

Formal Recommendation
From: National Organic Standards Board (NOSB)
To: the National Organic Program (NOP)

Date: October 29, 2015

Subject: Prevention Strategy Guidance for Excluded Methods proposal

NOSB Chair: Jean Richardson

The NOSB hereby recommends to the NOP the following:

Rulemaking Action:

Guidance Statement: X

Other:

Statement of the Recommendation:

In response to a memorandum from the National Organic Program, regarding best management practices for prevention of unintended GMO presence, the NOSB prepared the following proposal and recommendations.

NOSB Vote:

Motion to accept the Prevention Strategy Guidance for Excluded Methods

Motion by: Francis Thicke

Seconded by: Zea Sonnabend

Yes: 13 No: 0 Abstain: 1 Absent: 0 Recuse: 0

Outcome: Motion passed

National Organic Standards Board
Materials Subcommittee
Proposal: Prevention Strategy Guidance for Excluded Methods
August 11, 2015

On April 24, 2014, the National Organic Program sent a memorandum to the NOSB titled "Improved Guidance on Preventing GMO Presence in Organic Products." The memorandum asked the NOSB to provide recommendations regarding best management practices for prevention of unintended GMO presence. In response, the Materials Subcommittee prepared the following proposal.

I INTRODUCTION

In an environment where GMOs are widely distributed throughout the food chain, it is imperative that organic producers and handlers have strategies and plans to prevent GMO contamination. A key tenet of "co-existence" is a shared responsibility for the exclusion of the methods and products of genetic engineering. The organic part of this shared responsibility is practiced extensively already, but it would be a stronger point in future policy statements and efforts against GMO contamination of organic products if it were spelled out thoroughly in guidance from the National Organic Program.

Many prevention strategies already exist in the organic and non-GMO community. These sources are being utilized to create a comprehensive set of steps and considerations that organic producers and handlers can use in their own operations and Accredited Certifying Agents (ACAs) can use to verify compliance with the contamination avoidance clause in the rule as it relates to GMOs.

II BACKGROUND

The Organic Foods Production Act (OFPA) of 1990 does not mention biotechnology, genetic engineering or genetically modified organisms, but OFPA prohibits synthetics unless they are on the National List. The first NOP proposed rule (1997) did not prohibit GMOs, resulting in a huge public outcry against GMOs being considered for use in organic production and handling. The proposed rule was withdrawn and the second NOP proposed rule (2000) excluded the use of GMOs 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)

Compliance with the organic Standards requires that operations have verifiable practices in place to avoid contact with GMOs. Since organic certification is process-based, the presence of detectable GMO residues alone does not necessarily constitute a violation of the regulation. The organic Standards make allowances for “Unavoidable residual environmental contamination,” which is defined (§ 205.2) as “Background levels of naturally occurring or synthetic chemicals that are present in the soil or present in organically produced agricultural products that are below established tolerances.”

The NOP relies on organic certifiers and producers to determine preventive practices that most effectively avoid contact with GMOs on an organic operation.

III RELEVANT AREAS OF THE RULE AND NOP GUIDANCE/POLICY

Rule 7 CFR

§205.105 Allowed and prohibited substances, methods, and ingredients in organic production and handling.

To be sold or labeled as “100 percent organic,” “organic,” or “made with organic (specified ingredients or food group(s)),” the product must be produced and handled without the use of:

(e) Excluded methods, except for vaccines: *Provided*, that, the vaccines are approved in accordance with §205.600(a);

§205.201 Organic production and handling system plan.

(a)...An organic production or handling system plan must include:

(3) A description of the monitoring practices and procedures to be performed and maintained, including the frequency with which they will be performed, to verify that the plan is effectively implemented;

(5) A description of the management practices and physical barriers established to prevent commingling of organic and nonorganic products on a split operation and to prevent contact of organic production and handling operations and products with prohibited substances;

(6) Additional information deemed necessary by the certifying agent to evaluate compliance with the regulations.

§205.272 Commingling and contact with prohibited substance prevention practice standard.

(a) The handler of an organic handling operation must implement measures necessary to prevent the commingling of organic and nonorganic products and protect organic products from contact with prohibited substances.

(b) The following are prohibited for use in the handling of any organically produced agricultural product or ingredient labeled in accordance with subpart D of this part:

(1) Packaging materials, and storage containers, or bins that contain a synthetic fungicide, preservative, or fumigant;

(2) The use or reuse of any bag or container that has been in contact with any substance in such a manner as to compromise the organic integrity of any organically produced product or ingredient placed in those containers, unless such reusable bag or container has been thoroughly cleaned and poses no risk of contact of the organically produced product or ingredient with the substance used.

§205.600 Evaluation criteria for allowed and prohibited substances, methods, and ingredients.

(a) Synthetic and nonsynthetic substances considered for inclusion on or deletion from the National List of allowed and prohibited substances will be evaluated using the criteria specified in the Act (7 U.S.C. 6517 and 6518).

§205.670 Inspection and testing of agricultural products to be sold or labeled as “100 percent organic,” “organic,” or “made with organic (specified ingredients or food group(s)).”

(a) All agricultural products that are to be sold, labeled, or represented as “100 percent organic,” “organic,” or “made with organic (specified ingredients or food group(s))” must be made accessible by certified organic production or handling operations for examination by the Administrator, the applicable State organic program's governing State official, or the certifying agent.

(b) The Administrator, applicable State organic program's governing State official, or the certifying agent may require pre-harvest or postharvest testing of any agricultural input used or agricultural product to be sold, labeled, or represented as “100 percent organic,” “organic,” or “made with organic (specified ingredients or food group(s))” when there is reason to believe that the agricultural input or product has come into contact with a prohibited substance or has been produced using excluded methods. Samples may include the collection and testing of soil; water; waste; seeds; plant tissue; and plant, animal, and processed products samples. Such tests must be conducted by the applicable State organic program's governing State official or the certifying agent at the official's or certifying agent's own expense.

(c) A certifying agent must conduct periodic residue testing of agricultural products to be sold, labeled, or represented as “100 percent organic,” “organic,” or “made with organic (specified ingredients or food group(s)).” Samples may include the collection and testing of soil; water; waste; seeds; plant tissue; and plant, animal, and processed products samples. Such tests must be conducted by the certifying agent at the certifying agent's own expense.

(d) A certifying agent must, on an annual basis, sample and test from a minimum of five percent of the operations it certifies, rounded to the nearest whole number. A certifying agent that certifies fewer than thirty operations on an annual basis must sample and test from at least one operation annually. Tests conducted under paragraphs (b) and (c) of this section will apply to the minimum percentage of operations.

NOP Guidance

- NOP 5025 Commingling and Contamination Prevention in Organic Production and Handling (Effective date: 7/22/2011)

NOP Policy Memo

- Policy Memo 11-13 Genetically modified organisms (Issue date: 4/15/11)

NOP Fact Sheets

- Can GMOs be used in Organic Products? (Published May 2013)

IV DISCUSSION

Education is needed for organic farmers and handlers and their employees on the specific opportunities for cross contamination in their operations and regions. Education could be provided through extension services, webinars, self-assessment tools, etc. Part of the best management for every organic operation is to stay informed on GMO issues and the best management practices.

Organic System Plan (OSP)

Production and handling operations should identify and address their GMO prevention strategies and organic control points in their OSP. The producer and handler's OSP should include a description of management practices established to prevent contact of organic crops and products with GMOs, and a

description of the monitoring practices performed to verify that such measures are effectively implemented.

Certifying agents should evaluate the preventive practices to determine if they are adequate to avoid contact with GMOs. The preventive practices described in the OSP should be based on information collected through an “at-risk” assessment of crops/products and possible sources of GMO contact. The inclusion of this information should be consistent with other guidance documents NOP has released to industry and Accredited Certifying Agencies (ACAs).

Best Management Practices

Because GMOs are widely used in conventional food and feed systems, they are nearly ubiquitous in our environment, and there are many potential opportunities for GMOs to contaminate organic food and feed. The following is a summary of management practices recommended to help prevent GMO contamination, drawn from the references listed at the end of this document, public comment on the draft discussion document on this subject put forward for spring 2015, and other sources.

Best Management Practices for seed and crop production

- Assess farm site and crops to be grown for potential sources of contamination.
- Identify at-risk crops¹ and potential points of contamination for each, including knowing what GMO crops are expected to be grown in the area.
- Communicate with neighboring farmers about what at-risk crops you will grow, if they will grow GMO varieties of those crops, and what might be done to help reduce the GMO contamination potential on your farm.
- Be certain that non-organic seeds that are used come with non-GMO verification from seed supplier.
- Seed growers and seed companies supplying organic seed to the organic community should follow protocols designed to intercept GE-contaminants and to deal with potential sources of contamination.
- Test at-risk seed, or get verification of clean seed from supplier, before planting.
- Avoid using bee pollinators that have been used in proximity to GMO fields and determine if neighboring feral hives exist that could carry GMO pollen to your farm.

- Know the life cycles of crops being planted, if the crops are self- or cross-pollinating, if the pollen is transported by wind or insects, etc.
- Isolate at-risk organic crops from GMO crops with suitable distances and/or planting timing, conferring with neighbors as needed.
- Control plants that could contaminate your crops, including volunteers, feral populations and wild relatives in proximity to your fields.
- Verify that all inputs, such as fertility and pest control materials, are non-GMO.
- Clean all equipment and facilities prior to use.
- Document equipment cleanout and keep records of all practices used to limit contamination.
- Inspect and clean storage facilities and be sure they are isolated from GMO storage.
- Avoid mixing during harvest, cleaning, storage, transport and sales.
- Be aware that GMO-laden dust from neighboring fields may require more thorough cleaning and

¹ High risk crops include alfalfa, canola, corn, cotton, soy, sugar beets, zucchini and yellow summer squash.

protection of organic products than just removing GMO seeds from equipment.

- Know the organic regulations for excluding GMOs and know your certifier's requirements
- Know your buyers' GMO requirements and testing protocols.
- Utilize "Identity Preservation" systems as part of quality control system.
- Transportation: Clean and inspect trucks and trailers (including tarps and trailer covers). Require and keep verification records/affidavits. Know where product is coming from and where it is going, and ensure that transportation is clean and that records to support clean transportation are available from farm to buyer.

Best Management Practices for livestock

- Assess farm site and facilities for potential sources of contamination.
- Maintain separate, isolated facilities for feed storage of organic and GMO feeds (if a split operation).
- Inspect and clean storage facilities before use.
- Receiving practices: quarantine incoming product and do not release until all supporting non-GMO paperwork and labels are reviewed. Make sure the product received is the product approved in the OSP. Check lot numbers. Non-GMO documentation must be collected and maintained on-file.
- Thoroughly clean and purge feed processing and handling equipment if used for GMO products.
- Document and maintain records of cleanout of equipment and facilities used for GMO products.
- Utilize "Identity Preservation" systems as part of quality control system.
- Transportation: Clean and inspect trucks and trailers (including tarps and trailer covers). Require and keep verification records/affidavits. Know where product is coming from and where it is going, and ensure that transportation is clean and that records to support clean transportation are available from farm to buyer.

Best Management Practices for handling

- Assess the site, facilities and organic products/inputs for possible sources of GMO contact.
- Receiving practices: quarantine incoming product and do not release until all supporting non-GMO paperwork and labels are reviewed. Make sure the product received is the product approved in the OSP. Check lot numbers. Non-GMO documentation must be collected and maintained on-file.
- All inputs must be traceable and must be of non-GMO source, even the nonorganic inputs contained in "made with organic" products.
- Organic and non-GMO materials must be strictly segregated from any GMO materials.
- Equipment must be thoroughly cleaned and purged if used for processing and handling GMO materials.
- Know which ingredients pose a GMO-contamination risk and what, if any, contamination levels are present in them.
- Determine minimum thresholds of GMO contamination for rejecting inputs in at-risk inputs.
- Create quality assurance and quality control procedures and practices for traceability, segregation, sampling and testing lots of inputs for GMO content, with adequate training of personnel to assure routine adherence to those procedures and practices.
- Utilize "Identity Preservation" systems as part of quality control system.
- Transportation: Clean and inspect trucks and trailers (including tarps and trailer covers). Require and keep verification records/affidavits. Know where product is coming from and where it is going, and ensure that transportation is clean and that records to support clean transportation

are available from farm to buyer.

The Role of ACAs and Oversight

- On-site inspections (observation), review of the OSP and records, and periodic testing verify that farmers and handlers are following their organic system plan and that the measures described are effective.
- Role of testing (by ACAs) as a tool for verifying adequate contact prevention measures
 - Certifying agents may conduct residue testing to determine if these preventive practices are adequate to avoid contact with substances such as prohibited pesticides, antibiotics, and GMOs
 - If GMOs are suspected or detected, certifiers must conduct an investigation to determine if a violation of organic farming or processing standards occurred.
 - Note: Certifiers may need additional guidance from NOP on GMO testing (sampling procedures, testing options, choosing labs). Guidance is also needed to address positive results given that there aren't specific threshold levels in the USDA organic regulations. See Appendix A
- Any certified organic operation found to use GMOs may face enforcement actions, including loss of certification and financial penalties.

Subcommittee Vote:

Motion to accept the Prevention Strategy Guidance for Excluded Methods in Crops and Handling Proposal

Motion by: Francis Thicke

Seconded by: Zea Sonnabend

Additional Discussion: none

Yes: 6 No: 0 Abstain: 0 Absent: 1 Recuse: 0

Sources/References

Riddle, Jim 2012. *GMO Contamination Prevention - What Does it Take?* University of Minnesota Southwest Research and Outreach Center.

OSGATA, 2014. *Protecting Organic Seed Integrity*. <http://www.osgata.org/organic-seed-integrity/>

Non-GMO Project Standard, 2013. Non GMO

Project. http://www.nongmoproject.org/?attachment_id=8561

USDA National Organic Program - <http://www.ams.usda.gov/AMSV1.0/nop>

Blue River Hybrids - www.blueriverorgseed.com/docs/PuraMaize-Fact Sheet.pdf

The Organic Center - <http://www.organic-center.org>

USDA/APHIS Biotech Regulatory Services (BRS) - <http://www.aphis.usda.gov/biotechnology/>

Appendix A

Guidance and training for ACAs on GMO testing

On November 9, 2012, NOP published a Final Rule on Periodic Residue Testing. The rule clarifies a provision of the Organic Foods Production Act (OFPA) of 1990 and the regulations issued that require periodic residue testing of organically produced agricultural products by ACAs. NOP received several comments regarding types of residues that would be considered acceptable targets for testing under the rule. Four commenters requested clarification on testing for GMOs.

NOP responded by saying that it does not intend for the testing conducted under section 205.670 to be limited to pesticides residues. Under 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.

Given the regulatory requirements and NOP clarification, ACAs are required to test if there is reason to believe that an organic product has come into contact with GMOs. ACAs may also test for GMOs under the periodic residue testing requirements. To date, however, NOP has not issued any instruction or guidance on GMO testing.

The Materials/GMO Subcommittee could draft a recommendation to NOP to create guidance and provide training to ACAs on conducting GMO sampling and testing under the residue-testing rule. Providing NOP with a recommendation that includes further guidance on testing falls directly under the specific responsibilities outlined in the OFPA starting at section 2119(k):

5. PRODUCT RESIDUE TESTING.—The Board shall advise the Secretary concerning the testing of organically produced agricultural products for residues caused by unavoidable residual environmental contamination.

Although NOP guidance on pesticide residue testing is available and USDA resources for GMO testing in organic feed do exist, further guidance on GMO testing of other crops for human consumption is greatly needed. It is extremely important that guidance offer clear and consistent sampling and testing protocols so ACAs may accurately assess the efficacy of an organic operation's system for ensuring that GMOs do not come in contact with organic product. 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 non-organic GMO crops as well as intentional or unintentional contact with GMOs.

Approved by C. Reuben (Calvin) Walker, Subcommittee Chair, to transmit to NOSB August 25, 2015