Summary of Changes from Version 14.3 of the Standard

Summary of Changes from v14.3 to v15 Published July 26, 2019

The redline below identifies changes made from Version 14.3 (v14.3) to Version 15 (v15) of the Standard. This redline is not the Standard and must not be used to evaluate Products, Ingredients, or Inputs for verification. Should text in this document not exactly match that present in either v14.3 or v15, text published in v15 always takes precedence.

Non-GMO Project Standard

Biennial public comment periods on the Non-GMO Project Standard in its entirety are held for 60 days beginning in April of even years (e.g., ~~2018,~~ 2020, 2022). Comments may be submitted online during the public comment period at https://www.nongmoproject.org/product-verification/the-standard/.
Comments may be sent at any time to standard@nongmoproject.org.

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~~I.~~1 Introduction

The Non-GMO Project is a nonprofit organization ~~committed~~whose mission is to preserv~~inge~~ and build~~ing~~ sources of ~~n~~Non-GMO products, educat~~inge~~ consumers, and provid~~inge~~ verified ~~n~~Non-GMO choices.

In support of our mission, the Non-GMO Project offers a Product Verification Program (PVP) whereby Participants may enroll wholesale goods and retail consumer goods as Products for evaluation against, and determination of compliance with, the Non-GMO Project Standard. The PVP also includes a written agreement between the Participant and the Non-GMO Project, and where applicable, a written agreement between the Participant and one or more Technical Administrators (TAs). If all elements of the PVP are satisfied, including meeting the compliance requirements set forth by the Non-GMO Project Standard, goods 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 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.

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 this Standard. Terms defined in Appendix A and used in this Standard are ~~defined in Appendix A~~capitalized throughout. Requirements listed under headers titled "Global Requirements" apply to the entirety of the section in which they appear (e.g., v15 Section 4.2, Global Chain of Custody Requirements, applies to all of v15 Section 4).

~~A.~~1.1 Purpose

~~The Non-GMO Project's Standard requires that all verified products have systems in place for:~~

~~1. **Testing:** Meaningful, ongoing testing of high-GMO-risk inputs~~

~~2. **Traceability:** Supply chain traceability, especially following input testing~~

~~3. **Segregation:** Protecting compliant inputs from commingling with non-compliant inputs~~

~~4. **Formulation:** Obtaining inputs in accordance with uniform and meaningful specifications~~

~~5. **Labeling:** Accurate and clear product labeling~~

~~6. **Quality assurance:** Maintaining operational consistency and addressing nonconformities promptly~~

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.

Commented [A1]: v14.3 Section I. was renumbered to v15 Section 1. Four additional paragraphs were added to give context around the three elements of the Product Verification Program, inform readers of the surveillance and auditing programs, and to explain the overall structure of the Standard.

Commented [A2]: v14.3 Section I.A. was renumbered to v15 Section 1.1. The v14.3 purpose statements (v14.3 Section I.A.1. through v14.3 Section I.A.6.) were moved to v15 Section 1.2. A new statement was added to more accurately represent the purpose of the Standard.

~~B.~~1.2 Methodology and Approach

~~1.~~ The ~~Non-GMO~~ Project's PVP ~~Product Verification Program ("Program")~~ is based on a practice and ~~/~~process-oriented Standard that uses both testing and Affidavits as ~~a~~ key strategic tools to confirm that practices and ~~/~~processes meet expectations.

~~2. A core goal of the Project is to identify, create, and/or maintain sources and practices that effectively minimize GMO risk to the supply chain.~~

~~**3. Verification of products shall be contingent on products meeting requirements regarding Non-GMO Project Standard compliance, including traceability, segregation, and testing.**~~

~~4.~~ Continuous improvement on the part of ~~Program~~ Participants is required with the common goal of ~~completely~~ eliminating any ~~GMO risk~~ ~~i~~Inputs ~~from~~and Ingredients derived from Genetically Modified Organisms (GMOs) from their supply chains ~~the production chain~~.

A Product is a unique branded formula and process, where process could be either the manufacturing or facility process. "Product" refers to wholesale goods and retail consumer goods that are enrolled in the PVP.

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 reviewed for compliance with the Segregation, Cleanout, Traceability, and Quality Assurance requirements outlined in this Standard. Products must comply, on an ongoing basis, with the Labeling requirements outlined in this Standard and cannot carry competing claims or 100% GMO absence claims. Before using the Trademark in connection with any Products, Participants will be required to sign a written agreement with the Project.

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

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

~~The Non-GMO Project's Standard requires that~~In summary, all Project ~~v~~Verified ~~p~~Products must have systems in place for:

Commented [A3]: v14.3 Section I.B. was renumbered to v15 Section 1.2. v14.3 Section I.B.1. was retained as part of the first paragraph, v14.3 Section I.B.4. was retained as part of the second paragraph, and v14.3 Section I.B.2. and v14.3 Section I.B.3. were both struck from v15. Additional narrative was added to give context around the way Products are evaluated under the Product Verification Program (PVP). The v14.3 Section 1.2 purpose statement was moved to the end of v15 Section 1.2.

Commented [A4]: The note at the end of v14.3 Section II.B.1. was moved to the last paragraph of v15 Section 1.2.

Commented [A5]: The first line under v14.3 Section I.A. was moved to the end of v15 Section 1.2.

- ~~5.~~ **~~Labeling~~:** Accurate and clear ~~p~~Product labeling
- ~~6.~~ **~~Quality assurance~~:** Maintaining operational consistency and addressing ~~n~~Non-conformities promptly
- ~~4.~~ **~~Formulation~~Procurement:** Obtaining ~~i~~Inputs **and Ingredients** in accordance with uniform and meaningful specifications
- ~~1.~~ **~~Testing~~:** Meaningful, ongoing testing of Major ~~h~~High-Risk ~~GMO risk~~ ~~i~~Inputs and Ingredients
- ~~3.~~ **~~Segregation~~ and Cleanout:** Protecting compliant ~~i~~Inputs and Ingredients from commingling with non-compliant materials~~inputs~~
- ~~2.~~ **~~Traceability~~:** Supply chain traceability, especially following ~~i~~Input and Ingredient testing or the establishment of a compliant Affidavit

~~II.~~2 Scope of Product Verification Program

The scope of the ~~Non-GMO Project~~ Standard and the PVP~~Program~~ encompasses the following Product~~products~~ categories, including their ~~i~~Inputs, Ingredients, and associated activities.

~~A.~~2.1 Product Categories

~~1.~~2.1.1 The following types of ~~products may be verified if found to be compliant with this Standard~~wholesale or retail goods are eligible for verification:

~~a.~~2.1.1.a Seed and ~~other~~vegetative propagation materials

~~b.~~2.1.1.b ~~Products~~Wholesale or retail goods for human or pet use that are either ingested or topically applied ~~directly to skin, such as human food, ingredients, supplements, and personal care products, including lotions, soaps, balms, makeup, etc.~~

~~c.~~2.1.1.b.i Over-the-counter (OTC) drugs~~, including~~ and homeopathic remedies

2.1.1.c Wholesale or retail goods for human or pet use that are not ingested or topically applied

~~d.~~2.1.1.d Livestock, poultry, bee, and seafood feed and supplements

~~e. Products that are not ingested or applied directly to skin, such as packaging, cleaning products, and textiles~~

~~f. Pet food~~

~~2.~~2.1.2 The following types of ~~products may not be verified under this Standard~~goods are ineligible for verification:

~~a.~~2.1.2.a ~~Products that include c~~Controlled substances under U.S. or Canadian law and all other prohibited Inputs and Ingredients listed under Section 2.2.3

~~b.~~2.1.2.b ~~Products~~Goods that are not sold in the U.S. or Canada

~~c.~~2.1.2.c Certain medicines and other medical ~~products~~goods

Commented [A6]: v14.3 Section II. was renumbered to v15 Section 2. "Product Verification Program" was added to the title of this section to clarify the meaning of "Scope."

Commented [A7]: v14.3 Section II.A. was renumbered to v15 Section 2.1. v15 Section 2.1 lists the types of goods that are eligible for verification under the PVP and the types of goods that are not eligible for verification under the PVP. Product categories were condensed. v14.3 Section II.A.1.f. was added to both v14.3 Section II.A.1.b and v14.3 Section II.A.1.e. and "poultry, bee, and seafood" was added to livestock feed and supplements (v14.3 Section II.A.1.d). All examples were struck.

Commented [A8]: v14.3 Section II.A.2. was renumbered to v15 Section 2.1.2.

Commented [A9]: v14.3 Section II.A.2.a. was renumbered to v15 Section 2.1.2.a. This section was expanded to include all substances prohibited for use under the Standard.

~~d.~~2.1.2.d Live animals

2.1.2.e Synthetic pesticides

~~e.~~2.1.2.f ~~Products~~Goods composed entirely of ~~n~~Non-~~r~~Risk ~~i~~Inputs and Ingredients and that are part of a ~~n~~Non-~~r~~Risk ~~c~~Category

2.1.2.f.i Non-Risk Categories include, but are not limited to, unflavored still beverages, unflavored carbonated beverages, and unflavored electrolyte beverages

~~B.~~2.2 Input and Ingredient Evaluation

~~1.~~2.2.1 **Mandatory ~~i~~Input ~~categories (input~~and Ingredient categories** (Input and Ingredient categories to Product formulations that must be evaluated and found compliant):

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

2.2.1.b All ~~i~~Inputs and Ingredients represented in, or present in, the Product formulation from the following categories must comply with the requirements of this Standard in order for the finished ~~p~~Product to be ~~v~~Verified.

~~a. Inputs present in the finished product, including but not limited to:~~

~~i.~~2.2.1.b.i Unprocessed raw agricultural ~~inputs,~~materials such as vegetables, grains, fruit, greens, herbs, other fresh foods, fibers~~, etc.~~

~~ii.~~2.2.1.b.ii Manufacturing ~~i~~Inputs and Ingredients, including flavorings, seasonings, colorings, additives, and all other substances present in final, manufactured ~~p~~Products

~~iii.~~2.2.1.b.iii Animal~~-derived inputs,~~ derivatives including dairy, meat, eggs, ~~bee-produced inputs,~~ wool, and hides~~, and~~ ; derivatives of apiculture including, but not limited to, honey and beeswax; derivatives of seafood ~~or inputs derived from aquaculture~~[1]

~~iv.~~2.2.1.b.iv Processed agricultural ~~i~~Inputs ~~or~~and ~~i~~Ingredients

~~v. Manufactured or processed food inputs or ingredients~~

Commented [A10]: "Synthetic Pesticides" was added to the list of Products ineligible for verification under v15 Section 2.1.2.e.

Commented [A11]: v14.3 Section II.A.2.e. was renumbered to v15 Section 2.1.2.f. The difference between a Non-Risk Category and a Non-Risk Input/Ingredient was clarified with the addition of language listing currently recognized Non-Risk Categories.

Commented [A12]: v14.3 Section II.B.1. was renumbered to v15 Section 2.2.2. Language was altered to clarify existing requirements.

Commented [A13]: v14.3 Footnote 1 was moved to v15 Section 2.2.3.d.

Commented [A14]: v14.3 Section II.B.1.a.v. was deleted.

[1] ~~Cloned animals and their progeny are not allowed.~~

~~vi.~~**2.2.1.b.v** Packaging that is directly immersed in or combined with liquid for the purpose of making the ~~p~~Product available for human consumption[2] ~~This includes, but is not limited to,~~ including tea, coffee, spice, and soup bags but not including any part of the packaging other than the bag

~~vii. Livestock feed components, such as grains, vitamins, enzymes minerals, etc.~~

2.2.1.b.vi Rations and supplemental feed for livestock, poultry, bees, seafood, and other animals

~~viii.~~**2.2.1.c** Other ~~i~~Inputs and Ingredients used in personal care and cosmetic ~~p~~Products, and textiles

~~b.~~**2.2.1.d** Dietary supplements, vitamins, and herbal preparations

~~c.~~**2.2.1.e** Microorganisms, Enzymes, and Growth Media ~~Microbial starters and enzymes, media, and derivatives, including those used for livestock feed (e.g., silage or hay inoculants, fermentation solids, or similar products) or human food~~

2.2.1.f Processing Aids present in the finished Product at 0.5% or more

2.2.1.g Processing Aids listed on the Ingredient panel of a retail consumer good, or Input/Ingredient disclosure documentation of a wholesale good

~~***Note: Addressing contamination of seed is a stated priority of the Non-GMO Project. Although traceability back to tested seed is not required for product verification, the Project is actively developing sources of compliant seed as the basis for a sustainable non-GMO supply chain.***~~

~~2. **Eligible input categories (input categories for optional evaluation):**~~

~~In addition to the finished product, Participants may choose to verify inputs in the following categories in order to market them with reference to the Non-GMO Project verification mark or name. Verification of inputs listed in this Section II.B.2. is not required in order for a product to be verified. In order for the following inputs themselves to be marketed with reference to the Non-GMO Project verification mark or name, they must meet all of the relevant requirements of this Standard. Such inputs may then be marketed as the product itself (e.g., selling Non-GMO Project Verified packaging materials to a final consumer or product manufacturer) or denoted as part of another product (e.g., "This product's packaging is Non-GMO Project Verified."). When the product itself, as opposed to an input to another product, the inputs below must be verified in accordance with this Standard and are not optional.~~

~~a. Seeds~~

~~b. Other agricultural inputs, such as fertilizers, pesticides, and herbicides~~

Commented [A15]: v14.3 Footnote 2 was moved to v15 Section 2.2.1.b.v.

Commented [A16]: The note at the end of v14.3 Section II.B.1. was moved to the last paragraph of v15 Section 1.2.

Commented [A17]: v14.3 Section II.B.2. was deleted.

~~[2] This includes, but is not limited to, tea, coffee, spice, and soup bags but does not include any part of the packaging other than the bag.~~

~~The scope of this Standard contains an exclusion for composted materials and animal manures. These may be used from any source, *except* manure from animals that have been genetically engineered. An example of an animal engineered to produce a novel material would be a goat that is genetically engineered to have antibiotics or hormones secreted in its milk. Examples of non-compliant fertilizers are oilcake/oilseed meal from genetically engineered soybeans, canola, or cotton, un-composted GMO cornstalks, etc. An example of a non-compliant pesticide is genetically altered *Bacillus thuringiensis* (Bt). An example of a non-compliant herbicide is corn gluten from genetically engineered corn.~~

~~c. Cleaning products~~

~~d. Packaging materials~~

~~e. Veterinary inputs such as vaccines, hormones, and medicines; *not* including recombinant bovine growth hormone (rBGH) and recombinant bovine somatotropin (rBST), which are prohibited inputs~~

~~3.~~2.2.2 **Input and Ingredient categories that are out of scope~~:~~ of the Standard** (Input and Ingredient 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 this Standard.)

~~a.~~2.2.2.a Processing Aids used in the manufacture or processing of a finished ~~p~~Product, ~~i~~Ingredient, or ~~i~~Input ~~shall be~~are out of the scope of review if present in the finished ~~p~~Product at less than 0.5% and not declared on the retail ~~i~~Ingredient panel or the ~~i~~Input/Ingredient disclosure documentation of a wholesale ~~p~~Product. For the purposes of this Standard, fermentation ~~m~~Microorganisms are not considered to be Processing Aids. See Section 9.3 for the evaluation of and compliance requirements for Microorganisms.

~~b.~~2.2.2.b Purified ~~C~~carbon ~~D~~dioxide (CO_2) from either biological or non-biological sources

2.2.2.c Fully composted materials and animal manures not sourced from Genetically Modified (GM) animals

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)

2.2.3.c Recombinant bovine somatotropin (rBST)

2.2.3.d GM animals including those that are cloned, their progeny, and their derivatives

2.2.3.d.i GM Salmon and their derivatives

2.2.3.e Manure sourced from GM animals

2.2.3.f Synthetic Biology and its derivatives

Commented [A18]: v15 Section 2.2.3 was created to combine all Inputs and Ingredients that are prohibited for use under the Standard into a single section.

Commented [A19]: Language from v14.3 Section II.B.2.e. prohibiting the use of recombinant bovine growth hormone (rBGH) was moved to v15 Section 2.2.3.b.

Commented [A20]: Language from v14.3 Section II.B.2.e. prohibiting the use of recombinant bovine somatotropin (rBST) was moved to v15 Section 2.2.3.c.

Commented [A21]: v14.3 Footnote 1 was renumbered as v15 Section 2.2.3.d.

Commented [A22]: Language from v14.3 Section II.B.2.b. was added to prohibit the use of manure sourced from GM animals.

Commented [A23]: v14.3 Section II.D.3.a.ii.c) was moved to v15 Section 2.2.3.f. Synthetic Biology and its derivatives are prohibited for use as Inputs or Ingredients to Products regardless of presence on a retail Ingredient panel or, for Products without retail labeling, presence on a wholesale Input/Ingredient disclosure.

~~C. Activities~~

~~The scope of the evaluation encompasses the following types of activities and sectors of food and related production systems. When relevant to the verification of the product, the following activities are subject to review and must be found compliant with the Standard (Table 1).~~

~~Table 1. Activities~~

~~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 chain of custody from seed to consumer, except for products enclosed in final retail packaging.~~
~~Storage~~	~~Includes all links in the chain of custody 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 to make the final product.~~
~~Packaging and labeling~~	~~Includes any and all events where the package or labeling of goods is altered.~~

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~~D.~~3 Input and Ingredient Classification

Each Input and ~~i~~Ingredient must be classified in accordance with this Section 3~~Section II.D.~~ and meet all applicable requirements under this Standard to be included in a ~~v~~Verified P~~p~~roduct.

3.1 Weight Percentage

All Inputs and ~~i~~Ingredients[3] must be classified according to their ~~w~~Weight ~~p~~Percentage~~s~~ as represented in, or as present in, the finished ~~p~~Product, not counting the weight of salt or added water present in the finished ~~p~~Product. Excluded from the ~~w~~Weight Percentage calculation are: 1) Processing Aids present in the finished ~~p~~Product at less than 0.5% and not declared on the retail ~~i~~Ingredient panel or the ~~i~~Input/Ingredient disclosure documentation of a wholesale ~~p~~Product, and 2) purified ~~Carbon Dioxide (CO_2).~~

For livestock, poultry, bee, and seafood feed other than pet food, the Weight Percentage categories below are calculated based on the weight of the ~~ingredient~~Input as a percentage of

Commented [A24]: v14.3 Section II.D. was moved to v15 Section 3.1. Language was added to clarify that livestock, poultry, bee, and seafood feed may demonstrate compliance on either an as-fed or dry matter basis.

Commented [A25]: v14.3 Footnote 3 was moved to the last line of the first paragraph of v15 Section 3.1.

[3] ~~Excluded from the weight calculation are: 1) Processing Aids present in the finished product at less than 0.5% and not declared on the retail ingredient panel or the input disclosure documentation of a wholesale product, and 2) purified Carbon Dioxide (CO_2).~~

the ~~r~~Ration fed to the animal. Rations demonstrating compliance on an as-fed basis have additional reporting requirements per Section 8.3.1.d. Rations demonstrating compliance on a dry-matter basis do not have any additional reporting requirements. Per Section 8~~Section VII.A,~~ all Minor~~Micro~~ and Micro~~Minor~~ Inputs~~Ingredients~~ of livestock and poultry Rations~~feed~~ are exempt from evaluation.

Unless a Verified-Status ~~Input~~Ingredient, the ~~components~~Inputs to each ~~compound~~ Major or Minor Ingredient must be classified and evaluated back to the point in the ~~input's~~ supply chain where ~~the input~~they can be confirmed compliant with the Standard's requirements ~~(e.g., sub-components can be confirmed as Low-Risk or meet an Action Threshold). If it is classified as an Exempt Micro Ingredient per Section II.D.3.b., a compound input does not require further breakdown and classification.~~ After the TA determines that a Micro Ingredient qualifies for Section 3.1.3.c no further breakdown or classification is required.

~~1.~~**3.1.1 Major Inputs and Ingredients**, each of which represents, or is present as, 5% or more of the finished ~~p~~Product ~~or is a defining ingredient~~.

~~2.~~**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 ~~p~~Product~~, and is not a defining ingredient~~.[4]

~~3.~~**3.1.3 Micro Inputs and Ingredients**, each of which represents, or is present as, less than 0.5% of the finished ~~p~~Product ~~and is not a defining ingredient~~. ~~The scope of review~~The depth of evaluation for these Inputs and ~~I~~Ingredients, including application of the limits in ~~Section 3.b.~~Section 3.1.3.a below, ~~shall be~~is limited to the ~~input used directly in the product~~organism from which they were derived, as opposed to ~~g~~Growth ~~m~~Medium or feed. Certain Micro Inputs and Ingredients are eligible for Micro Exemption under Section 3.1.3.b below.

~~a. **Micro Ingredients that require evaluation:**~~

~~i. **Any added nutrient, vitamin, or other active component contained in a finished supplement product must be non-GMO, regardless of amount.**[5]~~

~~ii. The following ingredients are not allowed if they are the direct product of genetic modification 1) For finished retail goods, if they are listed on the ingredient panel; or 2) For products sold without retail labeling, if they are listed on the input disclosure documentation:~~[6]

~~a) Viable Microbes.~~

~~b) Functional Enzymes.~~

Commented [A26]: v14.3 Footnote 4 was moved to the last line of the second paragraph of v15 Section 3.1.

Commented [A27]: v14.3 Footnote 4 was moved to the bottom of the second paragraph of v15 Section 3.1.

~~4 Per Section VII.A., all Micro and Minor Ingredients of livestock feed are exempt from evaluation.~~

1 7 C.F.R. § 66.1 (2018); 7 C.F.R. § 66.6 (2018).

~~5 This restriction takes effect on May 20, 2019.~~

~~6 For retail consumer goods without ingredient panels, such as beer and wine, GM microbes, enzymes derived from GMOs, and products of synthetic biology, are not allowed in the final production stages. These consumer goods will be held to the same level of evaluation as those with ingredient panels.~~

~~c) Products of synthetic biology (synbio).~~

3.1.3.a Inputs and Ingredients ineligible for Micro Exemption:

3.1.3.a.i **Bioengineered Foods**[1]. Compliance with this Section 3.1.3.a.i is required by January 1, 2022.

3.1.3.a.ii **High-Risk Ingredients not on the List of Bioengineered Foods**[2] 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. Compliance with this Section 3.1.3.a.ii is required by January 1, 2022.

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.

3.1.3.a.v **High-Risk Micro Ingredients**, other than artificial and natural flavors, Enzymes, and Microorganisms if they are either:

3.1.3.a.v.a) Named in text on the Principal Display Panel of a retail consumer Product and the same 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 Principal Display Panel of a retail consumer Product

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 directly above, and Inputs represented in Products as Micro Ingredients, may be exempt from further evaluation

Commented [A28]: v14.3 Section II.D.3.a.ii.b) was renumbered to v15 Section 3.1.3.b.ii.

Commented [A29]: The concept behind the v14.3 Defining Ingredient was rescoped and moved to v15 Section 3.1.3.b.iii.

Commented [A30]: v14.3 Section II.D.3.b. was renumbered to v15 Section 3.1.3.b and slightly altered to reflect the eligibility for Micro Exemption of both Inputs represented as Micro Ingredients in the finished Product and Micro Ingredients present in the finished Product.

[2] 7 C.F.R. § 66.6 (2018).

(Micro-exempted) provided no Product contains more than 0.9% total exempt Micro Ingredients, by Weight Percentage.

b. **Exempt Micro Ingredients**. All Micro Ingredients not listed in directly above are exempt from evaluation provided that any given product does not contain more than 0.9% total exempt Micro Ingredients.[7]

III. Risk Classification and Requirements

A.3.2 Risk StatusInput Categories

All Inputs and Ingredients must be classified according to their Risk Status. Risk Status denotes the likelihood that an Input or Ingredient is or is derived from a GMO. In order to focus the PVPProgram on iInputs and Ingredients at risk for GMO contamination throughout the CoC, the Standard recognizesclassifies inputs into five categoriesRisk Statuses (Table 3-1).

Table 3-1 The Five Risk Statuses

CategoryRisk Status	Definition
Verified-Status	InputsProducts that have been verified under the ProgramPVP as Verified Products, independent of the product for which they are an input.at wholesale or retail and are purchased for use as Inputs or Ingredients to different Products enrolled in the PVP
High-Risk (see Appendix B)	Inputs for which GM versionsOrganisms and the Inputs and Ingredients derived from them for which GMO counterparts are widely commercially available; this includes certain crops, their derivatives, and animal-derived inputs.[8]
Monitored-Risk (see Appendix C)	Certain inputs for which GM oOrganisms and the Inputs and Ingredients derived from them for which GMO counterparts are in the research and development stages, which have been developed but are not widely commercially available, or for which known GMO organism contamination has occurred.
Low-Risk	Organisms and the Inputs and Ingredients derived from thembiological organisms but that are not classified as in the Monitored- Risk or High-Risk categories.
Non-Risk	MaterialsInputs and Ingredients that are not derived from biological organisms and are not, therefore, susceptible to gGenetic mModification.

Commented [A31]: v14.3 Section III.A. was renumbered as v15 Section 3.2.

Commented [A32]: The "Category" and "Definition" columns of v14.3 Table 2. were moved to v15 Section 3.2, "Category" was renamed "Risk Status," and the new table was renumbered as Table 3-1. The Standard's intended use of the term risk was explained in the introductory paragraph of v15 Section 3.2.

[7] Until May 20, 2019, a product may contain up to 10 Exempt Micro Ingredients.

[8] Animal-derived inputs are included in the list of High-Risk Inputs because livestock feed commonly contains High-Risk Inputs. In addition, injections of rBGH are sometimes used to increase milk production.

Table 3-1 The Five Risk Statuses

~~Category~~Risk Status	Definition

Commented [A32]: The "Category" and "Definition" columns of v14.3 Table 2. were moved to v15 Section 3.2, "Category" was renamed "Risk Status," and the new table was renumbered as Table 3-1. The Standard's intended use of the term risk was explained in the introductory paragraph of v15 Section 3.2.

~~**Table 2. Input Categories**~~

~~Category~~	~~Definition~~	~~Required for Compliance~~
~~Non-Risk~~	~~Materials that are not derived from biological organisms and are not, therefore, susceptible to genetic modification.~~	~~Examine the complete input disclosure for compound inputs, including all components of the input in question, to confirm the absence of components with GMO risk.~~
~~Low-Risk~~	~~Inputs derived from biological organisms but that are not in the Monitored Risk or High-Risk categories.~~	~~1. Examine the complete input disclosure to confirm the absence of components with GMO risk, including compound ingredients.~~ ~~2. Verify that the input was produced under conditions designed to avoid cross-contamination with genetically modified (GM) materials.~~ ~~a. If the facility does not use any High-Risk Inputs, then demonstration of this fact is sufficient to fulfill this requirement.~~ ~~b. If the facility does use High-Risk Inputs, fulfillment of this requirement will involve demonstrating that procedures and systems are in place that effectively segregate the Low-Risk Input from potential sources of High-Risk contamination within the facility.~~

Commented [A33]: The "Category" and "Definition" columns of v14.3 Table 2. were moved to v15 Section 3.2, "Category" was renamed "Risk Status," and the new table was renumbered as Table 3-1. The Standard's intended use of the term risk was explained in the introductory paragraph of v15 Section 3.2.

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Category	Definition	Required for Compliance
Monitored-Risk (see Appendix C)	Certain inputs for which GM organisms are in the research and development stages, which have been developed but are not widely commercially available, or for which known GM organism contamination has occurred.	See requirements for Low-Risk.
High-Risk (see Appendix B)	Inputs for which GM versions are widely commercially available; this includes certain crops, their derivatives, and animal-derived inputs.[11]	1. Examine the complete input disclosure of the input to identify all High-Risk Inputs. For each unique input received from each supplier, a specification sheet or similar description disclosing all components contained in the input must be on file with the Technical Administrator (TA). 2. Comply with the traceability and segregation measures outlined in Section IV. 3. Comply with all applicable requirements in Section V. to Section VII. *For animal-derived inputs, verification is based on compliance with the requirements outlined in* Section VII.A.
Verified-Status	Inputs that have been verified under the Program as Verified Products, independent of the product for which they are an input.	1. Confirm the Verified Status of the input. 2. Components of the input do not need to be re-evaluated. 3. Comply with the traceability and segregation measures outlined in Section IV.

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B. Reclassification of Risk

1. **From High-Risk to Low-Risk:**

On a case-by-case basis, certain High-Risk Inputs may be downgraded to Low-Risk status based on source, documentation, protocols for contamination prevention/avoidance, and/or laboratory results demonstrating consistently low risk of GMO contamination (in accordance with this Standard). Individual inputs may only be downgraded by the TA with the approval of the Non-GMO Project.

[11] Animal-derived inputs are included in the list of High-Risk Inputs because livestock feed commonly contains High-Risk Inputs. In addition, injections of rBGH are sometimes used to increase milk production.

~~1. An example would be cornstarch produced in a country where GMOs are prohibited, Non-GMO Project Standard compliant seed was confirmed as having been used, and documented identity preservation (IP) procedures are in place for the manufacture and transport of the input.~~

~~1. **From High-Risk to Verified-Status:**~~
~~High-Risk Inputs that have been verified under the Program as Verified Products (also referred to as Verified-Status Inputs) are subject to a modified evaluation, as described in .~~

~~2. **From Low-Risk to High-Risk:**~~
~~The Project maintains a surveillance program, one purpose of which is to evaluate GM risk and GM content on a Project-wide basis, using cumulative data. Using data from the surveillance program, the Project may re-classify a Low-Risk Input classified as a High-Risk Input. In such case, the verification of the input shall be carried out according to the requirements for High-Risk Inputs.~~

3.3 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 deoxyribonucleic acid (DNA) or protein to return valid molecular or immunological test results, and acceptable molecular tests or immunological tests are publicly commercially available to cover all events for which the Project requires testing. Non-Testable Inputs and Ingredients do not have a point in the supply chain where the Input or Ingredient contains sufficient intact DNA or protein to return valid molecular or immunological test results and/or no acceptable molecular tests or immunological tests are publicly commercially available. Some organisms and their derivatives are both Testable and Non-Testable according to the above criteria.

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 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.

3.4 Product Compliance by Input and Ingredient Classification

A full Input and/or Ingredient disclosure is required in most cases for Products, Ingredients, and Inputs. Table 3-2 summarizes the compliance pathways available to Verified-Status, Monitored-Risk, Low-Risk, and Non-Risk Inputs and Ingredients. The compliance pathways of these four Risk Statuses are unaffected by Weight Percentage in the finished Product and Testability. Table 3-3 summarizes the various compliance pathways for Testable and Non-Testable High-Risk Inputs and Ingredients when they are Majors, Minors, and Micros. Table 3-2 and Table 3-3 are summaries; additional compliance requirements may apply.

Table 3-2 Compliance of Verified-Status, Monitored-Risk, Low-Risk, and Non-Risk Inputs, Ingredients, and Products

~~Required for Compliance~~
Verified Status
1. Provide proof of Verified-Status of appropriate scope. ~~Confirm the Verified-Status of the input.~~ 2. Participant complies with Section 4, Chain of Custody, from the point of procurement to the finished Product. ~~Components of the input do not need to be re-evaluated.~~ 3. Participant complies with Section 5, Onsite Inspections, from the point of procurement to the finished Product. ~~Comply with the traceability and segregation measures outlined in Section IV.~~
Monitored Risk
See requirements for Low-Risk.
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. ~~Examine the complete input disclosure to confirm the absence of components with GMO risk, including compound ingredients.~~ ~~2. Verify that the input was produced under conditions designed to avoid cross-contamination with genetically modified (GM) materials.~~ **AND EITHER** a. Provide a complete Input and Ingredient disclosure. ~~If the facility does not use any High-Risk Inputs, then demonstration of this fact is sufficient to fulfill this requirement.~~ **OR** b. Comply with Section 7.5, Monitored-Risk and Low-Risk Major, Minor, and Micro Inputs and Ingredients. ~~If the facility does use High-Risk Inputs, fulfillment of this requirement will involve demonstrating that procedures and systems are in place that effectively segregate the Low-Risk Input from potential sources of High-Risk contamination within the facility.~~
Non Risk
~~Examine the complete input disclosure for compound inputs, including all components of the input in question, to confirm the absence of components with GMO risk.~~ 1. Provide a complete Input and Ingredient disclosure. **OR** 2. Comply with Section 7.6, Non-Risk Major, Minor, and Micro Inputs and Ingredients.
Note: Inputs and Ingredients from the Verified-Status, Monitored-Risk, 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.

Commented [A34]: The "Required for Compliance" column of v14.3 Table 2. was moved to v15 Section 3.4 and split into multiple tables based on the intersection of the three attributes as described in the preceding sections. The "Required for Compliance" column covering compliance of Verified-Status, Monitored-Risk, Low-Risk, and Non-Risk Inputs and Ingredients was taken from v14.3 Table 2. and renumbered as Table 3-2, Compliance of Verified-Status, Monitored-Risk, Low-Risk, and Non-Risk Inputs, Ingredients, and Products.

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

~~Required for Compliance~~		
~~1. Examine the complete input disclosure of the input to identify all High-Risk Inputs. For each unique input received from each supplier, a specification sheet or similar description disclosing all components contained in the input must be on file with the Technical Administrator (TA).~~ ~~2. Comply with the traceability and segregation measures outlined in Section IV.~~ ~~3. Comply with all applicable requirements in Section V. to Section VII.~~ ~~*For animal-derived inputs, verification is based on compliance with the requirements outlined in* Section VII.A.~~		
Major	**Minor**	**Micro**
Testable High Risk		
1. Submit a complete Input and Ingredient disclosure. 2. Comply with Section 4, Chain of Custody. 3. Comply with Section 5, Onsite Inspections. **AND EITHER** a. Comply with Section 6, Sampling and Testing. **OR** b. Comply with Section 7.4, Affidavit Compliance Based on Country of Origin.	1. Comply as a Major. **OR** 2. Submit a complete Input and Ingredient disclosure. 3. Comply with Section 4, Chain of Custody. 4. Comply with Section 7.3, Testable High-Risk Minor and Micro Inputs and Ingredients.	1. Comply as a Major. **OR** 2. Comply as a Minor. **OR** 3. Comply with Section 3.1.3, Micro Inputs and Ingredients.
Non-Testable High Risk		
1. Submit a complete Input and Ingredient disclosure. 2. Comply with Section 4, Chain of Custody. 3. Comply with Section 5, Onsite Inspections. **AND EITHER** a. Comply with Section 7.2, Non-Testable High-Risk Inputs and Ingredients. **OR**	1. Submit a complete Input and Ingredient disclosure. 2. Comply with Section 4, Chain of Custody. **AND EITHER** a. Comply with Section 7.2, Non-Testable High-Risk Inputs and Ingredients. **OR** b. Comply with Section 7.4, Affidavit Compliance	1. Comply as a Major. **OR** 2. Comply as a Minor. **OR** 3. Comply with Section 3.1.3, Micro Inputs and Ingredients.

Commented [A35]: The "Required for Compliance" column of v14.3 Table 2. was moved to v15 Section 3.4 and split into multiple tables based on the intersection of the three attributes as described in the preceding sections. The "Required for Compliance" column covering compliance of High-Risk Inputs and Ingredients was taken from v14.3 Table 2. and renumbered as Table 3-3, Compliance of Testable and Non-Testable High-Risk Major, Minor, and Micro Inputs and Ingredients.

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

b. Comply with Section 7.4, Affidavit Compliance Based on Country of Origin.	Based on Country of Origin.	

Additional requirements, including those outlined in Section 10, Product Specifications and Labeling, and Section 11, Quality Assurance, may also apply to Products, Ingredients, and Inputs.

~~IV.~~4 Chain of Custody~~Traceability, Segregation, and Inspections~~

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

Commented [A35]: The "Required for Compliance" column of v14.3 Table 2. was moved to v15 Section 3.4 and split into multiple tables based on the intersection of the three attributes as described in the preceding sections. The "Required for Compliance" column covering compliance of High-Risk Inputs and Ingredients was taken from v14.3 Table 2. and renumbered as Table 3-3, Compliance of Testable and Non-Testable High-Risk Major, Minor, and Micro Inputs and Ingredients.

Commented [A36]: v14.3 Section IV. was renumbered as v15 Section 4 and renamed to "Chain of Custody." This section was restructured for clarity.

~~C.~~4.1 Activities

~~The scope of the evaluation encompasses the following types of activities and sectors of food and related production systems.~~ CoC requirements apply beginning at the point Non-Risk, Low-Risk, Monitored-Risk or Verified-Status of an Input or Ingredient is confirmed, at the point of testing, or at the point where compliant Affidavits are procured. When relevant to the verification of the ~~p~~Product, the following activities are subject to review and must be found compliant with the applicable Standard sections (Table 4-1~~Table 1~~).

~~**Table 1. Activities**~~

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~~chain of custody~~ from seed to consumer, except for ~~p~~Products enclosed in final retail packaging.
Storage	Includes all links in the CoC~~chain of custody~~ from seed to finished ~~p~~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, ~~i~~Inputs and Ingredients to make the ~~final~~finished ~~p~~Product.
Packaging and labeling	Includes any and all events ~~where~~during which the packageing or labeling of goods is added, removed, or altered.

4.2 Global Chain of Custody Requirements

4.2.1 All required procedures must 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 must be adequately trained in the required procedures.

4.2.3 All records must be maintained for a minimum of three (3) years.

~~**A. Traceability**~~

~~1. Each lot of Non-GMO Project Verified product must be traceable back to specific lots of the inputs used in its production. Systematic procedures shall be in place for tracking lot numbers and/or marking and labeling of packaging, containers, and storage facilities to ensure traceability of inputs, work-in-progress, and finished products at all points in the production process.~~

Commented [A37]: v14.3 Section II.C. and v14.3 Table 1 were moved to v15 Section 4.1.

Commented [A38]: v14.3 Table 1., Activities, was renumbered as v15 Table 4-1, Activities Along the Chain of Custody.

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~~2. Traceability records shall explicitly trace and track the Non-GMO Project Standard compliant status of inputs and the finished product. If lots of a given input are co-mingled in storage before use in production of a certain lot of product, the lot numbers related to all lots commingled shall be linked to that particular lot of product.~~

~~3. Tracking of lot numbers and labeling/marking on packaging and containers shall be used as necessary to identify and segregate Non-GMO Project Standard compliant materials from non-compliant materials.~~

4.3 Segregation

~~2.~~4.3.1 Systematic procedures ~~shall~~must be in place during ~~production~~activities to keep compliant ~~i~~Inputs, Ingredients, work ~~-~~in ~~-~~progress, and finished ~~p~~Products separate from all non-compliant High-Risk materials ~~that are not compliant with the Non-GMO Project Standard~~.

~~3.~~4.3.2 Segregation measures are also required for instances where any required testing occurs after the ~~i~~Input or Ingredient in question has entered the facility ~~(e.g., when a Participant, rather than an ingredient supplier, is taking responsibility for testing)~~.

~~B.~~4.4 Cleanout ~~and Segregation~~

~~1.~~4.4.1 Receiving, production, processing, manufacturing, transfer, and storage facilities, as well as shipping and transportation conveyances, ~~shall~~must be inspected and cleaned/purged as needed to remove sources of GMO contamination, and all relevant cleaning, purging, and inspections ~~shall~~must be documented.

~~2. Systematic procedures shall be in place during production to keep compliant inputs, work in progress, and finished products separate from all materials that are not compliant with the Non-GMO Project Standard.~~

~~3. Segregation measures are also required for instances where any required testing occurs after the input in question has entered the facility (e.g., when a Participant, rather than an ingredient supplier, is taking responsibility for testing).~~

~~A.~~4.5 Traceability

~~1.~~4.5.1 Each lot of ~~Non-GMO Project~~ Verified ~~p~~Product must be traceable back to specific lots of the ~~i~~Inputs and Ingredients used in its production. If lots of ~~a given~~ compliant ~~i~~Inputs and/or Ingredients are ~~co-mingled~~commingled in storage before use in production of a certain lot of ~~p~~Product, the lot numbers related to all ~~lots~~ commingled lots ~~shall~~must be linked to that particular lot of ~~p~~Product.

4.5.2 Testable High-Risk Inputs and Ingredients must be traceable back to the lots that demonstrate compliant test results. Non-Testable High-Risk Inputs and Ingredients must be traceable back to the lots associated with compliant Affidavits.

4.5.3 Systematic procedures ~~shall~~must be in place for tracking lot numbers and/or marking and labeling of packaging, containers, and storage facilities to ensure

Commented [A39]: v14.3 Section IV.B. was split into two sections, v15 Section 4.3, Segregation and v15 Section 4.4, Cleanout. The segregation requirements outlined in v14.3 Section B. were renumbered to v15 Section 4.3.

Commented [A40]: v14.3 Section IV.B.2. was renumbered to v15 Section 4.3.1.

Commented [A41]: v14.3 Section IV.B.3. was renumbered to v15 Section 4.3.2.

Commented [A42]: v14.3 Section IV.B. was split into two sections, v15 Section 4.3, Segregation and v15 Section 4.4, Cleanout. The cleanout requirements outlined in v14.3 Section IV.B.1. were renumbered to v15 Section 4.4.1.

Commented [A43]: v14.3 Section IV.A. was renumbered to v15 Section 4.5.

Commented [A44]: v14.3 Section IV.A.1. was renumbered to v15 Section 4.5.1.

Commented [A45]: The first line of v14.3 Section IV.A.2. was renumbered to v15 Section 4.5.4. The second line of v14.3 Section IV.A.2. was added to v15 Section 4.5.1.

Commented [A46]: The second sentence of v14.3 Section IV.A.1. was renumbered to v15 Section 4.5.3.

traceability of ~~i~~Inputs, Ingredients, work-~~-~~in-~~-~~progress, and finished ~~p~~Products at all points in the production process.

~~2.~~4.5.4 Traceability records ~~shall~~must explicitly trace and track the compliance~~Non-GMO Project Standard compliant status~~ of ~~i~~Inputs, Ingredients, and ~~the~~ finished ~~p~~Products.

~~C.~~5 Onsite Inspections

~~1.~~5.1 ~~Unless the producing facility is exempt from inspection by an applicable part of this Standard, all~~ At minimum, Producing ~~f~~Facilities are required to be inspected annually when Parallel Processing of the same Major High-Risk Input or Ingredient to a Product is occurring.

5.2 Contract processors that are not Participants are exempt from inspection as long as Products, Ingredients, and Inputs they manufacture are the result of a system that has been designed to avoid GMOs. This temporary exemption will be revisited during the 2020 comment period.

5.3 The TA may require additional inspections based on an overall risk analysis of the supply chain undergoing evaluation.

~~2.Unless the TA finds cause for inspection, inspections are not required for:~~

~~a. Products in which there are only Low-Risk Inputs~~

~~b. Products in which the only Low-Risk and/or High-Risk Inputs are excluded from evaluation under Section II.D.3. or approved under Section VI.B.1.~~

~~c. Products produced in a facility where there is no parallel processing of the specific Major High-Risk Inputs used in those products.~~

~~**d. Products of a facility that is dedicated to certified organic production, if no parallel processing of the specific Major High-Risk Inputs is occurring in the facility.**~~

~~e. Contract processors that comply with the requirements of~~

~~3.~~5.4 At the TA's discretion, unannounced inspections may be used to ensure compliance with this Standard.

~~V.~~6 Sampling and Testing

All High-Risk Inputs and Ingredients must comply with the relevant Action Threshold through either this Section 6 or Section 7, unless otherwise allowed by a different section of this 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.

~~For use in a Verified Product, compliance with this Section V. is required for (1) Testable High-Risk Major or Minor Ingredients; (2) High-Risk Inputs present in feed of an animal-derived~~

Commented [A47]: The first line of v14.3 Section IV.A.2. was renumbered to v15 Section 4.5.4. The second line of v14.3 Section IV.A.2. was added to v15 Section 4.5.1.

Commented [A48]: v14.3 Section IV.C., Inspections was moved to v15 Section 5 and renamed "Onsite Inspections." Language was added to clarify that some evaluations may require onsite inspections based either on Standard language or a TA's risk assessment of the operation.

Commented [A49]: Language from v14.3 Section IX.E.2. regarding the copacker inspection exemption was moved to v15 Section 5.2.

Major or Minor Ingredient;[9] and (3) Testable High-Risk Inputs present in the growth medium or feed of microbial Major or Minor Ingredients[10] (collectively referred to as "Testable High-Risk Inputs").[11] In order to be considered compliant under the Non-GMO Project Standard, tested samples are required to have sufficiently intact deoxyribonucleic acid (DNA).

A.6.1 Action Thresholds

Absence of all GMOs is the target for all Non-GMO Project Standard Verified pProducts. Continuous improvement practices toward achieving this goal must be part of the Participant's quality managementassurance systems. A key requirementoutcome of such quality managementassurance systems is to meet or continually be below the applicable Action Threshold. Testable High-Risk Inputs and Ingredients that do not comply with the testing requirements may notapplicable Action Threshold cannot be intentionally used in Verified pProducts, unless otherwise allowed by a different section of this Standard.

The Non-GMO Project has established the following Action Thresholds for Testable High-Risk Inputs and Ingredients (Table 6-1(Table 3).).

Table 3. Action Thresholds

[9] Compliance with Section VII.A. is also required for the animal-derived Major Ingredient.

[10] Compliance with Section VI. is also required for the microbial Major Ingredient.

[11] Compliance for Minor Ingredients may be established under Section VI. only if compliance with this Section V. is not available.

Table 6-1 Action Thresholds

Category	Action Threshold[a]
Seed and ~~other~~vegetative propagation materials	0.25%~~[a]~~
~~Inputs to~~Wholesale or retail goods for human ~~food, ingredients, supplements, personal care products, and other products~~or pet use that are either ingested or topically applied ~~directly to skin, and pet food~~including OTC drugs and homeopathic remedies	0.9%
Livestock, poultry, bee, and seafood feed and supplements, including those used for animal-derived ~~i~~Inputs and Ingredients to ~~human food~~all ~~p~~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 ~~products,~~supplies, and textiles ~~and other products that are not ingested or applied directly to skin~~	1.5%

[a] For all crops not listed in Appendix B.1.1 and Appendix C.1.1, there is no allowable presence.

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

~~[a] For seeds of species not listed in Appendix B, and for all species not listed in Appendix B, there is no allowable presence.~~

~~[b] This Action Threshold is based on the annual average of all lots tested.~~

~~B.~~6.2 Global Sampling ~~Compliance~~ Requirements

~~2.~~6.2.1 **A statistically valid sampling and testing plan** ~~shall~~must be designed based on a risk assessment of the production~~/~~ and handling system~~,~~ and ~~shall~~must 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 must 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.

~~1. Participants must demonstrate compliance with the applicable Action Threshold. In general, compliance should be demonstrated by ensuring that each batch of Testable High-Risk Input is compliant with this Section V.B. prior to its use in a Verified Product.~~

~~2. Testable High-Risk Inputs shall be compliant with the Standard if all of the following criteria are met:~~

~~a. Appropriate laboratory controls indicate that the DNA of the input or the input's precursor is sufficiently intact to allow valid quantitative analysis by polymerase chain reaction (PCR). Inputs that do not meet this criterion, and are therefore not "testable" in this manner, must be verified by lot-specific traceability back to testable precursors for the input.~~

Commented [A50]: Language from v14.3 Section IX.E.2. regarding the copacker inspection exemption was moved to v15 Section 5.2.

Commented [A51]: As represented in v15 Table 6-1, Footnote a, the concept of no allowable presence was extended to crops listed in v15 Appendix C.1.1.

Commented [A52]: As represented in v15 Table 6-1, Footnote b, compliance with the 5% Action Threshold for livestock, poultry, bee, and seafood feed was changed from an annual average to a quarterly average.

Commented [A53]: v14.3 Section V.C.2. was moved to v15 Section 6.2.1.

b. The testing was conducted by an approved laboratory in compliance with and references by lot number the specific lot of input and precursor (if applicable) used by the Participant.

c. A copy of the original result for the PCR test shows that the GMO content of the input or precursor in question is below the relevant Action Threshold.

d. From the point of the PCR testing forward, an IP system is in place to ensure the given lot of the input and precursor (if applicable) in question has not been exposed to any other GM material. All such systems are subject to review and must be approved by the TA.

3. Test results must be submitted to the TA for review prior to initial verification and annual renewal to ensure compliance with the applicable Action Threshold.

4. In cases where the requirements of are demonstrated to be problematic to achieve for every batch, and the product is not planting seed or other propagation material and does not contain an animal-derived input, compliance may be demonstrated by ensuring that test results for all batches of High-Risk Input used during each 6-month period average at or below the relevant Action Threshold, with no single batch of input ever exceeding the relevant Action Threshold by more than a factor of 2. The Participant is responsible for ongoing monitoring of test results to ensure compliance for each period.

5. **When a non-compliant tested lot is mixed with a compliant tested lot**, the Participant must:

a. Demonstrate that a homogenous blend was achieved prior to testing. In all cases, the finished lot tests below the relevant Action Threshold.

b.a. Investigate and document the cause of any individual lot's contamination over the relevant Action Threshold.

c.a. Implement and document practical continuous improvement practices to reduce, and ultimately eliminate, the need for any future blending of lots. An example of one such practice would be to help growers secure Non-GMO Project Standard compliant planting seed.

C. Genetics-based Testing Using the Real-Time or Digital PCR Method

1. **Genetics-based testing** of all Testable High-Risk Inputs is required before a finished product can be verified. The frequency and location of Real-Time or Digital PCR testing can be tailored to accommodate the Participant's supply chain.

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

a. Risk assessment and monitoring must be done according to a sampling and testing plan approved by the TA.

b.6.2.1.b Unless otherwise allowed by a different section of the Standard, Ccompliant sampling and testing must occur at least once post-harvest for all Inputs and Ingredients, depending on contamination risks.

Commented [A54]: The first half of v14.3 Section V.C.2.b. was moved to v15 Section 6.2.1.b.

~~Sampling plans must be designed to achieve 90% confidence in quantification of GMO at or below the applicable Action Threshold.~~

~~b.~~6.2.1.c When achieving ~~this level of confidence~~statistical validity through crop sampling cannot be done without destroying significant quantities of the consumer product (e.g., for large crops such as papaya, sweet corn, zucchini and ~~papaya~~yellow summer squash), the ~~testing~~TA may ~~be shifted~~ shift testing to the seed level with limited post-harvest spot testing.

Commented [A55]: The second half of v14.3 Section V.C.2.b. was moved to v15 Section 6.2.1.b.

~~3.~~6.2.2 **Compositing samples**

Commented [A56]: v14.3 Section V.C.3. was moved to v15 Section 6.2.2.

Statistical calculations can also be used to design compositing strategies ~~through~~under which portions of multiple samples can be combined and tested together ~~for the purpose of reducing~~to reduce the number of tests required ~~and therefore the cost for testing~~.

~~a.~~6.2.2.a Compositing must 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 ~~which~~that indicates that one or more single samples exceeds the relevant Action Threshold, the lot must be rejected, or if sub-lots ~~we~~are segregated and not commingled, then retesting of individual lot samples may be possible to salvage compliant lots.

6.3 Global Testing Requirements

6.3.1 Participants must demonstrate compliance with the applicable Action Threshold.

Commented [A57]: The first line of v14.3 Section V.B.1. was moved to v15 Section 6.3.

6.3.2 ~~In general, c~~Compliance ~~must~~~~should~~ be demonstrated by ensuring that each lot~~batch~~ of Testable High-Risk Input or Ingredient is compliant with this ~~Section V.B.~~ Section 6 prior to its use in a Verified Product.

Commented [A58]: The second line of v14.3 Section V.B.1. was moved to v15 Section 6.3.2.

6.3.3 The sample Matrix must be appropriate for the testing method to yield valid results. If necessary, the precursor from which the Input or Ingredient was derived must be tested.

6.3.3.a All GM events for which the Project requires testing must be tested for and the results must be conclusive.

6.3.3.b Test results must be traceable back to the lot number(s) of the precursor, Input, or Ingredient.

6.3.3.c From the point of testing forward, the activities associated with the precursor, Input, or Ingredient must comply with Section 4.

~~3.~~6.3.4 Test results must be submitted to the TA for review prior to initial verification ~~and annual renewal~~ to ensure compliance with the applicable Action Threshold.

Commented [A59]: v14.3 Section V.B.3. was renumbered to v15 Section 6.3.4.

6.3.5 All test results from the preceding year must be submitted to the TA for review at annual renewal to ensure continued compliance with the applicable Action Threshold.

Commented [A60]: The annual renewal requirement was moved from v14.3 Section V.B.3. to v15 Section 6.3.5.

~~4.~~6.3.6 In cases where the requirements of ~~Section V.A.~~ Section 6.1 are demonstrated to be problematic to achieve for every lot~~batch, and the product is not planting seed or other propagation material and does not contain an animal-derived input,~~ compliance may be demonstrated by ensuring that test results for all lots~~batches~~ 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~~batch~~ of precursor, ~~I~~Input, or Ingredient ever exceeding the relevant Action Threshold by more than a factor of two (2). ~~The Participant is responsible for ongoing monitoring of test results to ensure compliance for each period.~~ This compliance pathway will be revisited during the 2020 comment period.

6.3.6.a Planting seed, vegetative propagation materials, and livestock, poultry, bee, and seafood feed cannot demonstrate compliance via Section 6.3.6.

6.3.6.b The Participant must 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 ensure compliance for each 6-month period.

6.4 Molecular Testing Methods

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

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 approved laboratory in compliance with Section 6.4.2 and the analysis report is issued by the same laboratory and references by lot number the specific lot of precursor, Input, or Ingredient, where applicable, used by the Participant.

6.4.1.c A copy of the original result for the PCR test shows that the GMO contamination of the precursor, Input, or Ingredient in question is at or below the relevant Action Threshold.

~~4.~~6.4.2 ~~**Approved l**~~**L**aboratories **approved** by the Project must carry out testing, except in cases where Inputs and Ingredients are compliant with Section 7.4. Such laboratories ~~Testing shall be carried out by a laboratory that is~~ are accredited to ISO 17025~~,~~ and ~~approved by the Non-GMO Project, and shall~~must use ~~methods~~tests that are included within the scope of their ISO 17025 accreditation~~,~~ for the ~~input~~Testable precursor, Input, or Ingredient in question. Approved laboratories possess a Certificate of Approval and are listed on the Project's website.

~~5.~~6.4.3 **Laboratory testing** may employ quantitative, semi-quantitative, or qualitative PCR. ~~must target all commercialized GM events relevant to the input and the production system.~~

Commented [A61]: v14.3 Section V.B.4. was renumbered to v16 Section 6.3.6.

Commented [A62]: "and the Product is not planting seed or other propagation material and does not contain an animal-derived input" was taken from v14.3 Section V.B.4., renumbered to v15 Section 6.3.6.a, and the intention clarified.

Commented [A63]: The last line of v14.3 Section V.B.4. was moved to v15 Section 6.3.6.c.

Commented [A64]: v14.3 Section V.C.4. was moved to v15 Section 6.4.2.

Commented [A65]: v14.3 Section V.C.5. was moved to v15 Section 6.4.3.

~~a.~~ ~~Where quantitative results are required, the Real-Time or Digital PCR test must employ primers sufficient to accurately quantify the percent GM content for that event.~~

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

6.4.3.b.ii The upper limit of the range in which the result is reported must be at or below the relevant Action threshold.

~~b.~~ ~~Qualitative analysis using Real-Time PCR is sufficient if:~~

6.4.3.c Qualitative PCR may be used to demonstrate compliance with the Action Threshold if:

~~i.~~**6.4.3.c.i** The PCR limit of detection is 0.~~01%;~~ 1% or lower.

~~ii.~~**6.4.3.c.ii** Each test result for each Testable High-Risk precursor, Input, or Ingredient is negative.~~GMOs are not detected; and~~

~~iii.~~**6.4.3.c.iii** Should any test result be positive for a GM event, the Testable High-Risk precursor, Input, or Ingredient must 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 Product.~~Appropriate laboratory controls indicate that the DNA of the input is sufficiently intact to allow for valid quantitative analysis using PCR.~~

~~D.~~6.5 Immunological ~~-based~~ Testing ~~Using Strip Tests~~Methods

~~1. In cases where lateral flow strip tests are permissible, they must cover all commercialized GM events for the input in question.~~

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

Commented [A66]: v14.3 Section V.D. was renumbered to v15 Section 6.5.

Commented [A67]: v14.3 Section V.D.1. was renumbered to v15 Section 6.5.3.

the appropriate Action Threshold, when the methods meet the criteria in this Section 6.5.

~~**2. These methods shall be used when rapid,** qualitative in-field testing is needed and when accuracy, sensitivity, and ramifications of false negative results are not significant concerns. An example includes use of strip tests for the purpose of spot testing input samples. Compositing can be used for subsequent confirmatory Real-Time PCR testing. Frequency of Real-Time PCR testing and method of compositing to be determined such that there is 90% confidence in quantification of GMO at the relevant Action Threshold.~~

~~**3. A statistically valid sampling and testing plan** shall be designed on the basis of a risk assessment of the production/handling system and shall reflect the level of monitoring appropriate for the risks inherent in the production/handling system, as well as industry standards. Risk assessment and monitoring must be done according to a sampling and testing plan approved by the TA.~~

~~4.~~6.5.2 **Analysts must be trained, and their proficiency~~performance~~ established~~verified~~** to ensure that they use the tests reliably and according to the manufacturer's specifications. Participants must~~shall~~ document the in-house training and evaluation of performance.

Commented [A68]: v14.3 Section V.D.3. was renumbered to v15 Section 6.5.2.

~~1.~~6.5.3 **In cases where immunological ~~lateral flow strip tests~~ testing methods are permissible by this Standard**, they must cover all ~~commercialized~~ GM events for ~~the input in question~~which the Project requires testing. When all GM events for which the Project requires testing are not covered, samples must be tested in compliance with Section 6.4.

Commented [A69]: v14.3 Section V.D.1. was renumbered to v15 Section 6.5.3.

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 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 sum of each test panel for the Testable High-Risk precursor, Input, or Ingredient is at or below the relevant Action Threshold.

6.5.3.b Qualitative immunological methods may be used to demonstrate compliance with the Action Threshold when:

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 must 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.

~~VI.~~7 Affidavits

In the majority of 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.

~~D.~~7.1 Global Affidavit Requirements

Commented [A70]: v14.3 Section VI.D. was renumbered to v15 Section 7.1. New language was added that applies to all Affidavit compliance pathways.

7.1.1 At minimum, all Affidavits must include the signature and the printed name of the party signing the Affidavit, and the date.

7.1.2 The party signing the Affidavit must have sufficient knowledge of the supply chain to authoritatively sign.

~~2.~~**7.1.3** If appropriate, ~~a~~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 this Section 7.

7.1.5 Unless otherwise stated below, Affidavits must be updated as appropriate to reflect changes to the crops, precursors, Inputs, Ingredients, systems, processes, or operations they reference.

~~A.~~7.2 Non-Testable High-Risk Inputs and Ingredients

Commented [A71]: v14.3 Section VI.A. was renumbered as v15 Section 7.2.

~~1.~~**7.2.1** Non-Testable High-Risk Major, Minor, and Micro Inputs and Ingredients are identified in ~~Appendix B, Section B~~Appendix B.2. An ~~a~~Affidavit stating that any such Non-Testable High-Risk Major, Minor, or Micro Input or Ingredient is ~~not the product of genetic modification~~Non-GMO is required to establish compliance with this ~~Standard~~Section 7.2. Organisms, precursors, Inputs, or Ingredients identified as Non-Testable High-Risk Major, Minor, and Micro Inputs and Ingredients in Appendix B.2 that are subject to any European Union (EU) GMO Directives or Regulations[15], 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 this Standard; Non-Testable High-Risk 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.

[2] 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.

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 this 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, above.

Commented [A72]: New language was added to reinforce that the Project's standardized Affidavit is the only document that can demonstrate the compliance of a Non-Testable High-Risk Input or Ingredient under v15 Section 7.2.

~~2.~~**7.2.3** For any Non-Testable High-Risk Major, Minor, or Micro Input or Ingredient, an ~~a~~Affidavit must be submitted to the TA for review prior to initial verification and, at minimum, annually upon renewal ~~as required~~ to ensure compliance with this Section 7~~Section VI.A.~~.

~~3.~~**7.2.4** Testable ~~Major~~ High-Risk Major Inputs and Ingredients listed in ~~Appendix B, Section A.~~ Appendix B.1~~, having a precursor with sufficient DNA intact for PCR testing~~ must be compliant with ~~Section V.~~ Section 6 or Section 7.4. Testable and ~~are not eligible for compliance through an affidavit alone.~~Non-Testable High-Risk Inputs and Ingredients (listed in both ~~Appendix B, Section A,~~Appendix B.1 and ~~Appendix B, Section B~~Appendix B.2~~,~~), must comply with ~~Section V.~~both Section 6 and this Section 7~~Section VI.A.~~.

~~B.~~7.3 Testable High-Risk ~~Inputs as~~ Minor and Micro Inputs and Ingredients

Commented [A73]: v14.3 Section VI.B. was renumbered to v15 Section 7.3.

7.3.1 All Affidavits must include the Project's definitions of Biotechnology and GMO as they appear in Appendix A.

~~1.~~**7.3.2** ~~Only in cases where GMO analytical certificates or traceability linked to analytical certificates of precursors is not available, compliant status of~~ Testable High-Risk Minor and Micro Inputs and Ingredients may ~~be verified~~demonstrate compliance based on ~~a~~Affidavits ~~from suppliers,~~ as long as these ~~i~~Inputs and Ingredients are the ~~product~~result of a system that has been designed to avoid GMOs. ~~Organic certification is an example of such a system.~~ Suitability of ~~other IP~~ systems designed to avoid GMOs is subject to review by the TA with the approval of the ~~Non-GMO~~ Project.

~~3.~~**7.3.3** When available, valid certificates from third-party certifiers are acceptable alternatives to ~~a~~Affidavits under this ~~Section VI.~~Section 7.3, ~~when~~if the third-party certification program satisfies the requirements for which an ~~a~~Affidavit would be used in Section 7.3.2.

Commented [A74]: v14.3 Section VI.D.3. was renumbered to v15 Section 7.3.3.

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.

7.4 Affidavit Compliance Based on Country of Origin[2]

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 this 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 must 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 must be submitted to the TA for review prior to initial verification and, at minimum, annually upon renewal.

7.4.5 The Project has issued Affidavit templates for Section 7.4.3, above. These are the only Affidavits compliant with this 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.

~~C.~~7.5 Monitored-Risk and Low-Risk Major, Minor, and Micro Inputs and Ingredients

~~1.~~7.5.1 Affidavits may be used to confirm the compliance of Monitored-Risk and Low-Risk Major, Minor, and Micro Inputs and Ingredients.

~~2.~~7.5.2 The ~~a~~Affidavit must attest to compliance with the requirement for classification as either Monitored-Risk or Low-Risk as described in ~~Section III.A.~~ Section 3.2, Table 3-1.

~~**D. Affidavit Requirements**~~

~~1. Affidavits submitted under this Section VI. must be signed by the manufacturer of the input in question.~~

Commented [A75]: v15 Section 7.4 reframes v14.3 Section III.B.1.a. as compliance based on country of origin for High-Risk Inputs and Ingredients. The concept of a "risk downgrade" was struck from the Standard.

[2] The Project maintains the list of countries (and associated frequencies and necessities of testing) that comply with Section 7.4.2.

~~2. If appropriate, affidavits should be accompanied by supporting documentation.~~

~~3. When available, valid certificates from third-party certifiers are acceptable alternatives to affidavits under this Section VI., when the third-party certification program satisfies the requirements for which an affidavit would be used.~~

Commented [A76]: v14.3 Section VI.D.3. was renumbered to v15 Section 7.3.3.

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 must attest to compliance with the requirement for classification as Non-Risk as described in Section 3.2, Table 3-1.

~~VII. Special Requirements for Specific Product Sectors~~

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

Commented [A77]: Introductory paragraph originally taken from v14.3 Section VII. and added to both v15 Section 8 and v15 Section 9. "sampling" was added to the example in parentheses.

A.8 Livestock and Poultry~~Animal-Derived Inputs and Livestock Feed~~

Commented [A78]: v14.3 Section VII.A. was cleaved from Section VII. and given its own section v15 Section 8. New language was added to establish the scope of review for Livestock and Poultry Inputs, Ingredients, and Products.

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.

Commented [A79]: Paragraph originally taken from v14.3 Section VII. and added to both v15 Section 8 and v15 Section 9. "sampling" was added to the example in parentheses.

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

Livestock and poultry-derived Products, Ingredients, and Inputs are High-Risk because their Ration Inputs are within the scope of review and may be Testable or Non-Testable High-Risk. These Products, Ingredients, and Inputs comply with the sampling and testing requirements of the Standard through the sampling and testing of Inputs to the animals' Rations and/or the seed used to grow the Inputs to the animals' Rations. Feed Inputs to Rations must 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 cannot be GM; nor can they have been treated with or derived from Prohibited Substances listed under Section 2.2.3.

8.1 Compliance of Livestock and Poultry-derived Products, Ingredients, and Inputs

Commented [A80]: A new section was added to focus on the scope of evaluation when a livestock or poultry-derived material is a Product, Major, Minor, or Micro Input or Ingredient.

Livestock and poultry-derived Products, as well as livestock and poultry-derived Ingredients and Inputs to Products, are considered 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 Products/Majors, Minors, and Micros when the livestock or poultry-derived material is, or is present in, the Product under evaluation. Table 8-1 is a summary; additional compliance requirements may apply.~~Animal-Derived Inputs and Livestock FeedAnimal-derived inputs have no point in the production chain at which it is possible to identify GMO contamination using current testing methodologies. It is therefore necessary to control contamination based on testing feed and/or the seed used to grow the feed.~~

Table 8-1 Compliance of Livestock and Poultry-derived Products, Ingredients, and Inputs

Product/Major
1. Animals must comply with Section 8.2, Life Cycle. 2. Inputs to Rations are classified based on the combination of Weight Percentage as present in the Ration, Risk Status, and Testability. 3. Major Inputs to Rations are within the scope of review and must be found compliant with Table 8-2. 4. Major High-Risk Inputs to Rations must comply with: a. Section 4, Chain of Custody b. Section 8, Livestock and Poultry c. Section 8.8, Onsite Farm and Feed Mill Inspections 5. In addition to Ration compliance, the livestock or poultry-derived material must comply with: a. Section 4, Chain of Custody b. Section 5, Onsite Inspections c. Section 8.8, Onsite Farm and Feed Mill Inspections d. Section 10, Product Specifications and Labeling e. Section 11, Quality Assurance
Minor
1. Materials may comply with Standard requirements as a Product/Major. **OR** 2. Materials may comply with Section 7.3, Testable High-Risk Minor and Micro Inputs and Ingredients (e.g., Verified Status, organic certification).
Micro
1. Materials may comply with Standard requirements as either a Product/Major. **OR** 2. Materials may comply with Standard requirements as a Minor. **OR** 3. All Inputs to Rations are outside the scope of review; materials must comply with Section 3.1.3, Micro Inputs and Ingredients.

Commented [A81]: A new compliance table was created to gather all Standard sections pertinent to demonstrating compliance of livestock and poultry-derived materials based on Weight Percentage as represented in, or as present in, the finished Product into one location.

~~1.~~8.2 Life Cycle~~Scope~~

~~a. Animal-derived~~Livestock and poultry-derived Products, Ingredients, and ~~i~~Inputs must be from animals that comply with the following life cycle feed guidelines~~:~~.

~~i.~~**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

~~ii.~~**8.2.2** Poultry, including spent hens: starting ~~from~~on the 2nd day after hatching and ending at slaughter

iii.8.2.3 Dairy animals and lLaying hens: starting thirty (30) days prior to initial verification and continuously thereafterfor the remainder of the animal's productive life (including rest and molt periods)

8.2.4 Dairy animals: starting thirty (30) days prior to initial verification and for the remainder of the animal's productive life (including dry periods)

8.2.5 Animals cannot be intentionally cycled on and off compliant feed. The use of non-compliant Major Inputs to the animals' Rations trigger a Major Non-conformity.

8.2.6 Removal of animals from a Non-GMO-compliant group (e.g., herd, flock) for medical treatment is permitted, during which time their feed is out of the scope of review and no material (e.g., milk, eggs) may be collected from them for use in the Non-GMO supply chain. The animals must immediately resume Non-GMO-compliant feed once treatment is concluded and they are returned to the group.

b. Animal-derived Major Ingredients may be used in a verified product only if the feed of the animal from which the input is derived is compliant with this Section VII.A.

c. Animal-derived Minor Ingredients may be used in a verified product either by demonstration of compliance with this Section VII.A. or by an affidavit that the animal-derived input is the product of a system that has been designed to avoid GMOs in compliance with Section VI.C.

d. Animal-derived Verified-Status Inputs must comply with Section VI.C. and are exempt from review.

e. Live animals may not be verified under this Standard.

2. **Feed compliance based on use of compliant seed**

Under certain circumstances, compliance of livestock feed may be demonstrated based on use of compliant seed; in such cases post-harvest feed testing is not required.[17]

a. Strip testing below 0.25% Action Threshold. Farmer-saved seed and seed purchased from any neighboring farmer who does not have a retail seed operation must be strip tested annually. Frequency of testing should increase if there are any changes that would significantly increase the likelihood of contamination (e.g., a new neighbor planting GMOs). If the strip test results are positive for levels over the Action Threshold set forth in Section V.A., samples must be submitted to a lab for quantitative PCR testing. If the seed is over the 0.25% Action Threshold, the seed may not be planted. This provision is only available in cases where farmers are growing their own feed onsite.

Commented [A82]: v15 Section 8.2.5 was added to clarify the meaning behind "continuously thereafter" and "for the remainder of the animal's productive life" as they pertain to life cycle requirements.

Commented [A83]: v15 Section 8.2.6 was added to make an allowance in the relevant life cycle requirements for animals undergoing medical treatment.

[17] From the date of initial enrollment, Participants have a transition period to bring all seed into compliance with the requirements in Section VII.A.2.a. During the transition period, seeds must be the product of a system designed to avoid GMOs or comply with Section VII.A.2.a.

~~b. **High-moisture crops.** When post-harvest testing is not feasible for high-moisture crops, compliance may be demonstrated through seed testing.~~

~~i. When test results are available from the seed supplier, each lot of seed planted must be compliant with Section V. of this Standard and test below the Action Threshold.~~

~~ii. When test results are not available from the seed supplier, each lot of seed planted must have a receipt of the seed supplier seed tag, a letter from seed supplier establishing that the seed is non-GM, and an invoice and affidavit from the grower confirming planting location.~~

~~iii. In all cases, the grower must demonstrate traceability from the planted field to the harvested feed crop.~~

8.3 Compliance of Feed Rations

The Weight Percentage of Inputs to Rations is calculated based on the weight of the Input as present in the Ration. Table 8-2 is a summary; additional compliance requirements may apply.

Table 8-2 Compliance of Inputs to Rations for Livestock and Poultry-derived Products and Majors

Major	Minor	Micro
Testable High Risk		
1. Comply with Section 4, Chain of Custody, from the point of testing onward. 2. Operations must comply with Section 8.8, Onsite Farm and Feed Mill Inspections. **AND EITHER** a. Sampling and testing must 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** b. Comply with Section 7.4, Affidavit Compliance Based on Country of Origin.	1. Comply with Section 7, Affidavits. **OR** 2. Out of scope.	1. Comply with Section 7, Affidavits. **OR** 2. Out of scope.
Non-Testable High Risk		
1. 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 Section 7.4, Affidavit Compliance Based on Country of Origin, onward. 2. Operations must comply with Section 8.8, Onsite Farm and Feed Mill Inspections. **AND EITHER** a. Comply with Section 7.2, Non-Testable High-Risk Inputs and Ingredients. **OR** b. Comply with Section 7.4, Affidavit Compliance Based on Country of Origin.	1. Comply with Section 7, Affidavits. **OR** 2. Out of scope.	1. Comply with Section 7, Affidavits. **OR** 2. Out of scope.

8.3.1 Ration Reporting Requirements

8.3.1.a Dairy and laying operations must submit to the TA at initial verification a plan detailing the stages of life or production managed including, at minimum, corresponding durations and Rations fed.

8.3.1.a.i Weight Percentage, Risk Status, and Testability attributes apply to all Ration Inputs as they appear within each individual Ration.

8.3.1.a.ii Multiple Rations that are materially different cannot be combined into a single Ration.

8.3.1.a.iii Multiple Rations spanning different stages of life or production cannot be combined into a single Ration unless they are materially homogenous.

8.3.1.b Meat operations must submit to the TA at initial verification a plan detailing the stages of life or production, including, at minimum, corresponding durations and the Ration fed to the animals for the full length of their life cycle requirement as stated in Section 8.2.1.

8.3.1.c Poultry operations must submit to the TA at initial verification a plan detailing the stages of life or production, including, at minimum, corresponding durations and the Ration fed to the animals for the full length of their life cycle requirement as stated in Section 8.2.2.

8.3.1.d **The option for Rations to demonstrate compliance on an as-fed basis will be revisited during the 2020 comment period. Rations compliant on an as-fed basis are subject to additional reporting requirements including, at minimum, the following:**

8.3.1.d.i The corresponding dry matter conversion of each individual Ration must accompany each as-fed Ration.

8.3.1.d.ii A written rationale for why compliance of Rations has been established on an as-fed basis.

8.3.1.e Rations compliant on a dry matter basis have no additional reporting requirements.

~~3.~~8.4 Feed Sampling~~Feed compliance based on post-harvest testing~~

Compliance of Feed grown from commercially purchased seed and~~or~~ commercially purchased or produced feed ~~shall~~must ~~be~~ demonstrate~~d~~ compliance through the evaluation of, at minimum, Testable and Non-Testable Major Inputs~~Ingredients~~ to the animals' Rations.~~,~~ Ongoing ~~including~~ testing of Testable High-Risk Major Inputs~~Ingredients~~ is required.

~~a. **Testing methodology:** The testing method must yield valid results for all Testable Major High-Risk Ingredients. When feed inputs can be isolated into their raw material components, strip testing may be used. When feed inputs are tested as a composite, PCR testing must be used.~~

Commented [A84]: v14.3 Section VII.A.3. was renamed and renumbered to v15 Section 8.4.

~~b.~~8.4.1 ~~**Commercially purchased feed for c**~~**Certified organic farming operations in which ~~products~~goods are pooled before final processing (e.g., dairy, ground meat, egg mixtures)~~:~~**

Commented [A85]: v14.3 Section VII.A.3.b. was renumbered to v15 Section 8.4.1 and language from Participant-facing guidance was incorporated into the Standard for transparency.

The sampling plan for certified organic operations ~~shall~~must be based on testing a composite sample of the High-Risk feed ~~i~~Inputs from a representative selection of farms, with the intention of identifying and addressing any contamination occurring in the Participant's operation. ~~The f~~Farms will be chosen ~~for such~~based on the quarterly sampling density and selection requirements outlined in Table 8-3. Such sampling and testing ~~shall~~must be representative of the Participant's

operations in a ~~r~~Region.[13]

Commented [A86]: v14.3 Footnote 13 was moved to v15 Appendix A – Terms and Definitions: Region.

8.4.1.a Regions

Regions must 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 must supply the TA with:

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

This basic documentation must 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.

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 must be chosen at random from within that same Region.

Table 8-3 Quarterly Sampling Density Selection

Number of Farms per Region	Number of Farms to be Sampled and Tested
Fewer than 10 farms per region	M~~m~~inimum of 1 farm tested per region per quarter
10 to 20 farms per region	M~~m~~inimum of 2 farms tested per region
21 to 50 farms per region	10% of farms tested per region
51 to 100 farms per region	5% of farms tested per region
Over 100 farms per region	Minimum of 6 farms tested per region

The sampling plan within each ~~r~~Region ~~shall~~must include a random selection of farms each quarter. Annual sampling plans ~~shall~~must be

[13] ~~Region, as used in Section VII.A.3.b., is defined as a geographic area with relatively homogenous farm operations and sources of livestock feed, typically encompassing one or more states, in which farms ship unprocessed livestock products to one or a few processors.~~

reviewed with the TA and may be adjusted over time to provide the most technically sound basis for continuous improvement. ~~Adjustments shall be mutually agreed upon and might include increased/decreased sampling frequency or density in regions with unusually high/low percentages of samples over the Action Threshold.~~

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 must seek the cause of contamination.

8.4.1.c Ration Reporting within the Regional Model

All farms in the Participant's supply chain must 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, must 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 must be evaluated and found compliant.

8.4.1.d Testing within the Regional Model

Testing must comply with Section 6.3.3. Composite samples ~~shall~~must be tested on a quarterly basis. When more than one test is needed, results ~~shall~~may be averaged. Quarterly results or averages in excess of the Action Threshold ~~shall~~will trigger an assessment of the cause of contamination and appropriate steps to eliminate identified sources of contamination.

Upon renewal, Participants ~~shall~~must provide a report ~~upon renewal~~ of any significant changes in the frequency of GMO presence in ~~livestock~~ feed Inputs, the percentage of samples exceeding the Action Threshold, and steps taken to secure feed that tests at or below the Action Threshold.

~~c.~~8.4.2 ~~Commercially purchased feed for all non-~~ Certified organic farming operations in which ~~products~~goods are not pooled ~~or not pooled before final processing, and all certified organic operations in which products are not pooled before final processing~~ (e.g., shell eggs, cut meat)~~:~~, and conventional farming operations

The sampling ~~plan for non-organic operations~~ and testing plan for certified organic farming operations in which goods are not pooled and conventional farming operations ~~in which products are not pooled before final processing must~~ may include ~~quarterly composite testing~~ either of ~~feed samples for each shipment of feed purchased by each farmer in the Participant's operations.~~the following: ~~If more than 20% of the Participant's farmers fail to supply samples, it~~

Commented [A87]: v14.3 Section VII.A.3.c. was renumbered to v15 Section 8.4.2 and a new compliance pathway was added as v15 Section 8.4.2.a.

~~will be considered a major nonconformity, subject to Section IX.C.3.~~

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

Commented [A88]: The Internal Control System (ICS) concept was taken from v14.3 Section VII.A.4., expanded, and renumbered to v15 Section 8.4.3.

~~4.~~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 model. The group compliance model must include an Internal Control System (ICS). All components of the ICS are subject to final approval by the TA. At a minimum, the ICS must include:

8.4.3.a A clearly defined scope outlining the ICS management structure, including personnel, titles, roles, contact information, and conflict of interest policy.

8.4.3.b A listing of farms, facilities, and/or operations within the group being overseen (i.e., group members), the locations of all farms in the operation, locations of all feed mills, identification of which feed mills service which farms, locations of all processing facilities, locations where Parallel Processing is taking place, and the group member(s) are responsible for testing.

8.4.3.c A training plan for ICS personnel, including how ICS personnel educate their group members

8.4.3.c.i Each member of the group must have, and acknowledge access to, a copy of the most recent Standard version.

8.4.3.c.ii Each member of the group must have, and acknowledge access to, any relevant documents such as standard operating procedures (SOPs) and sampling and testing plans.

8.4.3.d A comprehensive plan for how each group member will comply with all relevant Standard sections based on the nature of their goods and Ration formulations, including Section 4, Section 8.2 through Section 8.8, Section 10, and Section 11.

8.4.3.d.i Frequency of inspection must be at least once per year by ICS personnel of all farms under the scope of the ICS.

8.4.3.d.ii Third-party inspections must 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.

8.4.3.d.iii The comprehensive plan must include how the ICS will handle Minor Non-conformities.

8.4.3.d.iv The comprehensive plan must include how the ICS will handle Major Non-conformities.

8.4.3.e For large certified organic farming operations where goods are pooled, a sampling and testing plan in compliance with Section 8.4.1 and Section 8.6 is required for each group member responsible for testing.

8.4.3.f For large certified organic farming operations where goods are not pooled and for large conventional farming operations where goods are 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 responsible for testing.

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.

~~a.~~8.5 Testing ~~m~~Methodology.

Commented [A89]: v14.3 Section VII.A.3.a. was renumbered as v15 Section 8.5.

The testing method must yield valid results for all Testable ~~Major~~ High-Risk Inputs~~Ingredients. When feed inputs can be isolated into their raw material components, strip testing may be used. When feed inputs are tested as a composite, PCR testing must be used.~~ Immunological testing methods may be used when compliant with Section 6.5. Molecular testing methods compliant with Section 6.4 must be used when immunological testing methods cannot be used and may be used in all cases in lieu of immunological testing methods.

~~2.~~8.6 Feed ~~c~~Compliance Through~~based on use of~~ ~~c~~Compliant ~~s~~Seed

Commented [A90]: v14.3 Section VII.A.2. was renumbered as v15 Section 8.6.

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.[12] ~~[19]~~ Neither seed compliant under Section 8.6.1 or Section 8.6.2 nor feed derived from seed compliant under Section 8.6.1 or Section 8.6.2 is eligible for verification.

~~a.~~8.6.1 ~~**Strip testing below 0.25% Action Threshold.**~~ **Farmer-saved seed** and seed purchased from any neighboring farmer who does not have a retail seed operation must be ~~strip~~ tested annually. Frequency of testing should increase if

[12] ~~From the date of initial enrollment, Participants have a transition period to bring all seed into compliance with the requirements in Section VII.A.2.a. During the transition period, seeds must be the product of a system designed to avoid GMOs or comply with Section VII.A.2.a.~~

there are any changes that would significantly increase the likelihood of contamination ~~(e.g., a new neighbor planting GMOs). If the strip test results are positive for levels over the Action Threshold set forth in Section V.A., samples must be submitted to a lab for quantitative PCR testing. If the seed is over the 0.25% Action Threshold, the seed may not be planted. This provision is only available in cases where farmers are growing their own feed onsite.~~ 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 must 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 cannot be planted.

~~b.~~8.6.2 ~~**High-moisture crops.**~~ **Freshly harvested and direct-fed forage, as well as silage and similarly fermented feeds.** When post-harvest testing of freshly harvested and direct-fed forage and/or silage and similarly fermented feeds is feasible, sampling must comply with Section 6.2, testing must comply with Section 6.3, and test results must comply with either Section 6.4 or Section 6.5. When post-harvest testing is not feasible ~~for high-moisture crops, compliance may be demonstrated through seed testing~~because compliance cannot be established with one or more of the sections listed above, these feed Inputs may demonstrate compliance through seed testing, Affidavit, or use of Verified-Status seed.~~iii.~~ In all cases, the grower must demonstrate traceability from the planted field to the harvested feed crop.

Commented [A91]: v14.3 Section VII.A.2.b. was renumbered as v15 Section 8.6.2 and the term "High-moisture crop" was replaced with a more descriptive sentence: "Freshly harvested and direct-fed forage, as well as silage and similarly fermented feeds."

Commented [A92]: v14.3 Section VII.A.2.b.iii. was moved to the bottom of v15 Section 8.6.2.

~~i.~~8.6.2.a When test results are available ~~from the seed supplier~~, each lot of seed planted must be compliant with ~~Section V. of this Standard~~Section 6 and test at or below the Action Threshold.

~~ii.~~8.6.2.b When test results are not available ~~from the seed supplier~~, each lot of seed planted must have a ~~receipt of the seed supplier~~ seed tag, an Affidavit ~~letter~~ from the seed supplier establishing that the seed is ~~n~~Non-GMO, ~~and~~ an invoice, and an ~~a~~Affidavit from the grower confirming planting location.

8.6.2.c When Verified-Status seed is planted, each lot of seed must have the seed supplier seed tag, an invoice, and an Affidavit from the grower confirming planting location.

~~d.~~8.7 ~~Commercially produced feed~~Feed Mills

Commented [A93]: v14.3 Section VII.A.3.d.ii. was renumbered to v15 Section 8.7.

~~Commercially produced feed may be verified on the basis of compliance of Major Ingredients, including the testing of Testable High-Risk Major Ingredients.~~

~~i. The testing method must yield valid results for all Testable Major High-Risk Ingredients.~~

~~ii. When feed inputs can be isolated into their raw material components, strip testing may be used as described in Section V.D.~~

~~iii. When feed inputs are tested as a composite, PCR testing must be used as described in Section V.C.~~

8.7.1 Rations formulated by feed mills may be found compliant if:

8.7.1.a Every lot of Testable Major High-Risk Input to the Ration complies with Section 6.

8.7.1.b Every lot of Non-Testable Major High-Risk 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 Section 6.

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 Sections 8.7.2.a and 8.7.2.b above is maintained through compliance with Section 4.

~~4.~~8.8 Onsite Farm and Feed Mill ~~i~~Inspections ~~for farms~~

~~This section is in addition to the provisions of Section IV.C. Inspections may be completed via a group certification model. In order to be considered compliant, the Participants' internal control system (ICS) staff must conduct a documented assessment visit to each farm at least once every year.~~

~~a. In addition to the ICS, third-party inspections must be conducted on 10% of all farms every year. Results of the third-party inspection will be compared with the results of the ICS assessment of the farms to verify the effectiveness of the ICS process.~~

~~b. For certified organic operations, additional inspections (beyond those required for organic certification) are not required.~~

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 this Standard.

Commented [A94]: v14.3 Section VII.A.4. was renumbered as v15 Section 8.8 and restructured to better flag situations in which onsite farm and feed mill inspections may be required.

8.8.4 Notwithstanding any of the above, large conventional farming operations compliant with Section 8.4.3 are required to 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 will be chosen by the TA.

~~VII.~~9 Special Requirements for Specific Products, Ingredients, and Inputs ~~Sectors~~

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.

~~B.~~9.1 Apiculture~~Honey and Bee-Produced Inputs~~

Honey and other ~~inputs produced~~goods derived from ~~bees~~apiculture must meet the following requirements:

~~1.~~9.1.1 The bees' forage area (defined as the area within a 4-mile radius of the hives) must be sufficiently free of GM commercial agriculture ~~to minimize contamination of the bees with GM pollen~~.

~~2.~~9.1.2 Any ~~non-forage~~supplemental bee feed ~~for the bees~~ must be evaluated for compliance with ~~the required compliance measures listed in with Section III.A. for High-Risk Inputs~~Section 3.

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 must:

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).[3]

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 Section 3.1.3.c, and must be Non-GMO.

9.2.2 Processing Aids used in the production of beer, wine, and liquor are subject to the compliance requirements in Section 2.2.2.

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

Commented [A95]: v14.3 Section VII.B., v14.3 Section VII.C., and v14.3 Section VII.D. were separated from v14.3 Section VII.A. and put in their own section.

Commented [A96]: Paragraph originally taken from v14.3 Section VII. and added to both v15 Section 8 and v15 Section 9. "sampling" was added to the example in parentheses.

Commented [A97]: v14.3 Section VII.B. was renumbered as v15 Section 9.1.

Commented [A98]: Language outlining additional and special compliance considerations for certified organic honey and other certified organic byproducts of apiculture as Products, Ingredients, and Inputs was provided in v15 Section 9.1.3.

Commented [A99]: New language was added to clarify the compliance requirements for beer, wine, and liquor Products, Ingredients, and Inputs.

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 must 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 Products or Major or Minor Ingredients, both the Microorganism and the Growth Media are within the scope of review and must be compliant.

9.3.2 An Affidavit meeting all the requirements of Section 7.2 must, in addition, confirm that the Microorganism is Non-GMO.

9.3.3 Inputs to Growth Media must 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.

9.3.4 When Microorganisms or Inputs or Ingredients derived from Microorganisms are Micro Ingredients, the Microorganism is within the scope of review, but the Growth Media are not.

9.4 Probiotics

9.4.1 When probiotic Microorganisms or Inputs or Ingredients derived from probiotic Microorganisms are Products, Major, Minor, or Micro Ingredients, the probiotic Microorganism is within the scope of review and must be compliant. The Growth Media for probiotic Microorganisms as Inputs, Ingredients, and Products are temporarily outside the scope of evaluation. This temporary removal from scope will be revisited during the 2020 comment period.

9.4.2 An Affidavit meeting all the requirements of Section 7.2 must, in addition, confirm that the probiotic Microorganism is Non-GMO.

~~C.~~9.5 ~~Wild-Caught and Farm-Raised~~ Seafood

This Section 9.5 applies to all saltwater and freshwater aquatic animals.

~~1. Wild-caught seafood shall be treated as Low-Risk Inputs if documentation or affidavit establish that the organism was caught in the wild.~~

~~2.~~9.5.1 Farm-raised seafood (in captivity from egg to harvest and/or where nutrient additions are provided) ~~shall~~will be fully evaluated as ~~an animal-derived~~a High-Risk Product, Ingredient, or Input and requires the evaluation ~~of feed~~ and ~~other inputs. Products or inputs derived from such seafood shall be evaluated in the same manner as animal-derived inputs in Section II.A. and Section VII.A.~~compliance of Ration Inputs.

Commented [A100]: Language was added to v15 Section 9.4 to clarify that Growth Media for probiotic Microorganisms, regardless of their Weight Percentage in the finished Product, is currently out of the scope of review.

Commented [A101]: v14.3 Footnote 14 moved to v15 Section 9.4.1 and v15 Section 9.6.1. and edited heavily.

Commented [A102]: v14.3 Section VII.C. was renumbered to v15 Section 9.5.

Commented [A103]: All animal-derived Inputs and Ingredients are considered High-Risk under v15, regardless of feed Ration composition. For this reason, v14.3 Section VII.C.1. was deleted.

9.5.2 Products, Ingredients, and Inputs derived from farm-raised seafood will be evaluated in the same manner as livestock and poultry Products, Ingredients, and Inputs in Section 3 and Section 8.

9.5.3 The feed of seafood may be compliant under Section 7.5 if the Affidavit establishes that the organism was caught in the wild.

~~D.~~9.6 ~~Growth Media for Certain Vitamin and Supplement Inputs~~Vitamins and Supplements

9.6.1 ~~Based on demonstrated lack of commercial availability, the growth media for probiotic microorganism inputs and microorganisms that produce enzyme inputs~~The Growth Media for Microorganisms from which Enzyme Inputs and Ingredients to vitamin and supplement ~~p~~Products are derived, are temporarily outside of the scope of evaluation.[14] ~~This temporary exclusion is in effect until after the~~removal from scope will be revisited during the 2020 comment period.

Commented [A104]: This section was separated from v14.3 Section VII.D. and renumbered as v15 Section 9.6.

Commented [A105]: v14.3 Footnote 14 moved to v15 Section 9.4.1 and v15 Section 9.6.1. and edited heavily.

~~VIII.~~10 Product Specifications and Labeling

~~A.~~10.1 Specifications for Obtaining Inputs and Ingredients

10.1.1 Major and Minor High-Risk Inputs and Ingredients must be sourced from Non-GMO sources. Micro High-Risk Ingredients should be sourced from Non-GMO sources.

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~~1.~~10.1.2 For ~~p~~Products verified under the ~~Program~~PVP, Participants ~~shall not~~cannot knowingly plant, purchase, or use ~~i~~Inputs or Ingredients that are not compliant with the Standard.

~~2.~~10.1.3 The written specifications for all ~~inputs~~Products, Ingredients, and ~~products shall~~Inputs must include requirements regarding Standard compliance and ~~shall~~must be updated when the Participant changes suppliers, Inputs, or ~~inputs.~~Ingredients.

~~3.~~10.1.4 When spot purchasing is necessary, unverified ~~i~~Inputs and Ingredients should be avoided; Participants must seek out ~~Non-GMO Project v~~Verified ~~inputs~~ Status Inputs and Ingredients of appropriate scope. If a spot purchase of unverified ~~i~~Input or Ingredient is made, the Participant must:

10.1.4.a ~~j~~Justify to the TA why a ~~v~~Verified ~~input~~ Status Input or Ingredient was not used. ~~Spot purchases of unverified inputs are only allowed on the following basis:~~

10.1.4.b Provide evidence that ~~A~~any Testable High-Risk Input or Ingredient that is spot purchased ~~must be~~has been tested in accordance with the

[14] ~~This temporary exclusion is in effect until after the 2020 comment period.~~

requirements of this Standard and ~~must be~~ that the test results are at or below the relevant Action Threshold~~.~~

~~a.~~10.1.4.c Demonstrate that all ~~Any n~~Non-~~t~~Testable High-Risk ~~Input, Verified-Status Input,~~Inputs or ~~Low-Risk Input~~Ingredients that ~~is~~are spot purchased ~~must be~~are compliant with all applicable ~~affidavit~~ requirements of Table 3-3~~this Standard.~~

10.1.4.d Demonstrate that all Verified-Status Inputs or Ingredients or Low-Risk Inputs or Ingredients that are spot purchased are compliant with all applicable requirements of Table 3-2

~~b.~~10.1.4.e The Participant must provide the TA with documentation of the purchase, including ~~a~~Affidavits, sampling information, and test results. This reporting ~~shall~~must be done ~~at least once per year, according to~~in a ~~schedule determined by the TA and the Participant~~timely manner.

~~c.~~10.1.5 Constraints on spot purchasing may be enforced at the discretion of the TA. For example, repeated spot purchases from the same supplier could be grounds for this allowance to be revoked or restricted.

~~B.~~10.2 Labeling

10.2.1 Wholesale and retail Products must comply with the labeling requirements outlined in this Standard.

~~3.~~10.2.2 The TA will review labels to assess compliance with these claim guidelines.

~~1.~~10.2.3 **Labeling claims must be accurate ~~and~~, truthful**, and ~~must~~ not mislead the consumer about the GMO content of the ~~p~~Product. Any reference to the Non-GMO Project or use of the verification mark must be approved by a written agreement with the ~~Non-~~Project. One-hundred percent (100%) GMO ~~Project. Examples of~~absence claims ~~that~~ are not acceptable ~~are~~and include, but are not limited to, "contains zero GMOs," "GMO-free," and "GE~~-~~-free."

10.2.4 High-Risk Micro Ingredients other than artificial and natural flavors, Enzymes, and Microorganisms that have been Micro exempted under Section 3.1.3.c cannot be listed with the same name, or any other common name, on the Principal Display Panel of a retail consumer Product.

10.2.5 Ingredients other than artificial and natural flavors, Enzymes, and Microorganisms cannot be named on the Principal Display Panel of a retail consumer Product if one or more of their sub-Ingredients (as they appear in a parenthetical Ingredient declaration or supplement facts panel) have been Micro exempted under Section 3.1.3.c and the Micro-exempted sub-Ingredient(s) is/are considered to reasonably characterize the Ingredient appearing on the Principal Display Panel.

~~**2. Certain products made with animal-derived, bee-produced inputs, or single compliant High-Risk Major Defining Ingredients may use a "made with" claim** in accordance with the following guidelines:~~

~~a. Animal-derived and bee-produced inputs may not collectively constitute more than 25% of the product and may not be a defining ingredient.~~

~~b. The product must contain compliant High-Risk Major Ingredients other than those from the animal-derived and bee-produced inputs (e.g., corn meal, soy flour) constituting more than 5% of the product.~~

~~c. The "made with" claim may only be made in relation to approved compliant High-Risk Major Ingredients. For example, a corn chip with a seasoning blend containing more than 5% of an unverified dairy ingredient could claim "Made with Non-GMO Project Verified Corn."~~

~~d. When a "made with" claim is being used for a product that does not contain any animal-derived or bee-produced inputs, the single compliant High-Risk Major Defining Ingredient must constitute at least 70% of the finished product (for example, an algae product in a vegetable capsule).~~

~~e. The "made with" claim is a text-only claim. The Non-GMO Project verification mark may not be used on products approved under Section VIII.B.2.~~

~~f. If the product contains dairy inputs, supplier affidavits must show that no rBGH or rBST was used.~~

~~3. The TA will review labels to assess compliance with these claim guidelines.~~

~~IX.~~11 Quality Assurance

~~A.~~11.1 Total Quality ~~Assurance~~Management Systems

~~1.~~11.1.1 The Participant's quality assurance and quality control program ~~shall~~, including SOPs, forms, and documents, must be revised as needed to ensure compliance with the Standard, and revisions must be documented.

~~2.~~11.1.2 Compliance with applicable requirements of the Standard ~~shall~~must be identified as ~~a~~ key quality indicators of the Participant's ~~products and SOPs shall~~total quality system.

11.1.3 The Participant must monitor and control the compliance of Inputs and Ingredients purchased and finished Products, and this must be ~~revised, or added where necessary, to incorporate measures that ensure such compliance with the Standard~~documented.

~~3.~~11.1.4 Where needed, additional training ~~shall~~must be provided to relevant staff to ensure that ~~they are capable~~SOPs in support of ~~fulfilling their duties in a manner that supports~~Standard compliance ~~of the operation,~~are followed and ~~the products produced, with the Standard.~~ training must be documented.

~~4. Documents and forms shall be revised, as necessary, to include compliance with the requirements of the Standard as a key quality indicator and to ensure that the Participant operates in a manner that fulfills the requirements of the Standard.~~

~~5.~~11.1.5 All SOPs, documents, forms, ~~reference materials,~~ and specifications needed by personnel to fulfill the requirements of the Standard ~~shall~~must be readily available to relevant personnel.

~~6.~~11.1.6 Records ~~shall~~must be retained for ~~3~~a minimum of three (3) years.

~~B. Monitoring of Critical Control Points~~

~~1. Monitoring and control of key parameters relevant to compliance with the Standard shall be incorporated into the Participant's quality assurance and quality control program. Key parameters include traceability, segregation, and testing for compliance with Action Thresholds.~~

~~2. The Participant shall monitor and verify the compliance of inputs purchased and products sold, and this shall be documented.~~

~~C.~~11.2 Non-conformities and Corrective Actions

11.2.1 Global Non-conformity and Corrective Action Requirements

11.2.1.a Full compliance with the Standard must be achieved prior to initial verification.

~~1.~~**11.2.1.b** ~~Nonconformities~~ Changes in processes, procedures, ~~i~~Inputs, Ingredients, or ~~p~~Products, ~~which~~that could impact compliance with any aspect of the Standard, ~~shall~~will be deemed Non-conformities and will trigger corrective actions.

~~2.~~**11.2.1.c** Non-conformities discovered during the ~~Program application or~~ renewal process must be addres~~olvs~~ed in order to ~~achieve or~~ maintain ~~compliance with the Standard.~~ verification.

~~2.~~**11.2.1.d** Mid-term ~~n~~Non-conformities discovered through internal quality assurance processes, complaints from customers, ~~or~~ third-party surveillance, ~~shall~~or third-party audits, will require corrective action as described in Section 11.2.2 or in Section 11.2.3~~below.~~ as appropriate.

~~3. Major nonconformities shall be reviewed at the time of occurrence, documented, and immediately reported in writing to the TA by the Participant.~~

~~a. Discovery of any major nonconformity must be followed by a timely root cause analysis. "Timely" is typically considered to be within 7 days and rarely longer than 30 days. Longer delays must be justified in writing including the planned root cause analysis. An explanation of the action steps already being taken must be provided along with the expected completion date of the root cause analysis.~~

~~b. Findings of the root cause analysis must be reported in writing to the TA, together with the planned corrective actions to be undertaken.~~

~~c. Corrective actions must be completed within 15 days of the completion of the root cause analysis. The TA will review and approve the planned corrective actions. Corrective action plans shall include the identification of persons responsible for their execution, defined timelines for actions, and the desired results of the corrective action plan. Documentary evidence must be submitted to the TA within 5 days of the completion of corrective actions.~~ ~~Such evidence might include new/modified quality assurance SOPs such as updates to training and record keeping or changes to sampling and testing plans, and, where possible, evidence that these updated SOPs are achieving compliance with the Standard. The TA will review and approve all corrective action evidence.~~

~~d. Any delays in the timeline from reporting to completion of corrective actions must be justified in writing and approved by the TA.~~

~~4. Any major known nonconformity that goes unreported and/or uncorrected according to the requirements in Section IX.C.3. shall be cause for the product or the Participant to be removed from the Program. Prior to removing the Participant or product from the Program, the TA must notify the Participant via email of this intended action. The Participant will have 10 days from date of said notice to provide all required documentary evidence to avoid withdrawal from the Program.~~

~~5.~~11.2.1.e Identification of ~~n~~Non-conformities, corrective actions, root cause analyses, and successful remediation of the ~~n~~Non-conformity ~~shall all~~must be documented.

Commented [A106]: v14.3 Section IX.C.5. was renumbered to v15 Section 11.2.1.e.

~~6. Repeated nonconformance with the Action Threshold may require mid-term reevaluation of the product, possibly including an onsite inspection and/or input supplier verification.~~

~~7. Minor nonconformities shall be reviewed at the time of the annual evaluation. Verification renewal shall be contingent upon appropriate resolution of any such nonconformity.~~

~~3.~~11.2.2 **Major ~~n~~Non-conformities** ~~shall~~

Major Non-conformities must be reviewed at the time of occurrence, documented, and immediately reported in writing to the TA by the Participant.

~~a.~~11.2.2.a Discovery of any ~~m~~Major ~~n~~Non-conformity must be followed by a timely root cause analysis~~.~~ and corrective action plan. "Timely" is typically considered to be within seven (7) days and rarely longer than thirty (30) days. ~~Longer delays must be justified in writing including the planned root cause analysis. An explanation of the action steps already being taken must be provided along with the expected completion date of the root cause analysis.~~

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

5.**11.2.2.b.i** ~~**When a non-compliant tested lot is mixed with a compliant tested lot,**~~Under certain circumstances, the Participant may propose blending a non-compliant tested lot with a compliant tested lot as part of their corrective action plan. This optional cure is temporary and must not be incorporated into the Participant's SOPs or implemented on a recurring basis. In this case, the Participant must:

- ~~a.~~Demonstrate that a homogenous blend was achieved ~~prior to testing.~~
- Retest the blend in accordance with Section 6
- ~~In all cases,~~ Confirm that the finished lot tests at or below the relevant Action Threshold~~.~~
- ~~b. Investigate and document the cause of any individual lot's contamination over the relevant Action Threshold.~~
- ~~c.~~Implement and document practical continuous improvement practices to reduce, and ultimately eliminate, the need for any future blending of lots~~. An example of one such practice would be to help growers secure Non-GMO Project Standard compliant planting seed.~~

~~b.~~**11.2.2.c** Findings of the root cause analysis must be reported in writing to the TA, together with the planned corrective actions to be undertaken.

~~c.~~**11.2.2.d** The TA will review and at their discretion approve the findings of the root cause analysis and the planned corrective actions.

~~c.~~**11.2.2.e** Corrective actions must be completed ~~within~~in a timely manner, typically within thirty (30)~~15~~ days and rarely longer than ninety (90) days of the completion of the root cause analysis and corrective action plan. Documentary evidence must be submitted to the TA within five (5) days of the completion of corrective actions. The TA will review and approve all corrective action evidence.

~~d.~~**11.2.2.f** Any delays in the timeline from reporting to completion of corrective actions must be justified in writing and approved by the TA.

~~4.~~**11.2.2.g** Any ~~major~~ known Major ~~n~~Non-conformity that goes unreported ~~and/~~or uncorrected or keeps recurring according to the requirements in ~~Section IX.C.3.~~ Section 11.2.2 ~~shall~~will be cause for the ~~p~~Product or the Participant to be removed from the PVP~~Program. Prior to removing the Participant or product from the Program, the TA must notify the Participant via email of this intended action. The Participant will have 10 days from date of said notice to provide all required documentary evidence to avoid withdrawal from the Program.~~

Commented [A107]: v14.3 Section V.B.5. was moved to v15 Section 11.2.2.b.i and is now a temporary cure for a Major Non-conformity.

Commented [A108]: v14.3 Section IX.C.3.b. was renumbered to v15 Section 11.2.2.c.

~~6.~~11.2.2.h Repeated non-conformance with the Action Threshold may require mid-term re-evaluation of the ~~p~~Product~~, possibly including an onsite inspection and/or input supplier verification~~.

11.2.3 Minor Non-conformities

11.2.3.a Minor Non-conformities will trigger corrective actions.

~~7.~~**11.2.3.b** Minor ~~n~~Non-conformities and corrective actions ~~shall~~must be reviewed, at minimum, at the time of ~~the annual evaluation~~renewal.

11.2.3.c ~~Verification r~~Renewal ~~shall~~will be contingent upon appropriate resolution of any such Minor ~~n~~Non-conformity.

~~D.~~11.3 Renewal

11.3.1 Renewal evaluation of every ~~v~~Verified ~~p~~Product ~~shall~~will be required at least annually.

11.3.2 Renewal evaluation must ensure that, at minimum:

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

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

11.3.2.c All Non-conformities have been addressed.

11.3.3 ~~n~~No changes to the ~~p~~Product or its manufacture ~~and~~or processing that would compromise the ~~p~~Product's compliance with this Standard have occurred ~~and that~~.

11.3.4 ~~t~~The ~~p~~Product is compliant with any applicable Standard revisions.

The TA may require a Participant to submit updates more frequently if history shows ~~cases~~a pattern of ~~m~~Major ~~n~~Non-conformities occurring as a result of unannounced changes to the operation. Such changes ~~could~~ include, but are not limited to, the following: changes in ~~p~~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 ~~i~~Inputs, Ingredients, or ~~p~~Products~~,~~; or changes in specifications of ~~a~~ High-~~-~~Risk ~~Input~~Inputs, Ingredients, or of a final ~~p~~Product that contains High-Risk Inputs or Ingredients.

~~E. Participation~~

~~1. **In addition to Participants,** suppliers and contract processors shall also provide information to TAs as necessary to verify compliance with the Standard.~~

~~a. In some cases, inputs certified by other non-GMO certification programs may be approved as equivalent for use in verified products. A program would be acceptable as long as that program is fully equivalent to or exceeds the requirements of the Non-GMO Project Standard. The decision on equivalency will be made by the Non-GMO Project Board of Directors based on an evaluation of said program by the TA using a procedure duly approved by the Board of Directors. In such cases,~~

Commented [A109]: v14.3 Section IX.E.1. was deleted.

~~certificates of compliance from such a program may be accepted as equivalent to verification by the Non-GMO Project.~~

~~2. **Participants with Contract Processors**~~

~~The Program follows a process-based approach that is supported by testing at strategic points in the supply chain. The Non-GMO Project acknowledges contractual agreements between certain Participants (e.g., brand owners) and their contract processors. Thus, any manufactured product that is made by an operation contracted by the Participant may be evaluated and approved under the Program as long as it is a product of a system that has been designed to avoid GMOs. Organic certification is an example of such a system. All such systems are subject to review by the TA, especially in cases where parallel processing occurs within the certified system (e.g., processing certified organic soybeans in both Non-GMO Project verified and non-verified forms). In such cases, lot-by-lot IPs will likely be necessary.~~

~~The Participant and/or the contract processor must provide evidence of testing as described in Section V. The contract processor's exemption from inspection under this Section IX.E.2. expires after 3 years, unless otherwise exempt from inspection. After that point, the Participant must EITHER:~~

~~a. Adopt a defined plan for bringing contract processor into full participation in the Product Verification Program and full standard compliance within a defined time frame; OR~~

~~b. Submit to a facility survey and onsite inspection for contract operations. Such inspections shall be completed by an approved inspector.~~

Commented [A110]: The contract processor inspection exemption in v14.3 Section IX.E.2. was moved to v15 Section 5.2 and the remainder of v14.3 Section IX.E.2. was deleted.

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.

Biotechnology[5] – 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
b. 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.

[5] 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

~~**Compliant/Compliance –** In accordance with the referenced and applicable requirement of this Standard. Compliance refers to particular requirements, as opposed to the Standard or Program as a whole.~~

~~**Component –** An input to an input (excluding processing aids).~~

Certificate of Approval – 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.

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 ~~microbes~~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.

~~**Defining Ingredient –** A defining ingredient is an ingredient whose name appears in the name of the product.~~

Enzyme – A protein molecule produced by a living organism~~, which~~ that acts as a catalyst to bring about a specific biochemical reaction~~; specific examples include chymosin, catalase, and amylase~~.

Functional Enzyme – An ~~e~~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

~~**GM –**~~**Genetically Modified or Genetic Modification (GM)** – A term referring to ~~processes~~the result of the application of ~~b~~Biotechnology ~~used to create GMOs~~.

~~**GMO or**~~ **Genetically Modified Organism (GMO)** – An organism in which the genetic material has been changed through ~~b~~Biotechnology in a way that does not occur naturally by multiplication and/or natural recombination; cloned animals are included within this definition.

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

Ingredient – Any ~~input, including an additive, used in the manufacture or preparation~~material or substance that is a component in the creation of a ~~product~~wholesale or retail consumer good and present in ~~the finished product although possibly~~said good in ~~a modified~~either its original or altered form.

Input – Any material or substance that ~~becomes a part of the finished product, or a component of which becomes a part of the finished product, or is used otherwise in the~~ is used in the production of a ~~product. These include the following:~~

- ~~Agricultural materials, such as seeds, fertilizers, and pesticides.~~
- ~~Unprocessed agricultural materials, such as vegetables, grains, fruit, greens, herbs, and other fresh foods.~~
- ~~Feed materials, such as grains, forage plants, vitamins, enzymes and minerals.~~
- ~~Livestock production materials, such as vaccines, hormones, and other veterinary materials.~~

~~Manufacturing and processing materials, including ingredients, flavorings, seasonings, colorings, additives, enzymes, cultures, and~~wholesale or retail consumer good. Not all ~~other substances~~Inputs are necessarily represented in, or present in ~~final manufactured products~~, said good.

~~This definition does not distinguish between "mono" (composed of only one component) or "compound" (composed of more than one component) inputs. If the product is made of only one input, with no components (e.g., a "single input product"), the input and the product are the same.~~

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.

Major Non-conformity ~~– A major nonconformity is –~~ aA deviation that could affect the compliance of an Input or ~~i~~Ingredient with the relevant Action Threshold, such as unintentional contamination of the ~~i~~Ingredient with GM material, or that could ~~affect~~impact the compliance of an ~~i~~Input or Ingredient with ~~Section VI.A.~~Section 7.2.

~~**Medicine (Veterinary) –** (i) Any synthetic material other than vitamins, minerals, or amino acids given to livestock at any time; or (ii) Any non-synthetic material given to an animal on a non-routine basis for the purposes of maintaining or restoring health.~~

~~**Microbe –** A microorganism, especially a bacterium or fungus causing fermentation or otherwise metabolizing media. Specific examples include yeasts (e.g., *Saccharomyces*) and bacteria (e.g., *Lactobacillus*).~~

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).

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

Minor Non-conformity ~~– A minor nonconformity is –~~ aA deviation that could not cause any of the relevant ~~i~~Inputs or Ingredients to the ~~p~~Product to exceed the relevant Action Threshold. This includes ~~minor~~immaterial changes to procedures, recordkeeping, documentation, or anything else ~~minor~~immaterial that does not have the potential to impact compliance with the relevant Action Threshold.

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

Non-GMO or Non-GM – An organism or derivative of such an organism whose genetic structure has not been altered by ~~b~~Biotechnology.

Non-Risk Category – A group of one or more types of wholesale or retail goods whose formulations involve no Inputs nor Ingredients of biological origin.

Non-Testable – 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.

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

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

Principal Display Panel[6] – 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).

Processing Aid ~~– An input~~[7] – (a) Substances [Inputs] that ~~is (1)~~are added to a food [Product or Ingredient] during the processing of ~~the product~~such food but ~~is~~are removed in some manner from the ~~product~~food before it is packaged in its ~~final~~finished form~~; (2)~~. (b) Substances [Inputs] that are added to a food [Product or Ingredient] during ~~the~~ processing ~~of the product and~~, are converted into constituents normally present in the ~~product~~food, and ~~which does~~do not significantly increase the amount of the constituents naturally found in the ~~product; or (3)~~food. (c) Substances [Inputs] that are added to ~~the product~~a food [Product or Ingredient] for ~~its~~their technical or functional effect ~~during~~in the processing but ~~is~~are present in the finished ~~product~~food at insignificant levels and do~~es~~ not have any technical or functional effect in ~~the finished product~~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. "Product" refers to ~~products that are involved in the Non-GMO Project Product Verification Program~~goods enrolled in the PVP.

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

Region – A geographic area with relatively homogenous 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.

Commented [A111]: Definition of "region" was moved from v14.3 Footnote 13.

~~**Shall or** **Must** – A mandatory requirement under the Standard.~~

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

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

[7] 21 C.F.R. § 101.100 (2018).

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

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

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

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

~~**Unintentional Contamination –** A contamination incident (event) will be deemed unintentional if available information confirms that: (i) the operator did not knowingly use GMOs or GMO-derived inputs; or (ii) the operator used all due diligence to prevent GMO contamination.~~

Testable – 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.

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

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

Appendix B – High-Risk List[15]

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 materialsinputs.

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

1.B.1.1 Crops

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

- Alfalfa
- Canola[8]
- Corn (except popcorn)
- Cotton
- Papaya
- Soy[9]
- Sugar beets
- Zucchini and yellow summer squash

2.B.1.2 ProcessedAnimal-derived Inputs/ and Ingredients[10]

a. **Livestock, Bee, and Aquaculture Feed[17]**

- Meat, dairy, eggs, wool, hides, honey, seafood, and any other materials or substances originating from animals
- Livestock and poultry feed[11]
- Bee forage and feed
- Fish and other aquatic animal feed

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[15] Inputs for which GM versions are widely commercially available; this includes certain crops, their derivatives, and animal-derived inputs.

[8] Note that canola is also on the list of Non-Testable High-Risk Inputs and Ingredients and must therefore be compliant with the requirements in both Section 6 and Section 7.

[9] Note that soy is also on the list of Non-Testable High-Risk Inputs and Ingredients and must therefore be compliant with the requirements in both Section 6 and Section 7.

[10] 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.

[17] Per Section VII.A., Section VII.B., and Section VII.C., verification of livestock, bee, and aquaculture products require the testing of feed.

[11] 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.

Commented [A112]: v14.3 Footnote 15 was moved to the introductory paragraph of v15 Appendix B – High-Risk List.

Commented [A113]: v14.3 Appendix B.A. was renamed to v15 Appendix B.1.

Commented [A114]: v14.3 Appendix B.A.1. was renamed to v15 Appendix B.1.1.

Commented [A115]: v14.3 Appendix B.A.2. was renamed to v15 Appendix B.1.2.

~~b.~~B.1.3 ~~Crop~~ Inputs, Ingredients, and Derivatives[1216]

- Ascorbic acid, sodium ascorbate, vitamin C
- Citric acid, sodium citrate – derived from glucose syrup
- Ethanol – derived from corn or GMO sugar beets
- Corn syrup
- Hydrolyzed vegetable protein
- Maltodextrins
- Molasses – derived from sugar beets
- Monosodium glutamate
- Sucrose – derived from sugar beets
- Textured vegetable protein – including soy protein

~~**c. Other Derivatives**~~

- Amino acids
- Aspartame
- Flavorings, "natural" and "artificial" – including all carriers and co-formulants
- Lactic acid
- Microbial ~~g~~Growth ~~m~~Media
- Vitamins – vitamin A (various forms), vitamin B6 (pyridoxine hydrochloride), vitamin B12 (cyanocobalamin), vitamin C (ascorbic acid), and vitamin E (various forms). Vitamins in general are often formulated with dispersants and related ingredients that also have GMO risk (e.g., corn oil)
- Xanthan gum
- ~~Yeast~~ products

B.2 Non-Testable High-Risk Inputs and Ingredients

B.2.1 Crops

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

- Canola ~~(ODM)~~[1318]
- Potato ~~(RNAi)~~
- Soy ~~(TALEN)~~[1419]

B.2.1.1 Non-Testable High-Risk Crops beginning January 1, 2022

[1216] This is a non-exhaustive list of Inputs, Ingredients, and derivatives that should be considered High-Risk when sourced from crops in Appendix B.1.1~~Appendix B.A.1.~~. It is meant to provide examples of materials that are considered High-Risk by the ~~Non-GMO~~ Project.

[1318] Note that canola is also on the list of Testable High-Risk Inputs and Ingredients and must therefore be compliant with the requirements in both ~~Section V~~Section 6 and ~~Section VI~~Section 7.

[1419] Note that soy is also on the list of Testable High-Risk Inputs and Ingredients and must therefore be compliant with the requirements in both ~~Section V~~Section 6 and ~~Section VI~~Section 7.

Commented [A116]: v14.3 Appendix B.A.2.b. was renamed to v15 Appendix B.1.3.

Commented [A117]: "Yeast" was moved from v14.3 Appendix B.A.2.c. to v15 Appendix B.2.3.

Commented [A118]: v14.3 Appendix B.B. was renamed to v14.3 Appendix B.2.

Commented [A119]: v14.3 Appendix B.1. was renamed to v15 Appendix B.2.1.

Beginning January 1, 2022, the following crops and their derivatives must be compliant as Non-Testable High-Risk crops under Appendix B Section B.2.1. The following list is exhaustive:

- Apple
- Eggplant
- Pineapple

B.2.2 Animal-derived Inputs and Ingredients[15]

- Meat, dairy, eggs, wool, hides, honey, seafood, and any other materials or substances originating from animals
- Livestock and poultry feed[16]
- Bee forage and feed
- Fish and other aquatic animal feed

~~2.~~B.2.3 ~~Microbe~~Microorganism and Enzyme Inputs and Ingredients

- Algae ~~from aquaculture~~
- Bacteria
- Enzymes ~~– including chymosin~~
- Microbial cultures and starters ~~– including yeast~~
- Yeast

~~3.~~B.2.4 Ingredients or Substances ~~Potentially Sourced via Synthetic Biology~~with Synbio Counterparts

Commented [A120]: v14.3 Appendix B.2. was renamed to v15 Appendix B.2.3.

Commented [A121]: v14.3 Appendix B.3. was renamed to v14.3 Appendix B.2.4.

[15] 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.

[16] 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.

Appendix C –Monitored-Risk List[20]

Organisms, and Products, Ingredients, and Inputs derived from those organisms, for which GM ~~organisms~~counterparts are in the research and development stages, which have been developed but are not widely commercially available, or for which known GMO ~~organism~~contamination has occurred.

~~A.~~C.1 Testable Monitored-Risk Inputs and Ingredients

~~1.~~C.1.1 Crops

- *Beta vulgaris,*(e.g., chard, table beets) – cross pollination risk from GM sugar beets
- *Brassica napa* (e.g., rutabaga, Siberian kale) – cross pollination risk from GM canola
- *Brassica rapa* (e.g., bok choy, mizuna, Chinese cabbage, turnip, rapini, tatsoi) – cross pollination risk from GM canola
- *Cucurbita pepo* (e.g., acorn squash, delicata squash, patty pan squash, pumpkin, and spaghetti squash) – cross-pollination risk from GM squash
- Flax
- Mustard
- Rice
- Wheat

~~B.~~C.2 Non-Testable Monitored-Risk Inputs and Ingredients

~~1.~~C.2.1 Crops

- ~~Apple~~
- Camelina (false flax)
- ~~Corn (CRISPR-Cas9, INzyme®)[21]~~
- Mushroom
- Orange
- ~~Pineapple~~
- ~~Salmon~~
- Sugarcane
- Tomato

~~2.~~C.2.2 Ingredients or Substances ~~Potentially Sourced via Synthetic Biology~~with Synbio Counterparts

- Spider silk

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[20] ~~Certain inputs for which GM organisms are in the research and development stages, which have been developed but are not widely commercially available, or for which known GM organism contamination has occurred.~~

[21] ~~Note that corn is also on the list of Testable High-Risk Inputs and must therefore be compliant with the requirements in Section V.~~

Commented [A122]: v14.3 Footnote 20 was moved to the introductory paragraph of v15 Appendix C – Monitored-Risk List and edited.

Commented [A123]: v14.3 Appendix C.A. was renamed to v15 Appendix C.1.

Commented [A124]: v14.3 Appendix C.A.1. was renamed to v15 Appendix C.1.1.

Commented [A125]: v14.3 Appendix C.B. was renamed to v15 Appendix C.2.

Commented [A126]: v14.3 Appendix C.B.1. was renamed to v15 Appendix C.2.1. Apple and Pineapple were moved from v14.3 Appendix C.B.1. to v15 Appendix B.2.1.1.

Commented [A127]: v14.3 Appendix C.B.2. was renamed to v15 Appendix C.2.2.