

**NON_GMO_ MEDICINE PRODUCT
STANDARD**



NON-GMO Food Control Council

1. Purpose

The purpose of the standard is to provide meaning and value to the marketing request.

"Non-GMO Project Verified", creating, maintaining and keeping public a series of challenging requirements where all GMO-free Project Veronay Products are measured.

Non GMO is based on an application-oriented and process-oriented Standard that uses both testing and Declarations as key strategic tools to verify that applications and processes meet expectations.

For participants, common decoding is necessary for a common purpose to eliminate inputs and components from Genetically Modified Organisms (GMOs) from supply chains.

The width and depth of the product evaluation are inherently informed of the Entries and components represented in the Product formulation or contained in the product. Entries and Materials are sorted by three attributes:

- 1) The percentage of weight represented in or contained in the product,
- 2) the possibility of deriding from a GMO and
- 3) Whether there is a testable premise at any point in the supply chain.

These three attributes are the percentage of weight, risk status, and testability, respectively, re-termed. Validation requires the eligibility of all Entries and Content associated with a Product that must be evaluated.

In summary, all Project Approved Products must have systems for:

- **Labeling:** Accurate and clear Product labeling
- **Quality assurance:** Maintaining operational consistency and immediate handling of noncompliances
- **Procurement:** Obtaining Input and Content in accordance with uniform and meaningful specifications
- **Test:** Meaningful, Ongoing Testing of Large High Risk Inputs and Components
- **Separation and Cleaning:** Protecting Compatible Inputs and Components from combining with incompatible materials
- **Traceability:** Supply chain traceability, especially following Input and Component testing or the establishment of a compliant Declaration

2. Application and Review

2.1 Application

- Application from www.gmolabel.org site,
 - Approval of GMO-Label label license,
- Product testing *
- GMO-Label field inspection after product approval
 - Approval of use of GMO-Label label
 - Using the GMO-Label label

*The laboratory where the product test will be performed must be authorized from ISO 17025 accreditation or approved by GMO-Label.

2.2. Application Review

Queue No.	Topic	Mark If Appropriate
1.	Make sure the product is suitable for GMO-LABEL	
2.	Contact the competent authority on GMO -Label	
3.	<u>Complete application</u> from www.gmolabel.org site	
4.	<u>Complete membership</u> in www.gmolabel.org site	
5.	Confirm license agreement for GMO-Label label	
6.	Prepare a technical file for the product that has a GMO -Label label request	
7.	Upload the technical file required for the GMO -Label label to the system	
8.	Send the product for GMO-Label label to the relevant laboratory for testing	
9.	GMO-Label field inspection	

2.3 Audit Period

For High Risk products; 3 times in 12 months

For Medium Risk products; Twice in 12 months

For Low Risk products; Audits are carried out once in 12 months. Inspections and checks are carried out unannounced.

2.4 Product Groups

Medicine products.

*** Prohibited entries; Substances controlled under U.S. law, Bovine growth hormone, Cloned ones and derivatives, Synthetic Biology and derivatives**

3. Risk Status

All entries and contents are divided into 3 classes according to the table below according to their risk status;

Low Risk; Organisms that are not classified as Monitored Risk or High Risk and the Inputs and Components obtained from them

Medium Risk ; Inputs and Components derived from organisms and their GM counterparts in the research and development stages, where gm contaminations developed but not widely commercially available or known occur

High Risk; Inputs and Components derived from organisms and their GM counterparts are widely available commercially

4. Test Operations

Entries and Components Can or Cannot Be Tested. Testable Inputs and Components have a point in the supply chain where the Input or Component contains enough intact deoxyribonucleic acid (DNA) or protein to return valid molecular or immunological test results, and acceptable molecular tests or immunological tests are commercially publicly available to all, covering all events that the Project requires testing. Untested Inputs and Components do not have a public point in the supply chain where the Input or component contains sufficient intact DNA or protein to return valid molecular or immunological test results, and/or acceptable molecular tests or immunological tests are available to the public. Some organisms and their derivatives are both Testable and Untested according to the criteria above.

The molecular method for Testable High Risk Inputs and Components other than animal feed (including use in pet food) is the only acceptable test methodology of polymerase chain reaction (PCR).

For Testable High Risk Inputs for a manufactured feed (other than pet food), molecular method PCR or immunological methods can be used to demonstrate compliance with the Threshold of Action.

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5. Activity

CoC requirements apply at the point of testing or at the point where compliant Declarations are provided, starting from the point where a Risk-Free, Low Risk, Monitored Risk or Verified Status of an Entry or Component is confirmed. When it comes to product verification, the following activities are subject to review and must be determined to be in compliance with the relevant Standard sections (Table 4-1).

Activity Type	Comment
Agricultural production— seeds and crops	It includes farm production, harvesting and post-harvest handling and storage in farm or farm-related facilities.
Processing	It includes all kinds of products, such as post-harvest movement, storage, conversion or labeling of goods throughout the CoC, from seed to consumer, except for the Products included in the final retail packaging.
Storage	It contains all connections from seed in CoC to finished Product.
Distribution	This may or may not include the physical processing of goods.
Processing	It includes all transportation, storage, processing, handling, assembly or packaging of goods in any production facility.
Production	Includes the production and combination of Entries and Components to make the Finished Product.
Packaging and labeling	Contains all events that are added, removed, or modified during the packaging or labeling of goods.

5.1 Global Chain of Oversight Requirements

All necessary procedures must be written and accessible to all appropriate personnel and updated as necessary.

All eligible personnel working with Compatible Entries, Materials and Products must be adequately trained in the necessary procedures.

All records must be kept for at least 5 years.

5.2 Separation

Systematic procedures should be applied during activities to keep Compatible Entries, Components, ongoing work and finished Products separate from all non-compliant High Risk materials.

Separation measures are also required for cases where necessary tests take place after such Entry or Component enters the facility.

5.3 Cleaning

In order to eliminate GMO contamination sources, transportation and transport transports, as well as the proper inspection and cleaning/cleaning of receiving, production, processing, production, transfer and storage facilities, and all relevant cleaning, purging and inspections must be documented.

5.4 Traceability

Each lot of the Verified Product must be traceable to a certain number of Entries and Components used in its production. If a particular product is combined in storage of a large number of compatible Entries and/or Materials before you manufacture a large number of products, the lot numbers for all-in-one lots must be linked to a specific Productlot.

Testable High Risk Inputs and Materials must be traceable up to lots showing compatible test results. Untested High Risk Entries and Components must be traceable up to lots associated with compliant Declarations.

Systematic procedures should be applied to monitor lot numbers and/or mark and label packaging, container and storage facilities to ensure traceability of Entries, Components, ongoing work and finished Products at all points in the production process.

Clearly monitor and monitor the compatibility of entries, Components and finished Products.

6. Inspections and Test Process

6.1 Audits

Organizations should be audited annually according to risk situations.

Non-participating contract processors are exempt from auditing as long as the Products, Components, and Entries they produce are the result of a system designed to avoid GMOs. The eligibility of this exemption will be re-examined during the next Standard revision.

Regardless of Percentage of Weight, Risk Status, or Input, Content, or Testing of Products, it may require additional audits based on a general risk analysis of the supply chain.

At GMO-LABEL's discretion, unannounced audits may be used to ensure compliance with the Standard, regardless of the Percentage of Weight, Risk Status, or Testability of Inputs, Components, or Products.

6.2 Test Process

GMO-LABEL can perform unannounced testing by obtaining products from the market outside the above test period.

Sampling Intensity

Number of Zones	Regions to Sample and Test
Less than 5	At least one region per quarter is tested per region
5 to 10	At least two regions are tested per quarter per region
10 to 20	15% of regions tested per quarter per region
20 to 40	10% of regions tested per quarter per region
Over 40	At least 7 regions are tested per quarter per region

The GMO-like Project has created the following Action Thresholds for Testable High Risk Entries and Components

Category	Action Threshold
Seed and vegetable spreading materials	0.25%
Swallowed for human or pet use or Applied topically, including OTC drugs and homeopathic drugs	0.9%
Feed and supplements, including livestock, poultry, bee and seafood, animal-derived Inputs and Those used for Materials to All Products	%5
Wholesale or retail products for human or pet use that are not ingested or topically applied, including but not limited to packaging, cleaning materials and textiles	1.5%

The sampling and testing plan must be approved by GMO-LABEL before any test results obtained on the basis of the specified sampling and test plan are used to demonstrate compliance with the threshold of action.

Otherwise, compliant sampling and testing should be carried out at least once for all Entries and Components, depending on the risks of contamination, unless they all owe a different part of the standard.

Participants must demonstrate compliance with the current Action Threshold.

All GM events that the project requires testing must be tested and the results must be accurate.

Test results must be traceable up to the lot numbers of the predecessor, Input, or Content.

Test results should be sent to GMO-Label for review before initial verification.

All tests from the previous year should be submitted to GMO-Label for review in the annual renewal.

6.2.1 Molecular Testing Methods

Appropriate laboratory checks show that the precursor, input or component DNA is sufficiently robust to allow the current amount and analysis by PCR.

The test is carried out by a properly approved laboratory, and the analysis report refers to a specific number of precursors, inputs or components used by Participant, when appropriate.

Laboratory tests can use quantitative, quantitative, or qualitative PCR. The PCR detection limit is 0.1% or lower.

6.2.2 Immunological Testing Methods

Analysts should be trained and their competencies should be determined to ensure that they are reliable and use the tests according to the characteristics of the manufacturer. Participants must document on-premises training and performance evaluation.

Where immunological testing methods are permitted by the Standard, the project must cover all GM events required by the project.

For each test, the result is below the detection limit or returns a number in the quantitative range and is not above the upper limit of the detection interval.

The sum of each test panel for testable High Risk predecessor, Input, or Content is on or below the relevant Action Threshold.

The Testable High Risk predecessor is negative for each GM event per Input or Content.

6.3 Declarations

In most cases, testing is a necessary verification tool to confirm compliance with the Testable High Risk Master Entries and Components Action Threshold. Untested

In the case of High-risk entries and components where tests are not an available verification tool, or Entries and Components classified as other Testable High Risk Majors, the Project uses a process-based approach that includes comprehensive Declarations as an alternative verification tool. In some cases, the frequency and necessity of testing or the need for certain Declarations can be reduced, depending on the country in which a crop is grown.

At the very least, all Declarations must include the signature and printed name and date of the party that signed the declaration.

The signer of the affidavit must have sufficient knowledge of the supply chain to sign it authoritatively.

If appropriate, supporting documents should be accompanied.

Unless otherwise stated, the Declarations must be updated appropriately to reflect changes in the crops, predecessors, Entries, Components, systems, processes or processes they refer to.

For the avoidance of doubt, All Untested High Risk Major, Minor and Micro Inputs and components are subject to evaluation and may be considered GMO in accordance with the Standard, regardless of whether such Entries or Contents are regulated as GMO by any EU GMO Directive or Regulation (or accepted as GMO-free) or subject to any EU GMO Directive or Regulation by a member State.

Unless otherwise specified by a different part of the Standard, declarations for the Untested High Risk Major, Small or Micro Entry or component must be submitted to GMO-LABEL for review before initial verification and updated and resubmitted annually at least every renewal after each renewal to ensure compliance.

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7. Tagging - Logo

Wholesale and retail Products must comply with the labeling requirements specified in the Standard.

Labelling requests must be accurate, accurate and should not mislead the consumer about the GMO content of the Product. The use of any citation or verification mark to the GMO-like Project must be approved by a written agreement with the Project.

The organization may use logos related to the GMO-Label label in the following ways (color, visual, etc.) and sizes.



The organization must define, implement and verify its process regarding the use of GMO-Label labels.

Note-1: The organization may not use the GMO-Label label except for approved products.

Note-2: The Organization must obtain approval from the certification body and maintain the records before using the GMO-Label ethics.

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8. Quality Management System

The organization should prepare, implement, maintain and continuously improve the necessary documents in accordance with the requirements of this standard.

8.1 Documentation Management

The organization must provide the necessary documentation for the GMO-Label management system and include the following;

- Documents required by the GMO-Label standard
- Identification (Document name, preparer, approver, document number, etc.)
- Document compliance must be approved and reviewed in terms of proficiency.
- Distribution (Documents must be accessed)
- Storage and Disposal

Note-1: Documents must be approved by senior management in terms of proficiency.

8.2 GMO-Label Policy

The organization should establish, announce and maintain a GMO-Label policy.

The policy should include:

- Compliance with GMO-Label requirements and continuous improvement
- Compliance with legal requirements
- Compliance with OHS and Environmental conditions

Note-1: The policy should be announced to the relevant stakeholders.

8.3 Duty Powers and Responsibilities

Tasks, responsibilities should be determined, communicated and documented for the GMO-Label processes within the organization. Employees should take full responsibility.

Note -1: Powers and responsibilities must ensure compliance with the requirements of the GMO-Label standard.

8.4 Assignment Letter

The organization must identify a staff member for monitoring, continuous improvement, implementation and continuity of the GMO-Label standard.

Note-1: The personnel to be determined cannot be a person from the senior management.

8.5 Education

Employees should be made aware of the following:

- Regarding GMO-Label standard activities,
- Regarding OHS conditions,
- About GMO-Label policy

8.6 Internal Audit

The organization should conduct internal audits at planned intervals to determine the status of the GMO-LABEL management system regarding:

a) whether it complies with:

- 1) the requirements for the organization's own GMO-LABEL management system, including the GMO-LABEL policy,
- 2) the conditions of this standard, whether it is applied effectively and whether it is maintained.

Internal Audit Program;

- a) plan, create and maintain an audit program/programs, taking into account the importance of related processes, including frequency, methods, responsibilities, consultation, planning conditions and reporting, and the results of previous audits,
- b) determine the criteria and scope of the examination for each examination,
- c) select the auditors and carry out the examinations in order to ensure the objectivity and impartiality of the audit process,

- d) ensure that the results of the audit are reported to the relevant management; ensure that the results of the relevant audit are reported to employees, employee representatives and other interested parties, if any, where they are located,
- e) take action to address nonconformity,
- f) as proof of the examination program and the results of the audit.

8.7 Improper Process

If the products labeled GMO-Label are not suitable, the organization should start to implement the necessary processes and keep them as documented records.

The inappropriate process is applied if:

- Using different products instead of GMO-Label products
- Misuse of GMO-Label label
- Inappropriate product input

8.8 Corrective Action

When an impropriety occurs, the organization:

- a) intervene immediately in nonconformity as appropriate from:
 - 1) take action to control and correct it;
 - 2) must fight the consequences;
- b) evaluate the need for action to eliminate the causes/causes of nonconformity so that it does not reappe up or occur there through;
 - 1) review of nonconformity;
 - 2) determination of the causes of nonconformity;
 - 3) determine whether similar nonconformities exist or are likely to occur;
- c) take all necessary actions;
- d) review the effectiveness of the corrective action;
- e) make changes to the anti-bribery management system if necessary.

Corrective activities should be in accordance with the effects of nonconformity encountered.

The organization must retain information written as proof of the following:

- the nature of the nonconformity and the actions taken afterwards;
- the results of corrective actions.

8.9 Complaint Management

The organization should document and record the process regarding complaints of products labeled GMO-Label.

8.10 Supplier Verification

Verifying GMO-Label input products is as follows:

- Control of GMO-Label inputs
- Records of GMO-Label entries
- Supplier information and verification must be provided.

8.11 Inappropriate Entry

The organization should take action from the improper entry situation and inform the relevant parties. GMO-Label max. 5 should be informed about inappropriate products within 5 working days.

8.12 Storage and Storage

The organization, GMO-Label labeled products and other products should be separated from each other and prevented from mixing.

8.13 Production Planning

The organization should pay attention to the following in its production planning labeled GMO-Label:

- Production must be defined as GMO-Label labeled.

The organization must create and maintain production records labeled GMO-Label.

The organization must take samples and keep them according to the frequency in the table below.

8.14 Traceability

The organization must ensure traceability in the input and output processes of products labeled GMO - Label.

8.15. Sales

The organization should pay attention to the following during the sale of products labeled GMO-Label:

- 6.1 Organization name and contact information,
- 6.2 The name and address of the customer,
- 6.3 Invoice date,
- 6.4 Product description,
- 6.5 Quantity of products sold,
- 6.6 GMO-Label label number of our company.

Title: NON GMO FOOD CONTROL COUNCIL

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ABOUT US

GMO stands for Genetically Modified Organism. When it comes to GMOs, many people only think of crops. Yet an 'organism' is not just a plant; refers to all living things, including bacteria and fungi.

Therefore, GMOs are living beings whose genetic codes have been modified in some way. While traditional breeding, which has been going on for centuries, involves mixing whole genes from two different sources, producing GMOs is much more targeted. Instead of crossing two plants in the field, they insert one or two genes into individual cells in a lab.

The GMO creation process starts very small. A scientist inserts a gene into the DNA in the nucleus of a single cell. The DNA used for modification is so small that it cannot be seen even under the most powerful microscope. No matter how small a cell is, it has a huge amount of DNA packed in its tiny nucleus.