Australian Government
Department of Agriculture and Water Resources

Policy for approval of alternative procedures and new technologies in export registered meat establishments

This policy is established to provide a clear statement on procedures for the approval of alternative procedures and new technologies in export registered meat establishments.

INTRODUCTION

Alternative procedures and technological advances can offer opportunities to the export meat industry and enable improvements in meat production and safety.

The Department of Agriculture and Water Resources has the legislative responsibility of approving alternative procedures and new technologies on export registered meat establishments, while ensuring continued compliance with export legislation, food safety standards, animal welfare standards and importing country requirements.

Practices and operations at export registered establishments are detailed in the establishment's approved arrangements.

Applicants may propose alternative procedures or new technology, which may or may not be on the grounds of scientific research, and differs from currently accepted and approved science and/or industrial practices within the Australian export meat industry, or those detailed in the relevant Australian Meat Standard. In such cases, the Delegate must be satisfied that the specified alternative procedure or new technology achieves the same purpose.

The occupier of a registered establishment must provide a written application to the Delegate through the Area Technical Manager (ATM) and ensure that the proposed procedure is not implemented unless and until a written approval is granted.

DEFINITIONS

Term	Definition
Alternative procedures	With regard to the Australian export meat industry, 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 EC(MMP)O and the Australian Meat Standard.
Animal Ethics Committee (AEC)	A committee constituted in accordance with the terms of reference and membership laid down in the NHMRC Code, to oversee the use of animals in research and teaching.
Australian Meat Standard	Australian Standard for the Hygienic Production and Transportation of Meat and Meat Products for Human Consumption (AS 4696:2007).
ATM	Area Technical Manager

Term	Definition
NHMRC Code	National Health and Medical Research Council's Australian Code of Practice for the Care and Use of Animals for Scientific Purposes. *At the time of publication, the NHMRC Code was in its eighth edition (2013) and available on the NHMRC website.*
Delegate	May be 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.
EC(MMP)O	Export Control (Meat and Meat Products) Orders 2005
EMIAC	Export Meat Industry Advisory Committee
FOM	Field Operations Manager
New technology	With regard to the Australian export meat industry, any new applications of equipment, processes or substances affecting the slaughter, dressing or processing of meat, offal or meat products that may impact on food safety, animal welfare or regulatory requirements either in Australia or in an importing country.
OPS	On-Plant Supervisor
OPV	On-Plant Veterinarian

LEGAL BASE

Export Control (Meat and Meat Products) Orders 2010:

- Part 9, Division I (Alternative Regulatory Arrangements) Orders 79.1 to 79.7
- Schedule I Part 2 (Variation of Registration and Approved Arrangements) Division II, Clauses 14.1, 14.2, 15.1 - 15.7, 16.1 - 16.4, 17.1 and 17.2.

APPLICATION PROCESS

Applications for approval of alternative procedures and new technologies are to be made in accordance with the requirements of the *Export Control (Meat and Meat Products) Orders 2005* (EC(MMP)O) and having regard to the relevant Australian Meat Standard 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 or not to lodge an application for a proposed new technology or procedure where initial indications are that no adverse impact would result from the introduction of the technology or procedure.

If the department considers that there is no adverse impact resulting from the proposed introduction of a new technology or procedure on all of the elements at item 2 below, applications for approval are not required to be made through the process described in this policy.

In addition, for pre-validated procedures or technologies, as part of the approval process the department may determine whether and to what extent an on-plant trial is required.

The initial application is provided to the Area Technical Manager (ATM), who will review the application in consultation with the Field Operations Manager (FOM). The application is then provided with recommendations to the Delegate for approval.

A flow chart of the process is provided at Appendix A.

APPLICATION REQUIREMENTS

The Application must:

1. Meet relevant legislative and ethical requirements
2. Identify any effects of the proposed procedure or technology on:
    a. food safety
    b. animal welfare
    c. product integrity
    d. work health and safety of departmental on-plant staff
    e. implementation of inspection and regulatory requirements
    f. overseas market requirements
    g. environmental matters that may have an adverse effect on the establishment's ability to prepare meat and meat products for export
    h. certification
3. Contain the following as appropriate:
    a. a descriptive title
    b. a brief description of the proposed new procedure
    c. reason for the introduction of the procedure
    d. statement regarding any adverse effects the new procedure may have as per item 2 above
    e. an independent organisation nominated for co-operative development, oversight and subsequent validation of on plant trials
    f. the name of the ATM responsible for the establishment at the time of lodging the application
    g. applicant and management contact details and export establishment registration number
    h. approval, in writing, by an Animal Ethics Committee (AEC) that is constituted and functioning in accordance with the NHMRC Code, should an on-plant trial be performed on animals delivered to the establishment.
4. Provide background information such as:
    a. any independent research results/scientific validation
    b. evidence of prior approvals from necessary bodies (such as State or Territory authorities) or importing country authorities
    c. regulatory changes or exemptions required to the relevant Australian Meat Standard, export regulations or importing country requirements.
5. Where necessary, provide a detailed experimental design proposal for an on-plant trial including:
    a. details of establishment at which trial is to be undertaken as appropriate

b. proposed duration of trial
c. details of how product involved in the trial will be identified and how product integrity will be assured
d. identification of the methods for controlling bias and incorporation of 'controls'
e. details of the observations and measurements to be taken and records to be maintained
f. proposed disposition of the product included in the trial
g. 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 National Health and Medical Research Council's Australian Code of Practice for the Care and Use of animals for Scientific Purposes (available on the NRMRC website)
h. adhering to all other relevant Codes of Practice and Guidelines required by the department.

6. 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 introduction of an alternative procedure or new technology. In these instances the independent validation data already available should be provided in the application, which will then be considered by the ATM, FOM and the Delegate. If approved, it is essential in these circumstances that the introduced procedure or technology 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 still 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 (where an on-plant trial is required)

If the application is successful to the point of undertaking on-plant trial, the trials;

- 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.
- 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 validation are to be provided by the independent organisation, one is sent directly to the applicant and one directly to the ATM.
- The ATM is then responsible for
  - assessing the results of the independent validation of the on-plant trial in consultation with the FOM
  - providing the validation data and recommendations to the Delegate
  - 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.

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.

RESPONSIBILITIES

Management

a) Provide to the department, in writing, all the appropriate details as outlined in this policy. It is essential that any existing independent validations and the proposed on-plant trial design are included in the application.

OPV / OPS

1. Forward enquiries about possible pre-validated procedures or technologies to the ATM.
2. Oversee the on-plant trial once approved.
3. Forward the results (raw data) of the on-plant trial to the ATM.

ATM

1. Follow up on enquiries about possible pre-validated procedures or technologies.
2. Receive and review the application including that for any trial of an alternative procedure and accept, reject or return it (via OPV / OPS) to applicant for amendment if required.
3. 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.
4. Inform the applicant in writing of the progress of the application, including estimated timeframes if consideration of the application requires extended consultation.
5. Inform the applicant of approval or rejection for the on- plant trial.
6. Review the approved on-plant trial results and independent validation findings as applicable.
7. Forward the independent validation results to the Delegate with recommendations.
8. Inform applicant and the OPV / OPS of the FOM and Delegate's decision.
9. Consider and approve any relevant variation to the occupier's Approved Arrangement as required.

FOM

1. Provide feedback to the ATM on applications made by establishments.
2. Advise ATM of decisions made in regard to an application.

Delegate

1. Consult as needed with appropriate experts.
2. Provide feedback to the ATM and FOM about pre-validated procedures or technologies.
3. Approve, conditionally approve or reject received applications for trials of alternative procedures in accordance with the requirements of the EC(MMP)O, the Australian Meat Standard and any particular overseas country requirements.
4. As provided for in this policy, discuss the application with appropriate industry representatives.
5. 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.
6. Where appropriate advise relevant industry bodies e.g. EMIAC of the result of the application.
7. Provide the occupier with a written notice approving or rejecting the alternative procedure/new technology.

Meat Exports Branch

1. Maintain a database of approved alternative procedures and new technologies for reference for future applications.

Appendix A: Flow chart of process