April 4, 2018

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-17-0057

RE: Materials Subcommittee (MS) – Discussion Document on Protecting the Genetic Integrity of Seed Grown on Organic Land

Dear Ms. Arsenault:

Thank you for this opportunity to provide comment on the Materials Subcommittee's Discussion Document on "Protecting the Genetic Integrity of Seed Grown on Organic Land."

The Organic Trade Association (OTA) is the membership-based business association for organic agriculture and products in North America. OTA is the leading voice for the organic trade in the United States, representing over 9,500 organic businesses across 50 states. Our members include growers, shippers, processors, certifiers, farmers' associations, distributors, importers, exporters, consultants, retailers and others. OTA's mission is to promote and protect organic with a unifying voice that serves and engages its diverse members from farm to marketplace.

OTA has submitted extensive comments on the discussion documents and proposals related to this topic since 2013. As discussed over multiple NOSB meetings, many public commenters—including OTA—agree that a seed purity standard is an appropriate critical control point to begin to use analytical methods and standards in organic production to limit GMO presence and meet consumer expectations. OTA and many of its member companies also believe it is not possible to put forward a workable proposal or standard at this time because of various obstacles identified through the NOSB public comment process and a shared need to collect more data to shape an effective and fair seed purity standard.

NOSB has issued four discussion documents including a seed purity report, a proposal on prevention strategies to keep GMOs out of organic agriculture, a proposal on increasing organic seed usage (in progress) and held an expert panel convened for NOSB on seed purity. The board is now revisiting the same basic questions on whether we should establish a seed purity standard and if so, what the threshold should be. The subcommittee is also asking questions about approved testing laboratories, GMO sampling methods and adequate seed label disclosure. The process appears to be starting over, without a clear analysis and inventory of the information that has already been submitted via public comment as well as by the seed expert panel. Despite the frustration this creates with respect to process and use of valuable time, we remain committed to finding solutions through new ideas and stakeholder participation. OTA offers the following comments, some old and some new.

Headquarters - The Hall of the States, 444 N. Capitol St. NW, Suite 445-A, Washington, D.C., 20001 • (202) 403-8513
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OTA GMO Policy

OTA has a comprehensive GMO policy in place, unanimously adopted by its Board of Directors in July 2011. The policy has two provisions relevant to continuous improvement of the organic practice standard that guide OTA's comments:

- **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 shall bolster organic as the gold standard by advocating for 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 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's GMO Policy also includes a provision that is relevant to the discussion regarding GMO contamination, cost, and liability:

- **OTA shall advocate for policies that assign the cost of contamination prevention and market loss to the developers of GMO technology.**

SUMMARY

OTA shares the desire to keep genetically modified organisms out of organic livestock feed, seed, crops, food and fiber. We agree with many that a seed purity standard is the appropriate critical control point to begin to use analytical methods and standards in organic production to limit GMO contamination and meet consumer expectations and we continue to support the development of a seed purity standard. However, it must be established per crop through a careful and deliberate process. OTA expects a threshold will likely need to be established to have a workable seed purity standard. We can expect that any established threshold is going to need to be acceptable to consumers and realistic for seed growers. It would also need to be based on adequate data and established on a crop-by-crop basis. While we do not believe there is enough data publicly available to adequately inform a seed purity standard at this time, we do think that guiding principles could and should be adopted to help inform the process moving forward.

OTA recommends the following guiding principles. A seed purity standard for non-organic should:

- Incentivize the development and use of organic seed
- Be established per crop (corn, soy, alfalfa, cotton, etc.)

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- Be based on data conducted through feasibility studies for this intended purpose
- Establish levels, if any, of unavoidable presence of GMOs per crop
- Apply to adventitious or unavoidable presence only. The intentional use or presence of GMOs will continue to be strictly prohibited with a zero tolerance level.
- Be acceptable to consumers, seed growers and users of organic and non-organic seed.
- Avoid inadvertent and negative impact on organic farmers and organic seed growers and genetic diversity of organic seed.

With respect to testing protocols and labs, certifiers are currently testing for GMO contamination under the requirements of § 205.670 (Inspection and testing of agricultural products to be sold as "organic") and industry is voluntarily testing as well. Accordingly, it would be appropriate for USDA to update NOP's Guidance on Periodic Residue Testing (NOP 2610, 2611 and 2613) to include procedures and criteria specific to GM testing. Guidance on GE testing should happen with or without a seed purity standard. Finally, a seed tag approach for demonstrating compliance with a seed purity standard is the most practical approach we know of. Under this model, the seed company would be responsible for the testing, and the seed label or tag would provide a guarantee that the seed meets the required threshold. Individual growers should not be expected to test individual lots of seed. As specified by the regulations, additional testing performed by certifiers under § 205.670 must occur at the certifying agents own expense.

We offer the following more detailed information in response to the Subcommittee's questions:

Should we move to quantify the extent of GMO contamination in order to better understand the scope of the problem? How could this be accomplished?
Yes, identifying the scope of the problem is the essential first step to developing a solution. Acknowledging the resource and priority limitations we face under this administration, OTA continues to believe that convening a "Seed Purity Advisory Task Force" is the next step in the process. We do not support putting forth a seed purity proposal unless it is aimed at a formal plan for collecting data that would inform a meaningful standard. Public comments were in strong support of the need to collect data as the next step, and we believe the collection process needs to be carried out by a formally convened expert group that would systematically design threshold feasibility studies (per crop), identify partners and develop a 3-5 year action plan for moving forward. This panel of experts would not only design the framework for the data collection the organic community continues to call for, but it would also act as an expert panel to interpret the data being collected. This, in turn, would help shape a NOSB recommendation to NOP on appropriate crop-specific testing thresholds for seed using agreed upon sampling protocols and testing specifications.

We emphasize that any data collection effort that will yield statistically significant and meaningful results needs to be designed systematically according to established sampling protocols and testing specifications. For obvious reasons, the project also needs to be adequately funded. The advisory task force we continue to recommend would be convened by USDA or some other reputable group or agency that would be resourced to carry out the project. Again, we recognize the realities of our current administration and the limited chance of USDA convening a seed purity task force anytime soon. We also believe we cannot move forward without more data to shape an effective and fair seed purity standard, and the formation of a task force needs to remain in the queue for future consideration. The Organic Trade Association recommends the following questions be explored:

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- What other means or private initiatives are there for convening a reputable task force or advisory group, with funding, that could do the work we have described?
- Is there any new data available that can definitively point to GMO contamination levels found in seed?
- What became of the information provided by the Expert Seed Panel that was convened for the fall 2014 meeting? There were several helpful suggestions that we have not seen summarized or included in any subsequent NOSB documents.

Should a requirement be in place establishing a seed purity threshold for purchased seed (either organic or non-organic, or both) planted on organic land?
OTA believes that setting a seed purity standard can be consistent with a process-based standard when analytical limits are used to evaluate and verify that adequate measures are in place to prevent contamination with excluded methods. This is analogous to the detection of prohibited pesticides and the existing residue testing rule. Organic standards prohibit the use of toxic and synthetic pesticides. Analytical testing and rejection levels are used to verify this process-based standard. All intentional use of prohibited pesticides deems a product non-compliant, and all detected levels of pesticide residue require investigation. Unintentional presence or Unintended Environmental Residual Contamination (UREC) is tolerated below a certain level (5% of the EPA tolerance). Above that level, the product is deemed to not meet consumer expectations for an organic product.

The same approach and system could be used to develop and implement a seed purity standard. Compliance with a seed purity standard (with an established rejection level) would be communicated on the seed bag (tag), and verified by Accredited Certifying Agencies (ACAs) through the same periodic residue-testing procedures in place for prohibited substances.

Keeping in mind that there is a need to collect data to shape an effective and fair seed purity standard whether it is applied to organic seed, non-organic seed, or both, OTA has previously supported a "**first step of action"** proposal that focuses on the seed purity of **non-organic seed** used under the commercial availability clause of the organic regulations. Establishing a seed purity standard for non-organic seed seems appropriate given the exception the organic regulation provides for the use of non-organic non-GMO seed. Non-organic (non-GMO) seed may only be used when organic seed is not available. The organic regulations prohibit the use of excluded methods and the certification system is designed to ensure this requirement is met for crops and products that are certified under the NOP regulations. Establishing a seed purity standard for **non-organic seed** would provide ACAs with a tangible method of verifying the required non-GMO status of non-organic seed.

Requiring a seed purity declaration on **non-organic seed** would obligate seed suppliers to test non-organic seed for GMOs and to withhold contaminated seed from entering the organic supply chain. This would shift the financial burden of routine GMO testing from organic seed producers to suppliers of non-organic seed, and would significantly reduce the inadvertent introduction of GMOs into organic production through seed supply. It would also show confidence in the processed-based standards that have proved successful in preventing pesticide contamination on organic products, and it could incentivize the expansion of the organic seed industry. OTA is entirely supportive of this end goal. Given the unfortunate reality of unavoidable presence of GMOs, we also acknowledge that ongoing monitoring and routine testing for GM presence in organic seed will also be necessary for quality assurance purposes. This speaks

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to our on-going request to NOSB to develop a recommendation to NOP requesting GMO testing guidance for ACAs and industry. See below.

If so, what should the threshold be? How will that threshold vary with crop?
The answer to this question has created the roadblock in this discussion over the past 5 years. Public comments were in strong support of the need to collect data regarding levels of unintended GMO presence in seed (organic and non-organic) as the next step. There is also strong recognition for the need to establish thresholds per crop. Many suggestions have been offered up ranging from zero-tolerance to non-detect (none found in 3000/10,000 seeds) to 0.25% (Non-GMO Project threshold for seed) to 0.9% (EU food labeling requirement). We expect that the appropriate threshold may fall somewhere within this range depending on the crop.

Again, the lack of data is the most significant source of reluctance to moving forward with a seed purity standard. OTA contends that sufficient data is likely available for establishing a threshold, but this data is not publically available. While some data have been collected and is publicly available and we can look to consumer acceptance of thresholds in Europe, we still don't believe we can suggest a threshold at this time. The question of an actual level for purity will best be handled after reliable data is presented about the baseline for GMO presence. For now, we urge NOSB to recommend a set of guiding principles.

Should there be an approved list of tests, and/or testing laboratories, for tracking the presence of GMO in seed and/or crops? Should there be an approved method of sampling for GMO traits?
For the sake of consistency and accuracy, a maintained list of tests and testing laboratories along with approved methods of sampling and testing methods would be very helpful whether it is used to support a seed purity standard or for general testing of excluded methods under the organic regulations. Seed testing requirements, protocols and thresholds have been and are being set by industry, and it is creating a situation where seed is being tested according to inconsistent testing methods, thresholds and policies. It is also important to keep in mind that testing methods and policies are constantly improving and changing, and it would be unwise to specify today what testing methods will be needed in the future. Guidance from USDA on sampling and testing methods that could be used alongside a seed purity standard under the organic regulations could allow for verification according to one standard with compliance labeled on the seed bag. Additional verification would be carried out by ACAs in the same manner as they currently conduct residue testing.

In many ways, the stage for guidance on GMO testing has already been set. 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 **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, including OTA, 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. NOP further clarified that under the existing residue testing 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.

OTA recommends that NOSB include a specific recommendation to NOP requesting guidance on GMO testing for ACAs and industry. Testing is one of the most definite and effective tools the organic sector

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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. To date, however, NOP has not issued any instruction or guidance on GMO testing. This is incongruent with the fact that testing for GMOs is required under the organic regulations whether it be in response to a contamination event or a complaint (§ 205.670(b)) or whether it be part of a certifying agent's periodic testing residue plan (§ 205.670(c)).

Providing NOP with a recommendation for further guidance on testing falls directly under the specific responsibilities of NOSB outlined in 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.

How much of a seed or crop should be tested to provide confidence that the entire lot is likely to be GMO free?

For commercial row crops that already contain inadvertent GMO traits, the concept of "GMO-free" is not realistic. As discussed above, there needs to be a threshold established based on the guiding principles we have provided. Furthermore, the only way to prove that a seed lot is 100% GE-free with 100% certainty is to test 100% of the seeds in the lot, which is obviously not feasible.

There are mathematical formulae to determine confidence levels of a quantitative result based on lot size. To help further in answering this question and others, OTA suggests reading OTA's GMO White Paper published in 2011 (**Attachment A**). Although the paper needs updating, most of the information on testing approaches, sampling and testing protocols is relevant and helpful (See Chapter 7: GMO Testing and Chapter 8: GMO Thresholds along with their associated attachments).

Would a seed label statement indicating the percentage of GMO traits detected by an approved testing regime be sufficient in providing the information needed by the purchaser of the seed? No detectable level of GMO traits, .1% or other levels are examples that could be provided.

As mentioned above, we believe compliance with a seed purity standard is best communicated on the seed label. While we expect this approach will not be popular with seed companies, it appears to be the most practical and reliable method of providing "non-GMO" information to a buyer. An example to consider is a seed tag that includes a statement of seed purity guarantee, rather than disclosing test results on each lot of seed. For example, the seed tag could state: "XX Brand Soybeans are guaranteed to be 99.9% GMO-free."

Conclusion

OTA encourages the subcommittee to focus on identifying reasonable suggestions and solutions that come out of this public comment period (starting with the low hanging fruit) and target the next action steps accordingly. It is notable that this Discussion Document made the agenda while the proposal on Organic Seed Usage did not. We find this to be unfortunate because the call for the organic seed usage proposal was born out of the Seed Purity discussion. Public commenters identified guidance on GMO contamination prevention practices and increasing organic seed usage as immediate actions that could be taken that would help keep GMOs out of organic food, feed and fiber. It's unclear why the

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Materials/GMO Subcommittee would prioritize rehashing a discussion document that met clear obstacles over a proposal to increase organic seed usage that was receiving very strong support.

The use of GMOs is prohibited in organic production and handling. OTA continues to be extremely supportive of moving recommendations forward to NOP that will improve the practices used to keep GMOs out of organic products. We encourage NOSB to focus on actions that have the best chance of successfully moving through the system in order to accomplish this goal.

Summary of recommendation:

1. OTA requests that the Organic Seed Usage proposal be a top priority.
2. OTA recommends the following guiding principles be adopted. A seed purity standard for non-organic should:
    - Incentivize the development and use of organic seed
    - Be established per crop (corn, soy, alfalfa, cotton, etc.)
    - Be based on data conducted through feasibility studies for this intended purpose
    - Establish levels, if any, of unavoidable presence of GMOs per crop
    - Apply to adventitious or unavoidable presence only. The intentional use or presence of GMOs will continue to be strictly prohibited with a zero tolerance level.
    - Be acceptable to consumers, seed growers and users of organic and non-organic seed.
    - Avoid inadvertent and negative impact on organic farmers and organic seed growers and genetic diversity of organic seed.
3. OTA recommends that NOSB develop a recommendation to NOP requesting guidance on GMO testing for ACAs and industry. We do not expect that NOSB would develop the guidance. Instead, we suggest a recommendation for guidance that is developed by GMO testing experts in conjunction with ACAs in the same way that the guidance on pesticide residue testing was developed.
4. After adopting guiding principles, OTA continues to believe that convening a Seed Purity Advisory Task Force or similar expert group must be the next step in the process of developing a seed purity standard. We do not support putting forth a seed purity proposal unless it is aimed at a formal plan for collecting data that would inform a meaningful standard and threshold.

On behalf of our members across the supply chain and the country, OTA thanks the National Organic Standards Board for the opportunity to comment, and for your commitment to furthering organic agriculture.

Respectfully submitted,

Gwendolyn Wyard
Vice President of Regulatory and Technical Affairs
Organic Trade Association

Headquarters - The Hall of the States, 444 N. Capitol St. NW, Suite 445-A, Washington, D.C., 20001 • (202) 403-8513
Member Services - 28 Vernon St., Suite 413, Brattleboro VT 05301 • (802) 275-3800 • fax: (802) 275-3801
www.OTA.com

cc: Laura Batcha
Executive Director/CEO
Organic Trade Association

Attachments

- **Attachment A: OTA GMO White Paper**

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OTA GMO White Paper

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Washington, DC: Hall of the States, 444 North Capitol Street NW, Suite 445A, Washington, DC 20001 USA ▸ (202) 403–8520

OTA GMO White Paper Contents

{An electronic version of the Organic Trade Association (OTA) GMO White Paper is available for download, including full Appendices, on OTA's website at www.ota.com/pp/regulatory/GE.html. Please note that any use, reproduction or dissemination of this information is strictly prohibited without prior permission from OTA. Contact Laura Batcha (lbatcha@ota.com), OTA's Executive Vice President, with questions.}

CHAPTER 1: WHY IS THERE CONCERN ABOUT GMOS?

Genetically modified organisms (more commonly referred to as GMOs) are organisms that have been created through the application of transgenic, gene-splicing techniques that are part of biotechnology. These methods for moving genes are also referred to as genetic engineering (GE).

This relatively new science allows DNA (genetic material) from one species to be transferred into another species, creating transgenic organisms with combinations of genes from plants, animals, bacteria, and even viral gene pools. Mixing genes from different species that have never shared genes in the past makes GMOs and GE crops unique. It is impossible to create such organisms through traditional crossbreeding methods.

Because of this uniqueness, there are many unknowns about genetically engineered (GE) crops and GMOs.

BACKGROUND

Asserting that food from GE crops was "substantially equivalent" to food from non-GE crops, the United States government first approved GE crops nearly 20 years ago depending largely on the studies provided by the companies developing the new technology. The United States went ahead with approvals although no human trials had ever been conducted to assess the safety and allergenicity of these novel proteins.

Governments outside the United States have proceeded with more caution, preventing GE crops from being planted because of outstanding concerns about environmental and/or food safety implications. Since GE crops were first approved in the United States, food allergies have risen dramatically, in step with GE crop market penetration[1]. For instance, according to a data brief published October 2008 by the Centers for Disease Control and Prevention, the prevalence of reported food allergies in the United States increased 18 percent among children under age 18 years from 1997 to 2007. Although no direct links have been made to GE crops, a report by the Pew Initiative on Food and Biotechnology[2] points out that existing research focuses on known allergens such as peanuts and milk, and there are almost no studies examining the allergenicity of novel proteins potentially introduced by foods created through biotechnology.

UNINTENDED CONSEQUENCES

A major area of concern focuses on unintended consequences. For instance, some major problems with GE crops are already emerging. The spread of resistant weeds has driven herbicide use up sharply, increasing human health and environmental impacts and raising farmer costs. Also, many GE crops are more prone to plant diseases, and some suffer micro-nutrient deficiencies because of subtle changes in soil microbial communities.

There is mounting evidence that GMOs from GE crops are showing up where they were never used. Contamination is a real threat, particularly in crops that easily cross-pollinate, such as corn and canola.

Meanwhile, more and more studies are confirming that there are genuine concerns about their use. The following looks at some of the concerns that are being raised.

ENVIRONMENTAL CONCERNS

- **Impact of pesticide use, yields**
  In November 2009, The Organic Center issued a Critical Issue Report[3] on the impact of the adoption of GE corn, soybean and cotton crops on U.S. pesticide use. The most striking finding: with the use of GE crops was

[1] Food Allergy Among U.S. Children: Trends in Prevalence and Hospitalizations, Amy M. Branum and Susan L. Lukacs, U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, October 2008 (http://www.cdc.gov/nchs/data/databriefs/db10.pdf).

[2] Pew Initiative on Food and Biotechnology, "A Snapshot of Federal Research on Food Allergy: Implications for Genetically Modified Food," June 11, 2002 (http://www.pewagbiotechn.org/research/allergy.pdf.)

[3] "Impacts of Genetically Engineered Crops on Pesticide Use in the United States: The First Thirteen Years," by Charles Benbrook

the application of an additional 318.4 million pounds of pesticides in the United States over the first 13 years of their commercial use (1996-2008).

Data from the 1996 through 2008 annual pesticide use surveys done by the USDA's National Agricultural Statistics Service (NASS) showed that *Bt* corn and cotton reduced insecticide use by 64.2 million pounds over the 13 years. However, herbicide-tolerant crops increased herbicide use by a total of 382.6 million pounds over the 13 years. Herbicide-tolerant soybeans increased herbicide use by 351 million pounds, accounting for 92 percent of the total increase in herbicide use across the three herbicide-tolerant crops.

The 318.4 million pound increase in overall pesticide use represents, on average, an additional 0.25 pound of pesticide active ingredient for every GE trait acre planted over the first 13 years of commercial use.

Although overall pesticide use decreased in the first three years of commercial introduction of GE crops, pesticide use increased by 20 percent in 2007 and 27 percent in 2008. There are two major factors for this: the emergence and rapid spread of weeds resistant to glyphosate due to excessive reliance on the herbicide, and incremental reductions in the average application rate of herbicides applied on non-GE crop acres.

- **GMOs persist in waterways**: A study by University of Notre Dame ecologist Jennifer Tank and colleagues published in 2010[4] has found that streams throughout the Midwest receive transgenic materials from corn crop byproducts even six months after harvest. In a 2007 paper in the *Proceedings of the National Academy of Sciences* (*PNAS*)[5], Tank and other researchers had shown transgenic materials from corn pollen, leaves and cobs do, in fact, enter streams in the agricultural Midwest and can be subsequently transported to downstream water bodies. Their later study, published in the Oct. 12, 2010, edition of *PNAS*, investigated the fate and persistence of the material and its associated Cry1Ab insecticidal protein in a survey of 217 stream sites in northwestern Indiana six months after crop harvest. "Our study demonstrates the persistence and dispersal of crop byproducts and associated transgenic material in streams throughout the Corn Belt landscape even long after crop harvest," the researchers concluded.

- **GE in the wild:** Researchers at the University of Arkansas, North Dakota State University and the Environmental Protection Agency have found evidence that GE crop plants can survive and thrive in the wild. Reporting the findings at the 95th annual meeting of the Ecological Society of America[6], scientists reported that they had found that more than 80 percent of canola plants sampled from more than 1,000 miles of roadsides around North Dakota were inadvertently genetically engineered to tolerate herbicides, either glyphosate or glufonisate. In addition, two of the plants analyzed contained two transgenes, indicating that they had cross-pollinated. "These observations have important implications for the ecology and management of native and weedy species, as well as for the management of biotech products in the U.S.," the researchers concluded.

- **Resistance of insect pests:** In 2010, Monsanto reported to the Genetic Engineering Approval Committee in India that pink bollworms, a common insect pest that feeds on cotton, have developed resistance to its GE cotton variety Bollgard I

[4] Jennifer L. Tank, Emma J. Rosi-Marshall, Todd V. Royer, Matt R. Whiles, Natalie A. Griffiths, Therese C. Frauendorf, and David J. Treering, "Occurrence of maize detritus and a transgenic insecticidal protein (Cry1Ab) within the stream network of an agriculturl landsacpe," PNAS 107 (41): 17645-17650 (Oct. 12, 2010).

[5] E.J. Rosi-Marshall, J.L. Tank, T.V. Royer, M.R. Whiles, M. Evans-White, C. Chambers, N.A. Griffiths, J. Pokelsek, and M.L. Stephen, "Toxins in transgenic crop byproducts may affect headwater stream ecosystems," PNAS 104 (41): 16204-16208 (Oct. 9, 2007).

[6] Meredith G. Schafer, Andrew X. Ross, Jason Londo, Connie A. Burdick, E. Henry Lee, Steven E. Travers, Peter K. Van de Water, and Cynthia L. Sagers, research reported at the 95th Ecological Society of America in August 2010 (http://eco.confex.com/eco/2010/techprogram/P27199.HTM.

in Gujarat, India[7]. The company noted it had detected the resistance during field monitoring in the 2009 cotton season. The GE crop contained the Cry1Ac gene derived from the bacterium *Bacillus thuringiensis* (*Bt*).

- **Weed resistance:** A 2010 report issued by The National Academies' National Research Council[8] warns that GE crops could lose their effectiveness and develop more weed problems as weeds evolve their own resistance to glyphosate, unless farmers use other proven weed and insect management practices. It reported to date that at least nine species of weeds in the United States have evolved resistance to glyphosate since GE crops were introduced.

- **Round-up resistant weeds:** A *New York Times* article[9] by William Newman and Andrew Pollack (May 4, 2010) reported on the increase of superweeds that are resistant to Round-up.

- **Herbicide resistance:** A survey by researchers at the Department of Crop Sciences, University of Illinois in Urbana, has found that *Amaranthus tuberculatus* (more commonly known as waterhemp), a major weed in crop fields in the Midwestern United States, has developed multiple herbicide resistance, including to glyphosate (Roundup). In their research article published in the *Journal of Agricultural and Food Chemistry*[10], they noted, "Herbicide resistance in *A. tuberculatus* appears to be on the threshold of becoming an unmanageable problem in soybean." They added, "On the basis of *A. tuberculatus's* history, there is no reason to expect it will not evolve resistance to glufosinate if this herbicide is widely used. If this happens, and no new soybean post-emergence herbicides are commercialized, soybean production may not be practical in many Midwest U.S. fields." At least 21 weed species have developed resistance to the herbicide glyphosate (Roundup) and some weeds are also developing resistance to alternative herbicides, according to articles published in the May-June 2011 issue of *Weed Science*[11]. For example, researchers at the University of Georgia in Tifton found multiple resistances in Palmer amaranth to glyphosate and the herbicide pyrithiobac. In addition, research confirmed resistance of Italian ryegrass in hazelnut orchards in Oregon to glufosinate ammonium, a non-selective broad-spectrum herbicide. Still another study confirmed the first documented glyphosate-resistant Johnson grass biotype in West Memphis, AR. "The herbicide resistance issue is becoming serious," wrote William K. Vencill, journal editor, adding, "It is spreading out beyond where weed scientists have seen it before."

POSSIBLE HEALTH CONCERNS

- **Organ failure (rats):** A study[12] analyzing the effects of GE foods on mammalian health linked three GE corn varieties to organ failure in rats. The researchers led by Gilles-Eric Séralini of CRIIGEN and the University of Caen in France found new side effects linked with GE corn consumption that were sex- and often dose-dependent. These effects mostly occurred with the kidney and liver, while other effects were noticed in the heart, adrenal glands, spleen and hematopoietic system. The researchers concluded that these data highlight signs of hepato-renal toxicity, possibly due to the new pesticides specific to each GE corn.

- **Glyphosate and birth defects:** Research published Aug. 9, 2010[13], confirms that glyphosate-based herbicides cause

[7] Science, March 19, 2010, "Hardy Cotton-Munching Pests Are Latest Blow to GM Crops," by Pallava Bagla.
[8] "The Impact of Genetically Engineered Crops on Farm Sustainability in the United States," The National Academies' National Research Council, 2010.
[9] http://www.nytimes.com/2010/05/04/business/energy-environment/04weed.html?hp
[10] Patrick J. Tranel, Chance W. Riggins, Michael S. Bell, and Aaron G. Haber, "Herbicide Resistances in Amaranthus tuberculatus: A Call for New Options," Jouranl of Agricultural and Food Chemistry November 2010.

[11] May-June 2011 Weed Science (http://allenpress.com/publications/journals/wees; http://www.wssajournals.org/doi/pdf/10.1614/WS-D-10-00132.1).
[12] *International Journal of Biological Sciences* (http://www.biolsci.org/v05p0706.pdf)
[13] *Chemical Research in Toxicology* (http://pubs.acs.org/doi/abs/10.1021/tx1001749)

malformations in frog and chicken embryos at doses significantly lower than those used in agricultural spraying and well below maximum residue levels in products currently approved in the European Union. Glyphosate is the active ingredient in Roundup. Publishing the research were researchers led by Professor Andrés Carrasco, director of the Laboratory of Molecular Embryology at the University of Buenos Aires Medical School and member of Argentina's National Council of Scientific and Technical Research. "The findings in the lab are compatible with malformations observed in humans exposed to glyphosate during pregnancy," Carrasco reported at a press conference during the 6th European Conference of GMO Free Regions. He explained that most of the safety data on glyphosate herbicides and GE soy were provided by industry and are not independent. Carrasco began researching the embryonic effects of glyphosate after seeing reports of high rates of birth defects in rural areas of Argentina where GE Roundup Ready soybeans are grown in large monocultures sprayed regularly from airplanes.

- **Impacts on animal health.** Researchers from Greece[14] reported that animal toxicology studies of GE foods indicate they can have toxic hepatic, pancreatic, renal and reproductive effects. Also, the use of recombinant growth hormones or its expression in animals should be re-examined since it has been shown that it increases IGF-1 which may promote cancer.

- **Serious human health risks.** The American Academy of Environmental Medicine, in a 2009 Genetically Modified Foods Position Paper[15], called for a moratorium on GE foods and warned that "GM foods pose a serious health risk in the areas of toxicology, allergy and immune function, reproductive health, and metabolic, physiologic and genetic health." This position paper cites animal studies that indicate such health risks associated with GM food consumption as infertility, immune dysregulation, accelerated aging, dysregulation of genes associated with cholesterol synthesis, insulin regulation, cell signaling and protein formation, and changes in the liver, kidney, spleen and gastrointestinal system. "Because of the mounting data, it is biologically plausible for genetically modified foods to cause adverse health effects in humans," the report notes, listing citations for numerous peer-reviewed studies as backup.

- ***Bt* toxin in human blood.** Most recently, a study[16] accepted for publication in the journal *Reproductive Toxicology* conducted by scientists at the University of Sherbrooke in Canada reports the presence of *Bt* toxin, widely used in GE crops, in human blood. Although scientists and multinational corporations promoting GE crops have maintained that *Bt* toxin poses no danger to human health as the protein, Cry1Ab, breaks down in the human gut, the findings from this study show this does not happen. Instead, it was found circulating in the blood of pregnant and non-pregnant women. The study also detected the toxin in fetal blood. Cry1Ab toxin was detected in 93 percent and 80 percent of maternal and fetal blood samples, respectively, and in 69 percent of tested blood samples from non-pregnant women.

LACK OF LABELING

Although biotechnology interests often argue that GE crops have not caused a single instance of harm to human health or the environment, there is mounting research showing that GE crops are not harmless, as evidenced by the research cited above. However, GE foods are not labeled.

As a result, the Organic Trade Association and many consumer groups have long called for labeling GE foods in the marketplace. But this concern goes

[14] Artemis Dona & Ioannis S. Arvanitoyannis, "Health Risks of Genetically Modified Foods," *Critical Reviews in Food Science and Nutrition*, February 2009, pages 164-175).

[15] American Academy of Environmental Medicine, Genetically Modified Foods Position Paper, May 8, 2009 (http://www.aaemonline.org/gmopost.html)

[16] Aziz Aris and Samuel Leblanc, "Maternal and fetal exposure to pesticides associated to genetically modified foods in Eastern Townships of Quebec, Canada, Reproductive Toxicology (article in press) (http://somloquesembrem.files.wordpress.com/2010/07/arisleblanc2011.pdf).

beyond consumers and organic interests. In 2010, for instance, the Indiana State Medical Association (ISMA, representing approximately 8,300 physicians in every county in Indiana) resolved that it would seek legislation requiring that any foods containing genetically engineered ingredients be clearly labeled[17].

ISMA's resolution, discussed at its 2010 annual meeting, noted that 40 countries require labeling of GE food, including the European Union, Australia, Japan, Russia, Chia, New Zealand, Brazil and South Africa. In addition, the American Public Health Association, American Nurses Association, the British Medical Association and the Irish Medical Organization all support the labeling of GE food products.

Meanwhile, the challenge for consumers who don't want to eat foods made with GMOS is to know what food products to avoid. The crops most often genetically modified in the United States—as well as the ingredients made from them—are corn, soybeans, canola, sugar beets and cotton. Thus, the following ingredients on labels, if not labeled as non-GMO or organic, are likely genetically modified.

- Corn syrup, starch, oil, meal, gluten
- Soy lecithin, protein, flour, isolate and isoflavone
- Sugar (unless it is made from cane)
- Vegetable oil
- Cottonseed oil

NEED FOR OPENESS IN SCIENTIFIC REVIEW

While genetic events are traceable through the supply chain via contracts and analytical testing, because GE foods are not labeled, they are not readily identifiable by consumers in the marketplace. Additionally the contractual information, test results and genetic information are not readily available to researchers and scientists. This greatly limits the ability to assess environmental and public health safety over time. As patented products, the primers and gene sequences related to GE crop events are not readily disclosed—greatly limiting independent scientific scrutiny. Prohibitions on land-grant universities conducting research on GE crop events without permission from patent holders further exacerbates the dearth of independent research.

There continues to be emerging evidence of environmental and public health concern from the adoption of GMOs in agriculture.

[17] http://www.ismanet.org/pdf/convention/2010/All-resolutions.pdf; http://www.ismanet.org/resolutions/actions09.html

CHAPTER 2: CURRENT STATUS GE CROP PRODUCTION

In 2010, there were 365 million acres of GE crops planted in 29 countries by 15.4 million farmers. This represents 10% of the world's farmland, up from 1% in 1995. Of the 29 countries with GE crop production, ten are developed countries, and 19 are developing nations.

STATE OF GE CROP ADOPTION WORLDWIDE – QUICK LOOK

The top ten countries in GE crop production are:

1. United States 165 million acres
2. Brazil 63 million acres
3. Argentina 56 million acres
4. India 23.5 million acres
5. Canada 22.25 million acres
6. China 8.75 million acres
7. Paraguay 6.5 million acres
8. Pakistan 6 million acres
9. South Africa 5.5 million acres
10. Uruguay 2.75 million acres

Of the GE crops produced, 222 million acres are planted in Herbicide Tolerant (HT) crops, 74 million acres in Insect Resistant (IR) crops, and 61 million acres in crops that are both HT and IR.

The following chart illustrates the percent of total acreage of GE production by crop worldwide in 2010, and the U.S. percentage of those acres of total global production.

CROP	WORLD	U.S.
Soybeans	81%	93%
Cotton	64%	93%
Corn	29%	86%
Canola	23%	93%
Sugar Beets	9%	95%
Papaya	> 1%	80%
Squash (Zucchini)	> 1%	13%

OTHER GE CROPS IN PRODUCTION:

Alfalfa – recently approved in the U.S., planting in 2011
Tomato - small quantities grown in China
Sweet Peppers – grown in China
Potato –approved by EU in 2010 although submitted 13 years ago – planted in Sweden, Germany and Czech Republic.

In addition, there are field trials of the following GE crops: sugar cane, cantaloupe, radish, wheat, eggplant, rubber, sorghum, cabbage and tobacco.

GE crops were first grown commercially in the United States in 1996. By 2010, 29 countries planted commercialized GE crops, while an additional 30 countries had granted regulatory approvals for GE crops for import, food and feed use and for release into the environment. By the end of 2010, a total of 973 approvals had been granted for 183 events for 24 crops, according to the International Service for the Acquisition of Agri-Biotech Applications[18]. In July 2011, Kenya joined the ranks of those with laws allowing GE crop production and imports.

Not surprisingly, the United States tops the list in terms of approvals, followed by Japan, (which does not plant GE crops), Canada, Mexico, Australia, South Korea, the Philippines, New Zealand, the European Union and China.

A record 15.4 million farmers in 29 countries planted 365 million acres of GE crops in 2010, up 10 percent, or 35 million acres, over 2009 plantings. In the United States, approximately 140 million acres of GE cropland are harvested each year. According to the U.S. Department of Agriculture (USDA), 94 percent of soybeans, 90 percent of cotton and 88 percent of corn seeds planted in the United States in 2011 were GE.[19] It is estimated that over 90 percent of canola is GE, and a comparable share of sugar beets are now herbicide tolerant. As a result of the market

[18] *ISAAA (International Service for the Acquisition of Agri-Biotech Applications) Brief 42: Global Status of Commercialized Biotech/GM Crops: 2010*, by Clive James.

[19] USDA's Economic Research Service, "Adoption of Genetically Engineered Crops in the United States," July 1, 2011.

dominance of GE seeds in crops that are common ingredients in most processed foods, GMO ingredients are now present in more than 80 percent of packaged products in the average U.S. or Canadian grocery store.

In August 2011, Monsanto announced it was set to launch a new genetically engineered sweet corn as its first GE commercial vegetable destined for U.S. supermarket shelves. The "triple-stack' sweet corn has been genetically modified to tolerate Monsanto's Roundup herbicide and to kill insects. Syngenta, another biotechnology company, already sells GE sweet corn in the retail market.

Globally, the leading GE crops are soybeans, corn, cotton and canola. Other GE crops include herbicide-tolerant sugar beets and alfalfa, Hawaiian papaya, zucchini, and yellow crookneck squash, and sweet pepper and tomatoes in China.

Three countries—Pakistan (*Bt* cotton), Myanmar *(Bt* cotton) and Sweden (Amflora, a GE potato)—approved planting of biotech crops for the first time in 2010, while Germany resumed adoption of GE crops by also planting Amflora.

GE TRAITS

According to ISAAA, GE soybeans, at 181 million acres, represented 50 percent of the global area planted to GE crops in 2010, up 6 percent from 2009 plantings. This was followed by 113 million acres of GE corn, up 10 percent from 2009. In third place was GE cotton, reaching nearly 52 million acres, up 30 percent from 2009. Meanwhile, GE canola reached 17 million acres, up 9 percent globally from 2009. Corn has the most approved events (60), followed by cotton (35), canola (15) potato and soybeans (14 each).

Herbicide tolerance remains the dominant GE trait. In addition, crops are also genetically engineered for insect resistance. Stacked traits (engineered for multiple traits in one crop), meanwhile, are becoming an increasing feature of GE crops. In fact 11 countries—of which eight were developing countries—planted GE crops with stacked traits in 2010.

The leading trait is herbicide-tolerant soybean event GTS-40-3-2, with 24 approvals, followed by herbicide-tolerant corn (NK603) and insect-resistant corn (MON810) with 21 approvals each, and insect-resistant cotton (MON531/757/1076) with 16 approvals worldwide.

Herbicide-tolerant soybeans were the dominant GE crop grown commercially in 11 countries in 2010 (listed in order of area): United States, Argentina, Brazil, Paraguay, Canada, Uruguay, Bolivia, South Africa, Mexico, Chile and Costa Rica. Globally, herbicide-tolerant soybeans were grown on 181 million acres, up 6 percent from 2009.

The second most dominant GE crop was corn with stacked traits, grown on 71 million acres, up 10 percent from 2009, and representing 19% of global GE crop area. It was planted in eight countries: United States, Canada, South Africa, the Philippines, Brazil, Honduras, Argentina and Chile. The stacked traits for corn include three combinations of traits:

- double stack with insect resistance and herbicide tolerance
- double stack with two traits for insect resistance
- triple stack with two types of insect resistance plus herbicide tolerance

The third leading crop was *Bt* cotton, planted on nearly 40 million acres and representing 11 percent of the global GE crop area, up 30 percent since 2009. *Bt* cotton was planted in 11 countries (in descending order): India, China, Pakistan, Myanmar, Burkina Faso, Brazil, United States, Argentina, Australia, Mexico and Costa Rica.

Fourth leading crop was *Bt* corn, planted on 25 million acres, representing 7 percent of global GE crop area, and planted in 15 countries: Brazil, United States, Argentina, South Africa, Uruguay, Canada, Spain, the Philippines, Portugal, Czech Republic, Poland, Egypt, Slovakia, Chile, and Romania.

Fifth leading crop was herbicide- tolerant corn, planted on 17 million acres, and representing 5% of global GE crop area. It is planted in eight countries: United States, Canada, Argentina, South Africa, Brazil, the Philippines, Honduras, and Chile.

The sixth leading crop was herbicide-tolerant canola, planted on 17 million acres, equivalent to 5% of global GE crop area and planted in four countries: Canada, United States, Australia, and Chile.

The seventh leading crop was stacked cotton, planted on 8.6 million acres, up 35% increase from 2009 and representing 2 percent of global GE crop land. It is planted in the United States, Australia, Argentina, Mexico, Colombia, and South Africa.

The eighth leading trait was herbicide-tolerant cotton planted on 3.4 million acres representing 1 percent of all GE crops globally, and planted in seven countries.

PETITIONED GE CROPS IN THE UNITED STATES

As of May 11, 2011, the United States had approved (or partially deregulated) 81 petitions for deregulating GE crops. At that time, 22 petitions were currently pending. Lists of those that had been granted as well as still pending are available at http://www.aphis.usda.gov/biotechnology/not_reg.html {*See accompanying pdf in the Appendix*}.

Most recently, USDA in early 2011 approved plantings of three GE crops in as many weeks, including Monsanto's Roundup Ready sugar beets and alfalfa engineered to tolerate Roundup Ready. In February 2011, USDA also legalized, without restriction, the world's first GE corn crop meant for biofuel production.

ATTACHMENTS

Appendix 1 {*PAGE 38*}
Lists of approved and pending petitions for GE crops

CHAPTER 3: THE NATIONAL ORGANIC PROGRAM AND THE USE OF GMOS

In December 1997, the U.S. Department of Agriculture (USDA) released its initial National Organic Program (NOP) proposed rule for organic agriculture that would have allowed the use of genetically modified organisms (GMOs) despite the National Organic Standards Board's (NOSB) recommendation that they be prohibited.

NOSB based its decision that GMOs are inappropriate for organic agriculture on the principal consideration that organic agriculture functions by using natural ecosystems whereas genetic engineering alters the molecular or cell biology of an organism by means that are not possible under natural conditions. Accordingly, NOSB, in its Biotechnology Policy of 1996, recommended that the class of GE organisms and their derivatives be prohibited in organic production and handling systems.

ARRIVAL OF REGULATION: EXCLUDED METHODS DEFINED & PROHIBITED

USDA sought to include GMOs in organic systems because federal policy takes the position that the safety evaluation of food is based on the properties of the product, not on the manner in which it was produced[20]. However, after receiving more than 275,000 public comments opposing the allowance of GMOs, USDA revised its proposed rule and released an updated version in March 2000. As a result, the NOP standards[21], 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.

For the March 2000 proposed rule, many commenters requested adding "the products of excluded methods" to the definition. USDA's response, as explained in the preamble to the rule, was to not accept the additional language:

> The emphasis and basis of these standards is on process, not product. We have specifically structured the provisions relating to excluded methods to refer to the use of methods. Including the products of excluded methods in the definition would not be consistent with this approach to organic standards as a process-based system. For the same reason, we have retained the term, "excluded methods," to reinforce that process-based approach.

USDA also rejected comments requesting that "intentional use" of excluded methods be referred to in the definition, explaining that the prohibition is most properly addressed in the appropriate provisions of the regulations, particularly in Section 205.105.

[20] Emily Marden, Risk and Regulation: U.S. Regulatory Policy on Genetically Modified Food and Agriculture, 44 B.C.L. Rev. 733 (2003), http://lawdigitalcommons.bc.edu/bclr/vol44/iss3/2.

[21] Title 7 CFR Part 205 - National Organic Program.

EXCLUDED METHODS: A GENERAL PROHIBITION IN A PROCESS-BASED STANDARD

The proposed rule included reference to the prohibition of excluded methods in various parts of the regulation. Commenters supported the prohibition but could not point to one provision that prohibited the use of excluded methods in all aspects of organic production and handling. In order to identify all aspects where excluded methods might be used, NOP included a provision in § 205.105 of the final rule generally prohibiting the use of these methods. The rule currently reads as follows:

> **§ 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 ingredients," 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)
> (f) ionizing radiation
> (g) sewage sludge

Many commenters also raised concerns regarding drift of the products of excluded methods on organic farms. The concern was that organic crops would be contaminated, and organic farmers could lose the premium for their organic products through no fault of their own. Therefore, organic proponents believed the rule should shift the burden to the technology providers that market the products of excluded methods or the farms that use the products. In response, USDA explained that while it understood these concerns, it could not use the regulation to impose restrictions on operations not covered by the Act. Re-emphasizing that the organic standards are processed-based, it responded with the following:

> This regulation prohibits the use of excluded methods in organic operations. The presence of a detectable residue of a product of excluded methods alone does not necessarily constitute a violation of this regulation. As long as an organic operation has not used excluded methods and takes reasonable steps to avoid contact with the products of excluded methods as detailed in their approved organic system plan, the unintentional presence of the products of excluded methods should not affect the status of an organic product or operation.

The regulatory language that was retained in the final rule and its relationship to a process-based system continues to play a central role in the execution and practice of the prohibition on excluded methods in organic agriculture.

DETECTION OF PRODUCTS DERIVED FROM EXCLUDED METHODS

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.

Many commenters suggested that the regulation establish a "threshold" for the "unintended or

adventitious presence of products of excluded methods in organic products," arguing that without the mandatory labeling of biotechnology-derived products, organic operations and certifying agents could not be assured that products of excluded methods were not being used. Others argued that without an established threshold, the regulations would constitute a "zero tolerance" for products of excluded methods, which would be impossible to achieve.

At that time, NOP did not believe there was "sufficient consensus upon which to establish such a standard." The information needed to set a threshold was considered largely unknown, and the understanding of how biotechnology in conventional agriculture might affect organic production was even less developed. Furthermore, the testing methodology for the presence of excluded methods had not been fully validated.

NOP, however, did anticipate that evolving industry best practices and standards for preserving product identity would become the standards for implementing the provisions in this regulation relating to the use of excluded methods {*SEE APPENDIX 2*[22]}.

HANDLERS, PROCESSED PRODUCTS & LABELING

In addition to the general provision under § 205.105 applying to certified producers and handlers, the regulation reiterates the prohibition for certified handling operations by cross-referencing Section § 205.105 under Organic Handling Requirements:

> **§ 205.270(c) The handler of an organic handling operation must not use in or on agricultural products intended to be sold, labeled, or represented as "100 percent organic," "organic," or made with organic ingredients," or in or on any ingredients labeled as organic:**
>
> (1) Practices prohibited under paragraphs (e) and (f) of 205.105.

The prohibition on the use of excluded methods is also included under the section of the rule addressing product composition:

> **205.301(f) All products labeled as "100 percent organic" or "organic" and all ingredients identified as "organic" in the ingredient statement of any product must not:**
>
> (1) Be produced using excluded methods, ***pursuant*** to 201.105(e).

Although the regulatory language under product composition does not explicitly prohibit the use of excluded methods in the non-organic portion of the 5% and 30% of "organic" and "made with organic" products, respectively, the Preamble to the final rule clarifies:

> The 5 percent of nonorganic ingredients in products labeled "organic" also are subject to the three prohibited practices. The nonorganic ingredients in products labeled "made with organic ingredients" must not be produced using ionizing radiation or excluded methods but may be produced using volatile synthetic solvents. The nonorganic ingredients in products containing less than 70 percent organically produced ingredients may be produced and processed using ionizing radiation, excluded methods, and synthetic solvents.

This clarification assures the consumer that the entire composition of a certified product has been produced without the use of excluded methods under the meaning of this regulation.

NOP CLARIFICATIONS

Shortly after the regulation's implementation, NOP posted several questions and answers[23] on its website providing further clarification on the issues of GMO drift, genetically modified farm inputs, and genetically modified non-organic ingredients *{SEE APPENDIX 3}*.

[22] Residue Testing Preamble: Changes Requested But Not Made.

[23] Referred to as the NOP-AQSS (Answers to Questions on NOP Standards by NOP Staff); removed from the NOP website on June 15, 2011, and replaced by the NOP Handbook.

On Sept. 2, 2010, NOP published the Organic Program Handbook comprised of Guidance Documents (Level 1)[24] and Instruction Documents (Level 2)[25]. Included in the NOP Handbook, as of April 15, 2011, is a Policy Memo (Level 2 Guidance Document) on the Use of Genetically Modified Organisms. This policy memo reiterates that the use of GMOs is prohibited under NOP regulations, and answers questions that have been raised concerning GMOs and organic production and handling. The clarification is consistent with the explanations provided in the preamble and in NOP-AQSS, thus re-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 {*SEE APPENDIX 4*}.

NOSB DEVELOPMENTS

There have been relatively few developments at the NOSB level on the topic of excluded methods since the implementation of the rule. The primary area of activity has been related to livestock standards, specifically vaccines and animal cloning.

Animal Cloning

A Final Recommendation[26] was passed in March 2007 to amend the section of the regulation dealing with Origin of Livestock (§ 205.236) clarifying that the existing NOP rule prohibits animal cloning technology, including all progeny and succeeding generations of those progeny. In addition, the recommendation revises the existing definition of excluded methods to ***include*** reference to "cloning" in the list of prohibited methods.

This NOSB recommendation has not been acted on by NOP. However, on Jan. 31, 2011, NOP released a Policy Memorandum in the NOP Handbook attaching three NOP memos[27] explaining its position on cloning and organic livestock production. NOP's position is that cloning as a production method is incompatible with the Organic Foods Production Act of 1990 (OFPA) and prohibited under NOP regulations. The organic status of progeny of animals derived using cloning technology will require a rulemaking process.

Vaccines

On Nov. 5, 2009, NOSB made a Final Recommendation[28] to clarify that vaccines produced through excluded methods are allowed under § 205.603 and do not need to be individually petitioned for allowance on the National List[29]. Further, NOSB recommended that vaccines produced from non-excluded methods be sought and used before those produced by excluded methods.

NOP responded to NOSB in a Sept. 30, 2010, memorandum to its November 2009 Recommendations. NOP requested a legal review from USDA's Office of General Counsel (OGC) to determine whether vaccines produced through excluded methods are currently allowed under 205.603(a)(4). OGC's opinion supported the position that GMO vaccines are allowed only if they are approved according to 205.600(a). NOP suggested that NOSB request a technical review for biologics-vaccines, review GMO vaccines under the provisions of § 205.600(a), and submit a recommendation to NOP to add GMO vaccines to the National List. The NOSB will readdress vaccines in the near future and provide the NOP with a recommendation based on additional public comment.

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[24] Level 1 Guidance Documents set forth interpretations of NOP statutory or regulatory requirements, changes in interpretation or policy, or address unusually complex or highly controversial issues.

[25] Level 2 Instruction Documents set forth or clarify existing NOP procedures. Level 2 Instructions are meant to inform certifying agents and certified operations about best practices for conducting business related to certification, accreditation, international activities, and compliance and enforcement.

[26] Formal Recommendation by the NOSB to the NOP, Cloning Recommendation, March 2007.

[27] January 31, 2007, "NOP Announcement on Cloning and Organic Livestock Production," and the January 15, 2008, "NOP Cloning and Organic Livestock Production Talking Points" and "NOP Cloning and Organic Livestock Production Q and A's."

[28] Formal Recommendation by the NOSB to the NOP, Vaccines, March 2009.

[29] Currently § 205.105(a)(6) provides that organic products must be produced and handled without the use of "Excluded methods, except for vaccines; Provided, That the vaccines are approved in accordance with § 205.600(a)". However, when the final rule was published, vaccines were listed, without annotation, as allowed synthetics at § 205.603(a)(4). The Preamble to the final rule addresses that § 205.105(a) (6) was structured so that vaccines produced using excluded methods could only be used if they are affirmatively included on the National List. This provision was created to allow for the use of vaccines that may only be available in a form produced using excluded methods.

NOSB Letter concerning GMO

At NOSB's April 2011 meeting, a letter from the public was circulated to Board members asking them to sign it in response to public testimony expressing a desire to keep GMOs out of the organic system. Board Chair Tracy Miedema proposed the GMO issue be taken up by the Executive Committee at the Fall NOSB meeting. The Board voted unanimously (14-0) on a motion to accept this proposed action.

VERIFICATION OF PROHIBITED METHODS IN PRACTICE

Compliance to the regulation is evaluated by the Accredited Certifying Agency (ACA) throughout the course of initial and continuing certification. The explanation of this process and the measures taken by both the certified operator and the ACA are best divided into production practices and input or ingredient verification. For the purposes of this paper, the focal area is organic crop and livestock production practices and their relationship to the increased unrestricted planting of GE crops. It's important to mention however, the evaluation of inputs and ingredients because the intentional use of either one, if produced by excluded methods, would be a violation of the NOP regulation and result in product contamination.

Production Practices

The evaluation of excluded methods is based on the information provided in the producer's Organic Systems Plan (OSP)[30] and is verified by the certifier through desk audit and during the 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 will disclose in the OSP any non-organic seed (and thus potentially GMO) they are using, and typically provide 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. A qualified inspector will take into consideration the types and varieties of genetically modified seed that are commercially available and focus on any relevant seed the producer may be using.

Contamination prevention measures are typically described in the OSP under sections addressing "Land Use" and "Maintaining Organic Integrity." Most if not all OSPs will include a farm map that describes adjoining land use and the buffer zones designated to prevent contamination due to potential drift of prohibited substances. During the on-site inspection, the inspector will evaluate nearby and adjoining land use and determine whether the buffer zones and any other contamination prevention measures taken are adequate. The OSP and subsequent inspection will also address the established practices to separate organic seed, crops, and feed from non-organic forms during harvest, storage and shipping.

Should an inspector have reason to believe that an agricultural input or product has been produced using excluded methods, he or she would report this information to the certifying agent. That certifier then may require pre-harvest or post-harvest testing of the input or product in question. A positive detection of prohibited substances, including products of excluded methods, would serve as a warning indicator and trigger an investigation by the certifying agent to determine if a violation of organic production or handling standards occurred. As explained in the Preamble[31], the presence of a detectable residue alone **does not necessarily indicate use of a product of excluded methods** that would constitute a violation of the standards. If the investigation determined the

[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.

[31] Residue Testing Preamble: Description of Regulations, General Requirements & Detection of Prohibited Substances or Products Derived from Excluded Methods.

intentional use of an excluded method or revealed a product produced using excluded methods, the product could not be sold or labeled as organically produced, and/or the certified operation would be subject to suspension or revocation of its organic certification[32].

Certifiers may also monitor certified operations for the presence of GMO residue through testing to determine whether adequate contamination prevention measures are in place. However, at this time, certifiers conduct very little GMO testing on a regular basis. According to an ACA survey conducted in March 2011[33], 13 of the 18 respondents currently test for GMOs, and only three of the 13 respondents test for GMOs on a periodic basis. Most testing, if any, is in response to a complaint or when contamination is suspected.

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

Measures taken to avoid contact with GMOs include, but are not limited to, protective buffer strips, testing seed sources for GMO presence, delayed or early planting to get different flowering times for organic and GMO crops, cooperative agreements with neighbors to avoid planting GMO crops adjacent to organic crops, cutting or mowing alfalfa prior to flowering, posting signs to notify neighboring farmers of the location of organic fields, and thorough cleaning of farm equipment used in non-organic crop production.

Whether or not the certified operator has identified all potential GMO contamination concerns in the OSP and implemented adequate preventive practices would help determine whether the unintentional presence of GMOs would affect the status of the organic operation and/or its products.

Input Evaluation

Crop & Livestock Inputs

Farm and livestock inputs are evaluated through a process commonly referred to as "Material Review." It's during this evaluation that the GMO status of seed, fertilizers, feed additives, vaccines and other health care inputs are considered. This is an area where the verification practice tends to vary from certifier to certifier depending on the GMO policy of the individual certifier or Material Review Organization (MRO).

Certifiers evaluate the GMO status of materials or inputs through the use of a document commonly referred to as a non-organic input affidavit/ questionnaire/declaration. Each certifier usually provides a form it has created that explains the form's purpose along with regulatory background and references. While the forms vary from one certifier to the next, they generally include a series of questions about the GMO status of the input in question followed by a date and signature section to be signed by the manufacturer (or supplier) of the input.

Ingredient and Processing Aids

Verification that a certified handler is not using excluded methods focuses on product formulation and the evaluation and approval of non-organic ingredients and processing aids.

As mentioned earlier, the 5% and 30% non-organic portion of a certified product must not be produced using excluded methods. For example, tocopherols are on the National List of non-organic ingredients allowed in the 5% or 30% of a NOP certified product, provided they are derived from vegetable oil. Tocopherols are typically derived from soybeans. Therefore, certifiers must verify that the tocopherols are derived from non-GMO soybeans. The evaluation of the non-organic ingredients is carried out using the same approach as described with crops and livestock, only certifiers will use a form commonly referred to as the "Non-organic Ingredient Affidavit/ Declaration/Questionnaire." The varying content of the form from one certifier to the next remains the same as with the forms used for crop and livestock inputs.

[32] Certifying agents would follow the compliance requirements specified in sections 205.662 and 205.663 of Subpart G.
[33] The ACA survey was sent to 42 NOP accredited certifiers and focused on questions about GMO testing.

The Problem

Crop and Livestock Input Evaluation

The regulations require organic products to be produced without the use of excluded methods. This extends to the non-organic inputs and ingredients that come into contact with or are used to produce organic products. As mentioned earlier, the use of inputs by a certified operator that have been produced using excluded methods largely falls outside the focus of this paper. However, their use does pose another potential risk of product contamination, especially because many of the inputs being used may contain GMOs because of the widespread prevalence of GE crops. From this perspective, consideration of their use and impact is relevant.

The Preamble to the rule specifically addresses the use of non-organic ingredients. However, it does not address the use of inputs used in crop and livestock other than the allowance of genetically modified vaccines if they are reviewed and added to the National List. The exception provided to vaccines implies that all other crop and livestock inputs must not be produced using excluded methods.

- Not all certifiers evaluate GMO status of crop and livestock inputs.
- GMO status of vitamins used in livestock operations is not consistently evaluated.
- There are several NOP Q & A's that support the idea that crop inputs that are "products of excluded methods" (such as cottonseed meal fertilizer made from GMO cotton) may be used because the producer has not "used an excluded method."
    - Cottonseed meal produced using GE cotton vs. cottonseed meal that contains unintentional traces of GMO contamination.

Non-organic Ingredient Evaluation

The Preamble and the NOP Policy Memo make it clear that non-organic ingredients must not be produced using excluded methods. Verification of the prohibition is problematic due to the difficulty of knowing how far back in the chain of ingredient suppliers to go.[34] Does the raw material used in the production of a processing aid used to produce the non-organic ingredient fall outside the scope of the prohibition? Does the use of excluded methods apply only to the manufacturer of the final non-organic ingredient?

As explained in the Preamble, "the emphasis and basis of the standards is on process, not product." Given this clarification, a handler (using a product of a GMO such as tocopherols) could submit a statement declaring they have not used excluded ***methods***, and the statement could be seen as accurate.

More commonly however, the statements submitted from non-organic ingredient manufacturers using corn or soy, for example, in the production of a non-organic ingredient will declare that the final product does not contain any GMO DNA or protein, but that the ingredient may have been produced using genetically modified raw materials. In situations where the non-organic ingredient in question has been produced using corn substrate, or the ingredient is extracted from soybeans, the company signing the form will typically provide a disclaimer stating that they cannot be certain that the raw materials are non-GMO, and they may or may not speak to the testing of the final ingredient.

In some cases, certifiers outright prohibit the use of GMOs at any stage of production. This approach may be seen as consistent with the idea of a process-based standard. In other cases, certifiers might accept the use of genetically modified raw materials in the production of a non-organic input, so long as there is no remaining GM DNA/protein in the final non-organic ingredient. This allowance follows a product-based approach. However, if the non-organic ingredient does not contain GMOs, then effectively the certified handler has not used excluded methods in the handling of the certified product, and the consumer is purchasing a product that does not contain detectable GMOs.

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Appendix 2 – Preamble: Residue Testing: Changes Requested But Not Made. {*PAGE 39*}

Appendix 3 - NOP Q & A's {*PAGE 40*}

Appendix 4 - NOP Policy Memorandum: Clarifications of Existing Regulations Regarding the Use of Genetically Modified Organisms in Organic Production and Handling. {*PAGE 41*}

[34] http://www.non-gmoreport.com/articles/apr06/organic.php.

CHAPTER 4: USDA'S STATUTORY AND REGULATORY AUTHORITY RELATING TO GE CROPS

The U.S. Department of Agriculture (USDA) has far greater statutory powers at its disposal than it currently uses in regulating GE crops. Specifically, USDA has not asserted its full statutory authority as provided in the Plant Protection Act of 2000 (PPA) when ruling on whether to regulate specific GE crops.

CURRENT LAW AND REGULATORY FRAMEWORK REGARDING GE CROP RELEASE

The Animal & Plant Health Inspection Service (APHIS) promotes biotech crops and makes the process of their commercialization as swift and efficient as possible. Historically, in ruling on the safety of GE crops, USDA has taken a narrow view centering only on whether such crops pose a plant pest risk rather than asserting a broader interpretation of potential negative outcomes from such deregulation. This is reflected in an inclination to approve biotech crops without considering significant impacts to the environment, farmers' livelihoods, and the rural economies they support.

This observation is buttressed by USDA's response to the Federal District Court decision in Geerston Seed Farms v. Johanns, where the Court determined that USDA's finding that GE contamination would not occur through deregulation of RR Alfalfa was "arbitrary and capricious" and that *inter-related* socio-economic impacts must be considered in the deregulation decision-making processes pursuant to the mandates of the National Environmental Policy Act (NEPA).

USDA responded by changing its position on its own authority, arguing in the GE Alfalfa Draft Environmental Impact Statement (DEIS) and the sugar beet lawsuit (Center for Food Safety v. Vilsack) that PPA provides only the power to determine whether the regulated article poses a plant pest risk and does not allow for consideration of socio-economic impacts and other necessary NEPA criteria.

In Congressional Research Service (CRS) reports to Members and Committees of Congress, Tadlock Cowan, CRS analyst in Natural Resources and Rural Development, has consistently pointed out that questions remain concerning the adequacy of the current regulatory structure to assess and manage any risks created by GE.[35] For GE in animal agriculture, he notes, concerns range from food safety and social resistance to potential negative impacts on animal welfare and on ecosystems. For GE in agriculture in general, ongoing concerns include not only the impact on food safety and on the environment, such as herbicide resistance, but whether GE foods should be labeled, and their potential contamination of conventionally and organically raised plants.

In addition, an April 4, 2011, CRS report notes, "The cases of GE alfalfa and sugar beet highlight continuing policy questions about the adequacy of APHIS's deregulation protocol, particularly regarding the environmental review process." {*SEE APPENDICES 5-7 FOR FULL CRS REPORTS*}.

CURRENT GE CROP REGULATION

Setting the basis for regulating biotech crops, the Plant Protection Act (PPA) gives the Secretary of Agriculture authority to adopt regulations preventing the introduction and dissemination of plant pests [7 U.S.C § 7711(a)]. Consistent with that authority, APHIS, a division of USDA, regulates the introduction of organisms and products altered or produced through genetically engineering that are plant pests or believed to be plant pests, or regulated articles. The regulations covering GE crops are contained in 7 C.F.R. § 340.

USDA, however, relies on an antiquated biotechnology crop regulatory system based the Federal Plant Pest Act (FPPA) and other "quarantine" authorities that were repealed as part of the enactment of the PPA in defining "plant pests."

[35] Tadlock Cowan, Biotechnology in Animal Agriculture: Status and Current Issues (May 19, 2011); Agricultural Biotechnology: Background and Recent Issues (June 18, 2011); Deregulating GE Alfalfa and Sugar Beets: Legal and Administrative Responses (co-authored with Kristina Alexander, April 4, 2011).

FPPA and those quarantine statutes were intended to protect agriculture against "plant pests" and have always been a legal stretch because crops only rarely act as pests on other plants. USDA continues to use these authorities as the basis for its existing comprehensive regulatory system for biotech crops, despite their failure to address the broader environmental and economic impacts of GE crops.

Under the existing regulatory framework, USDA limits its inquiry to whether the inserted genetic material poses a "plant pest risk," defined as "*any living stage of any of the following that can directly or indirectly injure, cause damage to …any plant of plant product"* [7 U.S.C. § 7702(14)]. APHIS regulations similarly define "plant pests" as *"any living state of … bacteria … or any organisms similar to allied with the foregoing … which can directly or indirectly injure, cause disease or damage in or to any plants or plant parts thereof, or any processed, manufactured or other product of plants"*[7 C.F.R. § 340.1]. Those same regulations reference plant pest analysis as including *"indirect plant pest effects on other agriculture products*" [7 C.F.R. § 340.6(c)(4)].

Consequently, in its GE alfalfa DEIS, APHIS concluded that "due to the lack of plant pest risk from the inserted genetic materials, the lack of weediness characteristics of alfalfa events J101 and J163 alfalfa, the lack of atypical responses to disease or plant pests in the field, the lack of deleterious effects on non-target or beneficial organisms in the agro-ecosystem, and the lack of horizontal gene transfer, Events J101 and J163 alfalfa are unlikely to pose a plant pest risk."

Even under this narrow regulatory framework, if APHIS considered the Roundup Ready crop system as the basis for analysis rather than focusing narrowly on the plant pest risk from the inserted genetic material, it would likely reach different conclusions, particularly those relating to the impact on non-target and beneficial organisms, on weediness potential and the development of glyphosate-resistant weeds. The inclusion of indirect injury/harm analysis would also require considering economic impacts to farmers. Even under the existing regulatory structure, this change in analyses would ultimately lead to different conclusions regarding the significance of impacts, and consequently, on USDA's decision to deregulate GE crops.

USDA argues that APHIS' authority is limited solely on whether the regulated article poses a plant pest risk. Once that determination is made, USDA contends that all inquiry ceases, and the agency is precluded from making further assessments/analyses, even those mandated by the National Environmental Policy Act (NEPA). This narrow analysis resulting in the conclusion that no plant pest risk exists is then used as a rationale for halting all further inquiry. APHIS concluded that since no plant pest risk was involved, it was powerless to:

- Impose isolation distances,
- Require regulatory restrictions,
- Establish/mandate management practices,
- Establish geographic restrictions, or
- Impose conditions to reduce impact to organic farmers.

The Supreme Court decision in Geertson Seed Company, holding that a permanent injunction was improper as USDA failed to consider alternatives such as partial deregulation, implicitly acknowledged USDA's authority to look beyond such a narrow approach to biotech regulation.

STATUTORY AUTHORITY

USDA has far greater powers at its disposal than it currently uses in regulating GE crops. As mentioned, USDA derives its primary authority for GE crop regulation from the Plant Protection Act (PPA) enacted in 2000. PPA consolidated a number of plant health laws including the Noxious Weed Act and the Federal Plant Pest Act (FPPA).

Eleven years have passed since PPA's enactment, yet USDA has yet to promulgate regulations consistent with the broad regulatory power it provides. Doing so would require USDA to broaden its assessments of environmental and economic impacts. Although a comprehensive overhaul of the biotech regulatory process was initiated through a Programmatic EIS (rulemaking) process in 2004 leading to the publication of Proposed Rules (APHIS-2008-0023), final regulations have not been implemented.

PPA provides expansive regulatory powers to USDA for the *"detection, control, eradication, suppression, prevention or retardation of the spread of plant pests or noxious weeds necessary for the protection of the agriculture, environment, and economy of the United States."* Thus, in addition to plant pests, APHIS can prevent the dissemination of noxious weeds, defined as *any plant or plant product that*

can directly or indirectly cause damage to crops, livestock, poultry, or other interests of agriculture, irrigation, navigation, the natural resources of the United States, the public health or the environment"[7 U.S.C. § 7712(a)].

According to PPA, APHIS clearly has much more authority that it acknowledges. The noxious weed authority was designed to address the full range of adverse agricultural, public health and environmental impacts associated with GE crops (7 U.S.C. § 7702 (10) in order to fulfill the PPA's purpose to protect agriculture, the environment and economy of the United States [7 U.S.C. § 7701(1)]. This authority provides clear authority for USDA to consider the economic impacts to farmers in the deregulation decision-making process. Thus, USDA has legitimate statutory authority to protect U.S. farmers and agricultural economies, but has not exercised it.

In fact, on July 9, 2011, APHIS issued two *Federal Register* notices confirming that it will not regulate Kentucky bluegrass genetically engineered for herbicide tolerance either as a plant pest or as a noxious weed. These notices were in response to a 2002 request from the International Center for Technology Assessment and the Center for Food Safety that the agency list glyphosate tolerant GE Kentucky bluegrass as a noxious weed, and to a Sept. 13, 2010, letter from the Scotts Miracle-Gro Company saying that it did not believe its GE Kentucky bluegrass variety needed to be regulated. APHIS made its decision without any extensive review.

NEPA MANDATES & BIOTECH REGULATION

Due to inaction by USDA to promulgate a comprehensive system of biotech crop regulation assessing the full range of environmental and economic impacts contemplated under PPA, those assessments have been accomplished through application of the mandates of the National Environmental Policy Act (NEPA).

NEPA requires agencies to take a "hard look" at the environmental and inter-related economic impacts prior to undertaking a major federal action – such as the commercialization of biotech crops. The analysis is quite different than that under PPA. Agencies are required to determine whether the proposed federal action poses a significant environmental impact. If it does, NEPA requires the agency to conduct an Environmental Impact Statement (EIS), which also includes an assessment of the inter-related socio-economic impacts. Federal District Courts have determined that USDA's Findings of No Significant Impact (FONSI) in the deregulation of bentgrass, alfalfa and sugar beets were arbitrary and capricious, and, accordingly, required the agency to prepare an EIS as a precondition to deregulation.

The problem with the reliance on NEPA is that the statute does not provide substantive powers or require that an agency take actions and make decisions consistent with the findings and conclusions contained in the EIS. The purpose of the EIS is merely to "inform" the decision-maker of the potential consequences of taking a proposed federal action. An EIS could conclude that a given biotech crop will contaminate the planet and destroy the U.S. agriculture economy, yet USDA could still decide to deregulate that biotech crop. Unfortunately, until USDA promulgates final regulations consistent with the authority provided in PPA and its Noxious Weed provisions, NEPA provides the only legal avenue for comprehensive assessment of biotech crop impacts.

PROPOSED BIOTECHNOLOGY REGULATORY REVISIONS

In October 2008, APHIS published a proposed rule to revise its regulations of GMOs. However, this rule has yet to be made final, pending the review and consideration of the many comments received by the agency. However, it is long overdue. The current Secretary of Agriculture indicated at OTA's 2011 Policy Conference that it can be expected to be released by the end of 2011.

Such a rule, once adopted, will focus on strengthening USDA's oversight authority as called for in public comment, especially in the area of protection against noxious weeds. This is because proposed revisions include aligning the regulations not only concerning plant pests but also noxious weed provisions of the PPA. In a fact sheet related to the proposed revisions, APHIS explained noxious weeds include plants that may pose a broader array of harm to plants, animals, agriculture, the environment, and public health.

In announcing the proposed rule, APHIS noted that new regulations were needed to allow the agency to keep pace with the increased complexity and scope of

biotechnology in the United States and the rapid development of new GMOs, and to ensure that these new products are safely developed and field tested.

The final rule is expected to provide a detailed description of the regulatory requirements for permit holders not in the current regulations. This includes new reporting and record-keeping requirements, requirements that field locations be identified with exact geographic coordinates, and the ability to impose binding conditions for all permits.

ADVISORY COMMITTEES

In other developments, in late January 2011, after announcing plans to allow commercial planting of GE alfalfa without waiting for the final Environmental Impact Statement, the Secretary of Agriculture unveiled a set of actions "to bolster the spirit of constructive coexistence among diverse segments of U.S. agriculture." These actions included renewing and reconstituting its National Genetic Resources Advisory Council (NGRAC) and reviving USDA's Advisory Committee on Biotechnology and 21st Century Agriculture (AC21), two bodies that it has established under the provisions of the Federal Advisory Committee Act (FACA).

The purpose of AC21 is to provide information and advice to the Secretary of Agriculture on the long-term impacts of biotechnology on the U.S. food and agriculture systems, and guidance on pressing international issues identified by the Office of the Secretary related to the application of biotechnology to agriculture. Its latest focus is to address the following topic: what practical measures and effective tools can be developed to strengthen coexistence so the United States can meet domestic and international markets in GE-sensitive markets while allowing continued production for other markets.

In late June 2011, USDA announced the names of those appointed to the reactivated AC21 (http://www.usda.gov/wps/portal/usda/usdahome?contentid=2011/06/0278.xml&contentidonly=true). The advisory committee is composed of 22 members from 16 states, and represents the biotechnology industry, the organic food industry, farming communities, the seed industry, food manufacturers, state government, consumer and community development groups, the medical profession, and academic researchers. Appointees will initially serve one- or two-year terms, and may be reappointed to serve up to six consecutive years.

Among the appointees are six organic representatives, five of whom are OTA staff or from OTA member companies: Laura Batcha (OTA's Executive Vice President), Charles Benbrook (Chief Scientist, The Organic Center), Lynn Clarkson (farmer and President, Clarkson Grain Company), Michael Funk (Chairman of UNFI), Melissa Hughes (Corporate Counsel and Director of Government Affairs for Organic Valley Family of Farms), and Mary-Howell R. Martens, farmer and Manager of Lakeview Organic Grain LLC.

USDA's National Genetic Resources Advisory Council, meanwhile, is charged with helping ensure that all farmers have the best seed for their particular farming operations. Its goals include developing a broad strategy for maintaining plant biodiversity available to agriculture, ensuring adequate opportunity for cross-sector stakeholder and customer input as USDA maintains U.S. germplasm collections, and determining how best to work with the private sector while strengthening public sector plant breeding to provide an adequate diversity of high-quality seeds for all U.S. farmers.

Because of the work of the two advisory bodies will intertwine, USDA plans to explore ways to ensure that the two benefit from each other's work.

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CHAPTER 5: CONSUMER PERSPECTIVES ON GMOS

Consumers' awareness of GMOs is relatively high. In a survey of the general population done in January 2011[1], nearly half of the general population (43%) is aware of the term "genetic modification" or "genetically modified organisms." Among those who are aware, over half are at least somewhat concerned about GMOs (19% very concerned, and 35% somewhat concerned), and a third purposely avoid foods/beverages because of genetic modification.

Consumers have limited understanding of genetically modified products. Per Nielsen's U.S. Consumer Trends study[2], a majority of consumers (43%) claim to neither agree nor disagree with the statement "genetically modified products are completely safe" – they just don't know. Only 18% agree that they are safe, and 39% disagree.

ORGANIC AND NATURAL CHANNEL CONSUMERS

Not surprisingly, organic and natural channel consumers are two times as likely as the general population to be aware of GMO food (>91%). Organic and natural consumers have a much more developed view of GMOs: 72% believe that GMOs are harmful to human and environmental health, while only 6% believe GMO's are not harmful and 22% are not sure. Ninety percent believe organic food is safer that GM food. These views drive more stringency in their purchasing: 80% have purposely avoided purchasing GM food[3].

Organic consumers expect and trust organic to be non-GMO. A national survey of organic consumers[4] shows that for these consumers, organic is inextricably linked with "non-GMO," and avoiding GMOs is a top reason for purchasing organic:

- 91% associate the characteristic of "free of genetically modified organisms (GMOs)" with organic food and beverages
- 83% purchase organic food specifically to avoid GMOs
- 29% say avoiding GMOs is the *main reason* they buy organic food

For those who purchase organic foods and beverages to avoid GMOs, 94% are doing so because they are concerned about the safety risk GMOs pose to themselves and their family. In addition, there are a host of secondary reasons consumers purchase organic to avoid GMOs including the adverse effects on small farmers (70%), risk to animal health and safety (67%), and potential harm to the environment (66%).

IMPLICATIONS

Consumers want transparency; they want the choice of knowing what is in their food. In all recent polls, the desire for labeling is very clear – they want mandatory labeling of GMOs.

- In a 2/25/11 MSNBC Health Poll with nearly 46,000 responses, 96% support mandatory GM labeling[5].
- In a 2/15/11 CBS NYT poll of nearly 750 consumers, 87% of consumers want labeling of GM foods[6].
- In a May 2010 proprietary study of 5,245 consumers, 88% supported labeling of GM foods[3].

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[1]Custom quantitative study, general pop, n=5,460, nationally projectable to adult pop +18.
[2] Nielsen, US Consumer Trends Survey
[3]5/10 Custom quantitative study, organic and natural shoppers, n=5,245
[4]9/10 custom quantitative survey (n=12,899), Organic consumers = purchase organic food or beverages at least 1x/week, ages 18+ with 72% of respondents in the 24-54 range.
[5]MSNBC poll, 2/11
http://health.newsvine.com/_question/2011/02/25/6131050-do-you-believe-genetically-modified-foods-should-be-labeled
[6] CBS/NYT poll, 2/11.
http://bittman.blogs.nytimes.com/2011/02/24/gmo-poll-results-and-more/?smid=tw-bittman&seid=auto

CONCLUSION

Organic consumers are more aware and more concerned about GMOs than the population as a whole.

Organic consumers expect and trust organic to be non-GMO.

Consumers want transparency; they want the choice of knowing what's in their food and how it was produced.

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Appendix 8 {*PAGE 47*}

Table 1: Summary of results from consumer surveys on views of GM foods[1,2,3,4]

Table 2: Consumer reasons for purchasing organic[3]

CHAPTER 6: ADVENTITIOUS PRESENCE OF GMOS IN ORGANIC AND IDENTITY- PRESERVED CROPS AND PRODUCTS- GENE FLOW & CONTAMINATION

In order to determine the level of GMO presence in the organic sector and the best practices and policy initiatives to prevent such contamination, it is important to first begin to analytically answer the question, "What is the incidence of low-level GMO presence or 'contamination' of organic products throughout the supply chain?" A clear understanding of the critical controls points in the supply chain can then be used to determine best practices for contamination prevention. Taken together, the fact-based analysis on incidence and best practices can help shape effective policy action(s).

INCIDENCE

One of the greatest challenges in setting effective policy to prevent the contamination of organic seed, crops and products is the lack of available base line 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, GMO testing labs, privately funded testing studies, and results from private sector verification programs (Non-GMO Project). Each potential source offers insights and limitations.

Test results from certifiers released to the public – surveys from OTA and the Accredited Certifiers Association turned up little in terms of concrete information regarding the level to which certifiers are conducting GMO tests, if any. 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, would only provide anecdotal information.

GMO testing labs

Attempting to obtain this information from GMO testing laboratories has limitations in terms of accurate and informative data for the following reasons:

- The testing laboratory usually receives 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 have a way to know which type of need the test is being conducted for.
- For those customers exporting product, the intended target market dictates the GM threshold allowable for the product. Therefore, a significant proportion of 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 ($\leq$ 0.9% GM content).

Privately funded testing studies

Initiators of privately funded studies released summaries of their work for use in this White Paper. Details of selection methodology and raw data are unavailable. Without full access to the testing design and results, it is difficult to draw conclusions that can be applied to the sector (population) as a whole. The number of products tested in these two studies is too small to support broad conclusions concerning GM contamination in organic foods across an entire industry. Additionally, finished product testing does little to identify the critical control point (seed, crop, ingredient, minor non-organic ingredients) at which contamination is likely to occur, and is therefore of limited value in terms specific contamination best practices and policy actions. The summaries do add a

snapshot of information that can inform the discussion and analysis, but still represent anecdotal information.

Non-organic products purchased in natural foods retailers were included in these two (and other) PCR testing studies. The findings are not summarized here because this paper concerns certified organic products. As a general observation, the frequency with which these non-organic products were contaminated was much higher, and the GMO content of some products was as much as 100%. This can be an indicator that GM contamination in certified organic is less than non-organic products sold in natural foods retailers.

Results from private sector verification programs (Non-GMO Project):
{SEE APPENDIX 9 FOR DETAILS ON THE NON-GMO PROJECT}. Test results from the verification of products enrolled in the Non-GMO Project are not available to the public.

Raw data released from companies that directly contract, process and sell specialty grain:
While there is a lack of publicly available data from which to draw conclusions, there is, in fact, quite a lot of testing that regularly occurs in the supply chain, whether through a private verification standard, the Non-GMO Project, or directly by companies engaged in trading, in order to meet buyer specifications for ingredients. Data released from traders are perhaps the most reliable in terms of informing the discussion of incidence of contamination. Tests results for corn and soy have been shared with the task force in order 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.

SOYBEANS: (Identity Preserved & Organic)			
Samples:	**5220**		
GMO Level		**% of Total**	
Non-detectible	4908	94.0%	
.1 - .5%	270	5.2%	99.2%
.51-.99	33	0.6%	99.8%
1.1-2.3	8	0.2%	100.0%

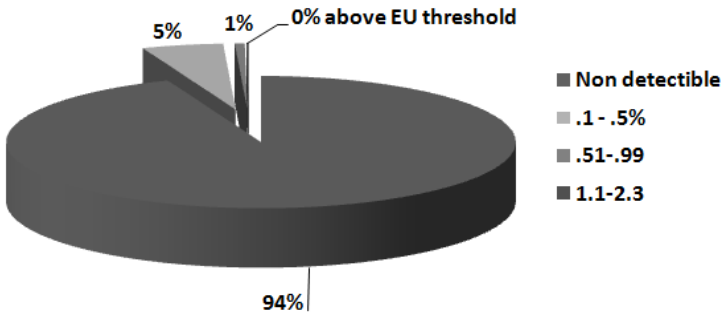
SOYBEANS: (Organic Only)			
Samples:	**2180**		
GMO Level		**% of Total**	
Non detectible	2065	94.7%	
.1 - .5%	93	4.3%	99.0%
.51-.99	17	0.8%	99.8%
1.1-2.3	5	0.2%	100.0%

CORN: (Identity Preserved & Organic)			
Samples:	**7293**		
GMO Level		**% of Total**	
Non detectible	6481	88.9%	
.1 - .5%	274	3.8%	92.6%
.51 - .99	311	4.3%	96.9%
1.0 -3.0	145	2.0%	98.9%
> 3.0	82	1.1%	100.0%

CORN: (Organic Only)			
Samples:	**2461**		
GMO Level		**% of Total**	
Non detectible	1713	69.6%	
.1 - .5%	224	9.1%	78.7%
.51 - .99	252	10.2%	88.9%
1.0 -3.0	225	9.1%	98.1%
> 3.0	47	1.9%	100.0%

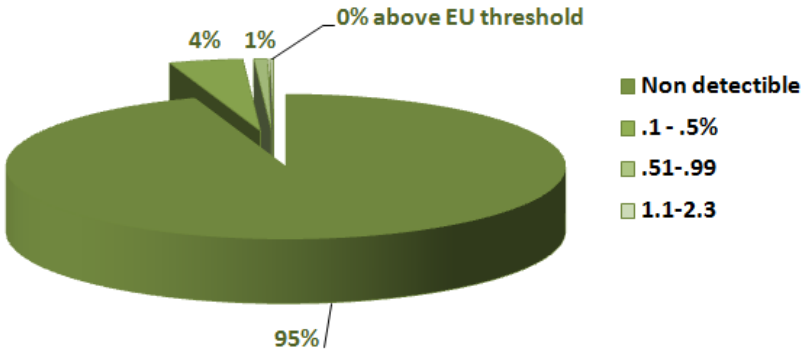
Soybeans (Identity Preserved & Organic): 2009-2011

5220 samples



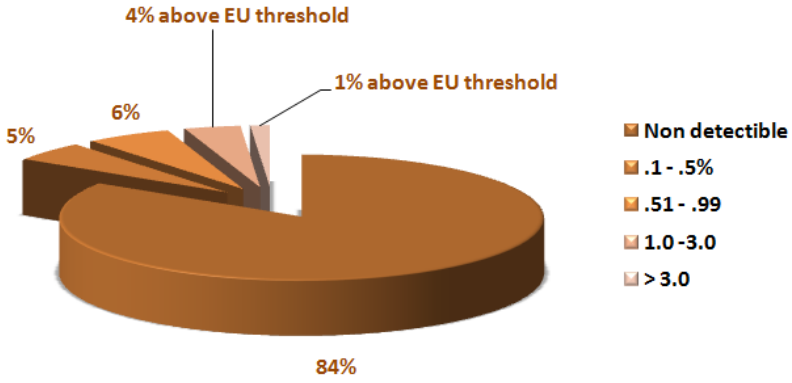
Soy Organic Only: 2009-2011

2180 samples



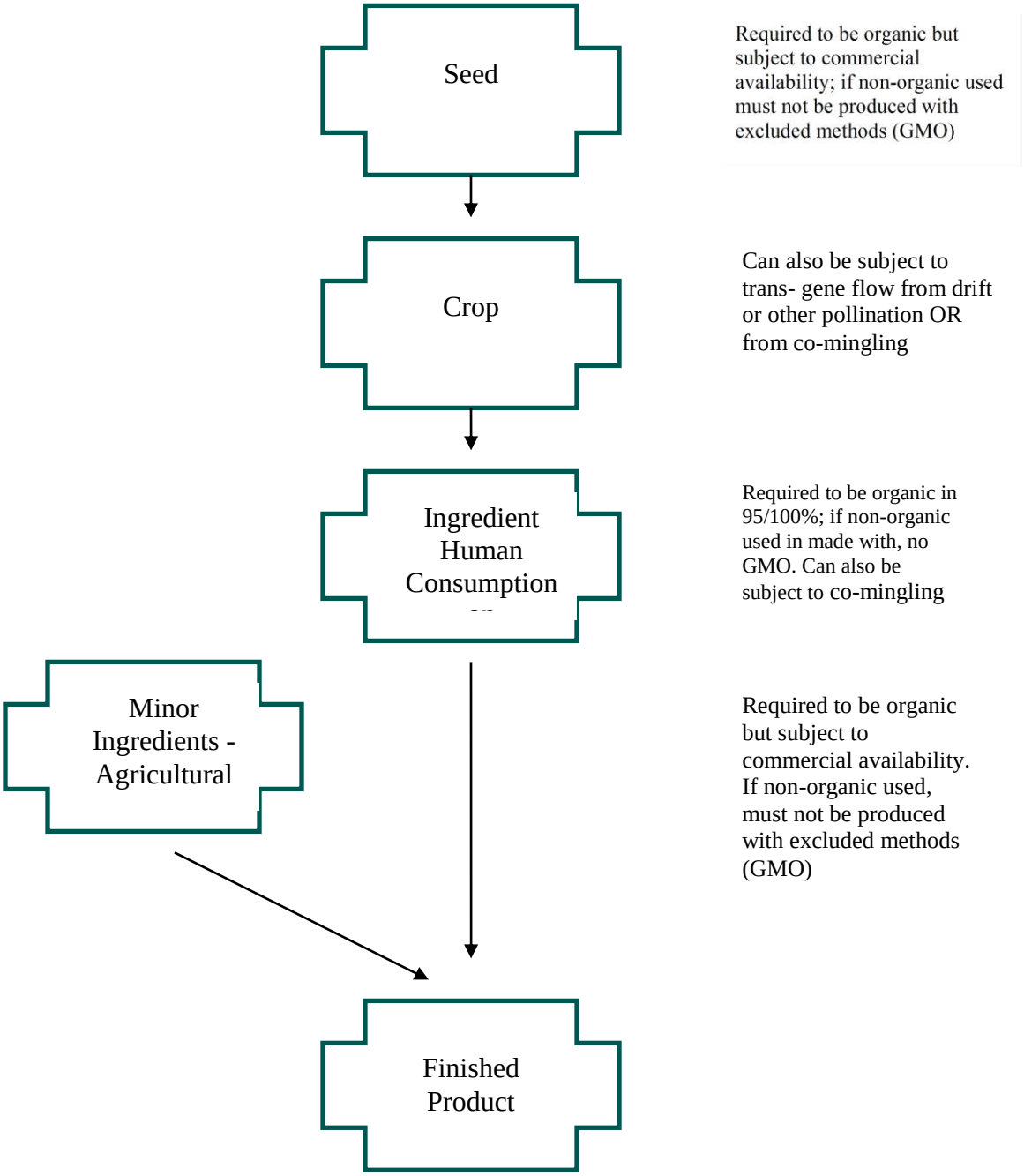
Corn-Identity Preserved & Organic: 2009-2011

9754 samples

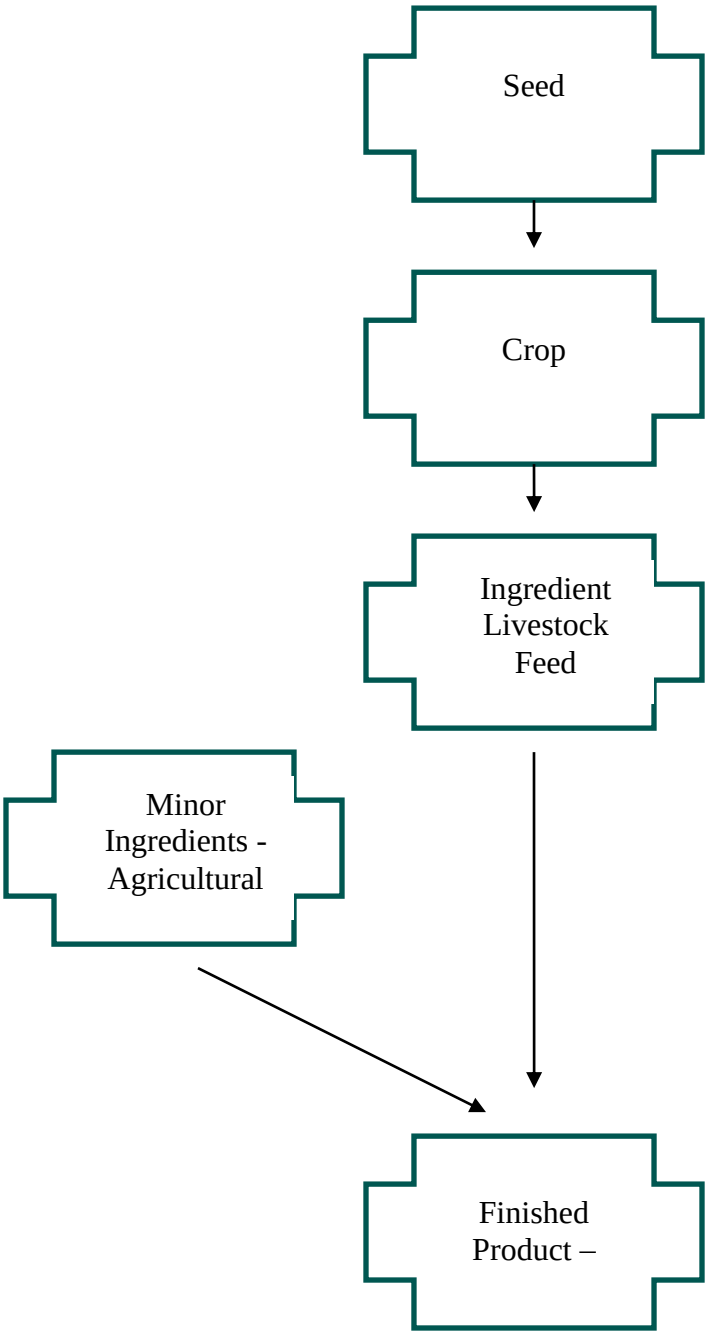


CRITICAL CONTROL POINTS

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)

PLANTING SEED – FOR AT-RISK CROPS

Certified organic farmers must use certified organic seed if commercially available. This means that often the same seed used in non-organic production may at times be used in certified organic production. Considering that non-organic products have typically shown higher GM content than organic, 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 suggested that bag by bag, pallet by pallet, 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 GMO contamination, the likelihood of producing a crop that exceeds 0.1% GMO is extremely low, and the likelihood of producing grain that contains more than 0.9% is close to zero.

Private sector initiatives are underway to address this most critical control point, including proposals to set a Genetic Purity Standard for seed used in organic production systems. The focus of the standard is the presence or absence of GE content, and the standard is equally applicable to conventional and organic seed. The authors propose a universal standard for the genetic purity of seed to be used in organic production of no GE seeds found in a 3,000 seed sample. "None found" in a 3,000 seed sample corresponds statistically to a 95% probability that the actual GE contamination level in the seed lot is between zero percent and 0.10%. {*SEE APPENDIX 10 FOR FULL DRAFT PROPSAL*}. The draft Genetic Purity Standard for Organic Seed includes the following considerations:

1. Seed versus crop distinction
2. Sampling
3. Detection in the sample
4. Type of seed
5. Level of detection
6. Type of test
7. Traits tested
8. Statistical expression
9. Sample size
10. Desired confidence level
11. Language and terms used

CROP

At the farm level, contamination prevention focuses on seed source (see above) and agronomic practices such as delayed planting—common among corn growers to reduce trans-gene flow through pollen drift and organic practice standards such as buffers. Specific practice standards should be crop specific. Testing at this phase would be most useful to verify that practice standards are adequate.

INGREDIENTS IN HUMAN CONSUMPTION

The pathway that a harvested crop follows from the farm-gate to become the food we eat can introduce GM contamination in numerous places: storage, cleaning, transportation, consolidation, crushing, refining, processing, manufacturing and more. Prevention of contamination during this part of the supply chain focuses on the practice standard to prevent co-mingling, including adequate cleanout. Testing at this phase would be most useful to verify that practice standards are adequate.

LIVESTOCK FEED

In the case of livestock derivative products, testing methods are not yet available that are capable of consistently detecting GM content in milk, meat, eggs, and other products from animals fed GM feed. For livestock, the feed must be tested to determine if it were produced using GMOs. As with ingredients for human consumption, this control point relies on the already identified upstream contamination prevention practices. In addition to prevention of co-mingling, including adequate cleanout, identified with human ingredients, there are anecdotal stories suggesting positive tests upstream means diverting ingredients to the livestock feed supply rather than the human feed supply. This is a factor in assessing risk and control. Testing at this phase would be most useful to verify that practice standards are adequate.

MINOR AGRICULTURAL INGREDIENTS

Ingredients such as soy lecithin are often subject to commercial availability. As outlined in the organic standards chapter, non-organic agricultural ingredients must still be produced without excluded methods. Since anecdotal evidence of GMO contamination of finished products may be higher than at the ingredient level, the sector could apply extra rigor to verifying that this is not an entry point for contamination of organic products. In addition to the affidavit system commonly used, testing could be applied to non-organic minor ingredients used in organic products that are derived from at-risk crops. The high degree of international trade in these ingredients could suggest that a threshold in line with EU labeling requirements could serve as a guideline.

In the case of livestock derivative products, testing methods are not yet available that are capable of consistently detecting GM content in milk, meat, eggs, and other products from animals fed GM feed. For livestock, the feed must be tested to determine if the products were produced using GM feed.

COMPENSATION

A crucial question is who pays for contamination that arises from coexistence of organic with GE crops. Currently, these costs are borne disproportionately by U.S. organic producers.

In the European Union, mandatory labels for GE products shift some of the cost of coexistence to GE produce processors and sellers. In fact, some EU countries require GE producers to use buffers and other prevention strategies, as well as to make them liable for economic damages to non-GE producers. Europe is also exploring the use of insurance markets to help compensate for economic losses experienced by organic and other non-GE producers.

In the United States, no such provisions protecting and compensating organic producers are currently provided. During the lead-up to the RR alfalfa deregulation in January 2011, the alfalfa working group established by USDA and consisting of private sector stakeholders attempted to address the question of compensation for market loss due to GMO presence in organic and IP crops. A consensus was not reached but a minority opinion was drafted entitled "USDA Monitoring, Mitigation, and Compensation Plan for GMO Contamination[36]" The document outlines a proposal for a fund for compensation due to market loss. {*SEE APPENDIX 11 FOR FULL DRAFT PROPSAL*}. The proposal identifies costs including but not limited to:

1. On-going and incident- triggered testing and related costs for both PCR and strip tests costs;
2. On-going buffer zone control, including production acreage losses and on-going maintenance required to secure or maintain access to contamination-sensitive markets;
3. Pollinator losses and related damages associated with the GMO event;
4. Loss of organic or other third-party certification and any costs associated with additional scrutiny, record-keeping, testing or surveillance required to regain certification or retain certification on impacted operations;
5. Segregation and co-mingling prevention plans, including on- farm and post-harvest costs and all related supply-chain integrity costs, above those required as part of routine on-farm best management practices. Such costs incurred by farmers producing the same crop for both the conventional and for contamination-sensitive markets would not qualify for coverage under this provision;
6. Seed contamination, including costs of seed replacement, crop and production losses, and the clean-up and decontamination of all germplasm collections, cultivar and breeding lines affected;
7. Crop, production, and post-harvest losses and associated costs of market rejections; including any IP price differentials;
8. Costs associated with the removal and destruction of Roundup Ready-contaminated plants when identified outside of GMO permit acreages;
9. Additional categories, as documented and deemed necessary to ensure viable non-GMO farming and marketing opportunities.

[36] USDA Monitoring, Mitigation and Compensation Plan for GMO Contamination, written by Michael Sligh and Chcuk Benbrook, See Appendix 11.

ATTACHMENTS

CHAPTER 7: GMO TESTING

For markets sensitive to GMOs, testing is the only way to measure their presence. Testing at this time is approached by measuring either proteins or DNA features unique to particular GMO events.

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, just 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.

There are multiple GMO events already in use in crops such as soybeans, corn and canola, and many more GMO events expected to be introduced in the near future. This multiplicity of events makes testing increasingly complicated and expensive.

TESTING APPROACHES

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, just 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 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. There is a section at the end of this paper referring to the relevant USDA GIPSA data.

Another version of the ELISA test, the "plate test," provides some indication of the quantity (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, with costs ranging from a few hundred to several 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. It is suggested that those wanting PCR tests to check to see that the lab carries 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.

TESTING REQUIREMENTS

Some forms of ingredients made from raw commodities may not have enough DNA or protein to support testing for GMO presence. For example, refined corn or soy oil generally does not have enough to give a meaningful test result. Crude oil (before refining) sometimes does not have enough. In such cases, it is extremely helpful and sometimes essential to test the raw materials before they are processed.

SAMPLING

Sampling is essential to the accuracy of any test. If the sample is not representative of the product lot being tested, the test will not be accurate. Securing a representative sample is not so easily accomplished in the field. Loads may segregate during transportation or be segregated in loading. GIPSA has recommended protocols for securing a representative sample.

SAMPLE SIZE REQUIREMENTS

Sample size can have a significant impact on the accuracy of a test. Recommended sample sizes vary depending on what crop is being tested, the type of test being performed, the size of the lot being sampled and tested, the accuracy needed, and the laboratory doing the testing. Farmers and grain companies testing one truck of corn at a time with a "test kit" might need half a pound or 800 kernels, while a processor wanting a very accurate PCR test on a large lot might need 6.25 pounds or 10,000 kernels.

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 at the processor. Accuracy at each step can limit the multiplication of GMO presence in subsequent positioning of raw materials.

ENVIRONMENTAL BACKGROUND LEVELS OF GMO

There is a very large non-GMO market led by the Japanese that moves millions of bushels of corn and soybeans annually, far greater tonnage than that used by the North American organic community. Data from companies serving that non-GMO market have been combined with data on organic shipments by cooperating members of this task force. While individual tests may spike above such levels, in general the environmental presence of GMOs in identity-preserved programs supplying non-GMO soybeans runs less than 0.1% in soybeans and less than 0.5% in corn. From what is known of the presence of GMO in crops across North America, organic certification remains the "gold standard" for non-GMO materials.

ATTACHMENTS

Appendix 12: Examples of related resources {*PAGE 54*}

1. Companies providing GMO test kits
2. Companies providing PCR testing
3. USDA data made available by GIPSA (Grain Inspection Packers and Stockyards Act) on sampling techniques and dealing with bio-tech testing
4. A sample recommendation as to sample size for PCR testing

CHAPTER 8: GMO THRESHOLDS, LABELING REQUIREMENTS & TRADE

The increase in commercial production of GE crops since the mid-1990s has created more risks for farmers who do not use GE seeds. Additionally, a plethora of inconsistent genetically modified (GM) food labeling laws creates obstacles to the trade of U.S. organic as well as all non-GMO agricultural products. This chapter summary focuses on GE thresholds and food labeling laws with an overview of the current status of global GE crop production.

CURRENT GM FOOD LABELING LAWS

In recent years, an increasing number of countries have adopted labeling policies for GM food. The first labeling policies were introduced by the European Union (EU) in 1997. Since then, many other countries, including developing countries, have adopted some type of labeling policy for GM food. There are 31 countries plus the 27 countries of the European Union that have promulgated GE food labeling laws or requirements. {*SEE OTA GLOBAL GMO THRESHOLDS AND LABELING ANALYSIS APPENDIX 13*}. As the analysis indicates, these labeling policies differ widely in their nature, scope, coverage, exceptions, and their degree of enforcement.

Voluntary or Mandatory Labeling

Only four countries of those with labeling laws—Argentina, Canada, Hong Kong, and the Philippines – allow voluntary labeling. Voluntary labeling guidelines dictate rules that define what food can be called GM or non-GM, allowing food companies to decide if they want to use such labels on their products.

The remaining countries have mandatory labeling that requires all or parts of the supply chain to label raw agricultural ingredients or finished food products with a phrase or mark that indicates that the product may contain, contains or is derived from GE crops. A certain number of countries with mandatory labeling for GM ingredients also have voluntary guidelines for the labeling of non-GM food (e.g., Japan, Korea and the EU).

The three original producers and exporters of GM crops (the United States, Argentina, and Canada) have adopted voluntary labeling approaches whereas the first countries to adopt mandatory labeling requirements are large importers (the EU and Japan) that do not produce GM crops or produce GM crops in very limited areas.

China and Brazil are the only major countries that are large producers **and** exporters of GE crops that require mandatory labeling. China only produces GM cotton on a significant scale. However, the main cotton products are not required to be labeled. Reports indicate that GMO labeling requirements are not currently fully enforced in China.

Brazil produces GE soybeans, which tend to be mostly exported and used as animal feed in countries that do not require labeling of meat produced using GM feedstock. In addition, it is reported that Brazil's labeling requirements are not yet fully implemented.

SCOPE OF LABELING REGULATIONS

The scope of the regulations differs widely among countries with mandatory labeling according to the following main characteristics:

Coverage: countries may require labeling for:

- A list of particular food ingredients *or* all ingredients in packaged food products that include detectable transgenic protein or DNA
- Highly processed products *derived* from GM ingredients--even without quantifiable presence of GM ingredients
- Animal feed
- Additives and flavorings
- Meat and animal products produced using GE feed
- Food sold by caterers and restaurants
- Unpackaged food.

Threshold level for labeling of GE ingredients:

- Applied to each ingredient or only to major three or five ingredients;
- Level, ranging from 0.9% to 5%. It is important to note one *AgBiotech* source reports that China has a 1% threshold. However, other sources indicate that China

has no threshold level. Therefore, this analysis indicates the 1% threshold but cautions that the Chinese threshold could be interpreted as zero.

- **De facto organic threshold**—The EU 0.9% threshold has become the de facto threshold for the adventitious presence of GMOs in organic commodities and products. Many organic certification and standard setting organizations advocate for a .1% threshold. Some private sector organic standards and marks of identity not restricted by government regulations have imposed this lower limit.

The common feature of the labeling laws is the quasi-generalized requirement to label products derived from GE crops that are *not substantially equivalent* to their conventional counterparts—for instance, GE products with novel traits, such as high-oleic-content canola, or the future nutritionally enhanced rice (Golden Rice). Labeling is mandatory for these products in all countries with regulations because it is recognized that consumers should be informed of the novel traits and properties of the food products in order to make informed decisions.

PRODUCT- OR PROCESS-BASED

In particular, one of the major differences in regulations among countries with mandatory labeling is whether the regulation targets the presence of GMOs in the *finished product* (like Australia, New Zealand, and Japan) or on GE technology as a *production process* (like the EU, Brazil, and China).

In the former case, only **products** with detectable and quantifiable traces of GE materials or ingredients are required to carry a label. In contrast, in the latter case of **process** requirements, any product derived from GE crops will have to be labeled, whether it contains any traces of GM material or not. This means that canola or soybean refined oils are required to be labeled even if current techniques cannot detect significant traces of transgenic DNA or proteins in the final product.

This difference is crucial for enforcement: a product-based system can be enforced with testing, whereas a process-based system requires viable and trustable traceability systems. Ultimately, and hopefully, this will lead to identity preservation or traceability requirements for the producer and importer systems that track or identify GM food or GM-free food from their origin to their final package.

LEVEL OF ENFORCEMENT

Of the countries that have mandatory labeling requirements, there are ten that have yet to complete the legislative and/or regulatory process, or have yet to fully implement or enforce their GM food labeling requirements. These countries are Brazil, Chile, Colombia, India, Israel, Kenya, Malaysia, Mexico, Thailand and Vietnam.

China has implemented labeling since 2004, but recent articles indicate that despite what is considered an effective labeling policy, there are many products containing GE ingredients that remain unlabeled.[37]

INTERNATIONAL GUIDELINES AND PROTOCOLS

Codex Alimentarius Commission

The Codex Committee on Food Labeling (CCFL) for 18 years discussed a guidance document on labeling GM foods. This proved to be a very controversial discussion at the CCFL meetings, and the Codex Alimentarius Commission imposed a deadline of 2011 for a conclusion to the discussion. At the May 9-13, 2011, CCFL meeting, a document was finally agreed upon. At the annual Codex Alimentarius Commission summit in Geneva July 4-9, 2011, the Commission adopted GM labeling guidance, thus allowing it to move forward to become official Codex text.

The document agreed upon is a compilation of other Codex texts, where references to Genetic Engineering/Modification or Labelling Claims are made. The document is intended to give guidance particularly to developing countries that may wish to develop labeling for GM foods. The particular significance of this document is that it represents recognition by Codex that countries can legislate and implement GMO labeling laws and requirements, and that such laws, if consistent with the Codex texts, would not be considered barriers to trade if a dispute were brought to the World Trade Organization (WTO).

[37] See http://www.chinadaily.com.cn/china/2010-02/12/content_9465789.htm; http://www.time.com/time/health/article/0,8599,1714218,00.html.

The final document is entitled "Compilation of Codex texts relevant to labelling of foods derived from modern biotechnology." The purpose "is only to recall and assemble in a single document some important elements of guidance from Codex texts, which are relevant to labeling of foods derived from modern biotechnology."

The following is included as a statement of considerations:
"Different approaches regarding labeling of foods derived from modern biotechnology are used. Any approach implemented by Codex members should be consistent with already adopted Codex provisions. This document is not intended to suggest or imply that foods derived from modern biotechnology are necessarily different from other foods simply due to their method of production."

Cartagena Protocol on Biosafety
The Cartagena Protocol on Biosafety, an additional treaty to the United Nations Convention on Biological Diversity, seeks to protect biological diversity from potential adverse effects by living modified organisms (LMO) resulting from modern biotechnology. The definition of the Cartagena LMO is "living organism that possesses a novel combination of genetic material obtained through modern biotechnology." The Protocol was adopted in January 2000 and entered into force in September 2003. To date, 160 countries and the European Union are party to the Protocol. The United States and Canada did not sign on to this Protocol, and WTO has not officially recognized the Protocol as a binding international agreement.

The objective of the Protocol is to contribute to ensuring an adequate level of protection in the field of the safe transfer, handling and use of LMOs that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, and specifically focusing on trans-boundary movements.

There are rules and procedures for movement of LMOs from one country to another, including countries that have not signed onto the Protocol, and a requirement that documentation accompanying shipments clearly identify the LMOs. These procedures and requirements are designed to provide importers with the information necessary for making informed decisions on whether to accept LMO imports and for handling them in a safe manner. The Protocol leaves open the possibility for future standards for handling, packaging, transport and identification of LMOs.

On Oct. 15, 2010, a supplementary treaty on damage resulting from LMOs was added to the Protocol. Under the Supplementary Protocol, parties have an obligation to provide, in new or existing domestic law, rules and procedures that address damage resulting from LMOs, including response measures to prevent or mitigate damage or to restore biological diversity. The Supplementary Protocol is the first international treaty to provide for a definition of "damage" to biodiversity.

The countries that signed the Supplementary Protocol are Austria, Bulgaria, Denmark, Colombia, the Czech Republic, European Union, Finland, France, Hungary, Ireland, Latvia, Lithuania, Luxembourg, Montenegro, the Netherlands, Panama, Peru, Romania, Slovenia, Sweden, Switzerland, and Tunisia.

It is important to note that these rules are not directly related to domestic labeling regulations. Instead, they support the use of GE labels for imported and exported shipments of LMOs that are to be intentionally introduced into the environment and LMOs intended for direct use as food, feed, or processing. However, the Cartagena Protocol is cited as a reference in domestic labeling regulations by several countries.

GMO–FREE INITIATIVES

In addition to labeling laws, there have been successful initiatives by civil society and governments to legislate or declare GMO-free zones that prohibit the production of GE crops within countries, provinces, states and counties. Support for GMO-free zones arises from uncertainties in environmental and health risk assessments or due to economic concerns over the effects of GMOs on sustainable development.

In 2007 the International Federation of Organic Agriculture Movements (IFOAM) released a publication, "GMO-Free Regions Manual: Case Studies from around the World," which states "the call for GMO-free zones and their implementation is, despite legal difficulties, a worldwide phenomenon. Examples can be found on all continents, especially in

those areas with a higher level of public awareness and information on GMOs and a longer experience with industrialized agriculture."

Examples of successful GMO-free initiatives outside the United States include:

- Europe: 169 regions, 123 provinces, prefectures and departments, and 4,713 municipalities and other local governments in Europe have declared themselves GMO-free. In six European countries, GMO-free zones almost cover the entire country: Poland, Greece, Austria, Switzerland, France, and Italy. Ireland has declared the country a GMO-free zone.
- Australia: nearly all Australian States have adopted moratoria on (certain) GMOs.
- Thailand has banned GMO field trials and does not allow commercial GE crop planting.
- Some Japanese local governments have banned or restricted GE crop planting.
- The Province of Bohol became the first GMO-free zone of the Philippines. Other provinces since then include Mindoro Oriental, Marinduque, Negros Occidental, and Negros Oriental.
- In 1999, Munich, Germany, was the first town that excluded GM plants. By June 2009, there were 190 German municipalities with a ban on GM plants.
- Switzerland has imposed a moratorium on the commercial use of GE plants and animals until 2013.
- In India, the States of Bihar, Madhya Pradesh, and Kerala have prohibited cultivation of GR crops.

Examples of successful GMO-free initiatives in the United States include:

- GMO moratoria in Trinity, Mendocino, Lake, Marin and Santa Cruz counties in California as well as the cities of Arcata and Point Arena
- In 2006, Alaska adopted a state law requiring labeling of genetically engineered fish and fish products.

ATTACHMENTS

Appendix 13: Global GMO thresholds and labeling requirements {*PAGE 57*}

APPENDIX 1 {Double-click table to see 4-page file}

List of approved and pending petitions for GE crops

Petitions for Nonregulated Status Granted or Pending by APHIS as of May 3, 2011

If you have trouble retrieving the documents below (requires Adobe Acrobat Reader 5.0 or higher), or want hard copies furnished instead, please contact us. Let us know the specific documents that you want, identified by the petition number(s).

Petitions for Nonregulated Status Pending

	Applicant Documents						APHIS Documents		
	Petition	Extension of Petition Number ***	Institution	Regulated Article	Transgenic Phenotype	Transformation Event or Line	FR Notices	Preliminary EA **** or Risk Assessment	Final EA & Determination
22	11-063-01p		Pioneer	Canola	Glyphosate Tolerant	DP-073496-4			
21	11-019-01p		ArborGen	Eucalyptus	Freeze Tolerant and Fertility Altered	FTE 427 and FTE 435			
20	10-338-01p		Syngenta	Corn	Corn Rootworm Resistant	SYN-Ø53Ø7-1			
19	10-281-01p		Monsanto	Corn	Tissue-selective Glyphosate Tolerant	MON-87427-7			
18	10-188-01p		Monsanto	Soybean	Dicamba Tolerant	MON-877Ø8-9			
17	10-161-01p		Okanagan Specialty Fruits	Apple	Non-browning	SD743 and GS784			
16	10-070-01p		Virginia Tech	Peanut	Sclerotinia Blight Resistant	N70, P39, and W171			
15	09-349-01p		Dow AgroSciences	Soybean	2,4-D and Glufosinate Tolerant	DAS-68416-4			
14	09-328-01p		Bayer Crop Science	Soybean	Glyphosate and Isoxaflutole Tolerant	FG72			
13	09-233-01p		Dow	Corn	2,4-D and ACCase-Inhibitor Tolerant	DAS-40278-9			
12	09-201-01p		Monsanto	Soybean	Improved Fatty Acid Profile	MON-877Ø5-6			
11	09-183-01p		Monsanto	Soybean	Stearidonic Acid Produced	MON-87769			
10	09-082-01p		Monsanto	Soybean	Lepidopteran Resistant	MON 87701			
9	09-063-01p		Stine Seed	Corn	Glyphosate Tolerant	HCEM485			
8	09-055-01p		Monsanto	Corn	Drought Tolerant	MON 87460			
7	09-015-01p		BASF Plant Science, LLC	Soybean	Imidazolinone Tolerant	BPS-CV127-9 Soybean			
6	08-340-01p		Bayer	Cotton	Glufosinate Tolerant, Lepidopteran Resistant	T304-40XGHB119			
5	08-338-01p		Pioneer	Corn	Male Sterile, Fertility Restored, Visual Marker	DP-32138-1	03-Jan-2011	08-338-01p_psa & 08-338-01p_pea	
4	08-315-01p		Florigene	Rose	Altered Flower Color	IFD-52401-4 and IFD-52901-9	13-Apr-2011	08-315-01p_psa 08-315-01p_pra	
3	07-108-01p		Syngenta	Cotton	Lepidopteran Resistant	COT67B			
2	03-323-01p & 98-329-01p		Monsanto and KWS SAAT AG	Sugar Beet	Glyphosate Tolerant	H7-1	8-Feb-2011 4-Nov-2010 8-Oct-2010 17-Mar-2005 19-Oct-2004	Draft EA (2005) 03-323-01p_psa Draft EA (2010) 03-323-01p_psa2	03-323-01p_com (2005 EA) The documents below refer to the partial deregulation of event H7-1 sugar beet root crop (event H7-1 sugar beet seed is regulated under 7 CFR part 340) 03-323-01p_Partial 98-329-01p_HSPA 98-329-01p_FONSI 98-329-01p_Determination
1	03-104-01p		Monsanto & Scotts	Creeping bentgrass	Glyphosate Tolerant	ASR368	Scoping & Status 19-Oct-2005 11-Apr-2005 18-Nov-2004 24-Sep-2004 6-Sep-2004	03-104-01p_ea & CBGWhite Paper	

Petitions for Nonregulated Status Granted

Applicant Documents							APHIS Documents	
		Extension of					Preliminary	

APPENDIX 2

Residue Testing – Preamble

Residue Testing - Changes Requested But Not Made

(3) *"Threshold" for Genetic Contamination*. Many commenters suggested that we establish a "threshold" for the unintended or adventitious presence of products of excluded methods in organic products. Some commenters argued that a threshold is necessary because, without the mandatory labeling of biotechnology-derived products, organic operations and certifying agents could not be assured that products of excluded methods were not being used. Others argued that, without an established threshold, the regulations would constitute a "zero tolerance" for products of excluded methods, which would be impossible to achieve.

We do not believe there is sufficient consensus upon which to establish such a standard at this time. Much of the basic, baseline information about the prevalence of genetically engineered products in the conventional agricultural marketplace that would be necessary to set such a threshold-e.g., the effects of pollen drift where it may be a factor, the extent of mixing at various points throughout the marketing chain, the adventitious presence of genetically engineered seed in non-engineered seed lots-is still largely unknown. Our understanding of how the use of biotechnology in conventional agricultural production might affect organic crop production is even less well developed.

Also, as was pointed out in some comments, the testing methodology for the presence of products of excluded methods has not yet been fully validated. Testing methods for some biotechnology traits in some commodities are becoming commercially available. Without recognized methods of testing for and quantifying of all traits in a wide range of food products, however, it would be very difficult to establish a reliable numerical tolerance. There are publicly and privately funded research projects underway that may provide useful baseline information. Efforts of Federal agencies to clarify the marketing and labeling of biotechnology- and non-biotechnology-derived crops may also help address these concerns. FDA, for example, is developing guidance for food producers who voluntarily chose to label biotechnology- and non-biotechnology-derived foods. USDA is also preparing a Federal Register Notice to seek public comment on the appropriate role, if any, that it can play in facilitating the marketing of agricultural products through the development of "quality assurance" type programs that help to preserve the identity of agricultural commodities. USDA, in cooperation with the technology providers, is also working to validate testing procedures and laboratories for some commodities.

All of these efforts may help to provide information on this issue. Practices for preserving product identity, including segregating genetically engineered and non-genetically engineered products, are evolving in some conventional markets. As we discussed in the preamble to the proposed rule, we anticipate that these evolving industry best practices and standards will become the standards for implementing the provisions in this regulation relating to the use of excluded methods. As was also discussed in the proposed rule, these regulations do not establish a "zero tolerance" standard. As with other substances not approve for use in organic production systems, a positive detection of a product of excluded methods would trigger an investigation by the certifying agent to determine if a violation of organic production or handling standards occurred. The presence of a detectable residue alone does not necessarily indicate use of a product of excluded methods that would constitute a violation of the standards.

APPENDIX 3

NOP-AQSS (Answers to Questions on NOP Standards by NOP Staff):

If a certified organic crop is unintentionally contaminated by a neighbor's GMO produced pollen, etc., is the organic crop still marketable as organic? According to the NOP regulations, I believe the organic crop contaminated by GMO pollen can still be sold as certified organic because it is not expressly prohibited by regulations to do so.

In the preamble to the final rule, we addressed this issue when we stated that, "drift has been a difficult issue for organic producer producers from the beginning...this regulation prohibits the use of excluded methods in organic operations. The presence of a detectable residue of a product of exclude methods alone does not necessarily constitute a violation of this regulation. As long as an organic operation has not used excluded methods and takes reasonable steps to avoid contact with the products of excluded methods as detailed in their approved organic system plan, the unintentional presence of the products of excluded methods should not affect the status of an organic product or operation."

Can nonagricultural substances not appearing on the National List of Allowed and Prohibited Substances be used as ingredients in or on a product labeled as 'made with organic (specified ingredients or foodgroup(s))?'

No. A 'made with organic (specified ingredients or food group(s))' product must, in accordance with § 205.105(c) be produced and handled without the use of nonagricultural substances used in or on processed products, except a otherwise provided in § 205.605. The reference to nonorganic ingredients in § 205.301(c) refers to *agricultural* ingredients only and should not be construed to include nonagricultural ingredients. Nonorganically produced agricultural products, raw or processed, that have been produced using synthetic, nonsynthetic, and nonagricultural substances without regard to §§ 205.601 through 205.605 except that the use of excluded methods, sewage sludge, and ionizing radiation are prohibited. Nonorganically produced agricultural products listed in § 205.606 must comply with the restrictions placed on that product by § 205.606.

Is cottonseed meal (6.7% N, 2% P2O5) allowable as an organic fertilizer source despite the fact that genetic traits (Bt and Roundup Ready) are present in the pulverized, mealed, extruded, and chipped seed?

Cottonseed meal is a non-synthetic and allowed as a soil amendment.

Can I use crop residue from GE corn as a bulking agent for my compost?

Yes. There is no restriction on manure, or components of manure, from non-organic sources. From the preamble to the final rule, "existing standards routinely permit the use of manure from nonorganic operations with appropriate oversight...a certifying agent can require residue testing when there is reasonable concern that manure, either raw or as a component of compost, contains sufficient quantities of prohibited materials to violate the organic integrity of the operation."

Is this true? "Organic" means that at least 95% of the ingredients are organic. The other 5%, however, still may have to be non-GMO."

Yes. For certified products, on the principal display panel, the label "organic" means that 95 percent of the ingredients are organic and the remaining 5 percent must still be non-GMO.

APPENDIX 4

NOP Policy Memorandum 11-13, April 15th, 2011: Clarifications of Existing Regulations Regarding the Use of Genetically Modified Organisms in Organic Production and Handling.

The National Organic Program (NOP) has recently received questions concerning the use of genetically modified organisms (GMOs) under the U.S. National Organic Standards. This policy memorandum addresses frequently asked questions concerning GMOs and reiterates the statements made in a 2004 letter from USDA Undersecretary Bill Hawks to the National Association of State Departments of Agriculture.

Compliance with the organic standards entails that operations have verifiable practices in place to avoid contact with GMOs. Since organic certification is process-based, presence of detectable GMO residues alone does not necessarily constitute a violation of the regulation. The NOP relies on organic certifiers and producers to determine preventative practices that most effectively avoid contact with GMOs on an organic operation.

The use of GMOs is prohibited in organic production and handling. The NOP regulations prohibit the use of GMOs as "excluded methods" under 7 CFR § 205.105, "Allowed and prohibited substances, methods, and ingredients in organic production and handling." Excluded methods are defined as:

A variety of methods to genetically modify organisms or influence their growth and development by means that are not possible under natural conditions or processes and are not considered compatible with organic production. Such methods include cell fusion, microencapsulation and macroencapsulation, and recombinant DNA technology (including gene deletion, gene doubling, introducing a foreign gene, and changing the positions of genes when achieved by recombinant DNA technology). Such methods do not include the use of traditional breeding, conjugation, fermentation, hybridization, in vitro fertilization, or tissue culture. (7 CFR § 205.2-Terms defined)

This policy memo reiterates that the use of GMOs is prohibited under the NOP regulations and answers questions that have been raised concerning GMOs and organic production and handling.

Issue: If a producer adheres to all aspects of the NOP regulations, including never utilizing genetically modified seeds, but a certifying agent tests and detects the presence of genetically modified material in the crop, is that crop's status determined to be no longer certified organic?

Reply: Organic certification is process based. That is, certifying agents attest to the ability of organic operations to follow a set of production standards and practices which meet the requirements of the Organic Foods Production Act of 1990 and the NOP regulations. The NOP regulations prohibit the use of excluded methods (i.e., "GMOs") in organic operations. If all aspects of the organic production or handling process were followed correctly, then the presence of a detectable residue from a genetically modified organism alone does not constitute a violation of this regulation. This policy was established at the promulgation of the NOP Regulation in the
Preamble to the Final Rule (FR Vol. 65, No. 246, p. 80556), December 21, 2000. The Preamble stated that:

> As long as an organic operation has not used excluded methods and takes reasonable steps to avoid contact with the products of excluded methods as detailed in their approved organic system plan, the unintentional presence of the products of excluded methods should not affect the status of the organic operation or its organic products.

Issue: Is the inadvertent presence of GMOs in organic seeds a violation of the NOP regulations?
Can organic producers use seeds that contain the inadvertent presence of GMOs?

Reply: 7 CFR § 205.105 of the NOP regulations prohibits the use of GMOs as excluded methods in organic production and handling. The use of excluded methods, such as planting genetically modified seeds, would require a specific intent, and would render any product ineligible for organic certification. However, the inadvertent presence of GMOs in organic seeds does not constitute a use because there was no intent on the part of the certified operation to use excluded methods. The presence of detectable GMO residues alone in an organic seed does not constitute a violation of the NOP regulations.

Issue: How do organic producers avoid contact with GMOs?

Reply: Organic producers utilize a variety of methods to avoid contact or the unintentional presence of GMOs including testing seed sources for GMO presence, delayed or early planting to get different flowering times for organic and GMO crops, cooperative agreements with neighbors to avoid planting GMO crops adjacent to organic crops, cutting or mowing alfalfa prior to flowering, posting signs to notify neighboring farmers of the location of organic fields, and thorough cleaning of farm equipment that has been used in non-organic crop production.

Issue: What are organic producers required to do in order to avoid the presence of GMOs in their products?

Reply: In order to become a certified organic operation, a producer must submit an organic system plan to a NOP accredited certifying agent for approval. The producer's organic system plan must include a description of management practices and physical barriers established to prevent contact of organic crops with prohibited substances. Certifying agents evaluate the preventative practices and buffer zones to determine if the producer has taken reasonable steps to avoid contact with GMOs.

Issue: Could a farm's organic certification status be threatened if sufficient buffers and barriers are not established and inadvertent contact with GMO material occurs?

Reply: Organic producers that implement preventive measures to avoid contact with GMOs will not have their certification threatened from the inadvertent presence of the products of excluded methods (GMOs). Crops grown on certified organic operation may be sold, labeled and represented as organic, even with the inadvertent presence of GMOs, provided that all organic requirements under 7 CFR Part 205 have been followed.

Issue: Is there a working definition of the word "contamination" within the NOP?

Reply: There is no definition in the NOP regulations for the word "contamination," even though it is mentioned frequently in the standards. The use of excluded methods in organic production is prohibited, as cited in 7 CFR § 205.105.

Issue: What actions are authorized or required when organic crops or products are found to contain unintended or inadvertent genetically modified substances?

Reply: The inadvertent presence of genetically modified material does not affect the status of the certified operation and does not result in loss of organic status for the organic product, provided it was produced in accordance with all of the organic requirements under 7 CFR Part
205. Certifying agents are responsible for working with organic producers to identify the source of the inadvertent GMOs and to implement reasonable steps to avoid contact with GMOs in the future.

Issue: Are organic products tested for genetically modified substances?

Reply: Under 7 CFR § 205.670(b) certifying agents may test organic products when there is reason to believe that excluded methods were used in the production or handling of an organic agricultural product. Certifying agents may also collect and test organic products from organic handlers to ensure that practices are in place to prevent commingling or contamination during handling and processing.

Issue: Are organic products free of GMO contaminants?

Reply: Organic standards are process based. The NOP regulations prohibit the use of genetically modified organisms, prohibit commingling or contamination during processing and handling, and require preventative practices to avoid contact with GMOs. Organic agricultural products should have minimal if any GMO contaminants; however, organic food products do not have a zero tolerance for the presence of GMO material.

Issue: Has a tolerance level (e.g. 5%) been established for the presence of GMOs in organic agricultural products?

Reply: The NOP regulations do not establish GMO tolerance levels. The NOP regulations establish a tolerance for the presence of pesticides registered by the U.S. Environmental
Protection Agency (EPA) that is set at 5% of the EPA tolerance level for the specific residue detected. No federal agency, including EPA or USDA has established tolerance levels for the inadvertent presence of the products of excluded methods

(GMOs).

Issue: Processed foods sold as "organic" must contain at least 95% organic ingredients. Are GMOs allowed in the remaining 5% of ingredients? Likewise, processed foods sold as "made with organic (specified ingredients or food group(s))" must contain at least 70% organic ingredients. Are GMOs allowed in the remaining 30% of ingredients for these products?

Reply: The use of GMOs is prohibited in all ingredients in "organic" and "made with organic (specified ingredients or food groups(s))." There is no provision within the NOP regulations that allows the use of excluded methods (GMOs) in ingredients or processing aids under the "organic" or "made with organic (specified ingredients or food group(s))" label categories.

APPENDIX 5 {Double-click CRS report to see 27-page file}

Biotechnology in Animal Agriculture: Status and Current Issues

Tadlock Cowan
Analyst in Natural Resources and Rural Development

May 19, 2011

Congressional Research Service
7-5700
www.crs.gov
RL33334

CRS Report for Congress
Prepared for Members and Committees of Congress

APPENDIX 6 {Double-click CRS report to see 44-page file}

Agricultural Biotechnology: Background and Recent Issues

Tadlock Cowan
Analyst in Natural Resources and Rural Development

June 18, 2011

Congressional Research Service
7-5700
www.crs.gov
RL32809

CRS Report for Congress
Prepared for Members and Committees of Congress

APPENDIX 7 {Double-click CRS report to see 18-page file}

Deregulating Genetically Engineered Alfalfa and Sugar Beets: Legal and Administrative Responses

Tadlock Cowan
Analyst in Natural Resources and Rural Development

Kristina Alexander
Legislative Attorney

April 4, 2011

Congressional Research Service
7-5700
www.crs.gov
R41395

CRS Report for Congress
Prepared for Members and Committees of Congress

APPENDIX 8

Table 1: Summary of results from consumer surveys on views of GM foods[1,2,3,4]

	General Population[1,2]			Natural/Organic Consumer[3,4]		
Statement	**Agree**	**Don't Agree**	**Not Sure**	**Agree2**	**Don't Agree3**	**Not Sure4**
"I am aware of the term genetic modification (GM)."	43%	57%	-	91%	9%	-
"I understand the term genetic modification (GM)."	68%	32%	-	91%	9%	-
"I am concerned about consuming GM foods."	54%	n/a	n/a	90%	8%	2%
"I purposely avoid foods that are GM."	34%	n/a	n/a	80%	20%	-
"GM foods are safe."	18%	39%	43%	6%	72%	22%
"I believe that organic foods are safer to eat than GM foods."	64%	n/a	n/a	90%	4%	6%
"I purchase organic foods to avoid GMs"	n/a	n/a	n/a	85%	12%	3%
"Using labels to identify food that is not Genetically Modified is important to me."	n/a	n/a	n/a	88%	4%	8%

Table 2: Consumer reasons for purchasing organic[3]

Please rank order your TOP 3 reasons for purchasing <u>organic</u> foods and beverages

(If you have less than 3 reasons, please leave other levels blank)	MOST important	SECOND MOST important	THIRD MOST important	**Weighted rank score***
To avoid ingredients exposed to pesticides	32%	20%	12%	**1.48**
To avoid artificial flavors, preservatives or additives	17%	14%	13%	**0.92**
To avoid genetically modified ingredients	15%	12%	12%	**0.81**
To avoid ingredients exposed to animal hormones	9%	17%	14%	**0.75**
To avoid ingredients exposed to antibiotics	3%	11%	17%	**0.48**
Because they are safer for the environment than non-organic foods	6%	8%	11%	**0.45**
Because they are more nutritious than non-organic foods	6%	5%	7%	**0.35**
Because they are of higher quality than non-organic foods and beverages	4%	5%	6%	**0.28**
Because they taste better than non-organic foods and beverages	3%	3%	6%	**0.21**
To avoid trans fat	3%	4%	2%	**0.19**
Total Reponses	2734	2702	2669	

**weight=1st*3+2nd*2+3rd*1*

<u>Sources</u>

[1]*Custom quantitative study, general pop, n=5,460, nationally projectable to adult pop +18.*

[2] *Nielsen, US Consumer Trends Survey*

[3,7]*5/10 Custom quantitative study, organic and natural shoppers, n=5,245*

[4]*9/10 custom quantitative survey (n=12,899), Organic consumers = purchase organic food or beverages at least 1x/week, ages 18+ with 72% of respondents in the 24-54 range.*

[5]*MSNBC poll, 2/11..* *http://health.newsvine.com/_question/2011/02/25/6131050-do-you-believe-genetically-modified-foods-should-be-labeled*

[6] *CBS/NYT poll, 2/11. http://bittman.blogs.nytimes.com/2011/02/24/gmo-poll-results-and-more/?smid=tw-bittman&seid=auto*

APPENDIX 9

Introduction to the Non-GMO Project

The Non-GMO Project could serve as a source for technical knowledge on best practices for avoiding GMO contamination that include traceability, segregation and PCR testing. According to the Non-GMO Project Product Verification Program (PVP), it provides a training ground for applicants to upgrade their quality control systems to accommodate the increased risk of GM contamination, which is directly associated with increased plantings of GM crops.

The Non-GMO Project:

- The Project has developed a rigorous standard that includes use of thresholds and PCR testing. Testing can be performed by any ISO17025 accredited laboratory as long as the statistical validity requirements of the Non-GMO Project Standard are met.
- The standard is updated every 6 months through a stakeholder comment process where consensus is sought.
- The Project Verification is available to certified organic and non-certified organic products as long as they meet the Non GMO Standard.
- The Verification process includes an annual inspection, similar to the certified organic system; more than 70 organic inspectors are currently trained to conduct these Non-GMO Project inspections.
- The application and verification process includes an audit review by a 3rd party Technical Reviewer, which at this time is contracted to Food Chain Global Advisors.

The Non-GMO Project Product Verification Program (PVP)

Key learnings as identified by the project:

1. Strip testing was not targeting all GM events which allowed GM contamination to enter the production system.
2. Representative sampling and PCR testing SOPs were installed preventing GM contamination from entering the production system.
3. PCR testing was adjusted to target all commercialized GM events.
4. PCR sample sizes were adjusted to meet the 90% confidence rule.
5. Compositing strategies were developed to reduce cost and frequency of PCR testing.
6. Through the PVP, the applicant brand-owner discovered that ingredient suppliers had changed ingredient formulations without advising the applicant organization. The applicant was then able to correct this practice so that they were consistently aware of any changes in ingredient formulations. For example, the applicant required only cane sugar to be used in their products, but the ingredient supplier had switched from cane sugar to GMO sugar beets. In another example, cane sugar had been replaced with GMO corn syrup.
7. The applicant organization discovered that their suppliers were not following or delivering to the written specifications provided by the applicant.
8. Through review of ingredients for the PVP, the quality team of a prominent brand noticed for the first time that a key incoming soy input was 100% GMO, even though the supplier spec sheet indicated such.
9. Supplier spec sheets did not disclose all ingredients creating a situation where even the suppliers were unaware of GM risk inputs, carriers, and additives present in certain ingredient formulas.
10. PVP review of products revealed that applicants were making non-GMO claims on the basis of ingredient supplier affidavits which were not supported by transparency.
11. Applicants discovered that they were accepting supplier non-GMO claims based on invalid PCR test results. Typically, tests did not detect the presence of GMOs, not because of absence of GMOs but because the sample did not contain sufficient DNA to allow valid GMO testing.
12. Applicants, were able to reduce risk of brand damage when they discovered through the PVP that they had been classifying a certain input or ingredient as low GM risk, when, in fact, it was high risk.
13. Through the PVP, the applicant discovered that ingredient buyers were not following ingredient procurement SOPs designed to keep GM contamination out of their products.

14. Applicants were using ingredients labeled low-GM risk based on supplier claims that the ingredients were being produced in GE free regions. The PVP verified that some of these claims were true. However, many were found not to be true, enabling the applicants to reduce brand risk.
15. The PVP frequently enables applicants to identify segregation SOPs that are insufficient and require improved rigor, especially in cases where parallel processing is involved.

APPENDIX 10

Discussion Paper (Draft 7/7/11)
Genetic Purity Standard for Organic Seed
Prepared by: Lowell Rheinheimer, Farm Resources Manager, CROPP Cooperative/Organic Valley
Chuck Benbrook, Chief Scientist, The Organic Center

Many factors must be considered in establishing a genetic purity standard for seed. Technical issues and challenges arise from the underlying genetics of the crop, whether and how the crop has been genetically engineered (GE), accessible testing methods, and use of appropriate statistical analysis.

Herein we describe and recommend adoption of a universal genetic purity standard for seed to be used in organic production systems. The focus of the standard is the presence or absence of GE content, and the standard is equally applicable to conventional and organic seed.

Genetic purity has historically been synonymous with varietal purity in the seed industry. However, with the introduction of the genetic engineering of crop cultivars, the issue of genetic purity has become more complex. The seed industry has long had to deal with varietal off-types and has effective systems and standards in place to protect varietal purity within the expectations of the marketplace. Genetic purity in seed can no longer be addressed solely through efforts to protect varietal purity through adherence to tolerances for various off-types. Genetic purity must also now encompass the presence or absence of GE contamination, with the protocols for making such a determination structured to meet the concerns and demands in the marketplace for GE-free foods, products, and animal feeds

We propose a universal standard for the genetic purity of seed to be used in organic production of no GE seeds found in a 3,000 seed sample. "None found" in a 3,000 seed sample corresponds statistically to an estimate of genetic purity in the seed lot between zero percent and 0.10% with 95% confidence. The only way to prove that a seed lot is 100% GE-free with 100% certainty is to test 100% of the seeds in the lot, which is obviously not feasible.

1. ***Seed versus crop distinction***. For two major reasons, the genetic purity standard for commercial seed suitable for use in organic production should be stricter than the standard applied to harvested crops. First, clean seed must be planted for the farmer to harvest uncontaminated food or feed. Second, the planting of contaminated seed guarantees that the crop will contain at least the level of contamination of the seed and, especially in the case of corn, would likely suffer from additional contamination from pollen. The annual planting of seed that meets the proposed genetic purity standard is the surest strategy to meet consumer expectations and prevent a gradual increase in levels of GE contamination in non-GE crops and foods.

2. ***Sampling.*** The testing of seed for genetic contamination requires the grinding of the seed being tested, and thus destroys its viability. Clearly, seed companies cannot test every seed in a lot without destroying the entire lot, and so they must rely on statistical sampling procedures to attain a defined level of genetic purity. All testing regimes assume a representative sample of seed from a homogenous lot.

3. ***Detection in the sample.*** Detection in the sample is the basis for determining the estimated level of contamination in the lot being tested. The organic industry's goal for all seed is zero presence of GE, of course, but since one cannot test every seed without destroying the entire lot, the closest one can get based on sampling is "none found in the sample."

4. ***Type of seed.*** Each type of seed has its own typical testing protocol reflecting differences in seed size, value, traits, etc. An appropriate, statistically sound seed purity testing protocol needs to be developed for each crop that is subject to potential GE contamination. Each crop-specific protocol will define the minimally acceptable level of certainty that a given lot of seed meets the proposed genetic purity standard. However, the statistical tools and methods used to determine the estimated level of contamination in a lot is the same for all types of seed. Thus, a standard of "none found in a 3,000 seed sample" can be applied to all types of seed.

5. ***Level of detection.*** The sampling and testing protocol must be sensitive enough to reliably detect one contaminated seed in the sample. This can be achieved by either testing the entire sample, or by dividing the sample into

pools and testing each of them separately. The important thing is to test with a protocol sufficiently sensitive to pick up even one contaminated seed in the sample without background noise from foreign matter. Because of limits to the level of detection, the most accurate estimates are sometimes derived from dividing samples into pools, testing each pool, and analyzing the results by an appropriate statistical method.

6. ***Type of test.*** 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, will 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 know GE events will be required for most samples.

7. ***Traits tested.*** This is a complex issue for many reasons. Some GE seed producers place legal constraints on how seed can be used, and even explicitly prohibit anyone from conducting research with the seeds. Companies also often tightly control access to primers and gene sequences needed to develop and validate test methods. Some GE seed varieties contain a single trait, while others contain multiple traits. Some GE varieties may contain GE traits that are not disclosed or advertised. Different testing protocols may be needed to deal with the influence of zygosity and GE-gene copy numbers on test performance and sensitivity. Seed genetic purity test methods should ideally be capable of detecting all commercially approved GE traits. In addition, the methods should also be able to detect any other GE traits that may have become established in seed breeding lines. Significant technical and legal constraints will have to be overcome to reach these goals. As a general rule, as new GE traits are deregulated, testing protocols must be revised to expand its range of sensitivity to encompass the new trait.

8. ***Statistical expression.*** Because sampling only reveals levels of contamination in the sample itself, statistical models must be used to estimate levels of GE contamination in a given seed lot. The statistical model recommended by the International Seed Testing Association for "testing for adventitious presence of levels of biotech traits in conventional seed lots" is SeedCalc 8.0 and is available for download at no cost at this link. Use the "Qual Impurity Estimation" worksheet to input different values for number of seed pools, number of seeds per pool, number of deviant pools (how many pools tested positive) and desired confidence level.

9. ***Sample size.*** Different sample sizes yield widely different statistical expressions of estimated genetic purity in any given lot that is being tested. For example, "none found" in a sample size of 10 seeds would yield a statistical estimate of "less than 25.89%" in the lot – clearly not an acceptable genetic purity standard. On the other hand, "none found" in a sample size of 30,000 seeds would yield a statistical estimate of "less than 0.01%" in the lot – a very high standard, and also a very expensive one to confirm and achieve. (Both examples assume a confidence level of 95%.) A sample size of 3,000 seeds is the standard adopted by most seed technologists.

10. ***Desired Confidence Level.*** The desired confidence level in the statistical estimate of genetic purity in a given lot of seed sampled should be at least 95%. Different confidence levels yield a different statistical expression, even with the same sample size and level of detection. For example, a test result of "none found" in a sample of 3,000 seeds would be expressed statistically as "less than 0.15% in the lot" if the desired confidence level was 99%, whereas it would be expressed statistically as "less than 0.10% in the lot" if the desired confidence level was 95%.

11. ***Language and Terms Used.*** A genetic purity standard for seed suitable for use in organic production should be expressed in a manner consistent with the organic industry's long-term goal of zero GE contamination. The use of terms like "non-detect" or "none found in the sample" is consistent with this goal and less confusing than the statistical estimate of genetic purity in the lot. For example, the genetic purity standard for corn seed should be described as "none found in a 3,000 seed sample," rather than the more ambiguous and misleading statement, "contamination is estimated to be between zero and 0.10% with 95% certainty".

APPENDIX 11

USDA Monitoring, Mitigation and Compensation Plan for GMO Contamination (Draft 1/8/11) Michael Sligh/Chuck Benbrook

Regardless of the particular option or combination of options employed to avoid GMO contamination, history thus far has been very clear that unintended consequences and contamination will occur. Therefore, for all four of the agricultural market streams to be able to compete on a fair and rational basis, there must be an on-going USDA oversight and compensation plan to ensure that all costs associated with the prevention and the immediate harm associated with contamination can be mitigated and compensated in both a timely and equitable manner. Such mechanisms should include the full seven-point plan provided to USDA to create a comprehensive framework. Absent meaningful federal mechanisms to protect, prevent and compensate, no real "co-existence" can occur. All reasonable plans for prevention must be coupled with mechanisms to ensure affected parties can be made whole and that they fully address the worse-case scenarios to ensure a lasting solution.

While the risks may vary by location, any plan adopted should in all cases cover costs associated with seeds, plants, forage and other associated contamination. We also are especially concerned about any geographical plans that ignore the fact that organic seed production is still its infancy; there are a growing number of small regional seed companies and future trends call for much more regional, on-farm participatory breeding as well as seed saving approaches to address climate change and the needs of a more site –specific agriculture. We cannot base any plans for prevention solely on the current macro geographic scenarios; rather, we must fully anticipate and allow for these very likely future scenarios as well. Additionally, the approval of more RR or other GMO crops will trigger and accelerate the need for more de-centralized seed production strategies to ensure local farmer access.

We strongly urge the establishment a seven-point plan including the following USDA GMO monitoring, mitigation and contamination plan that would both oversee and ensure compliance to any prevention plans as well as ensure that the costs of GMO contamination avoidance and any harm incurred are not borne by parties that do not benefit.

Such a USDA Monitoring, Mitigation and Compensation Fund should be administered by FSA, AMS or RMA through a fund from the GMO patent-holders based on strict liability, which would provide immediate assistance to all farmers and other supply chain participants, pending any applicable remedies of law and equity.

This plan should be established for each crop with GE events approved for commercial planting. The fund should be endowed via an initial payment from the company, or companies requesting approval or release of a new GE event. The initial payment into the compensation fund should be sufficient to cover three years of anticipated claims against the fund based on: (a) projected rates of adoption and an initial estimate of the number of non-GE acres that may be impacted by AP or other contamination or causes of market rejection, and (b) USDA's best current estimate of the difference between the non-GE market price and the conventional market price for the crop or foods manufactured from the crop. Applicants for compensation would be required to document expected market prices and differentials, or otherwise quantify and document losses incurred.

The USDA shall establish a multi-stakeholder compensation fund advisory committee; fairly representing all farming approaches; including organic, IP, conventional and GMO farmers and stakeholders, overseeing all approved crops and events. The committee shall review the projected income and payments against the fund, and as necessary, recommend any additional payments likely to be needed to cover expected claims against the fund over the coming three-year time horizon. Any such payments shall be collected from the applicant for approval, or licensees currently marketing the event. Payment rates shall be made per bag or unit of GE seed sold. The USDA shall set payments rates sufficient to assure the fund has adequate resources to cover current and projected claims over a three-year time horizon with the annual re-evaluations to ensure timely and adequate funds remain adequate. This committee shall be empowered to periodically include additional categories of contamination as documented and dictated to ensure on-going multiple marketplace fairness and viability.

GMO approval decisions shall be contingent on agreement by the applicant and any licensees to share the payments in a manner acceptable to them as required to establish the fund and assure that it contains adequate resources to cover expected claims. The fund will serve the purpose of augmenting liability protection for the technology applicant and licensees

marketing GE seeds, and as such, payments into the fund shall qualify as a routine cost of product stewardship programs. However the fund should be administered by USDA, not the industry participants.

In creating the fund, USDA should require all participating parties to expressly agree and acknowledge that the contamination harm in question is an irreparable harm that thus cannot solely be remedied by economic remuneration, because contamination also causes the fundamental loss of farmer and public choice of the crop they sow and eat, as well as the permanent transgenic alteration of natural plants. Accordingly, applicants for compensation from the fund shall, upon acceptance of payment for a given claim, retain full rights to seek further remedies at law and equity beyond the scope of those covered by these payments, including but not limited to declaratory and injunctive relief.

In cases where the similar loss reoccur, or new losses are suffered, a subsequent request for compensation can be made. Reasonable legal and application fees incurred by individuals or entities seeking compensation shall be included in the request for compensation and eligible for coverage from the fund.

In addition, the compensation fund shall cover routine costs incurred by non- GE farmers in order to avoid transgenic contamination, and monitor
cropland, crops, or food products for contamination. The compensation fund oversight committee shall recommend to USDA the criteria and basis for setting a crop-specific per acre rate of payment for farmers incurring such costs to preserve access to contamination-sensitive markets. A pplicants for routine monitoring costs must submit documentation of the acres of non-GE crops grown possibly subject to contamination, the possible or expected source of the contamination, and the contamination-sensitive market to which their crop will be sold. Payment rates shall be set by crop and region when justified, and reviewed annually, with input from the compensation fund oversight committee.

GMO contamination would be based on lowest detectable levels of transgenes and would ratchet down, as improved technology is available. This fund would cover all costs associated with the prevention of GMO commingling and contamination from seed to table and include both perpetual and price differential costs. These costs should include but not be limited to, at least the following costs:

- On-going and incident- triggered testing and related costs for both PCR and strip tests costs;
- On-going buffer zone control, including production acreage losses and on-going maintenance required to secure or maintain access to contamination-sensitive markets;
- Pollinator losses and related damages associated with the GMO event;
- Loss of organic or other third-party certification losses and any costs associated with additional scrutiny, record-keeping, testing or surveillance required to regain certification or retain certification on impacted operations;
- Segregation and commingling prevention plans, including on- farm and post-harvest costs and all related supply-chain integrity costs, above those required as part of routine on-farm best management practices. Such costs incurred by farmers producing the same crop for both the conventional and for contamination-sensitive markets would not qualify for coverage under this provision;
- Seed contamination, including costs of seed replacement, crop and production losses, and the clean-up and decontamination of all germplasm collections, cultivar and breeding lines affected;
- Crop, production, and post harvest losses and associated costs of market rejections; including any IP price differentials;
- Costs associated with the removal and destruction of RR contaminated plants when identified outside of GMO permit acreages;
- Additional categories, as documented and deemed necessary to ensure viable non-GMO farming and marketing opportunities.

APPENDIX 12

Examples of Related GMO Testing Resources

1. GMO test kit manufacturers

Agdia, www.agdia.com
EnviroLogix, Inc., www.envirologix.com
Investigen, Inc www.investigen.com
Neogen Corporation, www.neogen.com
Strategic Diagnostics, Inc., www.sdix.com

2. GMO testing labs

United States

Biogenetic Services, Inc., www.biogeneticservices.com
BioDiagnostics www.biodiagnostics.net
BioProfile Testing Laboratories www.bioprofilelabs.com
California Seed & Plant Lab, Inc., www.calspl.com
CII Laboratory Services, www.ciilab.com
GeneScan USA, Inc. www.gmotesting.com ISO 17025 accredited
Genetic ID, www.genetic-id.com ISO 17025 accredited
Illinois Crop Improvement Association www.ilcrop.com
Investigen, Inc www.investigen.com
Indiana Crop Improvement Association www.indianacrop.org
Iowa State University Seed Laboratory www.seeds.iastate.edu/seedtest
Mid-West Seed Services, www.mwseed.com
North Dakota State Seed Department www.ndseed.com
NSF International www.nsf.org
OMIC USA, Inc. www.omicusa.com ISO 17025 accredited
Oregon Department of Agriculture
http://egov.oregon.gov/ODA/LAB/gmo_test.shtml
Professional Seed Research www.psrcorn.com
SGS www.sgs.com

China

Hai Kang Life Corporation Ltd.
www.haikanglife.com **ISO 17025 accredited**
Hong Kong:
8/F, Hang Tung Resources Centre
18 A-Kung Ngam Village Rd.
Shau Kei Wan, Hong Kong SAR
P.R. China
Tel: (852) 2111-2123
Fax: (852) 2111-9762

Beijing, China:
Block A, Building 3, 1 Disheng Street North
Beijing Economic Technological Development Area

Beijing 100176 P.R. China
Tel: (86) 10-5802-2828
Fax: (86) 10-5802-2500

Italy

Biodiversa Molecular Laboratory
Molecular Laboratory
Via Mirandola 45
37026 Settimo di Pescantina
Verona, Italy
http://www.biodiversa.it ISO 17025 accredited
Contact: Elisa Zago
elisa.zago**-at-biodiversa.it**

3. USDA/GIPSA Guidelines for Handling Biotech Grain

USDA and FDA have established sampling and testing guidelines to assist the industry in going about the task of testing grain throughout the system, as well as all seed lots destined for planting. USDA's GIPSA has established a system for validating the claims of test kit manufacturers and certifying those tests for official use. In addition, GIPSA has established guidelines which deal with various aspects of handling biotech grain.

GIPSA/USDA recommendations

Practical Procedures For Sampling Grain At Farm Sites And Remote Locations

The Importance Of Sampling: Sampling is an essential part of the inspection process and is critical to the accuracy of the final grade. If the sample is not representative of the lot, the inspection result will not reflect the true quality of the lot. Basic Principles of Obtaining a GOOD sample:

- Collect several samples from different areas of the lot.
- Combine these samples to form a single sample.
- Consider the size of the sample needed for analysis.
- Completely mix or blend the final sample.

Rapid Test Performance Evaluation Programs
We maintain and improve reference methods and evaluate rapid tests for detecting mycotoxins and biotechnology-derived grains.

Biotechnology
We play a critical role in improving the reliability of testing for biotechnology-derived grains and oilseeds on a global basis through the USDA/GIPSA Proficiency Program and related activities.

Rapid Test Performance Evaluation Program
The Rapid Test Performance Evaluation Program established by GIPSA is a basic four step process where:

- The rapid test manufacturer submits a data package supporting their claims.
- The GIPSA staff reviews the data submitted by the manufacturer.
- If the data package is complete and the claims of the rapid test are supported by the data, GIPSA conducts an in-house performance verification of the rapid test.
- If the manufacturer's claims are verified by the GIPSA in-house performance testing, a Certificate of Performance is issued to the manufacturer for the rapid test.

Grain Inspection, Packers & Stockyards Administration Technical Services Division 10383 N Ambassador Drive Kansas City, MO 64153 (816) 891-0401 www.gipsa.usda.gov

Example of sample size recommended for PCR testing:

The following is a typical sample size recommendation by one leading laboratory for a highly accurate PCR test for several products. Such a testing program would be more likely at the processor level. Please note that testing the raw material behind a processed product is less expensive than testing the processed product.

Maximum lot sizes for sampling:	**Total Sample Collected**		**Keep archive sample for:**
	Minimum sample size send to lab	**Minimum sample size Archive**	
Corn flour: up to 475 MT	200 grams	200 grams	1 year
(If testing whole corn before processing) Whole corn: up to 500 MT	3.0 kg (lab needs 10,000 kernels to have sufficient DNA to test)	3.0 kg	1 year
Soy Ground Soy nut bits: up to 952 MT	200 grams	200 grams	1 year
Whole soy: up to 1,000 MT	2.5kg (lab needs 10,000 kernels to have sufficient DNA to test)	2.5 kg	1 year
Soy Oil: Crude soy oil: Size of tank lot (batch lots only, no continuous flow)	1 quart (1 liter). Note that it is possible that crude oil has reduced DNA. Therefore testing may have to happen on the soy beans.	1 quart (1 liter).	1 year
(If testing whole soy before processing) Whole soy: up to 1,000 MT	2.5 kg (lab needs 10,000 kernels to have sufficient DNA to test)	2.5 kg	1 year

APPENDIX 13

GLOBAL GMO Thresholds and Labeling Requirements

Information available as of May 2011

	Labeling Requirements								
Country Region	Mandatory or Voluntary	Other Requirements	Targeting GM as Finished product or as Production Process	Effective Date	Threshold	Specification	Terms Required/Allowed	Exemptions	Comments
Argentina	Voluntary		Product		5%	All products based on content			Information as of 2006
Australia & New Zealand	Mandatory		Product	December-01	Up to 1.0% unintended contamination	Required where foods have altered characteristics or when foods contain novel DNA or protein as a result of genetic modification	"Genetically Modified" "Not from a GM source" "May contain a GM food due to supply variation	1) Foods obtained from GM crops, but do not contain novel DNA or proteins. 2) Food additives and processing aides (unless novel DNA is presend in the final product). 3) Flavores (when present at less than 0.01% in the final product). 4) Foods obtained from crops that have been genetically modified through techniques other than rDNA.	
Austria	Mandatory	EU Member State Requirements			0.9%				Cultivation of GMO Crops Prohibited
Brazil	Mandatory - Detection based -May not be fully implemented		Process	August-04	1%	Food, feed, products derived from GM, meat and animal products	"T" - "Transgenetic XXX"	Almost None	Government Decree though largely ignored. New bill under debate in 2009

	Labeling Requirements								
Country Region	**Mandatory or Voluntary**	**Other Requirements**	**Targeting GM as Finished product or as Production Process**	**Effective Date**	**Threshold**	**Specification**	**Terms Required/Allowed**	**Exemptions**	**Comments**
Canada	Voluntary			April-04	5% for Positive and Negative claims	All products based on content	"Genetically modified organism" or "transgenically derived product	Canada label "Non-GMO" must be factual & not misleading or deceptive	Voluntary - prohibits absolute claims or symbols
Chile	Mandatory - Proposed		Product	September 2006 - Proposed	1%		"Genetically modified organism"; "Trasgenetically derived product"		
China	Mandatory - Certification required		Process	July-03 - Labeling. April-04 - Certification	1%	Labeling for biotech derived	List of products derived from GM material and area to be sold	Out side of List May exclude pre-packaged or processed foods	Caution: 2007 references could be interpreted as Zero % threshold for Imports
CODEX Committee on Food Labeling (CCFL) Proposal	Voluntary			May-11 Final CCFL document approved . To be sent to Codex Alimentarius for approval			Compilation of References to GMOs, definitions and labeling within all existing Codex documents		
Columbia	Mandatory-proposed regulations to implement legislation		Product	October-10		Labeling of traded products for human consumption that contain or may contain GMOs, raw materials that contain, may contain or are genetically modified	The use of statements such as “GMO free” or “not containing GMO” on the label of food products and raw materials used for the processing of food for human consumption is not permitted, unless not misleading.	Food additive; food prepared at point of sale (restaurants, hotels, fast food restaurants). Only required if GMO product or ingredient is an allergen, preparation or processing must be different, nutritional value is different, or has been improved in its physical, chemical or	Ingredients and products must be declared on import documents.

	Labeling Requirements								
Country Region	Mandatory or Voluntary	Other Requirements	Targeting GM as Finished product or as Production Process	Effective Date	Threshold	Specification	Terms Required/Allowed	Exemptions	Comments
								functional characteristics.	
Croatia	Mandatory		Process	May-05	0.9%		"Contains genetically modified organisms"		Similar to EU requirements
Cyprus	Mandatory	EU Member State Requirements	Process	April-11	0.9%	Separate shelves in stores for GM foods and foods with GM ingredients. Signage stating GM Foods in three languages			Food "Product" based labeling and segregation requirements
Czech Republic	Mandatory	EU Member State Requirements		January-02	0.9%	Produced or imported products containing GM-DNA	GMO variety must be approved by Ministry of Health		Importers and retailers have been asking for GMO free documentation or statement that Brands will label approved GMO varieties

	Labeling Requirements								
Country Region	Mandatory or Voluntary	Other Requirements	Targeting GM as Finished product or as Production Process	Effective Date	Threshold	Specification	Terms Required/Allowed	Exemptions	Comments
European Union (27 Member States) *	Mandatory	Additional national voluntary guidelines	Process	October-98; April-00; April-04, pending vote June-11 proposal to restrict or ban the cultivation of genetically-modified crop varieties, so as to allow national authorities to cite environmental grounds.	0.9% - "Technically unavoidable" threshold	Food produced from animals fed on GM feed, feed additives, flavorings, products derived from, containing or produced from genetic modification including processing aids	"this product contains genetically modified organisms" or "… produced from genetically modified >>>" Does not permit "may contain" or negative claims	Meat and animal products, solvents, media for additives or flavoring, processing aids,	Scope includes foods such as soya and maize oil produced from GM sources Includes restaurants
Hong Kong	Voluntary			February-01	5%	"Should be labeled" - Public consultancy underway	"Should be labeled"		Labeling requirements still in development
Hungary	Mandatory	EU Member State Requirements			0.9%				Cultivation of GMO Crops Prohibited
Indonesia	Mandatory		Product		5%	Listed of food products including maize and soya	"Genetically engineered food"	Unlisted Products	
Japan	Mandatory		Product	1999; 2002 & 2011	5% Maximum for adventitious presence of GMO	Specific List of foods; April, 2011 added GE Papaya to the list of foods	3 main ingredients in a product	Processed products	Requires labeling of "GM high oleic soybean oil", Highly refined maize oil & rape seed oils; April, 2011 Added GE Papaya to the list of foods
India	Mandatory - Not fully implemented			March 2006 - Proposed		Labeling based on origin of GMO	Declaration required on Import Documentation		GMO cultivation is very political in India with contrary positions being promoted by
India - Bihar									Prohibit Cultivation of GM Crops
India - Madhya Pradesh									Prohibit Cultivation of GM Crops

	Labeling Requirements								
Country Region	Mandatory or Voluntary	Other Requirements	Targeting GM as Finished product or as Production Process	Effective Date	Threshold	Specification	Terms Required/Allowed	Exemptions	Comments
India - Kerala									Prohibit Cultivation of GM Crops
Ireland	Mandatory	EU Member State Requirements	Process	October-09	0.9%	Voluntary GM-free label for food – including meat, poultry, eggs, fish, crustaceans, and dairy produce made without the use of GM animal feed.			Ban on GM crops
Israel	Mandatory - Not fully implemented		Process	2002 - Proposed	1%	Corn and Soya	"genetically modified"		Generally follow EU requirements
Kenya	Mandatory - Proposed			June-05	5%	Proposed for food, feed and GMO ingredients	"Genetically Modified"		
Korea	Mandatory - Certification required	Voluntary for Non - GMO claims	Product	June-01	zero tolerance - GMO Free for organic. 3% tolerance for non-organic		Required "GM food" or "Genetically modified" - Voluntary for 100% free of any biotech components "Non - GMO" or GMO-free"	Foods that do not contain novel DNA or proteins are exempt	Labeling required for bulk corn, soybeans and soybean sprouts for direct human consumption above 3% threshold
Malaysia	Mandatory - Proposed				more than 3 % GMOs				
Mexico	Legislation under consideration		Product				"Transgenetic food"		
Norway	Mandatory	EU Requirements	Process	January 99	0.9 % for food; 0.5% for seeds		"Genetically Modified X"		
Philippines	Mandatory - Announced		Product		5%	All products based on content			
Romania	Mandatory	EU Member State Requirements			0.9%		"Yellow Circle" and Text		

	Labeling Requirements								
Country Region	Mandatory or Voluntary	Other Requirements	Targeting GM as Finished product or as Production Process	Effective Date	Threshold	Specification	Terms Required/Allowed	Exemptions	Comments
Russia	Mandatory		Product	December-06	1%	Specific list of raw materials including Soya, Corn, Potato, Tomatoes ,Vegetable Purees, Melons, Papaya, Chicory and Food additives.	"Genetically modified product"; "product derived from genetically modified sources"; "this product contains components of genetically modified sources"	Feed; and " food products made of genetically modified sources which do not contain DNA or protein do not have to be labeled"	
Saudi Arabia	Mandatory - Certification required		Product	Dec-01 - Initially effective. July-09 - New proposal; Nov 2010 - Standards promulgated	1%	unprocessed agricultural products for human consumption (food, animal feed, seed)	"contains genetically modified product"; Genetically modified animal imports - prohibited		New proposals in 2009- Raw materials must have been approved in country of origin for human consumption; Restaurants
Serbia & Montenegro	Mandatory			June-05	0.9%		"Yellow Triangle, red border and black letters "GMO"		Similar to EU requirements
South Africa	Mandatory above 5%	Voluntary for Non - GMO claims	Product	Final April-11; Implemtation October-11	Complex percentage ingredient label claims	Not specified - all products based on content	>5% requires - "containing GMOs" 1% to 4.9% - may label "content is less than 5% <1% - may label "Does not contain GMOs" Where food is produced directly from GMO, like Maize Meal or Polenta, there will be no need for testing and the food packaging must be labeled as 'produced using		May require labeling when human or animal genes are put in plants. In cases where companies are able to argue/demonstrate that it is scientifically impractical and not feasible to test food for GM content, they may opt for the 'may contain GMOs' label

	Labeling Requirements								
Country Region	Mandatory or Voluntary	Other Requirements	Targeting GM as Finished product or as Production Process	Effective Date	Threshold	Specification	Terms Required/Allowed	Exemptions	Comments
							genetic modification'		
Sri Lanka	Mandatory			Not Implemented	1%		"Genetically modified X"		
Switzerland	Mandatory			January-99	GM Feeds containing more that 3%; Mixed feeds - 2%; Imported Seeds 0.5%		"Produced from Genetically Engineered 'X' _or "GMO product"		
Taiwan	Mandatory		Soy and Corn product	January-03 Bulk; January-04 Simple processed products; March-05 all packaged multi ingredient processed products	5%	Specific List of Food items	"GM" and "non-GM"	Un-listed food items	
Thailand	Mandatory	Implemented with "Voluntary enforcement" - Penalties for Fraud	Product	May-03	5%	Specific List of Food items		Un-listed food items	Labeling required for corn, and soybean products
Turkey	Mandatory		Product	October-09	0.9%	Require GMO analysis on "GMOs" and "GMOs and products derived thereof"; Includes cotton		Prohibits "Non-GMO" labeling	Only 3 approved GM soy events and only for animal feed. Otherwise zero tolerance for unapproved GMOs.
Ukraine	Mandatory	Legislation adopted			0.9%		"GMO" or "GMO Free"		
Viet Nam	Mandatory - Draft Legislation		Product	July-11	5%	Manufactured and Imported GMO foods must obtain a "Certificate of Eligibility to Use as Food" or on "List of GMO Foods Certified for Food	"Gene Modified"		Implementing Regulations and Guidelines to be developed by the Minister of Agriculture and Rural Development

	Labeling Requirements								
Country Region	Mandatory or Voluntary	Other Requirements	Targeting GM as Finished product or as Production Process	Effective Date	Threshold	Specification	Terms Required/Allowed	Exemptions	Comments
						Use"			
Non- GMO Project Product Verification Program	Voluntary - private verification program; Primarily in U.S. and Canada	Annual 3rd party verification via evaluation of documentation and on-site inspection (currently required for high risk inputs/products)" on-GMO Project Verified" means is that either the product does not contain major high-risk ingredients, or that if it does, those ingredients have been tested.	Process standard that uses testing as a key strategic tool to confirm that practices/ or processes are meeting expectations	Current version 7: February 2011	Action Thresholds set during current Non-GMO Project program-wide variance : 0.25% for planting seed and other propagation materials; 0.9% for human food, products, ingredients, supplements, and personal care products; 1.5% for animal feed and supplements	Current list of high risk GMO crops & inputs: Alfalfa, Canola, Corn, Cotton, Papaya, Soy, Sugar Beets, Zucchini and Yellow Summer Squash, milk, meat, eggs, honey/other bee products, rBGH/rBST, enzymes including chymosin, microbial cutlures and starters, plus processed/processing inputs & ingredients and related derivatives from crops, livestock, or microorganisms including amino acids, aspartame, ascorbic acid, sodium ascorbate, vitamin C, citric acid, sodium citrate, ethanol, natural and artificial flavorings, hydrolyzed vegetable protein, lactic acid, maltodextrins, microbial growth media, molasses, monosodium glutamate, sucrose, textured vegetable protein, xanthan gum, vitamins, yeast products	Non-GMO Project seal allowed for products verified to be in compliance with the standards	Temporary exclusion of vaccines and medicines used in livestock production and micro ingredients used in livestock feed formulations or products manufactured for human consumption with the exception of designated "high risk" micro inputs.	Aspects of production process relevant to producing Non-GMO Project verified products: traceability, segregation, action thresholds for inputs and products, operating procedures, quality system, quality assurance & quality control, training, document control. Compliance with Action Thresholds verified on basis of genetics-based testing or affidavits from suppliers as is consistent with the technical requirements applicable at each point in the production/storage/handling chain

	Labeling Requirements								
Country Region	Mandatory or Voluntary	Other Requirements	Targeting GM as Finished product or as Production Process	Effective Date	Threshold	Specification	Terms Required/Allowed	Exemptions	Comments

DEFINITIONS:

LABELING REQUIREMENTS: VOLUNTARY labeling guidelines dictate rules that define what food can be called GM or non–GM, and let the food companies decide if they want to use. A certain number of countries with mandatory labeling for GM ingredients also have voluntary guidelines for the labeling of non–GM food (e.g., Japan and the EU). This mixed mandatory/voluntary system is in place in countries with mandatory labeling for which consumers are willing to pay a premium to completely avoid GM ingredients, even at a residual level. In contrast

LABELING REQUIREMENTS: MANDATORY labeling requires food companies (processors, retailers, and sometimes food producers) to display whether the targeted product/ingredient contains or is derived from genetically engineered materials.

TARGETED GM IN PRODUCT: PRODUCT - finished product as target of labeling requirements. Only products with detectable and quantifiable traces of GM materials or ingredients are required to carry a label. Countries with product labeling base their regulation on consumer demand for product information.

TARGETED GM IN PROCESS: PROCESS - GM technology itself is the target of the labeling requirement. In such a program, any product derived from GM crops will have to be labeled, whether it contains any traces of GM material or not. Countries with labeling based on production process believe that at least some consumers base their purchasing decision not only on product related issues but also on environmental and/or religious, ethical, or other non–safety related reasons.

*** EU Member States:** Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, United Kingdom