NON GMO*

Food, Feed and Seed Certification Program

(*genetically modified organisms)

2nd Edition – May 2015

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1. INTRODUCTION

The NON GMO (Genetically Modified Organisms) Food, Feed and Seed Certification Program was developed by IBD based on the most recent concepts, with the purpose of controlling GMO presence in products.

The "Client Quality Manual", hereafter named Questionnaire of Production – QP – consists of a plan of practical measures, actions and analyses, including segregation, identification and traceability of NON GMO products.

Any change, on the clients´s part, of procedures and information reported in the QP must be revised and authorized by IBD during audit or at any time required by the client and also shall be duly documented.

IBD will inspect the procedures carried out by the client and issue the Certificate that attests compliance with this rule.

IBD is owner of the seal and of these standards. Any proposal for alteration is welcome.

2. SCOPE DEFINITION

This program allows (under any scope) for:

a) Ensuring that the final product's GMO content is in the maximum range levels specifically established by the client;
b) Comply with the requirement product labeling;
c) Minimize risks of GMO presence;
d) Check on suppliers and specifications;
e) Handling high risk situations of GMO presence through on-field controls, thus providing viable and reliable tools for identifying NON GMO materials.

The kind and extension of measures necessary to accomplish this Program´s final purpose will be defined upon a risk assessment on the presence of GMO products in the supply chain on a level that can affect the quality of the same.

Depending on the different combinations of the practical measures and actions taken, the following kinds of scope can be defined:

2.1 IBD N-GMO CONTROL.

This program applies to products with low risk profile (commercial prohibition of product from genetic engineering). The low risk level does not require batches segregation. Requires laboratory analysis and traceability within the program.

2.2 IBD N-GMO IP PRESERVED IDENTITY

This program applies to products with high risk profile (commercial permission of product from genetic engineering). The high risk level requires laboratory analysis and full traceability, from the origin to the end of the supply chain.

	IBD N-GMO Control	IBD N-GMO IP
GMO risk	Low	High
Sampling & tests	X	X
Segregation		X
Traceability	X 1	X 2

1 = traceability within the program

2 = traceability up to the seed or original material

3. MEASURES & ACTIONS

Organizational measures regarding handling, audit and certification.

3.1. Risk assessment

The client shall provide the following documents to demonstrate risk of GMO presence in relevant areas, such as approved and not approved GMO varieties, upon official documents and analytical experience, when applicable.

a) Official declaration of authorities allowing planting and commercial use of the GMO in question;
b) Declarations from seeds suppliers of no GMO contamination being supplied, and /or
c) Constantly updated control sheets containing all summarized analytical results.

These documents shall be kept constantly updated and available to IBD.

3.2. Renewing the risk assessment

a) In cases of adverse events, such as changes in laws allowing new varieties, materials or still voluntary or not for environmental contamination, GMO presence will be indicated by analytical result.
b) Before each year's sowing or exploration, there shall be a re-definition of sampling, segregation, and checking of minimal requirements for keeping the NON GMO certification.
c) At least each 12 months:

i. The client shall keep risk assessment renewal records.
ii. The client shall inform IBD about any development of the current risk status. Eventual suggestions of changes in filling out the QP shall be submitted to IBD by the client.

d) Risk assessment documents (QP and attached documents) shall be kept constantly updated and available for IBD, for review and inspection.

4. SPECIFYING THE CERTIFICATION SCOPE AND PURPOSE

a) The client shall specifically state the certification purpose, products and the array of specifications, for instance, maximum levels.
b) The client shall specify the certification scope, including production, processing and warehousing facilities, suppliers and transport structures, with the respective addresses, to be inspected by IBD.
c) The client shall provide a flow sheet showing the parts involved in the chain of supply and the product volume along the year.

5. RESPONSIBILITY AND COMMITMENT

a) All involved suppliers and identified services shall be documented.
b) Suppliers are linked to the program per contracts, thus being subject to IBD inspections.
c) The client's key staff (including the manager in charge of the IP program) must be identified and listed in the QP, as well as their substitutes.
d) The client will be the general responsible and the contact with IBD.
e) Responsibility, identification, documentation, internal control, internal audits and handling of non-compliances will be defined for each address/facility (client or supplier) during certification process.
f) There must be recordkeeping of sending samples for external inspection and analysis.
g) This information will be part of the QP and must be updated.
h) All staff involved with the IP program and their responsibilities must be documented in the QP and be available during inspections.

6. DOCUMENTS

6.1. Questionnaire of Production – QP – (Clients organic program QP or Management Plan may be used, when applicable. These standards requirements not available in the Management Plan must be complemented).

a) Clients shall fill out a questionnaire describing all locations/facilities and providing details about implementing the measures required for certification. This document will be the basis for implementing, keeping and checking the program.

b) The QP will define, for the client and the suppliers, all responsibilities related to the program. In addition, any policies and documents for data recording shall be defined.
c) The QP shall be filled out by the company's (client's) responsible person and IBD can request more details.
d) The QP must be submitted at least four weeks before inspection and reviewed by IBD in order to allow the inspection.

6.2. Documents, control sheets and data organization

a) The QP shall include a list of document copies and where to find them.
b) The QP shall be continuously updated, with reference to the dates of update.
c) Clients shall have procedures for controlling and updating all documents related to the program, and keep update records. This includes document updates, update approvals, distribution of updated documents and filing of old documents and filled out forms.
d) All documents and forms shall be numbered and identified regarding the update version.
e) All documents out of use, duly identified, and all data, sheets and technical information in use shall be kept as readable files for at least five years.

7. TRAINING

a) It will be the client's responsibility to ensure proper qualification to the staff involved with the IP program.
b) All staff shall be trained according to schedule and all new employees shall be given training before taking over their positions. Employees shall also be trained in any case of procedure update.
c) Training will focus procedures and recordkeeping as described in the QP.
d) Any training shall be duly recorded, with information on the training's contents and signed by instructors and attendants.

8. CONTROLLING

a) Clients and suppliers will establish appropriate documents and control measures to continuously ensure, check and comply with the procedures described in the QP.
b) When there is a quality system (for instance, ISO 9001:2001), all relevant procedures shall be regularly subject of documented internal audits. The frequency of internal audits shall be of once every two years.
c) Where there is no quality system, internal inspections carried out by the clients shall be defined and recorded in the QP. Depending on the client's level of risk and structure, those measures can be taken continuously or randomly, inspecting the critical points during processing as for instance sampling, checking on cleaning

methods, checking on commingling at high risk points etc. Those inspections shall be recorded.

d) Internal inspection reports shall be available to IBD.
e) Internal inspection reports shall be available to the client's staff, with due records of results and implemented amendments.
f) For any non-compliances, corrective actions will be agreed upon based on item 10.

9. HANDLING ADVERSE EVENTS – NON-COMPLIANCES

9.1. Non-Compliances and corrective actions

a) The client and the suppliers shall record and implement procedures to identify, report and correct non-compliances such as any accidental commingling of materials, or any other adverse event such as loss of traceability.
b) Corrective actions for resolving non-compliances (positive analyses, corrective measures) will be defined for each case.
c) The resolution of non-compliances shall be properly recorded, for IBD inspections.
d) When analytical results are above the allowed GMO material level, the affected products must be immediately segregated and excluded from the specific control chain. A new destination to that product will be given with documented evidence of the new destination.
e) When analytical results are frequently close to the maximum GMO level, an investigation on the cause for this must be carried out and measures must be taken to optimize production.

9.2. Emergency plan for critical situations

a) Clients shall define supply/production strategies for disasters or major contamination situations that affect the certified supply chain. This plan shall define measures to be taken during a certain timeframe for substituting affected products, including possible recall actions. The plan must be approved by IBD.

b) If the supply chain cannot be reformed within a reasonable timeframe to be agreed with IBD, the certification becomes invalid and must be discontinued. This includes discontinuing any current marketing activities. Clients must inform their buyers about certification discontinuance.

10. CHECKING SPECIFICATIONS OF EXTERNAL SUPPLIERS.

10.1. External suppliers

Companies or producers will only be considered suppliers when they are part of the supply chain but not linked to clients by a society contract. It is not possible to certify the supply chain beyond the external supplier.

10.2. Specifications

External suppliers' products can only be accepted in the certified supply chain if the supplied product complies with the specifications and principles of the four measures (segregation, traceability, representative sampling and analysis), in accordance with the program scope. Specific standards shall be approached by the QP or case y case.

10.3. Checking

a) The QP will define requirements and checking points for the client to accept or reject suppliers' products. Those can include evaluating other certifications, declarations, analyses or inspections.
b) Clients shall define, record and implement the checking of correspondent procedures and the need for recordkeeping. This procedure will be inspected by IBD.
c) Clients will be responsible for organizing data for the inspection.
d) If a product is not clearly compliant with pre-established criteria, clients shall resolve this issue with IBD. This procedure shall be described in the QP.

10.4. Checking on external suppliers

There are two kinds of external suppliers (to be recorded in the QP):

a) Suppliers with N-GMO certificates which demonstrate that the supplier's production fits into the client's scope and complies with the four principles (segregation, traceability, representative sampling and analysis).
b) Suppliers whose production is not traceable back to the seed or original material. In this case, safety measures will be obligatory, such as analysis per shipping to reception warehouse, accompanied by the corresponding laboratory test, within pre-established standards. This procedure will be subject to internal and external (IBD) audits.

11. PHYSICAL MEASURES – PRODUCTION AND PRODUCT

11.1. Segregation

a) Measures to prevent any commingling of certified and non-certified products shall be taken along the entire supply chain covered by certification.
b) Clients and suppliers shall record and check the supply chain for all involved products in accordance with HACCP principles, identifying all Critical Control Points with risk of GMO material commingling. These HACCP records shall be available for IBD as basis for control, inspection and Certification. Clients must keep HACCP analysis updated or demonstrate having an equivalent functional system, and inform IBD of any change / update.
c) For each identified critical point there must be established procedures for preventing, controlling and handling adversities.
d) The supply chain must have at least one "retention and clearance" point, which holds back any that have not been approved by a GMO limit test, preferably at the entrance of the supply chain. Exceptions: IP Monitor program does not require such "retention and clearance" point.
e) All facilities in the supply chain should, whenever possible, be exclusive for certified material.
f) Whenever possible, restrictive measures, such as cleaning, transport and storing procedures, should be defined before using any facility. These procedures shall be documented and implemented.
g) If facilities and equipment are used for both certified and non-certified products, there must be defined, documented and implemented procedures for cleaning them, including maximum prevention against contamination and commingling.

11.2. Traceability

a) There must be an implemented recordkeeping system to allow identifying the origin, destiny, quality and quantity of certified material at any point within the supply chain, at any moment. The total amounts of received and eliminated products must be recorded.
b) Certified product must always be identified in the production chain.
c) There must be direct correlation between lot numbers and analytical results.

11.3. Sampling

a) A sampling plan shall be defined and documented to allow representative verification of GMOs in products covered by the scope. The sampling plan will be valid only if approved by IBD and included into the QP.
b) The plan shall consider GMO presence risk in the area and the supply chain. Sampling shall be carried out at the points of high contamination risk or at "retention and clearance" points.
c) The sampling plan will part of the procedures described in the QP.

d) Sampling must be representative for each lot. Under certain circumstances, random sampling can be sufficient. Representative sampling must be carried out in accordance with international rules relevant for each product.
e) Maximum sampling quantities shall be defined by relevant rules.
f) A sample can be formed from (up to) 10 lots, depending on product, limit, circumstances, supply chain control and the risk of contamination with non-certified material.
g) Important: International sampling rules normally recommend a maximum of 500 MT; however, controlling previous steps on the chain can reduce the number of samples per shipping. In some cases, it can be recommended to start with a larger volume of samples and reduce the number after analysis shows a GMO status consistently lower than the maximum limit defined for the respective step.
h) The laboratory sample size must be sufficient to minimize false negative results occurrence or statistic deviations due to insufficient number of particles. Statistic trust must be optimized according to program's objectives (minimum 5.000 grains – soybean, approx 1 kg; corn, approx 1,5 kg).
i) Duplicate samples shall be kept in place for at least one year, sealed and properly stored to allow new analyses if requested.
j) Samples and duplicates shall be duly labelled for clear identification of the origin (lot/batch, sampling date and place, company name, sample quality and size).
k) If there is no quality system, sample collection will be carried out by IBD auditor, randomly. This shall be part of the company's QP.

11.4. Analysis

a) An analysis plan must be defined and documented to identify and quantify GMO presence. This procedure shall be part of the QP.
b) Samples shall be analyzed by appropriate methods, which can combine protein tests (ELISA, kit) and DNA (PCR) tests. Analysis strategies shall be described in the QP.
c) A protein test can be carried out in place as long as there are qualified facilities and staff. Procedures shall be maintained and recorded.
d) Any protein test can be used as long as approved.
e) If there are constantly negative results, IBD and the client can agree upon a reduction in the intensity of sampling and analysis.

12.5 Labelling

a) The seal to be used for both scopes for Non GMO certification will be the one indicated on the cover and on the initial page of this standard.
b) The issued certificate will indicate the specific scope.

12. GLOSSARY

DNA

Abbreviation for deoxyribonucleic acid. A long polymer chain of deoxyribonucleotides forms a double helix. DNA constitutes the genetic material of living organisms.

ELISA

Abbreviation for Enzyme-Linked Immuno Sorbent Assay. A sensitive method for determining specific proteins in samples. It shows the quantity of protein determined through a color change by enzymatic reaction.

External supplier

Suppliers that deliver products to the supply chain but are not part of the chain's controlled operations.

External Inspection

Inspections carried out by the certifier.

Internal Inspection

Inspections carried out by the client.

GMO

Abbreviation for Genetically Modified Organism. An organism which has been modified by recombinant DNA technology.

PCR

Abbreviation for Polymerase Chain Reaction. An enzymatic reaction which allows the identification of genetic modifications within the organism's DNA, by amplifying certain DNA sequences (that is, sequences that were introduced by recombinant DNA technology).

Retention and Clearance

A control point in the supply chain in which the products can only be approved if the NON GMO status has been verified by representative sampling and analyzing.

Testing Kit

Test with strip or marker.