Australian Organic

AUSTRALIAN CERTIFIED

NON-GMO STANDARD

Version 1.0, 2016, Australian Organic Limited

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1. INTRODUCTION

There is increasing awareness and interest in the community as to the importance of GM (Genetic Modification) technology, as it relates to health and environmental issues. While GM technology is often promoted as a solution to some of the major health and environmental challenges facing our society, and we are assured by the proponents and regulators of its safety, there is a growing demand from consumers around the world for labeling of produce as containing GMOs, or derivatives of GM technology.

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Regulation of GMOs in Australia is handled by the Office of the Gene Technology Regulator (OGTR), and Food Standards Australia New Zealand (FSANZ).

OGTR licence users of GM technology, and provide lists of approved GM crops and a map of their production locations in Australia.

FSANZ has in place a mandatory labelling code that requires all GM food sold in Australia to be labelled as such if novel DNA or protein is present in the final product. While this provides some information for consumers, given that some food products and many food ingredients do not contain DNA (eg. highly processed ingredients), such foods, or foods containing such ingredients, do not require labelling, even if they are derived from GMO technology. Furthermore, this regulation allows adventitious GMO contamination to a level of 1% by mass, per ingredient.

As the range and quantity of GM varieties of crops and livestock, as well as food ingredients and additives grows, the regulation and verification of non-GMO claims will need to increase in transparency and sophistication.

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2. PURPOSE

The purpose of this Standard and Certification Program is to provide companies with an independent certification service, which verifies that their procedures and products exclude GMOs and derivatives of GMOs, as far as is reasonably possible.

3. METHODOLOGY

The Methodology used to deliver assurance to consumers of Non-GMO status is to provide truly independent (third party) certification through a combination of quality assurance systems; risk assessment; identity preservation; tracing and segregation; laboratory testing; and third party auditing.

4. SCOPE

The Scope of this standard includes all aspects of the food supply chain, including agricultural production, procurement of inputs, processing, handling, storage, and labelling of food products.

5. QUALITY MANAGEMENT SYSTEM

5.1. A Quality Manual or equivalent must be documented for all certified operations, including farms and handling facilities. The manual must be a controlled document. The Quality Manual may be incorporated into existing manuals held by the certified operator. The Quality Manual must include at a minimum, the following.

5.1.1. Standard Operating Procedures (SOPs) or equivalents must be documented, outlining all activities conducted at the facility that are conducted for the purpose of managing risk of GMO presence or contamination.

5.1.2. Training plans and materials must be documented to allow provision of consistent training to relevant staff in the above procedures. Training must be conducted initially, prior to work in a given role; and where updates or changes have been made to processes; and where staff activities have been found to not fully comply with documented procedures, by any party. Records of such training are to be kept.

5.1.3. Roles and responsibilities for staff members.

5.2. Records of production and processing activities must enable the tracing of all products arriving on, stored at, leaving the facility, and all modifications of such products, and should be kept in a manner that allows a reconciliation of output of Non-GMO products against inputs or ingredients used.

5.3. Records must be kept for all monitoring, analyses, calculations and control measures relevant to verification of compliance with this Standard.

For more detailed information on the requirement for records relevant to your operation, refer to the Primary Production or Processing and Handling sections of this Standard.

5.4. An Internal Control System (ICS) must be in place which allows management to check and review all processes as documented in the Quality Manual, against what is occurring in the facility or on farm. The ICS at a minimum must include: Internal auditing; non compliance follow up; management review meeting; continuous improvement.

5.5. A customer complaints record must be kept, and where any such complaint relates to an Australian Certified Non-GMO product, and its compliance with this Standard, the certification office must be advised of the complaint and its investigation and outcome.

5.6. A product recall procedure must be documented and in place. This procedure must allow effective recalls or market withdrawals to be undertaken if required. In the event of a product recall or market withdrawal for an Australian Certified Non-GMO product due to a compliance issue, the certification office must be advised of the action and the circumstances surrounding the action.

5.7. The effectiveness of the above recall procedure must be tested annually, in the form of a mock recall. Records of the mock recall must be kept for verification purposes.

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6. RISK ASSESSMENT

6.1. All certified operations are required to conduct a thorough risk assessment, prior to being granted certification.

6.2. The risk assessment must address and discuss all relevant potential risks at the facility or farm, including external risks which may impact on the Non-GMO status of the product, or compliance with this Standard.

6.3. The risk assessment must include identification of Critical Points (CP) in the production or processing flow, where risks exist, and control measures must be documented and implemented for each CP.

6.4. The risk assessment will include classification of ingredients or products according to section 8.2 of this Standard.

7. PRIMARY PRODUCTION

7.1. Land being used for production of crops or pastures certified to this Standard must be verified to have not been used for production of GM variety crops for a period of not less than 3 years.

7.2. Procedures must be in place to minimise the risk of wild or volunteer plants on farm which may cross pollinate with GMO crops in the region, and in turn cross pollinate with Non-GMO crops on farm.

7.3. Neighbouring and regional land use shall be assessed for risks, as part of the risk assessment as required by section 6. This risk assessment must include the production and annual updating of aerial photography of the region within a 5 km distance from the boundaries of the farm. Maps must clearly show a scale, and be of sufficient quality to allow identification of cropping areas.

7.4. Records of production must be maintained which detail the use of all inputs, including lot numbers of the inputs, date and field of application, all significant ground works, and harvest.

7.5. Seed and propagation materials used for Non–GMO production must not be genetically modified, nor contain GMO material above the threshold. Where seed or propagation material could be considered "medium-risk" or "high-risk" under section 8.2 of this Standard, verification of GMO levels below the threshold by laboratory testing, will be required.

7.6. Plant material inputs, such as mulches or compost, must not consist of, or contain materials from crops which could be considered "medium-risk" or "high-risk" under section 8.2 of this Standard, unless such material is compliant with this Standard.

7.7. Animal manure inputs must not be sourced from GMO livestock, or cloned animals.

7.8. Animal origin inputs other than manures (eg. blood or bone meal) must be sourced from livestock produced in compliance with this Standard.

7.9. Other inputs including fertilisers, soil conditioners, pesticides etc must not be derived from GM technology, and this must be confirmed by obtaining declarations from suppliers of such inputs.

7.10. The production of GMO livestock varieties, cloned animals, and the use of GM or cloned breeding males is prohibited under this Standard.

7.11. For livestock or livestock products to be certified under this Standard, the relevant livestock must not have consumed feed containing GMO materials above the threshold.

7.12. For livestock or livestock products to be certified under this Standard, the relevant livestock must not have consumed feed from pastures grown from seed containing GMO content above the threshold.

7.13. Where feed is brought in for feeding to certified livestock, such feed must be certified according to this Standard.

7.14. Where feed supplements are brought in for feeding to certified livestock, such feed supplements must consist only of ingredients which could be classified as "no-risk" or "low-risk" under section 8.2 of this Standard.

7.15. For all livestock products, the animal must be managed in compliance with this Standard from the point of conception for mammals, or the day of hatching for birds.

7.16. Livestock treatments derived from GMO technology (such as vaccines or hormone treatments) are prohibited, unless where mandated by state or federal regulations.

7.17. Livestock identification and systems must be in place to allow identification of stock produced in accordance with this Standard, against those which are not.

7.18. Livestock produced in compliance with this Standard may not mingle with those which are not.

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8. PROCESSING & HANDLING

8.1. A Procurement Program, or Approved Supplier Program must be prepared and implemented which assures the sources of ingredients are assessed for risk to the Non-GMO status of the finished product.

8.2. For the purposes of this certification program, ingredients to be used in certified Non-GMO products must be classified into the following categories:

8.2.1. Ingredients which are produced from non biological sources (such as minerals), are exempt from assessment and can be used without limitation, provided sufficient documentation is available to confirm no biological content. Ingredients such as these may be referred to as "no-risk ingredients". These ingredients must be verified to not contain any biological material by means of assessment of detailed specification sheets, which must include a full ingredients list, and statement as to the method of manufacture.

8.2.2. Ingredients derived from plants for which there are no GMO varieties approved in the country of production, and are known to be unlikely to cross pollinate with species for which there are GMO varieties may be referred to as "low-risk ingredients". Such ingredients must be sourced from suppliers which have been assessed under the operator's Approved Supplier Program, and found to have sufficient segregation and tracing procedures in place to ensure no contamination with GMO material from other species. (eg. wheat from a facility which also handles GMO soy must have procedures in place to ensure no residues of soy are present in the wheat).

8.2.3. Ingredients derived from plants for which there are no GMO varieties approved in the country of production, and are known to potentially cross pollinate with species for which there are GMO varieties approved in the country of production, must be accompanied by laboratory certificates of analysis demonstrating GMO content below the threshold. The laboratory test must include all varieties which have potential to cross pollinate. Ingredients such as these may be referred to as "medium-risk ingredients".

8.2.4. Ingredients derived from species of plants for which there are GMO varieties approved in the country of production, must be certified Non-GMO under an approved certification program, and accompanied by laboratory certificates of analysis demonstrating GMO content below the threshold. The laboratory test must include all commercial varieties approved or known to be produced in the country of production. Ingredients such as these may be referred to as "high-risk ingredients".

8.2.5. Ingredients derived from animals are always classified as "high-risk", and as such are required to be certified Non-GMO under an approved certification program.

8.3. Traceability of all raw materials, in process materials, and finished products must be maintained and verifiable through records.

8.4. Reconciliation of incoming and outgoing product must be possible, and checked regularly by the operator. This may be achieved by means of a documented stock inventory, which is kept current at all times. Losses due to shrinkage, spoilage etc must be accounted for and explained. If output of Non-GMO product is at any time found to exceed input, an investigation must be conducted and if there is a risk to Non-GMO status of certified product, relevant batches of product will be decertified and/or recalled.

8.5. Segregation of Non-GMO raw materials, in process materials, and finished products, from products which are not compliant with this Standard, must be maintained throughout the entire supply chain, and verifiable through records.

8.6. Identification and labelling of ingredients, in process materials, and finished products must be in place at all times within a certified production facility.

8.7. Processing and handling of Non-GMO products must be isolated in space or time, from products not compliant with this Standard. This may be achieved by the use of dedicated facilities; dedicated equipment within facilities; or scheduling of Non-GMO handling.

8.8. Cleaning of processing and handling equipment must be sufficient to minimise potential co-mingling or contamination of Non-GMO material with material not

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compliant with this Standard. Prior to commencing Non-GMO handling, adequate cleaning; flushing; or purging procedures must be followed, and recorded. Flushing or purge material must be downgraded, and records of where the flush or purge material ends up must be kept. If flushing or purging is used, the quantity of material required to adequately clean the relevant equipment must be set, and verified to be sufficient to achieve the equivalent of a full manual clean down.

8.9. Transport activities must not put at risk the Non-GMO status of the product in transit. Cleaning procedures must be in place for bulk transport units, and cleaning records kept.

8.10. Record keeping at certified facilities must be such to allow easy verification of activities such as ordering, receiving, storing, processing, blending of all Non-GMO products, as well as other products which are not compliant to this standard which are also handled at the facility.

9. SAMPLING AND TESTING

9.1. The threshold for presence of GMO contamination is 0.1%, only where this contamination has been inadvertent, and through no identified systemic failure of the operator's risk assessment and management procedures.

9.2. For blended products, the threshold is relevant for each ingredient. Where an ingredient is found to exceed the 0.1% threshold, it may not be used in any certified Non-GMO product in any way, this includes "diluting" the contamination by blending with batches of ingredient which does not exceed the threshold.

9.3. Appropriate sampling and testing must be used as a tool for verifying the Non-GMO status of certified crops or products.

9.4. The frequency of testing must be determined based on the risk assessment conducted as per Chapter 6 of this Standard, and include consideration of the ingredient risk classification as per section 8.2.

9.5. A sampling plan must be prepared and documented, for each crop or product type. The plan must be designed in a manner that ensures a statistically valid result. This will include consideration of homogeneity of the sample, sample size, and distribution.

9.6. If samples are mixed and tested together as a composite sample, for the purpose of reducing the expense of the testing regime, this must be conducted using statistical methods to ensure that any single sample contained within the composite sample with levels of GMO above the threshold will return a positive result for the composite sample, with the laboratory analysis used. This may require specifying a lower limit of reporting with the laboratory. Where a result exceeding the threshold is returned for a composite sample, all constituent samples will require re-testing to ascertain the source of the exceedance.

9.7. Rapid qualitative (test strips), and quantitative (laboratory based Polymerase Chain Reaction) testing methods may be used in a manner fit for purpose. For example, as a screening method where laboratory testing is not practical or timely (eg. receipt of truck loads of soy beans into a cleaning facility). Where this is used, the procedure must be documented, and personnel must be appropriately trained to follow the testing procedure.

9.8. Where rapid qualitative testing is used, further follow up testing using quantitative PCR testing will also be required prior to dispatch of the product, for all ingredients or products which have been classified as "medium-risk" or "high-risk".

9.9. Laboratories used for testing must be ISO17025 accredited, and limits of reporting must be sufficiently low as to allow confirmation of GMO levels below the threshold.

9.10. Chain of Custody (COC) procedures must be in place, and followed for all laboratory testing. This will include a clear record of where, when, and by whom the sample was taken, and a record of persons with custody of the samples to the point of receipt at the laboratory.

9.11. Samples shall be retained for all lots or batches of raw materials and finished products for a period of 12 months, or the shelf life of the product, whichever is longer.

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10. MARKETING & LABELLING

10.1. Marketing and labelling claims must be accurate, and must not mislead customers or potential customers.

10.2. Retail labels for certified products must be submitted to the certification body for approval, and be approved, prior to market release.

10.3. Retail labels must display the statement, "Certified to the Australian Non-GMO Standard", as well as the certification body website address.

10.4. Non-retail labels may be submitted to the certification body for approval, and must include clear and unambiguous statement of certification status and body.

10.5. Labelling claims such as "GE-free" or "contains nil GMOs" are not permitted.

10.6. The display of the Australian Certified Non-GMO logo on marketing material such as websites or promotional material must not be misleading in any way (eg. where only some products in a product range are certified Non-GMO, the logo may only be displayed in clear association with the certified products).

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APPENDICES

Appendix A – Certification Process and Administration

I. Internal Check

The first step in the process of obtaining Australian Certified Non-GMO certification for a facility and product range is to conduct a self assessment, or "gap audit" to ascertain the level of compliance with this Standard.

It is a requirement for certification that operators understand the requirements, and have the resources available to allow compliance with all relevant requirements, and these issues are best addressed prior to applying for certification.

II. Application

Once an internal check has been conducted, and the operator is confident that compliance will be achievable, an application for certification can be prepared and submitted, along with payment of the application fee. Application forms can be obtained from the certification office. When completed, these forms must include company details, the address of the farm or handling facility or facilities to be included in the scope of the certification, as well as the list of products to be certified.

Along with the application form and payment, the documented procedures that have been prepared to allow compliance with this Standard must also be submitted for review. This will include the Quality Manual and/or Standard Operating Procedures, Risk Assessment, Ingredient Risk Classification, Sampling and Testing Plan and any other relevant documents that are to be used to demonstrate compliance.

III. Review of Application

Upon receipt of a complete application, the certification office will conduct a review of the application to assess the level of compliance with this Standard that the applicant is likely to achieve. Applicants may be asked to provide further information or documentation if it cannot be confirmed that compliance, and indeed certification is likely to be achievable for the applicant.

IV. Audit

Following successful review of the application for certification, along with the closing out of any issues arising from the review, and on site audit will be allocated. The operator will be informed of the allocation of the audit, and an auditor will contact the operator within a reasonable timeframe to arrange a mutually suitable time to conduct the on site audit.

The on site audit will include at a minimum the following:

- Opening meeting – to confirm intended certification scope, company and facility details etc.
- Systems and documentation inspection – assessment of documented quality system, record keeping system etc.
- Farm or facility tour to assess implementation of planned management practices. This may include interview of various staff charged with responsibilities relevant to compliance with this Standard.
- Closing meeting to discuss the findings of the audit, including areas of non compliance which will need to be addressed to allow granting of certification.

V. Audit Report and Review

The auditor will complete and submit a written report to the certification office within a reasonable timeframe, detailing all relevant observations made during the audit, as well as any identified non compliances which will need to be addressed by the applicant.

The audit report will be reviewed by the certification office, and if necessary, Corrective Action Requests (CARs) issued based on any non compliances identified during the audit. Depending on the severity of the CARs, some may be required to be addressed prior to certification being granted, others may be addressed prior to the next annual surveillance inspection.

VI. Granting Certification

Where a high level of compliance has been reported by the auditor, and confirmed by the certification office during review, and any major CARs have been addressed, certification may be granted. A certificate will be provided to the applicant listing the scope of the certification (facilities and products), the issue date, and the renewal or expiry date.

VII. Denial of Certification

Where an insufficient level of compliance was identified during the on site audit, and if CARs have not been addressed within the given timeframes, or to a level deemed satisfactory to the certification office, the operator will be provided with a letter of denial of certification. If the operator wishes to pursue certification, an entirely new application will be required in this instance.

VIII. Surveillance

Australian Certified Non-GMO certification is based on an annual audit surveillance schedule. The certification office will contact the operator prior to the renewal / expiry date, to advise of audit allocation, and request submission of an annual report, if necessary.

IX. Suspension and Decertification

If the certified operator is found to be non compliant to this Standard, and are not able to sufficiently address issued CARs within the specified timeframe, suspension of the certification may occur. Where certification is suspended, the operator will be informed in writing, and all relevant references to Australian Certified Non-GMO certification must be removed from sales and marketing material.

If the operator sufficiently addresses the compliance issues which led to the suspension, and this can be demonstrated to the certification office (which may require additional auditing, at the operator's expense) the suspension may be lifted.

If the operator does not sufficiently address the compliance issue(s) which led to the suspension of certification within a reasonable timeframe, decertification may follow.

X. Appeals

Should a certified operator, or applicant for certification disagree with the decision on certification, the operator has the right to appeal the decision by the certification body. Appeals must be made in writing, and clearly reference the relevant certification body decision or decisions in question. The appeal must also reference the relevant clause or clauses of this Standard, where appropriate. In the event of an appeal, the certification body will, within a reasonable timeframe, establish a committee consisting of staff or consultants who were not involved in the decision or decisions that are being appealed, to adjudicate on the matter. The decision by the committee will be final, and the detail of the decision will be provided by the certification body, to the certified operator or applicant, in writing.

Appendix B – Definitions

Adventitious – Unintentional, accidental, or unavoidable.

Compost – Plant or animal material which has gone through a biological decomposition process in compliance with, or achieving the same outcomes as AS4454.

Controlled document – Document for which a register of changes is kept.

GM – Genetic Modification, gene splicing, modification, recombinant DNA and transgenic technologies.

GMO – Genetically Modified Organism, an organism derived from the above GM technologies.

May – Non mandatory recommendation.

Must – Mandatory requirement.

Standard – where used in this document, this refers to this

Standard – the Australian Certified Non-GMO standard.

References

Australia New Zealand Food Standards Code - Standard 1.5.2 - Food Produced Using Gene Technology

ISO/IEC 17025:2005 General requirements for the competence of testing and calibration laboratories

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