WHITE PAPER

NON-GMO PROJECT VERIFICATION: WHAT TO EXPECT

With the rapid growth in consumer preference for non-GMO products across many categories, reliable third-party verification of the absence of genetically modified organisms is increasingly important to food producers, processors and brand owners to meet the growing and evolving demands and preferences of consumers.

In fact, in a survey by Consumer Reports, 92 percent of consumers polled said they believe genetically engineered ingredients should be labeled[1] and GMOs rank in consumers' top five food concerns at over 67 percent.[2] To keep pace with consumer wants, North American retailers are aggressively sourcing for non-GMO and other health and wellness product attributes. Many supermarkets and restaurants prefer suppliers with third-party verified claims to appeal to label-conscious consumers and reduce their exposure to risk.

WHAT IS NON-GMO PROJECT VERIFICATION

Non-GMO Project verification is a process-based standard, but only individual products can carry the claim: Each product is assessed from each facility. It's similar to traditional product certification like organic or kosher, but goes beyond product-level compliance in that products must be produced in accordance with compliant quality management systems. Non-GMO claims span many categories including beverages, snacks, fresh produce, dairy, body care and supplements.

Non-GMO Project verification is the fastest growing label in the natural channel by a wide margin, with more than 3,000 brands and over 43,000 products verified. Sales of Non-GMO Project verified items have been on an extreme growth curve, with more than $19.2 billion in sales as of April 2017[3].

NON-GMO PROJECT VERIFICATION REQUIREMENTS

The four main aspects of Non-GMO Project verification are:

- **Input Evaluation –** Determines levels of testing and what supporting verification documentation is needed
- **Traceability –** Tracks product through the supply chain
- **Segregation and Cleanout –** Protects product integrity
- **Testing of High-Risk Inputs –** Confirms non-GMO status

1 http://www.consumerreports.org/cro/2014/10/where-gmos-hide-in-your-food/index.htm
2 http://www.conecomm.com/2014-food-issues
3 https://www.nongmoproject.org

consumer values verified™

INPUT APPROVAL

Inputs are classified as Non-Risk, Monitored-Risk, Low-Risk, High-Risk, or Verified-status. Each classification has different levels of testing and approval requirements based on its risk.

NON-RISK, MONITORED-RISK AND LOW-RISK INPUTS

A non-risk input is any material that is not derived from biological organisms. Thus, it is not susceptible to genetic modification. This includes salt, lime and fossil-based products.

Monitored-Risk inputs include species for which genetically modified versions are in the research and development stages, species that have been developed but are not widely commercially available species or for which known GM organism contamination has occurred. These inputs are listed in Appendix C of the Non-GMO Project Standard, and should follow the same requirements as Low-Risk Inputs. Examples of Monitored-Risk Inputs are tomatoes, apples and rice.

Low-Risk Inputs are species derived from biological sources, that are not in the Monitored-Risk or High-Risk categories, such as sugar cane and green peppers.

It is fairly straightforward to determine which category single ingredients would fall under. For multi-ingredient or processed products, it can be a bit more challenging. For Low-Risk Inputs, the Non-GMO Project Standard requires a complete input disclosure from the supplier for each compound ingredient to confirm absence of High-Risk Inputs. Specification sheets or similar documents must disclose all components contained in the input, as well as the source when applicable (for example "sugar derived from cane"). For single ingredient products, documentation must confirm no other inputs are present in the product.

An input can only remain low-risk if it is produced in conditions designed to avoid cross-contamination with GM materials. One way to demonstrate this is through proof that the facility does not use high-risk inputs. If the facility does use high-risk inputs, compliance can be demonstrated by showing that procedures and systems are in place to effectively segregate the low-risk input from potential sources of high-risk contamination within the facility. Proof of traceability and segregation assures that the input was produced under conditions designed to avoid cross-contamination with GM materials.

HIGH-RISK INPUTS

High-Risk Inputs are species for which GM versions are widely commercially available. It includes certain crops (alfalfa, canola, corn, soy, cotton, papaya, sugar beets, yellow summer squash and zucchini), their derivatives (corn starch and soy lecithin) and animal derived-inputs (honey, dairy and meat).

Microbes, enzymes and inputs sourced via synthetic biology are examples of non-testable High-Risk Inputs, where no point in the production chain exists at which the GM can be identified using current testing methodologies. Appendix B of the Non-GMO Project Standard has a non-exhaustive list of derivatives with high GMO risk that are commonly used in food production.

A complete input disclosure must also be provided for each compound ingredient to identify all High-Risk Inputs. Ask your supplier to disclose the source when there is a chance of a High-Risk sub-ingredient. Additionally, it is essential to confirm that the input was produced following segregation and traceability measures to avoid cross-contamination with genetically modified materials.

VERIFIED-STATUS

Verified-status are inputs that have been verified under the Non-GMO Project as verified products. The components of the input do not need to be re-evaluated.

THRESHOLD LEVELS FOR HIGH-RISK TESTABLE INPUTS

Absence of all GMOs is the target for all Non-GMO Project Standard verified products. Continuous improvement practices toward achieving this goal must be part of the participant's quality management systems. A key requirement of such quality management systems is to meet or continually be below an action threshold. Testable High-Risk Inputs that do not comply with the testing requirements may not be intentionally used in verified products.

The Non-GMO Project has established these action thresholds for testable High-Risk Inputs:

Category	Action Threshold
Seed and other propagation materials	0.25%
Inputs to human food, ingredients, supplements, personal care products and other products that are either ingested or used directly on skin	0.9%
Livestock feed and supplements	5%
Inputs to packaging, cleaning products, textiles and other products that are not ingested or used directly on skin	1.5%

MAJOR, MINOR AND MICRO INGREDIENTS

Ingredients are further classified as major, minor or micro based on how much of the product they comprise (as percentage of weight, excluding the weight of salt or added water). For livestock feed, the categories are calculated based on the weight of the input as a percentage of the ration fed to the animal:

- **Major:** Represents 5 percent or more of the finished product or is a defining ingredient
- **Minor:** Represents at least 0.5 percent but less than 5 percent of the finished product, and is not a defining ingredient
- **Micro:** Represents less than 0.5 percent of the finished product and is not a defining ingredient

This classification helps to determine if high-risk inputs must be tested to meet or be below the action thresholds, or if the quantity and risk are small enough to be exempt from evaluation as defined in the standard under section II D.3.

As stated above, if an ingredient appears in the product name, it is deemed to be a major input (for example, honey in "Honey Cookies").

TESTING OF HIGH-RISK INPUTS

Genetic-based testing of all testable High-Risk Inputs is required before a finished product can be verified. A statistically valid sampling and testing plan based on a risk assessment must be established. Compliant sampling and testing must occur at least once post-harvest. Sampling plans must be designed to achieve 90 percent confidence in quantification of GMOs at or below the action thresholds.

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

Testing must be carried out by a laboratory accredited to ISO /IEC 17025 for methods included in the standard. A list of approved labs is available on the Non-GMO Project website.

Appropriate laboratory controls must indicate if the input DNA is sufficiently intact to allow valid quantitative analysis by polymerase chain reaction (PCR). (raw agricultural products such as seed, grains, legumes, raw milled products and flour have intact DNA). Highly processed inputs with insufficient intact DNA must instead be approved by lot-specific traceability back to precursors for the inputs that are testable. For example, refined soy oil is not testable, but soybeans are.

TRACEABILITY

Each lot of Non-GMO Project verified product must be traceable back to specific lots of the inputs used in its production. A document control system with systematic procedures must be in place for tracking lot numbers and/or marking and labeling of packaging, containers and storage facilities to assure traceability of inputs, work-in-progress and final products at all points in the production process. If the operation is dedicated strictly to Non-GMO Project Standard compliant production, it is sufficient to have a record-keeping system that records the lot numbers for all inputs used to make a specific lot of product.

Traceability records should explicitly trace and track the Non-GMO Project Standard compliant status of both inputs and the final product.

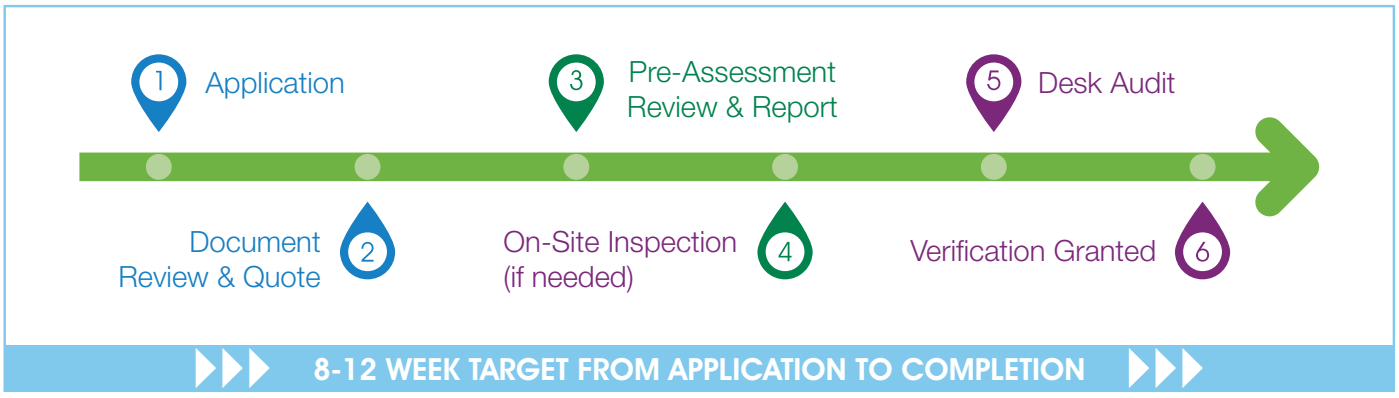
SEGREGATION AND CLEANOUT

Cleanout and segregation procedures prevent GMO contamination of inputs, work-in-progress and final products. Receiving, production, processing, manufacturing, transfer and storage facilities, as well as shipping and transportation conveyances, should be inspected and cleaned/purged to remove sources of GMO contamination. All relevant cleaning, purging and inspections must be documented.

If the operation is dedicated solely to Non-GMO Project compliant production, segregation measures are unnecessary. Segregation measures are required if a facility is not dedicated, and are critical where any required testing occurs after the input in question has entered the facility. Segregation activities should include lot number and work-in-progress tracking.

STEPS IN THE VERIFICATION PROCESS

There are six steps in the non-GMO Project verification process.



STEP ONE: APPLICATION

After you enroll with the Non-GMO Project, the technical a administrator requests and collects basic information about your products, ingredients and number of facilities. Depending on your type of operation (handler/processor, brand owner, producer or livestock operation), a different application is required, customized to your operation. You will also receive a contract and a licensing agreement.

STEP TWO: DOCUMENT SUBMISSION, REVIEW AND QUOTE

In this step, you supply detailed information about the products you are submitting for review. The technical a administrator reviews your documents to quote you properly and prepare your files for pre-assessment review.

This documentation includes:

- A compliance plan to guide and organize your ongoing adherence
- A product formula sheet for each multi-ingredient product processed at your operation
- An input supplier list of all suppliers of the inputs/ingredients used in each product
- A warehouse affidavit if you contract a storage facility storing inputs or work-in-progress
- A complete input disclosure identifying all components contained in the input

STEP THREE: PRE-ASSESSMENT REVIEW AND REPORT

An evaluator reviews your information and you are assigned a certification project manager. You receive a pre-assessment report that details compliance areas that are absent or insufficient, and may be asked for additional documentation. Depending on the input risk category, the following documentation may be required:

- Affidavits for non-testable High-Risk Inputs
- Affidavits for micro/minor High-Risk testable Inputs that are the product of a system designed to avoid GMOs
- Proof that supplier has a system to avoid commingling high-risk ingredients and GMOs (could be an organic certificate or a certified identity preservation system)
- Signed letter confirming the supplier does not handle high-risk ingredients
- For Non-GMO Project verified inputs, a web listing and verification certificate
- For testable inputs, lab results from an approved ISO /IEC 17025 accredited lab
- A statistically valid sampling and testing plan

STEP FOUR: ON-SITE INSPECTION

An on-site inspection consists of a walk-through of the facility, a review of the efficacy of the compliance plan, confirmation that processes referenced in the application and pre-assessment report are in place, a recordkeeping review and a check of the effectiveness of the segregation and traceback systems.

You may skip this step if a) your products contain only Low-Risk Inputs, b) your products contain only exempt High-Risk Inputs and/or micro/minor High-Risk Inputs that are the product of a system designed to avoid GMOs, c) there is no parallel processing of major High-Risk Inputs or d) your co-packer is in compliance with the Non-GMO Project requirements.

STEP FIVE: DESK AUDIT

Once you review findings in the pre-assessment report and make the necessary corrections and additions, you submit your response, which initiates the desk audit. The Technical Administrator reviews the original pre-assessment report, identifies the additional clarifications or corrections made to your program, and if it appears on paper that you comply with the Non-GMO Project requirements, you proceed to on-site inspection (or directly to verification, depending on your situation).

STEP SIX: VERIFICATION AND ONGOING COMPLIANCE

Once non-conformities noted in the desk audit and/or inspection are corrected, the verification decision is made. Once you've successfully completed the process, your products are verified to the Non-GMO Project Standard. You have the option to incorporate the "Non-GMO Project Verificated" seal on your packaging in accordance with the licensing agreement. You can also use non-GMO labeling claims.

USE OF NON-GMO PROJECT LABELING CLAIMS

Claims must be accurate and truthful, and not mislead the consumer about the GMO content of the product. Any reference to the Non-GMO Project or use of the Verification Mark must be approved by a written agreement with the Non-GMO Project.

Labels claims cannot be made about the absolute absence of GMOs (for example, "contains zero GMOs," "GMO-free" and "GE-free" are not valid claims). However, claims related to the process of verification, such as "the product was made without GMOs" or "the product never uses GMOs" are allowed.

AVOIDING COMMON PITFALLS IN VERIFICATION

It's not just non-compliances that lead to delays in verification, but also incomplete or inconclusive information. To make sure your company is on track, avoid these common pitfalls.

> **Inadequate Supplier Statements –** Letters or affidavits from suppliers indicating that the product/ingredient "does not contain GMOs" are not sufficient for verification to the Non-GMO Project Standard. When submitting documentation for your ingredients, your Technical Administrator can provide guidance on what types of documents are required based on the risk and content levels.

> **Incomplete Documentation –** Incomplete forms or input disclosures will delay your application. Check the documents your supplier sent before submitting them. For example, if your product contains sugar as a sub-ingredient, the source material should be listed as cane or beet. Make sure answers or "not applicable" are filled in every blank space. The more thorough your documentation, the quicker you will advance to verification.

> **Formulation Errors –** Be sure to submit formulas in the required format: List salt and water where applicable, but exclude them from the percentage calculation. Make sure your percentages add up to 100 percent without salt and water.

> **Irrelevant Forms –** Some forms apply only to certain operations or organizations, and are labeled "Required-if-Pertinent-Doc-Name." Only submit these if they are relevant to you.

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