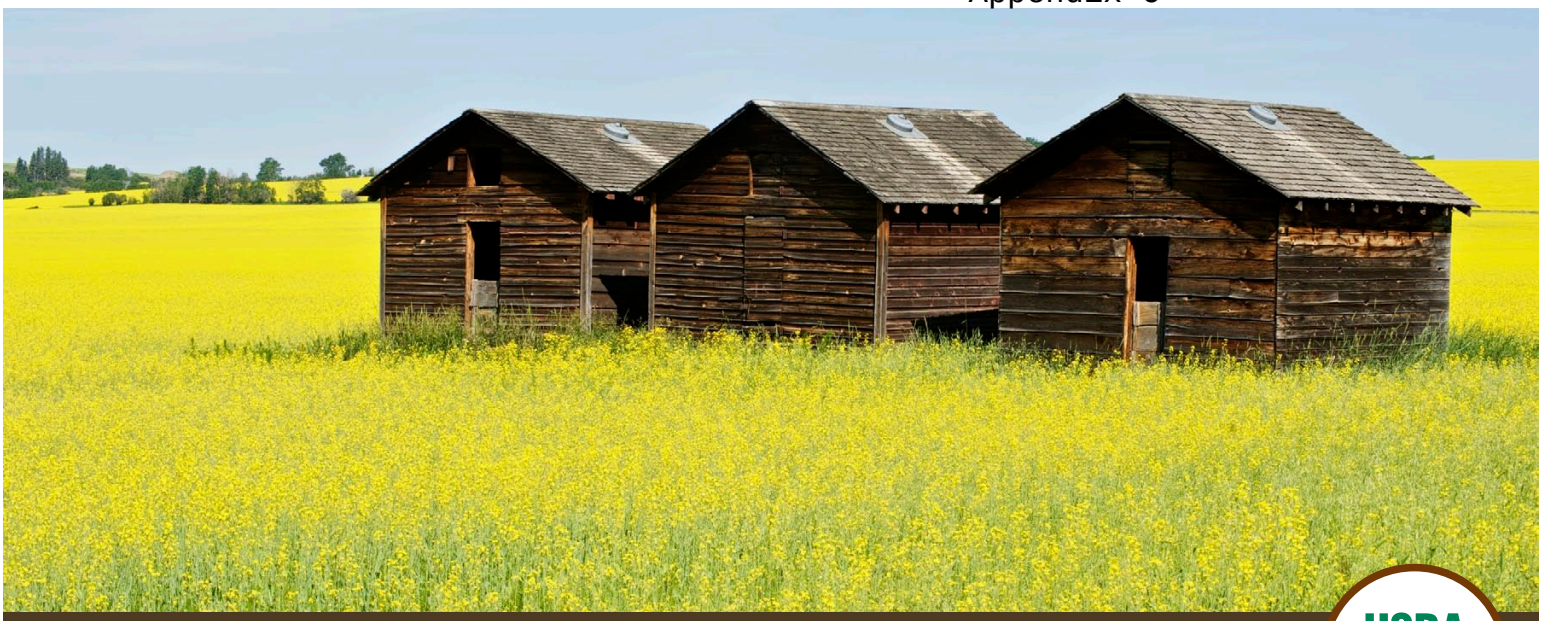
Organic operations implement preventive practices based on site-specific risk factors, such as neighboring conventional farms or shared farm equipment or processing facilities. For example, some farmers plant their seeds early or late to avoid organic and GMO crops flowering at the same time (which can cause cross-pollination). Others harvest crops prior to flowering or sign cooperative agreements with neighboring farms to avoid planting GMO crops next to organic ones. Farmers also designate the edges of their land as a buffer zone where the land is managed organically, but the crops aren't sold as organic. Any shared farm or processing equipment must be thoroughly cleaned to prevent unintended exposure to GMOs or prohibited substances.

All of these measures are documented in the organic farmer's organic system plan. This written plan describes the substances and practices to be used, including physical barriers to prevent contact of organic crops with prohibited substances or the products of "excluded methods" such as GMOs. On-site inspections and records verify that farmers are following their organic system plan. Additionally, certifying agents conduct residue testing to determine if these preventive practices are adequate to avoid contact with substances such as prohibited pesticides, antibiotics, and GMOs.

Any certified organic operation found to use prohibited substances or GMOs may face enforcement actions, including loss of certification and financial penalties. However, unlike many pesticides, there aren't specific tolerance levels in the USDA organic regulations for GMOs. As such, National Organic Program policy states that trace amounts of GMOs don't automatically mean the farm is in violation of the USDA organic regulations. In these cases, the certifying agent will investigate how the inadvertent presence occurred and recommend how it can be better prevented in the future. For example, they may require a larger buffer zone or more thorough cleaning of a shared grain mill.

USDA supports all methods of agriculture production, including organic, conventional, and biotechnology. To help these different methods coexist better, USDA has convened an Advisory Committee on Biotechnology and 21st Century Agriculture ("AC21"). Organic stakeholders are well-represented on AC21. Recent recommendations from the Advisory Committee are currently being implemented by USDA agencies.

Consumers purchase organic products expecting that they maintain their organic integrity from farm to market, and USDA is committed to meeting these expectations. No matter where it was grown, if a product has the USDA Organic label on it, it wasn't produced with GMOs.



CAN GMOS BE USED IN ORGANIC PRODUCTS?

The use of genetic engineering, or genetically modified organisms (GMOs), is prohibited in organic products. This means an organic farmer can't plant GMO seeds, an organic cow can't eat GMO alfalfa or corn, and an organic soup producer can't use any GMO ingredients.

To meet the USDA organic regulations, farmers and processors must show they aren't using GMOs and that they are protecting their products from contact with prohibited substances from farm to table.

PREVENTION PRACTICES

Organic operations implement preventive practices based on site-specific risk factors, such as neighboring conventional farms or shared farm equipment or processing facilities. For example, farmers:

- Plant their seeds early or late to avoid organic and GMO crops flowering at the same time (which can lead to cross-pollination).
- Harvest crops prior to flowering or sign cooperative agreements with neighboring farms to avoid planting GMO crops next to organic ones.
- Designate the edges of their land as a buffer zone where the land is managed organically, but the crops aren't sold as organic.
- Thoroughly clean any shared farm or processing equipment to prevent unintended exposure to GMOs or prohibited substances.

All of these measures are documented in the organic farmer's organic system plan. This written plan describes the substances and practices to be used, including physical barriers to prevent contact of organic crops with prohibited substances or the products of "excluded methods" such as GMOs.

OVERSIGHT

On-site inspections and records verify that farmers are following their organic system plan.

Additionally, certifying agents conduct residue testing to determine if these preventive practices are adequate to avoid contact with substances such as prohibited pesticides, antibiotics, and GMOs.

Any certified organic operation found to use prohibited substances or GMOs may face enforcement actions, including loss of certification and financial penalties. However, unlike many pesticides, there aren't specific tolerance levels in the USDA organic regulations for GMOs.

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For example, they may require a larger buffer zone or more thorough cleaning of a shared grain mill.

CAN GMOS BE USED IN ORGANIC PRODUCTS (continued)?

Can you show me an example of how this would work?

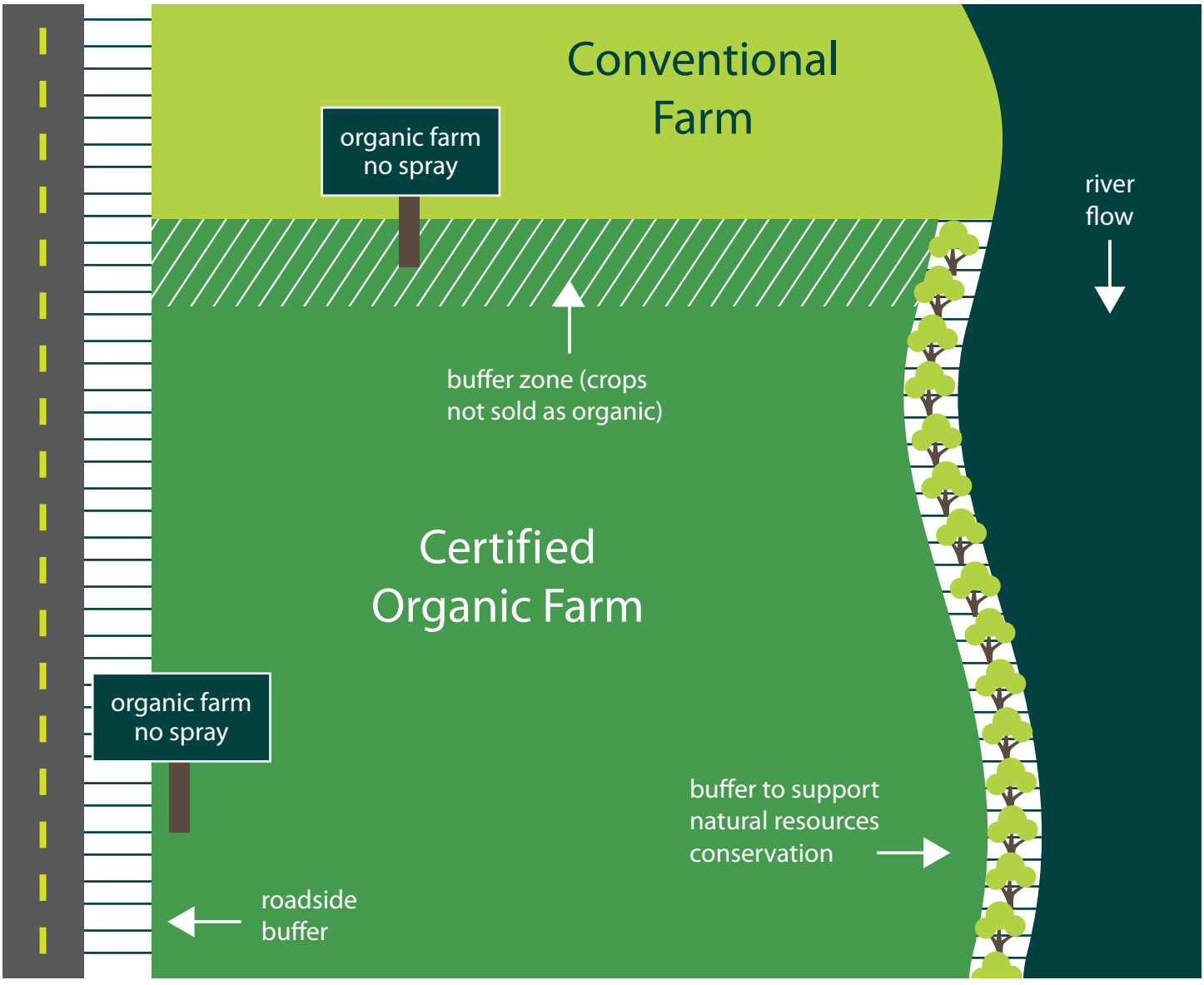
In the sketch below, the organic farmer has set up several buffer zones to protect the integrity of her organic crops from GMOs. Where her farm borders the conventional farm, she has set aside an area which she will farm organically (for example, she won't apply prohibited pesticides), but she won't sell that land's crops as organic.

She has also posted "no spray" signs on the borders of her property and has another buffer zone on the left side to protect her farm from unintended substances from the local road. A final buffer zone on the right side of her property includes a row of trees to reduce erosion and protect runoff into the bordering river.

How is USDA working to further address this topic?

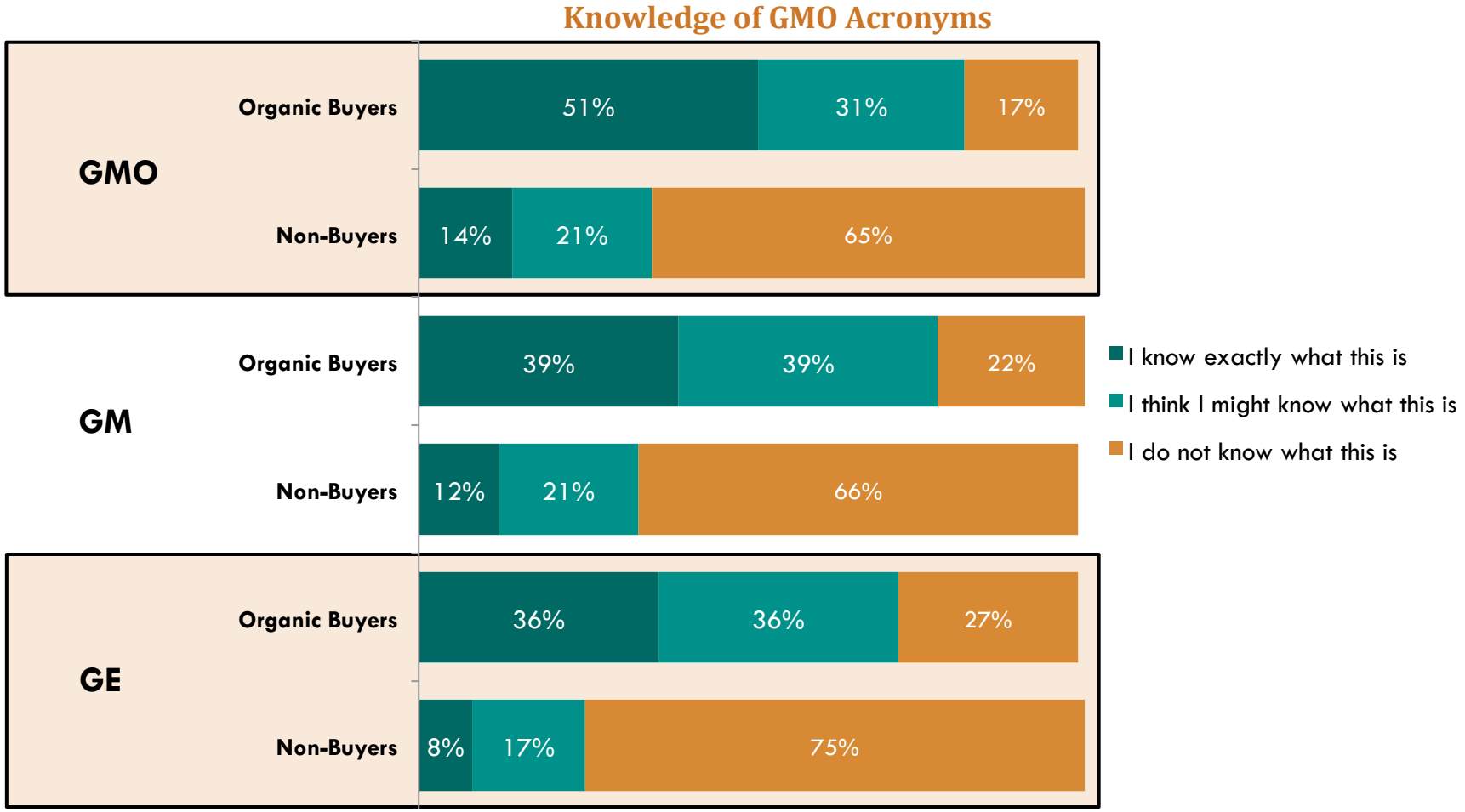
USDA supports all methods of agriculture production, including organic, conventional, and biotechnology. To help these different methods coexist better, USDA has convened an Advisory Committee on Biotechnology and 21st Century Agriculture ("AC21"). Organic stakeholders are well-represented on AC21.

Consumers purchase organic products expecting that they maintain their organic integrity from farm to market, and USDA is committed to meeting these expectations. No matter where it was grown, if a product has the USDA Organic label on it, it wasn't produced with GMOs.



Knowledge of GMO acronyms

1



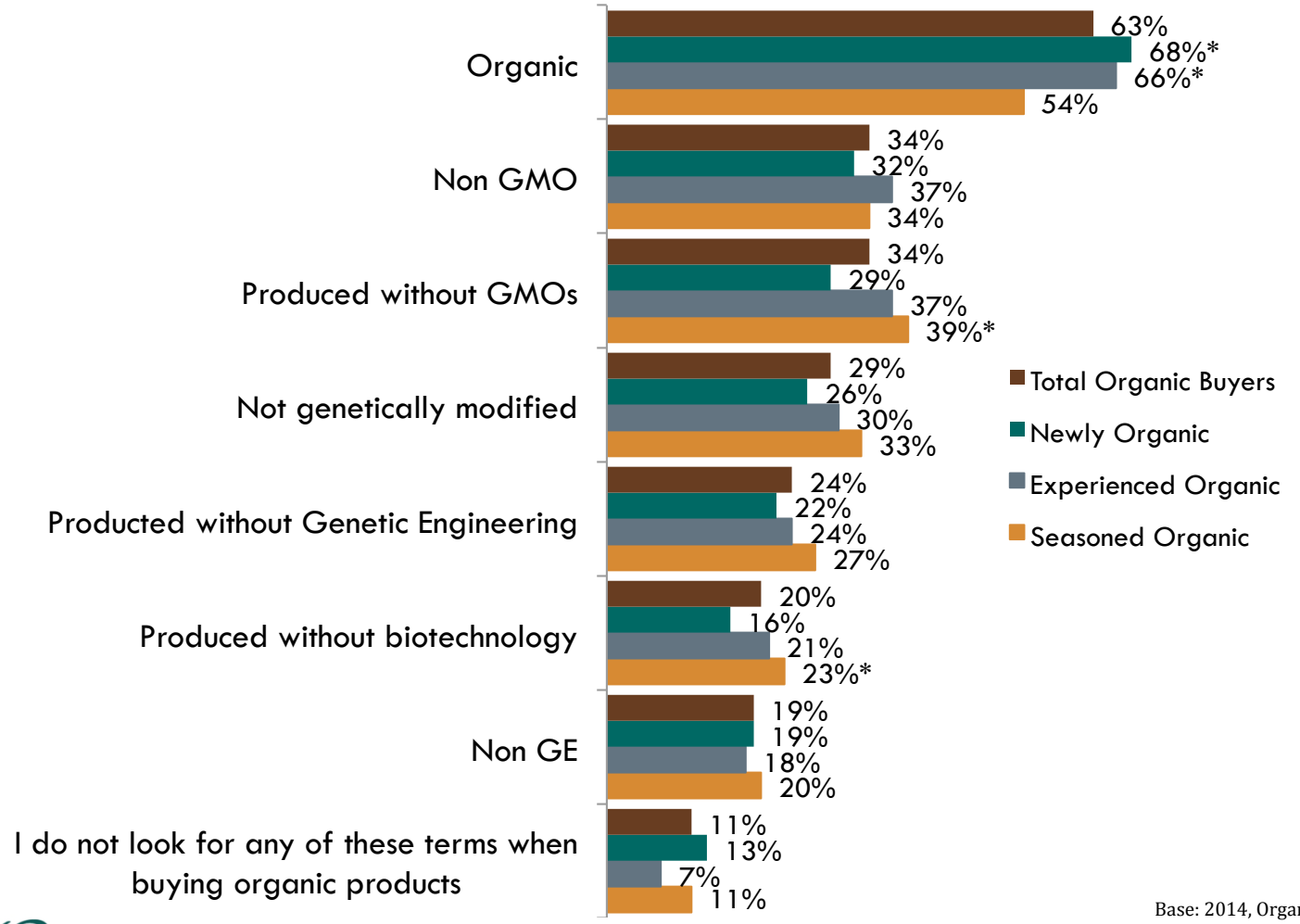
Base: 2014, Organic Buyers vs. Non-Buyers

GNO1: Next, using the scale shown below, please tell us how familiar you are, if at all, with each of the following abbreviations as they relate to foods specifically?

Parents' use of terms when shopping for organic products – *Among Organic Buyer Groups*

2

Parents' use of terms when shopping for organic products



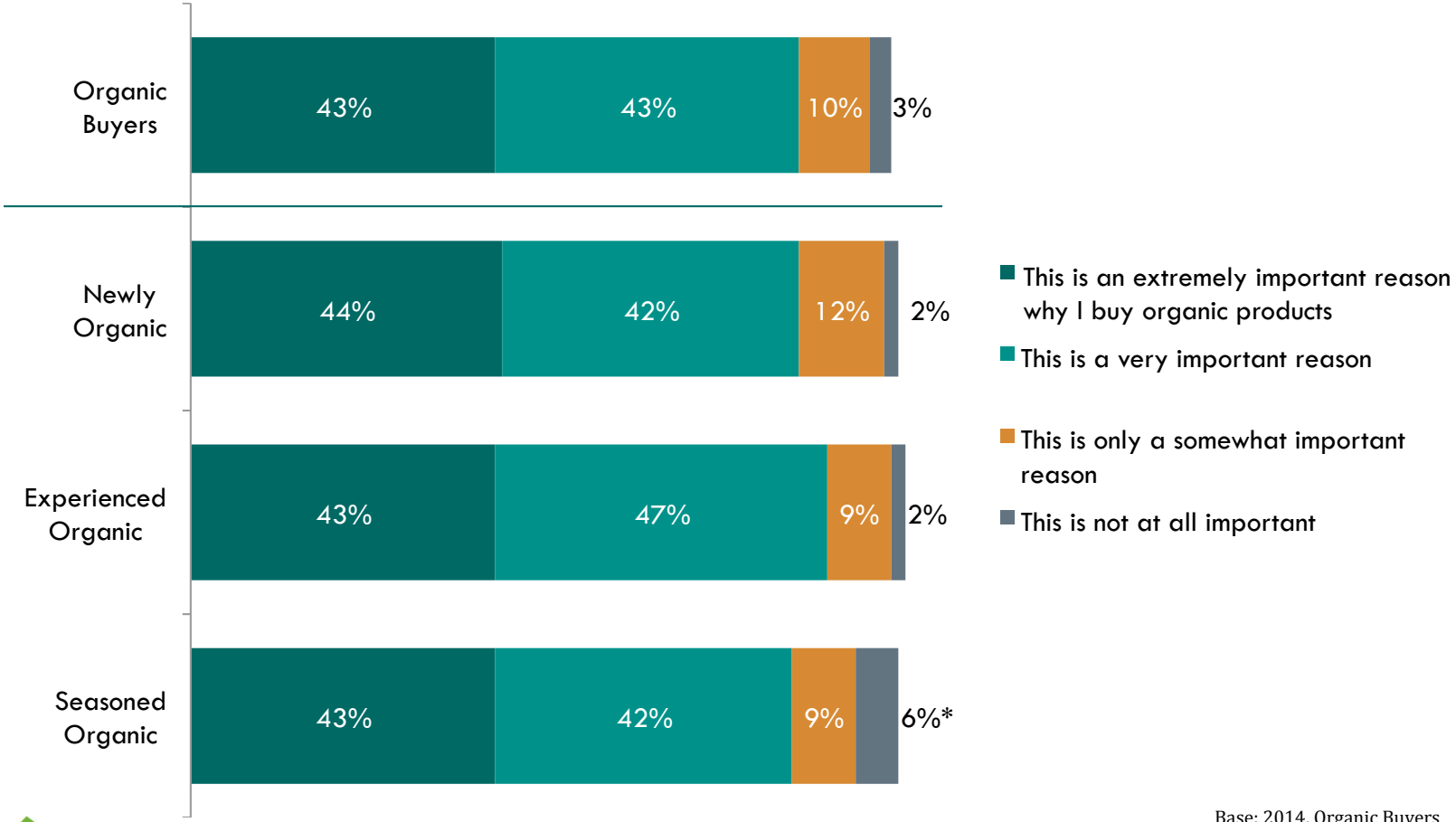
Base: 2014, Organic Buyers

GMO3. When shopping for certified organic products, which of the following terms, if any, do you typically look for on the packaging labels?

Buying organics to avoid GMOs
Among Organic Buyer Groups

3

Buying organic products in order to avoid genetic modification/engineering or bioengineering



Base: 2014, Organic Buyers

GMO2: to what extent, if at all, do you purchase organic products in order to avoid technologies such as genetic modification, genetic engineering or bioengineering?