



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**RE: Draft Guidance for Industry: Voluntary Labeling Indicating Whether Foods Have or Have Not Been Developed Using Bioengineering**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Thank you for the opportunity to provide comments on the Food and Drug Administration's ("FDA") Draft Guidance for Industry on "Voluntary Labeling Indicating Whether Foods Have or Have Not Been Developed Using Bioengineering" ("Draft Guidance").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<sup>1</sup>, parents were asked to characterize their knowledge of a set of acronyms used to refer to genetically engineered foods. This study revealed a higher

<sup>1</sup> 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.**

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**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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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-G: 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

Appendix G: Most important benefits among organic buyers



United States Department of Agriculture  
Agricultural Marketing Service  
National Organic Program

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

Policy Memo 11-13

## Policy Memorandum

**To:** Stakeholders and interested parties

**From:** Miles McEvoy, Deputy Administrator

A blue ink signature of the name "Miles McEvoy".

**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.



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**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



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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.



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**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 21<sup>st</sup> 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.

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.

# CAN GMOS BE USED IN ORGANIC PRODUCTS (continued)?

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

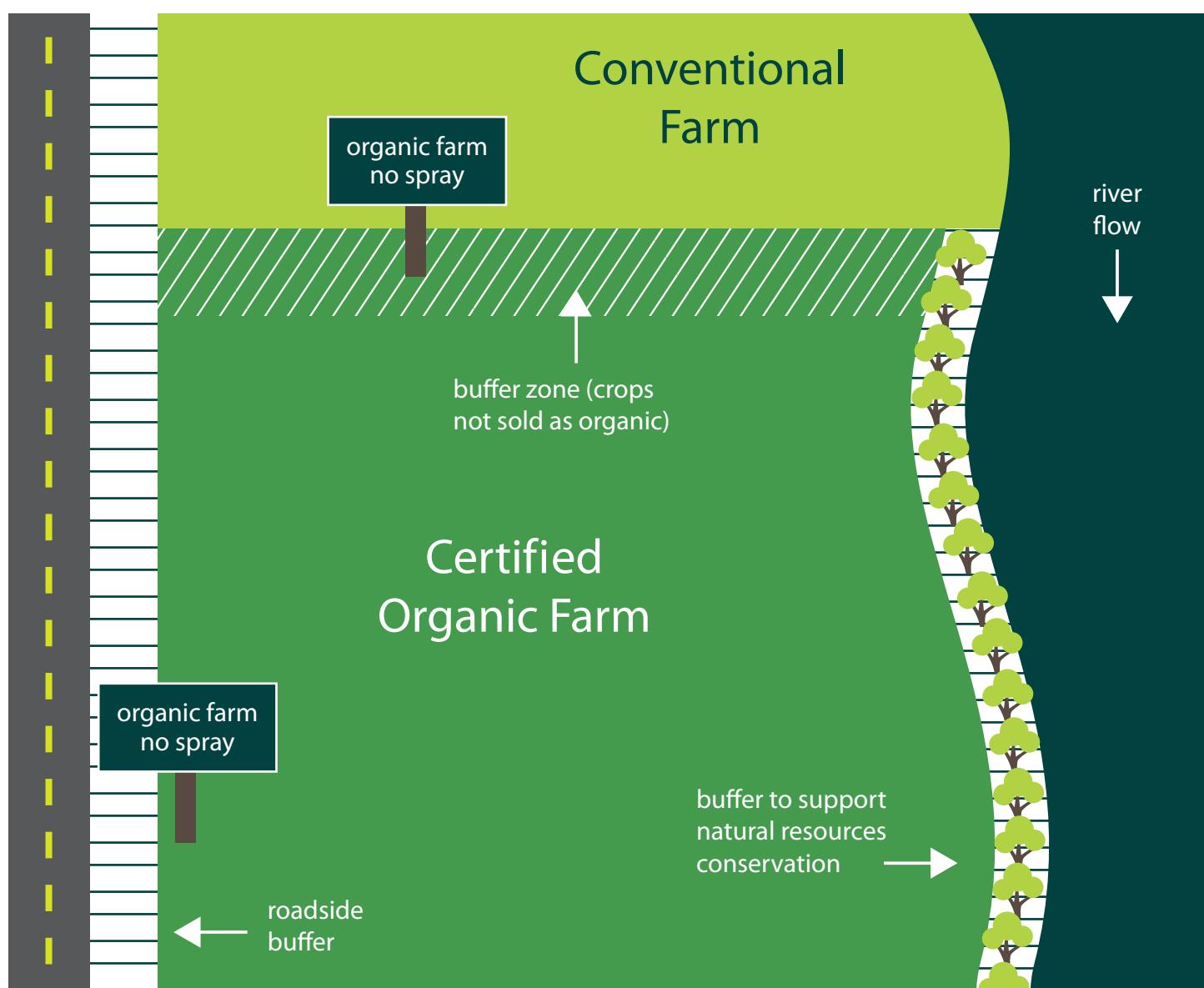
In the sketch below, the organic farmer has set up several buffer zones to protect the integrity of her organic crops from GMOs. Where her farm borders the conventional farm, she has set aside an area which she will farm organically (for example, she won't apply prohibited pesticides), but she won't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

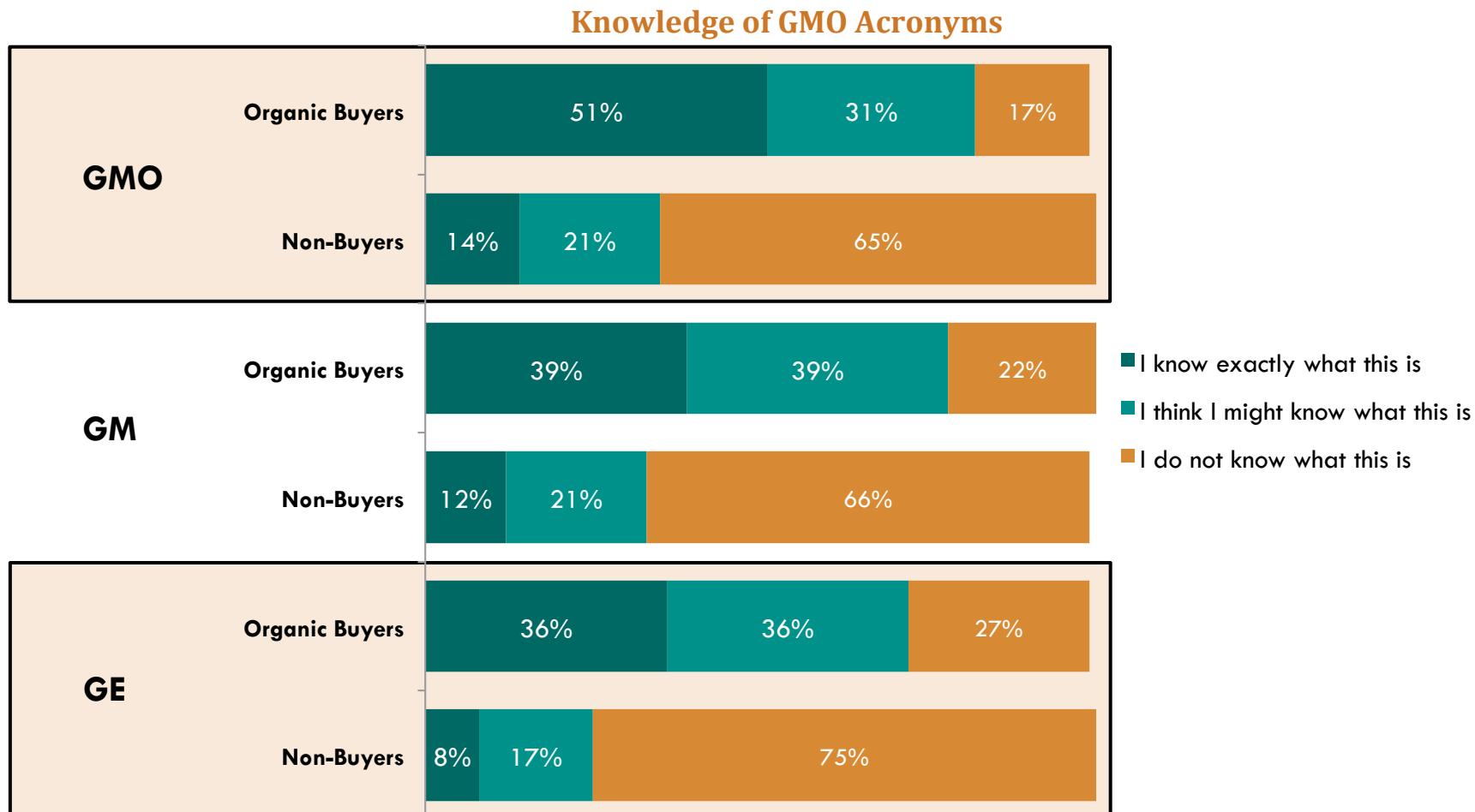
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Consumers purchase organic products expecting that they maintain their organic integrity from farm to market, and USDA is committed to meeting these expectations. No matter where it was grown, if a product has the USDA Organic label on it, it wasn't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



# Knowledge of GMO acronyms

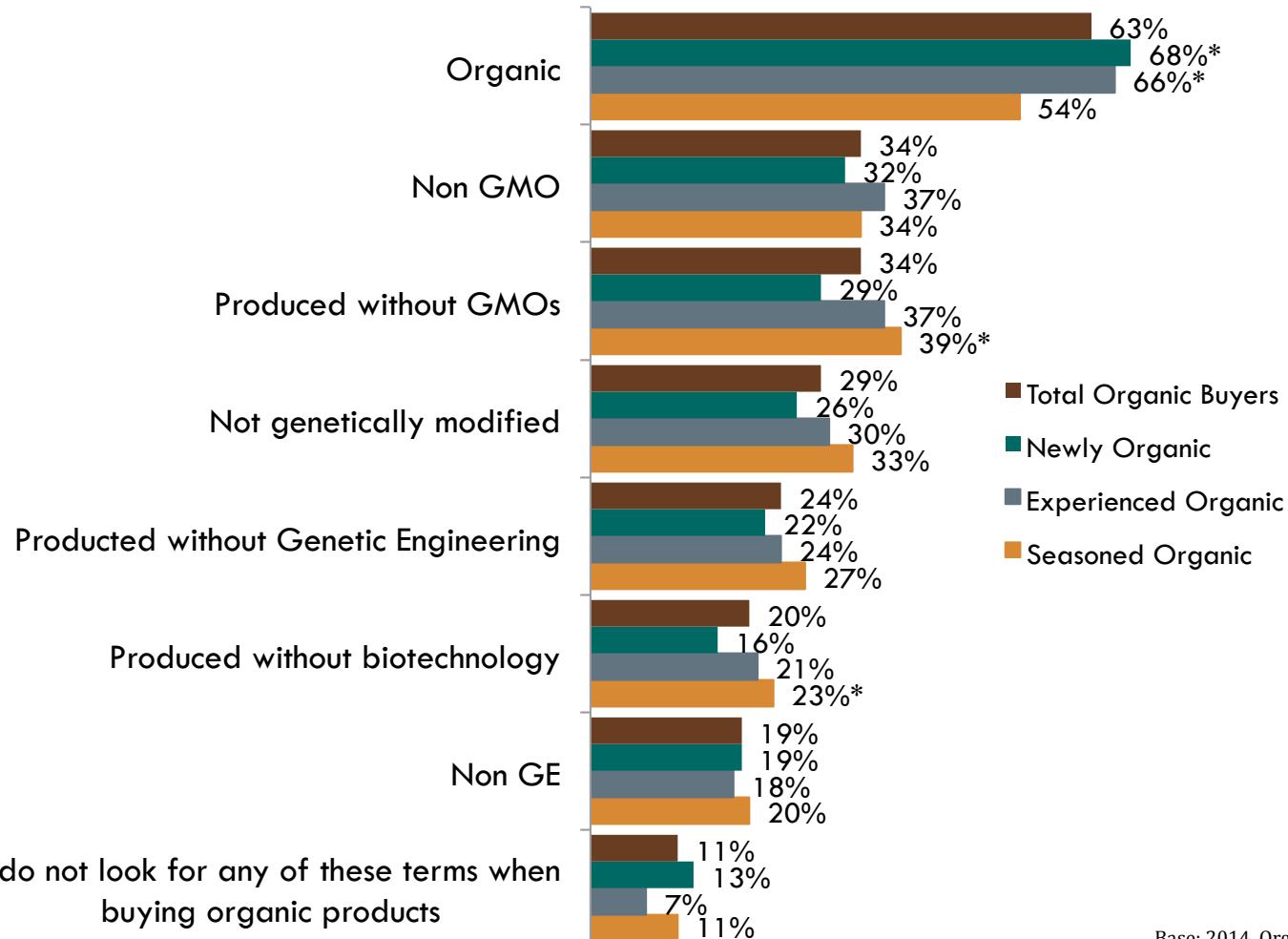
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# Parents' use of terms when shopping for organic products – *Among Organic Buyer Groups*

2

Parents' use of terms when shopping for organic products



Base: 2014, Organic Buyers

# Buying organics to avoid GMOs

## *Among Organic Buyer Groups*

3

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

