Non-GMO Project Standard

2025 General Standard Revision Redline Draft 2 – Second Public Comment – v16.1



Public comment periods on the Non-GMO Project Standard are held for 60 days beginning no later than April of revision years; for more information please visit our <u>website</u>. Comments received in the interim will be reviewed during the next scheduled public comment period. Comments may be submitted through our <u>Standard Comment Form</u>.

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The Non-GMO Project Standard (Version 16.1)

The Non-GMO Project

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1 Introduction

The Non-GMO Project is a nonprofit organization whose mission is to offer rigorous product verification and trustworthy education that empowers people to care for themselves, the planet, and future generations.

In support of our mission, the Non-GMO Project offers a Product Verification Program (PVP) whereby Participants may enroll wholesale goods and retail goods as Products for evaluation against, and determination of compliance with, the Non-GMO Project Standard. The PVP also includes the Non-GMO Project Program Rules and Procedures, the Non-GMO Project Trademark Use Guide, and a written agreement between the Participant and the Non-GMO Project, collectively referred to as Program Documents. Where applicable, a written agreement between the Participant and one or more Technical Administrators (TAs) is also required. If all elements of the PVP are satisfied, including meeting the compliance requirements set forth by the Non-GMO Project Standard, Products may attain Non-GMO Project verification.

To monitor compliance with the PVP, the Non-GMO Project maintains surveillance and auditing programs. The surveillance program routinely tests Verified Products and Inputs and Ingredients to same, for compliance with the Action Thresholds outlined in the Non-GMO Project Standard. The auditing program is in place to ensure that the appropriate supporting documentation associated with Verified Products is on file and fulfills the requirements of the PVP.

Compliance with all Program Documents listed in <u>Table 1-1</u> is required to attain Non-GMO Project verification.

Table 1-0-1 Product Verification Program Documents

Product Verification Program Documents:

https://www.nongmoproject.org/resources/#program-documents_

The Non-GMO Project Standard

The Non-GMO Project Program Rules and Procedures

The Non-GMO Project Trademark Use Guide

The Non-GMO Project Trademark License and Program Participation Agreement

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Hereafter, the Non-GMO Project will be referred to as "the Project" and the Non-GMO Project Standard as "the Standard."

English is the original and official language of the Standard. Terms defined in <u>Appendix A</u> and used in the Standard are capitalized throughout. Requirements listed under headers titled "Global Requirements" apply to the entirety of the section in which they appear (e.g., <u>Section 4.2</u>, Global Chain-of-Custody Requirements, applies to all of <u>Section 4</u>).

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1.1 Purpose

The purpose of the Standard is to offer meaning and value to the marketing claim "Non-GMO Project Verified" by creating, maintaining, and keeping publicly available, a set of rigorous requirements against which all Non-GMO Project Verified Products are measured.

1.2 **Defining Genetically Modified Organisms**

The Standard employs a definition of Genetically Modified Organism (GMO) that focuses on the application of Biotechnology rather than comparing the observable or measurable traits of an engineered organism to those of a "natural" organism. Under this approach, any organism modified using Biotechnology, such as through recombinant DNA techniques or new genomic techniques (e.g., CRISPR, TALEN) is classified as a GMO, along with its derivatives. For instance, if corn is Genetically Modified using techniques such as recombinant DNA or gene editing and then processed into corn oil, both the corn and the resulting oil are classified as Genetically Modified. This definition ensures a rigorous evaluation framework, emphasizing transparency, compliance, and alignment with consumer expectations.

1.3 Methodology and Approach of the Standard

The Project's PVP is based on a practice-oriented and process-oriented Standard that uses both testing and Affidavits as key strategic tools to confirm that practices and processes meet expectations.

Continuous improvement on the part of Participants is required with the common goal of eliminating any Inputs and Ingredients derived from Genetically Modified Organisms (GMOs) from their supply chains.

A Product is a unique branded formula and process, where process could be either the manufacturing or facility process.

The breadth and depth of Product evaluation is informed by the nature of the Inputs and Ingredients that are represented in, or present in, the Product formulation. Inputs and Ingredients are classified according to three attributes: 1) weight percentage as represented in, or present in, the Product, 2) likelihood that they are derived from a GMO, and 3) whether a testable precursor exists at any point in the supply chain. These three attributes are termed Weight Percentage, Risk Status, and Testability, respectively. Compliance of all Inputs and Ingredients associated with a Product, and whose evaluation is mandatory, is required for verification.

Activities occurring along the chain of custody (CoC) for Products and their Ingredients and Inputs are <u>evaluated</u> for compliance with the segregation, cleanout, traceability, and quality assurance requirements outlined in the Standard. Products must comply, on an ongoing basis, with the <u>Project's</u> labeling requirements and cannot carry competing claims or 100% GMO absence claims. Before using the Non-GMO Project verification mark in connection with any Product, Participants will be required to sign a written agreement with the Project.

Although requiring the compliance of all Inputs and Ingredients to Products, the <u>Standard</u> is highly focused on Inputs <u>and Ingredients</u> that are or are likely to be derived from GMOs. Testable High-Risk Inputs <u>and Ingredients</u> must comply with the appropriate Action Threshold, and Non-Testable High-Risk Inputs <u>and Ingredients</u> must comply with Affidavit requirements.

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Addressing the contamination of seed is a stated priority of the Project. Although traceability back to tested seed is not required for Product verification in general, the Project is actively developing sources of compliant seed as the basis for a sustainable Non-GMO supply chain.

In summary, all Verified Products must have systems in place for:

- Labeling: Accurate and clear Product labeling
- Quality assurance: Maintaining operational consistency and addressing Non-conformities promptly
- Procurement: Obtaining Inputs and Ingredients in accordance with uniform and meaningful specifications
- Testing: Meaningful, ongoing testing of Major High-Risk Inputs and Ingredients
- Segregation and Cleanout: Protecting compliant Inputs and Ingredients from commingling with non-compliant materials
- Traceability: Supply chain traceability, especially following Input and Ingredient testing or the establishment of a compliant Affidavit

2 Scope of the Standard

2.1 **Product Eligibility**

2.1.1 The following types of wholesale or retail goods are eligible for verification:

- **2.1.1.a** Seed and vegetative propagation materials
- **2.1.1.b** Wholesale or retail goods for human or pet use that are either ingested or topically applied including over the counter (OTC) drugs and homeopathic remedies
- **2.1.1.c** Wholesale or retail goods for human or pet use that are not ingested or topically applied
- **2.1.1.d** Feed and supplements for livestock, poultry, bees, and aquatic animals
- **2.1.2** The following types of goods are ineligible for verification:

2.1.2.a Controlled or illegal substances, narcotics, or any similarly regulated or designated substances, materials, Inputs, Ingredients, and/or Products (as reasonably determined by the Project in its sole discretion) under U.S., Canadian, and/or Mexican law, including the laws of any individual states, provinces, territories, or agencies therein, or under the law in the country or region in which the Product is being manufactured or sold. For the avoidance of doubt, this could include any substance that is currently undergoing review for legality by any state, federal, and/or applicable governmental authority.

2.1.2.b All prohibited substances listed under Section 2.2.1

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Deleted: feed and supplements

Deleted: Controlled substances under U.S. or Canadian law and all other prohibited Inputs and Ingredients listed under Section 2.2.3

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2.1.2.c Certain medicines and other medical goods	[Deleted: 2.1.2.b
2.1.2.d Live animals		Deleted: 2.1.2.c
2.1.2.e Synthetic pesticides		Deleted: 2.1.2.d
2.1.2.f Goods composed entirely of Non-Risk Inputs and Ingredients and that are part of a Non-Risk Category		Deleted: 2.1.2.e
2.1.2.f.i Non-Risk Categories include, but are not limited to, 100% salt goods, unflavored still beverages, unflavored carbonated beverages, and unflavored electrolyte beverages		Deleted: 2.1.2.e.i
2.1.2.g Goods making a voluntary or mandatory disclosure under The National Bioengineered Food Disclosure Standard ¹		Deleted: 2.1.2.f
2.2 Input and Ingredient Evaluation		
2.2.1 The following substances shall be prohibited at any Weight Percentage as Inputs		Deleted: 2.2.3
and Ingredients:	``- [Deleted: Prohibited Inputs and Ingredients:
2.2.1.a Controlled or illegal substances, narcotics, or any similarly regulated or	(Deleted: 2.2.3.a
designated substances, materials, Inputs, Ingredients, and/or Products (as reasonably determined by the Project in its sole discretion) under		Deleted: Controlled substances under U.S. or Canadian law
U.S., Canadian, and/or Mexican law, including the laws of any individual		
states, provinces, territories, or agencies therein, or under the law in		
the country or region in which the Product is being manufactured or		

applicable governmental authority.

2.2.1.b Recombinant bovine growth hormone (rBGH)²

2.2.1.c GM animals including those that are cloned, their progeny, and their derivatives

sold. For the avoidance of doubt, this could include any substance that is currently undergoing review for legality by any state, federal, and/or

2.2.1.d Synthetic Biology,³ its derivatives, and any organisms, Inputs, or Ingredients, or derivatives thereof, represented as synthetic biology³ in any public communications⁴

2.2.1.e Biological Compounds⁵ that are structurally identical to, or intended or

Deleted: 2.2.3.c.i GM Salmon and their derivatives¶ **2.2.3.d** Manure sourced from GM animals¶ **2.2.3.e...**

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¹ 7 CFR § 66 (2018).

² Recombinant bovine growth hormone is also known as recombinant bovine somatotropin (rBST).

³ The terms "Synthetic Biology" (uppercase and defined in Appendix A) and "synthetic biology" (lowercase) are referenced intentionally here. As there is no universally accepted definition for synthetic biology, the term "synthetic biology" (lowercase) includes usage of that term (and comparable terms) by industry even if such terms are not necessarily in full alignment with the Standard's definition.

⁴ Public communications include, but are not limited to, marketing materials, patent filings, SEC filings and other regulatory documents.

⁵ <u>Biological Compounds are substances such as proteins, sugars, fats, and other natural materials that are normally produced by living organisms. For the purposes of this requirement, if a compound is typically sourced from the purposes of this requirement.</u>

represented as a substitute for,	an animal-derived c	compound (including
human) and are:		

2.2.1.e.i produced by organisms that do not naturally produce the compound without the use of Biotechnology, or

2.2.1.e.ii produced by cell-free systems⁶ Enzymes shall be exempt from this prohibition.

2.2.2 The following Inputs and Ingredients are within the scope of evaluation:

2.2.2.a Seeds and vegetative propagation materials only when the same seeds or vegetative propagation materials are the Products seeking verification.

2.2.2.b Compost only when the same compost is the Product seeking verification.

2.2.2.c All Inputs and Ingredients represented in, or present in, the Product formulation from the following categories shall comply with the requirements of the Standard in order for the finished Product to be Verified.

<u>2.2.2.c.i</u>Unprocessed raw agricultural materials such as vegetables, grains, fruit, greens, herbs, other fresh foods, fibers

2.2.2.c.ii Manufacturing Inputs and Ingredients, including flavorings, seasonings, colorings, additives, and all other substances present in final, manufactured Products

2.2.2.c.iii Animal derivatives including dairy, meat, eggs, wool, and hides; derivatives of apiculture including, but not limited to, honey and beeswax; derivatives of aquatic animals

<u>2.2.2.c.iv</u> Processed agricultural Inputs and Ingredients

Packaging that is directly immersed in or combined with liquid for the purpose of making the Product available for human consumption including tea, coffee, spice, and soup bags but not including any part of the packaging other than the bag

<u>2.2.2.c.vi</u> Rations and supplemental feed for livestock, poultry, bees, <u>aquatic animals</u>, and other animals

2.2.2.dOther Inputs and Ingredients used in personal care, cosmetic, and textile Products Deleted: 2.2.1

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animals (including humans), it must come from a Non-GMO animal source to be eligible for use in a Verified Product. Substances that are produced using other organisms or systems, such as yeast, bacteria, fungi, plants, or cell-free systems, even if they replicate the structure or function of the animal-derived compound, or are intended or represented as its substitute, are not permitted.

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⁶ Cell-free systems are production methods that make Biological Compounds outside of whole, living organisms. They combine molecular components from cells (e.g., the machinery used to assemble proteins) with DNA or RNA instructions to build proteins and other molecules without growing Microorganisms or animal cells.

2.2.2.e Dietary supplements, vitamins, and herbal preparations

2.2.2.f Microorganisms, Enzymes, and Growth Media

2.2.2.g Processing Aids present in the finished Product at 0.5% or more

<u>2.2.2.h</u> Processing Aids listed on the Ingredient panel of a retail good, or Input/Ingredient disclosure documentation of a wholesale good

2.2.3 The following Inputs and Ingredients are excluded from the scope of evaluation;

2.2.3.a Processing Aids present in the finished Product at less than 0.5% and not declared on the retail Ingredient panel or the Input/Ingredient disclosure documentation of a wholesale Product. For the purposes of the Standard, fermentation Microorganisms are not considered to be Processing Aids. See Section 9.3 for the evaluation of and compliance requirements for Microorganisms.

<u>2.2.3.b</u> Purified carbon dioxide (CO₂) from either biological or non-biological sources

2.2.3.c Fully composted materials, when used as Inputs.

2.2.3.d Growth Media, feed, and mushroom cultivation substrates, including Inputs to livestock, poultry, bee, and aquatic animal Rations, when the Microorganism, animal, or mushroom grown on or with such materials is represented or present in the finished Product as a Micro Ingredient

2.2.3.e Minor and Micro Inputs to livestock and poultry Rations when the Ration is not a Product

2.2.3.f Growth Media used in the production of Probiotic Ingredients

2.2.3.g Growth Media to Microorganisms from which Enzyme Inputs and Ingredients to vitamin and supplement Products are derived

2.2.4 When Inputs and Ingredients listed in Section 2.2.3 are used in the manufacture or production of Inputs or Ingredients within the scope of evaluation, they shall be subject to attestation that they do not contain and have not incorporated substances prohibited under Section 2.2.1.

3 Input and Ingredient Classification

Each Input and Ingredient <u>shall</u> be classified in accordance with Section 3 and meet all applicable requirements under the Standard to be included in a Verified Product.

3.1 Weight Percentage

All Inputs and Ingredients shall be classified according to their Weight Percentage as represented in, or as present in, the finished Product Excluded from the Weight Percentage calculation are: 1) salt, 2) added water, 3) Processing Aids present in the finished Product at less

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Deleted: Input and Ingredient categories that are out of the scope of the Standard (categories that do not affect the evaluation of the overall Product formulation, including Weight Percentage, Risk Status, and Testability, do not need to be evaluated and do not need to demonstrate compliance with the Standard.)

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Deleted: and animal manures not sourced from Genetically Modified (GM) animals

Deleted: 2.2.3 Prohibited Inputs and Ingredients:¶

2.2.3.a Controlled substances under U.S. or Canadian law¶

2.2.3.b Recombinant bovine growth hormone (rBGH)⁷¶
2.2.3.c GM animals including those that are cloned, their

2.2.3.c GM animals including those that are cloned, the progeny, and their derivatives¶

2.2.3.c....i GM Salmon and their derivatives
i GM Salmon and their derivatives

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Deleted: 2.2.3.d Manure sourced from GM animals¶ **2.2.3.e** Synthetic Biology, ⁸ its derivatives, and any organisms, Inputs, or Ingredients, or derivatives thereof, represented as synthetic biology³ in any public communications²

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than 0.5% and not declared on the retail Ingredient panel or the Input/Ingredient disclosure documentation of a wholesale Product, and 4) purified CO₂.

For livestock, poultry, bee, and <u>aquatic animal</u> feed other than pet food, the Weight Percentage categories <u>under Section 3.1.1</u>, <u>Section 3.1.2</u>, <u>and Section 3.1.3</u>, <u>shall be</u> calculated based on the weight of the Input as a percentage of the Ration fed to the animal. Rations demonstrating compliance on an as-fed basis have additional reporting requirements per <u>Section 8.3.1.d</u>. Rations demonstrating compliance on a dry-matter basis do not have any additional reporting requirements. Per <u>Section 8</u>, all Minor and Micro Inputs of livestock and poultry Rations <u>may be</u> <u>excluded</u> from <u>the scope of</u> evaluation.

Unless a Verified Ingredient, the Inputs to each Major or Minor Ingredient shall be classified and evaluated back to the point in the supply chain where they can be confirmed compliant with the Standard's requirements. If the TA determines that a Micro Ingredient qualifies for Section 3.1.3.b no further breakdown or classification is required.

- **3.1.1** Major Inputs and Ingredients, each of which represents, or is present as, 5% or more of the finished Product.
- **3.1.2** Minor Inputs and Ingredients, each of which represents, or is present as, at least 0.5% but less than 5% of the finished Product.
- **3.1.3** Micro Inputs and Ingredients, each of which represents, or is present as, less than 0.5% of the finished Product. The depth of evaluation for these Inputs and Ingredients, including application of the limits in Section 3.1.3.a, is limited to the organism from which they were derived, as opposed to Growth Medium or feed. Certain Micro Inputs and Ingredients may be eligible for Micro Exemption under Section 3.1.3.b.
 - 3.1.3.a Inputs and Ingredients ineligible for Micro Exemption:
 - 3.1.3.a.i High-Risk Ingredients on the List of Bioengineered Foods.⁵⁷
 - 3.1.3.a.ii High-Risk Ingredients not on the List of Bioengineered Foods⁶⁸ for which the Participant has actual knowledge that the Ingredients contain detectable modified genetic material, and said Ingredients retain detectable modified genetic material in the finished Product.
 - **3.1.3.a.iii** Viable Microorganisms present in the finished Product.
 - **3.1.3.a.iv** Functional Enzymes present in the finished Product and listed on the retail Ingredient panel, or for Products sold without retail labeling, listed on the Input/Ingredient disclosure documentation.

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⁷ 7 CFR § 66.1 (2018); 7 CFR § 66.6 (2018).

⁸⁷ CFR § 66.6 (2018).

3.1.3.a.v High-Risk Micro Ingredients, other than artificial and natural **Deleted:** Enzymes, and Microorganisms flavors, if they are either: Named in text on the Principal Display Panel 3.1.3.a.v.a) (PDP) of a retail Product and the same Deleted: consumer name or any common names by which the Ingredients are known, are listed on the Ingredient declaration or supplement facts panel 3.1.3.a.v.b) Named in parenthetical Ingredient declarations or supplement facts panels and are reasonably considered to characterize a Major, Minor, or Micro Ingredient that is named on the PDP of a retail Product Deleted: consumer See Section 3.2 for an explanation of Risk Status. 3.1.3.b Ingredients present in Products as Micro Ingredients and not listed in Section 3.1.3.a, and Inputs represented in Products as Micro Ingredients, may be approved for use without demonstrating Non-GMO **Deleted:** exempt from further evaluation sourcing (Micro exempted) provided no Product contains more than Deleted: 0.9% total exempt Micro Ingredients by Weight Percentage. Risk Status All Inputs and Ingredients shall be classified according to their Risk Status. Risk Status denotes Deleted: must the likelihood that an Input or Ingredient is or is derived from a GMO. In order to focus the PVP on Inputs and Ingredients at risk for GMO contamination throughout the CoC, the Standard recognizes three Risk Statuses (Table 3-1). Deleted: five Table 3-1 The Three Risk Statuses Deleted: Five **Definition Risk Status Deleted:** Verified Status High Risk Organisms and the Inputs and Ingredients derived from them for which [1] (see Appendix B) GM counterparts are widely commercially available **Deleted:** Monitored Risk (see Appendix C) Organisms and the Inputs and Ingredients derived from them that are [2] Low Risk not classified as High Risk Deleted: Monitored Risk or Inputs and Ingredients that originate entirely outside living systems, with Deleted: Inputs and Ingredients that are not derived from biological organisms and are not, therefore, susceptible to Genetic no history of being alive or derived from a living organism. They contain Modification.. Non-Risk no cells, cellular components, or genetic material and, by their nature, cannot be Genetically Modified. Redline Draft 2 - Second Public Comment - v16.1 October 1, 2025 Testability Inputs and Ingredients are either Testable or Non-Testable. Testable Inputs and Ingredients have a point in the supply chain where the Input or Ingredient contains sufficient intact

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deoxyribonucleic acid (DNA) or protein to return valid molecular or immunological test results. Additionally, molecular tests or immunological tests are publicly commercially available to cover all events for which the Project requires testing. Non-Testable Inputs and Ingredients either lack a point in the supply chain with sufficient intact DNA or protein for valid molecular or immunological test results or do not have commercially available testing methods for the relevant GM events as required by the Project. Some organisms and their derivatives may meet the criteria for being both Testable and Non-Testable, depending on the specific circumstances.

- **3.3.1** For Testable High-Risk Inputs and Ingredients (including for use in pet food) other than animal feed, the molecular method polymerase chain reaction (PCR) is the only acceptable testing methodology.
- **3.3.2** For Testable High-Risk Inputs and Ingredients to animal feed (other than pet food), either the molecular method PCR or immunological methods may be used to demonstrate compliance with the Action Threshold.

Product Compliance by Input and Ingredient Classification

Full Input and/or Ingredient disclosure is required in most cases for Products. Table 3-2 summarizes the compliance pathway for Verified Inputs and Ingredients. Table 3-3 summarizes the compliance pathways available for Low-Risk and Non-Risk Inputs and Ingredients. The compliance pathways of these two Risk Statuses are unaffected by Weight Percentage in the finished Product and Testability. <u>Table 3-4 and Table 3-5</u> summarize, the various compliance pathways for Testable and Non-Testable High-Risk Inputs and Ingredients, respectively, when they are Majors, Minors, and Micros. <u>Table 3-2, Table 3-3, Table 3-4</u>, and <u>Table 3-5</u> are summaries; where appropriate, additional compliance requirements, including those outlined in Section 10, Product Specifications and Labeling, and Section 11, Quality Assurance, could also apply.

Table 3-2 Compliance of Verified Inputs and Ingredients

Verified Major, Minor, and Micro Inputs and Ingredients

1. Provide proof of verification of appropriate scope.

2. Participant complies with Section 4, Chain of Custody, from the point of procurement to the finished Product.

AND

3. Comply with Section 5, Onsite Inspections.

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Table 3-3 Compliance of Low-Risk and Non-Risk Inputs and Ingredients

Low Risk

1. Comply with Section 4.3, Segregation. If the facility does not use any High-Risk Inputs or Ingredients, then demonstration of this fact is sufficient to fulfill this requirement.

AND EITHER

a. Provide a complete Input and Ingredient disclosure.

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Table 3-3 Compliance of Low-Risk and Non-Risk Inputs and Ingredients

OR

b. Comply with Section 7.5, Low-Risk Major, Minor, and Micro Inputs and Ingredients.

Non-Risk

 ${\bf 1.} \ \ {\bf Provide} \ {\bf a} \ {\bf complete} \ {\bf Input} \ {\bf and} \ {\bf Ingredient} \ {\bf disclosure}.$

OR

2. Comply with <u>Section 7.6</u>, Non-Risk Major, Minor, and Micro Inputs and Ingredients.

Note: Inputs and Ingredients from the Low-Risk and Non-Risk Risk Statuses have the same compliance pathways regardless of Testability or Weight Percentage attributes. For example, Non-Risk Major, Minor, and Micro Inputs and Ingredients have the same compliance pathways.

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Table 3-4 Compliance of Testable, High-Risk Major, Minor, and Micro Inputs and Ingredients

<u>Testable High-Risk</u>					
Major	Minor	Micro			
Submit a complete Input and Ingredient disclosure.	1. Comply as a Major. OR	Comply as a Major. OR			
 Comply with Section 4, Chain of Custody. Comply with Section 5, Onsite Inspections. 	 Submit a complete Input and Ingredient disclosure. Comply with <u>Section 4</u>, Chain of Custody. 	 Comply as a Minor. OR Comply with 			
AND EITHER a. Comply with Section 6, Sampling and Testing.	4. Where eligible, comply with <u>Section 7.3</u> , Testable High-Risk Minor and Micro	Section 3.1.3, Micro Inputs and Ingredients. 4. Comply with Section 10, Product Specifications and			
b. Where eligible, comply with Section 7.4, Affidavit Compliance Based on Country of Origin. 4. Comply with Section 10, Product Specifications and Labeling.	 Inputs and Ingredients. Comply with Section 10, Product Specifications and Labeling. Comply with Section 11, Quality Assurance. 	Labeling. 5. Comply with Section 11, Quality Assurance.			
5. Comply with <u>Section 11</u> , Quality Assurance.					

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Table 3-5 Compliance of Non-Testable, High-Risk Major, Minor, and Micro Inputs and Ingredients,

ingredients,				
	Non-Testable High-Risk			
Major	Minor	Micro		
 Submit a complete Input and Ingredient disclosure. Comply with <u>Section 4</u>, Chain of Custody. 	Comply as a Major. OR Submit a complete Input	 Comply as a Major. OR Comply as a Minor. 		
3. Comply with Section 5, Onsite Inspections. AND EITHER	and Ingredient disclosure. 3. Comply with Section 4, Chain of Custody. AND EITHER	3. Comply with Section 3.1.3, Micro Inputs and Ingredients.		
a. Comply with Section 7.2, Non-Testable High-Risk Inputs and Ingredients. OR b. Where eligible, comply with Section 7.4, Affidavit Compliance	a. Comply with Section 7.2, Non-Testable High-Risk Inputs and Ingredients. OR b. Where eligible, comply with Section 7.4, Affidavit Compliance	 4. Comply with Section 10, Product Specifications and Labeling. 5. Comply with Section 11, Quality Assurance. 		
Based on Country of Origin. 4. Comply with Section 10, Product Specifications and Labeling. 5. Comply with Section 11, Quality Assurance.	Based on Country of Origin. 4. Comply with Section 10, Product Specifications and Labeling. 5. Comply with Section 11, Quality Assurance.			

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4 Chain of Custody

Compliant Products, Ingredients, and Inputs shall maintain their integrity while being moved through various activities along the CoC.

4.1 Activities

CoC requirements apply beginning at the point of procurement for Verified Inputs and Ingredients, the point that Risk Status is confirmed as Non-Risk or Low Risk for an Input or Ingredient, at the point of testing, or at the point where compliant Affidavits are procured.

When relevant to the verification of the Product, the following activities shall be subject to evaluation and shall be found to be compliant with the applicable Standard sections (Table 4-1).

Table 4-1 Activities Along the Chain of Custody

Type of Activity	Comment				
Agricultural production—seeds and crops	Includes farm production, harvest, and post-harvest handling and storage on farm or farm-related facilities.				
Handling	Includes any form of post-harvest movement, storage, transformation, or labeling of goods along the entire CoC from seed to consumer, except for Products enclosed in final retail packaging.				
Storage	Includes all links in the CoC from seed to finished Product.				
Distribution	This may or may not involve physical handling of goods.				
Processing	Includes all conveyance, storage, processing, handling, assembly, or packaging of goods within any given production facility.				
Manufacturing	Involves the production, and combination of, Inputs and Ingredients to make the finished Product.				
Packaging and labeling	Includes any and all events during which the packaging or labeling of goods is added, removed, or altered.				

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4.2 Global Chain of Custody Requirements

- **4.2.1** All required procedures <u>shall</u> be written and accessible to all appropriate staff and updated as necessary.
- **4.2.2** All appropriate staff working with compliant Inputs, Ingredients, and Products shall be adequately trained in the required procedures.
- **4.2.3** All records <u>shall</u> be maintained for a minimum of 3 years.

4.3 Segregation

4.3.1 Systematic procedures <u>shall</u> be in place during activities to keep compliant Inputs, Ingredients, work-in-progress, and finished Products separate from all non-compliant High-Risk materials.

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of an Input or Ingredient is confirme

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	4.3.2	Segregation measures are also required for instances who ccurs after the Input or Ingredient in question has enter		
4.4	Clear	nout		
	4.4.1	Receiving, production, processing, manufacturing, transf as well as shipping and transportation conveyances, <u>shal</u> cleaned/purged as needed to remove sources of GMO co	be inspected andontamination, and all	Deleted: must
		relevant cleaning, purging, and inspections shall be docu	mented.	Deleted: must
4.5		ability		
	4.5.1	Each lot of Verified Product shall be traceable back to sp and Ingredients used in its production. If lots of compliar Ingredients are commingled in storage before use in pro-	nt Inputs and/or	Deleted: must
		of Product, the lot numbers related to all commingled lo particular lot of Product.		Deleted: must
	4.5.2	Testable High-Risk Inputs and Ingredients shall be tracea		Deleted: must
		demonstrate compliant test results. Non-Testable High-Fingredients shall be traceable back to the lots associated		Deleted: must
		Affidavits.	,	
	4.5.3	Systematic procedures <u>shall</u> be in place for tracking lot n and labeling of packaging, containers, and storage faciliti of Inputs, Ingredients, work-in-progress, and finished Proproduction process.	es to ensure traceability	Deleted: must
	4.5.4	Traceability records shall explicitly trace and track the co- Ingredients, and finished Products.	mpliance of Inputs,	Deleted: must
5	Onsi	te Inspections		
5.1		nimum, Producing Facilities shall undergo annual inspectio	n when Parallel	Deleted: are required to be inspected annually
	Proces	ssing: the same Major High-Risk Input or Ingredient, or		Deleted: of the same Major High-Risk Input or Ingredient to a Product is occurring.
		a Verified Ingredient (comprising a single Ingredient) deriv	ad from a High Rick	
	3.1.2	crop.	eu nom a mgn-nisk	
5.2	Produ	act processors that are not Participants are exempt from in cts, Ingredients, and Inputs they manufacture are the resu		
		designed to avoid GMOs.		Deleted: The availability of this exemption will be revisited during the next Standard revision.
5.3	chain	A may require additional inspections based on an overall ri undergoing evaluation, regardless of the Weight Percenta pility of Inputs <u>or</u> Ingredients		Deleted: ,
5.4		TA's discretion, unannounced inspections may be used to	ensure compliance with	Deleted: , or Products.
J. 4		andard, regardless of the Weight Percentage, Risk Status,	•	Deleted: ,
	or Ing	redients.		Deleted: , or Products.
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6 Sampling and Testing

All High-Risk Inputs and Ingredients shall comply with the relevant Action Threshold through either Section 6 or Section 7, unless otherwise allowed by a different section of the Standard. The combination of Weight Percentage, Risk Status, and Testability determines the pathways available for the demonstration of compliance with the relevant Action Threshold. Refer to Table 3-2 and Table 3-3 for summaries of the appropriate compliance pathways.

6.1 Action Thresholds

Absence of all GMOs is the target for all Verified Products. Continuous improvement practices toward achieving this goal <u>shall</u> be part of the Participant's quality assurance systems. A key outcome of such quality assurance systems is to meet or continually be below the applicable Action Threshold. Testable High-Risk Inputs and Ingredients that do not comply with the applicable Action Threshold cannot be intentionally used in Verified Products, unless otherwise allowed by a different section of the Standard.

The Project has established the following Action Thresholds for Testable High-Risk Inputs and Ingredients (Table 6-1).

Table 6-1 Action Thresholds

Category	Action Threshold ^a
Seed and vegetative propagation materials	0.25%
Wholesale or retail goods for human or pet use that are either ingested or topically applied including OTC drugs and homeopathic remedies	0.9%
Livestock, poultry, bee, and <u>aquatic animal</u> feed and supplements, including those used for animal-derived Inputs and Ingredients to all	
Products	5% ^b
Wholesale or retail goods for human or pet use that are not ingested or topically applied including, but not limited to, Inputs and Ingredients to packaging, cleaning supplies, and textiles	1.5%

For all crops not listed in Appendix B.1.1, there is no allowable presence.

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6.2 Global Sampling Requirements

6.2.1 A statistically valid sampling and testing plan shall be designed based on a risk assessment of the production and handling system and shall reflect the level of monitoring appropriate for the risks inherent in the production and handling system, as well as industry standards.

6.2.1.a The sampling and testing plan <u>shall</u> be approved by the TA before any test results acquired on the basis of said sampling and testing plan may be used to demonstrate compliance with the Action Threshold.

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b Compliance with this Action Threshold may be based on the quarterly average of all lots tested.

	6.2.1.b	Unless otherwise allowed by a different section of the Standard, compliant sampling and testing shall occur at least once post-harvest for all Inputs and Ingredients, depending on contamination risks.	+		Deleted: must	
	6.2.1.c	When achieving statistical validity through crop sampling cannot be done without destroying significant quantities of the consumer good (e.g., for large crops such as papaya, sweet corn, zucchini and yellow summer squash), the TA may shift testing to the seed level with limited post-harvest spot testing.				
6.2.2	Compos	iting samples				
	which p	al calculations can also be used to design compositing strategies under ortions of multiple samples can be combined and tested together to the number of tests required.				
	6.2.2.a	Compositing shall be done in a manner that ensures that any single sample in excess of the relevant Action Threshold produces a positive result for the composite sample as a whole. If a result is obtained for the composite that indicates that one or more single samples exceeds the relevant Action Threshold, the lot shall be rejected, or if sub-lots are segregated and not commingled, then retesting of individual lot			Deleted: must Deleted: must	
		samples may be possible to salvage compliant lots.				
Globa	ıl Testin	g Requirements				
6.3.1		ants shall demonstrate compliance with the applicable Action Threshold.	+		Deleted: must	
	Participa Complia High-Ris			\equiv	Deleted: must Deleted: must	
6.3.1	Participa Complia High-Ris Verified The sam	ants shall demonstrate compliance with the applicable Action Threshold. nce shall be demonstrated by ensuring that each lot of Testable k Input or Ingredient is compliant with Section 6 prior to its use in a Product. uple Matrix shall be appropriate for the testing method to yield valid				
6.3.1 6.3.2	Participal Compliantigh-Rist Verified The same results.	ants shall demonstrate compliance with the applicable Action Threshold. nce shall be demonstrated by ensuring that each lot of Testable k Input or Ingredient is compliant with Section 6 prior to its use in a Product. sple Matrix shall be appropriate for the testing method to yield valid If necessary, the precursor from which the Input or Ingredient was	1 1		Deleted: must Deleted: must	
6.3.1 6.3.2	Participa Complia High-Ris Verified The sam results. derived	ants shall demonstrate compliance with the applicable Action Threshold. nce shall be demonstrated by ensuring that each lot of Testable k Input or Ingredient is compliant with Section 6 prior to its use in a Product. pple Matrix shall be appropriate for the testing method to yield valid If necessary, the precursor from which the Input or Ingredient was shall be tested.			Deleted: must Deleted: must Deleted: must	
6.3.1 6.3.2	Participa Complia High-Ris Verified The sam results. derived	ants shall demonstrate compliance with the applicable Action Threshold. nce shall be demonstrated by ensuring that each lot of Testable k Input or Ingredient is compliant with Section 6 prior to its use in a Product. pple Matrix shall be appropriate for the testing method to yield valid If necessary, the precursor from which the Input or Ingredient was shall be tested. All GM events for which the Project requires testing shall be tested for			Deleted: must Deleted: must Deleted: must Deleted: must	
6.3.1 6.3.2	Participa Complia High-Ris Verified The sam results. derived, 6.3.3.a	ants shall demonstrate compliance with the applicable Action Threshold. nce shall be demonstrated by ensuring that each lot of Testable k Input or Ingredient is compliant with Section 6 prior to its use in a Product. The Matrix shall be appropriate for the testing method to yield valid if necessary, the precursor from which the Input or Ingredient was shall be tested. All GM events for which the Project requires testing shall be tested for and the results shall be conclusive. Test results shall be traceable back to the lot number(s) of the			Deleted: must Deleted: must Deleted: must	
6.3.1 6.3.2	Participa Complia High-Ris Verified The sam results. derived 6.3.3.a	ants shall demonstrate compliance with the applicable Action Threshold. nce shall be demonstrated by ensuring that each lot of Testable k Input or Ingredient is compliant with Section 6 prior to its use in a Product. pple Matrix shall be appropriate for the testing method to yield valid if necessary, the precursor from which the Input or Ingredient was shall be tested. All GM events for which the Project requires testing shall be tested for and the results shall be conclusive. Test results shall be traceable back to the lot number(s) of the precursor, Input, or Ingredient. From the point of testing forward, the activities associated with the			Deleted: must Deleted: must Deleted: must Deleted: must Deleted: must	
6.3.1 6.3.2 6.3.3	Participal Compliant High-Rist Verified The sammer results. derived, 6.3.3.a 6.3.3.b	ants shall demonstrate compliance with the applicable Action Threshold. nce shall be demonstrated by ensuring that each lot of Testable k Input or Ingredient is compliant with Section 6 prior to its use in a Product. The Matrix shall be appropriate for the testing method to yield valid if necessary, the precursor from which the Input or Ingredient was shall be tested. All GM events for which the Project requires testing shall be tested for and the results shall be conclusive. Test results shall be traceable back to the lot number(s) of the precursor, Input, or Ingredient. From the point of testing forward, the activities associated with the precursor, Input, or Ingredient shall comply with Section 4.			Deleted: must Deleted: must Deleted: must Deleted: must Deleted: must Deleted: must Deleted: must	
6.3.1 6.3.2	Participal Compliant High-Rist Verified The sammer results. derived, 6.3.3.a 6.3.3.b	ants shall demonstrate compliance with the applicable Action Threshold. nce shall be demonstrated by ensuring that each lot of Testable k Input or Ingredient is compliant with Section 6 prior to its use in a Product. The Matrix shall be appropriate for the testing method to yield valid if necessary, the precursor from which the Input or Ingredient was shall be tested. All GM events for which the Project requires testing shall be tested for and the results shall be conclusive. Test results shall be traceable back to the lot number(s) of the precursor, Input, or Ingredient. From the point of testing forward, the activities associated with the precursor, Input, or Ingredient shall comply with Section 4. ults shall be submitted to the TA for evaluation prior to initial			Deleted: must Deleted: must Deleted: must Deleted: must Deleted: must Deleted: must	
6.3.1 6.3.2 6.3.3	Participal Compliant High-Rist Verified The same results. derived 6.3.3.a 6.3.3.b 6.3.3.c Test results verificate The same results.	ants shall demonstrate compliance with the applicable Action Threshold. nce shall be demonstrated by ensuring that each lot of Testable k Input or Ingredient is compliant with Section 6 prior to its use in a Product. pple Matrix shall be appropriate for the testing method to yield valid if necessary, the precursor from which the Input or Ingredient was shall be tested. All GM events for which the Project requires testing shall be tested for and the results shall be conclusive. Test results shall be traceable back to the lot number(s) of the precursor, Input, or Ingredient. From the point of testing forward, the activities associated with the precursor, Input, or Ingredient shall comply with Section 4. ults shall be submitted to the TA for evaluation prior to initial ion.			Deleted: must Deleted: must Deleted: must Deleted: must Deleted: must Deleted: must Deleted: must	
6.3.1 6.3.2 6.3.3	Participal Compliant High-Rist Verified The samme results. derived, 6.3.3.a 6.3.3.b 6.3.3.c Test results verificated All test in the complex c	ants shall demonstrate compliance with the applicable Action Threshold. nce shall be demonstrated by ensuring that each lot of Testable k Input or Ingredient is compliant with Section 6 prior to its use in a Product. The Matrix shall be appropriate for the testing method to yield valid if necessary, the precursor from which the Input or Ingredient was shall be tested. All GM events for which the Project requires testing shall be tested for and the results shall be conclusive. Test results shall be traceable back to the lot number(s) of the precursor, Input, or Ingredient. From the point of testing forward, the activities associated with the precursor, Input, or Ingredient shall comply with Section 4. ults shall be submitted to the TA for evaluation prior to initial			Deleted: must Deleted: must Deleted: must Deleted: must Deleted: must Deleted: must Deleted: must	

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ensuring that test results for all lots of High-Risk precursor, Input, or Ingredient used during each 6-month period average at or below the relevant Action Threshold, with no single lot of precursor, Input, or Ingredient ever exceeding the relevant Action Threshold by more than a factor of two.

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6.3.6.a Planting seed, vegetative propagation materials, and livestock, poultry, bee, and <u>aquatic animal</u> feed cannot demonstrate compliance via Section 6.3.6.

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6.3.6.b The Participant shall justify in writing to the TA why the requirements of Section 6.1 are problematic to achieve for every lot at initial verification and at each renewal.

6.3.6.c The Participant is responsible for ongoing monitoring of test results to

Molecular Testing Methods

6.4

6.4.1 Testable High-Risk Inputs and Ingredients will be compliant with Section 6.4 if all the following criteria are met:

ensure compliance for each 6-month period.

6.4.1.a Appropriate laboratory controls indicate that the DNA of the precursor, Input, or Ingredient is sufficiently intact to allow valid quantitative analysis by PCR.

6.4.1.b The testing is conducted by an <u>Approved Laboratory</u> in compliance with Section 6.4.2 and the analysis report references the specific lot of precursor, Input, or Ingredient, where applicable

6.4.1.c The analysis report shows that the GM contamination of the precursor, Input, or Ingredient in question is at or below the relevant Action Threshold.

6.4.2 Approved Laboratories shall carry out testing, except in cases where Inputs and Ingredients are compliant with Section 7.4.

Laboratory testing may employ quantitative, semi-quantitative, or qualitative 6.4.3

6.4.3.a Quantitative PCR may be used to demonstrate compliance with the Action Threshold if:

> 6.4.3.a.i For each test panel conducted on a precursor, Input, or Ingredient, the sum of all test results is at or below the relevant Action Threshold.

6.4.3.b Semi-quantitative PCR may be used to demonstrate compliance with the Action Threshold if:

> **6.4.3.b.i** The upper limit of the range in which the result is reported is at or below the relevant Action Threshold.

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- **6.4.3.c** Qualitative PCR may be used to demonstrate compliance with the Action Threshold if:
 - **6.4.3.c.i** The PCR limit of detection is 0.1% or lower.
 - **6.4.3.c.ii** Each test result for each Testable High-Risk precursor, Input, or Ingredient is negative.
 - 6.4.3.c.iii Should any test result be positive for a GM event, the Testable High-Risk precursor, Input, or Ingredient shall be tested in compliance with Section 6.4.3.a or Section 6.4.3.b to demonstrate compliance with the Action Threshold. If the Testable High-Risk precursor, Input, or Ingredient cannot be tested in compliance with Section 6.4.3.a or Section 6.4.3.b, compliance with the appropriate Action Threshold cannot be demonstrated and the lot cannot be used in a Verified

6.5 Immunological Testing Methods

- **6.5.1** Immunological testing methods such as Enzyme-linked Immunosorbent Assay (ELISA) or lateral flow strip tests may be used in lieu of molecular testing methods to demonstrate compliance of animal feed (other than pet food) with the appropriate Action Threshold, when the methods meet the criteria in Section 6.5.
- 6.5.2 Analysts shall be trained, and their proficiency established, to ensure that they use and interpret the tests reliably and according to the manufacturer's specifications. <u>In-house training and performance evaluations shall be conducted</u>, and this shall be documented.
- 6.5.3 In cases where immunological testing methods are permissible by the Standard, they shall cover all GM events for which the Project requires testing. If all GM events for which the Project requires testing are not covered, samples shall be tested in compliance with Section 6.4.
 - **6.5.3.a** Quantitative immunological methods may be used to demonstrate compliance with the Action Threshold when:
 - **6.5.3.a.i** The result for each assay counted toward overall contamination is either below the limit of detection or returns a number within the range of quantification and is not above the upper limit of the range of detection.
 - **6.5.3.a.ii** The overall contamination of the Testable High-Risk precursor, Input, or Ingredient is indicated by the sum of each test panel or by following the manufacturer's instructions for the interpretation of test panel results.
 - **6.5.3.b** Qualitative immunological methods may be used to demonstrate compliance with the Action Threshold when:

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6.5.3.b.i	Each test result for each GM event per Testable High-Risk
	precursor, Input, or Ingredient is negative.

6.5.3.b.ii Should any test results be positive, the Testable High-Risk precursor, Input, or Ingredient shall be tested according to Section 6.5.3.a, Section 6.4.3.a, or Section 6.4.3.b to demonstrate compliance with the Action Threshold.

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7 Affidavits

In most cases, testing is a required validation tool for confirming compliance with the Action Threshold of Testable High-Risk Major Inputs and Ingredients. In the case of Non-Testable High-Risk Inputs and Ingredients, where testing is not an available validation tool, or in the case of Inputs and Ingredients classified as other than Testable High-Risk Major, the Project uses a process-based approach that includes comprehensive Affidavits as an alternate validation tool. In some situations, the frequency and necessity of testing or the need for certain Affidavits may be reduced based on the country in which a crop was grown.

7.1 Global Affidavit Requirements

- **7.1.1** At minimum, all Affidavits shall include the signature and the printed name of the party signing the Affidavit, and the date.
- 7.1.2 The party signing the Affidavit shall have sufficient knowledge of the supply chain to authoritatively sign.
- **7.1.3** If appropriate, Affidavits should be accompanied by supporting documentation.
- **7.1.4** At the discretion of the TA or the Project, Affidavits may be required in additional situations not explicitly identified in Section 7.
- **7.1.5** Unless otherwise stated, Affidavits shall be updated as appropriate to reflect changes to the crops, precursors, Inputs, Ingredients, systems, processes, or operations they reference.

7.2 Non-Testable High-Risk Inputs and Ingredients

7.2.1 Non-Testable High-Risk Major, Minor, and Micro Inputs and Ingredients are identified in <u>Appendix B.1</u>. An Affidavit stating that any such Non-Testable High-Risk Major, Minor, or Micro Input or Ingredient is Non-GMO <u>shall be</u> required to establish compliance with Section 7.2. Organisms, precursors, Inputs, or Ingredients identified as Non-Testable High-Risk Major, Minor, and Micro Inputs and Ingredients in <u>Appendix B.1</u> that are subject to any European Union (EU) GMO Directives or Regulations, ⁷⁹ including but not limited to any such items that an EU Member State has determined are subject to such GMO Directives or Regulations, are GMO under the Standard; Non-Testable High-Risk

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⁹ See, e.g., without limitation, Council Regulation 1829/2003/EC on genetically modified food and feed; Council Regulation 1830/2003/EC concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC.

Affidavits accompanying such organisms, precursors, Inputs, or Ingredients do not establish them as Non-GMO and will not be considered for compliance with Section 7.

For the avoidance of doubt, all Non-Testable High-Risk Major, Minor, and Micro Inputs and Ingredients remain subject to evaluation, and may be deemed GMO, under the Standard, regardless of whether such Inputs or Ingredients are regulated as GMOs (or have been deemed Non-GMO) by any EU GMO Directive or Regulation, or have been deemed subject to any EU GMO Directive or Regulation by a Member State.

- **7.2.2** The Project has issued a standardized Non-Testable High-Risk Affidavit. This is the only Affidavit compliant with Section 7.2.1.
- 7.2.3 Unless otherwise allowed by a different section of the Standard, Affidavits for any Non-Testable High-Risk Major, Minor, or Micro Input or Ingredient shall be submitted to the TA for evaluation prior to initial verification and, at minimum, updated and resubmitted annually upon each renewal to ensure compliance with Section 7.
- **7.2.4** Testable High-Risk Major Inputs and Ingredients listed in <u>Appendix B.1 shall</u> be compliant with <u>Section 6</u> or <u>Section 7.4</u>. Testable and Non-Testable High-Risk Inputs and Ingredients listed in <u>Appendix B.1 shall</u> comply with both <u>Section 6</u> and <u>Section 7</u>.

7.3 Testable High-Risk Minor and Micro Inputs and Ingredients

- **7.3.1** All Affidavits shall include the definitions of Biotechnology and GMO as they appear in Appendix A.
- **7.3.2** Testable High-Risk Minor and Micro Inputs and Ingredients may demonstrate compliance based on Affidavits as long as these Inputs and Ingredients are the result of a system that has been designed to avoid GMOs. The suitability of systems designed to avoid GMOs is subject to evaluation by the TA with final determination by the Project.
- **7.3.3** When available, valid certificates from third-party certifiers are acceptable alternatives to Affidavits under Section 7.3, if the third-party certification program satisfies the requirements for which an Affidavit would be used in Section 7.3.2.
 - 7.3.3.a Except for honey and other derivatives of apiculture, Testable High-Risk Minor and Micro Inputs and Ingredients that are certified organic do not require an Affidavit.

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7.4 Affidavit Compliance Based on Country of Origin⁸¹⁰

- 7.4.1 Certain Testable and Non-Testable High-Risk crops and their derivatives that comprise a single Input may demonstrate compliance with aspects of the Standard based on country of origin.
- **7.4.2** The necessity or frequency of testing of certain Testable High-Risk crops and their single Input derivatives may be reduced by the TA based on an Affidavit.
- **7.4.3** The Affidavit shall state that:
 - **7.4.3.a** Procurement procedures that require that the crop source or single Input derivative is grown strictly in specific countries are in place throughout the supply chain.
 - **7.4.3.b** No crop or crop-derivatives from outside those specific countries may be commingled.
 - **7.4.3.c** Procedures throughout the supply chain are in place for the segregation, cleanout, and traceability of compliant materials from non-compliant materials.
- 7.4.4 The Affidavits shall be submitted to the TA for evaluation prior to initial verification and, at minimum, updated and resubmitted annually upon each renewal.
- **7.4.5** The Project has issued standardized Affidavits for Section 7.4.3. These are the only Affidavits compliant with Section 7.4.
- **7.4.6** When available, valid third-party Identity Preservation (IP) certificates are acceptable alternatives to Affidavits when the scope of the third-party certification program satisfies the requirements for which an Affidavit would be used in Section 7.4.2.

7.5 Low-Risk Major, Minor, and Micro Inputs and Ingredients

- **7.5.1** Affidavits may be used to confirm the compliance of Low-Risk Major, Minor, and Micro Inputs and Ingredients.
- 7.5.2 The Affidavit shall attest to compliance with the requirement for classification as Low Risk as described in Table 3-3.

7.6 Non-Risk Major, Minor, and Micro Inputs and Ingredients

- **7.6.1** Affidavits may be used to confirm the compliance of Non-Risk Major, Minor, and Micro Inputs and Ingredients.
- **7.6.2** The Affidavit shall attest to compliance with the requirement for classification as Non-Risk as described in Table 3-3.

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¹⁰ The Project maintains the list of countries (and associated frequencies and necessities of testing) that comply with <u>Section 7.4.2</u>.

7.7 Inputs and Ingredients Excluded from the Scope of Evaluation

- 7.7.1 For Inputs and Ingredients excluded from the scope of evaluation under Section 2.2.3, compliance with Section 2.2.4 shall be demonstrated by Affidavit.
- 2.7.2 The Affidavit shall attest that no substances prohibited under Section 2.2.1 have been intentionally incorporated and that, to the best of the signatory's knowledge, commercially reasonable efforts have been undertaken in the ordinary course of business to prevent their use in production. Such efforts shall include due diligence, reliance on reputable vendors, and acceptance of reasonable representations.
- 7.7.3 Such Affidavits shall not impose any Non-GMO sourcing or other compliance requirements under the Standard on the associated Inputs or Ingredients and shall not modify the scope of evaluation established in Sections 2.2.2 and 2.2.3.

8 Livestock and Poultry

The following requirements are intended to complement other sections of the Standard. Where specific topics are addressed (e.g., sampling, testing), these requirements are authoritative. Where special requirements are not given, requirements from elsewhere in the Standard apply.

Absence of all GMOs is the target for all Verified Products. Continuous improvement practices toward achieving this goal shall be part of the Participant's quality assurance systems.

Livestock- and poultry-derived Inputs and Ingredients are High Risk and their Ration Inputs are within the scope of evaluation and could be Testable or Non-Testable High Risk. These Inputs and Ingredients comply with the sampling and testing requirements of the Standard through the sampling and testing of Inputs to the animals' Rations or the seed used to grow the Inputs to the animals' Rations. Feed Inputs to Rations shall be classified based on their Weight Percentage within the Ration, Risk Status, and Testability. Unless otherwise specified, compliance with the 5% Action Threshold is based on the quarterly average of all lots tested. In all cases, the animals shall be sourced Non-GMQ and shall not have been treated with or derived from prohibited substances listed under Section 2.2.1.

8.1 Compliance of Livestock- and Poultry-derived_Inputs and Ingredients

Livestock- and poultry-derived Inputs and Ingredients, are High Risk and have different compliance pathways depending upon their Weight Percentage as present in the finished Product. Table 8-1 outlines the compliance requirements for livestock- and poultry-derived Majors, Minors, and Micros when the livestock or poultry-derived material is present in the Product under evaluation. Table 8-1 is a summary; additional compliance requirements could apply.

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Table 8-1 Compliance of Livestock- and Poultry-derived Inputs and Ingredients based on Weight Percentage	'	Deleted: Products, Ingredients, and
Major		Deleted: Product/
Animals shall be Non-GMO.		Formatted: Font: Not Bold
2. Animals shall comply with Section 8.2, Life Cycle.	•	Deleted: must
3. Inputs to Rations shall be classified based on the combination of Weight Percentage as	-2 4-	Formatted: Default Paragraph Font
present in the Ration, Risk Status, and Testability.	1,	Formatted: Indent: Left: 0", Hanging: 0.24"
4. Major Inputs to Rations are within the scope of <u>evaluation</u> and <u>shall</u> be found compliant		Deleted: 2.
with <u>Table 8-2</u> .	111	Deleted: are
5. Major High-Risk Inputs to Rations shall comply with:	111	Deleted: 3.
a. Section 4, Chain of Custody		Deleted: review
b. Section 8, Livestock and Poultry	'''	Deleted: must
c. Section 8.8, Onsite Farm and Feed Mill Inspections	`\	Deleted: 4.
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in addition to Ration compliance, the livestock or poultry-derived material shall comply with:		Deleted: 5.
a. Section 4, Chain of Custody		Deleted: must
b. Section 5, Onsite Inspections		
c. Section 8.8, Onsite Farm and Feed Mill Inspections		
d. Section 10, Product Specifications and Labeling		
e. <u>Section 11</u> , Quality Assurance		
Minor		
1. Animals shall be Non-GMO		
AND EITHER		Formatted: Font: Bold
a. Comply with Standard requirements as a Major.	'	Deleted: 1.
OR	17-	Deleted: Materials may c
<u>b.</u> <u>C</u> omply with <u>Section 7.3</u> , Testable High-Risk Minor and Micro Inputs and Ingredients (e.g.,		Deleted: Product/
Verified, organic certification).		Deleted: 2.
Micro		Deleted: Materials may c
1. Animals shall be Non-GMO		Deleted: Status
AND EITHER	:	Formatted: Font: Not Bold
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a Comply with Standard requirements as a Major.	·-<[-[Deleted: 1. Deleted: Materials may c
OR		Deleted: waterials may t Deleted: either a Product/
b. Comply with Standard requirements as a Minor.		Deleted: 2.
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<u>c.</u> All Inputs to Rations are <u>excluded from</u> the scope of <u>evaluation; Comply</u> with		Deleted: Materials may c
Section 3.1.3, Micro Inputs and Ingredients.	111	Deleted: outside
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8.2 Life Cycle

Livestock- and poultry-derived, Inputs and Ingredients, shall be from animals that comply with the following life-cycle feed guidelines.

8.2.1 Meat animals, including culls (other than poultry): starting at birth (the feed of nursing mothers is not evaluated) and ending at slaughter

- **8.2.2** Poultry, including spent hens: starting on the second day after hatching and ending at slaughter
- **8.2.3** Laying hens: starting 30 days prior to initial verification and for the remainder of the animal's productive life (including rest and molt periods)
- **8.2.4** Dairy animals: starting 30 days prior to initial verification and for the remainder of the animal's productive life (including dry periods)
- **8.2.5** Animals <u>shall not</u> be intentionally cycled on and off compliant feed. The use of non-compliant Major Inputs to the animals' Rations triggers a Non-conformity.
- 8.2.6 Animals may be removed from a Non-GMO-compliant group (e.g., herd, flock) for medical treatment, <u>During this</u> time, their feed is <u>excluded from</u> the scope of <u>evaluation</u>, and no material (e.g., milk, eggs) <u>shall</u> be collected from them for use in the Non-GMO supply chain. The animals <u>shall</u> immediately resume Non-GMO-compliant feed once treatment is concluded and they are returned to the group.

8.3 Compliance of Feed Rations

The Weight Percentage of Inputs to Rations <u>shall be</u> calculated based on the weight of the Input as present in the Ration. <u>Table 8-2</u> is a summary; additional compliance requirements <u>could</u> apply.

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Table 8-2 Compliance of Inputs to Rations for Livestock- and Poultry-derived Major Ingredients

<u>Ingredients</u>				
Major	Minor	Micro		
Testable				
 Comply with Section 4, Chain of Custody, from the point of testing onward. Operations shall comply with Section 8.8, Onsite Farm and Feed Mill Inspections. AND EITHER Sampling and testing shall comply with Section 8.4, Feed Sampling, Section 8.5, Testing Methodology, Section 8.6, Feed Compliance Through Compliant Seed, and Section 8.7, Feed Mills, as applicable. OR Where eligible comply with Section 7.4, Affidavit Compliance Based on Country of Origin. 	1. Excluded from the scope of evaluation. OR 2. Comply as a Major. OR 3. Comply with Section 7.3, Testable High-Risk Minor and Micro Inputs and Ingredients.	1, Excluded from the scope of evaluation. OR 2. Comply as a Major. OR 3. Comply as a Minor. OR 4. Comply with Section 7.3, Testable High-Risk Minor and Micro Inputs and Ingredients.	Formatted: Font: Not Bo Formatted: Font: Not Bo Formatted: Font: Not Bo Deleted: Out of scope. Deleted: must Deleted: must Deleted: 3.	old
	ole High Risk			
 Comply with Section 4, Chain of Custody, from the point of compliance with either Section 7.2, Non-Testable High-Risk Inputs and Ingredients or where eligible Section 7.4, Affidavit Compliance Based on Country of Origin, onward. Operations Shall comply with Section 8.8, Onsite Farm and Feed Mill Inspections. AND EITHER Comply with Section 7.2, Non-Testable High-Risk Inputs and Ingredients. OR Where eligible comply with Section 7.4, 	1. Excluded from the scope of evaluation. OR 2. Comply as a Major. OR -3. Comply-with Section 7.2, Non-Testable High-Risk Inputs and Ingredients.	1. Excluded from the scope of evaluation. OR 2. Comply as a Major. OR 3. Comply as a Minor. OR 4. Comply with Section 7.2, Non-Testable High-Risk Inputs	Deleted: Out of scope. Deleted: Out of scope. Formatted: Font: Bold Deleted: must	
Affidavit Compliance Based on Country of Origin.		and Ingredients.		

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8.3.1	Ration F	Reporting R	equirements				
	8.3.1.a	plan detai	laying operations shall submit to ling the stages of life or producti , corresponding durations and Ra	on managed, including, at	D	Deleted: must	
		8.3.1.a.i	Weight Percentage, Risk Status, shall apply to all Ration Inputs a individual Ration.	•			
		8.3.1.a.ii	Multiple Rations that are mater combined into a single Ration.	ially different <u>shall not</u> be		Deleted: cannot	_
		8.3.1.a.iii	Multiple Rations spanning difference production shall not be combined they are materially homogeneous	ed into a single Ration unless		Deleted: cannot	
	8.3.1.b	detailing t	rations shall submit to the TA at in the stages of life or production, in the stages of life or production feed in the station feed in the cycle requirement as stages.	ncluding, at minimum, d to the animals for the full	D	Deleted: must	
	8.3.1.c	detailing t	perations shall submit to the TA and the stages of life or production, inding durations and the Ration fe their life cycle requirement as states.	ncluding, at minimum, d to the animals for the full	D	Deleted: must	
	8.3.1.d	V	ompliant on an as-fed basis shall requirements, including, at minir		co	Deleted: The option for Rations to demonstrate ompliance on an as-fed basis will be revisited during the ext Standard revision.	e
		8.3.1.d.i	The corresponding dry-matter of Ration shall accompany each as		D	Deleted: are Deleted: must	_
		8.3.1.d.ii	A written rationale for why comestablished on an as-fed basis.				
	8.3.1.e	Rations co	ompliant on a dry-matter basis ha ents.	ave no additional reporting			
Feed grown fr shall demonst	trate com	mercially pu pliance thro	rchased seed and commercially pough the evaluation of, at minim of Testable High-Risk Major Inpu	um, the Major Inputs to the	Deleted:	must	_
8.4.1		-	rming operations in which good irry, ground meat, egg mixtures)	-			
	compos farms, v	ite sample o	for certified organic operations state of the High-Risk feed Inputs from ention of identifying and address	a representative selection of ing any contamination		eted: must	
			cipant's operation. Farms <u>shall</u> be density and selection requireme		< >	eted: to	<u> </u>
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Such sampling and testing <u>shall</u> be representative of a Participant's operations in a Region.

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8.4.1.a Regions

Regions shall be designed such that farms within a Region are relatively similar and source their feed from the same or similar location(s). In order to inform the design of Regions, Participants shall supply the TA with:

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- Farm locations
- · Feed mill locations
- · List of feed mills serving each farm
- Processing facility locations
- Proposed Regions

This basic documentation shall be accompanied by a global rationale for what factors are considered in creating the different Regions, how the consideration of these factors leads to variation within the Participant's operation being captured among Regions, and how farms within a Region are more alike than different.

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8.4.1.b Quarterly Sampling Density and Selection

The number of farms within a Region determines the number of farms to be sampled. Fractions of farms are rounded up to the next whole number. Should a farm be chosen for sampling and testing and not have any Major High-Risk Inputs to sample and test onsite, another farm shall be chosen at random from within that same Region.

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Table 8-3 Quarterly Sampling Density and Selection

Number of Farms per Region Number of Farms to be Sampled and Tested	
Fewer than 10	Minimum of one farm tested per Region per quarter
10 to 20	Minimum of two farms tested per Region per quarter
21 to 50	10% of farms tested per Region per quarter
51 to 100	5% of farms tested per Region per quarter
Greater than 100	Minimum of six farms tested per Region per quarter

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The sampling plan within each Region shall include a random selection of farms each quarter. Annual sampling plans shall be reviewed with the TA and may be adjusted over time to provide the most technically sound basis for continuous improvement.

Farms should retain a portion of each sample until test results come back compliant in case re-testing is necessary or a sample tests above the Action Threshold and the Participant shall seek the cause of

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contamination.

8.4.1.c Ration Reporting within the Regional Model

All farms in the Participant's supply chain shall be prepared to supply full Rations to TAs. Full Ration reporting may include all Rations fed annually from every farm that is part of the Participant's operation or, at minimum, shall include the full Rations from the previous quarter and any additional Major High-Risk Inputs to the current Rations, if not captured in the previous quarter's Rations, of each farm randomly selected for sampling and testing by the TA. The Major High-Risk Inputs to the Rations shall be evaluated and found compliant.

8.4.1.d Testing within the Regional Model

Testing shall comply with Section 6.3.3. Composite samples shall be tested on a quarterly basis. When multiple tests are needed within a single Region, the results may be averaged within that Region.

Averaging of test results across more than one Region shall not be permitted. Quarterly results or averages in excess of the Action Threshold will trigger an assessment of the cause of contamination and appropriate steps to eliminate identified sources of contamination.

Upon renewal, Participants <u>shall</u> provide a report of any significant changes in the frequency of GMO presence in feed inputs, the percentage of samples exceeding the Action Threshold, and steps taken to secure feed that tests at or below the Action Threshold.

8.4.2 Certified organic farming operations in which goods are not pooled (e.g., shell eggs, cut meat) and conventional farming operations

The sampling and testing plan for certified organic farming operations in which goods are not pooled and conventional farming operations may include either of the following:

- 8.4.2.a Sampling of every incoming lot of Testable High-Risk Major Input, testing each sample in compliance with Section 6.4 or Section 6.5 by each farmer in the Participant's operations, and quarterly averaging of results to comply with the Action Threshold
- **8.4.2.b** Sampling of every incoming lot of Testable High-Risk Major Input, compositing of samples, and quarterly testing of composite samples by each farmer in the Participant's operations in compliance with Section 6.2.2

8.4.3 Group Compliance Model

Large certified organic farming operations where goods are pooled, large certified organic farming operations where goods are not pooled, and large conventional farming operations where goods are either pooled or not pooled, may demonstrate compliance with the Standard through a group compliance

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		compliance model <u>shall</u> include an Internal Control System		Deleted: must
(ICS). Al	I componer	nts of the ICS are subject to final <u>determination</u> by the TA. At a		Deleted: approval
minimu	m, the ICS 💈	<u>hall</u> include:		Deleted: must
8.4.3.a		defined scope outlining the ICS management structure, personnel, titles, roles, contact information, and conflict of olicy.		
8.4.3.b	overseen locations which fari Parallel Pr	f farms, facilities, and/or operations within the group being (i.e., group members), locations of all farms in the operation, of all feed mills, identification of which feed mills service ms, locations of all processing facilities, locations where rocessing is taking place, and the group member(s) le for testing.		
8.4.3.c		plan for ICS personnel, including how ICS personnel educate p members.		
	8.4.3.c.i	Each member of the group shall have, and acknowledge access to, a copy of the most recent Standard version.		Deleted: must
	8.4.3.c.ii	Each member of the group shall have, and acknowledge access to, any relevant documents such as standard operating procedures (SOPs) and sampling and testing plans.		Deleted: must
8.4.3.d	relevant S Ration for	hensive plan for how each group member will comply with all standard sections based on the nature of their goods and mulations, including Section 4, Sections 8.2 through 8.8,, and Section 11.		Deleted: Section
	8.4.3.d.i	Frequency of inspection shall be at least once per year by ICS personnel of all farms under the scope of the ICS.		Deleted: must
	8.4.3.d.ii	Third-party inspections shall be conducted annually on 10% of all conventional farms that are Parallel Processing the same Major High-Risk Inputs to Rations. Farms are chosen by the TA.		Deleted: must
	8.4.3.d.iii	The comprehensive plan shall include how the ICS will handle Non-conformities.	 	Deleted: must Deleted: Minor
8.4.3.e	a samplin	certified organic farming operations where goods are pooled, g and testing plan in compliance with <u>Section 8.4.1</u> and <u>6</u> is required for each group member responsible for testing.	_ — — -	Deleted: 8.4.3.d.iv The comprehensive plan must include how the ICS will handle Major Nonconformities
8.4.3.f	For large of	certified organic farming operations where goods are not d for large conventional farming operations where goods are		

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responsible for testing.

pooled or not pooled, a sampling and testing plan in compliance with Section 8.4.2 and Section 8.6 is required for each group member

- **8.4.3.g** Documentation that outlines the frequency with which group members submit test results to the ICS.
- **8.4.3.h** Documentation that outlines how the results will be handled (quarterly averaging) or pass-fail.

8.5 Testing Methodology

The testing method <u>shall</u> yield valid results for all Testable High-Risk Inputs. Immunological testing methods may be used when compliant with <u>Section 6.5</u>. Molecular testing methods compliant with <u>Section 6.4 shall</u> be used when immunological testing methods cannot be used and may be used in all cases in lieu of immunological testing methods.

8.6 Feed Compliance Through Compliant Seed

Under certain circumstances, compliance of livestock and poultry feed may be demonstrated based on use of compliant seed; in such cases post-harvest feed testing is not required. Neither seed compliant under Section 8.6.1, Section 8.6.2, or Section 8.6.3 is eligible for verification.

- 8.6.1 Farmer-saved seed and seed purchased from any neighboring farmer who does not have a retail seed operation shall be tested annually. Frequency of testing should increase if there are any changes that would significantly increase the likelihood of contamination. Testing may be conducted in compliance with either Section 6.4 or Section 6.5. If testing is conducted in compliance with Section 6.5, and the immunoassay is positive for any event, samples shall be re-tested with molecular testing methods per Section 6.4 to demonstrate compliance with the 0.25% Action Threshold. If the sample tests above the Action Threshold, it shall not be planted.
- **8.6.2** Freshly harvested and direct-fed forage, as well as silage and similarly fermented feed. When post-harvest testing of freshly harvested and direct-fed forage and/or silage and similarly fermented feed is feasible, sampling shall comply with Section 6.2, testing shall comply with Section 6.3, and test results shall comply with either Section 6.4 or Section 6.5. When post-harvest testing is not feasible because compliance cannot be established with one or more of Sections 6.2 through 6.5, these feed Inputs may demonstrate compliance through seed testing, Affidavit, or use of Verified seed. In all cases, the grower shall demonstrate traceability from the planted field to the harvested feed crop.
 - **8.6.2.a** When test results are available, each lot of seed planted <u>shall</u> be compliant with Section 6 and test at or below the Action Threshold.
 - 8.6.2.b When test results are not available, each lot of seed planted shall have a seed tag, an Affidavit from the seed supplier establishing that the seed is Non-GMO, an invoice, and an Affidavit from the grower confirming planting location.
 - **8.6.2.c** When Verified seed is planted, each lot of seed shall have the seed supplier seed tag, an invoice, and an Affidavit from the grower

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confirming planting location.

8.6.3 Alfalfa hay grown onsite and fed to resident animals may demonstrate compliance by using Verified seed, where each lot of seed is accompanied by a seed supplier seed tag, an invoice, and an Affidavit that includes confirmation of planting locations.

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8.7 Feed Mills

- **8.7.1** Rations formulated by feed mills may be found compliant if:
 - **8.7.1.a** Every lot of Testable High-Risk Major Input to the Ration complies with Section 6.
 - **8.7.1.b** Every lot of Non-Testable High-Risk Major Input to the Ration complies with Section 7.
- **8.7.2** Or, feed sold by feed mills may be found compliant if:
 - **8.7.2.a** Every incoming lot of Testable High-Risk crop destined for the Non-GMO supply chain, regardless of future Weight Percentage in the on-farm Ration, complies with <u>Section 6</u>.
 - **8.7.2.b** Every incoming lot of Non-Testable High-Risk crop destined for the Non-GMO supply chain, regardless of future Weight Percentage in the on-farm Ration, complies with Section 7.
 - **8.7.2.c** The Non-GMO integrity of every Testable and Non-Testable High-Risk crop compliant with <u>Section 8.7.2.a</u> and <u>Section 8.7.2.b</u> is maintained through compliance with <u>Section 4</u>.

8.8 Onsite Farm and Feed Mill Inspections

- **8.8.1** All farms and feed mills may be subject to annual inspections at the discretion of the TA.
- **8.8.2** Unless the TA finds cause for inspection, inspections may not be required for:
 - **8.8.2.a** Certified organic farming operations in which goods are pooled or not pooled during final processing
 - **8.8.2.b** Conventional farming operations that are not Parallel Processing the same Major High-Risk Input to a Ration
 - **8.8.2.c** Feed mills that are not Participants
- **8.8.3** At the TA's discretion, unannounced inspections may be used to ensure compliance with the Standard.
- **8.8.4** Large conventional farming operations that are compliant with Section 8.4.3 shall have 10% of all farms that are Parallel Processing the same Major High-Risk Inputs to Rations inspected by a third party on an annual basis. Farms shall be chosen by the TA.

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9 Special Requirements for Specific Products, Ingredients, and Inputs

The following requirements are intended to complement other sections of the Standard. Where specific topics are addressed below (e.g., sampling, testing), these requirements are authoritative. Where special requirements are not given, requirements from elsewhere in the Standard apply.

9.1		icu	

Honey and other goods derived from apiculture shall meet the following requirements:

- 9.1.1 The bees' forage area (defined as the area within a 4-mile radius of the hives) shall be sufficiently free of GM commercial agriculture.
- **9.1.2** Any supplemental bee feed <u>shall</u> be evaluated for compliance with <u>Section 3</u>.
- **9.1.3** Certified organic honey and other Inputs or Ingredients derived from certified organic apiculture may be deemed compliant with the Standard based on a signed Affidavit from the organic certifier. The Affidavit shall:
 - **9.1.3.a** Meet all requirements of Section 7.
 - 9.1.3.b Attest that the organic certifier has confirmed that the apiary is adhering to the Organic Apiculture Standard as formally recommended by the National Organic Standards Board (NOSB) to the National Organic Program (NOP).⁹¹¹

9.2 Beer, Wine, and Liquor

- **9.2.1** Fermentation Microorganisms used in the production of beer, wine, and liquor Products, Ingredients, and Inputs are not considered Processing Aids under the Standard, are ineligible for <u>Section 3.1.3.b</u>, and <u>shall</u> be Non-GMO.
- **9.2.2** Processing Aids used in the production of beer, wine, and liquor are subject to the compliance requirements in <u>Section 2.2.2</u>.
- 9.2.3 Inputs to the fermentation media for beer, wine, and liquor Products, Ingredients, and Inputs are classified according to their Weight Percentage as represented in the finished Product, Risk Status, and Testability and shall be compliant with the appropriate compliance pathways.
- **9.2.4** Beer, wine, and liquor Products will be held to the same level of evaluation as Products with Ingredient panels.

9.3 Microorganisms

9.3.1 When Microorganisms or Inputs or Ingredients derived from Microorganisms are Major or Minor Ingredients, both the Microorganism and the Growth Media are within the scope of <u>evaluation</u> and <u>shall</u> be compliant.

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¹¹ NOSB. 2010. Formal Recommendation by the National Organic Standards Board (NOSB) to the National Organic Program (NOP), Subject: Apiculture Recommendation. October 28, 2010.

- **9.3.1.a** A standardized Non-Testable High-Risk Affidavit in compliance with Section 7.2 is required.
- 9.3.2 Inputs to Growth Media <u>shall</u> be categorized into Major, Minor, and Micro Ingredients based on their representative Weight Percentage in the finished Product and be compliant according to the appropriate compliance pathways.
- 9.3.3 When Microorganisms or Inputs or Ingredients derived from Microorganisms are Micro Ingredients, the Microorganism shall be within the scope of evaluation and the Growth Media shall be excluded from the scope of evaluation.
 - 9.3.3.a A standardized Non-Testable High-Risk Affidavit in compliance with Section 7.2 is required and shall be supplied to the TA at initial verification. Updated standardized Non-Testable High-Risk Affidavits shall be resubmitted to the TA no later than by the third annual renewal and every 3 years thereafter.

9.4 Mushrooms

- 9.4.1 When mushrooms are Major or Minor Inputs or Ingredients, both the mushroom and the cultivation substrate shall be within the scope of evaluation.
 - 9.4.1.a Mushroom cultivation substrates may be excluded from the scope of evaluation by confirming that the Inputs have undergone a composting process in which they become Compost.
 - 9.4.1.b Mushroom cultivation substrates that are not Compost shall be evaluated by assessing the Inputs based on their Weight Percentage within the substrate, Risk Status, and Testability.
- 9.4.2 When mushrooms are Micro Inputs or Ingredients, the mushroom shall be within the scope of evaluation, and the cultivation substrate shall be excluded from the scope of evaluation.

9.5 Probiotics

- 9.5.1 When Probiotics or Inputs or Ingredients derived from Probiotics are Major, Minor, or Micro Ingredients, the Probiotics shall be within the scope of evaluation and shall be compliant. The Growth Media for Probiotics as Inputs and Ingredients shall be excluded from the scope of evaluation.
 - 9.5.1.a A standardized Non-Testable High-Risk Affidavit in compliance with Section 7.2 is required.

9.6 Saltwater and Freshwater Aquatic Animals

9.6.1 Farm-raised <u>saltwater and freshwater aquatic animals</u> (in captivity from egg to harvest and/or where nutrient additions are provided) <u>shall</u> be evaluated as High Risk and <u>shall</u> require the evaluation and compliance of Ration Inputs.

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	aquatic animals shall be evaluated in the same manner as livestock- and poultry-	€	Deleted: Products, Ingredients, and
	derived Inputs and Ingredients in Section 3 and Section 8.		Deleted: seafood
	9.6.3 The feed of saltwater and freshwater aquatic animals may be compliant under		Deleted: will
	Section 7.5 if the Affidavit establishes that the organism was caught in the wild.	``.	Deleted: Products, Ingredients, and
			Deleted: 9.5.3
<u>9.7</u>	Vitamins and Supplements	`	Deleted: seafood
	<u>9.7.1</u> The Growth Media for Microorganisms from which Enzyme Inputs and		Deleted: 9.6
	Ingredients to vitamin and supplement Products are derived shall be excluded		Deleted: 9.6.1
	from the scope of evaluation,	17-	Deleted: , are
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10.1	Specifications for Obtaining Inputs and Ingredients		Deleted: The availability of this exemption will be revisited during the next Standard revision.
	10.1.1 Major and Minor Inputs and Ingredients shall be sourced from Non-GMO	•	Deleted: must
	sources. Micro Inputs and Ingredients should be sourced from Non-GMO sources.	/	Deleted: 10.1.2 For Products verified under the PVP, Participants cannot knowingly plant, purchase, or use Inputs or Ingredients that are not compliant with the Standard.
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	10.1.2 Verified Inputs and Ingredients shall meet the requirements for Risk Status and	/	Deleted: must
	<u>Testability prior to procurement and may be used at any Weight Percentage, subject to the criteria outlined in Table 3-2.</u>	//	Deleted: 10.1.4 When spot purchasing is necessary, unverified Inputs and Ingredients should be avoided;
	10.1.3 The written specifications for all Products, Ingredients, and Inputs shall include requirements regarding Standard compliance and shall be updated if the		Participants must seek out Verified-Status Inputs and Ingredients of appropriate scope. If a spot purchase of unverified Input or Ingredient is made, the Participant must:
	Participant changes suppliers, Inputs, or Ingredients.		Deleted: 10.1.4.a Justify to the TA why a Verified-Status Input or Ingredient was not used ¶ 10.1.4.b Provide evidence that any Testable High-Risk Input or Ingredient that is spot purchased has been tested in accordance with the requirements of the Standard and that the test results are at or below the relevant Action Threshold ¶ 10.1.4.c Demonstrate that all Non-Testable High-R [7
40.0			Deleted: 10.1.5 Constraints on spot purchasing ma [8]
10.2	Labeling		Deleted: Wholesale and retail Products must comply [9]
	10.2.1 Products shall be labeled in compliance with The Non-GMO Project Program	Ζ΄,	Deleted: 10.2.2 The TA will review labels to assess [10]
	Rules and Procedures and The Non-GMO Project Trademark Use Guide.	1	Deleted: 10.2.3
	v.	11/	Deleted: must
	10.2.2 Labeling claims shall be accurate, truthful, and not mislead the consumer about	11	Deleted: Any reference to the Non-GMO Project or [11]
	the GMO content of the Product. One-hundred percent GMO absence claims are		Deleted: not acceptable
	<u>unacceptable</u> and include, but are not limited to, "contains zero GMOs," "GMO-		Deleted: No other non-GMO certifications may be [12]
	free," and "GE-free."		Deleted: 10.2.4
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	<u>10.2.3</u> High-Risk Micro Ingredients other than artificial and natural flavors, that have been Micro exempted under <u>Section 3.1.3.b</u> cannot be listed with the same	£=	Deleted: and Microorganisms
	name, or any other common name, on the PDP of a retail Product.		Deleted: consumer
	<u> </u>		Deleted: 10.2.5
	<u>10.2.4</u> Ingredients other than artificial and natural flavors cannot be named on the PDP	<u> </u>	Deleted: , Enzymes, and Microorganisms
	of a retail Product if one or more of their sub-Ingredients (as they appear in a		Deleted: consumer

October 1, 2025

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<u>9.6.2</u> Jnputs and Ingredients derived from farm-raised saltwater and freshwater

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parenthetical Ingredient declaration or supplement facts panel) have been Micro exempted under <u>Section 3.1.3.b</u> and the Micro-exempted sub-Ingredient(s) is/are considered to reasonably characterize the Ingredient appearing on the PDP.

11 Quality Assurance

11.1 Total Quality Management Systems

- **11.1.1** The Participant's quality assurance and quality control program, including SOPs, forms, and documents, shall be revised as needed to ensure compliance with the Standard, and revisions shall be documented.
- **11.1.2** Compliance with applicable requirements of the Standard shall be identified as key quality indicators of the Participant's total quality system.
- **11.1.3** The Participant <u>shall</u> monitor and control the compliance of Inputs and Ingredients purchased and finished Products, and this <u>shall</u> be documented.
- 11.1.4 Where needed, additional training <u>shall</u> be provided to relevant staff to ensure that SOPs in support of Standard compliance are followed, and training <u>shall</u> be documented.
- **11.1.5** All SOPs, documents, forms, and specifications needed by personnel to fulfill the requirements of the Standard shall be readily available to relevant personnel.
- **11.1.6** Records shall be retained for a minimum of 3 years.

11.2 Non-conformities and Corrective and Preventive Actions

- 11.2.1 Products shall comply with the Non-conformity and corrective and preventive action requirements outlined in The Non-GMO Project Program Rules and Procedures.
- 11.2.2 Changes from approved processes, procedures, Inputs, Ingredients, or Products, that could impact compliance with any aspect of the Standard, shall be deemed Non-conformities and shall trigger corrective and preventive actions.

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and Preventive Action Requirements

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must be achieved prior to initial verification.

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Deleted: 11.2.1.e Identification of Non-conformities, corrective and preventive actions, root cause analyses, and successful remediation of the Non-conformity must be documented.¶

11.2.1.f All documentation associated with ongoing application of approved corrective and preventive actions must be made available to the TA upon request.

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Deleted: 11.2.2.a Discovery of any Major Non-conformity must be followed by a timely root-cause analysis and corrective and preventive action plan. "Timely" is typically considered to be within 7 days and rarely longer than 30 days.¶

11.2.2.b Corrective and preventive action plans must include the identification of persons responsible for their execution, defined timelines for actions, and the desired results.

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11.2.2.d The TA will review, and at their discretiq ... [1

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Renewal	\ \ \
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Deleted: 11.2.2.f Any delays in the timeline from completion of corrective and preventive actions must be justified in writing and approved by the TA. ¶ 11.2.2.g Any known Major Non-conformity that goes unreported or uncorrected or keeps recurring according to the requirements in Section 11.2.2 will be cause for the Product or the Participant to be removed from the PVP. ¶ 11.2.2.h Repeated non-conformance with the Action Threshold may require mid-term re-evaluation of the Product.

Deleted: 11.2.3 Minor Non-conformities

Deleted: 11.2.3.a Minor Non-conformities will trigger corrective and preventive actions.

Deleted: 11.2.3.b Minor Non-conformities and corrective and preventive actions must be reviewed, at minimum, at the time of renewal.

Deleted: 11.2.3.c Renewal will be contingent upon appropriate resolution of any such Minor Non-conformity.

Deleted: Renewal evaluation of every Verified Product will be required at least annually.

Deleted: 11.3.2 Renewal evaluation must ensure that, at minimum:

Deleted: 11.3.2.a The Product and all Ingredients and within the scope of review are compliant under the current Standard version.

Deleted: 11.3.2.b All evidence of compliance on file with the TA is current and active.

Deleted: 11.3.2.c All Non-conformities have been addressed.

Deleted: 11.3.3 No changes to the Product or its manufacture or processing that would compromise the Product's compliance with the Standard have occurred.

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Deleted: The TA may require a Participant to submit updates more frequently if history shows a pattern of Major Nonconformities occurring as a result of unannounced changes to the operation. Such changes include, but are not limited to, the following: changes in Product composition that involve High-Risk Inputs or Ingredients; changes in suppliers of High-Risk Inputs or Ingredients; changes in processes or procedures that alter the segregation, cleanout, or traceability of Inputs, Ingredients, or Products; or changes in specifications of High-Risk Inputs, Ingredients, or of a final Product that contains High-Risk Inputs or Ingredients.

11.3

Appendix A –Terms and Definitions

Affidavit – A formal document either created and supplied by the Project or TA, or provided by a Participant, that includes a written and signed statement confirming specific characteristics of a given organism, crop, precursor, Input, Ingredient, system, process, or operation.

Approved Laboratory – A testing laboratory compliant with, and participating in, the Non-GMO Project Approved Laboratory Program.

Biological Compound – A substance produced by or derived from a living organism.

Biotechnology 4012 – the application of:

- a. in vitro nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA)
 and the direct injection of nucleic acid into cells or organelles; or
- fusion of cells beyond the taxonomic family, that overcame natural physiological, reproductive, or recombination barriers and that are not techniques used in traditional breeding and selection.

Certificate of Approval – <u>A document confirming an Approved Laboratory's current status</u> within the Non-GMO Project Approved Laboratory Program.

Certificate of Verification (COV) – An annually renewed document demonstrating compliance with the PVP which includes a signed written agreement with the Project, a signed written agreement with the TA (where applicable), and Product-level compliance with the Standard.

Compost – Decayed organic material used as a fertility amendment in agricultural production that is produced by a combination of actions over time by Microorganisms, invertebrates, temperature, and other elemental factors (e.g., moisture content, aeration). Composted material shows practically no macroscopic indication as to the original substrate(s) from which it was made.

Enzyme – A protein molecule produced by a living organism that acts as a catalyst to bring about a specific biochemical reaction.

Functional Enzyme – An Enzyme that has not been denatured (e.g., by being subjected to high heat, harsh acids or bases, ultrafiltration, or centrifugation) and thus retains its catalytic functioning capability.

Genetically Engineered or Genetic Engineering (GE) – See Genetically Modified or Genetic Modification.

Genetically Modified or Genetic Modification (GM) – A term referring to the result of the application of Biotechnology,

Genetically Modified Organism (GMO) – An organism to which Biotechnology, has been applied and derivatives of such an organism; cloned animals are included within this definition.

Deleted: An annually renewed document confirming a laboratory's compliance with, and participation in, the Non-GMO Project Approved Laboratory Program. It includes the list of High-Risk crops for which the laboratory is approved to test.

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¹² Adapted from Secretariat of the Convention on Biological Diversity (2000). Cartagena Protocol on Biosafety to the Convention on Biological Diversity: text and annexes. Montreal: Secretariat of the Convention on Biological Diversity.

Growth Media – Materials or mixtures of materials designed to support the growth of Microorganisms.

High Risk – Organisms and the Inputs and Ingredients derived from them for which GM counterparts are widely commercially available.

Ingredient – <u>Input that becomes part of a Product during its creation and is present in the final</u> Product in either its original or altered form.

Input – Material used in the production of a Product at any point in the supply chain.

Internal Control System (ICS) – A robust internal oversight structure that functions as the administrative body responsible for maintaining compliance of all members with one or more set(s) of requirements.

Low Risk – Organisms and the Inputs and Ingredients derived from them that are not classified as High Risk.

Matrix – All sample constituents other than the analyte of interest. This encompasses the composition of the sample (single or multi Ingredient) and the state of processing (raw grain vs. flour).

May – A permissive statement under the Standard.

<u>Micro Exemption</u> – A provision allowing specific Micro Ingredients to be included in a Verified Product without demonstrating that they are derived from a Non-GMO source.

Microorganism – A microscopic organism (such as a bacterium, yeast, fungus, or alga).

Must - See Shall

Non-conformity – Any deviation in operations that has not been approved by the TA.

Non-GMO or Non-GM – An organism to which Biotechnology, has not been applied and derivatives of such an organism.

Non-Risk — Inputs and Ingredients that originate entirely outside living systems, with no history of being alive or derived from a living organism. They contain no cells, cellular components, or genetic material and, by their nature, cannot be created, altered, sustained, or used as a platform for Biotechnology.

Non-Risk Category – A <u>designation by the Project for a group of one or more types of wholesale or retail goods that are made solely from Non-Risk Inputs.</u>

Non-Testable – Attribute of having precursors in the supply chain associated with GM events for which no quantifiable molecular testing method is available to distinguish between Non-GM and GM counterparts, or for which the Project does not require testing.

Parallel Processing – The practice of using the same facility for handling both Project-compliant and non-compliant Inputs, Ingredients, and/or Products.

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Deleted: Any material or substance that is a component in the creation of a wholesale or retail consumer good and present in said good in either its original or altered form.

Deleted: Any material or substance that is used in the production of a wholesale or retail consumer good. Not all Inputs are necessarily represented in, or present in, said good.

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Deleted: Major Non-conformity – A deviation that could affect the compliance of an Input or Ingredient with the relevant Action Threshold, such as unintentional contamination of the Ingredient with GM material, or that could impact the compliance of an Input or Ingredient with Section 7.2.

Deleted: Minor Non-conformity — A deviation that could not cause any of the relevant Inputs or Ingredients to the Product to exceed the relevant Action Threshold. This includes immaterial changes to procedures, recordkeeping, documentation, or anything else immaterial that does not have the potential to impact compliance with the relevant Action Threshold.

Deleted: Monitored Risk – Organisms and the Inputs and Ingredients derived from them for which GM counterparts are in the research and development stages, which have been developed but are not widely commercially available, or for which known GM contamination has occurred.

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Deleted: whose formulations involve no Inputs or Ingredients of biological origin.

Deleted: Not having any precursor at any point in the supply chain for which current testing methodologies can distinguish between the Non-GM and GM versions or where publicly commercially available tests do not exist.

Participant – A company that is seeking verification within the PVP and signs a License Agreement with the Project.

Principal Display Panel (PDP)^{±413} – Portion of the package label that is most likely to be seen by the consumer at the time of purchase (often the front face of the packaging).

Probiotics¹⁵¹⁴ – Live Microorganisms that, when administered in adequate amounts, confer a health benefit on the host.

Processing Aid¹⁵ – (a) Substances [Inputs] that are added to a food [Product or Ingredient] during the processing of such food but are removed in some manner from the food before it is packaged in its finished form. (b) Substances [Inputs] that are added to a food [Product or Ingredient] during processing, are converted into constituents normally present in the food, and do not significantly increase the amount of the constituents naturally found in the food. (c) Substances [Inputs] that are added to a food [Product or Ingredient] for their technical or functional effect in the processing but are present in the finished food at insignificant levels and do not have any technical or functional effect in that food.

Producing Facility – Location where Inputs and Ingredients are combined to create the finished Product and/or where bulk Product is packaged for final sale and/or where bulk Product is labeled for final sale.

Product – A unique branded formula and process, where process could be either the manufacturing or facility process.

Program Documents – The Non-GMO Project Standard, The Non-GMO Project Program Rules and Procedures, The Non-GMO Project Trademark License and Program Participation Agreement, and The Non-GMO Project Trademark Use Guide.

Ration – The feedstuffs offered to an animal during a 24-hour period.

Region – A geographic area with relatively homogeneous farm operations and sources of livestock or poultry feed, typically encompassing one or more states, in which farms ship unprocessed livestock or poultry materials to one or a few processors.

Risk Status – The attribute assigned to a material that denotes the likelihood that a material is or is derived from a GMO.

Shall – A requirement under the Standard.

Should or May – A non-mandatory recommendation or recommended practice.

Standard – The Standard for the Non-GMO Project Product Verification Program, which is this document.

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Appendix A – Terms and Definitions

October 1, 2025

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Deleted: "Product" refers to goods enrolled in the PVP

¹³ U.S. Department of Health and Human Services. 2013. A Food Labeling Guide, Guidance for Industry. January, 2013.

¹⁴ Hill, C., Guarner, F., Reid, G. et al. The International Scientific Association for Probiotics and Prebiotics consensus statement on the scope and appropriate use of the term probiotic. Nat Rev Gastroenterol Hepatol 11, 506–514 [online], (2014).

¹⁵ 21 CFR § 101.100 (2018).

Supplier – Any party from whom an Input and/or Ingredient is obtained.

Synthetic Biology – The development of novel, artificial nucleic acid sequences, biological pathways, organisms, or devices or the redesign of existing natural biological systems.

Technical Administrator (TA) – A certification body approved by the Project to assess compliance with the Standard on behalf of the Project.

Testable - Attribute of having precursors in the supply chain associated with GM events, for which at least one molecular testing method is available to quantify GM contamination, and for which the Project requires testing.

Verified _ Confirmed to comply with all applicable requirements of the Standard and all other elements of the Product Verification Program.

Viable Microorganism – A microscopic organism (such as a bacterium, yeast, fungus, or alga) that performs metabolic functions and reproduces/multiplies.

Weight Percentage - The percentage by weight of a material as present in, or represented in, a finished Product after the removal of salt, added water, qualifying Processing Aids, and purified CO_2 .

Deleted: Having one or more precursors at at least one point in the supply chain for which current testing methodologies can distinguish between the Non-GM and GM versions and where publicly commercially available tests exist.

Deleted: A finished Product's status when the TA establishes that the Product is compliant with all applicable requirements of the Standard and has satisfied all other elements of the Product Verification Program. Verified refers to the Product Verification Program as a whole, as opposed to particular requirements.

Deleted: Verified Status - Products that have been Verified under the PVP at wholesale or retail and are purchased for use as Inputs or Ingredients to different Products enrolled in the PVP.

Appendix B – High-Risk List

Organisms, and Products, Ingredients, and Inputs derived from organisms, for which GM versions are widely commercially available; this includes certain crops, their derivatives, and animal-derived materials.

B.1 Testable and Non-Testable High-Risk Inputs and Ingredients

B.1.1 Crops

The following list of Testable and Non-Testable High-Risk crops is exhaustive:

	Testable	Non-Testable
Alfalfa	✓	
Apple		✓
• Canola ¹⁶	~	~
Corn (except popcorn)	~	
• Cotton	~	
Eggplant		~
Papaya	✓	
Pineapple		~
Potato		~
• Soy,	~	<u> </u>
Sugar beets	/	
• Sugarcane		<u>~</u>
Zucchini and yellow summer squash	✓	

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Deleted: ¹⁶Note that this crop is both Testable and Non-Testable and must therefore be compliant with the requirements in both Section 6 and Section 7.¶

¹⁷Animal-derived Products, Ingredients, and Inputs are High-Risk

"Animal-derived Products, Ingredients, and Inputs are High-Risk because their feed Inputs are within the scope of review and may be Testable or Non-Testable High-Risk.¶

be Testable or Non-Testable High-Risk.¶

18-Per Section 8, Section 9.1, and Section 9.5, verification of livestock and poultry, bee, and seafood Products and Major Inputs and Ingredients requires the testing of feed.¶

Ingredients requires the testing of feed.¶

19 Note that Non-Testable Inputs and Ingredients must be compliant with Section 7.¶

B.1.2 Animal-derived Inputs and Ingredients¹⁷

	Testable	Non-Testable
 Meat, dairy, eggs, wool, hides, honey, <u>aquatic animals</u>, and any other materials or substances originating from animals 		
 Livestock and poultry feed¹⁸ 	~	~
Bee forage and feed	~	~
Fish and other aquatic animal feed	/	✓

B.1.3 Microorganism and Enzyme Inputs and Ingredients

		Testable	Non-Testable ¹⁹
•	Algae		~
•	Bacteria		~
•	Enzymes		✓
•	Microbial cultures and starters		~
•	Yeast		~

B.1.4 Ingredients or Substances with Synthetic Biology Counterparts

	Testable	Non-Testable
		✓

Examples of Inputs and Ingredients that could be derived from the High-Risk organisms in Appendix B can be found in the publication <u>High-Risk Inputs: Examples</u>. Inputs and Ingredients that could be derived from High-Risk organisms are High Risk under the Standard and <u>shall</u> be sourced Non-GMO where required.

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Deleted: Appendix C – Monitored-Risk List

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Deleted: C.1 Testable and Non-Testable Monitored-Risk Inputs and Ingredients

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Deleted: Page **42** of **42** March 3, 2025¶ Appendix C – Monitored-Risk List