Verification

For animal products businesses under the Animal Products Act

5 December 2019

TITLE

Operational Code: Verification

COMMENCEMENT

This Operational Code is effective from 1 March 2020.

REPLACEMENT

This Operational Code replaces:

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

ISSUING BODY

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

Dated at Wellington, 5 December 2019

Nigel Lucas Manager Animal Products Ministry for Primary Industries

Contact for further information Ministry for Primary Industries (MPI) New Zealand Food Safety Food Regulation 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

The purpose of verification is to gather evidence to assist in determining whether an operator who processes animal material and animal products is consistently meeting the regulatory requirements relevant to their business.

This Operational Code describes the expectations for recognised agencies and recognised persons performing external verification under the Animal Products Act 1999 (APA), for businesses producing animal material and products, other than live animals and germplasm. This Operational Code only applies to businesses producing animal material or products for domestic sale or those that are to be exported without an official assurance.

This Operational Code contains:

- a) expectations for recognised agencies and persons performing verification; and
- b) verification steps for performance based verification; and
- c) the default initial verification step, performance measures around changing verification steps and the ceiling steps that apply to businesses covered by this Operational Code; and
- provisions to vary to the initial verification step, standard verification steps and minimum or ceiling steps.

Background

External verification is an integral part of ensuring compliance with the APA. Verification is a way of confirming whether operators who process animal material and animal products are complying with the requirements of their risk management programmes (RMP), regulated control scheme (RCS) and the APA. External verification is carried out by competent third party verifiers who are recognised by MPI, with knowledge of applicable standards and requirements as well as knowledge of the nature of the operators' business.

Who should read this Operational Code?

This Operational Code should be read by persons to whom section 1.1 of this Code applies.

Why is this important?

This Operational Code explains to business operators, recognised agencies and recognised persons the external verification activities and frequencies that are appropriate to animal product business under the APA.

Document History

| Version Date | Section Changed | Change(s) Description |
|---------------|-----------------|--|
| December 2019 | All | New document combining and updating the Verification 2005 Statement of Policy, the 2012 amendment to 2005 Verification Statement of Policy and Sections 29 to 32 of DPC 3. |

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Part 1: Preliminary Provisions

1.1 Application

- (1) This Operational Code applies to:
 - all animal product businesses (both dairy and non-dairy), that are listed, or registered, or have registered RMPs under the APA, including those that are exporting to countries where official assurances are not required; and
 - b) businesses operating under a RCS made under the APA where that scheme specifically provides that the verification set out in this Operational Code applies; and
 - c) recognised agencies, persons and classes who perform verification for animal product businesses.
- (2) This Operational Code does not apply to:
 - a) registered exporters; and
 - b) animal products businesses that are exporting with an official assurance; and
 - c) animal products businesses that are handling live animals (other than processed live animals) and germplasm for export; and
 - d) animal products businesses that operate under the <u>Animal Products Notice: Raw Milk for Sale to Consumers</u>; and
 - e) animal products businesses that operate under a risk based measure under the Food Act 2014.
- (3) If there is any conflict, duplication or inconsistency between the content of this Operational Code and the requirements in the APA, including Animal Products Notices and the overseas market access requirements (OMARs), the requirements in those documents prevail.

1.2 Definitions

(1) In this Operational Code

acceptable outcome means the verifier is satisfied:

- a) that the operator is substantially complying with applicable regulatory requirements; and
- b) where there have been any departures from requirements, that the operator's corrective and preventative actions have been, or are being applied appropriately and are effective

APA means the Animal Products Act 1999

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

ceiling step means the longest interval between verification visits for animal product businesses that consistently achieve acceptable verification outcomes, as set out in Schedule 2

emerging business includes an animal product business that is involved with processing animal material or product that has not traditionally been processed in NZ, 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 under a registered RMP

initial verification step means the first verification step that automatically applies to all new animal products businesses and is the time between when the business is registered or listed and the first verification to occur

MPI means the Ministry for Primary Industries

new business means a business that 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 RCS (that links to this Operational Code) for the first time

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

regulatory requirement means any requirement of the APA, Food Act, associated regulations and notices that apply, and the registered RMP or RCS

shutdown means where an animal product business temporarily ceases some or all of its operations (e.g. due to maintenance activities, financial difficulties, or the seasonal availability of animal material or product) or operations are suspended under section 27(4A) of the APA

unacceptable outcome means the verifier has determined that the operator is not in substantial compliance with applicable regulatory requirements

unannounced verification means a verification visit that has minimal or no prior notification to the business, other than that necessary to ensure access and availability of required staff

unscheduled verification means a visit that is notified to the business in a shorter timeframe than would be expected for a scheduled visit (e.g. notified approximately a week in advance of the visit)

verifier means a recognised person who performs verification functions and activities

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

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Part 2: General Verification Requirements

2.1 Application

(1) Refer to section 1.1 for the application of this Part.

2.2 Roles and responsibilities of verifiers

- (1) The verifier is responsible for ensuring that:
 - a) the structure of the verification activities are in line with standard verification practices and protocols as laid out in their agency's quality management system; and
 - b) they schedule verification visits to adequately cover all periods of operation, including night shifts; and
 - c) they do not carry out any tasks that are the responsibility of the operator to perform; and
 - d) unscheduled verification visits are carried out in accordance with section 2.8.

Guidance

Different verifiers of the same recognised agency may verify a business on separate occasions if regular peer reviews and dialogue, including any meetings or joint visits, are maintained between those verifiers.

2.3 Performing verification

- (1) Operators of animal product businesses are to arrange for a verifier to verify their animal product business in accordance with this Operational Code.
- (2) Subject to <u>sections 3.4</u> to <u>3.6</u>, the first verification visit for a new business is to occur in accordance with the appropriate initial verification step stated in Schedules 1 and 2.
- (3) Prior to commencing verification of a new business the recognised verifier is to discuss each of the following points relevant to the business in a start-up meeting with the operator, and to provide the information by a means suitable for their future reference:
 - a) the responsibilities of the recognised agency and the verifier; and
 - b) the duties of the recognised agency and the verifier; and
 - the rights of the verifiers and the powers of animal product officers and where relevant, official assessors; and
 - the operator's responsibilities and duties in relation to verification performed in accordance with this Operational Code; and
 - e) the regulatory framework, including the role and purpose of verification; and
 - f) the appeal process in relation to verification.
- (4) At the commencement of each verification visit, the verifier should advise the operator of the scope of verification, which should 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 relevant activities unless an alternative approach has been included in a document issued by MPI or agreed by the Manager Animal Products, MPI.

Guidance

The verifier should advise the operator of any other relevant verification requirements covered under the Animal Products Notice: Recognised Agencies and Recognised Persons and Animal Products Notice: Dairy Recognised Agencies and Recognised Persons.

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- (5) Despite advising the scope, the verifier is not restricted to that scope during the verification visit should it be justified.
- (6) The verifier must assign one of the following outcomes on the completion of a verification visit:
 - a) an acceptable outcome; or
 - b) an unacceptable outcome.

Guidance

Examples of where an outcome would be considered unacceptable and **not** in substantial compliance, include when:

- · operator verification repeatedly fails to identify deficiencies; or
- 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
- the required records, including procedures and other forms of evidence, are absent, incomplete or have been altered, to a degree that prevents the verifier having confidence in the system being verified; or
- the operator is not in substantial compliance with their duties.

2.4 Reporting responsibilities of verifiers

- (1) On completion of a verification visit the verifier should inform the operator verbally of:
 - a) any deficiencies found during the verification visit; and
 - b) the likely outcome of the verification as either acceptable or unacceptable; and
 - c) any likely consequential change to the verification step, in accordance with section 2.6; and
 - d) when the next verification visit is likely to take place.
- (2) On completion of a verification, the verifier should provide the recognised agency and operator with a written report as soon as practicable.
- (3) In relation to non-dairy operators, the written report referred to in section 2.4(2) is to include:
 - a) the name of the recognised person(s) responsible for the on-site verification; and
 - b) the premises name, address, RMP or RCS ID; and
 - c) the type of on-site verification (e.g. scheduled or unannounced), the date, verification period, and the report issue date; and
 - d) sufficient information to enable the reader to clearly understand the commentary and findings; and
 - e) the verification scope along with details of RMP or RCS components or elements covered; and
 - the outcome of the verification and any change to the verification step in accordance with <u>section</u> 2.6; and
 - g) details of any deficiencies together with details of the agreed corrective actions and the timeframe for those actions to be carried out; and
 - h) 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 2.8.

Guidance

The content of a dairy verification report is specified in clause 2.5 of the <u>Animal Products Notice: Dairy</u> Recognised Agencies and Recognised Persons.

2.5 Follow-up action of verifiers

(1) 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 defined timeframe.

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- (2) The verifier should confirm with the operator the status of outstanding actions, as per section 2.4(3)(g), once the agreed timeframe for resolution has been reached.
- (3) 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.

2.6 Criteria for moving between verification steps

- (1) To move from Step 1 to Step 2, and Step 2 to Step 3 of <u>Schedule 1</u>, the operator must achieve 3 consecutive acceptable outcomes between each step.
- (2) Subject to <u>Schedule 2</u>, to move to any higher step between Step 3 and Step 10 of <u>Schedule 1</u>, the operator must achieve 2 consecutive acceptable outcomes between each step.
- (3) In the event of an unacceptable outcome, the operator will be placed on a lower step.
- (4) Where a business is assigned an unacceptable outcome on Step 1 or Step 2, despite the verification frequencies set out in <u>Schedule 1</u>, the recognised agency should agree with Manager Animal Products, MPI or the Manager Food and Live Animal Assurance, MPI an appropriate course of action.

Guidance

Actions could include:

- the need for an agreed corrective action management plan;
- issuing of a Notice of Direction under section 81 of the APA;
- suspension of the RMP or RCS;
- suspension of exports (without OAs);
- issuing an improvement notice under section 86A of the APA;
- the need for direct MPI oversight.

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

2.8 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 recognised agency considers that it is necessary to ensure the operator is operating in compliance with regulatory requirements; or
 - c) required by the Manager Animal Products, MPI or Manager Food and Live Animal Assurance, MPI.

Guidance

Issues leading the verifier to have concerns about the operator's compliance with regulatory requirements may be identified during previous verification visits or at any time after the last verification visit.

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When carrying out an unannounced verification visit, sufficient notice needs to be provided to the operator to ensure that access to the premises and required personnel is available, but no further advance notice is to be given.

(2) The verifier will use their professional judgement when determining the scope of the verification for an unscheduled or unannounced visit.

2.9 Premises shutdown or infrequent processing

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

Guidance

During shutdown, the scope of the verification visit should be sufficient to cover the operations that continue and to ensure that the verifier has confidence that the premises remains in a fit state to resume processing.

- (3) The operator is required to advise the verifier in advance of resuming operations.
- (4) Where a business is an infrequent processor and verification falls at a time when there is no processing so that only documentation and records can be reviewed, and consequently the business "artificially moves up" the steps in <u>Schedules 1</u> and <u>2</u>, the verifier may adjust the verification step to limit the number of steps that maybe advanced before processing can be subject to verification.

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Part 3: Specific Clarifications of the Verification Steps

3.1 Application

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

3.2 Verification step for multi-business, multi-site, or multi-RMP situations

- (1) Where more than one RMP applies to a business site, the operator and the recognised agency may agree that the site may be verified as a whole. When this is the case, the most frequent verification step will be applicable to the whole site.
- (2) Where an RMP applies to more than one site (other than for farm dairies), then each site will be subject to this Operational Code or the verification step applied may be in accordance with any alternative approach agreed with the Manager Animal Products, MPI.

Guidance

For example, the verification step applied to each site may vary, or a number of sites may be sampled each time the verification is due rather than verifying every site on every occasion.

(3) Where a business is under a multi-business RMP, then each business entity (other than farm dairies) will be subject to this Operational Code or the verification step applied may be in accordance with any alternate approach agreed with Manager Animal Products, MPI.

Guidance

For example, the verification step may vary between individual businesses, or a number of businesses may be sampled each time the verification is due rather than verifying every business on every occasion.

(4) For farm dairies that come under a multi-business or multi-site RMP, the number of farm dairies to be subject to on-farm verification will be advised by the Manager Animal Products, MPI.

3.3 Verification step for emerging businesses

- (1) Where an animal product business is an emerging business and the verification steps in <u>Schedules 1</u> and <u>2</u> are not considered appropriate by the verifier, the verifier can advise the operator to make a written request to their recognised agency for a dispensation to be made on a case-by-case basis.
- (2) The application will be considered by the recognised agency in conjunction with the Manager Animal Products, MPI and a decision will be made on what verification arrangement will be applied.
- (3) The operator will be notified of the decision by the recognised agency.
- (4) In all cases where an altered verification arrangement is applied, it will be subject to the requirement that the operator provides its recognised agency with written advice of any change in operations that mean that it is more appropriate for the steps in <u>Schedules 1</u> and <u>2</u> to apply to the business.

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3.4 Verification step for businesses moving from the Food Act regime

(1) Where a business that had been operating with a food control plan (FCP) or national programme (NP) under the Food Act moves to an RMP and the scope of operations is essentially the same, the verification step that was applied under the Food Act may be used as an initial verification step for the RMP, unless a condition on the RMP registration indicates otherwise.

3.5 Verification step when included in the conditions of a RMP

(1) If a specific verification step is imposed by a condition on the registered RMP, that step will apply instead of the schedules in this Operational Code.

3.6 Verification step for businesses moving from the Export Verification Programme

- (1) This section applies to a business that had been operating under the <u>Animal Products Notice: Export Verification Requirements</u> (export notice) but has moved to operating in accordance with this Operational Code, and where the scope of operations is essentially the same (other than they no longer export to countries requiring an Official Assurance).
- (2) They will be placed on a verification step in this Operational Code that coincides with the frequency of verification applied under the export notice.

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Schedule 1 – Verification steps for businesses

A verification step listed under column 1 of Table 1 carries the corresponding verification interval attributed to it under column 2.

Guidance

Businesses that are on their ceiling step under the Verification 2005 Statement of Policy (Statement) need to complete the next verification visit in accordance with the Statement and may move to the new ceiling step under this Code by achieving an acceptable outcome during that verification visit.

Table 1: Verification steps and the corresponding verification intervals

| Verification step | Verification interval |
|-------------------|--|
| 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 | 1.5 yearly or 18 monthly |
| Step 9 | 2 yearly |
| Step 10 | 5 yearly (20% of businesses within the business category each year as selected by the recognised agencies) |

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Schedule 2 – Verification steps for domestic and export (without official assurances) businesses

A business listed under column 1 of Table 2 is subject to the corresponding initial verification step in column 2. On achieving an acceptable outcome during the initial verification visit, the business will be moved to the verification step indicated in column 3.

Table 2: Different businesses with the corresponding initial verification step and ceiling step

| Animal product business | Initial verification | Verification step if initial verification | Ceiling step |
|---|----------------------|---|-----------------|
| | step | is acceptable | · |
| 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 |
| Primary processors of mammals and birds for animal consumption | Step 5 | Step 7 | Step 7 |
| Secondary processors of mammals and birds for animal consumption | 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 product processors that have a RMP | Step 7 | Step 7 | Step 8 |
| Farm dairies | Step 5 | Step 6 | Step 8 |
| Dairy manufacturers | Step 5 | Step 6 | Step 8 |
| Stores | Step 5 | Step 6 | Step 7 |
| Dairy transporters of dairy material that is not packaged or is not shelf stable | Step 5 | Step 6 | Step 9 |
| Transporters (excluding dairy transporters of dairy material that is not packaged or is not shelf stable) | Step 5 ¹ | No verification required | |
| Apiarists | | | |
| All other processors of animal product for human consumption | Step 5 | Step 7 | Step 8 |
| All other processors ² 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 |

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¹ There is a one off verification unless there is a specific reason to undertake another verification, e.g. complaint.

² This includes processors that are 'further (pet food) processors', as defined in the Animal Products Notice: Specifications for Products Intended for Animal Consumption, who sell animal material or animal product by wholesale or undertake processes other than size reduction and/or packing.