

## EADRA GUIDANCE DOCUMENT

### Guidelines for Determining Whether an Unlisted Disease is an EAD

#### INTRODUCTION

These Guidelines are provided to Parties for use in the process of requesting Animal Health Australia to determine whether a disease should be listed in Part 1 of Schedule 3 of the *Government and Livestock Industry Cost Sharing Deed in Respect of Emergency Animal Disease Responses* (“EADRA”).

While the EADRA prescribes in detail the process to be followed to determine an applicable category for an unknown EAD or an uncategorised disease, it is less prescriptive on the process to determine whether an unknown or as yet unlisted EAD is an EAD for the purpose of the Deed in the first instance. Such determination should logically precede any categorisation attempt. These Guidelines attempt to assist with this process.

Relevant sections of the EADRA that should be referred to are:

- Clause 2.1 DEFINITIONS
- Clause 8.3 DETERMINATION OF APPLICABLE CATEGORY FOR AN UNKNOWN EAD OR AN UNCATEGORISED DISEASE
- Schedule 3 CATEGORIES OF EMERGENCY ANIMAL DISEASES (Clause 8)

The latest version of the EADRA can be downloaded from the AHA website (<http://www.animalhealthaustralia.com.au/programs/ealp/eadra.cfm>).

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#### 1. DEFINITIONS (FROM THE EADRA)

In this Deed<sup>1</sup>, unless the contrary intention appears, an:

“**Emergency Animal Disease**” or “**EAD**” is a disease that has met one or more of the following criteria:

- (a) It is a known disease that does not occur in endemic form in Australia, including without limitation the diseases listed in **Parts 1.2 to 1.5 inclusive** of **Schedule 3**, and for which it is considered to be in the national interest to be free of the disease.
- (b) It is a variant form of an endemic disease which is itself not endemic, caused by a strain or type of the agent, which can be distinguished by appropriate diagnostic methods, and which if established in Australia, would have a national impact.

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<sup>1</sup> see Clause 2.1

- (c) It is a serious infectious disease of unknown or uncertain cause, which may on the evidence available at the time, be an entirely new disease, or one not listed in the categorised disease list set out in **Parts 1.2 to 1.5 inclusive of Schedule 3**.
- (d) It is a known endemic disease, but is occurring in such a fulminant outbreak form (far beyond the severity expected), that an emergency response is required to ensure that there is not either a large-scale epidemic of national significance or serious loss of market access.

## 2. BACKGROUND

In respect of a previously unknown disease or a disease that has not been categorised, any Party to the Deed may ask Animal Health Australia to obtain a categorisation of the disease. Before such categorisation is undertaken in line with Clause 8.3 and Schedule 3, there needs to be a determination whether the disease under consideration is an EAD for the purposes of the Deed, because only EADs – not diseases in general – fall under the scope of the Deed.

Consistent with Clause 8.3, Animal Health Australia will, once it has sufficient information to consider a request for categorisation substantiated, request Animal Health Committee together with representatives of relevant industries, to meet to determine whether or not the disease is an EAD.

The decision tree approach below provides guidance on how such a determination may be made.

## 3. DECISION TREE APPROACH

At the beginning of this process, there is the question:

### **Is the disease under consideration an EAD as defined in Clause 2.1 of the Deed?**

To qualify as an EAD for the purposes of the Deed, a disease must meet at least one of four criteria. The four major questions below paraphrase the four criteria that define an EAD for the purposes of the Deed. Each question is split into sub-questions, each of which should be answered by 'yes' or 'no'. The answer determines where to go next (hence 'decision tree'). The text in italics behind some questions provides guidance on how to answer the question and – where applicable – refers to sources of information that may assist in the process.

By following this approach, at the end of the process, the answer to the question above will be either 'yes, the disease under consideration is an EAD as defined in the Deed' or 'no, the disease under consideration is not an EAD as defined in the Deed'.

The decision tree approach that is described here is completed if one criterion that defines an EAD is met. However, a disease could meet several criteria, and demonstrating that it does could strengthen the argument in borderline cases.

**Question (a) Is the disease under consideration a known disease that does not occur in endemic form in Australia (is it an exotic disease)?** *Check in the National Animal Health Information System<sup>2</sup> (for example, in the latest Animal Health in Australia<sup>3</sup> report) on the status of the disease in Australia.*

- i. If no, the disease is not an EAD under this criterion. Proceed to Question (b).
- ii. If yes, go to (a.1)

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<sup>2</sup> <http://www.animalhealthaustralia.com.au/programs/adsp/nahis/nahis-home.cfm>

<sup>3</sup> <http://www.animalhealthaustralia.com.au/programs/adsp/nahis/ahia.cfm>

**Question (a.1) Is it in the national interest to be free of the disease?** *If not free of the disease, would Australia suffer from significant public health or environmental consequences, or would there be national socio-economic consequences through international trade losses, national market disruptions, or severe production losses in the livestock industries that are involved? Refer to Biosecurity Australia's Import Risk Analyses<sup>4</sup> for information.*

- i. If no, the disease is not an EAD under this criterion. Proceed to Question (b).
- i. If yes, the disease is an EAD under this criterion. This completes the determination whether the disease is an EAD for the purposes of the EADRA. The assessment has shown that the disease is an EAD as defined under Clause 2.1 of the Deed.

**Question (b) Is the disease under consideration a variant form of an endemic disease that is itself not endemic?** *Check in the National Animal Health Information System<sup>5</sup> (for example, in the latest Animal Health in Australia<sup>6</sup> report) for a list of endemic diseases, and to see whether the disease under consideration is a variant of one of those.*

- i. If no, the disease is not an EAD under this criterion. Proceed to Question (c).
- ii. If yes, go to (b.1).

**Question (b.1) Is the disease caused by a strain or type of the agent of the endemic disease?** *The disease under consideration must not simply be condition that presents clinically in a way similar to endemic disease (e.g. respiratory signs in cattle). Rather, it must be causally related to the 'parent' endemic disease, i.e. it must be caused by a new, or atypical, strain or serotype of the organism that causes the 'parent' endemic disease.*

- i. If no, the disease is not an EAD under this criterion. Proceed to Question (c).
- ii. If yes, go to (b.2).

**Question (b.2) Can the disease be distinguished from the endemic disease by appropriate diagnostic methods?** *Obtain advice (for example, from Animal Health Committee's Sub-Committee on Animal Health Laboratory Standards<sup>7</sup>) whether there are diagnostic methods available in Australia that can reliably distinguish the disease under consideration from the 'parent' endemic disease, for example, a laboratory test that can differentiate between the different strains or serotypes of the causative organism.*

- i. If no, the disease is not an EAD under this criterion. Proceed to Question (c).
- ii. If yes, go to (b.3).

**Question (b.3) If established in Australia, would the disease have a national impact?** *If the disease became established, would Australia suffer from significant public health or environmental consequences, or would there be national socio-economic consequences through international trade losses, national market disruptions, or severe production losses in the livestock industries that are involved? Given that the*

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<sup>4</sup> <http://www.daff.gov.au/ba/ira>

<sup>5</sup> <http://www.animalhealthaustralia.com.au/programs/adsp/nahis/nahis-home.cfm>

<sup>6</sup> <http://www.animalhealthaustralia.com.au/programs/adsp/nahis/ahia.cfm>

<sup>7</sup> <http://www.scahls.org.au/>

*'parent disease' already exists in Australia, a comparative assessment of the impact of the two forms of the disease would be required.*

- i. If no, the disease is not an EAD under this criterion. Proceed to Question (c).
- ii. If yes, the disease is an EAD under this criterion. This completes the determination whether the disease is an EAD for the purposes of the EADRA. The assessment has shown that the disease is an EAD as defined under Clause 2.1 of the Deed.

**Question (c)** **Is the disease under consideration a serious infectious disease of unknown or uncertain cause, perhaps an entirely new disease?** *Expert opinion and literature research are required to answer this question. If the disease (or condition) under consideration has been reported overseas, then information will be available from those sources. Whether the disease is 'unknown' or of 'uncertain cause' may be readily answered; however, an assessment of its seriousness may be more difficult to make.*

- i. If no, the disease is not an EAD under this criterion. Proceed to Question (d).
- ii. If yes, the disease is an EAD under this criterion. This completes the determination whether the disease is an EAD for the purposes of the EADRA. The assessment has shown that the disease is an EAD as defined under Clause 2.1 of the Deed.

**Question (d)** **Is the disease under consideration a known endemic disease?** *Check in the National Animal Health Information System<sup>8</sup> (for example, in the latest Animal Health in Australia<sup>9</sup> report) on the status of the disease in Australia.*

- i. If no, the disease is not an EAD under this criterion. This completes the determination whether the disease is an EAD; the assessment has shown that the disease is not an EAD as defined under Clause 2.1 of the Deed, i.e. it does not meet any of the four criteria that define an EAD for the purposes of the Deed.
- ii. If yes, go to (d.1).

**Question (d.1)** **Is the disease occurring in such a fulminant outbreak form (far beyond the severity expected), that an emergency response is required to ensure that there is not a large-scale epidemic of national significance or serious loss of market access?** *Given that the disease, which is not listed in Schedule 3 of the EADRA, already exists in Australia, a comparative assessment of the usual outbreak severity and the one currently experienced is required. To answer this question, there will also need to be a prediction on the progression of the outbreak in the absence of an emergency response, i.e. it would need to be demonstrated that the outbreak would progress into a large-scale event of national significance or serious loss of market access (e.g. significant public health or environmental consequences, or national socio-economic consequences through international trade losses, national market disruptions, or severe production losses in the livestock industries that are involved).*

- i. If no, the disease is not an EAD under this criterion. This completes the determination whether the disease is an EAD; the assessment has shown that the disease is not an EAD as defined under Clause 2.1 of the Deed, i.e. it does not meet any of the four criteria that define an EAD for the purposes of the Deed.

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<sup>8</sup> <http://www.animalhealthaustralia.com.au/programs/adsp/nahis/nahis-home.cfm>

<sup>9</sup> <http://www.animalhealthaustralia.com.au/programs/adsp/nahis/ahia.cfm>

- ii. If yes, the disease is an EAD under this criterion. This completes the determination whether the disease is an EAD for the purposes of the EADRA. The assessment has shown that the disease is an EAD as defined under Clause 2.1 of the Deed.

#### **4. NEXT STEPS**

If it has been determined that the disease under consideration meets at least one of the four criteria that define an EAD in Clause 2.1 in the EADRA, then the categorisation can progress as stipulated in the Deed (Clause 8.3 and Schedule 3).

If the unlisted disease is not an EAD, i.e. if none of the four criteria that define an EAD in Clause 2.1 in the EADRA are met, the matter is referred back to the Party that originally requested Animal Health Australia to categorise the disease. No further action will be taken under the provisions of the EADRA.