Australian Government
Department of Agriculture, Fisheries and Forestry

November 2024

Export Meat Operational Guideline

3.19 HACCP requirements for US listed establishments.

Purpose

The purpose of this guideline is to:

- Provide Approved arrangement Holder's (AA Holder) with guidance to comply with the import requirements of the United States of America, regarding Hazard analysis and critical control point (HACCP) systems.
- Provide details on how the department provides audit services and export certification of the HACCP system.

Scope

The guideline is applicable to all export-registered establishments holding a listing for the United States of America (US).

Legislative basis

Under the *Export Control Act 2020* ('the Act') and its subordinate legislation, an AA Holder must:

- Have an approved arrangement that covers all stages of operation. This arrangement must provide for the implementation of a HACCP plan for each stage of operation to prepare the prescribed goods.
- Comply with the requirements of the Australian standard relevant to the commodity produced.
- Comply with the requirements of importing countries.

In this document

Requirements for HACCP systems

Export-registered establishments are required to have a department approved HACCP program in accordance with US Food Safety and Inspection Service, Department of Agriculture (FSIS) directives. In addition to the general requirements for HACCP plans, FSIS has specific requirements that must be met for the ongoing management of HACCP and the control of certain food safety hazards.

To maintain eligibility for the US markets, all HACCP plans must be signed and dated by the person in charge (responsible establishment official) and must be reassessed annually. Establishments producing beef, raw ground beef components (RGBC) and raw ground beef products (RGDP) must also consider the potential hazard of Shiga toxin-producing *Escherichia coli* (STEC) in ongoing management of HACCP.

Requirements will be further outlined in the following sections of this guideline and can also be found in Micor ,the Approved arrangement guidelines-meat and directly from the FSIS website.

Establishment validation

FSIS require that all establishments undertake initial validation of their HACCP plan in the practical setting to determine if it is functioning as intended - appropriately designed and fit to control the food safety hazards that were identified during the hazard analysis.

Initial validation must include the following:

- Repeated testing of the adequacy of the CCPs and their accompanying critical limits.
- Repeated testing of monitoring procedures.
- Repeated testing of record keeping procedures.
- Repeated testing of corrective actions as set out in the HACCP plan.
- Review of records. This should be undertaken in the context of the other validation activities.

The US, Food safety inspection service (FSIS) HACCP Guidance describes the documentation that is expected to support the validation.

Establishment verification

The Export Control Meat Rules and importing countries require the AA Holder to undertake ongoing verification of the HACCP plan to ensure its effectiveness. Each US listed establishment's verification activities must include the following:

- Calibration of monitoring equipment used to monitor CCPs (frequency of calibration must be stated in the Hazard audit table).
- Observing CCP monitoring activities undertaken by trained establishment staff (check-the-checker).
- Monitoring the effectiveness of corrective actions implemented when a CCP critical limit has not been met.
- Monitoring of microbiological sampling and testing.
- Review of CCP monitoring records (daily record review).

provides further information on verification activities for product destined for the US.

HACCP plan reassessment

The AA holder must ensure that reassessment of the HACCP plan is conducted on (at least) an annual basis to determine its maintained adequacy, or to reassess if changes arise that could affect the hazard analysis. Changes that require a HACCP reassessment, include (but are not limited to) the following:

- If an unforeseen hazard arises. For example, a hazard that has not been previously considered or was considered not significant. This may include a residue detection above a maximum residue limit (MRL), or STEC detections.

- If changes occur that could affect the hazard analysis or alter the HACCP plan. This could include (but not limited to) changes in raw materials, processing methods and volumes, personnel or intended use of the product.

The HACCP reassessment must be undertaken by an individual trained in HACCP plan development and modification. This training must cover the application of the 7 principles of HACCP (for meat processing), the development of a HACCP plan for specific product and record review. As described in, A Guide to the implementation and auditing of HACCP.

Records must be maintained pertaining to HACCP reassessments undertaken as a result of changes indicated by the bullet points above. Refer to Table 2: HACCP records. For annual reassessments, if the determination finds the HACCP plan to be adequate to control hazards, then the basis of this determination is not required to be documented.

If any reassessment determines that the HACCP plan is no longer adequate to control hazards, then it must be immediately modified. The revised HACCP plan must be signed and dated by the person in charge (responsible establishment official).

If the establishment is not currently listed for exporting RGBC to the US, they will have to reassess and validate their HACCP plan before commencing or recommencing export. Effectiveness of process controls must be verified by undertaking enhanced departmental verification testing (as outlined in the Microbiological manual for sampling and testing of export meat and meat products).

Management of STEC by HACCP reassessment

The HACCP reassessment should identify the predominant STEC serotypes identified in the classes of stock being processed; and it must determine which STECs will be used to verify process control and in the robust testing of lots. Table 1 describes the requirements based upon the determination.

Table 1: HACCP reassessments of predominant STEC serotypes

HACCP reassessment determination	Testing requirement
Non-O157 STEC are **likely** to occur; or control measures are inadequate to control the risk.	Establishments must test for '**Top 7' STEC** in each lot for export.
Non-O157 STEC are **not likely** to occur; or control measures are adequate to control the risk.	Establishments may test for ***E. coli*-O157 only** in each lot for export. If establishments are testing for *E. coli*-O157 only, they must provide justification resulting from the reassessment. Monthly departmental verification sample results may contribute to HACCP reassessment determination.

The HACCP reassessment determination may vary over time depending on the outcome of regular HACCP reassessments**.** If the determination changes, then testing of lots of RGBP and RGBC must be amended accordingly to reflect the change in risk.

HACCP records

The *Export Control Act 2020* requires that AA Holders retain records pertaining to the production of meat and meat products, primarily those that demonstrate compliance. FSIS have specific requirements regarding HACCP record keeping. These can be found in the Code of Federal Regulations, Title 9.(9 CFR 417.5) and are summarised in Table 2.

Table 2: HACCP records

Record scope	Type
Hazard analysis	• Flow charts describing the step of each process and product flow and intended use of the product. • Any other supporting documents.
HACCP Plan	• HACCP plan for each product type produced (where the hazard analysis reveal 1 or more food safety hazards are likely to occur). Such products may include (but not is not limited to): raw product (ground/not ground), thermally processed, not heat treated and heat treated (shelf stable), fully cooked (not shelf stable), heat treated but not fully cooked (not shelf stable) and any product with secondary inhibitors (not shelf stable). • List of food safety hazards. • List of CCP for each food safety hazard and their critical limits along with decision making documentation.
Monitoring records	• List of the CCP monitoring procedures and their frequency. • Records of monitoring must show the actual values and observations obtained during monitoring. • Time, date and signature of person undertaking the procedures.
Corrective action	• Procedures undertaken in response to deviations from the critical limits (including person responsible). • Records must contain date, time and signature/initials of responsible person. • Measures taken to prevent reoccurrence.
Verification	• Procedures and their frequency. • Results (product codes/name, slaughter production lot, time and date of record). • Calibration records. • Production record review (pre-shipment review) undertaken by someone who did was not involved in the record taking and is HACCP trained.
Reassessment	• Reassessment records and determinations. • Reasoning for HACCP plan modifications as a result of the reassessment. • Reassessment and validation records for recommencing export of RGBC.

Prior to shipping US eligible product, establishments must undertake a review of CCP monitoring records (also referred to as a pre-shipment review) to verify that at each CCP the product has met the critical limits. Establishments undertaking a daily review of CCP monitoring records are compliant with the record requirements of the Code of Federal Regulations (9 CFR 417.5, c). FSIS accepts that daily CCP monitoring record review meets the requirements for pre-shipment review.

The *Export Control Act 2020* requires records to be retained for at least 2 years from the date the record was made. This complies with the FSIS requirements for document retention outlined in the Code of Federal Regulations (9 CFR 417).

Zero tolerance macroscopic contamination

The US(FSIS) has a zero tolerance (ZT) standard for visible faecal material, ingesta and milk contamination on carcases and carcase parts. Under FSIS regulations (9 CFR chapter III, subchapter A and C respectively), establishments must handle livestock carcases and carcase parts to prevent contamination for faecal material.

Slaughter establishments must implement effective controls for ZT contamination of carcases and carcase parts on the slaughter floor, including critical limits for their control. The HACCP plan must include a critical control point (CCP) on the slaughter floor (inclusive of any offal products that may be used for ground meat). These CCPs must be monitored daily and are verified by the department.

Microbiological testing

As FSIS consider *E. coli* O157:H7 a hazard that is reasonably likely to occur in beef products, the AA holder must include *E. coli* O157:H7 and other STEC as potential hazards and incorporate CCP's for their control in the HACCP plan. The US have pre-export sampling and testing requirements for raw RGBC, RGBP and ready-to-eat products (RTE).

As the US have a 'zero-tolerance' policy for microbial pathogens, *E. coli* O157, *Salmonella* and *Listeria monocytogenes* in ready-to-eat (RTE) products (meat and poultry), all establishments that produce RTE products (that are exposed to the environment after lethality treatments) are required to implement procedures (HACCP systems) to control *Listeria monocytogenes* in the final product.

All US registered establishments must participate in the monthly department verification testing program to maintain market access. Refer to section: Department audit and verification.

On at least an annual basis, establishments must select a random shipment (from a health certificate) to test the lot identification, product recall, and to verify that microbiological independence was maintained. This must be department verified.

Detailed information on microbiological testing requirements for the US can be found in the department's Microbiological manual for sampling and testing of export meat and meat products.

Department audit and verification

Under the *Export Control Act 2020*, the department has the legislative authority for the purposes of providing audit services and export certification; and this is achieved via the Export meat system audit program (EMSAP) and the Meat establishment verification system (MEVS). Relevant program and system components are described under the headings to follow.

Export meat system audit program

Audits of Tier 2 export-registered abattoirs, export-registered wild game processing establishments and independent boning rooms are performed under the EMSAP.

EMSAP audits assess the establishment's documentation and records in the context of its AA, operational performance and outcomes. Documentation, product standards and process compliance will be assessed and verified during the audit. This will be achieved by the following:

- Audit of each element of the approved arrangement (including HACCP, importing country requirement and sampling programs).
- Product and process evaluation within the various areas of the establishment.

  Product/process evaluation will include check-the-checker of establishment employees at operations where product hygiene index (PHI) key performance indicators and HACCP CCP's are monitored.

Further information on this program can be found in the Export meat operation guideline: 5.2 Export Meat System Audit Program (EMSAP).

Meat establishment verification system

The Meat establishment verification system (MEVS) is the inspection and verification system employed at export establishments. Its key system components verify that the AA holder's approved arrangement is effective and operated in accordance with Australian export legislation, providing assurance that products are wholesome, fit-for-human consumption and comply with importing country requirements.

The MEVS incorporates structured activities performed by department authorised officers to verify the AA Holder's procedures are meeting the critical limits defined in their HACCP plan. These activities include the following:

- Zero tolerance CCP verification activities are undertaken to objectively measure the physical standards of meat hygiene and verify that processes are being undertaken in accordance with good manufacturing practice (GMP). Verification of the slaughter floor CCP's by the department must include weasand, head and cheek meat.
- Five (5) establishment daily record reviews (pre-shipment reviews) are verified monthly to ensure all CCP's have been complied with.
- Monthly STEC department verification testing. See section: Microbial sampling and testing verification.

Further information on this verification system can be found in Export Meat Operational Guideline: 9.2 Meat Establishment Verification System (MEVS) – Establishments and Export Meat Operational Guideline: 9.3 Meat Establishment Verification System (MEVS) – Independent boning rooms.

Microbial sampling and testing verification

All establishments listed to export RGBC and RGBP to the US must participate in the department verification testing program, the frequency of which is determined by central office (monthly at minimum) and will be based on the compliance history of the establishment.

Monthly departmental verification (for both product types) tests for all seven (7) STEC serotypes. The conditions, actions and reporting requirements for the two programs are detailed in the Microbiological manual for sampling and testing of export meat and meat products.

Related material

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

- Webpage: *Export Control Act 2020*
- Webpage: Export Control (Meat and Meat Products) Rules 2021
- Webpage: Manual of Importing Country Requirements
- Webpage: Microbiological Manual for Sampling and Testing of Export Meat and Meat Products
- Webpage: Export meat operation guideline: 5.2 Export Meat System Audit Program (EMSAP).
- Webpage: Export Meat Operational Guideline: 9.2 Meat Establishment Verification System (MEVS) – Establishments
- Webpage: Export Meat Operational Guideline: 9.3 Meat Establishment Verification System (MEVS) – Independent boning rooms
- Webpage: Approved arrangement guidelines-meat

The following related material is available on the internet or for purchase in print:

- A Guide to the implementation and auditing of HACCP Standing Committee of Agriculture and Resource Management. (SCARM Report 60). CSIRO publishing 1997
- Australian Standard for the Hygienic Production and Transportation of Meat and Meat Products (AS4696):2023 (available for purchase from Intertek Inform)
- US Department of Agriculture FSIS (2021) HACCP Model for Beef Slaughter
- Food Safety Inspection Service (FSIS), US Department of Agriculture Code of Federal Regulations 9 CFR 417. Hazard analysis and critical control point (HACCP)systems
- Food Safety and Inspection Service (FSIS) HACCP Guidance

Attachment 1: Implementation of establishment verification activities

Verification activities for product destined for the US. The intent is to finalise the full daily record review (pre-shipment review) before the product leaves establishment control.

On at least a daily basis:

- confirm that critical limits at each CCP were met. Where critical limits were not met, ensure appropriate corrective and preventative action was taken and recorded. Ensure that the proper disposition was made on the affected product.
- view other monitoring and verification records to ensure there is no impediment to inter-establishment transfer or loading for export.

Ensure, wherever practicable, that the daily record review (pre-shipment review):

- is carried out by establishment employees who are trained in HACCP; and that the review is carried out by someone other than the person who created the record.
- is summarised as a consolidated document, which list the CCP's and the various daily monitoring records. Each entry must have a comment as to acceptability (or otherwise), must be dated and the signature of the person who carried out the review of each record must be applied.

Where product freezing is carried out at a different establishment to the packaging establishment, the freezing establishment is responsible for monitoring freezing and for carrying out a daily record review for the parts relevant to its activities. The signing of a meat transfer certificate (MTC) at the sourcing establishment acknowledges that the critical limits have been satisfied at the CCP's relevant to that establishment.

The record review summary must be readily available to department officers on request.

Attachment 2: Definitions

Approved arrangement

An approved arrangement under Chapter 5 of the *Export Control Act 2020*.

An arrangement for a kind of export operations in relation to a kind of prescribed goods approved by the Secretary.

An approved arrangement:

- documents the controls and processes to be followed when undertaking export operations in relation to prescribed goods for export
- enables the Secretary to have oversight of specific export operations.

AUS-MEAT

AUS-MEAT Limited ABN 44 082 528 881 is a company owned by Australian meat and livestock industries. It is primarily responsible for the development, approval, and maintenance of standards for meat trade description. AUS-MEAT is the body responsible for setting trade description standards for meat and meat products derived from bovine, caprine, ovine, and porcine animals for export from Australian territory.

Critical Control point (CCP)

As defined in AS4696, a point or operation or stage in the food chain, including raw materials, at which control can be applied and is essential to prevent or eliminate a hazard or reduce it to an acceptable level.

Critical Limit (CL)

The maximum or minimum value to which a physical, biological, or chemical hazard must be controlled at a critical control point to prevent, eliminate, or reduce to an acceptable level the occurrence of the identified food safety hazard.

Department authorised officers

As per the *Export Control Act 2020*, means an authorised officer who is an officer or employee of a Commonwealth body and has presence during production for export at an export-registered establishment.

FSIS refers to the competent controlling authorities inspectors as 'in plant inspection personnel. (IPP).

***E. coli* O157**

An organism which gives a positive test for detection of *E. coli* serotype O157 from an enrichment broth, and a pure isolate from the enrichment broth is:

- confirmed with biochemical and serological tests as *E. coli* O157, and
- confirmed to contain one or more of the Shiga toxin genes (stx1/2) and the eae gene.

Food Safety Inspection Service (FSIS)

An US government agency (Department of Agriculture) that regulated food safety and food defense. FSIS ensures food safety through the authorities of the Federal Meat Inspection Act, the Poultry Products Inspection Act, and the Egg Products Inspection Act, as well as humane animal handling through the Humane Methods of Slaughter Act.

HACCP (Hazard Analysis and Critical Control Point) System

The HACCP Plan in operation, including the HACCP plan itself.

Lethality Treatment

A process or treatment that eliminates or reduces the number of pathogenic microorganisms on or in a RTE product to a level that is considered safe. Levels that are considered safe for human consumption are those that meet the microbiological criteria specified in the Australia New Zealand Food Standards Code.

Raw ground beef components (RGBC)

Raw ground beef components include all beef and veal bulk packed manufacturing trimmings and other beef and veal components such as primal cuts, sub primal cuts, head meat, cheek meat, oesophagus meat, heart meat and advanced meat recovery product intended for grinding in the US and/or Canada

Raw ground beef products (RGBP)

Are raw comminuted (chopped or ground) meat food products that are made from cattle (beef and/or veal), such as ground beef, hamburger, veal patties, and beef patty mix, which may be distributed to consumers as such. It is important to note that products comprised only of beef from advanced meat recovery systems are not considered a raw ground beef product.

Ready-to-eat (RTE)

Means meat products that are ordinarily consumed in the same state as that in which they are sold and do not require further processing (such as cooking), but may be defrosted, reheated or portioned before consumption.

Shiga toxin-producing *E. coli* (STEC)

STEC comprise serotypes O157, O26, O45,O103, O111, O121 and O145. The organism isolated from an enrichment broth must be: - Confirmed with biochemical and serological tests as *E. coli* O157, O26, O45, O103, O111, O121 or O145, and - Confirmed to contain one or more of the Shiga toxin genes (stx1/2) and the eae gene.

Shiga toxin-producing *E. coli* (STEC) including O157:H7 testing program

This is a test and hold program designed to satisfy the requirements to export raw ground beef components (RGBC) to the US and other markets where STEC testing is required for export. Product may not be released for export until the result of any testing under this program is known and known to be negative. All confirmed positive or deemed positive results must be notified to the department and a disposition applied.

Note: RGBC consignments must have their US *E. coli* O157: H7 test status referenced on the meat transfer certificate (MTC).