



# Animal Products Regulations 2021

Cindy Kiro, Governor-General

## Order in Council

At Wellington this 29th day of November 2021

Present:

Her Excellency the Governor-General in Council

These regulations are made under sections 9, 15, 40, 44, 49, 77C, 77F, 77H, 117, 166, and 166A and clause 5 of Schedule 1 of the Animal Products Act 1999—

- (a) on the advice and with the consent of the Executive Council; and
- (b) on the recommendation of the Minister for Food Safety given in accordance with sections 9(2) and (3), 15(3), 40(2) and (3), 44(7), 49(3), 117(5), and 163 of that Act.

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### Regulations

#### 1 Title

These regulations are the Animal Products Regulations 2021.

#### 2 Commencement

- (1) These regulations, subject to subclauses (2) and (3), come into force on 1 July 2022.
- (2) Clause 3 of Schedule 1 comes into force on 28 February 2022.
- (3) Regulations 107 and 108 come into force on 1 July 2023.

#### 3 Interpretation

In these regulations, unless the context otherwise requires,—

**accreditation body** means an organisation that provides accreditation services that entail an independent assessment and confirmation of competence to perform specific tasks

**Act** means the Animal Products Act 1999

**agricultural compound** has the meaning given in section 2(1) of the Agricultural Compounds and Veterinary Medicines Act 1997

**corrective action** includes an action—

- (a) to restore control; or
- (b) to identify any affected animal material or animal product, and—
  - (i) ensure its fitness for intended purpose; or
  - (ii) manage its disposal; or
- (c) to prevent recurrence of a loss of control

**critical control point**, in relation to a hazard of significance referred to in section 17(3)(b) of the Act, means a point at which it is essential to use processes or procedures to control the hazard (whether by preventing or eliminating it, or reducing it to an acceptable level)

**critical limit** means a criterion, observable or measurable, relating to a control measure at a critical control point that separates acceptability from unacceptability of animal material or animal product

**critical measurement** means a parameter identified as critical—

- (a) in any regulations or regulated control scheme; or

- (b) in any notice issued under section 167(1) of the Act or any supplementary notice; or
- (c) by the operator of a risk management programme (including a parameter of the type referred to in section 17(3)(c) of the Act)

**critical non-compliance** means, in relation to a breach of a regulatory requirement, a breach that makes it reasonably likely that 1 or more of the following may occur:

- (a) animal or human health is adversely affected:
- (b) access to overseas markets is jeopardised:
- (c) the integrity of the official assurance system is threatened:
- (d) the integrity of test results is threatened

**essential services** includes gases for processing, lighting, refrigeration, ventilation, water, waste management, and other services essential to the production or processing and handling of animal material and animal product

**evaluator** means a recognised person or recognised agency who is recognised under the Act to carry out independent evaluations of the validity of risk management programmes and the validity of significant amendments to those programmes

**further petfood processor** means a person whose secondary processing of petfood is referred to in clause 17 of Schedule 2

**hunter** means a person who, for reward or the purposes of trade,—

- (a) carries out or directly supervises the killing or evisceration of wild mammals, game estate mammals, or farmed mammals that have gone feral; or
- (b) captures live possums

**input** includes animal material, animal product, or any thing (such as an additive, a processing aid, an ingredient, or packaging) that is intended to be contained within, attached to, enclosed with, or otherwise in contact with, animal material or animal product

**label** includes any written, pictorial, or other descriptive matter that—

- (a) relates to any animal material or animal product; and
- (b) appears on, is attached to, or is associated with that animal material or animal product, or its packaging

**loss of control** means that the operator of an animal product business or a risk management programme—

- (a) has breached a regulatory requirement; or
- (b) is likely to breach a regulatory requirement unless corrective action is taken

**maintenance compound** means any compound used—

- (a) for maintaining, repairing, servicing, cleaning, or sanitising equipment or surfaces that may be a source of contamination of animal material or animal product; or
- (b) for treating water; or
- (c) for controlling pests; or
- (d) for the personal hygiene of people; or
- (e) on live animals, other than for their therapeutic benefit, to improve, or maintain, or both, the hygiene and suitability of animal material for processing

**multi-business risk management programme** means a risk management programme approved under section 17A of the Act

**multi-site business** means an animal product business that operates out of more than 1 premises or place

**multi-site risk management programme** means a risk management programme that applies to a multi-site business

**non-conforming**, in relation to animal material or animal product, means any material or product that is known—

- (a) not to meet regulatory requirements; or
- (b) not to have been processed in accordance with regulatory requirements

**operator-defined limit** means a measurable limit, established by the operator of a risk management programme, to manage fitness for intended purpose of animal material or animal product

**packaging**—

- (a) includes inner and outer packaging of any kind; but
- (b) does not include bulk cargo containers

**pest** means any animal that is likely to transfer contaminants to animal material or animal product, but does not include—

- (a) animals used under direct supervision or control for the purpose of maintaining security; or
- (b) animals being processed or intended for processing

**recognised laboratory** means a person recognised under the Act as an agency to carry out laboratory functions and activities in relation to animal material or animal product

**regulatory limit** means a measurable regulatory requirement that is critical to the fitness for intended purpose of animal material or animal product

**regulatory requirement** includes any requirement lawfully made or imposed by or under this Act or the Food Act 2014, including the following:

- (a) regulations:
- (b) notices issued under section 167(1) of the Act:
- (c) supplementary notices:
- (d) other notices, and directions and conditions:
- (e) the Food Standards Code

**restore control**, in relation to an animal product business, means to ensure that the business is operating in a way that does not breach, nor is likely to breach, any regulatory requirements

**veterinary medicine** has the meaning given in section 2(1) of the Agricultural Compounds and Veterinary Medicines Act 1997

**waste** means any unwanted animal material, animal product, or associated things, including solids, liquids, and gases.

#### **4 Transitional, savings, and related provisions**

The transitional, savings, and related provisions set out in Schedule 1 have effect according to their terms.

## **Part 1**

### **Risk management programmes**

#### **Subpart 1—Contents and general requirements**

#### **5 Identifying information**

In addition to the requirements in section 17 of the Act, a risk management programme must set out the following information:

- (a) the trading name (if applicable) of the business:
- (b) the position, or name and position, of the person responsible for the day-to-day management of the programme:
- (c) the registration number or other unique identifier of the programme, when available:
- (d) any unique location identifier of the premises or place, if—
  - (i) the operator of the risk management programme is required by supplementary notice to have 1 or more unique location identifiers; and
  - (ii) it has been already assigned:
- (e) in relation to the premises or place,—
  - (i) its physical address; or

- (ii) if the premises are mobile, the location where the premises are based principally; or
- (iii) if the premises are a vehicle, any vehicle registration number and the location where the vehicle is based principally; or
- (iv) if the premises are a craft or fishing vessel, the name of the craft or fishing vessel, the physical address of the operator of its risk management programme, and (if applicable) the fishing vessel registration number under the Fisheries Act 1996.

## **6 Physical boundaries of risk management programme**

A risk management programme must—

- (a) identify the physical boundaries within which the programme applies; and
- (b) describe those boundaries in accordance with any method prescribed in a supplementary notice; and
- (c) identify any location, or activities that occur, within those boundaries if they are required to be identified by a supplementary notice; and
- (d) identify the location or activities in accordance with any method prescribed in a supplementary notice.

## **7 Regime when other activities within physical boundaries of programme**

- (1) The operator of a risk management programme must ensure that the effectiveness of the programme is not compromised when a person uses areas within the physical boundaries of the programme for any activity that is not covered by the programme.
- (2) The risk management programme must describe—
  - (a) how the interfaces between the programme and that activity are managed, including between the programme and—
    - (i) the other risk management programme; and
    - (ii) another regulatory regime; and
  - (b) the authorities and accountabilities for resolving any issues associated with that activity; and
  - (c) any animal material, animal product, or food that is within the physical boundaries but is not covered by the programme because—
    - (i) it is covered under a different risk management programme; or
    - (ii) it is covered under a different regulatory regime (for example, under the Food Act 2014).

**8 Describing animal material and animal product and intended use**

A risk management programme must set out, in relation to animal material or animal product to be processed,—

- (a) its name or type when it enters the physical boundaries of the programme; and
- (b) its name or type when it leaves the physical boundaries of the programme; and
- (c) the intended use of the animal material or animal product that leaves, including—
  - (i) whether it is intended for human or animal consumption or some other purpose; and
  - (ii) whether it—
    - (A) is to be subject to further processing; or
    - (B) requires additional preparation by the final consumer; or
    - (C) is ready to eat or consume.

**9 Process description**

A risk management programme must set out every process or operation carried out under the programme, including—

- (a) the main activities or steps; and
- (b) all inputs used; and
- (c) all outputs that are animal material or animal product.

**10 Procedures for risk factors**

- (1) A risk management programme must set out procedures that are appropriate and effective in relation to the requirements of section 17(2) and (3) of the Act, so that animal material and animal product is fit for its intended purpose.
- (2) A risk management programme must include procedures that are appropriate and effective in relation to the requirements of Part 2.
- (3) The procedures must—
  - (a) be appropriate to the operation, having regard to the animal material or animal product to be processed; the nature of the processes involved; and the range of animal products to be produced; and
  - (b) contain sufficient detail, including any critical measurements, to enable people with obligations under the risk management programme to know what to do; and
  - (c) include any relevant monitoring and corrective actions; and
  - (d) include any matters specified in a supplementary notice in relation to any matter in paragraphs (a) to (c).

- (4) A risk management programme must include a procedure for a particular activity or other matter that is specified by supplementary notice.
- (5) The operator of the risk management programme must—
  - (a) be able to demonstrate that the procedures are working effectively; and
  - (b) periodically review the procedures to ensure that they remain appropriate and effective.

#### **11 Limits must be specified**

A risk management programme must set out—

- (a) all relevant regulatory limits; and
- (b) all operator-defined limits.

#### **12 Justifying operator-defined limits**

The operator of a risk management programme must retain the information justifying each operator-defined limit.

#### **13 Specifying actions when limits not met**

A risk management programme must set out procedures for the actions to be taken when any regulatory limit or operator-defined limit is not met.

#### **14 Identifying risk factors**

When identifying risk factors for the purposes of section 17(2) of the Act, the operator of a risk management programme must—

- (a) consider all relevant sources of risk factors that may affect the animal material or animal product, or associated things, or operations; and
- (b) include in the programme sufficient evidence to show that all relevant sources have been identified and considered.

#### **15 Critical control points for significant hazards**

A risk management programme must set out, in relation to any significant hazards identified for the purposes of section 17(3) of the Act,—

- (a) reasons why those particular points are identified as critical control points; and
- (b) reasons why those particular parameters or limits are identified as critical limits.

#### **16 Identifying uncontrolled hazard**

- (1) If an uncontrolled hazard is likely to be present in animal material or animal product leaving the physical boundaries of a risk management programme, the programme must set out why the operator of the programme considers it appropriate for the animal material or animal product to leave the physical boundaries of the programme.

- (2) In this regulation, **uncontrolled hazard** means a hazard that—
- (a) has been identified in a hazard analysis for the processing activity or animal material or animal product; and
  - (b) is one for which the operator of the risk management programme has no control measure available; and
  - (c) is not subject to any regulatory limit or operator-defined limit.

## **17 Critical measurements**

A risk management programme must set out any critical measurements.

## **18 Corrective action procedures**

- (1) A risk management programme must set out corrective action procedures, in relation to foreseen types of loss of control, for—
- (a) restoring control; and
  - (b) identifying, managing, or disposing of affected animal material and animal product; and
  - (c) preventing recurrence of a loss of control.
- (2) A risk management programme must set out a general procedure for managing unforeseen types of loss of control for which no specific corrective action is set out in the programme under subclause (1).
- (3) The procedure under subclause (2) must specify that the operator of the risk management programme must nominate an appropriate person—
- (a) to manage the action; and
  - (b) to record the loss of control and corrective actions taken.

## **19 Identification of persons responsible for key tasks**

A risk management programme must identify by position, or by name and position, the persons responsible for the following key tasks:

- (a) sign-off on documents that make up part of the programme before they are implemented;
- (b) verification by the operator of the programme;
- (c) corrective actions;
- (d) recalls;
- (e) monitoring at a critical control point;
- (f) any other key tasks that are specified as such in a supplementary notice.

## **20 Competency and skills of certain persons**

- (1) A risk management programme must identify in relation to the key tasks in regulation 19—

- (a) any competencies required by these regulations and supplementary notices; and
  - (b) if no competency is required by these regulations or by supplementary notices, any skills the operator considers are necessary; and
  - (c) how the required competencies or necessary skills will be achieved and maintained.
- (2) The operator of a risk management programme must ensure that anyone carrying out a task that is not a key task and that could affect the suitability of animal material for processing or the fitness for intended purpose of animal product is suitably skilled to carry out the task.

## **21 Notices about competency**

- (1) Supplementary notices may do any or all of the following in relation to the key tasks and competency of persons referred to in regulation 20(1):
  - (a) specify any training, experience, knowledge, or qualification that is required;
  - (b) require the matters referred to in paragraph (a) to be maintained;
  - (c) specify who may provide training or a qualification;
  - (d) require operators of risk management programmes to document and implement a training programme.
- (2) The Director-General may approve for 1 or more named persons an alternative training or qualification if it is at least equivalent to the one specified in the supplementary notice.
- (3) The Director-General may approve, in regard to 1 or more named persons, the persons' knowledge and experience as being at least equivalent to the training or qualification set out in the supplementary notice.

## **22 Verification by operator of risk management programme**

- (1) A risk management programme must set out procedures for verification of the programme by the operator of the risk management programme.
- (2) The procedures must—
  - (a) specify the activities to be performed by the operator in relation to verification; and
  - (b) specify the activities' frequency; and
  - (c) specify the actions that must be taken when verification shows that all or part of the programme is not effective; and
  - (d) specify the matters that must be recorded or reported; and
  - (e) include a periodic review of the whole risk management programme.
- (3) An operator must comply with any detailed requirements specified in a supplementary notice in relation to verification by the operator.

**23 Record keeping**

- (1) The risk management programme must set out a procedure for record keeping.
- (2) The operator of a risk management programme must store records for whichever is the longer of 4 years or the shelf life of the animal material or animal product to which the records relate.
- (3) The operator of a risk management programme must ensure that all records are legible and are stored—
  - (a) in a manner that protects the records from damage, deterioration, or loss; and
  - (b) in an easily accessible form.

**24 Document control procedures**

- (1) A risk management programme must set out procedures for effective control of the documents that make up the risk management programme.
- (2) Those procedures must include provisions specifying—
  - (a) how significant and minor amendments will be made to the programme; and
  - (b) how amendments or the nature of the amendments will be identified or described; and
  - (c) how documents will be authorised before they are implemented; and
  - (d) how the programme will be updated with amendments, including updating the date or version of any documents.
- (3) A risk management programme must identify all the documents that make up the programme.
- (4) A multi-business risk management programme must identify which documents relate to which business.
- (5) All the documents that make up the programme must be legible, and dated or marked to identify the programme's version.
- (6) One of the following people must authorise each document before it is implemented into the risk management programme:
  - (a) the operator of the programme;
  - (b) the day-to-day manager of the programme;
  - (c) a person nominated to do so in the document control procedures.

**25 Procedure for meeting reporting requirements**

A risk management programme must set out a procedure for meeting reporting requirements under the Act.

## Subpart 2—Registration

### *Application to register risk management programme*

#### **26 Information requirements for all applications**

- (1) A person applying for registration of a risk management programme under the Act must provide—
  - (a) a statement in writing indicating that the verifier or verifying agency is prepared to carry out verification of the programme; and
  - (b) a validation protocol, if validation information under regulation 34(1) is necessary and is not available before registration; and
  - (c) any other information specified in a supplementary notice.
- (2) A person applying for registration of a risk management programme must ensure that the information that is provided with the application accurately represents the programme at that time.

#### **27 Part of risk management programme that may be provided with application**

For the purposes of section 20(2)(a)(ii) of the Act, an application for registration of a risk management programme under the Act must be accompanied by—

- (a) all the information referred to in section 17(1)(b) and (c) of the Act; and
- (b) all the information that demonstrates compliance with section 17(3)(a) to (c) of the Act; and
- (c) a list of all the documents that make up the proposed programme, including the date or version of each document; and
- (d) the parts of the programme that set out the information required by the following regulations:
  - (i) regulation 5:
  - (ii) regulation 6:
  - (iii) regulation 7:
  - (iv) regulation 8:
  - (v) regulation 9:
  - (vi) regulation 11:
  - (vii) regulation 15; and
- (e) information specified in a supplementary notice.

#### **28 Approval of multi-business risk management programme**

A person applying for approval of a multi-business risk management programme to apply to the business of another person under section 17A of the

Act must provide the following information, whether at the time of application for registration of the programme or at the time of application for registration of a significant amendment to the programme:

- (a) evidence in writing that, once registered, the operator of the multi-business risk management programme will have sufficient control, authority, and accountability for all matters covered by the programme in relation to each business;
- (b) evidence in writing that the person applying for approval has obtained the consent or otherwise taken into account the views of any person whose business is to be covered by the programme;
- (c) any other information specified in a supplementary notice.

*Application to register significant amendments*

**29 Application to register significant amendment to risk management programme**

- (1) An application to register a significant amendment to a risk management programme must identify the amendments to the programme, and be accompanied by—
  - (a) either—
    - (i) all the information required under regulation 27; or
    - (ii) the whole risk management programme, as amended; and
  - (b) a validation protocol, if validation information under regulation 34(1) is necessary and is not available before the application for registration; and
  - (c) a copy of an independent evaluation report carried out no more than 6 months before the date of application for registration of the amendment to the risk management programme; and
  - (d) any other information specified in a supplementary notice.
- (2) A person applying to register a significant amendment to a risk management programme must ensure that the information that is provided with the application accurately represents the programme at that time.
- (3) The Director-General may waive or modify the requirement to provide a copy of an independent evaluation report in a particular instance if—
  - (a) the risk management programme or part of the programme being amended is fully based on a template, model, or code of practice of a kind referred to in section 12(3A) of the Act; or
  - (b) the risk management programme is a multi-business risk management programme; or
  - (c) the risks to human or animal health are negligible, and the Director-General is satisfied that the nature of the business does not require an

independent evaluation report to ensure validity in terms of sections 12 and 17 of the Act.

### **30 Significant amendment to risk management programme**

The kinds of amendments to a risk management programme that require registration as a significant amendment under section 25 of the Act are—

- (a) amendments that result from any of the following activities:
  - (i) alterations to premises or place, facilities, or equipment that may adversely affect the fitness for intended purpose of the animal material or animal product:
  - (ii) relocating a processing operation to a new physical address (except where this is already provided for in the risk management programme in relation to mobile premises, vehicles, and vessels):
  - (iii) processing animal material or animal product that is not covered by the existing programme, unless—
    - (A) the animal material or animal product is substantially similar to what is covered under the existing programme; and
    - (B) a documented risk factor identification and hazard analysis has shown that all risk factors associated with that animal material or animal product are already adequately addressed by the programme:
  - (iv) setting up a new process or process modification that is not covered by the programme, unless—
    - (A) the process or process modification is substantially similar to existing processes under the programme; and
    - (B) a documented risk factor identification and hazard analysis has shown that all risk factors associated with that process are already adequately addressed by the programme; and
- (b) changes that introduce new risk factors, or have an adverse effect on existing risk factors; and
- (c) the merging of the risk management programme with 1 or more other programmes; and
- (d) the splitting of the risk management programme into 2 or more programmes; and
- (e) a change or an addition of premises or a place to which the programme applies that affects the physical boundaries of the programme and could introduce new hazards; and
- (f) minor amendments that together have a cumulative effect on the fitness for intended purpose of animal material or animal product, or on the validity of the programme.

### Subpart 3—Further requirements for operator of risk management programme

#### *Document control*

#### **31 Control of risk management programme documents**

- (1) The operator of a risk management programme must have an up-to-date version of the risk management programme.
- (2) Every document, or part of a document, that makes up a risk management programme must be accessible to any person with responsibilities under the programme.

#### **32 Archived documents**

- (1) The operator of a risk management programme must keep a copy of every document that has formed part of a risk management programme but has since been—
  - (a) replaced by a more recent version; or
  - (b) taken out of the programme.
- (2) The operator must keep the copy for the longer of the following:
  - (a) 4 years;
  - (b) the shelf life of the animal material or animal product to which the risk management programme relates.
- (3) The operator must keep the copy in a manner that—
  - (a) protects the documents from damage and deterioration; and
  - (b) prevents confusion with documents currently making up the programme.

#### **33 Making documents available**

The operator of a risk management programme must ensure that the programme, all reference material relating to the programme, any record, and any archived documents are readily accessible or can be retrieved and made available, upon request, within 2 working days to the following persons:

- (a) the Director-General;
- (b) a person authorised by the Director-General;
- (c) a recognised person or recognised agency;
- (d) an animal product officer.

#### *Validation*

#### **34 Validation of risk management programme effectiveness**

- (1) The operator of a risk management programme must have evidence available to validate the effectiveness of the programme, when it is necessary to demon-

strate that the programme is capable of consistently producing animal material or animal product that is fit for its intended purpose.

- (2) If validation information under subclause (1) is not available before the application for registration, the operator of a risk management programme must develop a validation protocol that sets out—
  - (a) how evidence will be collected to demonstrate the effectiveness or continuing effectiveness of the programme; and
  - (b) how the animal material or animal product resulting from the implementation of the validation protocol will be managed; and
  - (c) the estimated time frame for completion of the validation.
- (3) After registration, the operator of a risk management programme who has developed a validation protocol must—
  - (a) follow the validation protocol; and
  - (b) provide evidence to the evaluator—
    - (i) to demonstrate the effectiveness or continuing effectiveness of the programme; and
    - (ii) to show how animal material or animal product resulting from the implementation of the validation protocol has been managed.

### **35 Notices about validation**

Supplementary notices may set further requirements for validation, which may include—

- (a) the form or content of the validation information; and
- (b) the components of a validation protocol; and
- (c) the types of evidence to be collected; and
- (d) the time frame for completion of the validation; and
- (e) competencies for people carrying out validation; and
- (f) how long the validation information must be kept, if that is different from the time frame provided for in regulation 23(2).

### *Reporting*

### **36 Reporting to verifier or verifying agency**

- (1) The operator of a risk management programme must notify the verifier or verifying agency in writing and without unnecessary delay if—
  - (a) the following occur:
    - (i) anything within the physical boundaries of the programme is used for additional purposes or by persons not covered by the programme; and

- (ii) the programme has not adequately considered relevant hazards or other risk factors relating to that use; or
  - (b) there is significant concern about fitness for intended purpose of any animal material or animal product; or
  - (c) there has been a critical non-compliance by the operator; or
  - (d) the operator of the risk management programme no longer considers the programme to be effective; or
  - (e) the premises identified as being used by the programme are not, or no longer, suitable for use; or
  - (f) any loss of control that occurs is due to unforeseen circumstances and adversely affects the suitability of animal material for processing or the fitness for intended purpose of animal product.
- (2) Information that must be provided under subclause (1) must be provided in an easily accessible form.
- (3) The operator of a risk management programme must provide a copy of each evaluation report to their verifier or verifying agency.

### **37 Notifying Director-General**

- (1) The operator of a risk management programme must notify the Director-General of any emerging, new, or exotic biological hazard or new chemical hazard in relation to the programme as soon as practicable after its discovery.
- (2) The operator must notify the Director-General in writing, without unnecessary delay, of any change to the position, or name and position, of the person responsible for the day-to-day management of the programme.

### **38 Operator of risk management programme must report certain information to Director-General**

The operator of a risk management programme must report to the Director-General or the operator's verifier or verifying agency if the operator has reasonable grounds to believe that information a supplier provides about animal material or animal product is materially false or misleading.

## **Subpart 4—Specific inclusions and exemptions**

### **39 Rendering and blood-drying operations for mammals and birds**

A person who carries out the following operations for trade purposes in relation to mammal or bird material or product that is not intended for human consumption must operate under a registered risk management programme:

- (a) rendering operations:
- (b) blood-drying operations.

Compare: SR 2000/209 cl 20

**40 Technical grade dairy product**

- (1) A person who processes technical grade dairy product must operate under a registered risk management programme if—
- (a) that processing is carried out at the same place as certain other processing; or
  - (b) the product is for export, and an official assurance is required.

- (2) In this regulation,—

**certain other processing** means processing—

- (a) of dairy material that is for sale or export for human or animal consumption; and
- (b) that is required by or under the Act to be carried out in accordance with a risk management programme

**technical grade dairy product** means dairy product for sale or export that is not intended for human or animal consumption.

Compare: SR 2000/209 cl 20A

**41 Certain exemptions from requirements to have registered risk management programme**

Operators are exempt from the requirement to have a risk management programme in respect of the operations specified in Schedules 2 and 3.

**Part 2****Good operating practices****Subpart 1—Design and construction of premises, places, facilities, equipment, and essential services****42 How premises, etc, must be designed, located, and constructed**

- (1) The operator of a risk management programme must ensure that premises, places, facilities, equipment, and essential services are located, designed, and constructed so that—
- (a) animal material is suitable for processing; and
  - (b) animal products are fit for their intended purpose.
- (2) For the purposes of subclause (1), the operator must have regard to the following:
- (a) the animal material or animal product to be processed or produced;
  - (b) the nature of the processes or activities involved;
  - (c) holding or storage requirements, or both;
  - (d) the capacity required for processing or activities to be carried out;

- (e) the surrounds and external areas:
- (f) the proximity to other operations.

#### **43 How premises, etc, must be operated**

- (1) The operator of a risk management programme must ensure that premises, places, facilities, equipment, and essential services are operated in a manner that minimises and manages the exposure of animal material, animal product, or other input to risk factors.
- (2) For the purposes of subclause (1), the operator must have regard to the following:
  - (a) the animal material or animal product to be processed or produced; and
  - (b) the operational capability and capacity of the premises or places, facilities, equipment, and essential services.

#### **44 Notices for premises, places, facilities, equipment, and essential services**

Supplementary notices may specify matters relating to premises, places, facilities, equipment, and essential services, for the purposes of regulations 42 and 43, including—

- (a) location, design and construction requirements for specific sectors, operations, or types of premises or places; and
- (b) facility and equipment requirements for specific sectors, operations, or types of premises or places; and
- (c) where or when specific functional elements must be incorporated; and
- (d) the types, durability, and placement of materials, finishings, fixtures, and fittings.

### **Subpart 2—Operation of facilities, equipment, essential services, and waste**

#### **45 Operation of essential services**

The operator of a risk management programme must ensure that—

- (a) all essential services are managed to minimise contamination of animal material and animal product; and
- (b) lighting is of sufficient intensity to enable satisfactory performance of all activities in the processing environment; and
- (c) ventilation is sufficient to manage air temperature or pressure and condensation or humidity.

**46 Water**

The operator of a risk management programme must ensure that water is fit for its intended purpose at its point of use, and of sufficient quantity for the operations of the animal product business.

**47 Operator must manage waste**

The operator of a risk management programme must ensure that waste is collected, managed, and disposed of in a manner that—

- (a) minimises contamination of animal material and animal product and associated things; and
- (b) prevents it from being used for animal material and animal product; and
- (c) prevents it from attracting or harbouring pests.

**48 Calibrating measuring equipment and monitoring equipment**

The operator of a risk management programme must ensure that measuring equipment or monitoring equipment used for critical measurements—

- (a) is appropriate for the activity to be carried out; and
- (b) is accurate; and
- (c) where appropriate, is uniquely identifiable; and
- (d) where necessary, is managed to prevent unauthorised adjustments; and
- (e) is calibrated; and
- (f) functions as intended.

**49 Notices for purposes of this subpart**

For the purposes of regulations 45 to 48, supplementary notices may specify detailed requirements relating to—

- (a) managing essential services to minimise the risk of their being a source of contamination; and
- (b) lighting intensity; and
- (c) ventilation; and
- (d) ensuring that water is fit for intended purpose; and
- (e) the collection, management, and disposal of waste; and
- (f) measuring or monitoring equipment.

**Subpart 3—Cleaning, maintenance, and pest management****50 Operator must ensure appropriate cleaning and sanitising procedures**

- (1) The operator of a risk management programme must ensure that cleaning and sanitising procedures are carried out using materials (including maintenance compounds) and equipment in a manner that ensures—

- (a) the suitability of animal material for processing; and
  - (b) the fitness for intended purpose of animal product.
- (2) Supplementary notices may, for the purposes of this regulation, specify further requirements relating to cleaning and sanitising procedures, including the materials and equipment used.

### **51 Maintenance must be carried out to suitable standard**

- (1) The operator of a risk management programme must ensure that premises, places, facilities, equipment, and essential services are maintained to a standard that ensures—
  - (a) the suitability of animal material for processing; and
  - (b) the fitness for intended purpose of animal product.
- (2) The operator of a risk management programme must cease processing if—
  - (a) subclause (1) is not complied with; and
  - (b) the suitability of animal material for processing or the fitness for intended purpose of animal product is adversely affected and it is necessary to cease processing to address those effects.
- (3) Supplementary notices may, for the purposes of this regulation, specify further requirements relating to maintaining premises, places, facilities, equipment, and essential services.

### **52 Maintenance must not affect processing adversely**

- (1) The operator of a risk management programme must carry out maintenance in a manner that does not adversely affect, directly or indirectly, the suitability of animal material for processing or the fitness for intended purpose of animal product.
- (2) The operator of a risk management programme must cease processing in a situation where maintenance is adversely affecting animal material or animal product, if it is necessary to cease processing to address those effects.
- (3) Supplementary notices may, for the purposes of this regulation, specify further requirements relating to maintenance during processing.

### **53 Use of maintenance compounds**

- (1) The operator of a risk management programme must use, store, transport, and handle maintenance compounds in a manner that ensures—
  - (a) the suitability of animal material for processing; or
  - (b) the fitness for intended purpose of animal product.
- (2) The operator of a risk management programme who uses maintenance compounds must ensure that the maintenance compounds—
  - (a) are appropriate to the task; and

- (b) will not cause contamination of animal material or animal product, including contamination—
    - (i) by a maintenance compound itself; or
    - (ii) by a substance that may result from the breakdown of materials (for example, equipment components) that a maintenance compound may come into contact with.
- (3) Supplementary notices may specify—
  - (a) when a maintenance compound approved by the Director-General under regulation 247 must be used—
    - (i) by a particular type of animal product business; and
    - (ii) in particular premises, or a particular place or area; and
    - (iii) for a particular purpose or type of use; and
    - (iv) in relation to particular equipment; and
  - (b) further requirements relating to using, storing, transporting, and handling maintenance compounds.

#### **54 Practices must minimise effects of pests**

- (1) The operator of a risk management programme must minimise opportunities for pests to infest, soil, or contaminate animal material, animal products, associated things, premises, places, facilities, equipment, or essential services.
- (2) Supplementary notices may, for the purposes of subclause (1), specify detailed requirements relating to minimising opportunities for infestation, soiling, or contamination by pests.

### **Subpart 4—People: hygiene, health, and clothing and equipment**

#### **55 Protecting against contamination by people**

##### *Personal hygiene*

- (1) The operator of a risk management programme must ensure that any person at the premises or place—
  - (a) follows an appropriate routine of personal hygiene that minimises the risk of contamination of animal material and animal product; and
  - (b) behaves in a way that minimises the risk of contamination of animal material and animal product.

##### *Health of persons*

- (2) The operator of a risk management programme must ensure that any person at the premises or place who is known to have or suspected of having an illness or condition does not, directly or indirectly, contaminate animal material or animal product.
- (3) Complying with subclause (2) includes that the operator must ensure that—

- (a) any person who is known to have or suspected of having an illness or condition is excluded from areas where animal material or animal product may be contaminated, directly or indirectly; and
  - (b) there is a system for persons to report to the operator if they have or suspect they may have an illness or condition; and
  - (c) there is an appropriate assessment of—
    - (i) whether a person no longer creates a risk of contamination; or
    - (ii) whether and how the risk can be appropriately managed.
- (4) For the purposes of this regulation, **illness or condition** means an illness or a condition that can be transmitted from humans through animal material or animal product.

*Clothing and equipment*

- (5) The operator must ensure that any person whose presence or actions may contaminate, directly or indirectly, animal material or animal product wears appropriate clothing and equipment that minimises the risk of contamination.

*Supplementary notices*

- (6) Supplementary notices may, for the purposes of this regulation, specify detailed requirements for the prevention and management of contamination relating to personal hygiene at premises or places, illnesses and conditions, and appropriate clothing and equipment.

Subpart 5—Fitness for intended purpose

**56 Operator must ensure suitability of animal material, animal product, and other inputs**

- (1) The operator of a risk management programme must ensure that animal material, animal product, and other inputs that the operator produces or receives from a supplier are suitable for processing.
- (2) The operator of a risk management programme must—
  - (a) manage risk factors in relation to inputs; and
  - (b) take actions (including application of processing steps) to control those risk factors.

**57 Notices relating to ensuring suitability of animal material, animal product, and other inputs**

Supplementary notices may specify matters in relation to ensuring suitability of animal material, animal product, and other inputs, including—

- (a) criteria or requirements for incoming animal material, animal product, or other inputs; and
- (b) required competencies for persons involved in checking suitability; and

- (c) requirements for ensuring suitability; and
- (d) risk factors in relation to animal material, animal product, and other inputs and the way in which those risks must be managed, including processing steps that must be applied.

## **58 Processing must minimise contamination and deterioration**

- (1) The operator of a risk management programme must ensure that animal material, animal product, and other inputs are processed and handled in a way that manages and minimises their contamination and deterioration.
- (2) The operator of a risk management programme must ensure that animal material, animal product, and other inputs are protected from adulteration.

## **59 Notices in relation to processing**

For the purposes of regulation 58, supplementary notices may specify matters in relation to processing, including—

- (a) methods, techniques, or activities for processing animal material or animal product; and
- (b) how premises, places, facilities, and equipment must be operated to minimise contamination and deterioration of animal material and animal product; and
- (c) parameters for certain activities associated with processing; and
- (d) requirements for animal material, animal product, and other inputs; and
- (e) the maximum permissible levels of substances that animal material or animal product may contain; and
- (f) requirements for monitoring, including monitoring plans; and
- (g) contingency plans for unexpected occurrences and emergencies; and
- (h) corrective actions.

## **60 Exemption from processing requirements**

- (1) The Director-General may exempt an operator from 1 or more of the requirements of regulation 56 or 58 if satisfied that the resulting risk to human or animal health would be negligible.
- (2) The exemption may be subject to conditions.

## **61 Restriction on processing animal material or animal product from animals imported live**

The operator of a risk management programme must not process animal material or animal product from animals imported live for slaughter, unless the Director-General gives approval under regulation 120.

## Subpart 6—Examining, sampling, and testing

### 62 General testing

- (1) The operator of a risk management programme must ensure that premises, places, facilities, equipment, essential services, animal material, animal product, and associated things are examined, sampled, and tested where necessary to ensure the suitability of animal material for processing and the fitness for intended purpose of animal product.
- (2) The Director-General may exempt an operator from 1 or more of the requirements of subclause (1) if the Director-General considers that the risks to animal or human health of doing so are negligible.
- (3) The exemption may be subject to conditions.

### 63 Operator must take corrective action

The operator of a risk management programme must take corrective action if examination, sampling, or testing identifies that any premises or place, equipment, essential services, animal material, animal product, or associated things—

- (a) do not meet regulatory requirements; or
- (b) do not comply with the operator's risk management programme.

### 64 Persons examining, etc, must be skilled

The operator of a risk management programme must ensure that any person (other than a recognised agency or person) carrying out examination, sampling, or testing—

- (a) is appropriately skilled to carry out those activities; and
- (b) meets any requirements of relevant notices in relation to competencies; and
- (c) uses examination, sampling, and testing techniques that do not adversely affect—
  - (i) the fitness for intended purpose of animal products; or
  - (ii) the suitability of animal material for processing; or
  - (iii) the integrity of samples.

### 65 Notices for examination, sampling, and testing

For the purposes of regulations 62 to 64, supplementary notices may specify matters in relation to examination, sampling, and testing, including—

- (a) what must be examined, sampled or tested; and
- (b) the types of tests, sampling, and examination and the methods or procedures for them; and

- (c) when the examination, sampling, and testing must be done; and
- (d) who must do the examination, sampling, and testing, for example, whether testing has to be done in a recognised laboratory; and
- (e) requirements relating to reporting of test results; and
- (f) required competencies for persons carrying out examination, sampling, and testing; and
- (g) whether an operator must have a particular sampling or testing plan; and
- (h) requirements for samples, including identification, packaging, storage, and time frames; and
- (i) any particular actions that must be taken that are necessary to ensure that risks to human and animal health identified as a result of examination, sampling, and testing are managed and minimised.

#### Subpart 7—Labelling, identification, and packaging

##### **66 Labelling and identification requirements**

- (1) The operator of a risk management programme must ensure that any labelling or identification clearly relates to the animal material or animal product to which it applies.
- (2) The operator of a risk management programme must ensure that any relevant labelling and identification of animal material or animal product is appropriately and accurately amended if the animal material or animal product is no longer fit for its original intended purpose.

##### **67 Notices about labelling and identification**

Supplementary notices may, for the purposes of regulation 66, specify requirements relating to the labelling or identification of animal material or animal product.

##### **68 Packaging requirements for animal material and animal product**

The operator of a risk management programme must ensure that any packaging (including reusable packaging and inner and outer packaging of any kind) used for animal material or animal product is designed, made, stored, and used in a manner that—

- (a) maintains the suitability of the animal material for processing; and
- (b) maintains the fitness for intended purpose of the animal product; and
- (c) minimises contamination and deterioration of the animal material or animal product.

##### **69 Notices for packaging requirements**

Supplementary notices may, for the purposes of regulation 68, specify requirements relating to packaging, including—

- (a) standards for packaging; and
- (b) how packaging is to be stored and used.

#### Subpart 8—Non-conforming animal material or animal product

##### **70 Processing non-conforming animal material or animal product**

- (1) The operator of a risk management programme must ensure that non-conforming animal material that is not suitable for processing or non-conforming animal product that is not fit for its intended purpose is not—
  - (a) used or traded for that purpose; or
  - (b) a source of contamination of other animal material or animal product.
- (2) However, the operator may do the following things if in accordance with their risk management programme and any relevant supplementary notice referred to in regulation 71:
  - (a) process the animal material or animal product so that it is fit for its original intended purpose or a different purpose; and
  - (b) then use or trade it.

##### **71 Notices about non-conforming product**

Supplementary notices may, for the purposes of regulation 70, specify requirements relating to disposing of or dealing with non-conforming animal material or animal product, or animal material or product suspected to be non-conforming, including—

- (a) corrective actions relating to non-conforming animal material or animal product; and
- (b) requiring the written consent of the Director-General (which may be subject to conditions) or a recognised agency or recognised person before disposal of or dealing with non-conforming animal material or animal product; and
- (c) identification requirements for non-conforming animal material or animal product; and
- (d) requirements or procedures for processing, such as when, where, and how reprocessing may be carried out.

## **Part 3 Evaluation**

#### Subpart 1—Provisions that apply generally to evaluators and evaluations

##### **72 Application of this subpart**

This subpart applies to evaluators and evaluations generally.

**73 Who may carry out evaluations**

An evaluation of a risk management programme or a significant amendment to a risk management programme may only be carried out by an evaluator.

**74 Evaluator restrictions and requirements**

- (1) An evaluator who was involved in the design or development of a risk management programme or a significant amendment to that programme must not evaluate the programme for a period of 2 years after the date on which the programme or amendment is registered, unless the Director-General agrees otherwise in writing.
- (2) An evaluator must not use a technical expert for the purposes of regulation 77(3) or 81(3) if the technical expert was also involved in the design or development of that programme or the amendment being evaluated, for a period of 2 years after the date on which the programme or amendment is registered, unless the Director-General agrees otherwise in writing.

**75 Independent evaluation report**

- (1) An evaluator must, after carrying out the evaluation of a risk management programme or a significant amendment to the programme, provide the operator of the business with a report of the evaluation.
- (2) The report must—
  - (a) state whether the evaluator has determined that the programme is valid in terms of sections 12 and 17 of the Act; and
  - (b) specify any conditions that the evaluator recommends should be imposed on, amended, or removed from the registration of the programme or any significant amendment; and
  - (c) state whether the operator has validation information under regulation 34(1) or a validation protocol under regulation 34(2); and
  - (d) contain any information specified by supplementary notice.

**Subpart 2—Evaluation of risk management programme for initial registration**

**76 Application of this subpart**

This subpart applies to the evaluation of a risk management programme for the purposes of registration under section 20 of the Act.

**77 Evaluation for registration of risk management programme**

- (1) An evaluator must assess a risk management programme to determine whether the programme is valid in terms of sections 12 and 17 of the Act.

- (2) The evaluator may request that the operator provide any information about the animal product business that the evaluator reasonably requires to carry out the evaluation.
- (3) An evaluator must obtain supporting reports and assistance from a technical expert or other evaluator for any aspect of the risk management programme evaluation that is outside their area of expertise.

## **78 On-site assessment**

- (1) When carrying out an on-site assessment, the evaluator must assess the appropriateness and accuracy of the risk management programme against—
  - (a) the physical boundaries of the premises or place to which the programme applies; and
  - (b) the design and construction of the premises or place; and
  - (c) the operations described in the programme; and
  - (d) any other matters that a supplementary notice requires to be assessed against a risk management programme.
- (2) The evaluator must carry out an on-site assessment of each premises or place covered by the risk management programme.

## **79 Exemption from requirement for on-site assessment**

- (1) The Director-General may grant an exemption from the requirement to carry out an on-site assessment of particular premises or places as part of the evaluation of a proposed risk management programme, if satisfied that—
  - (a) the level of risk to human or animal health is such that an on-site visit is unnecessary; or
  - (b) an on-site visit would not contribute to the assessment of the validity of the risk management programme.
- (2) The Director-General must provide the exemption in writing and may include conditions.
- (3) The evaluator must attach a copy of the exemption to the evaluation report.
- (4) An exemption granted under this regulation is secondary legislation (*see* Part 3 of the Legislation Act 2019 for publication requirements), unless the exemption applies only to 1 or more named persons.

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### **Legislation Act 2019 requirements for secondary legislation made under this regulation**

|                     |                                                                                             |                  |
|---------------------|---------------------------------------------------------------------------------------------|------------------|
| <b>Publication</b>  | The maker must publish it in accordance with the Legislation (Publication) Regulations 2021 | LA19 s 74(1)(aa) |
| <b>Presentation</b> | The Minister must present it to the House of Representatives                                | LA19 s 114       |
| <b>Disallowance</b> | It may be disallowed by the House of Representatives                                        | LA19 ss 115, 116 |

*This note is not part of the secondary legislation.*

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### Subpart 3—Evaluation of significant amendment to risk management programme

#### **80 Application of this subpart**

This subpart applies to the evaluation of a significant amendment to a risk management programme for the purposes of its registration under section 25 of the Act.

#### **81 Evaluation of significant amendment to risk management programme**

- (1) An evaluator must assess the significant amendment to the risk management programme to determine whether it is valid in terms of sections 12 and 17 of the Act.
- (2) The evaluator may request that the operator provide any information about the animal product business that the evaluator reasonably requires to carry out the evaluation.
- (3) The evaluator must obtain supporting reports and assistance from a technical expert or other evaluator for any aspect of the risk management programme evaluation that is outside their area of expertise.
- (4) Supplementary notices may, for the purposes of this regulation, specify details of how an evaluation must be carried out for a significant amendment to a risk management programme.

## **Part 4 Verification**

### Subpart 1—What is subject to verification and who may verify

#### **82 Subject to verification**

An animal product business is subject to the verification requirements and must be verified as set out in this Part and any relevant supplementary notices if it—

- (a) operates under a risk management programme; or
- (b) operates under a regulated control scheme that identifies that the verification requirements apply to the animal product business operating under the scheme; or
- (c) operates a game estate; or
- (d) operates an animal material depot of a type referred to in regulation 127 that stores animal material for human consumption; or
- (e) produces or processes animal material or animal product for export for which an official assurance is required; or
- (f) is a further petfood processor.

**83 Verification must be done by verifier or verifying agency**

Verification under this Part must be carried out by a verifier or verifying agency.

**84 Restriction on verification by previous evaluator**

A verifier must not verify a risk management programme that they previously evaluated, or for which they evaluated a significant amendment, for a period of 2 years after the date of the evaluation, unless the Director-General agrees otherwise in writing.

**Subpart 2—General verification requirements***Verification frequency***85 Verification frequency**

- (1) An animal product business that is subject to verification must ensure that an initial verification is carried out within the time frame specified in a supplementary notice.
- (2) An animal product business that is subject to verification must ensure that verification takes place with the verification frequencies specified in a supplementary notice.
- (3) An animal product business that is subject to verification must move between verification frequencies as specified in the supplementary notice.
- (4) An animal product business must ensure that verification is carried out in relation to other matters as specified in the supplementary notice.
- (5) The timing for the beginning of verification after the initial verification of a business must be calculated from the date on which the initial verification begins.

**86 Setting verification frequency**

The Director-General must take into account 1 or more of the following when issuing a supplementary notice that sets verification frequency:

- (a) the animal material or animal product involved:
- (b) the nature of the processes involved:
- (c) the nature of the risks to be managed:
- (d) the frequency set for other comparable operations:
- (e) the facilitation of access to overseas markets.

**87 Varying verification frequency**

The Director-General may, in respect of a particular animal product business that is subject to verification, change the time frame for the initial verification

or vary the verification frequency from that specified in the supplementary notice referred to in regulation 85(2) in the following circumstances:

- (a) if the business continues to be non-compliant with a regulatory requirement so that the likely result is animal material or animal product not being fit for its intended purpose:
- (b) if a business ceases, or partially ceases, processing activities for a period of time, for example, due to maintenance, financial difficulties of the operator, or seasonal availability:
- (c) if the operations under the business's risk management programme have been suspended under section 27 of the Act:
- (d) if a business carries out only infrequent processing or processing that is yet to commence:
- (e) if a business carries out only intermittent processing under a food control plan—
  - (i) that is operated on an intermittent basis; and
  - (ii) that is recognised as a risk management programme under section 34 of the Act; and
  - (iii) to which the Director-General has specified that the verification requirements of the Act apply:
- (f) if the relevant verification frequency is not appropriate because the nature of the new activity means an increased or unknown risk in relation to human or animal health or trade from the processing of animal material or animal product.

## **88 Varying verification dates**

The Director-General may, in respect of a particular animal product business that is subject to verification, vary the time frame for verification calculated by reference to the verification frequencies specified in the supplementary notice referred to in regulation 85(2) if matters outside the business's control mean that the verifier or verifying agency has not been able to carry out verification within the calculated time frame.

### *Unscheduled verifications*

## **89 Unscheduled verification**

- (1) The Director-General may require a verifier or verifying agency to carry out an unscheduled verification of an animal product business that is subject to verification if the Director-General considers there are issues with the fitness for intended purpose of animal material or animal product or there are risks to facilitating access to overseas markets.
- (2) The Director-General may require an unscheduled verification referred to in subclause (1) because of 1 or more of the following:

- (a) any recall of animal material or animal product carried out by the animal product business;
  - (b) any contamination, or suspected contamination, of animal material or animal product by any hazard;
  - (c) any information, including from monitoring or surveillance under Part 8, that the Director-General considers is reasonable grounds for suspecting that any animal material or animal product is no longer fit for its intended purpose or otherwise does not comply with any applicable regulatory requirements;
  - (d) any information that the Director-General considers is reasonable grounds for suspecting that the animal product business is not complying with any applicable regulatory requirements;
  - (e) it is necessary to meet export requirements specified by notice issued under section 167(1) of the Act to facilitate the entry of animal product into overseas markets;
  - (f) any other factors that the Director-General considers relevant.
- (3) The Director-General—
  - (a) must, in writing, advise the verifier or verifying agency of the matters referred to in subclause (2); and
  - (b) may set the time frame for carrying out the verification; and
  - (c) must set the minimum notice, not less than 24 hours, that the verifier or verifying agency must give to the animal product business of the unscheduled verification.
- (4) The verifier or verifying agency must—
  - (a) give notice to the business as specified in subclause (3)(c) and any supplementary notice; and
  - (b) carry out a verification of the animal product business—
    - (i) as soon as practicable after receiving the Director-General's advice; or
    - (ii) within the time frame (if any) specified by the Director-General; and
  - (c) comply with any detailed requirements in the supplementary notice in relation to unscheduled verification.

#### *Multi-business verification*

### **90 Verification of multi-business risk management programme**

- (1) Verification of a multi-business risk management programme must be carried out in relation to the proportion of businesses subject to the programme that are

required to be verified on each occasion and any other matters as specified in the supplementary notice referred to in regulation 85(2).

- (2) For the purposes of any subsequent verification of a multi-business risk management programme,—
  - (a) the verifier or verifying agency may treat the verification outcome of 1 or more businesses that are subject to the programme as applying to all businesses that are subject to the programme; and
  - (b) the verifier or verifying agency may have a different verification scope for each business.
- (3) The Director-General may, in respect of a particular multi-business risk management programme, decide which businesses must be verified generally or on any particular occasion and may vary the proportion of businesses that must be verified generally or on any particular occasion from that specified in the supplementary notice.

#### **91 Verification of multi-site risk management programme**

- (1) Verification of a multi-site business risk management programme must be carried out in relation to the proportion of sites required to be verified on each occasion and any other matters specified in a supplementary notice.
- (2) For the purposes of any subsequent verification of a multi-site business risk management programme,—
  - (a) the verifier or verifying agency may treat the verification outcome of 1 or more sites as applying to all sites that are subject to the programme; and
  - (b) the verifier or verifying agency may have a different verification scope for each site.
- (3) The Director-General may, in respect of a particular multi-site business risk management programme, decide which sites must be verified generally or on any particular occasion and may vary the proportion of sites that must be verified generally or on any particular occasion from that specified in the supplementary notice.

### **Subpart 3—Verification consequences**

#### *Verification outcomes*

#### **92 Verification outcomes**

- (1) After carrying out verification of an animal product business, the verifier or verifying agency must—
  - (a) assign an acceptable outcome or an unacceptable outcome to the verification; and
  - (b) provide a written report to the animal product business.

- (2) An **acceptable outcome** must be assigned if the verifier or verifying agency is satisfied that the animal product business substantially complies with the applicable regulatory requirements.
- (3) An **unacceptable outcome** must be assigned if—
  - (a) the verifier or verifying agency is not satisfied that the animal product business substantially complies with the applicable regulatory requirements; or
  - (b) the animal product business has failed to identify or effectively address a critical non-compliance; or
  - (c) the verifier or verifying agency has no confidence in the operations of the animal product business because of—
    - (i) the combined effect of several instances of non-compliance; or
    - (ii) the extent to which records required under the applicable requirements of the Act are absent, incomplete, or altered; or
  - (d) the verifier or verifying agency determines that the risk management programme of the animal product business is no longer effective or no longer appropriate.
- (4) For the purposes of subclause (3)(b), the verifier or verifying agency must consider whether any corrective action has been, or is being, carried out appropriately.
- (5) In assigning an acceptable outcome or an unacceptable outcome, the verifier or verifying agency must consider the matters specified in a supplementary notice.

### **93 Verifier or verifying agency must require corrective action**

- (1) A verifier or verifying agency that reasonably considers applicable regulatory requirements are not being complied with by an animal product business must require the business—
  - (a) to determine the appropriate corrective action; and
  - (b) to carry out the corrective action within a specified time frame.
- (2) The animal product business must carry out the corrective action to the satisfaction of the verifier or verifying agency within the time frame specified under subclause (1)(b).

### **94 Consequences of unacceptable outcome**

- (1) If a verifier or verifying agency assigns an unacceptable outcome to the verification of an animal product business, the verifier or verifying agency and the animal product business must—
  - (a) agree to a time frame within which the business must prepare a corrective action plan for the consideration of the verifier or verifying agency; and

- (b) agree to a corrective action plan, which must address matters leading to the unacceptable outcome and the time frame within which each matter must be addressed.
- (2) The animal product business must comply with the corrective action plan to the satisfaction of the verifier or verifying agency within the time frame specified under subclause (1)(b).

*Notices: requirements for conducting verification*

**95 Notices about requirements for conducting verification**

The verifier or verifying agency must meet the detailed requirements for conducting a verification that are specified in a supplementary notice.

*Reconsideration*

**96 Reconsideration**

- (1) An animal product business subject to verification under this Part may seek a reconsideration of a verification outcome by applying,—
  - (a) in the case of a decision of a verifier, to the verifying agency of the verifier or, if there is no verifying agency, to the Director-General; or
  - (b) in the case of a decision of a verifying agency, to the Director-General.
- (2) The verification frequency resulting from an unacceptable outcome continues to apply until the animal product business is notified of the reconsideration decision.
- (3) The person or body responsible for reconsidering the verification decision must—
  - (a) reconsider the decision within 20 working days after receiving the application for reconsideration, or a later date if the applicant agrees; and
  - (b) take into account any matters specified in a supplementary notice; and
  - (c) give written notice of the reconsideration decision to the applicant and the verifier or verifying agency.
- (4) Regulation 92 applies, with any necessary modifications, to the reconsideration of a verification decision.

**Subpart 4—General verification matters**

**97 Exemption from verification requirements in emergency**

- (1) The Director-General may exempt any animal product business from any verification requirements during an emergency if the verification requirements applying to some or all types of animal product businesses are impossible or impracticable to achieve.

- (2) An exemption is secondary legislation (*see* Part 3 of the Legislation Act 2019 for publication requirements), unless it applies only to 1 or more named animal product businesses.

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**Legislation Act 2019 requirements for secondary legislation made under this regulation**

**Publication** The maker must publish it in accordance with the Legislation (Publication) Regulations 2021 LA19 s 74(1)(aa)

**Presentation** The Minister must present it to the House of Representatives LA19 s 114

**Disallowance** It may be disallowed by the House of Representatives LA19 ss 115, 116

*This note is not part of the secondary legislation.*

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## **98 Giving access or assistance**

- (1) An animal product business that is subject to verification must comply with any matter in relation to giving access or assistance specified in a supplementary notice.
- (2) A person who is subject to verification requirements must give a verifying agency—
- (a) the access to places, things, and information that the verifying agency reasonably needs to carry out the verification; and
  - (b) any reasonable assistance requested by the verifying agency to carry out the verification.

## **99 Animal product business must pay verification costs**

An animal product business that is subject to verification must pay the costs of the verification.

## **100 Reporting**

- (1) A verifier or verifying agency must report to the Director-General any critical non-compliance that it identifies or that is reported to them under regulation 36 or 38.
- (2) The report must include any actions that the verifier or verifying agency recommends that the Director-General should take.

## **101 Notices about reporting**

For the purposes of regulations 92 and 100, supplementary notices may specify matters in relation to reporting by verifiers and verifying agencies, including—

- (a) the manner and form of reports; and
- (b) what reports must contain; and
- (c) what information must be included; and
- (d) what software application or program may be used for reporting; and
- (e) time frames for reporting.

## **Part 5**

### **Traceability and recall**

#### **Subpart 1—Application of Part**

##### **102 Application of this Part**

This Part applies to—

- (a) the operator of a risk management programme; and
- (b) the operator of an animal product business that exports animal material or animal product.

#### **Subpart 2—Traceability**

##### *Traceability procedures*

##### **103 Traceability procedures**

- (1) An operator that this Part applies to must have in place and implement traceability procedures that enable the operator—
  - (a) to trace animal material and animal product—
    - (i) from the supplier to the operator; and
    - (ii) from the operator to the next recipient in the supply chain (other than the final consumer); and
  - (b) to identify and locate animal material and animal product while it is under the control of the business.
- (2) The operator must ensure that the information required under subclause (1) or by a supplementary notice referred to in subclause (4) is accurate.
- (3) The operator must ensure that the information required under subclause (1) is also sufficient to allow an effective recall to be carried out.
- (4) Supplementary notices may specify details of further matters required in traceability procedures.

##### *Providing traceability information*

##### **104 Providing traceability information on request**

When requested to do so by the Director-General or an animal product officer, an operator that this Part applies to must provide information about the matters in regulation 103(1) or required by a supplementary notice—

- (a) in a readily accessible format; and
- (b) within 24 hours after the request, or within any reasonable shorter period specified by the Director-General or animal product officer.

## Subpart 3—Recalls

### *Recall procedures*

#### **105 Recall procedures**

- (1) An operator that this Part applies to must—
  - (a) have in place recall procedures for animal material and animal product that—
    - (i) include criteria for deciding when a recall will be made; and
    - (ii) set out how retrieval and reprocessing or disposal of the animal material and animal product will be managed; and
    - (iii) comply with any requirements in supplementary notices; and
  - (b) recall animal material and animal product in accordance with those procedures.
- (2) Supplementary notices may specify further matters required in recall procedures.

### *Details of recall to be provided to Director-General*

#### **106 Providing details of recall**

- (1) If an operator that this Part applies to decides to recall animal material or animal product, the operator must notify the Director-General or an animal product officer as soon as practicable, but no later than 24 hours after making the decision.
- (2) The operator must also provide the Director-General or animal product officer with the following details within 24 hours after the recall:
  - (a) the animal material or animal product affected by the recall;
  - (b) the reason for the recall;
  - (c) any information required by a supplementary notice.
- (3) The operator must provide the information required under subclause (2) in a readily accessible format.

### *Simulated recall*

#### **107 Simulated recall to demonstrate procedures effective**

- (1) An operator that this Part applies to must carry out a simulated recall of animal material and animal product using their traceability and recall procedures.
- (2) The simulation must demonstrate the effectiveness of the operator's traceability and recall procedures.
- (3) In this Part, **effectiveness** is measured by—

- (a) the proportion of animal material or animal product that would have been or was successfully recalled; and
  - (b) the time taken to trace and recall affected animal material or animal product; and
  - (c) matters specified in a supplementary notice.
- (4) Supplementary notices may specify matters that must be tested by a simulated recall and matters relating to measuring the effectiveness of traceability and recall procedures.

#### **108 Frequency of simulated recall**

An operator that this Part applies to must carry out a simulated recall referred to in regulation 107 at least every 12 months—

- (a) after a simulated recall; or
- (b) after a genuine recall, if the recall demonstrated the traceability and recall procedures to be effective.

## **Part 6 Suppliers**

### **Subpart 1—Supply requirements for specific animal material**

#### **109 Farmed animals suitable for processing**

- (1) A supplier or other person in charge of farmed animals must ensure that, if farmed animals under their control have been treated with, been fed, or had access to any agricultural compound, veterinary medicine, or other substance that is likely to adversely affect the suitability of animal material for processing, they are managed to ensure that they are suitable for processing.
- (2) A supplier or other person in charge must not supply a farmed animal for processing for human consumption if the animal has been treated with an unregistered veterinary medicine that is not exempt from registration under the Agricultural Compounds and Veterinary Medicines Act 1997, unless approval is given under regulation 120.
- (3) A supplementary notice may, for the purposes of this regulation, specify detailed requirements relating to—
  - (a) agricultural compounds, veterinary medicines, or other substances that may adversely affect suitability for processing; and
  - (b) criteria or requirements for managing farmed animals; and
  - (c) requirements for confirming suitability for processing.

**110 Game estate animals suitable for processing**

- (1) A game estate operator or hunter must ensure that, if game estate animals kept on the game estate (whether all of the time or only some of the time) are treated with, fed, or allowed access to, any agricultural compound, veterinary medicine, or other substance that is likely to adversely affect the suitability of animal material for processing, they are managed to ensure that they are suitable for processing.
- (2) A game estate operator or hunter must not supply game estate animals for processing for human consumption if the animal has been treated with an unregistered veterinary medicine that is not exempt from registration under the Agricultural Compounds and Veterinary Medicines Act 1997, unless approval is given under regulation 120.
- (3) A supplementary notice may, for the purposes of this regulation, specify detailed requirements relating to—
  - (a) agricultural compounds, veterinary medicines, or other substances that may adversely affect suitability for processing; and
  - (b) criteria or requirements for managing game estate animals; and
  - (c) requirements for confirming suitability for processing.

**111 Supply of game estate animal material**

A hunter, supplier, or other person in charge of game estate animal material—

- (a) must not present it for primary processing unless it has been procured from a game estate where the animals have been fully confined within the game estate; and
- (b) must comply with any further detailed requirements, related to supply of game estate animal material, specified in a supplementary notice for the purposes of this regulation.

**112 Supply of animal material from wild, game estate, and formerly-farmed feral animals**

- (1) A hunter, supplier, or other person in charge of animal material must not present animal material for primary processing from a wild animal, game estate animal, or an animal that was farmed but has gone feral if the animal was procured from an area of land specified in a supplementary notice.
- (2) A supplementary notice may, for the purposes of this regulation, specify—
  - (a) when animal material procured from geographic locations or types of land must not be or may be presented for primary processing; and
  - (b) for the purposes of paragraph (a), substances present in geographic locations and types of land; and
  - (c) geographic locations and types of land identified for the purposes of paragraph (a).

**113 Health of farmed animals for supply**

- (1) A supplier or other person in charge of farmed animals for primary processing for human or animal consumption must—
  - (a) comply with any procedures specified in a supplementary notice to ensure that farmed animals are in a generally healthy condition for presentation for processing; and
  - (b) present the animals in a generally healthy condition; and
  - (c) comply with any further detailed requirements related to supply of farmed animals for primary processing specified in a supplementary notice.
- (2) In this regulation, **generally healthy** means that an animal appears outwardly healthy and the supplier or other person in charge has no reason to suspect that the animal is or was moribund or infected with disease that would make the animal unsuitable for processing.

**114 Supply of farmed mammals and farmed birds**

A supplier or other person in charge of farmed mammals or farmed birds for primary processing for human or animal consumption must—

- (a) present the mammals or birds live; and
- (b) comply with any further detailed requirements related to supply of farmed mammals and farmed birds specified in a supplementary notice.

**115 Supply of animal material from animals imported live into New Zealand**

- (1) A supplier or other person in charge of animals or animal material must not supply animal material derived from an animal imported live into New Zealand for slaughter unless the Director-General gives approval under regulation 120.
- (2) A supplier or other person in charge must comply with any further detailed requirements, related to supply of animal material from animals imported live, specified in a supplementary notice.

**116 Hunter supplying animal material for human consumption must be listed**

A hunter supplying animal material for human consumption must be listed in accordance with Part 10.

**117 Hunter must comply with written agreement in certain situations**

A hunter must ensure that any animal material they supply to a primary processor for human or animal consumption—

- (a) complies with requirements in a supplementary notice relating to—
  - (i) obligations of hunters in regard to animal material intended or provided for primary processing; and
  - (ii) condition or procurement; and

- (b) is supplied in accordance with a written agreement with the processor that complies with the applicable requirements of the supplementary notice.

#### **118 Supply of animal material used in experiments, trials, or research**

- (1) A supplier or other person in charge of animal material must not present it for primary processing if the animal material has been used in experiments, trials, or research, unless approval is given under regulation 120.
- (2) A supplier or other person in charge must also comply with any further detailed requirements, related to supply of animal material used in experiments, trials, or research, specified in a supplementary notice.

#### **119 Presentation of animal material for primary processing**

A supplier or other person in charge of animal material must not present it for primary processing unless—

- (a) the supplier or other person in charge has met regulatory requirements; or
- (b) the Director-General approves the presentation under regulation 120 and any conditions of presentation are complied with.

#### **120 Director-General may allow presentation for primary processing of particular animal material**

- (1) The Director-General may give approval in writing for a supplier or other person in charge of particular animal material that does not meet regulatory requirements to present the material for primary processing if—
  - (a) the supplier or other person in charge of the animal material applies to the Director-General before it is presented for primary processing; and
  - (b) there is good reason in the special circumstances of the case why the regulatory requirements cannot be met; and
  - (c) the Director-General is satisfied that the risk to human or animal health is negligible.
- (2) The Director-General may give the approval subject to conditions.

Subpart 2—General requirements for suppliers, other persons in charge,  
game estate operators, and hunters

#### **121 Competency**

- (1) A supplier, other person in charge of animal material, game estate operator, or hunter must ensure that they and their personnel (if any) are suitably skilled to carry out tasks that could affect—
  - (a) the suitability of animal material for processing;
  - (b) the traceability or recall of animal material:

- (c) the management of systems in relation to the supply of animal material.
- (2) A supplier, other person in charge of animal material, game estate operator, or hunter must meet any competency or other requirements specified in a supplementary notice.
- (3) A supplementary notice may, for the purposes of this regulation, specify requirements relating to competency and other matters, including—
  - (a) any training, experience, knowledge, or qualification that is required; and
  - (b) requiring the matters referred to in paragraph (a) to be maintained; and
  - (c) who may provide training or a qualification; and
  - (d) requiring operators to document and implement a training programme.
- (4) The Director-General may approve for 1 or more named persons an alternative training requirement or qualification that is at least equivalent to the one specified in the supplementary notice.
- (5) The Director-General may approve, in regard to 1 or more named persons, the person's knowledge and experience as being at least equivalent to the training or qualification set out in the supplementary notice.

## **122 Checks**

- (1) A supplier, other person in charge of animal material, game estate operator, or hunter must carry out regular checks to ensure that they are compliant with regulatory requirements.
- (2) The checks must be carried out in accordance with any requirements specified in supplementary notices.
- (3) Supplementary notices may specify requirements in relation to checks, including—
  - (a) what must be checked; and
  - (b) how checks must be made; and
  - (c) who must carry out the checks; and
  - (d) the frequency of checks; and
  - (e) actions to be taken as a consequence of the checks.

## **123 Procedures for supply of animal material**

A hunter, supplier, or other person in charge of animal material for supply must,—

- (a) if required by a supplementary notice, have in place procedures for managing the supply of animal material; and
- (b) meet any further requirements specified in supplementary notices for the purposes of this regulation.

**124 Supply and movement declarations for farmed animals**

- (1) A person required by notice issued under section 167(1) of the Act for the purposes of section 81A of the Act to complete and supply a declaration must use the form approved by the Director-General, if a form has been approved.
- (2) A form approved by the Director-General is secondary legislation (*see* Part 3 of the Legislation Act 2019 for publication requirements), unless the form is approved for use only by 1 or more named persons.

**Legislation Act 2019 requirements for secondary legislation made under this regulation**

|                     |                                                                                             |                  |
|---------------------|---------------------------------------------------------------------------------------------|------------------|
| <b>Publication</b>  | The maker must publish it in accordance with the Legislation (Publication) Regulations 2021 | LA19 s 74(1)(aa) |
| <b>Presentation</b> | The Minister must present it to the House of Representatives                                | LA19 s 114       |
| <b>Disallowance</b> | It may be disallowed by the House of Representatives                                        | LA19 ss 115, 116 |

*This note is not part of the secondary legislation.*

**125 How records must be kept**

- (1) A supplier, other person in charge of animal material, game estate operator, or hunter must keep records—
  - (a) to demonstrate their compliance with relevant requirements under this Part; and
  - (b) in accordance with any supplementary notices or notices under section 167(1) of the Act for the purposes of section 77H(2) of the Act.
- (2) The supplier, other person in charge of animal material, game estate operator, or hunter must ensure that the records are legible and are stored—
  - (a) in a manner that protects the records from damage, deterioration, or loss; and
  - (b) in an accessible form.

**Part 7****Animal material depots, transporters, further petfood processors, beekeepers, and dairy processors****126 Interpretation**

For the purposes of subparts 1 and 6, **animal material depot** means a depot described in any of paragraphs (a) to (d) of regulation 127.

**Subpart 1—Animal material depots****127 Application of this subpart**

This subpart applies to the operator of any 1 or more of the following that is storing animal material for human consumption, except to the extent that they

operate under a risk management programme or a regulated control scheme that covers a matter dealt with in this subpart:

- (a) a depot storing wild mammals after they are killed, and before their primary processing:
- (b) a depot storing any 1 or more of the following after they are killed, and before their primary processing, as if they were wild mammals:
  - (i) mammals from a game estate:
  - (ii) mammals that were farmed but have gone feral:
- (c) a depot on land storing fish—
  - (i) that is not bivalve molluscan shellfish (such as oysters, clams, mussels, pipis, or scallops); and
  - (ii) that is exempted from the requirement to have a risk management programme under clause 4 of Schedule 2:
- (d) a depot storing deer velvet, after it is harvested and before further primary processing, that is—
  - (i) harvested from wild deer, farmed deer, or deer from a game estate; and
  - (ii) exempted from the requirement to have a risk management programme under clause 10 of Schedule 2.

#### **128 Storing animal material**

- (1) The operator of an animal material depot must ensure that activities at the depot are restricted to storing.
- (2) In this regulation, **storing** includes processes incidental to storage that ensure the suitability of the animal material for processing.

#### **129 Animal material depot must be listed**

- (1) The operator of an animal material depot must apply for the animal material depot to be listed in accordance with Part 10.
- (2) Subclause (1) does not apply to the operator of an animal material depot storing only deer velvet.

*Good operating practices for animal material depot operators*

#### **130 Animal material depot location, design, and construction**

- (1) The operator of an animal material depot must ensure that the animal material depot is—
  - (a) designed and located to minimise the contamination of animal material, including from the external environment; and
  - (b) designed and constructed—

- (i) of materials that are durable, non-toxic, and free from defects that may adversely affect the suitability of animal material for processing; and
  - (ii) to enable cleaning and, where necessary, sanitising; and
  - (iii) to minimise the entry, harbouring, or accumulation of pests and contaminants in the depot; and
  - (iv) to be of adequate capacity for the intended maximum throughput of animal material; and
  - (v) to contain a refrigeration facility or other means to chill the animal material where necessary to maintain its suitability for processing.
- (2) The operator of an animal material depot must comply with any detailed requirements specified in a supplementary notice in relation to animal material depot location, design, and construction.

**131 Operation of animal material depot facilities, equipment, and essential services**

- (1) The operator of an animal material depot must ensure that the animal material depot is operated—
  - (a) in a manner that minimises the contamination and deterioration of animal material; and
  - (b) within its designed capacity; and
  - (c) in a manner that complies with any detailed requirements specified in supplementary notices.
- (2) The operator must ensure that all persons accessing or using the animal material depot are adequately trained and comply with any relevant requirements specified in a supplementary notice.
- (3) The operator must ensure that—
  - (a) water is fit for its intended purpose and of sufficient quantity at its point of use; and
  - (b) other essential services are managed to minimise their being a source of contamination; and
  - (c) the animal material depot and equipment are maintained, cleaned, and, where necessary, sanitised to ensure the suitability of animal material for processing; and
  - (d) cleaning and maintenance equipment is not a source of contamination; and
  - (e) maintenance compounds are labelled, used, and stored in a manner that ensures the suitability of animal material for processing; and

- (f) only maintenance compounds approved by the Director-General under regulation 247 are used within the animal material depot and they are used in accordance with conditions for use; and
- (g) waste is collected, managed, and disposed of in a way that prevents it from harbouring pests or being a source of contamination of animal material; and
- (h) opportunities for pests to infest, soil, or contaminate animal material, the animal material depot, equipment, or essential services are minimised.

### **132 Animal material depot packaging requirements**

The operator of an animal material depot must ensure that any packaging used for animal material—

- (a) maintains the suitability of animal material for processing; and
- (b) minimises contamination of the animal material; and
- (c) complies any detailed requirements specified in a supplementary notice in relation to animal material depot packaging requirements.

### **133 Protecting against contamination by people at animal material depot**

- (1) The operator of an animal material depot must ensure that any person at the depot—
  - (a) follows an appropriate routine of personal hygiene that minimises contamination of animal material; and
  - (b) behaves in a way that minimises contamination of animal material; and
  - (c) wears clothing that is not a source of contamination of animal material; and
  - (d) complies with any further detailed requirements, related to protecting animal material from contamination by people, specified in a supplementary notice.
- (2) The operator must ensure that any person at the depot who is known to have or suspected of having an illness or condition does not, directly or indirectly, contaminate animal material.
- (3) For the purposes of this regulation, **illness or condition** means an illness or a condition that can be transmitted from humans through animal material.

### **134 Animal material depot record keeping**

- (1) An operator that this subpart applies to must—
  - (a) keep records of all incoming and outgoing animal material; and
  - (b) ensure that the records are retained for at least 4 years; and
  - (c) comply with detailed record-keeping requirements specified in a supplementary notice.

- (2) An operator that this subpart applies to must ensure that documentation that a hunter is required to supply cannot be accessed by another hunter.

**135 Requirements for certain animal material depots**

The operator of an animal material depot that stores animal material from mammals that are wild, are from a game estate, or were farmed but have gone feral must—

- (a) provide a calibrated measuring device to monitor the operating temperature of the animal material depot at the warmest point within the depot; and
- (b) comply with any further detailed requirements, related to calibrated temperature measuring devices and monitoring of temperatures, specified in a supplementary notice.

**136 Additional requirements for animal material depots that are mobile**

- (1) The operator of an animal material depot that is mobile and stores animal material from mammals that are wild, are from a game estate, or were farmed but have gone feral must—
- (a) ensure that there is a calibrated temperature measuring device that automatically records temperatures at the warmest point within the depot; and
  - (b) provide records to the primary processor of temperatures measured by the calibrated measuring device relating to each load of animal material transferred to the primary processor from the time the animal material is stored; and
  - (c) have in place corrective action procedures to manage refrigeration temperature failure within the depot when storing animal material, including notifying the person responsible for the animal material; and
  - (d) comply with any detailed requirements related to the operation of an animal material depot that is mobile that are specified in a supplementary notice.
- (2) The operator of an animal material depot that is mobile and stores animal material from mammals that are wild, are from a game estate, or were farmed but have gone feral must not, at the same time, store any other animal material that may contaminate the mammal material.
- (3) The operator of an animal material depot that is mobile must not store or transport anything that is not associated with the activity of being an animal material depot while it is operating as an animal material depot.
- (4) The operator of an animal material depot that is mobile must clean and sanitise the depot before receiving new animal material for storing.

## Subpart 2—Transporters

### **137 Application of this subpart**

This subpart applies to any transporter of animal material or animal product who does not transport live animals, except to the extent that the transporter is operating under a risk management programme that covers a matter dealt with under this subpart.

### **138 Good operating practice for transporters**

The transporter of animal material or animal product must ensure that it is transported in a manner that ensures that it—

- (a) remains suitable for processing or fit for its intended purpose; and
- (b) meets any requirements specified in a supplementary notice.

## Subpart 3—Further petfood processors

### **139 Application of this subpart**

This subpart applies to any further petfood processor except to the extent that the further petfood processor is operating under a risk management programme that covers a matter dealt with in this subpart.

### **140 Further petfood processors must be listed**

Further petfood processors must be listed with the Director-General in accordance with Part 10.

### **141 Further petfood processor must source from risk management programme, etc**

A further petfood processor must ensure that any animal material or animal product that they source for further processing has been subject to primary processing or rendering in accordance with a risk management programme or a risk-based measure.

### **142 Further petfood processor must have traceability procedure**

- (1) A further petfood processor must have in place and implement a documented traceability procedure that enables them—
  - (a) to trace animal material, animal product, and other inputs—
    - (i) from the supplier to the further petfood processor; and
    - (ii) from the further petfood processor to the next recipient in the supply chain (other than the final consumer); and
  - (b) to identify animal material, animal product, and other inputs while they are under the control of the further petfood processor.

- (2) A further petfood processor must comply with any detailed requirements relating to further petfood processor traceability procedures specified in supplementary notices.

#### **143 Further petfood processor must keep records**

- (1) In addition to the requirements of regulation 155, a further petfood processor must—
  - (a) keep records of—
    - (i) the name and address of the business from which animal material or animal product was sourced; and
    - (ii) all animal material or animal product sourced, including a description of the animal material or animal product, the quantity received, and the date on which it was received; and
    - (iii) all animal product produced, including any animal material or animal products used in the processing of the product produced; and
  - (b) comply with any detailed requirements relating to further petfood processor record-keeping requirements specified in supplementary notices.
- (2) A further petfood processor must ensure that the records—
  - (a) are retained for at least 4 years; and
  - (b) can be retrieved within 2 working days after a request by the Director-General, an animal product officer, or a verifier or verifying agency.

### **Subpart 4—Beekeepers**

#### **144 Application of this subpart**

This subpart applies to beekeepers who harvest animal material or animal products produced by bees (including any associated storage or transport operations) and who are exempt under clause 11 of Schedule 2 from the requirement to operate under a risk management programme.

#### **145 Good operating practices for beekeepers**

- (1) A beekeeper must ensure that—
  - (a) beehives are constructed of material that is not a source of hazard to the honey or other bee products; and
  - (b) beehives are maintained to ensure that hazards that may affect honey or other bee products are minimised; and
  - (c) honey supers are stored in a manner that minimises contamination, including before and after extraction; and
  - (d) honey supers are transported in a manner that minimises contamination, including from dust and fumes.

- (2) A beekeeper must comply with any detailed requirements relating to beekeepers specified in supplementary notices.

### Subpart 5—Dairy processors

#### **146 Application of this subpart**

This subpart applies to any dairy processor except to the extent that the dairy processor operates under a risk management programme, regulated control scheme, or risk-based measure under the Food Act 2014 that covers a matter dealt with in this subpart.

#### **147 Dairy material and product must be wholesome and free from hazard**

- (1) A dairy processor must ensure that dairy product is wholesome and free from hazard.
- (2) Supplementary notices may specify requirements for dairy material or dairy product, including—
  - (a) their risk factors; and
  - (b) how hazards and risk factors must be controlled; and
  - (c) acceptable or unacceptable levels of hazards, contaminants, or substances.
- (3) The dairy processor must meet any further requirements specified in a supplementary notice for the purpose of this regulation.

#### **148 Dairy processor requirements for premises, places, facilities, equipment, and essential services**

- (1) A dairy processor must ensure that premises, places, facilities, equipment, and essential services are located, designed, and constructed so that—
  - (a) dairy material is suitable for processing; and
  - (b) dairy products are fit for their intended purpose.
- (2) The dairy processor must meet any further requirements relating to premises, places, facilities, equipment, or essential services that are specified in a supplementary notice for the purposes of this regulation.
- (3) Supplementary notices may specify further requirements relating to premises, places, facilities, equipment, or essential services for the purposes of this regulation.

#### **149 Dairy processor requirements for maintaining and operating premises, places, facilities, equipment, and essential services**

A dairy processor must ensure that premises, places, facilities, equipment, and essential services are maintained and operated in a manner that minimises and manages the exposure of dairy material, dairy product, or inputs to risk factors.

**150 Dairy material and product must be processed in manner that minimises contamination and deterioration**

- (1) A dairy processor must ensure that dairy material and dairy product are processed and handled in a manner that manages and minimises their contamination and deterioration.
- (2) A dairy processor must meet any requirements about how dairy material and dairy product must be processed to minimise contamination and deterioration that are specified in a supplementary notice.
- (3) Supplementary notices may specify how dairy material and dairy product must be processed or handled in order to minimise contamination and deterioration.

**151 Dairy material and product transport requirements**

- (1) A dairy processor must ensure that dairy material and dairy product are transported in a manner that ensures that—
  - (a) it remains fit for its intended purpose; and
  - (b) risk factors associated with transport and delivery are managed; and
  - (c) contamination or deterioration of dairy material or dairy product is minimised.
- (2) A dairy processor must meet any further requirements relating to the transport and delivery of dairy material and dairy product specified in a supplementary notice.
- (3) Supplementary notices may specify further transport and delivery requirements relating to the transport and delivery of dairy material and dairy product for the purposes of this regulation.

Subpart 6—General provisions relating to animal material depot operators, transporters, further petfood processors, beekeepers, and dairy processors

**152 Competency**

- (1) An animal material depot operator, or a transporter, further petfood processor, beekeeper, or dairy processor must ensure that they and their personnel (if any) are suitably skilled to carry out tasks that could affect—
  - (a) the suitability of animal material for processing;
  - (b) the traceability of animal material;
  - (c) the management of systems relating to the production or supply of animal material.
- (2) An animal material depot operator, or a transporter, further petfood processor, beekeeper, or dairy processor must meet any competency or other requirements specified in a supplementary notice.

- (3) A supplementary notice may, for the purposes of this regulation, specify requirements relating to competency and other matters, including—
  - (a) any training, experience, knowledge, or qualification that is required; and
  - (b) requiring the matters referred to in paragraph (a) to be maintained; and
  - (c) who may provide training or a qualification; and
  - (d) requiring operators to document and implement a training programme.
- (4) The Director-General may approve for 1 or more named persons an alternative training requirement or qualification that is at least equivalent to the one specified in the supplementary notice.
- (5) The Director-General may approve, in regard to 1 or more named persons, the persons' knowledge and experience as being at least equivalent to the training or qualification set out in the supplementary notice.

### **153 Checks**

- (1) An animal material depot operator, or a transporter, further petfood processor, beekeeper, or dairy processor must carry out regular checks to ensure they are compliant with regulatory requirements.
- (2) The checks must be carried out in accordance with any requirements in supplementary notices.
- (3) Supplementary notices may specify detailed requirements in relation to checks, including—
  - (a) what must be checked; and
  - (b) how checks must be made; and
  - (c) who must make the checks; and
  - (d) the frequency of checks; and
  - (e) actions to be taken as a consequence of the checks.

### **154 Systems and procedures for procurement and supply**

An animal material depot operator, or a transporter, further petfood processor, beekeeper, or dairy processor, in accordance with any relevant supplementary notices, must have and implement procedures for corrective actions—

- (a) to restore control; and
- (b) to identify, manage, or dispose of affected animal material or animal product; and
- (c) to prevent recurrence of a loss of control.

### **155 How records must be kept under this Part**

- (1) An animal material depot operator, or a transporter, further petfood processor, beekeeper, or dairy processor must keep records—

- (a) to demonstrate their compliance with relevant requirements under this Part; and
  - (b) in accordance with any supplementary notices or notices under section 167(1) of the Act for the purposes of section 77H(2) of the Act.
- (2) The animal material depot operator, transporter, further petfood processor, beekeeper, or dairy processor must ensure that the records are legible and are stored—
  - (a) in a manner that protects the records from damage, deterioration, or loss; and
  - (b) in an accessible form.

## Part 8

### Regulated control scheme: monitoring and surveillance

#### Subpart 1—Preliminary provisions

#### 156 Interpretation

In this Part, unless the context otherwise requires,—

**contaminating agent**, in relation to a contaminant, means a thing (including an animal or a place) or person that or who may, directly or indirectly,—

- (a) cause the contaminant to be, or to develop, in animal material or animal product; or
- (b) transfer the contaminant to animal material or animal product

**hygiene indicator** means a risk management metric that, following the outcome of sampling and testing for microorganisms, or for specific markers or other traits at a specified point of the animal material or animal product chain, can indicate—

- (a) the acceptability of animal material or animal product; or
- (b) the performance of either a process or a food safety control system, including the processing environment

**integrity indicator**, in relation to animal material, animal product, or a sample of animal material or animal product, means a risk management metric that indicates—

- (a) its suitability for testing, the truth in its labelling, or good agricultural or manufacturing practice; or
- (b) the adulteration of the animal material, animal product, or sample

**monitoring** means—

- (a) ongoing sampling and testing to identify—

- (i) the absence or presence, extent, and distribution of physical, chemical, and biological substances in animal material or animal product; or
  - (ii) whether there is a risk of those substances being present in animal material or animal product; and
- (b) testing to establish the validity of a sample for further testing

**residue** means a chemical that remains in or on animal material or animal product and is regulated by or under the Act or the Food Act 2014

**risk source** means a source or possible source of a contaminating agent and includes, as appropriate to the animal material, animal product, or contaminant involved,—

- (a) a place where contamination of animal material or animal product may occur; and
- (b) a grouping of animals that may harbour or may be exposed to a contaminating agent; and
- (c) a person in charge of animal material, animal product, or a place, that may contain or be exposed to a contaminating agent

**risk source operator** means—

- (a) the person in charge of a risk source; or
- (b) a person who is listed in a surveillance list as a risk source of the type described in paragraph (c) of the definition of risk source

**sampling** includes—

- (a) sample selection; and
- (b) taking a sample; and
- (c) gathering information about a sample; and
- (d) safeguarding a sample; and
- (e) sending a sample to a laboratory; and
- (f) transporting a sample; and
- (g) any associated activities set out in supplementary notices

**specified agricultural compound** means an agricultural compound identified by the Director-General by supplementary notice as an agricultural compound to which subpart 4 applies

**substance** includes a residue, an agricultural compound, a veterinary medicine, and a contaminant

**surveillance** means—

- (a) sampling and testing to identify the absence or presence, extent, and distribution of contaminants in animal material or animal product, through monitoring or other means, after—

- (i) a contaminant is found to be present; or
- (ii) a risk of contaminants being present is identified; and
- (b) applying measures to a risk source or animal material or animal product to manage the presence or risk of contaminants

**surveillance animal material** or **surveillance animal product** means, as the case may require, a class of animal material or animal product—

- (a) that originates from a risk source; and
- (b) that is specified as surveillance animal material or surveillance animal product in a surveillance list

**surveillance list** means the list of risk sources under surveillance that is kept by the Director-General under regulation 170

**surveillance notice** means a notification to a risk source operator under regulation 173

**testing** includes analysis or examination.

#### **157 Regulated control scheme imposed**

- (1) This Part imposes a regulated control scheme (the **scheme**) for animal material and animal product, including dairy material and dairy product.
- (2) The scheme provides for the following risk management measures:
  - (a) monitoring of animal material and animal products of a kind specified in regulation 162 and associated supplementary notices:
  - (b) surveillance of animal material and animal product:
  - (c) the control of specified agricultural compounds.
- (3) The scheme comprises these regulations, together with any associated supplementary notices.

Compare: SR 2004/396 r 3

#### **158 Prime purpose of scheme**

The prime purpose of the scheme is to impose risk management measures by providing a framework for monitoring and surveillance—

- (a) to identify the absence or presence, extent, and distribution of substances in animal material and animal product, including by measurement of hygiene indicators and integrity indicators; and
- (b) to address the risks from hazards to human or animal health associated, directly or indirectly, with animal material and animal product from a risk source (whether identified under the scheme or by other means); and
- (c) to monitor good agricultural and manufacturing practice, and the applicable systems control.

Compare: SR 2004/396 r 4

## Subpart 2—Monitoring

### 159 Outline of this subpart

This subpart—

- (a) imposes powers and duties in respect of monitoring; and
- (b) provides for monitoring, which may include—
  - (i) a sampling regime imposing requirements for the sampling of animal material or animal product;
  - (ii) a sampling plan;
  - (iii) systems for monitoring.

Compare: SR 2004/396 r 7

### 160 Application of this subpart

This subpart applies to—

- (a) persons in charge of animal material or animal product from which samples are to be taken; and
- (b) recognised agencies (including recognised laboratories) and recognised persons; and
- (c) animal product officers; and
- (d) persons authorised by the Director-General to take samples.

Compare: SR 2004/396 r 8

### 161 Who may carry out monitoring

- (1) Monitoring may only be carried out—
  - (a) by or on behalf of the Director-General, or by an animal product officer, a recognised agency, or a recognised person; and
  - (b) in accordance with the scheme provided for in this subpart, including any applicable supplementary notices.
- (2) The general requirements of subpart 5 of this Part, including testing of samples, also apply to monitoring.

### 162 Scope of monitoring

The substances, animal material, and animal product that may be monitored are—

- (a) agricultural compounds and veterinary medicines, as specified in supplementary notices, in relation to all live animals in New Zealand; and
- (b) agricultural compounds and veterinary medicines, contaminants, hygiene indicators, and integrity indicators in relation to animal material or animal product, from—
  - (i) bees and other insects as specified in supplementary notices; and

- (ii) fish (excluding bivalve molluscan shellfish); and
- (iii) poultry, ostriches, emus, and other birds as specified in supplementary notices; and
- (iv) farmed cattle, sheep, goats, pigs, deer, horses, rabbits, and possums; and
- (v) mammals of any species shot in game estates and in the wild (including farmed mammals referred to in subparagraph (iv) that have gone feral); and
- (vi) any other mammals specified in supplementary notices.

### **163 Issuing of requirements for monitoring**

For the purposes of regulations 161 and 162, supplementary notices may—

- (a) list the substances or group of substances that may be monitored under this subpart; and
- (b) list the types of animal material and animal product that may be monitored under this subpart; and
- (c) specify other requirements in relation to monitoring, including—
  - (i) how and what sampling must be done and by whom; and
  - (ii) how and what testing must be done and by whom; and
  - (iii) what results need to be reported and to whom.

Compare: SR 2004/396 Schedule 1 cl 3

### **164 Issuing of sampling regime for monitoring**

- (1) For the purposes of regulation 161, supplementary notices may specify 1 or more sampling regimes imposing requirements for the sampling of animal material or animal product for monitoring purposes.
- (2) A sampling regime must include requirements for—
  - (a) the commencement date and the expiry date (where appropriate) of the regime; and
  - (b) a general description of the animal material or animal product or the class of animal material or animal product from which samples will be taken; and
  - (c) a general description of the types of samples to be taken and the approximate total number of samples to be taken; and
  - (d) a general description of the nature of the substances being monitored.

Compare: SR 2004/396 r 9

### **165 Issuing of sampling plan for monitoring**

- (1) The Director-General may issue, in writing, 1 or more sampling plans to an animal product officer, a recognised person, a recognised agency, or other per-

son authorised to collect samples, for the purpose of monitoring animal material or animal product.

- (2) A sampling plan may set out—
  - (a) a sampling pattern to be used by the person issued with the plan to determine which particular animal material or animal product will be sampled; or
  - (b) a sampling selection process to be used by the person issued with the plan in order to determine a sampling pattern.
- (3) A sampling plan may also include other matters for the purposes of a sampling regime, including—
  - (a) the period or periods during which the samples or a certain number of samples must be taken; and
  - (b) provision for selection of other details to help determine when or where sampling will be carried out; and
  - (c) the laboratory or intermediate facility to which samples must be sent for testing.

Compare: SR 2004/396 r 10

### Subpart 3—Surveillance

#### **166 Outline of this subpart**

This subpart—

- (a) imposes powers and duties in respect of surveillance; and
- (b) provides for surveillance, which may include—
  - (i) a sampling regime imposing requirements for the sampling of animal material or animal product for surveillance purposes; and
  - (ii) a sampling plan that may modify the requirements of the sampling regime; and
  - (iii) certain risk management measures that may be imposed by the Director-General if they suspect that there is a risk of contamination of animal material or animal product; and
- (c) provides for the Director-General to keep a surveillance list, entries on which may be amended or revoked.

Compare: SR 2004/396 r 12

#### **167 Application of this subpart**

This subpart applies to—

- (a) processors of surveillance animal material or surveillance animal product; and
- (b) risk source operators; and

- (c) recognised persons and recognised agencies (including recognised laboratories); and
- (d) persons who have an interest or involvement in the supply of surveillance animal material or surveillance animal product for processing or the distribution of potential contaminants in the primary production environment; and
- (e) animal product officers; and
- (f) persons authorised by the Director-General to take samples.

Compare: SR 2004/396 r 13

### **168 Who may carry out surveillance**

- (1) Surveillance may only be carried out—
  - (a) by or on behalf of the Director-General, or by an animal product officer, a recognised agency, or a recognised person; and
  - (b) in accordance with the scheme provided for in this subpart, including any applicable supplementary notices.
- (2) The general requirements of subpart 5, including testing of samples, also apply to surveillance.

### **169 Application of risk management measures**

- (1) The Director-General may apply a risk management measure set out in subclause (2) to a risk source if they have reasonable grounds to suspect that there is a risk of contamination of animal material or animal product from the risk source after having regard to the following matters:
  - (a) available evidence of the possible presence and distribution of the suspected contaminant in the primary production environment, or the primary or secondary processing environment;
  - (b) the availability and known pattern of use of the suspected contaminant and the potential for its abuse or misuse;
  - (c) the nature, likely persistence, and potential for transfer (that is, cross-contamination) of the suspected contaminant;
  - (d) the potential harm to human or animal health from the suspected contaminant;
  - (e) any applicable regulatory limits for the suspected contaminant;
  - (f) the availability of effective and reliable sampling and testing methods for the suspected contaminant;
  - (g) any other matters that the Director-General considers relevant.
- (2) The risk management measures are—
  - (a) making an entry on the surveillance list in accordance with regulation 170; and

- (b) requiring the identification of the animal material or animal product and associated things in the manner specified by the Director-General; and
- (c) applying conditions in relation to the supply of animal material or animal product from the risk source; and
- (d) requiring a recognised person, a recognised agency, or an animal product officer to take responsibility for investigating and reporting on the risk source and potential for wider contamination; and
- (e) requiring a recognised person, a recognised agency, or an animal product officer to verify whether the risk source operator is complying with the risk management measures that apply to the risk source; and
- (f) any other measure for managing risk imposed under the Act.

Compare: SR 2004/396 r 14

#### **170 Surveillance list**

- (1) The Director-General—
  - (a) may keep a surveillance list in respect of dairy material or dairy product; and
  - (b) must keep a surveillance list in respect of any other animal material or animal product.
- (2) The purposes of the list are—
  - (a) to enable surveillance animal material and surveillance animal product to be identified, isolated, dealt with, and disposed of in accordance with notices; and
  - (b) to enable measures to be applied to risk sources.
- (3) The list may be kept in the manner and form determined by the Director-General, including on an Internet site maintained by or on behalf of the Ministry.
- (4) The Director-General may,—
  - (a) if the Director-General considers it appropriate to enable measures to be applied to the risk sources, enter any risk sources onto the surveillance list; and
  - (b) if the Director-General considers it appropriate, revoke or amend the entries on the list.
- (5) Each entry must, to the extent practicable,—
  - (a) identify the risk source, for example, by name, type, or location; and
  - (b) identify the risk source operator; and
  - (c) specify the class of material or product that is surveillance animal material or surveillance animal product; and

- (d) specify the class or description of identified contaminant, in connection with the surveillance animal material or surveillance animal product.
- (6) The Director-General must notify relevant processors and recognised agencies or recognised persons (as appropriate) of the details entered on the surveillance list, and any amendments to those details, in accordance with section 165 of the Act.

Compare: SR 2004/396 r 15

#### **171 Amendment of incorrect or unreasonable entry on surveillance list**

- (1) A risk source operator may apply in writing to the Director-General to request that an entry relating to the risk source operator on the surveillance list be amended because it is incorrect or unreasonable.
- (2) The Director-General must amend the entry unless the Director-General is satisfied that the entry is correct and reasonable.
- (3) The Director-General must provide written reasons to the risk source operator if they decide not to amend the entry.

Compare: SR 2004/396 r 16

#### **172 Amendment or revocation of entry on surveillance list if risk under control or eliminated**

- (1) A risk source operator may apply in writing to the Director-General to request that a relevant entry relating to the risk source operator on the surveillance list be amended or revoked because the risk of contamination of animal material or animal product has been brought under control or eliminated at source.
- (2) The Director-General must amend or revoke the surveillance notice and the relevant entry on the surveillance list if the risk source operator satisfies the Director-General that the risk of contamination of animal material or animal product has been brought under control or eliminated at source.
- (3) The Director-General must provide written reasons to the risk source operator if they decide not to amend or revoke the entry.

Compare: SR 2004/396 r 17

#### **173 Surveillance notices**

- (1) The Director-General must provide a surveillance notice in writing to the affected risk source operator as soon as practicable after making a new entry or revoking or amending an existing entry in the surveillance list.
- (2) A surveillance notice must be notified in accordance with section 164(2) to (4) of the Act and must specify—
  - (a) the date on and from which the notice takes effect:
  - (b) details of the contaminant under surveillance:
  - (c) any requirements on or conditions applying to the risk source operator (which may include controls imposed under section 81B of the Act):

- (d) any relevant risk management measures applied under regulation 169;
- (e) any other matters as the Director-General considers appropriate.

Compare: SR 2004/396 r 18

#### **174 Amendment or revocation of surveillance notice condition**

- (1) A risk source operator may apply in writing to the Director-General to request that a condition of a surveillance notice be amended or revoked because the relevant contaminant can be contained either by applying the condition as amended or without applying the condition.
- (2) The Director-General must amend or revoke the condition if the risk source operator satisfies the Director-General that the contaminant can be contained either by applying the condition as amended or without applying the condition.
- (3) The Director-General must provide written reasons to the risk source operator if they decide not to amend or revoke the condition.

Compare: SR 2004/396 r 19

#### **175 Application for retesting**

- (1) A risk source operator may apply in writing to the Director-General for a sample to be retested.
- (2) The Director-General must agree to retest a sample if,—
  - (a) in the Director-General's opinion, it is practicable and reasonably necessary; and
  - (b) the risk source operator meets the cost of the retesting before it is carried out.

Compare: SR 2004/396 r 20

#### **176 Obligations of risk source operators**

- (1) A risk source operator (including any person to whom a copy of a surveillance notice is supplied under subclause (2)) must—
  - (a) notify the Director-General in writing as soon as practicable, but not later than 48 hours, after disposal of all or part of the risk source and any associated surveillance animal material or surveillance animal product to another person other than a processor; and
  - (b) provide the name and address of that other person as soon as practicable, but not later than 48 hours, after the disposal referred to in paragraph (a).
- (2) If a risk source operator ceases to own or control the surveillance animal material or surveillance animal product or risk source or any part of it, the risk source operator must, before the transfer (other than transfer to a processor or a processor's agent),—
  - (a) inform the person who takes over ownership or control of the surveillance animal material, animal product, or risk source that it is surveil-

lance animal material or animal product or a risk source, and of any conditions imposed in relation to the material, product, or risk source; and

- (b) supply the person with a copy of the surveillance notice.
- (3) A person who takes over ownership or control of all or part of surveillance animal material, surveillance animal product, or risk source from a risk source operator who ceases to own or control that surveillance animal material, surveillance animal product, risk source, or part, must notify the Director-General in writing of the transfer of ownership or control as soon as practicable after the transfer, if—
  - (a) the person has been informed of the status of the animal material, animal product, or risk source under subclause (2); and
  - (b) the person is not the processor or the processor's agent.
- (4) A risk source operator must comply with the requirements of this regulation whether or not the risk source operator has applied for amendment or revocation of an entry on the surveillance list under regulation 171 or 172.

Compare: SR 2004/396 r 21

#### **177 Obligations of processors**

- (1) A processor must notify the Director-General of any information in relation to surveillance animal material or surveillance animal product in accordance with any relevant notices.
- (2) When processing surveillance animal material or surveillance animal product received from a risk source (whether directly or indirectly), a processor must ensure that the material or product is identified, processed, held, and disposed of in accordance with notices (if any).
- (3) A processor who receives surveillance animal material or surveillance animal product must ensure that a recognised agency or recognised person is notified of the receipt as soon as practicable after receipt.

Compare: SR 2004/396 r 22

#### **178 Issuing of sampling regime for surveillance**

- (1) For the purposes of regulation 168, supplementary notices may specify 1 or more sampling regimes imposing requirements for the sampling of surveillance animal material or surveillance animal product.
- (2) A sampling regime must include requirements for—
  - (a) the commencement date and the expiry date (where appropriate) of the regime; and
  - (b) the class or description of animal material or animal product from which samples are to be taken; and
  - (c) a general description of the types of samples to be taken and the approximate total number of samples to be taken; and

- (d) a general description of the contaminants or group of like contaminants subject to surveillance.

Compare: SR 2004/396 r 23

### **179 Issuing of sampling plan for surveillance**

- (1) The Director-General may issue, in writing, 1 or more sampling plans to an animal product officer, a recognised person, a recognised agency, or other person authorised to collect samples, for the purpose of sampling surveillance animal material or surveillance animal product.
- (2) A sampling plan may set out—
  - (a) a sampling pattern to be used by the person issued with the plan to determine which particular animal material or animal product will be sampled; or
  - (b) a sampling selection process to be used by the person issued with the plan in order to determine a sampling pattern.
- (3) A sampling plan may also include other matters for the purposes of a sampling regime, including—
  - (a) the period or periods during which the samples or a certain number of samples must be taken; and
  - (b) provision for selection of other details to help determine when or where sampling will be carried out; and
  - (c) the laboratory or intermediate facility to which samples must be sent for testing.

Compare: SR 2004/396 r 24

## **Subpart 4—Requirements relating to specified agricultural compounds**

### **180 Requirements relating to specified agricultural compounds**

- (1) An operator, veterinarian, person in charge of animals, or other user of specified agricultural compounds must ensure that the following are carried out in the manner specified in any relevant supplementary notice made under regulation 182:
  - (a) administering specified agricultural compounds:
  - (b) identifying, separating, and processing animals affected by any specified agricultural compound:
  - (c) labelling specified agricultural compounds:
  - (d) keeping records of administration of specified agricultural compounds:
  - (e) putting measures in place to safeguard information required under paragraph (d) from unauthorised use and disclosure:
  - (f) putting documented systems or procedures in place for the administration of specified agricultural compounds.

- (2) A person must not administer specified agricultural compounds to food-producing animals, or expose the animals to specified agricultural compounds, if the animals are specified in supplementary notices referred to in regulation 182(d).
- (3) A person must not use food-producing animals for the supply of animal product for human consumption, if the animals have been administered with or exposed to specified agricultural compounds in breach of any relevant supplementary notices.

### **181 Exemption from regulation**

- (1) The Director-General may exempt a person from the requirements of regulation 180—
  - (a) if the agricultural compound is a proprietary product registered under the Agricultural Compounds and Veterinary Medicines Act 1997 solely as a growth promotant for use in bovine animals, and is labelled accordingly; or
  - (b) on application to the Director-General, if the agricultural compound is administered by a research institute, including in a research programme carried out at a tertiary institute.
- (2) The application referred to in subclause (1)(b) must—
  - (a) be in writing; and
  - (b) be made by the person responsible for the research institute or programme; and
  - (c) describe the controls to be applied by the research institute or under the programme to ensure that no animal treated with a specified agricultural compound will leave its place of residency, or be on-sold or submitted for slaughter, other than in accordance with the described controls.
- (3) The Director-General may include in an exemption granted under subclause (1) any conditions the Director-General considers necessary to ensure compliance with any regulatory requirements.

### **182 Notices relating to control of specified agricultural compounds**

Supplementary notices may specify matters relating to the control of agricultural compounds, including—

- (a) how specified agricultural compounds must be administered and who must administer them; and
- (b) how animals that are affected by specified agricultural compounds are identified (including what identification devices must be used, how they must be used, and for how long); and
- (c) how affected animals must be processed; and

- (d) animals or classes of animals to which specified agricultural compounds must not be administered or that must not be exposed to specified agricultural compounds; and
- (e) records that must be—
  - (i) maintained with respect to the administration of specified agricultural compounds; and
  - (ii) provided to the Director-General or a recognised person or a recognised agency or an animal product officer; and
- (f) measures that must be in place to protect information required by paragraph (e) from unauthorised access or disclosure; and
- (g) documented systems or procedures that must be maintained and implemented in relation to administration of specified agricultural compounds or identification or processing of animals affected by specified agricultural compounds.

### Subpart 5—General provisions

#### **183 Test methodologies for monitoring and surveillance**

For the purposes of regulations 161 and 168, supplementary notices may specify test methods and methodologies for monitoring and surveillance.

#### **184 Director-General may carry out surveys, etc**

- (1) The Director-General may carry out or may cause to be carried out surveys, research, development, investigation, or other work if the Director-General considers that it is desirable in order to—
  - (a) determine whether to, or how to, exercise a power or perform a function or carry out an activity under the Act, these regulations, or applicable supplementary notices in connection with or for the purposes of monitoring or surveillance; or
  - (b) determine how best to achieve the prime purpose of the regulated control scheme in relation to any monitoring or surveillance, including developing or testing legislative, administrative, technical, or other measures (whether current or contemplated) that may be used or applied in connection with or for the purposes of monitoring or surveillance; or
  - (c) investigate or confirm the absence, presence, extent, or distribution of a substance or thing in New Zealand; or
  - (d) investigate or confirm the risk posed by a substance or thing in relation to animal material or animal product.
- (2) The Director-General may carry out or may cause to be carried out targeted or random sampling for the purpose of surveying substances.

- (3) Prior consultation in accordance with section 163(3) of the Act is required unless the work relates to an emergency control scheme under section 41 of the Act.

Compare: SR 2004/396 r 27

#### **185 On-site and off-site testing**

- (1) For the purposes of regulations 161 and 168, supplementary notices may provide for on-site or off-site testing of samples.
- (2) The purposes of the testing may include—
- (a) screening samples of animal material or animal product for the absence or presence of a contaminant or class of contaminants; or
  - (b) producing final test results.
- (3) The Director-General may require testing of another sample of the animal material or animal product from which the first sample was taken if the Director-General considers it appropriate.

Compare: SR 2004/396 r 32

#### **186 Obligations to supply samples, assist, provide access and facilities, etc**

The operator of an animal product business must, on request by the Director-General, a person authorised by the Director-General, an animal products officer, a recognised agency, or a recognised person,—

- (a) supply samples in the manner and time specified by that person or agency; and
- (b) take all reasonable steps to co-operate with and assist persons carrying out monitoring and surveillance under this Part, including by providing access to animal material or animal product to be sampled; and
- (c) provide any facilities that are required by supplementary notices.

#### **187 Obligation to supply information**

- (1) This regulation applies to the following:
- (a) an owner or a person in control or reasonably appearing to be in control of an animal, animal material, animal product, an associated thing, or an animal product business:
  - (b) a risk source operator:
  - (c) a person engaged in the transport and delivery of monitored or surveillance animal material or monitored or surveillance animal product:
  - (d) a laboratory that receives a sample collected under the scheme:
  - (e) all persons who have or have had ownership, management, or control over any thing or person that may, directly or indirectly,—
    - (i) result in animal material or animal product becoming contaminated; or

- (ii) transfer a contaminant to animal material or animal product:
    - (f) a person who, at any earlier relevant time, was a person to whom any of paragraphs (a) to (e) applied.
  - (2) An animal product officer may require a person to whom this regulation applies to provide information held by that person that the animal product officer believes on reasonable grounds is necessary for the purposes of the scheme.
- Compare: SR 2004/396 r 36

## **Part 9**

### **Recognised agencies and persons**

#### **188 Application of this Part**

- (1) This Part applies to the following:
  - (a) the recognition of agencies under section 101 of the Act:
  - (b) the recognition of natural persons under section 103 of the Act.
- (2) This Part does not apply to the following:
  - (a) the recognition of agencies under section 102 of the Act:
  - (b) the recognition of natural persons under section 104 of the Act:
  - (c) the recognition of classes of natural persons under section 105 of the Act.

#### **Subpart 1—Recognised agencies**

#### **189 Scope of this subpart**

This subpart sets out requirements for the recognition, and maintenance of recognition, of agencies under section 101 of the Act.

#### **190 Recognised agencies**

- (1) A person applying to be a recognised agency must demonstrate either or both of the following:
  - (a) that the person—
    - (i) has in place a written quality management system that complies with regulation 220; and
    - (ii) is able to comply with procedures set out in the quality management system:
  - (b) that the person—
    - (i) holds accreditation with an accreditation body, and to a particular standard, as specified in a supplementary notice, as relevant to the specified functions and activities in relation to which the person is seeking recognition; and

- (ii) has documented procedures and systems as set out in regulation 221.
- (2) A person must hold accreditation with an accreditation body as set out in subclause (1)(b)(i), if—
  - (a) the person carries out specified functions and activities; and
  - (b) a supplementary notice requires accreditation with an accreditation body for carrying out those functions and activities.
- (3) Supplementary notices may specify—
  - (a) the relevant standard for the purposes of subclause (1)(b)(i); and
  - (b) the functions and activities for which a person must hold accreditation under subclause (2).
- (4) A person must undergo assessment of a person's ability to carry out the functions and activities for which recognition is sought, if a supplementary notice requires assessment for recognition in relation to those types of functions and activities.
- (5) The assessment must be carried out in relation to following matters specified in the supplementary notice:
  - (a) the levels of assessment:
  - (b) the assessment processes:
  - (c) assessments for different circumstances and types of functions and activities:
  - (d) any other matters relating to the form and content of the assessment.

#### **191 Person in agency responsible for day-to-day management**

- (1) A recognised agency must—
  - (a) appoint a person in the agency as a person responsible for its day-to-day management; and
  - (b) notify the Director-General of the person's name and position.
- (2) A recognised agency must ensure that the person in the agency who is responsible for its day-to-day management is able to demonstrate an understanding of the role of the recognised agency within the relevant regulatory requirements.

#### **192 Recognised agency applying for recognition of natural person**

- (1) This regulation applies to a recognised agency that is—
  - (a) required as a condition of its recognition to manage or supply recognised persons to carry out some or all of the permissible functions and activities for which it is recognised; or
  - (b) applying under the Act for a natural person employed in, or engaged or managed by, the agency to be a recognised person.

- (2) The agency must confirm to the Director-General that the natural person meets all the competencies and requirements relevant to the natural person's proposed functions and activities as a recognised person.
- (3) The agency must have in place procedures for—
  - (a) managing applications for recognising persons; and
  - (b) regularly reviewing the performance of recognised persons; and
  - (c) any other matter specified in a supplementary notice that relates to applications under this regulation.
- (4) Supplementary notices may, for the purposes of this regulation, specify requirements that must be met by recognised agencies applying for recognition of natural persons.

### **193 Performance standards for recognised agency**

- (1) A recognised agency must perform its role to a standard and in such a way that ensures that it is carrying out its specified functions and activities effectively.
- (2) Supplementary notices may specify or set performance standards for agencies that carry out specified functions and activities under the Act.

### **194 Record-keeping requirements for recognised agency**

- (1) A recognised agency must keep the following for at least 4 years:
  - (a) records relating to the qualifications, training, work-related experience, and performance of any recognised person it employs, engages, or manages:
  - (b) records in relation to the specified functions and activities, and any related activity, of the agency, or any recognised person it employs, engages, or manages:
  - (c) records relating to each animal product business for which the agency, person, or any recognised person it employs, engages, or manages provides services, including any reports provided to the animal product business:
  - (d) records required to be kept under any regulatory requirements.
- (2) The recognised agency must ensure that records or reports referred to in sub-clause (1)—
  - (a) are made available at the request of the Director-General or an animal product officer as soon as practicable, but within 2 working days after the request; and
  - (b) are kept in a readily accessible format.

*Notifying and reporting to Director-General***195 Recognised agency must notify Director-General**

- (1) A recognised agency must notify the Director-General as soon as practicable if the agency is, or recognised persons employed, engaged, or managed by the agency are, prevented by an animal product business from carrying out their functions and activities.
- (2) A recognised agency must include in the notification any actions that the agency recommends that the Director-General should take.

**196 Recognised agency must report certain matters to Director-General**

- (1) A recognised agency must report to the Director-General (within the specified time frame) on becoming aware of any of the following:
  - (a) if the agency holds accreditation, any matter or information that may affect its accreditation status (within 1 working day of becoming aware of the matter or information):
  - (b) that the agency is to cease to operate (as soon as reasonably practicable, but within 5 working days after ceasing to operate):
  - (c) any non-compliance in relation to the recognised agency's activities that has the potential to affect the integrity or effectiveness of the service provided (within 1 working day after becoming aware of the non-compliance):
  - (d) if the agency employs, engages, or manages recognised persons, that any recognised person under its management ceases to be employed, engaged, or managed by that agency (within 5 working days after the event):
  - (e) if the agency employs, engages, or manages recognised persons, any matter that brings into question the ability of a recognised person associated with the agency to continue to be considered a fit and proper person under section 103 of the Act or to be considered capable of carrying out their specific functions and activities (at the time when the agency has formed that view).
- (2) A recognised agency reporting to the Director-General in accordance with sub-clause (1)(a) or (c) must also notify the Director-General, within 5 working days after the original notice, of the corrective action the agency will take.
- (3) A recognised agency reporting to the Director-General under this regulation must, on the request of the Director-General, within the time frame specified in the request, provide additional information in relation to the performance of its functions and activities.
- (4) A recognised agency must report to the Director-General on any other matter that is specified in a supplementary notice for the purposes of this regulation.

*Maintaining recognition for recognised agencies***197 Requirements for recognised agency to maintain recognition**

For the purpose of maintaining recognition, a recognised agency must—

- (a) continue to have in place the systems, processes, and procedures required for granting recognition; and
- (b) continue to comply with those systems, processes, and procedures; and
- (c) continue to meet regulatory requirements; and
- (d) continue to meet any assessment requirements relevant to its specified functions and activities; and
- (e) if the recognised agency holds accreditation, continue to hold accreditation to the required standard.

**198 Director-General may require agency or person to undergo assessment before and after granting recognition**

- (1) Before recognising a person as a recognised agency under the Act, the Director-General may require the person to undergo an assessment of—
  - (a) their procedures; or
  - (b) their ability to perform the functions and activities for which recognition is sought.
- (2) The Director-General may require a recognised agency to undergo assessment of—
  - (a) their procedures; or
  - (b) their performance of the specified functions and activities.
- (3) The Director-General may require an assessment under subclause (1) or (2) to be carried out by the Director-General or any other body or person as specified by the Director-General.
- (4) The Director-General may require an assessment under subclause (2) to be carried out by a date and with any frequency and in any manner specified by the Director-General.

**199 Assessment reports for recognised agency**

- (1) A recognised agency must provide assessment reports to the Director-General—
  - (a) when requested by the Director-General; or
  - (b) in accordance with, and with the frequency specified in, a supplementary notice.
- (2) Supplementary notices may, for the purposes of this regulation, specify—
  - (a) the types of reports to be provided; and

- (b) the frequency of providing the reports; and
- (c) the circumstances in which reports are required.

### *Recognised laboratories*

#### **200 Additional requirements for agency as recognised laboratory**

- (1) In addition to meeting all other requirements for recognised agencies in this subpart, a recognised laboratory or a person applying for recognition as a recognised laboratory must—
  - (a) ensure that all testing and other specified functions and activities are carried out properly and competently at all times, by—
    - (i) having suitable facilities, equipment, procedures, and materials; and
    - (ii) employing, engaging, and managing suitable persons; and
  - (b) have a person in its laboratory who is responsible for each test within the scope of its recognition; and
  - (c) meet any technical requirements specified in a supplementary notice for the tests its laboratory performs as part of its specified functions and activities; and
  - (d) ensure that a change to any of the following is carried out in a manner that ensures that the integrity of its testing is maintained:
    - (i) the person responsible for its day-to-day management;
    - (ii) the person responsible for each test within its scope of recognition;
    - (iii) the premises;
    - (iv) the equipment;
    - (v) the facilities;
    - (vi) its disciplines; and
  - (e) meet detailed requirements for recognised laboratories, including any competencies specified in a supplementary notice for any person employed, engaged, or managed by the recognised laboratory.
- (2) If required by supplementary notice, a recognised laboratory must participate in a proficiency programme that meets the requirements specified in the supplementary notice.

#### **201 Requirements for recognition as recognised laboratory in particular circumstances**

The Director-General may recognise a person as a recognised laboratory even if the person does not meet any or all of the requirements of these regulations if the Director-General—

- (a) is satisfied that the application for recognition relates to the function and activity of carrying out a specific test; and
- (b) has confidence in the integrity of the laboratory's processes; and
- (c) is satisfied that the laboratory can demonstrate the competence of its systems and staff, and the reliability of test results; and
- (d) is satisfied that no laboratory is recognised in relation to carrying out the test and at least 1 of the following circumstances exists:
  - (i) there is an urgent need for the particular test to be carried out;
  - (ii) given the nature of the test, there is limited commercial value in providing the test;
  - (iii) the laboratory holds accreditation with a scope that includes another test of a similar discipline to the discipline required for carrying out the test.

## **202 Misleading statements**

A recognised laboratory must not make—

- (a) any misleading statement in relation to its recognition; or
- (b) any statement either directly or by implication that the laboratory's recognition is in itself an assurance in relation to an animal product.

## **203 Samples and tests**

In carrying out tests within the scope of its recognition, a recognised laboratory must comply with any requirement specified in a supplementary notice, such as how and when—

- (a) to take samples; and
- (b) to perform tests; and
- (c) to authorise test results; and
- (d) to provide test results to an operator or the Director-General.

## **204 Subcontracting tests**

A recognised laboratory may subcontract tests to another recognised laboratory.

## **205 Tests carried out overseas**

The Director-General may approve a particular recognised laboratory to contract out a particular test within its scope of recognition to a specific laboratory overseas, if the Director-General is satisfied that the overseas laboratory is sufficiently qualified to carry out the test.

**206 Reporting by recognised laboratories**

- (1) A recognised laboratory must report to the Director-General as soon as is reasonably practicable if there is any significant change to any of the matters referred to in regulation 200(1)(d).
- (2) A recognised laboratory must report to the Director-General—
  - (a) at least 5 working days before the event,—
    - (i) any planned temporary closure; or
    - (ii) any change to its legal ownership; and
  - (b) within 30 days after a proposed change in its directorship, management, or control; and
  - (c) within 1 working day from the time non-compliance is identified,—
    - (i) any non-compliance by the recognised laboratory in relation to testing within its scope of recognition that affects or is likely to affect the integrity of test results; and
    - (ii) any information in relation to the non-compliance.
- (3) A recognised laboratory must comply with any reporting requirements for recognised laboratories as specified in a supplementary notice.

**Subpart 2—Recognised persons****207 Scope of this subpart**

This subpart sets out requirements for the recognition and maintenance of recognition of natural persons under section 103 of the Act.

**208 General requirements for recognised person**

- (1) A natural person applying to be recognised under section 103 of the Act must demonstrate knowledge and understanding of—
  - (a) the applicable regulatory requirements; and
  - (b) particular sectors, industries, or processes that are relevant to the person's specified functions and activities; and
  - (c) the roles of—
    - (i) the Director-General and animal product officers; and
    - (ii) as appropriate, authorised persons and official assessors; and
  - (d) requirements relating to the suitability for processing and fitness for the intended purpose of relevant animal material and animal products; and
  - (e) good operating practices for animal product businesses, as relevant to the person's specified functions and activities.
- (2) A natural person must undergo assessment of the person's ability to perform the functions and activities for which recognition is sought, if a supplementary

notice requires assessment for recognition in relation to those types of functions and activities.

- (3) The assessment must be carried out in relation to the following matters specified in a supplementary notice:
  - (a) the levels of assessment;
  - (b) the assessment processes;
  - (c) assessments for different circumstances and types of functions and activities;
  - (d) any other matters relating to the form and content of the assessment.
- (4) A natural person must meet any qualification or competency requirements relevant to the person's functions and activities, and any specific requirements, including qualifications and competencies as specified in a supplementary notice.
- (5) The Director-General may approve, for 1 or more named persons, an alternative qualification or competency if it is at least equivalent to the one specified in the notice.

#### **209 Additional requirements for verifiers**

In addition to the requirements of regulation 208, a natural person applying for recognition as a verifier must demonstrate knowledge and understanding of—

- (a) their role as a verifier within the regulatory requirements; and
- (b) identification and control of risk factors that may affect animal material or animal product; and
- (c) hazard analysis and critical control points, where relevant; and
- (d) how to perform audits competently.

#### **210 Additional requirements for evaluators**

In addition to the requirements of regulation 208, a natural person applying for recognition as an evaluator must—

- (a) demonstrate knowledge and understanding of—
  - (i) their role as an evaluator within the regulatory requirements; and
  - (ii) identification and control of risk factors that may affect animal material or animal product; and
  - (iii) hazard analysis and critical control points; and
  - (iv) how to perform audits competently; and
- (b) demonstrate the ability to assess—
  - (i) the quality of evidence; and
  - (ii) systems and processes before they are in operation.

**211 Application for recognition through recognised agency**

A natural person who is employed, engaged, or managed by a recognised agency must apply for recognition through the recognised agency.

**212 Performance standards for recognised person**

- (1) A recognised person must perform their role to a standard and in a way that ensures that they are carrying out their specified functions and activities effectively.
- (2) Supplementary notices may specify or set performance standards for persons who carry out specified functions and activities under the Act.

*Maintaining recognition for recognised persons***213 Requirements for recognised person to maintain recognition**

- (1) For the purpose of maintaining recognition, a recognised person must—
  - (a) continue to demonstrate knowledge and understanding of the matters referred to in regulation 208, and, if applicable, in regulation 209 or 210; and
  - (b) continue to have in place the systems, processes, and procedures required for granting recognition; and
  - (c) continue to comply with those systems, processes, and procedures; and
  - (d) continue to meet regulatory requirements; and
  - (e) continue to meet any competency and assessment requirements relevant to their specified functions and activities; and
  - (f) continue to hold accreditation with an accreditation body, to the required standard, if the person holds accreditation.
- (2) Supplementary notices may set detailed requirements for the purposes of maintaining recognition, including a continuing professional development programme.

*Assessments for recognised person***214 Director-General may require natural person to undergo assessment before and after granting recognition**

- (1) Before recognising a natural person under the Act, the Director-General may require the person to undergo an assessment of—
  - (a) their procedures; or
  - (b) their ability to perform the functions and activities for which recognition is sought.
- (2) The Director-General may require a recognised person to undergo assessment of—

- (a) their procedures; or
  - (b) their performance of the specified functions and activities.
- (3) The Director-General may require an assessment under subclause (1) or (2) to be carried out by the Director-General or any other body or person as specified by the Director-General.
- (4) The Director-General may require an assessment under subclause (2) to be carried out by a date and with any frequency and in any manner specified by the Director-General.

**215 Assessment reports for recognised person**

- (1) A recognised person must provide assessment reports to the Director-General—
  - (a) when requested by the Director-General; or
  - (b) in accordance with and with the frequency specified in a supplementary notice.
- (2) Supplementary notices may, for the purposes of this regulation, specify—
  - (a) the types of reports to be provided; and
  - (b) the frequency of providing the reports; and
  - (c) the circumstances in which reports are required.

*Additional recognition requirements for person independent of recognised agency*

**216 Recognition for natural person independent of recognised agency**

- (1) A natural person who is applying to be a recognised person and who is not employed, engaged, or managed by a recognised agency must demonstrate either or both of the following:
  - (a) that the person—
    - (i) has in place a written quality management system that complies with regulation 220; and
    - (ii) is able to comply with procedures set out in the quality management system:
  - (b) that the person—
    - (i) holds accreditation with an accreditation body, and to a particular standard, as specified in a supplementary notice, as relevant to the specified functions and activities in relation to which the person is seeking recognition; and
    - (ii) has documented procedures and systems as set out in regulation 221.

- (2) A person must hold accreditation with an accreditation body as set out in sub-clause (1)(b), if—
  - (a) the person carries out specified functions and activities; and
  - (b) a supplementary notice specifies that accreditation with an accreditation body is required for carrying out those activities.

**217 Record-keeping requirements for recognised person independent of recognised agency**

- (1) A recognised person who is not employed, engaged, or managed by a recognised agency must keep the following for at least 4 years:
  - (a) records in relation to the specified functions and activities, and any related activity, of the recognised person;
  - (b) records relating to each animal product business for which the person provides services, including any reports provided to the animal product business;
  - (c) records required to be kept under any regulatory requirements.
- (2) The recognised person must ensure that records or reports referred to in sub-clause (1)—
  - (a) are made available at the request of the Director-General or an animal product officer as soon as practicable, but within 2 working days after the request; and
  - (b) are kept in a readily accessible format.

**218 Recognised person independent of recognised agency must notify Director-General**

- (1) A recognised person who is not employed, engaged, or managed by a recognised agency must notify the Director-General as soon as practicable if prevented from carrying out their functions and activities.
- (2) A recognised person must include in their notification any actions that the person recommends that the Director-General should take.

**219 Recognised person independent of recognised agency must report to Director-General**

- (1) A recognised person who is not employed, engaged, or managed by a recognised agency must report to the Director-General (within the specified time frame) on becoming aware of any of the following:
  - (a) if the person holds accreditation, any matter or information that may affect their accreditation status (within 1 working day after becoming aware of the matter or information);
  - (b) that the person is to cease to operate (as soon as reasonably practicable, but within 5 working days after ceasing to operate):

- (c) any non-compliance in relation to the person's activities that has the potential to affect the integrity or effectiveness of the service provided (within 1 working day after becoming aware of the non-compliance).
- (2) A recognised person reporting to the Director-General in accordance with sub-clause (1)(a) or (c) must also notify the Director-General, within 5 working days after the original notice, of the corrective action the person will take.
- (3) A recognised person reporting to the Director-General under this regulation must, on the request of the Director-General and within the time frame specified in the request, provide additional information in relation to the performance of their functions and activities.
- (4) A recognised person must report to the Director-General on any other matter that is specified in a supplementary notice.

### Subpart 3—Quality management procedures and documented procedures and systems

#### **220 Procedures for quality management system**

For the purposes of regulations 190(1)(a)(i) and 216(1)(a)(i), the procedures for the quality management system are—

- (a) managing conflicts of interest; and
- (b) managing recognised persons, if applicable; and
- (c) managing contractual relationships; and
- (d) maintaining skills and competencies; and
- (e) ensuring that the agency or person—
  - (i) has adequate resources; and
  - (ii) maintains its systems; and
- (f) how the agency or person is to perform its functions and activities; and
- (g) meeting applicable record-keeping and reporting requirements under the Act, these regulations, and supplementary notices; and
- (h) managing complaints and disputes; and
- (i) reviewing the performance of its specified functions and activities; and
- (j) any other matters specified in a supplementary notice.

#### **221 Documented procedures and systems**

For the purposes of regulations 190(1)(b)(ii) and 216(1)(b)(ii), the documented procedures and systems are—

- (a) managing conflicts of interest; and
- (b) managing recognised persons, if applicable; and
- (c) managing contractual relationships; and

- (d) maintaining skills and competencies; and
- (e) ensuring that the agency or person—
  - (i) has adequate resources; and
  - (ii) maintains its systems; and
- (f) how the agency or person is to perform its functions and activities; and
- (g) meeting applicable record-keeping and reporting requirements under the Act, these regulations, and supplementary notices; and
- (h) any other matters specified in a supplementary notice.

## **Part 10**

### **Listing**

#### **222 Application of this Part**

This Part—

- (a) applies to any person, thing, or premises required to be listed under these regulations; but
- (b) does not apply to—
  - (i) any person, thing, or premises required, by notices made under section 167(1) of the Act, to be listed for the purposes of section 60 of the Act; or
  - (ii) persons required to have their operations listed under section 65H of the Act as a game estate or to be listed under section 75 of the Act as a homekill or recreational catch service provider.

#### *List of persons, premises, or things*

#### **223 List of persons, premises, and things**

- (1) The Director-General must keep and maintain a list of all persons, premises, and things required by regulations to be listed.
- (2) The Director-General may keep the list in any manner that the Director-General thinks fit (such as having separate parts for different kinds of listed person).
- (3) However, the listing of—
  - (a) a person must include the name and contact details for the listed person; and
  - (b) premises or things, or both, must include—
    - (i) a description of the thing listed; and
    - (ii) the address or location of the premises listed; and

- (iii) the name and contact details of the person responsible for the premises or thing.
- (4) The purposes of the list include the following:
  - (a) enabling members of the public to know—
    - (i) who is authorised to carry out particular activities under the Act, regulations, notices issued under section 167(1) of the Act, and supplementary notices; and
    - (ii) what things are authorised to be used in the carrying out of activities under the Act, regulations, notices issued under section 167(1) of the Act, and supplementary notices; and
    - (iii) what premises are authorised as places for carrying out those activities:
  - (b) facilitating the compliance, audit, and other supporting administrative functions of the Ministry under the Act:
  - (c) facilitating the ability of the Director-General to advise persons required to be listed of related requirements that apply to them:
  - (d) facilitating the object of the Act.
- (5) The Director-General must—
  - (a) make the list available for public inspection at all reasonable times, free of charge, by publishing it on an Internet site maintained by, or on behalf of, the Ministry; and
  - (b) supply a copy of information contained in the list at no more than a reasonable cost to a person who requests the information.
- (6) Despite subclause (5), the Director-General may direct that a person's name or address (as entered in the list) must not be available for public inspection or otherwise disclosed if the Director-General is satisfied, on the person's application, that the disclosure of the person's name or physical address (as entered in the list) would be prejudicial to the personal safety of the person or the person's family.

### *Listing process*

#### **224 Application for listing**

- (1) An application for listing must—
  - (a) be in a form provided by the Director-General; and
  - (b) be accompanied by the prescribed fee, if any; and
  - (c) contain any information required by supplementary notices under subclause (4).
- (2) The Director-General may require an applicant to supply further information or other material before determining whether—

- (a) to list the applicant; or
  - (b) to list the premises or thing.
- (3) The application for listing lapses if the information or material is not supplied within 3 months after the date of the request, or within any additional time that the Director-General allows.
- (4) Supplementary notices may specify what further information or documents the applicant must provide with the application.

## **225 Listing**

The Director-General must, as soon as practicable after listing a person, premises, or a thing, give the person, or person responsible for the premises or thing, a notice stating—

- (a) the period of listing, if any; and
- (b) any conditions imposed by the Director-General.

## **226 Duration of listing**

Listing continues in force until the earliest of the following:

- (a) any period specified in the notice given under regulation 225 ends;
- (b) the person, premises, or thing is delisted under regulation 233;
- (c) the person, or the person recorded in the list as responsible for the premises or thing, surrenders the listing under regulation 232.

## **227 Conditions of listing**

- (1) The Director-General may impose any conditions on listing that the Director-General considers reasonable.
- (2) Conditions may be imposed, revoked, or amended at the time of listing or at any time while the person, premises, or thing remains listed.
- (3) If the Director-General proposes to impose or amend any conditions of listing after listing a person, premises, or a thing, the Director-General must give the person, or the person recorded in the list as responsible for the premises or thing,—
  - (a) notice of the reasons and the facts or assumptions on which the proposed decision to impose or amend conditions is based; and
  - (b) a reasonable opportunity to make written submissions on the matter.
- (4) The imposition, revocation, or amendment takes effect on the date specified in the notice.

## **228 Refusal to list**

- (1) The Director-General may refuse to list a person, premises, or a thing if the Director-General considers that—

- (a) there has been a serious or repeated failure by the applicant, or any person involved in the control or management of the applicant, to comply with the requirements imposed by—
    - (i) the Act, regulations, notices under section 167(1) of the Act, or supplementary notices; or
    - (ii) the following Acts or secondary legislation made under them:
      - (A) the Agricultural Compounds and Veterinary Medicines Act 1997:
      - (B) the Animal Welfare Act 1999:
      - (C) the Biosecurity Act 1993:
      - (D) the Fisheries Act 1996:
      - (E) the Food Act 2014:
      - (F) the National Animal Identification and Tracing Act 2012:
      - (G) the Wine Act 2003:
      - (H) any other enactments that regulate the husbandry, harvest, production, extraction, processing, import, export, or labelling of animal material, animal products, or other food; or
  - (b) there are other reasonable grounds for believing that the applicant, or any person concerned in the management of the applicant, is not likely to comply with those requirements in future; or
  - (c) the person, premises, or thing does not meet any relevant requirements specified in the Act, regulations, notices under section 167(1) of the Act, or supplementary notices.
- (2) If the Director-General proposes to refuse to list a person, premises, or a thing after considering an application and any further information or material supplied following a request under regulation 224, the Director-General must give the applicant or person involved in the control or management of the applicant—
- (a) notice of the reasons and the facts or assumptions on which the proposed decision is based; and
  - (b) a reasonable opportunity to make written submissions on the matter.
- (3) If the Director-General finally determines to refuse to list the person, premises, or thing, the Director-General must, as soon as practicable, notify that fact to the applicant in writing, giving reasons.

*Notifying changes and renewal of listing*

**229 Duty to notify change of circumstances**

- (1) A listed person, or a person recorded in the list as responsible for listed premises or a listed thing, must give the Director-General written notice in a form

provided by the Director-General of any significant change in circumstances that occurs—

- (a) between applying for listing and being listed; and
  - (b) after listing.
- (2) For the purposes of this regulation, a **significant change of circumstances** includes any of the following:
  - (a) a change to information submitted as part of the listing process, such as a change of address or contact details, or a change of the person responsible for the premises or thing;
  - (b) in the case of a listed person who is a natural person, the person's death or bankruptcy;
  - (c) in any other case, the receivership, voluntary administration, or liquidation of the listed person;
  - (d) any other matter specified in regulations or in notices applying to the listing of the person, premises, or thing.
- (3) The notice must be given—
  - (a) before the significant change in circumstances occurs; or
  - (b) if compliance with paragraph (a) is not practicable, as soon as is reasonably practicable after the significant change in circumstances occurs.
- (4) If the significant change in circumstances is the death, bankruptcy, receivership, voluntary administration, or liquidation of a listed person, the person who assumes charge or control of the operations or business must give the written notice required by subclause (1).
- (5) If the significant change in circumstances is a change of the person recorded in the list as responsible for the premises or thing, the person in charge or control of the listed person's operations or business must give the written notice required by subclause (1).

### **230 Renewal of listing**

- (1) Any application for renewal of listing must be made before the listing is due to expire.
- (2) The application for renewal must comply with the requirements in regulation 224(1).
- (3) The Director-General may refuse to renew the listing of a person, premises, or a thing on the same grounds as the Director-General may, under regulation 228, refuse listing.
- (4) If the Director-General fails to decide the application for renewal before the expiry date, the person, premises, or thing is deemed to be listed until the date on which the Director-General notifies the applicant of the decision.

*Suspension, surrender, and delisting***231 Voluntarily suspending listing**

- (1) A listed person, or person recorded in the list as responsible for listed premises or a listed thing, may suspend listing voluntarily for a period of between 3 and 12 months, and must—
  - (a) give written notice to the Director-General of the period of suspension; and
  - (b) cease operations related to the listing for the period stated in the notice.
- (2) The Director-General may impose conditions relating to the suspension and resumption of listing.
- (3) The Director-General—
  - (a) must notify any relevant recognised agency or person of any suspension or extension under this regulation; and
  - (b) must ensure that any suspension or any extension under this regulation is recorded in the list.

**232 Surrender of listing**

- (1) A listed person, or a person recorded in the list as responsible for listed premises or a listed thing, may surrender their listing by notifying the Director-General in writing.
- (2) On being notified of a surrender of listing, the Director-General must—
  - (a) remove the name of the person, premises, or thing from the list; and
  - (b) notify any relevant recognised agency or person of any surrender under this regulation.
- (3) When a person surrenders their listing, or the listing of premises or a thing, the Director-General may direct the person, or any other person who is in charge of the relevant operations, to take appropriate action to deal with any affected animal material or animal product.

**233 Delisting**

- (1) A person or a thing is delisted, and premises are delisted, when their name is removed from the list kept under regulation 223.
- (2) The Director-General may delist a person, premises, or a thing if the Director-General considers that—
  - (a) there has been a serious or repeated failure by the person, or any person involved in the control or management of the person, premises, or thing, to comply with the requirements imposed by—
    - (i) the Act, regulations, notices under section 167(1) of the Act, or supplementary notices; or

- (ii) the following Acts, and any secondary legislation made under them:
    - (A) the Agricultural Compounds and Veterinary Medicines Act 1997:
    - (B) the Animal Welfare Act 1999:
    - (C) the Biosecurity Act 1993:
    - (D) the Fisheries Act 1996:
    - (E) the Food Act 2014:
    - (F) the National Animal Identification and Tracing Act 2012:
    - (G) the Wine Act 2003:
    - (H) any other enactments that regulate the husbandry, harvesting, production, extraction, processing, import, export, or labelling of animal material, animal products, or other food; or
  - (b) there are other reasonable grounds for believing that the person, or the person recorded in the list as responsible for the premises or thing, is not likely to comply with those requirements in future; or
  - (c) the listed person, or the person who is in charge of the relevant operations, has ceased the operations to which the listing relates; or
  - (d) the person, premises, or thing does not meet any relevant requirements specified in the Act, regulations, notices under section 167(1) of the Act, or supplementary notices.
- (3) If the Director-General proposes to delist a person, or premises, or a thing, the Director-General must—
  - (a) notify the person in writing of the Director-General's intention, giving the reasons for that intention and the facts and assumptions on which it is based; and
  - (b) give the person a reasonable opportunity, within the time specified in the written notice, to provide evidence, information, and submissions as to why they should not be removed from the list.
- (4) After considering the material (if any) supplied by the person, the Director-General must—
  - (a) make a final decision as to whether to delist the person, premises, or thing; and
  - (b) as soon as practicable,—
    - (i) notify the person of the decision in writing, giving—
      - (A) the reasons and the facts or assumptions on which the decision is based; and

- (B) the date on which or time that the delisting commences (which must not be earlier than the date or time of notification); and
  - (ii) notify their relevant recognised agency or person (if any) of the decision to delist the person, premises, or thing, if the decision is to delist them.
- (5) When a person or a thing is delisted, or premises are delisted,—
  - (a) the Director-General may direct the person, or any other person who is in charge of the relevant operations, to take appropriate action to deal with any affected animal material or animal product; and
  - (b) the delisted person, or the person responsible for the premises or thing, must cease operations on and from the date on which or time that the delisting commences.

### *Review rights*

#### **234 Right of review**

- (1) A person specified in subclause (2) may seek a review by the Director-General under section 162 of the Act of any decision made by a person other than the Director-General under any of the following:
  - (a) a decision under regulation 227 to impose, amend, or revoke any condition on listing;
  - (b) a decision under regulation 228 to refuse to list a person, premises, or a thing;
  - (c) a decision under regulation 233 to delist a person, premises, or a thing.
- (2) The person who may seek a review is,—
  - (a) if the decision relates to the person, that person; and
  - (b) if the decision relates to premises or a thing, a person recorded in the list as responsible for the premises or thing.

## **Part 11**

### **Official assessors**

#### *Competencies, qualifications, etc, for appointment as official assessor*

#### **235 Official assessor competencies, etc**

- (1) A person applying to be appointed as an official assessor to carry out ante-mortem and post-mortem examinations for export purposes must have 1 or more of the following qualifications:
  - (a) the qualifications specified in a supplementary notice:

- (b) qualifications that the Director-General decides are equivalent to 1 or more of the qualifications in a supplementary notice referred to in paragraph (a):
  - (c) registration as a veterinarian under the Veterinarians Act 2005.
- (2) A person relying on a qualification referred to in subclause (1)(a) or (b) that was acquired 3 years or more before the date of the application must demonstrate to the Director-General that the applicant has had meaningful involvement in performing ante-mortem and post-mortem examinations since obtaining the qualification.

### **236 Official assessor knowledge requirements**

A person applying to be appointed as an official assessor to carry out ante-mortem and post-mortem examinations for export purposes must, to the extent relevant, demonstrate knowledge and understanding of—

- (a) the applicable regulatory requirements; and
- (b) the particular sectors, industries, or processes that are relevant to the role of an official assessor.

### **237 Other requirements for appointment**

A person applying to be appointed as an official assessor to carry out ante-mortem and post-mortem examinations for export purposes must meet any further requirements specified in a supplementary notice.

### **238 Conflict of interest**

The Director-General must not appoint a person as an official assessor to carry out ante-mortem and post-mortem examinations for export purposes unless the Director-General is satisfied that the person does not have a conflict of interest that would affect their ability to carry out their functions and activities as an official assessor.

#### *Assessment before and after appointment*

### **239 Assessment before and after appointment**

- (1) The Director-General may require the following persons to undergo assessment of their ability to carry out ante-mortem and post-mortem examinations for export purposes:
  - (a) a person applying to be appointed as an official assessor to carry out ante-mortem and post-mortem examinations for export purposes:
  - (b) an official assessor appointed to carry out ante-mortem and post-mortem examinations for export purposes.
- (2) The Director-General may require the assessment to be carried out by the Director-General or any other body or person specified by the Director-General.

- (3) The assessment must be carried out in relation to the following matters as specified in a supplementary notice:
  - (a) the form of assessment:
  - (b) the assessment process:
  - (c) other matters relating to the form and content of the assessment.

### *Reporting after appointment*

#### **240 Reporting conflict of interest after appointment**

- (1) While appointed to carry out ante-mortem and post-mortem examinations for export purposes, an official assessor must report any conflict of interest that arises to the Director-General, as soon as practicable after the assessor becomes aware of it, if the conflict of interest may affect the assessor's ability to carry out their functions and activities as an official assessor.
- (2) The Director-General may approve an official assessor to engage in employment or another activity that might otherwise constitute a conflict of interest if, in the view of the Director-General, any such conflict can be managed.
- (3) The approval may be subject to conditions.

#### **241 Other reporting to Director-General**

- (1) While appointed to carry out ante-mortem and post-mortem examinations for export purposes, an official assessor who is prevented from carrying out their functions and activities as an official assessor must, as soon as practicable, report that to the Director-General.
- (2) An official assessor who carries out ante-mortem and post-mortem examinations for export purposes must report to the Director-General or the assessor's recognised agency, as soon as practicable, if the assessor, in the course of carrying out their functions and activities,—
  - (a) detects any uncorrected non-compliance with any relevant requirements under the Act; and
  - (b) considers that the non-compliance may result in 1 or more of the following:
    - (i) the exposure of humans or animals to an unacceptable level of hazard;
    - (ii) the potential to jeopardise overseas market access;
    - (iii) a threat to the integrity of the official assurance scheme.
- (3) An official assessor reporting under subclause (1) or (2) must also recommend any actions to be taken that the assessor considers to be appropriate.

**242 Performance standards for official assessor**

- (1) An official assessor appointed to carry out ante-mortem and post-mortem examinations for export purposes must perform the role to a standard and in a way that ensures that they are carrying out their specified functions and activities effectively.
- (2) Supplementary notices may specify or set performance standards for official assessors who carry out specified functions and activities under the Act.

**243 Maintaining competency**

An official assessor carrying out ante-mortem and post-mortem examinations for export purposes must, for the purpose of maintaining competency for their role,—

- (a) continue to have the competencies and qualifications required for appointment under regulation 235; and
- (b) continue to demonstrate the knowledge and understanding required for appointment under regulation 236; and
- (c) continue to meet regulatory requirements; and
- (d) continue to meet any assessment requirements under regulation 239.

## **Part 12 Offences**

**244 Offences**

A person who fails to comply with any regulation listed in Schedule 4 commits an offence for the purposes of section 135(1)(b) of the Act.

**245 NAIT offences**

- (1) A person who does either of the following in relation to a NAIT animal commits an offence against section 135(1)(b) of the Act and is liable on conviction to a fine not exceeding \$2,400:
  - (a) fails to supply information on the status of a NAIT animal when transferring the animal to another person;
  - (b) fails to comply with the requirements of the tracking system relating to record keeping and the availability of records.
- (2) A person who fails to supply information about the status of a NAIT animal as required by these regulations, a notice issued under section 167(1) of the Act for the purposes of section 81A of the Act, or a supplementary notice commits an offence against section 135(1)(b) of the Act and is liable on conviction to a fine not exceeding \$1,200.
- (3) An offence against subclause (1) is an infringement offence with an infringement fee of \$800.

- (4) An offence against subclause (2) is an infringement offence with an infringement fee of \$400.
- (5) In this regulation, **NAIT animal** has the same meaning as in section 4 of the National Animal Identification and Tracing Act 2012.

## **Part 13**

### **Miscellaneous**

#### Subpart 1—Ensuring animal material or animal product not associated with false or misleading representations

#### **246 Animal material or animal product must not be associated with false or misleading representations**

The operator of an animal product business must ensure that animal material or animal product, or its labelling, identification, or packaging, is not associated with a false or misleading representation of any kind, including about—

- (a) the unique location identifier of the processing premises:
- (b) the lot identifier (if applicable) of the product or product identification:
- (c) the fitness of the material or product for its intended purpose:
- (d) the nature and condition of the material or product:
- (e) the origin of the material or product:
- (f) the composition of the material or product:
- (g) the ingredients of the material or product:
- (h) the proportions of ingredients or other constituents of the material or product:
- (i) the type of processing applied to the material or product:
- (j) the net contents of the material or product.

#### Subpart 2—Maintenance compounds

#### **247 Approval of maintenance compounds**

- (1) The Director-General may, with or without an application, approve maintenance compounds for use in any 1 or more of the following:
  - (a) a particular type of animal product business:
  - (b) particular premises or a particular place or area:
  - (c) a particular purpose or type of use:
  - (d) particular equipment.
- (2) The Director-General may impose conditions on the use of approved maintenance compounds.

- (3) In deciding the type of use under subclause (1) and conditions (if any) under subclause (2), the Director-General must assess—
  - (a) the risk that the maintenance compound may contaminate animal material or animal product; and
  - (b) the ability to control that risk through the application of conditions under subclause (2).
- (4) The Director-General may refuse to grant an application for approval if, in the opinion of the Director-General,—
  - (a) the risk cannot be sufficiently controlled by imposing conditions; or
  - (b) insufficient information is available to assess the risks likely to result from the use of the maintenance compound.
- (5) The Director-General must keep and maintain a list of all approved maintenance compounds.
- (6) The Director-General may keep the list in any manner that the Director-General thinks fit (such as having separate parts for different kinds of animal product businesses).
- (7) The Director-General must—
  - (a) make the list available for public inspection at all reasonable times, free of charge, by publishing it on an Internet site maintained by, or on behalf of, the Ministry; and
  - (b) supply a copy of information contained in the list at no more than a reasonable cost to a person who requests the information.
- (8) An approval under subclause (1) is secondary legislation (*see* Part 3 of the Legislation Act 2019 for publication requirements), unless it applies only to 1 or more named persons.

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**Legislation Act 2019 requirements for secondary legislation made under this regulation**

|                     |                                                                                             |                  |
|---------------------|---------------------------------------------------------------------------------------------|------------------|
| <b>Publication</b>  | The maker must publish it in accordance with the Legislation (Publication) Regulations 2021 | LA19 s 74(1)(aa) |
| <b>Presentation</b> | The Minister must present it to the House of Representatives                                | LA19 s 114       |
| <b>Disallowance</b> | It may be disallowed by the House of Representatives                                        | LA19 ss 115, 116 |

*This note is not part of the secondary legislation.*

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## **248 Application for approval of maintenance compounds**

- (1) An application for approval of maintenance compounds must be—
  - (a) in a form provided by the Director-General; and
  - (b) accompanied by the prescribed fee, if any.
- (2) The Director-General may require an applicant to supply further information or other material before determining whether to approve the maintenance compound.

- (3) The application for approval lapses if the information or material is not supplied within 3 months after the date of the request, or within any additional time that the Director-General allows.

#### **249 Renewals of existing approvals**

- (1) An application for renewal of approval of a maintenance compound must be made before the approval is due to expire.
- (2) The application for renewal must comply with the requirements in regulation 248(1).
- (3) The Director-General may require an applicant to supply further information or other material before determining whether to renew the approval of the maintenance compound.
- (4) The application for renewal lapses if the information or material is not supplied within 3 months after the date of the request, or within any additional time that the Director-General allows.
- (5) The Director-General may refuse to grant an application for renewal of approval if, in the opinion of the Director-General,—
  - (a) the risk referred to in regulation 247(3)(a) cannot be sufficiently controlled by imposing conditions; or
  - (b) insufficient information is available to assess the risks likely to result from the use of the maintenance compound.

#### **250 Notification of approval or renewal of approval of maintenance compounds**

The Director-General must, as soon as practicable after approving a maintenance compound or renewing its approval, give the applicant written notice stating—

- (a) the period of approval; and
- (b) any conditions imposed by the Director-General.

#### **251 Duty to notify change of circumstances**

- (1) An approval holder must give written notice to the Director-General if any of the following occurs:
  - (a) a change to the name of the approved maintenance compound;
  - (b) a change in the circumstances of the approval holder;
  - (c) a change in the composition of the approved maintenance compound.
- (2) For a change of the kind referred to in subclause (1)(c), the Director-General may reassess the maintenance compound at the approval holder's cost (if any).
- (3) Approval of a maintenance compound is revoked if the approval holder fails to give notice as required by subclause (1).

### Subpart 3—Exporter registration and exemptions

#### *Exporter registration*

**252 Exporters of glands, bile, blood, or deer velvet must be registered, whether or not material or product intended for human or animal consumption**

Exporters of the following animal material or animal products must be registered as exporters under Part 5 of the Act, whether or not the material or products are intended for human or animal consumption:

- (a) the glands or bile of any animal:
- (b) animal blood or blood products:
- (c) deer velvet or deer velvet products.

Compare: SR 2000/209 cl 21

**253 Exporters of live animals, embryo, semen, or ova must be registered**

Exporters of live animals, embryos, semen, and ova must be registered as exporters under Part 5 of the Act if the export is for the purposes of trade or reward.

Compare: SR 2000/209 cl 21A

#### *Exporter exemptions*

**254 Exemption for owners of live animals exported for non-commercial purposes**

A person who owns an animal and who exports the animal live for non-commercial purposes is, in respect of the export of that animal, exempt from—

- (a) the requirement to register as an exporter under Part 5 of the Act; and
- (b) the duties set out in section 51(c)(i) and (d) of the Act.

Compare: SR 2000/209 cl 15

**255 Exemption for persons exporting samples for scientific analysis**

- (1) A person who exports a sample of animal material or animal product for scientific or analytical purposes is, in respect of that export, exempt from—

- (a) the requirement to register as an exporter under Part 5 of the Act; and
  - (b) the duties set out in section 51(c)(i) and (iii) and (d) of the Act.

- (2) The exemption under subclause (1) applies only to persons who are not primarily in the business of sending samples for examination overseas for the purposes of trade or reward.

Compare: SR 2000/209 cl 16

**256 Exemption from export requirements for certain foods**

- (1) Consignments of the following material or products (being material or products that consist of or contain animal material or animal products) are exempt from the requirements of Part 5 of the Act:
  - (a) multi-ingredient foods and other prepared foods that, despite containing 1 or more ingredients that are animal material or animal product, do not consist principally of animal material or animal products (for example, biscuits, cakes, bread, soups, sauces, snack goods, pastries, confectionery, and prepared meals that do not consist principally of meat);
  - (b) alcoholic beverages and formulated caffeinated beverages;
  - (c) food for consumption on any vessel or aircraft by passengers, crew, and animals during transit from New Zealand, being meals in a ready-to-eat state or other food for human or animal consumption (for example, airline meals, ships' stores, and feed for animals being transported).
- (2) Nothing in subclause (1) operates to exempt from the requirements of Part 5 of the Act any consignment or class of consignments for which an official assurance is required.
- (3) In this regulation,—

**alcoholic beverage** means an alcoholic beverage that contains dairy product or alcohol derived from dairy material or dairy product

**formulated caffeinated beverage** has the meaning set out in section 1.1.2—6 of the Food Standards Code.

Compare: SR 2000/209 cl 17

**Subpart 4—Exemption from requirements in Parts 2 to 4 of Act****257 Exemption for certain animal products forming part of agricultural compound**

Parts 2 to 4 of the Act do not apply to the secondary processing of animal material or animal product that is, or will form part of, an agricultural compound or veterinary medicine (including oral nutritional compounds), if—

- (a) the processing does not require a risk management programme under regulation 39; and
- (b) an official assurance is not required; and
- (c) the animal material or animal product being processed—
  - (i) is eggs, honey, or other animal material that does not result from the death of the source animal; or
  - (ii) results from the death of the source animal and will not be used for petfood; or
  - (iii) is acquired as rendered material; or

- (iv) is acquired from the operator of a risk management programme or a person operating under a risk-based measure by a business that—
  - (A) sells unpackaged or packaged petfood; and
  - (B) does not carry out further processing of the petfood, other than its transport or storage.

## **258 Medicines and related products covered by Medicines Act 1981**

- (1) Parts 2 to 4 of the Act do not apply to the secondary processing of animal product or the processing of dairy material, being product or material that is, or is being processed to become or form part of, a medicine or related product that is subject to the Medicines Act 1981.
- (2) The exemption under subclause (1) includes—
  - (a) the secondary processing of animal product or the processing of dairy material, for the purposes or in the course of manufacturing, packing, or labelling, or selling or supplying any medicine that consists of or contains that animal product or dairy material, by—
    - (i) a person licensed under Part 3 of the Medicines Act 1981 to manufacture, pack or label, or sell by wholesale any medicine; or
    - (ii) a person permitted by regulations under that Act to manufacture, pack or label, or sell by wholesale any medicine otherwise than in accordance with a licence issued under Part 3 of that Act; or
    - (iii) a person subject to an exemption under any of sections 25 to 34 of that Act;
  - (b) the secondary processing of animal product or the processing of dairy material for the purposes of manufacturing, packing or labelling, or selling or supplying any cosmetic or dentifrice or food that is a related product within the meaning of section 94 of the Medicines Act 1981.
- (3) The exemption in this regulation does not apply if the medicine or related product is intended for export in circumstances that would require an official assurance to be issued, and the official assurance may only be issued on the basis of compliance with the relevant provisions of Parts 2 to 4 of the Act.

Compare: SR 2000/209 cl 5

### **Subpart 5—Exemptions from requirements in Part 6 of Act**

## **259 Taxidermists**

Taxidermists are exempt from the requirements of Part 6 of the Act to the extent specified in clause 4 of Schedule 3.

**260 Certain tourist and charter fishing vessel operators and fishing guides exempt from listing requirements**

A person who is exempt under clause 3 of Schedule 2 from the requirement to have a risk management programme in respect of fishing and catch support activities is also exempt from the requirement to be listed as a homekill or recreational catch service provider in respect of those activities under Part 6 of the Act.

**261 Transporters of homekill or recreational catch need not be listed**

A person who for trade or reward transports homekill or recreational catch is exempt from the requirement to be listed as a homekill or recreational catch service provider under Part 6 of the Act if that is the only service the person provides in relation to homekill or recreational catch.

**Subpart 6—Total exemption from Act**

**262 Certain fish taken in exclusive economic zone exempt from Act**

- (1) Fish taken in the exclusive economic zone (as defined by section 9 of the Territorial Sea, Contiguous Zone, and Exclusive Economic Zone Act 1977), and any animal product derived from such fish, are exempt from the requirements of the Act if—
  - (a) the fish, or animal product derived from the fish, is not landed in New Zealand; and
  - (b) the fish, or animal product derived from the fish, is not claimed to be New Zealand fish or product.
- (2) For the purposes of subclause (1)(a), fish or animal product derived from the fish will not be treated as having been landed in New Zealand if—
  - (a) it has been brought on shore in New Zealand for the sole purpose of being transferred to another vessel for dispatch to another country, and has not been processed on-shore; or
  - (b) its landing in New Zealand has been necessitated by vessel breakdown, weather or sea conditions, or other unavoidable circumstances, and it has not been processed on-shore (except to the extent necessary for its preservation or maintenance in good condition); or
  - (c) it has been landed in New Zealand for the sole purpose of complying with any provision of, or regulation or requirement made under, the Fisheries Act 1996 that requires the fish to be landed, and is then—
    - (i) returned to the vessel from which it was landed immediately after the relevant Fisheries Act procedures are complete, without being processed on-shore (except to the extent necessary for its preservation or maintenance in good condition); or

- (ii) transferred to another vessel for dispatch to another country, without being processed on-shore (except to the extent necessary for its preservation or maintenance in good condition).

Compare: SR 2000/209 cl 4

### Subpart 7—When food must be dealt with under risk management programme as if animal material or animal product

#### **263 Food must be dealt with under risk management programme as if it were animal material or animal product**

Food must be dealt with under a risk management programme as if it were animal material or animal product if—

- (a) the risk management programme, as referred to in section 17(5) of the Act, contains—
  - (i) a food control plan as a component part of the risk management programme; or
  - (ii) components of a national programme; and
- (b) the food is the type of food to which the food control plan or national programme applies.

### Subpart 8—Supplementary notices

#### **264 Supplementary notices permitted by these regulations**

- (1) The Director-General may make supplementary notices to supplement the provisions of these regulations that refer to a supplementary notice.
- (2) The supplementary notices are secondary legislation because of section 167(6) of the Act (*see* Part 3 of the Legislation Act 2019 for publication requirements).
- (3) This regulation does not apply to supplementary notices of the kind referred to in section 167(2)(a) of the Act (which empowers the making of supplementary notices that are referred to in the Act).

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#### **Legislation Act 2019 requirements for secondary legislation made under this regulation**

|                     |                                                                                             |                  |
|---------------------|---------------------------------------------------------------------------------------------|------------------|
| <b>Publication</b>  | The maker must publish it in accordance with the Legislation (Publication) Regulations 2021 | LA19 s 74(1)(aa) |
| <b>Presentation</b> | The Minister must present it to the House of Representatives                                | LA19 s 114       |
| <b>Disallowance</b> | It may be disallowed by the House of Representatives                                        | LA19 ss 115, 116 |

*This note is not part of the secondary legislation.*

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## Subpart 9—Amendments and revocations

*Amendments***265 Amendments to Animal Products (Fees, Charges, and Levies) Regulations 2007**

- (1) This regulation amends the Animal Products (Fees, Charges, and Levies) Regulations 2007.
- (2) In Schedule 1, Part 1, replace items 22, 23, 32, 33, 34, 35, 44, and 45 with the corresponding items in the following table:

|    |                                                                                                                                       |                                                                                                               |
|----|---------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------|
| 22 | Registration of transport operator, vehicle docking facility operator, or wharf operator under a notice issued under section 38(2)(b) | \$135 per application                                                                                         |
| 23 | Application to list or renew listing of an animal material depot as required under Part 7 of the Animal Products Regulations 2021     | \$135 per application                                                                                         |
| 32 | Application to list a hunter as required under Part 6 of the Animal Products Regulations 2021                                         | \$135 per application                                                                                         |
| 33 | Application to renew listing of a hunter under Part 10 of the Animal Products Regulations 2021                                        | \$135 per application                                                                                         |
| 34 | Application to list a further petfood processor as required under Part 7 of the Animal Products Regulations 2021                      | \$135 per application                                                                                         |
| 35 | Application to renew listing of a further petfood processor under Part 10 of the Animal Products Regulations 2021                     | \$67.50 per application                                                                                       |
| 44 | Application for approval of any maintenance compound under Part 13 of the Animal Products Regulations 2021                            | \$135 per approval plus assessment charge on hourly basis after the first 120 minutes as specified in Part 2  |
| 45 | Application to renew approval of any maintenance compound under Part 13 of the Animal Products Regulations 2021                       | \$67.50 per approval plus assessment charge on hourly basis after the first 90 minutes as specified in Part 2 |

**266 Amendment to Animal Products (Dairy Industry Fees, Charges, and Levies) Regulations 2015**

- (1) This regulation amends the Animal Products (Dairy Industry Fees, Charges, and Levies) Regulations 2015.
- (2) In the Schedule, Part 1, replace the item relating to maintenance compounds with:

*Maintenance compounds*

|                                                            |                    |           |
|------------------------------------------------------------|--------------------|-----------|
| Application for approval of any maintenance compound under | \$135 per approval | Applicant |
|------------------------------------------------------------|--------------------|-----------|

|                                                                                                                 |                                                                                                               |           |
|-----------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------|-----------|
| Part 13 of the Animal Products Regulations 2021                                                                 | plus assessment charge on hourly basis after the first 120 minutes as specified in Part 2                     |           |
| Application to renew approval of any maintenance compound under Part 13 of the Animal Products Regulations 2021 | \$67.50 per approval plus assessment charge on hourly basis after the first 90 minutes as specified in Part 2 | Applicant |

### *Revocations*

## **267 Revocations**

The following are revoked:

- (a) the Animal Products (Dairy) Regulations 2005 (SR 2005/104):
- (b) the Animal Products (Exemptions and Inclusions) Order 2000 (SR 2000/209):
- (c) the Animal Products (Regulated Control Scheme—Contaminant Monitoring and Surveillance) Regulations 2004 (SR 2004/396):
- (d) the Animal Products Regulations 2000 (SR 2000/207):
- (e) the Animal Products (Risk Management Programme Registration—Required Part) Regulations 2020 (LI 2020/10):
- (f) the Dairy Industry (National Residue Monitoring Programme) Regulations 2002 (SR 2002/139).

## Schedule 1

### Transitional, savings, and related provisions

r 4

### Part 1

#### Provisions relating to these regulations as made

#### 1 Interpretation

In this Part, unless the context otherwise requires,—

**commencement** means 1 July 2022

**existing risk management programme** means a risk management programme that immediately before commencement was a registered risk management programme.

#### 2 Amendments required to update existing risk management programme

- (1) The operator of an existing risk management programme must ensure that the programme is updated by 1 November 2023 to accurately reflect the requirements of the Act, these regulations, and any supplementary notices.
- (2) Until 1 November 2023, any amendments made to an existing risk management programme that are only for the purpose of subclause (1) are not, for the purpose of section 25 of the Act, significant amendments.

#### 3 Existing notices declared to be continuing notices

- (1) On and from 28 February 2022, the following notices are each declared to be a continuing notice for the purpose of clause 5 of Schedule 1 of the Act:
  - (a) the Animal Products (Dairy Processing Specifications) Notice issued 1 July 2011:
  - (b) the Animal Products Notice: Ante-mortem and Post-mortem Examination of Mammals, Ostrich and Emu Intended for Human Consumption issued 31 May 2015:
  - (c) the Animal Products Notice: Contaminant Monitoring and Surveillance issued 1 July 2021:
  - (d) the Animal Products Notice: Contaminant Specifications issued 3 June 2021:
  - (e) the Animal Products Notice: Dairy Recognised Agencies and Persons Specifications issued 11 May 2020:
  - (f) the Animal Products Notice: Disposal of Non-conforming Dairy Material or Dairy Product issued 6 December 2016:

- (g) the Animal Products Notice: Manufacture of Dairy Based Infant Formula Products and Formulated Supplementary Foods for Young Children issued 21 April 2017:
  - (h) the Animal Products Notice: Raw Milk Products Specifications issued 10 September 2020:
  - (i) the Animal Products Notice: Regulated Control Scheme – Dairy Export Quota Products issued 26 August 2015:
  - (j) the Animal Products Notice: Risk Management Programme Specifications Amendment and Requirements for Risk Management Programme Outlines Revocation issued 11 May 2020:
  - (k) the Animal Products Notice: Specifications for Animals Treated with Buparvaquone issued 21 October 2014:
  - (l) the Animal Products Notice: Specifications for Laboratories issued 11 May 2020:
  - (m) the Animal Products Notice: Specifications for National Microbiological Database Programme issued 15 April 2021:
  - (n) the Animal Products Notice: Specifications for Products Intended for Animal Consumption issued 7 May 2021:
  - (o) the Animal Products Notice: Specifications for Products Intended for Human Consumption issued 14 August 2020:
  - (p) the Animal Products Notice: Specifications for the Ante-mortem and Post-mortem Examination of Poultry Intended for Human or Animal Consumption issued 2 March 2021:
  - (q) the Animal Products (Official Assessors: Ante-Mortem and Post-Mortem Inspectors) Notice issued 1 May 2009:
  - (r) the Animal Products (Official Assessors: Ante-Mortem and Post-Mortem Inspectors) Amendment Notice issued 7 October 2013:
  - (s) the Animal Products (Recognised Agencies and Persons Specifications) Notice issued 21 August 2015:
  - (t) the Animal Products (Requirement for Recognised Agencies to Notify of Termination of Contract) Notice issued 3 June 2008:
  - (u) the Animal Products (Risk Management Programme Specifications) Notice issued 5 June 2008:
  - (v) the Animal Products (Specifications for Limited Processing Fishing Vessels) Notice issued 13 September 2005.
- (2) The notices specified in subclause (1) are revoked on 1 July 2022.

#### **4 Listing of further petfood processors**

- (1) This clause applies to a further petfood processor who, immediately before commencement, was a listed further petfood processor under the Animal Prod-

ucts Notice: Specifications for Products Intended for Animal Consumption issued 7 May 2021.

- (2) The further petfood processor is, until the expiry date, treated as if they were a listed further petfood processor under regulation 140 and Part 10.
- (3) In this clause, **expiry date** means the date that is 2 years after the further petfood processor was listed under the Animal Products Notice: Specifications for Products Intended for Animal Consumption issued 7 May 2021.

## **5 Listing of animal material depot**

- (1) This clause applies to an animal material depot that, immediately before commencement, was a listed animal material depot under the Animal Products Notice: Specifications for Products Intended for Human Consumption issued 14 August 2020.
- (2) The animal material depot is, until the expiry date, treated as if it were a listed animal material depot under regulation 129 and Part 10.
- (3) In this clause, **expiry date** means the date that is 5 years after the animal material depot was listed under the Animal Products Notice: Specifications for Products Intended for Human Consumption issued 14 August 2020.

## **6 Certified suppliers and certified game estate suppliers**

- (1) This clause applies to a person who, immediately before commencement, was listed as a certified supplier or a certified game estate supplier under the Animal Products Notice: Specifications for Products Intended for Human Consumption issued 14 August 2020.
- (2) The certified supplier or certified game estate supplier is, until the expiry date, treated as if they were a listed hunter under regulation 116 and Part 10.
- (3) In this clause, **expiry date** means the date that is 2 years after the certified supplier or certified game estate supplier was listed under the Animal Products Notice: Specifications for Products Intended for Human Consumption issued 14 August 2020.

## **7 Dairy maintenance compounds**

- (1) This clause applies to a dairy maintenance compound that, immediately before commencement, was approved or recognised by the Director-General under regulation 30 of the Animal Products (Dairy) Regulations 2005.
- (2) The dairy maintenance compound is, until the expiry date, treated as if it were approved and listed by the Director-General under regulation 247.
- (3) In this clause, **expiry date** means the date that is 5 years after the maintenance compound was approved or recognised by the Director-General under regulation 30 of the Animal Products (Dairy) Regulations 2005.

**8 Non-dairy maintenance compounds**

- (1) This clause applies to a non-dairy maintenance compound that, immediately before commencement, was approved or listed by the Director-General under regulation 11 of the Animal Products Regulations 2000.
- (2) The non-dairy maintenance compound is, until the expiry date, treated as if it were approved and listed by the Director-General under regulation 247.
- (3) In this clause, **expiry date** means the date that is 5 years after the maintenance compound was listed or approved by the Director-General under regulation 11 of the Animal Products Regulations 2000.

**9 Verification frequency for certain animal product businesses**

- (1) This clause applies to an animal product business in respect of which verification—
  - (a) was carried out before commencement; but
  - (b) was not required under an enactment (for example, was required under an operational code).
- (2) The initial frequency with which the animal product business must be verified under these regulations is the frequency closest to the frequency with which the business was verified before commencement.

## Schedule 2

### Product-specific exemptions from requirement to have registered risk management programme

r 41

#### *Eggs*

#### **1 Certain primary processors of eggs**

A risk management programme is not required for the production, processing, or sale of eggs by a primary processor of eggs who—

- (a) produces eggs for sale for human or animal consumption from 100 female birds or fewer (all species included); and
- (b) sells all eggs that are intended for human or animal consumption direct to the consumer or end user; and
- (c) does not sell any of the eggs to any person for further sale.

Compare: SR 2000/209 cl 11F

#### *Fish*

#### **2 Fish on retail premises**

A risk management programme is not required for primary processing of fish where fish is sold by retail sale (or retail and wholesale) from the same premises if—

- (a) no fish from those premises is exported; and
- (b) the premises operate under a risk-based measure.

Compare: SR 2000/209 cl 10

#### **3 Certain tourist or charter fishing vessel operators and fishing guides**

- (1) A risk management programme is not required in respect of fishing and catch support activities by a person who—

- (a) provides a fishing vessel or fishing guidance services; and
- (b) provides any services for sailing or operating the vessel, guidance in respect of fishing, or catch support activities; and
- (c) at no stage owns the fish or is involved in the sale of the fish.

- (2) In this clause, **catch support activities** means storage, gutting, filleting, and other preparation activities for the catch of a fishing party.

#### **4 Storage places for fish**

- (1) A risk management programme is not required for operations at any premises or place used only for the storage of fish pending transport or delivery to the

premises of a subsequent processor of fish, whether or not that processor is exempt from the requirements of Part 2 of the Act.

- (2) The following activities are the main examples of what constitutes the storage of fish:
- (a) keeping live fish in containers in the sea, or in the freshwater environment, where the fish were taken:
  - (b) keeping whole fish (whether or not chilled or refrigerated) on or in a fishing vessel, or in a means of land transport that transports the fish to a storage depot or facility or to a primary processor:
  - (c) keeping whole fish (whether or not chilled or refrigerated) on or in a storage depot or other facility until they are removed for transport to a further storage depot or facility or to a primary processor.

Compare: SR 2000/209 cl 11

## **5 Fish processed on registered limited processing fishing vessels**

A risk management programme is not required for the processing of fish on a fishing vessel that is registered as a limited processing fishing vessel under Part 3 of the Animal Products (Regulated Control Scheme—Limited Processing Fishing Vessels) Regulations 2001.

Compare: SR 2000/209 cl 11A

## **6 Processors of fish bait, fish berley, chum, or ground bait**

A risk management programme is not required for processing operations that involve only fish bait, fish berley, chum, or ground bait.

Compare: SR 2000/209 cl 11B

## **7 Whitebait activities**

- (1) A risk management programme is not required in respect of whitebait-related activities by a person who—
- (a) catches or harvests whitebait from the natural environment; and
  - (b) provides limited processing, such as chilling, washing, and storage, to maintain the whitebait in a condition fit for human consumption; and
  - (c) sells whitebait for consumption or processing.
- (2) In this clause, **whitebait** means—
- (a) the young or fry of the following *Galaxias* species:
    - (i) *Galaxias maculatus* (inanga):
    - (ii) *Galaxias brevipinnis* (kōaro):
    - (iii) *Galaxias argenteus* (giant kōkopu):
    - (iv) *Galaxias postvectis* (shortjaw kōkopu):
    - (v) *Galaxias fasciatus* (banded kōkopu):

- (b) the young or fry of the fish (commonly known as smelt) whose scientific name is *Retropinna retropinna*.

Compare: SR 2000/209 cl 11D

## 8 Fish auctions

A risk management programme is not required for the primary processing of fish, other than bivalve molluscan shellfish (which include oysters, clams, mussels, pipi, cockles, and scallops), that are caught at fishing competitions and sold by auction, for cultural, benevolent, philanthropic, or charitable purposes, if—

- (a) the person auctioning the fish is approved as provided for in paragraph (b) of the definition of sale in section 2(1) of the Fisheries Act 1996; and
- (b) any crustaceans or pāua that are auctioned have not been taken from areas where there is a marine biotoxin warning in place; and
- (c) from the time of catching to sale, the fish are handled in a manner that keeps them fit for human consumption; and
- (d) the fish are sold only to the end consumer.

### *Muttonbirds*

## 9 Muttonbirds

- (1) A risk management programme is not required for the primary processing of muttonbirds for human or animal consumption.
- (2) In this clause, **muttonbird** means a member of the species *Puffinus griseus* (sooty shearwater), *Puffinus tenuirostris* (short-tailed shearwater), or *Pterodroma macroptera* (grey-faced petrel).

Compare: SR 2000/209 cl 11E

### *Deer velvet*

## 10 Deer velvet

- (1) A risk management programme is not required for the harvest, collection, storing, grading, or transport of raw deer velvet.
- (2) The exemption under subclause (1) does not apply if the relevant person also dries the velvet, slices it, grinds it, preserves it, or otherwise processes it to the point that it may be used as an ingredient in further processing or packaged for retail sale.

Compare: SR 2000/209 cl 12

*Beekeepers***11 Beekeepers**

A risk management programme is not required for the harvesting operations of animal material or animal products produced by bees (including any associated storage or transport operations).

Compare: SR 2000/209 cl 13

*Dairy***12 Processing dairy material or dairy product for human consumption**

- (1) This clause applies to processing of dairy material or dairy product that is intended for human consumption.
- (2) A risk management programme is not required for dairy processors in relation to activities other than transporting if the dairy processors—
  - (a) are not farm dairy operators; and
  - (b) process dairy material for the New Zealand market or Australia only; and
  - (c) process the dairy material in accordance with a risk-based measure under the Food Act 2014.
- (3) The exemption under subclause (2) does not apply if the processed product is intended to be exported other than to Australia (whether or not the export would require an official assurance).
- (4) A risk management programme is not required for transporting dairy material or dairy product intended for export without official assurances or for the New Zealand market, if the transporter is operating under—
  - (a) a risk-based measure under the Food Act 2014; or
  - (b) a regulated control scheme under the Animal Products Act 1999.
- (5) In subclause (3) and in clause 13(3), **transporting**—
  - (a) means transporting by vehicle or any other mode of transport; and
  - (b) includes transferring dairy material or dairy product between vehicles or any other mode of transport used.

Compare: SR 2000/209 cl 8A

**13 Processing of dairy material or dairy product for animal consumption**

- (1) A risk management programme is not required for the processing of dairy material for animal consumption if the processing occurs at premises or a place where no other operations requiring a risk management programme take place.
- (2) The exemption in subclause (1) does not apply if the processed product is intended for export (whether or not the export would require an official assurance).

- (3) A risk management programme is not required for the transporting of dairy material or dairy product for animal consumption for export without official assurances or for the New Zealand market.

Compare: SR 2000/209 cl 8B

#### **14 Raw milk produced and processed under regulated control scheme**

- (1) A risk management programme is not required for the following operators:
- (a) a farm dairy operator who produces and processes RCS raw milk;
  - (b) a depot operator who stores RCS raw milk on behalf of farm dairy operators;
  - (c) a transport operator who transports RCS raw milk on behalf of farm dairy operators.
- (2) In this clause, **depot operator**, **RCS raw milk**, and **transport operator** have the meanings given to each of them by regulation 4(1) of the Raw Milk for Sale to Consumers Regulations 2015.

Compare: SR 2000/209 cl 8BA

#### **15 Processing of certain dairy products consumed on premises**

- (1) Parts 2 to 4 of the Act do not apply to the processing of dairy products for human consumption if—
- (a) the processing is carried out under a risk-based measure under the Food Act 2014; and
  - (b) the processing is carried out at the premises where all the resulting product is consumed; and
  - (c) no dairy product is exported from those premises; and
  - (d) the dairy product is sold only by way of retail sale.
- (2) However, the exemption in subclause (1) does not apply to raw milk to which the regulated control scheme imposed by regulation 7 of the Raw Milk for Sale to Consumers Regulations 2015 applies.

Compare: SR 2000/209 cl 7A

#### **16 Processing of certain dairy products that are food**

- (1) Parts 2 to 4 of the Act do not apply to the processing of the following dairy material or dairy products (being material or products that consist of or contain dairy material or dairy products) if the processing is carried out under a risk-based measure under the Food Act 2014:
- (a) multi-ingredient foods and other prepared foods that, despite containing 1 or more ingredients that are dairy material or dairy products, do not consist principally of dairy material or dairy products (for example, biscuits, cakes, bread, soups, sauces, snack goods, pastries, confectionery, and prepared meals that do not consist principally of dairy product):

- (b) alcoholic beverages and formulated caffeinated beverages.
- (2) The exemption in this clause does not apply to the processing of ice cream.
- (3) The exemption in this clause does not apply if the product or material to which this clause applies is intended for export in circumstances that would require an official assurance to be issued, and the official assurance may be issued only on the basis of compliance with the relevant provisions of Parts 2 to 4 of the Act.
- (4) In this clause,—

**alcoholic beverage** means an alcoholic beverage that contains dairy product or alcohol derived from dairy material or dairy product

**formulated caffeinated beverage** has the meaning set out in section 1.1.2—6 of the Food Standards Code

**ice cream** has the meaning set out in section 1.1.2—3 of the Food Standards Code.

Compare: SR 2000/209 cl 7B

### *Petfood for secondary processing*

## **17 Further petfood processing**

A risk management programme is not required for the secondary processing of animal material or animal product intended for cats or dogs if—

- (a) the animal material or animal product results from the death of the source animal; and
- (b) the processing does not require a risk management programme under regulation 39; and
- (c) an official assurance is not required; and
- (d) the acquired animal material or animal product has been rendered or it has been subject to primary processing by an earlier processor in accordance with a registered risk management programme or a risk-based measure.

### Schedule 3

#### General exemptions from requirement to have registered risk management programme

r 41

#### **1 Animal food processed in accordance with Food Act regime**

- (1) A risk management programme is not required for the secondary processing of animal product for animal consumption if—
- (a) the processing is carried out in accordance with the Food Act 2014 regime for human consumption; and
  - (b) the resulting product that is fit for human consumption is voluntarily made available for animal consumption.
- (2) The exemption under subclause (1) does not apply in circumstances where the resulting product is downgraded under the Food Act 2014 regime as unfit for human consumption.

Compare: SR 2000/209 cl 9

#### **2 Primary processing of animal material for purposes other than human or animal consumption: skinning, shearing, etc**

- (1) A risk management programme is not required for the primary processing of animal material if—
- (a) the resulting product is not intended for human or animal consumption; and
  - (b) the processing occurs at premises or a place where no other operations requiring a risk management programme take place.
- (2) Without limiting the generality of subclause (1), the following activities are an illustration of various kinds of processing operations that do not require a risk management programme if they meet the requirements of subclause (1):
- (a) the skinning of slinks, possums, or rabbits in the field, or at a place where such activities are carried out exclusively;
  - (b) the shearing of sheep, goats, and alpacas;
  - (c) feather and fibre removal;
  - (d) the collection or extraction of reproductive material.
- (3) The exemption in subclause (1) does not apply if the processed product is intended for export in circumstances that would require an official assurance to be issued, and the official assurance may only be issued on the basis of compliance with the requirements of a risk management programme.

Compare: SR 2000/209 cl 8

**3 Airline holding facilities operators**

A risk management programme is not required for an operator of facilities for the temporary holding of goods for export by air during aircraft loading and unloading procedures if the facilities are within the confines of the airport and adjacent to the tarmac.

Compare: SR 2000/209 cl 11G

**4 Taxidermy operations**

A person who performs taxidermy operations is not required to have a risk management programme for those operations if—

- (a) the person does not trade any part of the animals to which the operations relate for human or animal consumption, or any such trade is only to a person carrying out rendering operations under a risk management programme; and
- (b) the person does not provide any other type of homekill or recreational catch services on the same premises.

Compare: SR 2000/209 cl 14

**5 Transporting of animal material or animal product for animal consumption**

- (1) A risk management programme is not required for the transporting of animal material or animal product (other than dairy material or dairy product) for animal consumption for export without official assurances or for the domestic market.
- (2) In subclause (1), **transporting**—
  - (a) means transporting by vehicle or any other mode of transport; and
  - (b) includes transferring animal material or animal product between vehicles or any other mode of transport used.
- (3) Despite subclause (1), clause 13(1) of Schedule 2 applies to the processing of dairy material and dairy product for animal consumption.

Compare: SR 2000/209 cls 9A, 18

## **Schedule 4**

### **Offences**

r 244

Regulation 7(1) (regime when other activities within physical boundaries of programme)

Regulation 10(5) (procedures for risk factors)

Regulation 12 (justifying operator-defined limits)

Regulation 20(2) (competency and skills of certain persons)

Regulation 22(3) (verification by operator of risk management programme)

Regulation 23(2) or (3) (record keeping)

Regulation 31(1) (control of risk management programme documents)

Regulation 32 (archived documents)

Regulation 33 (making documents available)

Regulation 34 (validation of risk management programme effectiveness)

Regulation 36 (reporting to verifier or verifying agency)

Regulation 37 (notifying Director-General)

Regulation 38 (operator of risk management programme must report certain information to Director-General)

Regulation 43(1) (how premises, etc, must be operated)

Regulation 45 (operation of essential services)

Regulation 46 (water)

Regulation 47 (operator must manage waste)

Regulation 48 (calibrating measuring equipment and monitoring equipment)

Regulation 50(1) (operator must ensure appropriate cleaning and sanitising procedures)

Regulation 51(1) or (2) (maintenance must be carried out to suitable standard)

Regulation 52(1) or (2) (maintenance must not affect processing adversely)

Regulation 53(1) or (2) (use of maintenance compounds)

Regulation 54(1) (practices must minimise effects of pests)

Regulation 55(1), (2), or (5) (protecting against contamination by people)

Regulation 56 (operator must ensure suitability of animal material, animal product, and other inputs)

Regulation 58 (processing must minimise contamination and deterioration)

Regulation 61 (restriction on processing animal material or animal product from animals imported live)

Regulation 62(1) (general testing)

Regulation 63 (operator must take corrective action)

Regulation 64 (persons examining, etc, must be skilled)

Regulation 66 (labelling and identification requirements)

Regulation 68 (packaging requirements for animal material and animal product)

Regulation 70(1) (processing non-conforming animal material or animal product)

Regulation 74 (evaluator restrictions and requirements)

Regulation 84 (restriction on verification by previous evaluator)

Regulation 98 (giving access or assistance)

Regulation 100 (reporting)

Regulation 103(1) (traceability procedures)

Regulation 104 (providing traceability information on request)

Regulation 105(1) (recall procedures)

Regulation 106 (providing details of recall)

Regulation 107(1) (simulated recall to demonstrate procedures effective)

Regulation 108 (frequency of simulated recall)

Regulation 109(1) or (2) (farmed animals suitable for processing)

Regulation 110(1) or (2) (game estate animals suitable for processing)

Regulation 111 (supply of game estate animal material)

Regulation 112(1) (supply of animal material from wild, game estate, and formerly-farmed feral animals)

Regulation 113(1) (health of farmed animals for supply)

Regulation 114 (supply of farmed mammals and farmed birds)

Regulation 115 (supply of animal material from animals imported live into New Zealand)

Regulation 116 (hunter supplying animal material for human consumption must be listed)

Regulation 117 (hunter must comply with written agreement in certain situations)

Regulation 118 (supply of animal material used in experiments, trials, or research)

Regulation 119 (presentation of animal material for primary processing)

Regulation 121(1) or (2) (competency)

Regulation 122(1) or (2) (checks)

Regulation 123 (procedures for supply of animal material)

Regulation 124(1) (supply and movement declarations for farmed animals)

Regulation 125 (how records must be kept)

Regulation 128(1) (storing animal material)

- Regulation 129(1) (animal material depot must be listed)
- Regulation 130 (animal material depot location, design, and construction)
- Regulation 131 (operation of animal material depot facilities, equipment, and essential services)
- Regulation 132 (animal material depot packaging requirements)
- Regulation 133(1) or (2) (protecting against contamination by people at animal material depot)
- Regulation 134 (animal material depot record keeping)
- Regulation 135 (requirements for certain animal material depots)
- Regulation 136 (additional requirements for animal material depots that are mobile)
- Regulation 138 (good operating practices for transporters)
- Regulation 140 (further petfood processors must be listed)
- Regulation 141 (further petfood processor must source from risk management programme, etc)
- Regulation 142 (further petfood processor must have traceability procedure)
- Regulation 143 (further petfood processor must keep records)
- Regulation 145 (good operating practices for beekeepers)
- Regulation 147(1) or (3) (dairy material and product must be wholesome and free from hazard)
- Regulation 148(1) or (2) (dairy processor requirements for premises, places, facilities, equipment, and essential services)
- Regulation 149 (dairy processor requirements for maintaining and operating premises, places, facilities, equipment, and essential services)
- Regulation 150(1) or (2) (dairy material and product must be processed in manner that minimises contamination and deterioration)
- Regulation 151(1) or (2) (dairy material and product transport requirements)
- Regulation 152(1) or (2) (competency)
- Regulation 153(1) or (2) (checks)
- Regulation 154 (systems and procedures for procurement and supply)
- Regulation 155 (how records must be kept under this Part)
- Regulation 176 (obligations of risk source operators)
- Regulation 177 (obligations of processors)
- Regulation 180 (requirements relating to specified agricultural compounds)
- Regulation 186 (obligations to supply samples, assist, provide access and facilities, etc)
- Regulation 187(2) (obligation to supply information)

Regulation 194 (record-keeping requirements for recognised agency)

Regulation 202 (misleading statements)

Regulation 217 (record-keeping requirements for recognised person independent of recognised agency)

Regulation 240 (reporting conflict of interest after appointment)

Michael Webster,  
Clerk of the Executive Council.

### Explanatory note

*This note is not part of the regulations, but is intended to indicate their general effect.*

These regulations are made under the Animal Products Act 1999 (the **Act**). These regulations reflect changes made to the Act as part of the new food safety regime established by the Food Safety Law Reform Act 2018.

Most of these regulations come into force on 1 July 2022. *Clause 3 of Schedule 1* comes into force on 28 February 2022. It saves certain existing notices from being revoked under clause 4 of Schedule 1 of the Act by declaring them to be continuing notices. *Regulations 107 and 108*, which relate to the simulated recall of animal material and animal product, come into force on 1 July 2023.

Under the Act, most persons in control of an animal product business are required to operate under a risk management programme. The programme is intended to ensure that animal product resulting from the production and processing of animal material is fit for its intended purpose. *Part 1* deals with the required content of risk management programmes, other general and further requirements, registering risk management programmes, and some specific inclusions in the requirement to have a risk management programme. *Part 1* and *Schedules 2 and 3* also provide product-specific and general exemptions from the requirement to have a registered risk management programme.

Good operating practices are dealt with in *Part 2*, including aspects of those practices such as the design and operation of animal processing premises, cleaning and maintenance, and ensuring fitness of animal material and animal product for its intended purpose.

A risk management programme and any significant amendment to a registered risk management programme must be evaluated for its validity in terms of sections 12 and 17 of the Act, and *Part 3* applies to evaluators and the independent evaluation reports that they provide.

Verification is a function carried out periodically by verifiers or verifying agencies to give assurance about matters such as compliance with risk management programmes by animal product businesses, and *Part 4* relates to aspects of verification.

*Part 5* provides for tracing and recall of animal material and animal product by operators of risk management programmes and operators of animal product businesses that export animal material or animal product. Traceability and recall requirements are essential to food safety.

Suppliers of certain animals or animal material for primary processing must meet requirements set out in *Part 6* that relate to the circumstances of supply, the animals or animal material involved, and the intended use of the animal material or animal product.

The requirements for some particular groups and activities are dealt with in *Part 7*. Operators of depots for storing animal material, transporters, further petfood processors, beekeepers, and dairy processors have specific obligations under that Part.

*Part 8* imposes a regulated control scheme for animal material and animal product, including dairy material and dairy product. The scheme provides for the risk management measures of monitoring, surveillance, and the control of specified agricultural compounds, as specified in that Part.

Recognised agencies and persons carry out many specified functions and activities under the Act. The regulations related to their recognition, and how they must perform duties once recognised and maintain recognition, are set out in *Part 9*.

The listing of persons, premises, and things is the subject matter of *Part 10*. That Part includes the listing process, some duties once listed, the renewal of listing, and its ending, voluntarily or otherwise.

The qualities necessary for appointment as an official assessor and for performing the roles of an official assessor are set out in *Part 11*.

*Part 12* and *Schedule 4* set out regulations that are offences for the purposes of section 135(1)(b) of the Act. *Part 12* also includes offences, in relation to animals, under the National Animal Identification and Tracing Act 2012.

*Part 13* provides for miscellaneous matters, such as maintenance compounds, some exemptions, and amendments and revocations.

*Schedule 1* provides for transitional, savings, and related matters including, in particular, for the transition to the requirements of these regulations from those of the Animal Products Regulations 2000, which these regulations replace.

### **Regulatory impact statement**

The Ministry for Primary Industries produced a regulatory impact statement on 23 August 2019 to help inform the decisions taken by the Government relating to the contents of this instrument.

A copy of this regulatory impact statement can be found at—

- <https://www.mpi.govt.nz/dmsdocument/48532-Impact-Summary-strengthening-food-recalls-and-risk-management-programmes>
- <https://treasury.govt.nz/publications/informationreleases/ris>

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These regulations are administered by the Ministry for Primary Industries.