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NON-GM STANDARDS

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## SECTION – 1

**DEFINITIONS**

**Affidavit** – A formal document, that includes a written and signed statement confirming specific characteristics of a given organism, crop, precursor, Input, Ingredient, system, process, or operation.

**Biotechnology** – the application of:

* + 1. in vitro nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and the direct injection of nucleic acid into cells or organelles; or
    2. Fusion of cells beyond the taxonomic family, that overcame natural physiological, reproductive, or recombination barriers and that are not techniques used in traditional breeding and selection.

## Certificate of Approval –

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

**Certificate of Certification (COV)** – An annually renewed document demonstrating compliance with the NON-GM Standard which includes a signed written agreement with the Applicant/Customer,, and Product-level compliance with the Standard.

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

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

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

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

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

**Genetically Modified Organism (GM)** – An organism in which the genetic material has been changed through 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 Microorganisms.

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

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

**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 deviation that could affect the compliance of an Input or Ingredient with the relevant Action Threshold, such as unintentional contamination of the Ingredient with GM material, or that could impact the compliance of an Input or Ingredient with [Section 9.2.](#_bookmark48)

**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 deviation that could not cause any of the relevant Inputs or Ingredients to the Product to exceed the relevant Action Threshold. This includes immaterial changes to procedures, recordkeeping, documentation, or anything else immaterial that does not have the potential to impact compliance with the relevant Action Threshold.

**Non-conformity** – Any deviation in operations that has not been approved by EKO- GUARANTEE.

**Non-GM or Non-GM** – An organism or derivative of such an organism whose genetic structure has not been altered by 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 compliant and non-compliant Inputs, Ingredients, and/or Products.

**Customer/Applicant**– A company that is seeking certification and signs a License Agreement with the EKO-GUARANTEE.

**Principal Display Panel** – 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 –

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

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

**Product** – A unique branded formula and process, where process could be either the manufacturing or facility process. “Product” refers to goods seeking NON-GM CERTIFICATION.

**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.

**Must** – A mandatory requirement under the Standard.

**Should or May** – A non-mandatory recommendation or recommended practice. **Standard** – The Standard for the Non-GM CERTIFICATION, which is this document. **Supplier** – Any party from whom an 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.

**Testable** – Having one or more precursors 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.

**Certified** – A finished Product’s status when EKO-GUARANTEE establishes that the Product is compliant with all applicable requirements of this Standard.

**Viable Microorganism** – A microscopic organism (such as a bacterium, yeast, fungus, or

alga) that performs metabolic functions and reproduces/multiplies.

**Cropping Seasons- Kharif Crops (July - October) Harvest (September to October), Rabi Crops Sowing between October & November Harvest (February to April), Zaid Crops sowing between march & June (Between Rabi & Kharif)**

# SECTION – 2

**Scope of NON-GM Standard**

The scope of the Standard encompasses the following Product categories, including their Inputs, Ingredients, and associated activities.

## Product Categories

* + 1. The following types of wholesale or retail goods are eligible for Certification:
       1. Seed and vegetative propagation materials
       2. Wholesale or retail goods for human or pet use that are either ingested or topically applied Over-the-counter (OTC) nutraceuticals
       3. Textiles
       4. Animal and Aqua Feed,
       5. Livestock and livestock products, poultry and poultry products, bee and bee products and fish
       6. Cosmetics and its ingredients
    2. The following types of goods are ineligible for Certification:
       1. medicines and medical goods containing GM’S or any excludes of GM’s
       2. Synthetic pesticides

## Input and Ingredient Evaluation

* + 1. **Mandatory Input and Ingredient categories** (Input and Ingredient categories to Product formulations that must be evaluated and found compliant either by certification or by testing):
       1. Seeds and vegetative propagation materials need to be authenticated from non gm source either by testing or by certification.
       2. All 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 Product to be certified.
          1. Unprocessed raw agricultural materials such as vegetables, grains, fruit, greens, herbs, otherfresh foods, fibers
          2. Manufacturing Inputs and Ingredients, including flavorings, seasonings, colorings, additives, and all other substances present in final, manufactured Products
          3. Animal derivatives including dairy, meat, eggs, wool, and hides; derivatives of apiculture including, but not limited to, honey and beeswax; derivatives of seafood
          4. Processed agricultural Inputs and Ingredients
          5. Packaging that is directly immersed in or combined with liquid for the purpose of making the Product available for human consumption including tea, coffee, spice, and soup bags but not including any part of the packaging other than the bag
          6. Rations and supplemental feed for livestock, poultry, bees, seafood, and other animals
       3. Other Inputs and Ingredients used in personal care and cosmetic Products, and textiles
       4. Dietary supplements, vitamins, and herbal preparations
       5. Microorganisms, Enzymes, and Growth Media
       6. Processing Aids present in the finished Product
       7. Processing Aids listed on the ingredient panel of a retail consumer good
    2. **Input and Ingredient categories that are out of scope of the Standard**

A Water

B common salt

C Inert gases CO2 & nitrogen

## Prohibited Inputs and Ingredients:

* + - 1. Recombinant bovine growth hormone (rBGH)
      2. Recombinant bovine somatotropin (rBST)
      3. GM animals including those that are cloned, their progeny, and their derivatives

**2.2.3.d.i** GM Salmon and their derivatives

* + - 1. Manure sourced from GM animals

## CROP PRODUCTION IN GENERAL- PRIMARY ACTIVITY

* + 1. **Conversion Requirements**

Non-GM system of production is a process of production which is without the use of any GM organisms in all the farming operations from seed to harvest. There is no requirement of conversion period. The farming unit is deemed converted to Non-GM system of production when any crop is produced without any GM organisms.

Simultaneous production of GM production and Non-GM production of crops or animal products which cannot be clearly distinguished from each other, will not be allowed.

## Fertilization Policy

No GM products or products with GM are allowed to be used as fertilizers in any form

## Pest, Disease and Weed Management including Growth Regulators

No GM products or products with GM are allowed to be used as pest control and weed control or as growth regulators.

## Contamination Control

All relevant measures should be taken to avoid all possible contamination of GM organisms from outside and from within the farm.

* + 1. **Organisation for Group Production of NON GM Crops and Livestock Production ( In Equivalence with NPOP Standards)**

This system shall be based on the internal quality system and shall apply to producer groups, farmer’s cooperatives, contract production and small scale processing units. The producers in the group must apply similar production systems and the farms should be in geographical proximity. Farms with land holding of 4 ha and above can also belong to a group but will have to be inspected annually by the external Inspection and Certification Agency. The total area of such farms shall be less than 50% of the total area of the group. Processors and exporters can be a part of the same group but will have to be inspected annually by the external Inspection and Certification Agency.

***CONSTITUTION OF THE GROUP ORGANIZATION***

The group will have a legal status or constitution of the organization and shall be presented by an organizational chart.

For implementation of the procedures to maintain the internal control system, responsibilities shall be delegated to individual members / committees for carrying out specific activities.

#### **INTERNAL QUALITY SYSTEM (IQS)**

Group certification is based on the concept of an Internal Quality System comprising of the following: -

x Implementation of the internal control system

x Internal standards

x Risk assessment.

An external inspection and certification body should be identified for conducting annual inspection of the individual group / unit. The external inspection agency shall evaluate by checking the IQS documentation, staff qualifications and re-inspecting some farms.

#### **HOW TO DEVELOP AN IQS**

The following are the minimum requirements for setting up an IQS for grower groups: -

x Development of Internal Control System (ICS)

x Identification of producer groups

x Creation of awareness about group certification

x Identification of qualified personnel for maintaining the internal control system

x Give necessary training in production and IQS development

x Preparation of IQS manual containing policies and procedures

x Implementation of the policies and procedures

x Review and improvement of the IQS document for maintaining a harmonized IQS.

#### **Internal quality system manager (IQS Manager)**

IQS manager shall develop and implement the IQS and would be responsible to organize internal inspections, coordinate between field staffs, approval staff, and the external inspection agency. The IQS manager shall have defined procedures to approve or sanction farmers.

The responsibility of IQS manager shall be to ensure that all the standards requirements are fully implemented by the group.

##### Internal inspectors

Adequate number of internal inspectors shall be identified from within the group. The inspectors shall be qualified and well versed with the standards to perform internal inspections.

##### ***Approval manager / committee***

Qualified person or approval committee shall be designated from within the group to take the approval decision. The approval manager/committee shall be well versed with organic procedures of IQS, internal standards and NPOP standards.

##### ***Field officers***

Field officers should be identified among the group, one at each production area. The field officer shall train the farmers by organizing field extension services.

##### ***Purchase officers***

Purchase officers shall be identified who would be responsible for correct purchase of produce from the farmers. The purchase officer is required to be well versed with IQS.

##### ***Warehouse manager***

If there are separate warehouses, it may be necessary to have a warehouse manager who would be responsible for handling the produce. He / she shall be well versed with the procedures of IQS for proper implementation.

##### ***Processing manager***

If a processing unit is operated by the IQS operator, it may be necessary to assign a processing manager. The processing manager is required to be trained in the handling procedures. When the processing of the produce is being organized in a company, the latter needs to be inspected by the certifier and would be responsible for processing according to the internal handling rules. In such case, the processing unit shall have a formal contract with the grower group.

##### ***INTERNAL STANDARDS***

The internal standards shall be prepared in local language by the IQS manager for the region of operations under the framework of NPOP standards. If the farmers are illiterate, the internal standards shall contain illustrations in the text for better understanding. The internal standards would contain: -

x Definition of production unit

x How to deal with part conversion

x Conversion period

x Farm production norms for the entire production unit (e.g. seeds, nutrient management, pest management, soil management, approved inputs, prevention of drifts, livestock husbandry management)

x Harvest and post harvest procedures

##### ***CONFLICT OF INTEREST***

The IQS personnel shall not have any conflict of interest that might hinder the work. All possible conflicts shall be declared in a written statement. In such cases, the IQS shall ensure that alternative solutions are found.

#### **SCOPE OF CERTIFICATION**

The certification shall be granted to the group with reference to the regulations / standards adopted by the group.

#### **TRADE**

The group will market the products under a single entity. For trading the products from the group of producers, the IQS shall draw up relevant procedures.

#### **PROCEDURES FOR IMPLEMENTATION OF INTERNAL CONTROL SYSTEM**

For maintaining the internal control system, the following procedures shall be adopted by the grower group.

#### **Registration of members**

All members of the group will be formally (legally) registered under a single entity.

##### ***Provision of documents to the members of the grower group***

Each member of the grower group will be supplied with docket in local languages, which will contain the following –

x Copy of IQS manual

x Internal standards document

x NPOP document (Each member / staff shall be communicated when there is a revision in the standards.)

x Definition of the production unit

x Farm Entrance Form (farm data sheet), including last use of prohibited inputs

x Field records (main cultivation measures, use of inputs, harvested quantities, post harvest procedures): remark: may be included in internal farm checklist.

x Prevailing farming system and package of practices available for the area

x Details and description of the various steps required for the process flow right from cultivation to harvest and sales of the products.

x Written contract (for formal commitment) of each grower within the group

x Annual farm inspection checklist

x Information on training programmes and provision of advisory services by the field officers.

#### **OPERATING DOCUMENT**

The quality manager shall prepare the operating document, which shall be followed by all the members of the group. The operating document will contain the following: -

An overview map (village or community map) showing location of each member’s production unit. The map should indicate the crops cultivated in rotation and also mark any farm in an area, which could be identified as high risk due to drift from non-conventional farms.

Farmer’s list with code and name of the farmer, total area, area under crop (or number of plants), date of registration with the group, date of last use of forbidden products, date of internal inspection, name of internal inspector, result of internal inspection (separate lists for in-conversion farmers)

List of farmers who have been issued sanctions with the reason and the duration of the sanction (if relevant).

The risk shall be assessed by IQS manager for the grower group every year. The risk assessment should be made at the farm level, processing, transporting and

during trade. The IQS will take all measures to minimize the identified relevant risks.

***Critical control points for risk assessment***

x Measures taken by the farmers to deal with part conversion (if farmers still grow some non-organic crops).

x Conversion period

x Production rules for the whole production unit, e.g., seeds, fertilization and soil management, pest management, approved inputs, prevention of drifts, animal husbandry.

x Harvest and post harvest procedures.

x Processing and handling standards

#### **INTERNAL INSPECTIONS**

x At least two inspections of the group (one in growing season of each crop) shall be carried out by the internal inspector and will be documented.

x The inspection will be carried out in presence of the member or his representative and must include a visit of the whole farm, storage of inputs, harvested products, post harvest handling and animal husbandry.

x The internal inspector will also verify if the internal standards have been followed and whether the conditions of the previous internal inspection have been fulfilled.

x The visit of the internal inspector will be documented in the farm inspection checklist duly signed by the inspector and counter-signed by the member or his representative.

x In case of severe non-compliance, the results will be reported immediately to the IQS manager and all measures will be taken according to the internal sanction procedures.

#### **EXTERNAL INSPECTIONS**

The external Inspection and Certification Agency will inspect some of the farms for the evaluation of the grower group for efficient internal control system for compliance with the NPOP Standards.

The sampling plan for inspection shall be based on the inspector’s perception of risk based on the following factors:

1. Size of holding
2. Number of the members in the group
3. Degree of similarity between the production system and crop system
4. Inter-mingling / contamination
5. Local hazards

Inspection man day sampling methods for different size of the grower group shall be based on the square root of the total number of farmers in the ICS. Inspection Man day shall be estimated on the basis of the following:

* For farmers with land area below 4 hectares will be estimated as 8 to 10 farmers in one man day
* For farmers with land area above 4 Hectares will be estimated as .5 manday for each farmer.
* For Trading and Processing man day calculation will be done on the basis of total no. of products and amount of transactions(domestic/international) on case to case basis.
* The Actual man day may vary from the estimated manday calculated at the time of inspection assignment depending on the complexity involved on site and actual time required by the auditor.

Details as per following table given below: -

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Number in the grower group (N)** | **Number of producers to be inspected** | | | | | |
|  | **Initial audit** | | **Reassessment** | | **Surveillance visit** | |
|  | Number to be inspected  (n=— N) | % of total | Number to be inspected  (n=0.8— N) | % of total | Number to be inspected  (n=0.6— N) | % of total |
| < 25 | 5 | 20 | 4 | 16 | 3 | 12 |
| 26-50 | 5-7 | 19-14 | 4-6 | 15-12 | 3-4 | 12-8 |
| 51-100 | 7-10 | 14-10 | 11-8 | 22-8 | 4-6 | 8-6 |
| 101-250 | 10-16 | 10-6 | 8-13 | 8-5 | 6-10 | 6-4 |
| 251-500 | 16-22 | 6-4 | 13-18 | 5-4 | 10-13 | 4-3 |
| 501-750 | 22-27 | 4 | 18-22 | 4-3 | 13-16 | 3-2 |
| 751-1000 | 27-32 | 4-3 | 22-26 | 3 | 16-19 | 2 |
| 1001-1500 | 32-39 | 3 | 26-31 | 3-2 | 19-23 | 2 |
| 1501-2000 | 39-45 | 3-2 | 31-36 | 2 | 23-27 | 2-1 |
| 2001-2500 | 45-50 | 2 | 36-40 | 2 | 27-30 | 1 |
| >2500 | 50 | 2 | 40 | 2 | 30 | 1 |

#### **YIELD ESTIMATES**

Yields will be estimated for each crop for individual farmer in the group. This activity should be carried out especially during harvesting and should be counter-checked with the estimates during buying.

#### **INTERNAL APPROVALS**

The IQS manager will have a defined procedure to approve or impose sanction on the farmers in the group. All internal farm checklist are screened by internal approval staff with special focus on the critical control points of risk / difficult cases.

x The approval committee for providing internal certification status will check the assessment of the internal inspector. If necessary, conditions will be set out for achieving compliance with the NPOP.

x The next competent person or committee must confirm results of the internal inspection in an approval procedure.

#### **NON-COMPLIANCES AND SANCTIONS**

In case of non-compliances, the IQS shall take corrective or mitigating measures.

x Procedures for implementation of sanctions will be defined in case of non- compliance.

x Sanctions have to be documented (list of farmers issued sanctions, documentation of identified non-conformities in the files).

x Farmers who have used prohibited inputs on their farms must undergo again the full conversion period (if they remain in the group). In such cases, it has to be checked whether the farmers have already delivered produce and whether this (now no longer certified) produce has been mingling with other produce. If this has been the case, the certification body needs to be notified immediately and the mingled produce kept separate until further instructions.

#### **TRAINING OF IQS PERSONNEL**

1. Each internal inspector will be trained annually by a competent person.
2. The date of the training, list of Clients will be documented.
3. The date of participation and content of the training of all IQS staff needs to be documented in the staff files.

#### **TRAINING OF FARMERS**

The IQS manager will organize regular training to the farmers in the group: -

Each farmer needs to receive at least one initial advisory visit by the extension service or in a organized training.

The list of Clients and content of the training needs to be documented.

#### **BUYING PROCEDURES**

To ensure genuineness of the products from the group, the following minimum requirements should be followed during buying: -

The status of the farmer in the group should be checked.

The supplied amount should be compared with the harvested amount and estimated yield. In case of doubt, the produce is kept apart until clarified by the IQS Coordinator.

The delivered quantity of the product will be registered in the purchase record.

Farmer will be issued a receipt duly signed by the purchase officer stating the quantities of the product delivered with date.

All documents have to indicate the status of the certified product (organic or in- conversion).

Bags should be labeled as ‘organic’ or as ‘in-conversion’.

#### **STORAGE AND HANDLING PROCEDURES**

The purchase or the warehouse manager during the handling of produce shall check the document to ensure the compliance with the NPOP standards. The following are the minimum requirement that will be followed during storage and handling: -

x Identification of the product at all stages of product flow during transition.

x Segregation of organic products from in-conversion products.

x Fumigation of containers, irradiation / ionization, etc. are prohibited.

x The location in the warehouse during storage must be labeled as ‘organic’ or ‘in- conversion’.

#### **PROCESSING**

During the handling of the produce, the documentation must be checked for compliance with the NPOP standards.

x Central Processing Units will be inspected by the external inspection and certification body.

x Ingredients and processing aids must be used as defined in Annexe-4 and 5 of Section-3 of NPOP standards.

x During the product flow (transition), the products should be separated from non- organic products.

x The processing steps will be documented.

# SECTION – 3

## Compliance of Livestock and Poultry and their derived Products, Ingredients, and Inputs

## 3.1 Livestock and poultry for meat production

## Livestock and poultry for meat production will have the following compliance standards

* + 1. Animals for meat starting from birth should demonstrate non-GM parentage
    2. In case of poultry (both for eggs and for meat) the eggs of the hatched hens should be traceable to non-GM parentage.

## 3.2 Livestock and Poultry Derived Products

The following products of livestock and poultry are covered under the scope of this standard:

1. Milk
2. Eggs
3. Honey
4. Wool

For Milk, Wool and Egg Production

* Milk, Wool and egg can be certified as non-GM when no GM is used or applied to the milk, wool and egg production animals or birds in the form of feed, fodder, medicines or in any hormonal ingestions at least 30 days prior to the initial inspections and till the remainder of animal or bird’s life.

For Honey Production ( Refer Section 4.1)

1. Farm Production
2. Wild Collection

**3.3 Feed**

1. **Green and Dry Fodder**

All green and dry fodder should be from non-GM verified sources.

1. **Feed Rations**

In case of feed rations the rations should be non-GM verified or tested to be non-GM

# SECTION 4

## REQUIREMENTS FOR OTHER SPECIFIED PRODUCTS, INGREDIENTS, AND INPUTS

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

## Apiculture

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

* + 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.
    2. Any supplemental bee feed must be evaluated for compliance with [Section5](#_bookmark21).
    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:
       1. Meet all requirements of [Section9](#_bookmark46).
       2. Attest that the organic certifier has confirmed that the apiary is adhering to the Organic Apiculture Standard as per any recognized Organic Standards.

## Beer, Wine, and Liquor

* + 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 5.1.3.b,](#_bookmark24) and must be Non-GM.
    2. Processing Aids used in the production of beer, wine, and liquor are subject to the compliance requirements in[Section2.2.2.](#_bookmark1)
    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.
    4. Beer, wine, and liquor Products will be held to the same level of evaluation as Products with Ingredient panels.

## Microorganisms

* + 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.
    2. An Affidavit meeting all the requirements of [Section 9.2.](#_bookmark48) must, in addition, confirm that the Microorganism is Non-GM.
    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.
    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.

## Probiotics

* + 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.
    2. An Affidavit meeting all the requirements of [Section 9.2](#_bookmark48) must, in addition, confirm that the probiotic Microorganism is Non-GM.

## Seafood

This Section 4.5 applies to all saltwater and freshwater aquatic animals.

* + 1. Farm-raised seafood (in captivity from egg to harvest and/or wherenutrient additions are provided) will be fully evaluated as a High-Risk Product, Ingredient, or Input and requires the evaluation and compliance of Ration Inputs.
    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 5](#_bookmark21) and [Section 3](#_bookmark2).
    3. The feed of seafood may be compliant under [Section 9.5](#_bookmark53) if the Affidavit establishes that the organism was caught in the wild.

## Vitamins and Supplements

* + 1. The Growth Media for Microorganisms from which Enzyme Inputs and Ingredients to vitamin and supplement Products are derived, are temporarily outside of the scope of evaluation.

# SECTION 5

## CLASSIFICATION OF INPUT AND INGREDIENTS

Each Input and Ingredient must be classified in accordance with this [Section 5](#_bookmark21) and meet all applicable requirements under this Standard to be included in a Certified Product.

## Weight Percentage

All Inputs and Ingredients must be classified according to their Weight Percentage as represented in, or as present in, the finished Product, not counting the weight of salt or added water present in the finished Product. Excluded from the Weight Percentage 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/Ingredient disclosure documentation of a wholesale Product, and 2) purified CO2.

For livestock, poultry, bee, and seafood feed other than pet food, the Weight Percentage categories below are calculated based on the weight of the Input as a percentage of the Ration fed to the animal. Rations demonstrating compliance on an as-fed basis have additional reporting requirements per [Section 3.](#_bookmark11) Rations demonstrating compliance on a dry-matter basis do not have any additional reporting requirements. Per [Section 3](#_bookmark2), all Minor and Micro Inputs of livestock and poultry Rations are exempt from evaluation.

Unless a Certified-Status Ingredient, the Inputs to each Major or Minor Ingredient must be classified and evaluated back to the point in the supply chain where they can be confirmed compliant with the Standard’s requirements. After EKO-GUARANTEE determines that a Micro Ingredient qualifies for [Section 5.1.3.b](#_bookmark24)no further breakdown or classification is required.

* + 1. **Major Inputs and Ingredients**, each of which represents, or is present as, 5% or more of the finished Product.
    2. **Minor Inputs and Ingredients**, each of which represents, or is present as, at least 0.5% but less than 5% of the finished Product.
    3. **Micro Inputs and Ingredients**, each of which represents, or is present as, less than 0.5% of the finished Product. The depth of evaluation for these Inputs and Ingredients, including application of the limits in [Sectio](#_bookmark23)n [5.1.3.a](#_bookmark23)below, is limited to the organism from which they were derived, as opposed to Growth Medium or feed. Certain Micro Inputs and Ingredients are eligible for Micro Exemption under [Section 5.1.3.b](#_bookmark24) below.

## Inputs and Ingredients ineligible for Micro Exemption:

* + - * 1. **Bioengineered Foods**1. Compliance with this Section 5.1.3.a.i is required.
        2. **High-Risk Ingredients not on the List of Bioengineered Foods**2 for which the Client 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 5.1.3.a.ii is required.
        3. **Viable Microorganisms** present in the finished Product.
        4. **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.
        5. **High-Risk Micro Ingredients**, other than artificial and natural flavors, Enzymes, and Microorganisms if they are either:

**5.1.3.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

**5.1.3.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 5.2](#_bookmark25) for an explanation of Risk Status.

* + - 1. **Ingredients present in Products as** Micro Ingredients and not listed in [Section 5.1.3.a](#_bookmark23) directly above, and Inputs representedin Products as Micro Ingredients, may be exempt from further evaluation

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

## Risk Status

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 GM. In order to focus the Standard on Inputs and Ingredients at risk for GM contamination throughout the CoC, the Standard recognizes five Risk Statuses ([Table 5-1](#_bookmark26)).

**Table 5-1** The Five Risk Statuses

|  |  |
| --- | --- |
| **Risk Status** | **Definition** |
| Certified-Status | Products that have been certified under the NON-GM STANDARD at wholesale or retail and are purchased for use as Inputs or Ingredients to different Products enrolled under NON-GM Standard  Plan |
| High-Risk  (see [Appendix B](#_bookmark58)) | Organisms and the Inputs and Ingredients derived from them for  which GM counterparts are widely commercially available |
| Monitored-Risk (see [Appendix C](#_bookmark62)) | Organisms and the Inputs and Ingredients derived from them for which GM counterparts are in the research and development stages, which have been developed but are not widely commercially  available, or for which known GM contamination has occurred |
| Low-Risk | Organisms and the Inputs and Ingredients derived from them that  are not classified as Monitored Risk or High Risk |
| Non-Risk | Inputs and Ingredients that are not derived from biological  organisms and are not, therefore, susceptible to Genetic Modification |

## 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 which 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.

* + 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.
    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.

## 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 5-2](#_bookmark27)summarizes the compliance pathways available to Certified-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 5-3](#_bookmark28)summarizes the various compliance pathways for Testable and

Non-Testable High-Risk Inputs and Ingredients when they are Majors, Minors, and Micros. [Table 5-2](#_bookmark27)and [Table 5-3](#_bookmark28)are summaries; additional compliance requirements may apply.

**Table 5-2** Compliance of Certified-Status, Monitored-Risk, Low-Risk, and Non-Risk Inputs, Ingredients, and Products

|  |
| --- |
| **Verified**  **Status** |
| 1. Provide proof of certified-Status of appropriate scope. 2. Client complies with [Section 6](#_bookmark29), Chain of Custody, from the point of procurement to the finished Product. 3. Client complies with[Section7](#_bookmark31), Onsite Inspections from the point of procurement to the finished Product. |
| **Monitored**  **Risk** |
| See requirements for Low-Risk. |
| **Low Risk** |
| 1. Comply with [Section 6.3,](#_bookmark30) Segregation. If the facility does not use any High-Risk Inputs or Ingredients, then demonstration of this fact is sufficient to fulfill this requirement.   **AND EITHER**   * 1. Provide a complete Input and Ingredient disclosure.   **OR**   * 1. Comply with [Section 9.5,](#_bookmark53) Monitored-Risk and Low-Risk Major, Minor, and Micro Inputs and Ingredients. |
| **Non Risk** |
| 1. Provide a complete Input and Ingredient disclosure.   **OR**   1. Comply with [Section 9.6,](#_bookmark54) Non-Risk Major, Minor, and Micro Inputs andIngredients. |
| Note: Inputs and Ingredients from the Certified-Status, Monitored-Risk, Low-Risk, and Non- 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. |

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

|  |  |  |
| --- | --- | --- |
| **Majo**  **r** | **Mino**  **r** | **Micr**  **o** |
| **Testable High Risk** | | |
| 1. Submit a complete Input and Ingredient disclosure. | 1. Comply as a Major.   **OR**   1. Submit a complete Input and Ingredient disclosure. 2. Comply with [Section 6](#_bookmark29), Chain of Custody. 3. Comply with [Section 9.3](#_bookmark50) Testable High-Risk Minor and Micro Inputs and Ingredients. | 1. Comply as a Major.  **OR** |
| 2. Comply with [Section 6](#_bookmark29), Chain of Custody. | 2. Comply as a Minor.  **OR** |
| 1. Comply with [Section 7](#_bookmark31), Onsite Inspections.   **AND EITHER**  a. Comply with [Section 8](#_bookmark32), Sampling and Testing.  **OR** | 3. Comply with [Section 5.1.3,](#_bookmark22) Micro Inputs and Ingredients. |
| b. Comply with [Section 9.4,](#_bookmark52) Affidavit Compliance Based on Country of Origin. |
| **Non-Testable High**  **Risk** | | |
| 1. Submit a complete Input and Ingredient disclosure. | 1. Submit a complete Input and Ingredient disclosure. 2. Comply with [Section 6](#_bookmark29), Chain of Custody.   **AND EITHER**   * 1. Comply with [Section 9.2.](#_bookmark48)Non-Testable High- Risk Inputs and Ingredients.   **OR**   * 1. Comply with [Section 9.4,](#_bookmark52) Affidavit Compliance Based on Country of Origin. | 1. Comply as a Major.   **OR**   1. Comply as a Minor.   **OR**   1. Comply with [Section 5.1.3,](#_bookmark22) Micro Inputs and Ingredients. |
| 2. Comply with [Section 6](#_bookmark29), Chain of Custody. |
| 3. Comply with [Section 7](#_bookmark31), Onsite Inspections.  **AND EITHER** |
| a. Comply with [Section 9.2.](#_bookmark48)  Non-Testable High- Risk Inputs and Ingredients.  **OR** |
| b. Comply with [Section 9.4,](#_bookmark52) Affidavit Compliance Based on Country of Origin. |

Additional requirements, including those outlined in [Section 10](#_bookmark55), Product Specifications and Labeling, and [Section 11](#_bookmark56), Quality Assurance, may also apply to Products, Ingredients, and Inputs.

# SECTION 6

**CHAIN OF CUSTODY**

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

## Activities

CoC requirements apply beginning at the point Non-Risk, Low-Risk, Monitored-Risk or Certified-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 Product, the following activities are subject to review and must be found compliant with the applicable Standard sections ([Table 8-1](#_bookmark34)).

**Table 6-1** Activities Along the Chain of Custody

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

## Chain of Custody Requirements

* All required procedures must be written and accessible to all appropriate staff and updated as necessary.
* All appropriate staff working with compliant Inputs, Ingredients, andProducts must be adequately trained in the required procedures.
* All records must be maintained for a minimum of three (3) years.

## Segregation

* Systematic procedures must be in place during activities to keep compliant Inputs, Ingredients, work-in-progress, and finished Products separate from all non- compliant High-Risk materials.
* Segregation measures are also required for instances where any required testing occurs after the Input or Ingredient in question has entered thefacility.

## Cleanout

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

## Traceability

* Each lot of Certified Product must be traceable back to specific lots of the Inputs and Ingredients used in its production. If lots of compliant Inputs and/or Ingredients are commingled in storage before use in production of a certain lot of Product, the lot numbers related to all commingled lots must be linked to that particular lot of Product.
* 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.
* Systematic procedures must be in place for tracking lot numbers and/or marking and labeling of packaging, containers, and storage facilities to ensure traceability of Inputs, Ingredients, work-in-progress, and finished Products at all points in the production process.
* Traceability records must explicitly trace and track the compliance of Inputs, Ingredients, and finished Products.

# SECTION 7

**7.1 INSPECTIONS CONDUCTED ONSITE**

At minimum, Producing Facilities are required to be inspected more than once annually when parallel processing of the same Major High-Risk Input or Ingredient to a Product is occurring.

EKO-GUARANTEE may require additional inspections based on an overall risk analysis of the supply chain undergoing evaluation.

At EKO-GUARANTEE discretion, unannounced inspections may be used to ensure compliance with this Standard.

# SECTION 8

**SAMPLING AND TESTING OF APPLIED PRODUCT**

All High-Risk Inputs and Ingredients must comply with the relevant Action Threshold through either this [Section 8](#_bookmark32) or [Section 9](#_bookmark46), 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 5-2](#_bookmark27) and [Table 5-3](#_bookmark28) for summaries of the appropriate compliance pathways.

## Action Thresholds

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

EKO GUARANTEE NON GM STANDARDS has established the following Action Thresholds for Testable High-Risk Inputs and Ingredients ([Table 8-1](#_bookmark35)).

**Table 8-1**Action Thresholds

|  |  |
| --- | --- |
| **Category** | **Action Threshold** |
| Seed and vegetative propagation materials | 0.25% |
| Wholesale or retail goods for human or pet use that are either ingested or topically applied including OTC drugs and homeopathic remedies | 0.9% |
| Livestock, poultry, bee, and seafood feed and supplements, including those used for animal-derived Inputs and Ingredients to all Products | 5% b |
| Wholesale or retail goods for human or pet use that are not ingested or topically applied including, but not limited to, Inputs and Ingredients to  packaging, cleaning supplies, and textiles | 1.5% |
| 1. For all crops not listed in [Appendix B.1.1](#_bookmark59) and [Appendix C.1.1,](#_bookmark63) there is no allowable presence. 2. Compliance with this Action Threshold may be based on the quarterly average of all lots tested. | |

## Requirements of Sampling

* + 1. **A statistically valid sampling and testing plan** must be designed based on arisk assessment of the production and handling system andmust reflect the level of monitoring appropriate for the risks inherent in the production and handling system, as well as industry standards.
       1. The sampling and testing plan must be approved EKO-GUARANTEE before any test results acquired on the basis of said sampling and testing plan may be used to demonstrate compliance with the Action Threshold.
       2. Unless otherwise allowed by a different section of the Standard, compliant sampling and testing must occur at least once post-harvest for all Inputs and Ingredients, depending on contamination risks.
       3. When achieving 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 yellow summer squash), EKO-GUARANTEE may shift testing to the seed level with limited post-harvest spot testing.

## Compositing samples

Statistical calculations can also be used to design compositing strategies under which portions of multiple samples can be combined and tested together to reduce the number of tests required.

* + - 1. Compositing must be done in a manner that ensures that any single sample in excess of the relevant Action Threshold produces apositive

result for the composite sample as a whole. If a result is obtained for the composite that indicates that one or more single samples exceeds the relevant Action Threshold, the lot must be rejected, or if sub-lots are segregated and not commingled, then retesting of individual lot samples may be possible to salvage compliant lots.

## Requirements of Testing

* + 1. Clients must demonstrate compliance with the applicable Action Threshold.
    2. Compliance must be demonstrated by ensuring that each lot of Testable High-Risk Input or Ingredient is compliant with this [Section 8](#_bookmark32) prior toits

use in a Certified Product.

* + 1. The sample Matrix must be appropriate for the testing methodto yieldvalid results. If necessary, the precursor from which the Input or Ingredient was derived must be tested.
       1. All GM events which requires testing must be tested for and the results must be conclusive.
       2. Test results must be traceable back to the lot number(s) ofthe precursor, Input, or Ingredient.
       3. From the point of testing forward, the activities associated with the precursor, Input, or Ingredient must comply with [Section 6](#_bookmark29).
    2. Test results must be submitted to EKO-GUARANTEE for reviewprior to initial verification to ensure compliance with the applicable Action Threshold.
    3. All test results from the preceding year must be submitted to EKO- GUARANTEE forreview at annual renewal to ensure continued compliance with the applicable Action Threshold.
    4. In cases where the requirements of [Section 8.1](#_bookmark33) are demonstrated to be problematic to achieve for every lot, compliance may be demonstrated by ensuring that test results for all lots of High-Risk precursor, Input, or Ingredient used during each 6-month period average at or below the relevant Action Threshold, with no single lot of precursor, Input, or Ingredient ever exceeding the relevant Action Threshold by more than a factor of two (2). This compliance pathway will be revisited during the 2020 comment period.
       1. Planting seed, vegetative propagation materials, and livestock, poultry, bee, and seafood feed cannot demonstrate compliance via Section 8.3.6.
       2. The Client must justify in writing to EKO-GUARANTEE why the requirements of [Section 8.1](#_bookmark33) are problematic to achieve for every lot at initial verification and at each renewal.
       3. The Client is responsible for ongoing monitoring of test results to ensure compliance for each 6-month period.

## Molecular Testing Methods

* + 1. Testable High-Risk Inputs and Ingredients will be compliant with this Section 8.4 if all the following criteria are met:
       1. Appropriate laboratory controls indicate that the DNA of the precursor, Input, or Ingredient is sufficiently intact to allow valid quantitative analysis by PCR.
       2. The testing is conducted by an approved laboratory in compliance with [Section 8.4.2](#_bookmark41) 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 Client.
       3. A copy of the original result for the PCR test shows that the GM contamination of the precursor, Input, or Ingredient in question is at or below the relevant Action Threshold.
    2. **Laboratories approved** by the NABL must carry out testing, except in cases where Inputs and Ingredients are compliant with [Section 9.4.](#_bookmark52) Such laboratories are accredited to ISO 17025 and must use tests that are included within the scope of their ISO 17025 accreditation for the Testable precursor, Input, or Ingredient in question. Approved laboratories possess a Certificate of Approval and are listed on the [website.](https://www.nongmoproject.org/)
    3. **Laboratory testing** may employ quantitative, semi-quantitative, or qualitative PCR.
       1. Quantitative PCR may be used to demonstrate compliance with the Action Thresholdif:

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.

* + - 1. Semi-quantitative PCR may be used to demonstrate compliance with the Action Threshold if:

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

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

* + - 1. Qualitative PCR may be used todemonstrate compliance with the Action Threshold if:

The PCR limit of detection is 0.1% or lower.

Each test result for each Testable High-Risk precursor, Input, or Ingredient is negative.

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 8.4.3.a](#_bookmark42) or [Section](#_bookmark43)

[8.4.3.b](#_bookmark43) to demonstrate compliance with the Action Threshold. If the Testable High-Risk precursor, Input, or Ingredient cannot be tested in compliance with [Section](#_bookmark42)

[8.4.3.a](#_bookmark42) or [Section 8.4.3.b,](#_bookmark43) compliance with the appropriate Action Threshold cannot be demonstrated and the lot cannot be used in a Certified Product.

## Immunological Testing Methods

* + 1. Immunological testing methods such as Enzyme-linked Immunosorbent Assay (ELISA) or lateral flow strip tests may be used in lieu of molecular testing methods to demonstrate compliance of animal feed (other than pet food) with the appropriate Action Threshold,when the methods meet the criteria in this Section 8.5.

## Analysts must be trained, and their proficiency established to

ensure that they use the tests reliably and according to the manufacturer’s

specifications. Clients must document the in-house training and evaluation of performance.

* + 1. **In cases where immunological testing methods are permissible by this Standard**, they must cover all GM events which requires testing. When all GM events which requirestesting are not covered, samples must be tested in compliance with [Section 8.4.](#_bookmark40)
       1. Quantitative immunological methods may be usedto demonstrate compliance with the Action Threshold when:

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.

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

* + - 1. Qualitative immunological methods may be used to demonstrate compliance with the Action Threshold when:

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

Should any test results be positive, the Testable High-Risk precursor, Input, or Ingredient must be tested according to [Section 8.5.3.a](#_bookmark45)[, Section 8.4.3.a,](#_bookmark42) or [Section 8.4.3.b](#_bookmark43) to demonstrate compliance with the Action Threshold.

# SECTION 9

**Requirements of Affidavit**

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, EKO GUARANTEE uses a process-based approach that includes comprehensive Affidavits as an alternate validation tool.

## Requirements Of Affidavit

* + 1. At minimum, all Affidavits must include the signature and the printed name of the party signing the Affidavit, and the date.
    2. The party signing the Affidavit must have sufficient knowledge of the supply chain to authoritatively sign.
    3. If appropriate, Affidavits should be accompanied by supporting documentation.
    4. At the discretion EKO-GUARANTEE, Affidavits may be required in additional situations not explicitly identified in this [Section 9](#_bookmark46).
    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.

## Non-Testable High-Risk Inputs and Ingredients

* + 1. Non-Testable High-Risk Major, Minor, and Micro Inputs and Ingredients are identified in [Appendix B.2.](#_bookmark61) An Affidavit stating that any such Non-Testable

High-Risk Major, Minor, or Micro Input or Ingredient is Non-GM is required to establish compliance with this [Section 9.2.](#_bookmark48). Organisms, precursors, Inputs, or Ingredients identified as Non-Testable High-Risk Major, Minor, and Micro Inputs and Ingredients in [Appendix B.2](#_bookmark61) ; Non-Testable High-Risk Affidavits accompanying such organisms, precursors, Inputs, or Ingredients do not establish them as Non-

GM and will not be considered for compliance with [Section 9](#_bookmark46).

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 GM, under this Standard, regardless of whether such Inputs or Ingredients are regulated as GMs (or have been deemed Non-GM).

* + 1. EKO GUARANTEE has issued a standardized Non-Testable High- Risk Affidavit. This is the only Affidavit compliant with [Section 9.2.1](#_bookmark49), above.
    2. For any Non-Testable High-Risk Major, Minor, or Micro Input or Ingredient, an Affidavit must be submitted to EKO-GUARANTEE for review prior to initial Evaluation.
    3. Testable High-Risk Major Inputs and Ingredients listed in [Appendix](#_bookmark60)

[B.1](#_bookmark60) must be compliant with [Section 8](#_bookmark32) or [Section 9.4.](#_bookmark52) Testable and Non- Testable High-Risk Inputs and Ingredients (listed in both [Appendix B.1](#_bookmark60) and [Appendix B.2](#_bookmark61)), must comply with both [Section 8](#_bookmark32) and this [Section 9](#_bookmark46).

## Testable High-Risk Minor and Micro Inputs and Ingredients

* + 1. All Affidavits must include the definitions of Biotechnology and GM as they appear in [Section 1](#_bookmark0).
    2. Testable High-Risk Minor and Micro Inputs and Ingredients may demonstrate compliance based on Affidavits as long as these Inputs and Ingredients are the result of a system that has been designed to avoid GMs. Suitability of systems designed to avoid GMs is subject to reviewby EKO- GUARANTEE.
    3. When available, valid certificates from third-party certifiers are acceptable alternatives to Affidavits under this [Section 9.3](#_bookmark50)if the third- party certification program satisfies the requirements for which an Affidavit would be used in [Section 9.3.2.](#_bookmark51)

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.

## Affidavit Compliance Based on Country of Origin4(to be read in compliance with FSSAI Circular )

* + 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.
    2. The necessity or frequency of testing of certain Testable High-Risk crops and their single Input derivatives may be reduced by EKO- GUARANTEE based on an Affidavit.
    3. The Affidavit must state that:
* 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.
* No crop or crop-derivatives from outside those specific countries may be commingled.
* Procedures throughout the supply chain are in place for the segregation, cleanout, and traceability of compliant materials from non-compliant materials.
  + 1. The Affidavits must be submitted to EKO-GUARANTEE for review prior to initialverification and, at minimum, annually upon renewal.

## Monitored-Risk and Low-Risk Major, Minor, and Micro Inputs and Ingredients

* + 1. Affidavits may be used to confirm the compliance of Monitored- Risk and Low-Risk Major, Minor, and Micro Inputs and Ingredients.
    2. The Affidavit must attest to compliance with the requirement for classificationas either Monitored-Risk or Low-Risk as described in [Section 5.2, Table 5-1.](#_bookmark26)

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

* + 1. Affidavits may be used to confirm the compliance of Non-Risk Major, Minor, and Micro Inputs and Ingredients.
    2. The Affidavit must attest to compliance with the requirement for classificationas Non-Risk as described in [Section 5.2, Table 5-1.](#_bookmark26)

# SECTION 10

**LABELLING AND PRODUCT SPECIFICATION**

## Specifications for Obtaining Inputs and Ingredients

* + 1. Major and Minor High-Risk Inputs and Ingredients must be sourced from Non-GM sources. Micro High-Risk Ingredients should be sourced from Non-GM sources.
    2. 10.1.2 For Products Certified under the NON-GM STANDARD, Clients cannot knowingly plant, purchase, or use Inputs or Ingredients that are not compliant with theStandard.
    3. 10.The written specifications for all Products, Ingredients, and Inputs must include requirements regarding Standard compliance and must be updated when the Client changes suppliers, Inputs, or Ingredients.
    4. When spot purchasing is necessary, unverified Inputs and Ingredients should be avoided; Clients must seek out Certified-Status Inputs and Ingredients of appropriate scope. If a spot purchase of unverified Input or Ingredient is made, the Client must:
       1. Justify to EKO-GUARANTEE why a Certified-Status Input or Ingredientwas not used
       2. Provide evidence that any Testable High-Risk Input or Ingredient that is spot purchased has been tested in accordance with the requirements of this Standard and that the test results are at or below the relevant Action Threshold
       3. Demonstrate that all Non-Testable High-Risk Inputs or Ingredients that are spot purchased are compliant with all applicable requirements of [Table 5-3](#_bookmark28)
       4. Demonstrate that all Certified-Status Inputs or Ingredients or Low- Risk Inputs or Ingredients that are spot purchased are compliant with all applicable requirements of [Table 5-2](#_bookmark27)
       5. The Client must provide EKO-GUARANTEE with documentation of the purchase, including Affidavits, sampling information, and test results. This reporting must be done ina timely manner.
    5. Constraints on spot purchasing may be enforced at the discretion of EKO- GUARANTEE. For example, repeated spot purchases from the same supplier could be groundsfor this allowance to be revoked or restricted.

## Labeling

* + 1. Wholesale and retail Products must comply with the labeling requirements outlined in this Standard.
    2. EKO-GUARANTEE will review labels to assess compliance with theseclaim guidelines.
    3. **Labeling claims must be accurate, truthful,** and not mislead the consumer about the GM content of the Product. Any reference to the Non-GM or use of the Certification mark must be approved by a written agreement with the EKO-

GUARANTEE. One-hundred percent (100%) GM absence claims are not acceptable and include, but are not limited to, “contains zero GMs,” “GM-free,” and “GE-free.”

* + 1. High-Risk Micro Ingredients other than artificial and natural flavors, Enzymes, and Microorganisms that have been Micro exempted under [Section 5.1.3.b](#_bookmark24) cannot be listed with the same name, or any other common name, on the Principal Display Panel of a retail consumer Product.
    2. 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 5.1.3.b](#_bookmark24) and the Micro- exempted sub- Ingredient(s) is/are considered to reasonably characterize the Ingredient appearing on the Principal Display Panel

# SECTION 11 QUALITY ASSURANCE

## EKO GUARANTEE NON-GM SYSTEM PLAN

* + 1. The Client’s quality assurance and quality control program, including SOPs, forms, and documents, must be revised as needed to ensure compliance with the Standard, and revisions must be documented.
    2. Compliance with applicable requirements of the Standard must be identified as key quality indicators of the Client’s total quality system.
    3. The Client must monitor and control the compliance of Inputs and Ingredients purchased and finished Products, and this must be documented.
    4. Where needed, additional training must be provided to relevant staff to ensure that SOPs in support of Standard compliance are followed and training must be documented.
    5. All SOPs, documents, forms, and specifications needed by personnel to fulfill the requirements of the Standard must be readily available to relevant personnel.
    6. Records must be retained for a minimum of three (3) years.

## Non-conformities and Corrective Actions

* + 1. **Non-conformity and Corrective Action Requirements**
       1. Full compliance with the Standard must be achieved prior to initial verification.
       2. Changes in processes, procedures, Inputs, Ingredients, or Products, that could impact compliance with any aspect of the Standard, will bedeemed Non-conformities and will trigger corrective actions.
       3. Non-conformities discovered during the renewal process must be addressed in order to maintain verification.
       4. Mid-term Non-conformities discovered through internal quality assurance processes, complaints from customers, third-party surveillance, or third-party audits, will require corrective action as described in [Section 11.2.2](#_bookmark57) as appropriate.
       5. Identification of Non-conformities, corrective actions, root cause analyses, and successful remediation of the Non-conformity must bedocumented.

## Major Non-conformities

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

* + - 1. Discovery of any Major 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.
      2. Corrective action plans must include the identification of persons responsible for their execution, defined timelines for actions, and the desired results of the corrective action plan.
         1. Under certain circumstances, the Client 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 Client’s SOPs or implemented on a recurring basis. In this case, the Client must:

Demonstrate that a homogenous blend was achieved

Retest the blend in accordance with [Section 8](#_bookmark32) 11.2.2.2.1.3 Confirm that the finished lot tests at or

below the relevant Action Threshold

11.2.2.2.1.4 Implement and document practical continuous improvement practices to reduce, and ultimately eliminate, the need for any future blending oflots

* + - 1. Findings of the root cause analysis must be reported in writing to EKO-GUARANTEE, together with the planned corrective actions to beundertaken.
      2. EKO-GUARANTEE will review and at their discretion approve the findings of the root cause analysis and the planned corrective actions.
      3. Corrective actions must be completed in a timely manner, typically within thirty (30) days and rarely longer thanninety

(90) days of the completion of the root cause analysis and

corrective action plan.

Documentary evidence must be submitted to EKO-GUARANTEE

within five (5) days of the completion of corrective actions. EKO- GUARANTEE will review and approve all corrective action evidence.

* + - 1. Any delays in the timeline from reporting to completion of corrective actions must be justified in writing and approved by EKO-GUARANTEE
      2. Any known Major Non-conformity that goes unreported or uncorrected or keeps recurring according to the requirements in [Section 11.2.2](#_bookmark57) will be cause for the Product or the Client to be removed from the Certification Program
      3. Repeated non-conformance with the Action Thresholdmay require mid-term re-evaluation of the Product.

## Minor Non-conformities

* + - 1. Minor Non-conformities will trigger corrective actions.
      2. Minor Non-conformities and corrective actions must be reviewed, at minimum, at the time of renewal.
      3. Renewal will be contingent upon appropriate resolution of any such Minor Non-conformity.

## Renewal

* + 1. Renewal evaluation of every Certified Product will be required at leastannually. 11.2.2Renewal evaluation must ensure that, at minimum:
       1. The Product and all Ingredients and Inputs within the scope of review are compliant under the current Standard version.
       2. All evidence of compliance on file with EKO-GUARANTEE is current and active.
       3. All Non-conformities have been addressed.
    2. No changes to the Product or its manufacture or processing that would compromise the Product’s compliance with this Standard have occurred.
    3. The Product is compliant with any applicable Standard revisions.
    4. EKO-GUARANTEE may require a Client to submit updates more frequently if history shows a pattern of Major Non-conformities occurring asa result of unannounced changes to the operation.
    5. Such changes include, but are not limited to, the following: changes in Product composition that involve High-Risk Inputs or Ingredients; changes insuppliers of High-Risk Inputs or Ingredients; changes in processes or procedures that alter the segregation, cleanout, or traceability of Inputs, Ingredients, or Products; or changes in specifications of High-Risk Inputs, Ingredients, or of a final Product that contains High-Risk Inputs or Ingredients.

## Appendix B – High-Risk List

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

## Testable High-Risk Inputs and Ingredients Crops

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

* Alfalfa
* Canola
* Corn (except popcorn)
* Cotton
* Papaya
* Soy
* Sugar beets
* Zucchini and yellow summer squash

## Animal-derived Inputs and Ingredients

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

## Inputs, Ingredients, and Derivatives

* Ascorbic acid, sodium ascorbate, vitamin C
* Citric acid, sodium citrate – derived from glucose syrup
* Ethanol – derived from corn or GM 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
* Amino acids
* Aspartame
* Flavorings, “natural” and “artificial” – including all carriers and co-formulants
* Lactic acid
* Microbial Growth 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 haveGM risk (e.g., corn oil)
* Xanthan gum

## Non-Testable High-Risk Inputs andIngredients Crops

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

* Canola
* Potato
* Soy

## Non-Testable High-Risk Crops

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

## Animal-derived Inputs and Ingredients

* Meat, dairy, eggs, wool, hides, honey, seafood, and any other materials or substances originating from animals
* Livestock and poultry feed

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 6](#_bookmark29) and [Section 7](#_bookmark31).

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 6](#_bookmark29) and [Section 7](#_bookmark31).

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-TestableHigh-Risk.

Per [Section 8](#_bookmark32), [Section 9.1,](#_bookmark47) and [Section 9.5,](#_bookmark53) verification of livestock and poultry, bee, and seafood Products and Major Inputs and Ingredients requires the testing of feed.

* + Bee forage and feed
  + Fish and other aquatic animal feed

## Microorganism and Enzyme Inputs and Ingredients

* + Algae
  + Bacteria
  + Enzymes
  + Microbial cultures and starters
  + Yeast

## Ingredients or Substances with Synbio Counterparts

**Appendix C –Monitored-Risk List**

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

## Testable Monitored-Risk Inputs and Ingredients Crops

* + *Beta vulgaris,*(e.g., chard, table beets) – cross pollination risk from GM sugarbeets
  + *Brassica napa* (e.g., rutabaga, Siberian kale) – cross pollination risk from GMcanola
  + *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

## Non-Testable Monitored-Risk Inputs andIngredients Crops

* + Camelina (false flax)
  + Mushroom
  + Orange
  + Sugarcane
  + Tomato

## Ingredients or Substances with Synbio Counterparts

* + Spider silk

Appendix A

Rationale of Approving the Sampling for Testing Plan

SYSTEMATIC/GRIDSAMPLING

OVERVIEW

Systematic sampling, also called grid sampling or regular sampling, consists of collecting samplesat locations or over time in a specified pattern. For example, samples might be collected from a square grid over a set geographical area or at equal intervals over time. Systematic designs are good for uniform coverage, ease of use, and the intuitive notion that important features of the population being sampled will not be missed. Also, samples taken at regular intervals, such as at every node of an area defined by a grid, are useful when the goal is to estimate spatial or temporal correlations or to identify a pattern.

Sampling will be determined by the Certification officer at time of assigning the Inspection Assignment to the Inspecting officer on the basis of Established Risk ( As per Appendix B and C at the time os application review) and Perceived Risk( Actual risk identifies as per appendix B and C )

. Established risk is the risk that the certification officer identifies or foresees after evaluation of the documents received before the onsite / offsite inspection. Perceived risk is identified by the inspecting officer at the time of the inspection which could not be established by evaluation of the documents by the certification officer ( Eg. Adjoining Non Gm crop) such risk is perceived at the point of inspection. In case of established risk the certification officer mentions the samples to be taken in the inspection assignment, but the inspector is free to take samples at the incidence of perceived risk

Sampling and testing is based on the risk envisaged, sampling and testing is required where incidence of GM is prevalent in that area. On submission of the application and documents, the Certification officer will determine which part of the Plant (Seed, flower, fruit) the sample is required to be taken by the Inspecting Officer as per the GRID system (Even Row, Odd Column). The Instruction for the Sample to be taken by the Inspecting officer shall be mentioned on the Inspection assignment generated by the Certification officer at the time of filed visit. The inspecting officer shall identify on site the plant grid for which the sample is required to be taken.

In case of Warehouse audit (usually in trading units) composite samples based on row and column shall be taken from all four dimensions. No sample is required if the risk not Envisaged at all.

Decision for testing shall be taken by the certification officer after evaluation of the inspection reports and other certification documents.

Samples are collected in every case of certification, however whether the samples shall be tested shall be determined by the certification officer after evaluation of the Inspection report and documents generated post inspection. In case the perceived risk is less than the established risk , sample testing may not be required unless otherwise necessary.

Sampling in case of fraudulent affidavit submitted by the client: The inspecting officer shall verify all the affidavits submitted by the client for Non Gm declaration (eg. NON GM Seed, NO GM Crop stored). If during verification a fraudulent affidavit is found, the inspecting officer shall take a composite sample of the product at each level of production, cultivation, processing and trading.

Appendix D

FSSAI Circular Imported crops in India



FSSAI Circular on NON Gm Crops.pdf