



LIVE ANIMAL AND GERMPLOASM EXPORT VERIFICATION PROGRAMME

This document details the programme that Recognised Agencies should apply in regard to the performing of verification, under the Animal Products Act 1999, of export approved premises. This programme contains:

- (a) MAF recommendations for the performance of verification activities at export approved premises supplying live animals and germplasm to the export market; and
- (b) the initial verification frequencies that will apply to an export approved premises, the performance measures around changing verification frequencies, and the ceiling frequencies that apply; and
- (c) specific provisions allowing for variation from the standard verification frequencies and changes for certain business situations.

Signed at Wellington this 26th day of January 2012.

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Director Animals and Animal Products
Standards Branch
Ministry of Agriculture and Forestry
(pursuant to delegated authority)

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Part 1

Application and Definitions

1 Application

- (1) Subject to sub-clause (2), this programme applies to:
 - (a) all animal product businesses that operate under the Animal Products Act 1999 as export approved premises for handling, processing or storing live animals or germplasm for export; and
 - (b) Animal Products (Export Approved Premises) Notice; and
 - (c) Animal Products (Export Verification Requirements) Notice; and
 - (d) recognised verifying agencies and verifiers.
- (2) This programme does not apply to:
 - (a) animal product businesses processing, storing or handling for the NZ market only.

2 Commencement

- (1) This programme applies from 1 February 2012.

3 Interpretation

- (1) In this Programme, unless the context otherwise requires—

Accountable person is the verifier with overall technical accountability for the recognised verification agency's activities provided to an animal product business site

Act means the Animal Products Act 1999

Business means an **animal product business** as described in section 4(1) of the Act. For the purposes of this Programme this excludes an animal product business that does not produce products or materials for export

Ceiling means the maximum verification interval achievable, as set out in Schedule 2 of this programme

Closure means the permanent cessation of all operations of an animal product business

Country listing means an importing country requires animal product businesses to be on a specific list in order to process or store animal material or animal product for export to that country. This requirement is separately notified as an overseas market access requirement by MAF

Deficiency means any departure from a regulatory or export requirement which is reasonably likely to—

- (a) result in an unacceptable level of animal health risk; or
- (b) jeopardise overseas market access; or
- (c) threaten the integrity of the official assurance system.

In this context, a deficiency has the same meaning as a critical non-compliance. A deficiency is also repetitive or a collection of departures from regulatory requirements even though these would be unlikely to trigger the impacts listed in (a) to (c)

Dormancy (dormant) means a shut-down where no level of activity is present and where there is no intended date for restarting processing, and includes an animal product business with a suspended programme

Export for the purposes of this programme export means export subject to overseas market access requirements, or intended to be eligible for an official assurance. Exportable, exporting and other related terms have an equivalent meaning

Export certificate is the form of an official assurance determined by the Director General pursuant to section 62 of the Act

Initial step means the verification step which automatically applies to all new animal product businesses

MAF means the Ministry of Agriculture and Forestry

Overseas market access requirements (OMAR) means overseas market access requirements (or Export Requirements) notified or made available under section 60 of the Animal Products Act 1999

Operator means the owner or other person in control of an animal product business

Operator verification process means—

- (a) the operator verification activities to be undertaken (including internal audits and verification of supporting documents prior to signing eligibility declarations); and
- (b) corrective actions to restore control; and
- (c) any actions to be undertaken when corrective actions are not effective; and
- (d) management of export eligibility disposition; and
- (e) preventive actions; and
- (f) follow-up actions to ensure control is maintained

Recognised Agency Technical Manager is the Recognised Agency manager with overall technical accountability for the agency

Recognised agency means an agency recognised under section 103 of the Act to perform verification

Regulatory requirement means any legal requirement as required by the Animal Products Act 1999, associated regulations and relevant notices

Routine verification means verifications done in accordance with Schedule 2. This includes unscheduled and unannounced verifications carried out under clause 17(1)(b) and 17(2)

Shut down occurs where an animal product business temporarily ceases all or some of its functioning under the Act and there is an anticipated re-start date

Site means a single distinct geographical location

Start-up meeting means a meeting between the accountable person and the operator prior to commencement of the first verification. This is because either: the operation is a new animal product business; or the Recognised Agency is verifying the business for the first time

Unannounced verification means a visit that has minimal or no prior notification.

Unscheduled verification means a visit that is notified a week or more advance, but is occurring within a shorter timeframe than the step would normally indicate

Verifier means a person recognised under section 103 of the Act to undertake verification

- (2) Any term or expression that is defined in the Animal Products Act 1999, Animal Products (Ancillary and Transitional Provisions) Act 1999, or regulations made under those Acts and used, but not defined, in this Programme has the same meaning as in those Acts or regulations.

Part 2

General Export Verification Requirements

4 General

- (1) Overseas market access requirements take precedence over the requirements of this programme.
- (2) A verifier should be confident in the eligibility for export of any animal material or product. If not, the verifier should take appropriate actions to ensure those animal materials or animal products are excluded from affected markets. Such actions may include:
 - (a) notifying MAF of a recommendation for the suspension of official assurances issued on behalf of that premises to affected markets
 - (b) increasing the verification frequency and/or intensity.

Note: The verifier is obligated to verify compliance with the requirements of export notices, such as Official Assurance Specifications and OMARs.

5 Right of appeal

- (1) An operator dissatisfied with a decision made by a verifier can seek a review of that decision. When requesting a review, the operator should follow any Recognised Agency procedure, or procedure published by MAF.
- (2) An operator seeking a review of an assigned performance level must operate according to the notified level until a decision from the appeal process is made.

6 Premises shutdown

- (1) An animal product business that is in shut-down must meet the minimum verification requirements for any activities that continue to function (eg ongoing storage of animal products at a premises).
- (2) The verifier, in consultation with the Recognised Agency Technical Manager, may reassess the verification needs, and apply a suitable interval during this period.

Note: After an extended shut down, the verifier should conduct a pre-start verification, at the discretion of the Recognised Agency Technical Manager.

- (3) Animal product businesses with country listings: The operator must maintain the business in a manner that permits processing to start at short notice for those countries.
- (4) Sub-clause (3) does not apply to parts of an animal product business premises that are subject to substantial alteration or maintenance work.

7 Dormancy

- (1) Animal product businesses with specific country listings: Prior to re-starting, the operator should arrange a regulatory market access review by the verifier before the restart of operation. The review should confirm compliance with specifications and any overseas market access requirements for the listed country.
- (2) Where an animal product business is in an extended period of dormancy, country listings for that animal product business may be removed.
- (3) The verifier, in consultation with the Recognised Agency Technical Manager, may reassess the verification needs, and apply a suitable interval during this period.

- (4) An operator may elect to maintain a dormant animal product business in a state of shut-down.

Note: After extended dormancy, the verifier should conduct a pre-start verification, at the discretion of the Recognised Agency Technical Manager.

8 Closure

To maintain eligibility for official assurances, the operator must transfer animal material and animal product to another suitable animal product business prior to closure. The operator must ensure the applicable requirements for animal material and animal product transfers are met.

9 Key responsibilities of verifiers

- (1) The accountable person should —
- (a) structure verification activities in line with standard verification practices and protocols (verifiers are to include unscheduled visits in accordance with the requirements of this Programme); and
 - (b) schedule verification to adequately cover all periods of operation, including any shifts; and
 - (c) not take over any tasks which are the responsibility of the operator to perform; and
 - (d) determine an outcome after each verification and,
 - (i) assign a verification interval, as set out in schedules 1 and 2, to the animal product business premises.

10 Initial meeting for new businesses or businesses being verified by a Recognised Agency for the first time

The accountable person should have a start-up meeting with the operator, and ensure the following points, as relevant, are discussed and recorded—

- (a) Recognised Agency and verifier responsibilities; and
- (b) the duties of the Recognised Agency and verifiers; and
- (c) the operator's responsibilities and duties in relation to verification performed in accordance with this Programme; and
- (d) an overview of the regulatory framework including, as applicable:
 - (i) verification,
 - (ii) official assurance requirements,
 - (iii) overseas market access requirements and country listings,
 - (iv) general requirement for export; and
- (e) the appeal process in relation to verification.

Note 1: A new business is 'new' because it has either

- *commenced operations for the first time or*
- *had a significant change in scope.*

11 Performing verification

- (1) The verifier should advise the operator in advance of the scope of the upcoming verification visit. The scope should broadly include, as a minimum—
- (a) an assessment of the operator's verification activities, including monitoring and corrective actions; and
 - (b) an assessment of any records relating to those activities; and
 - (c) a physical check of the business during the verification visit.

Note: Monitoring includes operator monitoring activities and market access testing.

- (2) Despite advising the scope, the verifier is not restricted to the planned scope should it be justified to expand the areas of verification.
- (3) The verifier's objective is to determine whether the operator is consistently meeting relevant regulatory and export requirements.

- (4) The verifier should ensure verification activities adequately cover all periods of operation at a premises, including shifts.
- (5) The verifier should assign one of the following outcomes on the completion of a verification visit—
 - (a) **An acceptable outcome**, where the verifier is satisfied that—
 - (i) the operator is substantially complying with regulatory or export requirements; and
 - (ii) where there have been any departures from requirements, the operator's corrective actions are appropriate and being applied effectively.
 - (b) **An unacceptable outcome**, where the verifier has determined that the operator is not in substantial compliance with regulatory or export requirements.

*Note 1: An operator is considered to be **not** in substantial compliance where:*

- (a) *the operator verification process repeatedly fails to identify deficiencies; or*
- (b) *the operator verification is ineffective: operator deficiencies are not effectively managed, or there are numerous non-compliances that collectively indicate a trend towards loss of control; or*
- (c) *the accountable person lacks confidence in the system because the required records are absent, or incomplete, or have been altered; or*
- (d) *the operator is not in substantial compliance with their duties as an operator.*

Note 2: The following should contribute to the report and collective findings, but are not of themselves reasons for an unacceptable outcome:

- (a) *the outcome of any overseas market rejecting that has occurred within the verification period, and*
 - (b) *the issuing of any corrective action requests.*
- (6) Each audit outcome will determine the subsequent premises verification step according to the performance-based verification stepping protocol set out in Schedule 3.

12 Reporting responsibilities of accountable persons

Accountable persons should ensure verification reports are provided to the operator for all verification activities carried out under this programme.

13 Follow-up action

- (1) The operator should confirm to the verifier that any deficiencies have been addressed within the agreed period of time.
- (2) The verifier may make unscheduled visits, in line with standard verification practices and protocols, to confirm follow-up actions have been completed as agreed.
- (3) As part of the follow-up verification, the verifier may request that documented evidence of the corrective actions is supplied.

14 Poor performing operations (Step 1 or Step 2)

- (1) A poor performing operation is one which is on Step 1 or Step 2 prior to the unacceptable outcome.
- (2) When there is an unacceptable outcome on Step 1 or Step 2 —
 - (a) the operator should prepare a written corrective action management plan
 - (b) the verifier should provide written notification to the operator of issues required to be addressed in the plan, and
 - (c) the operator should send the plan to the verifier for their agreement within 10 working days of receiving the notification.
- (3) The operator should include in their written corrective action management plan—

- (a) a description of the investigation process covering what will be done to identify the root cause of the deficiency; and
- (b) the specific actions they intend to take to resolve the root causes, and
- (c) description of how these actions are expected to prevent recurrence of the deficiencies; and
- (d) the expected time frames for implementation of the specific actions.
- (e) how, in the interim, they will produce product fit for intended purpose, including compliance with overseas market access requirements.

Note: Where an operator is appealing an unacceptable outcome, they are not required to prepare a written corrective action management plan. If the appeal decision upholds the unacceptable outcome, the operator's 10 working day deadline commences from the day the decision is notified. Despite this, the operator should still actively address any deficiencies identified even when the outcome of the appeal is pending.

15 Verifiers

Different verifiers, from the same Recognised Agency, may verify an animal product business premises on separate occasions. The Recognised Agency should have a system in place to manage communication and continuity between verifiers.

16 Notice

Verifiers should give at least two weeks notice to the operator of their intention to conduct routine verification visits required by this programme. Notice is not required in the case of unscheduled verification, or unannounced verification.

17 Unscheduled verification

- (1) The verifier should perform unscheduled verification visits at each animal product business premises.
 - An unscheduled verification visit may occur when the verifier has reason to believe that the operator is not meeting regulatory or export requirements.
 - An unscheduled verification visit should occur for 1 out of 5 routine visits.
- (2) 1 out of 2 unscheduled verification visits must be unannounced. Despite clause 11(1), verifiers are not required to advise the scope of unannounced visits in advance.
- (3) The accountable person should use their professional judgment when determining the scope of the unscheduled visit.

Note: verifiers should take account of health and safety requirements and obligations when they arrange for unscheduled and unannounced verification visits.

18 Consequences of unacceptable outcomes

- (1) Following an unacceptable outcome on Step 1 (in addition to the requirements of clause 14)—
 - (a) the operator should be placed on Step 00,
 - (b) MAF, in consultation with the Recognised Agency Technical Manager, will decide on an appropriate verification interval for the operation,
 - (c) MAF, in consultation with the Recognised Agency Technical Manager and the operator, will determine the conditions for return to step 1 verification interval,
 - (d) the operation can only return to step 1 when the agreed conditions have been met.

Note: The Recognised Agency should consider the serious operator failure Step 00 represents, particularly in respect of eligibility for official assurances. Verifiers should regard the issuing of official assurances for an export approved premises while on Step 00 as inconsistent with overseas market expectations.

19 Reporting responsibilities of verifiers

- (1) On completion of a verification visit, the verifier should —
 - (a) Inform the operator in writing of —
 - (i) any deficiencies found during the verification visit; and
 - (ii) the likely outcome of the verification visit; and
 - (iii) the consequential change to the verification interval, if any in accordance with schedule 3; and
 - (iv) the intended date of next routine verification (this does not prevent unscheduled verifications, see clause 17 of this Programme).
 - (b) advise the Recognised Agency Technical Manager as soon as practical if an unacceptable outcome. The Recognised Agency Technical Manager, unless otherwise specified, must advise the Director (Compliance), as soon as practical, if adverse effects on human health or export certification are likely.
 - (c) After completing any follow-up activities, the verifier has 10 working days to provide a written report to the recognised verifying agency and the operator. The report should confirm (or amend as necessary), and provide further detail as needed, the information required in sub-clause (1)(a).

20 Verification requirements for seasonal operations

- (1) This clause addresses situations where an animal product business is on a verification interval which exceeds the length of their operating season, but is less than annual. For instance an animal product business that only operates for four months per year, but who is on step 6 (6 month interval).
- (2) If the situation in sub-clause (1) arises the verifier should conduct two routine verifications during the operating period.

Note: Where an acceptable or unacceptable outcome leads to a corresponding verification step change this clause may no longer be applicable.

21 Verification where more than one export approved premises applies to a business site or an export approved premises applies to more than one business premises

- (1) In, general one business site means one verification interval.
- (2) Where more than one export approved premises applies to a business premises, the site will normally be verified as a whole. The premises whose activities correspond to the lowest ceiling step determines the ceiling step for the whole site.
- (3) Each premises may be subject to separate verification intervals if the premises on a business site do not interact in any way. The Recognised Agency Technical Manager and the operators of the premises should agree to this in writing.
- (4) Where a export approved premises applies to more than one business site, then each business site will be verified independently of the other sites.

Part 4 Provisions for Recognition of Prior Performance

22 Application

This Part puts in place criteria that allow for accelerated progression towards the ceiling frequency. The operator should demonstrate prior satisfactory performance, and achieve an acceptable outcome for the initial export verification.

23 Criteria for Recognition of prior performance for businesses taking export opportunities

- (1) This recognition of prior performance provision applies to the following categories of animal product businesses—
 - (a) premises supplying the domestic market only.
- (2) Businesses will be subject to the relevant initial verification step. An acceptable outcome permits the verifier to re-assign the business to any verification step up to the ceiling step.
- (3) In determining the subsequent verification step in accordance with sub-clause (2), the verifier should consider—
 - (a) the outcome of the initial or any subsequent verification visit, and
 - (b) any known history of regulatory compliance, and
 - (c) the adequacy and suitability of the systems in place to give the verifier confidence in the business' ongoing animal health performance.
- (4) This recognition of prior performance provision does not override—
 - (a) the verification ceilings established by Schedule 2, or
 - (b) any specific, relevant, overseas market access requirements, including where a country requires and initial listing inspection visit.
- (5) This recognition of prior performance provision can only be applied with the consent of the Recognised Agency Technical Manager.

Schedule 1**Performance Based Verification (PBV) intervals**

Verification step	Verification interval
Step 00	To be determined by the Director (Compliance)
Step 1	2 weeks
Step 2	1 month
Step 3	6 weeks
Step 4	2 months
Step 5	3 months
Step 6	6 months
Step 7	1 year

Schedule 2**Initial export verification steps and ceilings for premises**

Animal product business		
	Initial Step	Ceiling Step
Poultry hatcheries	Step 6	Step 7
Germplasm	Step 6	Step 7

Schedule 3**Change in verification interval**

Verification Step	Number of consecutive acceptable outcomes required to move to a higher step	Number of unacceptable outcomes to move to a lower step
1	3 (move to step 2)	1 (Move to step 00)
2	3 (move to step 3)	1 (move to step 1)
3	2 (move to step 4)	1 (move to step 2)
4	2 (move to step 5)	1 (move to step 3)
5	2 (move to step 6)	1 (move to step 4)
6	2 (move to step 7)	1 (move to step 5)
7	—	1 (move to step 6)