



# final report

Project code: A.MFS.0163  
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Date submitted: November 2008

PUBLISHED BY  
Meat & Livestock Australia Limited  
Locked Bag 991  
NORTH SYDNEY NSW 2059

## **Guide for dealing with a positive detection for E. coli 0157:H7 in raw ground beef components**

Meat & Livestock Australia acknowledges the matching funds provided by the Australian Government and contributions from the Australian Meat Processor Corporation to support the research and development detailed in this publication.

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## **1 Purpose**

The Guide is intended to provide assistance to establishments in response to advice of a confirmed positive detection for E. coli 0157:H7 detected in the supply chain for raw ground beef components (RGBC).

The scope of the Guide considers the response pathway where an establishment is implicated as a supplying establishment either in a confirmed detection of E. coli 0157:H7 or in a disease outbreak associated with E. coli 0157:H7.

The Guide can be used irrespective of market or whether in dealing with an E. coli 0157:H7 response to regulatory agencies or commercial organisations.

The principles described in this Guide can be applied more broadly in the case of other forms of E. coli or in relation to other pathogens such as Salmonella.

## **2 Background**

### **2.1 Testing within Australia**

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A number of establishments have participated for over a decade in a commercial E. coli 0157:H7 protocol for the routine testing of boneless manufacturing meat entering the global supply chain of the large hamburger chains.

This commercial testing protocol was superseded in December 2007 by new requirements for the lot testing of raw ground beef components destined for grinding in the US from all processing establishments supplying this export market. These new requirements for a national E. coli 0157:H7 testing program are in response to regulatory developments in the US reflected in announcements by FSIS of verification activities they are implementing for raw ground beef components and the introduction of testing container loads at ports of entry in the US.

Under these new requirements no less than 5 pieces of meat are collected from 12 cartons in each lot of no more than 700 cartons of raw ground beef components to provide a sample of at least 375 g for testing for E. coli 1057:H7 at a laboratory approved by the Australian Quarantine and Inspection Service (AQIS) using an approved method.

This lot testing program for raw ground beef components intended for export to the US is described in detail in AQIS Meat Notice 2008/05. Only raw ground beef components cleared under this lot testing regime is eligible for export to the US. Any lot that is confirmed positive for E. coli 0157:H7 must be treated to ensure public health safety in accordance with arranged approved by AQIS regardless of proposed market.

### **2.2 Testing within the Supply Chain**

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Testing within the regulatory framework within the US - FSIS / State/Local health authorities – port of entry, verification testing at grinding establishments and finished product testing and follow-up.

Testing within the commercial framework – raw supply, blended ground, finished beef patty.

### 3 About the Guide

This Guide is in two parts:

**Part 1:** describing points on the supply chain from packing to final product line where testing could be undertaken and a qualitative assessment of relative risk;

**Part 2:** describing response mechanisms based upon the information provided to the establishment of packing through either commercial or regulatory channels.

The key strategy is to be in the position to respond effectively to a confirmed positive when required. This may be at the time of notification. A number of crucial factors should be borne in mind:

1. The implicated or offending product could have spent considerable time in storage prior to grinding, and consequently, may be six months or older from the date of packing;
2. There could be little information about production dates in the implicated or offending product where the confirmed detection is from ground or finished products, or where product is implicated within an outbreak scenario.
3. The response time may need to be instantaneous where an establishment is implicated in a disease outbreak. In such an event, immediate demands may be required by regulatory bodies. Also there could be direct media interest in pursuing a public interest.
4. The national E. coli 0157:H7 lot testing program described above relates to equivalency arrangements between AQIS and FSIS in accessing the US market. This testing program does not represent a defence where an establishment is implicated as a supplying establishment either in a confirmed detection of E. coli 0157:H7 or in a disease outbreak associated with E. coli 0157:H7. The data from this testing program is however useful in assessing the hygienic performance of an establishment from which conclusions about relative risk could generally be drawn.

Notwithstanding, all packing establishments should be able to make a number of statements immediately upon notification of a positive finding for E. coli 0157:H7. These include statements to the effect:

1. All lots of RGBC exported to the US from this establishment have been tested and found negative for E. coli 0157:H7. These lots have been cleared under the parameters of the Australian E. coli 0157:H7 testing program and, accordingly, have been certified by the Australian Quarantine and Inspection Service for export to the US.
2. All RGBC has been produced in accordance with the disciplines of an established HACCP plan supported by written procedures for good manufacturing practice within the framework of an Approved Arrangement with the Australian Quarantine and Inspection Service. The control measures identified within the HACCP plan for E. coli 0157:H7 are subject to continuous monitoring and verification by competent personnel. The effectiveness of these measures in the control of E. coli 0157:H7 are assessed no less than annually.

In addition to these statements, slaughter establishments preparing RGBC can also attest:

3. The effectiveness of process controls in the manufacture of beef carcasses are subject to daily testing for indicator organisms - generic E. coli and total plate count – in context of a national regulatory testing program for assuring the safety and wholesomeness of Australian meat intended for export.

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**3.1 Part 1**

**Scenario Development: Point in Chain Detection of E. coli 0157:H7 in Raw Ground Beef Components**

<b>Point-Chain</b>	<b>In Supply</b>	<b>Likelihood</b>	<b>Type of product</b>	<b>Actions</b>	<b>Key Considerations</b>
1. Establishment testing		Lot testing not more than 700 cartons (N60 375g sample)	Time of packing prior to freezing. Provision for testing frozen.	Lot rejected food chain in accordance with Approved Arrangement. Review effectiveness of control measures. On-going positive detections – escalating corrective actions. Increased regulatory interest/testing in control measures.	Determine RGBC. Clearly defined process to determine boundaries between lots produced daily. Ability to withdraw in event of positive.
2. AQIS testing	Verification	Not less than quarterly. Independent lot test not more than 700 cartons (N60 375g sample)	Time of packing prior to freezing.	Lot rejected food chain in accordance with Approved Arrangement. Review effectiveness of control measures. On-going positive detections – escalating corrective actions. Increased regulatory interest/testing in control measures. Reconciliation between establishment testing results and AQIS testing results	Clearly defined process to determine boundaries between lots produced daily. Ability to withdraw in event of positive. On-going independent testing by AQIS (?? samples) to “clear” establishment.
3. FSIS	Port of Entry	Periodic from ?? number of	Frozen Block	Aust/US agreement.	Quality of response to FSIS.

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testing	containers annually from total containers for US. Lot test (N60 375g sample)		Advice from FSIS to establishment through AQIS. Detailed written submission to FSIS of investigation and corrective actions. Increased regulatory interest/testing in control measures.	
4. Establishment testing of RGBC	Lot test (N60 375g sample)	Frozen or tempered block	Advice from grinder to establishment.	
5. FSIS Verification testing of RGBC	Lot test (N60 375g sample)	Frozen or tempered block	Advice from FSIS to establishment through AQIS. Detailed written submission to FSIS of investigation and corrective actions. Increased regulatory interest/testing in control measures.	
6. Establishment testing of Ground Beef	???	Batched & Blended	Advice from grinder to establishment. Submission of investigation to grinder. Review of response by FSIS.	
7. FSIS Verification testing of Ground Beef	FSIS has identified presence of E. coli 0157:H7 at higher incidence nationally. Number of product recalls from positive detections	Batched & Blended	Advice from FSIS to implicated establishment(s) through AQIS.	

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	during past decade involving very substantial quantities of ground beef.			
8. Establishment testing of Final Product	???	Frozen patty	Advice from grinder to establishment. Submission of investigation to grinder. Review of response by FSIS.	
9. Outbreak resulting in Human Illness	Periodic outbreaks in US over past decade at least from imperfectly cooked beef patties.	Cooked patty		Possibility of media in high profile event.



**3.2 Part 2**

**Steps in Preparing a Response to Positive Detection for E. coli 0157:H7**

<b>Response Elements</b>	<b>Objective</b>	<b>Description</b>	<b>Discussion</b>
<b>A. Investigation</b>			
1. Identify implicated product			
2. Define and assess relevant process control data			
3. Assess relevant pathogen testing data			
4. Assess HACCP compliance at relevant CCPs			
5. Review most recent annual HACCP re-assessment. Undertake new assessment in light of additional information/event.			
6. Review independent audit and product outcomes			
7. Conclusions from Investigations			
<b>B. Corrective Actions</b>			
<b>C. Surveillance</b>			
<b>D. Verification</b>			
<b>2. Communications Strategy</b>	<b>Objective</b>	<b>Description</b>	<b>Discussion</b>