aic agricultural industries confederation ®

NON-GM MODULE

June 2013

Feed Materials Assurance Scheme

Feed Materials FEMAS Assurance Scheme

To be read in conjunction with FEMAS Core Standard/Intermediate Supplier Standard

NOTE: Although these Additional Requirements may be translated into various languages for the convenience of users, the English version remains the definitive reference document in the event of any dispute.

SECTION 1 INTRODUCTION

1.1 Scope

Certification against this Module is available to:

- All participants seeking FEMAS certification and marketing feed ingredients on the basis that they do not contain Genetically Modified Organisms (GMOs) or are not derived from GMOs.

AND

- All participants who market feed ingredients derived from organisms for which there is a commercially available GM alternative, but who do not label these feed ingredients as containing GM.

Participants located in, or exporting to, the EU should refer to **Regulation (EC) No 1829/2003 on GM Food & Feed** and **Regulation (EC) No 1830/2003 on Traceability & Labelling of Feed Products Produced From GMOs**. Participants may also wish to refer to the UK **Guidance Notes from Food Standards Agency and Department For Environment, Food And Rural Affairs** and other appropriate Guidance issued by National Competent Authorities with regard to the above EU Regulations.

The term 'Non-GM' has no legal status but, as this term is now in common use, it will be used to describe feed ingredients covered by this document.

The aim of this Module is to exclude GM products from any feed ingredients supplied as 'Non-GM'. Under EU Regulations, a 0.9% adventitious contamination threshold is applicable for GM varieties approved in the EU. This same threshold will apply for FEMAS certification against these Additional Requirements, unless a **lower** level has been agreed between the participant and the purchaser or is required by national regulations in the country where the feed ingredient is produced or in which the participant will place it on the market, in which case the lower limit will apply. It is emphasised that adventitious presence represents a practical tolerance level and is NOT an allowance level. To achieve certification against this Module, participants must provide evidence that they have taken all reasonable steps to avoid GM products entering into their supply chain at any point.

Participants must also be aware that there is no tolerance under EU Regulations for GM traits that are not approved in the EU. Products containing such GM material may not be produced or marketed in the EU and will not be certified by FEMAS for the EU market.

Robust traceability and control at all stages of the supply chain will be essential in achieving FEMAS certification against this Module. The effectiveness of such controls must also be verified by analysis. To achieve certification against this Module FEMAS assessments will include audits of all levels of the supply chain necessary to verify the effectiveness of a participant's controls and this may include visits to the country in which any Non-GM crops are being grown.

Participants are reminded that any participant seeking certification against this Module will also require full and successful assessment against the **FEMAS International Core Standard** or **FEMAS Standard for Intermediate Suppliers**, as appropriate[1], regardless of their geographical location, before a FEMAS certificate can be granted. Under FEMAS rules, it is not possible to certificate feed ingredients solely on the basis of their GM status.

FEMAS is not intended to enable a "GM-Free" claim to be made. "GM-Free" implies a much wider freedom from the use of GM technology in the supply of feed ingredients and would require more stringent controls than those required by this Module.

1.2 How to Use This Module

This Module is laid out in the same format as the **FEMAS International Core Standard**. Where additional requirements exist, the clause reference is to the appropriate section of the **FEMAS International Core Standard**. It is emphasised that the requirements included in this document apply **in addition** to those of the **FEMAS International Core Standard** and are not to be considered in isolation. For clauses where no additional requirements are provided in this document, the original requirements of the **FEMAS International Core Standard** continue to apply without any additions or exclusions.

[1] Certification is also possible where feed safety is assured by other feed safety programmes acceptable to FEMAS. Confirmation of accepted feed safety programmes must be sought from the authorised FEMAS Certification Body.

Certification against this Module is also possible for participants certified against the **FEMAS Standard for Intermediate Suppliers** but clause references may not align in all cases between this document and the **FEMAS Standard for Intermediate Suppliers**.

1.3 Statements Regarding FEMAS and the GM Status of Feed Ingredients

Because the term 'Non-GM' has become widely used in common parlance, this term shall be used as a brief description in relation to feed ingredients certificated against this Module. However, the following wording must be used on all promotional documentation and contracts associated with feed ingredients certificated against this Module and marketed within or to the EU:

'Certified under the FEMAS Programme as NOT requiring a GMO declaration under Regulation (EC) No. 1830/2003'

Any reference to FEMAS certificated feed ingredients without further clarification, as detailed above, shall be deemed **NOT** to include any assurance as to the GM status of the feed ingredients.

1.4 Updates To This Document

As an aid to users, each revision of this document will be published with the areas of significant change highlighted in *blue italics*.

1.10 Definitions

Adventitious Contamination: The accidental or unavoidable presence of GM material in a non-GM source. In the context of FEMAS all reasonable precautions must be taken to avoid the deliberate or accidental introduction of GM DNA into supply lines handling feed ingredients certified against this Module.

Commercial Scale: The production of GM on a scale that is commercially viable, whether or not legally approved, and from which products may enter the commercial trade. Trial or experimental production of GM under strict government control will not usually fall into this category, as long as the products derived from such work are destroyed or otherwise segregated from the commercial supply chain.

Genetically Modified Organism (GMO), 'GM': An organism in which the genetic material has been altered in a way that does not occur naturally by mating and / or natural recombination. (Directive 2001/18/EC adapted)

GM Product: A product that consists of, contains, or is derived from Genetically Modified Organisms. (Regulation (EC) No 1829/2003 adapted)

Non-GM Feed Ingredient: A feed ingredient in which all reasonable precautions have been taken to ensure that it does not consist of, contain, nor is derived from Genetically Modified Organisms, nor is a product of Genetically Modified Micro-Organisms. This term has no legal basis, but is used as an abbreviated means of identifying feed ingredients approved under this Module.

SECTION 2 QUALITY MANAGEMENT SYSTEM

2.5 Record Keeping

Records relating to the traceability and testing of Non-GM feed ingredients must be kept for 5 years.

2.6 Management of Information Relating To Safety

The participant must ensure that any technical literature supplied to purchasers is accurate and current with regard to the status of any Non-GM feed ingredients supplied.

The participant must keep up-to-date with any changes in the GM status of sources of raw materials and legal obligations with regard to GM and Non-GM feed ingredients. In the event of any changes control measures must be adjusted accordingly.

SECTION 3 RESOURCES AND GOOD HYGIENIC PRACTICES

3.2 Personnel

Participants must ensure that personnel training specifically addresses GM issues and relevant personnel are kept up-to-date with any developments in this area.

3.4 Storage Facilities

All storage facilities must be operated in a manner that maintains the segregation of both Non-GM raw materials and Non-GM feed ingredients from GM products or those of unknown status.

Where either Non-GM raw materials or Non-GM feed ingredients necessarily utilise the same facilities as GM products or those of unknown status, formal procedures and flushing must be underpinned by testing to demonstrate the maintenance of effective segregation.

3.8 Cross-Contamination

Participants must ensure that control systems at all levels of the supply chain prevent accidental cross-contamination between either Non-GM Raw Materials or Non-GM feed ingredients and GM products or products of unknown status.

GM and Non-GM varieties of the same species must be treated as different products and considered as such in any assessment of cross-contamination.

Participants must carry out verification trials and testing to confirm that the segregation processes throughout the supply chain are capable of maintaining the Non-GM status of any feed ingredients supplied.

3.11 Cleaning

Participants must ensure that cleaning practices prevent accidental cross-contamination between either Non-GM Raw Materials or Non-GM feed ingredients and GM products or products of unknown status.

3.17 Sieves, Screens, Filters & Separators, Magnets & Metal Detectors

3.17.4 The GM status of any screenings returning to the process must be known and appropriate measures taken to avoid any risk of cross-contamination to Non-GM feed ingredients.

Where feed ingredients are the co-products or by-products of grain, oilseed or pulse processing, risk assessments must give consideration to potential contamination of feed ingredients by admixtures removed during cleaning and screening processes and added into feed ingredients. In particular consideration must be given to the concentration in feed ingredients of GM seeds included in admixture removed during cleaning processes.

SECTION 4 TRANSPORT REQUIREMENTS

4.1. General Requirements

All transport used to carry Non-GM raw materials and Non-GM feed ingredients must be controlled to avoid contamination with GM products or products of unknown status.

SECTION 5 PRODUCT MANAGEMENT

5.1 Risk Assessment

A documented risk assessment must form the basis for procedures and controls implemented by the participant in order to retain the Non-GM status of feed ingredients and the raw materials utilised to produce Non-GM feed ingredients.

The validity of documented risk assessments will be tested as part of the FEMAS assessment process.

5.1.3 Feed Ingredient Specifications

Within the EU and for feed ingredients sold to EU countries, specifications associated with feed ingredients supplied in compliance with this Module, must state: **'Certified under the FEMAS Programme as NOT requiring a GMO declaration under Regulation (EC) No. 1830/2003 '.**

The use of this wording on specifications is only authorised in cases where the specific feed ingredients referred to are confirmed as complying with all requirements of both the FEMAS Core Standard or FEMAS Standard for Intermediate Suppliers (or another recognised feed or food safety programme[2]) **and** this Module.

The Term 'FEMAS' on a specification does not in itself offer any specific assurance with regard to the GM status of a feed ingredient.

5.1.5 Hazard Analysis / Identification (CODEX Principle 1)

The participant must identify contamination of feed ingredients with GM products as a hazard and produce a documented risk assessment detailing the controls in place to prevent GM products entering the Non-GM raw material and Non-GM feed ingredient supply chains.

Documented risk assessments must consider the risk of GM presence from the origin of the raw materials, through any transport, storage, handling and processing to the point at which responsibility for the Non-GM feed ingredients transfers to the purchaser.

5.1.6 Determination of Control Measures

Controls must avoid contamination by any product of GM origin and not be restricted solely to the avoidance of GM varieties of the product being supplied as Non-GM.

[2] Confirmation of recognised Feed Safety Programmes is available from the authorised Certification Body.

5.1.11 HACCP System Reviews (CODEX Principle 6)

Documented Risk Assessments must be reviewed as circumstances change. With regard to the Non-GM status of crops, this will require documented reviews to be undertaken each crop year.

5.2 Raw Materials

To ensure that any trace of GM DNA in raw materials is adventitious, participants must comply with the following requirements:

i) Participants must have control over the procurement and supply of raw materials such that all reasonable measures are taken to exclude GM products from the supply chain.

And / or

ii) Where raw materials are purchased via a third party, the participant must require verification of the Non-GM status of any raw materials so supplied, by a recognised and independent verifier acceptable to FEMAS.

Participants' controls over raw materials will be assessed as part of the FEMAS certification process.

5.3 Buying-in and Trading of Feed Ingredients

Where participants buy-in or trade Non-GM feed ingredients to meet commercial contracts, such materials must either be:

i) Supplied from a company holding a current FEMAS Non-GM certificate (or other feed safety **AND** Non-GM certificates acceptable to FEMAS[3]) issued with a scope equivalent to that of the participant;

Or

ii) Clearly identified on all associated labels and documentation as: '**Not FEMAS Non-GM Assured**'.

[3] Confirmation of acceptable feed safety and non-GM Standards is available from the authorised Certification Body.

5.4.1 Raw Materials Suppliers

Participants must require that the adventitious presence of GM DNA in any raw materials supplied to them, and from which Non-GM feed ingredients will be derived, is at a level low enough to ensure the FEMAS requirement for Non-GM feed ingredients are met. These are set as follows:

i) <0.9% (or lower levels if specified by Buyers) adventitious presence of GM DNA for traits approved by the Regulatory Authorities in the receiving country;

ii) For EU countries only, there is no acceptable level for GM DNA that is not authorised in the receiving country.

5.5 Sales Contracts

Within the EU and for feed ingredients sold to EU countries, contracts associated with feed ingredients supplied in compliance with this Module, must state: **'Certified under the FEMAS Programme as NOT requiring a GMO declaration under Regulation (EC) No. 1830/2003 '**

The Term 'FEMAS' on a contract does not in itself offer any specific assurance with regard to the GM status of a feed ingredient.

5.10 Feed Ingredient Delivery Documents & Labels

Participants may if they wish append the term 'FEMAS Non-GM' to the feed ingredient name on delivery documents and labels associated with feed ingredients supplied in compliance with *this Module* (except in the Republic of Ireland[4]). The use of this term on delivery documents and labels is only authorised in cases where the specific batch of feed ingredients so identified is confirmed as complying with all requirements of both the FEMAS Core Standard (or another recognised feed safety programme[5]) **and** this Module.

[4] The Irish Department of Agriculture and Food has ruled that the term 'Non-GM' should not be used on labels and delivery notes.

[5] Confirmation of recognised Feed Safety Programmes is available from the authorised Certification Body.

5.13.3 Personnel Taking Samples & Undertaking Tests

Only personnel with adequate training may undertake 'quick tests' using semi-quantitative strip tests, or similar equipment, to determine the presence of GM DNA. Such training must be demonstrable and recorded.

5.13.4 Analysis

Participants must conduct semi-quantitative tests to validate the GM status of both raw materials and feed ingredients, established through traceability.

The frequency and location of sampling and semi-quantitative testing of both raw materials and feed ingredients must be set at the level identified as necessary to establish their Non-GM status, following formal risk assessment of the GM presence at the source of the raw materials and potential cross-contamination during subsequent handling, transport, storage and processing. Both PCR and validated 'quick tests' may be considered as means of providing data on the GM status of raw materials and feed ingredients along the supply chain.

For ships (including barges and coasters), one composite PCR test per hold is set as a minimum requirement for confirming Non-GM status, whether they are carrying Non-GM raw materials or Non-GM feed ingredients.

Raw Materials and Feed Ingredients Where DNA Is Not Detectable

For raw materials or feed ingredients where DNA tests will not be effective, either because DNA is absent (e.g. fats and oils, some products of GM technology) or where the DNA is so disrupted as to be undetectable, participants must demonstrate that the raw materials or feed ingredients have been derived from products or processes of Non-GM status.

Participants must demonstrate segregation back to the point where DNA testing can be considered valid (e.g. for fats and oils, the whole oilseed; for some products where GM technology may be utilised, the production process) and provide test evidence of the non-GM status at this point (e.g. for fats and oils, the non-GM status of the oilseed; for some products where GM technology may be utilised, the non-GM nature of the production process).

5.13.7 Testing Laboratories

Participants must be able to demonstrate that any laboratory conducting semi-quantitative tests for the presence of GM DNA on their behalf is competent to do so. Laboratories undertaking PCR tests must be accredited for PCR testing by a recognised Accreditation Body.

5.14.1 Traceability of Raw Materials

Testing below the adventitious threshold of GM DNA is, in isolation, insufficient to validate the Non-GM status of raw materials. Participants must either hold or have access to traceability records that offer confirmation of the *Non-GM* status of each parcel of raw materials purchased.

Raw Materials From Sources Where GM Technology Is NOT Used On A Commercial Scale

Where raw materials intended for the production of Non-GM feed ingredients are procured from sources where GM technology is not used on a commercial scale for the production of the raw materials concerned (e.g. Maize from sources where no GM Maize is grown on a commercial scale), documentary evidence must be available to demonstrate that raw materials have been sourced from the stated origin and that their Non-GM status has been maintained during transit, storage and handling.

Reliance upon the absence of GM technology at the source of the raw materials must be supported by documentary evidence that factors precluding the presence of GM technology at the source (whether regulatory, technical, economic, geographic, climatic or some other) are effective in precluding the presence of GM technology in the raw materials concerned.

FEMAS assessments will include 'desk top audits' of such supplies. Among the evidence required for such assessments, participants must provide the following:

i) Evidence confirming the country(ies) and region(s) producing the Non-GM raw materials concerned;
ii) An inclusive list of all stores and ports utilised for the storage and handling of Non-GM raw materials and Non-GM feed ingredients and documentary evidence that no products of GM origin will be stored or handled in these facilities;
iii) Evidence that systems and procedures are in place to confirm cleanliness prior to loading of all means of transport utilised to carry Non-GM raw materials and Non-GM feed ingredients;
iv) Where GM trials are being undertaken, evidence must be produced to confirm that the products of such trials cannot enter the commercial supply chain.

Where the above evidence cannot be provided, audits of the facilities concerned will form part of the FEMAS assessment of the participant.

Raw Materials From Sources Where GM Technology IS Used On A Commercial Scale

Where raw materials intended for the production of Non-GM feed ingredients are procured from sources where GM technology is used on a commercial scale for the production of the raw materials concerned (whether officially authorised or not), it will be necessary to include assessment and validation of the supply chain by a FEMAS Assessor back to the source of the raw materials, unless the entire supply chain is already certificated to this Module or an alternative Non-GM Standard acceptable to FEMAS[6]

5.14.2 Traceability of Feed Ingredients

Participants must be able to demonstrate the Non-GM status of all feed ingredients supplied. This will include the ability to identify the parcels of Non-GM raw materials used to produce any Non-GM feed ingredients, along with validation of the Non-GM status of any raw materials used. Although the participant need not hold all relevant records, they must be capable of accessing such records if required to do so.

5.15 Non Conforming Products

The GM status of feed ingredients must be taken into account when considering the management of non-conforming products.

Wherever semi-quantitative testing is undertaken, a maximum threshold of 0.9% adventitious GM DNA presence must apply within the established sample. Raw materials or feed ingredients exceeding this level must be deemed non-conforming and considered unacceptable as Non-GM products.

[6] Confirmation of acceptable Non-GM Standards is available from the authorised Certification Body.