National Organic Standards Board
Materials/GMO ad hoc Subcommittee
Report
Seed Purity from GMOs
+February 25, 2014

Introduction

The GMO ad hoc Subcommittee has issued a discussion document on Seed Purity from GMOs over a period of two NOSB meetings that were six months apart. This report summarizes the public comment received from this effort and provides the subcommittee analysis of the situation. The subcommittee has chosen not to submit a proposal at this time.

Organic stakeholders are concerned about keeping genetically modified organisms (GMOs) (i.e., the products of transgenic plant or animal breeding) out of organic livestock feed, crops, and food. The production and handling of organic goods prohibits the use of "excluded methods" including transgenic modification. This prohibition applies to seeds used on organic farms. The organic community continues to be proactive in developing positions, procedures, and practices to prevent GMO contamination. An important part of such prevention is ensuring genetic purity of seed used on organic farms. Pure seed is a cornerstone of true sustainability in an organic farming system.

Policy Memo 11-13 from the National Organic Program (NOP) affirms that organic certification is process based. Part of that process is implementing measures to prevent and exclude GMOs. In order to determine that these preventative practices are adequate to avoid contamination with prohibited substances or excluded methods, there may be a role for seed purity testing, similar to the role for residue testing.

In the Discussion Document the suggested standard would be based on presence or absence of GE content in a specified seed sample size (e.g. 3000 seeds). The use of terms like "non-detect" or "none found in the sample" is less confusing than the statistical expression summarizing what "none found" in a sample means relative to the level of certainty that the whole lot is not contaminated.

The public comments to National Organic Standards Board (NOSB) and NOP continue to indicate a strong concern by both producers and consumers of organic foods for stronger steps to limit the potential and/or unintended presence of GMOs. Seed may be the most impactful and efficient point in the supply chain at which GMO contamination of organic feed, crops, and food could be limited and controlled.

The conclusion of the GMO ad hoc Subcommittee is that a seed purity standard can be consistent with a process-based standard when analytical limits[1] are used to verify that adequate measures are in place to prevent contamination with excluded methods. This would also be consistent with the residue testing program under NOP.

The challenges of doing this and the valid issues raised by the public are examined here.

[1] Using analytical limits means that the sample size is specified in which no contamination is found, as opposed to stating a percentage of contaminated seed. The "analytical limit" approach is appropriate for two reasons: (1) No contamination is acceptable to the organic community, and (2) the only way to specify a zero contamination level is statistically, through specifying the sample size in which no contamination is found.

Background

• The NOP Organic Rule refers to Genetic Engineering (GE) as an "excluded method". “Organic” is a label that indicates that a process has been followed to exclude GMOs.

• Producing organic feed, crops, and food uncontaminated by GMOs requires starting with seed that is not contaminated by GMOs.

• Public and marketplace expectations for the absence of GMOs in organic goods call for implementing best practices on conventional and organic farms to minimize the potential for such contamination.

• We suggest that the process for ensuring genetic purity of commercial seeds in organic production must be stricter than conventional crop production. Clean seed must be planted for the farmer to harvest uncontaminated food or feed. Planting and harvesting contaminated seed can increase the likelihood of “creeping contamination” from year to year, since any additional GE contamination in seed handling or pollen drift into a field planted with partially contaminated seed would produce food, crops, or feed with a higher level of contamination than in the original seed.

• This strict process must protect organic seed growers in order to protect seed purity.

• In spite of conventional agriculture's discomfort with the reference to "contamination" from genetically altered DNA in organics (such as on page 4 of the public comment from the American Seed Trade Association from Sept. 2012[2]), the entire organic community considers GMO movement outside of the areas that they are grown in to be pollution. Therefore the encroachment into organic seed and crops is considered to be contamination of organic crops, and that is the vernacular used in this report.

• For the past two years since Genetic Engineering has been addressed in discussion by the NOSB, we have received many[3] public comments from consumers and farmers alike that organic means no GMOs, and maximum effort must be taken to keep them out of organic food.

• The public comment process on the Discussion Document raised several fundamental concerns about adopting a Seed Purity Standard. These are discussed below. The subcommittee analysis and discussion around these concerns is addressed in separate sections.

Relevant areas in the Rule

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[2] Andrew LaVigne, commenting on behalf of the American Seed Trade Association (ASTA) to Docket AMS-NOP-12-0040, Sept. 2012.

[3] Ninety-three comments pertaining to the April 2011 NOSB meeting on the Regulations.gov website mentioned GE, despite the fact that nothing on the agenda addressed genetically modified organisms. In addition, eight people used at least part of their precious three minutes of comment time to address GE. The comments came from a variety of viewpoints and reflected a wide range of concerns.
Fourteen comments were received on seed purity discussion paper in October 2012.
Sixteen commenters submitted comments on the seed purity discussion paper in April 2013. Ten of these were commenters who did not submit comments in October 2012. In addition to comments specifically addressing agenda issues, 85 comments expressed general concern about GE contamination of organic crops and products. 216 comments were received in the Fall of 2013, when no agenda item addressed GE.
The largest outpouring of public comments was close to 300,000 comments opposed to GMOs (along with irradiation and sewage sludge) in organic production in the original proposed rule in 1998.

NOP standards[4] adopted by USDA in a final rule published in December 2000 and fully implemented in October 2002 prohibited the use of GMOs in the production and handling of organic products certified to national organic standards.

The terminology used for GMOs in the NOP Regulation is "excluded methods" and is specified under section 205.2 (Terms Defined) as:

> **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). Excluded methods do not include the use of traditional breeding, conjugation, fermentation, hybridization, *in vitro* fertilization, or tissue culture.
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> **Detection and Testing Requirements:** Under the residue testing requirements of NOP, products from certified organic operations may require testing when there is reason to believe that certified products have come into contact with prohibited substances or have been produced using excluded methods.

This requirement is specified in Subpart G (Administrative) of the regulations:
§ 205.670 Inspection and testing of agricultural product to be sold or labeled "organic."
(b) The Administrator, applicable State organic program's governing State official, or the certifying agent may require pre-harvest or post-harvest 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. 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.

NOP Policy: The NOP finalized a Policy Memo on July 22, 2011 (Policy Memo 11-13) on GMO. This policy memo reiterates that the use of GMOs is prohibited under NOP regulations, and answers questions that have been raised concerning GMOs, organic production, and handling. The clarification provided is consistent with the explanations provided in the preamble, thus emphasizing that organic certification is a process-based standard and the presence of detectable GMO presence alone does not necessarily constitute a violation of the regulation.

Commercial Availability of Organic Seed: The NOP regulations at 7 CFR § 205.204 require that organic producers use organic seeds, annual seedlings, and planting stock. The regulations allow producers to utilize non-organic seeds and annual or perennial planting stock when organic varieties are not commercially available.

The term "commercial availability" is defined under section 205.2 (Terms Defined) as:
The ability to obtain a production input in an appropriate form, quality, or quantity to fulfill an essential function in a system of organic production or handling, as determined by the certifying agent in the course of reviewing the organic plan.

[4] Title 7 CFR Part 205 - National Organic Program

Discussion of Public Comments & Subcommittee Evaluation

This section summarizes the comments from the public and then reports on the GMO subcommittee's thinking for each point raised. Quotes were taken from selected comments that illustrate each point, but not every commenter is quoted separately.

The large majority of public commenters wants to keep GMOs out of the organic system and is in favor of a proposal to address seed purity. Among the commenters from affected parties (farmers, seed companies, trade associations, certifiers), the majority were in favor and felt they could meet such a standard with enough time. The primary areas of concern among organic industry stakeholders about the example seed purity standard that was described in the Discussion Document are the following:

- Inconsistent with the "process" standard
- Not enough data about testing protocols and thresholds for rejection
- Not ready to implement because source material is unavailable
- Expensive for organic farmers, especially organic small-scale farmers
- Seed availability decreased, especially organic seed
- Policy must distinguish between organic and conventional seed
- Genetic diversity decreased because of contamination of breeding lines
- Should be the responsibility of the greater USDA to regulate, not just NOP

We will address each point with reference to public comment in particular.

<u>Inconsistent with the "process" standard</u>

Public Comment
"...setting a purity standard can be consistent with a process-based standard when analytical limits are used to verify that adequate measures are in place to prevent contamination with excluded methods. This can be analogous to the detection of prohibited pesticides. Organic standards prohibit the use of toxic and synthetic pesticides. Analytical testing and rejection levels are used to verify this process- based standard." (Organic Trade Association [OTA] public comment, spring 2013)

Subcommittee Evaluation
The Subcommittee agrees with this position and would like to move toward a recommendation, although there are some hurdles to overcome as discussed below. Any seed purity testing would be an analytical enforcement tool that would be used to supplement an overall seed purity protocol required as part of the organic systems plan that would include documenting seed sources, selection of appropriate field locations, maintaining appropriate buffer zones, and documenting equipment cleaning for both planting and harvest.

<u>Not enough data about testing protocols and thresholds for rejection</u>

Public Comment
The request for company data that was included in the discussion document did not result in enough information to help the subcommittee know what is currently occurring in the marketplace. "USDA should conduct a comprehensive analysis of existing contamination at the seed level." (Organic Seed Association [OSA] public comment, fall 2012) This recommendation coincides with one made in 2012 by the USDA Advisory Committee on Biotechnology and 21st

Century Agriculture ("AC21"). [5] USDA is currently developing implementation plans for the AC21 2012 recommendations.

Subcommittee Evaluation
The subcommittee supports any efforts made by the USDA in collecting relevant information. If good data is not provided through the NOSB public comment process, the NOSB does not have the ability to mandate data collection, only to suggest it to other parts of USDA. Any recommendation would have a significant amount of time for phase-in so that data can be collected and analyzed. We hope that such data will help inform us as to the scope of the problem.

Not ready to implement because source material is unavailable

Public Comment
Several commenters in the seed trade commented on the difficulty of finding breeding lines that are not already contaminated. Often they cannot test their incoming materials due to licensing rules.

Subcommittee Evaluation
We agree that source materials are limited and will become less and less available and contamination worse and worse in the future. Therefore, any proposal that eventually is recommended will certainly require a long lead time for starting a testing scheme and even longer for breeders and researchers to evaluate source materials that can comply. Our goal is to create a thriving organic seed industry for all crops, and we believe that to do this we need better tools to keep GMOs from encroaching into our seed supply and crops.

Expensive for organic farmers, especially organic small-scale farmers

Public Comment
Many stakeholders pointed out that organic farmers already assume the burden of taking many preventive measures to keep GMOs out of their products. Maintaining buffer zones in fields, delayed planting to avoid GMO pollen, cleaning procedures for harvest and seed cleaning equipment and final product testing are a few of such measures.

"The issue of both cost effectiveness and costs of testing escalating to the point of being prohibitive could actually reduce organic acreage or cause certified operators to leave the organic industry altogether." (OFARM public comment, fall 2012) This was a common sentiment expressed by seed companies and farmers and their representatives.

Subcommittee Evaluation
After reading all the public comment and inviting several key stakeholders to the subcommittee calls, the subcommittee discussed how any threshold for GMO contamination of seed would place a significant burden on organic farmers and small seed companies, and such cost burden should be coupled with liability for the GMO patent holders..

The subcommittee is unanimous in believing that the costs of preventing contamination should be borne by the GE seed patent holders. We don't believe that farmers who grow GMO crops

[5] The AC21 recommendation was part of the report, "Enhancing Coexistence." The specific recommendation at page 22 reads, "Conduct research…including…gathering and aggregating, on an ongoing basis, data from seed companies on unintended GE presence in commercial non-GE seed supplies intended for IP uses."

should be held responsible for losses. The patent holders need to be held accountable for the pollution caused by the escape of their genes into organic fields through seeds.

Most of the public comment from direct stakeholders was concerned with cost, timeline for implementation, and logistics of obtaining and maintaining pure source material, but not as much with the reasoning behind needing an analytical tool, or the specifics of a seed sampling size.

Achieving true accountability for the pollution of organic crops from those who cause it is a challenging concept to implement. The Subcommittee acknowledges that this issue goes beyond the scope of the NOSB and the NOP and therefore the usual type of NOSB recommendation cannot be used to reach this goal. We recognize that without larger changes outside the scope of NOP and USDA itself, imposing a seed purity standard on organic producers might be damaging to the overall growth of organic production and use of organic seed.

Nonetheless, three concepts for compensation by outside entities were discussed by the subcommittee, with the acknowledgement that neither the NOSB nor the NOP has the ability to implement any of them alone. Each of these concepts would appear to require Congressional action. These suggestions would only apply to compensation for seed purity testing and compensation when GE contamination is found.

A. CERCLA model - The objective of the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA or Superfund) is to clean up uncontrolled releases of hazardous substances. The name "Superfund" comes from the fact that clean-up activities are financed by a fund originally created by taxes on oil and chemical industries.[6] We discussed applying the Superfund model to compensation for testing for seed purity and contamination.

B. Crop Insurance for polluters - Rather than make organic farmers pay for crop insurance, we would like the patent holders of GMO seed be required to get crop insurance in order to sell the seed. This could be built into the cost of the GMO seed. A portion of this crop insurance fund would be available to pay for the organic farmers and organic seed companies to test seed lots.

C. Government administered compensation - This concept is for the government to use taxpayer money or perhaps money assessed through the patent process and regulatory review of new GMO crops and products. This would make sure that conventional farmers would not bear the burden directly but the patent holders would. We realize that this approach would require Congressional action. However, this would place responsibility on the parties who are responsible for the pollution.

The topic of "GMO contamination insurance" for organic producers was also discussed, along the lines of what was suggested by the AC21 recommendations. Discussion points included whether insurance should be voluntary or mandatory and whether this was a solution for enough people to make pursuing it worthwhile. The majority of the past and present members of the subcommittee felt this approach was untenable because it places the entire burden on

[6] Three dedicated taxes on oil and chemical industries -- on petroleum, chemical feedstock, and corporate income[6]— historically provided the majority of the trust fund's income. Those taxes expired at the end of 1995, however, and the amount of unobligated money in the fund gradually dwindled. Since President Obama has been in office, he has regularly proposed reinstatement of the Superfund taxes. General funds have been used for site cleanup meanwhile.

organic producers and involves no acknowledgement or accountability on the part of the patent holders, or any incentive for them to contain their pollution.

Seed availability decreased, especially organic seed

Public Comment
Commenters expressed that seed availability would certainly decrease if the proposal went into effect soon. Several suggested that a long time frame for the entire organic community to start working towards this as a goal could make this achievable in the future.

Subcommittee Evaluation
Increasing the variety and quantity of organic seed is very important and the NOSB has issued several past recommendations in support of organic seed. Yet, just as trueness-to-type, good viability, and high performance are important traits in seeds for organic systems, so is keeping GMOs out of the seed supply.

We recognize that there are significant challenges to overcome and among them are the needs for data on what seed is already available that can meet the standard, as well as a need for basic research on whether GMO content in breeding lines can be bred out over time to re-gain a wider assortment of germplasm to produce clean organic seed.

An important step would be to create a timeline by which to measure forward progress. We want all stakeholders notified of our intentions to keep working on this topic, and would like continued support from stakeholders on this effort if we are ever able to move forward with a recommendation.

Policy must distinguish between organic and conventional seed

Public Comment
Several commenters called for a distinction in policy between testing of organic seed and testing conventional seed used in organic production. "The organic community needs to aggressively support and increase the use of organic seed, or we risk losing access to many genetic traits and varieties..."(Blue River Hybrids public comment, Fall, 2012)

Subcommittee Evaluation
The NOSB as a whole has issued recommendations to favor the use of organic seeds. Yet we are concerned that preferring contaminated organic seeds over identity-preserved non-GMO conventional seed may not be desirable. We welcome more public comment on how a seed purity standard should address this dilemma, including incentives to favor the use of organic seed. Possibilities to favor organic seed in any future proposal could include a longer timeline for implementation, a less stringent sample size, less frequency of testing based on other preventative practices taken, or other ideas for spurring on the use of organic seed.

Genetic diversity decreased because of contamination of breeding lines

Public Comment
Not only has the seed supply available to organic farmers been contaminated, but the breeding lines and foundation stock used to produce seed have often been contaminated. From the survey of seed companies done by the Organic Seed Alliance came the following information: "....some companies relayed that it’s not uncommon for germplasm licensing agreements to prohibit testing for GE content. This puts companies who want to protect their reputation as a supplier of “clean” seed in a vulnerable position of risking litigation if they decide to test illegally.

Public plant breeders have also relayed similar experiences regarding limited access to germplasm that does not come with restrictions or fears of unintended patent infringement" (OSA public comment, fall 2012). If we do not act soon, the choice of available breeding material that meets any seed purity standard may end up being of poorer genetic quality as a result (OSA public comment, fall 2012).

Subcommittee Evaluation
The subcommittee strongly agrees with this concern and believes it is a vital part of an organic system to encourage genetic diversity. Addressing this issue will take even longer than it may take to bring a standard into existence. Therefore we would suggest a longer period of time for breeding lines and foundation seed, such as the 5 additional years suggested in the Discussion Document, with a variance or waiver to provide yet additional time if found to be necessary. We intend to re-visit this over the time we spend doing further work on this issue, while at the same time putting forward a strong call for research into procuring and maintaining clean breeding materials. We additionally recommend the development of more strategies that the GMO farmer may use to reduce or eliminate contamination from GMO agriculture farm systems.

<u>Should be the responsibility of the greater USDA to regulate, not just NOP</u>

Public Comment
In light of recent events concerning the detection of GMO wheat escaping into a farm field, the lack of regulation and oversight of genetically modified crops has become more and more apparent. Many of our public commenters expressed this quite eloquently.

> "USDA should play an assertive role in safeguarding the private property rights of American organic farmers when it comes to preventing unwanted trespass and genetic drift by GE patent-holders onto organic farms. Organic farmers have a right to farm in the way they choose on their farm without threat of intimidation and transgenic trespass." (Organic Seed Grower and Trade Association [OSGATA] public comment, spring 2013)
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> "A meaningful regulatory framework for GE seed and crops would mandate proven containment measures in the field, from field trials to commercialized production, and strict post-market monitoring and evaluation of their effects on the environment and other production systems and markets, especially organic. The framework would also include routine monitoring of gene flow, and a comprehensive evaluation of the genetic purity of our nation’s foundation seed." (OSA public comment, fall 2012)
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> "Demand that Congress create laws and authorize funds for the USDA to map planting of GE crops and non GE crop contamination, and hold contaminators accountable for cleanup cost and organic farmer losses." (Dietrick Inst. for Applied Insect Ecology public comment, spring 2013)

Subcommittee Evaluation
We echo the points raised by our stakeholders above. Organic producers are already going more than half way to bear the costs of maintaining organic integrity. It is not the conventional farmers who should be penalized for this; it is the patent holders who cannot keep their genes contained and the regulators who have not done enough to enable all farmers to produce crops in the way that they choose. We also recognize that the regulators are hampered by underlying limitations in their authority to act on the concerns of the stakeholders on GMO issues. However change can only happen by speaking out at every opportunity and this report is the ad hoc GMO subcommittee's opportunity to do so.

Conclusions

The GMO ad hoc Subcommittee has concluded that a genetic purity standard is desirable for seed used in organic production systems where there are conventional genetically engineered varieties of that crop. The main reasons why it is desirable are:

- •• It can be a useful tool to verify compliance with the excluded methods process standard, much as residue testing is a tool to verify compliance with other sections of the rule.
- •• The marketplace is increasingly demanding it. As awareness of GMOs grow among consumers because of labeling efforts, the consumers need assurance that organic represents a label from which GMOs are truly excluded, thereby leading to organic food that is less likely to be contaminated with GMOs. .
- •• There is no way to prove irreparable harm when a contamination event occurs if there is no benchmark for rejection from the organic supply chain.
- •• Developers of future GMO traits and varieties are claiming that there is no impact of their agricultural trespass on organic producers because there are no grounds for rejecting contaminated seeds.
- •• Genetic engineering is not compatible with organic food or farming and the organic community needs all the tools it can possibly use to keep GMOs out.

We believe that this is an urgent issue but as we have noted above, there are several fundamental problems with designing and implementing such a standard (lack of clean breeding lines, disincentives to be organically certified, lack of data on where the problem actually exists, excessive costs, etc.). Because of these unknowns and obstacles, it is not possible to put forward a workable standard at this time.

Based on the comments received and our own discussion, we believe that an eventual seed purity standard should have the following features:

- The standard we have discussed would be based on presence or absence of GE content in a specified seed sample size (e.g. 3000 seeds). The use of terms like “non-detect” or” none found in the sample” is consistent with this goal, and less confusing than the statistical expression summarizing what “none found” in a sample means relative to the level of certainty that the whole lot is not contaminated. We see this as an analytical tool to verify compliance with the process-based standard for excluded methods.
- Organic seed growers should be protected from and compensated for contamination of their seed crops.
- The cost should not be borne by organic seed producers. The cost of seed testing and costs resulting from detected contamination of the seed supply should be borne by the patent holders of the contaminating genes.
- The standard should apply equally to organic seed and untreated conventional seed used for planting organic fields, however provisions to favor organic seeds should be explored.
- More details on how often to test, what method of testing, and what to do with seed that does not pass should be worked out between now and the time this moves forward, acknowledging that these issues and detection limits can change as technology advances.
- Initially, additional time will be needed to achieve purity for breeding lines and foundation seed, and this time period should be extended with variances or waivers based on experience and need.

As noted in this report, the third bullet point above is outside the authority of the NOSB and the National Organic Program. The subcommittee welcomes constructive suggestions from the public on funding mechanisms and the other points raised in this discussion that are within the scope of the NOP and NOSB to work on going forward.

We understand that the role of the NOP is limited in this matter, and in fact some points raised extend beyond the USDA and into the Coordinated Framework[7]. Therefore, solution-oriented comments to this report must be addressed to areas within our ability to work on.

The subcommittee also urges increased research into testing protocols, contamination avoidance methods and technologies, methods to minimize or eliminate contamination from breeding lines and foundation seed, rejection levels, and amount of contamination currently being found in the field be prioritized by the USDA and organic funders. These needs should be included in the NOSB's research recommendations to USDA.

Subcommittee Vote

Motion to accept the Seed Purity report presented February 25 as outlined above.

Motion by: Zea Sonnabend
Seconded by: C. Reuben Walker
Yes: 5 No: 0 Absent: 1 Abstain: 0 Recuse: 0

Approved by Zea Sonnabend, Subcommittee Chair, to transmit to NOSB February 25, 2014

[7] The U.S. "Coordinated Framework for Regulation of Biotechnology" document was issued by the Office of Science and Technology Policy in 1986. See *Fed Regist.* 51 (123): 23302–50.