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Organic trade association

September 24, 2012

Ms. Michelle Arsenault
National Organic Standards Board
USDA-AMS-NOP
1400 Independence Avenue, SW
Room 2648-So, Ag Stop 0268
Washington, DC 20250-0268

Docket: AMS-NOP-12-0040

RE: GMO Ad hoc Subcommittee – GMO's and Seed Purity Discussion Document

Dear Ms. Arsenault:

Thank you very much for this opportunity to provide comment on the Discussion Document on GMO's and Seed Purity. OTA supports the work of the GMO Ad hoc Subcommittee on this topic and shares the desire to keep genetically modified organisms out of organic livestock feed, crops, and food. We commend the Ad hoc Sub-committee for beginning with a discussion document on the complex and ground-breaking topic and encourage the Sub-committee to work towards a recommendation on a seed purity standard. The information contained in OTA's comments is based on the extensive work of OTA's GMO Task Force in 2010 and 2011, and resulting OTA GMO White Paper, available at: http://www.ota.com/pics/documents/OTA-GMO-White-Paper.pdf

OTA is the membership-based business association for organic agriculture and products in North America. OTA is the leading voice for the organic trade in the United States, representing organic businesses across 49 states. Its members include growers, shippers, processors, certifiers, farmers' associations, distributors, importers, exporters, consultants, retailers and others. OTA's Board of Directors is democratically elected by its members. OTA's mission is to promote and protect the growth of organic trade to benefit the environment, farmers, the public, and the economy.

OTA has a comprehensive GMO policy in place, unanimous adopted by its Board of Directors in July 2011. It includes two provisions relevant to continuous improvement of the organic practice standard:

- OTA shall adopt policy positions that strengthen the organic standards to minimize GMO contamination & increase enforcement on the prohibition of the use of GMO crop varieties while minimizing the negative impact to farmers.
    - OTA shall advocate for GMO testing by certifiers as part of the requirement for periodic residue testing to verify compliance and enforcement of the standards.
    - OTA shall adopt policies that encourage the reduction of testing costs to organic farmers, handlers, and certifiers wherever possible.
    - OTA supports the incorporation of a GMO threshold, for crops that have genetically engineered counterparts, into the NOP regulations at the appropriate time. OTA will work with industry stakeholders, the NOSB, and NOP to that end.

OTA shall facilitate data collection and analysis on the extent of low-level contamination or adventitious presence of GMOs in organic and the best practices for prevention at critical control points in the supply chain.

- **OTA recognizes the critical role of seed in the supply chain** and shall advocate for policies that secure a seed supply to the organic sector that is free of GMOs. To that end:

    - OTA shall advocate for a seed purity standard.
    - OTA shall advocate for more robust germplasm repositories for non-GMO seed.
    - OTA shall advocate for re-emphasis of classical plant breeding.

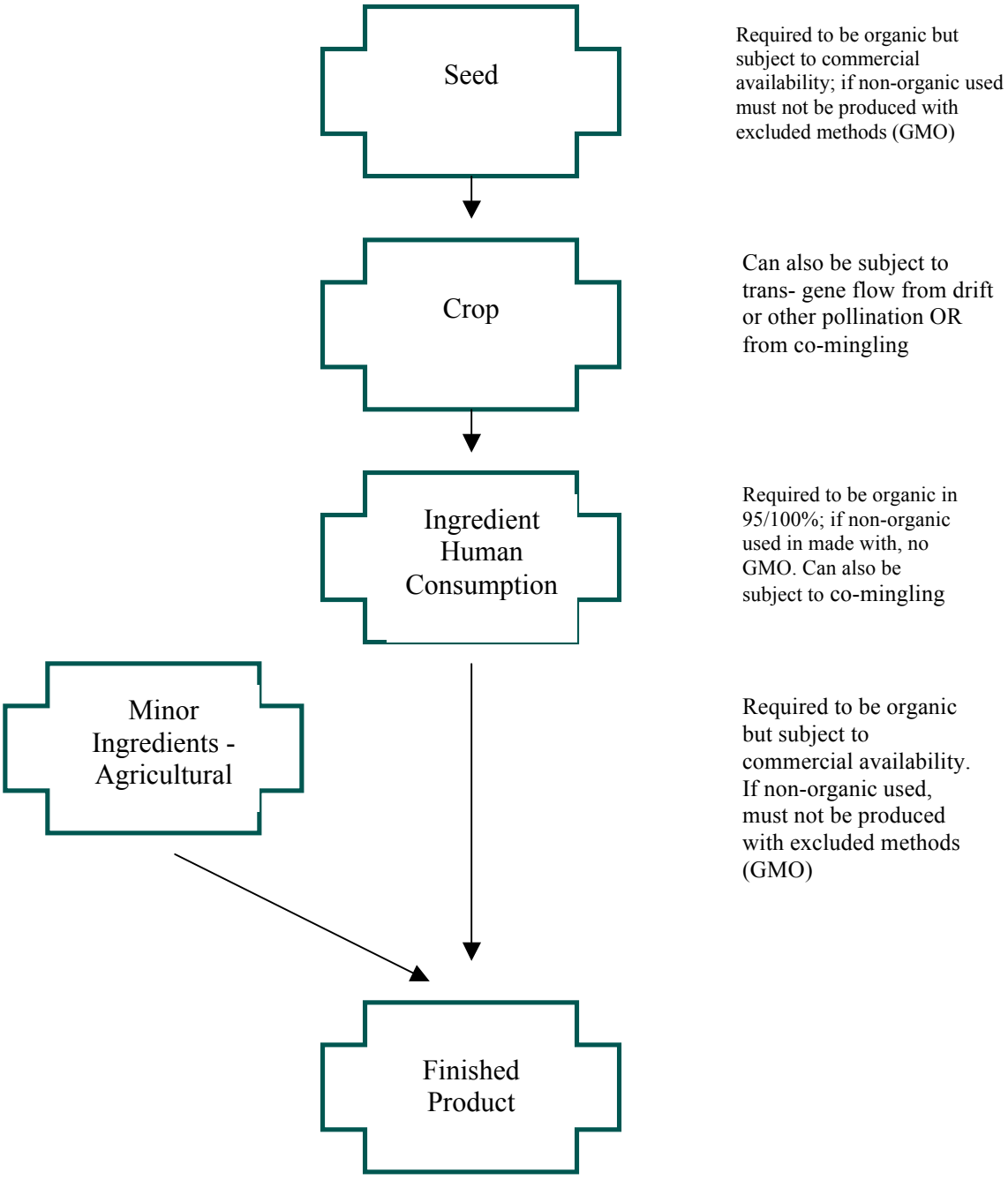
OTA agrees with many in the organic sector that seed is the most impactful and appropriate point in the value chain to set limits for controlling GMO contamination in feed, crops and food. OTA believes setting a seed purity standard can be consistent with a process-based standard when analytical limits are used to verify that adequate measures are in place to prevent contamination with excluded methods.

A seed purity standard, if properly established, would protect rather than burden organic farmers. By requiring a standard for seed, seed companies could provide verification as part of the seed lot's certificate of analysis (COA) - and could label compliance on the bag. This would: 1) reduce ad-hoc testing requirements for farmers; 2) enable organic farmers to use the standard to meet marketplace demands for GMO limits on organic crops, and focus on contamination prevention such as buffer strips, planting schedules and equipment cleaning; and 3) require verification of the seed purity standard by ACAs as part of the final rule on residue testing.

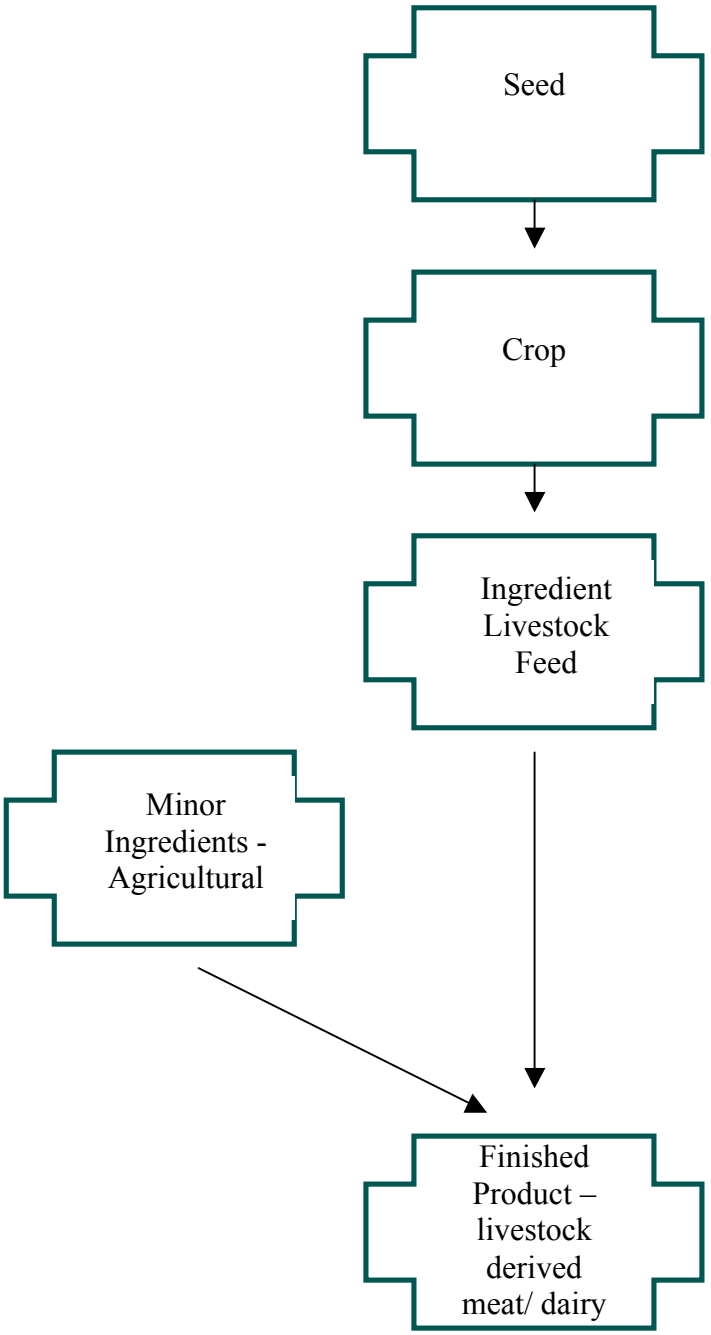
Whether a food crop or livestock feed, seed is the appropriate critical control point to use analytical methods and standards in organic production to limit GMO contamination and meet consumer expectations.

CRITICAL CONTROL POINTS

GM contamination is more than an issue of what happens in the farmer's field. Multi-layered, complex supply chains add risk of GM contamination in certified organic products.



Livestock derived organic products: Dairy, Meat



Required to be organic but subject to commercial availability; if non-organic used must not be produced with excluded methods (GMO)

Can also be subject to trans- gene flow from drift or other pollination OR from co-mingling

Required to be organic. Can also be subject to co-mingling

Required to be organic but subject to commercial availability. If non-organic used, must not be produced with excluded methods (GMO)

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Answers to questions posed in the discussion document:

1. **Is there a need to establish a seed purity protocol to ensure that planting seed meets the requirements of the NOP rule?**

   According to NOP: *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.*

   A seed purity protocol is not necessary to comply with the NOP rule. However, having a seed purity protocol would be an additional method of verifying that excluded methods have not been used. It is certainly within the purview of NOSB to recommend to the Secretary of Agriculture that a seed purity standard be enacted in NOP regulations.

   Certified organic farmers must use certified organic seed if commercially available. This means that when organic seed is not commercially available, seed used in non-organic production may be used in certified organic production. Given that non-organic products have generally shown higher GM content than organic products, seed purity is critical to contamination prevention in organic.

   Based on anecdotal reports from private PCR testing involving corn planting seed claimed by the seed producer to be non-GMO, it was found that GM content ranged widely within the same lot of seed. GM events within the lot also ranged widely. It has also been reported that once a producer group began PCR testing seed and only accepted seed for planting that tested in the range of 0.01% or lower, the rate of post-harvest rejection due to GM contamination exceeding 0.1% became very low. This and other testing indicates that, if one starts with seed that is verified by test to contain very low or no GM contamination, the likelihood of producing a crop that exceeds 0.1% GM contamination is extremely low, and the likelihood of producing grain that contains more than 0.9% is close to zero.

   Currently the evaluation of excluded methods is based on the information provided in the producer's Organic Systems Plan (OSP) [1] and is verified by the certifier through desk audit and during on-site inspection. The areas of focus are: 1) the seed used by the producer; 2) the contamination prevention measures taken to ensure that crops (including post-harvest) do not come in contact with GMOs; and 3) evaluation of crop and livestock inputs. With respect to seed, the operator discloses any non-organic seed being used, and typically provides an affidavit from the supplier of the seed stating that the non-organic seed is not genetically modified. The inspector will then review on-site receipts, seed labels, and any other pertinent documentation to further verify this claim.

[1] 30 A large majority of the certifiers have built their Organic System Plan forms from the OSP templates provided by the National Sustainable Agriculture Information Service (ATTRA). In many cases, certifiers use the exact templates available on their website. The *Organic Farm Plan* template—as well as *Organic Farm Plan Update* and the *Organic Handling Plan* templates—were originally authored by Jim Riddle and Joyce Ford. They were created for the Independent Organic Inspectors Association (IOIA) and the Organic Certifiers Council (OCC) with funding from the Federal-State Marketing Improvement Program (FSMIP). Revisions were later made with funding assistance from the John Deere Company's "Go Organic" project. In 2002, the National Organic Standards Board (NOSB) approved all three templates as guidance documents. In August 2005, the NOSB approved specific additions to the template recommended by the Wild Farm Alliance and the National Center for Appropriate Technology (NCAT). These additions solicited more information on farm biodiversity planning and practices.

Certifiers **may** require testing under § 205.670 when there is reason to believe that certified products have been produced using excluded methods. On April 29, 2011, NOP released a proposed rule that would require certifiers, on an annual basis, to conduct residue testing from a minimum of five percent of the operations they certify. The required testing would be in addition to testing conducted when contamination is suspected.

OTA in its comments on the proposed rule on residue testing requested the following:

*Consistent with OFPA, we are pleased to see the proposed rule require "**residue testing**" under § 205.670 "Inspection and testing of agricultural products labeled as "100 percent organic," "organic," or " made with organic (specified ingredients or food group(s))." In addition to ensuring that certified production and handling operations are in compliance with the requirements set forth in the regulations, required testing of **any type of prohibited residue** will add to the certifiers' means for monitoring drift and unavoidable residue contamination of certified products. This comes at a critical time for the organic sector because of the proliferation of genetically modified (GM) organisms in the environment due to unrestricted deregulation of genetically modified crops such as Round-up Ready Alfalfa.*

The continued health and growth of the organic industry require that our supply chain not be compromised. Contamination by GM crops threatens the organic sector's ability to meet consumer demand. Therefore, we encourage NOP to explore the explicit incorporation of required periodic residue testing for GM contamination into the NOP residue testing program along with supporting guidance documents in order to monitor its presence, and ensure that certified operators are meeting the standards by adequately implementing contamination prevention measures. OTA welcomes this conversation, and we provide our support.

*Provided that specific contaminants or residues are not called out in the proposed rule, it's our understanding that the required 5% minimum for periodic residue testing includes the testing of **any prohibited material** collected from a certified operation. In other words, testing for antibiotics in milk, sulfites in certified wine (total concentrations over 100 ppm), genetically modified organisms in organic corn, and nitrogen isotopes in fertilizer will all count towards the required five percent minimum of testing. OTA respectfully asks NOP to clarify this point in the preamble to the final rule.*

The rule, once finalized, may result in the increase of GMO testing conducted by certifiers as a means of monitoring whether contamination prevention measures used by certified operators are adequate.

2. What is currently known about the level of GMO contamination of seed used by organic farmers?

One of the greatest challenges in setting effective policy to prevent the contamination of organic seed, crops and products is the lack of available baseline on incidence levels for detection. In order to determine the level of GMO contamination in organic and identity-preserved seed and grain, it is necessary to design a study in which samples are obtained from a representative group of growers and processors in this market sector. Sources of potential data include test results from certifiers released to the public, raw data released from traders, and GMO testing labs. Each potential source offers insights and limitations.

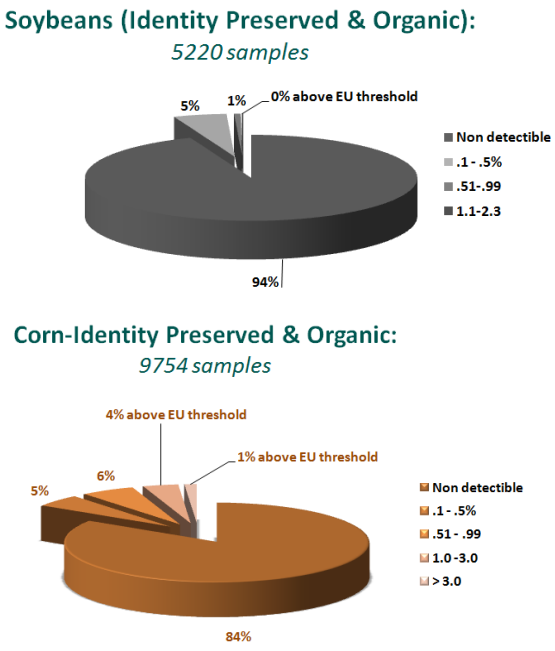
Surveys from OTA and the Accredited Certifiers Association (ACA) turned up little in terms of concrete information regarding the level to which certifiers are conducting GMO tests. Certifiers are required by the Organic Foods Production Act to release the results of testing to the public. However,

there are no mechanisms for results to be collected and analyzed and, even if released, they would only provide anecdotal information.

Data from GMO testing laboratories is limited in terms of accuracy and level of information. Testing laboratories usually receive sample type and customer information, not necessarily organic and/or identity-preserved status. Thus, organic and non-organic data cannot be separated. Those customers who send in IP product for testing often deal in conventional, non-IP product as well and sometimes use testing results to determine whether to place the product in the IP or conventional production queue. The laboratory does not know which type of need the test is being conducted for. For customers exporting product, the intended target market dictates the GM threshold allowable for the product. Therefore, samples may have GM levels > 0.1%. For example, in order to confirm that a product is suitable for entry into the EU market, a customer may request a quantitative test to confirm that the sample is below the threshold for GM labeling (< 0.9% GM content).

OTA has compiled data on GM presence in organic and IP crops, but not for seed stock. The data aggregated for crops does indicate, however, a need to reduce the incidence of GM presence – with seed purity being the appropriate starting point toward this goal.

Tests results for corn and soy have been shared with OTA to inform this discussion. The raw data, representing 17,000 test results over three years, are summarized below. It should be noted that due to international acceptance of EU thresholds, these traders, in practice, do not sell ingredients exceeding that threshold into the organic market, whether as an ingredient or feed.



3. **What testing methods are appropriate to use in order to determine and label seed purity to verify compliance to a seed purity standard?**

As the number and diversity of approved GE crop traits expand, including varieties encompassing multiple GE traits, the complexity of analytical challenges facing those carrying out seed purity testing will increase. Issues will arise over the specificity and sensitivity of certain test methods, as well as the frequency of false negatives and false positives. The companies developing new GE crops will have control of primers and gene sequences that will be helpful, if not necessary, for accurate identification of the presence of specific events. Whether such primers and gene sequences will be accessible to outside laboratories and/or government agencies is uncertain. Accordingly, it would be unwise to specify today the testing methods that will be needed in the future to assure that seed purity goals are being met. Any test method with a level of detection of one seed in a 3,000 seed sample, or a number of pools totaling 3,000 seeds, should be regarded as acceptable. For example, a SDIX RUR HS test strip validated for the detection of the CP4 EPSPS protein is sensitive enough to reliably detect one Roundup Ready alfalfa seed in 600 alfalfa seeds, and is thus capable of yielding a none found in a 3,000 seed sample result when used to test five pools containing 600 seeds each. Generally, however, PCR testing for all known GE events will be required for most samples.

Background on GMO testing

Protein Approach - The two most commonly used methods are lateral flow test strips and plate-based enzyme-linked immunosorbent assays (ELISA). The technology is similar in both, but the presentation and devices differ. Test strip kits are available from several companies for quick assays in the field, such as at seed companies, farms, receiving stations and transfer stations. Such kits typically analyze protein to detect specific GMO events. If used in compliance with the manufacturers' instructions, these kits provide accurate, reliable results within a few minutes.

The test procedure typically involves grinding a well-mixed and representative sample of the seed/crop material being tested, adding distilled water and mixing to extract the protein. The strip is then read—either by eye or by a computerized reader. Strips that will check for multiple events typically cost about $20/strip. Including the cost of labor and materials likely raises the cost of each test to ~ $30. Some strips can be used only for qualitative testing. Others can be used for both qualitative and quantitative testing. The Grain Inspection, Packers and Stockyards Administration (GIPSA) of the USDA offers a rigorous system for voluntarily certifying GMO test kits for accuracy.

Another version of the ELISA test, the plate test, provides some indication of the percentage of the tested sample that is the GMO in question. Intensity of color indicates the amount of the protein present. The plate test can take two to four hours, and is more laborious and costly than the strip test.

Protein strip tests and related ELISA plate tests are used primarily to help farmers and elevators test raw grains and oilseeds to separate GMO from non-GMO deliveries. ELISA tests are preferred for such applications because they allow rapid turnaround times and require a relatively small investment in equipment and personnel. However, they do have some disadvantages. For example, ELISA or strip assays are limited to proteins of specific events. Thus, such tests are not useful for detecting any GMO in a commodity or product. Nor do they work well with foods in which proteins may have been denatured, compromised or removed. They work best on whole grains and oilseeds prior to processing.

DNA Approach - Many laboratories offer to test samples of grains/oilseeds/foods for the presence of GMOs by analyzing DNA through two associated techniques – PCR (polymerase chain reaction) and agarose gel electrophoresis. The PCR approach is generally regarded as the best and most accurate methodology. A major advantage of PCR-based methods of detection is that you can assay for any GMO using appropriate PCR primers to quantify the presence of GMOs. But there are disadvantages of cost and time. Such tests require sending samples to sophisticated labs. The tests are expensive, costing at least a few hundred dollars per test. The time from taking a sample to learning the test results can often be several days instead of the few minutes needed at a receiving station.

Not all labs offering PCR testing are certified to the same level or to handle all products that might be submitted for GMO testing. Testing should be conducted by labs that carry ISO 17025 or comparable certification for the specific product(s) and GMO events to be tested. With a significant number of GMO events already in use and more being added, it is important to make sure that the laboratory chosen is certified to test for all the commercially available GMO events being used in the subject crop. Only complete testing can assure good results.

Sample and Testing Control Points - Testing is considered most accurate in qualifying and quantifying GMO presence when raw material is being sampled and tested; it is less accurate when a processed ingredient or processed food is being tested. Critical control points with the greatest probability of offering good information would be at the level of seed approval prior to planting, upon harvest by the farmer, upon receiving by the first purchaser, and upon receiving by the processor. Accuracy at each step can limit the multiplication of GMO presence in subsequent positioning of raw materials.

7. **What training, guidance, and resources do certifiers need to verify compliance for a seed purity standard?**

   Similar resources to those provided for pesticide residue testing would be required, including instruction on sampling, testing, and lab selection. But verification of the seed purity standard could fall under the residue testing requirement for 5% of operations, rather than exist as an additional testing requirement. Seed bags could come labeled to meet the seed purity standard and be subject to verification.

In Summary

OTA agrees with many in the organic sector that seed is the most impactful and appropriate point in the value chain to set limits for controlling GMO contamination in feed, crops and food. OTA believes 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.

A seed purity standard, if properly established would protect rather than burden organic farmers.

Respectfully submitted,
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Laura Batcha
Executive Vice President
Organic Trade Association (OTA)