

# **Export Meat Operational Guideline**

13.10 Critical incident response



### **Purpose**

This document describes the process that the department implements to address a critical incident. This may be either:

- a violation of importing country requirements (detected at point of entry)
- a failure of specific department audit or verification programs conducted on plant.

## Scope

The scope of this guideline includes:

- export-registered red meat abattoirs (including Tier 1 establishments)
- independent boning rooms
- wild game meat processing plants.

## Legislative basis

Under the *Export Control Act 2020* ('the Act') and its subordinate legislation there are legislative requirements relating to:

- inspection (ante-mortem)
- verification (post-mortem, food safety, animal welfare, market access requirements and product integrity/certification).

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## Critical incident types and level of department response

Critical incidents (as defined in this guideline) arise from either a violation of importing country requirements (detected at point of entry) or from failure of specific department audit or verification programs conducted on plant.

There are three Levels (1, 2 and 3) of departmental response that are influenced by the:

- source of the critical incident
- importing country authority expectation of the department to take particular action(s) within a particular timeframe.

The Meat Exports Branch (MEB) (Export Meat Operations; <a href="mailto:exportmeatoperations@aff.gov.au">exportmeatoperations@aff.gov.au</a>) maintains a critical incident register to track individual establishments and to advise on the level of response required for each incident.

Rejections relating to labelling defects, transport damage and other miscellaneous causes are not considered critical incidents (as defined in this guideline) provided that:

- the importing country authority has not specifically requested an investigation and report from Australia, and
- the establishment can conclusively prove that it was not at fault.

Where critical incidents have occurred (as distinct from labelling defects, transport damage and miscellaneous rejections described above), the establishment may be issued with a Corrective Action Request (CAR) directing them to undertake a documented investigation to rule out establishment fault. If excessive or repetitive rejections are found to be attributable to the establishment of origin, then a Critical Incident Response (CIR) may be triggered at the discretion of the National Veterinary Technical Manager (NVTM) in consultation with the Field Operations Manager (FOM) and the Export Standards Branch (ESB).

## **USA and Canada point of entry violations**

For USA and Canada point of entry violation (POEV), the department automatically applies a 12-month moving window with three levels of response. The window is reset after 12 months if the establishment has:

- had no further POEVs in the 12-month window
- passed the associated Critical Incident Response Audits (CIRAs)
- regained market listing (i.e. if sanctions had been applied and the department had removed the USA/Canada listing).

When a Level 3 CIR is triggered by a third POEV, the department may not automatically apply a Level 3 response if, at the time of notification, the establishment was in an open Level 2 response and can demonstrate that:

- products were limited to production in a defined period related to the Level 2 CIR
- root cause(s) have been identified
- effective corrective and preventative actions have been implemented
- it has received acceptable department verification.

Where the above conditions have been met, the department may:

- advise the USA or Canadian authorities that access will not be immediately suspended.
- conduct an additional verification audit no more than 30 days after the third USA POEV.

## China point of entry violations

Where the establishment has been suspended from exporting to China by the General Administration of Customs of China (GACC), the department will apply three levels of response beginning at Level 1 (in the first instance); then escalating the level depending on the outcome of the CIRA.

The department automatically applies a 12-month moving window. The window is reset after 12 months if the establishment has:

- had no further POEVs in the 12-month window
- passed the associated CIRAs
- regained China listing (i.e. if sanctions had been applied and the department had removed the China listing or China had applied an import suspension on the establishment).

When a Level 3 CIR is triggered by a third China POEV, the department may not automatically apply a Level 3 response if, at the time of notification, the establishment was in an open Level 2 response and can demonstrate that:

- products were limited to production in a defined period related to the Level 2 CIR
- root cause(s) have been identified
- effective corrective and preventative actions have been implemented
- it has received acceptable department verification.

Where the above conditions have been met, the department may conduct an additional verification audit no more than 30 days after the third China POEV.

For non-compliances that do not involve a GACC suspension, each incident is assessed on a case-by-case basis. Where required, the department will apply three levels of response beginning at Level 1 (in the first instance); then escalating the level depending on the outcome of the CIRA.

## Other country point of entry violations

For POEVs, other than for the USA, Canada or China, the department does not automatically apply the 12 -month moving window process. Each incident is assessed on a case-by-case basis taking into consideration any requirements for departmental action as directed by the relevant importing country authority. The department will apply three levels of response beginning at Level 1 (in the first instance); then escalating the level depending on the outcome of the CIRA.

## **On-plant critical incidents**

Three levels of response are applied beginning at Level 1 (in the first instance); then escalating the level depending on the outcome of the CIRA.

In relation to unacceptable responses to CARs issued by department officers and CARs issued during systems audits that are not closed out, a Level 1 response is applied following consultation and agreement between the Establishment ATM and the relevant FOM.

The establishment may apply to extend a CAR beyond the date that would trigger a CIRA. However, the establishment must request the CAR extension in writing before the deadline has passed for long term action, and the request must include the reason for required CAR extension. CAR extensions may not be granted if the non-compliance is related to animal welfare or food safety (each requiring immediate action).

For establishments that are audited annually, a marginal or unacceptable audit outcome will result in the establishment returning to a six-monthly audit frequency after an acceptable critical incident response audit. A return to an annual audit frequency will require the establishment to have three consecutive six-monthly acceptable audit outcomes. In relation to Tier 1 abattoirs under the jurisdiction of a State Regulatory Authority (SRA), a Level 1 response is arbitrarily applied following consultation and agreement between the department and the relevant SRA. This guideline does not supersede or supplant any memorandum of understanding (MOU) between the department and the SRA.

The following table describes the types of critical incidents and the levels of response that the department applies during a critical incident response.

Critical incident type	Critical incident description	Level of department response
USA or Canada (Ca) POEV	<ul> <li>POEV for Shiga Toxin producing Escherichia.coli (STEC).</li> <li>POEV for faeces, ingesta, milk, off condition, chemical or physical hazards, other harmful material or conditions, pathological and parasitic lesions.</li> </ul>	<ul> <li>Level 1 – first USA/Ca POEV in 12-month moving window.</li> <li>Level 2 – second USA/Ca POEV in 12-month moving window.</li> <li>Level 3 – third USA/Ca POEV in 12-month moving window.</li> <li>Note: When a Level 3 response is triggered, the department will automatically suspend access to that market. Access to other markets will be reviewed to assess whether compliance with their requirements have been maintained.</li> <li>Levels subsequent to Level 1 are also triggered by unacceptable CIRA ratings (for example, an unacceptable Level 1 CIRA triggers a Level 2 CIRA).</li> </ul>
China POEV	Any non-compliance with China's importing country requirements that results in suspension of export by GACC.	<ul> <li>Level 1 – first China POEV in 12-month moving window.</li> <li>Level 2 – second China POEV in 12month moving window.</li> <li>Level 3 – third China POEV in 12-month moving window.</li> <li>Note: Levels subsequent to Level 1 are also triggered by unacceptable CIRA ratings (for example, an unacceptable Level 1 CIRA triggers a Level 2 CIRA).</li> </ul>
China noncompliance notification	Non-compliance to China's importing country requirements – other than those involving suspension.	<ul> <li>Level 1 (in the first instance); as required on case-by-case determination.</li> <li>Levels subsequent to Level 1 are triggered by unacceptable CIRA ratings.</li> </ul>
POEV (other than for USA, Canada or China)	POEV reported by an importing country authority.	<ul> <li>Level 1 (in the first instance), as required on case-by-case determination.</li> <li>Levels subsequent to Level 1 are triggered by unacceptable CIRA ratings.</li> </ul>
Department systems audit	Marginal or unacceptable rating.	<ul> <li>Level 1 (in the first instance).</li> <li>Levels subsequent to Level 1 are triggered by unacceptable CIRA ratings.</li> </ul>
Unacceptable response to a CAR	An unacceptable response by the due date to a CAR issued during a systems audit, or issued by a department officer at an abattoir or a Food Safety Assessor at an independent boning room.	<ul> <li>Level 1 (in the first instance).</li> <li>Levels subsequent to Level 1 are triggered by unacceptable CIRA ratings.</li> </ul>
Marginal, unacceptable SRA audit or a critical noncompliance	SRA audit of Tier 1 establishment.	Level 1 where there has been joint agreement between the department and the SRA.

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Monthly STEC <sup>1</sup> confirmed positive verification – USA and Canada raw ground beef	Confirmed positive STEC detections in the 15-follow up verification sample window following a confirmed positive on monthly department STEC verification of raw ground beef components intended for export to the USA and Canada	<ul> <li>Level 1 – first confirmed positive in the 15-sample window.</li> <li>Level 2 – second confirmed positive in the 15-sample window.</li> <li>Level 3 – third confirmed positive in the 15-sample window.</li> </ul>
Small stock POE <sup>2</sup> hygiene verification – USA-eligible product	Re-inspection failure triggered by a POE defect detection during daily hygiene verification of finished USA-eligible sheep, lamb and goat product.	<ul> <li>Level 1 – first reinspection failure in 12-month moving window.</li> <li>Level 2 – second reinspection failure in 12-month moving window.</li> <li>Level 3 – third reinspection failure in 12-month moving window.</li> <li>Note: Levels subsequent to Level 1 are also triggered by unacceptable CIRA ratings (for example, an unacceptable Level 1 CIRA triggers a Level 2 CIRA).</li> </ul>
Breach of the Salmonella testing performance standards	Failure of a third consecutive Salmonella window coupled with an unsatisfactory establishment investigation and corrective action.	<ul> <li>Level 1 (in the first instance).</li> <li>Levels subsequent to Level 1 are triggered by unacceptable CIRA ratings.</li> </ul>

 $^{1}$ In relation to monthly department STEC verification, if there is a third STEC confirmed positive within a follow up 15-sample verification window, the department will:

- review the establishment's compliance with requirements of other markets
- conduct an additional CIR audit no more than 30 days after the third STEC confirmed positive
- consider suspension of the establishment's USA or Canada listing for raw ground beef components or raw ground beef products.

<sup>2</sup>In relation to department daily product hygiene verification of finished USA-eligible sheep, lamb and goat product where there is a third point of entry (POE) defect detection, then, the department will:

- $\bullet \quad \hbox{review the establishment's compliance with requirements of other markets} \\$
- conduct an additional CIR audit no more than 30 days after the third POE defect detection
- withdraw USA certification for the species concerned.

#### Official notification

The process of official notification depends upon the nature of the critical incident.

In relation to incidents that are raised by an SRA, the response will be in accordance with the notification process agreed between the department and the relevant SRA.

#### Official notification of a point of entry violation

The following table outlines the process for official notification of a POEV to the department.

Stage	Process	Responsible party
1.	The department is officially notified of the POEV. The notification will contain the details of the critical incident including but not limited to:	ESB
	date of notification	
	defect report	
	health certificate.	
	Note: In some cases, further information such as photographs of defects may be requested from the importing country authority.	
2.	MEB is emailed the official notification as soon as it is available.	ESB
3.	Official notification will be immediately forwarded to the:	MEB/FOM/ERIA
	relevant FOM and Veterinary Export Meat Branch (VEMB) Director.	
	the FOM will notify the relevant ATM of the incident and direct them to initiate an investigation on plant.	
	<ul> <li>Export Regulatory Integrity and Assurance (ERIA), will notify therelevant SRA of the incident on a Tier 1 abattoir.</li> </ul>	
4.	The ATM requests the OPV/FSA to issue a Corrective Action Request (CAR) directing the establishment to immediately undertake an investigation and to develop and implement a Corrective Action Plan (CAP).	ATM/OPV/FSA
5.	The department may increase on-plant verification. Any increases will be notified to the relevant VEMB Director.	FOM
6.	The critical incident is captured on the CIR register.	MEB

#### Risk assessment

The NVTM, in consultation with the relevant FOM, has discretion in directing an establishment to conduct a risk assessment of the likelihood of further rejections due to systemic failure of the establishment's processes. The decision is based on the circumstances of the incident and if there are any specific directions from the importing country authority.

A risk assessment is mandatory for the following critical incidents:

- Positive detection within a 15-sample follow-up verification window that is opened by a
  positive detection of a monthly department STEC verification of raw ground beef
  components or raw ground beef products intended for export to the USA or Canada.
- USA or Canada POEV for STEC or macroscopic defects.
- Re-inspection failure triggered by a POE defect detected during daily hygiene verification of finished USA eligible sheep, lamb or goat product.

The following table outlines the risk assessment process required to be undertaken by an establishment (the purpose is to determine the likelihood of further rejection/verification failures of similar USA-eligible product due to systemic failure at the establishment).

Stage	Process	Responsible party
1.	For POEV STEC detections, within four (4) working hours of official notification, the establishment will provide to the department:	Establishment management
	details of all cartons and sampled lots	
	confirmation of the microbiological independence of the lots	
	<ul> <li>confirmation that there is no other product, from the sampled lots, that has either been exported or is in store and is USA or Canada eligible.</li> </ul>	
	Within 48 hours of a POEV (faeces or ingesta detection) or POE defect detected during daily hygiene verification of finished USA eligible sheep, lamb or goat product, the establishment management will:	
	<ul> <li>review its production process and relevant AA records to determine the extent of the problem (i.e. is it a one off event or part of a production system failure). This will include a risk assessment of any similar product (in store and/or in transit)</li> </ul>	
	<ul> <li>make their findings available to theOPV or FSA.</li> </ul>	
	<ul> <li>notify the department of any product that is at risk of rejection that cannot be withdrawn from entering the market.</li> </ul>	
2.	Verify the establishment's determination of microbiological independence of the sampled lots, including confirmation of the location of any product from the sampled lots.	On-plant officer
	Immediately provide the establishment risk assessment report to the:	
	• ATM	
	• FOM	
	MEB.	
3.	Within 5 working days notify ESB of the microbiological risk assessment outcome.	MEB

## Corrective action plan

Regardless of the level of response, the establishment must develop a Corrective Action Plan (CAP) to address a critical incident within ten working days of the official notification.

The key objective is to determine and address the fundamental cause/s of the critical incident and prevent recurrence of the rejection/verification failure.

The establishment's senior management must appoint an investigation team which is responsible for developing the CAP.

The table below outlines the steps the establishment's investigation team will follow to develop a CAP.

1.	Address any immediate corrective actions relating to food safety.
2.	Undertake an immediate and comprehensive assessment of all operations at the establishment to determine the likely root cause/s.
3.	Re-examine the Hazard Analysis and Critical Control Point (HACCP) plan and relevant approved arrangement (AA) programs that are within scope of the critical incident.
4.	Determine whether the incident is an isolated case or is due to systemic failure.
5.	Ensure that the scope of the investigation covers a reasonable timeframe before and after the date of the critical incident.

The CAP must be signed by a person who is in a senior position or management or control within the establishment. The signed report must be provided to the FOM once the ATM is satisfied that the CAP is suitably prepared.

The FOM will consider the effectiveness of the CAP prior to approving it. The FOM will also determine whether increased department verification is required during a critical incident response.

In cases where the establishment has an open critical incident and a CAP already in place and is notified of another similar critical incident for the same market, then the original CAP can be reviewed and amended to cover the subsequent incident. However, if the subsequent critical incident is unrelated to the existing incident, then a separate CAP is required.

In relation to critical incidents in a Tier 1 establishment, the requirement for the establishment to develop a CAP will be dependent upon the MOU between the SRA and the department.

## Critical incident response audit

Unless advised otherwise, a CIRA will be conducted within twenty (20) working days of the official notification. There are exceptions to this timeframe:

- for marginal or unacceptable department audit outcomes, a CIRA must be done within three (3) months.
- for POEVs, if the plant is in shutdown or not producing a particular species at the time of
  official notification, then a longer timeframe may be negotiated between the FOM, NVTM
  and ESB if approved by the importing country.

The scope of the audit will be the establishment's CAP and the department's on-plant records.

If the outcome of the audit identifies a systemic failure, then the department will consider the status of any similar product in store and in transit.

For non-USA market related critical incidents, the NVTM, in consultation with the FOM, has the discretion to determine the level of response and the members of the audit team.

In relation to a Tier 1 abattoir under the jurisdiction of the relevant SRA, the audit team will be determined by the department and the SRA in accordance with the MOU.

The table below outlines the makeup of the audit team at each critical incident response level.

Level 1	Level 1 Regional FOM (lead auditor) and Establishment ATM (auditor)	
Level 2	Independent FOM (lead auditor) and Establishment ATM (auditor)	
Level 3	Independent FOM (lead auditor) and Establishment ATM (auditor)	

## **Critical Incident Response audit ratings**

CIRAs are rated as either acceptable or unacceptable.

The table below describes the outcome of audits at each response level.

Level 1	Acceptable: establishment returns to normal audit frequency.
	Unacceptable: Level 2 CIRA is triggered
Level 2	Acceptable: establishment returns to normal audit frequency
Level 2	Unacceptable: Level 3 CIRA is triggered.
Level 3	Acceptable: establishment remains on an increased audit frequency (determined by the lead auditor) until such time that the establishment has demonstrated sustained compliance with legislation and importing country requirements.
	Unacceptable: the department may apply sanctions which are at the discretion of the Assistant Secretary.

#### Show cause letter

At any level of response and depending on the outcome of the CIRA, the department may issue a show cause letter requesting the establishment management to provide satisfactory justifiable reasons as to why appropriate sanctions should not be applied.

The establishment's response must be able to demonstrate to the department that it can continue to certify product for the affected market(s). The department will review the establishment's compliance with requirements for other markets and it may require additional verification by the establishment to ensure certification integrity.

The department will issue a show cause letter for USA market access critical incidents (including POEVs and on plant critical incidents) where there has been a second or third critical incident within a 12-month moving window.

#### **Sanctions**

Possible sanctions that the department may apply include:

- Additional inspection presence
- Increased audit frequency
- Withdrawal of export certification
- Market delisting
- Suspension or revocation (whole or part) of the AA
- Suspension or revocation (whole or part) of the export registration.

## Interim report

An interim report is required (from both the establishment and the OPV) for a USA POEV for STEC.

The establishment's interim report must address the following:

- The initial investigation and the CAP development.
- Any immediate corrective actions.
- Where required, assessment of the risk of further rejection or verification failure of similar product either in-store or on route to the affected market.

In a separate report, the OPV must verify all aspects of the establishment's interim report.

Within five working days of official notification, both the establishment and OPV interim reports must be verified by the ATM and the FOM before providing them to MEB.

For all USA STEC POEVs, these interim reports are required by the department within seven (7) working days (or sooner) of the official notification; and will inform for the department's response to the USA Food Safety Inspection Service (FSIS).

## Final report

The final report summarises the actions (including the CAR, interim reports, CIR audit report and results of any increased verification) taken by the department as well as the establishment's CAP.

It contains a statement as to whether the establishment has been able to demonstrate whether or not it has identified the root cause/s and implemented effective and sustainable corrective/preventative actions to ensure that there is no further risk to the market in question.

The department also advises of its decision in relation to the establishment's market listing/s.

In all cases of a POEV, a final report is compiled by the FOM. MEB provides this report to ESB at least three (3) working days before the final importing country authority due date. Should there be extraordinary circumstances that do not allow for this to occur, ESB must be provided sufficient notice to seek a formal extension, if necessary, from the relevant importing country authority.

## **Record keeping**

- MEB maintains a CIR Register of all official critical incidents.
- CIR official notifications, interim reports and final reports are maintained by the MEB.
- CIR audit reports are maintained in the department's audit management system (AMS).
- All on-plant verification records relating to the critical incident are maintained within AMS and the on-plant national standard filing system.



#### **Related Material**

#### **Export legislation**

The following related material is available on the internet:

- Webpage: <u>Export Control Act 2020</u>
- 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

#### Reference material

- Webpage: Export Meat Regulatory Action and Sanctions policy
- Webpage: <u>Manual of importing country requirements</u>
- Webpage: Microbiological manual for sampling and testing of export meat and meat products.

#### Work health and safety

The following related material is available on the internet:

- Webpage: Work Health and Safety Act 2011
- Webpage: Work Health and Safety Regulations 2011
- Webpage: Model WHS Regulations

## **Attachment 1: Roles and responsibilities**

#### **Establishment Area Technical Manager (ATM)**

- Notify the On-Plant Veterinarian (OPV)/Food Safety Assessor (FSA) of POEV critical incidents.
- Notify Meat Exports Branch (MEB) of critical incidents that originate on plant.
- Verify the establishment's CAP prior to the CIRA.
- Participate as an auditor during a CIRA.

#### **Export Regulatory Integrity and Assurance (ERIA)**

- Manage MOUs with SRA.
- Notify the relevant SRA of a critical incident.
- Notify MEB of a critical incident raised by an SRA.

#### **Establishment Management**

- Address a department CAR issued in response to a critical incident official notification.
- Develop a CAP in response to a critical incident.
- Where required, undertake a risk assessment of similar product likely to fail department verification or be subject to further market rejection.

#### **Export Standards Branch (ESB)**

- Provide official notification of POEV to MEB.
- Advise MEB of any deadlines for reporting back to the importing country authority of the department's response to the critical incident.
- Provide results of department STEC verification testing including serotypes to the United States Department of Agriculture (USDA) or Canadian Food Inspection Agency (CFIA).
- Provide the department's response to the importing country authority in the case of a POEV.

#### Field Operations Manager (FOM)

- Liaise with the NVTM on the level of response and audit team for non-USA POEVs.
- Approve the establishment's final CAP.
- Determine whether increased department verification is required during a critical incident.
- Undertake the lead auditor role during a CIRA.
- Write the final report following a CIRA.

#### Food Safety Meat Assessor (FSMA)

• When required during a critical incident, increases frequency of department verification on an abattoir.

#### **Meat Exports Branch (MEB)**

- Contacted at exportmeatoperations@aff.gov.au
- Initiate the CIR process when an official notification is provided either by ESB (in the case of POEVs) or by the FOM (in the case of failed department audit/verification) or by ERIA (for Tier 1 related critical incidents).
- Maintain the CIR register.
- Coordinate the completion of interim and final reports by the due dates.
- Notify ERIA in the event of a critical incident response.

#### Meat Exports Branch, Assistant Secretary

• Following recommendation of FOM/NVTM, approval of non-US POE and other critical non-compliance issues identified/reported for an establishment.



- Issue show cause letters.
- Apply sanctions to an establishment in response to an unacceptable Level 3 CIRA, lifting of a sanction, and revocation of an approved arrangement.

#### National Veterinary Technical Manager (NVTM)

- Decide the level of response and audit team for non-USA POEVs when warranted on a case-by-case basis in consultation with the relevant FOM.
- In consultation with the FOM, authorise risk assessments of the likelihood of further rejections/verification failures for markets other than the USA.

#### **On-plant officers (On-Plant Veterinarian and Food Safety Assessor)**

- Issues CARs in response to official notification of a critical incident.
- Oversee the establishment's CAP development.
- Verify establishment CAP monitoring and verification activities.
- Verify the establishment's interim report.
- Undertake increased department verification when directed.
- Maintain on-plant department verification records.

#### **Veterinary and Export Meat Branch (VEMB) Director, Inspection Services**

• Provide OPV/FSMA resources as required by the FOM to enable increased department verification during a critical incident.

#### **Attachment 2: Definitions**

#### Approved arrangement (AA)

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.

#### **Authorised officer**

A person who is authorised under section 291 to be an authorised officer under the Act. For the purpose of this document, the term 'authorised officer' refers only to authorised officers under the employ of the Commonwealth and includes On-Plant Veterinarians, Food Safety Meat Assessors and Food Safety Auditors.

#### **CIR** register

The department's Meat Exports Branch maintain a Critical Incident Response register to track all critical incidents.

#### Corrective action plan (CAP)

A comprehensive documented plan that ensures deficient activities are addressed in a sustainable manner and are agreed between the management of an export meat establishment and the department.

The plan must contain investigation of the cause, consideration of corrective and preventive measures, and implementation of corrective action, monitoring, assessment and verification.

It is developed by the establishment in response to a critical incident and direction from the department to undertake an investigation into the likely cause.

#### Corrective action request (CAR)

A formal written directive issued by the department to the establishment management to take corrective action when a non-conformity is identified and *reasonably likely* to affect food safety, product wholesomeness, animal welfare, product integrity or market access requirements.

#### Critical incident response audit (CIRA)

A comprehensive audit conducted by a Field Operations Manager (FOM) and Area Technical Manager (ATM) of the applicable elements of the establishment's approved arrangement that were in scope of the critical incident.

The scope of this audit is the implementation of the agreed CAP at the establishment. It is undertaken following approval of an establishment's CAP.

#### **Critical incident**

A violation detected at point of entry on a particular day, of an entire consignment of product with the same port mark and on the same health certificate and related to food safety, unsound condition or pathological defects directly attributable to the establishment(s) of origin.

An incident that occurs on an establishment and is related to a marginal or unacceptable department EMSAP audit outcome, an unacceptable response to a CAR, a failed department STEC window, a breach of the Salmonella performance standard, a failed department small stock USA daily hygiene verification reinspection and an SRA notification on a Tier 1 establishment that requires department intervention.

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A violation of China's importing country requirements related to labelling, trade descriptions and/or certification.

Point of entry violations relating to labelling defects, transport damage and other miscellaneous causes, other than for China, are **not** considered critical incidents if the importing country authority has not specifically requested an investigation and report from Australia and the establishment can conclusively prove that it was not at fault.

## Department daily product hygiene verification of finished USA-eligible sheep, lamb and goat product

Department verification of 10 cartons/carcases sampled from USA-eligible product lines from the boning room and/or carcase bagging area immediately prior to packing.

#### Note:

- Bobby calves are not in scope.
- USA point of entry defects include faeces, ingesta, milk, off condition, chemical or physical hazards, other harmful material or conditions, pathological and parasitic lesion(s).

#### **Department STEC verification**

A monthly department verification test for the presence of STEC undertaken on USA-listed establishments that produce raw ground beef components intended for export to the USA.

#### Point of entry violation (POEV)

This is a formal notification to the department from an importing country authority advising that re-inspection or testing of product at point of entry does not meet their requirements.

#### Raw ground beef components (RGBC)

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, and advanced meat recovery (AMR) product intended for grinding in the USA or Canada.

#### Raw ground beef products (RGBP)

Include 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, that may be distributed to consumers as such. It is important to note that products comprised only of beef from AMR and beef sausages are not considered as RGBPs.

#### Salmonella performance standard breach

In accordance with National Carcass Microbiological Monitoring Program (NCMMP) (formerly known as ESAM), a failure by the establishment to meet the standard for the third consecutive sample window, conducted for the class of product, constitutes a failure to maintain the minimum standard for slaughter hygiene and sanitation.

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

Shiga toxin producing *E. coli* are one of the seven 0 types (0157, 026, 045, 0103, 0111, 0121 and 0145).

#### Note:

- If O157 is detected, then there must be an isolate with an 'stx' gene.
- If any of the other 0 types are detected (026, 045, 0103, 0111, 0121 or 0145), then there must be an isolate with an 'stx' and an 'eae' gene.

#### STEC 15-sample follow up department STEC verification testing window

Any STEC confirmed positive result, recorded in the follow up 15-sample verification window.

Note: the window excludes the department monthly STEC confirmed positive result that opened the 15-sample window.

#### Tier 1 establishment

An export-registered establishment that is audited by the relevant State Regulatory Authority on behalf of the department. Tier 1 establishments have limited export market access. They do not have department officers (i.e. OPVs and FSMAs) on site.

#### **USA** point of entry defects

Microscopic defects include STECs.

*Macroscopic defects* include faeces, ingesta, milk, off condition, chemical or physical hazards, other harmful material or conditions, pathological and parasitic lesion.

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**Export Meat Operational Guideline:** 13.10 Critical incident response 19 August 2024

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