Ministry for Primary Industries
Manatū Ahu Matua

Proposed amendment to requirements relating to export approved premises

MPI Discussion Paper No: 2018/11

Prepared for all exporters of animal material and animal products
By the MPI Food & Live Animal Assurance Team

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Growing and Protecting New Zealand

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Contents

Page

1. Submission

The Ministry for Primary Industries (MPI) invites your comment on this discussion paper, which proposes certain changes to the requirements relating to export approved premises as specified under the Animal Products (Export Approved Premises) Notice 2011.

The proposed changes relate specifically to export approved premises that process germplasm and live poultry for export with official assurances. While all other requirements in the Notice remain unchanged, the structure has been amended and some provisions have been reworded for uniformity and clarification purposes.

Consultation closes on Wednesday 5 September 2018 at 5:00 pm.

1.1 HOW TO HAVE YOUR SAY

MPI encourages submitters to make their submission electronically so please email your submission to: food.assurance@mpi.govt.nz.

If you choose to convey your submission in writing, it should be posted to the following address:

Amendments – Export Approved Premises
Food & Live Animal Assurance Team (Level 11 TSB Tower)
PO Box 2526
Wellington

Please include the following information in your submission:

- the title and number of the discussion document;
- your name and title (if applicable);
- your organisation's name (if applicable); and
- your address

The following points may be of assistance in preparing comments:

- where possible, comment should be specific to a particular section in the document. All major sections are numbered and these numbers should be used to link comments to the document;
- where possible, reasons and data to support comments may be provided;
- the use of examples to illustrate particular points is encouraged;
- as a number of copies may be made of your comments, please use good quality type, or make sure the comments are clearly hand-written in black or blue ink.

1.2 THE OFFICIAL INFORMATION ACT 1982 (THE OIA)

Everyone has the right to request information held by government agencies, known as "official information". Under the OIA, information is to be made available to requesters unless there are reasonable grounds for withholding it. The grounds for withholding information are outlined in the OIA.

If you are submitting on this discussion document, you may wish to indicate any grounds for withholding information contained in your submission. Reasons for withholding information could include commercially sensitivity or privacy. MPI will consider such grounds when deciding whether or not to release information.

Any decision to withhold information requested under the OIA may be reviewed by the Ombudsman.

For more information please visit http://www.ombudsman.parliament.nz/resources-and-publications/guides/official-information-legislation-guides

1.3 WHAT HAPPENS NEXT

MPI will consider all submission after consultation has closed and a recommendation will be made to the relevant decision maker about the final version of the proposed Notice to be issued. A summary of submissions and analysis will be sent to all submitters and posted on the MPI website.

The new Notice is scheduled to be issued on Monday 1 October 2018.

Indicative timeframes

Key dates	Action
Wednesday 8 August 2018	Consultation starts
Wednesday 5 September 2018	Consultation closes (4 weeks consultation)
Wednesday 19 September 2018	Consideration of submissions (2 weeks)
Wednesday 26 September 2018	Final review (1 week)
Monday 1 October 2018	Notice is issued

2. Background

The Animal Products (Export Approved Premises) Notice 2011 (the Notice) specifies requirements in relation to the processing of the following two classes of animal material and animal products for export to countries for which official assurances are required:

(a) animal material and animal products that are not intended for human or animal consumption and are therefore not required to be processed within the scope of a risk management programme (RMP) or regulated control scheme (RCS); and

(b) animal material and animal products that are intended for human or animal consumption but are not required to be processed within the scope of an RMP or RCS.

Examples of the class of animal material and animal products referred to in paragraph (a) include animal fibre, hides and skins, animal embryos, animal semen, live poultry and marine shells. Examples of the class of animal material and animal products referred to in paragraph (b) include animal material and animal products that are, or are being processed to become or form part of, a medicine or related product that is subject to the Medicines Act 1981.

Both classes of animal material and animal products are not required to be processed within the scope of an RMP or RCS. However, since the intended importing countries require official assurances, it is necessary that the processing of those animal material and animal products are subject to certain requirements that:

(a) appropriately manage any associated risks; and

(b) safeguard the integrity of associated official assurances; and

(c) are in accordance with, or can reasonably be expected to satisfy, the requirements of the relevant authority of importing countries.

MPI proposes to amend the Notice. The proposed changes under consultation specifically relate to export approved premises that process germplasm and live poultry for export with official assurances. All other requirements in the Notice remain unchanged although, as stated, the structure of the Notice and the wording of some provisions have been amended for uniformity and clarification purposes. The proposed amended Notice is published next to this discussion document.

If the proposed changes are adopted after consultation, the amended notice will be issued, revoking and replacing the Animal Products (Export Approved Premises) Notice 2011.

To assist readers and submitters, the specific provisions in the Notice that are under consultation are highlighted.

3. Summary of proposed changes

For a quick overview, the following table summarises the changes under consultation.

Issue/Subject	Proposal
Germplasm and live poultry premises to have Standard Operating Procedures (SOPs)	• Germplasm and live poultry export approved premises must have approved SOPs. • SOPs and any subsequent amendments to be approved by the premises' veterinarian and the official assurance

	verifier. • SOPs to be re-assessed every two years. • In addition, for premises that are also approved as a compartment, the SOPs and any subsequent amendments to them to be approved by MPI prior to implementation • SOPs to specify the countries to which germplasm and live poultry processed at the premises are eligible.
Germplasm and live poultry premises to be associated with a veterinarian	• Germplasm and live poultry export approved premises to be associated with a veterinarian. • Veterinarian to be approved by MPI on the recommendation of the premises' official assurance verifier, has adequate knowledge of what is happening on the premises on a day-to-day basis, and able to be present at the premises at reasonable notice. • This is consistent with the requirement and expectation of importing countries
Approval of germplasm and live poultry premises as a compartment (animal disease status purposes)	• Where a country-specific OMAR for germplasm and live poultry can only be satisfied if the export approved premises has a recognised disease status, the premises may be approved as a compartment (as per OIE *Terrestrial Animal Health Code* guidelines).
Responsibility of all premises operators to notify MPI of intention to cease operation	Operators to notify the Director-General in writing of an intent to cease operations. This proposed requirement would apply to all operators of export approved premises, not just operators of premises processing germplasm and live poultry.
Definition changes in the Notice	• A definition for the term "**compartment**" is inserted. This is to facilitate the interpretation of new provisions relating to compartments that are being proposed under clause 2.8.5 of the Notice. Supplementary to this, a definition of the term "subpopulation" is inserted. That term is used in the definition of "compartment" and defining it with provide clarity. • The following terms, which are currently defined in the current Notice (i.e. the 2011 version) are deleted from the definition section as it is unnecessary to defined those terms: - "animal product and animal material"; - "export approved premises"; - "germplasm premises"; - "list"; - "MAF"; - "official assurance specification"; - "operator"; - "overseas market access requirements" - "premises"; - "significant change"

4. Proposed changes

4.1 EXPORT APPROVED PREMISES FOR LIVE POULTRY AND GERMPLASM TO HAVE DOCUMENTED OPERATING PROCEDURES

Proposal

MPI proposes that the requirement for export approved premises which process germplasm and live poultry to have documented operating procedures underpinning the premises' operation is explicitly specified in the Notice.

The operating procedures will be required to set out the premises' activities and steps for ensuring the premises' operation complies with export requirements, including OIE (World Organisation for Animal Health) requirements, applicable country-specific OMARs and official assurance requirements.

The procedures and any subsequent amendments will require the approval of the premises' veterinarian and official assurance verifier. It is also proposed that operating procedures are re-assessed every two years by the premises' official assurance verifier.

Rationale

Requiring germplasm and live poultry export approved premises to have documented procedures will provide clarity and certainty in relation to specific steps that operators will have to follow to ensure that their operation complies with export requirements, including OIE requirements, OMARs, and official assurance requirements. This is consistent with the requirement and expectation of importing countries. The proposal also provides clarity in relation to the legal basis on which verification, compliance monitoring and enforcement will be carried out.

The proposed approval of the operating procedures by the veterinarian and the official assurance verifier is necessary for ensuring compliance with the OMARs of countries that the export approved premises can export to. Those countries expect the veterinarian and official assurance verifier to play a role in the approval of the premises' operating procedures. A list of countries to which the export approved premises can export is required so the veterinarian and official assurance verifier can assess the procedures against the relevant OMARs for those countries.

The proposed requirement for operating procedures to be re-assessed by the verifier every two years is intended to ensure continuous compliance with OMARs. OMARs are susceptible to change so the proposed re-assessment will provide the verifier the opportunity to check if the procedures continue to comply with the requirements of the Notice or OMARs. The re-assessment will also allow the verifier to assess if the procedures continue to accurately reflect the operation being carried out at the premises.

Question 1: Do you agree with this proposal to specify the requirements for premises' operating procedures in the Notice for clarification and verification purposes?

4.2 EXPORT APPROVED PREMISES FOR LIVE POULTRY AND GERMPLASM TO BE ASSOCIATED WITH A VETERINARIAN

Proposal

MPI proposes that export approved premises processing live poultry and germplasm are associated with a veterinarian who would carry out specific functions as outlined in the Notice.

The veterinarian will be required to be approved by MPI on the recommendation of the premises' official assurance verifier. The official assurance verifier will have to ensure that a veterinarian they recommend meets specified criteria, which includes all of the following:

- The veterinarian is registered as a practising veterinarian with the Veterinarian Council of New Zealand;
- The veterinarian has adequate knowledge of the day to day operations of the premises;
- The veterinarian has sound knowledge of applicable export requirements and industry standards;
- The veterinarian will be present at the premises at reasonable notice (full time presence is not required);
- The veterinarian will be present during verification.

The veterinarian, along with the premises' official assurance verifier, will be responsible for the approval of the premises' operating procedures.

Rationale

Several Overseas Market Access Requirements (OMARs) for germplasm and live poultry require a government approved veterinarian who is to be responsible for supervising germplasm and live poultry premises. The OMARs explicitly require the approval of veterinarians by the Director-General (MPI); however, neither the OMARs nor the current Notice specify any requirements to provide clarity about the approval criteria or process, or the responsibilities of veterinarians. This proposal will address this regulatory gap.

It is essential that the veterinarian has adequate knowledge of the day-to-day operations of the premises. This will ensure that any confirmation that the veterinarian makes to support the issuing of official assurances is within the veterinarian's knowledge and therefore validates any such confirmation. The presence of the veterinarian during verifications is intended as a mechanism for the veterinarian to demonstrate adequate oversight of the premises' operations to the official assurance verifier, which is an expectation in OMARs.

Question 2: Do you agree with the proposal to provide clarification in the Notice about the criteria and process for approval of premises' veterinarians and their responsibilities?

4.3 EXPORT APPROVED PREMISES FOR LIVE POULTRY AND GERMPLASM TO BE APPROVED AS COMPARTMENTS WHERE A RECOGNISED DISEASE STATUS IS REQUIRED

Proposal

Importing countries may impose sanitary requirements in relation to germplasm and live poultry, which can only be satisfied if an export approved premises processing such animal products has a recognised disease status. MPI proposes that the Notice includes a provision that will allow MPI to approve export approved premises processing germplasm and live poultry as a compartment.

The term "compartment" is defined in the Notice as follows:

> **compartment** means an animal subpopulation contained in one or more establishments under a common risk management system with a distinct health status with respect to a specific disease or specific diseases for which required surveillance, control and measures have been applied for the purpose of international trade.

The approval process for a germplasm and live poultry premises as a compartment will be as specified in the OIE *Terrestrial Animal Health Code* guidelines. The Standard Operating Procedures for the premises will have to contain matters relating to its status as a compartment. The Standard Operating Procedures, and any subsequent amendments, which relate to its compartment status will have to be approved by MPI prior to implementation. This MPI approval is additional to approval by the premises' veterinarian and the official assurance verifier.

Rationale

Including provisions for approval of germplasm and live poultry premises as a compartment in the Notice will ensure that we have the appropriate legal mechanism enabling us to respond effectively to any future requirements by importing countries in relation to animal disease status recognition. The proposed approval of the operating procedures by MPI, in addition to approval by the veterinarian and the official assurance verifier is necessary to confirm compartment recognition by MPI as the responsible competent veterinary authority of New Zealand.

Question 3: Do you agree with this proposal to add future proofing provisions in the notice regarding the approval of germplasm and live poultry EAPs as compartments?

4.4 OTHER GENERIC CHANGES

4.4.1 Operators to notify the Director-General in writing of an intent to cease operations

MPI proposes that operators of export approved premises notify MPI (the Director-General) of intent to cease operation.

Currently there is no obligation for an operator of an export approved premises to notify MPI if their operation has ceased or if they intend to cease operation. The result is that MPI's register of export approved premises may be out of date as operators have not notified MPI, and operators may continue to receive notifications and updates.

Notification, as proposed, would ensure that MPI's register of export approved premises is up to date. Overseas countries, official assurance verifiers and authorised persons rely on the register being kept current so this is important to ensure overseas countries confidence in MPI's systems as well as to safeguard the integrity of official assurances issued by New Zealand.

4.4.2 Clarification on verification

MPI has added guidance in the Notice to clarify that verification of the Notice is subject to the Animal Products Notice: Export Verification Requirements. Frequency of verification of export approved premises are as set out in that Notice.

4.4.3 Changes to the Format and structure of the notice

The format and structure of the proposed Notice differs from that of the Animal Products (Export Approved Premises) Notice 2011. The structural changes are set out in the table below, which compares the location of certain provisions in the Animal Products (Export Approved Premises) Notice 2011 against where the provisions are now located in the proposed notice.

Subject	Location in 2011 Notice	Location in proposed Notice
Operator Systems Requirements	Clause 4	Clause 3.1
Obligations of operators	Clause 5	Clause 3.2
Initial verification	Clause 6	Clause 2.7.1
Ongoing verification	Clause 7	Guidance box under cl 2.7.1
Application for approval	Clause 8	Clause 2.2
Refusal to approval a premises	Clause 13	Clause 2.3(2)
Director-General to maintain a list of Export Approved Premises	Clause 14	Clause 2.5
Matters to be shown on the list	Clause 15	Clause 2.5(2)
Withdrawal of approval	Clause 16	Clause 2.6
Country listing	Clause 18	Guidance box under cl 2.5(2)
Exemption of animal fibre suppliers	Clause 9	Clause 1.1(2)(b)
Exemption of hides and skins suppliers	Clause 10	Clause 1.1(2)(b)
Exemption of game trophy operators	Clause 11	Clause 1.1(2)(c) and guidance box under that clause
Other exemption	Clause 12	Deleted – not required

5. Submissions

You may compile your submissions by answering the questions in this discussion document or commenting on any provisions in the proposed notice relating to germplasm and live poultry.

MPI recommends that the body of your submission is set out in a format that is identical or similar to the table in Annex 1 below.

Annex 1: Recommended table of submissions

If you prefer to make your submission by responding to the questions in this discussion paper, you may write down your answer and any additional comments to each question in the format below.

Question number in the discussion paper	Comments
1	
2	
3	

If you prefer to make your submission by commenting on specific clauses in the draft amended Notice, you may write down your comments in the format below.

Clause(s) in the Notice	Comments