



# Certification Requirements for Non-GMO Project's Approved Laboratories

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## Requirements for Application & Full Renewal

The following list shows a summary of the documents that need to be submitted to the Non-GMO Project (the Project) for consideration of laboratory approval and during each full renewal. Each subsequent section details the specific needs for that requirement as well as how to complete relevant forms. For additional context regarding these requirements, please refer to [Section 6.4](#) of the Non-GMO Project Standard and/or reach out to the Project's Quality Assurance team.

*Note: Documents do not need to be submitted all at once. Laboratories may submit documents as they are ready and may be approved at any time during the year.*

- ☐ A. Approved Laboratory Questionnaire
  - ☐ B. Proof of ISO 17025 Accreditation & Scope
  - ☐ C. Testing Capacity & Accreditation Tables
  - ☐ D. Sample Reports & Interpretation Guide
  - ☐ E. Proficiency Testing Results
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### A. Approved Laboratory Questionnaire

The Non-GMO Project Approved Laboratory Questionnaire must be completed and signed.

### B. ISO Accreditation

All Non-GMO Project Approved Laboratories must be ISO 17025 Accredited. Copies of the following must be submitted to the Project:

- a. ISO 17025 Certificate of Accreditation
- b. ISO 17025 Scope of Accreditation

*Note: Both documents must clearly indicate a date of renewal or expiration, or in the alternative, the laboratory must provide official documentation from the accrediting body specifying such date.*

### C. Testing Capacity & Accreditation

The enclosed PCR test tables, for Qualitative and Quantitative testing, respectively, specify the GM events which are required to be covered for approval of each High-Risk Crop/Input. In the space



provided on each table, please complete the following information:

a. Indicate Available Testing Methods:

Indicate which events your laboratory can test for and specify the PCR test(s) used to detect each event. Use the specific test name as it is displayed on the analysis report issued to customers. If you offer multiple tests for a given event, please list the methods that are most common, or most likely to be used. **(Please complete both tables)**

*Note: We do not prescribe specific tests to be used; our main requirement is that each of the listed events must be detected. Therefore, it is not necessary to employ event-specific testing for each event, as we encourage the use of suitable screeners.*

b. Requirements for Approval of Testing:

i. A laboratory will be approved for testing a given crop only if the laboratory:

1. Is able to provide in-house testing for all the events listed in the table for said crop
2. Is ISO 17025 accredited for all such tests

ii. Laboratories can be approved exclusively for Qualitative testing, Quantitative testing, or both, depending on their offering of tests and accreditation and pursuant to the restrictions below:

1. For commodity crops (such as canola, corn, soybeans), both Qualitative and Quantitative testing capabilities are required.
2. For other crops (alfalfa, cotton, papaya, sugar beets and zucchini/summer squash), laboratories can be approved exclusively for Qualitative testing, Quantitative testing, or both.
3. Laboratories must be approved for Quantitative testing for at least one crop. A laboratory will not be approved if they can only offer Qualitative testing across all crops.

*Note: If a Non-GMO Project Participant receives a positive result on a Qualitative sample, they are required to follow up with a Quantitative test of the sample to demonstrate compliance with the Action Threshold.*

iii. If approved for testing of a High-Risk Crop, testing panels used for NGP Participants must cover all listed events as outlined in the Testing Capacity Tables. To meet this requirement, we expect laboratories to use commercially reasonable efforts to identify clients that are NGP Participants.

D. Analytical Reports & Interpretation

The following sections outline requirements for Approved Laboratory analysis reports, as well as samples and interpretation guides that must be submitted for consideration of approval.

*Note: The Project will issue Testing and Reporting Guidelines to approved laboratories annually. These requirements are subject to change.*

a. Reporting Requirements:

Laboratories must use commercially reasonable efforts to identify clients that are NGP Participants, to ensure that the following required reporting requirements are met:

- i. When DNA is insufficient for testing, or results are inconclusive, this must be clearly indicated on report.



- ii. The address listed on reports must match the address on the laboratory's ISO Accreditation Certificate.
- iii. All GMO tests performed must be listed on reports.

*Note: This allows both Participants and Technical Administrators (TAs) to confirm that all testing required by the Project has been performed.*

b. Sample Analytical Reports:

Laboratories must provide anonymized exemplar reports as specified below, from actual samples the lab has analyzed (simulated reports will not be accepted). The reports must represent how various types of GMO testing results are reported, based on the type of testing your laboratory provides (e.g. Qualitative and/or Quantitative).

- i. Samples must be derived from High-Risk crops (as defined in the Project's [Testable High-Risk List](#))
- ii. The following are types of testing outcomes we are looking for, though the list is not exhaustive:
  - 1. Samples for which the laboratory has determined the DNA is sufficiently intact for testing (e.g., whole soybeans, cornmeal)
  - 2. Samples for which the laboratory has determined DNA is not sufficiently intact (e.g., RBD canola oil)
  - 3. Positive results
  - 4. Negative results

c. Interpretation Guides:

Laboratories must submit a guide for interpretation of all sample reports. This will be shared with Non-GMO Project Participants, to aid their understanding of test results.

*Note: Participants are responsible for interpreting their test results in accordance with the Standard. However, we recognize that not all reporting formats look the same and that instructions on how to read test results are helpful to TAs and Participants.*

- i. Interpretation Guide Template: Please refer to the attached Template to see what information must be explained on the various sample analytical reports. Instructions and explanations on the Template are listed in blue text, comment bubbles, and endnotes.

*Note: If you already have a document that explains report interpretations, and which meets these requirements, please feel free to submit this instead.*
- ii. Instructions: Please complete the following steps for all sample analytical reports that you selected in section *b*, above
  - 1. Start with a screenshot or PDF of each sample analytical report.
  - 2. On each report, use comment bubbles, or endnotes to provide guidance on where to find the required information, and how to interpret the result. Each report should have an interpretation that is unique to the particular result on the sample report.
  - 3. Required Information: At a minimum, the interpretations on each sample report must address where to find and how to understand the following information:
    - a. Quality of DNA



b. Total GMO Content

E. Proficiency Testing

Laboratories must provide a copy of results from their participation in proficiency testing with a provider acceptable to the Project. The proficiency testing must be conducted on one or more of the High-Risk crops as defined by the Project, and for GM events found in those crops. A complete report from the proficiency testing provider is required, as well as a letter indicating the laboratory's participant number. No internal summary or report will be accepted.

a. Participation Requirements:

- i. Laboratories must provide at least 8 results from proficiency testing programs they have participated in within the last 2 years.

1. At least 4 of the results must be Quantitative. These results must be positive and have an associated z-score.
2. At least 2 of the tests must detect a High-Risk event required by the Project.

- ii. Laboratories must submit proficiency testing results that meet the requirements outlined in this section to the Project during each full renewal. You may share results with us at any time, as they are released. Otherwise, we will check in to collect and review results each fall, so that laboratories have enough time to complete any necessary follow-up before renewal.

*Note: We routinely review the USDA FGIS reports as they are released. If you participate in any other programs separately or in addition to this, we ask that you share these results with us.*

- b. Expectations for results: These expectations apply to each individual round of PT results that are shared with us.

- i. At minimum, 90% of all results must have a Z-score within +/-2.
- ii. No outliers, including false negatives and/or positives.

c. Unexpected Results:

- i. For results that are outside of the listed expectations, we will follow up with a request for a Root Cause Analysis and a Corrective Action Plan.
- ii. Repeated performance outside of the expected results may result in further follow-up and/or non-compliance.

d. Examples of Programs Deemed Acceptable by the Project:

The following list are examples but is not exhaustive. If you have another Program that you would like to participate in, contact the Project for approval:

- i. USDA FGIS Biotechnology Proficiency Program
- ii. International Seed Testing Association (ISTA) GMO Proficiency Test
- iii. Fapas GM Scheme (GeMMA)



## Requirements Following Approval

### F. Laboratory Agreement

If approved, laboratories will receive the Non-GMO Project Approved Laboratory Agreement (the “Lab Agreement”). This must be dated and signed by an authorized signatory of the laboratory.

### G. Payment of Yearly Licensing Fees

Upon approval, laboratories will receive an invoice from the Non-GMO Project’s Finance Team for the first year of certification. Laboratories must submit payment as outlined in the invoice upon approval and then annually at renewal, prior to June 30.

## Maintaining and Returning to Compliance

### H. Maintaining Compliance

To maintain approved status, all Non-GMO Project Approved Laboratories must remain in compliance with the Certification Requirements at all times and ensure that the Project has current documents on file.

The Project will conduct annual renewals, as outlined below, to confirm laboratory compliance.

Renewals must be completed by June 30 each year and must include, at a minimum, a signed Laboratory Agreement Addendum and Summary of Changes form.

#### a. Half Renewals:

On odd numbered years, laboratories must submit the minimum documentation listed above.

#### b. Full Renewals:

On even numbered years, the laboratory must complete a full renewal of Certification requirements. In addition to the yearly requirements, this will include all documents that were required at renewal (Sections A-E).

*Note: The Certification Requirements may be revised annually, at the Project’s sole discretion. When such requirements change, Laboratories will be notified 6 months before the renewal documents are due.*

### I. Curing and Correction of Non-Compliance

If a laboratory is found to be out of compliance with the Certification Requirements, the Project will notify the laboratory via email of their non-compliant status. At this time, the procedure for returning to compliance, described below, is triggered.

a. In a timely manner, and in no event more than thirty (30) days post-notification, the laboratory must provide the Project with a written plan and proposed cure period for returning to compliance.

b. If the Project is unable to accept the proposed cure period, the Project may propose an alternative cure period.

c. If at the end of the agreed-upon cure period the laboratory is still unable to comply with all requirements, the laboratory shall be deemed a “Defective Laboratory” and/or a



“Terminated Laboratory”, as outlined in the Laboratory Agreement.

## Eligibility

- J. Any Laboratory "affiliated with" any Participant (defined below) in the Product Verification Program (“PVP”) is ineligible to, and therefore may not, become a NGP Approved Laboratory.
  - a. A Laboratory is “affiliated with” a Participant if the Laboratory owns or controls, is owned or controlled by, or is under common ownership or control with a Participant.
  - b. A “Participant” is any entity, including without limitation, any company, corporation, LLC, partnership, joint venture, or other person or organization, or any brand that (a) has products enrolled; and/or (b) sells or distributes, and/or uses its private-brand label in connection with, any Non-GMO Project Verified Product that has been manufactured, supplied, co-packed, labeled, or otherwise provided by a third-party Participant.
- K. A Laboratory that owns or administers a competing GMO avoidance scheme as a certifying body for retail products may not become an NGP Approved Laboratory.