National Organic Standards Board
Materials Subcommittee Proposal
Genetic Integrity Transparency of Seed Grown on Organic Land
August 14, 2018

I INTRODUCTION

The USDA National Organic Program (NOP) regulations do not allow the use of "excluded methods" in certified organic production. The term "excluded methods" in the USDA organic regulations refers to organisms including seed, bacteria, insects, animals and vaccines that have been produced through genetic engineering. According to the most recent U.S. production information, at least 94% of soybean, 92% of corn, 94% of cotton, 75% of Hawaiian papaya, 98% of sugar beets and 90% of canola are genetically engineered. By contrast, less than 1% of crops grown in Europe are genetically modified, and that production is limited to a handful of countries in southern Europe. Nursery stock such as vegetables and fruit can also be genetically engineered (for example, the GE non-browning apple), as well as fish and pigs. A range of engineered traits exist; however, so-called "input traits" that make crops resistant to herbicides and plant incorporated protectants (for example Bt corn) account for the overwhelming majority of genetically modified crops under cultivation. As molecular genetic methods become more sophisticated, disease resistance, drought tolerance and other traits are expected to be packaged in with the input traits, a process referred to as "gene stacking."

II BACKGROUND

The National Organic Standards Board (NOSB), in separate recommendations in 2016 and 2017, defined terms used when describing gene altering technologies, and identified which technologies are to be considered excluded methods. These definitions are as follows:

Genetic engineering (GE) – A set of techniques from modern biotechnology (such as altered and/or recombinant DNA and RNA) by which the genetic material of plants, animals, organisms, cells and other biological units are altered and recombined.

Genetically Modified Organism (GMO) – A plant, animal, or organism that is from genetic engineering as defined here. This term will also apply to products and derivatives from genetically engineered sources. (Modified slightly from IFOAM Position cited above)

Modern Biotechnology – (i) in vitro nucleic acid techniques, including recombinant DNA and direct injection of nucleic acid into cells or organelles, or (ii) fusion of cells beyond the taxonomic family, that overcomes natural, physiological reproductive or recombination barriers, and that are not techniques used in traditional breeding and selection. (From Codex Alimentarius)

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

Non-GMO – The term used to describe or label a product that was produced without any of the excluded methods defined in the organic regulations and corresponding NOP policy. The term "non-GMO" is consistent with process-based standards of the NOP where preventive practices and procedures are in place to prevent GMO contamination while recognizing the possibility of inadvertent presence.

Classical/Traditional plant breeding – Classical (also known as traditional) plant breeding involves natural plant reproductive processes (*e.g.,* pollination) but relies on phenotypic selection, field-based testing and statistical methods for developing varieties or identifying superior individuals from a population, rather than on techniques of modern biotechnology. The steps to conduct breeding include: generation of genetic variability in plant populations for traits of interest through controlled crossing (or starting with genetically diverse populations), phenotypic selection among genetically distinct individuals for traits of interest, and stabilization of selected individuals to form a unique and recognizable cultivar. Classical plant breeding does not exclude the use of genetic or genomic information to more accurately assess phenotypes, however the emphasis must be on whole plant selection. Furthermore, classical plant breeding does not bypass the plant's reproductive process.

In addition, the following criteria are used when determining if a technology should be excluded from organic production.

1. The genome is respected as an indivisible entity and technical/physical insertion, deletions, or rearrangements to the genome are refrained from (e.g. through transmission of isolated DNA, RNA, or proteins). *In vitro* nucleic acid techniques are considered to be invasion into the plant genome.

2. The ability of a variety to reproduce in a species-specific manner has to be maintained, and genetic use restriction technologies are refrained from (e.g. Terminator technology).

3. Novel proteins and other molecules produced from modern biotechnology must be prevented from being introduced into the agro-ecosystem and into the organic food supply.

4. The exchange of genetic resources is encouraged. In order to ensure farmers have a legal avenue to save seed and plant breeders have access to germplasm for research and developing new varieties, the application of restrictive intellectual property protection (e.g., utility patents and licensing agreements that restrict such uses to living organisms, their metabolites, gene sequences or breeding processes) are refrained from.

This list of excluded methods is continually being worked upon, but at the time of the writing of this proposal, the following technologies were recommended by the NOSB to be considered excluded methods:

- Sequence-specific nucleases (SSNs)
- Meganucleases Zinc finger nuclease (ZFN)
- Mutagenesis via Oligonucleotides
- CRISPR-Cas system (Clustered regularly interspaced short palindromic repeats) and associated protein genes
- TALENs (Transcription activator-like effector nucleases)
- Oligonucleotide directed mutagenesis (ODM) Rapid Trait Development System

- RNA-dependent DNA methylation (RdDM)
- Silencing via RNAi pathway RNAi pesticides
- Reverse Breeding
- Genome Elimination
- FasTrack
- Fast flowering
- Creating new DNA sequences
- Synthetic chromosomes
- Engineered biological functions and systems
- Somatic nuclear transfer
- Plastid transformation
- Cisgenesis
- Intragenesis
- Agro-infiltration

Currently, in the U.S., testing is not required to verify if seeds planted on organically certified farms were produced using an excluded method. Organic farmers plant both organic seed and non-organic seed (when the organic seed is not commercially available in the form, variety or quantity they require). Some, but not all, certification agencies perform GE testing on finished product or seed, as part of their residue sampling program.

Farmers are required to provide documentation that the seed they use is not produced through excluded methods. If it is organic seed no documentation is required, since the seed supplier would have gone through their own organic inspection to verify excluded methods were not used in the production of that seed. For non-organic seed, a non-GE affidavit is required if the crop is one that has a genetically engineered equivalent in the marketplace. Affidavits typically state the seed was not produced through excluded methods, but they do not state if there is any contamination of the seed with genetic material from these prohibited excluded methods. Under the organic regulation, the presence of genetically engineered material within an organism is not considered noncompliant. Only the *intentional* use of a product produced by an excluded method would prevent that seed (or another organism) from being certified as organic. Non-GE affidavits have been accepted as proof by their organic certifiers that the seed is acceptable in organic systems.

It is known that seed at risk for genetic contamination, such as corn, has been found to have various levels of contamination. Some, but not all, seed suppliers test their seed lots to determine the presence of GE traits, and/or the level of contamination. Some, but not all, companies test, and they make this information available to their customers upon request or it may be publicly available in their catalogs or advertisements.

The organic marketplace, on the other hand, has developed a fairly robust testing protocol for both human and livestock feeds. Depending on the market being served, various tolerance levels of genetic contamination must be met in order to sell into that market. In most cases, the amount of GE contamination found in seed will be the baseline contamination level, and when the farmer grows this seed into a crop, that level will not be lower than the seed's contamination level. To meet organic market demand, and to provide farmers with what they need to make informed decisions when choosing seeds, transparency of GE contamination levels has become a necessity.

The NOSB put forth discussion documents on this subject in 2013, 2014, 2015, 2016 and 2017. Public comment has clearly shown this to be an important issue for organic farmers, processors, and consumers. In developing this proposal, the Materials' Subcommittee has considered the many written and oral public comments and has attempted to address these issues in a pragmatic way, employing systems that many seed suppliers and buyers are already using.

III RELEVANT AREAS OF THE STATUTE, RULE and RELATED DOCUMENTS

NOP standards adopted by USDA in a final rule published in December 2000 and fully implemented in October 2002 prohibit the use of excluded methods in the production and handling of organic products certified to national organic standards. The terminology used for Genetically Engineered or GMOs in the NOP Regulation, "excluded methods," 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.*

At its October 2016 meeting, the NOSB passed a recommendation to update and clarify the definition of Excluded Methods. The definitions and criteria are described in the previous section.

Detection and Testing Requirements: Under the NOP residue testing requirements, 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 as "100 percent organic," "organic," or "made with organic (specified ingredients or food group(s))."

(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 issued a Policy Memo on April 15, 2011 (Policy Memo 11-13) on GMOs. 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 residue alone does not necessarily constitute a violation of the regulation.

IV DISCUSSION and PUBLIC COMMENT

As noted above, this issue has been discussed by the NOSB and the public every year since 2013. The creation of a task force determining the extent of GE contamination of seed for all types of crops at risk of contamination has been requested by all sectors of the organic industry, including seed breeders, farmers, consumers and advocacy groups. To date, the NOP continues to consider this request.

In 2015, an invited panel of seed breeders presented testimony at the NOSB meeting, detailing the extent of seed contamination they have experienced. Statistical data of GE contamination of corn seed, and the significant negative economic impact this has had on their businesses was clearly described. They discussed how organic seed breeders take on the expense of GE testing, whereas nonorganic seed suppliers who sell to organic farmers, typically do not. This extra testing expense, as well as the destruction of seed lots with unacceptable levels of contamination, drives up the price of organic seed. These higher costs place the organic seed suppliers at a competitive disadvantage with nonorganic seed suppliers who are not transparent with their customers concerning possible GE contamination of their seed. As stated above, most nonorganic seed dealers state they did not use excluded methods in the production of their seed, but do not take the extra step to determine if there is presence of GE contamination.

Since there is an allowance for the use of non-organic seed when organic seed of an equivalent variety in the quality and quantity desired is not available, the risk of GE contamination of organic crops is increased. If a farmer starts out with GE contaminated seed, many of their defensive management tactics are ineffective in producing a GE free crop. The contaminated seed they plant will cross fertilize other cultivars of that crop on their farm and could result in compounding the contamination problem.

The issue of maintaining the genetic integrity of organic and non-organic seed, and planting stock grown on organic land and sold in the organic marketplace is complex. The marketplace demands some assurance quantifying the presence of GE in seed and crops, and has responded by instituting testing at various levels of the supply chain. Non-GMO labeling such as the Non-GMO Project does not guarantee 100% GMO free products, but has a 0.9% tolerance level allowed in foods for human consumption and a 5% allowance of GMO contamination in livestock feeds whose final product would then be labeled as non-GMO. The Non-GMO Project currently has a tolerance of 0.25% for seed.

Many organic farmers sell into markets that will test their at-risk crops for GE contamination, where entire grain loads are rejected if their level of GE contamination exceeds a specific tolerance level. Without transparency detailing GE contamination of seed, a farmer could spend the growing season using expensive organically approved inputs, expending the extra labor and time tending to their crops using organic methods, and end up with a crop that is rejected due to seed GE contamination. This crop would then typically be sold on the nonorganic market, even though it did not lose its

organic certification. These economic losses are significant, and are occurring in crops where the U.S. needs to increase domestic organic production to reduce dependence on organic imports.

Several discussion documents and subsequent public comments addressed the issue of tolerance levels, testing and sampling protocols. Most seed suppliers and producers did not favor tolerance levels, due to concerns that this approach would narrow the availability of needed crop traits, and the overall crop choice. Concern was also raised that strict tolerance levels could result in the unintended consequence of causing damage to the growth and integrity of organic agriculture, as well as negatively impacting organic growers and seed breeders. However, all commenters felt contamination of organic seed and crops by excluded methods negatively affects the integrity of organic foods. Testing and sampling protocols are now widespread in the seed industry, with models that have clear statistical accuracy both in sampling procedures and testing.

V PROPOSAL DISCUSSION

It is important to move forward on these issues to provide certainty and clarity in the marketplace for those who grow seeds and those who buy and plant them. Transparency about GE contamination provides the confidence to those entering organic production, and can help increase the acreage of domestic organic crops. The NOSB Materials Subcommittee feels the proposal described below addresses numerous aspects of this complex subject.

Based on discussions with seed suppliers and testing laboratories, the requirements in this proposal mirror what is currently being done in the marketplace, and should not add significant cost for those already doing testing for GE contamination. Currently, there are in-house tests that cost less than a polymerase chain reaction (PCR) test and have statistical accuracy down to 0.9%. . These detection limits would be acceptable, but only when they meet the proposal's requirements, as noted below. The seed seller can make a choice to describe their seed as having at least a 0.9% level of purity, even though their seed may actually have been found to have a lower level if they had performed the more expensive PCR test. By not requiring specific types of tests or laboratories, this proposal allows for future improvement and innovation in testing for GE contamination, while at the same time requiring rigor and consistency.

The levels of purity chosen represent the various levels of GE contamination currently tested for in the marketplace on seed and finished crops. This transparency will allow farmers to decide which level of purity they are most comfortable choosing, in order to meet specific market demands for their final crop. Since field corn is the mostly widely tested crop for GE contamination, the Subcommittee suggests starting with this crop, and after a period of implementation, expand this to requirement to other at-risk crops.

The NOP can choose to maintain the information provided by certifiers detailing the levels of purity from GE contamination, and the location the seed was grown. Alternatively, the NOP can seek to contract this work out to an organic certification agency or a materials review organization. The NOP or an outside entity can develop a system by which certifiers will transmit this information, to enable certifiers to setup their internal systems to track and provide this information to the NOP. It is anticipated this information will be sent once per year to whatever entity is tracking the information. Since the information for this database does not contain the seed supplier, nor farmer name, privacy is preserved while providing the organic industry with important information to aid in development of benchmark low to no-detectable amounts of GE contamination in seed used on organic land.

The Materials Subcommittee believes this proposal is practical and would be feasible to implement within one or two years of the NOSB passage of a recommendation. There is sufficient existing testing infrastructure, the sampling protocols are clear and achievable, and the organic community could implement this rapidly since much of the procedures are already being done by organic seed suppliers. The main roadblock to implementation would be for nonorganic seed suppliers to begin this testing. Since the cost of organic seed already includes the fees paid for testing and would be required under this proposal, the extra cost added to nonorganic seed only serves to level the playing field between organic and nonorganic seed. Farmers would need to do the testing themselves if they choose to plant non-organic seed, however. They could also choose to purchase seed from suppliers that value the patronage of their organic customers and would maintain the transparency needed to establish the level of purity from excluded method contamination.

The initial focus of this proposal requires the sampling, testing, and documentation describing the level of purity from GE contamination of field corn seed, including the state/province/country of origin. Field corn seed was chosen since it is a high-risk crop, and is already widely tested in the marketplace. This proposal is intended to be a starting point, to learn how best to provide information to producers and track the contamination risk, while expending a limited amount of resources. It is anticipated that in the future similar, species specific protocols would be instituted for additional types of seeds at risk of GE contamination.

VI. PROPOSAL

1. A system of sampling, testing and transparency of findings of GE contamination on all field corn seed planted on organic land is required. Once this has been implemented for one or two years, other at-risk crops could be added.
2. We request the NOP develop an "Instruction to Certifiers" based upon this recommendation and place this in the NOP Program Manual.
3. All field corn seed lots planted on organic land, both organic and nonorganic seed, and whether sold or used to feed on-farm livestock, shall be tracked in the farm Organic System Plan (OSP) with information detailing the state/province and country of origin of the seed, as well as the level of purity from GE contamination. In addition, certified organic field corn seed suppliers must track these items in their OSPs. If nonorganic field corn seed is planted, the organic farmer is mandated to obtain the level of purity information, determined through approved protocols, and document this in their OSP. The organic farmer would need to have this test performed before planting each lot of nonorganic seed they purchase. This information can be supplied in the submitted OSP at the beginning of the crop year, or at the annual inspection.
4. Seed suppliers or farmers have the option of five levels of purity, determined through approved sampling and testing protocols.
   The detectable levels of purity from GE contamination for organic field corn seed are:
   a. 0.1% or less
   b. 0.25% or less
   c. 0.9% or less
   d. 5% or less
   e. Over 5%
5. Documentation that the testing and sampling met these requirements must be provided to buyers of the seed.

6. The level of purity must be included on the seed tag, or for bulk shipments, on the invoice or other sales document.
7. Testing must include all known GE traits available in that crop species.
8. Outside labs used for this testing must be accredited to ISO 17025.
9. The testing technology must be capable of providing accuracy within a 20% relative standard deviation of the target concentration of GE contamination.
10. If in-house testing is done, the equipment must be validated to have the accuracy required to declare the specific targeted level of purity from GE contamination. Additionally, personnel using the in-house equipment must have training and demonstrate proficiency on an annual basis, through the quantitative analysis of a blind sample.
11. Sampling protocols must be recognized as having at least a 90% statistical rate of accuracy for confidence in the quantification of GE presence. Sampling protocols, such as those performed by various state "crop improvement" agencies, would meet this requirement. Information on various state and international agencies that subscribe to these protocols and can explain these protocols can be found here. https://www.aosca.org/seed-certifying-agencies/
    An example of the seed sampling protocol, from the California Crop Improvement Association is here. http://ccia.ucdavis.edu/files/178676.pdf
12. Sampling must include a demonstrated method of achieving a homogeneous blend representative of the finished seed lot derived from the cleaned and ready-for-sale seed.
13. Sampling must be documented to illustrate the sample was sufficiently intact for valid PCR quantitative analysis.
14. Each lot of seed must be sampled and tested.
15. The certifier will keep track of this information and send this information to a central database, without the farmer or seed supplier information. This information would help the organic community gain a better understanding of the levels of seed purity from GE contamination used on organic land, as well as regional differences in seed production.
16. This GE purity testing and information transparency is required of all organic field corn seed suppliers and must be documented in the annual organic seed handler OSP. The organic field corn farmer would document the information from their organic field corn seed supplier in their OSP as well.
17. Organic farmers should retain samples of each lot of seed they planted for at least one year after their crop grown from this seed has been sold.

VI Subcommittee vote

Motion to approve the proposal on "Genetic integrity transparency of seed grown on organic land".
Motion by: Dan Seitz
Seconded by: Harriet Behar
Yes: 4 No: 0 Abstain: 0 Absent: 3 Recuse: 0

Approved by Harriet Behar, Subcommittee Chair to transmit to NOSB, August 20, 2018