



GUIDELINE

Critical incident response

Direction to staff

This document is instructional material for the Department of Agriculture and Water Resources (the department) under its Practice Statement Framework. All staff must comply with it.

Summary of main points

This document outlines the:

- Critical incident types and levels of department response
- Official notification steps
- Risk assessment steps
- Corrective Action Plan (CAP) requirements
- Critical incident Response Audit (CAP) procedure and ratings
- Issuing show cause letters and sanctions
- The reporting lines and timeframes for responding to an official importing country point of entry violation (POEV) notification and on-plant critical incidents.

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Purpose of this document

This document describes the process that the department implements to address a critical incident.

The scope of these guidelines includes:

- Export registered red meat abattoirs (including Tier 1 establishments)
- Independent boning rooms
- Wild game meat processing plants.

A critical incident on a Tier 1 abattoir is managed in accordance with the Memorandum of Understanding (MOU) between the appropriate State Regulatory Authority (SRA) and the department.

Definitions

The following table defines terms used in this document.

| Term | Definition |
|---------------------------------|---|
| Approved Arrangement (AA) | <p>An arrangement approved under clause 5 of Schedule 1 or under subclause 22.1 of Schedule 7 and includes variation of such an arrangement in the circumstances specified in clause 17 of Schedule 1 or clause 27 of Schedule 7 of the Export Control (Meat and Meat Products) Orders 2005.</p> <p>Or:</p> <p>An arrangement approved under Schedule 1, as varied in accordance with the Export Control (Wild Game Meat and Wild Game Meat Products) Orders 2010.</p> |
| Audit Management System (AMS) | <p>The department's web-based audit reporting system that is used to record the results of verification activities, weekly meetings, NCIs, CARs, audit checklists, audit reports.</p> |
| Corrective Action Plan (CAP) | <p>A comprehensive documented plan that ensures deficient activities are addressed in a sustainable manner and is agreed between the management of an export meat establishment and department.</p> <p>The plan must contain investigation of the cause, consideration of corrective and preventive measures, and implementation of corrective action, monitoring, assessment and verification.</p> <p>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.</p> |
| Corrective Action Request (CAR) | <p>A formal written directive issued by the department to the establishment management to take corrective action when a non-conformity is identified and <i>reasonably likely</i> to affect food safety, product wholesomeness, animal welfare, product integrity or market access requirements.</p> |

| Term | Definition |
|---|---|
| Critical incident response audit (CIRA) | <p>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.</p> <p>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.</p> |
| China point of entry violations | A notification from the General Administration of Quality Supervision, Inspection and Quarantine (AQSIQ), People's Republic of China, either directly to the Department, or via the AQSIQ website, of a violation with China Importing Country Requirements. |
| CIR register | A Critical Incident Response register is maintained by the department's Food Safety Unit to track all critical incidents. |
| Critical incident | <ul style="list-style-type: none"> 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, a failed department STEC window, a breach of the Salmonella performance standard, a failed department small stock United States of America (USA) daily hygiene verification reinspection and an SRA notification on a Tier 1 establishment that requires department intervention. A violation of China's importing country requirements related to labelling, trade descriptions and/or certification. <p>Note:</p> <p>Point of entry violations relating to labelling defects, transport damage and other miscellaneous causes, other than for China, are not considered critical incidents as long as 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.</p> |
| Department daily product hygiene verification of finished USA-eligible sheep, lamb and goat product | <p>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.</p> <p>Note:</p> <ul style="list-style-type: none"> 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. |
| 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. |

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| Term | Definition |
|--|--|
| Non-Compliance Issue (NCI) | <p>A written record (generated in AMS) made by department on-plant staff and given to the establishment who must address the non-compliance that had the <i>potential</i> to affect food safety, product wholesomeness, animal welfare, product integrity or market access requirements.</p> <p>Note: The intent of an NCI is to record the details of the non-compliance and the associated actions taken by the establishment to correct the issue and reduce the likelihood of its recurrence.</p> |
| Periodic audit | A department audit conducted by an Area Technical Manager (ATM) at abattoirs, wild game processing plants and independent boning rooms where an establishment has opted <i>out</i> of biannual systems auditing. |
| 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 (RBGC) | 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 product intended for grinding in the USA. |
| Salmonella performance standard breach | In accordance with <i>E. Coli</i> and Salmonella Monitoring Program (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 <i>E. coli</i> (STEC) | <p>Shiga toxin producing <i>E. Coli</i> are one of the seven O types (i.e. O157, O26, O45, O103, O111, O121 and O145).</p> <p>Note:</p> <ul style="list-style-type: none"> • If O157 is detected, then there must be an isolate with a stx gene. • If any of the other O types are detected (i.e. O26, O45, O103, O111, O121 or O145), then there must be an isolate with a stx and an eae gene. |
| STEC 15-sample follow up department STEC verification testing window | <p>Any STEC confirmed positive result, recorded in the follow up 15-sample verification window.</p> <p>Note: the window excludes the department monthly STEC confirmed positive result that opened the 15-sample window.</p> |
| Systems audit | A department audit conducted by an independent lead ATM and the supervisory ATM at abattoirs, wild game processing plants and independent boning rooms where an establishment has opted <i>into</i> biannual systems auditing. |
| 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. |

| Term | Definition |
|----------------------------|---|
| USA point of entry defects | <p>Microscopic defects are STECs.</p> <p>Macroscopic defects include faeces, ingesta, milk, off condition, chemical or physical hazards, other harmful material or conditions, pathological and parasitic lesion.</p> |

Legislative framework

The following list outlines the legislation that applies to export registered establishments covered in the scope of this guideline:

- *Export Control Act 1982*
- *Export Control (Prescribed Goods-General) Order 2005*
- *Export Control (Meat and Meat Products) Orders 2005*
- *Export Control (Wild Game Meat and Wild Game Meat Products) Orders 2010*

Roles and responsibilities

The following table outlines the roles and responsibilities undertaken in this guideline.

| Role | Responsibility |
|------------------------------------|--|
| Area Technical Manager (ATM) | <ul style="list-style-type: none"> • Notify the OPV/FSA of POEV critical incidents. • Notify FSU Coordinator of critical incidents that originate on plant. • Verify the establishment's CAP prior to the CIRA. • Participate as an auditor during a CIRA. |
| Certification Integrity Unit (CIU) | <ul style="list-style-type: none"> • Manage MOUs with SRA. • Notify the relevant SRA of a critical incident. • Notify the Export Meat Program (EMP) of a critical incident raised by a SRA. |
| Establishment Management | <ul style="list-style-type: none"> • 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) | <ul style="list-style-type: none"> • Provide official notification of POEV to the EMP FSU Co-ordinator. • Advise the EMP FSU Co-ordinator 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). • Provide the department's response to the importing country authority in the case of a POEV. |

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| Role | Responsibility |
|---|---|
| Field Operations Manager (FOM) | <ul style="list-style-type: none"> • 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 CIR audit. • Write the final report following a CIR audit. |
| Food Safety Meat Assessor (FSMA) | <ul style="list-style-type: none"> • (When required during a critical incident) increases frequency of department verification on an abattoir. |
| Food Safety Unit (FSU) Coordinator | <ul style="list-style-type: none"> • 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 CIU for Tier 1 related critical incidents. • Maintain the CIR register. • Monitor the CIR 12-month moving window for USA market access critical incidents. • Co-ordinate the completion of interim and final reports by the due dates. • Notify the CIU in the event of a critical incident response. |
| Meat Exports Branch <ul style="list-style-type: none"> • Assistant Secretary | <ul style="list-style-type: none"> • Issue show cause letters. • Apply sanctions to an establishment in response to an unacceptable Level 3 CIRA. |
| National Veterinary Technical Manager (NVTM) | <ul style="list-style-type: none"> • Decide the level of response and audit team for non-USA POEVs where 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 Officer <ul style="list-style-type: none"> • On-plant Veterinarian (OPV) • Food Safety Auditor (FSA) | <ul style="list-style-type: none"> • 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 Services (VEMS) <ul style="list-style-type: none"> • Director, Inspection Services | <ul style="list-style-type: none"> • Provide OPV/FSMA resources as required by the FOM to enable increased department verification during a critical incident. |

Work health and safety

Each member of the on-plant regulatory team must be aware of the establishments work health and safety (WHS) policy and procedures prior to entering the site.

- The person conducting a business or undertaking (PCBU) and employers, premises owners or managers at a third party premises advise each member of the on-plant regulatory team of any possible health and safety risks the assessment team may be exposed to.
- Whilst on-site the on-plant regulatory team is provided with an induction that includes emergency procedures, personal protective equipment requirements and hazard safety disclosures prior to gaining access to any secure areas.
- Each member of the on-plant regulatory team must conform to any work health and safety (WHS) procedure, protective equipment, vaccination requirements and any other task-related duties of the department and third party premises.
- While attending the third party premises, each member of the on-plant regulatory team must take reasonable care to:
 - ensure their own health and safety
 - that their acts or omissions do not adversely affect the health and safety of other persons ensure the safety of others in the workplace
 - cooperate with health and safety guidelines, instructional material and procedures
 - comply with any reasonable instruction given in relation to health and safety to enable the department to meet its obligations under the [Work Health and Safety Act 2011 \(Commonwealth\)](#) (WHS law) and any legislative instruments executed under that Act
 - comply with any reasonable instruction given in relation to health and safety to enable a third party to meet its obligations under the WHS law.

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 of department response that is 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 FSU Co-ordinator 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, as long as 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. In these incidents the establishment may be issued with a 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 CIR may be triggered at the discretion of the NVTM in consultation with the FOM and ESB.

USA point of entry violations

For a USA POEV, the department automatically applies a 12-month moving window with three levels of response. The window is reset after 12 months as long as the establishment has:

- Had no further POEVs in the 12-month window
- Passed the associated CIRAs
- Regained USA market listing (i.e. if sanctions had been applied and the department had removed the USA listing).

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

- Products were produced in an isolated period of time
- Root cause/s have already been identified
- Effective corrective and preventative actions have been implemented
- It has received acceptable department verification.
- **Note:** Where the above conditions have been met the department may:
 - Advise the USA authorities that access will not be immediately suspended
 - Conduct an additional verification audit no more than 30 days from the last CIRA.

China point of entry violations

Where the establishment has been suspended from exporting to China by AQSIQ, the department will apply three levels of response beginning at Level 1 in the first instance, and then escalating the level depending on the outcome of the CIRA audit.

The department automatically applies a 12-month moving window with three levels of response. The window is reset after 12 months as long as 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 three CIR is triggered by a third China POEV the department may not automatically apply a Level three response if, at the time of notification, the establishment was already in an open Level two response and can demonstrate that:

- Products were produced in an isolated period of time
- Root cause/s have already been identified
- Effective corrective and preventative actions have been implemented
- It has received acceptable department verification.
- **Note:** Where the above conditions have been met the department may conduct an additional verification audit no more than 30 days from the last CIRA.

For non-compliances that do not involve an AQSIQ 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, and then escalating the level depending on the outcome of the CIRA audit.

Other Country point of entry violations

For POEV's, other than for the USA 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 the department to take 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, and then escalating the level depending on the outcome of the CIRA audit.

On-plant critical incidents

Apart from USA market access related department verification, the department does not automatically apply the 12-month moving window to critical incidents that arise on plant. However, it will apply three levels of response beginning at Level one in the first instance, and then escalating the level depending on the outcome of the CIRA audit.

In relation to department audits, for establishments that have opted for periodic audits, an allowance of one marginal or unacceptable audit outcome within a 12-month timeframe is allowed before a critical incident response may be triggered. This allowance ensures equivalency of regulatory action with establishments that have opted for systems audits.

In relation to Tier 1 abattoirs under the jurisdiction of an SRA, a Level one response is arbitrarily applied following consultation and agreement between the department and the relevant SRA. This guideline does not supersede any MOU between the department and the SRA.

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 verification audit no more than 30 days from the last CIRA.
- Consider suspension of the establishment's USA listing for raw ground beef components.

In relation to department daily product hygiene verification of finished USA-eligible sheep, lamb and goat product where there is a third POE defect detection then, the department will:

- Review the establishment's compliance with requirements of other markets.
- Conduct an additional verification audit no more than 30 days from the last CIRA.
- Withdraw certification for the species concerned.

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 POEV | <ul style="list-style-type: none">• POEV for STECs• POEV for faeces, ingesta, milk, off condition, chemical or physical hazards, other harmful material or conditions, pathological and parasitic lesions | <ul style="list-style-type: none">• Level 1 – first USA POEV in 12-month moving window• Level 2 – second USA POEV in 12-month moving window• Level 3 – third USA POEV in 12-month moving window <p>Note: Subsequent levels are triggered by unacceptable CIRA ratings (e.g. an unacceptable Level 1 CIRA triggers a Level 2 CIRA).</p> |

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| Critical Incident Type | Critical Incident Description | Level of Department Response |
|---|--|---|
| CHINA POEV | <ul style="list-style-type: none"> Any non-compliance with China's importing country requirements that results in suspension of export by AQSIQ | <ul style="list-style-type: none"> Level 1 – first CHINA POEV in 12-month moving window Level 2 – second CHINA POEV in 12-month moving window Level 3 – third CHINA POEV in 12-month moving window <p>Note: Subsequent levels are triggered by unacceptable CIRA ratings (e.g. an unacceptable Level 1 CIRA triggers a Level 2 CIRA).</p> |
| CHINA- non-compliance notification | <ul style="list-style-type: none"> Non-compliance to China's importing country requirements – other than those involving suspension. | <ul style="list-style-type: none"> Level 1 in the first instance, as required on case-by-case determination. Subsequent levels are triggered by unacceptable CIRA ratings. |
| POEV (other than for USA or China) | POEV reported by an importing country authority. | <ul style="list-style-type: none"> Level 1 in the first instance, as required on case-by-case determination. Subsequent levels are triggered by unacceptable CIRA ratings. |
| Department systems audit | Marginal or unacceptable rating | <ul style="list-style-type: none"> Level 1 in the first instance. Subsequent levels are triggered by unacceptable CIRA ratings. |
| Department periodic audit | Where the marginal/unacceptable rating threshold has been breached (i.e. > 1 out of 12 periodic audits have been rated marginal/unacceptable) | <ul style="list-style-type: none"> Level 1 in the first instance. Subsequent levels are triggered by unacceptable CIRA ratings. |
| Marginal, unacceptable SRA audit or a critical non-compliance | SRA audit of Tier 1 establishment | <ul style="list-style-type: none"> Level 1 where there has been joint agreement between the department and the SRA. |

| Critical Incident Type | Critical Incident Description | Level of Department Response |
|--|---|---|
| Monthly STEC confirmed positive verification – USA 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 | <ul style="list-style-type: none"> Level 1 – 1st confirmed positive in the 15-sample window Level 2 – 2nd confirmed positive in the 15-sample window Level 3 – 3rd confirmed positive in the 15-sample window |
| Small stock POE 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 style="list-style-type: none"> Level 1 – 1st reinspection failure in 12-month moving window Level 2 – 2nd reinspection failure in 12-month moving window Level 3 – 3rd reinspection failure in 12-month moving window <p>Note:</p> <ul style="list-style-type: none"> Subsequent levels are triggered by unacceptable CIRA ratings (e.g. an unacceptable Level 1 CIRA triggers a Level 2 CIRA). |
| Breach of the Salmonella testing performance standards | Failure of a third consecutive Salmonella window coupled with an unsatisfactory establishment investigation and corrective action | <ul style="list-style-type: none"> Level 1 in the first instance. Subsequent levels are triggered by unacceptable CIRA ratings. |

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.

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

| 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: <ul style="list-style-type: none">• 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. | ESB |
| 2. | FSU Coordinator is emailed the official notification as soon as it is available. | ESB |
| 3. | Official notification will be immediately forwarded to the: <ul style="list-style-type: none">• relevant FOM and VEMS Director of Inspection Services who will notify the relevant ATM of the incident and direct him/her to initiate an investigation on plant.• CIU in relation to a Tier 1 abattoir who will notify the relevant SRA of the incident on a Tier 1 abattoir. | FSU Coordinator |
| 4. | A Corrective Action Request (CAR) is issued directing the establishment to immediately undertake an investigation and to develop and implement a CAP. | ATM |
| 5. | The department may increase on-plant verification. Any increases will be notified to the relevant VEMS Director of Inspection Services. | FOM |
| 6. | The critical incident is captured on the CIR register. | FSU Coordinator |

The following table outlines the process for official notification of a marginal or unacceptable audit.

| Stage | Process | Responsible party | | | | | | |
|-----------------------------------|--|--------------------|---------|--------------------|---|-----------------------------------|---|---------------------|
| 1. | <table><tr><th>If the audit is...</th><th>Then...</th></tr><tr><td>a department audit</td><td><p>The lead auditor will:</p><ul style="list-style-type: none">• issue a CAR directing the establishment to develop a CAP within 10 working days of the audit• send a notification report to CIU for actioning appropriately• notify the FSU Coordinator</td></tr><tr><td>an SRA audit on a Tier 1 abattoir</td><td><p>The SRA will:</p><ul style="list-style-type: none">• notify the CIU</td></tr></table> | If the audit is... | Then... | a department audit | <p>The lead auditor will:</p> <ul style="list-style-type: none">• issue a CAR directing the establishment to develop a CAP within 10 working days of the audit• send a notification report to CIU for actioning appropriately• notify the FSU Coordinator | an SRA audit on a Tier 1 abattoir | <p>The SRA will:</p> <ul style="list-style-type: none">• notify the CIU | Lead auditor SRA |
| If the audit is... | Then... | | | | | | | |
| a department audit | <p>The lead auditor will:</p> <ul style="list-style-type: none">• issue a CAR directing the establishment to develop a CAP within 10 working days of the audit• send a notification report to CIU for actioning appropriately• notify the FSU Coordinator | | | | | | | |
| an SRA audit on a Tier 1 abattoir | <p>The SRA will:</p> <ul style="list-style-type: none">• notify the CIU | | | | | | | |
| 2. | The critical incident will be captured on the CIR register. | FSU Coordinator | | | | | | |

The following table outlines the process for official notification of a confirmed positive department STEC verification (within the 15-sample window) of raw ground beef components intended for export to the USA.

| Stage | Process | Responsible party |
|-------|---|-------------------|
| 1. | A CAR is issued to the establishment directing them to immediately undertake an investigation and to develop and implement a CAP. Send a notification report to CIU for advising the SRA. | OPV |
| 2. | <p>The outcome of the verification and CAR will be notified to the:</p> <ul style="list-style-type: none"> • ATM • FOM • Director, Inspection Services • CIU • FSU Coordinator | OPV |
| 3. | The critical incident is captured on the CIR register. | FSU Coordinator |

The following table outlines the process for official notification of a re-inspection failure triggered by a POE defect detected during daily hygiene verification of finished USA eligible sheep, lamb or goat product.

| Stage | Process | Responsible party |
|-------|---|-------------------|
| 1. | A CAR is issued to the establishment directing them to immediately undertake an investigation and to develop and implement a CAP. | OPV |
| 2. | The outcome of the verification and CAR will be notified to the: <ul style="list-style-type: none"> • ATM • FOM • Director, Inspection Services • FSU Coordinator | OPV |
| 3. | The critical incident is captured on the CIR register. | FSU Coordinator |

The following table outlines the process for official notification of a third consecutive Salmonella window breach.

| Stage | Process | Responsible party |
|-------|--|-------------------|
| 1. | A CAR is issued to the establishment directing them to immediately undertake an investigation and to develop and implement a CAP. The ATM will send a notification report to the: <ul style="list-style-type: none"> • CIU for advising the SRA • FSU Coordinator | ATM |
| 2. | The critical incident is captured on the CIR register. | FSU Coordinator |

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 intended for export to the USA
- USA 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. | <p>For POEV STEC detections, within four hours of official notification the establishment will provide to the department:</p> <ul style="list-style-type: none"> ○ details of all cartons and sampled lots ○ confirmation of the microbiological independence of the lots ○ confirmation that there is no other product, from the sampled lots, that has either been exported or is in store and is USA-eligible. <p>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:</p> <ul style="list-style-type: none"> • 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) • Make their findings available to OPV or FSA. • Notify the department of any product that is at risk of rejection that cannot be withdrawn from entering the market. | Establishment Management |
| 2. | <p>Verify the establishment's determination of microbiological independence of the sampled lots, including confirmation of the location of any product from the sampled lots</p> <p>Immediately provide the establishment risk assessment report to the:</p> <ul style="list-style-type: none"> • ATM • FOM • FSU Coordinator. | On Plant Officer |
| 3. | <p>Within 5 working days notify ESB of the microbiological risk assessment outcome.</p> | FSU Coordinator |

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 who 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) and relevant approved arrangement 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. |
| 6. | Implement corrective/preventative actions. |
| 7. | Verify any corrective/preventative actions to ensure effectiveness and sustainability of the changes undertaken to address 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 on a Tier 1 abattoir the requirement for the establishment to develop a CAP will be dependent upon the MOU between the SRA and the department.

CIR audit

Unless advised otherwise, a CIRA will be conducted within 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 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 | Regional FOM (lead auditor) and establishment supervisory ATM (auditor) |
| Level 2 | Independent FOM (lead auditor) and establishment supervisory ATM (auditor) |
| Level 3 | Independent FOM (lead auditor) and establishment supervisory ATM (auditor) |

CIR audit ratings

CIRAs are rated as either acceptable or unacceptable.

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

| | |
|---------|---|
| Level 1 | <ul style="list-style-type: none">• Acceptable: establishment returns to normal audit frequency.• Unacceptable: Level 2 CIRA is triggered. |
| Level 2 | <ul style="list-style-type: none">• Acceptable: establishment returns to normal audit frequency.• Unacceptable: Level 3 CIRA is triggered. |
| Level 3 | <ul style="list-style-type: none">• 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.

When a Level 3 USA POEV 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.

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 only required (from both the establishment and the OPV) for a USA POEV for STEC.

The establishment's interim report must address:

- 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 en-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, the establishment and OPV interim reports must be verified by the ATM and the FOM before providing them to the FSU Co-ordinator.

For all USA STEC POEVs these interim reports form the basis of the department's initial response back to the USA Food Safety Inspection Service (FSIS), which is required within 7 days of the official notification.

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.

This is a CONTROLLED document. Any documents appearing in paper form are not controlled and should be checked against the online version prior to use.

In all cases of a POEV, a final report is compiled by the FOM. The FSU Co-ordinator provides this report to ESB at least three 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

- The EMP FSU maintains a CIR Register of all official critical incidents.
- CIR official notifications, interim reports and final reports are maintained by the FSU Co-ordinator.
- CIR audit reports are maintained in the department's 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 Meat Systems Sanctions Policy (department website)
- Export Meat Systems Audit Program (EMSAP) Policy (department website)
- SRA notification work instruction (department instructional material library)

Document information

The following table contains administrative metadata.

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| Instructional material owner: | National Veterinary Technical Manager, Export Meat Program |
| Freedom of information exemption: | No |
| Records manager container number: | 2015/08798E |
| Review date: | November 2020 |

Version history

The following table details the published date and amendment details for this document.

| Version | Date | Amendment details |
|---------|------------|--|
| 1.0 | 04/11/2016 | First publication of this guideline. |
| 2.0 | 06/10/2017 | Amendment of guideline to reflect requirements issued in Meat Notice 2017/04 |