

# **Approved arrangement**

# 12.3 – heat treatment Conditions

Version 1.0



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#### **Cataloguing data**

This publication (and any material sourced from it) should be attributed as: Approved arrangements section, 2019, *Approved arrangement heat treatment* Department of Agriculture, Canberra, August. CC BY 4.0.

ISBN 978-1-76003-214-2

This publication is available at <a href="mailto:agriculture.gov.au/import/arrival/arrangements/requirements">agriculture.gov.au/import/arrival/arrangements/requirements</a>.

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# Version control

Updates to this document will occur automatically on the departments website and the revision table below will list the amendments as they are approved.

Date	Version	Amendments	Approved by
27 August	1.0	First release	Approved
2019			Arrangements section

### **Contents**

Version control	3
Guide to using this document	4
Definitions	4
Other documents	4
Nonconformity guide	
Key arrangement outcomes	
Objective	6
Scope	6
Conditions	
Table 1 Personnel	7
Table 2A Process	7
Table 2B Process – prior to treatment	8
Table 2C Process – prior to treatment	9
Table 2D Process – heat treatment	
Table 2E Process – recording the heat treatment	11
Table 3 Records	12
Table 4A Compliance	13
Table 4B Compliance	

## Guide to using this document

This document sets out the conditions that must be met before the relevant Director will consider approval for the provision of biosecurity activities under section 406 of the *Biosecurity Act 2015*, otherwise known as an approved arrangement.

This document specifies the conditions to be met for the approval, operation and audit of this class of approved arrangement. Compliance with the conditions will be assessed by audit.

In the event of any inconsistency between these conditions and any Import Permit condition, the Import Permit condition applies. If the applicant chooses to use automatic language translation services in connection with this document, it is done so at the applicant's risk.

Unless specified otherwise, any references to 'the department' or 'departmental' means the Department of Agriculture. Any references to contacting the department mean contacting your closest regional office.

Further information on approved arrangements, department contact details and copies of relevant approved arrangement documentation is available on the department's website: <a href="mailto:agriculture.gov.au">agriculture.gov.au</a>.

#### **Definitions**

Definitions that are not contained within the <u>approved arrangements glossary</u> can be found in the *Biosecurity Act 2015*, the *Heat treatment methodology* or the most recent edition of the Macquarie Dictionary.

#### Other documents

The <u>Approved Arrangements General Policies</u> should be read in conjunction with these conditions. They will assist in understanding and complying with the obligations and conditions for the establishment and operation of an approved arrangement.

### Nonconformity guide

The nonconformity classification against each condition is provided as a guide only. If more than one nonconformity is listed against a condition, the actual nonconformity applied will correspond to the gravity of the issue. The nonconformity recorded against any conditions remains at the discretion of the biosecurity officer.

Nonconformity classifications are detailed in the *Approved Arrangements General Policies*.

# Key arrangement outcomes

Key arrangement outcomes (KAOs) are high level outcomes the biosecurity industry participant is responsible for meeting under an approved arrangement.

Each class condition for an approved arrangement is assigned a KAO.

KAOs are met by complying with the class conditions.

Table 1 List of KAOs including their purpose and description

KAO	Purpose	Further information
Containment	Goods subject to biosecurity control are contained in a way that prevents them, or any biosecurity risk material escaping into the environment.	<ul> <li>Generally applies to the biosecurity areas.</li> <li>Prevent goods subject to biosecurity control and their contaminants from accidental or deliberate release or escape.</li> <li>Both infrastructure and procedural practices for confining goods subject to biosecurity control within a defined space.</li> </ul>
Identification	Goods subject to biosecurity control and areas in which biosecurity activities are carried out must be visually identifiable as such.	
Traceability	Goods that are or were, subject to biosecurity control, are linked to records of the origin and movement of the goods and the biosecurity activities carried out in relation to the goods.	
Movement	Goods subject to biosecurity control only move beyond the site in accordance with departmental conditions and any required departmental authorisation.	
Awareness	People performing activities involving goods subject to biosecurity control have the knowledge and capability to carry out those activities in accordance with the conditions of the approved arrangement.	
Treatment	The biosecurity industry participant has the processes and/or equipment and facilities to perform treatments of goods subject to biosecurity control in accordance with the conditions of the approved arrangement.	Required treatments will be advised on import permits, directions, class conditions, nonstandard conditions (variations), process management systems (PMS) and standard operating procedures (SOPs).  Note: SOPs are only required in those classes where there is a specific condition for a SOP to be in place.
Arrangement compliance	The biosecurity industry participant is required to carry out biosecurity activities in accordance with the arrangement.	
Notification	The department is advised of any event or circumstance for which it has specified that notification must be provided.	Those events to be notified are advised on import permits, directions, class conditions, non-standard conditions (variations), PMS and SOPs.  Note: SOPs are only required in those classes where there is a specific condition for a SOP to be in place.

## Objective

Class 12.3 approved arrangement authorises the performance of heat treatment to mitigate biosecurity risks associated with imported goods and packaging material that are subject to biosecurity control.

### Scope

Biosecurity activities performed under a class 12.3 approved arrangement are limited to the heat treatment of goods subject to biosecurity control, directed by the department under the *Biosecurity Act 2015* for heat treatment at an approved arrangement class 4.1 site. Any other biosecurity activities will require approval for the relevant approved arrangement class.

Class 12.3 requires heat treatment to be performed in accordance with the department's *Heat treatment methodology*.

The types of heat treatment performed are limited to:

- forced dry heat
- · humidity controlled forced air
- kiln drying.

The types of heat treatment enclosures are limited to:

- a dedicated chamber
- · containerised, using a hardstand area
- sheeted, using a hardstand area.

Heat treatment is used to mitigate biosecurity risks, such as:

- disease pathogens in or on goods made of plant material (e.g. seeds)
- insects e.g. borers and seasonal hitchhiker pests including Brown Marmorated Stink Bug (BMSB).

## **Conditions**

#### **Table 1 Personnel**

#### Information

- Accreditation training requirements are available on the department's website.
- The definition of directly supervise is contained in the <u>Approved arrangements glossary</u>.
- Capability includes accredited persons having the understanding/skill/ability to deal with the biosecurity risks associated with their role/function.
- Personnel includes employees and others working (paid or unpaid) for the biosecurity industry participant at the approved arrangement site.
- Accredited person records can be:
  - o copies of training certificates
  - o register containing the information required in the conditions below.

KAO	Condition	Nonconformity guide
Awareness	1.1 The biosecurity industry participant must ensure only accredited persons or those persons under the direct supervision of an accredited person have physical access to goods subject to biosecurity control.	Major
Traceability	1.2 Records must be maintained of accredited persons.	Minor
Awareness	1.3 An accredited person must personally conduct or directly supervise activities involving physical contact with, or handling of items, subject to biosecurity control.	Major
Awareness	1.4 Accredited persons must have successfully completed accreditation training for the relevant approved arrangement class as specified on the department's website.	Major
Awareness	1.5 Accredited persons must be able to demonstrate an understanding of conditions applicable to the activities performed under this arrangement.	Major

#### **Table 2A Process**

KAO	Condition	Nonconformity guide	
Arrangement compliance	2.1 The biosecurity industry participant must be in possession of a biosecurity direction issued by the department that authorises heat treatment at an approved arrangement class 4.1 site.	Critical	
Treatment	2.2 Heat treatments performed under this approved arrangement class must comply with the requirements of the <i>heat treatment methodology</i> .	Major or critical	
Containment	2.3 Knockdown spray must be made available at time of opening the container doors and during preparation of the enclosure for treatment.	Major	
Containment	2.4 The accredited person must prevent the escape of any biosecurity pests into the Australian environment when preparing the enclosure for treatment. This includes, but is not limited to:		
	• minimising the time that container doors remain open during all stages of the preparation process up to commencement of the treatment	Critical	
	<ul> <li>being vigilant for insects once container doors are opened and during all stages of the preparation process up to commencement of the treatment</li> </ul>		
	• immediately applying knockdown spray to insects where detected to have left the chamber or sheeted enclosure.		

### Table 2B Process – prior to treatment

#### Information

- Prior to treatment the accredited person must verify that the goods subject to biosecurity control presented by
  the biosecurity industry participant for the approved arrangement site matches the target of the heat treatment
  specified on the biosecurity direction.
- The target of the heat treatment is defined in the *heat treatment methodology*.
- Certain goods, such as those subject to hitchhiker seasonal measures (e.g. BMSB) must be treated at the container level i.e. unpack is prohibited.

КАО	Condition	Nonconformity guide	
	2.5 The accredited person must assess the biosecurity direction to confirm:		
	• the target of the heat treatment, whether the container, goods within the container or both		
	• the required treatment temperature		
Arrangement	• the required duration of the treatment period	Major	
compliance	<ul> <li>whether the treatment requires the relative humidity of the ambient air inside the enclosure to be measured</li> </ul>	Мајог	
	whether core temperature requirements are specified		
	<ul> <li>whether the direction authorises unpack of the goods subject to biosecurity control from the container.</li> </ul>		
	2.6 Where any of the following is detected, the treatment must not be performed and the accredited person must immediately notify the biosecurity industry participant for the approved arrangement class 4.1 site and advise them that treatment cannot occur.		
Containment	• approved arrangement site has unpacked the container, in contravention of the biosecurity direction	Major or critical	
	• biosecurity direction does not prescribe the target of the heat treatment		
	<ul> <li>biosecurity direction does not prescribe the required treatment temperature</li> </ul>		
	<ul> <li>biosecurity direction does not prescribe the required duration of the treatment period.</li> </ul>		
Notification	2.7 Where any of the following is detected, the department must be notified immediately:		
	<ul> <li>the approved arrangement site has unpacked the container, in contravention of the biosecurity direction</li> </ul>		
	• biosecurity direction does not prescribe the target of the heat treatment	Major	
	<ul> <li>biosecurity direction does not prescribe the required treatment temperature</li> </ul>		
	<ul> <li>biosecurity direction does not prescribe the required duration of the treatment period.</li> </ul>		

### **Table 2C Process – prior to treatment**

КАО	Condition	Nonconformity guide
Traceability	2.8 The accredited person must physically verify the goods subject to biosecurity control to confirm the target of the heat treatment matches the biosecurity direction. Where the target of the treatment is the:	
	<ul> <li>container, the container number must match that listed on the biosecurity direction</li> </ul>	Major
	• goods within the container, the goods (e.g. description on product labelling) must match the line description on the biosecurity direction.	
	2.9 Where the target of the heat treatment does not match the biosecurity direction, the:	
Containment	• treatment must not be performed	Major or critical
Contamment	<ul> <li>accredited person must immediately notify the biosecurity industry participant for the approved arrangement class 4.1 site and advise them that treatment cannot occur.</li> </ul>	rajor or orrown
Notification	2.10 The department must be notified immediately where the target of the heat treatment does not match the biosecurity direction.	Major
Treatment	2.11 The accredited person must inspect the heat treatment enclosure to confirm it complies with requirements of the <i>heat treatment methodology</i> .	Major
Arrangement compliance	2.12 Treatment must not be performed if the enclosure does not comply with requirements of the <i>heat treatment methodology</i>	Major or critical
Treatment	2.13 Loading the enclosure for treatment must comply with the requirements of the <i>heat treatment methodology</i> .	Major or critical
	2.14 The accredited person must not unpack the container where the biosecurity direction does not authorise unpack. This includes for the purpose of:	
Containment	<ul> <li>loading the enclosure for treatment to ensure sufficient free air space</li> </ul>	Major or critical
	<ul> <li>ensuring correct placement of temperature sensors and humidity sensors.</li> </ul>	
Containment	2.15 The container doors must be immediately closed where the accredited person determines that unpack of the container is required and the biosecurity direction does not authorise it	Major or critical
Notification	2.16 The department must be notified immediately where the accredited person determines that unpack of the container is required and the biosecurity direction does not authorise it.	Major
Notification	<ul> <li>2.17 The department must be notified of the reason that unpack of the container is required. This includes:</li> <li>insufficient free air space to enable effective distribution of hot air</li> <li>inability to place temperature and humidity sensors correctly.</li> </ul>	Major

### **Table 2D Process – heat treatment**

#### Information

• Where equipment calibration has not been conducted by the accredited person, for example the class 4.1 approved arrangement site has calibrated chamber sensors, the accredited person must verify the calibration is compliant with requirements of the *heat treatment methodology*.

KAO	Condition	Nonconformity guide
Treatment	2.18 Where the <i>heat treatment methodology</i> and/or the biosecurity direction applicable to the treatment prescribes core temperature measurement for the goods, core temperature sensors must be used to measure this temperature.	Major or critical
Treatment	2.19 Where the biosecurity direction applicable to the treatment specifies relative humidity of the ambient air inside the enclosure be maintained, humidity sensors must be used to measure the relative humidity.	Major or critical
	2.20. The use of temperature sensors and humidity sensors must comply with requirements of the <i>heat treatment methodology</i> . This includes ensuring:	
	<ul> <li>treatment measuring equipment is calibrated at time of use</li> </ul>	
Treatment	<ul> <li>sensors are capable of measuring the required temperature range and humidity, where required, for the prescribed treatment duration</li> </ul>	Major or critical
	• temperature readings are taken at intervals no greater than sixty seconds	
	<ul> <li>correct number and placement of sensors</li> </ul>	
	• sensors are identified for data monitoring, recording and calibration.	
	2.21 The treatment has failed and must be restarted where any or more of the following events occurs:	
Treatment	<ul> <li>temperature sensors record that the temperature has fallen below the required temperature prescribed on the biosecurity direction</li> </ul>	
	<ul> <li>humidity sensors record that the relative humidity has fallen below the required humidity specified on the biosecurity direction</li> </ul>	Critical
	<ul> <li>required temperature and humidity, where required, was not maintained for the required duration of the treatment period prescribed on the biosecurity direction</li> </ul>	
	• temperature sensors and humidity sensors, where required, fail to record accurate readings for the prescribed treatment duration.	

# Table 2E Process – recording the heat treatment

#### Information

• Provision of the completed *Record of heat treatment* to the department, for successful treatments only, is needed to obtain subsequent direction from the department or a release from biosecurity control.

KAO	Condition	Nonconformity guide
Arrangement compliance	<ul> <li>2.22 A Record of heat treatment must be completed:</li> <li>for all successful (passed) and failed treatments</li> <li>at the same time and same approved arrangement site the heat treatment occurred.</li> </ul>	Major
Traceability	2.23 Where the treatment has failed, the reason for the treatment failure must be recorded on the <i>Record of heat treatment</i> .	Major
Arrangement compliance	2.24 All sections / fields of the <i>Record of heat treatment</i> must be completed in accordance with the requirements of the <i>heat treatment methodology</i> .	Minor or major
Arrangement compliance	2.25 The <i>Record of heat treatment</i> must be signed by the accredited person who conducted or directly supervised the heat treatment.	Major
Arrangement compliance	2.26 A copy of the completed <i>Record of heat treatment,</i> for successful treatments, must be provided to the:	
	<ul> <li>biosecurity industry participant of the approved arrangement class 4.1 site where the treatment occured</li> </ul>	Major
	<ul> <li>department using the contact details specified on the biosecurity direction to treat.</li> </ul>	

### **Table 3 Records**

#### **Information**

- Records and systems maintained by the biosecurity industry participant are able to track goods subject to biosecurity control through the stages of the biosecurity goods pathway they are responsible for. This includes receipt, handling, treatment, disposal and release.
- There must be two-way traceability, from the:
  - o records to the physical goods
  - o physical goods to the records.

KAO	Condition	Nonconformity guide
	3.1 Records for heat treatment must include:	
	biosecurity direction	
	<ul> <li>the completed Record of heat treatment for successful treatments, including the date and time it was provided to the department</li> </ul>	
Traceability	• the completed <i>Record of heat treatment</i> for failed treatments, including the reason for the failure	Major
	<ul> <li>date, time and method the department was notified</li> </ul>	
	<ul> <li>additional records required by the heat treatment methodology, other than the Heat Treatment Certificate.</li> </ul>	
Treatment	3.2 Records of calibration for temperature sensors and humidity sensor, where applicable must include:	Major
Heatment	<ul> <li>date on which the calibration was performed</li> </ul>	Major
	<ul> <li>name and organisation of the person that performed the calibration.</li> </ul>	
	3.3 Accredited persons records must include:	
	<ul> <li>name of accredited person</li> </ul>	
m 1:1:	<ul> <li>date accreditation training completed</li> </ul>	N/ :
Traceability	<ul> <li>method of accreditation training (online or in-house)</li> </ul>	Major
	<ul> <li>copy of online training accreditation certificate – if applicable</li> </ul>	
	• copy of in-house training attendance record – if applicable.	
Traceability	3.4 The biosecurity industry participant must ensure records are kept for a minimum of two years for goods subject to biosecurity control.	Minor or major
Traceability	3.5 Records must be made available to the department upon request.	Minor or major

### **Table 4A Compliance**

KAO	Condition	Nonconformity guide
Arrangement compliance	<ul> <li>4.1 The biosecurity industry participant must:</li> <li>carry out the biosecurity activities in accordance with the arrangement</li> <li>comply with the requirements of the arrangement</li> <li>comply with all conditions to which the arrangement is subject.</li> </ul>	Major or critical
Arrangement compliance	4.2 Goods subject to biosecurity control must be maintained and processed in accordance with the requirements of the relevant approved arrangement class.	Major or critical
Arrangement compliance	4.3 Goods subject to biosecurity control must be maintained and processed at an approved arrangement site appropriate for the biosecurity risk associated with the items.	Minor or major or critical
Arrangement compliance	4.4 Goods subject to biosecurity control must be maintained and processed in accordance with import conditions specified in the department's Biosecurity Import Conditions Database (BICON).	Minor or major or critical
Arrangement compliance	4.5 Goods subject to biosecurity control must be maintained and processed in accordance with an import permit.	Major or critical
Arrangement compliance	4.6 Goods subject to biosecurity control must be maintained and processed in accordance with any other direction from the department.	Minor or major or critical
Arrangement compliance	4.7 Goods subject to biosecurity control must be handled and maintained and processed in accordance with the Biosecurity Act 2015 and subordinate legislation.	Minor or major or critical
Arrangement compliance	4.8 Departmental officers or department approved auditors, must be provided with facilities and assistance as requested, and any required documents, records or things relevant to the audit.	Major or critical
Arrangement compliance	4.9 Department approved auditors must be permitted to collect evidence of compliance and noncompliance with approved arrangement requirements through actions including the copying of documents and taking of photographs.	Major or critical
Notification	4.10 The department must be notified of any reportable biosecurity incident as soon as practicable, in accordance with the determination made by the Director of Biosecurity.  Information on reporting biosecurity incidents is available on the departments website.	Critical
Movement	4.11 Goods subject to biosecurity control are not permitted to leave the biosecurity area of an approved arrangement site, inadvertently or deliberately, without prior written direction or approval from the department.	Critical
Identification	<ul> <li>4.12 If there is any doubt as to whether goods:</li> <li>are subject to biosecurity control</li> <li>remain subject to biosecurity control</li> <li>become subject to biosecurity control</li> <li>then the goods must be handled in accordance with requirements for goods subject to biosecurity control.</li> </ul>	Major

### **Table 4B Compliance**

KAO	Condition	Nonconformity guide
Arrangement compliance	4.13 The biosecurity industry participant must notify the department, <a href="mailto:aa.canberra@agriculture.gov.au">aa.canberra@agriculture.gov.au</a> , within 15 working days of becoming aware of any change of status, not previously been notified to the department, of the biosecurity industry participant or their associates relevant to the operation of the approved arrangement in relation to any of the following matters:	Critical
	• conviction of an offence or order to pay a pecuniary penalty under the Biosecurity Act 2015, Quarantine Act 1908, Customs Act 1901, the Criminal Code or the Crimes Act 1914	
	<ul> <li>debt to the Commonwealth that is more than 28 days overdue under the Biosecurity Act 2015, Quarantine Act 1908, Customs Act 1901, the Criminal Code or the Crimes Act 1914</li> </ul>	
	<ul> <li>refusal, involuntary suspension, involuntary revocation/cancelation or involuntary variation of an Import Permit, quarantine approved premises, compliance agreement or approved arrangement under the Quarantine Act 1908 or the Biosecurity Act 2015.</li> </ul>	
Notification	4.14 The biosecurity industry participant must notify the department at, <a href="mailto:aa.canberra@agriculture.gov.au">aa.canberra@agriculture.gov.au</a> , within 15 days of any change in:	
	<ul> <li>persons in positions responsible for controlling, directing, enforcing or monitoring people performing activities associated with the approved arrangement</li> </ul>	
	<ul> <li>biosecurity industry participant details, including:</li> </ul>	
	o entity name	Major or critical
	o Australian business number or Australian company number	
	o postal address	
	o email address	
	o facsimile number	
	o telephone number.	