

Non-GMO Project Working Standard



February 2008

This Working Standard is a “living document.” It is the culmination of over a year of input and refinement from many stakeholders, and includes adjustments made in response to feedback received during a 60-day public comment period in the fall of 2007.

Ongoing semi-annual reviews, scheduled for each fall and spring, will include 30-day public comment periods. Feedback can be submitted to standard@nongmoproject.org, and is reviewed by a Standard Revision Committee comprised of representatives from the Non-GMO Project’s Technical Advisory Board, Outreach Policy Board, and Technical Administrator.

To learn more about the Non-GMO Project and the Product Verification Program, please visit www.nongmoproject.org.

Non-GMO Project Working Standard

| 1. INTRODUCTION | |
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| Explanation of layout of this Standard: | |
| <p><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 |
| 1.1. Purpose: The Non-GMO Project's Product Verification Program (the "Program") aims to verify: | See Section 1.4, "Additional Terms and Definitions", for meaning of "product" and definitions of other terms. |
| 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"). | 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. |
| 1.1.2. That the Participant consistently operates their systems according to those procedures. | Annual third-party verification of conformity to this Standard, via review of Participant documentation and on-site visits, is part of the Program. |
| 1.1.3. That the resultant products are compliant with the Standard. | The Non-GMO Project's Product Verification Program is a practice/process-oriented standard that uses testing as a key strategic tool to confirm that practices/processes are meeting expectations. |
| 1.2. Scope: The scope of the Program encompasses the following products, activities, and aspects: | |
| 1.2.1. Products | |
| 1.2.1.1. Agricultural inputs, such as seeds, fertilizers, pesticides, and herbicides. | <p>Examples of non-compliant fertilizers are oilcake/oilseed meal from genetically engineered soybeans, canola, or cotton, un-composted GMO cornstalks, etc.</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> |
| 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 | |

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| grains, vitamins, enzymes, minerals. | |
| 1.2.1.4. Manufacturing and processing inputs (“inputs”), including ingredients, flavorings, seasonings, colorings, additives, and all other substances present in final, manufactured products. | |
| 1.2.1.5. Animal products, including dairy, meat, eggs, honey, wool and hides. | |
| 1.2.1.6. Veterinary inputs such as vaccines, semen, and medicines, including rBGH/rBST (recombinant bovine growth hormone). | For the purposes of the Standard, cloned animals and their progeny are not allowed. |
| 1.2.1.7. Processed agricultural products or ingredients, manufactured food products and textiles. | |
| 1.2.1.8. Dietary supplements, vitamins, and herbal preparations. | |
| 1.2.1.9. Health-care products. | |
| 1.2.1.10. Personal care products and cosmetics. | Includes lotions, soaps, balms, makeup, etc. |
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| 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. 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. The Product Verification Program aims to verify non-GMO content of inputs used in product sales and manufacturing, and to provide the manufacturer with information about their production system that will assist them in redesigning aspects of their system to more effectively avoid GMO contamination |

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| | resulting from handling activities. |
| 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 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, 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-GM materials may be necessary, especially when any inputs of high GMO risk 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 verified as non-GMO, versus like 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 | |
| 1.2.3.6. Quality Assurance and Quality Control | Specific procedures and practices relevant to traceability, segregation, and sampling and testing of lots for GMO content—with associated documentation 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 | |

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| 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. Farming operation | Any operation involved with production, handling, storage, or management of crops until legal ownership or physical transformation of crops occurs. |
| 1.3.2. 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. |
| 1.3.3. 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. |
| 1.3.4. Input | <p>The term “input” includes any material or substance that becomes a part of the final product, or a component of which becomes a part of the 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, minerals. • Manufacturing and processing inputs, including ingredients, flavorings, seasonings, colorings, additives, and all other substances present in final manufactured products. |
| 1.3.5. Non-GMO or Non-GM | A plant, animal, or other organism or derivative of such an organism whose genetic structure has not been altered by gene splicing, or a process or product that does not employ GM processes or inputs. |
| 1.3.6. The Non-GMO Project | The Non-GMO Project is a non-profit organization, created by leaders representing all sectors of the organic and natural products |

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| | industry in the U.S. and Canada, to offer consumers a consistent “non-GMO” choice of products that are produced without genetically modified ingredients. |
| 1.3.7. Participant | A company or other entity independent of the Non-GMO Project that undertakes the Program. |
| 1.3.8. Product | The term “product” refers to that which 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. |
| 1.3.9. Shall or Must | A mandatory requirement under the Standard. |
| 1.3.10. Should or May | A non-mandatory recommendation or recommended practice. |
| 1.3.11. Standard | The “Standard” herein refers to the Standard for The Non-GMO Project Product Verification Program, which is this document. |
| 1.3.12. Supplier | Any party from whom an input is obtained. |
| 1.3.13. Technical Administrator | The organization responsible for conducting the Program on behalf of the Non-GMO Project. |
| 1.3.14. 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. iii. Any contamination present was at levels below the relevant Action Threshold set by this Standard. |
| 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. | <p>If the operation is dedicated strictly to non-GM 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.</p> <p>If the operation is not dedicated to non-GMO production, systematic procedures shall be in</p> |

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| | 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 status of both inputs and the final product. | If lots of a given input are comingled in storage before use in production of a certain lot of product, the lot numbers related to all lots comingled 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, 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. | |
| 2.2.1.2. Procedures shall be appropriate to the operation and may likely differ significantly between agricultural producer, manufacturer, etc. | |
| 2.2.2. Segregation | If the operation is dedicated strictly to non-GM production, then segregation measures within the production operation are unnecessary, since only non-GMO inputs will enter the operation. |
| 2.2.2.1. If the operation is not dedicated to non-GMO 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 may contain GM material. | |
| 2.2.2.2. Tracking of lot numbers and labeling/marking on packaging and containers shall be used as necessary to identify and segregate non-GMO from GMO-risk materials. | |
| 2.3. Specifications for Inputs and Products | The intent of the program is to design production processes and input specifications that exclude GMOs from the Participant's |

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| | products. This not only requires that one not use genetically modified inputs, but also that one employ practices that control unintentional contamination with GM material. |
| 2.3.1. Participants shall not knowingly plant, purchase, or use genetically modified organisms or inputs derived from genetically modified organisms. | |
| 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 necessary because risk of unintentional contamination of inputs and products with GMOs is increasing due to the growing use of GMOs in conventional agriculture. |
| 2.3.3. The written specifications for all inputs and products shall include requirements regarding non-GMO status, 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 regarding non-GMO status, including traceability, segregation and GMO content. | Methodology for determining this is given in sections 2.4, 2.5, and 2.6 of this Standard. |
| 2.3.5. Release of products to the marketplace shall be contingent on products meeting requirements regarding non-GMO status, including traceability, segregation and GMO content. | Participants shall have a written methodology 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: salt, lime, and water. |
| 2.4.1.1. Preventive measures for Non-Risk Inputs consist of examining the specification sheet for the input 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: Genetically modified versions of the many species that have not been commercialized (biotechnologists are engaged in laboratory experimentation with | Crops, ingredients, and production inputs derived from such species (for example, cherries, wheat, and green peppers) have extremely low risk of being contaminated. |

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| <p>most species).</p> | |
| <p>2.4.2.1. Preventive measures for Low-Risk Inputs consist of:</p> | |
| <p>2.4.2.1.1. Examining the specification sheet for the input to verify absence of high-risk ingredients.</p> | <p>Specification sheets must fully disclose all components of the input in question.</p> |
| <p>2.4.2.1.2. Verifying that the input was produced under conditions designed to avoid cross-contamination with GM materials.</p> | <p>a. If the facility does not use any High-Risk Inputs, then demonstration of this fact is sufficient to fulfill this requirement.</p> <p>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.</p> |
| <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:</p> <ul style="list-style-type: none"> ▪ genetically modified crops that are grown on a large scale in North America and certain other parts of the world; and ▪ close relatives of these crops that are subject to cross-pollination. <p>There is greater risk that any lot of these crops, whether natural or 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 may be 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. However, because these are not in wide or common use in the food production system at this time, this</p> |

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| | Standard does not classify them as high-risk. |
| 2.4.4. Participants shall undertake preventative measures to assure the non-GMO status 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 (defined below), 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. |
| 2.4.4.4. 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. ethanol derived from GMO corn. |
| 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. | One 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 flourmill or during other post-harvest activities. This also applies to most other flours, many of which may be made in the same mill. |
| 2.5.2. On a case-by-case basis, certain High-Risk Inputs may be downgraded to Low-Risk status based on source, documented, protocols | An example would be cornstarch produced in a country where GMOs are prohibited, clean seed was verified as having been used, and |

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| <p>for contamination prevention/avoidance, and empirical results demonstrating consistently low risk of GMO contamination.</p> | <p>documented IP procedures are in place for the manufacturing and transport of the product.</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"> • Planting Seed and Other Propagation Materials: 0.1% • Human Food, Products, Ingredients, Supplements, and Body Care Products: 0.5% • Animal Feed and Supplements: 0.9% | <p>Absence of all GMOs is the target for the Participant’s products. However, current risk of contamination makes it necessary to establish quality management systems to assure that GMO contamination stays within acceptable bounds.</p> <p>A key requirement of such quality management systems is to establish Action Thresholds, 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>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 PCR method.</p> <p>Where genetic testing is most appropriate, the following applies:</p> | <p>Genetics-based testing shall be used when sensitive and/or quantitative analytical results are required.</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>Sampling plans must be designed to achieve 95% confidence in quantification of GMO at the Action Threshold set by this Standard.</p> <p>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, provided that there are identity preservation and contamination avoidance practices in place.</p> |

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| | <p>Technical guidance on sampling plans can be obtained from the GIPSA, ISO, GAFTA, and other international sources.</p> <p>The Non-GMO Project shall stay informed of industry standards and trends and provide a framework in which stakeholders may periodically review relevant issues and make corresponding changes to this Standard.</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>Blending lots in order to achieve an overall lot that is below the Action Threshold not allowed.</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>This can be documented by the ISO17025 accreditation certificate and statement of scope of accreditation.</p> |
| <p>2.6.1.2. Immunologically-based testing using strip tests.</p> <p>In cases where lateral flow strip tests are suitable, the following applies:</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.</p> |
| <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 training and 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>2.6.1.3.1. The affidavit must reference testing done on the particular lot of input/product in question or on lots of precursors traceable to</p> | |

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| the specific input/product lot in question, and confirm that the testing was done using methods and by a laboratory that meets the Non-GMO Project proficiency standards. | |
| 2.6.1.3.2. The affidavit must be signed by the manufacturer. | |
| 3. Quality Assurance and Quality Control | |
| 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. | 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. |
| 3.1.1. Non-GMO status 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 necessary to assure compliance of products with the Non-GMO Project Standard. | |
| 3.1.1.1. Where needed, additional training shall be provided to staff to assure that they are 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 non-GMO status 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. | |

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| <p>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:</p> | <p>The Participant shall create or revise documentation accordingly to show compliance with each aspect identified below.</p> |
| <p>3.2.1. Traceability</p> | |
| <p>3.2.2. Segregation</p> | |
| <p>3.2.3. Compliance with Action Thresholds</p> | |
| <p>3.2.4. Labeling</p> | <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>An example of a claim that would not be acceptable is “contains zero GMOs.”</p> <p>The Technical Administrator will review labels to assess compliance with these claim guidelines.</p> |
| <p>3.3. The Participant organization shall monitor and verify the Non-GMO status 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 status of each specific lot of input.</p> |
| <p>3.4. The Participant organization shall monitor and verify the Non-GMO status 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 status of each specific lot of product.</p> |
| <p>3.5. Corrective actions. Nonconformities in processes, procedures, inputs, or products, which could impact compliance with the Non-GMO Project standard, shall trigger:</p> | <p>Nonconformities can be discovered through internal quality-assurance processes, complaints from customers, or third party surveillance.</p> |
| <p>3.5.1. Timely root-cause analysis.</p> | <p>“Timely” is considered to be typically within 7 days, and rarely longer than 30 days. Longer delays must be justified in writing.</p> |
| <p>3.5.2. Corrective actions designed to improve the system and products to achieve compliance with the Non-GMO Project Standard.</p> | <p>Corrective action plans shall include identification of persons responsible for their execution and defined timelines for actions and realization of the desired results of the corrective action plan.</p> |
| <p>3.5.3 Identification of non-conformities, 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> |

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| <p>3.5.3.1. Major non-conformities shall be reported and reviewed at the time of occurrence.</p> | <p>A major non-conformance is a deviation that directly affects the non-GMO integrity of the product, such as accidental contamination of the product with GM material.</p> <p>Appropriate next steps shall be proposed by the operator and then reviewed and mutually agreed upon with the Technical Administrator.</p> <p>Major non-conformities that go uncorrected may be cause for a product or company to be removed from the Product Verification Program.</p> |
| <p>3.5.3.2. Minor non-conformities shall be reviewed at the time of the annual inspection.</p> | <p>A minor non-conformance is a deviation in procedures, recordkeeping, documentation, or other part of the program that does not directly affect the GMO status of the product.</p> |
| <p>3.6. Suppliers and contractors shall participate in the Non-GMO Project Product Verification Program to verify compliance with the Standard.</p> | <p>In some cases, certification by other non-GMO certification programs may be used as the basis for qualifying suppliers and contractors. A program would be acceptable as long as it is fully equivalent to or exceeds the requirements of the Non-GMO Project Product Verification Program. 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>3.7. A Product Verification Program update shall be required in any case where changes are implemented that potentially influence the compliance of a product, ingredient, production operation, or manufacturing facility with the Standard.</p> | <p>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> |
| <p>4. Transition Period and Continuous Improvement</p> <p>It is expected that with systematic efforts within each sector of the industry, it should be possible within 5 years (March 2013) for the industry to be successfully operating uniformly and consistently to the Action Thresholds stated in Section 2 of this Standard. During this transition period, compliance will be assessed according to program-wide variances set in Appendix A.</p> | |

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| <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 that require Participants to operate to the most stringent conditions practical at that time, while also requiring Participants to work 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, the criteria required to verify the absence of GMO contamination, or other aspects of the verification process. 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 Outreach Policy Board), and will be based on input received from stakeholders during semi-annual public comment periods. 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 aimed at eliminating the need for that variance.</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> |
| <p>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> | <p>All percentages noted below are weight percentages of the product, not counting the weight of added water in the finished product.</p> |
| <p>4.5.1. Major Inputs, each of which represents 3% or more of the product.</p> | |
| <p>4.5.2. Minor Inputs, each of which represents 0.3% to 3% of the product.</p> | |
| <p>4.5.3. Micro Inputs, each of which represents less than 0.3% of the product</p> | |
| <p>4.5.4. Any given product formulation included in the Program must not contain more than 12 unique non-verified High-Risk Micro Inputs.</p> | <p>Formulations exceeding 12 unique High-Risk Micro Inputs must either be reformulated or enough of the micro inputs verified as Non-GMO in line with section 2.6 of this Standard,</p> |

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| | to reduce the amount of non-verified inputs to 12 or less. |
| APPENDIX A: Current Variances to the Standard | |
| Variance #1—Elevated Action Thresholds | <p>Current variances for the Action Threshold are as follows:</p> <ul style="list-style-type: none"> • Planting Seed and Other Propagation Materials: 0.25% • Human Food, Products, Ingredients, Supplements, and Body Care Products: 0.9% • Animal Feed and Supplements: 1.5% <p>Allowed use of this variance is contingent on the participant demonstrating sustained, active efforts to develop non-GMO sources of that input.</p> |
| Variance #2—Including on the list of crops with high risk of GMO contamination only those crops species for which genetic modification is widely and commonly used. | <p>Appendix B is a list of the GMO crops and inputs considered “High-Risk” by the Non-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 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 GMO varieties have never been commercialized, but where accidental contamination has taken place both in the US and China. 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 sustained, active efforts to develop non-GMO sources of High-</p> |

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| | Risk Inputs. |
| <p>Variance #3—No production facility review for Low-Risk Inputs</p> | <p>a. The stringent approach to evaluating Low-Risk Inputs involves two steps. First, the specification sheet for the input is reviewed to verify that it contains no high-risk GM materials. Second, the plant or production facility where the input is produced is evaluated to assure that manufacturing is carried out in a way that avoids contamination with GM risk materials (for instance, if the ingredient is buckwheat flour, this step requires inspection of the flour mill to verify that the buckwheat flour is not contaminated with soy flour during milling).</p> <p>For Low-Risk Inputs, the Non-GMO Project will not, at this time, review the production facility, but will only review the specification sheet for that input. However, such a review can be required for inputs that are formally classified as low-risk, but that have high risk due to cross-contamination during production. Under these conditions, evaluation of the production facility is reserved only for situations where risk of contamination is known to be very high, such as implied in section 2.5. of this Standard.</p> <p>Eliminating the facility assessments for Low-Risk and Non-Risk Inputs greatly reduces the time, cost, and effort required for verifying Low-Risk and Non-Risk Inputs, because it reduces the number of inputs that require in-depth review. In some cases this variance will make the difference between the Program being feasible or not for certain sectors of the industry.</p> <p>b. 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>The following are steps that could be taken along these lines:</p> |

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| | <ol style="list-style-type: none"> 1. Identify which suppliers of the input of interest also make or handle high-risk materials. 2. Work with such suppliers to make sure procedures are in place to minimize the risk that the Low-Risk Input used by the Participant might be contaminated by the high-risk materials produced or handled by the supplier. 3. Use surveillance testing to assess the degree to which cross-contamination is actually occurring. 4. Work with the producer to improve segregation and cleanout procedures as necessary to more effectively segregate the Low-Risk Input of interest from potential sources of cross-contamination with high-risk materials. 5. Work with suppliers to control GMO risk in high-risk materials that they produce or handle, thereby reducing the risk of GMO contamination of the Low-Risk Input that is used by the Participant. If this is achieved, the supplier will have, in effect, converted the high-risk material into a low-risk material, and segregation within the facility will no longer be required. <p>c. The participant must document continuous improvement efforts in order to maintain compliance with Variance #3.</p> |
| <p>Variance #4—Temporary exclusion of all Micro Inputs and of Micro/Minor Inputs that are demonstrated to be unavailable in non-GMO form</p> | <p>a. All micro-ingredients shall be excluded from the Verification Process at this time.</p> <p>b. Where there is agreement by the Standard Revision Committee that a particular minor input is not available in non-GMO form, then the conventional form of that input may be used, unless information emerges indicating potentially high risk of high-level GMO contamination of a specific Micro Ingredient. Micro Minor Inputs admitted under this variance shall be listed on the Product Verification Program website.</p> |

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| | Allowed use of this variance is contingent on the participant demonstrating sustained, active efforts to develop non-GMO sources of the exempted Micro/Minor Input. |
| Variance #5—Verification of Non-GMO status of Minor Inputs using Supplier Affidavits | <p>In cases where GMO analytical certificates or traceability linked to analytical certificates of precursors is not available, GMO status of Minor Inputs may be verified based on affidavits from suppliers. Suppliers shall agree to provide further information or demonstration in support of affidavit when requested by the Project.</p> <p>Allowed use of this variance is contingent on the participant demonstrating sustained, active efforts to develop non-GMO sources of that input that are verified by test and traceability documentation.</p> |
| APPENDIX B: List of Crops and Derivatives with GMO Risk | |
| Crops - The following crops carry risk of being genetically engineered, because engineered varieties of these crops are grown large-scale in the North America and certain other parts of the world: | Listed here roughly in order of decreasing prevalence in the North American marketplace. |
| Soy | |
| Corn | |
| Cotton | The seed is also used to make vegetable oil and animal feed. |
| Canola and other <i>Brassica napa</i> (e.g. rutabaga, Siberian kale), and <i>Brassica rapa</i> (e.g., bok choy, mizuna, Chinese cabbage, turnip, rapini, tatsoi) | There is a risk of contamination of these other <i>Brassica</i> crops by cross-pollination from GM canola. |
| Papaya | |
| Alfalfa | |
| Zucchini, Yellow crook-neck squash, and other <i>Cucurbita pepo</i> (e.g. patty pan squash, pumpkin, delicata squash, acorn squash, spaghetti squash) | There is a risk of contamination of these other <i>Cucurbita</i> crops by cross-pollination from GM squash. |
| Sugar beets and other <i>Beta vulgaris</i> , (e.g. chard, table beets) | Planted after 2007 crop. (Prevalence as yet undetermined.) |
| Animal Derivatives - These include products derived from cattle, sheep, pigs, chickens, and other common livestock, fowl, and fish, and include the following: | Most animal-derived products have GMO risk because soy, corn, cottonseed, alfalfa, and canola are commonly used in feed, and because injections of recombinant bovine growth |

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| | <p>hormone is sometimes used to increase milk production.</p> <p>GMO veterinary inputs such as vaccines, semen, and medicines are also commonly used in livestock production systems.</p> |
| Milk | |
| Meat | Hides and skins are also included in this category. |
| Eggs | |
| Honey and other bee products | |
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| Processed/processing inputs and ingredients, and related derivatives: | The following is a non-exhaustive list of 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. |
| Aspartame | |
| Bacterial starters | |
| Ascorbic Acid, Sodium Ascorbate, Vitamin C | |
| Citric Acid, Sodium Citrate | Derived from glucose syrup. |
| Enzymes, including chymosin | |
| Ethanol | Derived from corn or GMO sugar beets. |
| Flavorings, “natural” and “artificial” | The carry of which also may be GM. |
| Hydrolyzed Vegetable Protein | |
| Maltodextrins | |
| 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 | |
| Vaccines | |
| Yeast and yeast products | |
| rBGH, rBST, Recombinant Bovine Growth Hormone | |
| Veterinary Medicines | |
| Sperm from cloned animals | See Guidance at 1.2.1.6. |