

# **Operational Code**

# Verification Statement

[Document Date]

# Consultation

Issued by the Ministry for Primary Industries

New Zealand Government

# TITLE

Operational Code: Verification Statement

# COMMENCEMENT

This Operational Code is effective from date of signing.

# REPLACEMENT

This Operational Code replaces:

- a) The Verification 2005 Statement of Policy, dated 31 March 2005
- b) The Amendment to 2005 Verification Statement of Policy, dated 23 April 2012.
- c) Sections 29 to 32 in DPC 3: Animal Products (Dairy): Approved Criteria for the Manufacturing of Dairy Material and Product.

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# **ISSUING BODY**

This Operational Code is issued by the Ministry for Primary Industries.

Dated at Wellington, [Document Date]

[Approver] Manager Animal Products Ministry for Primary Industries

Contact for further information Ministry for Primary Industries (MPI) Regulation & Assurance Branch PO Box 2526 Wellington 6140.

Email: animal.products@mpi.govt.nz

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# Introduction

This introduction is not part of the Operational Code, but is intended to indicate its general effect.

# Purpose

This statement specifies what MPI will apply in regard to the performing of verification under the Animal Products Act 1999 (APA) for businesses producing animal material and products other than, live animals and germplasm. This statement does not apply to businesses producing animal material or products which are to be exported with an official assurance.

This statement contains:

- a) the MPI requirements in respect of the performance of verification activities for animal product businesses; and
- b) the standard initial verification frequencies, the performance measures around changing verification frequencies and the minimum or ceiling frequencies that apply to businesses covered by this statement; and
- c) provisions allowing for variation to the standard verification frequencies, changes and minimum or ceilings frequencies for certain business situations.

# Background

Verification is an integral part of ensuring compliance with the APA. Verification is a way of ensuring that operators who process animal material and animal products for export are complying with the requirements of their risk management programmes (RMP). Verification is carried out by competent third party verifiers with knowledge of existing standards and requirements as well as knowledge of the nature the operators' business operations.

# Who should read this Operational Code?

This code applies to those agencies and persons performing verification under the APA for animal material and products other than, live animals and germplasm.

# Why is this important?

This Code is a guidance document on how to meet APA requirements.

## **Document History**

Version Date	Section Changed	Change(s) Description
31 March 2005	New	Verification 2005 Statement of Policy
23 April 2012		Amendment to Verification 2005 Statement of Policy
October 2018	All	Completely revised document

# Part 1: Requirements

# 1.1 Application

- (1) Subject to clause (2), this statement applies to:
  - a) all animal product businesses, that are listed, or registered, or have registered RMPs under the APA ; and
  - b) businesses operating under a regulated control scheme made under the APA where that scheme specifically provides that the verification set out in this Statement applies; and
  - c) recognised verifying agencies and recognised verifiers.
- (2) This statement does not apply to:
  - a) animal product businesses that are exporting with an official assurance; and
  - b) animal products businesses that are handling live animals (other than processed live animals) and germplasm for export.

## 1.2 Definitions

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

APA means the Animal Products Act 1999

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

business means an animal product business as described in section 4(1) of the APA

ceiling means the maximum verification step achievable, as set out in Schedule 2 of this statement

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

deficiency means any departure from a regulatory requirement that is reasonably likely to ---

- a) result in exposure of humans or animals to an unacceptable level of hazard; or
- where there is significant repetitive or collection of departures from regulatory requirements, even though these would be unlikely to trigger the impacts listed in (a)

**emerging business** includes an animal product business that is involved with processing animal material or product that has not traditionally been processed in NZ, and processes irrespective of the length of time that particular business has been established

**fishing vessel** means any vessel registered under the Fisheries Act 1996 that is operating a registered RMP

MPI means the Ministry for Primary Industries

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

**operator verification** means the application of methods, procedures, tests and other checks by an operator to confirm the ongoing:

- a) compliance of the RMP with the legislative requirements: and
- b) compliance of the operation with the RMP as written; and
- c) applicability of the RMP to the operation; and
- d) forms part of confirmation as described in section 17(3)(f) of the APA

**new business** is 'new' because it has either commenced operations for the first time or because it has had a RMP registered for the first time or become subject to a regulated control scheme (that links to this Statement) for the first time

**recognised verifying agency** means an agency recognised under section 101 or 102 of the APA to perform verification

**regulatory requirement** means any requirement of the APA, associated regulations and notices that apply, and the registered RMP

**risk management programme (RMP)** means a risk management programme that is registered under Part 2 of the Act

**shut down** means where, due to maintenance or the seasonal unavailability of animal material or product, or suspension of the RMP under section 27(4A) of the APA an animal product business temporarily ceases all or some of its functions

verifier means a person recognised under section 103 or 104 of the APA to undertake verification.

(2) Any term or expression that is defined in the APA, or regulations made under the APA and used, but not defined, in this Statement has the same meaning as in the APA or regulations.

# Draft for Consultation

# Part 2: General Verification Requirements for Businesses

# 2.1 Application

(1) This Part applies to all businesses covered by this Statement

## 2.2 Roles and responsibilities of verifiers

- (1) The verifier must:
  - a) structure verification activities in line with standard verification practices and protocols as laid out in agency's quality management system; and
  - b) include an unscheduled visit in accordance with the requirements of clause 2.4 of this Statement; and
  - c) schedule verification visits to adequately cover all periods of operation, including night shifts; and
  - d) not carry out any tasks that are the responsibility of the operator to perform; and
  - e) determine an outcome after each verification and accordingly assign a verification frequency, as set out in Schedule 1, to each business.
- (2) Different verifiers of the same recognised verifying agency may verify a business on separate occasions if regular dialogue, including any meetings or joint visits, is maintained between those verifiers.

# 2.3 Start-up meeting for new businesses

- (1) Prior to commencing verification of a new business the recognised verifying agency must ensure that each of the following points relevant to the business are discussed (and provided by a means suitable for future reference by the operator) in a start-up meeting with the operator
  - a) the responsibilities of the recognised verifying agency and verifier; and
  - b) the duties of the recognised verifying agency and verifier; and
  - c) the rights of verifiers and the powers of animal product officers and where relevant official assessors; and
  - d) the operator's responsibilities and duties in relation to verification performed in accordance with this Statement; and
  - e) an overview of the regulatory framework, including verification; and
  - f) the appeal process in relation to verification.

# 2.4 Performing verification

- (1) The objective of the verification is to make a determination as to whether the operator is consistently meeting the regulatory requirements relevant to their business.
- (2) At the commencement of verification, the verifier must advise the operator of the scope of verification, which must include:
  - 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 unless an alternative has been agreed by the Manager Animal Products.
- (3) Despite advising the scope, the verifier is not restricted to that scope during the verification visit should it be justified to expand the areas of verification.
- (4) The verifier must 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 requirements; and
  - ii) where there have been any departures from requirements, this has been identified by the operator and their corrective and preventative actions have been, or are being applied appropriately and are effective.
- b) An unacceptable outcome, where the verifier has determined that the operator is not in substantial compliance with regulatory requirements.

#### Guidance

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

- 1. operator verification repeatedly fails to identify deficiencies; or
- 2. operator verification is implemented in a manner that is ineffective because deficiencies are not effectively managed or there are numerous non-compliances that individually do not constitute a deficiency, but collectively indicate a trend towards loss of control; or
- 3. the required records are absent or are incomplete or have been altered, to a degree that prevents the verifier having confidence in the system being verified; or
- 4. the operator is not in substantial compliance with their duties as an operator.

### 2.5 Unscheduled and unannounced verification

- (1) An unscheduled or unannounced verification visit may occur when
  - a) the verifier has reason to believe that the operator is not meeting regulatory requirements; or.
  - b) the agency technical manager considers that it is necessary to ensure the operator is operating in compliance with regulatory requirements; or
  - c) required by the Manager Animal Products or Manager Food and Live Animal Assurance, MPI.
- (2) The verifier will use their professional judgment when determining the scope of the verification for an unscheduled or unannounced visit.

#### 2.6 Premises shutdown

- (1) During periods of shutdown, the verification frequency of the business may be reassessed by the verifier, in consultation with the agency technical manager and taking into account any conditions on the RMP relating to verification, and a suitable frequency applied.
- (2) A business that is in shut-down must meet the minimum verification requirements (including frequencies) for any activities that continue to function.

## 2.7 Reporting responsibilities of verifiers

- (1) On completion of a verification visit the verifier must inform the operator verbally of:
  - a) any deficiencies found during the verification visit; and
  - b) the likely outcome of the verification; and
  - c) any consequential change to the verification frequency, in accordance with Schedule 3; and
  - d) when the next verification will take place (this does not prevent the verifier from making an unscheduled or unannounced verification visit in accordance with section 2.5).
- (2) On completion of a verification visit, the verifier must provide the recognised verifying agency and operator with a written report within 5 working days which includes
  - a) the outcome of the verification and any change to the verification frequency in accordance with Schedule 3; and
  - any deficiencies and the follow up actions to be carried out by the verifier to confirm that the operator has addressed each deficiency; and

- c) when the next verification will take place (this does not prevent the verifier from making an unscheduled or unannounced verification visit in accordance with section 2.5).
- (3) Recognised verifying agencies must operate a system whereby verification reports and outcomes are centrally recorded for performance monitoring and audit purposes.

# 2.8 Follow-up action

- (1) The verifier must confirm with the operator that any follow-up actions have been addressed within the agreed period of time.
- (2) The verifier may perform follow-up actions, which may include unscheduled or unannounced visits, at their discretion to confirm that the operator has undertaken any corrective and preventative actions in the manner and timeframe agreed.
- (3) As part of the follow-up action, the verifier may request that documented evidence of the corrective and preventative actions are supplied and within a certain timeframe.

## 2.9 Unacceptable outcomes on step 1 or step 2

- (1) Where a business is assigned an unacceptable outcome on step 1 or step 2, despite the verification frequencies set out in Schedule 1 of this Statement,
- (2) The agency technical manager must agree with Manager Animal Products, MPI or the Manager Food and Live Animal Assurance, MPI an appropriate course of action that will assist the premises to meet regulatory requirements. This must include how in the interim any continued processing will be managed to produce product that is fit for its intended purpose.

#### Guidance

Actions could include:

- corrective action management plan
- Notice of Direction under section 81 of the APA
- conditions added to the RMP
- suspension of the RMP
- suspension of exports
- increased verification
- issuing an improvement notice under the APA.

# 2.10 Right of appeal

- (1) An operator who is dissatisfied with a decision made by a verifier can seek a review of that decision by applying to the recognised verifying agency.
- (2) If the operator is dissatisfied with the decision of the recognised verifying agency they can seek a review of that decision with Manager Food and Live Animal Assurance, MPI.
- (3) An operator seeking a review of a verification frequency assigned by a verifier must operate according to that frequency until a decision from the recognised verifying agency or MPI is given.

# Part 3: Specific Clarifications of the Verification Frequencies

# 3.1 Application

- (1) This Part applies to the following businesses:
  - a) multi-business, multi-site, or multi- RMP situations;
  - b) emerging businesses;
  - c) businesses moving from the Food Act; and
  - d) businesses where the RMP conditions contain specific requirements around verification.

## 3.2 Verification frequencies for multi-business, multi-site, or multi-RMP situations

- (1) Where more than one RMP applies to a business site, then the business operator and the recognised verifying agency may agree that the site may be verified as a whole, and when this is the case, the most frequent verification frequency will be applicable to the whole site.
- (2) Where an RMP applies to more than one business site (other than for farm dairies), then each business site will be subject to this Statement (as if it had its own RMP) in accordance with any direction provided by the Manager Animal Products, MPI. The verification frequency can vary between the individual sites.
- (3) Where a business is under a multi-business RMP, then each business entity (other than farm dairies) will be subject to this Statement in accordance with any direction provided by the Manager, Animal Products, and the verification frequency may vary between the individual businesses.
- (4) Where a multi-business RMP relates to farm dairies, the number of farms subject to verification will be in accordance with the procedure issued by the Manager Dairy Products, MPI.

# 3.3 Verification frequencies for emerging businesses

- (1) Where an animal product business is an emerging business and the application of the verification frequencies determined from Schedules 1 and 2 are not considered appropriate by the verifier, then the verifier can advise the operator to make a written request to the applicable agency technical manager for a dispensation to be made on a case-by-case basis.
- (2) The application will be considered by the recognised verifying agency's technical manager in conjunction with the Manager, Animal Products, and a decision will be made on what verification arrangement will be applied.
- (3) This decision will be notified by the verifying agency to the operator.
- (4) In all cases where an altered verification arrangement is applied, it will be subject to the requirement that the operator must provide its recognised verifying agency with written advice of any change in the processing profile that mean that it is more appropriate for the frequencies in Schedules 1 and 2 to apply to the business.

# 3.4 Verification for businesses moving from the Food Act regime

(1) Where a business which has been operating a food control plan or national programme under the Food Act moves to an RMP and the registration or scope of operations is essentially the same, the verification step that applied under the Food Act may be used as a starting verification step for the RMP.

# 3.5 Verification when included in the conditions of a RMP

(1) If specific verification frequencies are included in the condition on the registered RMP those frequencies will apply instead of the ones in the Schedules to this statement.

# Draft for Consultation

# Schedule 1 – Verification frequency for premises

Verification step	Verification frequency	
Step 1	2 weekly	
Step 2	1 monthly	
Step 3	6 weekly	
Step 4	2 monthly	
Step 5	3 monthly	
Step 6	6 monthly	
Step 7	1 yearly	
Step 8	18 monthly	
Step 9	3 yearly	
Step 10	5 yearly (20% of businesses within the business category each year)	

# Draft for Consultation

# Schedule 2 – Initial verification frequencies and ceilings

Animal product business	Highest initial frequency	Frequency after initial acceptable verification	Ceiling frequency
Primary processors of mammals and birds for human consumption	Step 5	Step 7	Step 7
Secondary processors of mammals and birds for human consumption	Step 5	Step 7	Step 8
Primary and secondary processors of seafood for human and animal consumption, including fishing vessels	Step 5	Step 7	Step 8
All other processors of animal product for human consumption	Step 5	Step 7	Step 8
Primary processors of mammals and birds for animal consumption <sup>1</sup>	Step 5	Step 7	Step 7
Secondary processors of mammals and birds for animal consumption	Step 5	Step 7	Step 8
All other processors <sup>1</sup> of animal product for animal consumption	Step 5	Step 7	Step 8
All other businesses that have a RMP but not covered by the above animal product business descriptions	Step 5	Step 7	Step 8
Killed wild mammal material depots	Step 5	Step 7	Step 8
Fish (other than bivalve molluscan shellfish) material depots	Step 8	Step 10	Step 10
Bee processors that have a RMP	Step 7	Step 7	Step 8
Farm dairies	Step 7	Step 7	Step 9
Dairy processors	Step 5	Step 7	Step 8
Stores, transporters and apiarists	Step 5 <sup>2</sup>		

<sup>&</sup>lt;sup>1</sup> This includes processors that are 'further (pet food) processors', as defined in the Animal Products Notice: Specifications for Products Intended for Animal Consumption 2017, who sell animal material / animal product by wholesale or undertake processes other than size reduction and/or packing.

<sup>&</sup>lt;sup>2</sup> There is a one off verification unless there is a specific reason, e.g. complaint to undertake another verification

# Schedule 3 – Changes in verification frequency

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 (removal of premises from verification programme)
2	3 (move to step 3)	1 (move to step 1)
3	<b>2</b> (move to step 4)	1 (move to step 2)
4	<b>2</b> (move to step 5)	1 (move to step 3)
5	<b>2</b> (move to step 6)	1 (move to step 4)
6	2 (move to step 7)	1 (move to step 5)
7	2 (move to step 8)	1 (move to step 6)
8	DIAILI	1 (move to step 7)

# Consultation