

Non-GMO Project Working Standard



Spring 2011

Non-GMO Project Working Standard

This version of the Non-GMO Project Standard highlights changes based on the Spring 2011 Public Comment Period.

The next round of public comment on the Working Standard in its entirety will be from October 10th through November 10th 2011. Comments may be submitted online at <http://www.nongmoproject.org/non-gmo-project-standard/comment-on-the-standard/> or may be sent to standard@nongmoproject.org

Non-GMO Project Working Standard

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Megan Westgate 6/20/11 10:45 AM

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Minimum Isolation Distances For ... [1]

Non-GMO Project Working Standard

1. INTRODUCTION	
<p>Explanation of layout of this Standard: <i>This Standard is published in two columns. The left-hand column contains clauses of the Standard itself. The corresponding right-hand column contains Guidance notes that are included to help interpret and explain the intent of the given standard clause, offer additional relevant details, and/or place the clause into the context of current realities. Guidance notes should be read along with the Standard's clauses and must be followed accordingly. Where no Guidance is offered, the Standard alone suffices.</i></p>	
STANDARD	GUIDANCE
<p>1.1. Purpose: The Non-GMO Project's Product Verification Program (the "Program" or "PVP") aims to verify:</p>	<p>See Section 1.3, "Additional Terms and Definitions," for meaning of "product" and definitions of other terms.</p>
<p>1.1.1. That the systems and procedures of the participant company or organization (the "Participant") are capable of delivering products that comply with the Non-GMO Project's Standard (the "Standard").</p>	<p>Each Participant company or organization has the freedom to design its own systems to reflect its particular operational needs and practicalities, so long as the objectives of the Standard are met.</p>
<p>1.1.2. That the Participant consistently operates their systems according to those procedures.</p>	<p>Annual third-party verification of conformity to this Standard, via evaluation of Participant documentation and on-site inspection, is part of the Program.</p>
<p>1.1.3. That the resultant products are compliant with the Standard.</p>	<p>The Non-GMO Project's Product Verification Program ("PVP") is a practice/process-oriented standard that uses testing as a key strategic tool to confirm that practices/processes are meeting expectations.</p>
<p>1.2. Scope: The scope of the Program encompasses the following products, activities, and aspects:</p>	<p>Refer also to Section 4 and Appendix A regarding specific variances to this Standard and its scope.</p>
<p>1.2.1. Products</p>	
<p>1.2.1.1. Agricultural inputs, such as seeds, fertilizers, pesticides, and herbicides.</p>	<p>Examples of non-compliant fertilizers are oilcake/oilseed meal from genetically engineered soybeans, canola, or cotton, un-composted GMO cornstalks, etc.</p>
<p>The scope of this Standard includes an exclusion for composted materials and animal manures. These may be used from any source, <i>except</i> manure from animals that have been genetically engineered to produce a novel material.</p>	<p>An example of a non-compliant pesticide is genetically altered <i>Bacillus thuringiensis</i> (<i>Bt</i>).</p> <p>An example of a non-compliant herbicide is corn gluten from genetically engineered corn.</p> <p>An example of an animal engineered to produce a novel material would be a goat that is genetically engineered to have antibiotics or</p>

Sandy Kepler 7/17/11 5:32 PM

Comment [1]: Exclude these or variance them out temporarily. This makes it too difficult on farmer applicants at this time. Request to stay focused only on seed/crop/feed. Concerned even requiring farmers to insure manure is not from GE animals.

PROPOSED EXEMPTION ADDED TO VARIANCE 8

Megan Westgate 7/17/11 5:32 PM

Comment [2]: Deleted the word "permanent" for consistency. This requirement is no more and no less permanent than everything else in this standard.

Megan Westgate 5/26/11 2:46 PM

Deleted: permanent

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	hormones secreted in its milk.
1.2.1.2. Unprocessed agricultural products, such as vegetables, grains, fruit, greens, herbs, and other fresh foods, fibers, etc.	
1.2.1.3. Livestock feed components, such as grains, vitamins, enzymes, minerals, etc.	
1.2.1.4 Microbial starters, media, and products.	Includes those used for animal feed (e.g., silage or hay inoculants, fermentation solids or similar products) or human food.
1.2.1.5. Manufacturing and processing inputs (“inputs”), including ingredients, flavorings, seasonings, colorings, additives, and all other substances present in final, manufactured products. Processing aids used by the Participant and present in the final product are also included in the scope of this Standard.	
1.2.1.6. Animal products, including dairy, meat, eggs, bee products, wool and hides.	
1.2.1.7. Veterinary inputs such as vaccines, hormones, semen and medicines.	For the purposes of the Standard, cloned animals and their progeny are not allowed.
1.2.1.8. Processed agricultural products or ingredients and manufactured food products.	
1.2.1.9 Dietary supplements, vitamins and herbal preparations.	
1.2.1.10. Health-care products.	
1.2.1.11. Personal care products and cosmetics.	Includes lotions, soaps, balms, makeup, etc.
1.2.1.12. Cleaning products,	
1.2.1.13. Packaging, textiles and other agriculturally derived mercantile products.	
1.2.2. Activities: The scope of the Program encompasses the following types of activities and sectors of food and related production systems:	A core goal of the Project is to identify, create, and/or maintain sources and practices that effectively minimize GMO risk to the supply chain. High-Risk Inputs (see below) will ultimately be able to be downgraded to low-risk status as a result of such efforts.
1.2.2.1. Agricultural production—seeds and crops	Includes farm production, harvest, and post-harvest handling and storage on farm or farm-related facilities.

Megan Westgate 7/17/11 5:32 PM
Comment [3]: Since we are proposing that textiles have a different threshold than food (see proposed changes to 2.6), they should be listed separately in the scope.

Megan Westgate 6/3/11 6:36 PM
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Megan Westgate 6/3/11 6:36 PM
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Megan Westgate 6/3/11 6:38 PM
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Megan Westgate 7/17/11 5:32 PM
Comment [4]: SUGGEST CHANGES TO THIS SECTION BASED ON DISCUSSION ABOUT PACKAGING; if we are going to propose a separate threshold for packaging, it should probably apply to other similar items (textiles, cleaning products, etc.), and these should be listed in the scope.

Megan Westgate 6/3/11 6:38 PM
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	Reduction of background contamination levels in seed supplies is of primary importance toward reduction of GMO content of consumer goods.
1.2.2.2. Handling	Includes any form of post-harvest movement, storage, transformation, or labeling of goods along the entire chain of custody from seed to consumer, except for products enclosed in final retail packaging.
1.2.2.3. Storage	Includes all links in the chain of custody from seed to finished product.
1.2.2.4. Distribution	This may or may not involve physical handling of goods.
1.2.2.5. Processing	Includes all movements, storage, transformations, combinations, or labeling of goods within any given production facility.
1.2.2.6. Manufacturing	Involves the combination of inputs to make the final product sold by the operation in question.
1.2.2.7. Packaging and labeling	Includes any and all events where the package or labeling of goods is altered.
1.2.3. Program Elements: The scope of the Program encompasses all aspects of the production process relevant to producing Non-GMO Project verified products, including the following:	
1.2.3.1. Traceability	Special attention needs to be paid to inputs and products that are verified as Non-GMO Project Standard compliant, versus like inputs or products that are not explicitly verified or included in the Program as such. This applies even if the presumed chance that non-verified goods have GMO content is low.
1.2.3.2. Segregation	Additional segregation measures for Non-GMO Project Standard compliant materials may be necessary, especially when any high-risk inputs are handled. Appendix B of this Standard lists high-risk crops and their derivatives. Segregation is also necessary between distinct lots of goods that are Non-GMO Project verified, versus inputs or products that are not explicitly verified or included in the program as such.
1.2.3.3. Specifications for Inputs and Products	Refers to GMO action thresholds, etc. This Standard specifies relevant quantitative limits.
1.2.3.4. Operating Procedures	
1.2.3.5. Quality System	

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1.2.3.6. Quality Assurance and Quality Control	Specific procedures and practices relevant to traceability, segregation, sampling and testing of lots for GMO content—with associated <u>ingredient procurement SOPs</u> and training of personnel—are a necessary inclusion in any operation’s routine activities when assuring adherence to this Standard. Existing procedures and documents can be amended or new ones created, as deemed most appropriate by the operation in question.
1.2.3.7. Training	
1.2.3.8. Document Control	
1.2.3.9. Maintenance of Records and Data	
1.3. Additional Terms and Definitions	In addition to explanations of terms provided by other Guidance notes, the terms in this section are explicitly defined.
1.3.1. Compost	Decayed organic material used as a fertility amendment in agricultural production, produced by a combination of actions over time by microbes, invertebrates, temperature, and other elemental factors (e.g., moisture content, aeration). <u>Composted material shows practically no macroscopic indication as to the original substrate(s) from which it was made.</u>
1.3.2. Farming operation	Any operation involved with production, handling, storage, or management of crops until legal ownership or physical transformation of crops or livestock products occurs.
1.3.3. GM	Genetically Modified or Genetic Modification—A term referring to products or processes employing gene splicing, gene modification, recombinant DNA technology, or transgenic technology, and referring to products of the gene-splicing process, either as inputs or as process elements.
1.3.4. GMO or Genetically Modified Organism	A plant, animal, microorganism, or other organism whose genetic makeup has been modified using recombinant DNA methods, also called gene splicing, gene modification, or transgenic technology. Cloned animals and their progeny are also considered GMOs under this Standard.
1.3.5. Input	The term “input” includes any material or substance that becomes a part of the final product, or a component of which becomes a

Sandy Kepler 7/17/11 5:32 PM
Comment [5]: Insert ingredient procurement SOPs
 OKAY- Clarifying change
 Megan Westgate 6/3/11 6:01 PM
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Megan Westgate 6/3/11 6:03 PM
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 Sandy Kepler 7/17/11 5:32 PM
Comment [6]: Is this statement defensible scientifically? If not, please delete it.
 Change substantive to macroscopic (clarifying change)

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	<p>part of the product, or is used otherwise in the production of a product. These include the following:</p> <ul style="list-style-type: none"> • Agricultural inputs, such as seeds, fertilizers, and pesticides. • Unprocessed agricultural products, such as vegetables, grains, fruit, greens, herbs, and other fresh foods etc. • Feed components, such as grains, forage plants, vitamins, enzymes and minerals. • Livestock production inputs such as vaccines, hormones, and other veterinary materials. • Manufacturing and processing inputs, including ingredients, flavorings, seasonings, colorings, additives, enzymes, cultures, and all other substances present in final manufactured products. <p>The PVP distinguishes between inputs as being “mono” (composed of only one component) or “compound” (composed of more than one component).</p>
<u>1.3.6. Medicine (Veterinary)</u>	<u>(i) Any synthetic material other than vitamins, minerals, or amino acids given to livestock at any time; or (ii) Any non-synthetic material given to an animal on a non-routine basis for the purposes of maintaining or restoring health.</u>
<u>1.3.7. Non-GMO or Non-GM</u>	A plant, animal, or other organism or derivative of such an organism whose genetic structure has not been altered by gene splicing. <u>A</u> process or product that does not employ GM processes or inputs. Cloned animals and their progeny are considered GM.
<u>1.3.8. Participant</u>	A company or other entity independent of the Non-GMO Project that enrolls in the Program.
<u>1.3.9. Product</u>	The term “product” refers to <u>a distinct product name</u> that the Participant offers to the marketplace, at whatever stage of the production chain (i.e., final consumer product, ingredient for further manufacturing, raw agricultural crop or commodity, etc., as applicable). “Product” refers to products that are involved in the Non-GMO Project Product Verification Program.
<u>1.3.10. Shall or Must</u>	A mandatory requirement under the Standard.

Megan Westgate 7/17/11 5:32 PM
Comment [7]: Propose adding definition for clarity

6/8/11 1:26 PM
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Megan Westgate 5/26/11 3:22 PM
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Megan Westgate 5/26/11 3:22 PM
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Sandy Kepler 7/17/11 5:32 PM
Comment [8]: Replace with “a distinct product name.” This aligns with the NOP.
 OKAY—Clarifying change

Sandy Kepler 4/8/11 9:59 AM
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1.3.11. Should or May	A non-mandatory recommendation or recommended practice.
1.3.12. Standard	The “Standard” herein refers to the Standard for The Non-GMO Project Product Verification Program, which is this document.
1.3.13. Supplier	Any party from whom an input is obtained.
1.3.14. Technical Administrator	The organization responsible for conducting the Program on behalf of the Non-GMO Project.
1.3.15. Unintentional Contamination	A contamination incident (event) will be deemed unintentional if available information confirms that: <ul style="list-style-type: none"> i. The operator did not knowingly use GMOs or GMO-derived inputs. ii. The operator used all due diligence to exclude GMO contamination.
2. CORE REQUIREMENTS	
2.1. Traceability	
2.1.1. Each lot of Non-GMO Project-verified product or input must be traceable back to specific lots of the inputs used in its production.	If the operation is dedicated strictly to Non-GMO Project Standard compliant production then it is sufficient to have a record-keeping system that records the lot numbers for all lots of inputs used to make a specific lot of product. Systematic procedures shall be in place for tracking lot numbers and/or marking and labeling of packaging, containers, and storage facilities to assure traceability of inputs, work-in-progress, and final products at all points in the production process.
2.1.2. Traceability records shall explicitly trace and track the Non-GMO Project Standard compliant status of both inputs and the final product.	If lots of a given input are co-mingled in storage before use in production of a certain lot of product, the lot numbers related to all lots commingled shall be linked to that particular lot of product.
2.1.3. The producer/manufacturer must be prepared to provide the Technical Administrator of the Program with traceability information.	
2.2. Cleanout and Segregation	The aim of cleanout and segregation procedures is to prevent GMO contamination of inputs, work-in-progress, and final products.
2.2.1. Cleanout:	
2.2.1.1. Receiving, production, processing,	

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<p>manufacturing, transfer, and storage facilities, as well as shipping and transportation conveyances, shall be inspected and cleaned/purged as needed to remove sources of GMO contamination, and all relevant cleaning, purging, and inspections shall be documented.</p>	
<p>2.2.1.2. Procedures shall be appropriate to the operation and may likely differ significantly between agricultural producer, manufacturer, etc.</p>	
<p>2.2.2. Segregation</p>	<p>If the operation is dedicated strictly to Non-GMO Project Standard compliant production, then segregation measures within the production operation are unnecessary, since only Non-GMO Project verified inputs will enter the operation.</p> <p>Segregation measures are also required for instances where any required testing occurs after the input in question has entered the facility. For example, when a Participant, rather than an ingredient supplier, is taking responsibility for testing.</p>
<p>2.2.2.1. If the operation is not dedicated to Non-GMO Project verified production, systematic procedures shall be in place during production to keep Program verified inputs, work-in-progress, and finished products separate from all materials that are not compliant with the Non-GMO Project Standard.</p>	
<p>2.2.2.2. Tracking of lot numbers and labeling/markings on packaging and containers shall be used as necessary to identify and segregate Non-GMO Project Standard compliant materials from non-compliant materials.</p>	
<p>2.3. Specifications for Inputs and Products</p>	<p>The intent of the program is for the Participant to design production processes and input specifications that exclude GMOs from the Participant's products. This not only requires that one use inputs that are compliant with the Non-GMO Project Standard, but also that one employ practices that control unintentional contamination with GM material.</p>
<p>2.3.1. For products enrolled in the PVP,</p>	

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Participants shall not knowingly plant, purchase, or use inputs that are not compliant with the Non-GMO Project Standard.	
2.3.2. Preventive measures, as defined below, must be undertaken by Participants to prevent or reduce unintentional GMO contamination in excess of the action thresholds set by this Standard.	This requirement is necessitated because risk of unintentional contamination of inputs and products with GMOs is increasing due to the growing use of GMOs in non-organic agriculture.
2.3.3. The written specifications for all inputs and products shall include requirements regarding Non-GMO Project Standard compliance, and shall be updated when the Participant changes suppliers or inputs.	
2.3.4. Purchase and use of inputs shall be contingent on inputs being compliant with requirements of the Non-GMO Project Standard, including traceability, segregation and GMO content.	<p>Methodology for determining this is given in sections 2.4., 2.5., and 2.6. of this Standard.</p> <p>Spot purchasing from unverified suppliers should be avoided. Participants must seek out Non-GMO Project Verified inputs and if they are available, and a spot purchase is used instead, the Participant must justify to the Technical Administrator why the verified input was not used. Spot purchases are allowed on the following basis:</p> <ul style="list-style-type: none"> (i) Any input that is spot purchased must be tested in accordance to the requirements of this Standard, and must be below the relevant Action Threshold. (ii) The Participant must provide the Technical Administrator with documentation of the purchase, including sampling information and test results <u>on a periodic basis determined between the Technical Administrator and the Participant, with a minimum frequency of annual reporting.</u> (iii) Constraints on spot purchasing may be enforced at the discretion of the Technical Administrator. For example, repeated spot purchases from the same supplier could be grounds for this allowance to be revoked or restricted.
2.3.5. Release of products to the marketplace	Participants shall have a written methodology

Sandy Kepler 7/17/11 5:32 PM

Comment [9]: To know if unverified suppliers are being used, at enrollment, we must ask for a list of all suppliers and their spec sheets. In many situations, inputs are purchased based on favorable pricing gaged by the market activity daily. We have the experience of renewal applicants changing suppliers mid-term and we have no means to enforce this section. Better if we enable applicants to use their quality system including NGP approved ingredient procurement practices that allow an applicant to determine a new input to be equivalent to one that is already approved for use. Then, we review how those practices are being applied, at renewal. Otherwise our PVP requirements are creating obstacles that are leading to participant dissatisfaction and non-conformance on something we can't policy, anyway.

Proposed changes to guidance clarify intention and ensure that this is enforceable.

Megan Westgate 6/3/11 6:09 PM

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Megan Westgate 6/3/11 6:09 PM

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shall be contingent on products meeting requirements regarding Non-GMO Project Standard compliance, including traceability, segregation and GMO content.	and rationale for determining this. Success must be documented, with adjustments made and documented as necessary to meet this Standard. Methodology for determining this as described in sections 2.4., 2.5., and 2.6. of this Standard may be applied.
2.4. Input Categories	Appropriate preventive measures depend on the category of the input, and are elaborated below.
2.4.1. Non-Risk Inputs: Materials that are not derived from biological organisms and are not, therefore, susceptible to genetic modification.	Examples: lime, water and fossil-based products.
2.4.1.1. Preventive measures for Non-Risk Inputs consist of examining the specification sheet for compound ingredients to confirm the absence of components with GMO-risk.	Specification sheets must fully disclose all components of the input in question.
2.4.2. Low-Risk Inputs: Species for which genetically modified versions have not yet been commercialized.	Although biotechnologists are engaged in laboratory experimentation with most species, the crops, ingredients, and production inputs derived from such species (for example, cherries, wheat, and green peppers) have extremely low risk of being contaminated.
2.4.2.1. Preventive measures for Low-Risk Inputs consist of:	
2.4.2.1.1. Examining the specification sheet for compound ingredients to verify absence of high-risk ingredients.	Specification sheets must fully disclose all components of the input in question.
2.4.2.1.2. Verifying that the input was produced under conditions designed to avoid cross-contamination with GM materials.	<ol style="list-style-type: none"> a. If the facility does not use any High-Risk Inputs, then demonstration of this fact is sufficient to fulfill this requirement. b. If the facility does use High-Risk Inputs, fulfillment of this requirement will involve demonstrating that procedures and systems are in place that effectively segregate the Low-Risk Input under consideration from potential sources of high-risk contamination within the facility.
2.4.2.2. Monitoring of Low-Risk Inputs with suspected contamination. Monitored crops are listed in Appendix C.	Certain crops for which genetically modified versions have not yet been commercialized may be subject to higher contamination risk. Such crops are subject to monitor testing by the technical administrator, and will be reclassified as High-Risk Inputs by the

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	<p>Standard Committee and Board of Directors if results indicate persistent contamination in accordance to section 2.5.1. Crops may be added to Appendix C for either of the following reasons:</p> <ul style="list-style-type: none"> • Suspected or known incident of contamination at any point in the production chain. Examples include flax, for which known contamination by an unapproved variety has occurred. • Genetically modified relatives are in commercial production with which cross-pollination is possible. Examples include table beets, which have a risk of cross-pollination with genetically modified sugar beets.
<p>2.4.3. High-Risk Inputs: Crops and their derivatives that carry high risk of being genetically modified are listed in Appendix B.</p>	<p>Genetically modified varieties of the crops listed in Appendix B include genetically modified crops that are grown on a large scale in North America and certain other parts of the world.</p> <p>There is greater risk that any lot of these crops, whether conventional, natural or certified organic, could become contaminated, either via cross-pollination or admixture during storage, shipping, handling or processing.</p> <p>Animal products are included in the list of High-Risk Inputs because animal feed commonly contains High-Risk Inputs. In addition, injections of recombinant bovine growth hormone are sometimes used to increase milk production, and other High-Risk Inputs may be used to treat problems encountered in livestock production.</p> <p>There are other GM crops and biological materials, in addition to those in Appendix B, that have been commercialized (for example, tomatoes). However, because these are not in wide or common use in the food production system at this time, this Standard does not classify them as high-risk.</p>
<p>2.4.4. Participants shall undertake preventative</p>	

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measures to assure the Non-GMO Project Standard compliance of High-Risk Inputs, and shall consist of at least the following:	
2.4.4.1. Examining the specification sheet of the input to identify all high-risk ingredients.	A specification sheet or similar description must be on file with Participants for each unique input received from each supplier, which discloses all components contained in that input.
2.4.4.2. Verifying that the input was produced under conditions designed to avoid cross-contamination with GM materials (traceability and segregation).	Participants must be able to show their methodology and due diligence in this.
2.4.4.3. Monitoring for GMO contamination against an Action Threshold, which, if exceeded, triggers the Participant to investigate the cause of the contamination and to correct that cause when identified.	Monitoring and associated testing regimens may be conducted by the supplier and/or the user of any given input. The validity of the testing regimen shall be evaluated.
2.4.4.5. Compliance of animal products with the Standard is not necessarily verified by testing of the animal product, but by showing that inputs (feed, supplements, etc.) are compliant with the Standard, and that adequate traceability, cleanout, and segregation measures have been used in handling the inputs and the resulting animal products.	A similar approach is applicable to other inputs where GMO content or origin is not readily determined by analysis, e.g. refined vegetable oil derived from GM canola.
2.5. Reclassification of Specific High- and Low-Risk Materials Based on Experience in the Field	
2.5.1. A Low-Risk Input that is found through verified, random testing to contain GM material at levels above the Action Threshold (defined below) at a frequency of greater than 1 sample per 50 samples tested, or that is projected to contain such GM material at a frequency greater than 1 in 50 samples based on existing test results, shall be classified as a High-Risk Input, the verification of which shall be carried out according to the requirements for High-Risk Inputs.	Such risks will be evaluated on a Project-wide basis, i.e., from compiled experience with Product Verification Program Participants using any given Low-Risk Input. In addition to the examples given in the guidance to section 2.4.2.2., another example of a Low-Risk Input that might be classified as High-Risk according to this criterion would be wheat flour. GM wheat itself has not been commercialized. However, due to rotation with soy, cross-contamination frequently takes place in the fields, and, due to accidental admixture, cross-contamination of wheat flour with soy or corn often takes place in the flour mill or during other post-harvest activities. This also applies to most other flours, many of which

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<p>2.5.2. On a case-by-case basis, certain High-Risk inputs may be downgraded to Low-Risk status based on source, documentation, protocols for contamination prevention/avoidance, and <u>laboratory results (in accordance with this standard)</u> demonstrating consistently low risk of GMO contamination.</p>	<p>may be made in the same mill.</p> <p>An example would be cornstarch produced in a country where GMOs are prohibited, Non-GMO Project Standard compliant seed was verified as having been used, and documented IP procedures are in place for the manufacturing and transport of the product.</p> <p>Another example would be honey produced by bees whose forage area is free of commercial agriculture involving GM risk crops within a 4 mile radius of hives, <u>provided no other feed is used unless it is compliant with the Non-GMO Project Verified Standard.</u></p>
<p>2.6. Action Thresholds for High-Risk Inputs: The Non-GMO Project has established the following long-term Action Thresholds for High-Risk Inputs and Products based on input from a broad range of stakeholders:</p> <ul style="list-style-type: none"> • Seed and Other Propagation Materials (see sections 2.7 and Appendix B): 0.1%. • Human Food, Ingredients, Supplements, Personal Care Products, <u>and other products that are either ingested or used directly on skin</u>: 0.5% • Animal Feed and Supplements: 0.9% • <u>Packaging, Cleaning Products, Textiles and other products that are not ingested or used directly on skin</u>: 0.9% <p>For species not listed in Appendix B, there is no allowable presence.</p>	<p>Absence of all GMOs is the target for all Non-GMO Project Standard compliant products. Continuous improvement practices toward achieving this goal must be part of the Participant’s quality management systems.</p> <p>A key requirement of such quality management systems is to establish an Action Threshold, which, if exceeded, triggers the Participant to investigate the cause of the contamination, and to correct that cause when identified. Inputs contaminated above the action thresholds may not be intentionally used.</p> <p>When tested lots are <u>mixed</u> after testing has been conducted, the Participant must:</p> <ol style="list-style-type: none"> a. <u>Demonstrate reasonable efforts to achieve homogeny prior to testing.</u> b. Investigate and document the cause of any individual lot’s contamination over the relevant action threshold c. Implement and document practical continuous improvement practices to reduce, and ultimately eliminate, the need for any future blending of lots. An example of one such practice would be to help growers secure Non-GMO Project Standard compliant planting seed.

Sandy Kepler 7/17/11 5:32 PM
Comment [11]: Change to “produced from corn grown in”
 OKAY—Clarifying change

Megan Westgate 6/3/11 6:13 PM
 Deleted: empirical

Sandy Kepler 7/17/11 5:32 PM
Comment [10]: Please define this in objective terms
 DG: Better to say “laboratory results (in accordance with this Standard)”
 OKAY—Clarifying change

Sandy Kepler 7/17/11 5:32 PM
Comment [12]: Provided no other feed is used,
 DG: Suggest adding to the above “unless it is compliant with the Non-GMO Project Standard.”
 OKAY—Clarifying change

Sandy Kepler 10/1/11 2:36 PM
Comment [13]: Need an action threshold for packaging. Consider using the same as for animal feed.

Megan Westgate 6/3/11 6:31 PM
 Deleted: Products,

Megan Westgate 6/3/11 6:31 PM
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Sandy Kepler 7/17/11 5:32 PM
Comment [14]: Mixing needs some definitions like “in a way that produces in a completely homogenous lot.”
 OKAY—Clarifying change (see new wording under letter a)

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	d. In all cases, the finished lot must be below the relevant Action Threshold.
<p>2.6.1. Compliance with Action Thresholds shall be verified on the basis of test results or affidavits from suppliers, as is consistent with the technical requirements applicable at each point in the production/storage/handling chain. The following methods shall be used where appropriate:</p>	
<p>2.6.1.1. Genetics-based testing using the Real-Time PCR method.</p> <p>Where genetic testing is most appropriate, the following applies:</p>	<p>Genetics based testing is required before a finished product can be verified. The frequency and location of Real Time PCR testing can be tailored to accommodate an applicant’s supply chain.</p>
<p>2.6.1.1.1. A statistically valid sampling and testing plan shall be designed on the basis of risk assessment of the production/handling system, and shall reflect the level of monitoring appropriate for the risks inherent in the production/handling system, as well as industry standards.</p>	<p>Risk assessment and monitoring must be done by the Participant, and the sampling and testing plan shall be approved as part of the Product Verification Program.</p> <p><u>Compliant sampling and testing must occur at least once post harvest, depending on contamination risks.</u> Sampling plans must be designed to achieve 90% confidence in quantification of GMO at the action threshold set by this Standard. When achieving this level of confidence through crop sampling is impractical (e.g. for large crops such as zucchini and papaya), the testing program may be shifted to the seed level.</p>
<p>2.6.1.1.2. Statistical calculations can also be used to design compositing strategies through which portions of multiple samples can be combined and tested together for the purpose of reducing the number of tests required and therefore the costs for testing.</p>	<p>Compositing must be done in a manner that assures that any single sample in excess of the relevant action threshold produces a positive result for the composite sample as a whole. If a positive result is obtained for the composite, it will be necessary to retest all samples individually.</p>
<p>2.6.1.1.3. Testing shall be carried out by a laboratory that is accredited to ISO17025 and uses methods that are included within the scope of their ISO17025 accreditation, for the crops/inputs in question.</p>	<p>A list of approved labs that have provided this criteria, along with instructions to laboratories regarding being added to this list, is available on the Non-GMO Project website, www.nongmoproject.org.</p>
<p>2.6.1.1.4. Appropriate laboratory controls must indicate that the DNA of the input is sufficiently intact to allow valid quantitative</p>	<p><u>Inputs that do not meet this criterion and are therefore not “testable” in this manner, must be verified by lot-specific traceability</u></p>

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Sandy Kepler 7/17/11 5:32 PM

Comment [15]: add “harvest, depending on contamination risks.”

Propose moving this language and the suggested edit to 2.6.1.1.1.

Megan Westgate 6/2/11 9:31 AM

Deleted: Compliant sampling and testing must occur at least once, post harvest. Testing of planting seed can reduce the amount of post-harvest testing, depending on contamination risks.

Megan Westgate 7/17/11 5:32 PM

Comment [16]: Moved language from 2.6.1.1.1. and added “depending on contamination risks such as whether or not the planting seed has been tested.”

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Deleted: such as whether or not the planting seed has been tested

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Sandy Kepler 4/8/11 10:53 AM

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Non-GMO Project Working Standard

analysis by PCR. ▾	<u>back to precursors for the input that are testable.</u>
<p>2.6.1.1.5. Laboratory testing must target all commercialized GM events relevant to the product and the production system. Where Quantitative results are required, the Real-Time PCR test must employ primers sufficient to accurately quantify the % GMO for that event.</p> <p>Qualitative analysis using Real-Time PCR is sufficient if 1) the PCR limit of detection is 0.01%; and 2) GMOs are not detected; and 3) appropriate laboratory controls indicate that the DNA of the input is sufficiently intact to allow for valid quantitative analysis by PCR.</p>	<p>See guidelines for recommended primers for each crop (see Non-GMO Project Real Time PCR Primer Table for GMO Detection).</p> <p>Examples of sample types for which the DNA is sufficiently intact to allow for valid quantitative analysis by Real-Time PCR: raw agricultural products such as seed, grain, legumes; raw milled products; flour.</p>
<p>2.6.1.2. Immunologically-based testing using strip tests.</p> <p>In cases where lateral flow strip tests are suitable, <u>they must cover all commercialized GM events for the crop in question.</u></p>	<p>These methods shall be used when rapid, qualitative in-field testing is needed and when accuracy, sensitivity, and ramifications of false negative results are not large concerns. An example includes use of strip tests for the purpose of spot testing input samples.</p> <p>Compositing can be used for subsequent confirmatory Real-Time PCR testing. Frequency of Real-Time PCR testing and method of compositing to be determined such that there is 90% confidence in quantification of GMO at the action threshold set by the <u>Standard.</u></p>

Megan Westgate 6/2/11 9:52 AM

Deleted: (Inputs that do not meet this criterion and are, therefore not "testable" in this manner, must be verified by lot-specific traceability back to precursors for the input that are testable.)

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Comment [17]: Moved to guidance.

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Comment [18]:

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Comment [19]: Deleted extraneous guidance.

Megan Westgate 6/2/11 9:52 AM

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Sandy Kepler 4/8/11 11:04 AM

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Megan Westgate 6/2/11 9:55 AM

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Comment [20]: Add: Strip should cover all commercialized GM events. Strip testing does not replace the need for PCR testing (this should be made clear wherever in the Standard we talk about strip testing).

OKAY—Clarifying change.

Non-GMO Project Working Standard

<p>2.6.1.2.1. A statistically valid sampling and testing plan shall be designed on the basis of risk assessment of the production/handling system and shall reflect the level of monitoring appropriate for the risks inherent in the production/handling system, as well as industry standards.</p>	<p>See guidance to 2.6.1.1.1.</p>
<p>2.6.1.2.2. Analysts must be trained and their performance verified to assure they use the tests reliably.</p>	<p>Participants shall document the in-house evaluation of performance.</p>
<p>2.6.1.3. Supplier Affidavits. In cases where a non-GMO affidavit is appropriate, the following applies:</p>	<p>This option is available in cases where an input that is normally classified as High Risk is shown to be produced under conditions where the risk does not exist, for example, a crop <u>grown in</u> a country where no GMO production has been allowed, or a class of enzyme for which no GMO form has been developed.</p>
<p>2.6.1.3.1. The affidavit must attest that the origin of the input as well as its chain of custody merits the classification of the input as Low Risk as described in section 2.4.2 of this Standard.</p>	
<p>2.6.1.3.2. The affidavit must be signed by the manufacturer of the input.</p>	
<p>3. Quality Assurance and Quality Control</p>	
<p>3.1. The Participant’s quality assurance and quality control program shall be revised as needed to assure compliance with the Non-GMO Project Standard.</p>	<p>These modifications will, in most cases, involve additions or revisions to existing procedures, but where necessary, may include new procedures specific to processes, procedures, and record keeping critical to compliance with the Non-GMO Project Standard.</p>
<p>3.1.1. Compliance with applicable requirements of the Non-GMO Project Standard shall be identified as a key quality indicator of the Participant’s products, and standard operating procedures shall be revised, or added where necessary, to incorporate measures that assure such compliance of products with the Non-GMO Project Standard.</p>	
<p>3.1.1.1. Where needed, additional training shall be provided to staff to assure that they are</p>	

Sandy Kepler 7/17/11 5:32 PM
Comment [21]: Replace from with “grown in.”
 OKAY-Clarifying change.
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Non-GMO Project Working Standard

capable of fulfilling their duties in a manner that supports compliance of the operation, and the products produced, with the Non-GMO Project Standard.	
3.1.1.2. Documents and forms shall be revised, as necessary, to include compliance with the requirements of the Non-GMO Project Standard as a key quality indicator, and to assure that the Participant organization operates in a manner that fulfils the requirements of the Non-GMO Project Standard.	
3.1.1.3. All documents, forms, reference materials, and specifications needed by personnel to fulfill the requirements of the Non-GMO Project Standard shall be readily available to relevant personnel.	
3.1.1.4. Records shall be retained for 3 years.	
3.2. Monitoring and control of key parameters relevant to compliance with the Non-GMO Project Standard shall be incorporated into the quality assurance and quality control program of the Participant organization. Key parameters are:	The Participant shall create or revise documentation accordingly to show compliance with each aspect identified below.
3.2.1. Traceability	
3.2.2. Segregation	
3.2.3. Compliance with Action Thresholds	Periodic monitoring of compliance with Action Thresholds is typically done via additional analytical testing at strategic times and points in the system to corroborate and support the regular sampling and testing program that the operation has implemented.
3.2.4. Labeling	<p>Labeling claims must be accurate and truthful, and must not mislead the consumer about the GMO content of the product. Any reference to the Non-GMO Project or use of the seal must be approved by a written agreement with the Non-GMO Project.</p> <p>Examples of claims that are not acceptable are “contains zero GMOs,” “GMO-free” and GE-free.</p> <p>The Technical Administrator will review labels to assess compliance with these claim guidelines.</p>

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Comment [22]: Expand to include GE Free and GMO Free.
- OKAY—Clarifying change
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Non-GMO Project Working Standard

<p>3.3. The Participant organization shall monitor and verify the Non-GMO Project Standard compliance of inputs purchased, in line with section 2.3. of this Standard, and this shall be documented.</p>	<p>Record-keeping procedures shall be revised as necessary to assure that records include relevant information regarding the Non-GMO Project Standard compliance of each specific lot of input.</p>
<p>3.4. The Participant organization shall monitor and verify the Non-GMO Project Standard compliance of final products sold, in line with section 2.4. of this Standard, and this shall be documented.</p>	<p>Record-keeping procedures shall be revised as necessary to assure that records include relevant information regarding the Non-GMO Project Standard compliance of each specific lot of product.</p>
<p>3.5. Corrective actions. Non-conformities in processes, procedures, inputs, or products, which could impact compliance with the Non-GMO Project Standard, shall trigger corrective actions.</p>	<p>Nonconformities discovered during the program application or renewal process must be satisfied in order to achieve or maintain compliance with the Non-GMO Project Standard.</p> <p>Mid-term nonconformities discovered through internal quality-assurance processes, complaints from customers, or third party surveillance, require corrective action as described below.</p>
<p>3.5.1. Major nonconformities shall be reviewed at the time of occurrence, documented, and reported to the Product Verification Program's Technical Administrator.</p>	<p>A major nonconformity is a deviation that directly affects the compliance of the product with the Non-GMO Project Standard, such as accidental contamination of the product with GM material.</p> <p>Any major non-conformities that go unreported and/or uncorrected according to the requirements below may be cause for product or the company to be removed from the Non-GMO Project Product Verification Program. Prior to removing company or product from the program, the Technical Administrator will notify company via email of this intended action. Company will have 5 days from date of said notice to provide all required documentary evidence in order to avoid withdrawal from the program.</p> <p>The Technical Administrator will notify the Non-GMO Project of any withdrawal from the program. Additionally, if the company/products withdrawal impacts other Non-GMO Project Verified companies (such as the withdrawal of an ingredient supplier),</p>

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	<p>the Technical Administrator will notify the other companies and require that a substitute supplier be found. Please see guidance in 3.6 for requirements for bringing in new suppliers. Any notice of product/company withdrawal from the program issued by the Technical Administrator will be devoid of any company confidential information.</p>
<p>3.5.1.2. Timely root-cause analysis.</p>	<p>Discovery of any major nonconformity must be immediately reported in writing to the Technical Administrator. “Timely” is considered to be typically within 7 days, and rarely longer than 30 days. Longer delays must be justified in writing. Accompanying the notice must be an explanation of the action steps being taken, and the expected completion date of the root-cause analysis.</p> <p>Findings of the root-cause analysis must be reported in writing to the Technical Administrator, together with expected corrective actions to be undertaken.</p>
<p>3.5.1.3. Corrective actions designed to improve the system and products to achieve compliance with the Non-GMO Project Standard.</p>	<p>Corrective actions must be completed within 15 days of completing the root-cause analysis. The Technical Administrator will review and approve the planned corrective actions.</p> <p>Corrective action plans shall include identification of persons responsible for their execution, defined timelines for actions, and realization of the desired results of the corrective action plan. Documentary evidence must be submitted to the Technical Administrator within 5 days of completing corrective actions. Such evidence might include new/modified quality assurance SOPs such as updates to training and record keeping or changes to sampling and testing plans, and, where possible, evidence that these updated SOPs are achieving compliance with the Standard. The Technical Administrator will review and approve all corrective evidence. Repeated non-conformance with the action threshold may require company mid-term re-evaluation of the facility and possibly including an onsite inspection and/or input</p>

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	<p>supplier enrollment the Non-GMO Project's product verification program.</p> <p>Any delays in the timeline from reporting to completion of corrective actions must be justified in writing and approved by the Technical Administrator.</p>
<p>3.5.1.4. Identification of nonconformities, corrective actions, root-cause analysis, and successful remediation of the non-compliance shall all be documented.</p>	<p>This documentation shall be available to the Technical Administrator and its inspectors.</p>
<p>3.5.3.2. Minor non-conformities shall be reviewed at the time of the annual inspection.</p>	<p>A minor non-conformity is a deviation in procedures, recordkeeping, documentation, or other part of the program that does not cause any of the relevant ingredients used throughout the operation to exceed action thresholds.</p> <p>Renewal of verified status shall be contingent upon appropriate resolution of any such non-conformities.</p>
<p>3.6. In addition to Participants, suppliers and contractors shall also participate in the Non-GMO Project Product Verification Program to verify compliance with the Standard.</p>	<p>In some cases, inputs certified by other non-GMO certification programs may be approved as equivalent for use in Non-GMO Project compliant products. A program would be acceptable as long as that program is fully equivalent to or exceeds the requirements of the Non-GMO Project Product Verification Program. The decision on equivalency will be made by the Board of Directors based on evaluation of said program by the Technical Administrator via a procedure duly approved by the Board. In such cases, certificates of compliance from such a program may be accepted as equivalent to verification by the Non-GMO Project.</p> <p>Such suppliers and contractors must still, in all cases, input their product, ingredient and facilities data into the Non-GMO Project Product Verification Program database.</p>
<p>3.6.1. A Product Verification Program update shall be required at least annually.</p>	<p>The Technical Administrator may require a Participant to submit updates more frequently, if history shows cases of major non-conformities occurring as a result of unannounced changes to the operation.</p>

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	Such changes could include the following: changes in product composition that involve High-Risk Inputs, changes in suppliers of High-Risk Inputs, changes in processes or procedures that alter segregation or traceability of products, or changes in specifications of a high-risk ingredient or of a final product that contains High-Risk Inputs.
<p>4. Transition Period and Continuous Improvement</p> <p>It is expected that with systematic efforts within each sector of the industry, it should eventually be possible for the industry to be successfully operating uniformly and consistently with all aspects of this Standard. Until that time, compliance will be assessed according to program-wide variances set in Appendix A. All variances are meant to be temporary, and will be reviewed on at least an annual basis by the Standard Revision Committee. Each variance shall be removed from this Standard as quickly as is practically feasible on an industry-wide level.</p>	
<p>4.1. During this transition period Participants will develop systems, procedures, and source materials required to enable their companies and the industry to operate effectively and sustainably to the Action Thresholds.</p>	
<p>4.2. During this transition period, while the industry is working cooperatively and dynamically to achieve the ability to consistently operate to these target Action Thresholds, temporary variances will be set on a sector-by-sector basis. Participants are required to operate to the most stringent conditions practical at this time, while also working with others in their sector to develop sources that are progressively closer to the Action Thresholds described above.</p>	<p>A primary goal of the Project is that sufficient experience (systems) and data will be generated to downgrade some sources of high-risk materials to low-risk status.</p>
<p>4.3. Variances can, in principle, be applied to any aspect of the Standard or the verification process, including the Action Thresholds, the risk classification of a given crop or input, or the criteria required to verify compliance with other aspects of the Non-GMO Project Standard. Variances are applied on an industry-wide basis, and apply uniformly to all companies.</p>	<p>Recommended changes to variances will be made by the Standard Revision Committee (which includes members of the Technical Advisory Board), and will be based on input received from stakeholders. These recommendations will be approved and finalized by the Board of Directors.</p>
<p>4.4. Individual Participants may choose to either operate to long-term action thresholds or avail themselves of current variances. Use of a variance is contingent upon participation in industry-wide continuous improvement efforts</p>	<p>Variances have been set in acknowledgement of current industry-wide limitations, but the goal is to eventually overcome those limitations through collaborative efforts.</p>

Megan Westgate 7/17/11 5:32 PM

Comment [23]: Given the existence of 2.3.4 and 3.6.1, section 3.7 was deemed extraneous

Megan Westgate 6/2/11 10:04 AM

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Non-GMO Project Working Standard

aimed at eliminating the need for that variance.	
4.5. For manufactured food and feed products, distinct variances may be established for each of the following categories of High Risk Inputs (see Appendix A for currently applicable variances):	<p>All percentages noted below are weight percentages of the product, not counting the weight of salt or added water in the finished product.</p> <p>For livestock feed, the categories below are calculated based on the weight of the input as a percentage of the ration fed to the animal.</p>
4.5.1. Major Ingredients, each of which represents 5% or more of the product or is a defining ingredient.	A defining ingredient is one whose name appears in the name of the product.
4.5.2. Minor Ingredients, each of which represents at least 0.5% but less than 5% of the product, and is not a defining ingredient.	
4.5.3. Micro Ingredients, each of which represents less than 0.5% of the product and is not a defining ingredient.	
APPENDIX A: Current Variances to the Standard	
Variance #1—Elevated Action Thresholds	Current variances for the Action Threshold are as follows:
<i>Relates primarily to Section 2.6.</i>	<ul style="list-style-type: none"> • Planting Seed and Other Propagation Materials that are listed in Appendix B: 0.25%. For all other species, below the limit of detection. • Human Food, Products, Ingredients, Supplements, and Personal Care Products <u>and other products that are either ingested or used directly on skin</u>: 0.9% • Animal Feed and Supplements: 1.5% • <u>Packaging, Cleaning Products, Textiles and other products that are not ingested or used directly on skin</u>: 1.5% <p>Absence of all GMOs is the target for all Non-GMO Project Standard compliant products. However, current risk of contamination makes it necessary to establish quality management systems to assure that GMO contamination stays within the applicable Standard.</p> <p>A key requirement of such quality management</p>

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Comment [24]: I do not think exclusion of water and salt make sense for this standard, This was taken from NOP, but for organic products the exclusion of water and salt makes total sense. If water is considered organic then lots of products would qualify as certified organic. If it is not considered organic, then a lot of products would not qualify, hence it is excluded.

The current way the Standard is worded is because the burden of doing two sets of calculations by the entire organic industry looked like a deal-breaker. This was arrived at after discussion in previous comment rounds.

Sandy Kepler 7/17/11 5:32 PM

Comment [25]: Add packaging threshold? Perhaps equal to animal feed?

Proposed revisions correspond to those from 2.6

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	<p>systems is to establish an Action Threshold, which, if exceeded, triggers the Participant to investigate the cause of the contamination, and to correct that cause when identified. Participants must demonstrate compliance with the Action Threshold in one of two ways (please note that option 2 is NOT available for planting seed and other propagation material):</p> <ol style="list-style-type: none"> 1. By ensuring that each batch of high-risk input used has tested below 0.9% prior to its use in verified product. In this case, test results are submitted to the technical administrator for review at the time of annual renewal. <p style="text-align: center;">OR</p> <ol style="list-style-type: none"> 2. By ensuring that test results for all batches of high-risk input used during each 6 month period average at or below the relevant Action Threshold, with no single batch of input ever exceeding the relevant Action Threshold by more than a factor of 2. In this case, all test results are submitted to the technical administrator for review at least annually, and the Participant is responsible for ongoing monitoring of test results to ensure compliance for each period. A Participant may not use this option for a period in excess of three years from initial verification. <p>Allowed use of this variance is contingent upon the Participant demonstrating their role in sustained, active efforts to develop sources of the relevant input that are below the Action Thresholds specified in section 2.6. The focus of such efforts should be enrollment of the entire supply chain, with an ultimate goal of supporting farmers in planting seed that has tested below the relevant Action Threshold.</p>
<p>Variance #2—Including on the list of crops with high risk of GMO contamination</p>	<p>Appendix B is a list of the GMO crops and inputs considered “High-Risk” by the Non-</p>

Sandy Kepler 7/17/11 5:32 PM

Comment [26]: Twice yearly isn't relevant as these are not fixed 6 months terms. The 6 months is decided by the Participant, depending on when the first elevated GM result occurs. Suggest that Participant is responsible for recording the averaging, and that reporting to the Technical Administrator happens at renewal, along with a narrative of corrective actions taken by Participant to reduce future risk of occurrence.

OKAY—Change made for enforceability.

Megan Westgate 6/2/11 10:13 AM

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<p>only those crops species for which genetic modification is widely and commonly used.</p> <p><i>Relates primarily to Appendix B</i></p>	<p>GMO Project—this is the Project’s Operational list of High-Risk Inputs. It does not include all GMO crops that have been commercialized. Some of GMO crops that were commercialized at one time are not in commercial use today. For instance, potatoes and tomatoes were once produced commercially but today are not in North America. Another example is rice, where accidental contamination occurred in both in the US and China before any varieties being commercialized. In all of these cases, the GM crop is present today in only low, residual amounts in the food system.</p> <p>These and other low-incidence GMOs have been excluded from the Project’s operational list of High-Risk Inputs (see Appendix B for list). This substantially reduces the number of products and ingredients that are classified as High-Risk and thereby reduces the number of inputs that require in-depth review.</p> <p>Allowed use of this variance is contingent on the Participant demonstrating their role in sustained, active efforts to develop non-GMO sources of High-Risk Inputs.</p>
<p>Variance #3—Exemptions from production facility review</p> <p><i>Relates primarily to Section 2.4.2.1.2. and 2.5.</i></p>	<p>Production facility reviews are not required for:</p> <ul style="list-style-type: none"> a. <u>Low-Risk inputs</u> b. <u>Products in which the only Low-Risk and/or High-Risk Inputs are approved under variances 4 or 5</u> c. <u>Products produced in a facility where the only high-risk ingredients are already Non-GMO Project Verified prior to entering the facility parallel processing of same ingredients.</u> <p>Use of this variance is contingent on the Participant demonstrating sustained, active efforts to work with suppliers of the Low-Risk Input to enable them to comply with Section 2.4.2.1.2. of the Standard.</p>
<p>Variance #4—Temporary exclusion of all Micro Ingredients</p>	<p>All Micro Ingredients used in livestock feed formulations or products manufactured for</p>

Sandy Kepler 7/17/11 5:32 PM
Comment [27]: Clarify language used to: Manufacturing facility evaluation and onsite inspection are not required for enrolled products made with No-Risk, Low-Risk, High-Risk inputs approved using Variance 4 and 5 (and Non-GMO Project Verified Inputs?). Two questions, though: a) sunset period to be defined? B) HR/LR is relative to enrolled products. Shall we expand that to say risk is defined by what the facility processes, regardless of whether enrolled products contain that risk input in major quantities?

Megan Westgate 6/3/11 11:43 AM
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Non-GMO Project Working Standard

<p><i>Relates primarily to Section 4.5.3.</i></p>	<p>human consumption may be excluded from the Verification Process at this time, with the exception of:</p> <ol style="list-style-type: none"> a. Viable microbes and their functional components, which replicate their action. Examples include yeasts and dairy cultures. b. Microbial products that have no viable microbes, or functional enzymes, but which are not isolates. Examples include cheese, bread, wine, beer and fruit puree. c. Enzymes. Examples include Chymosin. d. Recombinant bovine growth hormone (rBGH, rBST). <p>Any given product formulation included in the Program must not contain more than 10 unique non-verified High-Risk Micro Ingredients. Formulations exceeding 10 unique High-Risk Micro Ingredients must either be reformulated or enough of the micro inputs verified as Non-GMO Project Standard compliant in line with section 2.6. of this Standard, to reduce the amount of non-verified inputs to 10 or less.</p> <p>Allowed use of this variance is contingent on the Participant demonstrating their role in sustained, active efforts to develop Non-GMO Project compliant sources of the exempted Micro Ingredients.</p>
<p>Variance #5—Verification of Non-GMO Project compliance of Minor and Micro Ingredients using supplier affidavits</p> <p><i>Relates primarily to Section 2.6.</i></p>	<p>In cases where GMO analytical certificates or traceability linked to analytical certificates of precursors is not available, Non-GMO Project compliant status of Minor and Micro Ingredients may be verified based on affidavits from suppliers, as long as these ingredients are the product of a system that has been designed to avoid GMOs. Examples of such systems are organic certification and other identity preservation systems. Suitability of these other identity preservation systems are subject to review by the Technical Administrator. Suppliers shall agree to provide further information or demonstration in support of affidavit when requested by the Technical Administrator.</p>

Non-GMO Project Working Standard

	<p>Allowed use of this variance is contingent on the Participant demonstrating their role in sustained, active efforts to develop Non-GMO Project compliant sources of that Ingredient.</p>
<p>Variance #6—Eliminated Spring 2010</p>	<p>This variance has been combined with Variance #5</p>
<p>Variance #7—Verification of inputs based on testing alone at any stage of the production chain.</p> <p><i>Relates primarily to Section 1.2., 2.6.1.1.1. and 2.6.1.1.3.</i></p>	<p>The intention of the Standard is that compliance be verified at all levels of the production chain regarding the use (intentional or accidental) of all production inputs.</p> <p>A. This variance allows for high-risk inputs to be verified as compliant with the Non-GMO Project Standard if:</p> <ul style="list-style-type: none"> (i) A copy of the original result for the PCR test shows that the GMO content of the input in question is below the relevant action threshold; and (ii) The testing must have been conducted by a laboratory in compliance with sections 2.6.1.1.1 and 2.6.1.1.3 of this Standard and must reference by lot number the specific lot of product used by the Participant; and (iii) Appropriate laboratory controls indicate that the DNA of the input is sufficiently intact to allow valid quantitative analysis by PCR. (Inputs that do not meet this criterion and are, therefore not “testable” in this manner, must be verified by lot-specific traceability back to precursors for the input that are testable.) <p>B. This variance also allows for high-risk inputs to be verified as compliant with the Non-GMO Project Standard if:</p> <ul style="list-style-type: none"> (i) The precursor(s) to the input used by the Participant are tested by PCR; and (ii) For each precursor to an input used

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	<p>by the Participant, a copy of the original result for the PCR test of the specific lot of the precursor in question must show that the GMO content is below the relevant action threshold: and</p> <ul style="list-style-type: none"> (iii) The testing must have been conducted by a laboratory in compliance with sections 2.6.1.1.1 and 2.6.1.1.3 of this Standard and must reference by lot number the specific lot(s) of the precursor used for lot of product used by the Participant; and (iv) Appropriate laboratory controls indicate that the DNA of the tested precursor is sufficiently intact to allow valid quantitative analysis by PCR; and (v) From the point of the PCR testing forward, an identity preservation system is in place to ensure the given lot of the input in question has not been exposed to any other high-risk GMO material. All such systems are subject to review and must be approved by the Technical Administrator. <p>Allowed use of this variance is contingent on the Participant demonstrating sustained, active efforts to obtain Non-GMO Project compliant sources of the ingredient in compliance with the fully applicable scope of this Standard as described in section 1.2.</p>
<p>Variance #8 – Temporary Exclusion of vaccines and medicines used in livestock production as well as all fertilizers, pesticides, and herbicides.</p>	<p>All vaccines and medicines used in livestock production, except for rBGH, as well as all fertilizers, pesticides, and herbicides may be excluded from the Verification Process at this time.</p> <p>Allowed use of this variance is contingent on the Participant demonstrating their role in sustained, active efforts to develop Non-GMO Project compliant sources of these inputs.</p>
<p>Variance #9 – Approval of a Participant’s</p>	<p>The Non-GMO Project Standard’s Product</p>

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Comment [28]: Change to "test result"
 OKAY—clarifying change
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Comment [29]: The definition of medicines needs to be clarified. In organic, it is something that is used in "times of stress." Considerations are supplements added for different phases of life, nutrients and external applications. The question is, do we align with organic, or do we set up our own definitions?
INSERTED IN DEFINITIONS SECTION

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<p>Co-Processed Products Based on a Process Certification Combined with Analytical Testing.</p>	<p>Verification Program follows a process-based approach that is supported by testing at strategic points in the supply chain, as applicable and taking into consideration the other variances of this Standard. The Non-GMO Project acknowledges that pre-existing contractual agreements between certain Participants (e.g., brand owners) and their contracted processors, may pose barriers to enrollment in the early stages of the Program. This variance enables Participants who manufacture their products in contracted facilities (also known as co-packers or co-processors) to more quickly enter the Program while still adhering to the Program's process-based approach.</p> <p>Under this variance, any manufactured product that is made by an operation contracted by the Participant may be evaluated and approved under the PVP as long as it is a product of a system that has been designed to avoid GMOs. Examples of such systems are organic certification and other identity preservation systems. All such systems are subject to review by the Technical Administrator, especially in cases where parallel processing occurs within the certified system. For example, processing certified organic soybeans in both Non-GMO Project verified and non-verified forms. In such cases lot by lot identity preservation will likely be necessary.</p> <p>The Participant and/or the contracted operation provides evidence of testing as described in Variance #7 of the Non-GMO Project Standard.</p> <p>Allowed use of this variance is contingent on the Participant having a defined plan for bringing contracted operations into full enrollment in the PVP within a defined time frame, not to exceed three years, to be reviewed and approved by the Technical Administrator with oversight by the Standards Committee.</p>
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<p><u>Variance #10—“Made with” claims for certain products containing livestock and bee product inputs</u></p> <p><i>Relates primarily to Section 2.6. and section 4.5.1</i></p>	<p>Under this variance, certain products made with livestock and bee product inputs may use a “Made with” claim in accordance with the following guidelines:</p> <ul style="list-style-type: none"> (i) <u>Livestock/bee product inputs may not collectively constitute more than 25% of the product, and may not be a defining ingredient (appearing in the product name).</u> (ii) <u>The product must contain approved major, high-risk inputs other than those from the livestock/bee products (e.g. corn meal, soy flour, etc. constituting more than 5% of the product).</u> (iii) <u>The “made with” claim may only be made in relation to approved major, high-risk inputs. For example, a corn chip with a seasoning blend containing more than 5% of an unverified dairy ingredient could claim “Made with Non-GMO Project Verified Corn.”</u> (iv) <u>The “made with” claim is a text only claim. The Non-GMO Project Verification Mark may not be used on products approved under this variance. For more details, see the Non-GMO Project Licensing Agreement.</u> (v) <u>If the product contains dairy inputs, supplier affidavits must show that no recombinant bovine growth hormone (rBGH, rBST) was used.</u> <p><u>Allowed use of this variance is contingent on the Participant demonstrating their role in sustained, active efforts to develop Non-GMO Project compliant sources of livestock and bee products.</u></p>
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Megan Westgate 10/1/11 2:35 PM

Comment [30]: Previous Variance #10 was deleted, and replaced with this much more specific variance regarding livestock. Additional work will be done on Livestock verification in the Fall 2011 public comment period.

APPENDIX B: List of Crops, Processed/Processing Inputs, Production Inputs, and other Organisms with GMO Risk	
Crops - The following crops carry risk of being genetically engineered, because	These crops may not be used in Non-GMO Project approved products unless verified as

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engineered varieties of these crops are grown large scale in North America and certain other parts of the world:	compliant with the Non-GMO Project Standard.
Alfalfa	
Canola	
Corn	Except popcorn
Cotton	
Papaya	
Soy	
Sugar beets	
Zucchini and yellow summer squash	
Animal Derivatives - These include products derived from cattle, sheep, pigs, chickens, and other common livestock, fowl, and fish, and include the following:	<p>Most animal-derived products have GMO risk because soy, corn, cottonseed, and canola are commonly used in feed. Micro Inputs for feed such as vitamins may also carry risk of not being compliant with the Non-GMO Project Standard (see below).</p> <p>These animal derivatives may not be used in Non-GMO Project approved products unless verified as compliant with the Non-GMO Project Standard.</p>
Milk	
Meat	Hides and skins are also included in this category.
Eggs	
Honey and other bee products	Due to potential for contamination with GMO crop pollen.
Livestock Production Inputs	The following inputs may not be used unless verified as compliant with the Non-GMO Project Standard.
rBGH, rBST (recombinant Bovine Growth Hormone or recombinant Bovine Somatotropin)	
Semen	See Guidance at 1.2.1.6.
Vaccines	
Veterinary Medicines	
Microbes and microbial products	
Enzymes, including chymosin	
Microbial cultures and starters	Including yeast.
Processed/processing inputs and	The following is a non-exhaustive list of

Sandy Kepler 7/17/11 5:32 PM
Comment [31]: Define medicines per Variance 8 comments.
Added to definitions

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ingredients, and related derivatives, derived from crops, livestock, or microorganisms:	derivatives with high GMO risk that are commonly used in food production. It is meant to provide examples of materials that will be considered high-risk in the Non-GMO Project Product Verification Program. The following inputs may not be used unless verified as compliant with the Non-GMO Project Standard.
Amino Acids	
Aspartame	
Ascorbic Acid, Sodium Ascorbate, Vitamin C	
Citric Acid, Sodium Citrate	Derived from glucose syrup.
Ethanol	Derived from corn or GMO sugar beets.
Flavorings, “natural” and “artificial”	Also the carrier may have GMO risk.
High-Fructose Corn Syrup	
Hydrolyzed Vegetable Protein	
Lactic acid	
Maltodextrins	
Microbial growth media	
Molasses	Derived from sugar beets, beginning 2008 crop.
Monosodium Glutamate	
Sucrose	Derived from sugar beets, beginning 2008 crop.
Textured vegetable protein	Including soy protein,
Xanthan Gum	
Vitamins	Vitamin A (various forms), Vitamin B6 (pyridoxine hydrochloride), Vitamin B12 (cyanocobalamin), Vitamin C (ascorbic acid), and Vitamin E (various forms) are known to have GMO risk. Vitamins in general are often formulated with dispersants and related ingredients that also have GMO risk (e.g., corn oil).
Yeast products	

APPENDIX C: List of Monitored Crops

Crops - The following crops carry potential risk of being contaminated with GMOs:	Monitored crops include those for which suspected or known incidents of contamination have occurred, and those crops which have genetically modified relatives in commercial production with which cross-pollination is possible.
<i>Beta vulgaris</i> , (e.g., chard, table beets)	Cross pollination risk from GM sugar beets
<i>Brassica napa</i> (e.g., rutabaga, Siberian kale)	Cross pollination risk from GM canola

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<i>Brassica rapa</i> (e.g., bok choy, mizuna, Chinese cabbage, turnip, rapini, tatsoi)	Cross pollination risk from GM canola
<i>Curcubita</i> (acorn squash, delicata squash, patty pan squash, pumpkin, and spaghetti squash)	Cross-pollination risk from GM squash
Flax	
Rice	

Sandy Kepler 7/17/11 5:32 PM

Comment [32]: Since we took out the seed section of the Standard, can Appendix D also be deleted? I don't think we have sufficient data to demonstrate these recommendations are correct.

Could and probably should be saved for future Guidance.

6/8/11 2:17 PM

Deleted: Appendix D – Recommended Minimum Isolation Distances For Production Of *SEED* ... [Z]