New Zealand Food Safety
Haumaru Kai Aotearoa

This Animal Product Notice has been revoked. For more information on these changes:

Changes to animal products regulations and notices

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Animal Products (Risk Management Programme Specifications) Notice 2008

Under sections 167(1)(b), (c) and (o) of the Animal Products Act 1999, I Carol Barnao, Director (Standards), issue the following notice for the purpose of —

(a) setting specifications and recordkeeping requirements in relation to risk management programmes for the purposes of section 17, 34 and 159 of that Act; and

(b) specifying matters in relation to the amendment of risk management programmes under section 25 of that Act, including specifying the kinds of changes that do not constitute an amendment requiring registration, and specifying the amount of notice of a future amendment that may be required; and

(c) specifying matters in relation to the updating of risk management programmes under section 26 of that Act.

Signed at Wellington this 5th day of June 2008

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Carol Barnao

Director (Standards)

New Zealand Food Safety Authority

(Acting under delegated authority)

Certified in order for signature:

Solicitor

Legal Services

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Notice

1 Title

This notice is the Animal Products (Risk Management Programme Specifications) Notice 2008.

2 Commencement

This notice comes into force on 1 July 2008.

Part 1
Preliminary Provisions

3 Application

This notice contains specifications that apply to, set out, and amplify requirements for the content of risk management programmes (section 17 of the Act), amending and updating risk management programmes (sections 25 and 26 of the Act), and specifying recordkeeping requirements in relation to risk management programmes (section 159 of the Act).

4 Interpretation

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

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Act means the Animal Products Act 1999;

control (noun) means the state where correct procedures are being followed and standards and other applicable criteria are being met;

control (verb) means to take all necessary actions to ensure and maintain compliance with standards and other applicable criteria;

control measure means any action and activity that can be used to prevent or eliminate an animal product related hazard or other risk factor, or to reduce it to an acceptable level;

critical control point means a step at which control can be applied that is essential to prevent or eliminate a hazard or reduce it to an acceptable level, as described in section 17(3)(b) of the Act;

critical limit means a criterion which separates acceptability from unacceptability at a critical control point, and includes acceptable parameters as described in section 17(3)(c) of the Act;

day-to-day manager means the person identified in a risk management programme either by name, position or designation as being responsible for the day-to-day management of that programme;

evaluate means the process of independent assessment of the validity of a risk management programme for the purposes of providing an independent evaluation report as required under section 20(2)(b) of the Act;

external verification means the process of verification of activities conducted under a risk management programme by a recognised verifier;

food—

(a) means anything that is used or represented for use as food or drink for humans; and

(b) includes—

(i) any ingredient or nutrient or other constituent of any food or drink, whether that ingredient or nutrient or other constituent is consumed or represented for consumption on its own by humans, or is used in the preparation of, or mixed with or added to, any food or drink; and
(ii) anything that is or is intended to be mixed with or added to any food or drink; and
(iii) chewing gum, and any ingredient of chewing gum, and anything that is or is intended to be mixed with or added to chewing gum; and
(iv) anything that is declared by the Governor-General, by Order in Council, to be food for the purposes of this Act; but

(c) does not include—
(i) any tobacco; or
(ii) any cosmetics; or
(iii) any substances used only as medicines (within the meaning of the Medicines Act 1981) or any controlled drugs (within the meaning of the Misuse of Drugs Act 1975); or
(iv) any cookware and related products; or
(v) any packaging (except edible packaging)

good operating practice (including good agricultural practice, good hygienic practice and good manufacturing practice) means documented procedures relating to practices that —
(a) are required to ensure animal material and animal product are fit for intended purpose; and
(b) are appropriate to the operating circumstances;

input means any animal material, animal product, additive, processing aid, ingredient, packaging, or other associated thing where that associated thing is contained within, attached to, enclosed with, or in contact with, the animal material or animal product;

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NZFSA means the New Zealand Food Safety Authority;

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

operator verification means the application of methods, procedures, tests and other checks by a risk management programme operator to confirm the ongoing —
(a) compliance of the risk management programme with the legislative requirements; and
(b) compliance of the operations with the risk management programme; and
(c) applicability of the risk management programme to the operation;
and forms part of confirmation as described in section 17(3)(f) of the Act.

output means animal material or animal product resulting from an operation undertaken under a risk management programme;

recognised evaluator means a person recognised under section 103 of the Act to perform risk management programme evaluation functions and activities;

recognised verifier means a person recognised under section 103 of the Act to verify operations that are subject to a risk management programme, regulated control scheme, standards and specifications, or export requirements;

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

shelf life means the period nominated by the operator during which a product maintains its fitness for intended purpose;

uncontrolled hazard means a hazard which has been identified in a hazard analysis for a particular process or product, and for which the operator has no

control measure available, and there is no mandatory requirement to control that hazard;

unique location identifier means a unique identification code to indicate the location or premises within a risk management programme;

validate means the process by which evidence is obtained to demonstrate that animal material or animal product will be fit for intended purpose, through the achievement of any regulatory limit or operator-defined limit;

(2) For the avoidance of doubt, references to a 'risk management programme' relate to both a 'multi-business risk management programme' and a 'single-business risk management programme' except where a specific reference is made to either.

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

Part 2
Risk Management Programme Requirements

The requirements for risk management programmes set out in this Part 2 apply in addition to the requirements set out in section 17 of the Act, and apply to all risk management programmes, unless otherwise stated.

5 Scope of a risk management programme

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(1) A risk management programme must contain a description of the physical boundaries to which the risk management programme applies.

(2) The physical boundaries of a farm dairy may be documented in the risk management programme by assigning a farm dairy identifier to each farm dairy and maintaining a register showing the physical location of each farm dairy.

(3) A risk management programme that covers dairy processing (other than a farm dairy or the transport of dairy material) and includes more than one location, must contain a unique location identifier for each location identified within the risk management programme.

(4) A risk management programme must contain consideration of all relevant sources of potential risk factors that may affect the animal material, animal product, operations or directly associated things within the physical boundaries of the risk management programme.

(5) For the purposes of section 17(1)(b)(ii) of the Act, a risk management programme must specify whether any animal material, animal product or food that is within the physical boundaries of the risk management programme, is excluded because it is covered under a different risk management programme or a different regulatory regime, and if so clearly explain how the interfaces are managed.

(6) If a person other than the risk management programme operator uses areas inside the physical boundaries of the risk management programme for any activity not covered by the risk management programme, a risk management programme must address the interfaces with this activity to ensure that the effectiveness of the programme is not compromised, and the operator must document in the risk management programme the authorities and accountabilities for resolving issues associated with that activity.

6 Animal material and animal product description

(1) For the purposes of section 17(1)(c) of the Act, a risk management programme must specify the name or type of all animal materials or animal products entering the physical boundaries of the risk management programme.

(2) A risk management programme must specify the name or type of all animal materials or animal products leaving the physical boundaries of the risk management programme.

(3) A risk management programme must specify the intended use of each animal material or animal product described in clause 6(2) when it leaves the physical boundaries of the risk management programme, including —

(a) whether the material or product is intended for human or animal consumption, and

(b) whether the material or product —

(i) is to be subject to further processing; or

(ii) requires additional preparation by the final consumer; or

(iii) is ready to eat or consume.

7 Limits

A risk management programme must, in relation to each animal material or animal product described in clause 6(2), specify any relevant regulatory limits and any operator-defined limits in relation to —

(a) risks from hazards to animal or human health; and

(b) risks from false or misleading labelling or representation; and

(c) risks to the wholesomeness of animal material or animal product.

8 Actions when limits are not met

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A risk management programme must specify the actions to be taken if the limits in clause 7 are not met.

9 Description of the process or operation

A risk management programme must specify every process or operation carried out under that programme, including —

(a) all inputs; and

(b) the main activities or steps; and

(c) all outputs.

10 Identification of risk factors and analysis of hazards

In addition to the requirements in sections 17(2) and (3) of the Act, a risk management programme must specify any uncontrolled hazards that are likely to be present in animal product leaving the physical boundaries of the risk management programme and the operator must be able to justify that this is appropriate considering the intended use of the product.

11 Control of hazards and other risk factors

(1) A risk management programme must contain sufficient procedures to ensure that —

(a) animal material or animal product subject to the risk management programme is fit for its intended purpose and that it complies with the programme; and

(b) legislative requirements (including regulatory limits) are met.

(2) The procedures referred to in subclause (1) must cover —

(a) good operating practice; and

(b) all matters set out in sections 17(2) and 17(3) of the Act; and

(c) any corrective action procedures that are to be applied in the event of loss of control, including —

(i) how control will be restored; and

(ii) how any affected animal material or animal product will be identified, controlled or disposed of; and

(iii) any measures to be taken to prevent recurrence of the loss of control; and

(iv) where the loss of control is due to unforeseen circumstances and there is no specific corrective action already documented, nomination of a suitably skilled person to manage the corrective action, recording of the issue and corrective actions taken, and reporting of such matters to the recognised risk management programme verifier without unnecessary delay.

(3) A risk management programme must specify the following for each identified critical control point —

(a) the justification for its identification; and

(b) the critical limits to be met and the justification for those limits.

12 Document list

(1) A risk management programme must contain a list of all documents that comprise the programme with their date or version at the time of registration of the programme or any significant amendment to that programme.

(2) For multi-business risk management programmes, the document list must also specify, where necessary, which documents relate to which business.

13 Notifications

(1) A risk management programme must contain a procedure for notification of the Director-General in writing, without unnecessary delay, of any change to the name or position or designation of the person(s) responsible for the day-to-day management of the programme.

(2) A risk management programme must contain a procedure for notification of the Director-General of any emerging, new or exotic biological hazards or new chemical hazards that come to the operator's notice in relation to the programme as soon as practical after their discovery.

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(3) A risk management programme must contain a procedure for notifying the recognised risk management programme verifying agency in writing, without unnecessary delay, of the following issues relating to the operation of the programme —

(a) any significant concern about the fitness for intended purpose of animal material or animal product:

(b) where the cumulative effect of minor amendments necessitates the registration of a significant amendment to the programme as provided in section 25 of the Act:

(c) where the risk management programme is no longer considered to be effective:

(d) where the premises identified as being used by the programme are not or no longer suitable for use:

(e) where anything within the physical boundaries of the programme is used for additional purposes or by other operators and the programme has not adequately considered relevant hazards or other risk factors.

14 Recall of animal material or animal product

(1) For the purposes of section 17(2)(c) of the Act where, due to the nature of the animal material or animal product it is possible to recall it from trade, distribution or consumers, a risk management programme must contain a recall procedure, including —

(a) the criteria for deciding when a recall will be initiated; and

(b) how retrieval and disposition of the relevant animal material or animal product will be managed.

(2) A risk management programme must contain a system for notifying the following people as soon as possible when animal material or animal product is recalled from

trade, distribution or from consumers because it is not or may not be fit for its intended purpose —

(a) the Director-General; and

(b) the recognised risk management programme verifier or recognised risk management programme verifying agency.

15 Identification and competency of responsible persons

(1) A risk management programme must specify the identity (either by position, designation or name) of—

(a) the day-to-day manager of the risk management programme; and

(b) those persons authorising all or part of the risk management programme on behalf of the operator in accordance with clause 19(1)(c); and

(c) those persons performing key tasks under the risk management programme including monitoring, corrective action, and operator verification activities.

(2) A risk management programme must specify the competencies needed by the persons identified under subclause (1) to enable the effective operation of the risk management programme.

(3) A risk management programme must provide for the keeping of records, in an easily accessible form, demonstrating that the competencies documented under subclause (2) have been achieved and maintained.

16 Operator verification

(1) A risk management programme must specify an operator verification system including —

(a) the activities to be performed in relation to the risk management programme, and their frequency; and

(b) any actions to be taken when all or part of the risk management programme is not effective; and

(c) any recording and reporting requirements.

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(2) A risk management programme must contain a mechanism for ensuring that, wherever possible, persons carrying out operator verification are independent of the activities being verified.

17 Allowing verifiers to carry out verification functions and activities

(1) Taking into account the duties imposed on an operator under section 16(1)(e) of the Act and the requirement in section 17(4) of the Act, a risk management programme must include provisions allowing recognised risk management programme verifiers to have the freedom of access to carry out their verification functions and activities, including provisions allowing —

(a) such freedom to access premises, places, or facilities covered by a risk management programme as is necessary to enable a recognised risk management programme verifier to carry out his or her functions and activities; and

(b) such access to documents, records, and information that relate to a risk management programme as is necessary to enable a recognised risk management programme verifier to carry out his or her functions and activities; and

(c) such access to things (including containers and packages) that are used in connection with producing and processing animal material and animal products under a risk management programme as is necessary to enable a recognised risk management programme verifier to carry out his or her functions and activities; and

(d) such access to animal material, animal product, equipment, packages, containers, and other associated things used in processing animal material and animal product under a risk management programme as is necessary to enable a recognised risk management programme verifier to carry out his or

her functions and activities (including identifying and marking any of those things); and

(e) such freedom to examine and take samples (for the purpose of analysis or retention) of animal material, animal product, or any other outputs, substance, or associated thing which has been, is, or may be used in contact with, or in the vicinity of animal material or animal product being produced or processed under a risk management programme as is necessary to enable a recognised risk management programme verifier to carry out his or her functions and activities.

(2) By way of explanation, in the case of a significant risk to the fitness for intended purpose of animal product or suitability of animal material for processing, a recognised risk management programme verifier may —

(a) recommend to the operator that processing under the risk management programme be temporarily interrupted; and

(b) recommend to the operator that any affected animal product that may not, or no longer, be fit for its intended purpose be detained; and

(c) recommend to an Animal Product Officer that the officer exercises his or her powers of interruption of operations under section 89 of the Act which (in the case only of the powers under section 89(b) and (c)) may be exercised by the Animal Product Officer over the phone if he or she considers that appropriate.

18 Document checks and validation

(1) A risk management programme or any significant amendment to a risk management programme, where necessary, must contain —

(a) evidence to demonstrate the effectiveness of the risk management programme; or

(b) a protocol containing —

(i) details of the evidence to be collected to demonstrate the effectiveness of the risk management programme, and

(ii) a proposal for the disposition of animal material or animal product until the effectiveness of the programme has been demonstrated.

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Part 3
Document Control and Record-Keeping

19 Document control

(1) Every document or part of a document that makes up a risk management programme must be —

(a) legible; and

(b) dated or marked to identify its version; and

(c) authorised prior to use, either directly or within the document control system, by —

(i) the operator; or

(ii) the day-to-day manager of the programme; or

(iii) a person nominated to do so in the programme's document control system; and

(d) available in a readily accessible form when required to any person with responsibilities under the programme.

(2) A risk management programme must contain procedures for effective document control of the documents that form the risk management programme including how —

(a) significant and minor amendments will be made to the risk management programme so that the programme is current and reflects the actual operation; and
(b) the amendments, or the nature of the amendments to the programme will be identified or described; and
(c) documents are authorised prior to issue and use; and
(d) all amended parts of the risk management programme will be removed from use and replaced with the current versions at all locations to which it has been distributed without unnecessary delay after authorisation and, where necessary, after registration in accordance with section 25 of the Act.

(3) An operator must retain (by archive or otherwise) for four years, one copy of all obsolete documents from a registered risk management programme in a manner that protects the documents from damage, deterioration or loss, and prevents confusion with current documents.

(4) An operator must ensure that the registered risk management programme and all reference material relating to the risk management programme, and any archived documents are readily accessible, or can be retrieved and made available within two working days of any request to:
(a) recognised persons; and
(b) animal product officers; and
(c) the Director-General; and
(d) persons authorised by the Director-General.

20 Requirements for records

(1) An operator must include record keeping procedures in the risk management programme to ensure that all records necessary to demonstrate compliance with the documented programme are —
(a) legible; and
(b) stored for four years, or for the shelf life of the product to which the records relate (whichever is longer), in a manner which protects the records from damage, deterioration or loss; and
(c) can be retrieved and made available to persons referred to in subclause (3) within two working days of any request.

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(2) Records relating to the risk management programme's monitoring, corrective action and operator verification activities must include —
(a) the date and where appropriate the time of the activity; and
(b) a description of the results of the activity; and
(c) a means to identify the person or persons who performed the activity.

(3) An operator must make all records relevant to the risk management programme available to the following persons on request —
(a) recognised persons; and
(b) animal product officers; and
(c) the Director-General; and
(d) persons authorised by the Director-General.

Part 4
Amendments to Risk Management Programmes

21 Documentation to be submitted for registration of a significant amendment of a risk management programme

An application for registration of a significant amendment of a risk management programme must be accompanied by the following —

(a) the risk management programme pages affected by the amendment with the changes clearly identified; and
(b) where appropriate, the protocol in accordance with clause 18(1)(b).

22 Significant amendments to the risk management programme

(1) The following activities that result in changes to the risk management programme require registration as an amendment in accordance with section 25 of the Act (except where they are done on a trial basis and the affected animal material or animal product is not traded) —
(a) making major alterations to the processing facilities or equipment which may impact on fitness for intended purpose of the animal material or animal product:
(b) relocating processing operations to a new physical address (except where this is already provided for mobile premises and vessels):
(c) processing animal material or animal product that is not covered by the risk management programme, except —
(i) where the product and process are similar, and
(ii) 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 risk management programme:
(d) setting up a new process or process modification that is not covered by the risk management programme, except —
(i) where the process or process modification is similar to existing processes, and
(ii) a documented risk factor identification and hazard analysis has shown that all risk factors associated with that process are already adequately addressed by the risk management programme:
(e) making any other changes that introduce new risk factors, or adversely impact on existing risk factors:
(f) merging two or more registered risk management programmes:
(g) splitting a registered risk management programme into two or more risk management programmes:
(h) adding a business to a multi-business risk management programme except where the Director-General's approval under section 17A of the Act applies to a type of business, premises or place rather than to specific businesses.

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Part 5
Revocations and Transitional

23 Revocations

(1) The following notices are revoked with effect from 1 December 2008 —
(a) Animal Products (Risk Management Programme Specifications) Notice 2003; and
(b) Animal Products (Risk Management Programme Specifications) Amendment Notice 2004; and
(c) Animal Products (Dairy Risk Management Programme Specifications) Notice 2005.

(2) Despite the revocation of the notices listed in subclause (1) —
(a) the validity, effect or consequence of any reports, confirmations, statements or endorsements made under those notices is not affected; and
(b) the revoked notices continue to have effect as if they had not been revoked for the purpose of —
(i) investigating any offence or breach of those notices; and
(ii) commencing or completing proceedings for the offence or breach; and
(iii) imposing a penalty for the offence or breach.

24 Transitional provisions

(1) For the purpose of offences under sections 128 or 135 of the Act, after commencement of the notice and until 1 December 2008, an operator may elect to comply with either the Animal Products (Risk Management Programme Specifications) Notice 2008, or the Animal Products (Risk Management Programme Specifications) Notice 2003, or the Animal Products (Dairy Risk Management Programme Specifications) Notice 2005, and until 1 December 2008 a risk management programme may be evaluated under any of those notices, but not a combination of them.

(2) A risk management programme that was registered while the Animal Products (Risk Management Programme Specifications) Notice 2003 or the Animal Products (Dairy Risk Management Programme Specifications) Notice 2005 were in effect continues to be valid provided it is amended by the operator to meet the requirements of this notice by 1 August 2009.

Issued under section 167(1)(b), (c) & (o) of the Animal Products Act 1999.

Date of notification in *Gazette*:

This notice is administered in the New Zealand Food Safety Authority.

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