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Department of Agriculture

Instruction & Guideline

The Animal Biosecurity Branch

Guidelines on the management of the biosecurity risks of foot-and-mouth disease virus in imported commodities

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Summary of main points

- This document provides guidance to officers of the Animal Biosecurity Branch on the approach to recognising the foot-and-mouth disease (FMD) status of trading partners, the application of the Department of Agriculture FMD-Free Approved Country List and the response to FMD outbreaks in trading partners.
- FMD is considered the single greatest threat of any disease to Australia's livestock industries.
- Imports of FMD risk materials are only permitted from countries evaluated as free from FMD (that is, countries recognised in the Department of Agriculture FMD-Free Approved Country List), unless alternative conditions have been assessed by the department and found to manage the FMD risks.
- The Animal Biosecurity Branch has established procedures to assess the FMD status of countries and zones for trade purposes.
- Recognition of a country or zone's FMD status by the World Organisation for Animal Health (OIE) is taken into account. However, due to the extreme consequences associated with an FMD outbreak and some limitations associated with the OIE evaluation process, the Animal Biosecurity Branch conducts its own evaluation.
- The development and provision of advice to operational areas on biosecurity import policies is a core responsibility of the Animal Biosecurity Branch. Part of this involves the evaluation and recognition of the FMD status of countries and zones for trade purposes, and the maintenance of the Department of Agriculture FMD-Free Approved Country List. The Animal Biosecurity Branch also monitors and provides advice on FMD outbreaks in approved countries.
- The Animal Biosecurity Branch contributes to the development and revision of domestic and international standards on FMD.

The guidance contained in this paper represents a collation of Animal Biosecurity Branch documents applicable to trade in FMD risk materials, outbreak response activities and Competent Authority evaluations—including policy and guideline documents, minutes and other advice. Amongst other things, this document aims to further promote consistency in the approach taken by the Animal Biosecurity Branch. For information about specific import conditions, officers are directed to the relevant commodity import policies and/or policy advices.

Contents

1 Acronyms and abbreviations

ALOP	appropriate level of protection
CA	Competent Authority
Code	OIE *Terrestrial animal health code*
department	Australian Government Department of Agriculture (formerly Department of Agriculture, Fisheries and Forestry, DAFF)
FMD	foot-and-mouth disease
FMDV	foot-and-mouth disease virus
OIE	World Organisation for Animal Health
PVS Tool	*Tool for the evaluation of performance of Veterinary Services*
SPS Agreement	World Trade Organization Agreement on the Application of Sanitary and Phytosanitary Measures
WAHID	World Animal Health Information Database
WAHIS	World Animal Health Information System
WTO	World Trade Organization

2 Definitions

Relevant definitions:

Term	Definition
appropriate level of protection	the level of protection deemed appropriate by a country to protect human, animal or plant life or health within its territory (WTO 2013)
biosecurity	the prevention of the entry, establishment or spread of unwanted pests and infectious disease agents to protect human, animal or plant health or life, the environment and the economy (Beale et al. 2008; DAFF 2011a)
case	individual animal infected by a pathogenic agent, with or without clinical signs (OIE 2013e)
commodity	live animals, products of animal origin, animal genetic material, biological products and pathological material (OIE 2013e)
Competent Authority	Veterinary Authority or other Governmental Authority of a country having the responsibility and competence for ensuring or supervising the implementation of animal health and welfare measures, international veterinary certification and other standards and recommendations in the whole territory (OIE 2013e)
country	for the purpose of this document, 'country' also includes defined zones. It is noted that the Department of Agriculture has not yet assessed the FMD status of any zones, and therefore does not currently recognise any zones as free from FMD for trade purposes. However, the department's evaluation of a country's or zone's freedom from FMD follows the same process. The evaluation considers the specific FMD and trade risks for the applicant country/zone, and therefore any heightened risks that may

Term	Definition
	be associated with specific zones would be assessed accordingly.
Department of Agriculture FMD-Free Approved Country List	list of countries evaluated and approved by the Australian Government Department of Agriculture as free from FMD for the export of certain commodities. Formerly the 'DAFF FMD Approved Country List'
emerging disease	a new infection or infestation resulting from the evolution or change of an existing pathogenic agent, a known infection or infestation spreading to a new geographic area or population, or a previously unrecognised pathogenic agent or disease diagnosed for the first time and which has a significant impact on animal or public health (OIE 2013e)
foot-and-mouth disease (FMD) risk material	commodity that poses a risk of FMD, e.g. susceptible to infection and/or presence/contamination with foot-and-mouth disease virus, as assessed by the Department of Agriculture[1]
incubation period	longest period which elapses between the introduction of the pathogen into the animal and the occurrence of the first clinical signs of the disease (OIE 2013e)
index case	first case to come to the attention of investigators (Thrusfield 1995)
market access request	request from an exporting Competent Authority, agency or individual to export a good to Australia (DAFF 2011a)
outbreak	occurrence of one or more cases in an epidemiological unit [that is, a group of animals with a defined epidemiological relationship] (OIE 2013e)
primary case	initial case (Thrusfield 1995)
risk analysis	an assessment of the level of biosecurity risk associated with the importation, or proposed importation of animals, plants or goods and, if necessary, identification of risk management options to limit the level of quarantine risk to achieve Australia's appropriate level of protection (Beale et al. 2008; DAFF 2011a)—a process composed of hazard identification, risk assessment, risk management and risk communication (OIE 2013e)
risk assessment	evaluation of the likelihood and the biological consequences of entry, establishment and spread of a hazard within the territory of an importing country (OIE 2013e)
risk management	process of identifying, selecting and implementing measures that can be applied to reduce the level of risk (OIE 2013e)
verification	confirmation through the provision of objective evidence that specified requirements have been fulfilled. Includes inspection and audit activities (Beale et al. 2008)
Veterinary Authority	Governmental Authority of a country, comprising veterinarians, other professionals and para-professionals, having the responsibility and competence for ensuring or supervising the implementation of animal

[1] FMD risk materials are not permitted to be exported to Australia unless the risk has been managed to meet Australia's appropriate level of protection

Term	Definition
	health and welfare measures, international veterinary certification and other standards and recommendations in the OIE *Terrestrial Animal Health Code* in the whole territory (OIE 2013e)
Veterinary Services	governmental and non-governmental organisations that implement animal health and welfare measures and other standards and recommendations in the territory. The Veterinary Services are under the overall control and direction of the Veterinary Authority. Private sector organisations, veterinarians, veterinary paraprofessionals or aquatic animal health professionals are normally accredited or approved by the Veterinary Authority to deliver the delegated functions (OIE 2013e)
zone/region	clearly defined part of a territory containing an animal subpopulation with a distinct health status with respect to a specific disease for which required surveillance, control and biosecurity measures have been applied for the purpose of international trade (OIE 2013e)

3 Introduction

3.1 Purpose

The purpose of this document is to provide officers of the Animal Biosecurity Branch with guidance on the management of the biosecurity risks associated with trade in foot-and-mouth disease (FMD) risk materials. This includes the approach to recognising the FMD status of trading partners, the application of the Department of Agriculture FMD-Free Approved Country List and the response to FMD outbreaks in trading countries.

Amongst other things, this document aims to further promote consistency in the approach taken by the Animal Biosecurity Branch.

The information contained in these guidelines is derived from a number of sources relevant to the current Animal Biosecurity Branch approach to trade in FMD risk materials. This includes import policies, reviews and other policy advices (for example, minutes). It is complementary to other Animal Biosecurity Branch documents and guideline resources (see Section 9).

This document is not intended to replace advice from the Animal Biosecurity Branch to other departmental areas. These queries should continue to be directed to the Animal Biosecurity Branch in the first instance.

3.2 Scope

This document provides background and general guidance for officers in the Animal Biosecurity Branch on the biosecurity management of trade in FMD risk materials—particularly commodities required to be sourced from approved countries recognised by the Australian Government Department of Agriculture (the department) as free from FMD.

As with other activities of the Animal Biosecurity Branch to manage biosecurity risks, the overarching principles of science-based risk analyses apply.

This document does not provide information on the processes used to determine FMD risk management measures in specific import policies, or to outline the import requirements for specific commodities. **Officers are directed to the relevant import policies and/or policy advices for this information.**

This document likewise does not focus on disease intelligence scanning or reporting activities, or the process of reporting to, or commenting on documents of, the World Organisation for Animal Health (OIE).

These guidelines are not applicable to the management of an exotic disease outbreak, such as FMD, in Australia. Australia's disease strategy for the management of an outbreak of FMD is outlined in:

> Animal Health Australia (2014). Disease strategy: Foot-and-mouth disease (Version 3.4). Australian Veterinary Emergency Plan (AUSVETPLAN), Edition 3, Agriculture Ministers' Forum, Canberra, ACT.

AUSVETPLAN is available on the internet at www.animalhealthaustralia.com.au/

Background

3.3 FMD and its significance in Australian biosecurity policies and operations

FMD is an OIE-listed disease of multiple species and is nationally notifiable in Australia (DAFF 2013; OIE 2014d).

FMD is one of the most serious exotic livestock diseases and is considered to be the single greatest biosecurity threat of any disease to Australia's livestock industries (Matthews 2011). Australia has been free from FMD since 1872 (Bunn et al. 1986; Jamal and Belsham 2013; Productivity Commission 2002).

A review of Australia's preparedness for the threat of FMD (Matthews 2011), found that in the event of an FMD outbreak in Australia, severe direct and indirect economic losses to the livestock industry would be expected. This includes losses to the country's competitive advantage and large export market. A 2013 report by the Australian Bureau of Agricultural and Resource Economics and Sciences estimated that the direct impact of a large multi-state FMD outbreak in Australia would extend to economic losses of between $49.3 billion and $51.8 billion over 10 years, not including the costs of disease control (Buetre et al. 2013). Accordingly, the department has a rigorous assessment process for establishing risk management measures and determining a country's[2] FMD status for the purpose of trade.

- FMD is associated with severe trade and economic consequences and is considered the greatest biosecurity threat of any disease to Australia's livestock industries. As a result, the department has a rigorous process for establishing risk management measures for trade and determining the FMD status of trading partners.

3.4 Australia's international trade obligations

As a Member of the World Trade Organization (WTO), Australia adheres to the WTO Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement). Under the SPS Agreement, members may introduce or maintain a higher level of sanitary or phytosanitary protection than would be achieved by the relevant international standards, guidelines or recommendations, if there is a scientific justification or is identified in an assessment of risk and is in accordance with the determined appropriate level of sanitary or phytosanitary protection (WTO 2013). This principle is also acknowledged in the *Terrestrial Animal Health Code* (the Code) of the World Organisation for Animal Health (OIE) (OIE 2013g).

The SPS Agreement defines the concept of an appropriate level of sanitary or phytosanitary protection as 'the level of protection deemed appropriate by a WTO member to protect human, animal or plant life or health within its territory'. In assessing risk and establishing risk management measures, members may take into account relevant economic factors—that is, potential damage from loss of production/sales from the entry, establishment or spread of a pest or disease; costs of control or eradication; and relative cost-effectiveness of alternative approaches to limiting risks. When applying risk management measures, a WTO Member should ensure that these are not more restrictive than required to achieve its appropriate level of protection (ALOP) (WTO 2013).

Australia has a risk-based approach to biosecurity management and its ALOP is stated as 'providing a high level of sanitary and phytosanitary protection, aimed at reducing risk to a very low level, but not zero' (DAFF

[2] For the purpose of this document, 'country' also includes defined zones. It is noted that the Department of Agriculture has not yet assessed any zones and therefore does not currently recognise any zones as free from FMD for trade purposes. However, the department's evaluation of a country's or zone's freedom from FMD follows the same process. The evaluation considers the specific FMD and trade risks for the applicant country/zone, and therefore any heightened risks that may be associated with specific zones would be assessed accordingly.

2011a). If the level of risk associated with the importation of a specific commodity is deemed to exceed Australia's ALOP, biosecurity measures are recommended to reduce the risk to an acceptable level. If it is not possible to reduce the level of risk to an acceptable level, trade is not permitted.

- The Animal Biosecurity Branch's biosecurity policies are based on the principles of science-based risk analyses.
- Risk management measures are based on international standards where they exist and achieve Australia's ALOP. Otherwise, Australia exercises its rights under the SPS Agreement to apply science-based risk management measures that are not more trade restrictive than required to achieve Australia's ALOP.

3.5 The OIE and FMD

The OIE is the WTO designated international reference organisation for standards relating to animal health (OIE 2014c; Poissonnier and Teissier 2013).

The OIE publishes science-based standards on FMD risk and risk management in the OIE Code that can be applied for international trade (OIE 2013b; OIE 2014e), as well as standards for diagnostic tools and vaccines for FMD in its *Manual of diagnostic tests and vaccines for terrestrial animals* (OIE 2012b). The OIE has documented the procedures for setting these standards and recommendations (OIE 2014e). As a Member Country, Australia contributes to development of these.

The OIE acknowledges that a higher level of protection than that provided by these standards may be adopted if there is scientific justification or if the level of protection provided by the relevant international texts is considered to be inappropriate (subject to a country being compliant with its risk assessment obligations and having a consistent approach to risk management), in accordance with the SPS Agreement (OIE 2013g; WTO 2013).

The OIE also publishes a list of its Member Countries that it recognises as free from FMD, based on the adoption of a resolution by the World Assembly of Delegates of the OIE. This includes countries and zones that are recognised as free where vaccination is not practised and free where vaccination is practised. In addition to this, the OIE also has a list of countries with an OIE endorsed official control program for FMD (OIE 2013c; OIE 2013f).

A Member Country wishing to be officially recognised by the OIE as free from FMD is instructed to submit a response to the relevant questionnaire as contained in the Code (*Procedures for self declaration and for official recognition by the OIE*) (OIE 2013i) and comply with the requirements specified in the Code. The OIE Scientific Commission for Animal Diseases, on behalf of the World Assembly of Delegates, is said to assess the compliance of submissions with the relevant OIE standards. This assessment is usually based on the recommendations formulated by a relevant ad hoc Group (OIE 2013c).

The OIE publishes *Standard Operating Procedures for the official recognition of disease status of Member Countries* (OIE 2013k). This includes the stipulation that dossiers submitted do not exceed 50 pages (excluding any appendices).

The OIE recognises the need for transparency in its processes and decision-making. However, due to the sensitivities and trade implications of its evaluations, the OIE does not release details of Member Countries that have submitted a dossier until the Scientific Commission provides a recommendation on the recognition of a Member Country's disease-free status. This means that not all information about Member Countries that have applied for recognition of freedom is made public. The details of Member Countries that have applied and not met the requirements—that is Member Countries for which recognition of disease-free status is not recommended—are not publically released by the OIE (OIE 2012a). The OIE also does not publish any of their reports on the disease status of Member Countries, nor provide an applicant Member Country's submission to other Member Countries (also see Section 5.2).

Member Countries are required to notify the OIE of FMD outbreaks (see Section 8), at which time their status is revoked. Recognition of freedom by the OIE may also be suspended for reasons other than the self-notification of disease outbreaks—for example, Member Countries failing to submit annual status reports or failing to comply with the requirements in the relevant chapters of the Code (OIE 2013k).

In addition to providing standards that can be applied to international trade and lists of countries it recognises as being free from FMD, the OIE provides other support and tools for Member Countries. This includes the OIE *Tool for the evaluation of performance of Veterinary Services* ('OIE PVS Tool')—an evaluation tool to assist Veterinary Services establish their current level of performance, identify weaknesses and establish priorities for improvement (OIE 2013h).

- The OIE is the international reference organisation for animal health matters. It publishes standards that can be applied for international trade and also a list of Member Countries it recognises as free from FMD.
- However, the current OIE processes for recognising Member Countries' FMD-status means that Member Countries' submissions and the OIE's reports and are not released to other Member Countries.

3.6 The role of Animal Biosecurity Branch in managing FMD biosecurity risks

A key role of the Animal Biosecurity Branch is to develop and review biosecurity policies for the importation, or proposed importation, of commodities that relate to animal matters through a science- and evidence-based risk evaluation process. These evaluations may recommend the need for risk management measures to meet Australia's ALOP. For FMD, such risk management measures include:

- trade being restricted to countries recognised by the department as free from FMD (that is, approved countries that have been evaluated by the department as free from FMD), or
- trade being restricted to materials that have been subject to specified treatments that will reduce the risk to meet Australia's ALOP (for example, heat treatment or gamma irradiation).

Due to the extreme consequences of an FMD outbreak in Australia, more than one FMD risk management measure for trade in a commodity (that is, a combination of risk management measures) is generally required to meet Australia's ALOP.

Trade is generally not permitted if a biosecurity policy had not been completed for the commodity in question, or a risk analysis had concluded that the risk cannot be managed to meet Australia's ALOP.

As part of its responsibilities, the Animal Biosecurity Branch performs a range of risk management activities related to FMD. These include:

- evaluating the disease status of countries, and the operations of the relevant Competent Authority, for recognition of freedom from FMD and their eligibility to export certain FMD risk materials to Australia
- maintaining a list of countries recognised by the department as free from FMD for trade purposes (the Department of Agriculture FMD-Free Approved Country List) and providing this list to operational and permit-issuing areas of the department
- providing advice to operational and permit-issuing areas on FMD outbreaks in countries (previously) recognised as free from FMD for trade purposes, to manage the risks posed by materials exported to Australia
- contributing to international and domestic standards and policies.

It should be noted that trade in a specific commodity may also be contingent on the department verifying that other requirements have been met. This includes other treatments, testing and/or sourcing from places that are free from other disease(s). This means that for some commodities, in addition to being sourced from an FMD-free approved country or being subject to approved treatments, the source country and/or export production facilities must also be approved for other purposes.

Approval of an exporting Competent Authority usually extends to examination of its ability to ensure that individual consignments fulfil the relevant import conditions. For information about Competent Authority evaluations, see Section 9.

In addition to developing and reviewing biosecurity import policies, the Animal Biosecurity Branch also provides advice about these policies to operational and permit-issuing areas and negotiates health certificates with overseas Competent Authority.

- The Animal Biosecurity Branch has a number of responsibilities relating to managing the biosecurity risks of imported FMD risk materials. It develops, reviews and provides advice on biosecurity import policies; evaluates the FMD status of countries and the relevant Competent Authorities for trade purposes; maintains the Department of Agriculture FMD-Free Approved Country List; monitors and advises on FMD outbreaks in trading partners; and contributes to domestic and international standards on FMD.
- Due to the extreme consequences of an FMD outbreak in Australia, a combination of risk management measures for FMD are generally required to meet Australia's ALOP.
- Import policies may recommend that trade in FMD risk materials be restricted to approved countries that have been recognised by the department as free from FMD and/or restricted to materials that have been subject to specified treatments. If the risk cannot be managed to meet Australia's ALOP or a policy does not exist for the commodity in question, trade is not permitted.

3.7 Department policies which contain biosecurity measures for FMD

Animal Biosecurity Branch import policies which require commodities to be sourced from a country recognised by the department as free from FMD for trade purposes include:

- FMD-susceptible animals (including zoo animals)
- pig meat for petfood or human consumption
- ruminant-derived meat for petfood (other than canned or rawhide chews) or human consumption (other than canned or meat flavours)
- natural sausage casings
- genetic material (semen and embryos) derived from FMD-susceptible species
- stockfeed of plant origin (depending on processing and treatment requirements)
- hides and skins (depending on processing and treatment requirements)
- dairy products including colostrum, yogurt, fresh milk, powdered milk and cheeses (excepting some ripened cheeses)
- certain commodities (including some dairy products, meat jerky and biltong) listed in the Quarantine Proclamation which do not require an import permit
- biological products produced from FMD-susceptible species (for example, veterinary and human pharmaceuticals, laboratory reagents)
- veterinary vaccines.

It is noted that there are other policies which require commodities to be undergo treatment to address FMD risks that do not require the commodity to be sourced from a country/zone recognised as free from FMD without vaccination. Although this is not an exhaustive list, this includes conditions for:

- retorted meat
- retorted dairy products
- meat-based flavours
- stockfeed of plant origin (highly heat processed)
- retorted pet food
- rawhide chews
- some ripened cheeses
- fully tanned hides and skins
- scoured wool.

It should be noted that there are other commodities that pose FMD risks, for example by acting as fomites. This includes farm equipment, saddles and tack, fertiliser, soil, peat and mail. Passengers and their belongings may also act as fomites. FMD risk management measures apply for these commodities/pathways as well. Although the Animal Biosecurity Branch does not have primary carriage for some of the policies for these commodities, it is responsible for providing guidance and recommendations on the applicable FMD risk management measures.

- There are a number of biosecurity import policies that contain risk management measures for FMD. This includes policies that require commodities to be sourced from a country that is recognised by the department as FMD-free.

4 Rationale for evaluating trading partners' FMD status

4.1 Source country freedom from FMD as a risk management measure

To manage the biosecurity risks associated with international trade and meet Australia's ALOP, risk analyses conducted by the Animal Biosecurity Branch may recommend that the sourcing of a commodity be limited to countries that are, among other things, recognised (through assessment) as free from FMD—see Section 4.

Alternative risk management measures (for example, heat treatment or diagnostic testing) cannot be substituted for the requirement for a commodity to be sourced from a country that is recognised by the department as free from FMD, unless an assessment of those risk management measures has concluded otherwise.

Because FMD is one of the most serious livestock diseases and is considered to be the single greatest biosecurity threat of any disease to Australia's livestock industry, the Animal Biosecurity Branch has a rigorous assessment process to determine a country's FMD status for trade purposes (see Section 6). The Animal Biosecurity Branch process takes into account the OIE's recognition of a country's FMD status. However, due to the extreme consequences that could result from an FMD outbreak in Australia, the Animal Biosecurity Branch does not rely solely on the OIE recognition status and conducts a separate evaluation (see Section 5.2).

This is a similar approach to that of other countries—for example, the United States (APHIS 2013). While the approach is similar, the department's list of countries recognised as free from FMD for trade purposes differs from that maintained by other nations. This is a function of various factors, including differing ALOPs (and therefore different risk evaluations) and the range of trading partners (and therefore different requests for evaluation).

- The Animal Biosecurity Branch has a rigorous assessment process to determine a country's FMD status for trade purposes. Recognition of a country's FMD status by the OIE is taken into account, but due to the extreme consequences associated with an FMD outbreak and the limitations associated with the OIE evaluation process, the Animal Biosecurity Branch conducts its own evaluation.
- Alternative risk management measures cannot be substituted for the requirement for a commodity to be sourced from a country recognised to be free from FMD, unless a risk assessment has concluded otherwise.

4.2 Considerations for recognition of freedom from FMD

Any country seeking recognition of its freedom from FMD for trade purposes is required to undergo an evaluation by the department (that is, by the Animal Biosecurity Branch). It is evaluated and recognised under the relevant Competent Authority.

The evaluation process is conducted in accordance with the findings of a review of Australia's preparedness for the threat of FMD (Matthews 2011). This review identified a need for Australia to be more proactive in monitoring conditions in exporting countries and ensure the standard of assurances that exporting country Competent Authorities are operating to Australian biosecurity requirements:

> *Much of the quarantine risk product imported into Australia is cleared through quarantine on the basis of accompanying documentation—such as exporting-country official health certificates, various forms of 'statutory declarations' by manufacturers or exporters, and manufacturer letterhead declarations. Yet even with well-established trade, there can be significant risks in these processes. Inadequate or out of date knowledge relating to overseas competent authorities, and the systems in place to validate exporter assurances, can undermine the veracity of import documentation and increase the risk of an FMD incursion.*
>
> *Even routine trade can present FMD risk if inadequate or out of date assurance is provided by the authorities in exporting countries. Excessive reliance on the FMD recognition system of the World*

> *Organisation for Animal Health (OIE) for determining a country or zone's FMD status should be avoided, as the system does not include any in-country verification of the FMD status claims submitted to the OIE, or allow third party access to country submissions and their evaluation.*
>
> *A detailed evaluation by Australia of a country's FMD animal health controls and certification systems will often be warranted before acceptance of any claim concerning FMD status, and robust evaluation will often require an in-country verification visit* (Matthews 2011).

The Animal Biosecurity Branch is committed to proactively contributing to international standards. This includes commenting on the Code and other OIE documents, both as an individual Member Country and through the Animal Health Quadrilateral Group with Canada, New Zealand and the United States. It is noted that reports in 2014 indicate that the OIE has performed in-country verification visits (OIE 2014a). However, without access to the country submission and the content of the OIE's evaluation (see Section 4.3), ascertaining the congruence of the OIE's assessment with Australia's ALOP remains problematic. It is also unclear what standards or guidelines are used for the in-country verification visits performed by the OIE or the competency required of the assessors (for example, auditing skills or guidelines). The department has provided feedback to the OIE on these matters.

The evaluation of a country's FMD status, as conducted by the department (that is, the Animal Biosecurity Branch), includes the assessment and verification of the country's relevant animal health, production, inspection and certification systems. It also considers the ability of the Competent Authority to prevent future FMD outbreaks (DAFF 2011b).

It has been reported that

> *The ability to comply with the requirements of the Terrestrial Code, and eventually achieve the desired official disease status recognition by the OIE, did not initially seem a major obstacle to most OIE Member Countries. However, it soon became apparent that maintaining that disease free status was a different matter. In some cases, Member Countries found themselves continually under challenge from the risk of disease re-introduction while, for others, the additional burden of high maintenance costs for retaining their disease-free status was not sustainable. Some Member Countries soon realised that the cost of gaining their initial disease-free status, compared with the cost of maintaining it, differed considerably. To implement a sustainable maintenance system to protect their status, countries had to make significant additional investments, such as maintaining a continuous surveillance system; preventing the introduction of the pathogen through revised import and border controls; revising their import requirements, appointing additional personnel and controlling the movements of animals and animal products* (OIE 2013d).

As a trading partner, it is critical that countries recognised as free from FMD maintain their status. This is particularly important given that in the event of an outbreak, the disease agent may be circulating for a period of time before it is recognised or reported (Matthews 2011), meaning that there is a risk that affected commodities may be imported in the interim (see Section 8).

- Countries requesting recognition of freedom from FMD for trade purposes are required to be evaluated by the department. This ensures that the trade enabled by that recognition meets Australia's ALOP.
- Without access to Member Country's submissions to the OIE and the content of the OIE's evaluation, ascertaining the congruence of the OIE's recognition of FMD-freedom with Australia's ALOP is problematic. The Animal Biosecurity Branch is committed to providing feedback to the OIE, with the aim of assisting to improve the OIE's practices.
- The department's evaluation includes the assessment and verification of the country's relevant animal health, production, inspection and certification systems. It also considers the ability of the Competent Authority to prevent future FMD outbreaks.

4.3 Recognition of freedom from FMD in relation to vaccination status

The Animal Biosecurity Branch does not currently recognise country freedom from FMD where vaccination is practised[3] as a sufficient risk management measure for trade purposes.

The success of vaccination campaigns rely on a number of factors, including those identified by Bruckner and Saraiva-Vieira (2010):

- vaccine quality: vaccines should meet international standards, including those for purity, safety, potency and efficacy. They should be licensed by the official Veterinary Services, independently tested for safety and potency. The ability of vaccination to prevent clinical disease is said to be strongly related to the potency of the vaccines administered, amongst other things.

  In addition to a suitable formulation (including the vaccine adjuvant), the stability of the vaccine (and its shelf-life) needs to also be considered (Garland 1999)

- vaccine matching: the vaccine should contain the appropriate serotypes and subtypes of FMD virus (FMDV)—that is, the vaccine should be of a suitable antigenic composition.

  As Parida (2009) outlined, the efficacy of vaccination is complicated by the antigenic diversity of FMDV—with its seven serotypes (each with many variants)—and the lack of cross-protection between serotypes. Additionally, there can be incomplete protection afforded between subtypes of the same serotype, and there is also the risk of new variants emerging periodically

- vaccine delivery: achieving an adequate level of population-immunity relies on effective delivery of the vaccine, including maintenance of the cold chain and proper injection. Government or private schemes may assist in supporting local distribution

- vaccine coverage and administration: there should be proper preparation for vaccine campaigns, including suitable communication to stakeholders, and the administration of vaccines should be properly supervised and documented. This provides some evidence of vaccination coverage of the target population(s).

  Coordinated, centralised planning and organisation is recognised as an important factor on which the success of mass vaccination campaigns relies (Garland 1999). It is also dependent on sufficient resourcing.

  It has also been highlighted that the post-vaccination duration of immunity may not correspond with frequency of vaccination campaigns, leading to the risk of 'immunity gaps' (Domenech et al. 2010). This means that, amongst other things the frequency of vaccination needs to be carefully considered when planning these campaigns

- vaccine banks: vaccine banks in regions where vaccination is practised should ensure that sufficient stocks of vaccines are available. Different viral antigens for vaccine production can also be ready for thawing and formulation as part of a rapid response to new strains of FMDV. These vaccine banks should be supported by laboratories that can undertake vaccine matching tests.

  Vaccine production should also satisfy internationally accepted standards of quality assurance / quality control (OIE/FAO 2012). The OIE provides standards for laboratory testing and vaccine production, which should be met (OIE 2012c).

- population-immunity: vaccination programs should aim to achieve a level of population-immunity sufficient to avoid the spread and persistence of FMDV. If certain species or populations are excluded from the vaccination program, the epidemiological rationale should be documented. The vaccination

[3]The Code contains requirements that countries must fulfil to be recognised by it as free from FMD 'where vaccination is practised' (sometimes referred to by others as 'free with vaccination') and free 'where vaccination is not practised' (or 'free without vaccination') (OIE 2013b).

program should include periodic surveys to assess the level of population immunity and identify potential areas or production systems where the level of immunity is not adequate.

This can then be used to perform assessments about the risks of the introduction of FMDV into the vaccinated population, as well as to target 'risk-based surveillance' to substantiate freedom from FMD, amongst other things (Caporale et al. 2012).

It should be noted that there can be differences in individual vaccinated animal's resistance to infection, despite evidence of an antibody response to vaccination. It is also possible for vaccinated ruminants to become carriers following challenges with live virus (Parida 2009). A carrier in this instance is defined as an animal from which live virus can be recovered more than 28 days after infection. This can occur regardless of vaccination status, however experimental results suggest that cattle challenged a few days after vaccination may be more likely to become persistently infected. However, the role of carrier animals in transmitting the virus remains unresolved (Doel et al. 1994; Doel 2003; Geale et al. 2013; Kitching 2002).

It has been stated that the 'ideal vaccine' for FMD should be:

> *... safe and efficient, induce very fast and long-lasting clinical and virological protection, be easily administered and only require a minimum number of applications to achieve protection, allow the distinction between vaccination and infected animals, allow storage at room temperature and be inexpensive. Few of these criteria have been met by recently developed vaccines* (Domenech et al. 2010).

It has been recognised that vaccination does not prevent infection in all cases but helps prevent the occurrence of clinical signs and reduces viral shedding. The reduced clinical expression of FMD may complicate the detection and reporting of incursions (Bruckner and Saraiva-Vieira 2010).

Serological surveillance is recommended by the OIE to not only monitor the efficacy of vaccination, but, amongst other things, to help substantiate absence of infection (Bruckner and Saraiva-Vieira 2010; OIE 2012c). In contrast to places were vaccination is not practised, tests that allow for the 'differentiation of infected from vaccinated animals' (DIVA tests) are critical for substantiating the absence of infected animals and virus circulation as part of surveillance strategies in places where vaccination is practised. During the production of most commercially available inactivated vaccines, most of the viral non-structural proteins should be removed in a purification process. Protection afforded by these vaccines is derived from antibodies induced against FMDV structural proteins, meaning that the presence of antibodies against non-structural proteins can be an indicator of infection rather than vaccination[4]. Although advancements have been made in DIVA tests, the level of confidence with which they are used is said to be affected by the lack of data on the amount of subclinical infection under different field conditions. The need for improvements to current vaccines and DIVA tests to detect infections in vaccinated populations has been identified (Uttenthal et al. 2010).

It has been recommended that once countries have adequate evidence documenting the absence of virus circulation, countries should consider ceasing the use of vaccination—pending that country's confidence in the absence of areas or 'pockets' where the virus may be present and its confidence in managing the risk of virus re-introduction (Bruckner and Saraiva-Vieira 2010). Vaccination is only one part of a larger control program, and should not be considered in isolation (Bruckner and Saraiva-Vieira 2010; Garland 1999).

[4] It is noted that, depending on the purity of the vaccines used, antibodies to viral non-structural proteins may be detected in repeatedly vaccinated animals, despite those animals not having been exposed to live FMDV. It may then be difficult to distinguish these animals from infected vaccinated animals in places where repeated vaccination has been performed. Non-structural protein DIVA tests are considered to be a herd test, rather than being reliable for individual animals.

The Animal Biosecurity Branch considers that in the absence of additional risk management measures, the current risks associated with countries that claim freedom from FMD where vaccination is practised differ from those that are free from FMD where vaccination is not practised.

Therefore, for the purpose of this document, references to a country's freedom from FMD relate to freedom where vaccination is not practised.

- Country freedom from FMD 'where vaccination **is** practised' is not currently recognised by the Animal Biosecurity Branch as being a sufficient risk management measure for trade.
- The efficacy of vaccination is complicated by a number of factors, such as the antigenic diversity of FMDV and the lack of cross-protection between serotypes and subtypes, the differences in the individual vaccinated animal's resistance to infection and the limited duration of immunity. Vaccination may reduce clinical expression of disease and may not prevent infection occurring or animals becoming carriers.
- Coordinated and centralised planning has been recognised as an important factor in the success of vaccination campaigns. The success of vaccination in achieving the intended outcomes should be carefully monitored through active surveillance and well documented.
- Serological surveillance is a very important aspect of substantiating freedom from FMD. Confidence in DIVA testing is therefore also crucial in places where vaccination is practised. The need for continuing improvements to DIVA tests has been identified.
- Vaccination should be considered in the context of a larger control program. Once countries have adequate evidence to substantiate freedom from FMD with confidence, it has been recommended that they consider ceasing vaccination against FMD.
- In the absence of additional risk management measures, the current risks associated with countries that claim freedom from FMD 'where vaccination is practised' differ from those that are free from FMD 'where vaccination is not practised'.

5 The Animal Biosecurity Branch FMD evaluation process

5.1 Prioritisation of evaluations

An evaluation of a country's FMD status is a significant piece of work that requires appropriate resourcing and needs to be prioritised and planned along with other activities undertaken by the department. This prioritisation process takes into account the level of trade that may be facilitated by the evaluation, and genuine commercial interest in this access.

Other factors, including knowledge of the Competent Authority (for example, through other completed evaluations, existing trade and/or bilateral meetings) may also be considered when prioritising such work. Existing knowledge can provide important background that reduces the information required to be evaluated, and thereby streamline the evaluation process. This may have an impact on the required resources, which is considered as part of the prioritisation process. Existing knowledge may also provide some confidence in the claims being made by that Competent Authority. Additionally, being an OIE Member Country may provide some knowledge of the Competent Authority (including its history of notifying disease incursions). Being an OIE Member Country is also associated with disease reporting obligations (see Section 8), which may provide some further assurances.

It is recommended that OIE Member Countries applying to the department for recognition of freedom from FMD, first gain (or, in the case of an outbreak, regain) OIE recognition of freedom from FMD where vaccination is not practised[5]. This may provide some evidence to support the applicant's FMD-free status and its ability to supply some of the required information, and therefore an indication that the evaluation may result in a successful outcome and be an efficient use of the department's resources. Consequently this may be one of the factors considered by the Animal Biosecurity Branch when prioritising an evaluation.

The evaluation process also requires significant commitment from the applicant Competent Authority, in providing a technical dossier(s), submitting further information as requested, facilitating an in-country verification visit and providing comments on the draft (and final) evaluation reports—see Section 6.3. Initially, a detailed technical submission, supporting any claim for country freedom from FMD where vaccination is not practised, is required. It should include all information regarding FMD status and controls provided to the OIE (including any additional information provided to the OIE after its initial dossier) and any other relevant information on animal health status and controls (DAFF 2011b). Therefore, prioritisation of these evaluations by the Animal Biosecurity Branch also takes into account factors such as the receipt of the required technical submission(s)—see Section 6.2— and the commitment from the applicant Competent Authority to be responsive to any requests to provide information and facilitate an in-country verification visit.

The evaluation process for recognising a specific country as free from FMD for trade purposes typically commences only after it has been prioritised in the branch's work program, and the applicant Competent Authority has provided a commitment to supporting the evaluation process and submitted a detailed technical submission to the department. It is therefore suggested that applicant Competent Authorities submit the technical dossier, as well as further information about the potential for the evaluation to facilitate trade, as soon as practicable to assist the department to assign a priority to the evaluation.

The Animal Biosecurity Branch maintains an issues register to prioritise and plan its work program. On the receipt of a market access request and/or request for an evaluation to be performed, an issues register form

[5] It is noted that the OIE applies minimum waiting periods for countries seeking to regain their FMD-free status (OIE 2013b; OIE 2013g). However, these waiting periods can be arbitrary. From a practical perspective, the activities required to be undertaken to obtain recognition of freedom (for example, decontamination, serological surveillance and the preparation of the required technical dossier) may take longer than the minimum waiting period. This means that the assigned waiting period may not dictate the actual time taken to regain OIE recognition of freedom (Buetre et al. 2013; Geale et al. 2013; Junker et al. 2009).

needs to be completed to enable the prioritisation of the evaluation and addition of the activity to the branch issues register and therefore the branch work plan. The completed form is used by the Assistant Secretary of the Animal Biosecurity Branch to assign a priority ranking for the item on the issues register. A copy of the form, and the issues register itself are available on the branch's Sharepoint site[6].

- Before commencing an evaluation of a country's FMD status, it must be prioritised in the branch's work program.
- Prioritisation of work by the Animal Biosecurity Branch takes into account a number of factors. This typically includes the level of trade that may be facilitated by an evaluation, the availability of the required information and other factors that influence the resourcing required.

5.2 Information to be collected for the evaluation

The structure of the Animal Biosecurity Branch's FMD evaluation report is based on the OIE's FMD questionnaire contained in the Code (OIE 2013i). The OIE directs Member Countries applying for new recognition of freedom to complete the questionnaire in full. Those applying for recovery of status are directed by the OIE to only provide detailed information as specified in sections 3.a (FMD eradication – history), 3.b (FMD eradication – strategy), 3.c. (FMD eradication – vaccines and vaccination) and 5.b (serological surveillance) of that questionnaire, with the OIE stating that information in relation to other sections need only be supplied if relevant. In general, the Animal Biosecurity Branch views that information for all sections of the questionnaire should be provided so its relevance can be assessed—including countries applying for reinstatement of status. This is because factors covered under the other sections may have contributed to the preceding outbreak and/or are subject to change (for example, Veterinary Services, FMD prevention, control measures and contingency planning). These may be critical to, for example, understanding the background to the outbreak and providing confidence in the applicant country's ability to prevent future outbreaks (also see Section 5.2 of this document). As such, the department generally requires applicant Competent Authorities to complete the OIE's FMD questionnaire in full in the first instance, regardless of whether it is applying for new or reinstatement of recognition. It is noted that the department has provided comments to the OIE recommending that the questionnaire for countries applying for recovery of status in the Code is modified accordingly.

If there is limited knowledge of the applicant country (and Competent Authority), then a modified version of the OIE PVS Tool (OIE 2013h)—see Section 9 of this document—is also used to complement the information about the Competent Authority required under the FMD questionnaire.

The reasons for an evaluation of a country's FMD status being performed are also be taken into consideration in formation of the scope of the evaluation. For example, if it is being conducted with the aim of facilitating market access for a specific commodity, the FMD evaluation may be combined with an evaluation of that specific commodity and any specific import conditions (for example, treatments or tests) relevant to that commodity. This means that the FMD evaluation may encompass elements of a broader Competent Authority evaluation, commodity evaluation and/or evaluation of specific treatments/tests, depending on the request. Careful planning and discussions about the scope of the evaluation are critical. For further information and guidance about Competent Authority evaluations, see Section 9 of this document.

- The full FMD questionnaire contained in the Code (OIE 2013i) provides the basic framework for the FMD evaluation. A modified version of the OIE PVS Tool (OIE 2013h) may also be used if there is limited information about the applicant country.
- The reasons for initiating the evaluation must be considered, and may result in the evaluation also encompassing other matters (for example, specific commodities and/or associated import conditions).

[6] http://intranet.bas.daff.gov.au/animal/Resources/Forms/

- Careful planning is required when conducting an evaluation of a country's FMD status.

5.3 FMD evaluation process

An ad hoc team is formed to perform an evaluation of a country's FMD status, with an emphasis on team members having complementary expertise. In some cases, officers from other areas of the department (for example, operational or permit-issuing areas) may be members of the evaluation team. For further information on Competent Authority evaluations, please refer to the resources listed in Section 9.

The team conducts a thorough desk assessment of the technical submission provided by the applicant Competent Authority (Section 6.2). It considers the specific FMD and trade risks associated with the country (as well as any other issues to be evaluated), and any measures applied to manage these. Depending on the content of the submission(s), further clarification and the provision of additional information may be required from the applicant Competent Authority. There may be a series of requests for information and review of information until the team is satisfied that the all areas of the information requirements have been met. The evaluation of the documents then follows a similar process to a 'gap analysis', where the information provided is compared to the parameters outlined in the scope (which includes any relevant import policy requirements) and the questionnaire(s) provided. The need and extent for which a verification of the documented processes is required becomes apparent through this analysis.

In most cases, the evaluation typically involves an in-country verification visit based on the findings of the desk assessment (see Figure 1). Guidance documents have been developed by the Animal Biosecurity Branch to assist in the planning of verification visits (see Section 9).

Once the Animal Biosecurity Branch has completed a draft report for the evaluation, it is provided to the applicant Competent Authority, which is invited to examine the draft for factual accuracy and provide comments. A deadline for the receipt of comments may be specified (for example, 60 days). These comments are considered before the evaluation is drawn to a close and the final report is provided to the evaluated Competent Authority for its records.

The draft and final reports for the evaluation are considered to be in-confidence between the Australian and applicant country's governments. It is not currently the Animal Biosecurity Branch's intention for these reports to be published on the department's website.

A definitive timeframe for the evaluation process cannot be provided as it is contingent on a number of factors, many of which are outside the department's control—such as the time taken by the applicant Competent Authority to provide the necessary information and facilitate the in-country verification visit. If significant delays are experienced during the course of the evaluation (for example, delays in the applicant Competent Authority providing the required information, facilitating an in-country verification visit or providing comments on the draft report) the need to suspend the evaluation may be considered. If the scope of the evaluation changes or there are concerns about the currency of the information being assessed, further information may be sought from the applicant Competent Authority at any time of the evaluation process. Likewise, there may be a need for more than one in-country verification visit (for example, due to the reasons listed above or due to issues identified during the first verification visit), which may also delay the evaluation process.

- The Animal Biosecurity Branch has established processes for evaluating of a country's FMD status. This includes requesting and assessing a technical dossier from the applicant Competent Authority, completing a desk assessment, planning and conducting an in-country verification visit, completing a draft report and seeking feedback on its factual content, before completing the final report and finalising the evaluation.
- A definitive timeframe for the evaluation process cannot be provided as it is contingent on a number of factors, some of which are outside the department's control.

1. Evaluation requested	• request for evaluation from CA (or stakeholder with support of CA) • evaluation process explained to applicant CA (including requirement for a technical dossier to be submitted and in-country verification visit to be performed)
2. Evaluation prioritised	• request prioritised in the Animal Biosecurity Branch's issues register - consideration given to factors such as the potential for the evaluation to facilitate trade, the OIE's recognition of FMD status, and the receipt of a technical dossier from applicant CA • relevant operational areas in the department informed
3. Evaluation commenced	• project planning commenced • evaluation team members selected
4. Desk assessment	• technical dossier assessed using the FMD questionnaire in the Code (Chapter 1.6.) for report structure • gap analysis (the extent to which information addresses risks of concern) performed on information provided • if required, further information requested from the applicant CA • desk assessment report completed with recommendations for the in-country verification visit team [or if an in-country verification visit is not required, the draft evaluation report completed]
5. In-country verification visit planned	• verification visit team selected/confirmed • visit objectives and scope clarified • in-country visit plan established • applicant CA notified and visit arranged – dates of intended visit, requirements for visit (including sites to be visited)
6. In-country verification visit	• entry meeting conducted • audit and examination of the CA, Veterinary Services and other relevant sites/establishments • exit meeting conducted and preliminary findings presented
7. Evaluation report completed	• draft evaluation report prepared; cleared by Assistant Secretary of the Animal Biosecurity Branch • applicant CA provided with draft evaluation report for comment • comments received from applicant CA acknowledged and incorporated (as required) • final evaluation report completed; cleared by Assistant Secretary of the Animal Biosecurity Branch • time from which recognition of freedom will be effective from considered; for re-instatement of recognition, exclusion periods for trade considered
8. Evaluation finalised	• final evaluation report and recommendations provided to applicant CA • acknowledgement received from applicant CA • operational and permit-issuing areas informed of the outcome of the evaluation and changes to the 'Department of Agriculture FMD-free Approved Country List' • collaboration with operational and permit-issuing areas to inform internal and external stakeholders

Figure 1 Flowchart summary of events in the Animal Biosecurity Branch's evaluation of a country's FMD status [CA = Competent Authority]

5.4 Determining dates of recognition of freedom and commencement of trade

Recognition of freedom from FMD for trade purposes is typically effective from the date on which the FMD evaluation was finalised. This is the date on which the final report was completed and cleared by the relevant Senior Executive Service officer (the Assistant Secretary of the Animal Biosecurity Branch). However, if the evaluation recommends a definitive alternative date from which freedom should be recognised, that date is applied. Products collected, produced or manufactured from the assigned date may be eligible for importation, provided the commodity meets all other import requirements. Those products collected, produced or manufactured before this time typically remain ineligible for importation.

For some commodities there may be a delay between finalisation of the evaluation and trade in relevant commodities commencing—for example, if health certificates need to be negotiated and/or other operational issues need to be addressed.

In the case of a country that was previously recognised as free from FMD for trade purposes, and for which recognition (and relevant trade) was suspended due to an outbreak, an exclusion period for trade may be instituted when recognition is reinstated. Generally, this would apply for the period during which the country was not recognised as free from FMD for trade purposes, see Section 8. However, as discussed in Section 8, the Animal Biosecurity Branch considers the specific risks associated with the commodity in question and circumstances of the outbreak when determining these suspension periods. For example, if the Animal Biosecurity Branch cannot determine with sufficient confidence a 'start date' for the suspension, or if the risks cannot be managed with sufficient confidence, or if a significant period of time had lapsed between the previous recognition of freedom and the re-instatement of recognition of freedom, freedom may instead be recognised from a specific date (for example, date on which the FMD evaluation was finalised), with trade not permitted in previously collected, produced or manufactured items.

- The date on which trade commences (or re-commences) following a successful FMD evaluation may differ from the date on which the FMD evaluation is finalised and recognition of freedom is conferred.
- Following recognition of freedom from FMD there may be a delay in trade in relevant products commencing—for example, if health certificates need to be negotiated and/or other operational issues need to be addressed.
- For re-instatement of recognition of FMD-freedom after an outbreak, an exclusion period for trade may apply (see Section 8).

6 Department of Agriculture FMD-Free Approved Country List

6.1 History of the development of the list of approved FMD-free countries

The Animal Biosecurity Branch maintains a list of countries that are approved and recognised as free from FMD for trade purposes, the Department of Agriculture FMD-Free Approved Country List.

Following a 2009 internal discussion paper, the Animal Biosecurity Branch provided formal advice on 12 February 2010 (MN# R148) about the development of this list of countries approved for the purpose of exporting products to Australia for which, amongst other things, freedom from FMD is required.

Previously, a number of different methods had been used by operational and permit-issuing areas of the department to decide whether or not a country or zone was free from FMD. The OIE FMD official disease status had been the main reference point for the determination of a country or zone's disease status in a number of import policies developed during the previous decade that had been applied operationally.

The discussion paper and subsequent advice found that simply applying the OIE FMD recognition system for exports of FMD risk materials to Australia may not provide sufficient rigour to meet Australia's ALOP. The reasons for this included the lack of in-country verification visits, and the OIE not making applicant submissions and the resulting OIE reports available to other OIE members. Other reasons cited were potential conflicts of interests amongst the experts on the OIE Commission that may affect the outcome of the reports and recommendations, and the evaluation process not including a full evaluation of the relevant Veterinary Services.

For the initial development of the department's list, factors taken into consideration included the:

- list of countries and zones recognised by the OIE as free from FMD
- history of trade with Australia and knowledge of the Competent Authority
- FMD status of neighbouring countries
- Competent Authority's reporting history to the OIE
- duration of reported freedom from FMD.

The list has previously been referred to as the 'Biosecurity Services Group (BSG) FMD Country List' and the 'Department of Agriculture, Fisheries and Forestry (DAFF) FMD Approved Country List'. The list has been referenced in the *Quarantine Proclamation 1998.*

- In 2009, the Animal Biosecurity Branch identified a need for the development of a single centralised list of countries recognised as free from FMD for trade purposes. To compile the initial list, a number of factors were considered (MN#R148).
- The Department of Agriculture FMD-Free Approved Country List has been in place since 2010. However, the title of this list has changed over that time due to departmental rebranding.

6.2 Application of the Department of Agriculture FMD-Free Approved Country List

The Department of Agriculture FMD-Free Approved Country List is to be used by all areas of the department when determining whether a country is considered as free from FMD for trade purposes (DAFF 2011b). This ensures consistency throughout the department.

Departmental areas applying this list include those involved in:

- issuing permits—for example, Animal and Biological Imports Assessments Branch, Plant Import Operations Branch
- clearing goods (including pre-clearance based on documentation)—for example, Compliance Division
- clearing passengers and mail—for example, Compliance Division.

These areas are to consult the list when assessing import permit applications and issuing import permits for commodities that must be sourced from an FMD-free country. If a country is not included in the list, the Animal Biosecurity Branch expects that import permits for applicable commodities from that country will not be issued until such time as an evaluation has been completed and the country approved and recognised as FMD-free, and included in the list.

It should be noted that some countries appearing on list have approval that is restricted to specific commodities (that is, plant-based stockfeed products). Further assessment would be required for these countries to gain market access for other relevant FMD risk materials, and as such the status cannot be extrapolated for application to other commodities.

All areas should ensure they access the most recent version, available through Sharepoint (see Section 7.3).

- The Department of Agriculture FMD-Free Approved Country List applies to policies that require, amongst other things, commodities to be sourced from countries recognised by the department as free from FMD.
- All departmental areas are to refer to this list when assessing import permits and issuing import commodities for commodities that are to be sourced from an FMD-free country.
- Some countries appearing on this list have approval that is restricted to specific FMD risk materials (that is, plant-based stockfeed). Further assessment would be required for other FMD risk materials.

6.3 Administration of the Department of Agriculture FMD-Free Approved Country List

The current list is available publically via the department's import conditions database, ICON (Department of Agriculture 2014), as well as on the Sharepoint site[7].

Countries not listed are either FMD-affected or have not been assessed by the department for this purpose (DAFF 2011b). Until a country has satisfied the evaluation conducted by the department and recognised as free from FMD for trade purposes, it is not recognised in the list and is not approved for the export of products to Australia for which freedom from FMD is required.

Countries recognised in the list remain approved until a review of its status is triggered (for example, a confirmed or suspected outbreak of FMD, detected serious non-conformities in either products or certification, or changes in the relevant country's FMD risk management or Competent Authority)—see Section 8.

The Animal Biosecurity Branch is responsible for notifying other relevant departmental areas (see Section 7.2) when the list is revised. This includes revisions to:

- remove recognition of a country's FMD-free status—for example, in the event that an FMD outbreak is confirmed in a previously approved country or its FMD status becomes questionable due to increased risks (for example, trade becoming established with countries of lesser FMD status) or concerns relating to the Competent Authority
- recognise a country as free from FMD
- reinstate recognition of a country as free from FMD.

After any necessary consultation, the Animal Biosecurity Branch provides formal advice (that is, via a minute) to the relevant departmental areas outlining the revisions to the list and any recommended action. The Animal Biosecurity Branch collaborates with the relevant operational and permit-issuing areas to notify stakeholders of any changes to the list. This includes working together to draft ICON alerts and any other messages to stakeholders (for example, the Biological Consultative Group) and highlighting these changes to border staff via, for example, *Biosecurity operational notices* to Passenger and Mail managers in the department).

[7] http://intranet.bas.daff.gov.au/animal/BSGshared/default.aspx

There are circumstances in which there is a change to the OIE's recognition of one of its Member Country's FMD status that does not affect the Department of Agriculture FMD-Free Approved Country List. This includes instances when, due to the notification of an FMD outbreak, the OIE suspends its recognition of the FMD-free status of a country that had not been recognised by the department as FMD-free; and when the OIE confers (or re-instates) recognition of the FMD-free status of a country, for which the department is not recognising. The change in the OIE's recognition may generate significant media attention. An internal notification from the Animal Biosecurity Branch to relevant departmental officers should be issued to advise of the department's position regarding the change in the OIE's recognition. The notification also reminds officers that the Department of Agriculture FMD-Free Approved Country List is to be used when assessing whether the country is considered to be FMD-free for trade. Such a notification also serves as a record that the Animal Biosecurity Branch was aware of, and appropriately responded to, relevant events. A sample template for this notification is provided in Attachment 1 of this document. This should be adapted to the specific circumstances in which it is to be used.

The Animal Biosecurity Branch is also responsible for notifying other areas in the departmental of any current or planned activity to evaluate a country's FMD status. However, any such country continues to be considered unlisted and unapproved for import purposes until approval has been granted and the Department of Agriculture FMD-Free Approved Country List updated accordingly (unless specifically advised otherwise by the Animal Biosecurity Branch).

The list is regulated using a version control system. Any changes made to the list are recorded to ensure that the list remains up-to-date and the reasons for the changes are documented.

- The current Department of Agriculture FMD-Free Approved Country List is publically available on the department's ICON website. It is also available on the department's internal Sharepoint site.
- The Animal Biosecurity Branch is responsible for notifying operational and permit-issuing areas of any changes to the Department of Agriculture FMD-Free Approved Country List. These areas are responsible for applying this list for screening of commodities carried by passengers and sent via mail or cargo, and for assessing and issuing import permits.
- The Animal Biosecurity Branch works collaboratively with operational and permit-issuing areas to notify stakeholders accordingly.

7 Response to changes in the FMD status of approved countries

7.1 Removal of recognition of freedom from FMD

A change in status of a country listed in the Department of Agriculture FMD-Free Approved Country List (that is, a Department of Agriculture FMD-Free Approved Country) may be required if there is a confirmed or suspected presence of FMDV in that country. Likewise, removal of recognition of freedom may also be prompted by changes in the country that affects the department's confidence in its freedom, or ability to maintain that freedom. This includes changes to the Competent Authority, its FMD risk management (such as import requirements resulting in trade with countries of a lesser FMD status) or its ability to verify/certify against the department's requirements.

This information may be derived from a variety of sources, and may be the result of the scanning and intelligence gathering activities of the Animal Biosecurity Branch.

- Removal of recognition of FMD-freedom may be the result of the confirmed or suspected presence of FMDV, or changes that affect confidence in its ongoing freedom or certification.
- Information that results in these changes may come from a number of sources.

7.2 Notification of FMD outbreaks in the international community

Providing information to the OIE is an international legally binding obligation for Member Countries (Vallat et al. 2013). Among other requirements, Member Countries of the OIE are required

> *to make available to other Member Countries, through the OIE, whatever information is necessary to minimise the spread of important animal diseases, their aetiological agents, and to assist in achieving better worldwide control of these diseases.*

This includes providing a notification through the OIE's World Animal Health Information System (WAHIS) within 24 hours of the first occurrence of a listed disease, infection or infestation in a country, a zone or a compartment (OIE 2013a). The OIE's World Animal Health Information Database (WAHID) provides access to all data contained in WAHIS (OIE 2014g).

It is noted that the OIE has stated (OIE 2013j) that:

> *Information published by the OIE is derived from declarations made by the OIE Delegate of Member Countries. The OIE is not responsible for publication and maintenance of Member Countries or zonal disease free status based on inaccurate information or non-reporting of changes in epidemiological status or other significant events subsequent to the time of declaration of freedom from FMD.*

This reinforces the importance of evaluating information on FMD from a variety of sources in addition to the official OIE notification database, WAHID.

The detection (and therefore reporting) of an FMD case may not always be closely aligned to the initial infection of animals. The delay can be due to a variety of factors but may be associated firstly with the absence of obvious clinical signs in some species and the similarity of clinical signs with other differential diagnoses (Matthews 2011). The need for laboratory confirmation of a possible case may often then further delay official notification. For example, it is estimated that by the time the 2010 FMD outbreak in Japan was detected and reported, at least four weeks had passed since the virus had entered that country (APHIS 2011). Therefore the requirement for a country to provide a notification through WAHIS within 24 hours does not necessarily reflect the 'at risk' time period elapsed between disease incursion and its confirmation and reporting.

This has been recognised by the OIE Terrestrial Animal Health Standards Commission (OIE 2014f):

> *...an emerging disease[8] is extremely unlikely to be recognised as such within 24 hours of first occurrence. The Code Commission reflected that it can take weeks or months before it is realised that an observed disease is new and emerging...*

- The detection and reporting of an FMD outbreak in a trading partner country can be delayed due to a variety of factors.
- Officers of the Animal Biosecurity Branch scan for pertinent information from a variety of sources. For information about FMD outbreaks, officers should not solely rely on notifications directly from the affected country or those submitted through the official OIE notification database (WAHID).

7.3 The response of Animal Biosecurity Branch to FMD outbreaks in trading partners

It is critical that even in the case of a suspected outbreak in a Department of Agriculture FMD-Free Approved Country, precautionary action is commenced. Officers in the Animal Biosecurity Branch are to refer to the Work Instruction *Animal disease outbreak in a foreign country – ABB evaluation and response* and associated *Disease outbreak in a foreign country* form, as found at the department's Techspace site[9] when an outbreak is suspected. This work instruction prompts officers to consider the credibility of information available, the potential impact on the biosecurity risk of exports to Australia, and the action to be undertaken on this basis. Existing trade that may be affected by a (possible) outbreak needs to be identified promptly to minimise the likelihood of FMD risk materials from the outbreak country arriving and being released from quarantine in Australia.

Official advice (minute) to operational and permit-issuing areas should be considered, and is required in the event that Animal Biosecurity Branch recommends the suspension of trade. An example template response is provided for illustrative purposes in Attachment 2 of this document. However, it is noted that this template must be adapted to the specific circumstances and the details verified for currency before being used.

Because of the difficulties that can be associated with accurately determining the date of first disease incursion, the Animal Biosecurity Branch generally recommends the suspension of trade in all relevant risk materials collected, produced or manufactured from 28 days—twice the maximum incubation period for FMD, as specified by AUSVETPLAN and the OIE (Animal Health Australia 2014; OIE 2013b)—before the 'start date' of the outbreak as assessed by the Animal Biosecurity Branch. This date may be modified as more information about the outbreak becomes available, particularly the identification of the primary case (first disease incursion) which is usually not known with confidence until later in the outbreak investigation. It is noted though that each situation has unique circumstances and the implementation of any suspension period is determined on a case-by-case basis, after consideration of the specific circumstances.

When assessing the 'start date' of an outbreak, it is important to note that the dates required by the OIE to be provided by Member Countries notifying a disease outbreak do not necessarily correspond to the actual start date of an outbreak (that is, the date of first disease incursion—the primary case). According to the OIE's guidelines (OIE 2014b), Member Countries are instructed that the 'date of start of the event' is

> *...the date when the event was first observed (for example, first manifestation of a disease or infestation as observed by the livestock holder, etc.) or, for subclinical infection, the date of collection of samples.*

This therefore refers to the index rather than the primary case (see Glossary). If the exact date is unknown Member Countries are instructed to provide an estimate date.

[8] See glossary for definition
[9] http://mylink.agdaff.gov.au/team/techspace/animal/poltech/Pages/DiseaseAlerts.aspx

Meanwhile, the 'date of pre-confirmation of the event', is defined as either being:

- *for an infection/infestation with clinical signs: the date of the first time the disease was diagnosed (clinically, post-mortem or in the laboratory [in which case use the date of the basic test if any])*
- *for an infection without clinical signs: the date of the first confirmation by laboratory or penside testing;*
- *for other events: the date of the first detection of the change (e.g. evidence of a change in the prevalence of an OIE-listed disease, a sudden and unexpected increase in the distribution, incidence, morbidity or mortality of an OIE-listed disease prevalent within a country or zone/compartment, etc.).*

This reinforces the importance of carefully evaluating the date from which trade should be suspended. This includes considering whether an earlier date to that provided to the OIE should be used to calculate the appropriate suspension date.

When determining any suspension period, the risks associated with the specific commodities in question and the circumstances of the outbreak are considered. For example, the risks of FMDV contamination of ruminant reproductive material (for example, frozen embryos) stored in a country with FMDV circulating may need to be considered and may mean that materials collected prior to 28 days before the outbreak but stored in that country may be considered ineligible for export to Australia on a case-by-case basis.

It is also noted that if suspicious cases are confirmed to have occurred before the designated start date, or if there is uncertainty about the designated start date, the Animal Biosecurity Branch may recommend the suspension date is revised. Based on risk assessment, all trade in relevant commodities may be recommended to be suspended, regardless of the date of collection, production or manufacture.

The Animal Biosecurity Branch may approach the Competent Authority of the relevant country seeking clarification and/or further information to inform its decision-making.

Operational and permit-issuing areas are responsible for taking appropriate action, taking into consideration of the recommendations from the Animal Biosecurity Branch, including revocation or amendment of existing permits, and notifying affected stakeholders (see Section 7.3).

The Animal Biosecurity Branch is responsible for monitoring the outbreak situation for events/issues of relevance and providing updated advice to the relevant areas as necessary.

- The Animal Biosecurity Branch has established procedures for responding to reports of FMD outbreaks in Department of Agriculture FMD-Free Approved Countries.
- Officers in the Animal Biosecurity Branch are to consider commencing precautionary action, even in the event of suspected (unconfirmed) outbreaks. This includes requesting further information from the relevant Competent Authority (see *Animal disease outbreak in a foreign country* work instruction—Section 8).
- In recognition of the potential limitations concerning the identification of the primary case and knowledge about spread dynamics at the start of an outbreak, the Animal Biosecurity Branch typically recommends the suspension of trade in risk commodities collected, produced or manufactured before the assessed start date of the outbreak. The date from which trade is suspended is typically twice the maximum incubation period for FMD. However specific risks associated with the particular commodity or outbreak are considered and may influence action taken. The date from which trade is suspended may also be revised as new information is discovered.
- The Animal Biosecurity Branch closely collaborates with operational and permit-issuing areas to ensure relevant action is taken and stakeholders informed.

8 Further Animal Biosecurity Branch resources

8.1 Branch guidelines

- *Evaluation of competent authorities and the application of sanitary measures for animals and animal products exported to Australia* (2009)[10]
- *Animal Division guideline on external audit programs and scheduling*[11]
- *Work Instruction - Animal disease outbreak in a foreign country – ABB evaluation and response*[12]

8.2 Example documents[13]

- FMD evaluations
    - Japan
      Electronic network folder: s. 47E(d)

      Paper records: 2012/09301
    - Chile
      Electronic network folder: s. 47E(d)

      Paper records: 2013/07660

  Also, the FMD status evaluations of Cyprus and the United Kingdom.
- FMD outbreak responses
    - Japan
      Electronic network folder: s. 47E(d)

      Paper records: 2012/09301
    - Bulgaria
      Electronic network folder: s. 47E(d)

      Paper records: 2011/01906
    - Republic of South Africa
      Electronic network folder: s. 47E(d)

      Paper records: 2012/00761
- Other
    - Argentina
      Electronic network folder: s. 47E(d)

      Paper records: 2008/13009

[10] http://mylink.agdaff.gov.au/team/techspace/animal/poltech/Pages/AuditVerification.aspx
[11] http://mylink.agdaff.gov.au/team/techspace/animal/poltech/Pages/AuditVerification.aspx
[12] http://mylink.agdaff.gov.au/team/techspace/animal/poltech/Pages/DiseaseAlerts.aspx
[13] Please note, these documents were created and filed prior to the transition to digital recordkeeping. Future documents will be maintained in accordance with the digital recordkeeping requirements.
Please also note, that a single paper records reference is provided, from which other parts can be found through the TRIM system.

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10 Detailed version history

Version Number	Version Date	Amendment Details
Version 1	8/08/2014	-

Attachment 1

SAMPLE TEMPLATE: Internal departmental notification in response to the OIE suspending its FMD-free recognition of a country or zone[14] that was not recognised as FMD-free by the department[15]

Foot-and-mouth disease (FMD) outbreak in [country]

Purpose

To advise relevant officers of the recent notification of an outbreak of foot-and-mouth disease (FMD) in [country], noting that the approach of the Department of Agriculture (the department) to imports from [country] remains unchanged.

Background

[Country] has not been recognised by the department as being free from FMD [since ...]. This means that restrictions are already in place to manage the FMD risks associated with commodities imported from [country].

The recent notification of an FMD outbreak in [country] therefore does not represent a change in its trading status with Australia for 'FMD risk materials'. The only commodities that have been, and continue to be, permitted to be imported from [country] are those which have been highly processed in order to inactivate FMD virus or products which are not considered to present a risk of FMD transmission [as assessed by the Animal Biosecurity Branch].

[Country] was previously recognised by the World Organisation for Animal Health (OIE) as [being a country / having a zone] that is free from FMD where vaccination [is / is not] practised. On [date], the OIE received a notification from [country] of an outbreak of FMD in that country, and as a result the OIE has suspended its previous recognition.

Due to the extreme consequences that could result from an FMD outbreak in Australia, the department does not solely rely on the OIE's recognition of a country's FMD status for trade purposes. A separate evaluation is performed by the department before a country is recognised as being free from FMD for traded with Australia (that is, a 'Department of Agriculture FMD-Free Approved Country'),

Action

1. Note the recent notification of an outbreak of FMD in [country]
2. Note the department's position on imports from [country] remains unchanged
3. Officers are to continue to exercise heightened awareness at relevant facilities to manage any risks associated with travellers, goods or mail arriving from countries not recognised as free from FMD by the department (that is, all countries not appearing in the '*Department of Agriculture FMD-Free Country List*')—this includes items such as some dairy and meat products, equipment and personal effects that may contain soil
4. Officers are to follow relevant ICON cases to inform clearance decisions

Implementation date

Effective immediately

[14] This sample template is to be adapted to the specific circumstances, including whether a country or zone is involved

[15] It is not intended that notifications will be issued on an ongoing basis during the course of an outbreak, or for outbreaks in countries that were not recognised by others as being free from FMD. It is intended that the notification is issued at the time of the initial reports of an outbreak (for example, the time that an immediate notification is published on the OIE's WAHID site) when the OIE announces the suspension of its recognition, with follow-up notifications after the confirmation of the change in status not routinely expected.

Sample template: Internal departmental notification in response to the OIE recognising a country or zone[16] as FMD-free, that has not been evaluated and recognised as FMD-free by the department

Foot-and-mouth disease (FMD) status of [country]

Purpose

To advise relevant officers of the recent notification of the recognition by the World Organisation for Animal Health (OIE) of [country] as [being a country / having a zone] that is free from foot-and-mouth disease (FMD) where vaccination [is / is not] practised, noting that the approach of the Department of Agriculture (the department) to imports from [country] remains unchanged.

Background

[Country] continues **not** to be recognised by the department as being free from FMD [since ...].

[Country] was recognised by the OIE as [being a country / having a zone] that is free from FMD where vaccination [is / is not] practised on [date]. However, due to the extreme consequences that could result from an FMD outbreak in Australia, the department does not solely rely on the OIE's recognition of a country's FMD status for trade purposes. A separate evaluation is performed by the department before a country is recognised as being free from FMD for traded with Australia (that is, a 'Department of Agriculture FMD-Free Approved Country'). Officers will be notified if an evaluation is conducted and recognition is granted.

The recent recognition of [country's / zone's] FMD status therefore does not represent a change in its trading status with Australia for 'FMD risk materials'. The only commodities that have been, and continue to be, permitted to be imported from [country] are those which have been highly processed in order to inactivate FMD virus or products which are not considered to present a risk of FMD transmission [as assessed by the Animal Biosecurity Branch].

Action

1. Note the recent notification of the OIE's recognition of the FMD status of [country / zone]
2. Note the department's position on imports from [country] remains unchanged
3. Officers are to continue to exercise heightened awareness at relevant facilities to manage any risks associated with travellers, goods or mail arriving from countries not recognised as free from FMD by the department (that is, all countries not appearing in the '*Department of Agriculture FMD-Free Country List*')—this includes items such as some dairy and meat products, equipment and personal effects that may contain soil
4. Officers are to follow relevant ICON cases to inform clearance decisions

Implementation date

Effective immediately

[16] This sample template is to be adapted to the specific circumstances, including whether a country or zone is involved

Attachment 2

Sample template: Minute advice to relevant departmental areas about the removal of FMD-free recognition of a Department of Agriculture FMD-Free Approved Country

ADVICE ON RISK MATERIALS IMPORTED FROM [COUNTRY/ZONE] IN RESPONSE TO ITS FOOT-AND-MOUTH DISEASE OUTBREAK

Recommendation/s:

1. The Animal Biosecurity Branch recommends the suspension until further notice of the importation of animals susceptible to foot-and-mouth disease (FMD), their products (including genetic material, dairy products, hides/skins etc) and other relevant risk materials from [country / zone].

   The Animal Biosecurity Branch has amended the Department of Agriculture FMD-Free Approved Country List to reflect this change in disease status (Attachment A). This document is available on the sharepoint site: [web address]

   Noted / Please discuss

2. The Animal Biosecurity Branch recommends that this suspension includes all FMD-susceptible animals, products derived from FMD-susceptible animals and other relevant risk materials that were collected, produced or manufactured from 28 days (twice the maximum incubation period for FMD, as specified by the World Organisation for Animal Health, OIE[17], and Animal Health Australia[18]) before the start date of the outbreak of [date] onwards. Therefore the commencement date of the suspension will be [date]. The conditions recommended in this minute should be applied to all commodities collected, produced or manufactured on or after this date. Exceptions will be made for specific products for which there are existing conditions to manage the FMD risk(s).

   Note: If cases are suspected or confirmed to have occurred before [start date], the above suspension date may be revised accordingly. The Animal Biosecurity Branch will monitor the outbreak and provide updated advice as necessary.

   Noted / Please discuss

3. The Animal Biosecurity Branch recommends that specific processed meat and dairy products for which there are existing conditions to manage the FMD risk(s) should be evaluated and approved on a case-by-case basis. For example, retorted meat and dairy products, meat-based flavours, infant formula, chocolate and confectionary and some ripened cheeses.

   Noted / Please discuss

[17] OIE (2013) Foot and mouth disease (chapter 8.6), *Terrestrial Animal Health Code*, Edition 22, Paris, France.
[18] Animal Health Australia (2014) Disease strategy: Foot-and-mouth disease (version 3.4).*Australian Veterinary Emergency Plan (AUSVETPLAN)*, Edition 3, Agriculture Ministers' Forum, Canberra, ACT.

Signatory:	Date:
Comments:	

Key Points:

1. The purpose of this minute is to provide advice to relevant departmental areas on the import requirements for animals, animal products and other relevant commodities in response to [official notification of] FMD in [country / zone] in [month year].

2. [Include information about the outbreak—including any information about reporting of the outbreak and attach any relevant notifications to the minute, as well as information about suspicious cases, laboratory confirmation, virus serotype, and the location of cases within the country / zone]

3. The incubation period for FMD is affected by a number of factors—including the strain of FMD virus, the infecting dose, the route of infection, individual animal susceptibility and the environment in which the animals are kept. The international standards for terrestrial animal health states that 'the incubation period for foot and mouth disease (FMD) shall be 14 days' (OIE *Terrestrial animal health code* 2013, Article 8.6.1.).

4. Ungulates are the natural domestic and wild hosts of FMD virus. They includes cattle, sheep, pigs, goats, water buffalo, camel, bison, African buffalo, deer, antelope, reindeer, moose, llama, alpaca, vicuna, chamois, giraffe, wild boar, bush pig and warthog. Elephants are also known to be susceptible.

5. [Include information about existing trade in, and import conditions for, FMD risk materials with the country in question]

6. The Animal Biosecurity Branch recommends that the department suspends until further notice the importation of the following products from [country / zone] for which treatments or conditions do not manage the FMD risk(s). The suspension will include all FMD-susceptible animals, products derived from FMD-susceptible animals and other risk materials that were collected, produced or manufactured within 28 days (twice the maximum incubation period) before the start of the outbreak on [date].

   i. lightly processed cheeses

   ii. milk products with more than 10% dairy content (including yoghurt, fresh milk, powdered milk)

   iii. semen and embryos from FMD-susceptible species

   iv. biological products produced/derived from FMD-susceptible species (veterinary and human pharmaceuticals, laboratory reagents).

7. The Animal Biosecurity Branch recommends that the importation of the following types of products from [country / zone], for which there are existing conditions to manage the FMD risk(s), should be evaluated and approved on a case-by-case basis under existing policies and conditions.

i. processed meat and dairy products (e.g. prepared meals, heat-treated shelf-stable meat and dairy products, meat flavours, infant formula, chocolate and confectionary, some ripened cheeses)—additional advice for these products are provided in Attachment C

ii. biological products from species that are not susceptible to FMD (veterinary and human pharmaceuticals, laboratory reagents)

iii. pet food which is retorted or highly heat processed

iv. scoured wool

v. scoured animal hair and leather products

vi. new and used saddles, harnesses and tack

vii. second-hand farming equipment used in rural areas

Note: *Quarantine Proclamation 1998* stipulates that leather, chocolate and dairy products with less than 10% dairy content and meat products containing less than 5% meat may be imported without an import permit.

8. [Include details of consultation]

[Name]
[Position]
[Division/Branch]
Ph: [Landline]
Mob: [Mobile]
/ /2014

Contact Officer: [EL2 or above]
[Section]
[Landline]
[Mobile]

ATTACHMENTS

A: Department of Agriculture FMD-Free Approved Country List (Version [number], [date])
B: [Notification of outbreak]
C: Additional advice on processed meat and dairy products

Attachment C

Additional advice on processed meat and dairy products

1. Thermally processed food

These undergo a high level of thermal processing which would inactivate FMD virus. Products include retorted meat and dairy products that are shelf stable and hermetically sealed, and heat processed meat based flavours and sauces.

2. Dried milk powder

Although FMD virus can survive in dried milk powder for several years, personal consignments of infant formula are permitted. This is for the convenience of mothers and the welfare of their infants. It is justified on the basis that the end-use is assured and the potential for exposure of susceptible animals is insignificant. In the case of [country / zone], this assessment is still relevant as it is for other countries with FMD.

Commercial consignments of dried milk products are permitted from approved FMD-free countries only.

3. Ripened cheeses

In order for cheese from an FMD-affected country to be eligible for importation into Australia, it must have been processed in one of the following ways:

a) If the milk from which the cheese was made was pasteurised:

- the milk from which the cheese was made was pasteurised at a minimum of 72°C for 15 seconds or equivalent treatment, in terms of phosphatase destruction, **and**
- the cheese has attained a pH of less than 6 prior to and after being ripened, **and**
- the cheese has been ripened for 30 days or more

OR

b) If the milk from which the cheese was made was not pasteurised:

- the cheese has attained a pH of less than 6 prior to and after being ripened, **and**
- the cheese has been ripened for 120 days or more at a temperature not less than 2°C.

The Animal Biosecurity Branch recommends that cheeses meeting these requirements (and all other import requirements of the dairy import policy) be permitted from [country / zone] under permit. This is in-line with existing policy for cheese from FMD-infected countries.

4. Chocolate

Section 40 of the *Quarantine Proclamation 1998* allows commercially prepared and packaged chocolate from any country to be imported without an import permit.

5. Border activities

Goods presented at the border with passengers or mail from [country / zone] should be treated according to the procedures currently in place for clearing passengers and goods from FMD-infected countries.

Australian Government
Department of Agriculture and Water Resources

Guidelines

Animal Biosecurity Branch

Guidelines on the management of the biosecurity risks of lumpy skin disease virus in imported commodities

Document owner: Animal Biosecurity Branch

Version Number V1.0

Availability: Internal

Published Date Click here to enter a date.

Summary of main points

- This document provides guidance to officers of the Animal Biosecurity Branch (the branch) and Animal & Biological Import Assessments Branch (ABIAB) on its approach to recognising the lumpy skin disease (LSD) status of trading partners, and the use of the Department of Agriculture and Water Resources *LSD-Free Approved Country List*.
- It also explains the branch's role in responding to changes in LSD status of other countries or trading partners.
- LSD is considered a serious biosecurity risk, and would have significant economic and social consequences if the disease was reported or were to establish and spread in Australia.
- Import policies recommend that trade in LSD risk materials be restricted to countries that are recognised by the department as free from LSD; that is those countries on the department's *LSD-Free Approved Country List*, unless the department has established alternative risk management measures.
- The World Organisation for Animal Health (OIE) process for official disease status recognition of Member Countries does not include LSD, although Member Countries are required to self-report their LSD status to the OIE in accordance with the criteria in the *Terrestrial Animal Health Code (Terrestrial code)*. A country's self-reported status to the OIE is taken into account, however, due to the extreme consequences associated with an LSD outbreak in Australia, the branch conducts its own evaluation.
- When evaluating a trading partner's LSD status, the branch also considers the ability of the competent authority to maintain their LSD status and prevent future LSD outbreaks and to manage LSD vaccination. The branch also evaluates the trading partner's animal health systems, and the oversight of the competent authority in delivering and maintaining these systems. The evaluation may include a desk assessment and a formal in-country verification visit.
- Concerns with the quality and efficacy of currently available vaccines means vaccination against LSD does not provide an equivalent level of risk management for LSD when compared to country freedom from LSD without vaccination. Therefore, the branch does not recognise countries where vaccination is practiced as free from LSD for trade purposes.
- The guidelines have been divided into two parts for useability. Part A contains background information and rational for evaluating the LSD status in trading partners, and Part B contains guidance on operational processes for the application of the department's *LSD-Free Approved Country List*.

1 Contents

2 Acronyms and abbreviations

ABIAB	animal & biological import assessment branch
ALOP	appropriate level of protection
BICON	biosecurity import conditions system
BIRA	biosecurity import risk analysis
branch	Animal Biosecurity Branch of the Australian Government Department of Agriculture and Water Resources
Terrestrial Code	OIE *Terrestrial animal health code*
department	Australian Government Department of Agriculture and Water Resources (formerly Australian Government Department of Agriculture, and before that the Department of Agriculture, Fisheries and Forestry, DAFF)
DAWR	Australian Government Department of Agriculture and Water Resources
DIVA	Differentiation of Infected from Vaccinated Animals
FMD	foot-and-mouth disease
Goods determination	*Biosecurity (Prohibited and Conditionally Non-prohibited Goods) Determination 2016*
LSD	lumpy skin disease
LSDV	lumpy skin disease virus
OIE	World Organisation for Animal Health
SPS Agreement	World Trade Organization Agreement on the Application of Sanitary and Phytosanitary Measures
WAHIS	World Animal Health Information System
WTO	World Trade Organization

Definitions

Relevant definitions:

Term	Definition
appropriate level of protection	The level of protection deemed appropriate by a country to protect human, animal or plant life or health within its territory (WTO 2016).
biosecurity	The prevention of the entry, establishment or spread of unwanted pests and infectious disease agents to protect human, animal or plant health or life, the environment and the economy (Beale et al. 2008; DAFF 2011).
case	Individual animal infected by a pathogenic agent, with or without clinical signs (OIE 2017b)
biosecurity import risk analysis (BIRA)	An evaluation of the level of biosecurity risk associated with particular goods, or a particular class of goods, that may be imported, or are proposed to be imported, into Australian territory, including, if necessary/appropriate, the identification of conditions that must be met to manage the level of biosecurity risk associated with the goods, or the class of goods, to a level that achieves the ALOP for Australia (DAWR 2016b).
commodity	Live animals, products of animal origin, animal genetic material, biological products and pathological material (OIE 2017b).
competent authority	Veterinary authority or other governmental authority of a country having the responsibility and competence for ensuring or supervising the implementation of animal health and welfare measures, international veterinary certification and other standards and recommendations in the whole territory (OIE 2017b).
country	For the purpose of this document, 'country' also includes defined zones. It is noted that the Department of Agriculture and Water Resources has not yet assessed the LSD status of any zones, and therefore does not currently recognise any zones as free from LSD for trade purposes. However, the department's evaluation of a country or zone freedom from LSD follows the same process. The evaluation considers the specific LSD and trade risks for the applicant country/zone, and therefore any heightened risks that may be associated with specific zones would be assessed accordingly.
FMD- Free Approved Country List	List of countries evaluated and approved by the Department of Agriculture and Water Resources as free from FMD for the export of certain commodities to Australia. Formally known as the *Department of Agriculture and Water Resources FMD-Free Approved Country List*.
LSD-Free Approved Country List	List of countries evaluated and approved by the Department of Agriculture and Water Resources as free from LSD for the export of certain commodities to Australia. Formally known as the *Department of Agriculture and Water Resources LSD-Free Approved Country List*.
emerging disease	A new occurrence in an animal of a disease, infection or infestation, causing a significant impact on animal or public health resulting from: a

Term	Definition
	change of a known pathogenic agent or its spread to a new geographic area or species; or, a previously unrecognised pathogenic agent or disease diagnosed for the first time (OIE 2017b).
LSD risk material	Commodity that poses a risk of LSD, e.g. susceptible to infection and/or presence/contamination with lumpy skin disease virus, as assessed by the Department of Agriculture and Water Resources[1].
incubation period	Longest period which elapses between the introduction of the pathogen into the animal and the occurrence of the first clinical signs of the disease (OIE 2017b).
market access request	An import proposal provided to the department by government authorities of an exporting country (DAFF 2011).
outbreak	Occurrence of one or more cases in an epidemiological unit [that is, a group of animals with a defined epidemiological relationship] (OIE 2017b).
primary case	Initial case (Thrushfield 1995).
risk assessment	Evaluation of the likelihood and the biological consequences of entry, establishment and spread of a hazard within the territory of an importing country (OIE 2017b).
risk management	Process of identifying, selecting and implementing measures that can be applied to reduce the level of risk (OIE 2017b).
transboundary disease	A disease of significant economic, trade and/or food security importance for a considerable number of countries; which can easily spread to other countries and reach epidemic proportions; and where control/management, including exclusion, requires cooperation between several countries (FAO 2004).
veterinary authority	Governmental authority of a country, comprising veterinarians, other professionals and para-professionals, having the responsibility and competence for ensuring or supervising the implementation of animal health and welfare measures, international veterinary certification and other standards and recommendations in the OIE *Terrestrial Animal Health Code* in the whole territory (OIE 2017b).
veterinary services	Governmental and non-governmental organisations that implement animal health and welfare measures as well as other standards and recommendations in the territory. The veterinary services are under the overall control and direction of the veterinary authority. Private sector organisations, veterinarians, veterinary paraprofessionals or aquatic animal health professionals are normally accredited or approved by the veterinary authority to deliver the delegated functions (OIE 2017b).
zone/region	Clearly defined part of a territory containing an animal subpopulation with a distinct health status with respect to a specific disease for which

[1] LSD risk materials are not permitted to be exported to Australia unless the risk has been managed to meet Australia's appropriate level of protection

Term	Definition
	required surveillance, control and biosecurity measures have been applied for the purpose of international trade (OIE 2017b).

3 Introduction

3.1 Purpose

This document aims to establish a consistent and transparent approach to the management of the biosecurity risks associated with international trade in LSD risk materials.

The document provides guidance on:

- background information and rationale for the an evaluation of LSD status in trading partners;
- the application and administration of the department's *LSD-Free Approved Country List*; and
- the evaluation of the LSD status of trading partners.

These guidelines are for use with existing policies, guidelines, minutes and other advice on regulatory imports to manage LSD risks (see Further Resources section).

3.2 Scope

This document provides background information and general guidance for officers in the branch and support to ABIAB, on the biosecurity management of trade in LSD risk materials—particularly for commodities required to be sourced from approved countries which are recognised by the department as free from LSD.

For useability, the guidelines have been divided into two parts. Part A contains background information on the significance of LSD to Australia and the rationale for evaluating the LSD status of trading partners, and Part B contains guidance on operational processes including the application and administration of the department's *LSD-Free Approved Country List*.

The overarching principles of science-based risk analysis apply, as they do to other activities of the branch which manage biosecurity risks.

This document does not provide information on the processes used to determine LSD risk management measures in specific import policies, or to outline the import requirements for specific commodities. Officers are directed to the relevant import policies and/or policy advices for this information.

For the procedures to follow in response to an LSD outbreak alert, branch officers are to refer to the work instruction called *Animal disease outbreak in a foreign country – ABB evaluation and response* and associated *Disease outbreak in a foreign country* form, as found on the ABB SharePoint site[2] when an outbreak is suspected. This work instruction prompts officers to consider the credibility of information available, the potential impact on the biosecurity risk of exports to Australia, and the action to be undertaken on this basis.

This document does not focus on the branch's activities for disease intelligence scanning or reporting activities, or the process of reporting to, or commenting on documents of the OIE.

This document does not apply to the management of an exotic disease outbreak such as LSD in Australia. The Australian Veterinary Emergency Plan (AUSVETPLAN) disease strategy for an outbreak of LSD is in the latest version of the documents outlined below and available on the internet at www.animalhealthaustralia.com.au/

- Animal Health Australia (2009). *Disease strategy: Lumpy skin disease*.

[2] http://mylink.agdaff.gov.au/team/abb/Resources/Forms/AllItems.aspx

4 Part A – Background information and rationale

4.1 Australia's international trade obligations and approach to biosecurity management

As a member of the World Trade Organization (WTO), Australia adheres to the WTO Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement). Under the SPS Agreement, members may introduce or maintain a higher level of sanitary or phytosanitary protection than would be achieved by the relevant international standards, guidelines, or recommendations if there is a scientific justification, or if it is identified in a risk assessment and is in accordance with the determined appropriate level of sanitary or phytosanitary protection (WTO 2016). This principle is acknowledged in the *Terrestrial Code* (OIE 2017f).

The SPS Agreement defines the concept of an appropriate level of sanitary or phytosanitary protection as 'the level of protection deemed appropriate by a WTO member to protect human, animal or plant life or health within its territory. In assessing risk and establishing risk management measures, members may take into account relevant economic factors—that is, potential damage from loss of production/sales from the entry, establishment or spread of a pest or disease, costs of control or eradication, and relative cost-effectiveness of alternative approaches to limiting risks. When applying risk management measures, a WTO member should ensure that these are not more restrictive than required to achieve its appropriate level of protection (ALOP) (WTO 2016).

Australia has a risk-based approach to biosecurity management. Australia's ALOP is legislated in the *Biosecurity Act 2015*, stated as 'a high level of sanitary and phytosanitary protection aimed at reducing biosecurity risks to a very low level, but not to zero.' Under the *Biosecurity Act 2015*, a Biosecurity Import Risk Analysis (BIRA) may be performed to evaluate the level of biosecurity risk associated with particular goods that are proposed to be imported to Australia. The BIRA may identify conditions that must be met to manage the level of biosecurity risk to a level that achieves Australia's ALOP. If, through a BIRA or risk review, it is not possible to identify conditions to reduce the level of risk to an acceptable level, trade is not permitted.

4.2 LSD and its significance in Australian biosecurity policies and operations

LSD is an OIE-listed disease of bovidae. According to the OIE, LSD susceptible animals are bovines (*Bos indicus* and *B. taurus*) and water buffaloes (*Bubalus bubalis*) and certain wild ruminants (OIE 2017e). It is a nationally notifiable in Australia (DAWR 2016a, DAWR 2016c), and has never been recorded in Australia (Animal Health Australia 2015).

An outbreak in a previously free country such as Australia would result in a high morbidity rate with severe economic and social consequences. As LSD is primarily a vector borne disease, the mode of transmission (arthropods) greatly reduces the potential for intervention and would make control of the disease challenging. Although the economic impact of an LSD outbreak in Australia has not been quantified, a study in Ethiopia found that the financial cost related to infected herds (sum of production losses due to morbidity and mortality arising from milk loss, beef loss, traction power loss, and treatment and vaccination costs) was estimated to be between USD $42-73 head of Holstein Friesian crossbred cattle (Bonnet et al 2011). Another study in Ethiopia found that the median loss of USD 1250 in Holstein-Friesian local zebu cross cattle was estimated per dead animal (Molla et al 2017). In addition to the financial costs for control of LSD, the disease can lead to restrictions on, or a total ban of, international trade of live animals and animal products. From 2015 to 2016, LSD spread through several countries in the Baltic Peninsula that were previously free from the disease. As a result, the department suspended the importation of animals susceptible to LSD and their products (including reproductive material, dairy products, hides/skins etc.) from these countries.

Under Australia's Emergency Animal Disease Response Agreement, LSD is a Category 3 Emergency Animal Disease that has the potential to cause significant (but generally moderate) national socio-economic consequences. This would be via international trade losses, domestic market disruptions involving two or more states, and severe production losses to affected industries. There would be minimal or no effect on human health or the environment (DLA Piper 2016). If an outbreak were to occur in Australia, these costs would be further compounded by immediate loss of trade in affected commodities to international markets and in international market opportunities.

The branch has a number of responsibilities for managing the risk associated with the import of LSD risk materials. It performs risk analyses and reviews on the importation of LSD risk materials; provides advice on existing import conditions; monitors and advises on LSD outbreaks in trading partners; and contributes to domestic and international standards on LSD. Import policies may recommend that trade in LSD risk materials be restricted to countries with freedom of LSD and/or restricted to materials that have been subject to specified treatments. If the risk cannot be managed to meet Australia's ALOP or a policy does not exist for the commodity in question, trade is not permitted.

4.3 The OIE and LSD

The OIE is the WTO designated international reference organisation for animal health matters, and publishes standards that can be applied for international trade.

The OIE publishes science-based standards on LSD risk and risk management in the *Terrestrial Code* and standards for diagnostic tools for LSD in its *Manual of diagnostic tests and vaccines for terrestrial animals*, as well as in the Resolutions of the World Assemble of OIE delegates (OIE 2017c, OIE 2017d). As a Member Country, Australia contributes to the development of these standards.

In the case where there is no relevant international standard or where Member Countries require a higher level of sanitary safety to reach their ALOP, a science based risk analysis should be undertaken in accordance with OIE standards (the standards for risk analysis are set out in the *Terrestrial Code* to establish the appropriate sanitary standards) (OIE 2009). This is done in accordance with a country's rights and obligations under the WTO SPS Agreement (WTO 2016).

The OIE also maintains and operates the World Animal Health Information System (WAHIS) system, which works in real-time to notify the international community and keep record of disease notifications that are received from Member Countries. LSD is included on the OIE list of notifiable diseases as a cattle disease. Therefore, all OIE member countries that have been free from the disease are to notify the OIE within 24 hours of confirming the presence of LSD (OIE 2017a).

The OIE process for official disease status recognition of Member Countries does not include LSD, however, Member Countries are required to self-report their LSD status to the OIE in accordance with the criteria in the *Terrestrial Animal Health Code*.

4.4 Rationale

Requirement for country freedom from LSD

LSD is a serious biosecurity threat to Australia's cattle industry, therefore it is imperative that risks associated with trade in LSD risk materials are managed effectively.

To manage the biosecurity risks associated with international trade and meet Australia's ALOP, risk analyses conducted by the branch may recommend that the sourcing of a commodity be limited to countries that are, amongst other conditions, recognised by the department as free from LSD when alternative treatments or processes will not address the risks sufficiently.

Alternative risk management measures (for example, heat treatment or diagnostic testing) cannot be substituted for the requirement for a commodity to be sourced from a country that is recognised by the department as free from LSD, unless an assessment of those risk management measures has concluded that those measures will meet Australia's legislated ALOP.

Requirement for disease freedom without LSD vaccination

Current LSDV vaccination practice

Currently, only live attenuated vaccines are commercially available for vaccination against LSD, noting that none are approved for importation and use in Australia.

These vaccines can be roughly divided into two classes - homologous vaccines and heterologous vaccines. Homologous vaccines are based on strains of LSDV (e.g. Neethling strain vaccine). Heterologous vaccines are

based on sheep and goat pox virus strains (e.g. Gorgon™) (Klement 2017). As cross-immunity occurs between the three members of the *Capripoxvirus* genus (LSDV, sheep pox virus and goat pox virus), attenuated sheep and goat pox vaccines are used for vaccination against LSD. The OIE does not recommend use of the sheep and goat pox strain live attenuated vaccines in regions free from these diseases due to the risk of introducing these diseases (OIE 2017i).

The two commercially available homologous vaccines are manufactured in South Africa by two producers and are based on Neethling strain LSDV. They have been used for control of LSD in the European Union when LSD outbreaks occurred in Greece and Bulgaria in 2015 and 2016 respectively (Antoniou et al 2017, Alexandrov et al 2017). In August 2016, Croatia became the first country to implement preventative vaccination using live attenuated LSDV strain vaccines (in advance of natural infection) in an attempt to control the spread of LSD from the Balkans further into the European Union, Bosnia and Herzegovina followed suit immediately thereafter, beginning vaccination in March 2017 (OIE 2017j).

Vaccination against LSDV is also used in many countries where the disease is endemic in order to control the overall disease burden (Tuppurainen et al 2015). Sheep and goat pox virus strain vaccines (Penpox-M) are used for disease control in Turkey (Gulyaz V 2017). A Romanian sheep pox virus strain vaccine is also used in Egypt (Tuppurainen et al 2015), where the disease remains endemic.

An annual booster of vaccination is recommended by vaccine manufacturers, as the maximum duration of protection is thought to be 22 months (Tuppurainen et al 2015; Kitching 2003).

Limitations of LSD Vaccination

An ideal vaccine against LSD would provide rapid onset of lifelong humoral and cell mediated immunity within 14 days of a single administration, be safe, not cause clinical disease or spread to non-vaccinated animals, be inexpensive and be thermostable (Tuppurainen et al 2015) and facilitate DIVA via serological methods. Currently, there are no commercially available vaccines against LSD that can meet these criteria. Sheep and goat pox virus strain vaccines are not recommended for use in countries free from LSD, such as Australia, due to the risk of disease introduction associated with the use of a live attenuated vaccine.

The largest amount of information regarding safety and efficacy currently exists for the Neethling vaccine. The branch's review of the available scientific literature has found inconsistent and conflicting results, and significant concerns with the safety and efficacy of commercially available vaccines against LSD have been identified:

- Vaccine efficacy: Currently, there are only a small number of laboratory studies and these have returned inconsistent results. A 2015 study including vaccine challenge experiments found the Neethling vaccine failed to provide adequate protection against LSDV, with 70% of vaccinated cattle (7 out of 10) displaying clinical signs post challenge with a virulent LSDV field strain (Gari et al 2015). Comparatively, a field study performed in Israel showed a 2.45% incidence of lumpy skin disease in cattle vaccinated with the Neethling strain vaccine (J.Ben-Gera et al, 2015). Between 2008 and 2009, many herds in Ethiopia that were vaccinated with the Neethling strain vaccine were re-infected (Ayelet et al 2014). Additionally, as the LSD vaccines may only provide partial immunity to vaccinated animals, clinical signs of LSD may be masked in partially protected animals, yet they could still be viraemic and capable of spreading the virus.

- Vaccine safety: There is conflicting information about the safety of the Neethling vaccine. In a study carried out in 2013 during a large LSD epidemic in Israel, 0.38 percent of cows vaccinated with the attenuated Neethling vaccine developed an adverse effect as a result of the vaccination that resembled a very mild form of LSD (Klement 2017). In contrast to this, during the preventative vaccination campaign in Croatia, significant losses due to vaccination occurred including increased morbidity and mortality of cattle and significant reduction of milk production (Council of the European Union 2017). In a study performed in Croatia, the presence of vaccine associated viral particles were detected in milk and skin nodules, blood, and nasal swabs in seven out of eight herds of vaccinated cattle. The presence of vaccine virus in skin nodules could be a potential source of LSD spread via mechanical transmission by insects or ticks feeding on skin lesions (Bedekovic 2017).

- Inability to evaluate herd immunity: The immune response to vaccination using any of the currently available strains has not been well characterised. The small number of studies demonstrate that the antibody response to vaccination is inconsistent and not directly linked to efficacy. In vaccinated regions, some individuals showing mild disease may develop only a low level of neutralizing antibodies that cannot be detected using currently available tests (Tuppurainen 2015). Because of this, evaluation of herd immunity in vaccinated herds is currently not possible on the basis of serology.

  Vaccine quality: several factors apart from the efficacy of the vaccination itself can result in breakdown and gaps in a vaccination program. The only LSD vaccines available are live attenuated and produced in South Africa. There have been multiple vaccine quality control issues; a vaccine marketed as a sheep and goat pox virus strain was recently revealed to be LSDV strain vaccine (Tulmen et al 2002). In June 2016, a scientific study identified contaminant Bluetongue virus in commercial batches of sheep pox and lumpy skin disease vaccine (Bumbarov et al 2016). In the commercially available live attenuated vaccines no incidence of LSDV infection from vaccination has been documented (Ben-Gera et al. 2015), but LSDV was recovered from cattle vaccinated with an unregulated vaccine during an outbreak in Jordan which may have resulted in clinical LSD (Abutarbush et al. 2014).

- Lack of Differentiation of Infected from Vaccinated Animals (DIVA) vaccine: there are no commercially available LSD vaccines with a DIVA-component (Tasioudi et al 2016; Tuppurainen et al 2015). Therefore the antibody response elicited by vaccines cannot be distinguished from natural infection and thus sero-surveillance of herds when trying to re-establish country freedom is currently not possible in the presence of a vaccination program. A concern with the use of the LSD Neethling strain vaccine is that vaccinated animals can sometimes show clinical signs that resemble mild LSD (referred to as "Neethling disease"). Differentiation between the vaccine and wild type virus would take 1-2 days using differential PCR or sequencing, leading to delay of slaughter and control of affected animals (FAO 2016). Use of these vaccines in an outbreak situation may extend the duration and range of the outbreak, resulting in a larger number of animals destroyed before the incursion is controlled.

Given the problems identified with currently available LSD vaccines, the branch does not consider freedom with vaccination to provide an equivalent level of protection to country freedom from LSD without vaccination.

Re-establishment of country freedom after LSD vaccination

For country level freedom from LSD the 2017 *Terrestrial Code* requires that:

- LSDV is notifiable in the country;
- Importation of bovines and water buffalo and their commodities is carried out in accordance with the *Terrestrial Code* chapter; and
- Either:
  - The country or zone is historically free, or
  - For at least 3 years, vaccination has been prohibited in the country or zone and a clinical surveillance programme in accordance with the *Terrestrial Code* chapter has demonstrated no occurrence of infection with LSDV, or
  - For at least 2 years, vaccination has been prohibited in the country or zone and a clinical, virological and serological surveillance programmed in accordance with the *Terrestrial Code* chapter has demonstrated no occurrence of infection with LSDV.
- A country or zone free from LSD that is adjacent to an infected country or zone should include a zone in which surveillance is conducted in accordance with the *Terrestrial Code* chapter (OIE 2017a).

Australia does not consider clinical surveillance alone to be an effective surveillance measure. A high proportion of animals infected with LSDV (up to 50%) have subclinical infection but are still viraemic and capable of transmitting the disease via vectors (Tuppurainen et al 2015; Weiss 1968; Tuppurainen et al 2005; Osuagwuh et al 2007; Annandale et al 2010). There is also a lack of evidence on the duration of effective immunity provided by available LSD vaccines. As currently available LSD vaccines are only partially protective, clinical signs of LSD may be masked in vaccinated animals and therefore reduce the reliability of clinical surveillance.

The 2017 *Terrestrial Code* does not require the disposal of vaccinated herds from the population in order to achieve country freedom, despite the retention of vaccinated herds in a population increasing the likelihood of undetected cases and inaccuracies in disease reporting or surveillance.

The lack of LSD DIVA tests and vaccines, means the antibody response elicited by LSD vaccines cannot be distinguished from natural infection. Following vaccination sero-surveillance of herds to re-establish country freedom is hindered by the presence of vaccinated animals. The issues with sero-surveillance are further complicated by the lack of reliable information available on the duration of immunity provided by LSD vaccines and the period of time to expect vaccine-induced antibodies in serology tests post vaccination.

In order for a country to gain/re-gain approval for inclusion on the *LSD-Free Approved Country List*, particularly post vaccination, careful evaluation with particular attention on the country's surveillance programs, surveillance data and the management of previously vaccinated herds is essential.

Evaluation of exporting country competent authorities and official Veterinary Services

A previously affected country seeking recognition of its freedom from LSD for trade purposes will be required to undergo an evaluation by the branch of its competent authority and systems relevant for claiming and maintaining freedom from LSD.

Clearance through biosecurity and approval for import of LSD risk material into Australia relies on our confidence in official veterinary services in the exporting country to provide reliable inspection and certification. Inadequate or out of date knowledge of overseas competent authorities, and the systems in place to validate exporter assurances, can undermine the veracity of import documentation and increase the risk of LSD incursion.

Confidence in a country's official veterinary services also relates to their ability to maintain their animal health status (through disease monitoring, surveillance and control programs etc.). This is particularly important given that in the event of an outbreak, the disease agent may be circulating for a period of time before it is recognised or reported, meaning that there is a risk that affected commodities may be imported in the interim.

In addition to this, sole reliance on the self-reporting system of the OIE when determining a country or zone's LSD status should be avoided, as the system does not include any in-country verification of the LSD status claims submitted to the OIE. Whilst countries can self-declare freedom from LSD in accordance with criteria in the *Terrestrial Code*, the OIE does not provide a procedure for verification of self-declaration regarding LSD (OIE 2017g).

For these reasons, the evaluation of a country's LSD status, as conducted for the department by the branch, will include the assessment and verification of the country's relevant animal health, production, inspection and certification systems. It will also consider the ability of the competent authority to maintain their LSD status and prevent future LSD outbreaks.

Adoption of zones

Transboundary Nature of LSD spread

Highly infectious, transboundary diseases such as LSD present a challenge to disease surveillance and control programs. The main mode of transmission is mechanically through arthropods, with the prevalence and movement of arthropods being affected by synoptic systems, geography and climate. Other factors for the risk of LSD introduction includes the neighbouring countries' disease status and the movement of asymptomatic viraemic animals (Tuppurainen et al 2015). Spread through direct contact with LSD risk materials and fomites is also possible.

Since 2012, LSD has been spreading throughout the Middle East, including Egypt and Israel, into Turkey (reported steadily since 2013) where it is now considered endemic (EFSA, 2018). Israel has had three outbreaks of LSD. The source of each outbreak was difficult to determine due to the transboundary nature of the disease. A recent study (Klausner et al 2015) analysed synoptic system wind trajectories and produced strong evidence for Egypt being the source of the first two outbreaks and the Gaza Strip region for the third. This study demonstrates that countries neighbouring affected countries are at risk of introduction of LSD. Patterns of LSD spread are erratic and hard to predict, often skipping local farms and administrative regions to appear fifty or more kilometres from the last outbreak site, even if movement controls and quarantine have been implemented. This has occurred during the past three outbreaks in Israel and spread of LSD through the Balkans (Klausner et al 2015).

A recent scientific report which analysed the spatial and temporal patterns of LSD epidemics in affected south-eastern Europe countries in 2016 and 2017 found that LSD spreads mostly up to 4km (e.g. via vectors), but with transmission occurring over much longer distances (e.g. via animal movement) (EFSA 2018).

Although studies have revealed that the primary mode of LSD spread has recurring links to movement of infected wind-borne vectors and infected animals or products, many aspects of transmission pathways are uncertain (Klausner et al 2015; Abutarbush et al 2014; Tasioudi et al 2016; Sevik & Dogan 2015).

Vector-borne transmission of LSDV is known to be mechanical rather than biological (Klausner et al 2015); however, the range of hematophagous insect species is not yet known. *Culicoides punctatus* has recently been suggested to have a role in transmission (Sevik & Dogan 2015). The role of ticks in the maintenance of lumpy skin by trans-ovarial, intra-stadial, and trans-stadial transmission prior to mechanical transmission to bovines is becoming increasingly recognised in recent years (Tuppurainen et al 2015; Tuppurainen et al 2011; Lubinga et al 2013, Lubinga et al 2014).

The role of wildlife in transmission and/or maintenance of the virus is unknown. A variety of species such as giraffes, springbok and impalas are known to be susceptible to LSD (Fagbo et al 2014; Davies 1982), and LSDV-specific antibodies have been demonstrated in various wild ruminants such as eland and greater kudu and symptomatic infection of oryx has been observed. (Barnard 1998; Tuppurainen et al 2015**)**

Although transmission of LSDV by direct contact is considered to be relatively ineffective, infected cattle excrete the virus in saliva and nasal discharged which may contaminate common feeding or watering sites. Affected animals with skin lesions shed virus-containing crusts into the environment and on equipment (Tuppurainen 2017).

As discussed above, as many aspects of the transmission pathways of LSD remain uncertain there may be implications on the ability to control and eradicate LSDV (OIE 2017c).

Recognition of zoning

Due to the erratic, transboundary nature spread of LSD, the gaps in knowledge about disease transmission and the severe consequences if it enters Australia, the department does not currently recognise zoning for LSD.

Further discussion is required to consider recognition of zoning for LSD for trade purposes. The branch will assess feasibility of recognition of zoning for LSD within a country (based on scientific evidence) on a case-by-case basis.

5 Part B – Guidance on operational procedures

5.1 Import conditions for LSD risk materials

Depending on the commodity and the level of assessed risk it presents, Australia's import conditions may require commodities to be either sourced from a country free from LSD or to have undergone treatment to manage LSD risks. *Table 1* summarises the key commodities which have import requirements to manage the risk of LSD.

It should be noted that trade in a specific commodity may also be contingent on the department verifying that other requirements have been met. This includes other treatments, testing and/or sourcing from places that are free from other disease(s). This means that for some commodities, in addition to being sourced from an LSD-free approved country or being subject to approved treatments, the source country and/or export production facilities must also be approved for other purposes. The information provided in *Table 1* does not provide the import conditions required to address other biosecurity risks (such as foot-and-mouth disease (FMD), Bovine Spongiform Encephalopathy BSE), refer to the relevant policies for this information.

LSD susceptible species are considered to be:

- bovines (*Bos indicus* and *B. taurus*)
- water buffalo
- other wild ruminants including giraffes, springbok, impalas, oryx, possibly eland and greater kudu.

There are LSD risk materials/products that are not required to be sourced from a country recognised as free from LSD, as the import conditions require them to undergo a high level of thermal processing or other treatments to address other biosecurity risks i.e. foot-and-mouth disease (FMD) which also inactivates LSD virus, this includes policies for:

- retorted meat >5% meat
- meat-based flavours (without discernible pieces of meat)
- retorted dairy products
- retorted pet food.

Under the *Biosecurity (Prohibited and Conditionally Non-prohibited Goods) Determination 2016 (Goods determination)* there are LSD risk materials that are exempt from an import permit if they comply with the specified conditions. These conditions manage the LSD risk for these products and include:

- Fully tanned hides and skins in accordance with *Section 13* of the *Goods determination*
- Retorted meat or meat products <5% meat in accordance with Section 15 of the *Goods determination*
- Dairy products in accordance with *Section 16* of the *Goods determination* subject to compliance with the requirements to be sourced from countries on the DAWR *FMD-free Approved Country List*
- Rawhide Chews in accordance with *Section 20* of the *Goods determination.*

It should be noted that there are other commodities that pose LSD risks, for example by acting as fomites. Scientific studies on the spread of LSD virus via fomites are limited, however, virus can last up to 6 months in shaded pens or bedding (Animal Health Australia 2009) and transmission through fomites contaminated with secretions from infected animals are possible routes of LSD virus transmission. Therefore, farm and veterinary equipment, boots, saddles and tack, fertiliser, soil, peat, mail, passengers and their belongings may act as fomites.

LSD risk management measures apply for these commodities/pathways as well. Although the branch does not have primary carriage for some of the policies for these commodities, it is responsible for providing guidance and recommendations on the applicable LSD risk management measures.

LSD risk material	Import requirements to address LSD risk		Policy
	DAWR Approved LSD-Free country	DAWR Approved LSD-Free country OR Approved pre-export treatment	
Fresh beef and beef products	✓		Fresh (chilled or frozen) beef and beef products from Japan, the Netherlands, New Zealand, the United States and Vanuatu
Genetic Material (semen and embryos)	✓		*OIE Terrestrial Code* criteria for LSD free country
Bovine dairy products (other than cheese or butter) containing greater than 10% dairy	✓		IRA for the *Importation of dairy products into Australia for human consumption*
Finished game trophies from LSD-susceptible species		✓	*Guidelines on the import conditions for ornamental animal products* IRA for *Hides and Skin*
Partially tanned hides, skins and game trophies from LSD-susceptible species		✓	*Guidelines on the import conditions for mammalian hides and skins from all countries* *Guidelines on the import conditions for ornamental animal products* IRA for *Hides and Skins*
Unprocessed hides, skins and game trophies from LSD-susceptible species	✓		*Guidelines on the import conditions for mammalian hides and skins from all countries*
Museum specimens and rawhide handicrafts		✓	*Guidelines on the import conditions for ornamental animal products*
Biological Products (veterinary and human therapeutics, laboratory reagents etc)	✓	If treatment of the material is allowed by the relevant policy as an alternative to country freedom, efficacy of the treatment against LSD should be verified with ABB as required.	*Guidelines for the importation of biological materials* ('Green Book')
Stockfeed of plant origin		✓	*Guidelines on the policy for imported stockfeed of plant origin* ('Plant-Based Stockfeed Guidelines')
Extruded pet food (e.g. kibble) containing ingredients derived from LSD-susceptible species	✓		*Guidelines for the quarantine assessment of pet food* ('Pet Food Guidelines'

Table 1: Import requirements for LSD risk materials

5.2 The Department of Agriculture and Water Resources LSD-Free Approved Country List

Australia has an established range of risk management measures for the importation of LSD susceptible livestock and products derived from or potentially contaminated by these animals. Risk management measures that restrict imports of these commodities according to the LSD status of the country or zone of origin and export is integral to preserving Australia's LSD free status. It is one component of a suite of risk management measures designed to reduce the likelihood of LSD virus entering via infected animals or animal products or fomites.

The geographical distribution of LSD has historically been linked to the distribution of FMD. Countries affected by LSD have also been affected by FMD and so countries listed in the department's *FMD-Free Approved Country List* could be used to identify countries also recognised by the department as free from LSD for trade purposes.

However, since late 2015 LSD has spread into some countries on the department's approved FMD-free country list. To address this issue, a separate list, the department's *LSD-Free Approved Country List,* for approved LSD-free countries has been created to address products with import conditions requiring freedom from LSD. The branch will maintain and update the list and provide this to ABIAB.

For the initial development of the department's list, the following factors were taken into consideration:

- history of trade with Australia and the department's knowledge of the competent authority as determined previously through the development and maintenance of the department's *FMD-Free Approved Country List*
- date of last report of LSD case
- LSD vaccination status of the country
- whether LSD is notifiable in the country in both domestic and wild animals
- LSD status of its neighbouring countries
- competent authority's reporting history to the OIE
- competent authority's ability for early detection of LSD
- competent authority's measures to respond to LSD spread.

Application of the DAWR LSD-Free Approved Country List

The department's *LSD-Free Approved Country List* is to be used by all areas of the department when determining whether a country is considered as free from LSD for trade purposes.

Departmental areas applying this list include those involved in:

- developing biosecurity policy and providing technical and scientific advice – for example, Animal Biosecurity Branch
- issuing permits—for example, Animal and Biological Imports Assessments Branch, Plant Import Operations Branch
- clearing goods (including pre-clearance based on documentation), mail and passengers — for example, Compliance Division.

These areas are to refer to the list when assessing import permit applications and issuing import permits for commodities that must be sourced from an LSD-free country. If a country is not recognised by the department as LSD- free or not yet assessed, then the exporting country will only be eligible to export LSD risk products to Australia where existing import conditions allow for that product to be sourced from unapproved countries. Typically this will require the product to be processed to manage the LSD risk - see *Table 1*. For LSD risk materials that do not require LSD country freedom, import conditions should reflect import policies and ensure LSD risks are managed through approved treatments or processes.

All areas should ensure they access the most recent version, available through the shared area of Animal Biosecurity's SharePoint site (permission to access the site is required):
http://mylink.agdaff.gov.au/team/abb/AB%20Shared%20Documents/Forms/AllItems.aspx

Administration of the DAWR LSD-Free Approved Country List

The current list is available publically via the department's biosecurity import conditions database, BICON, as well as on the SharePoint site.

Countries not listed are either LSD-affected or have not been assessed by the department for this purpose. Until a country is recognised by the department as free from LSD for trade purposes, it is not approved for the export of products to Australia, for which freedom from LSD is required.

Countries recognised in the list remain approved until a review of its status is triggered (for example, a confirmed or suspected outbreak of LSD).

A change in status of a country listed in the department's *LSD-Free Approved Country List* may be required if there is a confirmed or suspected presence of LSDV, or if vaccination for LSD has been performed in that country. Likewise, removal of recognition of freedom may also be prompted by changes in the country's ability to maintain LSD freedom, its LSD risk management measures (such as importing from countries that are not free from LSD), beginning vaccination against LSD, or its ability to verify/certify against the department's requirements. This information may be derived from a variety of sources, and may be the result of the scanning and intelligence gathering activities of the branch.

The list is regulated using a version control system. Any changes made to the list are recorded to ensure that the list remains up-to-date and the reasons for the changes are documented.

Notification regarding changes to the DAWR LSD-Free Approved Country List

The branch is responsible for notifying other relevant departmental areas when the list is revised/amended to add or remove a country based on its LSD status. This includes revisions to:

- remove recognition of a country's LSD-free status—for example, in the event that an LSD outbreak is confirmed in a previously approved country or its LSD status becomes questionable due to increased risks (for example, trade becoming established with countries of lesser LSD status) or concerns relating to the competent authority
- recognition of a country as free from LSD
- reinstatement of recognition of a country as free from LSD.

It is critical that even in the case of a suspected outbreak in a country on the department's *LSD-Free Approved Country list*, precautionary action is commenced. Officers in the Animal Biosecurity Branch are to refer to the Work Instruction *Animal disease outbreak in a foreign country – ABB evaluation and response* and associated *Disease outbreak in a foreign country* form when an outbreak is suspected, both of these documents are found on the branch's SharePoint site[3]. This work instruction prompts officers to consider the credibility of information available, the potential impact on the biosecurity risk of exports to Australia, and the action to be undertaken on this basis. Whenever there is an outbreak of significance in a foreign country, the branch must distribute an outbreak alert to relevant departmental areas. An outbreak alert template is available in the Work Instruction *Animal disease outbreak in a foreign country – ABB evaluation and response* and associated *Disease outbreak in a foreign country* form.

If changes to the list occur, the branch is to provide formal advice (see template – *'notification – outbreak in LSD-free approved country*[4]), along with an outbreak alert, to the relevant departmental areas outlining the

[3] http://mylink.agdaff.gov.au/team/abb/Resources/Forms/AllItems.aspx
[4] Insert site

revisions to the list and any recommended action. The branch will collaborate with relevant operational and permit-issuing areas to notify stakeholders of any changes to the list. This includes working together to draft BICON alerts and other messages to stakeholders.

The branch is also responsible for notifying other areas in the department of any current or planned activity to evaluate a country's LSD status. However, any such country continues to be considered unlisted and unapproved for import purposes until approval has been granted and the department's *LSD-Free Approved Country List* updated accordingly.

There are circumstances in which there is a change to the LSD status of a country that does not affect the department's *LSD-Free Approved Country List*. This includes instances when, a country provides notification of an LSD outbreak, and when a country declares freedoms from LSD, for which the department is not recognising/has not yet recognised as free from LSD.

To avoid confusion in this situation, an internal notification from the branch to relevant departmental officers should be issued along with an outbreak alert. The notification also reminds officers that the department's *LSD-Free Approved Country List* is to be used when assessing whether the country is considered to be LSD-free for trade. Such a notification also serves as a record that the branch was aware of, and appropriately responded to, relevant events. A sample template for this notification is provided in the LSD branch package[5]. This should be adapted to the specific circumstances in which it is to be used.

Determining the suspension period

Accurately determining the date of first disease incursion is difficult. For this reason the branch generally recommends the suspension of trade in all relevant LSD risk materials collected, produced or manufactured within 56 days of the 'start date' of the outbreak as assessed by the branch. The period of 56 days is twice the maximum incubation period for LSD specified by AUSVETPLAN and the OIE (Animal Health Australia 2009). Please note, the start date may be modified as more information about the outbreak becomes available, particularly the identification of the primary case, which is usually not known with confidence until later in the outbreak investigation.

When determining any suspension period, the risks associated with the specific commodities in question and the circumstances of the outbreak are considered. For example, higher risk products such as ruminant hides and skins collected prior to 56 days before the outbreak but stored in that affected country may be considered ineligible for export to Australia. Scenarios such as these will be considered on a case-by-case basis.

The branch may approach the competent authority of the relevant country seeking clarification and/or further information to inform its decision-making.

Once the start date of outbreak and therefore the suspension period have been determined, operational and permit-issuing areas are responsible for taking appropriate action, taking into consideration of the recommendations from the branch, including revocation or amendment of existing permits, and notifying affected stakeholders.

The branch is responsible for monitoring the outbreak situation for events/issues of relevance and providing updated advice to the relevant areas as necessary.

[5] Add site

5.3 The Animal Biosecurity Branch LSD evaluation process

Prioritisation of evaluations

An evaluation of a country's LSD status is a significant piece of work that requires appropriate resourcing and needs to be prioritised and planned along with other activities undertaken by the department. This prioritisation process takes into account the level of trade that may be facilitated by the evaluation, and genuine commercial interest in market access. The branch will develop an annual work plan identifying evaluations according to the priority determined and dependent upon available resources.

LSD evaluation process

The branch has established processes for evaluating a country's LSD status for trade purposes. A suite of guidance documents and templates, the *Competent Authority Toolkit Package*, have been developed by the branch to assist with conducting these evaluations. This package is found on the branch's SharePoint site[6].

Generally an evaluation includes requesting a completed questionnaire from the applicant competent authority, a desk assessment, planning and conducting an in-country verification visit, completing a draft report and seeking feedback on its factual content, before completing the final report and finalising the evaluation. The draft and final reports for the evaluation are considered to be in-confidence between the Australian and applicant country's government. It is not currently the branch's intention for these reports to be published on the department's website.

The reasons for an evaluation of a country's LSD status being performed are also taken into consideration in formation of the scope of the evaluation. For example, if it is being conducted with the aim of facilitating market access for a specific commodity, the LSD evaluation may be combined with an evaluation of that specific commodity and any specific import conditions (for example, treatments or tests) relevant to that commodity.

This means that the LSD evaluation may encompass elements of a broader competent authority evaluation, commodity evaluation and/or evaluation of specific treatments/tests, depending on the request. Careful planning and discussions about the scope of the evaluation are critical.

Determining dates of recognition of freedom and commencement of trade

Recognition of freedom from LSD for trade purposes is typically effective from the date on which an LSD evaluation of an exporting country is successful and finalised. This is the date on which the final report was completed and cleared by the relevant Senior Executive Service officer (the Assistant Secretary of the branch). However, if the evaluation recommends a definitive alternative date from which freedom should be recognised, then that date will be applied. Products collected, produced or manufactured from the assigned date may be eligible for importation, provided the commodity meets all other import requirements. Those products collected, produced or manufactured before this time typically remain ineligible for importation.

For commodities containing LSD risk materials which were collected or manufactured prior to a country being assessed and included on the department's *LSD-Free Approved Country List*, case-by-case advice may be required on the potential LSD risk. Veterinary vaccines, veterinary therapeutics and other biological products for *in vivo* use, particularly cell lines and master seeds, are the most likely commodities to contain such material as they can be established and maintained over long periods of time.

The branch will advise operational and permit-issuing areas of appropriate dates of recognition for use on import permits, BICON cases and other materials as required.

[6] http://mylink.agdaff.gov.au/team/abb/Resources/Forms/AllItems.aspx

6 Further Animal Biosecurity Branch resources

6.1 Branch guidelines and import policies

- *Competent Authority Evaluation Toolkit Package*
- *Disease outbreak Alert Package*
- Fresh (chilled or frozen) beef and beef products from Japan, the Netherlands, New Zealand, the United States and Vanuatu
- IRA for the *Importation of dairy products into Australia for human consumption*
- *IRA for the Importation of dairy products into Australia for human consumption*
- *Guidelines on the import conditions for ornamental animal products*
- *IRA for Hides and Skin*
- *Guidelines on the import conditions for mammalian hides and skins from all countries*
- *Guidelines for the importation of biological materials ('Green Book')*
- *Guidelines on the policy for imported stockfeed of plant origin ('Plant-Based Stockfeed Guidelines')*
- *Guidelines for the quarantine assessment of pet food ('Pet Food Guidelines').*

6.2 Example documents

- LSD preventative vaccination responses
    - Croatia

      Electronic network folder: s. 47E(d)

- LSD outbreak responses
    - Georgia

      Electronic network folder: s. 47E(d)

    - Albania

      Electronic network folder: s. 47E(d)

    - Bulgaria

      Electronic network folder: s. 47E(d)

    - Macedonia

      Electronic network folder: s. 47E(d)

    - Serbia

      Electronic network folder: s. 47E(d)

- Montenegro

  Electronic network folder: s. 47E(d)

- Cyprus

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8 Detailed version history

Version Number	Version Date	Amendment Details
Version 1		-

Australian Government
Department of Agriculture, Water and the Environment

Instruction & Guideline

Guidelines on the management of the country biosecurity risks of bovine spongiform encephalopathy (BSE) in imported commodities

Document owner Animal Biosecurity Branch **Version Number V1.0**

Availability Internal use only **Published Date 12/06/2020**

Summary of main points

- This document provides guidance to officers of Animal Biosecurity Branch (the branch) on the process for recognising the BSE status of countries, applying the department's *Bovine spongiform encephalopathy (BSE) Country List*, and responding to BSE cases reported by a trading partner.
- The BSE status of the country of origin and/or manufacturing of a commodity underpins the department's risk management measures for this disease.
- The BSE status of a country is based on a Competent Authority (CA) assessment. Exceptions in conducting a full competent authority assessment have been established for countries where compliant trade has been underway for a number of years. A country's World Organisation for Animal Health (OIE) BSE status is considered a component of the CA assessment, and contributes to the branch decision on country status. In addition, Food Standards Australia New Zealand (FSANZ) BSE food safety risk assessments are the basis of recognition for BSE country status for imported foods for human consumption.
- The branch monitors for BSE cases of epidemiological significance, and developments in the scientific literature, and provides advice to operational areas as required. The branch also contributes to domestic and international programs/standards on BSE.

1 Contents

2 Acronyms and abbreviations

ALOP	appropriate level of protection
AUSVETPLAN	the Australian Veterinary Emergency Plan
branch	Animal Biosecurity Branch
BSE	bovine spongiform encephalopathy
CA	Competent Authority
Code	OIE Terrestrial Animal Health Code
DAWE	Department of Agriculture, Water and the Environment
department	Australian Government Department of Agriculture, Water and the Environment (formerly the Department of Agriculture, Department of Agriculture and Water Resources, and the Department of Agriculture, Fisheries and Forestry)
FMD	foot-and-mouth disease
FSANZ	Food Standards Australia New Zealand
IFIS	Imported Food Inspection Scheme
OIE	World Organisation for Animal Health
PrP	prion protein, encoded by the gene PRNP, expressed by many cell types and many organisms
PrP^{C}	normal cellular prion protein (normal isoform)
PrP^{Res}	protease resistant prion protein (abnormal isoform resistant to enzymatic breakdown)
SPS Agreement	World Trade Organization Agreement on the Application of Sanitary and Phytosanitary Measures
TSEs	transmissible spongiform encephalopathies

vCJD	variant Creutzfeldt-Jakob disease
WAHID	World Animal Health Information Database
WAHIS	World Animal Health Information System
WTO	World Trade Organization

3 Glossary

Term	Definition
abnormal prion protein	Pathogenic (protease-resistant) isoforms of prion protein that are infectious (PrP^{Res}). Various types and strains identified on basis of molecular conformation, distribution in the central nervous system, species affected and disease presentation.
appropriate level of protection	Under the SPS Agreement, WTO members are entitled to maintain a level of protection they consider appropriate to protect life or health within their territory, known as the appropriate level of protection (ALOP). The ALOP for Australia is a high level of sanitary and phytosanitary protection aimed at reducing biosecurity risks to a very low level, but not to zero.
atypical BSE	A sporadic and spontaneous form of BSE of very low prevalence found in older cattle, and considered not linked to the consumption of feed contaminated with abnormal prion protein. Two types (L-type and H-type) have been identified. Occurrence is not considered for the purpose of OIE official BSE risk status (i.e. a detection does not change the existing country status).
biosecurity	The concept of protecting a population/country/region/environment from the introduction and establishment of undesirable pests and diseases of animals (including humans) and plants.
BSE approved country list	List of countries evaluated by the department and assigned a BSE risk status used for the assessment of BSE-risk materials for export to Australia.
case	An individual animal infected by a pathogenic agent, with or without clinical signs (OIE 2019).
commodity	Live animals, products of animal origin, animal genetic material, biological products and pathological material (OIE 2019).
Competent Authority	Veterinary Authority or other Governmental Authority of a [member] country having the responsibility and competence for ensuring or supervising the implementation of animal health and welfare measures, international veterinary certification and other standards and recommendations in the OIE Terrestrial Animal Health Code and in the OIE Aquatic Animal Health Code in the whole territory (OIE 2019).

Term	Definition
country	For the purpose of this document, 'country' also includes defined zones. It is noted that the department has not yet assessed the BSE status of any zones, and therefore does not currently recognise any BSE zones for trade purposes. However, the department's evaluation of a country's or zone's freedom from BSE follows the same process. The evaluation considers the specific BSE and trade risks for the applicant country/zone, and therefore any heightened risks that may be associated with specific zones would be assessed accordingly.
fomite	Inanimate object that can become contaminated with an infectious agent and serve as a mechanism for transfer of that agent between an infected animal and a susceptible animal or to the environment of a susceptible animal.
FMD-free approved country list	List of countries evaluated and approved by the department as free from foot-and-mouth disease for the export of certain commodities to Australia.
food safety	Regulation of imported food products intended for human consumption with the aim of lowering the incidence of foodborne illness (does not apply to non-food products for human consumption e.g. medicines, or to animal feed products).
import proposal	A generic term used to describe a proposal to bring plants, animals or other goods into Australia in circumstances where import conditions have not been established (Department of Agriculture and Water Resources 2016).
incubation period	Longest period which elapses between the introduction of the pathogenic agent into the animal and the occurrence of the first clinical signs of the disease (OIE 2019).
market access request	Import proposal provided to the department by government authorities of an exporting country (Department of Agriculture and Water Resources 2016).
outbreak	Occurrence of one or more cases in an epidemiological unit [that is, a group of animals with a defined epidemiological relationship] (OIE 2019).
prion	Ubiquitous glycoprotein mostly located at cell surface (PrP^C) with currently unresolved function (possibly scaffold protein helping assembly of various multicomponent signalling modules at cell surface (Linden 2017). Term 'prion' coined from 'protein-only infectious particle' on the basis of original identification of abnormal conformers of PrP^C identified in studies of transmissible spongiform encephalopathies (TSEs). Abnormal conformers named according to prion disease caused (see abnormal prion protein).
risk analysis	A generic term referring to the technical or scientific process for assessing biosecurity risk and the development of risk mitigation measures (Department of Agriculture and Water Resources 2016); a process composed of hazard identification, risk assessment, risk management and risk communication (OIE 2019).

Term	Definition
risk assessment	Evaluation of the likelihood and the biological consequences of entry, establishment and spread of a hazard (OIE 2019).
risk management	Process of identifying, selecting and implementing measures that can be applied to reduce the level of risk (OIE 2019).
Veterinary Authority	Governmental Authority of a member country, comprising veterinarians, other professionals and para-professionals, having the responsibility and competence for ensuring or supervising the implementation of animal health and welfare measures, international veterinary certification and other standards and recommendations in the *Terrestrial Code* in the whole territory (OIE 2019).
Veterinary Services	Governmental and non-governmental organisations that implement animal health and welfare measures and other standards and recommendations in the *Terrestrial* Code and the OIE *Aquatic Animal Health Code* in the territory. The Veterinary Services are under the overall control and direction of the Veterinary Authority. Private sector organisations, veterinarians, veterinary paraprofessionals or aquatic animal health professionals are normally accredited or approved by the Veterinary Authority to deliver the delegated functions (OIE 2019).
zone/region	Part of a country defined by the Veterinary Authority, territory containing an animal population or subpopulation with a specific animal health status with respect to an infection or infestation for the purposes of international trade or disease prevention or control (OIE 2019).

4 Introduction

4.1 Purpose

The document has been developed to ensure consistency in the process in which the BSE status of a country is determined and recorded by Animal Biosecurity Branch (on behalf of the department), and the application of this status in determining the eligibility for certain products for importation into Australia. In this document, **unless stated otherwise, the use of the term 'BSE' refers to classical BSE** (C type).

The guideline is intended to be used in conjunction with existing branch policies, guidelines, minutes and other advice on regulatory imports to manage BSE risks (see Section 8).

4.2 Scope

This document provides background and general guidance for officers in the branch on:

- the BSE risk classification of countries and its application as a risk management measure
- the development and maintenance of the department's *BSE Approved Country List*
- responding to BSE cases reported by trading partners.

All other TSEs are outside the scope of these guidelines.

This document does not provide guidance on BSE risk management measures in specific import policies, or import requirements. Officers should consult the relevant import policies and/or policy advices for this information.

For guidance on conducting CA evaluations officers are directed to the branch CA evaluation guidelines and toolkit. These are available on the branch SharePoint site: Resources - Competent Authority Toolkit Package

This document does not focus on the branch's activities in disease intelligence, scanning or reporting, nor on the process of commenting on OIE documents relating to BSE.

These guidelines are not applicable to the management of a BSE outbreak in Australia. Refer to the Australian Veterinary Emergency Plan (AUSVETPLAN) for the relevant BSE emergency response information.

5 Background

5.1 BSE – brief summary

BSE is an infectious, but not contagious, fatal neuro-degenerative disease in cattle caused by the proliferation and accumulation of abnormal prion protein (forming as amyloid fibrils) in the central nervous system. Grey matter vacuolation in the brain is associated with the deposition of the abnormal prion protein. The disease has occurred in cattle from the feeding of products containing the BSE prion protein such as meat and bone meal. Ingestion of a range of bovine tissues obtained from infected cattle is also known to cause transmissible spongiform encephalopathies in other animal groups such as felines (feline spongiform encephalopathy) and humans (vCJD). A range of species are susceptible by parenteral routes.

Atypical BSE (H and L strains) is a neuro-degenerative disease in cattle believed to be spontaneous in older animals. The disease form was initially identified during large scale, active BSE surveillance programs in Europe, and is now reported sporadically and with a very low prevalence in cattle populations globally. Oral transmission of L-type atypical BSE has been demonstrated (Okada et al. 2017) indicating a potential for recycling and amplification in cattle populations if atypical BSE cases were not effectively removed from the feed chain. The OIE official recognition for BSE-risk status applies only to classical BSE. Reported cases of atypical BSE in cattle do not impact on BSE-risk country status, on the basis that measures to avoid exposure in the ruminant feed chain are in place.

The ability to treat and deactivate abnormal prion protein is extremely limited because of the protein's inherent stability. Its significant resistance to physical, chemical and enzymic breakdown means destructive treatments used for viral and bacterial pathogens are generally ineffective for treatment of BSE prion protein. Detection of the abnormal prion protein in animals is limited to post-mortem diagnostic testing of specified sites in the brains of affected animals.

5.2 BSE – Relevance to Australia

All forms of BSE are nationally notifiable in Australia, however no BSE cases in cattle have been detected to date despite significant numbers of cattle being tested through the national TSE surveillance project, a component of the TSE Freedom Assurance Project.

Two cases of feline spongiform encephalopathy, caused by the BSE agent, have been identified in Australia in imported zoo felids (1992 and 2002). The animals were thought to have been infected through consumption of meat obtained from BSE affected cattle prior to importation from Europe, and are the only cases of BSE related infection detected in animals in Australia to date.

The OIE is the WTO designated international reference organisation for standards relating to animal health, and provides official recognition of country (and zone) disease status for a number of diseases, including BSE. Australia has been assessed by the OIE as a 'negligible' BSE risk country. The Australian Ruminant Feed Ban, institutionalised in 2001, forms part of the basis for Australia's recognition as a 'negligible' BSE risk country, the assessment based on epidemiological information, risk prevention methods, surveillance measures and reporting history.

Australia has a risk-based approach to biosecurity management and its ALOP is stated as 'providing a high level of sanitary and phytosanitary protection, aimed at reducing risk to a very low level, but not zero' (Department of Agriculture and Water Resources 2016). If the level of risk associated with the importation of a specific commodity is deemed to exceed Australia's ALOP, biosecurity measures are recommended to reduce the risk to an acceptable level. If it is not possible to reduce the level of risk to an acceptable level i.e. meet the ALOP, trade is not permitted.

Due to the consequences of a BSE outbreak in Australia, a combination of risk management measures is generally required to meet Australia's ALOP.

BSE risk management measures limit imports to:

- countries recognised by the department as negligible BSE risk, or controlled BSE risk, (that is, approved countries that have been evaluated by the department), and/or
- commodities/products containing or made from tissues/secretions/excretions that on the basis of scientific review have been deemed not to present a BSE risk (i.e. scientifically assessed as not sites for deposition of abnormal prion protein responsible for BSE), and/or
- end uses that do not expose susceptible species to assessed commodities/products e.g. therapeutic use in non-susceptible species.

NOTE:
- Import policies may recommend that trade in BSE risk materials be restricted to approved countries; restricted to materials that do not contain risk tissues; restricted to certain end uses, and/or a combination of a range of other measures.
- Alternative risk management measures cannot be substituted for the requirement for a commodity to be sourced from a country whose BSE risk has been assessed, unless a risk assessment has concluded otherwise.
- If the risk cannot be managed to meet Australia's ALOP, or a policy does not exist for the commodity in question, trade is **not** permitted.

5.3 BSE and safety of imported food for human consumption in Australia

All beef and beef products for human consumption imported into Australia must comply with Australia's biosecurity **and** food safety requirements.

In 2009, the Australian Government updated its long-standing policy for BSE and food safety - *Bovine Spongiform Encephalopathy (BSE): Requirements for the importation of beef and beef products for human consumption – Effective 1 March 2010*. The revision was undertaken to recognise the findings of an independent scientific review in 2009 that reported a strengthening of international BSE controls and assessed the risk of future variant Creutzfeldt-Jakob disease (vCJD) food-borne transmissions to be very low. The policy requires exporting countries, irrespective of whether they have had a case of BSE, to demonstrate that acceptable and verified risk mitigation processes are in place to address BSE risk in food safety, as indicated through animal health controls, traceability, surveillance, appropriate feeding and slaughter and processing practices.

Under the policy, FSANZ conducts BSE food safety risk assessments against established criteria and categorises countries that have applied for assessment. This includes, where necessary, an in-country assessment, to verify the application of BSE risk management measures.

Countries, as part of the BSE policy, must submit annually to FSANZ for review of status. An officer from the branch represents the department on FSANZ's Australian BSE Food Safety Assessment Committee that oversees the assessment process and annual country status reviews. FSANZ notifies the department of the results of its process for each new country that is categorised (or for a country whose categorisation changes as result of annual review, or other information indicating change in circumstances).

For beef and beef products for human consumption, the FSANZ category will apply to address to satisfy the Australian food safety requirements.

On completion of a FSANZ assessment, branch negotiations commence with the exporting country to institute an approved sanitary health certificate for retorted beef or beef products, or heat-treated, shelf-stable meat-based flavours for human consumption, addressing sanitary requirements for both food safety and biosecurity for eligible products. Imports of these products using the agreed sanitary certificate can then commence, with food safety compliance monitored through the department's Imported Food Inspection Scheme (IFIS).

The department has biosecurity import conditions for fresh (chilled or frozen) beef and beef products for human consumption from Japan, the Netherlands, New Zealand, the United States and Vanuatu only. Competent Authority assessments undertaken by the branch of the fresh beef production and processing systems in these countries is used to determine the country's ability to comply with the import requirements for diseases **other than** BSE.

5.4 Department policies which contain biosecurity (or human food safety) measures for BSE

The following import policies contain biosecurity measures for BSE:

- beef and beef products for human consumption
- natural sausage casings for human consumption
- live ruminants – cattle, sheep, goats, camelids, deer and zoo bovids
- ruminant meat and derivatives for petfood
- ruminant genetic material – semen and embryos
- stockfeed of plant origin
- stockfeed and fertilisers of animal origin
- fishmeal for stockfeed
- hides and skins
- biologicals derived from BSE-susceptible species destined for *in vivo* use (veterinary, medical, agricultural, environmental)
- importation of infectious agents (viable pathogens that include prions)
- importation of laboratory materials containing risk material.

There are other import commodities that may pose a biosecurity risk by acting as fomites for abnormal prion proteins, for example farm equipment, veterinary instruments, and soil. The branch provides recommendations to operational areas on risk management measures for such articles, as required.

5.5 Role of Animal Biosecurity Branch in BSE import risk management

To assist operational areas in the consistent application of BSE risk management measures, the branch performs a range of tasks that include:

- evaluating the disease status of countries, and the operations of the relevant CA, and their eligibility to export certain risk materials to Australia
- maintaining the department's *BSE Approved Country List,* a list of countries recognised by the department as negligible BSE risk or controlled BSE risk for trade purposes, and providing this list to operational and permit-issuing areas of the department
- providing advice to operational and permit-issuing areas on BSE outbreaks of epidemiological significance and briefing the department's senior executives and minister as required
- contributing to international and domestic BSE standards and policies.

NOTE:

- The branch has a number of responsibilities for managing the biosecurity risks of imported BSE risk materials. It develops, reviews and provides advice on biosecurity import policies; evaluates the BSE status of countries and the relevant CA for trade purposes; maintains the department's *BSE Approved Country List*; monitors and advises on BSE outbreaks of epidemiological significance in trading partners; contributes to domestic and international standards on BSEs; and assists in administering Australia's BSE food safety policy.

6 Animal Biosecurity Branch BSE country evaluation process

6.1 Factors triggering an evaluation

The department's evaluation includes an assessment of a country's relevant animal health, production, traceability, product integrity, inspection and certification systems. It also considers the ability of the CA to prevent the BSE prion protein from entering the country, to detect the disease if livestock were exposed and infected, and the ability to implement Australia's risk management measures if the disease is known to be (or likely to be) present e.g. preventing risk animal tissues from contaminating exports to Australia.

Potential triggers for an initial evaluation or re-evaluation of a country's BSE status may include:

- a change in the OIE's or FSANZ assessment of BSE status
- a confirmed or suspected presence of BSE
- a formal application for evaluation is received from the country's CA
- changes in the country that affects the department's confidence in its status, or the CA's ability to maintain that status; including changes to the CA or the CA's ability to verify/certify against the department's requirements, changes in BSE risk management policy and practice, and trade commencing with countries of a lesser status.

Information in relation to CA performance, or change in disease risk may be derived from a variety of sources. The OIE code requires members to report through the World Animal Health Information System (WAHIS) the first occurrence of a listed disease, or its re-occurrence after eradication. OIE members are also required to submit six-monthly reports on the absence or presence and evolution of listed diseases and information of epidemiological significance. Information may also be obtained directly from trading partners. The branch conducts scanning and intelligence gathering activities so as not to only rely on official disease reporting mechanisms e.g. Intelliriver monitoring. Feedback and reports from departmental operational areas, and state/territories authorities on the compliance irregularities detected at the border and post border may indicate the need to review the CA verification and certification processes.

Government initiated market access requests and commercial import proposals can also influence the decision to undertake an evaluation. Commencement of an evaluation will be dependent on branch prioritisation and other existing market access requests.

NOTE:

- Removal and/or re-assessment of the recognition of a country's BSE status may be the result of the confirmed or suspected presence of the particular prion protein disease, or changes that affect confidence in its ongoing freedom or certification.
- Information that results in these changes may come from a number of sources.

6.2 BSE evaluation process

The branch accepts the BSE food safety category assigned by FSANZ (as an equivalence to the department approval process), but applies the departmental equivalent category in the department's *BSE Approved Country List* (as shown in Table 1 below) in all cases excepting beef and beef products for human consumption. Because international health certificates for these products are also used for IFIS clearance, the branch has agreed that the FSANZ nomenclature be applied in these cases to reduce the need for unnecessary (and confusing) declarations. This is particularly relevant for countries where English is not the first language.

Table 1

FSANZ BSE Food Safety Risk Category	Department BSE Country Risk Category
Category 1	Negligible BSE Risk
Category 2	Controlled BSE Risk
Category 3	Undetermined

For an explanation of how the department implements FSANZ categorisation for imported beef and beef products, see Section 5.3.

In determining a country's BSE risk status the branch takes into account the OIE official recognition for BSE-risk status, but does not automatically accept that status. Some of the reasons that the branch has chosen to undertake separate assessments from the OIE are:

- The process does not include in-country verification of the information provided to the OIE in the questionnaire and the application submission (although regional visits may occur occasionally).
- The process lacks transparency –reports and records of the decision making process are not available to other OIE members for scrutiny.
- The outcome of the reports and subsequent recommendations may be affected by political conflicts of interest of OIE Scientific Commission for Animal Diseases (SCAD) members.
- The OIE SCAD process does not include a full evaluation of the veterinary services of the requesting member country which may impact on the future country BSE risk. The OIE requires an applicant country to provide an annual statement to confirm the country status. A full review of BSE status is not carried out unless it is determined there is a significant change in circumstances.

The strength of knowledge of the responsible CA, and the history of regular, compliant trade in animals and animal products, will be taken into account in any decision on the classification of country BSE risk status, reflecting the approach taken for the department's *FMD-Free Approved Country List*.

A country that has not previously been assessed by the branch, either as a new trading partner having limited trade history with Australia, or upgrading their OIE status from undetermined BSE risk, will generally be asked to undergo an in-depth evaluation of its BSE animal health controls, CA, and associated systems. The country will need to provide a detailed technical submission supporting the claim for country freedom. As an example, the country should provide its OIE submission, and the official OIE report on the country's application which will be assessed against the recommendations of the OIE code (country submissions and the OIE's assessments of them are not publicly available and the OIE will not provide them to other countries).

Should a country that is on the department's *BSE Approved Country List* as controlled BSE risk, be upgraded by the OIE to negligible BSE risk, the country will need to undergo some form of evaluation before being updated on the department's *BSE Approved Country List*. The extent of the evaluation would be dependent on the evidence being provided in support of the change. If the country is participating in the FSANZ BSE food safety risk assessment process, then a decision to update the department's *BSE Approved Country List* should be delayed until the department receives advice from FSANZ on the BSE food safety status.

Imports of animals, animal products and commodities, for which BSE import requirements exist, should not be processed for an unassessed country until such time as an evaluation of that country has been completed by

the branch, or in the case of beef and beef products for human consumption, FSANZ.

NOTE:
- There are a number of considerations for the branch in evaluating a country's status for BSE. The branch recognises assessments conducted by FSANZ, but does not accept OIE assessments without conducting its own assessment of a country's BSE status.
- Imports of animals, animal products and commodities which pose a BSE risk, should not be processed for an unassessed country. The department requires a CA evaluation prior to permitting imports, or in the case of beef and beef products for human consumption, a FSANZ BSE risk country assessment.

6.3 The response of Animal Biosecurity Branch to BSE outbreaks in trading partners

Action by Animal Biosecurity Branch is required when a BSE case is reported in a previously negligible BSE risk country. Even in the case of a suspected outbreak (i.e. prior to official confirmation), precautionary action may be required. Reports of atypical BSE do not impact on the OIE or FSANZ categorisation for country risk, and are not deemed to be a change in risk unless there is evidence that these animals are not being appropriately disposed of and removed from the human and animal feed chain.

For guidance on responding to an animal disease outbreak involving a trading partner, officers are directed to the branch Disease Outbreak Alert Package. The work instruction prompts officers to consider the credibility of information available, the potential impact on the biosecurity risk of exports to Australia, and the action to be undertaken. Existing trade that may be affected by a (possible) outbreak needs to be promptly identified to minimise the likelihood of risk materials from the outbreak country arriving in Australia and being released from biosecurity control.

Written advice to operational and permit-issuing areas should be considered, and is required in the event that the branch recommends the review of trade, or a change in risk management measures. An example response template is provided in the work instruction and should be adapted to the specific circumstances.

When determining any suspension period, the risks associated with the specific commodities in question and the circumstances of the outbreak are considered on a case-by-case basis. The branch may need to approach the CA of the relevant country seeking further information to inform its risk assessment. Depending upon the available information, suspension of all trade in relevant commodities may be recommended, regardless of the date of collection, production or manufacture.

The branch is responsible for monitoring the outbreak situation and providing updated advice to the relevant areas as necessary. Operational and permit-issuing areas are responsible for taking appropriate action, taking into consideration the recommendations from the branch, including revocation or amendment of existing permits, and notifying affected stakeholders.

NOTE:
- The branch has established procedures for responding to reports of disease outbreaks overseas.
- Officers in the branch should consider the merits of commencing precautionary action, even in the event of suspected (unconfirmed) outbreaks. This may include requesting further information from the relevant CA.
- The branch needs to closely collaborate with operational and permit-issuing areas to ensure relevant action is taken and stakeholders are informed.

6.4 Determining dates of recognition of freedom and commencement of trade

Because of the long incubation period of BSE (usually measured in years), it is very difficult to accurately determine the date of first disease incursion. The 'start date' for any suspension period is therefore determined by the branch on a case-by-case basis, giving consideration to the specific BSE strain and other relevant circumstances.

Commodities with BSE specific import requirements collected or manufactured prior to a country being assessed (and included on the department's *BSE Approved Country List*), need to be assessed on a case-by-

case basis after consideration of the specific circumstances. Veterinary vaccines, veterinary therapeutics and other biological products, particularly cell lines and master seeds, are the most likely commodities to contain such material as they can be established and maintained over long periods of time.

In the case of an outbreak of BSE in listed country, the branch will advise operational and permit-issuing areas in writing of appropriate dates of recognition for use on import permits, BICON cases and other materials as required.

NOTE:

- The risks of imports of commodities produced before the date that an assessment is completed require case-by-case consideration.
- Because of the long incubation period of BSE, it is very difficult to determine the date of first disease incursion. The branch generally recommends the start (production) date for any suspension period is determined on a case-by-case basis (country and commodity), after consideration of the specific circumstances. The date from which trade is suspended may also be revised as new information is discovered.

7 Department of Agriculture, Water and the Environment (DAWE) BSE Approved Country List

7.1 Application of the DAWE BSE Approved Country List

The department's *BSE Approved Country List* should be used by all areas of the department when referring to the BSE status of a trading partner. For beef and beef products for human consumption, the FSANZ category will apply to address the Australian food safety requirements.

The application of the *BSE Approved Country List* across the department aims to ensure consistency throughout the department. Areas that need to reference the *BSE Approved Country List* include those involved in:

- issuing permits and maintaining BICON cases e.g. Animal and Biological Imports Branch; Plant Import Operations Branch
- clearing goods (including pre-clearance based on documentation), passengers and mail and conducting investigations and enforcement activities e.g. Biosecurity Operations and Compliance Divisions.

Officers in these areas need to consult the list when assessing imported goods or issuing import permits for commodities that have import conditions relating to BSE. If an assessment of a country of export/manufacture/source and its listing has not been completed, the branch expects that importation of applicable commodities from that country will not be permitted until a CA evaluation has been completed.

Some countries appearing on the department's *BSE Approved Country List* have approval restricted to specific commodities (i.e. plant-based stockfeed products). This approval **does not** automatically extend to, or should be extrapolated to, other commodities. Further assessment would be required for these countries to gain market access for these other commodities presenting a BSE risk to ensure appropriate CA oversight and certification processes can be provided.

Certain Pacific island nation members of the Secretariat of the Pacific Community, formerly the South Pacific Commission, have been included on the department's *BSE Approved Country List* on the basis of history of trade and other factors including facilities audits, allowing trade in a limited range of plant-based stockfeeds and their derivatives. Officers should refer to the branch's *Guidelines on biosecurity requirements for imported plant based stockfeed* and *Importation of stockfeed and stockfeed ingredients – TSE risk management measures* for further information, in conjunction with the department's *FMD-Free Approved Country List*.

All areas of the department should have access to the most recent version of the department's *BSE Approved Country List.* The current *BSE Approved Country List* version will be available through BICON and the shared area of the branch's SharePoint site.

NOTE:
- All departmental areas should refer to the *BSE Approved Country List* when assessing import permit applications and import consignments for commodities that require BSE risk management measures.
- Some countries appearing on the department's BSE Approved Country List have approval restricted to specific commodities (i.e. plant-based stockfeed products). This approval **does not** automatically extend to, or should be extrapolated to, other commodities.

7.2 Administration of the DAWE BSE Approved Country List

Assessments remain current until a review of country status is triggered and any revised assessment is re-issued by the branch, through the department's *BSE Approved Country List* (see Section 7.112). The list is maintained using a version control system so that any changes made are recorded, the reasons for the changes and responsible officers are documented, and users can check that they are using the current version.

The branch is responsible for notifying other relevant departmental areas of assessments that:

- downgrade a country's assessment to a less favourable status
- upgrade a country's assessment to a more favourable status
- determine a country's BSE status for the first time.

In these cases, the branch must provide written advice to the relevant departmental areas outlining the assessments, any revisions and recommended actions. Collaboration with the relevant operational and permit-issuing areas should occur as required e.g. preparing stakeholder notifications, advising on alternative wording for permit conditions, information for border staff and briefings for the executive.

There are circumstances in which there can be an outbreak or a change to the OIE's recognition of one of its Member Country's BSE status that does not affect the department's *BSE Approved Country List*. This includes instances when, due to the notification of a BSE case, the OIE downgrades its recognition of 'negligible' BSE risk to 'controlled' BSE risk for a country that is already recognised by the department as controlled BSE risk. The reverse can also apply i.e. when the OIE confers (or reinstates) a 'negligible' BSE risk or 'controlled' BSE risk status for a country which the department has not assessed or has assessed as a lower status.

The change in the OIE's recognition, as well as reports of atypical BSE, may generate media attention. In these cases, an internal notification from the branch to relevant departmental officers should be considered to communicate the department's position on these reports, and their impact. The notification is also an opportunity to remind officers that the department's *BSE Approved Country List* is to be used when determining a country's status. The notification will serve as a record that the branch appropriately responded to relevant events. Example notifications of this kind are linked in Section 8.4 below.

NOTE:
- The current version of the department's *BSE Approved Country List* will be available through BICON and on the branch's SharePoint site. The list may be published on the department's website and will be incorporated into relevant BICON entries. This guideline however is an internal use document and not for distribution externally.
- The branch is responsible for notifying operational and permit-issuing areas of any changes to the *BSE Approved Country List*. These areas are then responsible for applying the relevant department approved country status when assessing import applications, issuing import permits and preparing relevant information for stakeholders e.g. BICON alerts.

8 Further information and Animal Biosecurity Branch resources

8.1 Australia's international trade obligations

As a Member of the World Trade Organization (WTO), Australia adheres to the WTO *Agreement on the Application of Sanitary and Phytosanitary Measures* (SPS Agreement).

The SPS Agreement defines the concept of an appropriate level of sanitary or phytosanitary protection as 'the level of protection deemed appropriate by the Member establishing a sanitary or phytosanitary measure to protect human, animal or plant life or health within its territory'. The agreement directs that measures are based on harmonised international standards unless an assessment of risk deems that a higher level of protection is required. The OIE is the WTO designated international reference organisation for standards relating to animal health.

Providing information to the OIE is an international legally binding obligation for Member Countries (Vallat et al. 2013). Among other requirements, Member Countries of the OIE are required:

> *to make available to other Member Countries, through the OIE, whatever information is necessary to minimise the spread of important animal diseases, their aetiological agents, and to assist in achieving better worldwide control of these diseases.*

This includes providing a notification through the OIE's World Animal Health Information System (WAHIS) within 24 hours of the first occurrence of a listed disease, infection or infestation in a country, a zone or a compartment. The OIE's World Animal Health Information Database (WAHID) provides access to all data contained in WAHIS.

8.2 The OIE and BSE

The OIE publishes standards on BSE risk management in the OIE code that can be applied to international trade, and standards for diagnostic tools for BSE in its *Manual of diagnostic tests and vaccines for terrestrial animals.*

The OIE criteria for determining BSE risk status for a country, zone or compartment are detailed in Chapter 11.4 Bovine Spongiform Encephalopathy of the Code. A Member Country wishing to be officially recognised by the OIE as 'negligible' BSE risk, or 'controlled' BSE risk, must submit to the OIE an application for official recognition, as per Chapter 1.8 Application for Official Recognition by the OIE of Risk Status for Bovine Spongiform Encephalopathy.

The OIE Scientific Commission for Animal Diseases, on behalf of the World Assembly of Delegates, assesses a member country's submission and on completion makes recommendation to the World Assembly for resolution and adoption of the recommended risk status. The OIE publishes a list of its Member Countries that it has assessed as 'negligible' BSE risk, or 'controlled' BSE risk, based on the adoption of a resolution by the World Assembly of Delegates of the OIE. Countries or zones not recognised as 'negligible' or 'controlled' BSE risk are considered to have an 'undetermined' BSE risk.

The OIE official recognition for BSE-risk status applies only to classical BSE. Currently, a reported case of atypical BSE in a 'negligible' BSE-risk country does not result in a change of status, as long as there is evidence that the animal was appropriately destroyed and disposed of, i.e. did not enter the animal food chain.

8.3 Branch guidelines

- *Guidelines on Animal Disease Outbreak in a Foreign Country – ABB Evaluation and Response*
- *Guidelines on Animal Biosecurity Branch competent authority evaluations* (and related toolkit package)
- *Guidelines on the management of the biosecurity risks of foot-and-mouth disease virus in imported commodities*

- *Guidelines on the management of the biosecurity risks of lumpy skin disease virus in imported commodities*
- *Guidelines for managing the risk of transmitting transmissible spongiform encephalopathies (TSEs) via veterinary vaccines and other in vivo veterinary products*
- *Importation of stockfeed and stockfeed ingredients – Finalised risk management measures for transmissible spongiform encephalopathies*
- *Guidelines for the biosecurity assessment of stockfeed and fertilisers of animal origin*
- *Guidelines on the biosecurity requirements for imported stockfeed of plant origin*
- *Guidelines for the biosecurity assessment of pet food*
- *Guidelines on thermal processing as a biosecurity measure and equivalent thermal processes*
- *Guidelines for the importation of biological materials*
- *Review of published tests to detect pathogens in veterinary vaccines intended for importation into Australia*
- *Gamma irradiation as a treatment to address pathogens of animal biosecurity concern – Final policy review*
- *Specific quarantine requirements for the importation of inactivated veterinary vaccines*
- *Australian quarantine policy and requirements for the importation of live and novel veterinary bulk and finished vaccines*
- *Animal quarantine policy on bovine spongiform encephalopathy (BSE) 1999*
- *Biosecurity Australia policy on bovine spongiform encephalopathy (BSE) 2002* (a review of the 1999 policy)
- *Import Risk Analysis Report on the Revision of Import Policy Related to Scrapie – Final Report, 2000*
- *Import Risk Analysis on the Importation of frozen bovine in vitro produced embryos from Canada and the United States- final review March 2017*

8.4 Example documents

- Ireland 2015 OIE BSE Status Downgrade – No Change to Department BSE Approved Country List
  Electronic network folder: s. 47E(d)

- Slovenia 2015 Atypical BSE Outbreak Response
  Electronic network folder: s. 47E(d)

  AND s. 47E(d)

- BSE Approved Country List and BSE Guidelines working documents
  Electronic network folder: s. 47E(d)

9 References

Department of Agriculture and Water Resources 2016, *Biosecurity import risk analysis guidelines 2016: managing risks for imports into Australia*, Canberra, available at http://www.agriculture.gov.au/biosecurity/risk-analysis/guidelines.

Linden, R 2017, 'The biological function of the prion protein: a cell surface scaffold of signaling modules', *Frontiers In Molecular Neuroscience*, vol. 10, p. 77, available at https://dx.doi.org/10.3389%2Ffnmol.2017.00077, accessed 13 September 2019.

OIE 2019, 'Glossary', in *Terrestrial animal health code (2019)*, World Organisation for Animal Health, Paris, available at http://www.oie.int/index.php?id=169&L=0&htmfile=glossaire.htm, accessed 12 September 2019.

Okada, H, Iwamaru, Y, Imamura, M, Miyazawa, K, Matsuura, Y, Masujin, K, Murayama, Y & Yokoyama, T 2017, 'Oral transmission of L-type bovine spongiform encephalopathy agent among cattle', *Emerging Infectious Diseases*, vol. 23, no. 2, pp. 284-7, available at https://dx.doi.org/10.3201%2Feid2302.161416, accessed 6 May 2020.

Vallat, B, Thiermann, A, Ben Jebara, K & Dehove, A 2013, 'Notification of animal and human diseases: the global legal basis', *Revue Scientifique et Technique de l'Office International des Epizooties*, vol. 32, no. 2, pp. 331-5, available at http://web.oie.int/boutique/index.php?page=ficprod&id_produit=1185&fichrech=1&lang=en, accessed 9 August 2019.

10 Detailed version history

Version Number	Version Date	Amendment Details
V1.0	12/06/2020	2017 Draft contained content related to scrapie and CWD country risk listing in addition to BSE. V1.0 updates BSE background information, list of BSE-related import policies, and BSE country risk assessment process and listing. Scrapie and CWD content removed as not relevant to BSE Approved Country Listing.

To: Gabrielle Vivian-Smith, Assistant Secretary, Plant Sciences and Risk Assessment (PSaRA)

s. 22(1)(a)(ii) a/g Assistant Secretary, Plant Import Operations (PIO)

Through: s. 22(1)(a)(ii) , Director, Nursery Stock, Timber & Cut Flowers, PSaRA

s. 22(1)(a)(ii), a/g Director, Propagative & Research Material, PIO

FOR APPROVAL: HIGH RISK NURSERY STOCK REVIEW PROCESS

Timing: by 26 June 2020 to meet AHMA project milestone reporting

Recommendations:

That you approve the management process (**Attachment A**) for the high risk nursery stock review project.

Approved / Not Approved

Assistant Secretary Gabrielle Vivian-Smith: Date:

Approved / Not Approved

a/g Assistant Secretary s. 22(1)(a)(ii) **:** Date:

Comments:

KEY POINTS

1. Imported live plant material (nursery stock) can introduce foreign plant pests and diseases, and the Department of Agriculture, Water and the Environment sets conditions for the import of all live plant material to Australia.
2. Plant material classified as 'high risk' (that is, significant agricultural, horticultural food and or fibre crops; or plants that are hosts to high impact pathogens) is normally taken directly to the government's post entry quarantine (PEQ) facility in Mickleham, Victoria. Plants then undergo insecticidal treatment, followed by growth and disease screening, as per

requirements specified on the department's Biosecurity Import Conditions system (BICON) and the import permit.

3. Where high risk plants aren't screened at the Mickleham PEQ facility, they are approved to undergo PEQ at a department approved arrangement site, such as the case for banana or sugarcane which go to Queensland Department of Agriculture and Fisheries Maroochy Research Station, or the QLD Sugar Research Australia respectively.
4. These import conditions need periodic review to ensure they are current and best able to protect Australian agriculture from new and emerging plant pests and diseases. In the last 10 years the department has conducted reviews of a number of existing nursery stock import pathways, but these reviews have not been regular and not all have involved stakeholder consultation (Appendix D contains further information).
5. This minute seeks your consideration and approval of the management process for conducting high risk nursery stock reviews, a sub-set of which have been included as part of the Accelerating Horticulture Market Access (AHMA) program. It is intended that this process be conducted in a rolling manner, so that each of the existing high risk commodity import conditions are reviewed at least every three years.
6. Establishing an internally approved process for these reviews is a milestone in the AHMA project plan for the High Risk Nursery Stock Review component of the AHMA program, and this milestone is scheduled for completion by 30 June 2020.
7. PIO (Propagative and Research Material), PSaS (Stakeholder Engagement Team), Operational Science and Surveillance (pathology lead at Mickleham) and the Post Entry Quarantine Group (Biosecurity Operations Group) have been consulted on this project, and their consultation is factored into each relevant step in the review process. Representatives of these areas also attended a stakeholder teleconference on 29 April 2020, where departmental representatives provided information on AHMA, explained the high risk nursery stock review process, and sought comment on a forward review schedule (more detail is in the background of this minute and **Attachments B, C and D**).
8. Two reviews, strawberry and *Rubus* propagative material, have already been conducted. These are two AHMA milestones for the 2019–20 financial year, and their conduct was used as a trial for the process presented for your approval.
9. As these reviews are for existing commodity pathways, the proposed process has streamlined governance and reporting requirements across the four phases of each assessment: planning, research, review and stakeholder engagement, and release. Reducing the administrative requirements for these reviews enables the incorporation of agile

management steps, enabling increased stakeholder engagement (internal and/or external) and collaboration as required, and faster turn-around.

10. The process is presented here for your approval (**Attachment A**).

BACKGROUND

11. The high risk nursery stock review project is funded through the AHMA program, established under the Australian government's 2019–20 budget commitment of $29.4 million, Enhancing Australia's Agriculture's Trade. AHMA supports further development of an internationally competitive and profitable horticulture sector.
12. The high risk nursery stock review project has been established to meet the need for periodic regular review of existing import conditions for high-risk plant groups, to ensure they are current and best able to protect Australian agriculture from new and emerging plant pests and diseases.
13. The review covers 16 different plant groups which have a relatively high biosecurity risk for Australia. This risk rating is based upon value and size of Australian industry, the rate of change in biosecurity risk and their capacity to carry high impact pests or pathogens.
14. The AHMA project however includes only 13 of the 16 nursery stock groups within its scope, with the remaining three plant groups to be processed separately (**Attachment D)**.
15. The prioritisation of these reviews was discussed and agreed in a teleconference with relevant peak bodies on 29 April 2020. The fact sheet given to these stakeholders (**Attachment B**), meeting record (**Attachment C**) and agreed and finalised work schedule (**Attachment D**) are provided for your background.

Clearing Officer: s. 22(1)(a)(ii)
Director, Nursery Stock, Timber and Cut Flowers
Plant Sciences and Risk Assessment
Biosecurity Plant Division
Ph.: s. 22(1)(a)(ii)
15/06/2026

Contact Officer: s. 22(1)(a)(ii)
Nursery Stock, Timber and Cut flowers
s. 22(1)(a)(ii) @agriculture.gov.au

Attachments

A: Proposed high risk nursery stock review process

B: Industry Fact Sheet – Review of import conditions for PEQ nursery stock

C: Record of meeting with industry

D: Forward review schedule agreed by industry (for AHMA reporting purposes)

Attachment A

AHMA – High Risk Nursery Stock Review Process

Summary of the steps involved in the review process:

Phase	Key elements
1. Planning	Project schedule and timeline reviewed and agreed upon by internal stakeholders. Project strategy drafted in consultation with internal stakeholders. Relevant industry contacts notified of commencement.
2. Research	Pest categorisation table drafted or updated by PSaRA. Risk management processes and current testing techniques reviewed and updated (if necessary) by PSaRA.
3. Review & stakeholder engagement	Internal stakeholders (PIO, OSS and PEQ) review of documents, and PSaRA incorporate comments. External stakeholders (key industry stakeholders, current and recent permit holders) consulted *
4. Release	Internal stakeholders notified of outcomes of review.
Implementation	Outside of timeframe of process: update of relevant BICON cases, PEQ requirements and other operational and legislative documents. External stakeholders (industry bodies, permit holders) notified of outcomes of the review.

*Level of stakeholder engagement and clearance is dependent on the significance of the changes proposed by the review. Significant changes include any variations to current phytosanitary requirements that impose significant change to current practices and increase cost, PEQ time and impact on industry. Significant changes to be cleared by Principal Scientific Analyst.

Planning

Review initiation

Reviews will be conducted according to the timeframe given in the AHMA project schedule, or as needed. The Nursery Stock, Timber and Cut Flowers team (NSTCF) will develop a brief 'project strategy' to determine: the scope of the work involved, current knowledge of the nursery stock commodity, current pathways and existing policies (including department-approved high health nursery stock sources, if they exist), key internal and external stakeholders (with input from Plant Systems and Strategies (PSaS, PIO, OSS and PEQ) and set milestone dates. Internal stakeholders (PIO, PSaS, OSS and PEQ) will be contacted for input of relevant information. This may include current TAP/CBR requests, other review processes within the division, new testing procedures and, or, trade and market access issues. Industry Biosecurity Plan contents and review dates will also be taken into account. The project strategy will be reviewed and approved within NSTCF, and agreed by PIO. External stakeholders will be informed of the review's commencement, to give them time to engage external experts, if they wish.

Research

Technical pest categorisation

NSTCF will conduct a pest categorisation process, using standard branch Pest Risk Analysis procedures. The pest categorisation will only be conducted for plant pathogens and existing pathways. This is in recognition that a new pathway would need to be subject to prioritisation and a full risk analysis. In cases where a pest categorisation already exists, only an update of the information will be required. Assessment of arthropods will not be conducted as current existing quarantine conditions, such as insecticidal treatments or fumigation, are used to mitigate the risk of these pests. The pest categorisation will be tailored to the pathway, for example, soil-borne pathogens will not be assessed for a pathway that does not include whole plants or plant roots.

The draft will be peer reviewed and approved by the NSTCF team leader. In situations where pest categorisation results in significant change, the draft is to be reviewed by the Principal Scientific Analyst. This review process can be performed at the same time as the review of the risk management processes and current testing techniques.

Review and stakeholder engagement

Review of risk management processes and current testing techniques

A review of the risk management processes and current testing techniques will be conducted. In addition, an assessment of current testing techniques will be performed and if feasible, recommendations to implement updated testing techniques will be provided. Upon completion, the draft will be peer reviewed and approved by the Director NSTCF. In situations that the review of risk management processes and current testing techniques result in significant change the draft is to be reviewed by the Principal Scientific Analyst.

Internal stakeholder engagement (PIO, OSS and PEQ)

The level of internal stakeholder engagement will be determined, based upon the significance of the changes proposed. Where the review recommends minor changes[1], the review documents will be emailed to internal stakeholders (PIO, OSS and PEQ) for input. Meetings can be held if needed, and NSTCF will consider all comments. Where major changes are suggested, the level of internal stakeholder engagement will be determined through consultation with PIO, OSS and PEQ.

Stakeholder comments will be considered and integrated into the documents as applicable. Prior to external stakeholder consultation the documents will be peer reviewed and approved by the Director NSTCF.

[1] Minor changes do not significantly affect the operational practices of the department and do not impart additional cost or PEQ time on permit holders.

External stakeholder engagement

Following the drafting of the primary review documents the level of external stakeholder engagement is determined, based upon the significance of the changes proposed. At a minimum, contact will be made with relevant peak bodies for that plant group, and current and recent permit holders.

Where a review proposes significant change, the list of external stakeholders may be more extensive, and include States and Territories, and Plant Health Australia. An email will be circulated containing an explanatory brief and drafts of the pest categorisation and pest risk management assessment.

The Stakeholder Engagement Team of PSaS will send the emails out, and collate comments, using the plantstakeholders@ inbox. Feedback will be requested via email within four weeks, and meetings can be organised if requested (teleconference preferred). Comments will be considered before the completion of the final draft.

Once stakeholder engagement processes have been completed, the final documents will be peer reviewed and approved by Director NSTCF. If significant changes are made, documents will be reviewed by Principal Scientific Analyst.

Release

Release of final review

Relevant internal stakeholders will be informed of the outcomes of the review and final documents will be circulated. Internal stakeholders to be engaged at this stage include PSaRA, PIO, OSS and PEQ, however this may be expanded as required.

Implementation

Following the release of the final review implementation of the recommendations will proceed. PIO will coordinate update of relevant BICON cases, PEQ testing requirements, vary relevant import permits, as well as update any other documents, where applicable, such as ‘Arrangement Document’ for overseas high health approved sources and ‘Process Management Document’ for class 6.7 Approved Arrangement. PIO will also notify stakeholders via BICON alert/s and, where required, emails to individual import permit holders.

Implementation of new conditions may also require additional resources, therefore sufficient time and support (from PSaRA, PIO and other internal stakeholders) is required for OSS and PEQ to research and test quarantine procedures prior to implementation.

Attachment B

Australian Government
Department of Agriculture, Water and the Environment

Review of import conditions for PEQ nursery stock

Fact sheet

PEQ nursery stock review project

Imported live plant material (nursery stock) can introduce foreign plant pests and diseases that could be harmful to Australia's environment, agriculture and economy. To protect against this risk, the Department of Agriculture, Water and the Environment sets conditions for the import of all live plant material to Australia.

The facility where the inspection and treatment of imported nursery stock occurs is based on risk criteria, and plant material classified as 'high risk' by the department is taken directly to a government post entry quarantine (PEQ) facility. Plants then undergo growth and disease screening, as per requirements specified on the department's Biosecurity Import Conditions system (BICON) and the import permit.

Our import conditions need periodic review to ensure they are current and best able to protect Australian agriculture from new and emerging plant pests and diseases. In the last 10 years, we have conducted reviews of a number of nursery stock import pathways.

What is the aim of the project?

The project will establish a process for the regular review of import conditions for 'PEQ' nursery stock and review the existing import conditions for a range of plant groups, based on their biosecurity risk. The project aims to deliver a range of benefits, which include:

- improving import conditions to better manage biosecurity risks
- updating post entry quarantine arrangements, which in some cases will result in updated pathogen testing and reduced time for plants undergoing post entry quarantine.

Department of Agriculture, Water and the Environment Biosecurity Plant Division

In reviewing existing import conditions, the project also aims to provide enhanced access to new plant varieties to assist Australian industry to meet export markets and consumer preferences.

Which plants are the focus of this project?

This project will focus on those groups of plants with existing import conditions that are economically significant and/or that can carry significant pests or pathogens, and that are currently required to undergo a screening period in a government PEQ facility.

These plant groups include (in no particular order):

- Table and wine grapes
- Banana
- Pome fruit
- Potato
- Stone fruit and almonds
- Strawberries
- Avocado
- Blueberry
- Mango
- Raspberry
- Citrus
- Hazelnut
- Kiwifruit
- Pomegranate
- Sugarcane
- Sweet potato

Next steps

Conducting reviews of all these plant groups concurrently is not possible, so we are looking to develop a prioritisation list. We will consult with industry stakeholders to help determine these priorities, and we will consider a range of information including industry needs, changes in biosecurity risk, and the time since our last review.

Further information

This project is funded through the Accelerating Horticulture Market Access program (AHMA) established under the Australian government's 2019–20 budget commitment of $29.4 million, Enhancing Australia's Agriculture's Trade. AHMA supports further development of an internationally competitive and profitable horticulture sector. More information on AHMA and the Enhancing Australia's Agriculture's Trade measure can be found here.

1800 900 090 (option 1, option 1)
imports@agriculture.gov.au
bicon.agriculture.gov.au/BiconWeb4.0/

Attachment C

Australian Government
Department of Agriculture, Water and the Environment

MEETING RECORD
Nursery stock review project

Date: Wednesday, 29 April 2020, 1:30pm (AEST)

Format: Teleconference

Chair: s. 22(1)(a)(ii)

Attendees:

Department of Agriculture, Water and the Environment	Industry
Executive staff • s. 47F(1) Technical staff • s. 22(1)(a)(ii) • • • • Stakeholder engagement staff • s. 22(1)(a)(ii) • • • Post Entry Quarantine staff • s. 22(1)(a)(ii) • BICON content staff • s. 22(1)(a)(ii)	• • s. 47G(1)(a) • • • • • • • • • • • • • • • • •

Agenda:

Item	Responsible
1. Welcome, apologies and introductions	Department
2. Introduction to the Accelerating Horticulture Market Access (AHMA) program • background on AHMA • aims of the program • projects under AHMA	Department

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3. Overview of the Nursery stock review project • aims of the project • review process explained	Department
4. Discussion and questions on prioritisation process	All
5. Next steps	Department
6. Meeting close	Department

Meeting record

Purpose: To update industry of the nursery stock review project, which will review the existing import conditions in place for some key groups of nursery stock that are required to undergo a period of post entry quarantine in a government facility.

Introduction to the Accelerating Horticulture Market Access (AHMA) program

- The department provided an overview of the Accelerating Horticulture Market Access program, which supports the nursery stock project. Industry requested a summary of this information. This has been added as an action item.

Overview of the nursery stock review project

- The department presented an overview of the nursery stock review project. This presentation referred to the fact sheet provided prior to the teleconference and included:
  - The overarching aims and focus of the project.
  - The criteria by which the chosen plant groups were chosen for review under AHMA.
  - An explanation of the review process of existing conditions of the selected plant groups.
- The department discussed justification behind the tentative review schedule (sent prior to teleconference), which considered factors such as the value of industry, frequency of changing risk, anticipated imports of nursery stock, emerging quarantine pests and how large the review is expected to be.
- The department provided an overview of the review process.
  - Review scientific literature and produce a pest categorisation table.
  - Following this, the department will produce a list of all known pathogens, noting whether they are present in Australia and are significant enough to require testing.
  - The department will then review existing conditions, including time taken and effectiveness of current testing methods.
- The department advised that external consultation with peak bodies, current import permit holders and any existing high health facilities overseas will take place, however, consultation will generally be limited to these groups as these are reviews of existing import conditions, not new trade proposals.
- Industry queried the resources allocated to the project, including staffing capacity, and how long each review would take to be completed.

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- The department indicated that two members from the technical team are funded by this project and that the time for review will be dependent on how complex the review is and how long ago the previous review took place. Smaller reviews will take roughly 3 months, and the larger reviews may take 6-9 months. Consultation times are additional to review times.

- Industry queried how the list of targeted pathogens for each commodity is maintained.
  - The department advised that industry would be provided with a list of pathogens that are tested for at the PEQ facility and assured that no pathogens would be removed from the list unless industry was consulted first.
- Industry expressed concern about the current pest list and that modelling of changing climate conditions should be considered for future emerging pests.
  - s. 47G(1)(a) has encountered various new outbreaks of pests previously not considered as having economic or environmental consequence at the time and have emerged in the future under different conditions.
  - The department indicated it will refer to each industry biosecurity plan in conducting its review, and encouraged industry to advise on these emerging pests of concern.
- Industry queried whether alternative pathways are considered when evaluating risks posed by a pest, such as through another commodity.
  - The department advised that it does take this into account and will do so during internal consultation with technical and PEQ staff.

<u>Discussion and questions on prioritisation process</u>

- Industry requested clarification regarding the 'low priority' for stone fruit in the review schedule. Industry also raised that cherries are missing from the schedule. The department clarified that:
  - the 'low priority' rating represents the department's estimate of low numbers of new emerging pathogens in that plant group
  - pome fruit, stone fruit and almonds are grouped together due to similar pathogens between groups, therefore these reviews will be done concurrently.
  - cherries are classified under stone fruit.
  - An amended version of the review schedule, that clarifies this, will be distributed as an action item.
- s. 47G(1)(a) indicated that a more detailed discussion with the hazelnut industry will need to be undertaken as it did not expect large numbers of future imports, and as such, the hazelnut review could be moved back in priority.
  - The department agreed and have added this as an action item.
- Industry asked for explanation about the three commodities referred to as 'outside this process' in the review schedule. The department advised that:
  - these are classified as 'outside this process' because they are different types of reviews. For example sugarcane and banana imports are looked after by other entities. The department will seek advice from the respective entities and conduct a desktop review of the testing protocols provided by those entities

Australian Government
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- The citrus review will involve substantial consultation with industry and will be a larger review.
- based on resources available, these three reviews will not be scheduled as part of this project, however, the department will still undertake the reviews.

- s. 47G(1)(a) advised that the Biosecurity plan for Sugarcane is due to be redone in the next 18 months which will be helpful to inform reviews.
- Industry queried whether the list has been prioritised based on amounts of material imported.
  - The department advised that it did not consider import amounts as some plant groups, such as hazelnut, had not recently imported new varieties but still required a review.
- Industry asked how well the current protocols are working.
  - The department advised that this will be reviewed in this project, namely the efficacy of the tests and the implementation of new PCR tests if required.
- Industry queried about the scope to review the import conditions of ornamental plant groups. s. 47G(1)(a) noted that s. 47G(1)(a) is currently reviewing the Biosecurity Plan for ornamental plant varieties.
  - The department advised that this project is focussed on plant groups that are high risk, namely those referred to a government-operated PEQ facility.
  - Ornamentals are classified by the department as medium risk nursery stock, some of which were subject to a review during the previous Agricultural Competitive White Paper program. Several recommendations from this review are being implemented under the AHMA program.
    - s. 47G(1)(a) requested to receive a copy of the Agricultural Competitive White Paper review. This has been listed as an action item.
- A discussion around consultation of the reviews occurred, in which industry raised that:
  - two-page fact sheets or summaries were helpful to summarise technical information
  - emailing peak industry bodies to ensure all interested parties are consulted for each commodity consultation would avoid consulting industries not affected by the reviews
  - consulting other technical groups would be useful. s. 47G(1)(a) indicated it will provide the department contacts for technical experts and requested the department to give notice of consultation in advance.
    - The department agreed to provide advance notice of consultation and will consult with industry experts or other technical groups if they are recommended by industry.
- Industry queried if the department is aware of new testing methods such as high throughput sequencing currently being funded through Hort Innovation.
  - The department advised that it is a key stakeholder of the new testing method and is currently working closely with that project. The department encouraged industry to advise of any new testing methods they are aware of.
- Industry requested that information of new viruses encountered at the PEQ facility be sent to industry to inform and advise a response to emerging pests.

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Department of Agriculture, Water and the Environment

- The department advised that while it will try to notify relevant industries of positive detections, it will be in a far better position to notify industries of everything found in material when high throughput sequencing has been implemented, validated and is live.
- The department advised that currently, if the pathogen is not tested for, it is unable to notify industry of positive detections of new pathogens.

Action items:

Action Item Number	Action item	Responsible
1	Distribute meeting record to all meeting participants.	The department
2	Distribute updated review schedule for next three years with amendments (including clarification, built-in forward notice, i.e. prior to consultation).	The department
3	Distribute information on the Accelerating Horticulture Market Access program and its projects.	The department
4	Distribute summary of medium risk nursery stock reviews conducted by the department under Agricultural Competitiveness White Paper program to Greenlife Industry.	The department
5	Engage with Hazelnut industry about upcoming imports of nursery stock.	The department and s. 47G(1)(a)

Attachment D

Accelerated Horticulture Market Access program – Post Entry Quarantine plant review schedule

The proposed schedule was discussed at an industry teleconference on 29 April 2020, and minor amendments were made in response to comments. The schedule was developed after consideration of:

- the time since the last major review (please note: minor reviews still occur as needed, for example when emerging pathogens are identified, so our BAU assessment work continues outside this process)
- the approximate production value of the industry
- an estimation of the frequency with which we see pathogen biosecurity risks changing in each industry (High, Medium, or Low)
- any other considerations particular to that industry—such as grouping plant groups with similar pathogen ranges
- resource availability to conduct the review (typically we will be able to do two larger and one smaller reviews a year)

	Industry group	Time since last major review	Production value ($million)	Estimate of changing biosecurity risk	Notes
Year 1: 2019-20					
1	Raspberry	2020	207.5	High	Review emailed out for industry consultation on 21 May 2020.
2	Strawberry	2019	392.4	High	Review sent for industry consultation in 2019, and revised conditions to be implemented on 30 June 2020.
Year 2: 2020-21					
3	Grapevines	2013	1,665.9 [1]	High	Formal review conducted in 2013, available on department's website. Minor reviews have been conducted since this time.

4	Potato	2013	752.6	High	A full review was conducted in 2013, available on department's website. Minor reviews have been conducted since this time.
5	Sweet potato	10 years +	80.0 [2]	Medium	Predicted to be a smaller review. Minor reviews have been conducted as needed.
Year 3: 2021-2					
6	Stone fruit and almonds	2013	1,296.1	High	Reviews of pome fruit, and stone fruit and almonds, will be conducted with similar timing as they are similar plants and are imported the same way.
7	Pome fruit	2002	632.4	Low	Formal review conducted in 2002, available on department's website. Minor reviews have been conducted since this time.
8	Hazelnut	2011	3.0	Low	Propagative material from Chile had a formal review in 2011, available on department's website. Any changes in pathogen status were rolled over into other import pathways. Year of review may be pushed back, dependent on advice from industry.
9	Pomegranate	2018	? [3]	Low	A minor internal review was conducted in 2018. Emerging industry.
Year 4: 2022-23					
10	Blueberry	2014	338.7	Medium	An internal review was conducted in 2014. Minor reviews have been conducted since this time.
11	Kiwifruit	10 years +	19.0	Medium	Minor reviews have been conducted in the interim.
12	Avocado	10 years +	444.0	Low	Predicted to be a smaller review. Minor reviews have been conducted as needed.
13	Mango	10 years +	198.6	Low	Predicted to be a smaller review. Minor reviews have been conducted as needed.

To be scheduled separately					
	Citrus	10 years +	829.3	High	Minor reviews have been conducted in the interim. This review will involve more substantial consultation with the citrus industry.
	Banana	10 years +	594.6	High	The Queensland Government manages the quarantine facilities and post-entry screening processes for banana propagative material. These import protocols are regularly reviewed by the responsible agency. A review by the department would verify the processes.
	Sugarcane	10 years +	1,600.0 [4]	High	Sugar Research Australia manages the quarantine facilities and post-entry screening processes for sugarcane propagative material. These import protocols are regularly reviewed by the responsible agency. A review by the department would verify the processes.

Source: The production values are from the 2018/19 Australian Horticulture Statistics Handbook, available at <www.horticulture.com.au/globalassets/hort-innovation/resource-assets/ha18002-australian-horticulture-statistics-handbook-fruit-2019-r.pdf>, unless otherwise indicated.

Note: 1. Total derived from the Australian Horticulture Statistics Handbook 2018-19 (table grapes $693.2m and dried grapes $29.2m) and Australian Bureau of Statistics Value of Agricultural Commodities produced, Australia, 2017-18 (wine grape production $942.5m).

2. Value is estimated gross value from the Australian Sweet potato Growers Inc. website, available at <www.aspg.com.au/sweetpotato-industry/>.

3. Value not readily available.

4. Value is sugarcane production for 2016-17 from Plant Health Australia website, available at <www.planthealthaustralia.com.au/industries/sugarcane/>

Guidelines for Disease Risk Assessments

Purpose

Disease risk assessments (DRAs) are done to complete three main tasks. They are done to identify pathogens that are associated with a plant species and that may be carried to Australia with imports of nursery stock or seed of that species. DRAs are also done to determine which pathogens are quarantine pests that require measures and to determine the appropriate measures to manage the risks presented by the pathogens on the nursery stock or seed pathways.

Initiation

DRAs are usually initiated after a request for technical advice posted on the Threat and Risk Application (TAP system). The request should identify the plant species to be assessed and should say whether the DRA will consider seed and nursery stock as potential pathways or will only consider seed as a pathway. Assessments for seed alone are relatively uncommon.

DRA process and documentation

There are seven main steps to the process.

1. A DRA document is compiled that makes recommendations and reports the DRA process and findings.
2. A systematic search for pathogen records is made and recorded in the document.
3. A search is made for evidence of pathogens associated with seed.
4. A search is made for reports of seedborne arthropods and nematodes.
5. Pathogens and pests that are satisfactorily named and associated with the plant species or seeds of the plant are assessed through a pest categorisation process and the categorisation is included in the document.
6. The need for measures is considered and BICON cases that provide appropriate measures are identified.
7. The document including the categorisation are entered into the TAP system and stored in the PDR.

The pest categorisation process differs from the standard process as it concludes with the pathogen being categorised either as a quarantine pest or as not a quarantine pest (a non-quarantine pest). A pest categorisation table is drafted in the normal way and at the same time text is developed for the modules that will be entered into the TAP system. If a pathogen is categorised as a quarantine pest, or if xylella or some other broadly regulated pathogen is recognised, then measures are required. Measures are almost always achieved by recommending that the plant species is assigned to an existing BICON case that includes appropriate measures. Following these steps, the DRA document does not usually propose specific measures.

After approval by the supervising Director, the contents of the DRA document should be copied to the TAP system as part of the response to the technical advice request. The response in the TAP system is usually the final record of the DRA. The DRA document should be attached to the response if it contains details that are not copied into modules.

Scope

Only the plant species identified in the technical advice request are assessed in the DRA, but a DRA can be broadened to encompass plants at a lower or higher taxonomic level, such as a genus if that is requested, in which case all the species in the genus would be assessed.

In a standard DRA, the only pathogens that are categorised are the ones associated with the plant species that are being assessed. Pathogens recorded on related plant species, such as those associated with other species in the same genus, are not included in a standard DRA, but pathogens linked to plant names that are synonyms of the plant species under assessment should be included.

Some fungi, other microbes and viruses will fall out of scope. Microbes and viruses that have not been identified and named to species level should not be categorised. Fungi that are only recorded as saprobes or saprophytes also need not be included in the pest categorisation, but the reports of association of saprobic fungi should be noted. Bacteria, stramenopiles (oomycetes) and viruses associated with the plant for which there is no evidence of pathogenicity may be treated similarly. Note, however, that reports of symptoms associated with a microbe or virus should be considered evidence of pathogenicity.

Pathogens for which there is insufficient information to progress to pest categorisation should still be noted in the DRA, and when a decision is made not to categorise a pathogen, the reason for not categorising should also be noted.

A decision may also be made not to categorise a pathogen if it has been assessed recently but this should only happen if the earlier assessment is applicable to the plant species and pathway assessed in the DRA. If an applicable assessment was done previously, it should be noted. Records of significant pathogens on the plant species or on congeneric plants, such as National Priority Pests, should also be noted and the supervising Director should be informed.

Full pest risk assessments and the justification of the measures

Full pest risk assessments are usually unnecessary, as it is expected that pest categorisation will be sufficient to determine the quarantine status of most pathogens, and measures to manage most pathogens will already have been implemented through existing BICON cases. If a decision is made to proceed to a full pest risk assessment, that assessment does not need to be incorporated into the DRA, unless the full assessment is not published or stored elsewhere. If it is not incorporated, then the DRA should refer to the assessment and link to it.

Likewise, it is usually unnecessary to produce a technical justification for measures in a DRA, as it is expected that in most cases the appropriate measures will match the conditions of an existing BICON case to which the plant species can be assigned, and the measures will have been justified elsewhere.

Recommended methods.

Initial steps

- The name of the plant species is confirmed using an appropriate plant taxonomy database. The Plants of the World database is recommended as it is based on IPNI and the APG IV classification system and provides lists of synonyms (Angiosperm Phylogeny Group 2016; IPNI 2023; Royal Botanic Gardens, Kew 2023).
- It is usually unnecessary to search for pathogen records connected to the synonyms of the plant species, but if a synonym is frequently or recently used, it may be important to search for such records, as well as records that use the accepted name. A commonly used synonym is usually recognised when it is mentioned in several references.
- BICON cases to which the species could be assigned are identified by searching the BICON database for the plant genus name. It is possible that the plant species may be listed in BICON under a synonym.
- The xylella host family list, or genus list, is checked to see if the plant species is considered a potential host of xylella.
- A DRA document is drafted following a current example.

Systematic search for pathogen records

- Systematic searches are done to find pathogen records, and the search terms used and the databases that are searched are recorded in the DRA document.
- All the pathogens associated with the plant species identified in these searches should be noted, and this is probably best done in a table.
- It is currently recommended that searches are made of the CABI Crop Compendium (CABI 2022), the USDA Fungus-Host Database (Farr and Rossman 2022) and the NCBI databases (NCBI 2022), along with searches of Google Scholar (Google 2022). It should be noted if one of these databases is unavailable.
- The CABI Crop Compendium, the Fungus-Host database and the NCBI databases should be searched using the scientific name of the plant or the name of the genus as search terms. NCBI searches may be narrowed by using the key words ‘virus’ and ‘viroid’ in combination with the plant name. Individual sequence records in the NCBI databases may need to be viewed.
- Google Scholar should be searched using the species name or the genus name as search terms. These words should be used alone and in combination with each of the following words: ‘disease’, ‘fungal’, ‘bacterial’, ‘phytophthora’, ‘phytoplasma’, ‘pythium’, ‘mildew’, ‘viroid’ and ‘virus’.

Pathogen taxonomy

- The names of fungi and stramenopiles should be confirmed by searching the Mycobank database (Mycobank 2022), and synonyms used in the pathogen records should be noted in the DRA.
- The names of bacteria should be confirmed by searching the LPSN database (Parte et al. 2020) and the NCBI taxonomy database, and the names of viruses and viroids should be confirmed by searching the NCBI taxonomy or sequence databases and the ICTV database (ICTV 2023).

Distinguishing pathogens and saprobes

- Before microbes and viruses are categorised, care should be taken to determine if there is evidence that the organism is pathogenic or not, as many microbes are only known to be saprobic (saprophytic), and many viruses are only known from symptomless infections. This evaluation of microbes and viruses should take into account the pathogenicity of the microbe to any plant species.
- Viroids should always be categorised, as should viruses from genera that include major pathogens.
- The saprobic or pathogenic nature of an organism should be determined from the records identified through the normal systematic searching process. If no useful information is found on fungal species, Wijayawardene et al. (2017) and He et al. (2019) may be used for information about likely interactions of fungi in the genus.
- If any record of a microbe or virus indicates that symptoms occur on living plants, then the organism should be considered a pathogen. If a virus is associated with symptoms when it is present in a mixed infection with other viruses then it should also be considered a pathogen, even if the etiology is unclear.
- Note that some microbes and viruses that are initially reported to be saprobic, are later found to cause plant disease. Given this possibility, a report that an organism is saprobic should not be used to permanently discount it from evaluation. The status of relevant microorganism and viruses should be reviewed with each new DRA in case new information has become available.

Pest categorisation

Seed association

- Every pathogen that is categorised should be checked for the capacity to be carried by seed. This process is started by searching standard google and Google Scholar using the name of the pathogen and the word ‘seed’ as search terms. If a report is found suggesting that the pathogen is associated with the seed of the plant that is being assessed, the potential of the pathogen to be carried by that seed should be evaluated with the assistance of the supervising Director and/or staff with experience in assessing the seed pathway and with reference to the seed association guidelines.
- The quality of the evidence that is reported about the association of the pathogen with seed needs to be considered. Several different kinds of evidence may indicate that a pathogen has the potential to be on the seed pathway. Often a fungus is considered to be carried by seed if reports are found of its spores or hyphae on or in the seed, and usually a virus or viroid will be considered to have the potential to be carried by seed if a paper is found that reports an experiment showing transmission through seed to seedlings or presence of the virus in the embryo. The ability of the pathogen to infect a seedling that grows from imported seed needs to be considered along with other factors that may affect the potential of the pathogen to establish.

Pest categorisation

- Pathogens should be categorised following the standard pest categorisation method, except that, as a last step of the process, a decision should be made on whether the pathogen is a quarantine pest or not. This decision is based on the answers developed through the categorisation and on the usual criteria that are used for determining the status as a quarantine pest.
- It is usually helpful to search the PDR for the pathogen, because the PDR contains assessments, and this may save work and help avoid inconsistencies.

Recommendations

The DRA document should start with recommendations. The following form of words can be used, if appropriate, for the recommendations of a DRA.

- Nursery stock of [*name of plant species*] should be permitted and assigned to the BICON case '[*title of nursery stock BICON case*].'
- Seeds of [*Name of plant species*] should be permitted and assigned to the '[seed *BICON case title*]' BICON case.
- No information was found suggesting that imports of *[name of plant species]* would present a risk that would require any management measures in addition to those currently used for permitted imports of seeds and plants of other *[name of plant genus]* species.

Normally, DRA recommendations are given to Plant Import Operations, so that the plant species can be correctly placed into a BICON case. If it is recommended that imports of nursery stock of the plant are permitted under a particular nursery stock case, then recommendations should also be made for seed of the plant to be assigned to a seed case, unless the plant does not produce seed. If recommendations are only made for seed, because only seed is likely to be imported, then recommendations for nursery stock do not need to be made. Usually, seeds of plants are assigned to the 'Permitted seeds for sowing' BICON case, unless a pathogen has been identified that could be carried by seed.

PIO maintains the permitted seed list separately from the BICON cases, and this list contains the names of all the plant species that currently may be imported. Ferns and mosses do not produce seed, but these plants are still listed on the permitted seeds list. When a DRA recommends that seed or nursery stock of a species is permitted, PIO will add its name to the permitted seed list.

Many plants that have been assessed using the DRA process in the past few years belong to plant families that contain species that are potential hosts of *Xylella fastidiosa*. Nursery stock of these plants is usually assigned to a BICON case with conditions for Xylella.

Background text of the DRA

The background text of the DRA should include a brief description of the searches that were done for pathogen records and explanations of the reasons for categorising certain pathogens or not categorising other pathogens. Search terms should be recorded in the background of the text and the findings of the search may be presented in a table like this example:

Database	Reference	Date searched	Pathogen records found
all databases of the NCBI	NCBI 2022	28 November 2022	*Puccinia sieversiae* Arthur (1904) subsp. *tatrensis* (Urban). Urban (1967) reported the infection on *Geum reptans*. An as yet unnamed *Peronospora* species. *Peronospora* species reported on *Geum* species causing disease in a commercial nursery Wallace et al. (2018).
USDA fungal databases	Farr & Rossman 2022	29 November 2022	none

References

References used in the DRA should be recorded in the DRA document and entered into the EndNote database following the standard practices.

Conclusion of the DRA

A concluding statement should be made in the DRA that summarises the outcome and justifies the recommendations for measures. Commonly, this concluding statement would be similar to this text:

> During the DRA process [*number*] pathogens were identified associated with the [*name of plant species*]. The quarantine pest(s), [*name of pathogens*], identified in this disease risk assessment (see Tables X and X) present(s) unrestricted risks that do not achieve the appropriate level of protection (ALOP) for Australia. Consequently, Plant Sciences and Risk Assessment recommends risk management measures to reduce the risk posed by the pest(s) to levels that achieve the ALOP for Australia. PSaRA considers that the current measures required by the BICON cases '[*nursery stock BICON case*]' and '[*BICON seed case*]' are suitable and will mitigate the risks posed by the identified quarantine pest(s) to a level that achieves the ALOP for Australia.

Preparation of text for modules

While preparing a DRA, it is handy to prepare text for the modules that are used to feed information into the Threat and Risk Application and the PDR. If a pest has been categorised then it is likely that modules will need to be completed for the taxon assessment, host assessment and regulatory status of the pest. The PDR should be searched for the pathogen before entering new data into modules.

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