

**MAF BIOSECURITY AUTHORITY
(PLANTS)**

OPERATIONAL STANDARD

PIT-GFP-ISR

**GRAIN FOR PROCESSING
IMPORT SYSTEM REQUIREMENTS**

Copy No. _____

Issued To: _____

MAF Biosecurity Authority Plants Biosecurity
PO Box 2526
Wellington
New Zealand

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REVIEW

This MAF Plants Biosecurity Standard is subject to periodic review. The next review date will be determined in consultation with operational standard stakeholder working group representatives. Amendments will be issued to ensure the standard continues to meet current needs.

ENDORSEMENT

This MAF Plants Biosecurity Authority Standard is hereby endorsed

Dr. Veronica Herrera

Acting Chief Technical Officer, Plants Biosecurity

Date: 25 August 2003

AMENDMENT RECORD & IMPLEMENTATION SCHEDULE

Amendments to this standard will be given a consecutive number and will be dated.

Please ensure that all amendments are inserted, obsolete pages removed, and the record below is completed.

Amendment No:	Date:	Specification:	Implementation Date:
1	24/11/03	Minor changes to:- Transportation of containerised grain, 1. Page 34, and Process Step 7. Section 2, 2 nd paragraph. Page 38	24/11/03
2			
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DISTRIBUTION LIST

Name	Position	Copy No.
File	PIT-GFP-ISR	0
Website	http://www.maf.govt.nz/biosecurity/imports/plants/standards/pit-gfp-isr.pdf	1

This standard will be available electronically and will not be officially held in hard copy format by MAF staff.

1. INTRODUCTION

1.1 SCOPE

This MAF Biosecurity Authority Standard outlines the requirements for the implementation of a grain import system (GIS) designed to establish biosecurity assurances and security leading to provision of biosecurity clearance for imported grain consignments.

This standard was produced by the MAF Biosecurity Authority in conjunction with stakeholder working group representatives. This standard provides guidelines for organisation representatives to produce a GIS for their own organisation and ensure that the grain imported for processing meets MAF's biosecurity requirements. Import health standard schedules detailing phytosanitary requirements for individual types of grain (e.g. barley, wheat etc) are held in the associated draft MAF Standard Grain for Processing, Plant Health Requirements (PIT-GFP-PHR). [Link]

The OR of the GIS must meet the requirements of this standard at all times.

1.2 REFERENCES

- Alinorm 95/13 Guidelines for the Application of the (Annex to Appendix iii) Hazard Analysis Critical Control Point (HACCP) System, Report of the 27th Session of Codex Committee on Food Hygiene (CCFH), October 1994.
- AS/NZS ISO/IEC 17020:1998 - General criteria for the operation of various types of bodies performing inspection.
- Biosecurity Act 1993
- Hazardous Substances and New Organisms Act 1996 (HSNO Act 1996)
- ISO 9001: 2000, Quality management systems-Requirements.
- ISO 9004: 2000, Quality management systems- Guidelines for performance improvements.
- ISO 10011-1: 1990, Guidelines for auditing quality systems - Part 1: Auditing.
- MAF Biosecurity Authority Draft Standard - PIT-GFP-PHR
Grain for Processing, Plant Health Requirements.

1.3 DEFINITIONS

For the purposes of this standard the following definitions apply:

Accreditation

A process for a supplier to become an accredited facility, operator or person.

Accredited Facility

Official recognition by a Chief Technical Officer that a facility has the capacity and resources to comply with the relevant MAF Biosecurity Authority standard.

Accredited Operator

Official recognition by a Chief Technical Officer that the operator is competent to provide a service in accordance with the relevant MAF Biosecurity Authority standard.

Accredited Person

A person that operates the processes set up by an inspector or authorised person, and is appointed as an accredited person by a Chief Technical Officer under section 103 of the New Zealand Biosecurity Act (1993). They do not have the same delegated authority as an inspector or authorised person.

AOSA

Association of Official Seed Analysts

Approved

Having received written approval from the Director - General of the MAF or delegated authority.

Association of Official Seed Analysts

The Association of Official Seed Analysts is an organization comprised of member laboratories which are staffed by certified seed analysts. Such seed testing facilities include official state, federal, and university seed laboratories across the United States of America and Canada.

Audit

An official evaluation to determine the degree of conformity with criteria prescribed in a MAF Biosecurity Authority standard.

Note: For continuation of an approved GIS audit requirements consists of an initial desktop audit, an annual system audit and two surveillance audits.

Authorised Movement (formerly Biosecurity Direction)

Authority from an inspector, given under section 25 of the Biosecurity Act, to move uncleared goods to a transitional facility, containment facility or biosecurity control area. For example, under the requirements of this standard, movement of imported grain to a transitional facility will be authorised by an inspector for mandatory post-entry storage or processing on arrival in New Zealand.

Authorised Person

A person for the time being appointed as an authorised person by a Chief Technical Officer under section 103 of the New Zealand Biosecurity Act (1993).

Note: Authorised people (officers of approved organisations) may conduct audit or other inspection functions to determine the degree of conformity with criteria prescribed in specific MAF Biosecurity Authority standards.

Biosecurity Act 1993

An Act to restate and reform the law relating to the exclusion eradication and effective management of pests and unwanted organisms.

Biosecurity Clearance

A clearance under section 26 of the New Zealand Biosecurity Act 1993 for the entry of goods into New Zealand.

Biosecurity Direction

See Authorised movement

Biosecurity Inspector

See Inspector

Bulk

Unbagged product usually carried in holds or shipping containers.

By-Product (Grain)

A secondary or incidental product of a grain manufacturing process.

CCP

Critical Control Point

Certificate

An official document which attests to the phytosanitary status of any consignment affected by phytosanitary regulations [FAO, 1990]. Refer to Appendix B for certificate requirements.

Chief Technical Officer

A person appointed by the Director General of MAF as a chief technical officer under section 101 of the Biosecurity Act 1993.

Compliance

The state of meeting specified requirements, whether in a specification, contract, regulation or standard.

Consignment

A quantity of plants, plant products and/or other articles being moved from one country to another and covered, when required, by a single phytosanitary certificate (a consignment may be composed of one or more commodities or lots). [FAO, 1990; ICPM Amendments, April 2001]

Contamination

Presence in a commodity, storage place, conveyance or container, of pests or other regulated articles, not constituting an infestation (Refer to Infestation) [CEPM, 1997; revised CEPM, 1999]. Note: For the purpose of this standard a contaminant includes material or an organism sometimes associated with the pathway, which poses a risk to human or animal or plant life or health (SPS Article 2).

Country of Origin (of a consignment of plant products)

Country where the plants from which the plant products are derived were grown [FAO, 1990; revised CEPM, 1996; CEPM, 1999].

Critical Control Point

A point, step or process (e.g. importation of grain, handling, segregation, processing, storage and transport) where control can be applied and where a hazard can be prevented, eliminated or reduced to acceptable levels.

Critical Limit

A value which separates acceptability from unacceptability.

CTO

Chief Technical Officer

Decontamination

Removal and/or sterilisation of contaminants within a secure environment.

Destroyed/Destruction

An approved method of destroying risk goods e.g. incineration, deep burial.

Eradication

Application of phytosanitary measures to eliminate a pest from an area [FAO, 1990; revised FAO, 1995; formerly Eradicate]

Fumigation

Treatment with a chemical agent that reaches the commodity wholly or primarily in a gaseous state [FAO, 1990; revised FAO, 1995].

Grain

A commodity class for seed intended for processing or consumption and not for planting.

Grain Import System (GIS)

The integrated organisational structure, responsibilities, operational procedures, processes and resources for implementing activities associated with importation of grain for processing. The GIS must provide an integrated management system of activities associated with importation of grain for processing to protect the biosecurity of New Zealand. The GIS must cover all activities associated with grain discharge at the border, authorised movement of grain by approved conveyances to approved transitional facilities, processing and other approved treatment requirements and the on-selling of grain by-products to third parties. The GIS must also cover all aspects of required certification and notifications to MAF prior to arrival of grain at the border.

HACCP

Hazard Analysis Critical Control Point

Hazard Analysis Critical Control Points

A system which identifies specific hazard(s) and preventative measures for their control.

Hazard

The potential to cause harm. Hazards can be biological, chemical or physical. For the purpose of this standard MAF's concerns relate to biological risks posed to the biosecurity of New Zealand by regulated pests or regulated contaminants.

IHS

Import Health Standard

Import Health Standard

A document issued under section 22 of the Biosecurity Act, which specifies the requirements to be met for the effective management of risks associated with importation of risk goods, before those goods may be imported, moved from a biosecurity control area or transitional facility, or given a biosecurity clearance.

Import Permit

Official document authorising importation of a commodity in accordance with specified phytosanitary requirements (FAO, 1990, revised FAO, 1995).

Infestation (of a consignment)

Presence in a commodity of a living pest of the plant or plant product concerned. Infestation includes infection [CEPM, 1997; revised CEPM 1999]. Note: For the purpose of this standard "pest" includes an organism sometimes associated with the pathway, which poses a risk to human or animal or plant life or health (SPS Article 2).

Inspection

Official visual examination of plants, plant products or other regulated articles to determine if pests are present and/or to determine compliance with phytosanitary regulations [FAO, 1990; revised FAO, 1995; formerly Inspect].

Inspector

Person authorized by a National Plant Protection Organization to discharge its functions [FAO, 1990]. In New Zealand, an inspector is a person appointed under section 103 of the New Zealand Biosecurity Act 1993 to undertake administering and enforcing the provisions of the Biosecurity Act.

International Plant Protection Convention (IPPC)

International Plant Protection Convention, as deposited with FAO in Rome in 1951 and as subsequently amended (FAP 1996).

International Standardisation Organisation (ISO)

A worldwide federation of national non-governmental standard bodies from approximately 100 member countries established to promote the development of standardisation and related activities.

International Seed Testing Association (ISTA)

The International Seed Testing Association is a worldwide, non-profit association whose primary purpose of the Association is to develop, adopt and publish standard procedures for sampling and testing seeds, and to promote uniform application of these procedures for evaluation of seeds moving in international trade.

IPPC

International Plant Protection Convention

ISTA Approved Laboratory

An ISTA member laboratory approved by ISTA according to ISTA Approval Standards and authorised to issue ISTA certificates.

ISO

International Standardisation Organisation

ISTA

International Seed Testing Association

ISTA Rules

The current rules of the International Seed Testing Association.

Line of Sacks

A series of sacks containing a single type of grain from the same source.

Lot

The number of units of a single commodity identifiable by its homogeneity of composition, origin, etc., forming part of a consignment. [FAO, 1990]

MAF Biosecurity Authority (MAF Biosecurity)

The section within MAF responsible for regulatory biosecurity functions.

Ministry of Agriculture and Forestry (MAF)

The NPPO of New Zealand.

MQS

MAF Quarantine Service

MQS Inspector

Refer to Inspector.

MAF Quarantine Service (MQS).

The section within MAF responsible for inspection and related activities at the border for commodities imported into New Zealand.

MQS Coordinator

The MQS Coordinator acts as the initial contact point for grain importing organisations to forward GIS details for approval and provides other functions. This person may be the regional MQS Group Leader responsible for grain importation and clearance or a specially designated MQS officer.

NA GP

National Adviser – Grain for Processing, MAF Biosecurity Authority. Responsible for the development and review of import health standards for the importation of grain for processing.

Non Compliance

An incident where a specific requirement or requirements of this standard are not met.

National Plant Protection Organisation (NPPO)

Official service established by the government to discharge the functions specified under the IPPC (FAO 1990). **Note: MAF is the NPPO of New Zealand.**

NPPO

National Plant Protection Organisation

Official

Established, authorized or performed by a National Plant Protection Organization [FAO, 1990]

Organisation Representative

The organisation operating the GIS must appoint an Organisation Representative. Their role is to represent the organisation on all matters relating to GIS with MAF Biosecurity, MQS or authorised people. They must be a legally identifiable person in the importing organisation responsible for the overall operation of the GIS with the ultimate responsibility for the provision of resources and compliance to MAF Biosecurity requirements.

OR

Organisation Representative

Organism

Biotic entity capable of reproduction or replication, vertebrate or invertebrate animals, plants and micro-organisms [ISPM Pub. No. 3, 1996].

Within New Zealand, an organism, defined by the New Zealand Biosecurity Act (1993) (as amended by the Biosecurity Amendment Act (1997)):

- a. Does not include a human being or a genetic structure derived from a human being;
- b. Includes a micro-organism;
- c. Subject to paragraph (a) of this definition, includes a genetic structure that is capable of replicating itself (whether that structure comprises all or only part of an entity, and whether it comprises all or only part of the total genetic structure of an entity):
- d. Includes an entity (other than a human being) declared by the Governor-General by Order in Council to be an organism for the purposes of this Act:
- e. Includes a reproductive cell or developmental stage of an organism:
- f. Includes any particle that is a prion.

Pathway

Any means that allows the entry or spread of a pest [FAO, 1990; revised FAO, 1995]

For New Zealand MAF it also means a series of activities that, when carried out according to documented procedures, form a discrete and traceable export system.

PC

Phytosanitary certificate

Pest

Any species, strain or biotype of plant, animal or pathogenic agent injurious to plants or plant products [FAO, 1990; revised FAO, 1995; IPPC, 1997].

Note: For the purpose of this standard “pest” includes an organism sometimes associated with the pathway, which poses a risk to human or animal or plant life or health (SPS Article 2).

Phytosanitary Certificate

A certificate patterned after the model certificates of the IPPC (FAO (1990)). A certificate issued by the exporting country NPPO, in accordance with the requirements of the IPPC, which verifies that the requirements of the relevant import health standard have been met.

Phytosanitary Certification

Use of phytosanitary procedures leading to the issue of a phytosanitary certificate [FAO, 1990]

Phytosanitary Regulation

Official rule to prevent the introduction and/or spread of quarantine pests, or to limit the economic impact of regulated non-quarantine pests, including establishment of procedures for phytosanitary certification. [FAO, 1990; revised FAO, 1995; CEPM, 1999; ICPM Amendments, April 2001].

Plant Pest

Any species, strain or biotype of plant, animal or pathogenic agent injurious to plants or plant products. Note: For the purpose of this standard "pest" includes an organism sometimes associated with the pathway, which poses a risk to human or animal or plant life or health (SPS Article 2).

Plant Product

Unmanufactured material of plant origin (including grain) and those manufactured plant products that, by their nature or that of their processing, may create a risk for the spread of pests. (FAO, 1990; revised IPPC, 1997).

Processing

A system of treatment that destroys the viability of grain and any quarantine pests (including contaminant seeds) contained in that grain.

Procedure

A document that specifies, as applicable, the purpose and scope of an activity; what must be done and by whom; when, where, and how it must be done; what materials, equipment, and documentation must be used; and how it must be controlled.

Quarantine

Official confinement of regulated articles for observation and research or for further inspection, testing and/or treatment [FAO, 1990; revised FAO, 1995; CEPM, 1999]
Within New Zealand, quarantine, defined by the New Zealand Biosecurity Act (1993) (as amended by the Biosecurity Amendment Act (1997)), means confinement of organisms or organic material that may be harbouring pests or unwanted organisms.

Quarantine Area

An area within which a quarantine pest is present and is being officially controlled [FAO, 1990; revised FAO, 1995]. Within New Zealand a quarantine area means a place so designated under section 41 of the New Zealand Biosecurity Act (1993).

Quarantine Contaminant

A contaminant is considered a quarantine contaminant if it is any one of the following:

- a. A quarantine pest (including weed seeds);
- b. A viable seed which is a new organism or potentially a new organism (species name unknown);
- c. Material (including soil, debris) able to vector quarantine pests.

Reshipped

A direction that risk goods are returned overseas.

Regulated Pest

A pest of potential economic importance to New Zealand and not yet present there, or present but either not widely distributed and being officially controlled, or a regulated non-quarantine pest, or having the potential to vector another regulated pest into New Zealand.

Risk Good

Any organism, organic material or other thing, or substance, that (by reason of its nature, origin, or other relevant factors) it is reasonable to suspect constitutes, harbours or contains an organism that may: cause unwanted harm to natural and physical resources or human health in New Zealand; or interfere with the diagnosis, management or treatment, in New Zealand, of pests or unwanted organisms.

Sack Certificate (SKC)

For grain in sacks, a certificate from the NPPO certifying that the sacks are new and free from soil, and regulated pests (excluding weed seeds) and any other contaminants that may harbour regulated pests.

Sample

Method of collecting a representation of a commodity based on a sampling plan in order to ascertain pest levels or for other testing (e.g. germination).

Sampling Certificate (SC)

A certificate issued by the NPPO in the country of origin which clearly identifies the consignment (eg hold number of ship, shipping container number(s) or line of sacks from which the samples were drawn. A certificate that the primary samples for each consignment were officially drawn, in accordance with a quality system approved by MAF Biosecurity or, during loading of the ship, at a rate of at least one primary sample per 100 tonnes of grain. The submitted samples were prepared and despatched in accordance with ISTA rules 2.6.6 and 2.6.7.

Seed

The structure formed in the fertilized ovule of an angiosperm, consisting of an embryo surrounded by a food store for nourishment during germination, with an outer hard seed coat, the testa.

For New Zealand MAF this includes spores but excludes vegetative propagules.

Seed Analysis Certificate (SAC)

A certificate documenting the purity and germination of a seed lot taken at a particular point in time. The purity is the percentage of actual seed of the species requested in the seed lot. It is expressed as a percent pure seed. The weeds, crops seed and inert plant material are accounted for and expressed as a per cent of the seed lot that is not pure seed. Germination refers to the percent germination of the seed. It is the number out of 100 seeds that germinate over 4 to 21 days.

Note: For the purposes of this standard, SACs must be issued by AOSA or ISTA approved seed testing laboratories (either in the country of origin or in New Zealand).

Soil

Soil is also defined as a regulated contaminant under this standard.

Specification

The document or part thereof, that prescribes the requirements with which the plant product or service has to comply.

Standard

Document established by consensus and approved by a recognized body, that provides, for common and repeated use, rules, guidelines or characteristics for activities or their results, aimed at the achievement of the optimum degree of order in a given context [FAO, 1995; ISO/IEC GUIDE 2:1991 definition]

Surveillance Audit

An audit, carried out at the site where inspection activities are undertaken, which examines the specific components of the GIS that are related to confirming that grain meets import specifications/MAF Biosecurity requirements.

The audit must include:

- confirmation that the GIS is operationally effectively;
- confirmation that biosecurity risks are managed or eliminated;

Systems Audit

An audit carried out on all of the components of the GIS that relate to its ability to meet the requirements of this MAF Biosecurity Standard.

Test(ing)

Official examination, other than visual, to determine if pests are present or to identify pests [FAO, 1990].

Transitional Facility

Any facility approved in accordance with section 39 of the New Zealand Biosecurity Act 1993 for the purpose of inspection, testing, storage, treatment, quarantine, holding or destruction of uncleared goods, which may be harbouring pests or unwanted organisms, until biosecurity clearance is approved.

Treatment

Officially authorized procedure for the killing, removal or rendering infertile of pests [FAO, 1990, revised FAO, 1995].

Verification

The confirmation by examination and provision of objective evidence that specified requirements have been fulfilled.

Vessel Certificate

For grain loose in the hold of a ship, a certificate from the NPPO in the port of place of loading stating that the holds carrying the loose grain have been inspected prior to loading and found to be free of pests and residues of previous cargo.

2. APPROVAL OPTIONS

2.1 APPROVAL OF IMPORTERS OF GRAIN FOR PROCESSING

For the importation of grain for processing into New Zealand, the following approval options are available

Option 1. The importer operates a MAF Biosecurity approved GIS where MAF Biosecurity approved inspectors, or authorised persons will check it for compliance with this standard at designated intervals.

Option 2. The importer uses the services of MAF Biosecurity approved inspectors and/or authorised persons to ensure compliance with this standard during the entire importation process.

Note: Option 2 will be available until the GIS is fully approved, and in addition, no organisation may import grain under this option on a continual basis.

3. APPROVAL PROCESS

3.1 APPROVAL OF GISs

The following applies to all Grain Import Systems (GIS). To have a GIS approved, an OR must forward to an appropriate **MQS co-ordinator**

- (1). an application and
- (2). full details of the GIS for evaluation, at least two months prior to the proposed starting date of service or operations, as per section 6 of this standard. MQS staff will be involved in the initial review of applications and MAF Biosecurity will provide final approval.

Note: Delays in approvals may result if information is submitted later than 2 months prior to the proposed starting date.

3.1.1 Assessments of GISs

The evaluation undertaken by the MQS inspector or authorised person involves a “desktop audit” of the documented GIS against this standard and where appropriate, other standard(s). Assessment include:-

- (a). an initial systems audit of the GIS and
- (b). any non compliances identified by the desktop audit being addressed immediately

3.1.2 Approval of GISs

If satisfied, the **MQS co-ordinator** will recommend the GIS for approval to the CTO. The CTO will formally offer approval by sending a signed letter of approval to the OR. Retention of approval depends on the GIS successfully meeting the requirements of the annual systems audit and twice yearly surveillance audits.

Note: During the period of time that it takes to approve a GIS (i.e. while the successful desktop and initial systems audits are being completed), MAF Biosecurity approved inspectors and/or authorised persons may be used to ensure compliance to biosecurity requirements (Refer to Section 2 - Approval Options, Option 2).

System Audits;

One system audit must be undertaken in the first year of operation. This must be conducted after 6 months of operation of the GIS, as there will be insufficient records available to conduct systems before this time. After the initial systems audit, a systems audit will be required on an annual basis.

Surveillance Audits;

In addition to the system audit (as above), surveillance audits must be conducted separately on a biannual basis.

3.2 SUSPENSION OF A GIS

3.2.1 Immediate Suspension

The approval may be suspended immediately by the CTO, in full or part, for a specified period (and may lead to termination - refer to Section 3.3), if:

- (a) a surveillance or systems audit identifies a critical non-compliance of such a nature that is a significant risk or potential risk to the biosecurity of New Zealand.
- (b) agreed corrective actions for critical or major non compliances are not implemented;
- (c) inspection or audit identifies falsification of certificates/records or any other fraudulent activities
- (d) the OR formally requests it.

3.2.2 Suspension after Recommendation by MQS inspector or Authorised Person

The CTO may suspend an approved GIS upon the recommendation of the MQS inspector or authorised person. This may occur on discovery of a non-compliance that presents a significant biosecurity risk to warrant immediate cessation of grain import activities. Suspension may be lifted once the non-compliance has been resolved and safeguards are in place to prevent reoccurrence.

Recommendations by the MQS inspector or authorised person for suspension of an approved GIS must include details of the reason for the recommendation. All recommendations for suspension will be investigated thoroughly by the MAF Biosecurity Authority, Plant Imports, National Advisor, Grain for Processing and the Plant Imports, Team Manager before it is brought to the attention of the MAF Biosecurity Authority, Director Plants Biosecurity.

Recommendations must be made by electronic mail or facsimile to the National Adviser, Grain for processing, MAF Biosecurity and the OR of the importing company in question

3.2.3 Advice from MAF Regarding Suspensions

The OR will be advised in writing by the CTO of the reasons and length of the suspension, and the conditions under which approval may be reinstated. Such advice must be sent by facsimile followed by a registered letter (or equivalent means). However, during suspension the organisation operating the GIS will not be eligible to import grain.

3.2.4 Lifting of Suspensions

Suspension will be lifted once the CTO is satisfied that the GIS is compliant with MAF Biosecurity requirements. The lifting of suspension will be communicated in writing to the OR of the GIS as appropriate.

3.3 TERMINATION OF AN APPROVED GIS

3.3.1 Reasons for termination

The GIS approval may be terminated if :-

- (a). requested by the OR.
- (b). the OR fails to meet requirements of system and/or surveillance audits
- (c). there is more than one critical non-compliance in a single audit, or there are more than two critical non compliances in any 12 month period. Under these circumstances an application to re-apply for approval will not be accepted within 6 months of the termination.
- (d). the CTO receives a recommended for termination from the MQS inspector or authorised person

Recommendations by the MQS inspector or authorised person for suspension or termination of an approved GIS must include details of the reason for the recommendation. All recommendations for termination will be investigated thoroughly by the MAF Biosecurity Authority, Plant Imports, National Advisor, Grain for Processing and the Plant Imports, Team Manager before it is brought to the attention of the MAF Biosecurity Authority, Director Plants Biosecurity.

Recommendations from the MQS inspector or authorised person must be made by electronic mail or facsimile to the National Adviser, Grain for processing, MAF Biosecurity and the OR of the importing company in question.

3.3.2 Advice from MAF Regarding Termination

The OR of the GIS will be advised in writing by the CTO of the reasons for the termination of the approval and the effective date of the termination. Such advice will be sent by facsimile followed by registered letter (or equivalent means).

Note 1: In the event of suspension or termination any grain or grain by-products that have passed through the GIS, between the last successful audit and the audit failure will be investigated. Grain or grain by-products may be retrospectively withdrawn, identified and segregated unless the OR is able to provide audit based evidence that the product met the New Zealand's biosecurity requirements or that effective measures or treatments were conducted to ensure biosecurity risks were controlled. All additional activities relating to the movement, processing on-selling etc of grain that is already imported will be on the basis of 100% supervision by a MQS inspector or authorised person.

Note 2: Where a GIS has been terminated (under agreement with MAF), an importer may import grain without an approved GIS on a temporary basis using import Option 2 (Section 2 – Approval Options). Importers must use the services of MAF Biosecurity approved inspectors to ensure compliance with this standard during the entire importation process.

3.4 GIS MODIFICATIONS INITIATED BY THE CTO

3.4.1 Major Modifications

Where it is determined that a major specification modification is required in the GIS, the MQS inspector or authorised person will evaluate those components of the importing organisation's GIS that require attention or modification. Modifications will be formally approved by the CTO after recommendations by the MQS inspector or authorised person.

3.4.2 Minor Modifications

Where a specification modification does not increase risk to biosecurity the OR of the approved GIS will be required to implement system modifications prior to the anniversary date of their approval.

3.5 GIS MODIFICATIONS INITIATED BY THE OR

3.5.1 Modifications That May Increase Biosecurity Risk

The OR must inform the MQS inspector or authorised person, of any intended modification(s) to their approved GIS. The MQS inspector or authorised person will evaluate those components of the importing organisation's GIS that require attention or modification. Where system modification are evaluated as a potential increased risk to New Zealand's biosecurity, the OR may not implement modifications until a full system evaluation has been completed by the MQS inspector or authorised person. Modifications will be formally approved by the CTO as being able to proceed after recommendations are received from the MQS inspector or authorised person.

3.5.2 Modifications That Do Not Increase Biosecurity Risk

Where evaluation of system modifications by the MQS inspector or authorised person determines that there are no potential increases in biosecurity risk, the OR of the approved GIS may implement system modification prior to the annual anniversary date of approval.

3.6 CLASSIFICATION OF NON COMPLIANCES

Imported grain consignments are risk goods (refer to Section 1.3) that may contain regulated pests. To stop introduction of regulated pests and prevent an increase in risks to the biosecurity of New Zealand, import specifications must be adhered to closely. Any deviations from the specifications listed in this standard or processes agreed to in approved GISs are regarded as non compliances.

Non compliance are classified as critical, major, or minor depending on how they affect the GIS's ability to provide confidence that the grains imported for processing meets MAF Biosecurity requirements.

3.6.1 Critical Non Compliances

A critical non compliance is defined as an incident that may or will cause a **SIGNIFICANT BIOSECURITY RISK** or result in a decrease in confidence to prevent the occurrence of a **SIGNIFICANT BIOSECURITY RISK**.

This will result in the immediate suspension of discharge or handling of such products. For example, the suspension of the transport company or transitional facility operator as approved operators (of components of the GIS), and suspension of the transitional facility as an approved facility to hold/process grain will automatically occur.

After the non compliance is effectively resolved, discharge, handling and clearance may resume (after re-approval of the non-compliant GIS (or GIS component) under an audit regime with increased frequency and supervision by a MQS inspector or authorised person. Importation may also occur using Option 2 – where the importer uses the services of MAF Biosecurity approved inspectors to ensure compliance with this standard during the entire importation process.

Note: For examples of critical non compliances refer to Appendix C.

Action:

(i) Where a critical non-compliance is identified during any audit, the OR must identify, implement and have verified agreed corrective action(s).

The failure of an OR of a GIS to comply with the agreed corrective action(s) within the agreed period will result in the immediate loss of approval until:

(a). an agreed corrective action strategy has been verified by the auditor as having been implemented; and

(b). another systems audit is successfully completed.

(ii) Where more than one critical non-compliance is identified during any audit, the OR's system is immediately suspended until further notice by the CTO.

(iii) Where staff of the GIS identifies a critical non compliance, it must be reported to the CTO and/or the MQS inspector or authorised person immediately.

3.6.2 Major Non Compliances

A major non compliance is defined as an incident that may cause a **BIOSECURITY RISK** or result in a decrease in confidence to prevent the occurrence of a **BIOSECURITY RISK**. (Refer to 3.6.1) from occurring. Corrective action needs to be implemented immediately in order to retain confidence that the GIS continues to meet MAF Biosecurity requirements.

Note: For examples of major non compliances refer to Appendix C.

Action: A critical non compliance is to be recorded for every three major non-compliances identified during a single audit.

3.6.3 Minor Non Compliances

A minor non compliance is defined as an incident that results in a decrease in confidence in the grain importation process but may not immediately cause or lead to a biosecurity risk. Corrective actions are required to comply with the GIS.

Note: For examples of minor non compliances refer to Appendix C.

Action: A major non compliance is to be recorded for every three minor non compliances identified during a single audit.

3.6.4 Additional Non Compliances

Where additional non compliances are discovered that are not covered by the examples and definitions, they are to be classified as major non compliances until clarified by the CTO.

3.6.5 Control of Non Compliant Grain Consignments

Grain consignments that do not comply with the specified requirements of the GIS must be segregated from all other products and the MQS inspector or authorised person informed immediately. The entire GIS or components of the system (including grain discharge, clearance and transportation to transitional facilities, processing etc) may be suspended immediately depending on the severity of the non-compliance.

3.7 CORRECTIVE ACTIONS

3.7.1 Time Frame for Implementation

A corrective action and a time frame for its implementation are to be determined between the MQS inspector or authorised person (auditor) and auditee for each non compliance. The auditor must verify that the corrective action has been implemented and is operating effectively within the agreed time frame.

3.7.2 Records of Corrective Actions

The GIS must record all agreed corrective actions taken to address the identified GIS non compliance. Corrective actions must outline:

- (a). what must be done;
- (b). by whom it must be done;
- (c). the time frame for completion of the corrective action;
- (d). the verification activities to be undertaken to ensure that corrective action has been successfully implemented

3.7.3 Advice to MAF on Non-Implementation of Corrective Actions

Where agreed corrective actions for critical or major non compliance are not implemented by the OR, the CTO must be informed immediately.

4. BUSINESS CONDUCT

4.1 REQUIREMENTS FOR ORGANISATIONS IMPORTING GRAIN

All ORs of GISs must be employees of:

- (a) a legally identifiable business entity or sole trader;
- (b) That business entity must have an organisational structure that enables them to operate the GIS to MAF Biosecurity specifications;
- (c) That business entity must operate a business environment that will not subject staff members to any pressure or inducement that might influence their judgement, impartiality, integrity or decisions impacting on MAF requirements;
- (d) and comply with this standard and with other MAF Biosecurity requirements as may be required by the CTO;
- (e) and provide the CTO or the MQS inspectors or authorised persons with the access necessary to carry out audits or validations;
- (f) only claim recognition in respect to those MAF Biosecurity requirements for which it has been approved;
- (g) not use MAF Biosecurity 's recognition of their GIS as to bring the CTO into disrepute;
- (h) ensure that no audit or inspection report or any part thereof is used or authorised for use for promotional or publicity purposes, if the CTO considers such use to be misleading; and
- (i) upon suspension or termination of approval take steps to ensure that no further use or reference occurs.

5. ORGANISATION AND STAFF RESPONSIBILITIES

5.1 RESPONSIBILITIES OF THE OR

The organisation's OR(s) must take ultimate responsibility for the GIS.

- (a) have demonstrated to the CTO, and/or the MQS inspectors or authorised persons as appropriate, that they meet the general requirements of this standard; and
- (b) be approved by the CTO prior to carrying out processes of grain importation or use the service of MQS inspectors or authorised persons at all stages of grain import; and
- (c) Document an organisation chart showing clearly the responsibility and reporting structure of the organisation.

5.2 CHANGES IN CONTROL OVER IMPORTED GRAIN

When control over grain changes, then the responsibility for adherence to the documented GIS changes from OR to OR or between agents of ORs such as transitional facility operators. The original importer will not be responsible for the entire fate of the grain if the control of the grain is transferred to the operator of an approved transitional facility for storage, processing or other MAF approved treatments.

Note: All grain transfers must be authorised to proceed by MQS and must be part of the documented GIS unless permission is obtained from MAF Biosecurity for approval to use an approved transitional facility that may not be originally part of the documented GIS.

6. GIS REQUIREMENTS

The OR must provide documentation of their GIS which demonstrates that the requirements specified in this standard can be met and that the following components are in place:

6.1 ORGANISATION OVERVIEW

6.1.1 Organisation Overview Requirements

The OR's organisation overview must include:

- (a) name of OR;
- (b) date the GIS document was prepared;
- (c) address (postal and residential), telephone and fax numbers and email address (if applicable);
- (d) a list of all countries and types of grain to be imported (refer to Section 6.4 – GIS Flow Chart for Hazard/CCP Identification 1. Pre-purchase activities (Leading to the Issuance of an Import Permit);
- (e) how their OR will maintain an up-to-date record of documents required for the importation and processing of grain.

6.1.2 Management Responsibility

The importing organisation must identify and list the contact person(s) who are responsible for:

- (a) management of their documented GIS;
- (b) establishing and confirming inspection or audit arrangements. The OR must arrange and confirm external and internal audits with a MQS inspector or authorised person. External audits are conducted by MQS inspector or authorised person and internal audits are conducted by the organisation;
- (c) submission of pertinent information relating to grain unloading, movement etc to the MQS inspector at least 5 working days prior to arrival of the grain consignment (for Australia refer to Section 6.12.2 (c));
- (d) implementing contingencies to address non-compliances (i.e. grain spills);
 - approved procedures must be specified
- (e) implementation of corrective actions to prevent re-occurrences after the reporting of non compliances to the MQS inspector or authorised person ;
- (f) notifying the MQS inspector(s) or authorised person s of GIS changes and fulfilling reporting requirements; and
- (g) the process, timing and carrying out of annual reviews of the GIS.

6.2 ADVICE ON OPERATING TIMES AND WEATHER CONDITIONS

ORs must provide the MQS inspector with the details of vessel arrival times, the start finish/times of shift operations for grain unloading and transport to approved transitional facilities. This will allow the MQS inspector to arrange inspections and audits accordingly. Occurrence of unsuitable weather conditions may result in delay of discharge or other components of the GIS.

6.3 HAZARD CONTROLS

6.3.1 Hazard Identification

Hazards that may allow spillage of grain or escape of regulated pests must be identified as critical control points (CCPs) in the import process and preventative measures developed for their control.

Note: HACCP principles may be useful for the identification of CCPs.

6.3.2 Definition of Critical limits

Critical limits must be defined and met to ensure CCPs are under control. The OR must identify the CCPs in the GIS. To do so the OR will have to complete a flow chart (refer to Section 6.4 – GIS Flow Chart for Hazard/CCP Identification) and identify all hazards, CCPs and control limits. For example, of a hazard to New Zealand biosecurity could be the lack of complete and accurate phytosanitary or control information required in the GIS (refer to Section 6.4 – GIS Flow Chart for Hazard/CCP Identification). For example, the OR of the GIS must maintain copies of required certificates from offshore NPPOs and other organisations (where necessary). Additionally, copies of control certificates for grain transfers, and other relevant data should be held for audit purposes as complete and accurate records. A checklist should be used to determine system compliance to the critical limits regarding certification and other information. The limit could also be “zero tolerance” where grain by-products must be free of viable regulated weed seeds or the by-products may require further treatment to allow further use. CCPs must be regularly monitored and corrective actions implemented where appropriate.

6.4 GIS FLOW CHART FOR HAZARD/CCP IDENTIFICATION

GIS flow charts must:-

- (a) identify the process pathway for grain import, from the country of origin, to arrival in New Zealand, and transportation, storage at the transitional facility followed by subsequent processing and use of processed material and by-products; and
- (b) specify the CCP's identified in the GIS at each stage of the import pathway.

Note: This section is designed to use HACCP principles to identify hazards and CCPs across the whole GIS.

MAF requires that imported grain is free from regulated pests (includes arthropods, fungi etc). Grain imported for consumption or processing that does not meet the phytosanitary requirements described above (e.g. additional declarations not

provided for all regulated pests or detection of regulated pests after audit testing on arrival) will not be given biosecurity clearance. The importer will be given the option to treat (if possible, e.g. by application of an appropriate pesticide or heat treatment), reship, or destroy the consignment. Any required treatments (including fumigation, processing or heat treatment) must be carried out in accordance with MAF's requirements.

Note 1: On application, MAF Biosecurity may approve other treatment methods to meet pest freedom requirements.

The following tabular guidelines and additional control information provide a template from which to produce a flow chart that details all aspects of a GIS for approval by MAF Biosecurity.

HACCP GUIDELINES FOR THE OPERATION OF AN APPROVED GIS

Process Step 1. Pre-Purchase Activities (Leading to the Issuance of an Import Permit)

PROCESS STEP	HAZARD(S)	CONTROL(S)	OUTPUT(S)
Importing organisation wants to bring grain into NZ.	Regulated pests that could enter with uncontrolled grain. (e.g. arthropods, fungi, weed seeds etc). For schedule pest list refer to Import Health Standard Schedules (IHS schedules) in MAF Draft Standard – PIT-GFO-PHR.	Unless MAF Biosecurity approves a GIS is prior to an import permit being granted grain importation is not permitted. Alternatively, on arrangement, all importation steps are subject to MQS control & supervision (refer to Section 2 – Approval Options).	Grain importer prepares, validates, submits their GIS for approval or arranges for MQS to act on their behalf.
GIS approval granted by MAF Biosecurity or authorised persons.	Detection of GIS non compliances that affect the effectiveness of the GIS & may result in suspension/termination.	Internal & external audits by MAF Biosecurity or authorised persons.	Corrective actions instigated immediately or the GIS is suspended or terminated.
Sources of imported grain (& associated hazards) identified.	Regulated pests (hazards) specified in the IHSS pest list.	Import (phytosanitary) requirements understood completely by importer & appropriate information sent to exporter	OR receives verification from exporter that NZ's import requirements & all required certification can be provided.
Importing organisation applies to MAF Biosecurity for a permit.	Ability of exporting NPPO to meet phytosanitary requirements is questioned by MAF.	Import under GIS. Required certification provided prior to consignment arrival. Audit sampling & inspection on arrival. MAF may investigate exporting country to determine if MAF's phytosanitary requirements can be met. However, this function is primarily up to the importer.	Import permit granted to the importer by MAF.

Additional Control Information - Pre-Purchase Activities

Importing organisations must have an approved GIS prior to being issued an import permit by MAF Biosecurity. Once the GIS is approved the importing organisation must locate a suitable grain consignment that meets MAF Biosecurity's phytosanitary requirements and then apply for an import permit.

Process Step 2. Post-Purchase Activities/Loading (Conducted by NPPO of Export Country)

PROCESS STEP	HAZARD(S)	CONTROL(S)	OUTPUT(S)
Comply with the conditions stated in the Import permit.	NZ phytosanitary standards not met.	Inspection, sampling, testing & reporting by NPPO. (Refer Appendix B – description of required documentation)	Issuance of compliant phytosanitary certificate & other accompanying documents.
	Inspection, sampling & testing not carried out correctly or not conducted	NPPO integrity, AOSA Rules, ISTA Rules, IPC/SPS Agreements etc.	Issuance of compliant phytosanitary certificate & other accompanying documents.
	Accuracy of documentation	Initial checking of documents by importer	Compliant documents lodged with MQS for pre-clearance scrutiny.

Additional Control Information – Post Purchase Activities

This process step is outside the direct control of MAF or the importing organisation. The required outcome is the issuance of required documents that comply with MAF’s phytosanitary requirements and prevent or reduce biosecurity risks. The activities conducted behind the issuance of the required certification are usually not influenced by anything other than international conventions. – WTO/SPS Agreements, AOSA Rules, ISTA Rules, etc.

If doubts exist over the accuracy or origin of required certificates or the integrity of the offshore NPPO, advice must be sought from the CTO immediately. Consignments that are represented by certificates that are not compliant with MAF’s phytosanitary requirements may be refused clearance.

Process Step 3. Grain Arrival at the Border/Pre-discharge.

PROCESS STEP	HAZARD(S)	CONTROL(S)	OUTPUT(S)
Pre-arrival notification (advice) sent to MQS	MQS staff not present or available	Appropriate notification received by MQS	Resources available
Presentation of certificates and/or other documents	Incomplete and/or non-compliant certificates and/or documents	MQS & OR has checklist for required documents, certificates and/or documents checked by MQS	Documents verified as correct & Biosecurity Authority Clearance Certificate provided by MQS, Verbal authorisation provided to proceed with discharge

Additional Control Information – Grain Arrival at the Border

Pre-discharge notification information for MQS

The OR of the GIS must provide the MQS inspector (at the proposed port of entry) with all pertinent details and required of the impending grain importation, at least 5 days notice in writing (or by e-mail) before the arrival of a grain shipment except for grain consignments from Australia (refer to Section 6.12.2 (c)). Information must include:

- Name of OR responsible for the GIS,
- a copy of the import permit,
- details of the shipment including type of grain and tonnage,
- name of ship and voyage number and estimated time of arrival,
- proposed ports of discharge, and tonnage discharged at each port,
- details of approved transitional facilities intended for storage,
- processing of the grain (and any other required treatment),
- the name of person(s) who will be accountable for operating components of the GIS, meeting the requirements of the import permit and receiving directions of a MQS inspector in quarantine areas, transitional facilities and any other places designated in the documented GIS or by the MQS inspector.

Discharge approval requirements (Refer to Section 6.12.2)

Prior grain discharge the OR must implement any instructions from the MQS inspector regarding components of the GIS prior to grain discharge. This includes any instructions regarding:-

- conditions of storage and processing plants (transitional facilities),
- trucks, trailers and other conveyances used in the transportation
- transport routes used by grain conveyances
- contingency plans outlining actions required in an event of a grain spillage
- certification presented to the MQS inspector (as required in the conditions of the import permit)
- any additional grain treatments that are required

Note: Grain consignments not meeting MAF's phytosanitary requirements are non compliant and may require treatment (if available), or the consignment may be re-shipped or destroyed.

Process Step 4. Arrival and Unloading from the Vessel

PROCESS STEP	HAZARD(S)	CONTROL(S)	OUTPUT(S)
Establishment of quarantine area on wharf (MQS activity)	Unauthorised people & vehicles in quarantine area leading to unauthorised movement of risk goods	Quarantine area identified by MAF signs, area policed by MQS, OR or OR's agent. Discharge is undertaken only within the approved quarantine area	Quarantine area established
Vessel clearance as per MAF Biosecurity requirements	Possible escape of regulated pests (e.g. arthropods, weed seeds, fungi).	Voluntary fumigation of vessel on voyage, on-wharf inspection/audit sampling by MQS	Clearance compliant with requirements, MQS allow discharge to continue
Discharge of grain from vessel	Spillage of grain & escape of regulated pests, risk goods contaminate equipment	Risk goods contained in quarantine area, continual cleaning area, equipment & external monitoring of conveyance cleanliness by MQS, OR or OR's agent	No major spillage of grain in quarantine area & no escape of regulated pests

Additional Control Information - Unloading from the Vessel/ Physical Discharge.

The OR is ultimately responsible for the entire GIS and must have an agent present at all times during discharge. The OR's agent is accountable for:-

- (a) actioning all instructions from the MQS inspector,
- (b) conveying all instructions to authorised people in the quarantine area (watersiders, drivers and stevedores etc).
- (c) ensuring that port authority staff, stevedores and other wharf operators and all sub-contractors are aware of MAF Biosecurity requirements during discharge
- (d) allowing only authorised persons and vehicles (directly involved with the discharge or unloading of grain) to be permitted entry to the quarantine area
- (e) providing the light level availability within the quarantine area is at least 600 lux during the operation (night and day)
- (f) providing that management of equipment used to discharge, load or unload grain and ensure that it is operated in such a manner that prevents unnecessary spillage
- (g) providing adequate staff and equipment to immediately remedy any grain spillage in any area of the wharf.
- (h) ensuring that all spilled grain is returned to the load or held securely for disposal as directed by the MQS inspector
- (i) ensuring that all equipment used in the discharge, loading or unloading of the grain is cleaned to the satisfaction of the MQS inspector before use for any other work, or the conclusion of the each working day.

Process Step 5. Grain Transportation to Approved Transitional Facilities

PROCESS STEP	HAZARD(S)	CONTROL(S)	OUTPUT(S)
Transport of grain to ATFs	Non-approved operators (not part of GIS)	Operators approved as part of GIS	Approved transport operators used as part of GIS
	Non-compliant conveyances	Audit/inspection by MQS and compliance	MQS authorised movement of risk goods (grain) to ATFs.
	Spillage of grain containing regulated pests leading to escape	SAC information and pest list in IHS schedules in MAF Draft Standard – PIT-GFO-PHR.); contingency plans for clean up held by OR, transport companies & drivers; immediate clean up of all spills;	
	Maximum grain level/load of conveyance exceeded	Compliance with maximum grain level/load of conveyance;	
	Unapproved release of grain containing regulated contaminants	Audit/inspection by MQS; approved transport routes taken; decontamination of conveyances;	Grain transported to ATF without spillage or non-compliances;

Additional Control Information – Grain Transportation and Security

Imported grain may only be carried by transport companies that have an accredited operator and use conveyances accredited by MQS. Final approval of transport operators and conveyances will be provided by MAF Biosecurity after recommendation from MQS. The MQS Co-ordinator must maintain a registry of accredited conveyances for audit purposes. For full details of minimum specifications please contact an appropriate MQS Co-ordinator.

Vehicle inspections for compliance are required 6 monthly and may be conducted for entire fleets of approved conveyances or as appropriate before the renewal date of approvals. Transport operators must ensure conveyances are compliant at all times. All conveyances are regarded as quarantine units from the time they begin operations until they are unloaded and are cleaned to MAF specifications at the end of the transport period or the end of the day.

The OR has responsibility for ensuring transport security and that grain goes to ATFs only. All transfers of grain must be covered in the GIS and must receive movement authorisation from MQS. All accredited conveyances must:-

- (a) be of appropriate construction and sealed to the satisfaction of the MQS inspector to eliminate spillage or leakage.
- (b) be operated by approved transport operators only.
- (c) be loaded (trucks/trailers) to a level no greater than 150mm from the lowest point around the topside of the tray).
- (d) not be permitted to use wooden additions to the top of trays
- (e) be secured with approved covers/lids/etc before leaving a quarantine area.

Transport of Containerised Grain

MAF will only allow containers to be trucked to MAF approved transitional facilities outside of the metropolitan areas of the entry ports if the following safeguards are used.

1. Containers must be moved on trucks that are approved by the MAF Inspector for this purpose. Such trucks must be constructed with either solid flat decks or of a “skeletal” type construction to ensure flexing and movement of containers during transportation is kept to a minimum.

And

2. All containers must be fully taped and either the containers have the ends covered and sealed with canvas shrouds/sealing systems or the trucks (with the containers on board) must be fully covered and sealed with canvas shrouds to prevent any spillage (MAF will also consider equivalent systems to prevent leakage).

Or

3. Specially modified containers may be used that are top loading with the front doors welded shut and effectively sealed to prevent spillage. The use of these containers must be approved by the MAF inspector prior to the movement of imported grain out of the metropolitan area of the entry port.

All containers will be subject to 100% inspection on the wharf before trucks are permitted to leave quarantine areas. Only MAF approved transport operators may operate trucks that transport containers with imported grain within the metropolitan areas of the entry ports or outside of these areas. All aspects of container transport (systems used to prevent spillage) must be specified in the documented GIS system for audit purposes.

Note: Imported grain and may not be transported by rail in containers

Process Step 6. Unloading and Storage of Grain at the Approved Transitional Facilities

PROCESS STEP	HAZARD(S)	CONTROL(S)	OUTPUT(S)
Grain arrival at ATF	Escape of regulated pests (associated with grain) from ATF	Grain intake managed & grain contained, Conveyances decontaminated in quarantine area, Drivers of conveyance are trained, roadways continually cleaned, Audits by MQS	Compliant trucks, compliant storage at ATF, no escape of risk goods from secure storage
Storage at ATF	Cross contamination, Rodents & birds taking grain, Access by unauthorised persons, Poor ATF maintenance & upkeep	Segregation of grain (where required), Good house keeping/pest control programme, Security maintained, Regular maintenance conducted	No cross contamination at ATF, verifiable storage/pest control records, no escape of risk goods from ATF verifiable maintenance records
Grain transfers from ATF	Unauthorised transfers, Use of unapproved conveyances, Cross contamination of grain with biosecurity clearance	OR advises MQS before grain transfer, Controlled movement using approved conveyances, approved routes used & contingency plans available, Decontamination of conveyances	MQS authorisation for transfer provided, records available of approved conveyance used, verifiable records of transfers, no escape of risk goods from ATF or conveyances
Movement within ATF	Cross contamination (as above), Movement Outside ATF quarantine areas	Decontamination of conveyances & controlled movement	Verifiable records, no escape of risk goods from ATF

Additional Control Information - Unloading Prior to Storage and Processing at ATFs.

The transitional facility operator and OR must ensure that:-

- unloading occurs only within the quarantine area at the ATF
- the grain intake is managed (e.g. enclosed or screened) to ensure no grain or risk material can escape to the external environment and dust is minimised.
- after unloading any conveyance used must have any closures made secure
- after unloading any conveyance used must have any covers replaced securely
- after unloading any conveyance used must have the exterior cleaned of loose grain and residues. The interior of conveyances must be cleaned at the end of the work period (day or night) or at the termination of the job, and the OR or transitional facility operator must ensure that any spillages or leaks at the transitional facility are rectified immediately.

Treatment, Storage and Processing.

Any ATF used to treat, store or process imported grain must be approved as part of the GIS. Operators of ATFs must also be approved to MAF Standard 152.04.03F – Requirements for holding and processing facilities (Class: Transitional Facilities) for uncleared risk goods.

Any building including silos, where the grain is cleaned, stored or processed must:-

- Have an enclosed, screened or managed grain intake (as approved by the MQS inspector) to ensure no grain or risk material can escape to the external environment and dust is minimised. **Note: This requirement may vary depending on transitional facility location and the type of grain that is imported.**
- be constructed and maintained to prevent the escape of unprocessed grain;
- be leakproof, substantially bird proof and rodent proof, and not subject to flooding;
- have a sealed floor in good repair;
- have easy all weather shingle or sealed vehicle access;
- have sealed areas (designated as quarantine areas) where vehicles are uncovered, loads are discharged, and vehicles cleaned. These areas must be effectively screened to prevent grain being blown in the wind.

Flat storage

Any flat storage used must meet the above conditions and additionally:-

- only designated doors are to be used for access;
- all other openings are to be sealed so that no grain can escape;
- grain must be stored in such a manner that it will not spread within 2 metres of unsealed openings;
- the storage area must not be used for any other purpose until the imported grain has been removed and store cleaned to the required standard;
- any elevator and conveyer that is not within a building must be sealed or enclosed in ducting so that no grain can escape;
- Imported grain of different origins must be segregated from each other by a minimum of 5 metres (or an equivalent method of segregation may be used) if all phytosanitary requirements have not been met and additional treatment is required (e.g. heat treatment).

Note: Storage and processing of imported grain may occur at the same ATF while other ATFs are storage facilities only.

Process Step 7. Processing at an Approved Transitional facility

PROCESS STEP	HAZARD(S)	CONTROL(S)	OUTPUT(S)
Grain received or transferred for processing	Escape of regulated pests (associated with grain) from ATF	Suitable ATF approved to hold & process grain	Grain held securely and processed appropriately
Processing method (e.g. cleaning, hammer milling)	Processing is insufficient to kill pests, MAF approved treatment not conducted	Using MAF-approved treatments (where required), Equipment calibrated correctly, MQS audit & monitoring, Sampling & testing of weed seed survival or viability & testing for other pests, Recall procedures available with records	Log of MAF approved treatment, Sample results available, Calibration records available for equipment, Non risk material produced that receives biosecurity clearance

Additional Control Information - Requirements for Processing at an Approved Transitional Facility

- (i) Security. Imported grain must not be substituted or mixed with other grain if biosecurity clearance is not provided by MAF and further treatment is required. Grain may not be moved from ATFs without MQS authorisation.
- (ii) Space. An adequate area must be available for any inspection that may be required.
- (iii) Lighting. There must be a minimum of 600 lux at the point at which grain or by-products are inspected.
- (iv) Serviced. Trained staff and other necessary facilities must be available on request of the MQS inspector or authorised person.
- (v) Location. ATFs may be located anywhere in New Zealand. However, ATFs must meet all MAF requirements for approval and are subject to conditions specified in relevant import permits for specific grain consignments.

Grain Milled into Flour for Human Consumption.

Any cleanings or trash removed before milling must be disposed of securely by MAF approved methods, for example by fine grinding (depending on end use), heat treatment, incineration, steam sterilisation or other methods as directed by the MQS inspector.

Grain Processed into Stock Food

Processing proper must not proceed until an MAF inspector is satisfied that the processing will be of such a standard that there are unlikely to be any whole regulated weed seeds present in the final product. If the approved AOSA or ISTA seed testing laboratory (approved to MAF standards for diagnostic and containment laboratories) find no viable regulated weed seeds there is 95% confidence that 3 or less regulated seeds are present per kg of processed product). Grain by-products or processed grain must be free from viable regulated weeds seeds.

Approval of Processing System & Process Control

To ensure freedom from regulated weed seeds an initial one-off trial shall be conducted to enable the MAF Inspector to assess the process capability of the facility.

One trial will be conducted per grain type to be processed as is required under the terms of the import permit and import health standard schedule for that type of grain. Once process capability is confirmed, approval shall be granted and then commercial production & process control monitoring can begin. Subsequent trials will not be required for each shipment once approval is gained from the MAF inspector for a particular grain type.

1. Initial Trial for Process Capability Validation

The trial batch shall be at least 1tonne of grain unless the normal batching volume of the process is less; in this case the normal batching volume should be used (appropriate volumes will be determined by the MAF inspector). **Note: Any trial processed material must be held securely until authorisation for further use & approval is received.**

The MAF Inspector shall advise the mill manager of results immediately once the results are available.

- a. Collect a 1kg sample from the bulk storage material at the ATF (following AOSA/ISTA) guidelines); or
- b. ATF operators must combine a minimum of 40 primary samples (of processed grain) from the trial volume to make a working sample of 1kg. (This method of sampling must be recommended by the MAF inspector or authorised person & included in the official GIS documentation); or
- c. ATF operators must produce working samples of 1 kg each at facilities with automatic samplers (this method of sampling must be recommended by the MAF inspector or authorised person & included in the official GIS documentation)

The 1 kg sample must be sent to an ISTA/AOSA approved testing laboratory that has been approved to MAF Biosecurity Authority Standard. - 152.04.03F. Requirement for Holding and Processing Facilities (Class: Transitional Facilities) for Uncleared goods. Milled grain or grain by-product may receive movement authorisation for other purposes if no viable regulated weed seeds are found, However, if viable regulated weeds seeds are found, trial/s shall be repeated following necessary adjustments to processing equipment until no regulated weed seeds are found or if the facility operator decides not to proceed with seeking approval for that grain type). The trial material, by product or remaining bulk grain must either be;

- a) Re-milled through the adjusted hammer mil; or
- b) Receive an effective treatment (e.g. heat) to ensure non-viability. or,
- c) Transported by approved transport operators to approved transitional facility for processing for either a) or b) above

2. Process Control Monitoring/Verification (Commercial Production)

To ensure process capability is maintained throughout commercial production, the ATF operator must:-

Sample the grain at appropriate intervals to obtain minimum working samples of 500gm minimum. It is recommended that sampling occurs at least twice every 12 hours by taking 1 representative sample from the processed material stream (or at intervals & amounts as approved in the GIS to meet different ATF shift requirements.)

Determine % limits for each sieve used for process control monitoring. The limits will ensure no whole grain is found in sieve analysis and therefore it is less likely that viable regulated weed seeds will be found in samples and sent to the seed testing laboratory. If changes are made to the process and viable regulated weed seeds are identified or whole grain is found then adjustments to % limits for sieve analysis will be required.

Sieve analysis should also be carried out following maintenance as well as on the regular scheduled basis. Pass the samples through a bank of sieves with recommended apertures of 2.0mm 1.4mm & 1mm (or use an equivalent method), and check for presence of whole grains and regulated weed seeds.

Maintain a “Processed Grain Sieve Sampling log” which will record:-

1. Date,
2. Grain Type
3. Screen size in the processing equipment (hammer mill),
4. Aperture sizes of test sieves (or equivalent method used)
5. Weight of different fractions recovered.
6. Number & identity of whole grain or regulated weed seeds detected in sample. Seeds apart from the commodity e.g. wheat seed/grain shall be sent to an approved laboratory for identification.
7. Corrective actions taken when results are above limits.

Corrective Actions:

If whole grain or seeds are found or % results for sieves are above limits in 2 consecutive samples, stop processing immediately. Adjust necessary equipment and resample until the sieve analysis results (% for sieves &/or whole grain/seeds) indicate the process is back in control.

On completion of the treatment, or processing of imported grain, the ATF operator must ensure that, all storage areas and machinery are cleaned to the standard specified in the GIS. The GIS must specify where the building and equipment are used solely for the ongoing cleaning and processing of imported grain.

Note: All imported grain or grain by-product must be segregated from domestic grain or grain/by-product that has received biosecurity clearance until MAF approved treatment is conducted or a biosecurity clearance is received from the MAF inspector after confirmation from audit test results. Grain segregation records (where required) must be kept for audit purposes.

Process Step 8. By products / Waste products

PROCESS STEP	HAZARD(S)	CONTROL(S)	OUTPUT(S)
Biosecurity risks removed from grain by-products	Escape of regulated pests (associated with grain) from ATF	Approved processes/treatments to hold/ treat/destroy risk goods	Biosecurity Clearance
	Failure to treat by-products correctly	Audits and monitoring	
	Contamination of non-risk goods with by-products containing regulated pests	Treat as risk goods	
	Non-authorized transfer/movement of risk goods	Check there is a BACC	

Additional Control Information - By products / Waste products

Further Use of Grain By-Products

The use of processed grain or by-products varies between different types of grain where under certain conditions grain or grain by-products may not be used for animal feed unless the material undergoes MAF Biosecurity approved processing or is free of regulated pests. In addition, certain grain by-products that are on-sold for human consumption may only be sold to 3rd party organisations that are specified in the GIS. However, biosecurity clearance may be granted if an approved process further treats the by-products or the grain is documented (meets phytosanitary requirements) to be free of regulated pests (e.g. comes from areas free from regulated pests or has been tested to show the absence or non-viability of regulated pests and also meets audit testing requirements). All cleanings/trash must be disposed of securely by MAF Biosecurity approved methods.

***Note: Refer to the individual IHS schedules in draft MAF Standard Grain for Processing, Plant Health Requirements (PIT-GFP-PHR). [Link] for specific details of permitted usage of grain/by-products e.g. *Triticum aestivum* (wheat) grain or *Zea mays* (maize) grain.**

6.5 WORK INSTRUCTIONS/PROCEDURES

All staff involved in making decisions impacting on biosecurity risk must have clear work instructions that indicate who does what, where, when and how to minimise hazard at CCPs.

6.6 DOCUMENT CONTROL

Document control must ensure:

- (a) the approved GIS is available at all locations where they apply and are used by the relevant staff;
- (b) all changes of documents or amendments are covered by the correct authorisations and processed in a manner which will ensure timely availability to the appropriate staff; and
- (c) superseded documents are removed from use with one copy retained for 2 years for audit purposes; and
- (d) there is a process for notifying the **MQS inspector** or authorised person of any changes to the GIS during the operating season and following its annual review.

6.7 GRAIN IDENTIFICATION AND TRACEABILITY

6.7.1 Identification and Isolation requirements

Imported grain must be initially identified and isolated to enable:

- (a) identification of grain from different origins where phytosanitary regulations and post entry requirements may differ until biosecurity clearance is provided;
- (b) identification of grain which has been fumigated or received other treatment;
- (c) control of grain consignments where there is contamination with regulated pests that may present a biosecurity risk;
- (d) trace back of grain to imported consignments; and
- (e) specific requirements for further treatment (where required) and movement authorisation to other transitional facilities or third party use.

6.7.2 Documentation Requirements

Access to relevant import and shipping documentation (e.g. import permits, phytosanitary certificates, consignment notes, air waybills, etc) must be available for traceback purposes where and when requested by the **MQS inspector** or authorised person.

6.8 APPROVAL OF TRANSPORT COMPANIES

GISs may only use transport companies accredited by MQS for that purpose. Accredited transport companies are required to have an accredited operator and use conveyances accredited by MQS. Transport companies (non-accredited) that wish to supply transport services for organisations that operate approved GISs must apply for accreditation to an appropriate MQS co-ordinator. MAF Biosecurity will provide final approval if recommended by the MQS co-ordinator. For more detail please refer to page 32, Section 6.4 - Flow Diagram, Process Step 5. Grain Transportation to Approved Transitional Facilities

6.9 APPROVAL OF TRANSITIONAL FACILITIES

GISs must specify that grain may be stored or processed at approved transitional facilities (ATFs) only. Organisations that wish to have new transitional facilities approved or use other transitional facilities than those currently in use must apply in writing to the MQS co-ordinator to commence the approval process. Failure to meet these requirements will be regarded as a major non compliance. For more detail please refer to pages 33 – 36, Section 6.4 - Process Step 6. Unloading and Storage of Grain at the Approved Transitional Facilities and Process Step 7. Processing at an Approved Transitional facility.

6.10 EQUIPMENT

6.10.1 Equipment Requirements

Documented procedures must ensure that all required equipment meets MAF Biosecurity specifications. Essential equipment identified in the GIS as CCPs must be calibrated to ensure critical limits are met. Calibration records for equipment identified in GISs must be provided on demand by the MQS inspector or authorised person.

6.10.2 Additional Requirements

In addition, the following equipment must be available for use by inspection and audit staff;

- (a) containers to hold pests for identification;
- (b) record sheets and a documented procedure for completing and filing them; and
- (c) other equipment (i.e. additional lighting, bags for samples etc) as required by the MQS inspector or authorised person to complete inspection or sampling.

6.11 INSPECTION AUDITS AND SAMPLING

A MQS inspector or authorised person may audit (inspect and sample grain consignments for arthropod pests and contaminants (other than regulated weed seeds) at any time after the consignment arrives at the border. The OR must ensure that all requirements of the MQS inspector or authorised person are met. For more detail please refer to Section 6.4 - GIS Flow Chart for Hazard/CCP Identification.

6.12 RECORDS

6.12.1 Provision of Records

The OR must provide all requested GIS data (within 2 days) to MQS inspector or authorised person as appropriate, (whether the OR is currently approved or not). Records must be fully completed and must be produced in an accurate, legible, readily accessible form. Records containing personnel information must be identified and maintained in accordance with the requirements of the Privacy Act 1993. All records must be securely stored for a specified period of not less than 2 years.

6.12.2 Record Maintenance

The following GIS records must be maintained:

- (a) Audit and inspection results. These records must include any non compliance and any associated corrective actions. In addition, all audit and inspection results/reports must be uniquely identified and dated and traceable to site of inspection and the name of the associated MQS inspector or IVA for a period at least 12 months from date of completion; and
- (b) Grain consignment records. These record must be maintained by the OR and transitional facility operator. These records must be available at all times for the MQS inspector or authorised person so that whole shipments may be accounted for. (Refer to Section 6.4 - GIS Flow Chart for Hazard/CCP Identification, for details of required consignment records).

Records for each consignment must contain the following information;

- date of grain into the transitional facility
- type of grain
- quantity/tonnage
- vessel and voyage number
- country of origin
- details of segregation from other consignments (where required) from different origins (where stored [flat storage or in silos] and details of cleaning of storage areas prior to new consignments arriving)
- details of cleaning/flushing of grain conveyers between grain consignments of differing origins (where required)

Copies of required certificates must be retained as above (Refer to Appendix B)

- Container certificate
- Import permit
- Phytosanitary certificate
- Sack certificate
- Sampling certificate
- Seed analysis certificate
- Vessel certificate

(c) Predischarge Notification Records.

The OR must notify the MQS inspector (at the proposed port of entry) of details of the impending grain importation, at least 5 days notice. With regard to consignments of grain from Australia, notification must be provided to MAF as soon as possible due to the short transport period between Australia and New Zealand. Notification may be in writing or via electronic means (e.g. e-mail) before the arrival of a grain shipment.

(d) Discharge Approval Records

Prior to discharge of grain the OR must implement any instructions from the MQS inspector regarding specific components of the GIS. All instructions must be provided by the MQS inspector in writing (handwritten instructions or e-mail may be used) and records of all instructions must be kept for audit purposes (Refer to Section 6.4 - GIS Flow Chart for Hazard/CCP Identification, Process Step 3. Grain Arrival at the Border/Pre-discharge).

6.13 REPORTING

Reports must be supplied to the CTO, MQS inspector or authorised person as follows:

Internal critical failure (refer to classification of non compliances) which may pose a biosecurity risk.

Appendix A - AUDIT INSPECTION AND SAMPLING PROCEDURES

Audit inspection and sampling procedures are approved by MAF Biosecurity to provide an appropriate level of detection for regulated pests and contaminants. MAF will audit sample imported grain consignments (on arrival in New Zealand) and conduct identification tests to ensure that offshore testing for regulated pests is accurate. **Note: However, audit inspection on arrival is not intended to exactly duplicate inspection and sampling for weed seeds as is conducted offshore and reported in ISTA/AOSA seed analysis certificates.**

Bulk Grain Clearance Audit Inspection

Grain consignments must be audit inspected for visually detectable regulated arthropod pests or contaminants (excluding weed seeds). Inspection of bulk grain consignments must be conducted by the MQS inspector in the vessel's hold(s) prior to, and during grain discharge. Grain consignments must be examined and sampled at the following rates:-

For arthropods

- (a) a minimum of 1 kg per 25 tonnes (for Class 1 grain until 31 December 2003) or a minimum of 5 kg per grain consignment may be examined and sampled; or
- (b) the OR may supply a fumigation certificate whereupon the MQS inspector will check for the presence of live arthropods on opening the ships holds and during the initial discharge.

For other regulated pests

Representative (ISTA/AOSA) sampling for other regulated pests (for identification testing) will also occur at this time. Samples will be sent to MAF approved laboratories at the importer's expense.

Container Inspection and discharge at Transitional Facilities

Containers of imported grain must be inspected for visually detectable regulated pests or contaminants (excluding weed seeds). After transportation from the wharf, the grain must be inspected at the appropriate MAF-approved transitional facility by the MQS inspector during discharge from the container(s). Grain consignments must be sampled at the following rates:-

For arthropods

- (a) a minimum of 1 kg per 25 tonnes (for Class 1 grain until 31 December 2003) or a minimum of 5 kg per grain consignment may be examined and sampled; or
- (b) the OR may supply a fumigation certificate whereupon the MQS inspector will check for the presence of live on opening the containers.

For other regulated pests

Representative (ISTA/AOSA) sampling for other regulated pests (for identification testing) will also occur at this time. Samples will be sent to MAF approved laboratories at the importer's expense.

After grain discharge the OR must ensure that each container is cleaned and all grains and residues are removed as specified in the GIS. Emptied containers are subject to audit by a MQS inspector or authorised person at any time.

Note: Discharge of grain must be suspended immediately if regulated arthropod pests or contaminants are detected. Appropriate action must be taken and grain discharge may resume when all non-compliances are resolved.

Appendix B – DESCRIPTION OF REQUIRED CERTIFICATION

(a) Container certificate (CC)

For grain shipped in containers, either loose or in sacks, a certificate from the NPPO in the port or place of loading certifying that the containers were inspected prior to loading and found to be free of pests and residues of previous cargo.

(b) Import permit

Official document authorising importation of a commodity in accordance with specified phytosanitary requirements (FAO, 1990, revised FAO, 1995).

(c) Phytosanitary certificate (PC)

A certificate patterned after the model certificates of the IPPC (FAO (1990)). A certificate issued by the exporting country NPPO, in accordance with the requirements of the IPPC, which verifies that the requirements of the relevant import health standard have been met.

(d) Sack certificate (SKC)

For grain in sacks, a certificate from the NPPO certifying that the sacks are new and free from soil, and regulated pests (excluding weed seeds) and any other contaminants that may harbour regulated pests.

(e) Sampling Certificate (SC)

A certificate issued by the NPPO in the country of origin which clearly identifies the consignment (eg hold number of ship, shipping container number(s) or line of sacks from which the samples were drawn. The SC certifies that the primary samples for each consignment were officially drawn, in accordance with a quality system approved by MAF Biosecurity or, during loading of the ship, at a rate of at least one primary sample per 100 tonnes of grain. The submitted samples were prepared and despatched in accordance with ISTA rules 2.6.6 and 2.6.7.

(f) Seed Analysis Certificate (SAC)

A certificate documenting the status of the consignment with respect to regulated weed seed and other seed contaminants or impurities. MAF Biosecurity accepts certificates issued by AOSA or ISTA approved seed testing laboratories only (either in the country of origin or in New Zealand). SACs must -

- (i) be issued by an ISTA or AOSA accredited seed testing laboratory (either in the country of origin or in New Zealand);
- (ii) cite the sampling certificate;
- (iii) certify that for each consignment a minimum working sample of 5kg has been inspected for seed impurities;
- (iv) give the scientific name of each identified species of seed and/or arthropod pest and contaminants found in the sample and record any unidentified genera or species;
- (v) specify the exact number of seeds of each contaminant genus/species found in the official sample
- (vi) be available 5 days prior to discharge at the port of entry into New Zealand (for consignments from Australia, refer to Section 6.12.2).

(g) Vessel certificate (VC)

For grain loose in the hold of a ship, a certificate from the NPPO in the port or place of loading stating that the holds carrying the loose grain have been inspected prior to loading and found to be free of pests and residues of previous cargo.

Appendix C – EXAMPLES OF NON COMPLIANCES

Non Compliance Definitions for MAF Biosecurity Grain for Processing GISs under Audit

ACTIVITY	N-C LEVEL
Grain discharge/unloading	
Loading into unapproved conveyances	Critical
Use of contaminated/dirty equipment	Major
Failure to continuously clean grain from wharf (and at end of day/end of discharge)	Major
OR Rep not present at all times (apart from temporary breaks)	Major
Non-authorized people/vehicles in quarantine area	Major
Use of untrained/incompetent staff	Major
Discharge under inappropriate conditions	Major
Transport of grain	
Use of unapproved conveyances	Critical
Over-filling of conveyance	Critical
Driver untrained/unaware of responsibilities.....	Critical
Driver has no access to contingency plans for spillage.....	Critical
Conveyance not cleaned as required prior to leaving wharf or ATF.....	Critical
Conveyances dirty prior to use	Major
Use of poorly maintained equipment that could lead to failure and spillage	Major
Driver fails to produce contingency plans for spillage	Major
Use of unapproved route to ATF or unapproved stops	Major
Lack of recording devices (distance/weight).....	Major
Failure of recording devices (distance/weight)	Minor
Unloading at ATFs	
Unloading in non-approved quarantine areas	Critical
Failure to clean grain spillage immediately (outside quarantine area).....	Critical
Conveyance cleaning done in non-approved area	Critical
Conveyance not cleaned as required at ATF prior to leaving.....	Critical
Non-authorized people/vehicles in quarantine area	Major
Grain storage/processing at ATF	
a. Pest Control	
- Pest control programme absent	Critical
- Pest exclusion measures absent.....	Critical
- Pest control programme not maintained (weeds present/birds etc in storage area)	Major
- Pest exclusion measures damaged	Major
- Weeds present in/immediately around quarantine area.....	Major
- Birds/rodents present in quarantine area	Major
b. Structural failings	
- Storage silo/building with holes in walls, doors/hatches/windows broken/damaged.....	Critical
- Quarantine signs missing	Major
- Quarantine signs illegible	Major
- Absence of required lights	Major
- Light bulbs blown.....	Minor
- Maintain required cleanliness	Minor
c. Staff/Personnel	
- Use of untrained/incompetent staff	Major
- Non-authorized people/vehicles in quarantine area	Major
d. Grain processing/handling requirements	
- Failure to use approved treatments (where directed by the MAF inspector)	Critical
- Failure of processing/hammer mill (regulated weed seeds detected)	Major
- Failure to maintain approved treatments (where directed) for sufficient time.....	Major
- Failure to segregate grain (where directed by the MAF inspector).....	Major
- Failure to maintain equipment calibration records but equipment working correctly	Minor

ACTIVITY	N-C LEVEL
e. Documentation	
- Import documents lost/absent	Critical
- Storage plan/records of grain movements or isolations lost/absent	Critical
- Heat treatment/other approved treatment (where required) and processing records lost/absent	Critical
- Import documents not produced within 2 days	Major
- Storage plan/records of grain movements/isolations not produced within 24 hours	Major
- Heat treatment/other approved processing records not produced within 24 hours	Major
- Heat treatment/other approved treatment (where required) and processing records not produced on demand.....	Minor
- Storage plan/records of grain movements or isolations (where required) not produced on demand	Minor
- Import documents not produced on demand	Minor
- Lack of housekeeping (non-critical) records	Minor
f. Grain transfers	
- Grain transfer to non-approved site (not ATF)	Critical
- Conveyance not cleaned after grain transfer to ATF or between ATFs.....	Critical
- Grain transfer using non-approved conveyance	Critical
- Grain transfer to ATF without approval from MQS inspector	Major

Note: This list provides examples of non compliances for reference only. However, this list is not exhaustive and other non compliances are possible.