



December 14, 2007

MEMORANDUM FOR AMI INSPECTION COMMITTEE

FROM: SKIP SEWARD

SUBJECT: AUSTRALIAN *E. COLI* O157:H7 TESTING & FOOD DEFENSE

Australian *E. coli* O157:H7 Testing

As discussed at this week’s Inspection Committee meeting, the following has been published by the Australian Quarantine and Inspection Service (AQIS), in response to the Food Safety and Inspection Service’s (FSIS) requirements for enhanced sampling and testing for imported products.

FSIS recently published several notices and informed AQIS that FSIS will commence point of entry (import) testing for *E. coli* O157:H7 from all countries on 20 January 2008. Product testing will be based on production lots of all beef intended for grinding. Provided below is the Australian sampling program reviewed by FSIS.

MARKET ACCESS ADVICE

Reference Number: MAA0741
 Date of Issue: 13 Dec 2007
 Date of Effect: Immediate
Escherichia coli O157:H7 testing of raw ground beef components destined for grinding in the USA

Attention	Industry	Beef Slaughter and Boning Establishments peak industry bodies, licensed meat exporters, etc
	AQIS	Central and Regional offices ATMs OPVs and Meat inspection staff EFOs, etc
Affected Markets		United States
Further Information		Contact: Paul Vanderlinde, Matt Thompson, Anand Deo

AQIS lodged a proposal seeking alternative arrangements and FSIS responded granting equivalence recognition of the Australian proposal. These arrangements include AQIS verification of *E. coli* O157:H7 sampling and testing procedures and these have been outlined in the AQIS Meat Notice "2007/17 *Escherichia coli* O157:H7 testing of raw ground beef components destined for grinding in the USA". This notice is available on the AQIS website: <http://www.daff.gov.au/aqis/export/meat/elmer-3/notices/2007>.

Please note the following three points of clarification on the notice:

1. The lot size must not exceed 700 cartons (or equivalent) and must be from a single day's production;
2. The Approved Arrangement must clearly identify any bulk packed product intended for grinding in the US; and,
3. Sampling from any one lot should be random, so may not include the first and last cartons.

Effective from 10 December 2007 all beef destined for grinding in the US will be accompanied with a health certificate with the following attestation:

"All production lots of manufacturing beef exported to the United States have been tested and cleared in accordance with the AQIS *E. coli* O157:H7 protocol."

Following a review of system requirements, the need for exporters to make a declaration in respect of *E. coli* is no longer required.

The information provided above is current at the time of writing and is intended for use as guidance only and should not be taken as definitive or exhaustive. The Commonwealth endeavors to keep information current and accurate, however, it may be subject to change without notice. Exporters are encouraged to verify these details with their importers prior to undertaking production/exports. The Commonwealth will not accept liability for any loss resulting from reliance on information contained in this notice.

AQIS MEAT NOTICE

<i>AQIS Notice Number</i> Meat 2007/17		<i>Escherichia coli</i> O157:H7 testing of raw ground beef components destined for grinding in the USA	
<i>NSFS Ref 17</i>		Contact Officers: Anand Deo Food Safety Manager Meat Operations 02 6272 5864 Paul Vanderlinde Manager Microbiology Animal Products Market Access Branch 07 3246 8712	
Date of Effect 10 December 2007	Date of Expiry UFN		
<i>Distribution Category</i>	Last Notice this Category	<i>Distribution Category</i>	Last Notice this Category
<input checked="" type="checkbox"/> Central & Regional Office		<input checked="" type="checkbox"/> Managers, Export Meat Establishments	
<input checked="" type="checkbox"/> OIC Inspection staff – Meat Establishments			
<i>IMPLEMENTATION SCHEDULE</i> (to be completed by the On-Plant Supervisor on the AQIS File Copy)			
Date Received		_____ / _____ / _____	
Date discussed with management		_____ / _____ / _____	
Initial Implementation Date		_____ / _____ / _____	
Date Completed		_____ / _____ / _____	
Signature of Company Representative		_____	
Signature of On-Plant Supervisor		_____	

PURPOSE

To advise establishments of revised requirements for *Escherichia coli* O157:H7 testing in beef products destined for grinding in the United States of America (US).

SCOPE

All export registered, US listed meat establishments that produce raw ground beef components destined for grinding in the US and all laboratories undertaking testing of such products for *E. coli* O157:H7.

This Notice supersedes AQIS Meat Notice 1998/18.

BACKGROUND

The Australian industry currently samples and tests trim and ground manufacturing beef exported to the United States of America (US) as part of commercial testing programs.

The United States Department of Agriculture's Food Safety and Inspection Service (FSIS) published a revision to their Directive 10.010.1 'Microbiological Testing Program and Other Verification Activities for *Escherichia coli* (*E. coli*) O157:H7 in Raw Ground Beef Products and Raw Ground Beef Components and Beef Patty Components'. Further, the FSIS has recently published several notices detailing sampling and other requirements for ground beef components (i.e. trim) for *E. coli* O157:H7.

- FSIS Notice 17- 07: Follow-Up Sampling of Certain Raw Ground Beef Products after an FSIS Verification Sample Tests Positive for *E. coli* O157:H7
- FSIS Notice 18- 07: Routine Sampling of Beef Manufacturing Trimmings Intended for Use in Raw Ground Beef
- FSIS Notice 62-07: Instructions for Verification Sampling Programs for *E. coli* O157:H7 in Raw Beef Products.
- FSIS Notice 66-07: Multiple Follow up Sampling after FSIS Positive *E. coli* O157:H7 Result.

The background behind these Notices is believed to come from a microbiological baseline study of beef trim started in November 2005. Based on the findings of this survey (which are not available), FSIS has expressed concern that control of the microbiological quality of trim might not be sufficient to meet their target of non-detection of *E. coli* O157:H7 in ground beef.¹ FSIS has implemented targeted domestic testing for *E. coli* O157:H7 in raw ground beef components destined for grinding in the US as part of its risk-based approach to the control of *E. coli* O157:H7 in ground beef.

Because of recent problems with a number of imported food ingredients and a rise in detection of *E. coli* O157:H7 in ground beef in the US, FSIS intends to intensify the testing of raw ground beef components destined for grinding in the US. This program is due to commence on 20 January 2008.

It is necessary for Australia to address the FSIS requirements to ensure Australian products continue to maintain their access to, and acceptability in, the US market. This notice forms part of an equivalence submission to FSIS. This submission is based on industry applying a "production lot" test and hold program for raw ground beef components destined for grinding in the US, which AQIS would verify, and verification testing by AQIS at a similar frequency to that employed by the FSIS domestically.

¹ FSIS Notice 63-06 Verification procedures involving *E. coli* O157. 9/27/06

1. Summary

Companies will test all production lots of beef destined for grinding in the US for the presence of *E. coli* O157:H7. Production lots with confirmed positive detections of *E. coli* O157:H7 will be subject to AQIS control and will not be exported to the US. In addition, AQIS will verify commercial testing programs to determine that they meet the requirements of this notice and that they are being performed correctly. AQIS will also undertake its own verification testing of beef destined for grinding in the US for *E. coli* O157:H7 at a minimum frequency of once per quarter. Samples will be analyzed in AQIS approved laboratories and all results reported directly to AQIS.

For both commercial and regulatory programs sampled lots will be held or controlled by the company until the test result for the lot has been obtained and is negative for *E. coli* O157:H7. If *E. coli* O157:H7 is confirmed as being present in the lot, the affected product will not be exported to the US and disposition will be determined by AQIS.

This Notice describes what is required to be included in the establishment's Approved Arrangement.

2. Definitions

2.1 Lot

For the purposes of testing raw ground beef components destined for grinding in the US for *E. coli* O157:H7, a lot is defined as comprising all those cartons, packages or containers of beef components either:

- packed on a given packing line and based on Sanitation SOPs; and/or
- determined by the establishment based on the implementation of a statistically based sampling program to distinguish between segments of production.
- A lot may be defined in either time or space but cannot exceed 700 cartons (a container equivalent) or more than a single day's production

NOTE: *A statistical sampling program based on time must ensure that the first and last cartons are sampled as part of the lot. The other samples should be spread evenly within the lot.*

NOTE: *The FSIS definition of a lot is provided, for information, in Annex 2.*

2.2 *E. coli* O157:H7

E. coli O157:H7 is an enterohaemorrhagic, Shiga toxin producing strain of *E. coli*. For the purpose of this Notice, it is defined as 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 the production of Shiga toxin(s) and/or presence of one or more of the Shiga toxin genes is demonstrated by an approved laboratory or serological and/or molecular test confirming the presence of the H7 antigen, *i.e.*, confirmed as *E. coli* O157:H7.

NOTE: *An approved laboratory is a laboratory approved by AQIS to conduct the relevant E. coli O157:H7 screening and/or confirmatory testing using methodology approved by AQIS for the detection and confirmation of E. coli O157:H7.*

NOTE: *The following terminology is used by FSIS and this document:
Presumptive positive = positive on a screening test
Confirmed isolate = serologically positive O157 that contains stx gene/s or produces Shiga toxin*

NOTE: *The FSIS definition is provided, for information, in Annex 3. The definition given here is functionally equivalent to the FSIS definition.*

2.3 Raw Ground Beef Components

Includes beef bulk packed manufacturing trimmings and other bulk packed beef components such as primal cuts, sub primal cuts, head meat, cheek meat, esophagus meat, heart, and advanced meat recovery (AMR) product intended for use in raw ground beef. If it can be demonstrated that a US bulk packed product is not intended for use in ground beef, the product would not be subjected to the testing requirements outlined in this notice. Whole muscle products that are trimmed in the US and those trimmings used for ground beef would be subject to testing under the current FSIS domestic testing program, *i.e.*, are not required to be tested in Australia.

Beef trim may also include product from veal carcasses that are packed and labeled as beef under the Australian Meat Classification System Manual 1 (Veal carcass >70kg, Hot Standard Carcass Weight).

3. Taking samples for testing

3.1 Lot identification

Samples collected from cartons need to be clearly identifiable to the production lots from which they are drawn for purposes of traceability, retention and recall.

3.2 Selection of Samples

Samples should be collected randomly from a lot so that all cartons within the lot have an equal opportunity of being sampled. The establishment must also ensure that the full range of beef destined for grinding in the US (including beef trim or raw ground beef components) is sampled over the lot. Samples are not to be collected from product that is not intended for grinding. The minimum number of cartons sampled per lot will be twelve.

3.3 Removing a sample

A minimum of 5 small pieces, surface slices or small 'grab' samples, of approximately 5-10g are selected from each of 12 cartons representing the lot. The total number of pieces sampled per lot must be at least 60 (*i.e.*, N60 method). The total sample weight must be at least 375 g.

3.4 Lot retention

The product must be under the control of the establishment (*i.e.*, able to be recalled) whilst waiting for the results of the screening test or confirmatory test. Product may be able to be stored in another registered establishment or even be containerized as long as it can be shown to still be under the control of the establishment (*i.e.*, not entered commerce). In the event that a lot is confirmed as being positive for *E. coli* O157:H7, the lot must be under AQIS control until disposition (see section 5).

3.5 Sample Labeling

Label the sample with adequate detail for identification. The label must include the following:

- Establishment number (if samples to be sent to an external laboratory)
- Date and time of sampling
- Packing line (if applicable)
- Lot identification on carton

When testing is not going to commence immediately samples should be transferred to active refrigeration (0°C to 4°C) without delay. If samples are to be held longer than overnight they must be frozen. If samples are collected from frozen cartons they must be kept frozen until analyzed by the laboratory.

3.6 Sample dispatch to an AQIS approved laboratory

Where samples are to be transferred to an off-site independent laboratory for analysis standard procedures for transport must be followed (*i.e.*, packing, temperature, labeling and warnings in the case of presumptive positive tests see Annex 1). It is the responsibility of the establishment's management to ensure that testing is carried out at AQIS approved laboratories.

4. Sample Testing

4.1 Approved Laboratory

All laboratories used for the analysis of export samples for *E. coli* O157:H7 must be approved by AQIS. Laboratories undertaking screening tests for *E. coli* O157:H7 can be either company owned or commercial laboratories. Only AQIS nominated commercial laboratories can be used for the analysis of verification samples collected by AQIS or for confirmation of presumptive positive samples.

NOTE: *A list of approved laboratories can be accessed at the AQIS export meat program website.*²

4.2 Testing methodology

All testing must be carried out using AQIS approved methods. Methods used for the analysis of verification samples and for confirmation of presumptive positive samples must have undergone an equivalence determination by the FSIS or be an FSIS approved method.

All samples with a positive screening test must either undergo further testing for confirmation of *E. coli* O157:H7 by an AQIS approved laboratory or the product lot treated as a confirmed positive.

Confirmation must include an immunomagnetic separation step to concentrate cells prior to isolation and identification.

NOTE *AQIS recommends that all presumptive positive results be confirmed as *E. coli* O157:H7.*

4.3 Sample preparation and testing

Follow the requirements outlined in Annex 1.

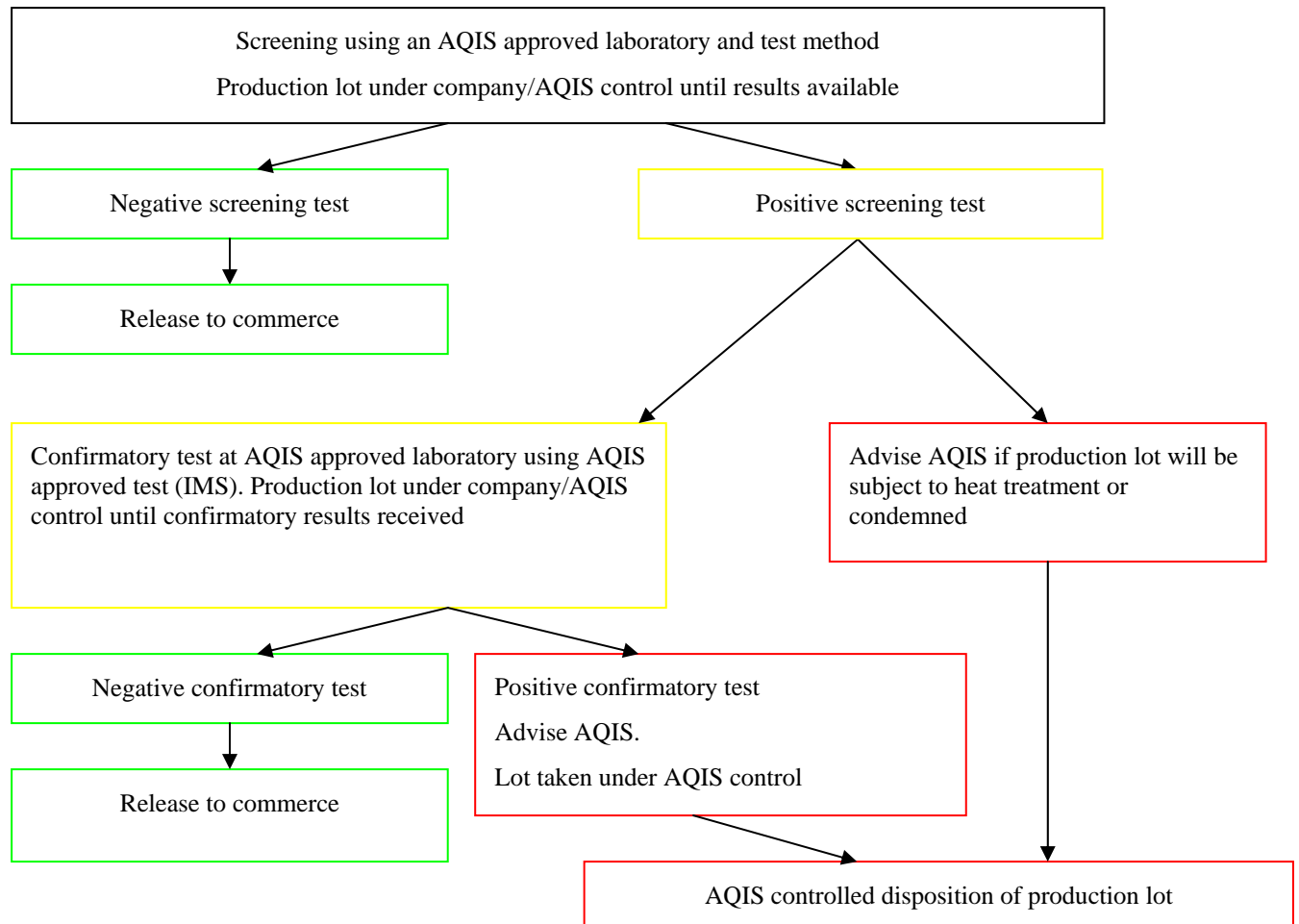
4.4 Reporting of results

All confirmed positive test results must be reported by the testing laboratory directly to the AQIS OPS or AQIS central office. All negative and presumptive positive results must be recorded by the company and the records reviewed by the AQIS OPS at least weekly. All test results, irrespective of outcome, must be entered into the national microbiological data base.

² http://www.daff.gov.au/__data/assets/pdf_file/0008/129662/approved_lab__list.pdf

5. Measures in response to a positive result

The following diagram shows the decision process for lots that have been tested under the requirements outlined in this Notice.



Disposition of product is to be made in accordance with the provisions specified in the company's Approved Arrangement. Disposition of a lot must be by heat treatment at an establishment with an approved thermal process or by condemnation through rendering or disposal at landfill.

Establishments must make and retain records of the screening test, confirmatory test and dispositions. Where product has been transferred for heat treatment or condemnation the records should show that responsibility for the disposition of that product has been transferred to the receiving establishment (e.g., Official Meat Transfer Certificate duplicates). Product under the control of AQIS can only be transferred with AQIS approval.

The establishment's Approved Arrangement will detail effective methods of identifying, securing, and where applicable transporting and disposing of the affected lot.

Establishments that can heat process product will have an Approved Arrangement detailing how the affected lot will be handled during receiving, storage and processing. The heat process used to eliminate *E. coli* O157:H7 must be validated as being at least equivalent to the Australian Standard definition for fully cooked (*i.e.*, 65°C for 10 minutes).

If confirmatory testing finds the sample negative for the presence of *E. coli* O157:H7 the lot is released.

6. Amendment of the Approved Arrangement

Establishments need to amend their approved arrangement to reflect their practices in regards to *E. coli* O157:H7 sample selection, testing, transport, and corrective and preventive action.

7. HACCP

In Australia, *E. coli* O157:H7 is recognized as a hazard that may be reasonably likely to occur in incoming cattle. As a consequence of this, establishments processing cattle for the US already include *E. coli* O157:H7 testing as a verification activity within their HACCP plans. Within existing HACCP plans *E. coli* O157 testing will need to be reconsidered in light of it becoming a production lot “test and hold” process, with appropriate amendments being made to monitoring and verification activities.

Establishment management are reminded that following a confirmed positive result, a re-assessment of the HACCP plan must be undertaken, including the effectiveness of corrective and preventive actions (AQIS Meat Notice 2002/13). Follow-up samples may also be collected by AQIS to verify the effectiveness of any corrective actions and to meet market requirements. The scope of the reassessment should cover the sourcing of the incoming livestock.

8. AQIS Verification Activities

8.1 Verification of company process

AQIS on plant staff shall audit the company process of sample selection and collection weekly in the same way as is currently conducted for the national *E. coli* and *Salmonella* Monitoring (ESAM) program. A new data entry field in the National Establishment Verification System Form 1 must be created for establishments engaged in the testing of trim and ground beef components for *E. coli* O157:H7. AQIS OPS must also verify that approved laboratories are used for the analysis of samples and that the methods used are also approved by AQIS.

Any deficiencies in technique shall be documented and a Corrective Action Request (CAR) raised to ensure that the company follows up on the detection with appropriate corrective and preventive action. An inadequate response to the CAR will be followed up as per current instructions to AQIS staff.

All laboratories approved for testing of trim and ground beef components for *E. coli* O157:H7 will be audited annually by AQIS (or an independent third party nominated by AQIS) for compliance to this Notice and for competency in the analysis of samples for *E. coli* O157:H7. All approved laboratories must be enrolled in a recognized proficiency program for *E. coli* O157:H7 and participate in proficiency rounds at least twice a year.

8.2 Verification of test results

AQIS central office will notify AQIS on site staff that a verification sample is to be collected and submitted to a nominated independent AQIS approved laboratory for testing for *E. coli* O157:H7. The notification will contain the address for the laboratory to which the sample must be sent. Verification samples cannot be tested in on-plant or company owned laboratories. All establishments exporting trim or ground beef components to the US will be scheduled for verification testing at least quarterly and at most monthly. The frequency of testing will be determined by AQIS based on the amount of product exported and on the establishment's compliance history.

To collect verification samples, AQIS staff will notify the establishment that a sample is required. The AQIS OPS will then directly supervise the establishment employee selecting the test cartons and collecting sufficient sample for both company and AQIS requirements. At this point AQIS will take charge of one of the samples. The sample will be identified as detailed in 3.5. The AQIS officer overseeing the process will place the sample into an AQIS tamper evident bag and forward the sample to a nominated AQIS approved laboratory. If storage is required on site it will be stored as per paragraph 3.5 and under conditions of security.

NOTE: *Detailed instructions for handling, storage and transport will be provided with the sample kits distributed to staff.*

8.3 National Microbiological Database

All test results (negative, presumptive or positive) must be entered into a new data field in the National Microbiological database (formally the ESAM database) on a weekly basis, by the AQIS OPS. The disposition of lots that have been confirmed positive or that are to be treated as positive must also be entered after disposal of the product has been confirmed.

9. Implementation Schedule

AQIS verification of company procedures (check the checker) and verification testing will commence soon and advice will be forthcoming in this regard.

RESPONSIBILITIES

Managements of export meat establishments must:

- Amend their approved arrangements to reflect their *E. coli* O157:H7 testing program as per this notice.
- Support AQIS check-the-checker and verification activities.
- Retain lots that are positive on a screening test (*i.e.*, presumptive positives).
- Report confirmed positives to the AQIS on-plant supervisor.
(*Note: Laboratories are required to report results directly to AQIS as a part of their approval*)
- Dispose of product in accordance with this notice and with their approved arrangement.

The AQIS OPS is required to:

- Consider any amendments made to the approved arrangement and make the appropriate recommendation to the Area Technical Manager (ATM).
- Ensure that weekly and other verification activities are conducted as required by this notice.
- Enter data into the national microbiological database.
- Retain lots that are confirmed positive and inform the ATM.

The AQIS ATM is required to:

- Consider any amendment to the approved arrangement and approve if appropriate.
- Verify at the frequency dictated by the National Establishment Verification audit schedule (form 2) that the company is complying with the Approved Arrangement.
- Verify that the AQIS OPS is performing the required check-the-checker and verification activities and report the results as appropriate.

Carol Sheridan
Manager
Meat Program

ANNEX 1 Testing for *E. coli* O157

A1.1 Sample collection and preparation

Equipment used for the collection of samples from a single production lot need not be washed and sanitized between samples, but must be washed and sanitized for the collection of samples for a different lot. Five slices or small pieces with a combined weight of at least 35 g are collected from each of 12 cartons representing the production lot. Depending on the test method used samples can be composited to give a total weight of at least 375g. Samples are then screened for *E. coli* O157 using an approved AQIS method. If samples cannot be tested immediately they must be refrigerated (0 to 4°C). Samples held for more than overnight must be frozen.

A1.2 Testing

There are two distinct stages of testing:

- Screening, which requires basic skills
- Confirmation, for which specialized tests and skills are required

A1.2.1 Screening

Screening tests are usually validated for the testing of 25g samples diluted 1:10 with enrichment broth. If compositing samples or using lower dilutions then the test method used must be validated for the sample size and/or the initial dilution used. AQIS must approve any modification to methods prior to their use for the analysis of samples

NOTE: *A report from the American Meat Institute (AMI) has validated several methods for the analysis of large composite samples.³ For samples of 375g the following tests have are approved by AQIS: BAX using 12 or 16 h incubation, SDI RapidChek and Neogen Reveal each using 8, 12, or 16 h incubation. Other currently approved test methods may be validated by the laboratory or other organization for use with 375g samples or lower initial dilutions. All variations to approved test methods must be approved by AQIS prior to their use for the analysis of samples. A list of approved variations to test methods will be provided on the AQIS web site when available*

³ http://www.amif.org/AMIFResearch/2005Reports/Compositingfinalreport02_15_05.pdf.

The following general procedure should be followed for the screening of samples. Weigh out the sample (composite samples can be used if validated for the method). Frozen samples should be thawed as detailed in the relevant Australian Standard. Place the sample into a stomacher bag or blender, add the required amount of enrichment broth for the weight of sample being tested and stomach or blend for one minute. If a stomacher or blender is not available then the sample can be palpated by hand for the same period. Incubate at the temperature and for the time specified in the test method. Analyze the sample as per AQIS requirements or if not specified as per the manufacturer's recommendations.

NOTE: *A list of approved test methods can be accessed at the AQIS export meat program website⁴*

NOTE: Some approved methods have variations required by AQIS. The laboratory should check to make sure that the correct methodology is being followed.

All samples with a positive screening test must either undergo further testing for confirmation of *E. coli* O157:H7 by an AQIS approved laboratory or the product treated as a confirmed positive.

NOTE: *A list of approved laboratories can be access at the AQIS export meat program website.⁵*

All confirmation of presumptive positive samples must be carried out on a sample of the enrichment broth. When transporting presumptive positive enrichment broths or other presumptive positive samples the laboratory should consult the appropriate regulations for the transportation of infectious substances (see Australian Government, Department of Transport and Regional Services website⁶).

A1.2.2 Confirmatory testing

Confirmatory tests must be performed in an AQIS approved laboratory.

Confirmatory tests must include isolation of cultures using an immunomagnetic separation technique and plating on a selective, differential medium (for example Rainbow Agar, or CTSMAC). Up to five typical colonies should receive a biochemical test for *E. coli* and serologically for the O157 antigen and where necessary for the presence of Shiga toxins or Shiga toxin genes and reactions. Some strains of *E. coli*

⁴ <http://www.affa.gov.au/content/output.cfm?ObjectID=A2D73418-971B-44A0-A92E2EDA40CA9BB6>

⁵ <http://www.affa.gov.au/content/output.cfm?ObjectID=4D70A85B-98F8-44F3-B19011955FFF4B47>

⁶ <http://www.dotars.gov.au/transport/australia/dangerous/pdf/guidnote-class62.pdf>

O157:H7 are non-toxicogenic. These strains should be considered in the confirmation of presumptive positive samples as they still fit the FSIS definition of *E. coli* O157:H7.

NOTE: *AQIS has approved certain methods. A list of test methods can be accessed at the AQIS export meat program website.*⁷

A confirmed positive is reported when at least one colony conforms to the definition of *E. coli* O157:H7.

Where positive samples are detected and confirmed, isolates will be typed by pulse field gel electrophoresis (PFGE) with the elucidated pattern forwarded to FSIS.

ANNEX 2 FSIS definition of Lot Size

The following is an excerpt from Attachment 1 of FSIS Notice 18-07:

The following factors may help the establishment in supporting the basis for defining the product represented by the sample:

- Any scientific, statistically-based sampling program for *E. coli* O157:H7 that the establishment uses to distinguish between segments of production.
- Sanitation Standard Operating Procedures (Sanitation SOPs) and any other prerequisite programs used to control the spread of *E. coli* O157:H7 cross-contamination between raw beef components during production. The controls that establishments use should adequately distinguish segments of production for lot identification purposes. Basic operational sanitation is generally not sufficient to distinguish between production lots.

Generally, FSIS recommends that establishments develop and implement statistical in-plant sampling plans scientifically designed to define production lots or sub-lots independent of other production lots or sub-lots. The establishment should design sampling and testing procedures to achieve a high degree of confidence of detecting contamination.

In the absence of a scientifically defensible testing plan to define production lots or sub-lots of beef manufacturing trimmings or other raw ground beef components, the Agency will consider all available data to discern the amount of product represented by the sample. FSIS may default to defining the product represented by the sample as all raw beef components derived from animals slaughtered on a particular production day. Therefore, product represented by a given sample may include raw product produced on more than one day. FSIS has outlined additional information on lot determination in Question and Answer documents on the FSIS web page with FSIS Directive 10,010.1, Revision 1.

⁷ <http://www.affa.gov.au/content/output.cfm?ObjectID=A2D73418-971B-44A0-A92E2EDA40CA9BB6>

ANNEX 3 FSIS definition of *E. coli* O157:H7 or O157: NM

The following definition of *E. coli* O157:H7 is given in the FSIS Microbiology Laboratory Guidebook, method 5.03, 2002.

The following definitions are used for reporting purposes. A potential positive sample causes a positive reaction on the screen test kit. A presumptive positive sample has typical colonies, observed on Rainbow Agar, and reacts specifically with O157 antiserum. A sample is a confirmed positive sample for *E. coli* O157:H7 or *E. coli* O157:NM when the isolate is confirmed biochemically and serologically, and the presence of Shiga toxin(s) or Shiga toxin gene(s) is demonstrated.

FDA Announces the Availability of Food Defense Self Assessment Tool

In 2003 the Food and Drug Administration (FDA), Center for Food Safety and Applied Nutrition (CFSAN) issued the Food and Cosmetic Security Preventive Measures Guidances. These documents were designed to be used as aids for several components of the food and cosmetic industry. The guidance documents could be used to identify the kinds of preventive measures that industry may take to minimize the risk that food and cosmetic products under their control would be subject to tampering or other malicious, criminal or terrorist actions. These guidance documents were designed to focus food and cosmetic industry operators' attention on each segment of the food and cosmetic products delivery system that is within their control, to minimize the risk of tampering or other malicious, criminal, or terrorist action at each segment.

The Agency received comments from industry and our stakeholders stating that these guidance documents were useful but that FDA should find a way to simplify the messages. With this in mind, FDA has made an attempt to simplify these documents by repackaging the information found in each guidance document into the Food Defense Self Assessment Tool. The information in each of the Food Defense Assessment Tools is the same information that is contained in each of the guidance documents issued in 2003, just in a more user friendly format. Each tool is available online and is attached as an appendix to its corresponding guidance document. Other than the addition of the tools, there is no new information in each of the guidance documents.

The Food and Cosmetic Security Preventive Measures Guidances and their associated Food Defense Self Assessment tools can be found on the CFSAN [Food Defense and Terrorism Guidance page](#).

If you have any questions regarding the information contained herein, please call Skip Seward at 202-587-4249 or e mail Skip at sseward@meatami.com .

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