

Export Meat Operational Guideline

2.7 Approval of alternative regulatory arrangements at export-registered meat establishments



Purpose

The purpose of this guideline is to outline the process for the approval of alternative regulatory arrangements (alternative procedures and new technologies) at export-registered meat establishments.

Scope

This guideline applies to the establishment approved arrangement holders of all export-registered meat establishments.

Legislative basis

Under the *Export Control Act 2020* ('the Act') and its relevant Rules:

Export Control Act 2020

- Export Control Act 2020, Chapter 11, Part 1A—Alternative regulatory arrangements.
- Export Control Act 2020, Chapter 5, Part 4—Variation of approved arrangement, Division 1—Variations by holder, Subdivision B—Significant variations and variation of conditions.

Meat Rules

- Export Control (Meat and Meat Products) Rules 2021, section 1-9 Circumstances in which alternative procedure, standard or other requirement is taken to meet requirements of Australian Meat Standard.
- Export Control (Meat and Meat Products) Rules 2021, Chapter 5, Division 4—Variation of approved arrangement, Subdivision A—Variations by holder.

Poultry Meat Rules

- Export Control (Poultry Meat and Poultry Meat Products) Rules 2021, 1 8 Circumstances in which alternative procedure, standard or other requirement is taken to meet requirements of Australian Poultry Meat Standard.
- Export Control (Poultry Meat and Poultry Meat Products) Rules 2021, Chapter 5, Part 4—Variation of approved arrangement, Division 1—Variations by holder.

Rabbit and Ratite Meat Rules

- Export Control (Rabbit and Ratite Meat and Rabbit and Ratite Meat Products) Rules 2021, 19 Circumstances in which alternative procedure, standard or other requirement is taken to meet requirements of Australian Meat Standard.

- Export Control (Rabbit and Ratite Meat and Rabbit and Ratite Meat Products) Rules 2021, Chapter 5, Part 4—Variation of approved arrangement, Division 1—Variations by holder.

Wild Game Meat Rules

- Export Control (Wild Game Meat and Wild Game Meat Products) Rules 2021, 1 10
Circumstances in which alternative procedure, standard or other requirement is taken to meet requirements of Australian Meat Standard or Australian Wild Game Meat Standard.
- Export Control (Wild Game Meat and Wild Game Meat Products) Rules 2021, Chapter 5, Part 4—Variation of approved arrangement, Division 1—Variations by holder.

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Introduction

Alternative procedures and technological advances can provide betterment to the export meat industry and enable efficiency in meat processing/production and safety.

The Department of Agriculture, Fisheries and Forestry (the department) has the legislative responsibility of approving alternative regulatory arrangements (ARAs) at export-registered meat establishments, whilst ensuring continued compliance with export legislation, food safety standards/wholesomeness requirements, animal welfare standards and importing country requirements.

Practices and operations at export-registered meat establishments should be detailed in the establishment's approved arrangement.

Occupiers may propose alternative regulatory arrangements. These alternative arrangements may or may not be on the grounds of scientific research and may differ from:

- currently accepted and approved science and/or industrial practices within the Australian export meat industry, or
- procedures detailed in the relevant Australian Meat Standards (AS 4696:2023, AS 4465:2005, AS 4464:2007).

In such cases, the Delegate must be satisfied that the specified alternative regulatory arrangement achieves the same purpose. The occupier must provide a written application to the department as outlined in this guideline.

Application Process

Applications for approval of ARAs are to be made in accordance with the requirements of the *Export Control Act 2020*, section 379B and having regard to the relevant Australian Meat Standards and relevant overseas country requirements; including those that may be affected by a proposed alternative.

Clarification from the department should be sought on the need to lodge an application. If the department considers that implementation of the proposed ARA poses no adverse impact on meeting legislative requirements, applications for approval are not required to be made through the process described in this guideline (but may require an approved arrangement significant variation (EX26b) application). For further information see: [Meat Export Policy Significant and non-significant variation of an Establishment approved arrangement by the holder under the Export Control Act 2020](#).

If an application for approval is required, a written application must be provided to the Delegate through the Area technical manager (ATM). The ATM will review the application in consultation with the Field operations manager (FOM), the application will then be provided to the Delegate along with recommendations. For pre-validated procedures or technologies (as part of the approval process) the department will determine whether and to what extent an on-plant trial is required. An overview of the process is provided in Attachment 2: Application process flow.

The establishment must ensure that the proposed alternative regulatory procedure is not implemented unless and until written approval is granted by the department.

Application requirements

The application must:

- Meet relevant legislative requirements including state and local government requirements.
- Identify any effects of the alternative regulatory arrangement on:
 - food safety.
 - animal welfare.
 - product integrity
 - work health and safety of departmental on-plant staff
 - implementation of inspection and regulatory requirements

- overseas market requirements
- environmental matters that may have an adverse effect on the establishment's ability to prepare meat and meat products for export certification.
- Contain the following as appropriate:
 - a descriptive title.
 - a brief description of the proposed alternative regulatory arrangement.
 - reason for the introduction of the alternative regulatory arrangement.
 - statement regarding any adverse effects the alternative regulatory arrangement may have (as per the second bullet list above).
 - an independent organisation nominated for co-operative development, oversight and subsequent validation of on-plant trials.
 - the name of the Establishment ATM at the time of lodging the application.
 - applicant and management contact details and export establishment registration number.
 - approval, in writing, by an Animal Ethics Committee (AEC) that is constituted and functioning in accordance with the Australian code for the care and use of animals for scientific purposes, should an on-plant trial be performed on animals delivered to the establishment.
- Provide background information such as:
 - any published independent research results/scientific validation.
 - evidence of prior approvals from necessary bodies (such as State or Territory authorities) or importing country authorities.
 - regulatory changes or exemptions required to meet the relevant Australian Meat Standard, export regulations or importing country requirements.
- Where necessary, provide a detailed experimental design proposal for an on-plant trial including:
 - details of the establishment at which the trial is to be undertaken.
 - proposed duration of trial.
 - details of how product involved in the trial will be identified and how product integrity will be assured.
 - identification of the methods for controlling bias and incorporation of 'controls'.
 - details of the observations and measurements to be taken and records to be maintained.
 - proposed disposition of the product included in the trial.
 - if applicable, a signed copy of the letter granting approval by a recognised Australian Animal Ethics Committee (AEC) to the applicant indicating that the proposed on-plant trial meets the Australian Code of Practice for the Care and Use of animals for Scientific Purposes (the Code).
 - adhering to all other relevant Codes of Practice and Guidelines required by the department.
- Provide any other information that will assist the Delegate in their deliberations.

In all cases, applications must ensure continued compliance with current legislation or apply for specific exemptions where appropriate. Please note that this may require the department to get approval from overseas or state authorities:

- to allow the trial to take place on the establishment, and/or
- to enable companies to export 'trial' product to these markets.

It is recognised that there will be some situations where it is not practical to require on-plant trials prior to the approval and implementation of an ARA. In these instances, the independent validation data already available should be provided in the application. If approved, it is essential in these circumstances that the ARA is monitored on-plant to verify the data provided and ensure that there is compliance with food safety, animal welfare, legislative and market requirements.

Where the applicant is not affiliated with an educational institute, they must approach an institutional Animal Ethics Committee if they are required to get approval from the department before the procedure is carried out.

All procedures presented to an Animal Ethics Committee must conform to all legal requirements (State and Commonwealth) and must not commence until written approval has been received (as stated in the Code) and provided to department management.

On-Plant Trial Guidelines

If the application is successful to the point of undertaking on-plant trial, the trial must:

- be carried out in consultation with the OPV.
- comply with any conditions that the department may have placed upon trial and product produced during the trial period.
- be overseen by the OPV and an independent organisation(s) as nominated, which will provide a full report on the outcome of the trial and provide an opinion on the validation of the process.
- Two copies of the trial validation are to be provided by the independent organisation. One is sent directly to the applicant and one directly to the Establishment ATM, who is then responsible for:
 - assessing the results of the independent validation of the on-plant trial in consultation with the FOM/Senior Scientific officers,
 - providing the validation data and recommendations to the Delegate, and
 - informing the applicant and OPV of the FOM and Delegate's final decision on the application.

For pre-validated procedures or technologies, the on-plant trial may not need to be full-scale. In these circumstances the extent of the trial will be determined by the department in consultation with specialist senior scientific officers from the department.

Commercial In-Confidence

The department will treat applications as commercial-in-confidence unless requested otherwise. The department will not divulge confidential information to other parties except as provided for in legislation. Applicants should prepare a non-confidential summary for discussion with industry representatives.

Attachment 1: Roles and responsibilities

Establishment management

Provide to the department, in writing, all the appropriate details as outlined in this guideline.

On-plant veterinarian/On-plant supervisor

- Forward enquiries about possible pre-validated alternative regulatory arrangement to the Establishment ATM.
- Oversee the on-plant trial once approved.
- Forward the results (raw data) of the on-plant trial to the Establishment ATM.

Establishment ATM

- Follow up on enquiries about possible pre-validated alternative regulatory arrangements.
- Receive and review the application (including that for any trial) for an alternative regulatory arrangement and accept, reject or return it (via OPV/OPS) to the applicant for amendment, if required.
- In consultation with the FOM, forward accepted applications with recommendations, to the Delegate. Notify the applicant (in writing) that the application is complete and has been forwarded for consideration.
- Inform the applicant (in writing) of the progress of the application, including estimated timeframes.
- Inform the applicant of approval or rejection for the on-plant trial.
- Review the approved on-plant trial results and independent validation findings as applicable.
- Forward the independent validation results to the Delegate with recommendations.
- Inform applicant and the OPV/OPS of the FOM and Delegate's decision.
- Consider and approve any relevant variation to the occupier's approved arrangement as required by submitting an EX26b.

FOM

- Provide feedback to the Establishment ATM on applications and advise of decisions made regarding an application.

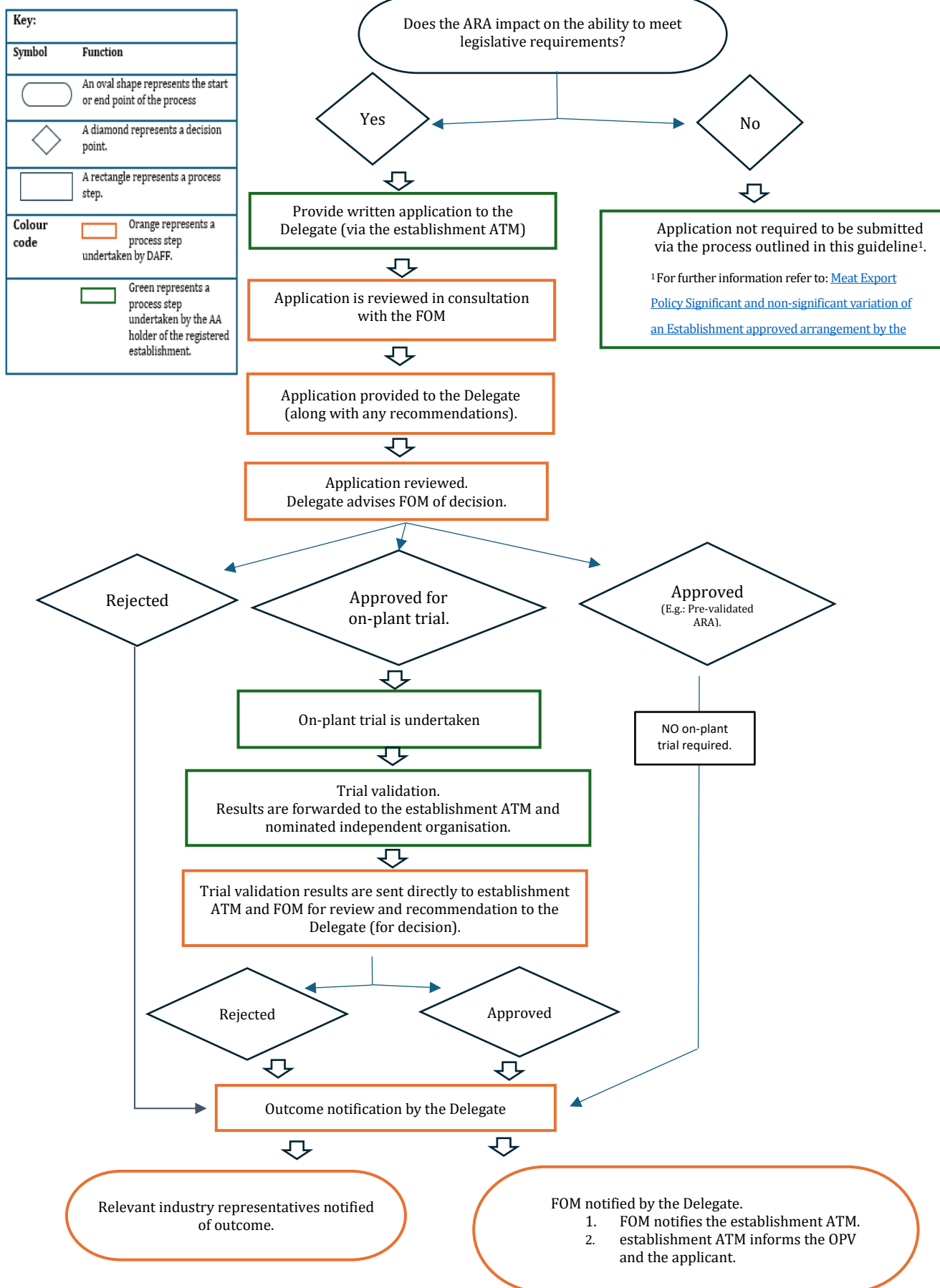
Delegate

- Consult (as needed) with appropriate experts.
- Provide feedback to the Establishment ATM and FOM about pre-validated procedures or technologies.
- Approve, conditionally approve or reject applications for trials of alternative regulatory procedures in accordance with the requirements of the relevant export meat commodity rules, relevant Australian Meat Standard and any particular overseas countries.
- Discuss the application with appropriate industry representatives.
- If the trial is successful, determine whether any ongoing approvals need to be addressed through legislative changes, exemptions, approved arrangements or other methods as deemed appropriate.
- Where appropriate, advise relevant industry bodies. For example, EMIAC of the result of the application.
- Provide the occupier with a written notice approving or rejecting the alternative regulatory arrangement.

Meat exports branch

- Maintain a database of approved alternative regulatory arrangements (for reference for future applications).

Attachment 2: Application process flow



Attachment 3: Definitions

Alternative regulatory arrangements

With regard to the Australian export meat commodity industries (meat, poultry meat, rabbit & ratite meat), any new applications of equipment, procedures, processes and technology affecting the slaughter, dressing or processing of meat, offal or meat products that achieve the purpose of a requirement under the export control meat commodity rules and the applicable Australian Meat Standard.

With regard to the Australian export wild game meat, any new applications of equipment, procedures, processes and technology affecting the dressing or processing of wild game meat, or wild game meat products that achieve the purpose of a requirement under the Wild Game Meat Rules and the Australian Wild Game Meat Standard.

Animal Ethics Committee (AEC)

A committee constituted in accordance with the terms of reference and membership laid down in the Code, to oversee the use of animals in research and teaching.

Establishment Area Technical Manager (ATM)

A Commonwealth authorised officer with veterinary qualifications who has responsibility for the supervision, technical performance, assessment and verification of technical standards and operations in a defined group of export meat establishments.

Australian Meat Standard

Australian standard for the hygienic production and transportation of meat and meat products for human consumption (AS 4696:2023).

Australian Poultry Meat Standard

Australian standard for the construction of premises and hygienic production of poultry meat for human consumption (AS 4465:2005).

Australian Wild Game Meat Standard

Australian standard for the hygienic production of wild game meat for human consumption (AS 4464:2007).

Delegate

One of several senior officers in the department to whom the Secretary has delegated the power to consider applications for the use of alternative procedures and new technologies. In most instances this will be either the Export Meat Program Manager or the Assistant Secretary of the Meat exports branch.

Export Meat Industry Advisory Committee (EMIAC)

A joint Department/industry consultative committee.

The Export Meat Industry Advisory Committee (EMIAC) was created as a consultative body between the export meat industry and the department. EMIAC's terms of reference are broad but its main function is to consider technical issues affecting the export meat sector. It also provides policy advice on many major issues such as residues, pathogens, international requirements including market access and food safety issues affecting meat.

EMIAC is not a statutory body, but it has a high profile within the industry.

Field Operations Manager (FOM)

A Commonwealth authorised officer with veterinary qualifications who has responsibility for the verification of the performance and effectiveness of system audits and providing technical advice to senior division management in relation to audit policy matters.

Occupier

A person in whose name the establishment is registered and who is in management and control of that establishment.

On-Plant Veterinarian (OPV)

A Commonwealth authorised officer (veterinarian) employed by the Department to conduct ante-mortem inspection at slaughter establishments and to provide daily supervision of post-mortem inspection and verification of the establishment's approved arrangement.

Pre-validated procedures

For the purposes of this guideline, pre-validated procedures are those alternate technologies that have been independently assessed to meet certain performance targets.

Attachment 4: Related material

The following related material is available on the department's website:

- Webpage: [ELMER 3 – Electronic legislation, manuals and essential references](#)
- Webpage: [Approved arrangement guidelines – Meat](#)
- Webpage: [Approved arrangement guidelines – Wild game meat](#)
- Webpage: [Approved arrangement guidelines – Poultry](#)
- Webpage: [Meat Export Policy Significant and non-significant variation of an Establishment approved arrangement by the holder under the *Export Control Act 2020* - DAFF \(\[agriculture.gov.au\]\(http://agriculture.gov.au\)\)](#)

The following related material is available on the internet:

- Webpage: [Export Control Act 2020](#)
- Webpage: [Export Control \(Meat and Meat Products\) Rules 2021](#)
- Webpage: [Export Control \(Wild Game Meat and Wild Game Meat Products\) Rules 2021](#)
- Webpage: [Export Control \(Rabbit and Ratite Meat and Rabbit and Ratite Meat Products\) Rules 2021](#)
- Webpage: [Export Control \(Poultry Meat and Poultry Meat Products\) Rules 2021](#)
- Webpage: [Australian code for the care and use of animals for scientific purposes | NHMRC](#)
- Webpage: [AS 4696 Hygienic production and transportation of meat and meat products for human consumption | Standards Australia Store](#)
- Webpage: [Australian standard for the hygienic production of wild game meat for human consumption \(AS4464\)](#)
- Webpage: [Australian standard for the construction of premises and hygienic production of poultry meat for human consumption \(AS4465\)](#)