



DEPARTMENT OF AGRICULTURE, FORESTRY AND FISHERIES

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STANDARD OPERATING PROCEDURE APPLICABLE TO NON-GMO STATUS CERTIFICATION

1. PURPOSE OF THE DOCUMENT

This document shall provide a standard operating procedure (SOP) with regard to the issuance of non-GMO (genetically modified organisms) status certificates by the Department of Agriculture, Forestry and Fisheries.

2. BACKGROUND

Polymerase chain reaction (PCR) is a recognised and appropriate standard for GMO testing to meet government and industry requirements globally. If performed correctly, PCR tests are precise and provide an accurate result with regard to content of subject being tested (Force, 2008). Lateral flow or strip test testing only provides qualitative results and does not accurately reflect the total GMO content in the specific sample being tested.

When exporting from South Africa, various countries request confirmation from Government regarding the GMO status of the consignment being exported. It is important to note that this function is not part of the Directorate's mandate under the GMO Act, 1997 and that certificates are only issued based on requirements imposed by importing countries.

For non-GMO certification, it is possible that a consignment may inadvertently contain a small percentage of adventitious GMO, due to agricultural practice, even if the consignment is in principal regarded as a non-GMO. In recognition of this, the Executive Council, i.e. the decision making body appointed in terms of the Genetically Modified Organisms Act, 1997 (Act No. 15 of 1997), on 8 February 2002, determined that any consignment will only be regarded as non-GMO if it contains less than 1.0% total GMO content for the specific consignment being subjected to testing (Registrar: Genetically Modified Organisms, 2002).

Non-GMO status certificates will verify that a representative sample from a specific consignment being exported is non-GM, based on quantitative PCR results for any specific GMO event(s) approved for commercial use in South Africa. An affidavit declaring the non-GMO status of crops listed on the South African variety list, should

also be included in the application. A certificate is issued for a consignment complying with non-GM status in terms of quantitative PCR results which are within the parameters for non-GM certification. For crops of which no commercial GM equivalents are cultivated in South Africa, certificates will be issued accordingly.

A consignment can include any biological group, such as a microbe, plant or animal or product thereof in unprocessed or processed form.

A consignment is considered homogeneous if it contains a single component e.g. sorghum grain or maize starch. However, a consignment is considered non-homogeneous if it contains more than one component e.g. mixed animal feed or a multi-component processed product. For certification of a consignment that is not heterogeneous, the certification will apply to the status of all the individual components of that consignment. Thus, the GM content of individual homogeneous components of a non-homogeneous consignment must collectively be less than 1%, respectively.

3. STANDARD OPERATING PROCEDURE

The procedure described below has been approved by the Directorate Biosafety as the standard operating procedure for GMO status certification of consignments being exported from SA.

An important factor in the determination of the GMO status of a consignment is whether the consignment contains an ingredient (e.g. crop) of which the equivalent has already been genetically modified (GM) and is commercially available in SA. A list of the GMO events approved for commercial production in SA is available on the website of the Department of Agriculture, Forestry and Fisheries at www.daff.gov.za under the division Biosafety.

All applications, for crops for which there is a GM equivalent, should be accompanied by a quantitative PCR test result with a LOD/LOQ of less than 1%. Dependent on the results, non-GMO status certificates will be crop(s) listed on the

application form for a particular consignment. This will also determine the specific requirements applicable for the different types of consignments being exported.

There are two types of consignments for which certification can be requested –

- Homogeneous consignment (examples – a single crop like apples, a shipment of maize grain, a single variety/hybrid or maize starch)
- Homogeneous component(s) of a non-homogeneous consignment (example – Mixture of soybean and maize in single shipment) for which all components of consignment to be indicated on application.

In terms of the SOP, negative GMO status certification is based on the sample representing the consignment being tested yielding results for GM content below the recommended threshold of 1% as prescribed by the Executive Council.

REQUIREMENTS APPLICABLE TO THIRD PARTIES PERFORMING GMO TESTING

Any third party involved in testing samples in support of GMO status certification, must comply to the following –

1. Be a registered facility in terms of the Genetically Modified Organisms Act, 1997
 2. Be an accredited laboratory by nationally and internationally recognized standards
 3. Only test method to be accepted by Department of Agriculture will be a quantitative PCR test with a LOQ of less than 1%
- For analysis in support of non-GMO certification, the LOD (limit of detection) or LOQ (limit of quantification) of the test must be below 1.0%. The LOD and LOQ is a measure of the sensitivity of the assay. Thus for practical reasons the LOD or LOQ of a particular assay must be below the 1.0% threshold allowed for non-GMO certification. For example, if the LOD of a strip test is 1.0% or higher, its sensitivity is not sufficient for non-GMO certification at a 1.0% threshold.

- The third party must, on request of the Department, be able to provide proof of competency to perform some or all of the test methods offered by providing relevant documentation or certification. Certification should include general laboratory certification e.g. SANAS as well as certification for test methods by an appropriate body e.g. international certification from organisation endorsing test methods.
- The registered facility may also be subject to inspection by an official from the Department in terms of the Genetically Modified Organisms Act, 1997.

APPLICATION PROCEDURES FOR APPLICANTS

The requirements for the applicant to obtain a GMO status certification in this category are as follows -

Examples of when a non-GMO status certificate may be applied for include:

When a GMO equivalent is commercially produced in South Africa

Example: A consignment of maize grain. GM maize is commercially produced in SA but specific consignment does not contain a GMO variety.

When there is no GM equivalent commercially produced in South Africa

Example: A consignment of green peppers. There are no GM green peppers commercially available in SA.

Applicants are required to submit the following:

Non-GMO certificate application process for crops with GM equivalents (certificate valid for 3 months)

- Application form for crop(s) listed per consignment
- Affidavit to verify test results and relevant information submitted (valid for 6 months)
- Quantitative PCR test results* (**original or certified copy****), from a facility registered in terms of the GMO Act, corresponding to the specific consignment to be exported. (test results valid for 6 months)
- Proof of payment

- Compliance with any other legislative requirements to facilitate the export of the consignment

*** Test results submitted with the application should be issued in the name of the exporter/entity responsible for the export of the specific consignment subjected to testing**

**** Any application submitted without the required test results, i.e. original or certified copy attached, will not be processed**

Current crops subjected to quantitative PCR testing are as follows:

Maize (*Zea mays*)

1. Flour corn — *Zea mays* var. *amylacea*
2. Popcorn — *Zea mays* var. *everta*
3. Dent corn — *Zea mays* var. *indentata*
4. Flint corn — *Zea mays* var. *indurata*
5. Sweet corn — *Zea mays* var. *saccharata* and *Zea mays* var. *rugosa*
6. Waxy corn — *Zea mays* var. *ceratina*
7. Amylomaize — *Zea mays*
8. Pod corn — *Zea mays* var. *tunicata* Larrañaga ex A. St. Hil.
9. Striped maize - *Zea mays* var. *japonica*

Cotton (*Gossypium* sp.)

Soybean (*Glycine max*)

Non-GMO certificate application process for crops with no GM equivalents (certificate valid for 6 months)

- Application form for all crops listed per consignment
- Affidavit indicating non-GM status of crops listed on the South African variety list
- Proof of payment
- Compliance with any other legislative requirements to facilitate the export of the consignment

NB: Bulk consignments that is unprocessed/raw products and that will be used for food & feed must be tested for all GM events approved for commercial cultivation for:

- **Maize (*Zea mays*)**
- **Cotton (*Gossypium sp.*)**
- **Soybean (*Glycine max*)**

Glossary

GMO- genetically modified organism; is an organism whose genetic material has been altered using genetic engineering techniques. These techniques are generally known as recombinant DNA technology. With this technology, DNA molecules from different sources are combined into one molecule to create a new set of genes. This DNA is then transferred into an organism, giving it modified or novel genes.

LMO- Living modified organism; is an organisms which have been genetically modified through the application of biotechnology including organisms that have been modified by novel recombinant DNA techniques as well as those that have been modified by mutagenesis or classical breeding and selection techniques

Adventitious presence-is the technically unavoidable/accidental presence of traces of genetically modified seed in conventional seed.

PCR- polymerase chain reaction. This is a technique to amplify a single or few copies of a piece of DNA across several orders of magnitude, generating millions or more copies of a particular DNA sequence

LOD – limit of detection, the lowest quantity of a substance that can be distinguished from the absence of that substance (a *blank value*) within a stated confidence limit (generally 1%).

LOQ – limit of quantification, LOQ is the limit at which we can reasonably tell the difference between two different values.

Force, I. G. (2008). Draft position paper on ISTA's view regarding the units for the reporting of quantitative results on adventitious presence of seeds with specified traits in conventional seed lots. *Seed Testing International No.136 October* , 6-7.

Registrar: Genetically Modified Organisms, A. (. (2002). *Minutes of the 1st meeting of the Executive Council for 2002-8 February 2002, 14H00 Dirk Uys Building , Room 343*. Pretoria: Department of Agriculture.