

s. 22(1)(a)(ii)

From: s. 22(1)(a)(ii) @awe.gov.au>
Sent: Wednesday, 20 October 2021 5:08 PM
To: s. 47F(1)
Cc: s. 22(1)(a)(ii); Melinda Skipper
Subject: RE: Checklist Enquiry [SEC=UNOFFICIAL]
Attachments: geneup-ehc-aoac-2020.06.pdf

Hi s. 47F(1),

Hope you are well. As you requested please find attached checklist of AOAC 2020.06 which we recently approved for STEC screening and confirmatory test. We are also planning to change the PTM number of O157:H7 method to OMA number (2019.03) including the temperature range if applicable.

Kind regards

s. 22(1)(a)(ii)

From: s. 47F(1) @mxns.com>
Sent: Wednesday, 20 October 2021 3:52 PM
To: s. 22(1)(a)(ii) @awe.gov.au>; s. 22(1)(a)(ii) @awe.gov.au>
Cc: Melinda Skipper <s. 47F(1) @mxns.com>
Subject: Re: Checklist Enquiry [SEC=UNOFFICIAL]

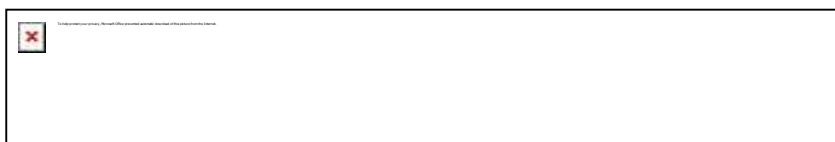
Hi s. 22(1)(a)(ii) and s. 22(1)(a)(ii),

Apologies for the urgency....is it possible to provide an updated Checklist for EHEC PTM 121806. We are looking at performing verification for the procedure and submitting for NATA accreditation.



Kind Regards



s. 47F(1)
Senior Technical Microbiologist



Mérieux NutriSciences
20 King Street, Blackburn, VIC, 3130, Australia
Phone: 1300 000 990
Direct: +s. 47F(1)
<http://www.merieuxnutrisciences.com/au>

Follow us on:  

On Fri, Oct 1, 2021 at 9:47 AM **s. 47F(1)**

@mxns.com> wrote:

Hi ^{s. 22(1)(a)(ii)},

s. 47G(1)(a)

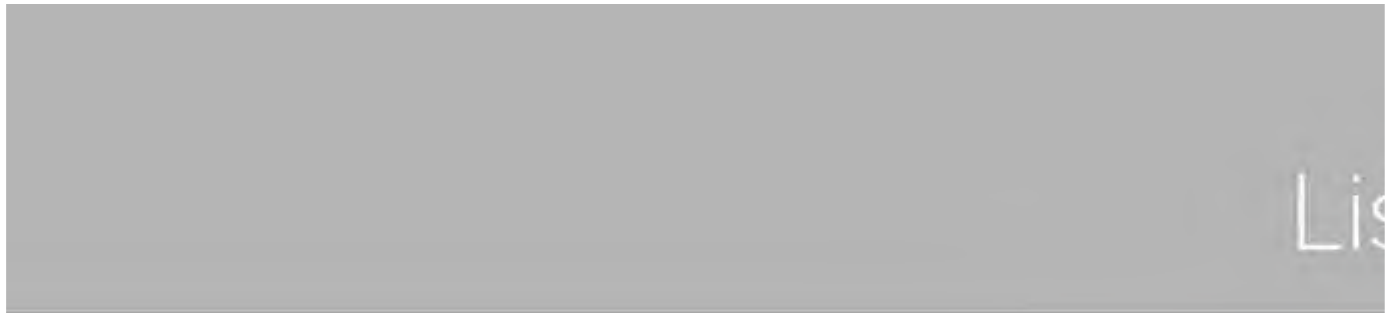
It's good to know that the approval from the DAWE should be completed in the next few weeks.

When reviewing documentation, it can get very confusing when the AOAC RI certificate number is quoted and not the AOAC OMA certificate number and vice versa.

This can become a problem during audits.

See below example:

In this instance the DAWE quotes the certificate AOAC RI number for E.coli 0157:H7 and EHEC Testing, while other related documentation may quote the AOAC OMA certificate numbers.



s. 47(1)(b)

In regards to the checklist for AOAC 121805, will this be updated to reflect the AOAC method and packet insert for incubation of enrichments to 42C +/- 1C rather than 41.5C +/- 1C ?

I think I may have previously confused you on this original enquiry.

AOAC 2019.03 (121805):

**AOAC Official Method 2019.03
E. coli O157:H7 in Select Foods
GENE-UP® E. coli O157:H7 2 (ECO 2) Kit
First Action 2019**

[Applicable to detection of *E. coli* O157:H7 in fresh raw ground beef (73% lean; 25 and 375 g), fresh spinach (200 g), raw milk cheese (25 g), raw ground chicken (25 g), raw beef trim (25 and 375 g), raw ground pork (375 g), Romaine lettuce (375 g), raw sausage (25 g), raw milk (25 g), raw ground veal (25 and 375 g), and processed water (25 mL).]

See Table 2019.03A for a summary of results of the interlaboratory study.

D. Sample Enrichment

Allow enrichment broths to reach 15–25°C before use. In some cases, enrichment media should be prewarmed to $41.5 \pm 1^\circ\text{C}$ or $42 \pm 1^\circ\text{C}$ before adding to food samples. Frozen samples should be thawed before analysis. To decrease occurrence of stressed cells, use a quick-thawing process. (This can be performed by thawing at temperatures less than 45°C in a water bath for no more than 15 min. Agitate the sample continuously.) Use a blender bag containing filter.

(a) *Fresh raw ground beef (25 g)*.—Add 225 mL BPW. Homogenize and incubate at $42 \pm 1^\circ\text{C}$ for 18–24 h.

(b) *Fresh raw ground beef (short protocol) (25 g)*.—Add 225 mL prewarmed BPW. Homogenize and incubate at $42 \pm 1^\circ\text{C}$ for 8–24 h.

(c) *Raw ground chicken (25 g)*.—Add 225 mL prewarmed BPW or modified tryptic soy broth (mTSB). Homogenize and incubate at $42 \pm 1^\circ\text{C}$ for 18–24 h.

(d) *Fresh spinach (200 g)*.—Add 800 mL BPW. Homogenize and incubate at $42 \pm 1^\circ\text{C}$ for 18–24 h.

(e) *Raw beef trim (325 g)*.—Add 975 mL mTSB. Homogenize and incubate at $42 \pm 1^\circ\text{C}$ for 15–24 h.

(f) *Raw beef trim, raw ground pork, and raw ground beef (375 g)*.—Add 1125 mL prewarmed ($42 \pm 1^\circ\text{C}$) BPW or mTSB. Homogenize and incubate at $42 \pm 1^\circ\text{C}$ for 10–24 h. mTSB enrichment is applicable to raw ground pork.

(g) *Romaine lettuce (375 g)*.—Add 1125 mL prewarmed BPW. Homogenize and incubate at $41.5 \pm 1^\circ\text{C}$ for 22–24 h.

DAWE Checklist:

GENE-UP® *E. coli* O157:H7 2 (ECO 2) – AOAC121805**SCOPE**

This method is applicable for testing of raw ground beef and raw beef trim for *E. coli* O157:H7.

PRINCIPLES

The GENE-UP® *E. coli* O157:H7 (ECO 2) is a qualitative real-time PCR assay. s. 47(1)(b)

s. 47(1)(b)

s. 47G(1)(a)

Biomerieux package Insert:

s. 47(1)(b)

Let me know if you need any further clarification.

Kind Regards

s. 47F(1)

Senior Technical Microbiologist



For correspondence:

Silliker Australia Pty Ltd
20 King Street Blackburn
VIC 3130 Australia

Phone: 1300 000 990

Direct: s. 47F(1)

E-mail: s. 47F(1) @mxns.com

<https://www.linkedin.com/company/merieux-nutrisciences-australia>

If you have received this email in error, please contact us immediately at s. 47F(1) @mxns.com and delete the message from your system.

On Fri, Oct 1, 2021 at 8:49 AM s. 22(1)(a)(ii)

@awe.gov.au> wrote:

Hi s. 47F(1),

We should be able to finalize this method in a couple of weeks. Are you planning to implement this method?

Kind regards

s. 22(1)(a)(ii)

From: s. 47F(1) @mxns.com>
Sent: Thursday, 30 September 2021 10:17 AM
To: s. 22(1)(a)(ii) @awe.gov.au>
Subject: Re: Checklist Enquiry [SEC=UNOFFICIAL]

Hi s. 22(1)(a)(ii),

Hopefully this is the last you hear of me today.

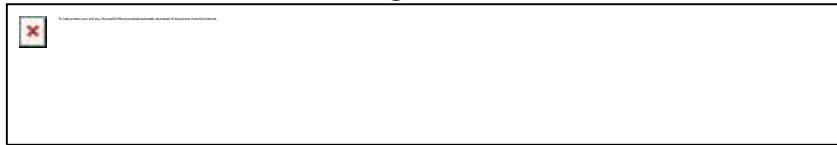
Are able to give us some indication when the DAWE is likely to approve the confirmation steps for EHEC confirmation using GENE-UP?

s. 47(1)(b)

Kind Regards

s. 47F(1)

Senior Technical Microbiologist



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On Thu, Sep 30, 2021 at 9:08 AM s. 47F(1)

[@mxns.com](mailto:s.47F(1)@mxns.com)> wrote:

Hi ^{s. 22(1)(a)(ii)},

See Below:

s. 47(1)(b)

Kind Regards

s. 47F(1)

Senior Technical Microbiologist



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If you have received this email in error, please contact us immediately at [s. 47F\(1\)@mxns.com](mailto:s.47F(1)@mxns.com) and delete the message from your system.

On Wed, Sep 29, 2021 at 4:54 PM [s. 22\(1\)\(a\)\(ii\)@awe.gov.au](mailto:s.22(1)(a)(ii)@awe.gov.au) wrote:

Hi [s. 47F\(1\)](mailto:s.47F(1)@mxns.com),

That temp is for 25 g of meat, can you please check the temp for 375 g of meat.

Regards

[s. 22\(1\)\(a\)\(ii\)](mailto:s.22(1)(a)(ii)@awe.gov.au)

From: [s. 47F\(1\)@mxns.com](mailto:s.47F(1)@mxns.com)>
Sent: Wednesday, 29 September 2021 4:41 PM
To: [s. 22\(1\)\(a\)\(ii\)@awe.gov.au](mailto:s.22(1)(a)(ii)@awe.gov.au)>
Subject: Re: Checklist Enquiry [SEC=UNOFFICIAL]

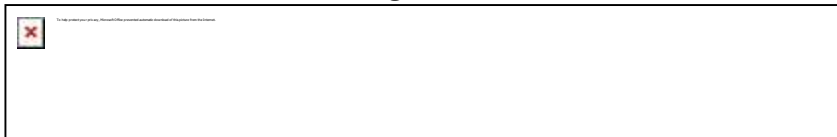
Hi [s. 22\(1\)\(a\)\(ii\)](mailto:s.22(1)(a)(ii)@awe.gov.au),

If you scroll down to the original email I've included the packet insert requirements which states 42C.

Let me know if you need any more information.

Kind Regards

[s. 47F\(1\)](mailto:s.47F(1)@mxns.com)
Senior Technical Microbiologist



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On Wed, Sep 29, 2021 at 3:24 PM s. 22(1)(a)(ii)

@awe.gov.au> wrote:

Hi s. 47F(1),

As for AOAC 121805, can you please check incubation temp for 375 g raw meat. We received an insert from the supplier that states 41.5 +/- 1 deg C.

Regards

s. 22(1)(a)(ii)

From: s. 47F(1) @mxns.com>
Sent: Wednesday, 29 September 2021 10:27 AM
To: s. 22(1)(a)(ii) @agriculture.gov.au>
Cc: Melinda Skipper <s. 47F(1) @mxns.com>
Subject: Checklist Enquiry [SEC=UNOFFICIAL]

Hi s. 22(1)(a)(ii),

I have several questions relating to the checklists that are provided by the DAWE.

Apologies if this email should be directed to someone else in the department.

The DAWE for method AOAC 996.08 requires for all resuscitation homogenates to be incubated at $37 \pm 1^\circ\text{C}$ for 24 – 26 hrs. or 18 ± 2 hrs for export samples, while the the AOAC and packet inserts specify incubation temperatures of 35°C for 24 ± 2 hours for homogenates.

The AOAC refers to AOAC 967.26 and BAM for guidance on incubation temperature.

AOAC 967.26 and BAM for all matrices specify incubation temperature of 35°C and not 37°C .

Is there a reason for the requirement of 37°C incubation rather than 35°C as specified by the AOAC?



VIDAS *Salmonella* (SLM) Assay - AOAC 996.08

SCOPE

This method is applicable to:

- Raw meats, meat products and carcass swabs.

PRINCIPLES

Detection of *Salmonella* is based on enzyme-linked fluorescent immunoassay performed in an automated VIDAS instrument. Following enrichment (see below) *Salmonella* is detected in boiled broth by specific monoclonal antibodies. A fluorescent marker is then added and *Salmonella* detected automatically by the VIDAS machine. The detection protocol can be broken down as follows:

- Pre-enrichment in non-selective liquid medium**
 Sample is diluted 1:10 in pre-warmed (room temperature or $37 \pm 1^\circ\text{C}$ for large volumes) buffered peptone water and pre-enriched at $37 \pm 1^\circ\text{C}$ for 18 ± 2 h. For carcass sponges, buffered peptone water is added to the moistened sponge to bring the total volume to 60–100 mL and the sample incubated at $37 \pm 1^\circ\text{C}$ for 18 ± 2 h. In the case of sponges BPW need not be warmed to room temperature before being used to re-hydrate the sponge, for all subsequent additions BPW should be warmed to room temperature.
- Selective Enrichment**
 Selenite cystine broth and tetrathionate broth are inoculated with pre-enrichment broth and incubated at 35 ± 1 and $42 \pm 1^\circ\text{C}$, respectively, for 18 ± 2 h.
- Post-enrichment**
 Selective enrichment broths are inoculated into M-broth and incubated for 6 h at $42 \pm 1^\circ\text{C}$.

Extract from AOAC 996.08:**E. Preparation of Test Suspension**

(1) *Pre-enrichment*.—Pre-enrich test sample in nonselective medium to initiate growth of salmonellae. Pre-enrichment varies with product type and must be performed as described in 996.1611 or 175.024 or in the *Bacteriological Analytical Manual*, 9th edition, 1995. AOAC INTERNATIONAL, Gaithersburg, MD 20877-2417, USA.

Extract from BAM:**15. Meats, meat substitutes, meat by-products, animal substances,**

glandular products, and meals (fish, meat, bone). Aseptically weigh 25 g sample into sterile blending container. Add 225 ml sterile lactose broth and blend 2 min. Aseptically transfer homogenized mixture to sterile wide-mouth, screw-cap jar (500 ml) or other appropriate container and let stand 60 ± 5 min at room temperature with jar securely capped. If mixture is powder or is ground or comminuted, blending may be omitted. For samples that do not require blending, add lactose broth and mix thoroughly; let stand for 60 ± 5 min at room temperature with jar securely capped.

Mix well by swirling and determine pH with test paper. Adjust pH, if necessary, to 6.8 ± 0.2 . Add up to 2.25 ml steamed (15 min) Tergitol Anionic 7 and mix well. Alternatively, use steamed (15 min) Triton X-100. Limit use of these surfactants to minimum quantity needed to initiate foaming. Actual quantity will depend on composition of test material. Surfactants will not be needed in analysis of powdered glandular products. Loosen jar caps 1/4 turn and incubate sample mixtures 24 ± 2 h at 35°C . Continue as in D. 1-14, below.

s. 47G(1)(a)

s. 47(1)(b)

Packet Insert:

s. 47(1)(b)

AOAC Official Method 2019.03 *E. coli* O157:H7 in Select Foods

GENE-UP® *E. coli* O157:H7 2 (ECO 2) Kit
First Action 2019

[Applicable to detection of *E. coli* O157:H7 in fresh raw ground beef (73% lean, 25 and 375 g), fresh spinach (200 g), raw milk cheese (25 g), raw ground chicken (25 g), raw beef trim (25 and 375 g), raw ground pork (375 g), Romaine lettuce (375 g), raw sausage (25 g), raw milk (25 g), raw ground veal (25 and 375 g), and processed water (25 mL).]

See Table 2019.03A for a summary of results of the interlaboratory study.

Caution: Differences of used enrichment treatments as well as incubation

Allow enrichment broths to reach 15–25°C before use. In some cases, enrichment media should be prewarmed to 42 ± 1°C or 42 ± 1°C before adding to food samples. Frozen samples should be thawed before analysis. To decrease occurrence of stressed cells, use a quick-thawing process. (This can be performed by thawing at temperatures less than 45°C in a water bath for no more than 15 min. Agitate the sample continuously.) Use a blender bag containing filter.

(a) *Fresh raw ground beef (25 g)*—Add 225 mL BPW. Homogenize and incubate at 42 ± 1°C for 18–24 h.

(b) *Fresh raw ground beef: short protocol (25 g)*—Add 225 mL prewarmed BPW. Homogenize and incubate at 42 ± 1°C for 8–24 h.

(c) *Raw ground chicken (25 g)*—Add 225 mL prewarmed BPW or modified tryptic soy broth (mTSB). Homogenize and incubate at

GENE-UP® *E. coli* O157: **s. 47(1)(b)**

SCOPE

This method is applicable for testing of raw ground beef and raw beef trim for *E. coli* O157:H7.

PRINCIPLES

The GENE-UP® *E. coli* O157:H7 (ECO 2) is a qualitative real-time PCR assay. **s. 47(1)(b)**

s. 47(1)(b)

Detection of *E. coli* O157:H7 involves the follow steps:

▪

s. 47(1)(b)

This causes some confusion during method audits and review of documents.
Let me know if you require any further information.

Looking forward to a response.

Kind Regards

s. 47F(1)

Senior Technical Microbiologist



For correspondence:

Silliker Australia Pty Ltd
20 King Street Blackburn
VIC 3130 Australia

Phone: 1300 000 990

Direct: +**s. 47F(1)**

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GENE-UP® EHEC Detection Method – AOAC 2020.06

SCOPE

This method is applicable for testing of raw ground beef and raw beef trim and some selected foods for *E. coli* (O157, O26, O45, O103, O111, O121 and O145). Standard method (AOAC 2020.06) must be followed without any modification.

PRINCIPLES

The GENE-UP® EHEC Detection Method is a qualitative real-time PCR assay. DNA is extracted using an automated process on the VIDAS or through bead beating using the GENE-UP Lysis Test Kit. DNA is analysed for EHEC virulence factors using the GENE-UP® STEC-*stx* & *eae* 2 assay, followed by GENE-UP® STEC Top 6 and *E. coli* O157:H7 2 PCR assays. The GENE-UP® Thermocycler is utilised to detect fluorescence at several wavelengths to allow for multi-target detections.

Detection of STEC involves the follow steps:

- **Enrichment**
Sample (375 g) is enriched in 1,125 mL of pre-warmed (to 41.5±1°C) buffered peptone water (BPW). Sample and enrichment media are placed in a stomacher bag and homogenised using a stomacher. Incubation is carried out at 41.5 ± 1°C for 10 - 24 h. It is essential that the temperature of the broth and sample is at 41.5±1°C for a minimum of 10 h. A positive and a negative control culture must be run through all procedures daily or when testing is carried out.
- **Immuno-concentration¹**
Immuno-concentration is to be carried out using the VIDAS® ESPT or using the bead beating with the GENE-UP® Lysis Kit as per the manufacturer's recommended protocol.
- **PCR Assays²**
Sample preparation for bacterial DNA extraction and PCR assays is carried out following the manufacturer's recommended protocol. PCRs are to be carried out separately: GENE-UP® STEC – *stx* & *eae* (EH1 2) for detection of *stx/eae* genes; if target genes are detected then GENE-UP® *E. coli* O157:H7 (ECO 2) and GENE-UP® STEC Top 6 (EH2) are to be performed for the detection of O157:H7 and top 6 non-O157 serogroups, respectively. Samples negative for these seven serogroups are considered negative for *E. coli* O157:H7 and non-O157 STEC.

Samples with a positive result are regarded as potential positives and must be confirmed. Inhibited samples must be retested as per the standard method. In the case of an inhibited result, the test must be repeated using the same enrichment cultures. If the re-test sample returns a further inhibited result, the equipment supplier must be contacted for advice, and the enrichment broth must be analysed using an alternate method or the sample deemed positive.

¹ Kit # 30229 for VIDAS UP *E. coli* Serogroups (ESPT) or Kit # 414057 for GENE-UP Lysis Kit must be used

² Kit # 423109 for GENE-UP STEC – *stx* & *eae* (EH1 2); Kit # 423108 for GENE-UP *E. coli* O157:H7 (ECO 2) and Kit # 414154 for GENE-UP STEC Top 6 (EH2) must be used.

- **Confirmation with VIDAS ESPT Kit**

- a) Concentration is carried out by VIDAS® ESPT2 test and a concentrated sample (30 µL) is to be transferred on to:

- CHROMID® EHEC agar - streak and incubate for 20-24 h at 37 ±1°C.
 - SMAC CT agar if *E. coli* O157:H7 is suspected - streak and incubate for 18-24 h at 37 ±1°C
 - CHROMID® Coli agar if non-O157 is suspected - streak and incubate 22-26 h at 37 ±1°C

- **Confirmation by Direct Streaking**

- b) Enrichment broth is to be directly plated (10µL) on to:

- Supplemented CHROMID® EHEC agar (supplemented with cefixime-tellurite³) - streak and incubate for 20-24 h at 37 ±1°C.
 - SMAC CT agar (if *E. coli* O157:H7 is suspected) - streak and incubate for 18-24 h at 37 ±1°C
 - CHROMID® Coli agar (if non-O157 is suspected) - streak and incubate 22-26 h at 37 ±1°C

- **Confirmation of isolated colonies**

Between one and five typical colonies are to be selected from each plate and tested for target serogroups either by latex test (SLIDEX *E. coli*, targeted serogroups) or by serogroup specific PCR (GENE-UP® STEC Top 6 and/or GENE-UP® *E. coli* O157:H7 2), followed by performing EHEC gene specific PCR (GENE-UP® STEC-*stx* & *eae* 2).

A positive result is to be reported as confirmed positive.

Discordant results must be tested by diluting 0.1 mL enrichment broth into 9 mL BPW, incubated at 37 ±1°C for 4 – 24 h, followed by repeating the confirmation procedure from the beginning.

(Optional) Positive enrichment broth can also be confirmed by MLG 5/MLG 5B or MLG 5C. In such case confirmation must be carried out at a DAWE approved laboratory.

³ Cefixime-tellurite mixture - Ref. 42606

CHECKLIST

Enrichment	Is the enrichment media pre-warmed to $41.5 \pm 1^\circ\text{C}$ before use?	_____
	Is enrichment carried out at $41.5 \pm 1^\circ\text{C}$ and is the enrichment broth and sample at $41.5 \pm 1^\circ\text{C}$ for a minimum of 10 h?	_____
	Is the correct amount of enrichment broth used?	_____
	Is a positive and a negative control run with each batch of samples/daily?	_____
	Are reference cultures inoculated into enrichment media at a level of 10-100 cells per sample?	_____
Immuno-concentration	Which method is utilized for concentration/DNA extraction? VIDAS® ESPT or GENE-Up Lysis Kit?	_____
	Are manufacturers' instructions followed?	_____
PCR Assay	Are correct kits used for different STEC serogroups?	_____
	Are manufacturer's instructions available for reference?	_____
	Are internal controls run with each batch of samples?	_____
	Are technicians familiar with and trained in the operation of PCR automated instruments and the associated software?	_____
	Is the shelf-life of media and kits controlled?	_____
Confirmation	Is confirmation carried out from the enrichment culture (BPW)?	_____
	Is VIDAS® ESPT2 Kit or direct plating methods carried out in the confirmation step?	_____
	Are 1-5 typical colonies run through GENE UP® STEC top 6 and GENE-UP® E. coli O157:H7 2 assay or latex agglutination test?	_____
	If positive, are STEC genes verified by GENE-UP® STEC- <i>stx</i> & <i>eae</i> PCR assay?	_____
	Is a discordant result (if any) retested and reconfirmed?	_____
	Is confirmation carried out using MLG 5/MLG 5B or MLG 5C at a DAWE approved laboratory?	_____

s. 22(1)(a)(ii)

From: s. 47F(1) @mxns.com>
Sent: Wednesday, 20 October 2021 3:52 PM
To: s. 22(1)(a)(ii)
Cc: Melinda Skipper
Subject: Re: Checklist Enquiry [SEC=UNOFFICIAL]

Hi s. 22(1)(a)(ii) and s. 22(1)(a)(ii),

Apologies for the urgency....is it possible to provide an updated Checklist for EHEC PTM 121806. We are looking at performing verification for the procedure and submitting for NATA accreditation.



Kind Regards



s. 47F(1)
Senior Technical Microbiologist



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Direct: +s. 47F(1)
<http://www.merieuxnutrisciences.com/au>

Follow us on:  

On Fri, Oct 1, 2021 at 9:47 AM s. 47F(1) @mxns.com> wrote:

Hi s. 22(1)(a)(ii),

s. 47G(1)(a)

It's good to know that the approval from the DAWE should be completed in the next few weeks.

When reviewing documentation, it can get very confusing when the AOAC RI certificate number is quoted and not the AOAC OMA certificate number and vice versa.

This can become a problem during audits.

See below example:

In this instance the DAWE quotes the certificate AOAC RI number for E.coli 0157:H7 and EHEC Testing, while other related documentation may quote the AOAC OMA certificate numbers.

s. 47(1)(b)

In regards to the checklist for AOAC 121805, will this be updated to reflect the AOAC method and packet insert for incubation of enrichments to 42C +/- 1C rather than 41.5C +/- 1C ?
I think I may have previously confused you on this original enquiry.

AOAC 2019.03 (121805):

**AOAC Official Method 2019.03
E. coli O157:H7 in Select Foods
GENE-UP® *E. coli* O157:H7 2 (ECO 2) Kit
First Action 2019**

[Applicable to detection of *E. coli* O157:H7 in fresh raw ground beef (73% lean; 25 and 375 g), fresh spinach (200 g), raw milk cheese (25 g), raw ground chicken (25 g), raw beef trim (25 and 375 g), raw ground pork (375 g), Romaine lettuce (375 g), raw sausage (25 g), raw milk (25 g), raw ground veal (25 and 375 g), and processed water (25 mL).]

See Table 2019.03A for a summary of results of the interlaboratory study.

D. Sample Enrichment

Allow enrichment broths to reach 15–25°C before use. In some cases, enrichment media should be prewarmed to $41.5 \pm 1^\circ\text{C}$ or $42 \pm 1^\circ\text{C}$ before adding to food samples. Frozen samples should be thawed before analysis. To decrease occurrence of stressed cells, use a quick-thawing process. (This can be performed by thawing at temperatures less than 45°C in a water bath for no more than 15 min. Agitate the sample continuously.) Use a blender bag containing filter.

(a) *Fresh raw ground beef (25 g).*—Add 225 mL BPW. Homogenize and incubate at $42 \pm 1^\circ\text{C}$ for 18–24 h.

(b) *Fresh raw ground beef short protocol (25 g).*—Add 225 mL prewarmed BPW. Homogenize and incubate at $42 \pm 1^\circ\text{C}$ for 8–14 h.

(c) *Raw ground chicken (25 g).*—Add 225 mL prewarmed BPW or modified tryptic soy broth (mTSB). Homogenize and incubate at $42 \pm 1^\circ\text{C}$ for 18–24 h.

(d) *Fresh spinach (200 g).*—Add 800 mL BPW. Homogenize and incubate at $42 \pm 1^\circ\text{C}$ for 18–24 h.

(e) *Raw beef trim (325 g).*—Add 975 mL mTSB. Homogenize and incubate at $42 \pm 1^\circ\text{C}$ for 15–24 h.

(f) *Raw beef trim, raw ground pork, and raw ground beef (375 g).*—Add 1125 mL prewarmed ($42 \pm 1^\circ\text{C}$) BPW or mTSB. Homogenize and incubate at $42 \pm 1^\circ\text{C}$ for 10–24 h. mTSB enrichment is applicable to raw ground pork.

(g) *Romaine lettuce (375 g).*—Add 1125 mL prewarmed BPW. Homogenize and incubate at $41.5 \pm 1^\circ\text{C}$ for 22–24 h.

DAWE Checklist:

GENE-UP® *E. coli* O157:H7 2 (ECO 2) – AOAC 121805**SCOPE**

This method is applicable for testing of raw ground beef and raw beef trim for *E. coli* O157:H7.

PRINCIPLES

The GENE-UP® *E. coli* O157:H7 (ECO 2) is a qualitative real-time PCR assay. **s. 47(1)(b)**

s. 47(1)(b)

s. 47G(1)(a)

Biomerieux package Insert:

s. 47(1)(b)

Let me know if you need any further clarification.

Kind Regards

s. 47F(1)

Senior Technical Microbiologist



For correspondence:

Silliker Australia Pty Ltd
20 King Street Blackburn
VIC 3130 Australia

Phone: 1300 000 990

Direct: s. 47F(1)

E-mail: s. 47F(1) [@mxns.com](mailto:s.47F(1)@mxns.com)

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@awe.gov.au> wrote:

Hi s. 47F(1),

We should be able to finalize this method in a couple of weeks. Are you planning to implement this method?

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Subject: Re: Checklist Enquiry [SEC=UNOFFICIAL]

Hi s. 22(1)(a)(ii),

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Are able to give us some indication when the DAWE is likely to approve the confirmation steps for EHEC confirmation using GENE-UP?

s. 47(1)(b)

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[@mxns.com](mailto:s. 47F(1) @mxns.com)> wrote:

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See Below:

s. 47(1)(b)

Kind Regards

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Hi s. 22(1)(a)(ii),

If you scroll down to the original email I've included the packet insert requirements which states 42C.

Let me know if you need any more information.

Kind Regards

s. 47F(1)

Senior Technical Microbiologist

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Hi s. 47F(1),

As for AOAC 121805, can you please check incubation temp for 375 g raw meat. We received an insert from the supplier that states 41.5 +/- 1 deg C.

Regards

s. 22(1)(a)(ii)

From: s. 47F(1) @mxns.com>
Sent: Wednesday, 29 September 2021 10:27 AM
To: s. 22(1)(a)(ii) @agriculture.gov.au>
Cc: Melinda Skipper <s. 47F(1) @mxns.com>
Subject: Checklist Enquiry [SEC=UNOFFICIAL]

Hi s. 22(1)(a)(ii),

I have several questions relating to the checklists that are provided by the DAWE.

Apologies if this email should be directed to someone else in the department.

The DAWE for method AOAC 996.08 requires for all resuscitation homogenates to be incubated at 37 +/-1C for 24 – 26 hrs. or 18+/- 2 hrs for export samples, while the the AOAC and packet inserts specify incubation temperatures of 35 C for 24 ± 2 hours for homogenates.

The AOAC refers to AOAC 967.26 and BAM for guidance on incubation temperature.

AOAC 967.26 and BAM for all matrices specify incubation temperature of 35C and not 37C.

Is there a reason for the requirement of 37C incubation rather than 35C as specified by the AOAC?



VIDAS *Salmonella* (SLM) Assay - AOAC 996.08

SCOPE

This method is applicable to:

- Raw meats, meat products and carcass swabs.

PRINCIPLES

Detection of *Salmonella* is based on enzyme-linked fluorescent immunoassay performed in an automated VIDAS instrument. Following enrichment (see below) *Salmonella* is detected in boiled broth by specific monoclonal antibodies. A fluorescent marker is then added and *Salmonella* detected automatically by the VID5 machine. The detection protocol can be broken down as follows:

- **Pre-enrichment in non-selective liquid medium**
Sample is diluted 1:10 in pre-warmed (room temperature or $37 \pm 1^\circ\text{C}$ for large volumes) buffered peptone water and pre-enriched at $37 \pm 1^\circ\text{C}$ for 18 ± 2 h. For carcass sponges, buffered peptone water is added to the moistened sponge to bring the total volume to 60–100 ml and the sample incubated at $37 \pm 1^\circ\text{C}$ for 18 ± 2 h. In the case of sponges BPW need not be warmed to room temperature before being used to re-hydrate the sponge, for all subsequent additions BPW should be warmed to room temperature.
- **Selective Enrichment**
Selenite cystine broth and tetrathionate broth are inoculated with pre-enrichment broth and incubated at 35 ± 1 and $42 \pm 1^\circ\text{C}$, respectively, for 18 ± 2 h.
- **Post-enrichment**
Selective enrichment broths are inoculated into M-broth and incubated for 6 h at $42 \pm 1^\circ\text{C}$.

Extract from AOAC 996.08:

E. Preparation of Test Suspension

(1) *Pre-enrichment*.—Pre-enrich test sample in nonselective medium to initiate growth of salmonellae. Pre-enrichment varies with product type and must be performed as described in *96.16* or *17.1* (12) or in the *International Sanitation Manual*, copyright 1991, AOAC INTERNATIONAL, Gaithersburg, MD 20877-2417, USA.

Extract from BAM:

15. Meats, meat substitutes, meat by-products, animal substances,

glandular products, and meals (fish, meat, bone). Aseptically weigh 25 g sample into sterile blending container. Add 225 ml sterile **lactose broth** and blend 2 min. Aseptically transfer homogenized mixture to sterile wide-mouth, screw-cap jar (500 ml) or other appropriate container and let stand 60 ± 5 min at room temperature with jar securely capped. If mixture is powder or is ground or comminuted, blending may be omitted. For samples that do not require blending, add lactose broth and mix thoroughly; let stand for 60 ± 5 min at room temperature with jar securely capped.

Mix well by swirling and determine pH with test paper. Adjust pH, if necessary, to 6.8 ± 0.2 . Add up to 2.25 ml steamed (15 min) Tergitol Anionic 7 and mix well. Alternatively, use steamed (15 min) Triton X-100. Limit use of these surfactants to minimum quantity needed to initiate foaming. Actual quantity will depend on composition of test material. Surfactants will not be needed in analysis of powdered glandular products. Loosen jar caps $1/4$ turn and incubate sample mixtures 24 ± 2 h at 35°C . Continue as in **D.1-14**, below.

s. 47G(1)(a)

s. 47(1)(b)

Packet Insert:

s. 47(1)(b)

AOAC Official Method 2019.03
***E. coli* O157:H7 in Select Foods**
GENE-UP® *E. coli* O157:H7 2 (ECO 2) Kit
First Action 2019

[Applicable to detection of *E. coli* O157:H7 in fresh raw ground beef (73% lean, 25 and 375 g), fresh spinach (200 g), raw milk cheese (25 g), raw ground chicken (25 g), raw beef trim (25 and 375 g), raw ground pork (375 g), Romaine lettuce (375 g), raw sausage (25 g), raw milk (25 g), raw ground veal (25 and 375 g), and processed water (25 mL).]

See Table 2019.03A for a summary of results of the interlaboratory study.

Caution: Differences of method utilized between normal and stressed cells

Allow enrichment broth to reach 15–25°C before use. In some cases, enrichment media should be prewarmed to 42 ± 1°C or 42 ± 1°C before adding to food samples. Frozen samples should be thawed before analysis. To decrease occurrence of stressed cells, use a quick-thawing process. (This can be performed by thawing at temperatures less than 45°C in a water bath for no more than 15 min. Agitate the sample continuously.) Use a blender bag containing filter.

(a) *Fresh raw ground beef (25 g)*—Add 225 mL BPW. Homogenize and incubate at 42 ± 1°C for 18–24 h.

(b) *Fresh raw ground beef short protocol (25 g)*—Add 225 mL prewarmed BPW. Homogenize and incubate at 42 ± 1°C for 8–24 h.

(c) *Raw ground chicken (25 g)*—Add 225 mL prewarmed BPW in modified tryptic soy broth (mTSB). Homogenize and incubate at

GENE-UP® *E. coli* O157:s. 47(1)(b)

SCOPE

This method is applicable for testing of raw ground beef and raw beef trim for *E. coli* O157:H7.

PRINCIPLES

The GENE-UP® *E. coli* O157:H7 (ECO 2) is a qualitative real-time PCR assay s. 47(1)(b)

s. 47(1)(b)

Detection of *E. coli* O157:H7 involves the follow steps:

s. 47(1)(b)

This causes some confusion during method audits and review of documents.

Let me know if you require any further information.

Looking forward to a response.

Kind Regards

s. 47F(1)

Senior Technical Microbiologist



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 20 King Street Blackburn
 VIC 3130 Australia

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s. 22(1)(a)(ii)

From: s. 47F(1) @mxns.com>
Sent: Thursday, 21 October 2021 8:26 AM
To: s. 22(1)(a)(ii)
Cc: s. 22(1)(a)(ii); Melinda Skipper
Subject: Re: Checklist Enquiry [SEC=UNOFFICIAL]

Hi s. 22(1)(a)(ii),

Thankyou for the checklist, much appreciated.

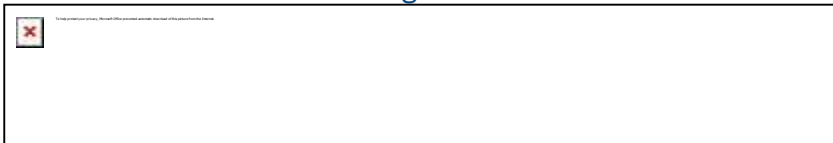
Yes, the updates to the checklists for O157:H7 will allow consistency and clarity between the reference standards. It can get confusing at times with audits from varying governing bodies and having conflicting reference numbers.

Thanks again for the update,

Kind Regards



s. 47F(1)
Senior Technical Microbiologist



Mérieux NutriSciences
20 King Street, Blackburn, VIC, 3130, Australia
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Direct: +s. 47F(1)
<http://www.merieuxnutrisciences.com/au>

Follow us on:  

On Wed, Oct 20, 2021 at 5:08 PM s. 22(1)(a)(ii)

@awe.gov.au> wrote:

Hi s. 47F(1),

Hope you are well. As you requested please find attached checklist of AOAC 2020.06 which we recently approved for STEC screening and confirmatory test. We are also planning to change the PTM number of O157:H7 method to OMA number (2019.03) including the temperature range if applicable.

Kind regards

s. 22(1)(a)(ii)

From: s. 47F(1) @mxns.com>
Sent: Wednesday, 20 October 2021 3:52 PM
To: s. 22(1)(a)(ii) @awe.gov.au>; s. 22(1)(a)(ii) @awe.gov.au>
Cc: Melinda Skipper <s. 47F(1) @mxns.com>
Subject: Re: Checklist Enquiry [SEC=UNOFFICIAL]

Hi s. 22(1)(a)(ii) and s. 22(1)(a)(ii),

Apologies for the urgency....is it possible to provide an updated Checklist for EHEC PTM 121806.

We are looking at performing verification for the procedure and submitting for NATA accreditation.

Kind Regards



s. 47F(1)

Senior Technical Microbiologist





Mérieux NutriSciences

20 King Street, Blackburn, VIC, 3130, Australia

Phone: 1300 000 990

Direct: +s. 47F(1)

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Follow us on:  

On Fri, Oct 1, 2021 at 9:47 AM s. 47F(1) @mxns.com> wrote:

Hi s. 22(1)(a)(ii),

s. 47G(1)(a)

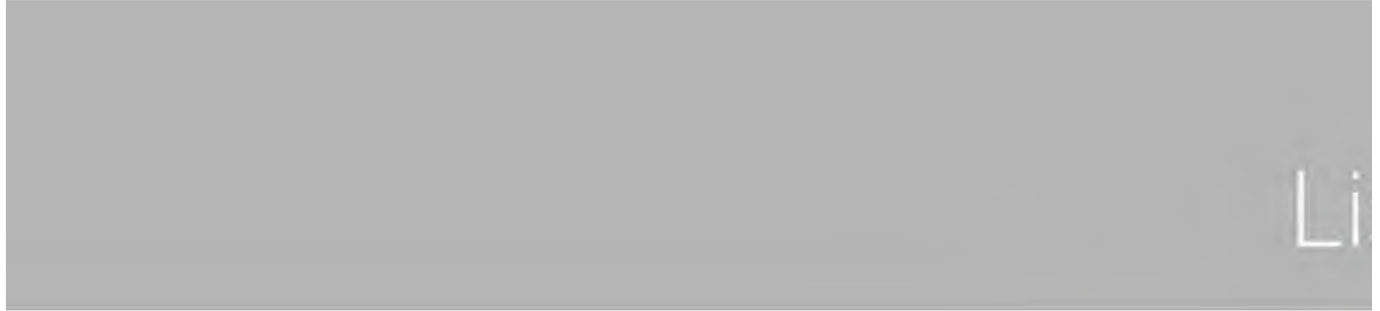
It's good to know that the approval from the DAWE should be completed in the next few weeks.

When reviewing documentation, it can get very confusing when the AOAC RI certificate number is quoted and not the AOAC OMA certificate number and vice versa.

This can become a problem during audits.

See below example:

In this instance the DAWE quotes the certificate AOAC RI number for E.coli 0157:H7 and EHEC Testing, while other related documentation may quote the AOAC OMA certificate numbers.



s. 47(1)(b)

In regards to the checklist for AOAC 121805, will this be updated to reflect the AOAC method and packet insert for incubation of enrichments to 42C +/- 1C rather than 41.5C +/- 1C ?

I think I may have previously confused you on this original enquiry.

AOAC 2019.03 (121805):

AOAC Official Method 2019.03
***E. coli* O157:H7 in Select Foods**
GENE-UP® *E. coli* O157:H7 2 (ECO 2) Kit
First Action 2019

[Applicable to detection of *E. coli* O157:H7 in fresh raw ground beef (73% lean; 25 and 375 g), fresh spinach (200 g), raw milk cheese (25 g), raw ground chicken (25 g), raw beef trim (25 and 375 g), raw ground pork (375 g), Romaine lettuce (375 g), raw sausage (25 g), raw milk (25 g), raw ground veal (25 and 375 g), and processed water (25 mL).]

See Table 2019.03A for a summary of results of the interlaboratory study.

D. Sample Enrichment

Allow enrichment broths to reach 15–25°C before use. In some cases, enrichment media should be prewarmed to $41.5 \pm 1^\circ\text{C}$ or $42 \pm 1^\circ\text{C}$ before adding to food samples. Frozen samples should be thawed before analysis. To decrease occurrence of stressed cells, use a quick-thawing process. (This can be performed by thawing at temperatures less than 45°C in a water bath for no more than 15 min. Agitate the sample continuously.) Use a blender bag containing filter.

(a) *Fresh raw ground beef (25 g)*.—Add 225 mL BPW. Homogenize and incubate at $42 \pm 1^\circ\text{C}$ for 18–24 h.

(b) *Fresh raw ground beef: short protocol (25 g)*.—Add 225 mL prewarmed BPW. Homogenize and incubate at $42 \pm 1^\circ\text{C}$ for 8–24 h.

(c) *Raw ground chicken (25 g)*.—Add 225 mL prewarmed BPW or modified tryptic soy broth (mTSB). Homogenize and incubate at $42 \pm 1^\circ\text{C}$ for 18–24 h.

(d) *Fresh spinach (200 g)*.—Add 800 mL BPW. Homogenize and incubate at $42 \pm 1^\circ\text{C}$ for 18–24 h.

(e) *Raw beef trim (325 g)*.—Add 975 mL mTSB. Homogenize and incubate at $42 \pm 1^\circ\text{C}$ for 15–24 h.

(f) *Raw beef trim, raw ground pork, and raw ground beef (375 g)*.—Add 1125 mL prewarmed ($42 \pm 1^\circ\text{C}$) BPW or mTSB. Homogenize and incubate at $42 \pm 1^\circ\text{C}$ for 10–24 h. mTSB enrichment is applicable to raw ground pork.

(g) *Romaine lettuce (375 g)*.—Add 1125 mL prewarmed BPW. Homogenize and incubate at $41.5 \pm 1^\circ\text{C}$ for 22–24 h.

DAWE Checklist:

GENE-UP® *E. coli* O157:H7 2 (ECO 2) – AOAC 121805**SCOPE**

This method is applicable for testing of raw ground beef and raw beef trim for *E. coli* O157:H7.

PRINCIPLES

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s. 47(1)(b)

s. 47G(1)(a)

Biomerieux package Insert:

s. 47(1)(b)

Let me know if you need any further clarification.

Kind Regards

s. 47F(1)

Senior Technical Microbiologist



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Cc: Melinda Skipper <[s.47F\(1\)@mxns.com](mailto:s.47F(1)@mxns.com)>
Subject: Checklist Enquiry [SEC=UNOFFICIAL]

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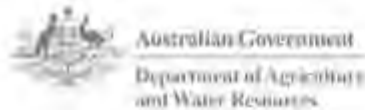
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VIDAS *Salmonella* (SLM) Assay - AOAC 996.08

SCOPE

This method is applicable to:

- Raw meats, meat products and carcass swabs.

PRINCIPLES

Detection of *Salmonella* is based on enzyme-linked fluorescent immunoassay performed in an automated VIDAS instrument. Following enrichment (see below) *Salmonella* is detected in boiled broth by specific monoclonal antibodies. A fluorescent marker is then added and *Salmonella* detected automatically by the VIDAS machine. The detection protocol can be broken down as follows:

- **Pre-enrichment in non-selective liquid medium**
Sample is diluted 1:10 in pre-warmed (room temperature or $37 \pm 1^\circ\text{C}$ for large volumes) buffered peptone water and pre-enriched at $37 \pm 1^\circ\text{C}$ for 18 ± 2 h. For carcass sponges, buffered peptone water is added to the moistened sponge to bring the total volume to 60–100 mL and the sample incubated at $37 \pm 1^\circ\text{C}$ for 18 ± 2 h. In the case of sponges BPW need not be warmed to room temperature before being used to re-hydrate the sponge, for all subsequent additions BPW should be warmed to room temperature.
- **Selective Enrichment**
Selenite cystine broth and tetrathionate broth are inoculated with pre-enrichment broth and incubated at 35 ± 1 and $42 \pm 1^\circ\text{C}$, respectively, for 18 ± 2 h.
- **Post-enrichment**
Selective enrichment broths are inoculated into M-broth and incubated for 6 h at $42 \pm 1^\circ\text{C}$.

Extract from AOAC 996.08:

E. Preparation of Test Suspension

(1) *Pre-enrichment*.—Pre-enrich test sample in nonselective medium to initiate growth of salmonellae. Pre-enrichment varies with product type and must be performed as described in *96.08* or *17.02* or *20.02* or *21.02* or *22.02* or *23.02* or *24.02* or *25.02* or *26.02* or *27.02* or *28.02* or *29.02* or *30.02* or *31.02* or *32.02* or *33.02* or *34.02* or *35.02* or *36.02* or *37.02* or *38.02* or *39.02* or *40.02* or *41.02* or *42.02* or *43.02* or *44.02* or *45.02* or *46.02* or *47.02* or *48.02* or *49.02* or *50.02* or *51.02* or *52.02* or *53.02* or *54.02* or *55.02* or *56.02* or *57.02* or *58.02* or *59.02* or *60.02* or *61.02* or *62.02* or *63.02* or *64.02* or *65.02* or *66.02* or *67.02* or *68.02* or *69.02* or *70.02* or *71.02* or *72.02* or *73.02* or *74.02* or *75.02* or *76.02* or *77.02* or *78.02* or *79.02* or *80.02* or *81.02* or *82.02* or *83.02* or *84.02* or *85.02* or *86.02* or *87.02* or *88.02* or *89.02* or *90.02* or *91.02* or *92.02* or *93.02* or *94.02* or *95.02* or *96.02* or *97.02* or *98.02* or *99.02* or *100.02* or *101.02* or *102.02* or *103.02* or *104.02* or *105.02* or *106.02* or *107.02* or *108.02* or *109.02* or *110.02* or *111.02* or *112.02* or *113.02* or *114.02* or *115.02* or *116.02* or *117.02* or *118.02* or *119.02* or *120.02* or *121.02* or *122.02* or *123.02* or *124.02* or *125.02* or *126.02* or *127.02* or *128.02* or *129.02* or *130.02* or *131.02* or *132.02* or *133.02* or *134.02* or *135.02* or *136.02* or *137.02* or *138.02* or *139.02* or *140.02* or *141.02* or *142.02* or *143.02* or *144.02* or *145.02* or *146.02* or *147.02* or *148.02* or *149.02* or *150.02* or *151.02* or *152.02* or *153.02* or *154.02* or *155.02* or *156.02* or *157.02* or *158.02* or *159.02* or *160.02* or *161.02* or *162.02* or *163.02* or *164.02* or *165.02* or *166.02* or *167.02* or *168.02* or *169.02* or *170.02* or *171.02* or *172.02* or *173.02* or *174.02* or *175.02* or *176.02* or *177.02* or *178.02* or *179.02* or *180.02* or *181.02* or *182.02* or *183.02* or *184.02* or 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15. Meats, meat substitutes, meat by-products, animal substances,

glandular products, and meals (fish, meat, bone). Aseptically weigh 25 g sample into sterile blending container. Add 225 ml sterile **lactose broth** and blend 2 min. Aseptically transfer homogenized mixture to sterile wide-mouth, screw-cap jar (500 ml) or other appropriate container and let stand 60 ± 5 min at room temperature with jar securely capped. If mixture is powder or is ground or comminuted, blending may be omitted. For samples that do not require blending, add lactose broth and mix thoroughly; let stand for 60 ± 5 min at room temperature with jar securely capped.

Mix well by swirling and determine pH with test paper. Adjust pH, if necessary, to 6.8 ± 0.2 . Add up to 2.25 ml steamed (15 min) Tergitol Anionic 7 and mix well. Alternatively, use steamed (15 min) Triton X-100. Limit use of these surfactants to minimum quantity needed to initiate foaming. Actual quantity will depend on composition of test material. Surfactants will not be needed in analysis of powdered glandular products. Loosen jar caps $1/4$ turn and incubate sample mixtures 24 ± 2 h at 35°C . Continue as in **D.1-14**, below.

s. 47G(1)(a)

s. 47(1)(b)

Packet Insert:

s. 47(1)(b)

AOAC Official Method 2019.03
***E. coli* O157:H7 in Select Foods**
GENE-UP® *E. coli* O157:H7 2 (ECO 2) Kit
First Action 2019

[Applicable to detection of *E. coli* O157:H7 in fresh raw ground beef (73% lean, 25 and 375 g), fresh spinach (200 g), raw milk cheese (25 g), raw ground chicken (25 g), raw beef trim (25 and 375 g), raw ground pork (375 g), Romaine lettuce (375 g), raw sausage (25 g), raw milk (25 g), raw ground veal (25 and 375 g), and processed water (25 mL).]

See Table 2019.03A for a summary of results of the interlaboratory study.

Caution: Presence of meat or animal products may inhibit detection.

Allow enrichment broths to reach 15–25°C before use. In some cases, enrichment broths should be prewarmed to 42 ± 1°C or 45 ± 1°C before adding to food samples. Frozen samples should be thawed before analysis. To decrease occurrence of stressed cells, use a quick-thawing process. (This can be performed by thawing at temperatures less than 45°C in a water bath for no more than 15 min. Agitate the sample continuously.) Use a blender bag containing filter.

(a) *Fresh raw ground beef (25 g)*—Add 225 mL BPW. Homogenize and incubate at 42 ± 1°C for 15–24 h.

(b) *Fresh raw ground beef: short protocol (25 g)*—Add 225 mL prewarmed BPW. Homogenize and incubate at 42 ± 1°C for 8–24 h.

(c) *Raw ground chicken (25 g)*—Add 225 mL prewarmed BPW or modified tryptic soy broth (mTSB). Homogenize and incubate at

GENE-UP® *E. coli* O157:s. 47(1)(b)

SCOPE

This method is applicable for testing of raw ground beef and raw beef trim for *E. coli* O157:H7.

PRINCIPLES

The GENE-UP® *E. coli* O157:H7 (ECO 2) is a qualitative real-time PCR assay. The GENE-UP Thermocycler detects fluorescence at several wavelengths to allow for multi-target detection in the same reaction vessel.

Detection of *E. coli* O157:H7 involves the follow steps:

s. 47(1)(b)

This causes some confusion during method audits and review of documents.
 Let me know if you require any further information.
 Looking forward to a response.

Kind Regards

s. 47F(1)

Senior Technical Microbiologist



For correspondence:

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 VIC 3130 Australia

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Direct: +s. 47F(1)

E-mail: s. 47F(1) [@mxns.com](mailto:s.47F(1)@mxns.com)

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If you have received this email in error, please contact us immediately at s. 47F(1) [@mxns.com](mailto:s.47F(1)@mxns.com) and delete the message from your system.

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s. 22(1)(a)(ii)

From: s. 22(1)(a)(ii) @awe.gov.au>
Sent: Tuesday, 23 November 2021 12:48 PM
To: s. 47F(1)
Cc: s. 22(1)(a)(ii)
Subject: RE: Checklist Enquiry [SEC=UNOFFICIAL]

Hi s. 47F(1),

Yes, we are going to update AOAC 121805 GENE-UP E. coli 0157 as below:

Method number AOAC 2019.03
Enrichment temp 42 +/- 1 degree C.

(f) Raw beef trim, raw ground pork, and raw ground beef (375 g).—Add 1125 mL prewarmed (42 ± 1°C) BPW or mTSB. Homogenize and incubate at 42 ± 1°C for 10–24 h. mTSB enrichment is applicable to raw ground pork.

Incubation temp for AOAC 121806 GENE-UP EHEC will remain same as below. We will also change the number of this method to AOAC 2020.06.

(e) Raw ground beef and raw beef trim (375 g).—Add 1125 mL BPW (prewarmed to 41.5°C). Homogenize for 30 s (by hand or mechanical means) and incubate at 41.5 ± 1°C for 10–24 h.

Kind regards

s. 22(1)(a)(ii)

From: s. 47F(1)
Sent: Tuesday, 23 November 2021 10:47 AM
To: s. 22(1)(a)(ii)
Cc: s. 22(1)(a)(ii) ; s. 47F(1)
Subject: Re: Checklist Enquiry [SEC=UNOFFICIAL]

Hi s. 22(1)(a)(ii),

Hope you're keeping well.

Are there plans to update the temperature conditions for AOAC 121805 GENE-UP E.coli 0157?

PRINCIPLES

The GENE-UP® *E. coli* O157:H7 (ECO 2) is a qualitative real-time PCR assay. s. 47(1)(b)

s. 47(1)(b)

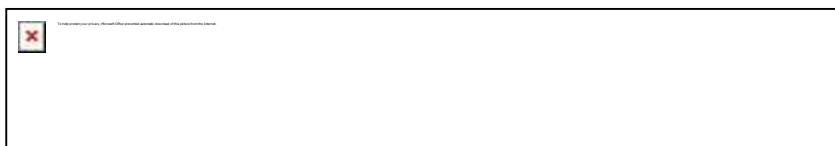
s. 47(1)(b)

Kind Regards





s. 47F(1)

Senior Technical Microbiologist



Mérieux NutriSciences
20 King Street, Blackburn, VIC, 3130, Australia
Phone: 1300 000 990
Direct: +s. 47F(1)
<http://www.merieuxnutrisciences.com/au>

Follow us on:  

On Wed, Oct 20, 2021 at 5:08 PM s. 22(1)(a)(ii)

@awe.gov.au wrote:

Hi s. 47F(1),

Hope you are well. As you requested please find attached checklist of AOAC 2020.06 which we recently approved for STEC screening and confirmatory test. We are also planning to change the PTM number of O157:H7 method to OMA number (2019.03) including the temperature range if applicable.

Kind regards

s. 22(1)(a)(ii)

From: s. 47F(1) @mxns.com>
Sent: Wednesday, 20 October 2021 3:52 PM
To: s. 22(1)(a)(ii) @awe.gov.au>; s. 22(1)(a)(ii) @awe.gov.au>
Cc: Melinda Skipper <s. 47F(1) @mxns.com>
Subject: Re: Checklist Enquiry [SEC=UNOFFICIAL]

Hi s. 22(1)(a)(ii) and s. 22(1)(a)(ii) ,

Apologies for the urgency....is it possible to provide an updated Checklist for EHEC PTM 121806.

We are looking at performing verification for the procedure and submitting for NATA accreditation.

Kind Regards



s. 47F(1)

Senior Technical Microbiologist





Mérieux NutriSciences

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Phone: 1300 000 990

Direct: +s. 47F(1)

<http://www.merieuxnutrisciences.com/au>

Follow us on:  

On Fri, Oct 1, 2021 at 9:47 AM s. 47F(1) @mxns.com> wrote:

Hi s. 22(1)(a)(ii),

s. 47G(1)(a)

It's good to know that the approval from the DAWE should be completed in the next few weeks.

When reviewing documentation, it can get very confusing when the AOAC RI certificate number is quoted and not the AOAC OMA certificate number and vice versa.

This can become a problem during audits.

See below example:

In this instance the DAWE quotes the certificate AOAC RI number for E.coli 0157:H7 and EHEC Testing, while other related documentation may quote the AOAC OMA certificate numbers.

Li

s. 47(1)(b)

In regards to the checklist for AOAC 121805, will this be updated to reflect the AOAC method and packet insert for incubation of enrichments to 42C +/- 1C rather than 41.5C +/- 1C ?

I think I may have previously confused you on this original enquiry.

AOAC 2019.03 (121805):

AOAC Official Method 2019.03
***E. coli* O157:H7 in Select Foods**
GENE-UP® *E. coli* O157:H7 2 (ECO 2) Kit
First Action 2019

[Applicable to detection of *E. coli* O157:H7 in fresh raw ground beef (73% lean; 25 and 375 g), fresh spinach (200 g), raw milk cheese (25 g), raw ground chicken (25 g), raw beef trim (25 and 375 g), raw ground pork (375 g), Romaine lettuce (375 g), raw sausage (25 g), raw milk (25 g), raw ground veal (25 and 375 g), and processed water (25 mL).]

See Table 2019.03A for a summary of results of the interlaboratory study.

D. Sample Enrichment

Allow enrichment broths to reach 15–25°C before use. In some cases, enrichment media should be prewarmed to $41.5 \pm 1^\circ\text{C}$ or $42 \pm 1^\circ\text{C}$ before adding to food samples. Frozen samples should be thawed before analysis. To decrease occurrence of stressed cells, use a quick-thawing process. (This can be performed by thawing at temperatures less than 45°C in a water bath for no more than 15 min. Agitate the sample continuously.) Use a blender bag containing filter.

(a) *Fresh raw ground beef (25 g).*—Add 225 mL BPW. Homogenize and incubate at $42 \pm 1^\circ\text{C}$ for 18–24 h.

(b) *Fresh raw ground beef short protocol (25 g).*—Add 225 mL prewarmed BPW. Homogenize and incubate at $42 \pm 1^\circ\text{C}$ for 8–14 h.

(c) *Raw ground chicken (25 g).*—Add 225 mL prewarmed BPW or modified tryptic soy broth (mTSB). Homogenize and incubate at $42 \pm 1^\circ\text{C}$ for 18–24 h.

(d) *Fresh spinach (200 g).*—Add 800 mL BPW. Homogenize and incubate at $42 \pm 1^\circ\text{C}$ for 18–24 h.

(e) *Raw beef trim (325 g).*—Add 975 mL mTSB. Homogenize and incubate at $42 \pm 1^\circ\text{C}$ for 15–24 h.

(f) *Raw beef trim, raw ground pork, and raw ground beef (375 g).*—Add 1125 mL prewarmed ($42 \pm 1^\circ\text{C}$) BPW or mTSB. Homogenize and incubate at $42 \pm 1^\circ\text{C}$ for 10–24 h. mTSB enrichment is applicable to raw ground pork.

(g) *Romaine lettuce (375 g).*—Add 1125 mL prewarmed BPW. Homogenize and incubate at $41.5 \pm 1^\circ\text{C}$ for 22–24 h.

DAWE Checklist:**GENE-UP® *E. coli* O157:H7 2 (ECO 2) – AOAC 121805****SCOPE**

This method is applicable for testing of raw ground beef and raw beef trim for *E. coli* O157:H7.

PRINCIPLES

The GENE-UP® *E. coli* O157:H7 (ECO 2) is a qualitative real-time PCR assay. 's. 47(1)(b)

s. 47(1)(b)

Detection of *E. coli* O157:H7 involves the follow steps:

s. 47(1)(b)

Biomerieux package Insert:

s. 47(1)(b)

Let me know if you need any further clarification.

Kind Regards

s. 47F(1)

Senior Technical Microbiologist



For correspondence:

Silliker Australia Pty Ltd
20 King Street Blackburn
VIC 3130 Australia

Phone: 1300 000 990

Direct: +s. 47F(1)

E-mail: s. 47F(1)@mxns.com

<https://www.linkedin.com/company/merieux-nutrisciences-australia>

If you have received this email in error, please contact us immediately at [s. 47F\(1\)@mxns.com](mailto:s.47F(1)@mxns.com) and delete the message from your system.

On Fri, Oct 1, 2021 at 8:49 AM [s. 22\(1\)\(a\)\(ii\)](#)

@awe.gov.au> wrote:

Hi [s. 47F\(1\)](#),

We should be able to finalize this method in a couple of weeks. Are you planning to implement this method?

Kind regards

[s. 22\(1\)\(a\)\(ii\)](#)

From: [s. 47F\(1\)](#) @mxns.com>
Sent: Thursday, 30 September 2021 10:17 AM
To: [s. 22\(1\)\(a\)\(ii\)](#) @awe.gov.au>
Subject: Re: Checklist Enquiry [SEC=UNOFFICIAL]

Hi [s. 22\(1\)\(a\)\(ii\)](#),

Hopefully this is the last you hear of me today.

Are able to give us some indication when the DAWE is likely to approve the confirmation steps for EHEC confirmation using GENE-UP?

s. 47(1)(b)

Kind Regards

s. 47F(1)

Senior Technical Microbiologist



For correspondence:

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<https://www.linkedin.com/company/merieux-nutrisciences-australia>

If you have received this email in error, please contact us immediately at s. 47F(1)@mxns.com and delete the message from your system.

On Thu, Sep 30, 2021 at 9:08 AM s. 47F(1) @mxns.com> wrote:

Hi s. 22(1)(a)(ii) ,

See Below:

s. 47(1)(b)

Kind Regards

s. 47F(1)

Senior Technical Microbiologist



For correspondence:

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20 King Street Blackburn
VIC 3130 Australia

Phone: 1300 000 990

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E-mail: s. 47F(1)@mxns.com

<https://www.linkedin.com/company/merieux-nutrisciences-australia>

If you have received this email in error, please contact us immediately at s. 47F(1)@mxns.com and delete the message from your system.

On Wed, Sep 29, 2021 at 4:54 PM **s. 22(1)(a)(ii)**

@awe.gov.au> wrote:

Hi **s. 47F(1)**,

That temp is for 25 g of meat, can you please check the temp for 375 g of meat.

Regards

s. 22(1)(a)(ii)

From: **s. 47F(1)** @mxns.com>
Sent: Wednesday, 29 September 2021 4:41 PM
To: **s. 22(1)(a)(ii)** @awe.gov.au>
Subject: Re: Checklist Enquiry [SEC=UNOFFICIAL]

Hi **s. 22(1)(a)(ii)**,

If you scroll down to the original email I've included the packet insert requirements which states 42C.

Let me know if you need any more information.

Kind Regards

s. 47F(1)
Senior Technical Microbiologist



For correspondence:
Silliker Australia Pty Ltd
20 King Street Blackburn
VIC 3130 Australia

Phone: 1300 000 990
Direct: +**s. 47F(1)**

E-mail: [s. 47F\(1\)@mxns.com](mailto:s.47F(1)@mxns.com)
<https://www.linkedin.com/company/merieux-nutrisciences-australia>

If you have received this email in error, please contact us immediately at [s. 47F\(1\)@mxns.com](mailto:s.47F(1)@mxns.com) and delete the message from your system.

On Wed, Sep 29, 2021 at 3:24 PM [s. 22\(1\)\(a\)\(ii\)@awe.gov.au](mailto:s.22(1)(a)(ii)@awe.gov.au) wrote:

Hi [s. 47F\(1\)](mailto:s.47F(1)@mxns.com),

As for AOAC 121805, can you please check incubation temp for 375 g raw meat. We received an insert from the supplier that states 41.5 +/- 1 deg C.

Regards

[s. 22\(1\)\(a\)\(ii\)](mailto:s.22(1)(a)(ii)@awe.gov.au)

From: [s. 47F\(1\)@mxns.com](mailto:s.47F(1)@mxns.com)
Sent: Wednesday, 29 September 2021 10:27 AM
To: [s. 22\(1\)\(a\)\(ii\)@agriculture.gov.au](mailto:s.22(1)(a)(ii)@agriculture.gov.au)
Cc: Melinda Skipper <[s. 47F\(1\)@mxns.com](mailto:s.47F(1)@mxns.com)>
Subject: Checklist Enquiry [SEC=UNOFFICIAL]

Hi [s. 22\(1\)\(a\)\(ii\)](mailto:s.22(1)(a)(ii)@awe.gov.au),

I have several questions relating to the checklists that are provided by the DAWE.

Apologies if this email should be directed to someone else in the department.

The DAWE for method AOAC 996.08 requires for all resuscitation homogenates to be incubated at $37 \pm 1^\circ\text{C}$ for 24 – 26 hrs. or 18 ± 2 hrs for export samples, while the the AOAC and packet inserts specify incubation temperatures of 35 ± 2 hours for homogenates.

The AOAC refers to AOAC 967.26 and BAM for guidance on incubation temperature.

AOAC 967.26 and BAM for all matrices specify incubation temperature of 35°C and not 37°C .

Is there a reason for the requirement of 37°C incubation rather than 35°C as specified by the AOAC?



VIDAS *Salmonella* (SLM) Assay - AOAC 996.08

SCOPE

This method is applicable to:

- Raw meats, meat products and carcass swabs.

PRINCIPLES

Detection of *Salmonella* is based on enzyme-linked fluorescent immunoassay performed in an automated VIDAS instrument. Following enrichment (see below) *Salmonella* is detected in boiled broth by specific monoclonal antibodies. A fluorescent marker is then added and *Salmonella* detected automatically by the VIDAS machine. The detection protocol can be broken down as follows:

- Pre-enrichment in non-selective liquid medium**
 Sample is diluted 1:10 in pre-warmed (room temperature or $37 \pm 1^\circ\text{C}$ for large volumes) buffered peptone water and pre-enriched at $37 \pm 1^\circ\text{C}$ for 18 ± 2 h. For carcass sponges, buffered peptone water is added to the moistened sponge to bring the total volume to 60–100 mL and the sample incubated at $37 \pm 1^\circ\text{C}$ for 18 ± 2 h. In the case of sponges BPW need not be warmed to room temperature before being used to re-hydrate the sponge, for all subsequent additions BPW should be warmed to room temperature.
- Selective Enrichment**
 Selenite cystine broth and tetrathionate broth are inoculated with pre-enrichment broth and incubated at 35 ± 1 and $42 \pm 1^\circ\text{C}$, respectively, for 18 ± 2 h.
- Post-enrichment**
 Selective enrichment broths are inoculated into M-broth and incubated for 6 h at $42 \pm 1^\circ\text{C}$.

Extract from AOAC 996.08:

E. Preparation of Test Suspension

(1) *Pre-enrichment*.—Pre-enrich test sample in nonselective medium to initiate growth of salmonellae. Pre-enrichment varies with product type and must be performed as described in [§ 47G\(1\)\(2\)](#) or as in *Bacteriological Analytical Manual*, current edition, AOAC INTERNATIONAL, Gaithersburg, MD 20877-2417, USA.

Extract from BAM:**15. Meats, meat substitutes, meat by-products, animal substances,**

glandular products, and meals (fish, meat, bone). Aseptically weigh 25 g sample into sterile blending container. Add 225 ml sterile [lactose broth](#) and blend 2 min. Aseptically transfer homogenized mixture to sterile wide-mouth, screw-cap jar (500 ml) or other appropriate container and let stand 60 ± 5 min at room temperature with jar securely capped. If mixture is powder or is ground or comminuted, blending may be omitted. For samples that do not require blending, add lactose broth and mix thoroughly; let stand for 60 ± 5 min at room temperature with jar securely capped.

Mix well by swirling and determine pH with test paper. Adjust pH, if necessary, to 6.8 ± 0.2 . Add up to 2.25 ml steamed (15 min) Tergitol Anionic 7 and mix well. Alternatively, use steamed (15 min) Triton X-100. Limit use of these surfactants to minimum quantity needed to initiate foaming. Actual quantity will depend on composition of test material. Surfactants will not be needed in analysis of powdered glandular products. Loosen jar caps $1/4$ turn and incubate sample mixtures 24 ± 2 h at 35°C . Continue as in [D. 1-14](#), below.

s. 47G(1)(a)

s. 47(1)(b)

Packet Insert:

s. 47(1)(b)

AOAC Official Method 2019.03 *E. coli* O157:H7 in Select Foods

GENE-UP® *E. coli* O157:H7 2 (ECO 2) Kit
First Action 2019

[Applicable to detection of *E. coli* O157:H7 in fresh raw ground beef (73% lean, 25 and 375 g), fresh spinach (200 g), raw milk cheese (25 g), raw ground chicken (25 g), raw beef trim (25 and 375 g), raw ground pork (375 g), Romaine lettuce (375 g), raw sausage (25 g), raw milk (25 g), raw ground veal (25 and 375 g), and processed water (25 mL).]

See Table 2019.03A for a summary of results of the interlaboratory study.

Caution: Differences of method and/or reagents may affect results.

Allow enrichment broths to reach 15–25°C before use. In some cases, enrichment media should be prewarmed to 42 ± 1°C or 45 ± 1°C before adding to food samples. Frozen samples should be thawed before analysis. To decrease occurrence of stressed cells, use a quick-thawing process. (This can be performed by thawing at temperatures less than 45°C in a water bath for no more than 15 min. Agitate the sample continuously.) Use a blender bag containing filter.

(a) *Fresh raw ground beef (25 g)*—Add 225 mL BPW. Homogenize and incubate at 42 ± 1°C for 18–24 h.

(b) *Fresh raw ground beef: short protocol (25 g)*—Add 225 mL prewarmed BPW. Homogenize and incubate at 42 ± 1°C for 8–24 h.

(c) *Raw ground chicken (25 g)*—Add 225 mL prewarmed BPW or modified tryptic soy broth (mTSB). Homogenize and incubate at

GENE-UP® *E. coli* O157:s. 47(1)(b)**SCOPE**

This method is applicable for testing of raw ground beef and raw beef trim for *E. coli* O157:H7.

PRINCIPLES

The GENE-UP® *E. coli* O157:H7 (ECO 2) is a qualitative real-time PCR assay. The GENE-UP Thermocycler detects fluorescence at several wavelengths to allow for multi-target detection in the same reaction vessel.

Detection of *E. coli* O157:H7 involves the follow steps:

s. 47(1)(b)

This causes some confusion during method audits and review of documents.
Let me know if you require any further information.

Looking forward to a response.

Kind Regards

s. 47F(1)

Senior Technical Microbiologist



For correspondence:

Silliker Australia Pty Ltd
20 King Street Blackburn
VIC 3130 Australia

Phone: 1300 000 990

Direct: +s. 47F(1)

E-mail: s. 47F(1) @mxns.com

<https://www.linkedin.com/company/merieux-nutrisciences-australia>

If you have received this email in error, please contact us immediately at s. 47F(1) @mxns.com and delete the message from your system.

----- IMPORTANT - This email and any attachments have been issued by the Australian Government Department of Agriculture, Water and the Environment. The material transmitted is for the use of the intended recipient only and may contain confidential, legally privileged, copyright or personal information. You should not copy, use or disclose it without authorisation from the Department. It is your responsibility to check any attachments for viruses and defects before opening or forwarding them. If you are not an intended recipient, please contact the sender of this email at once by return email and then delete both messages. Unintended recipients must not copy, use, disclose, rely on or publish this email or attachments. The Department of Agriculture, Water and the Environment is not liable for any loss or damage resulting from unauthorised use or dissemination of, or any reliance on, this email or attachments. If you have received this e-mail as part of a valid mailing list and no longer want to receive a message such as this one, advise the sender by return e-mail accordingly. This notice should not be deleted or altered -----

s. 22(1)(a)(ii)

From: s. 47F(1) @mxns.com>
Sent: Friday, 10 December 2021 10:36 AM
To: s. 22(1)(a)(ii)
Cc: s. 22(1)(a)(ii); s. 47F(1)
Subject: Re: Checklist Enquiry [SEC=UNOFFICIAL]

Hi s. 22(1)(a)(ii),

Apologies, another question I have regarding the Checklist for AOAC 121805 (AOAC 2019.03) GENE-UP *E. coli* O157 is around the confirmation step.

The AOAC and packet insert allow several options for confirmation.

Is there any chance that this will be updated to the Checklist. We are hoping to use the EHEC harmonised confirmation steps for *E. coli* O157

Table 2019.03B Interpretation of GENE-UP results

<i>E. coli</i> O157:H7 (540 nm)	Internal amplification control (705 nm)	Result
+	+	+
+	-	+
-	+	-
-	-	! Inhibition

G. Results and Interpretation

Results are automatically interpreted once the PCR run is completed. The routine software interprets data for each sample and gives a positive, negative, or inhibited result as indicated in Table 2019.03B.

H. PCR Inhibition Protocol

(a) In case of an inhibited result, dilute the lysate to 1:3 in the control buffer.

(b) Transfer 10 µL of control buffer in an adapted microtube.

(c) Follow the same procedure in *F. PCR Preparation*, using 10 µL of this dilution of lysate.

Note: It is recommended to retest in parallel the lysate without dilution. In case of inhibited results at 1:3, dilute the lysate to 1:10. Some matrices like aromatics herbs or cocoa powders may contain inhibitory molecules. For these matrices, 1 mL of enriched sample could be diluted 1:5 or 1:10 in TS or normal saline prior to the lysis step. If inhibition persists, proceed with an additional 1:3 dilution as described above.

I. Confirmation of Positive Results

All positive results shall be confirmed according to the BSL1, MFL1, or EEO reference methods, or following one of the following methods and GENE-UP® confirmation protocol.

Confirmation should be performed using the enrichment broth stored at 2–8°C after mixing thoroughly by hand and should be initiated within 72 h following the end of the incubation period.

(a) Isolate the enrichment broth on SMAC-CT agar and CHROMID® O157:H7 agar with CT or CHROMID® EHEC with CT.

(b) Isolate the enrichment broth on SMAC-CT agar and CHROMID® O157:H7 agar or CHROMID® EHEC after performing a magnetic immunoseparation for *E. coli* O157.

(c) Follow the enrichment steps on SMAC-CT agar and CHROMID® O157:H7 agar or CHROMID® EHEC after performing a magnetic immunoseparation.

(d) Incubate plates for 18–24 h at 37°C.

(e) Identify between one and five typical colonies using O157 and H7 latex test. The O157 latex assay can be performed from a culture colony on the selective agar.

In the event of discordant results (positive with the alternative method, not confirmed by one of the options described above), the laboratory must take the necessary steps to ensure that the results obtained are accurate. For example, isolation may be performed again using a procedure that was not followed the first time.

J. Quality Control

External quality control can be performed using one *E. coli* O157:H7 strain.

(a) Add one isolated colony from a fresh and pure culture in 9 mL BPW.

(b) Mix and incubate at 37 ± 1°C for 18–24 h.

(c) Dilute 1/100 of the culture in BPW in order to obtain a suspension containing approximately 10⁶ cells/mL of the strain.

(d) Follow the protocol from *E. Sample Lysis* to *I. Confirmation of Positive Results*.

(e) Check that the results obtained correspond to the characteristics of the tested strains.

K. Limitations of the Method

(a) The GENE-UP® ECO 2 kit has been evaluated on a large number of matrices. However, given the wide variety of products and manufacturing procedures, it is recommended to check that the composition of the matrices tested does not affect the reliability of GENE-UP® results.

Note: It is the responsibility of the user to perform quality control, taking into consideration the intended use of the medium, and in accordance with any applicable local regulations (frequency, number of strains, incubation temperature, etc.).

Reference: [J. AOAC Int. 103 \(333/2020\)](#)

DOI: 10.1093/jaoacint/qzq016 (First Action)

Posted: August 2019 (Pre-publication); January 31, 2020

(revision from author); April 2020 (First Action: online before print); October 2020 (First Action: post-publication)

GENE-UP® *E. coli* O157:H7 2 (ECO 2) – AOAC 121805**SCOPE**

This method is applicable for testing of raw ground beef and raw beef trim for *E. coli* O157:H7.

PRINCIPLES

The GENE-UP® *E. coli* O157:H7 (ECO 2) is a qualitative real-time PCR assay. s. 47(1)(b)

s. 47(1)(b)

s. 47(1)(b)

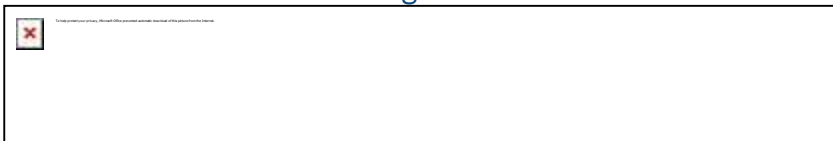
Method number AOAC 2019.03

Kind Regards





s. 47F(1)

Senior Technical Microbiologist



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Phone: 1300 000 990
Direct: +s. 47F(1)
<http://www.merieuxnutrisciences.com/au>

Follow us on:  

On Tue, Nov 23, 2021 at 12:48 PM **s. 22(1)(a)(ii)**

@awe.gov.au> wrote:

Hi **s. 47F(1)**,

Yes, we are going to update AOAC 121805 GENE-UP *E. coli* 0157 as below:

Method number AOAC 2019.03

Enrichment temp 42 +/- 1 degree C.

(f) Raw beef trim, raw ground pork, and raw ground beef (375 g).—Add 1125 mL prewarmed (42 ± 1°C) BPW or mTSB. Homogenize and incubate at 42 ± 1°C for 10–24 h. mTSB enrichment is applicable to raw ground pork.

Incubation temp for AOAC 121806 GENE-UP EHEC will remain same as below. We will also change the number of this method to AOAC 2020.06.

(e) Raw ground beef and raw beef trim (375 g).—Add 1125 mL BPW (prewarmed to 41.5°C). Homogenize for 30 s (by hand or mechanical means) and incubate at 41.5 ± 1°C for 10–24 h.

Kind regards

s. 22(1)(a)(ii)

From: **s. 47F(1)** @mxns.com>
Sent: Tuesday, 23 November 2021 10:47 AM
To: **s. 22(1)(a)(ii)** @awe.gov.au>
Cc: **s. 22(1)(a)(ii)** @awe.gov.au>; **s. 47F(1)** @mxns.com>
Subject: Re: Checklist Enquiry [SEC=UNOFFICIAL]

Hi **s. 22(1)(a)(ii)**,

Hope you're keeping well.

Are there plans to update the temperature conditions for AOAC 121805 GENE-UP *E. coli* 0157?

PRINCIPLES

The GENE-UP® *E. coli* O157:H7 (ECO 2) is a qualitative real-time PCR assay. s. 47(1)(b)

s. 47(1)(b)

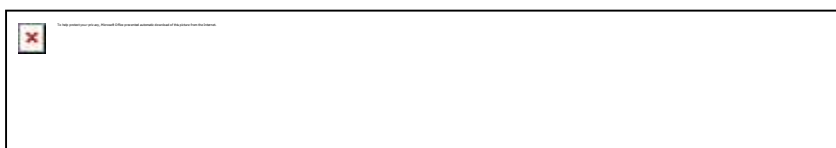
s. 47(1)(b)

Kind Regards



s. 47F(1)

Senior Technical Microbiologist





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Follow us on:  

On Wed, Oct 20, 2021 at 5:08 PM s. 22(1)(a)(ii)

@awe.gov.au> wrote:

Hi s. 47F(1),

Hope you are well. As you requested please find attached checklist of AOAC 2020.06 which we recently approved for STEC screening and confirmatory test. We are also planning to change the PTM number of O157:H7 method to OMA number (2019.03) including the temperature range if applicable.

Kind regards

s. 22(1)(a)(ii)

From: s. 47F(1) @mxns.com>
Sent: Wednesday, 20 October 2021 3:52 PM
To: s. 22(1)(a)(ii) @awe.gov.au>; s. 22(1)(a)(ii) @awe.gov.au>
Cc: Melinda Skipper <s. 47F(1) @mxns.com>
Subject: Re: Checklist Enquiry [SEC=UNOFFICIAL]

Hi s. 22(1)(a)(ii) and s. 22(1)(a)(ii),

Apologies for the urgency....is it possible to provide an updated Checklist for EHEC PTM 121806.

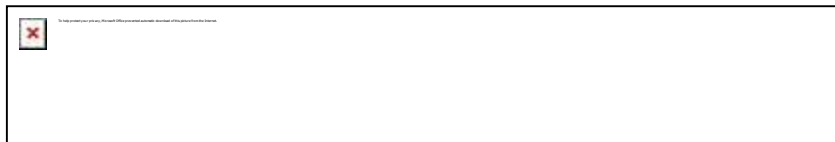
We are looking at performing verification for the procedure and submitting for NATA accreditation.

Kind Regards



s. 47F(1)

Senior Technical Microbiologist





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Follow us on:  

On Fri, Oct 1, 2021 at 9:47 AM s. 47F(1)

@mxns.com> wrote:

Hi ^{s. 22(1)(a)(ii)},

s. 47G(1)(a)

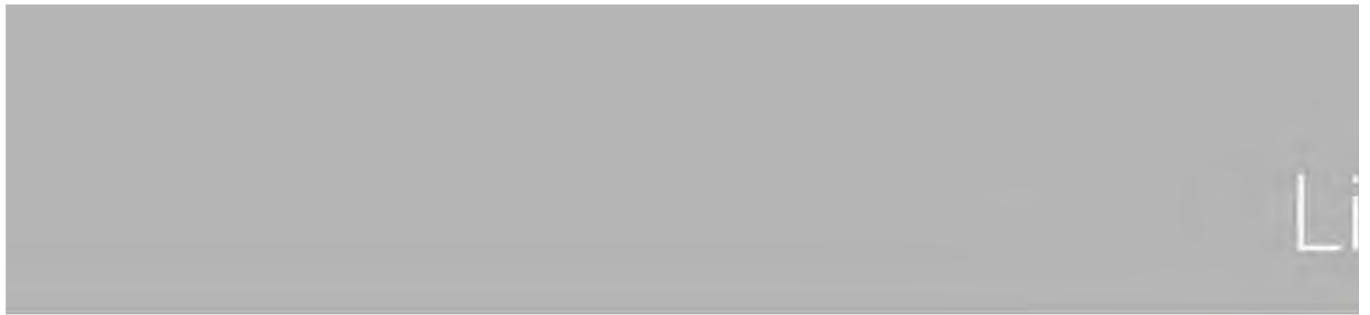
It's good to know that the approval from the DAWE should be completed in the next few weeks.

When reviewing documentation, it can get very confusing when the AOAC RI certificate number is quoted and not the AOAC OMA certificate number and vice versa.

This can become a problem during audits.

See below example:

In this instance the DAWE quotes the certificate AOAC RI number for E.coli 0157:H7 and EHEC Testing, while other related documentation may quote the AOAC OMA certificate numbers.



s. 47(1)(b)

In regards to the checklist for AOAC 121805, will this be updated to reflect the AOAC method and packet insert for incubation of enrichments to 42C +/- 1C rather than 41.5C +/- 1C ?

I think I may have previously confused you on this original enquiry.

AOAC 2019.03 (121805):

**AOAC Official Method 2019.03
E. coli O157:H7 in Select Foods
GENE-UP® *E. coli* O157:H7 2 (ECO 2) Kit
First Action 2019**

[Applicable to detection of *E. coli* O157:H7 in fresh raw ground beef (73% lean; 25 and 375 g), fresh spinach (200 g), raw milk cheese (25 g), raw ground chicken (25 g), raw beef trim (25 and 375 g), raw ground pork (375 g), Romaine lettuce (375 g), raw sausage (25 g), raw milk (25 g), raw ground veal (25 and 375 g), and processed water (25 mL).]

See Table 2019.03A for a summary of results of the interlaboratory study.

D. Sample Enrichment

Allow enrichment broths to reach 15–25°C before use. In some cases, enrichment media should be prewarmed to $41.5 \pm 1^\circ\text{C}$ or $42 \pm 1^\circ\text{C}$ before adding to food samples. Frozen samples should be thawed before analysis. To decrease occurrence of stressed cells, use a quick-thawing process. (This can be performed by thawing at temperatures less than 45°C in a water bath for no more than 15 min. Agitate the sample continuously.) Use a blender bag containing filter.

(a) *Fresh raw ground beef (25 g).*—Add 225 mL BPW. Homogenize and incubate at $42 \pm 1^\circ\text{C}$ for 18–24 h.

(b) *Fresh raw ground beef short protocol (25 g).*—Add 225 mL prewarmed BPW. Homogenize and incubate at $42 \pm 1^\circ\text{C}$ for 2–24 h.

(c) *Raw ground chicken (25 g).*—Add 225 mL prewarmed BPW or modified tryptic soy broth (mTSB). Homogenize and incubate at $42 \pm 1^\circ\text{C}$ for 18–24 h.

(d) *Fresh spinach (200 g).*—Add 800 mL BPW. Homogenize and incubate at $42 \pm 1^\circ\text{C}$ for 18–24 h.

(e) *Raw beef trim (325 g).*—Add 975 mL mTSB. Homogenize and incubate at $42 \pm 1^\circ\text{C}$ for 15–24 h.

(f) *Raw beef trim, raw ground pork, and raw ground beef (375 g).*—Add 1125 mL prewarmed ($42 \pm 1^\circ\text{C}$) BPW or mTSB. Homogenize and incubate at $42 \pm 1^\circ\text{C}$ for 10–24 h. mTSB enrichment is applicable to raw ground pork.

(g) *Romaine lettuce (375 g).*—Add 1125 mL prewarmed BPW. Homogenize and incubate at $41.5 \pm 1^\circ\text{C}$ for 22–24 h.

DAWE Checklist:

GENE-UP® *E. coli* O157:s. 47(1)(b)**SCOPE**

This method is applicable for testing of raw ground beef and raw beef trim for *E. coli* O157:H7.

PRINCIPLES

The GENE-UP® *E. coli* O157:H7 (ECO 2) is a qualitative real-time PCR assay. s. 47(1)(b)

s. 47(1)(b)

s. 47(1)(b)

Biomerieux package Insert:

s. 47(1)(b)

Let me know if you need any further clarification.

Kind Regards

s. 47F(1)

Senior Technical Microbiologist



For correspondence:

Silliker Australia Pty Ltd
20 King Street Blackburn
VIC 3130 Australia
Phone: 1300 000 990

Direct: +s. 47F(1)

E-mail: s. 47F(1) [@mxns.com](mailto:s.47F(1)@mxns.com)

<https://www.linkedin.com/company/merieux-nutrisciences-australia>

If you have received this email in error, please contact us immediately at s. 47F(1) [@mxns.com](mailto:s.47F(1)@mxns.com) and delete the message from your system.

On Fri, Oct 1, 2021 at 8:49 AM s. 22(1)(a)(ii)

@awe.gov.au> wrote:

Hi s. 47F(1),

We should be able to finalize this method in a couple of weeks. Are you planning to implement this method?

Kind regards

s. 22(1)(a)(ii)

From: s. 47F(1) [@mxns.com](mailto:s.47F(1)@mxns.com)>

Sent: Thursday, 30 September 2021 10:17 AM

To: s. 22(1)(a)(ii) @awe.gov.au>

Subject: Re: Checklist Enquiry [SEC=UNOFFICIAL]

Hi s. 22(1)(a)(ii),

Hopefully this is the last you hear of me today.

Are able to give us some indication when the DAWE is likely to approve the confirmation steps for EHEC confirmation using GENE-UP?

s. 47(1)(b)

Kind Regards

s. 47F(1)

Senior Technical Microbiologist



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*If you have received this email in error, please contact us immediately at
s. 47F(1) @mxns.com and delete the message from your system.*

On Thu, Sep 30, 2021 at 9:08 AM s. 47F(1) @mxns.com> wrote:

Hi ^{s. 22(1)(a)(ii)},

See Below:

S. 47(1)(b)

Kind Regards

s. 47F(1)

Senior Technical Microbiologist



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If you have received this email in error, please contact us immediately at s. 47F(1) [@mxns.com](mailto:s.47F(1)@mxns.com) and delete the message from your system.

On Wed, Sep 29, 2021 at 4:54 PM s. 22(1)(a)(ii)

@awe.gov.au> wrote:

Hi s. 47F(1),

That temp is for 25 g of meat, can you please check the temp for 375 g of meat.

Regards

s. 22(1)(a)(ii)

From: s. 47F(1) [@mxns.com](mailto:s.47F(1)@mxns.com)>
Sent: Wednesday, 29 September 2021 4:41 PM
To: s. 22(1)(a)(ii) @awe.gov.au>
Subject: Re: Checklist Enquiry [SEC=UNOFFICIAL]

Hi s. 22(1)(a)(ii),

If you scroll down to the original email I've included the packet insert requirements which states 42C.

Let me know if you need any more information.

Kind Regards

s. 47F(1)

Senior Technical Microbiologist



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VIC 3130 Australia
Phone: 1300 000 990

Direct: +s. 47F(1)

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If you have received this email in error, please contact us immediately at s. 47F(1) [@mxns.com](mailto:s.47F(1)@mxns.com) and delete the message from your system.

On Wed, Sep 29, 2021 at 3:24 PM s. 22(1)(a)(ii)

@awe.gov.au> wrote:

Hi s. 47F(1),

As for AOAC 121805, can you please check incubation temp for 375 g raw meat. We received an insert from the supplier that states 41.5 +/- 1 deg C.

Regards

s. 22(1)(a)(ii)

From: s. 47F(1) @mxns.com>
Sent: Wednesday, 29 September 2021 10:27 AM
To: s. 22(1)(a)(ii) @agriculture.gov.au>
Cc: Melinda Skipper <s. 47F(1) @mxns.com>
Subject: Checklist Enquiry [SEC=UNOFFICIAL]

Hi s. 22(1)(a)(ii),

I have several questions relating to the checklists that are provided by the DAWE.

Apologies if this email should be directed to someone else in the department.

The DAWE for method AOAC 996.08 requires for all resuscitation homogenates to be incubated at 37 +/-1C for 24 – 26 hrs. or 18+/- 2 hrs for export samples, while the the AOAC and packet inserts specify incubation temperatures of 35 C for 24 ± 2 hours for homogenates.

The AOAC refers to AOAC 967.26 and BAM for guidance on incubation temperature.

AOAC 967.26 and BAM for all matrices specify incubation temperature of 35C and not 37C.

Is there a reason for the requirement of 37C incubation rather than 35C as specified by the AOAC?



VIDAS *Salmonella* (SLM) Assay - AOAC 996.08

SCOPE

This method is applicable to:

- Raw meats, meat products and carcass swabs.

PRINCIPLES

Detection of *Salmonella* is based on enzyme-linked fluorescent immunoassay performed in an automated VIDAS instrument. Following enrichment (see below) *Salmonella* is detected in boiled broth by specific monoclonal antibodies. A fluorescent marker is then added and *Salmonella* detected automatically by the VIDAS machine. The detection protocol can be broken down as follows:

- **Pre-enrichment in non-selective liquid medium**
Sample is diluted 1:10 in pre-warmed (room temperature or $37 \pm 1^\circ\text{C}$ for large volumes) buffered peptone water and pre-enriched at $37 \pm 1^\circ\text{C}$ for 18 ± 2 h. For carcass sponges, buffered peptone water is added to the measured sponge to bring the total volume to 60–100 mL and the sample incubated at $37 \pm 1^\circ\text{C}$ for 18 ± 2 h. In the case of sponges BPW need not be warmed to room temperature before being used to rehydrate the sponge, for all subsequent additions BPW should be warmed to room temperature.
- **Selective Enrichment**
Selenite cystine broth and tetrathionate broth are inoculated with pre-enrichment broth and incubated at 35 ± 1 and $42 \pm 1^\circ\text{C}$, respectively, for 18 ± 2 h.
- **Post-enrichment**
Selective enrichment broths are inoculated into M-broth and incubated for 6 h at $42 \pm 1^\circ\text{C}$.

Extract from AOAC 996.08:

E. Preparation of Test Suspension

(1) *Pre-enrichment*.—Pre-enrich test sample in nonselective medium to initiate growth of salmonellae. Pre-enrichment varies with product type and must be performed as described in *96.161* or (72.02) or in *Bacteriological Analytical Manual*, copyrighted from AOAC INTERNATIONAL, Gaithersburg, MD 20877-2417, USA.

Extract from BAM:

15. Meats, meat substitutes, meat by-products, animal substances,

glandular products, and meals (fish, meat, bone). Aseptically weigh 25 g sample into sterile blending container. Add 225 ml sterile **lactose broth** and blend 2 min. Aseptically transfer homogenized mixture to sterile wide-mouth, screw-cap jar (500 ml) or other appropriate container and let stand 60 ± 5 min at room temperature with jar securely capped. If mixture is powder or is ground or comminuted, blending may be omitted. For samples that do not require blending, add lactose broth and mix thoroughly; let stand for 60 ± 5 min at room temperature with jar securely capped.

Mix well by swirling and determine pH with test paper. Adjust pH, if necessary, to 6.8 ± 0.2 . Add up to 2.25 ml steamed (15 min) Tergitol Anionic 7 and mix well. Alternatively, use steamed (15 min) Triton X-100. Limit use of these surfactants to minimum quantity needed to initiate foaming. Actual quantity will depend on composition of test material. Surfactants will not be needed in analysis of powdered glandular products. Loosen jar caps $1/4$ turn and incubate sample mixtures 24 ± 2 h at 35°C . Continue as in **D. 1-14**, below.

s. 47G(1)(a)

s. 47(1)(b)

Packet Insert:

S. 47(1)(b)

AOAC Official Method 2019.03
***E. coli* O157:H7 in Select Foods**
GENE-UP® *E. coli* O157:H7 2 (ECO 2) Kit
First Action 2019

[Applicable to detection of *E. coli* O157:H7 in fresh raw ground beef (73% lean, 25 and 375 g), fresh spinach (200 g), raw milk cheese (25 g), raw ground chicken (25 g), raw beef trim (25 and 375 g), raw ground pork (375 g), Romaine lettuce (375 g), raw sausage (25 g), raw milk (25 g), raw ground veal (25 and 375 g) and processed water (25 mL).]

See Table 2019.03A for a summary of results of the interlaboratory study.

Caution: Minimize spread of infected fragments to small scale activities.

Allow enrichment broths to reach 15–25°C before use. In some cases, enrichment media should be prewarmed to 42 ± 1°C or 45 ± 1°C before adding or food samples. Frozen samples should be thawed before analysis. To decrease occurrence of stressed cells, use a quick-thawing process. (This can be performed by thawing at temperatures less than 45°C in a water bath for no more than 15 min. Agitate the sample continuously.) Use a blender bag containing filter.

(a) *Fresh raw ground beef* (25 g).—Add 225 mL BPW. Homogenize and incubate at 42 ± 1°C for 18–24 h.

(b) *Fresh raw ground beef: short protocol* (25 g).—Add 225 mL prewarmed BPW. Homogenize and incubate at 42 ± 1°C for 8–24 h.

(c) *Raw ground chicken* (25 g).—Add 225 mL prewarmed BPW in modified tryptic soy broth (mTSB). Homogenize and incubate at

GENE-UP® *E. coli* O157:s. 47(1)(b)

SCOPE

This method is applicable for testing of raw ground beef and raw beef trim for *E. coli* O157:H7.

PRINCIPLES

The GENE-UP® *E. coli* O157:H7 (ECO 2) is a qualitative real-time PCR assay. s. 47(1)(b)

s. 47(1)(b)

Detection of *E. coli* O157:H7 involves the follow steps:

s. 47(1)(b)

This causes some confusion during method audits and review of documents.

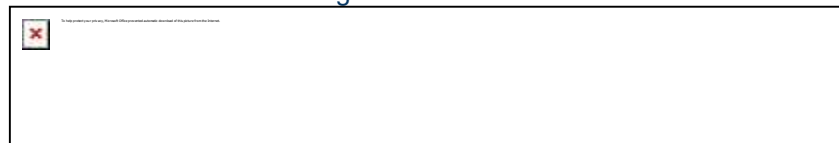
Let me know if you require any further information.

Looking forward to a response.

Kind Regards

s. 47F(1)

Senior Technical Microbiologist



For correspondence:

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 20 King Street Blackburn
 VIC 3130 Australia

Phone: 1300 000 990

Direct: +s. 47F(1)

E-mail: s. 47F(1) [@mxns.com](mailto:s.47F(1)@mxns.com)

<https://www.linkedin.com/company/merieux-nutrisciences-australia>

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s. 22(1)(a)(ii)

From: s. 22(1)(a)(ii) @awe.gov.au>
Sent: Friday, 10 December 2021 10:58 AM
To: s. 47F(1)
Cc: s. 22(1)(a)(ii)
Subject: RE: Checklist Enquiry [SEC=UNOFFICIAL]

Hi s. 47F(1),

We have updated AOAC 2019.03. A lab can now use any confirmatory methods (approved by DAWE) including GeneUp EHEC Detection Method – AOAC 2020.06 to confirm *E. coli* O157 or other STEC. The checklists will be published in a couple of weeks.

Kind regards

s. 22(1)(a)(ii)

From: s. 47F(1)
Sent: Friday, 10 December 2021 10:36 AM
To: s. 22(1)(a)(ii)
Cc: s. 22(1)(a)(ii) ; s. 47F(1)
Subject: Re: Checklist Enquiry [SEC=UNOFFICIAL]

Hi s. 22(1)(a)(ii),

Apologies, another question I have regarding the Checklist for AOAC 121805 (AOAC 2019.03) GENE-UP *E. coli* O157 is around the confirmation step.

The AOAC and packet insert allow several options for confirmation.

Is there any chance that this will be updated to the Checklist. We are hoping to use the EHEC harmonised confirmation steps for *E.coli* O157

Table 2019.03B Interpretation of GENE-UP results

<i>E. coli</i> O157:H7 (540 nm)	Internal amplification control (705 nm)	Result
+	+	+
+	–	+
–	+	–
–	–	! Inhibition

G. Results and Interpretation

Results are automatically interpreted once the PCR run is completed. The routine software interprets data for each sample and gives a positive, negative, or inhibited result as indicated in Table 2019.03B.

H. PCR Inhibition Protocol

(a) In case of an inhibited result, dilute the lysate to 1:3 in the control buffer.

(b) Transfer 10 µL of control buffer in an adapted microtube.

(c) Follow the same procedure in *E. PCR Preparation*, using 10 µL of this dilution of lysate.

Note: It is recommended to retest in parallel the lysate without dilution. In case of inhibited results at 1:3, dilute the lysate to 1:10. Some matrices like aromatics herbs or cocoa powders may contain inhibitory molecules. For these matrices, 1 mL of enriched sample could be diluted 1:5 or 1:10 in TS or normal saline prior to the lysis step. If inhibition persists, proceed with an additional 1:3 dilution as described above.

I. Confirmation of Positive Results

All positive results should be confirmed according to the B331 (MLA) or B30 reference methods, or following or the following methods and GENE-UP® confirmation protocol.

Confirmation should be performed using the enrichment broth stored at 2–8°C after mixing thoroughly by hand and should be initiated within 72 h following the end of the incubation period.

(a) Isolate the enrichment broth on SMAC-CT agar and CHROMID® O157:H7 agar with CT or CHROMID® EHBC with CT.

(b) Isolate the enrichment broth on SMAC-CT agar and CHROMID® O157:H7 agar or CHROMID® EHBC after performing a magnetic immunoseparation for *E. coli* O157.

(c) Culture the isolates on SMAC-CT agar and CHROMID® O157:H7 agar or CHROMID® EHBC with CT or CHROMID® EHBC with CT.

(d) Incubate plates for 18–24 h at 37°C.

(e) Identify between one and five typical colonies using O157:H7 latex test. The O157 latex test can be performed from a culture colony on the selective agar.

In the event of discordant results (positive with the alternative method, not confirmed by one of the options described above), the laboratory must take the necessary steps to ensure that the results obtained are accurate. For example, isolation may be performed again using a procedure that was not followed the first time.

J. Quality Control

External quality control can be performed using one *E. coli* O157:H7 strain.

(a) Add one isolated colony from a fresh and pure culture in 9 mL BPW.

(b) Mix and incubate at 37 ± 1°C for 18–24 h.

(c) Dilute 1:100 of the culture in BPW in order to obtain a suspension containing approximately 10⁶ cells/mL of the strain.

(d) Follow the protocol from *E. Sample Lysis* to *I. Confirmation of Positive Results*.

(e) Check that the results obtained correspond to the characteristics of the tested strains.

K. Limitations of the Method

(a) The GENE-UP® ECO 2 kit has been evaluated on a large number of matrices. However, given the wide variety of products and manufacturing procedures, it is recommended to check that the composition of the matrices tested does not affect the reliability of GENE-UP® results.

Note: It is the responsibility of the user to perform quality control, taking into consideration the intended use of the medium, and in accordance with any applicable local regulations (frequency, number of strains, incubation temperature, etc.).

Reference: [JAOAC Int. 10A 1338\(2020\)](#)

DOI: 10.1093/jaoacint/qz016 (First Action)

Posted: August 2019 (Pre-publication); January 31, 2020

(revision from author); April 2020 (First Action, online before print); October 2020 (First Action, post-publication)

GENE-UP® *E. coli* O157:H7 2 (ECO 2) – AOAC 121805**SCOPE**

This method is applicable for testing of raw ground beef and raw beef trim for *E. coli* O157:H7.

PRINCIPLES

The GENE-UP® *E. coli* O157:H7 (ECO 2) is a qualitative real-time PCR assay. 's. 47(1)(b)

s. 47(1)(b)

Detection of *E. coli* O157:H7 involves the follow steps:

s. 47(1)(b)

Method number AOAC 2019.03

Kind Regards



s. 47F(1)

Senior Technical Microbiologist





Mérieux NutriSciences

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<http://www.merieuxnutrisciences.com/au>

Follow us on:  

On Tue, Nov 23, 2021 at 12:48 PM s. 22(1)(a)(ii)

@awe.gov.au> wrote:

Hi s. 47F(1),

Yes, we are going to update AOAC 121805 GENE-UP E. coli 0157 as below:

Method number AOAC 2019.03

Enrichment temp 42 +/- 1 degree C.

(f) Raw beef trim, raw ground pork, and raw ground beef (375 g).—Add 1125 mL prewarmed (42 ± 1°C) BPW or mTSB. Homogenize and incubate at 42 ± 1°C for 10–24 h. mTSB enrichment is applicable to raw ground pork.

Incubation temp for AOAC 121806 GENE-UP EHEC will remain same as below. We will also change the number of this method to AOAC 2020.06.

(e) Raw ground beef and raw beef trim (375 g).—Add 1125 mL BPW (prewarmed to 41.5°C). Homogenize for 30 s (by hand or mechanical means) and incubate at 41.5 ± 1°C for 10–24 h.

Kind regards

s. 22(1)(a)(ii)

From: s. 47F(1) @mxns.com>

Sent: Tuesday, 23 November 2021 10:47 AM

To: s. 22(1)(a)(ii) @awe.gov.au>

Cc: s. 22(1)(a)(ii) @awe.gov.au; s. 47F(1) @mxns.com>

Subject: Re: Checklist Enquiry [SEC=UNOFFICIAL]

Hi ^{s. 22(1)(a)(ii)},

Hope you're keeping well.

Are there plans to update the temperature conditions for AOAC 121805 GENE-UP *E.coli* 0157?

PRINCIPLES

The GENE-UP® *E. coli* O157:H7 (ECO 2) is a qualitative real-time PCR assay. ^{s. 47(1)(b)}
s. 47(1)(b)

Detection of *E. coli* O157:H7 involves the follow steps:

s. 47(1)(b)

Kind Regards



s. 47F(1)

Senior Technical Microbiologist





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<http://www.merieuxnutrisciences.com/au>

Follow us on:  

On Wed, Oct 20, 2021 at 5:08 PM s. 22(1)(a)(ii)

@awe.gov.au wrote:

Hi s. 47F(1),

Hope you are well. As you requested please find attached checklist of AOAC 2020.06 which we recently approved for STEC screening and confirmatory test. We are also planning to change the PTM number of O157:H7 method to OMA number (2019.03) including the temperature range if applicable.

Kind regards

s. 22(1)(a)(ii)

From: s. 47F(1) @mxns.com

Sent: Wednesday, 20 October 2021 3:52 PM

To: s. 22(1)(a)(ii) @awe.gov.au; s. 22(1)(a)(ii)

@awe.gov.au

Cc: Melinda Skipper <s. 47F(1) @mxns.com>

Subject: Re: Checklist Enquiry [SEC=UNOFFICIAL]

Hi s. 22(1)(a)(ii) and s. 22(1)(a)(ii),

Apologies for the urgency....is it possible to provide an updated Checklist for EHEC PTM 121806.

We are looking at performing verification for the procedure and submitting for NATA accreditation.

Kind Regards



s. 47F(1)

Senior Technical Microbiologist





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Direct: +s. 47F(1)

<http://www.merieuxnutrisciences.com/au>

Follow us on:  

On Fri, Oct 1, 2021 at 9:47 AM s. 47F(1) @mxns.com> wrote:

Hi ^{s. 22(1)(a)(ii)},

s. 47G(1)(a)

It's good to know that the approval from the DAWE should be completed in the next few weeks.

When reviewing documentation, it can get very confusing when the AOAC RI certificate number is quoted and not the AOAC OMA certificate number and vice versa.

This can become a problem during audits.

See below example:

In this instance the DAWE quotes the certificate AOAC RI number for E.coli 0157:H7 and EHEC Testing, while other related documentation may quote the AOAC OMA certificate numbers.



s. 47(1)(b)

In regards to the checklist for AOAC 121805, will this be updated to reflect the AOAC method and packet insert for incubation of enrichments to 42C +/- 1C rather than 41.5C +/- 1C ?

I think I may have previously confused you on this original enquiry.

AOAC Official Method 2019.03
***E. coli* O157:H7 in Select Foods**
GENE-UP® *E. coli* O157:H7 2 (ECO 2) Kit
First Action 2019

[Applicable to detection of *E. coli* O157:H7 in fresh raw ground beef (73% lean; 25 and 375 g), fresh spinach (200 g), raw milk cheese (25 g), raw ground chicken (25 g), raw beef trim (25 and 375 g), raw ground pork (375 g), Romaine lettuce (375 g), raw sausage (25 g), raw milk (25 g), raw ground veal (25 and 375 g), and processed water (25 mL).]

See Table 2019.03A for a summary of results of the interlaboratory study.

D. Sample Enrichment

Allow enrichment broths to reach 15–25°C before use. In some cases, enrichment media should be prewarmed to $41.5 \pm 1^\circ\text{C}$ or $42 \pm 1^\circ\text{C}$ before adding to food samples. Frozen samples should be thawed before analysis. To decrease occurrence of stressed cells, use a quick-thawing process. (This can be performed by thawing at temperatures less than 45°C in a water bath for no more than 15 min. Agitate the sample continuously.) Use a blender bag containing filter.

(a) *Fresh raw ground beef (25 g).*—Add 225 mL BPW. Homogenize and incubate at $42 \pm 1^\circ\text{C}$ for 18–24 h.

(b) *Fresh raw ground beef short protocol (25 g).*—Add 225 mL prewarmed BPW. Homogenize and incubate at $42 \pm 1^\circ\text{C}$ for 2–24 h.

(c) *Raw ground chicken (25 g).*—Add 225 mL prewarmed BPW or modified tryptic soy broth (mTSB). Homogenize and incubate at $42 \pm 1^\circ\text{C}$ for 18–24 h.

(d) *Fresh spinach (200 g).*—Add 800 mL BPW. Homogenize and incubate at $42 \pm 1^\circ\text{C}$ for 18–24 h.

(e) *Raw beef trim (325 g).*—Add 975 mL mTSB. Homogenize and incubate at $42 \pm 1^\circ\text{C}$ for 15–24 h.

(f) *Raw beef trim, raw ground pork, and raw ground beef (375 g).*—Add 1125 mL prewarmed ($42 \pm 1^\circ\text{C}$) BPW or mTSB. Homogenize and incubate at $42 \pm 1^\circ\text{C}$ for 10–24 h. mTSB enrichment is applicable to raw ground pork.

(g) *Romaine lettuce (375 g).*—Add 1125 mL prewarmed BPW. Homogenize and incubate at $41.5 \pm 1^\circ\text{C}$ for 22–24 h.

DAWE Checklist:

GENE-UP® *E. coli* O157: s. 47(1)(b)

SCOPE

This method is applicable for testing of raw ground beef and raw beef trim for *E. coli* O157:H7.

PRINCIPLES

The GENE-UP® *E. coli* O157:H7 (ECO 2) is a qualitative real-time PCR assay. s. 47(1)(b)

s. 47(1)(b)

Detection of *E. coli* O157:H7 involves the follow steps:

s. 47(1)(b)

Biomerieux package Insert:

s. 47(1)(b)

Let me know if you need any further clarification.

Kind Regards

s. 47F(1)

Senior Technical Microbiologist



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VIC 3130 Australia

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<https://www.linkedin.com/company/merieux-nutrisciences-australia>

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On Fri, Oct 1, 2021 at 8:49 AM [s. 22\(1\)\(a\)\(ii\)](#) <@awe.gov.au> wrote:

Hi [s. 47F\(1\)](#),

We should be able to finalize this method in a couple of weeks. Are you planning to implement this method?

Kind regards

[s. 22\(1\)\(a\)\(ii\)](#)

From: [s. 47F\(1\)](#) <@mxns.com>
Sent: Thursday, 30 September 2021 10:17 AM
To: [s. 22\(1\)\(a\)\(ii\)](#) <@awe.gov.au>
Subject: Re: Checklist Enquiry [SEC=UNOFFICIAL]

Hi [s. 22\(1\)\(a\)\(ii\)](#),

Hopefully this is the last you hear of me today.

Are able to give us some indication when the DAWE is likely to approve the confirmation steps for EHEC confirmation using GENE-UP?

S. 47(1)(b)

Kind Regards

s. 47F(1)

Senior Technical Microbiologist



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<https://www.linkedin.com/company/merieux-nutrisciences-australia>

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On Thu, Sep 30, 2021 at 9:08 AM s. 47F(1) @mxns.com> wrote:

Hi s. 22(1)(a)(iii) ,

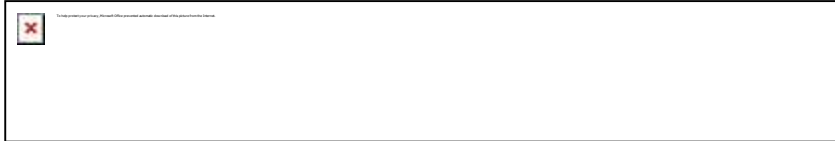
See Below:

s. 47(1)(b)

Kind Regards

s. 47F(1)

Senior Technical Microbiologist



For correspondence:

Silliker Australia Pty Ltd
20 King Street Blackburn
VIC 3130 Australia

Phone: 1300 000 990

Direct: +s. 47F(1)

E-mail: s. 47F(1) @mxns.com

<https://www.linkedin.com/company/merieux-nutrisciences-australia>

If you have received this email in error, please contact us immediately at s. 47F(1) @mxns.com and delete the message from your system.

On Wed, Sep 29, 2021 at 4:54 PM **s. 22(1)(a)(ii)**

@awe.gov.au> wrote:

Hi **s. 47F(1)**,

That temp is for 25 g of meat, can you please check the temp for 375 g of meat.

Regards

s. 22(1)(a)(ii)

From: **s. 47F(1)** @mxns.com>
Sent: Wednesday, 29 September 2021 4:41 PM
To: **s. 22(1)(a)(ii)** @awe.gov.au>
Subject: Re: Checklist Enquiry [SEC=UNOFFICIAL]

Hi **s. 22(1)(a)(ii)**,

If you scroll down to the original email I've included the packet insert requirements which states 42C.

Let me know if you need any more information.

Kind Regards

s. 47F(1)
Senior Technical Microbiologist



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On Wed, Sep 29, 2021 at 3:24 PM [s. 22\(1\)\(a\)\(ii\)](mailto:s.22(1)(a)(ii)@awe.gov.au)

@awe.gov.au> wrote:

Hi [s. 47F\(1\)](mailto:s.47F(1)@mxns.com),

As for AOAC 121805, can you please check incubation temp for 375 g raw meat. We received an insert from the supplier that states 41.5 +/- 1 deg C.

Regards

[s. 22\(1\)\(a\)\(ii\)](mailto:s.22(1)(a)(ii)@awe.gov.au)

From: [s. 47F\(1\) @mxns.com](mailto:s.47F(1)@mxns.com)>
Sent: Wednesday, 29 September 2021 10:27 AM
To: [s. 22\(1\)\(a\)\(ii\) @agriculture.gov.au](mailto:s.22(1)(a)(ii)@agriculture.gov.au)>
Cc: Melinda Skipper <[s. 47F\(1\) @mxns.com](mailto:s.47F(1)@mxns.com)>
Subject: Checklist Enquiry [SEC=UNOFFICIAL]

Hi [s. 22\(1\)\(a\)\(ii\)](mailto:s.22(1)(a)(ii)@awe.gov.au),

I have several questions relating to the checklists that are provided by the DAWE.

Apologies if this email should be directed to someone else in the department.

The DAWE for method AOAC 996.08 requires for all resuscitation homogenates to be incubated at $37 \pm 1^\circ\text{C}$ for 24 – 26 hrs. or 18 ± 2 hrs for export samples, while the the AOAC and packet inserts specify incubation temperatures of 35 ± 2 hours for homogenates.

The AOAC refers to AOAC 967.26 and BAM for guidance on incubation temperature.

AOAC 967.26 and BAM for all matrices specify incubation temperature of 35°C and not 37°C .

Is there a reason for the requirement of 37°C incubation rather than 35°C as specified by the AOAC?



VIDAS *Salmonella* (SLM) Assay - AOAC 996.08

SCOPE

This method is applicable to:

- Raw meats, meat products and carcass swabs.

PRINCIPLES

Detection of *Salmonella* is based on enzyme-linked fluorescent immunoassay performed in an automated VIDAS instrument. Following enrichment (see below) *Salmonella* is detected in boiled broth by specific monoclonal antibodies. A fluorescent marker is then added and *Salmonella* detected automatically by the VIDAS machine. The detection protocol can be broken down as follows:

- Pre-enrichment in non-selective liquid medium**
 Sample is diluted 1:10 in pre-warmed (room temperature or $37 \pm 1^\circ\text{C}$ for large volumes) buffered peptone water and pre-enriched at $37 \pm 1^\circ\text{C}$ for 18 ± 2 h. For carcass sponges, buffered peptone water is added to the moistened sponge to bring the total volume to 60–100 mL and the sample incubated at $37 \pm 1^\circ\text{C}$ for 18 ± 2 h. In the case of sponges BPW need not be warmed to room temperature before being used to re-hydrate the sponge, for all subsequent additions BPW should be warmed to room temperature.
- Selective Enrichment**
 Selenite cystine broth and tetrathionate broth are inoculated with pre-enrichment broth and incubated at 35 ± 1 and $42 \pm 1^\circ\text{C}$, respectively, for 18 ± 2 h.
- Post-enrichment**
 Selective enrichment broths are inoculated into M-broth and incubated for 6 h at $42 \pm 1^\circ\text{C}$.

Extract from AOAC 996.08:

E. Preparation of Test Suspension

(1) *Pre-enrichment*.—Pre-enrich test sample in nonselective medium to initiate growth of salmonellae. Pre-enrichment varies with media type and must be performed as described in 95.16.01 (72M12) or in *Bacteriological Analytical Manual*, copyrighted by AOAC INTERNATIONAL, Gaithersburg, MD 20877-2417, USA.

Extract from BAM:**15. Meats, meat substitutes, meat by-products, animal substances,**

glandular products, and meals (fish, meat, bone). Aseptically weigh 25 g sample into sterile blending container. Add 225 ml sterile **lactose broth** and blend 2 min. Aseptically transfer homogenized mixture to sterile wide-mouth, screw-cap jar (500 ml) or other appropriate container and let stand 60 ± 5 min at room temperature with jar securely capped. If mixture is powder or is ground or comminuted, blending may be omitted. For samples that do not require blending, add lactose broth and mix thoroughly; let stand for 60 ± 5 min at room temperature with jar securely capped.

Mix well by swirling and determine pH with test paper. Adjust pH, if necessary, to 6.8 ± 0.2 . Add up to 2.25 ml steamed (15 min) Tergitol Anionic 7 and mix well. Alternatively, use steamed (15 min) Triton X-100. Limit use of these surfactants to minimum quantity needed to initiate foaming. Actual quantity will depend on composition of test material. Surfactants will not be needed in analysis of powdered glandular products. Loosen jar caps 1/4 turn and incubate sample mixtures 24 ± 2 h at 35°C . Continue as in D. 1-14, below.

s. 47G(1)(a)

s. 47(1)(b)

Packet Insert:

S. 47(1)(b)

AOAC Official Method 2019.03 *E. coli* O157:H7 in Select Foods

GENE-UP® *E. coli* O157:H7 2 (ECO 2) Kit
First Action 2019

[Applicable to detection of *E. coli* O157:H7 in fresh raw ground beef (73% lean, 25 and 375 g), fresh spinach (200 g), raw milk cheese (25 g), raw ground chicken (25 g), raw beef trim (25 and 375 g), raw ground pork (375 g), Romaine lettuce (375 g), raw sausage (25 g), raw milk (25 g), raw ground veal (25 and 375 g), and processed water (25 mL).]

See Table 2019.03A for a summary of results of the interlaboratory study.

Caution: Do not use if used on untested reagents or media as antibodies

Allow enrichment broths to reach 15–25°C before use. In some cases, enrichment media should be prewarmed to 41.5 ± 1°C or 42 ± 1°C before adding to food samples. Frozen samples should be thawed before analysis. To decrease occurrence of stressed cells, use a quick-thawing process. (This can be performed by thawing at temperatures less than 45°C in a water bath for no more than 15 min. Agitate the sample continuously.) Use a blender bag containing filter.

(a) *Fresh raw ground beef (25 g)*—Add 225 mL BPW. Homogenize and incubate at 42 ± 1°C for 18–24 h.

(b) *Fresh raw ground beef: short protocol (25 g)*—Add 225 mL prewarmed BPW. Homogenize and incubate at 42 ± 1°C for 8–24 h.

(c) *Raw ground chicken (25 g)*—Add 225 mL prewarmed BPW or modified tryptic soy broth (mTSB). Homogenize and incubate at

GENE-UP® *E. coli* O157:s. 47(1)(b)

SCOPE

This method is applicable for testing of raw ground beef and raw beef trim for *E. coli* O157:H7.

PRINCIPLES

The GENE-UP® *E. coli* O157:H7 (ECO 2) is a qualitative real-time PCR assay. s. 47(1)(b)

s. 47(1)(b)

Detection of *E. coli* O157:H7 involves the follow steps:

s. 47(1)(b)

This causes some confusion during method audits and review of documents.
Let me know if you require any further information.

Looking forward to a response.

Kind Regards

s. 47F(1)

Senior Technical Microbiologist



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s. 22(1)(a)(ii)

From: s. 47F(1) @mxns.com>
Sent: Tuesday, 6 September 2022 11:54 AM
To: s. 22(1)(a)(ii)
Subject: Re: Introduction and advice [SEC=UNOFFICIAL]
Attachments: MLA Gene UP trial July 2022.pdf; 26082022081457-0001.pdf; Deed of Confidentiality - Signed by the Department (3).docx

Hello s. 22(1)(a)(ii),

Thank you very much for your support.

Please find attached signed copy of the Deed word document and PDF version.

I have also attached the copy of the experimental design/protocol.

I look forward to your feedback,



s. 47F(1)

s. 47F(1)



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<http://www.merieuxnutrisciences.com/au>
Follow us on:  

On Tue, Aug 23, 2022 at 3:49 PM s. 22(1)(a)(ii) @awe.gov.au> wrote:

Hi s. 47F(1),

As Australian Public Service (APS) employees we are subject to a range of Commonwealth laws that impose very strict confidentiality obligations (summarised below).

Summary of relevant Commonwealth laws

- Regulation 2.1(4) of the Public Service Regulations 1999 which provides that APS employees must not disclose information obtained or generated 'in connection' with their work that may harm the government, was communicated in confidence within the government or was received by the government from someone outside the government. Regulation 2.1(4) is part of the APS Code of Conduct. A wide range of sanctions can be imposed on a person determined to have breached the APS Code of Conduct - including termination of employment (section 15(1) of the Public Service Act 1999 (PSA)).
- Section 28 of the Public Governance, Performance and Accountability Act 2013 provides that a person who obtains information because they are an official of a Commonwealth entity must not improperly use the information to gain or seek to gain a benefit or an advantage for themselves or someone else or to cause or seek to cause detriment to the Commonwealth entity or someone else.
- Section 122.4(1) of the Criminal Code Act 1995 makes it an offence for a person to communicate information, if the person obtained the information by virtue of being a Commonwealth officer or was otherwise engaged to perform work for a Commonwealth entity and that person was under a duty, under a Commonwealth law, not to disclose the information. This offence is punishable by 2 years imprisonment.

We trust this gives you confidence that the department will keep the Project Protocol confidential. If however this is not satisfactory to MXNS, please let us know as the department would be open to signing the department's standard deed of confidentiality (copy attached for information).

Regards,

s. 22(1)(a)(ii)

From: s. 47F(1) @mxns.com>
Sent: Tuesday, 23 August 2022 1:06 PM
To: s. 22(1)(a)(ii) @awe.gov.au>
Subject: Re: Introduction and advice [SEC=UNOFFICIAL]

Hi s. 22(1)(a)(ii),

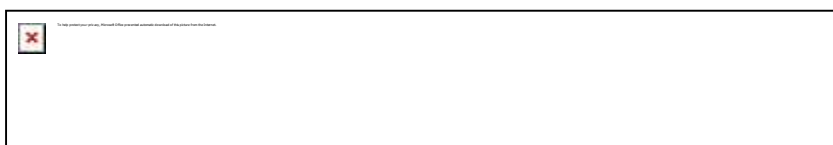
It's a new technology adoption case study project with the MLA.

The project will be funded through the individual processing sites - Plant Initiated Project (PIP).



s. 47F(1)

s. 47F(1)



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<http://www.merieuxnutrisciences.com/au>

Follow us on:  

On Tue, Aug 23, 2022 at 11:37 AM s. 22(1)(a)(ii) @awe.gov.au> wrote:

Hi s. 47F(1),

Our lawyers are in the process of providing me with some advice but have asked a clarifying question. Can you please remind me – I think you said your project is being funded by AMPC. Is that correct? Is that the connection between MXNS and AMPC for your project?

Regards,

s. 22(1)(a)(ii)

From: s. 47F(1) @mxns.com>
Sent: Thursday, 18 August 2022 9:20 AM
To: s. 22(1)(a)(ii) @awe.gov.au>
Subject: Re: Introduction and advice [SEC=UNOFFICIAL]

Hi s. 22(1)(a)(ii),

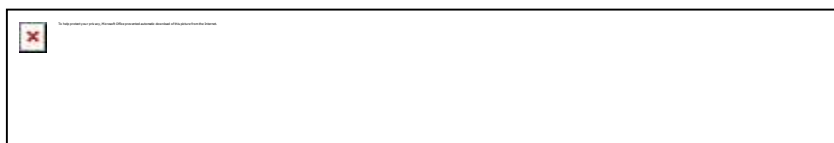
This is greatly appreciated under the circumstances as I'm asking for your help and advice on a subject matter. But requesting an NDA to be signed first.

However this has been the recommendation from my legal team that I must follow.



s. 47F(1)

s. 47F(1)



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On Thu, Aug 18, 2022 at 9:02 AM s. 22(1)(a)(ii) @awe.gov.au> wrote:

Thanks s. 47F(1). All going well here. I'll run this past our legal area and will then send back to you ASAP.

Kind regards,

s. 22(1)(a)(ii)

From: s. 47F(1) @mxns.com>
Sent: Wednesday, 17 August 2022 3:00 PM
To: s. 22(1)(a)(ii) @awe.gov.au>
Subject: Re: Introduction and advice [SEC=UNOFFICIAL]

Hi s. 22(1)(a)(ii),

How have you been?

Appologies for the slow response as I have been in contact with legal back and forth.

I really appreciate your support and advice on this matter of the project with MLA.

The advice from my legal team is that MXNS will require the department to sign the attached NDA before I share the protocol with you.

Let me know if you have any further questions?



s. 47F(1)

s. 47F(1)



Mérieux NutriSciences

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On Tue, Jul 26, 2022 at 4:16 PM s. 22(1)(a)(ii) @awe.gov.au wrote:

Sounds good s. 47F(1) – talk then.

Regards,

s. 22(1)(a)(ii)

From: s. 47F(1) [@mxns.com](mailto:s.47F(1)@mxns.com)>
Sent: Tuesday, 26 July 2022 4:07 PM
To: s. 22(1)(a)(ii) @awe.gov.au>
Subject: Re: Introduction and advice [SEC=UNOFFICIAL]

Apologies s. 22(1)(a)(ii),

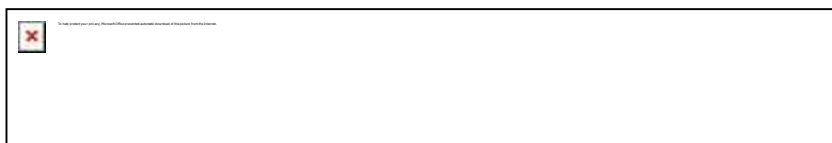
I meant I'll call you tomorrow between 4 & 5.

Ill send you a meeting invite as a reminder.



s. 47F(1)

s. 47F(1)



Mérieux NutriSciences

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On Tue, Jul 26, 2022 at 4:06 PM s. 47F(1) [@mxns.com](mailto:s.47F(1)@mxns.com) wrote:

Thanks s. 22(1)(a)(ii),

I'll call you now.



s. 47F(1)

s. 47F(1)



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On Tue, Jul 26, 2022 at 4:05 PM s. 22(1)(a)(ii) [@awe.gov.au](mailto:s.22(1)(a)(ii)@awe.gov.au) wrote:

Hi s. 47F(1),

I have some time tomorrow between 4 and 5. Would that work for you? Happy to discuss.

Regards,

s. 22(1)(a)(ii)

s. 22(1)(a)(ii)

Principal – Microbiology and Laboratory Oversight | Residues and Microbiological Policy | Export Standards Branch | Exports and Veterinary Services Division

Phone s. 22(1)(a)(ii) | **Mobile** s. 47F(1) | **Email** s. 22(1)(a)(ii)@agriculture.gov.au

Department of Agriculture, Fisheries and Forestry

255 Melrose Drive

Tullamarine VIC 3043 Australia

Postal address: PO Box 858 Canberra City ACT 2601

From: s. 47F(1) @mxns.com>

Sent: Tuesday, 26 July 2022 3:17 PM

To: s. 22(1)(a)(ii)@awe.gov.au

Subject: Introduction and advice [SEC=UNOFFICIAL]

Hello s. 22(1)(a)(ii),

I hope this email finds you well?

I would like to introduce myself my name is s. 47F(1) I'm Merieux Nutrisciences business development manager.

Your details have been passed onto myself as I seek your advice.

It's in regards to a project design we are currently working on for the export meat industry, currently we have hit a hurdle that I will need some clarification on.

When would be the best time for me to contact you to discuss further?

I look forward to your reply,



s. 47F(1)

s. 47F(1)



Mérieux NutriSciences

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S. 45(1)

S. 45(1)

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S. 45(1)

S. 45(1)

Deed of confidentiality

Commonwealth of Australia as represented by the Department of
Agriculture, Fisheries and Forestry
Department

[Insert name of organisation]

Organisation

Contents

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Deed of confidentiality

Date [insert date]

Parties Commonwealth of Australia as represented by the Department of Agriculture, Fisheries and Forestry (Department)
[insert name of organisation] ACN [insert number] (Organisation)

Background

- A. The Organisation has agreed to provide the Department with the Confidential Information.
- B. The Department has agreed not to disclose the Confidential Information, as set out in this Deed.

Operative provisions

1. Definitions

1.1 Definitions

In this Deed, unless the context requires otherwise:

Business Day means a day that is not a Saturday, Sunday, public holiday or bank holiday in the Australian Capital Territory.

Confidential Information means the information described in Annexure A, except for any information that:

- (a) is or becomes public knowledge otherwise than by breach of this Deed; or
- (b) has been independently developed or acquired by the Department.

Deed means this deed of confidentiality.

1.2 Interpretation

In this Deed, unless the context requires otherwise:

- (a) the singular includes the plural and vice versa, and a gender includes all other genders;
- (b) another grammatical form of a defined word or expression has a corresponding meaning;
- (c) a reference to a clause or annexure is to a clause or annexure to this Deed, and a reference to this Deed includes any annexure;
- (d) a reference to a document or instrument includes the document or instrument as assigned, novated, altered, supplemented or replaced from time to time;
- (e) a reference to a party is to a party to this Deed, and a reference to a party to a document includes the party's executors, administrators, successors, permitted assignees and substitutes;

- (f) a reference to a person includes a natural person, partnership, body corporate, association, governmental or local authority or agency or other entity;
- (g) the meaning of general words is not limited by specific examples introduced by including, for example or similar expressions;
- (h) a rule of construction does not apply to the disadvantage of a party because the party was responsible for the preparation of this Deed or any part of it;
- (i) if a day on or by which an obligation must be performed or an event must occur is not a Business Day, the obligation must be performed or the event must occur on or by the next Business Day; and
- (j) headings are for ease of reference only and do not affect interpretation.

2. Term of deed

2.1 Term of Deed

This Deed:

- (a) commences on the date that it is executed by the parties, and, if signed on different dates, the date the last party to this Deed executes it; and
- (b) continues until five (5) years from the date of execution of this Deed.

3. Disclosure of Confidential Information

3.1 Keep information confidential

The Department must not, without the prior written consent of the Organisation, disclose any Confidential Information to a third party during the Term of this Deed.

3.2 Exceptions to obligation

The Department's obligation under clause 3.1 will not be taken to have been breached to the extent that the Confidential Information is disclosed by the Department:

- (a) to any of its advisers;
- (b) to any responsible Minister;
- (c) in response to a request by a House or a Committee of the Parliament of the Commonwealth of Australia;
- (d) within the Commonwealth of Australia, or to a government agency; or
- (e) in circumstances in which the disclosure is authorised or required by law.

4. Notices

4.1 Service of Notices

- (a) A notice under this Deed must be:
 - (i) in writing, in English and signed by a person duly authorised by the sender; and

- (ii) hand delivered or sent by prepaid post or email to the recipient's address for notices specified below:

Department of Agriculture, Fisheries and Forestry

[insert details]

Organisation

[insert details]

- (b) Subject to clause 4.1(c), a notice given in accordance with clause 4.1(a) takes effect when it is taken to be received (or at a later time specified in it), and is taken to be received:
 - (i) if hand delivered, on delivery;
 - (ii) if sent by prepaid post, on the second Business Day after the date of posting (or on the seventh Business Day after the date of posting if posted to or from a place outside Australia); or
 - (iii) if sent by email, when the sender's system indicates that the notice has been successfully transmitted.
- (c) If a notice is given after 5:00pm on a Business Day, it will be taken to have been received at 9:00am on the next Business Day.

5. General

5.1 Applicable Law

- (a) This Deed is to be construed in accordance with, and any matter related to it is to be governed by, the laws of the Australian Capital Territory.
- (b) The parties submit to the non-exclusive jurisdiction of the courts of that jurisdiction.

5.2 Variations

This Deed may be varied only in writing signed by each party.

5.3 Assignment

A party may only assign its rights under this Deed with the prior written consent of the other party.

5.4 Costs

Each party must pay its own costs of negotiating, preparing, executing and complying with this Deed.

5.5 Counterparts

This Deed may be executed in counterparts. All executed counterparts constitute one document.

5.6 No merger

The rights and obligations of the parties under this Deed do not merge on completion of any transaction contemplated by this Deed.

5.7 Entire agreement

This Deed constitutes the entire agreement between the parties in connection with its subject matter and supersedes all previous agreements or understandings between the parties in connection with its subject matter.

5.8 Relationship

- (a) The parties must not represent themselves, and must ensure that their officers, employees, agents and subcontractors do not represent themselves, as being an officer, employee, partner or agent of the other party, or as otherwise able to bind or represent the other party.
- (b) This Deed does not create a relationship of employment, agency or partnership between the parties.

Executed as a deed.

Signed, sealed and delivered on behalf of the
Commonwealth of Australia as represented
by the Department of Agriculture, Fisheries
and Forestry by:

s. 47F(1)

Print name of delegate

s. 47F(1)

Signature

26-8/22

in the presence of:

Print name of witness

Signature of witness

Date

Executed by [insert name of organisation]
ACN [insert number] in accordance with
section 127 of the Corporations Act 2001 (Cth):

Signature of director

Signature of company secretary/director

Full name of director

Full name of company secretary/director

Date

Annexure A - Confidential Information

[List types of confidential information]

Deed of confidentiality

Commonwealth of Australia as represented by the Department of
Agriculture, Fisheries and Forestry
Department

Merieux NutriSciences Australia
Organisation

Contents

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Deed of confidentiality

Date **6th September 2022**

Parties **Commonwealth of Australia as represented by the Department of Agriculture, Fisheries and Forestry (Department)**

Silliker Australia Pty Ltd trading as and referred to herein as “**Mérieux NutriSciences**” **ACN 94006462 335 (Organisation)**

Background

- A. The Organisation has agreed to provide the Department with the Confidential Information.
- B. The Department has agreed not to disclose the Confidential Information, as set out in this Deed.

Operative provisions

1. **Definitions**

1.1 **Definitions**

In this Deed, unless the context requires otherwise:

Business Day means a day that is not a Saturday, Sunday, public holiday or bank holiday in the Australian Capital Territory.

Confidential Information means the information described in Annexure A, except for any information that:

- (a) is or becomes public knowledge otherwise than by breach of this Deed; or
- (b) has been independently developed or acquired by the Department.

Deed means this deed of confidentiality.

1.2 **Interpretation**

In this Deed, unless the context requires otherwise:

- (a) the singular includes the plural and vice versa, and a gender includes all other genders;
- (b) another grammatical form of a defined word or expression has a corresponding meaning;
- (c) a reference to a clause or annexure is to a clause or annexure to this Deed, and a reference to this Deed includes any annexure;
- (d) a reference to a document or instrument includes the document or instrument as assigned, novated, altered, supplemented or replaced from time to time;

- (e) a reference to a party is to a party to this Deed, and a reference to a party to a document includes the party's executors, administrators, successors, permitted assignees and substitutes;
- (f) a reference to a person includes a natural person, partnership, body corporate, association, governmental or local authority or agency or other entity;
- (g) the meaning of general words is not limited by specific examples introduced by including, for example or similar expressions;
- (h) a rule of construction does not apply to the disadvantage of a party because the party was responsible for the preparation of this Deed or any part of it;
- (i) if a day on or by which an obligation must be performed or an event must occur is not a Business Day, the obligation must be performed or the event must occur on or by the next Business Day; and
- (j) headings are for ease of reference only and do not affect interpretation.

2. Term of deed

2.1 Term of Deed

This Deed:

- (a) commences on the date that it is executed by the parties, and, if signed on different dates, the date the last party to this Deed executes it; and
- (b) continues until five (5) years from the date of execution of this Deed.

3. Disclosure of Confidential Information

3.1 Keep information confidential

The Department must not, without the prior written consent of the Organisation, disclose any Confidential Information to a third party during the Term of this Deed.

3.2 Exceptions to obligation

The Department's obligation under clause 3.1 will not be taken to have been breached to the extent that the Confidential Information is disclosed by the Department:

- (a) to any of its advisers;
- (b) to any responsible Minister;
- (c) in response to a request by a House or a Committee of the Parliament of the Commonwealth of Australia;
- (d) within the Commonwealth of Australia, or to a government agency; or
- (e) in circumstances in which the disclosure is authorised or required by law.

4. Notices

4.1 Service of Notices

- (a) A notice under this Deed must be:

- (i) in writing, in English and signed by a person duly authorised by the sender; and
- (ii) hand delivered or sent by prepaid post or email to the recipient's address for notices specified below:

Department of Agriculture, Fisheries and Forestry

[insert details]

Organisation

Mérieux NutriSciences

Unit C2/391 Park Rd, Regents Park NSW 2143, Australia

- (b) Subject to clause 4.1(c), a notice given in accordance with clause 4.1(a) takes effect when it is taken to be received (or at a later time specified in it), and is taken to be received:
 - (i) if hand delivered, on delivery;
 - (ii) if sent by prepaid post, on the second Business Day after the date of posting (or on the seventh Business Day after the date of posting if posted to or from a place outside Australia); or
 - (iii) if sent by email, when the sender's system indicates that the notice has been successfully transmitted.
- (c) If a notice is given after 5:00pm on a Business Day, it will be taken to have been received at 9:00am on the next Business Day.

5. General

5.1 Applicable Law

- (a) This Deed is to be construed in accordance with, and any matter related to it is to be governed by, the laws of the Australian Capital Territory.
- (b) The parties submit to the non-exclusive jurisdiction of the courts of that jurisdiction.

5.2 Variations

This Deed may be varied only in writing signed by each party.

5.3 Assignment

A party may only assign its rights under this Deed with the prior written consent of the other party.

5.4 Costs

Each party must pay its own costs of negotiating, preparing, executing and complying with this Deed.

5.5 Counterparts

This Deed may be executed in counterparts. All executed counterparts constitute one document.

5.6 No merger

The rights and obligations of the parties under this Deed do not merge on completion of any transaction contemplated by this Deed.

5.7 Entire agreement

This Deed constitutes the entire agreement between the parties in connection with its subject matter and supersedes all previous agreements or understandings between the parties in connection with its subject matter.

5.8 Relationship

- (a) The parties must not represent themselves, and must ensure that their officers, employees, agents and subcontractors do not represent themselves, as being an officer, employee, partner or agent of the other party, or as otherwise able to bind or represent the other party.
- (b) This Deed does not create a relationship of employment, agency or partnership between the parties.

Executed as a deed.

Signed, sealed and delivered on behalf of the
Commonwealth of Australia as represented
by the Department of Agriculture, Fisheries
and Forestry by:

s. 47F(1)

Print name of delegate

s. 47F(1)

Signature

26-8/22

In the presence of:

Print name of witness

Signature of witness

Date

Executed by [insert name of organisation]
ACN [insert number] in accordance with
section 127 of the Corporations Act 2001 (Cth):

Signature of director

Signature of company secretary/director

Full name of director

Full name of company secretary/director

Date

Annexure A - Confidential Information

Document: MLA Gene UP trial July 2022.docx

s. 22(1)(a)(ii)

From: s. 47F(1) @mxns.com>
Sent: Wednesday, 17 August 2022 3:00 PM
To: s. 22(1)(a)(ii)
Subject: Re: Introduction and advice [SEC=UNOFFICIAL]
Attachments: Copy of MXNS Mutual NDA template (1) (2).docx

Hi s. 22(1)(a)(ii),

How have you been?

Appologies for the slow response as I have been in contact with legal back and forth.

I really appreciate your support and advice on this matter of the project with MLA.

The advice from my legal team is that MXNS will require the department to sign the attached NDA before I share the protocol with you.



Let me know if you have any further questions?



s. 47F(1)

s. 47F(1)



Mérieux NutriSciences
Unit C2/391 Park Rd, Regents Park NSW 2143, Australia
Phone: 1300 000 990
Direct: +s. 47F(1)
Mobile: +s. 47F(1)
Email: s. 47F(1)@mxns.com
<http://www.merieuxnutrisciences.com/au>
Follow us on:  

On Tue, Jul 26, 2022 at 4:16 PM s. 22(1)(a)(ii)

@awe.gov.au> wrote:

Sounds good s. 47F(1) – talk then.

Regards,

s. 22(1)(a)(ii)

From: s. 47F(1) @mxns.com>
Sent: Tuesday, 26 July 2022 4:07 PM
To: s. 22(1)(a)(ii) @awe.gov.au>
Subject: Re: Introduction and advice [SEC=UNOFFICIAL]

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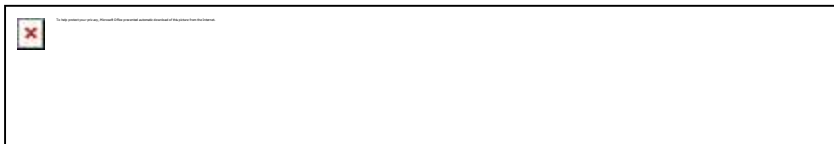
I meant I'll call you tomorrow between 4 & 5.

I'll send you a meeting invite as a reminder.



s. 47F(1)

s. 47F(1)



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Follow us on: 

On Tue, Jul 26, 2022 at 4:06 PM s. 47F(1) @mxns.com> wrote:

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I'll call you now.



s. 47F(1)

s. 47F(1)



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On Tue, Jul 26, 2022 at 4:05 PM s. 22(1)(a)(ii)

@awe.gov.au> wrote:

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Regards,

s. 22(1)(a)(ii)

s. 22(1)(a)(ii)

Principal – Microbiology and Laboratory Oversight | Residues and Microbiological Policy | Export Standards Branch | Exports and Veterinary Services Division

Phone s. 22(1)(a)(ii) | **Mobile** s. 47F(1) | **Email** s. 22(1)(a)(ii)@agriculture.gov.au

Department of Agriculture, Fisheries and Forestry

255 Melrose Drive

Tullamarine VIC 3043 Australia

Postal address: PO Box 858 Canberra City ACT 2601

From: s. 47F(1) @mxns.com>
Sent: Tuesday, 26 July 2022 3:17 PM
To: s. 22(1)(a)(ii)@awe.gov.au
Subject: Introduction and advice [SEC=UNOFFICIAL]

Hello ^{s. 22(1)(a)(ii)},

I hope this email finds you well?

I would like to introduce myself my name is s. 47F(1) I'm Merieux Nutriscines business development manager.

Your details have been passed onto myself as I seek your advice.

It's in regards to a project design we are currently working on for the export meat industry, currently we have hit a hurdle that I will need some clarification on.

When would be the best time for me to contact you to discuss further?

I look forward to your reply,



s. 47F(1)

s. 47F(1)



Mérieux NutriSciences

Unit C2/391 Park Rd, Regents Park NSW 2143, Australia



Phone: 1300 000 990

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Follow us on:  

----- IMPORTANT - This email and any attachments have been issued by the Australian Government Department of Agriculture, Water and the Environment. The material transmitted is for the use of the intended recipient only and may contain confidential, legally privileged, copyright or personal information. You should not copy, use or disclose it without authorisation from the Department. It is your responsibility to check any attachments for viruses and defects before

opening or forwarding them. If you are not an intended recipient, please contact the sender of this email at once by return email and then delete both messages. Unintended recipients must not copy, use, disclose, rely on or publish this email or attachments. The Department of Agriculture, Water and the Environment is not liable for any loss or damage resulting from unauthorised use or dissemination of, or any reliance on, this email or attachments. If you have received this e-mail as part of a valid mailing list and no longer want to receive a message such as this one, advise the sender by return e-mail accordingly. This notice should not be deleted or altered -----

MUTUAL NON DISCLOSURE AGREEMENT

This Mutual Non Disclosure Agreement (hereinafter the “ Agreement ”) entered into by and between “[COMPANY with its registered office [TO COMPLETE] represented by [TO COMPLETE], acting for itself and on behalf of its affiliates, (hereinafter “ Mérieux NutriSciences ”) AND [COMPANY, with its registered office [TO COMPLETE] represented by [TO COMPLETE], (hereinafter “[COMPANY]”), hereinafter both individually referred to as the “ Party ” and collectively as the “Parties”.

For the execution of this Agreement, « Affiliates» means, as to any Party hereto, any entity that is controlled by that Party where "Control" shall mean the power to direct the management and policies of an entity through the direct or indirect ownership of at least 50% of the voting securities, by contract or otherwise.

The Parties have recently initiated discussions with the view to collaborate together to PLEASE DESCRIBE IN SHORT (hereinafter the “Project”).

Parties have wished to conclude this Agreement so as to protect Confidential Information (as defined below) exchanged between the Parties in the course of the Project.

1. Definition of Confidential Information

This Agreement covers all of the confidential information and/or information of proprietary nature, including, but not limited to, trade secrets, know-how, methods, reports, documents or other data, including but not limited to, financial, marketing, legal, commercial, technical, non-technical, scientific, related to a Party or to the Project, the existence, terms and topic of the Agreement (hereinafter the “Confidential Information”) disclosed by a Party (hereinafter the “Discloser”) to the other (hereinafter the “Recipient”) since the start of the discussions of the Project, that is to say [TO COMPLETE with the date of the first exchanges]

2. Confidentiality

The Recipient shall only disclose Confidential Information to any person employed by itself or its affiliates (including but not limited to employees, agents or consultants) who have a need to know for the purpose of the Project, and, who are bound to confidentiality obligations similar to those contained in this Agreement.

The Recipient shall not disclose any Confidential Information to any non-authorized persons.

The Recipient shall maintain the Confidential Information in confidence and shall take:

- The appropriate precautions to not disclose any of the Confidential Information and,
- At least the same precautions to avoid disclosure of the Confidential Information that it would take with its own confidential information, but in any event no less than reasonable precautions in accordance with the business standard.

3. Use of Confidential Information

The Recipient shall only use Confidential Information for the sole purpose of the Project. The Parties shall not use Confidential Information for any other purpose.

4. Breach of the Agreement

The Recipient shall be held liable towards the Discloser for any breach of this Agreement by the ones to which it disclosed the Confidential Information.

5. Exceptions

Provided the Recipient's written evidence, the confidentiality and non-use obligations hereunder shall not apply to information which:

- is in its rightful possession prior to its receipt from Discloser; or
- is in or hereafter enters the public domain through no fault of the Recipient who has received it; or
- has been obtained in good faith from a third party, which to the Recipient's knowledge, has the legal right to use and disclose the same; or
- is independently developed by the Recipient, without using the Confidential Information disclosed for the purpose of the Project, as evidenced by contemporaneous written records.

6. Disclosures Required by Law

In the event that the Recipient is required by applicable law or regulation or by legal process to disclose any Confidential Information, the Recipient shall provide the Discloser with reasonable notice of such request(s) or legal process, unless otherwise prohibited by law, to enable the Discloser to seek an appropriate protective order so as to resist or narrow the scope of such request or process.

7. Return or destruction of Confidential Information

Upon request of the Discloser, the Recipient shall return to the Discloser, or shall destroy all Confidential Information received.

Destruction of Confidential Information under electronic form shall be led with all the care commercially reasonable taking into account technical limits.

However, the Recipient may retain in its confidential files, and within the respect of the Agreement,

- One (1) copy of Confidential Information written and/or one (1) copy of any notes, reports, or summaries written by the Recipient including Confidential Information for the exclusive purpose to be used as a proof or for the respect of internal compliance policy;

- Confidential Information under electronic form for which the extraction is technically hard or impossible.

8. Nature of the relations between the Parties

No right to license whatsoever, either expressed or implied, is granted pursuant to this Agreement under any copyright, trade secret, trademark, trademark application, patent, patent application, or any other proprietary right now or hereafter owned or controlled by each of the Parties and this Agreement shall create no obligation on the part of the Parties to initiate or continue any discussions, collaborations or further relationships, including but not limited to buy any goods or services to the other Party.

This Agreement does not create any agency, partnership, joint venture or other joint relationship between the Parties hereto.

9. Duration

The Agreement comes into force on the date of its execution by both Parties and for a period of [2 years].

10. Modification

No modification shall be effective unless made in writing and signed by duly authorized representative(s) of each Party.

11. Personal Data

The Recipient is informed that within the framework of the Agreement and its relationship with the Discloser, for the performance of the Project, each Party will collect, as data controller, employees' and representatives' personal data ("Data Subjects") such as the name, last name and electronic address ("Personal Data") in order to establish an updated file on the employees or representatives which are subject to confidential duties under this Agreement. The Personal Data will be hold for the time of the Agreement Duration. Henceforth, regarding the applicable laws and in particular the General regulation on personal data dated 27 April 2016 ("GDPR"), Data Subjects have the right to access their Personal Data, the right to rectify and to erase such data, the right to limit and to opt out of their Personal Data processing, and not to be subject to an automated data processing intended to determine their profile or to assess certain aspects of their personality, as well as the right to portability, which shall be strictly construed as regarding Personal Data directly collected from the Data Subject. In order to exercise such rights, the Data Subject(s) can contact each Party data protection officer at the following email address:

- for Mérieux NutriSciences : dpo@mxns.com
- for [TO BE COMPLETED]: [TO BE COMPLETED]

Data Subject(s) may also submit a complaint to the CNIL. Parties are informed and hereby agree that Personal Data of their employees or representatives bound by the confidentiality obligation defined in this Agreement, are collected in order to perform the Agreement and the relationship between the Parties.

12. Governing Law and Dispute Resolution

This Agreement shall be governed by the laws of XXXX, without reference to any conflict law provisions.

Any dispute related to this Agreement shall be only submitted under the exclusive jurisdiction of the XXXX, Court.

Made in [NUMBER] counterparts, [date to be completed],
To the extent permitted by applicable law, electronic or PDF signatures will be accepted and will be binding on the Parties.

For **MERIEUX NUTRISCIENCES**

For XXXX,

[Name]

[Title]

[Name]

[Title]

s. 22(1)(a)(ii)

From: s. 47F(1) @mxns.com>
Sent: Thursday, 18 August 2022 9:20 AM
To: s. 22(1)(a)(ii)
Subject: Re: Introduction and advice [SEC=UNOFFICIAL]

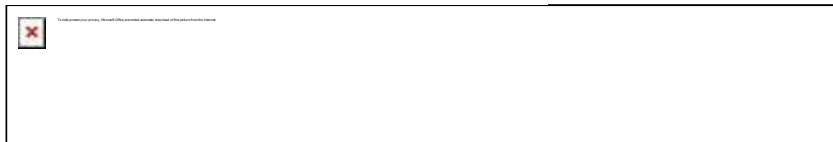
Hi s. 22(1)(a)(ii),

This is greatly appreciated under the circumstances as I'm asking for your help and advice on a subject matter. But requesting an NDA to be signed first.

However this has been the recommendation from my legal team that I must follow.



s. 47F(1)



Mérieux NutriSciences
Unit C2/391 Park Rd, Regents Park NSW 2143, Australia
Phone: 1300 000 990
Direct: +s. 47F(1)
Mobile: +s. 47F(1)
Email: s. 47F(1)@mxns.com
<http://www.merieuxnutrisciences.com/au>
Follow us on:  

On Thu, Aug 18, 2022 at 9:02 AM s. 22(1)(a)(ii) @awe.gov.au> wrote:

Thanks s. 47F(1). All going well here. I'll run this past our legal area and will then send back to you ASAP.

Kind regards,

s. 22(1)(a)(ii)

From: s. 47F(1) @mxns.com>
Sent: Wednesday, 17 August 2022 3:00 PM
To: s. 22(1)(a)(ii) @awe.gov.au>
Subject: Re: Introduction and advice [SEC=UNOFFICIAL]

Hi s. 22(1)(a)(ii),

How have you been?

Appologies for the slow response as I have been in contact with legal back and forth.

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The advice from my legal team is that MXNS will require the department to sign the attached NDA before I share the protocol with you.

Let me know if you have any further questions?



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Mérieux NutriSciences

Unit C2/391 Park Rd, Regents Park NSW 2143, Australia



Phone: 1300 000 990

Direct: +6s. 47F(1)

Mobile: +s. 47F(1)

Email: s. 47F(1)@mxns.com

<http://www.merieuxnutrisciences.com/au>

Follow us on:  

On Tue, Jul 26, 2022 at 4:16 PM s. 22(1)(a)(ii)

@awe.gov.au> wrote:

Sounds good s. 47F(1) – talk then.

Regards,

s. 22(1)(a)(ii)

From: s. 47F(1) @mxns.com>

Sent: Tuesday, 26 July 2022 4:07 PM

To: **s. 22(1)(a)(ii)** @awe.gov.au>
Subject: Re: Introduction and advice [SEC=UNOFFICIAL]

Apologies **s. 22(1)(a)(ii)**,

I meant I'll call you tomorrow between 4 & 5.

I'll send you a meeting invite as a reminder.



s. 47F(1)



Mérieux NutriSciences

Unit C2/391 Park Rd, Regents Park NSW 2143, Australia



Phone: 1300 000 990

Direct: +**s. 47F(1)**

Mobile: +**s. 47F(1)**

Email: **s. 47F(1)**@mxns.com

<http://www.merieuxnutrisciences.com/au>

Follow us on:  

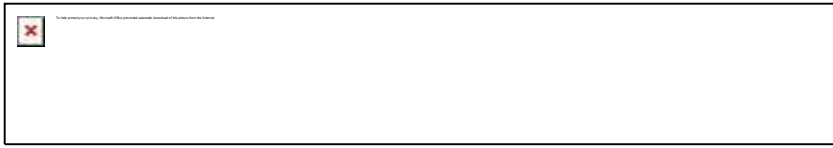
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Thanks **s. 22(1)(a)(ii)**,

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s. 47F(1)



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Regards,

s. 22(1)(a)(ii)

s. 22(1)(a)(ii)

Principal – Microbiology and Laboratory Oversight | Residues and Microbiological Policy | Export Standards Branch | Exports and Veterinary Services Division

Phone s. 22(1)(a)(ii) | **Mobile** s. 47F(1) | **Email** s. 22(1)(a)(ii)@agriculture.gov.au

Department of Agriculture, Fisheries and Forestry

255 Melrose Drive

Tullamarine VIC 3043 Australia

Postal address: PO Box 858 Canberra City ACT 2601

From: s. 47F(1) @mxns.com>

Sent: Tuesday, 26 July 2022 3:17 PM

To: s. 22(1)(a)(ii)@awe.gov.au

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^{s. 47F(1)}



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Follow us on:  

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receive a message such as this one, advise the sender by return e-mail accordingly. This notice should not be deleted or altered -----

S. 42(1)

S. 42(1)

s. 42(1)

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Sent: Wednesday, 17 August 2022 3:00 PM
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s. 47F(1)



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Follow us on:  

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Sent: Tuesday, 26 July 2022 4:07 PM
To: s. 22(1)(a)(ii) [@awe.gov.au](mailto:s.22(1)(a)(ii)@awe.gov.au)>
Subject: Re: Introduction and advice [SEC=UNOFFICIAL]

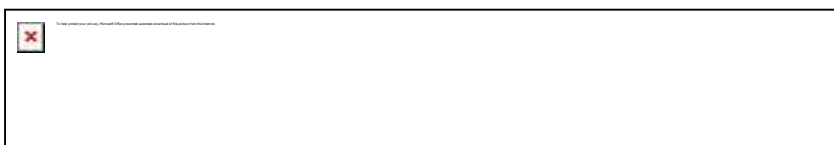
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I'll call you now.



s. 47F(1)



Mérieux NutriSciences

Unit C2/391 Park Rd, Regents Park NSW 2143, Australia


Phone: 1300 000 990

Direct: +**s. 47F(1)**

Mobile: +**s. 47F(1)**

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<http://www.merieuxnutrisciences.com/au>

Follow us on: 

On Tue, Jul 26, 2022 at 4:05 PM **s. 22(1)(a)(ii)** @awe.gov.au> wrote:

Hi **s. 47F(1)**,

I have some time tomorrow between 4 and 5. Would that work for you? Happy to discuss.

Regards,

s. 22(1)(a)(ii)

s. 22(1)(a)(ii)

Principal – Microbiology and Laboratory Oversight | Residues and Microbiological Policy | Export Standards Branch | Exports and Veterinary Services Division

Phone s. 22(1)(a)(ii) | Mobile s. 47F(1) | Email s. 22(1)(a)(ii)@agriculture.gov.au

Department of Agriculture, Fisheries and Forestry

255 Melrose Drive

Tullamarine VIC 3043 Australia

Postal address: PO Box 858 Canberra City ACT 2601

From: s. 47F(1) @mxns.com>
Sent: Tuesday, 26 July 2022 3:17 PM
To: s. 22(1)(a)(ii)@awe.gov.au
Subject: Introduction and advice [SEC=UNOFFICIAL]

Hello s. 22(1)(a)(ii) ,

I hope this email finds you well?

I would like to introduce myself my name is s. 47F(1) I'm Merieux Nutrisciences business development manager.

Your details have been passed onto myself as I seek your advice.

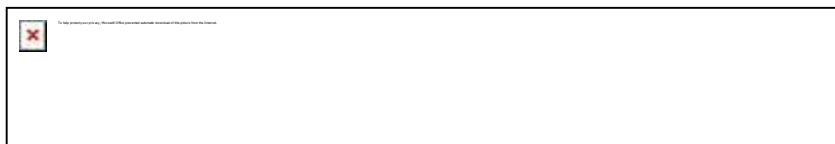
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S. 42(1)

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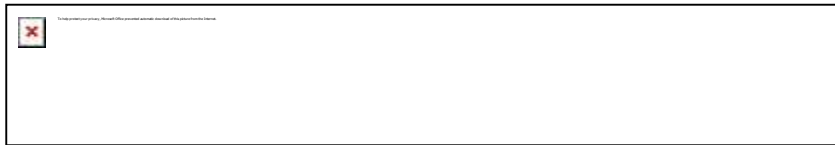
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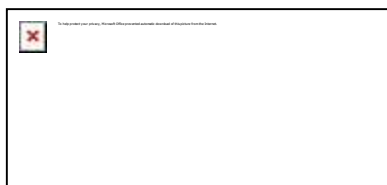
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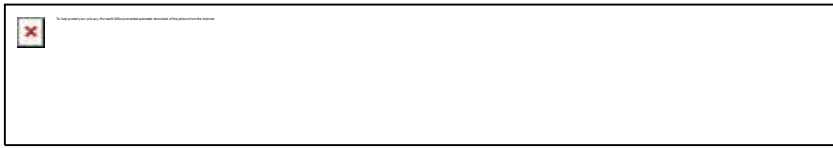
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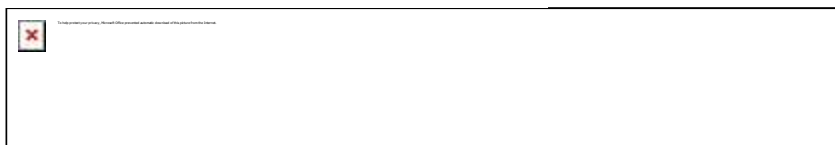
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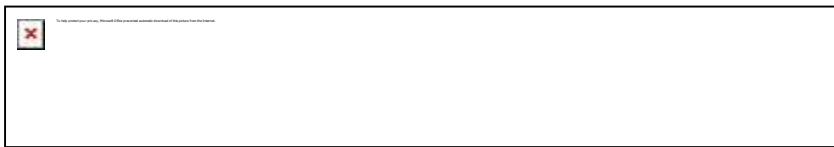
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s. 22(1)(a)(ii)

From: s. 47F(1) @mxns.com>
Sent: Tuesday, 13 September 2022 2:00 PM
To: s. 22(1)(a)(ii)
Subject: Re: Introduction and advice [SEC=UNOFFICIAL]
Attachments: 13092022134108-0001 (1).pdf

Hi s. 22(1)(a)(ii),

Appologies, see attached updated signed document.

Let me know if you have any more questions?

When would be a good time to touch base and discuss?



s. 47F(1)



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Follow us on:  

On Thu, Sep 8, 2022 at 11:11 AM s. 22(1)(a)(ii) @awe.gov.au> wrote:

Hi s. 47F(1),

Thanks for forwarding the signed deed and trial information.

However, I believe the deed has been signed incorrectly – it needs to be signed and witnessed in the section for your organisation at the bottom of the signing page, with the name of your organisation included where indicated.

Regards,

From: s. 47F(1) <[s.47F\(1\)@mxns.com](mailto:s.47F(1)@mxns.com)>
Sent: Tuesday, 6 September 2022 11:54 AM
To: s. 22(1)(a)(ii) <[s.22\(1\)\(a\)\(ii\)@awe.gov.au](mailto:s.22(1)(a)(ii)@awe.gov.au)>
Subject: Re: Introduction and advice [SEC=UNOFFICIAL]

Hello ^{s. 22(1)(a)(ii)},

Thank you very much for your support.

Please find attached signed copy of the Deed word document and PDF version.

I have also attached the copy of the experimental design/protocol.

I look forward to your feedback,



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As Australian Public Service (APS) employees we are subject to a range of Commonwealth laws that impose very strict confidentiality obligations (summarised below).

Summary of relevant Commonwealth laws

- Regulation 2.1(4) of the Public Service Regulations 1999 which provides that APS employees must not disclose information obtained or generated 'in connection' with their work that may harm the government, was communicated in confidence within the government or was received by the government from someone outside the government. Regulation 2.1(4) is part of the APS Code of Conduct. A wide range of sanctions can be imposed on a person determined to have breached the APS Code of Conduct - including termination of employment (section 15(1) of the Public Service Act 1999 (**PSA**)).
- Section 28 of the Public Governance, Performance and Accountability Act 2013 provides that a person who obtains information because they are an official of a Commonwealth entity must not improperly use the information to gain or seek to gain a benefit or an advantage for themselves or someone else or to cause or seek to cause detriment to the Commonwealth entity or someone else.
- Section 122.4(1) of the Criminal Code Act 1995 makes it an offence for a person to communicate information, if the person obtained the information by virtue of being a Commonwealth officer or was otherwise engaged to perform work for a Commonwealth entity and that person was under a duty, under a Commonwealth law, not to disclose the information. This offence is punishable by 2 years imprisonment.

We trust this gives you confidence that the department will keep the Project Protocol confidential. If however this is not satisfactory to MXNS, please let us know as the department would be open to signing the department's standard deed of confidentiality (copy attached for information).

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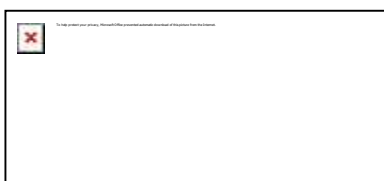
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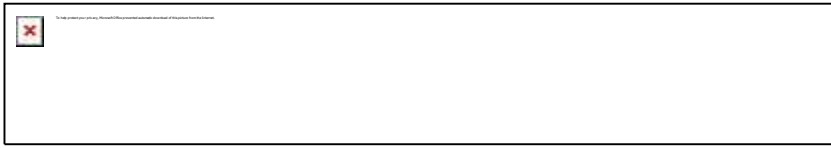
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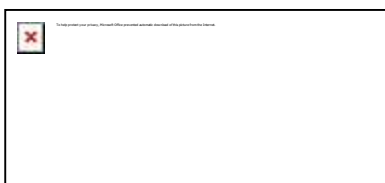
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I would like to introduce myself my name is s. 47F(1) I'm Merieux Nutriscines business development manager.

Your details have been passed onto myself as I seek your advice.

It's in regards to a project design we are currently working on for the export meat industry, currently we have hit a hurdle that I will need some clarification on.

When would be the best time for me to contact you to discuss further?

I look forward to your reply,



s. 47F(1)



Mérieux NutriSciences

Unit C2/391 Park Rd, Regents Park NSW 2143, Australia



Phone: 1300 000 990

Direct: +s. 47F(1)

Mobile: +s. 47F(1)

Email: s. 47F(1)@mxns.com

<http://www.merieuxnutrisciences.com/au>

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s. 22(1)(a)(ii)

From: s. 22(1)(a)(ii)
Sent: Thursday, 15 September 2022 8:28 AM
To: s. 22(1)(a)(ii)
Subject: FW: Introduction and advice [SEC=UNOFFICIAL]
Attachments: MLA Gene UP trial July 2022.pdf

Hi s. 22(1)(a)(ii),

Merieux Nutrisciences has been contracted by MLA to conduct a verification study on GeneUp EHEC Detection Method (AOAC 2020.06), including a comparison of testing time between GeneUp and MLG. The trial protocol is attached.

The protocol itself looks OK to me. Do you have any comments?

They have also asked what our position will be if STEC is confirmed in a sample for export. I think the position needs to be that we can't certify that particular lot.

Regards,

s. 22(1)(a)(ii)

From: s. 47F(1)
Sent: Tuesday, 6 September 2022 11:54 AM
To: s. 22(1)(a)(ii)
Subject: Re: Introduction and advice [SEC=UNOFFICIAL]

Hello s. 22(1)(a)(ii),

Thank you very much for your support.

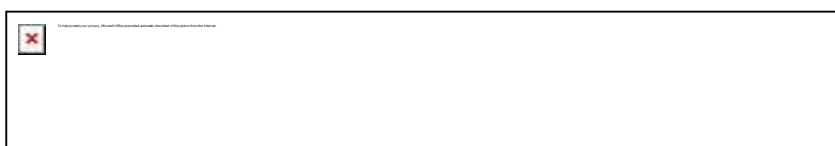
Please find attached signed copy of the Deed word document and PDF version.

I have also attached the copy of the experimental design/protocol.

I look forward to your feedback,



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On Tue, Aug 23, 2022 at 3:49 PM s. 22(1)(a)(ii) @awe.gov.au> wrote:

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- Section 28 of the Public Governance, Performance and Accountability Act 2013 provides that a person who obtains information because they are an official of a Commonwealth entity must not improperly use the information to gain or seek to gain a benefit or an advantage for themselves or someone else or to cause or seek to cause detriment to the Commonwealth entity or someone else.
- Section 122.4(1) of the Criminal Code Act 1995 makes it an offence for a person to communicate information, if the person obtained the information by virtue of being a Commonwealth officer or was otherwise engaged to perform work for a Commonwealth entity and that person was a under a duty, under a Commonwealth law, not to disclose the information. This offence is punishable by 2 years imprisonment.

We trust this gives you confidence that the department will keep the Project Protocol confidential. If however this is not satisfactory to MXNS, please let us know as the department would be open to signing the department's standard deed of confidentiality (copy attached for information).

Regards,

s. 22(1)(a)(ii)

From: s. 47F(1) [@mxns.com](mailto:s.47F(1)@mxns.com)>
Sent: Tuesday, 23 August 2022 1:06 PM
To: s. 22(1)(a)(ii) [@awe.gov.au](mailto:s.22(1)(a)(ii)@awe.gov.au)>
Subject: Re: Introduction and advice [SEC=UNOFFICIAL]

Hi [s. 22\(1\)\(a\)\(ii\)](#),

It's a new technology adoption case study project with the MLA.

The project will be funded through the individual processing sites - Plant Initiated Project (PIP).



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On Tue, Aug 23, 2022 at 11:37 AM **s. 22(1)(a)(ii)** <@awe.gov.au> wrote:

Hi **s. 47F(1)**,

Our lawyers are in the process of providing me with some advice but have asked a clarifying question. Can you please remind me – I think you said your project is being funded by AMPC. Is that correct? Is that the connection between MXNS and AMPC for your project?

Regards,

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From: **s. 47F(1)** <@mxns.com>
Sent: Thursday, 18 August 2022 9:20 AM
To: **s. 22(1)(a)(ii)** <@awe.gov.au>
Subject: Re: Introduction and advice [SEC=UNOFFICIAL]

Hi **s. 22(1)(a)(ii)**,

This is greatly appreciated under the circumstances as I'm asking for your help and advice on a subject matter. But requesting an NDA to be signed first.

However this has been the recommendation from my legal team that I must follow.



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On Thu, Aug 18, 2022 at 9:02 AM s. 22(1)(a)(ii) @awe.gov.au> wrote:

Thanks ^{s. 47F(1)}. All going well here. I'll run this past our legal area and will then send back to you ASAP.

Kind regards,

s. 22(1)(a)(ii)

From: s. 47F(1) @mxns.com>
Sent: Wednesday, 17 August 2022 3:00 PM
To: s. 22(1)(a)(ii) @awe.gov.au>
Subject: Re: Introduction and advice [SEC=UNOFFICIAL]

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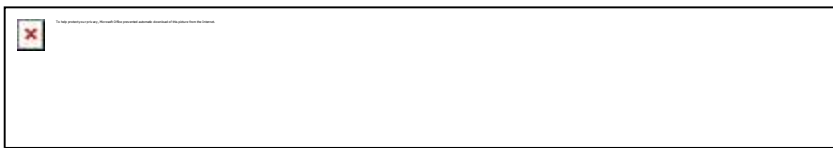
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The advice from my legal team is that MXNS will require the department to sign the attached NDA before I share the protocol with you.

Let me know if you have any further questions?



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On Tue, Jul 26, 2022 at 4:16 PM s. 22(1)(a)(ii)

[@awe.gov.au](mailto:s.22(1)(a)(ii)@awe.gov.au) wrote:

Sounds good s. 47F(1) – talk then.

Regards,

s. 22(1)(a)(ii)

From: s. 47F(1) @mxns.com>
Sent: Tuesday, 26 July 2022 4:07 PM
To: s. 22(1)(a)(ii) @awe.gov.au>
Subject: Re: Introduction and advice [SEC=UNOFFICIAL]

Apologies ^{s. 22(1)(a)(ii)},

I meant I'll call you tomorrow between 4 & 5.


I'll send you a meeting invite as a reminder.



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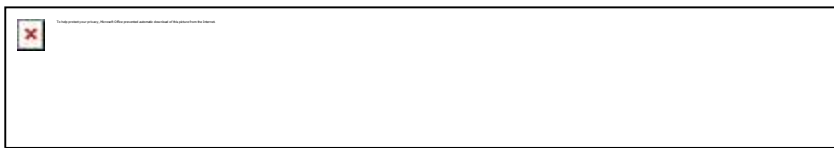
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Regards,

s. 22(1)(a)(ii)

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Principal – Microbiology and Laboratory Oversight | Residues and Microbiological Policy | Export Standards Branch | Exports and Veterinary Services Division

Phone +s. 22(1)(a)(ii) | **Mobile** s. 47F(1) | **Email** s. 22(1)(a)(ii)[@agriculture.gov.au](mailto:s.22(1)(a)(ii)@agriculture.gov.au)

Department of Agriculture, Fisheries and Forestry

255 Melrose Drive

Tullamarine VIC 3043 Australia

Postal address: PO Box 858 Canberra City ACT 2601

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Sent: Tuesday, 26 July 2022 3:17 PM

To: s. 22(1)(a)(ii)[@awe.gov.au](mailto:s.22(1)(a)(ii)@awe.gov.au)

Subject: Introduction and advice [SEC=UNOFFICIAL]

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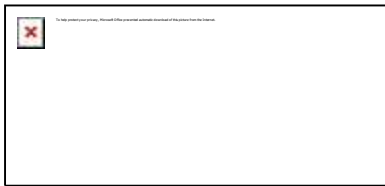
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s. 22(1)(a)(ii)

From: s. 22(1)(a)(ii)
Sent: Thursday, 15 September 2022 8:30 AM
To: s. 47F(1)
Subject: RE: Introduction and advice [SEC=UNOFFICIAL]
Attachments: Confidentialty deed signing page.jpg

Hi ^{s. 47F(1)},

Thanks for sending the signed document. Attached is the completed signing page. I'll send through a full scanned copy shortly.

My colleagues and I will have a look at the trial proposal. I understand the main question is what is DAFF's position if STEC is confirmed in export meat samples during the trial? Are there other aspects of the trial report that you want us to comment on?

Regards,

^{s. 22(1)(a)(ii)}

From: s. 47F(1)
Sent: Tuesday, 13 September 2022 2:00 PM
To: s. 22(1)(a)(ii)
Subject: Re: Introduction and advice [SEC=UNOFFICIAL]

Hi ^{s. 22(1)(a)(ii)},

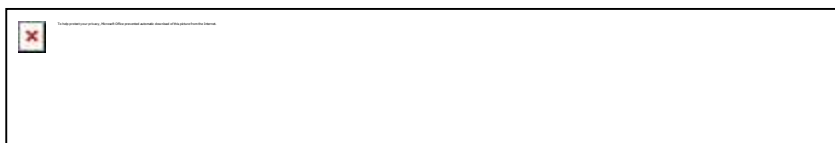
Appologies, see attached updated signed document.

Let me know if you have any more questions?

When would be a good time to touch base and discuss?



s. 47F(1)



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On Thu, Sep 8, 2022 at 11:11 AM s. 22(1)(a)(ii) @awe.gov.au> wrote:

Hi s. 47F(1),

Thanks for forwarding the signed deed and trial information.

However, I believe the deed has been signed incorrectly – it needs to be signed and witnessed in the section for your organisation at the bottom of the signing page, with the name of your organisation included where indicated.

Regards,

s. 22(1)(a)(ii)

From: s. 47F(1) @mxns.com>
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To: s. 22(1)(a)(ii) @awe.gov.au>
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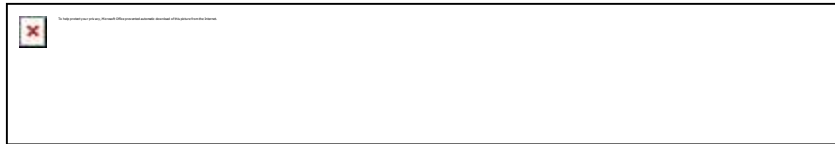
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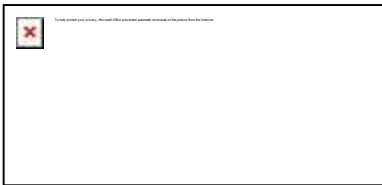
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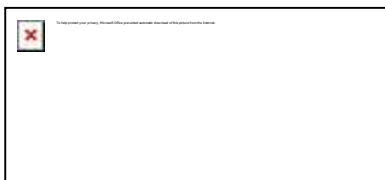
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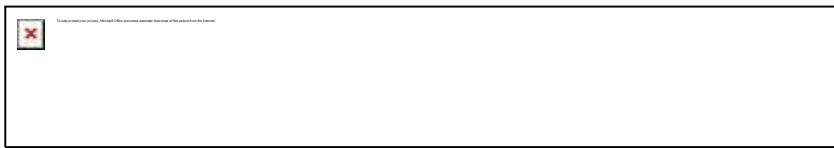
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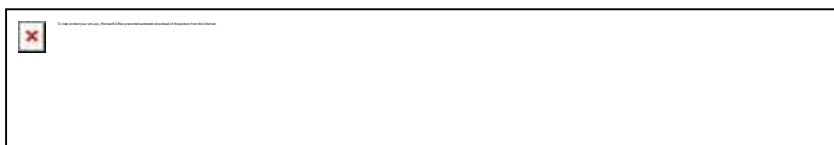
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Phone +s. 22(1)(a)(ii) | **Mobile** s. 47F(1) | **Email** s. 22(1)(a)(ii) [@agriculture.gov.au](mailto:s.22(1)(a)(ii)@agriculture.gov.au)

Department of Agriculture, Fisheries and Forestry

255 Melrose Drive

Tullamarine VIC 3043 Australia

Postal address: PO Box 858 Canberra City ACT 2601

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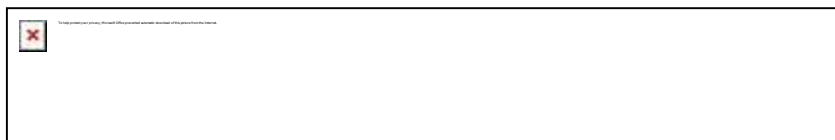
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Executed as a deed.

Signed, sealed and delivered on behalf of the Commonwealth of Australia as represented by the Department of Agriculture, Fisheries and Forestry by:

s. 22(1)(a)(ii)

Print name of delegate

s. 47F(1)

Signature

s. 47F(1)

in the presence of:

s. 47F(1)

Print name of witness

s. 47F(1)

Signature of witness

14/09/22

Date

Executed by Silliker Australia Pty Ltd trading as and referred to herein as "Mérieux NutriSciences" ACN 94006462 335 in accordance with section 127 of the Corporations Act 2001 (Cth):

s. 47F(1)

Signature of director

s. 47F(1)

Signature of company secretary/director

s. 47F(1)

Full name of director

s. 47F(1)

Full name of company secretary/director

13-9-22

Date

s. 22(1)(a)(ii)

From: s. 47F(1) @mxns.com>
Sent: Thursday, 15 September 2022 10:32 AM
To: s. 22(1)(a)(ii)
Subject: Re: Introduction and advice [SEC=UNOFFICIAL]

Hi s. 22(1)(a)(ii),

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Direct: +s. 47F(1)
Mobile: +s. 47F(1)
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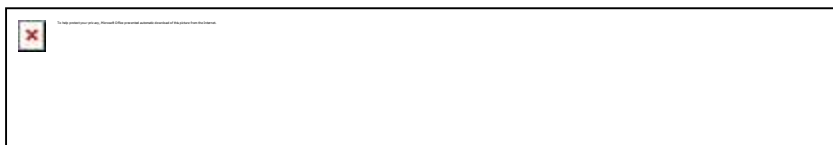
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When would be a good time to touch base and discuss?



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To: **s. 22(1)(a)(ii)** @awe.gov.au>
Subject: Re: Introduction and advice [SEC=UNOFFICIAL]

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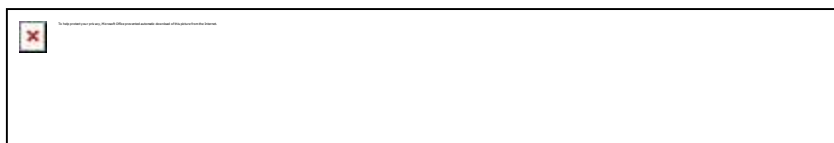
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- Section 28 of the Public Governance, Performance and Accountability Act 2013 provides that a person who obtains information because they are an official of a Commonwealth entity must not improperly use the information to gain or seek to gain a benefit or an advantage for themselves or someone else or to cause or seek to cause detriment to the Commonwealth entity or someone else.
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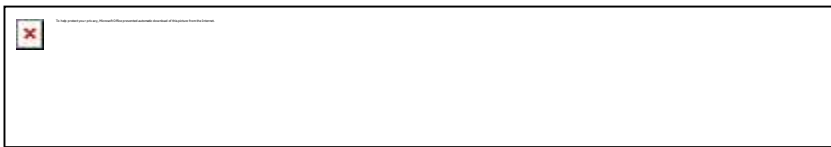
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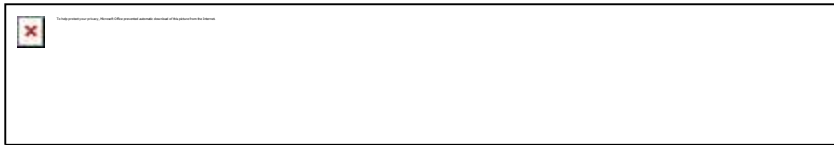
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Let me know if you have any further questions?



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Regards,

s. 22(1)(a)(ii)

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Sent: Tuesday, 26 July 2022 4:07 PM

To: s. 22(1)(a)(ii) @awe.gov.au>
Subject: Re: Introduction and advice [SEC=UNOFFICIAL]

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I'll send you a meeting invite as a reminder.



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I'll call you now.



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@awe.gov.au> wrote:

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Regards,

s. 22(1)(a)(ii)

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Principal – Microbiology and Laboratory Oversight | Residues and Microbiological Policy | Export Standards Branch | Exports and Veterinary Services Division

Phone +61 2 6272 3662 | **Mobile** s. 47F(1) | **Email** s. 22(1)(a)(ii)@agriculture.gov.au

Department of Agriculture, Fisheries and Forestry

255 Melrose Drive

Tullamarine VIC 3043 Australia

Postal address: PO Box 858 Canberra City ACT 2601

From: s. 47F(1) @mxns.com>

Sent: Tuesday, 26 July 2022 3:17 PM

To: s. 22(1)(a)(ii)@awe.gov.au

Subject: Introduction and advice [SEC=UNOFFICIAL]

Hello ^{s. 22(1)(a)(iii)},

I hope this email finds you well?

I would like to introduce myself my name is **s. 47F(1)** I'm Merieux Nutriscines business development manager.

Your details have been passed onto myself as I seek your advice.

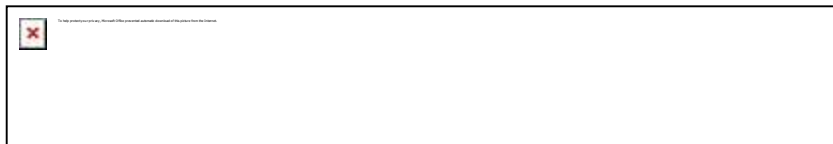
It's in regards to a project design we are currently working on for the export meat industry, currently we have hit a hurdle that I will need some clarification on.

When would be the best time for me to contact you to discuss further?

I look forward to your reply,



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longer want to receive a message such as this one, advise the sender by return e-mail accordingly. This notice should not be deleted or altered -----

s. 22(1)(a)(ii)

From: s. 22(1)(a)(ii)
Sent: Thursday, 15 September 2022 10:56 AM
To: s. 22(1)(a)(ii)
Cc: s. 22(1)(a)(ii)
Subject: STEC method trial - response following positives [SEC=UNOFFICIAL]

Hi s. 22(1)(a)(ii),

Wondering if I can get your thoughts. Merieux Nutrisciences is about to conduct a study for MLA, verifying the performance of a new dept-approved STEC confirmation method and comparing testing time with the standard US method. They'll be collecting samples of grinding beef and conducting their study after product has been exported. They want to know DAFF's position if any products test positive for STEC in their trial.

My view would be that we would need to take action if a pathogen is detected in meat and we know it would potentially breach an importing country requirement, regardless of whether exported lots passed STEC testing. It's possible some samples will be drawn from meat exported to Canada/US.

Do you have any thoughts?

Regards,

s. 22(1)(a)(ii)

From: s. 47F(1)
Sent: Thursday, 15 September 2022 10:32 AM
To: s. 22(1)(a)(ii)
Subject: Re: Introduction and advice [SEC=UNOFFICIAL]

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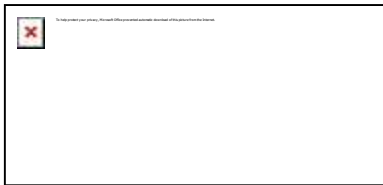
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s. 22(1)(a)(ii)

Principal – Microbiology and Laboratory Oversight | Residues and Microbiological Policy | Export Standards Branch | Exports and Veterinary Services Division

Phone +s. 22(1)(a)(ii) | **Mobile** s. 47F(1) | **Email** s. 22(1)(a)(ii)[@agriculture.gov.au](mailto:s.22(1)(a)(ii)@agriculture.gov.au)

Department of Agriculture, Fisheries and Forestry

255 Melrose Drive

Tullamarine VIC 3043 Australia

Postal address: PO Box 858 Canberra City ACT 2601

From: s. 47F(1) [@mxns.com](mailto:s.47F(1)@mxns.com)>
Sent: Tuesday, 26 July 2022 3:17 PM
To: s. 22(1)(a)(ii) [@awe.gov.au](mailto:s.22(1)(a)(ii)@awe.gov.au)
Subject: Introduction and advice [SEC=UNOFFICIAL]

Hello ^{s. 22(1)(a)(ii)},

I hope this email finds you well?

I would like to introduce myself my name is s. 47F(1) I'm Merieux Nutriscines business development manager.

Your details have been passed onto myself as I seek your advice.

It's in regards to a project design we are currently working on for the export meat industry, currently we have hit a hurdle that I will need some clarification on.

When would be the best time for me to contact you to discuss further?

I look forward to your reply,



s. 47F(1)



Mérieux NutriSciences

Unit C2/391 Park Rd, Regents Park NSW 2143, Australia



Phone: 1300 000 990

Direct: +s. 47F(1)

Mobile: +s. 47F(1)

Email: s. 47F(1) @mxns.com

<http://www.merieuxnutrisciences.com/au>

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S. 42(1)

S. 42(1)

S. 42(1)

From: s. 22(1)(a)(ii) <[s.22\(1\)\(a\)\(ii\)@agriculture.gov.au](mailto:s.22(1)(a)(ii)@agriculture.gov.au)>
Sent: Thursday, 15 September 2022 10:56 AM
To: s. 22(1)(a)(ii) <[s.22\(1\)\(a\)\(ii\)@agriculture.gov.au](mailto:s.22(1)(a)(ii)@agriculture.gov.au)>; s. 22(1)(a)(ii) <[s.22\(1\)\(a\)\(ii\)@agriculture.gov.au](mailto:s.22(1)(a)(ii)@agriculture.gov.au)>
Cc: s. 22(1)(a)(ii) <[s.22\(1\)\(a\)\(ii\)@agriculture.gov.au](mailto:s.22(1)(a)(ii)@agriculture.gov.au)>
Subject: STEC method trial - response following positives [SEC=UNOFFICIAL]

Hi s. 22(1)(a)(ii),

Wondering if I can get your thoughts. Merieux Nutrisciences is about to conduct a study for MLA, verifying the performance of a new dept-approved STEC confirmation method and comparing testing time with the standard US method. They'll be collecting samples of grinding beef and conducting their study after product has been exported. They want to know DAFF's position if any products test positive for STEC in their trial.

My view would be that we would need to take action if a pathogen is detected in meat and we know it would potentially breach an importing country requirement, regardless of whether exported lots passed STEC testing. It's possible some samples will be drawn from meat exported to Canada/US.

Do you have any thoughts?

Regards,

s. 22(1)(a)(ii)

From: s. 47F(1) <[s.47F\(1\)@mxns.com](mailto:s.47F(1)@mxns.com)>
Sent: Thursday, 15 September 2022 10:32 AM
To: s. 22(1)(a)(ii) <[s.22\(1\)\(a\)\(ii\)@awe.gov.au](mailto:s.22(1)(a)(ii)@awe.gov.au)>
Subject: Re: Introduction and advice [SEC=UNOFFICIAL]

Hi s. 22(1)(a)(ii),

I understand the main question is what is DAFF's position if STEC is confirmed in export meat samples during the trial?

s. 47F(1): Yes, correct this is the main point.

(1)****It should be highlighted that we are planning to not be testing the samples upon being delivered into the laboratory. The plan was to collect all the samples and test at a later stage in a batch/group. Meaning the product would potentially already be out there in the market.

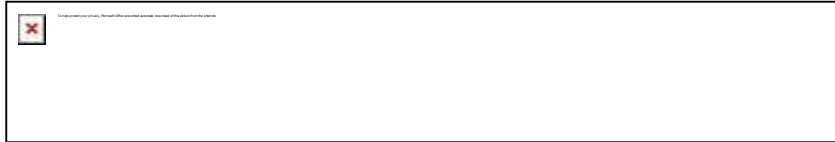
Happy for you to comment on this point (1) as well if the advice is that it should be done differently to get the project over the line.

Are there other aspects of the trial report that you want us to comment on?

s. 47F(1): Open to receiving any other comments or feedback you may have.



s. 47F(1)



Mérieux NutriSciences
Unit C2/391 Park Rd, Regents Park NSW 2143, Australia
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<http://www.merieuxnutrisciences.com/au>

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Hi s. 47F(1),

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My colleagues and I will have a look at the trial proposal. I understand the main question is what is DAFF's position if STEC is confirmed in export meat samples during the trial? Are there other aspects of the trial report that you want us to comment on?

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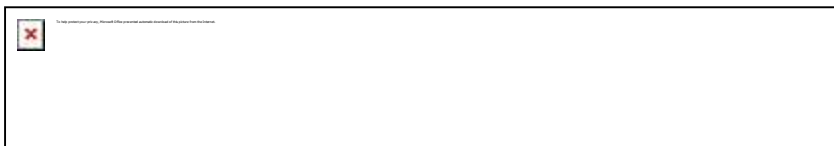
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Let me know if you have any more questions?

When would be a good time to touch base and discuss?



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However, I believe the deed has been signed incorrectly – it needs to be signed and witnessed in the section for your organisation at the bottom of the signing page, with the name of your organisation included where indicated.

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From: s. 47F(1) @mxns.com>
Sent: Tuesday, 6 September 2022 11:54 AM
To: s. 22(1)(a)(ii) @awe.gov.au>
Subject: Re: Introduction and advice [SEC=UNOFFICIAL]

Hello ^{s. 22(1)(a)(ii)},

Thank you very much for your support.

Please find attached signed copy of the Deed word document and PDF version.

I have also attached the copy of the experimental design/protocol.

I look forward to your feedback,



s. 47F(1)



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As Australian Public Service (APS) employees we are subject to a range of Commonwealth laws that impose very strict confidentiality obligations (summarised below).

Summary of relevant Commonwealth laws

- Regulation 2.1(4) of the Public Service Regulations 1999 which provides that APS employees must not disclose information obtained or generated 'in connection' with their work that may harm the government, was communicated in confidence within the government or was received by the government from someone outside the government. Regulation 2.1(4) is part of the APS Code of Conduct. A wide range of sanctions can be imposed on a person determined to have breached the APS Code of Conduct - including termination of employment (section 15(1) of the Public Service Act 1999 (PSA)).
- Section 28 of the Public Governance, Performance and Accountability Act 2013 provides that a person who obtains information because they are an official of a Commonwealth entity must not improperly use the information to gain or seek to gain a benefit or an advantage for themselves or someone else or to cause or seek to cause detriment to the Commonwealth entity or someone else.
- Section 122.4(1) of the Criminal Code Act 1995 makes it an offence for a person to communicate information, if the person obtained the information by virtue of being a Commonwealth officer or was otherwise engaged to perform work for a Commonwealth entity and that person was under a duty, under a Commonwealth law, not to disclose the information. This offence is punishable by 2 years imprisonment.

We trust this gives you confidence that the department will keep the Project Protocol confidential. If however this is not satisfactory to MXNS, please let us know as the department would be open to signing the department's standard deed of confidentiality (copy attached for information).

Regards,

s. 22(1)(a)(ii)

From: s. 47F(1) @mxns.com>
Sent: Tuesday, 23 August 2022 1:06 PM
To: s. 22(1)(a)(ii) @awe.gov.au>
Subject: Re: Introduction and advice [SEC=UNOFFICIAL]

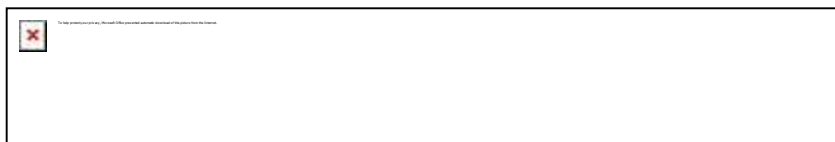
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It's a new technology adoption case study project with the MLA.

The project will be funded through the individual processing sites - Plant Initiated Project (PIP).



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On Tue, Aug 23, 2022 at 11:37 AM s. 22(1)(a)(ii) [@awe.gov.au](mailto:s.22(1)(a)(ii)@awe.gov.au) wrote:

Hi s. 47F(1),

Our lawyers are in the process of providing me with some advice but have asked a clarifying question. Can you please remind me – I think you said your project is being funded by AMPC. Is that correct? Is that the connection between MXNS and AMPC for your project?

Regards,

s. 22(1)(a)(ii)

From: s. 47F(1) [@mxns.com](mailto:s.47F(1)@mxns.com)>
Sent: Thursday, 18 August 2022 9:20 AM
To: s. 22(1)(a)(ii) [@awe.gov.au](mailto:s.22(1)(a)(ii)@awe.gov.au)>
Subject: Re: Introduction and advice [SEC=UNOFFICIAL]

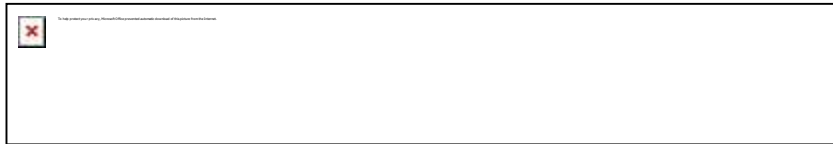
Hi s. 22(1)(a)(ii),

This is greatly appreciated under the circumstances as I'm asking for your help and advice on a subject matter. But requesting an NDA to be signed first.

However this has been the recommendation from my legal team that I must follow.



s. 47F(1)



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On Thu, Aug 18, 2022 at 9:02 AM s. 22(1)(a)(ii) [@awe.gov.au](mailto:s.22(1)(a)(ii)@awe.gov.au) wrote:

Thanks ^{s. 47F(1)}. All going well here. I'll run this past our legal area and will then send back to you ASAP.

Kind regards,

s. 22(1)(a)(ii)

From: s. 47F(1) [@mxns.com](mailto:s.47F(1)@mxns.com)>
Sent: Wednesday, 17 August 2022 3:00 PM
To: s. 22(1)(a)(ii) [@awe.gov.au](mailto:s.22(1)(a)(ii)@awe.gov.au)>
Subject: Re: Introduction and advice [SEC=UNOFFICIAL]

Hi ^{s. 22(1)(a)(ii)},

How have you been?

Appologies for the slow response as I have been in contact with legal back and forth.

I really appreciate your support and advice on this matter of the project with MLA.

The advice from my legal team is that MXNS will require the department to sign the attached NDA before I share the protocol with you.

Let me know if you have any further questions?



s. 47F(1)



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On Tue, Jul 26, 2022 at 4:16 PM **s. 22(1)(a)(ii)** <@awe.gov.au> wrote:

Sounds good ^{s. 47F(1)} – talk then.

Regards,

^{s. 22(1)(a)(ii)}

From: **s. 47F(1)** <@mxns.com>
Sent: Tuesday, 26 July 2022 4:07 PM
To: **s. 22(1)(a)(ii)** <@awe.gov.au>
Subject: Re: Introduction and advice [SEC=UNOFFICIAL]

Apologies ^{s. 22(1)(a)(ii)},

I meant I'll call you tomorrow between 4 & 5.

I'll send you a meeting invite as a reminder.




s. 47F(1)



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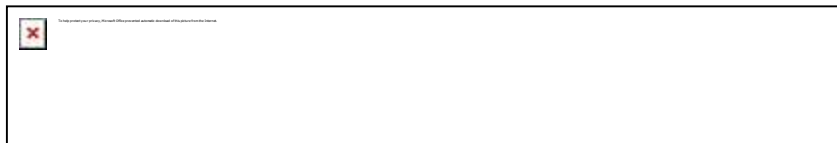
On Tue, Jul 26, 2022 at 4:06 PM s. 47F(1) @mxns.com> wrote:

Thanks s. 22(1)(a)(ii) ,

I'll call you now.



s. 47F(1)



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<http://www.merieuxnutrisciences.com/au>

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On Tue, Jul 26, 2022 at 4:05 PM s. 22(1)(a)(ii)

@awe.gov.au> wrote:

Hi ^{s. 47F(1)},

I have some time tomorrow between 4 and 5. Would that work for you? Happy to discuss.

Regards,

^{s. 22(1)(a)(ii)}

^{s. 22(1)(a)(ii)}

Principal – Microbiology and Laboratory Oversight | Residues and Microbiological Policy | Export Standards Branch | Exports and Veterinary Services Division

Phone ^{s. 22(1)(a)(ii)} | **Mobile** ^{s. 47F(1)} | **Email** ^{s. 22(1)(a)(ii)} @agriculture.gov.au

Department of Agriculture, Fisheries and Forestry

255 Melrose Drive

Tullamarine VIC 3043 Australia

Postal address: PO Box 858 Canberra City ACT 2601

From: ^{s. 47F(1)} @mxns.com>
Sent: Tuesday, 26 July 2022 3:17 PM
To: ^{s. 22(1)(a)(ii)} @awe.gov.au
Subject: Introduction and advice [SEC=UNOFFICIAL]

Hello ^{s. 22(1)(a)(ii)},

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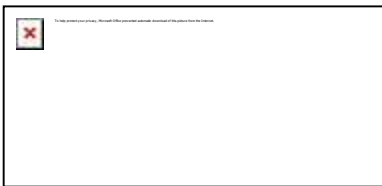
I would like to introduce myself my name is s. 47F(1) I'm Merieux Nutrisciences business development manager.

Your details have been passed onto myself as I seek your advice.

It's in regards to a project design we are currently working on for the export meat industry, currently we have hit a hurdle that I will need some clarification on.

When would be the best time for me to contact you to discuss further?

I look forward to your reply,



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S. 42(1)

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From: s. 22(1)(a)(ii) @agriculture.gov.au>
Sent: Thursday, 15 September 2022 10:56 AM
To: s. 22(1)(a)(ii) @agriculture.gov.au>s. 22(1)(a)(ii)
<s. 22(1)(a)(ii) @agriculture.gov.au>
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Do you have any thoughts?

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From: s. 47F(1) @mxns.com>
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To: s. 22(1)(a)(ii) @awe.gov.au>
Subject: Re: Introduction and advice [SEC=UNOFFICIAL]

Hi s. 22(1)(a)(ii),

I understand the main question is what is DAFF's position if STEC is confirmed in export meat samples during the trial?

s. 47F(1): Yes, correct this is the main point.

(1)***It should be highlighted that we are planning to not be testing the samples upon being delivered into the laboratory. The plan was to collect all the samples and test at a later stage in a batch/group. Meaning the product would potentially already be out there in the market.

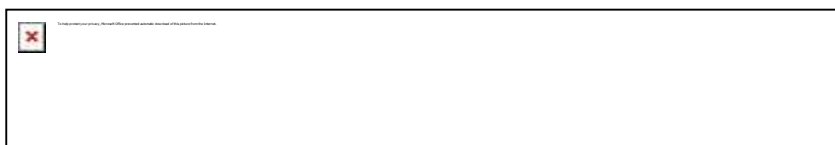
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Are there other aspects of the trial report that you want us to comment on?

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When would be a good time to touch base and discuss?



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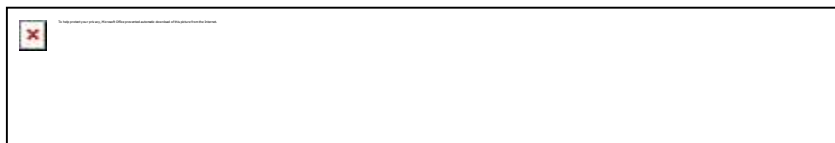
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I have also attached the copy of the experimental design/protocol.

I look forward to your feedback,



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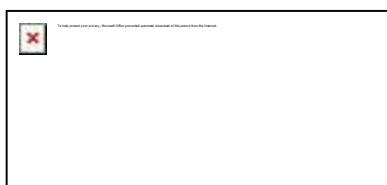
^{s. 22(1)(a)(ii)}

From: s. 47F(1) [@mxns.com](mailto:s.47F(1)@mxns.com)>
Sent: Tuesday, 23 August 2022 1:06 PM
To: s. 22(1)(a)(ii) [@awe.gov.au](mailto:s.22(1)(a)(ii)@awe.gov.au)>
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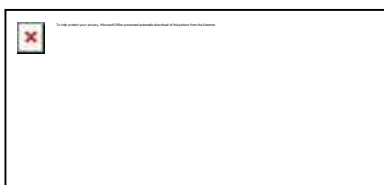
^{s. 22(1)(a)(ii)}

From: s. 47F(1) <@mxns.com>
Sent: Thursday, 18 August 2022 9:20 AM
To: s. 22(1)(a)(ii) <@awe.gov.au>
Subject: Re: Introduction and advice [SEC=UNOFFICIAL]

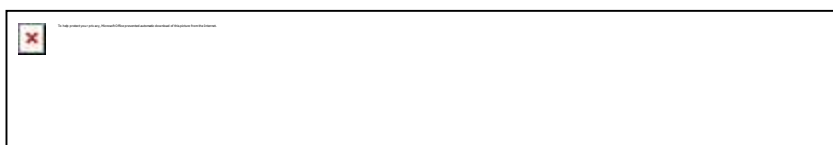
Hi ^{s. 22(1)(a)(ii)},

This is greatly appreciated under the circumstances as I'm asking for your help and advice on a subject matter. But requesting an NDA to be signed first.

However this has been the recommendation from my legal team that I must follow.



s. 47F(1)



Mérieux NutriSciences
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Phone: 1300 000 990

Direct: +s. 47F(1)

Mobile: +s. 47F(1)

Email: s. 47F(1) [@mxns.com](mailto:s.47F(1)@mxns.com)

<http://www.merieuxnutrisciences.com/au>

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On Thu, Aug 18, 2022 at 9:02 AM s. 22(1)(a)(ii) [@awe.gov.au](mailto:s.22(1)(a)(ii)@awe.gov.au)> wrote:

Thanks ^{s. 47F(1)}. All going well here. I'll run this past our legal area and will then send back to you ASAP.

Kind regards,

s. 22(1)(a)(ii)

From: s. 47F(1) [@mxns.com](mailto:s.47F(1)@mxns.com)>
Sent: Wednesday, 17 August 2022 3:00 PM
To: s. 22(1)(a)(ii) [@awe.gov.au](mailto:s.22(1)(a)(ii)@awe.gov.au)>
Subject: Re: Introduction and advice [SEC=UNOFFICIAL]

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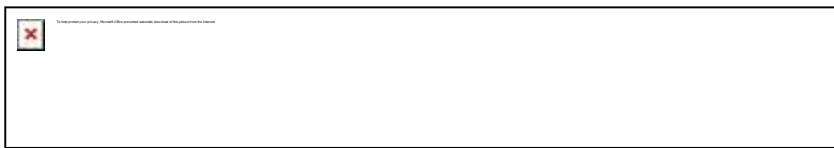
I really appreciate your support and advice on this matter of the project with MLA.

The advice from my legal team is that MXNS will require the department to sign the attached NDA before I share the protocol with you.

Let me know if you have any further questions?



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[@awe.gov.au](mailto:s.22(1)(a)(ii)@awe.gov.au)> wrote:

Sounds good s. 47F(1) – talk then.

Regards,

s. 22(1)(a)(ii)

From: s. 47F(1) [@mxns.com](mailto:s.47F(1)@mxns.com)>
Sent: Tuesday, 26 July 2022 4:07 PM
To: s. 22(1)(a)(ii) [@awe.gov.au](mailto:s.22(1)(a)(ii)@awe.gov.au)>
Subject: Re: Introduction and advice [SEC=UNOFFICIAL]

Apologies ^{s. 22(1)(a)(ii)},

I meant I'll call you tomorrow between 4 & 5.

I'll send you a meeting invite as a reminder.



s. 47F(1)



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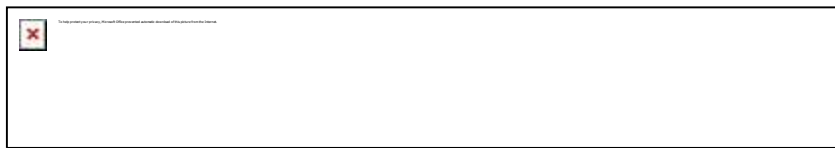
On Tue, Jul 26, 2022 at 4:06 PM s. 47F(1) [@mxns.com](mailto:s.47F(1)@mxns.com)> wrote:

Thanks ^{s. 22(1)(a)(ii)},

I'll call you now.



s. 47F(1)



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[@awe.gov.au](mailto:s.22(1)(a)(ii)@awe.gov.au)> wrote:

Hi ^{s. 47F(1)},

I have some time tomorrow between 4 and 5. Would that work for you? Happy to discuss.

Regards,

^{s. 22(1)(a)(ii)}

s. 22(1)(a)(ii)

Principal – Microbiology and Laboratory Oversight | Residues and Microbiological Policy | Export Standards Branch | Exports and Veterinary Services Division

Phone s. 22(1)(a)(ii) | Mobile s. 47F(1) | Email s. 22(1)(a)(ii)@agriculture.gov.au

Department of Agriculture, Fisheries and Forestry

255 Melrose Drive

Tullamarine VIC 3043 Australia

Postal address: PO Box 858 Canberra City ACT 2601

From: s. 47F(1) @mxns.com>
Sent: Tuesday, 26 July 2022 3:17 PM
To: s. 22(1)(a)(ii)@awe.gov.au
Subject: Introduction and advice [SEC=UNOFFICIAL]

Hello s. 22(1)(a)(ii),

I hope this email finds you well?

I would like to introduce myself my name is s. 47F(1) I'm Merieux Nutriscines business development manager.

Your details have been passed onto myself as I seek your advice.

It's in regards to a project design we are currently working on for the export meat industry, currently we have hit a hurdle that I will need some clarification on.

When would be the best time for me to contact you to discuss further?

I look forward to your reply,



s. 47F(1)



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S. 42(1)

S. 42(1)

S. 42(1)

s. 42(1)

From: s. 22(1)(a)(ii) @agriculture.gov.au>
Sent: Thursday, 15 September 2022 10:56 AM
To: s. 22(1)(a)(ii) @agriculture.gov.au; s. 22(1)(a)(ii) [<s. 22\(1\)\(a\)\(ii\) @agriculture.gov.au>](mailto:s. 22(1)(a)(ii) @agriculture.gov.au)
Cc: Cs. 22(1)(a)(ii) @agriculture.gov.au>
Subject: STEC method trial - response following positives [SEC=UNOFFICIAL]

Hi s. 22(1)(a)(ii),

Wondering if I can get your thoughts. Merieux Nutrisciences is about to conduct a study for MLA, verifying the performance of a new dept-approved STEC confirmation method and comparing testing time with the standard US method. They'll be collecting samples of grinding beef and conducting their study after product has been exported. They want to know DAFF's position if any products test positive for STEC in their trial.

My view would be that we would need to take action if a pathogen is detected in meat and we know it would potentially breach an importing country requirement, regardless of whether exported lots passed STEC testing. It's possible some samples will be drawn from meat exported to Canada/US.

Do you have any thoughts?

Regards,
s. 22(1)(a)(ii)

From: s. 47F(1) @mxns.com>
Sent: Thursday, 15 September 2022 10:32 AM
To: s. 22(1)(a)(ii) @awe.gov.au>
Subject: Re: Introduction and advice [SEC=UNOFFICIAL]

Hi s. 47F(1),

I understand the main question is what is DAFF's position if STEC is confirmed in export meat samples during the trial?

s. 47F(1): Yes, correct this is the main point.

(1)****It should be highlighted that we are planning to not be testing the samples upon being delivered into the laboratory. The plan was to collect all the samples and test at a later stage in a batch/group. Meaning the product would potentially already be out there in the market.

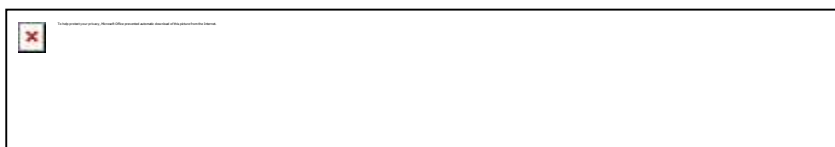
Happy for you to comment on this point (1) as well if the advice is that it should be done differently to get the project over the line.

Are there other aspects of the trial report that you want us to comment on?

s. 47F(1): Open to receiving any other comments or feedback you may have.



s. 47F(1)



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<http://www.merieuxnutrisciences.com/au>
Follow us on:  

On Thu, Sep 15, 2022 at 8:30 AM s. 22(1)(a)(ii) @awe.gov.au> wrote:

Hi B s. 47F(1),

Thanks for sending the signed document. Attached is the completed signing page. I'll send through a full scanned copy shortly.

My colleagues and I will have a look at the trial proposal. I understand the main question is what is DAFF's position if STEC is confirmed in export meat samples during the trial? Are there other aspects of the trial report that you want us to comment on?

Regards,

s. 22(1)(a)(ii)

From: s. 47F(1) @mxns.com>
Sent: Tuesday, 13 September 2022 2:00 PM
To: s. 22(1)(a)(ii) @awe.gov.au>
Subject: Re: Introduction and advice [SEC=UNOFFICIAL]

Hi s. 22(1)(a)(ii)

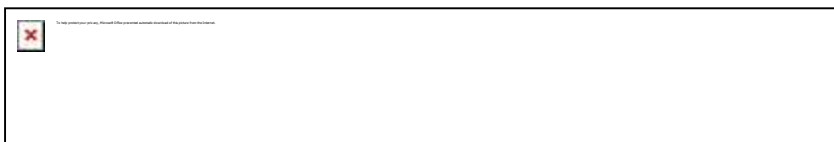
Appologies, see attached updated signed document.

Let me know if you have any more questions?

When would be a good time to touch base and discuss?



s. 47F(1)



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On Thu, Sep 8, 2022 at 11:11 AM s. 22(1)(a)(ii) [@awe.gov.au](mailto:s.22(1)(a)(ii)@awe.gov.au)> wrote:

Hi s. 47F(1),

Thanks for forwarding the signed deed and trial information.

However, I believe the deed has been signed incorrectly – it needs to be signed and witnessed in the section for your organisation at the bottom of the signing page, with the name of your organisation included where indicated.

Regards,

s. 22(1)(a)(ii)

From: s. 47F(1) [@mxns.com](mailto:s.47F(1)@mxns.com)>
Sent: Tuesday, 6 September 2022 11:54 AM
To: s. 22(1)(a)(ii) [@awe.gov.au](mailto:s.22(1)(a)(ii)@awe.gov.au)>
Subject: Re: Introduction and advice [SEC=UNOFFICIAL]

Hello s. 22(1)(a)(ii),

Thank you very much for your support.

Please find attached signed copy of the Deed word document and PDF version.

I have also attached the copy of the experimental design/protocol.

I look forward to your feedback,



s. 47F(1)



Mérieux NutriSciences

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On Tue, Aug 23, 2022 at 3:49 PM s. 22(1)(a)(ii) [@awe.gov.au](mailto:s.22(1)(a)(ii)@awe.gov.au)> wrote:

Hi s. 47F(1),

As Australian Public Service (APS) employees we are subject to a range of Commonwealth laws that impose very strict confidentiality obligations (summarised below).

Summary of relevant Commonwealth laws

- Regulation 2.1(4) of the Public Service Regulations 1999 which provides that APS employees must not disclose information obtained or generated 'in connection' with their work that may harm the government, was communicated in confidence within the government or was received by the government from someone outside the government. Regulation 2.1(4) is part of the APS Code of Conduct. A wide range of sanctions can be imposed on a person determined to have breached the APS Code of Conduct - including termination of employment (section 15(1) of the Public Service Act 1999 (PSA)).
- Section 28 of the Public Governance, Performance and Accountability Act 2013 provides that a person who obtains information because they are an official of a Commonwealth entity must not improperly use the information to gain or seek to gain a benefit or an advantage for themselves or someone else or to cause or seek to cause detriment to the Commonwealth entity or someone else.
- Section 122.4(1) of the Criminal Code Act 1995 makes it an offence for a person to communicate information, if the person obtained the information by virtue of being a Commonwealth officer or was otherwise engaged to perform work for a Commonwealth entity and that person was under a duty, under a Commonwealth law, not to disclose the information. This offence is punishable by 2 years imprisonment.

We trust this gives you confidence that the department will keep the Project Protocol confidential. If however this is not satisfactory to MXNS, please let us know as the department would be open to signing the department's standard deed of confidentiality (copy attached for information).

Regards,

s. 22(1)(a)(ii)

From: s. 47F(1) @mxns.com>
Sent: Tuesday, 23 August 2022 1:06 PM
To: s. 22(1)(a)(ii) @awe.gov.au>
Subject: Re: Introduction and advice [SEC=UNOFFICIAL]

Hi

s. 22(1)(a)(ii)

,

It's a new technology adoption case study project with the MLA.

The project will be funded through the individual processing sites - Plant Initiated Project (PIP).



s. 47F(1)



Mérieux NutriSciences

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[@awe.gov.au](mailto:s.22(1)(a)(ii)@awe.gov.au)> wrote:

Hi ^{s. 47F(1)},

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Regards,

^{s. 22(1)(a)(ii)}

From: s. 47F(1) @mxns.com>
Sent: Thursday, 18 August 2022 9:20 AM
To: s. 22(1)(a)(ii) @awe.gov.au>
Subject: Re: Introduction and advice [SEC=UNOFFICIAL]

Hi ^{s. 22(1)(a)(ii)},

This is greatly appreciated under the circumstances as I'm asking for your help and advice on a subject matter.
But requesting an NDA to be signed first.

However this has been the recommendation from my legal team that I must follow.



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Let me know if you have any further questions?



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[@awe.gov.au](mailto:s.22(1)(a)(ii)@awe.gov.au)> wrote:

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s. 22(1)(a)(ii)

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Sent: Tuesday, 26 July 2022 4:07 PM
To: s. 22(1)(a)(ii) [@awe.gov.au](mailto:s.22(1)(a)(ii)@awe.gov.au)>
Subject: Re: Introduction and advice [SEC=UNOFFICIAL]

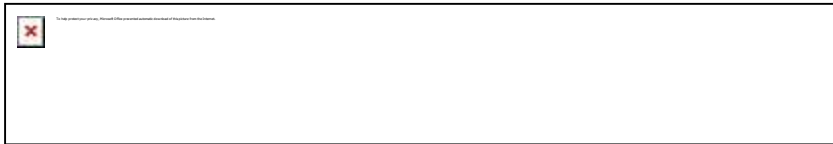
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Regards,

s. 22(1)(a)(ii)

s. 22(1)(a)(ii)

Principal – Microbiology and Laboratory Oversight | Residues and Microbiological Policy | Export Standards Branch | Exports and Veterinary Services Division

Phone s. 22(1)(a)(ii) | **Mobile** s. 47F(1) | **Email** s. 22(1)(a)(ii) [@agriculture.gov.au](mailto:s.22(1)(a)(ii)@agriculture.gov.au)

Department of Agriculture, Fisheries and Forestry

255 Melrose Drive

Tullamarine VIC 3043 Australia

Postal address: PO Box 858 Canberra City ACT 2601

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Sent: Tuesday, 26 July 2022 3:17 PM
To: s. 22(1)(a)(ii) <@awe.gov.au>
Subject: Introduction and advice [SEC=UNOFFICIAL]

Hello ^{s. 22(1)(a)(ii)} ,

I hope this email finds you well?

I would like to introduce myself my name is s. 47F(1) I'm Merieux Nutriscines business development manager.

Your details have been passed onto myself as I seek your advice.

It's in regards to a project design we are currently working on for the export meat industry, currently we have hit a hurdle that I will need some clarification on.

When would be the best time for me to contact you to discuss further?

I look forward to your reply,



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s. 22(1)(a)(ii)

From: s. 22(1)(a)(ii)
Sent: Friday, 28 October 2022 8:39 AM
To: s. 47F(1)
Subject: RE: Back from Leave [SEC=UNOFFICIAL]

Hi ^{s. 47F(1)},

Apologies for the delay with this one.

I've just had a question from our legal area. They've asked whether Merieux Nutrisciences is sourcing the meat samples for this trial directly from the meat processing businesses, or whether the Department of Agriculture, Fisheries and Forestry (DAFF) is involved in sampling in any way and passing on samples to Merieux Nutrisciences.

I presume DAFF isn't involved in sampling and Merieux Nutrisciences is sourcing meat samples directly. Can you please confirm?

Kind regards,

^{s. 22(1)(a)(ii)}

From: s. 47F(1)
Sent: Wednesday, 12 October 2022 9:35 AM
To: s. 22(1)(a)(ii)
Subject: Re: Back from Leave [SEC=UNOFFICIAL]

Thanks for the update ^{s. 22(1)(a)(ii)},

Greatly appreciated.

s. 47F(1)

Mérieux NutriSciences
Unit C2/391 Park Rd, Regents Park NSW 2143, Australia
Phone: 1300 000 990
Direct: +s. 47F(1)
Mobile: +s. 47F(1)
Email: s. 47F(1) @mxns.com
<http://www.merieuxnutrisciences.com/au>

Follow us on:

On Wed, Oct 12, 2022 at 9:22 AM **s. 22(1)(a)(ii)** <@awe.gov.au> wrote:

Hi **s. 47F(1)**,

I had a meeting with our legal area last week – they are in the process of providing me with some advice. I'll let you know as soon as I have something.

Regards,

s. 22(1)(a)(ii)

From: **s. 47F(1)** <@mxns.com>
Sent: Tuesday, 11 October 2022 10:13 AM
To: **s. 22(1)(a)(ii)** <@awe.gov.au>
Subject: Back from Leave [SEC=UNOFFICIAL]

Hi **s. 22(1)(a)(ii)**,

Are you back from leave? Do you have any further updates?

s. 47F(1)

Mérieux NutriSciences
Unit C2/391 Park Rd, Regents Park NSW 2143, Australia
Phone: 1300 000 990
Direct: **+s. 47F(1)**
Mobile: **+s. 47F(1)**

Email: [s. 47F\(1\) @mxns.com](mailto:s.47F(1)@mxns.com)

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S. 42(1)

S. 42(1)

s. 42(1)

From: s. 22(1)(a)(ii) @agriculture.gov.au>
Sent: Thursday, 15 September 2022 10:56 AM
To: s. 22(1)(a)(ii) @agriculture.gov.au; s. 22(1)(a)(ii)

<s. 22(1)(a)(ii) @agriculture.gov.au>

Cc: s. 22(1)(a)(ii) @agriculture.gov.au>

Subject: STEC method trial - response following positives [SEC=UNOFFICIAL]

Hi s. 22(1)(a)(ii),

Wondering if I can get your thoughts. Merieux Nutrisciences is about to conduct a study for MLA, verifying the performance of a new dept-approved STEC confirmation method and comparing testing time with the standard US method. They'll be collecting samples of grinding beef and conducting their study after product has been exported. They want to know DAFF's position if any products test positive for STEC in their trial.

My view would be that we would need to take action if a pathogen is detected in meat and we know it would potentially breach an importing country requirement, regardless of whether exported lots passed STEC testing. It's possible some samples will be drawn from meat exported to Canada/US.

Do you have any thoughts?

Regards,

s. 22(1)(a)(ii)

From: s. 47F(1) @mxns.com>

Sent: Thursday, 15 September 2022 10:32 AM

To: s. 22(1)(a)(ii) @awe.gov.au>

Subject: Re: Introduction and advice [SEC=UNOFFICIAL]

Hi s. 22(1)(a)(ii),

I understand the main question is what is DAFF's position if STEC is confirmed in export meat samples during the trial?

s. 47F(1): Yes, correct this is the main point.

(1)****It should be highlighted that we are planning to not be testing the samples upon being delivered into the laboratory. The plan was to collect all the samples and test at a later stage in a batch/group. Meaning the product would potentially already be out there in the market.

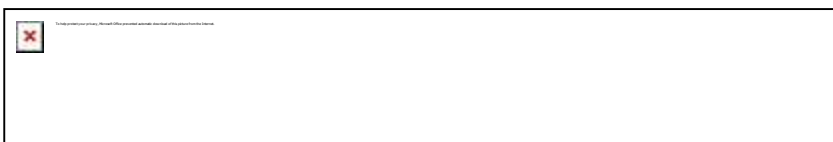
Happy for you to comment on this point (1) as well if the advice is that it should be done differently to get the project over the line.

Are there other aspects of the trial report that you want us to comment on?

s. 47F(1): Open to receiving any other comments or feedback you may have.



s. 47F(1)



Mérieux NutriSciences
Unit C2/391 Park Rd, Regents Park NSW 2143, Australia
Phone: 1300 000 990
Direct: +s. 47F(1)
Mobile: +s. 47F(1)
Email: s. 47F(1) @mxns.com
<http://www.merieuxnutrisciences.com/au>

Follow us on:  

On Thu, Sep 15, 2022 at 8:30 AM s. 22(1)(a)(ii) @awe.gov.au> wrote:

Hi s. 47F(1),

Thanks for sending the signed document. Attached is the completed signing page. I'll send through a full scanned copy shortly.

My colleagues and I will have a look at the trial proposal. I understand the main question is what is DAFF's position if STEC is confirmed in export meat samples during the trial? Are there other aspects of the trial report that you want us to comment on?

Regards,

s. 22(1)(a)(ii)

From: s. 47F(1) @mxns.com>
Sent: Tuesday, 13 September 2022 2:00 PM
To: s. 22(1)(a)(ii) @awe.gov.au>
Subject: Re: Introduction and advice [SEC=UNOFFICIAL]

Hi s. 22(1)(a)(ii),

Appologies, see attached updated signed document.

Let me know if you have any more questions?

When would be a good time to touch base and discuss?



s. 47F(1)



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Sent: Tuesday, 6 September 2022 11:54 AM
To: s. 22(1)(a)(ii) @awe.gov.au>
Subject: Re: Introduction and advice [SEC=UNOFFICIAL]

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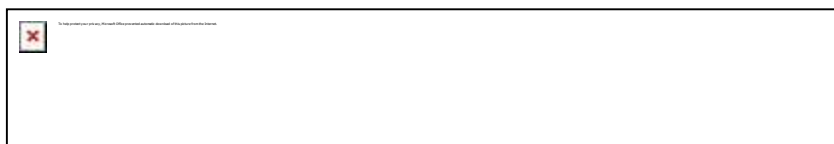
Please find attached signed copy of the Deed word document and PDF version.

I have also attached the copy of the experimental design/protocol.

I look forward to your feedback,



s. 47F(1)



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As Australian Public Service (APS) employees we are subject to a range of Commonwealth laws that impose very strict confidentiality obligations (summarised below).

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- Regulation 2.1(4) of the Public Service Regulations 1999 which provides that APS employees must not disclose information obtained or generated 'in connection' with their work that may harm the government, was communicated in confidence within the government or was received by the government from someone outside the government. Regulation 2.1(4) is part of the APS Code of Conduct. A wide range of sanctions can be imposed on a person determined to have breached the APS Code of Conduct - including termination of employment (section 15(1) of the Public Service Act 1999 (PSA)).
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We trust this gives you confidence that the department will keep the Project Protocol confidential. If however this is not satisfactory to MXNS, please let us know as the department would be open to signing the department's standard deed of confidentiality (copy attached for information).

Regards,

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From: s. 47F(1) @mxns.com>
Sent: Tuesday, 23 August 2022 1:06 PM
To: s. 22(1)(a)(ii) @awe.gov.au>
Subject: Re: Introduction and advice [SEC=UNOFFICIAL]

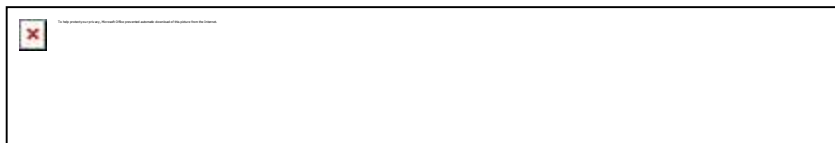
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The project will be funded through the individual processing sites - Plant Initiated Project (PIP).



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On Tue, Aug 23, 2022 at 11:37 AM **s. 22(1)(a)(ii)** <@awe.gov.au> wrote:

Hi ^{s. 47F(1)},

Our lawyers are in the process of providing me with some advice but have asked a clarifying question. Can you please remind me – I think you said your project is being funded by AMPC. Is that correct? Is that the connection between MXNS and AMPC for your project?

Regards,
^{s. 22(1)(a)(ii)}

From: **s. 47F(1)** <@mxns.com>
Sent: Thursday, 18 August 2022 9:20 AM
To: **s. 22(1)(a)(ii)** <@awe.gov.au>
Subject: Re: Introduction and advice [SEC=UNOFFICIAL]

Hi ^{s. 22(1)(a)(ii)},

This is greatly appreciated under the circumstances as I'm asking for your help and advice on a subject matter. But requesting an NDA to be signed first.

However this has been the recommendation from my legal team that I must follow.



s. 47F(1)



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On Thu, Aug 18, 2022 at 9:02 AM s. 22(1)(a)(ii) @awe.gov.au wrote:

Thanks ^{s. 47F(1)} All going well here. I'll run this past our legal area and will then send back to you ASAP.

Kind regards,

^{s. 22(1)(a)(ii)}

From: s. 47F(1) [@mxns.com](mailto:s.47F(1)@mxns.com)>
Sent: Wednesday, 17 August 2022 3:00 PM
To: s. 22(1)(a)(ii) @awe.gov.au>
Subject: Re: Introduction and advice [SEC=UNOFFICIAL]

Hi ^{s. 22(1)(a)(ii)},

How have you been?

Appologies for the slow response as I have been in contact with legal back and forth.

I really appreciate your support and advice on this matter of the project with MLA.

The advice from my legal team is that MXNS will require the department to sign the attached NDA before I share the protocol with you.

Let me know if you have any further questions?



s. 47F(1)



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On Tue, Jul 26, 2022 at 4:16 PM s. 22(1)(a)(ii)

[@awe.gov.au](mailto:s.22(1)(a)(ii)@awe.gov.au)> wrote:

Sounds good s. 47F(1) – talk then.

Regards,

s. 22(1)(a)(ii)

From: s. 47F(1) <[s.47F\(1\)@mxns.com](mailto:s.47F(1)@mxns.com)>
Sent: Tuesday, 26 July 2022 4:07 PM
To: s. 22(1)(a)(ii) <[s.22\(1\)\(a\)\(ii\)@awe.gov.au](mailto:s.22(1)(a)(ii)@awe.gov.au)>
Subject: Re: Introduction and advice [SEC=UNOFFICIAL]

Apologies ^{s. 22(1)(a)(ii)},

I meant I'll call you tomorrow between 4 & 5.


I'll send you a meeting invite as a reminder.



s. 47F(1)



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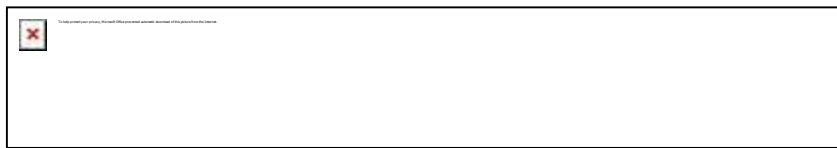
On Tue, Jul 26, 2022 at 4:06 PM s. 47F(1) <[s.47F\(1\)@mxns.com](mailto:s.47F(1)@mxns.com)> wrote:

Thanks ^{s. 22(1)(a)(ii)},

I'll call you now.



s. 47F(1)



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<http://www.merieuxnutrisciences.com/au>

Follow us on:  

On Tue, Jul 26, 2022 at 4:05 PM s. 22(1)(a)(ii)

[@awe.gov.au](mailto:s.22(1)(a)(ii)@awe.gov.au)> wrote:

Hi ^{s. 47F(1)},

I have some time tomorrow between 4 and 5. Would that work for you? Happy to discuss.

Regards,

^{s. 22(1)(a)(ii)}

s. 22(1)(a)(ii)

Principal – Microbiology and Laboratory Oversight | Residues and Microbiological Policy | Export Standards Branch | Exports and Veterinary Services Division

Phone s. 22(1)(a)(ii) | Mobile s. 47F(1) | Email s. 22(1)(a)(ii)@agriculture.gov.au

Department of Agriculture, Fisheries and Forestry

255 Melrose Drive

Tullamarine VIC 3043 Australia

Postal address: PO Box 858 Canberra City ACT 2601

From: s. 47F(1) @mxns.com>
Sent: Tuesday, 26 July 2022 3:17 PM
To: s. 22(1)(a)(ii)@awe.gov.au
Subject: Introduction and advice [SEC=UNOFFICIAL]

Hello s. 22(1)(a)(ii),

I hope this email finds you well?

I would like to introduce myself my name is s. 47F(1) I'm Merieux Nutriscines business development manager.

Your details have been passed onto myself as I seek your advice.

It's in regards to a project design we are currently working on for the export meat industry, currently we have hit a hurdle that I will need some clarification on.

When would be the best time for me to contact you to discuss further?

I look forward to your reply,



s. 47F(1)



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s. 22(1)(a)(ii)

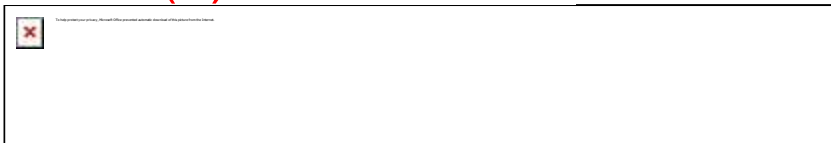
From: s. 47F(1) @mxns.com>
Sent: Monday, 31 October 2022 9:05 AM
To: s. 22(1)(a)(ii)
Subject: Re: Back from Leave [SEC=UNOFFICIAL]

Hi s. 22(1)(a)(ii),

Correct, Samples would be sourced directly from the plants as part of the adoption case study, PIP (Plant Initiated Program).



s. 47F(1)



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Follow us on:  

On Fri, Oct 28, 2022 at 8:38 AM s. 22(1)(a)(ii) @awe.gov.au> wrote:

Hi s. 47F(1),

Apologies for the delay with this one.

I've just had a question from our legal area. They've asked whether Mérieux NutriSciences is sourcing the meat samples for this trial directly from the meat processing businesses, or whether the Department of Agriculture, Fisheries and Forestry (DAFF) is involved in sampling in any way and passing on samples to Mérieux NutriSciences.

I presume DAFF isn't involved in sampling and Mérieux NutriSciences is sourcing meat samples directly. Can you please confirm?

Kind regards,

From: s. 47F(1) @mxns.com>
Sent: Wednesday, 12 October 2022 9:35 AM
To: s. 22(1)(a)(ii) @awe.gov.au>
Subject: Re: Back from Leave [SEC=UNOFFICIAL]

Thanks for the update ^{s. 22(1)(a)(ii)},

Greatly appreciated.

s. 47F(1)

Mérieux NutriSciences

Unit C2/391 Park Rd, Regents Park NSW 2143, Australia

Phone: 1300 000 990

Direct: +s. 47F(1)

Mobile: +s. 47F(1)

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Follow us on:

On Wed, Oct 12, 2022 at 9:22 AM s. 22(1)(a)(ii) @awe.gov.au> wrote:

Hi ^{s. 47F(1)},

I had a meeting with our legal area last week – they are in the process of providing me with some advice. I'll let you know as soon as I have something.

Regards,

From: s. 47F(1) <[s.47F\(1\)@mxns.com](mailto:s.47F(1)@mxns.com)>
Sent: Tuesday, 11 October 2022 10:13 AM
To: s. 22(1)(a)(ii) <[s.22\(1\)\(a\)\(ii\)@awe.gov.au](mailto:s.22(1)(a)(ii)@awe.gov.au)>
Subject: Back from Leave [SEC=UNOFFICIAL]

Hi ^{s. 22(1)(a)(ii)},

Are you back from leave? Do you have any further updates?

s. 47F(1)

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S. 42(1)

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From: s. 22(1)(a)(ii) @agriculture.gov.au>
Sent: Thursday, 15 September 2022 10:56 AM
To: s. 22(1)(a)(ii) @agriculture.gov.au>; s. 22(1)(a)(ii) @agriculture.gov.au>
Cc: s. 22(1)(a)(ii) @agriculture.gov.au>
Subject: STEC method trial - response following positives [SEC=UNOFFICIAL]

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I have also attached the copy of the experimental design/protocol.

I look forward to your feedback,

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Subject: Re: Introduction and advice [SEC=UNOFFICIAL]

Hi ^{s. 22(1)(a)(ii)},

This is greatly appreciated under the circumstances as I'm asking for your help and advice on a subject matter. But requesting an NDA to be signed first.

However this has been the recommendation from my legal team that I must follow.

s. 47F(1)

Mérieux NutriSciences

Unit C2/391 Park Rd, Regents Park NSW 2143, Australia

Phone: 1300 000 990

Direct: +s. 47F(1)

Mobile: +s. 47F(1)

Email: s. 47F(1) [@mxns.com](mailto:s.47F(1)@mxns.com)

<http://www.merieuxnutrisciences.com/au>

Follow us on:

On Thu, Aug 18, 2022 at 9:02 AM s. 22(1)(a)(ii) [@awe.gov.au](mailto:s.22(1)(a)(ii)@awe.gov.au)> wrote:

Thanks ^{s. 47F(1)}. All going well here. I'll run this past our legal area and will then send back to you ASAP.

Kind regards,

From: s. 47F(1) @mxns.com>
Sent: Wednesday, 17 August 2022 3:00 PM
To: s. 22(1)(a)(ii) @awe.gov.au>
Subject: Re: Introduction and advice [SEC=UNOFFICIAL]

Hi ^{s. 22(1)(a)(ii)},

How have you been?

Appologies for the slow response as I have been in contact with legal back and forth.

I really appreciate your support and advice on this matter of the project with MLA.

The advice from my legal team is that MXNS will require the department to sign the attached NDA before I share the protocol with you.

Let me know if you have any further questions?

s. 47F(1)

Mérieux NutriSciences
Unit C2/391 Park Rd, Regents Park NSW 2143, Australia
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<http://www.merieuxnutrisciences.com/au>

Follow us on:

On Tue, Jul 26, 2022 at 4:16 PM s. 22(1)(a)(ii) @awe.gov.au> wrote:

Sounds good s. 47F(1) – talk then.

Regards,

s. 22(1)(a)(ii)

From: s. 47F(1) @mxns.com>
Sent: Tuesday, 26 July 2022 4:07 PM
To: s. 22(1)(a)(ii) @awe.gov.au>
Subject: Re: Introduction and advice [SEC=UNOFFICIAL]

Apologies s. 22(1)(a)(ii),

I meant I'll call you tomorrow between 4 & 5.

I'll send you a meeting invite as a reminder.

s. 47F(1)

Mérieux NutriSciences

Unit C2/391 Park Rd, Regents Park NSW 2143, Australia

Phone: 1300 000 990

Direct: +s. 47F(1)

Mobile: +s. 47F(1)

Email: s. 47F(1) [@mxns.com](mailto:s.47F(1)@mxns.com)

<http://www.merieuxnutrisciences.com/au>

Follow us on:

On Tue, Jul 26, 2022 at 4:06 PM s. 47F(1) [@mxns.com](mailto:s.47F(1)@mxns.com)> wrote:

Thanks ^{s. 22(1)(a)(ii)},

I'll call you now.

s. 47F(1)

Mérieux NutriSciences

Unit C2/391 Park Rd, Regents Park NSW 2143, Australia

Phone: 1300 000 990

Direct: +6s. 47F(1)

Mobile: +s. 47F(1)

Email: s. 47F(1) @mxns.com

<http://www.merieuxnutrisciences.com/au>

Follow us on:

On Tue, Jul 26, 2022 at 4:05 PM s. 22(1)(a)(ii) @awe.gov.au> wrote:

Hi s. 47F(1),

I have some time tomorrow between 4 and 5. Would that work for you? Happy to discuss.

Regards,

s. 22(1)(a)(ii)

s. 22(1)(a)(ii)

Principal – Microbiology and Laboratory Oversight | Residues and Microbiological Policy | Export Standards Branch | Exports and Veterinary Services Division

Phone +s. 22(1)(a)(ii) | **Mobile** s. 47F(1) | **Email** s. 22(1)(a)(ii)@agriculture.gov.au

Department of Agriculture, Fisheries and Forestry

255 Melrose Drive

Tullamarine VIC 3043 Australia

Postal address: PO Box 858 Canberra City ACT 2601

From: s. 47F(1) <[s.47F\(1\)@mxns.com](mailto:s.47F(1)@mxns.com)>
Sent: Tuesday, 26 July 2022 3:17 PM
To: s. 22(1)(a)(ii) <[s.22\(1\)\(a\)\(ii\)@awe.gov.au](mailto:s.22(1)(a)(ii)@awe.gov.au)>
Subject: Introduction and advice [SEC=UNOFFICIAL]

Hello ^{s. 22(1)(a)(ii)},

I hope this email finds you well?

I would like to introduce myself my name is s. 47F(1) I'm Merieux Nutriscinces business development manager.

Your details have been passed onto myself as I seek your advice.

It's in regards to a project design we are currently working on for the export meat industry, currently we have hit a hurdle that I will need some clarification on.

When would be the best time for me to contact you to discuss further?

I look forward to your reply,

s. 47F(1)

Mérieux NutriSciences
Unit C2/391 Park Rd, Regents Park NSW 2143, Australia
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s. 22(1)(a)(ii)

From: s. 47F(1) @mxns.com>
Sent: Wednesday, 1 February 2023 4:43 PM
To: s. 22(1)(a)(ii)
Cc: Lucy Evans; s. 47F(1) ; s. 22(1)(a)(ii)
Subject: Re: Request for change to list of Approved Tests for Silliker Melbourne Site [SEC=UNOFFICIAL]

Yes that's right s. 22(1)(a)(ii), NATA have assessed both screening and confirmation for these methods. I will get our relevant documents together tomorrow and send them to you.

Thanks and best regards,



Melinda Skipper
National Quality Assurance Manager



Mérieux NutriSciences
20 King Street, Blackburn, Victoria 3130, Australia
Phone: 1300 000 990
Direct: +s. 47F(1)
<http://www.merieuxnutrisciences.com/au>

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On Wed, Feb 1, 2023 at 4:33 PM s. 22(1)(a)(ii)

@aff.gov.au> wrote:

Hi Melinda,

Further to my previous email, I presume NATA has assessed both screening and confirmation components of AOAC 2020.06. Could you kindly confirm this.

Kind regards

s. 22(1)(a)(ii)

From: s. 22(1)(a)(ii)
Sent: Wednesday, 1 February 2023 4:03 PM
To: Melinda Skipper <s. 47F(1) @mxns.com>

Cc: s. 47F(1) @mxns.com>; s. 47F(1)
<s. 47F(1) @mxns.com>; s. 22(1)(a)(ii) @aff.gov.au>
Subject: RE: Request for change to list of Approved Tests for Silliker Melbourne Site
[SEC=UNOFFICIAL]

Hi Melinda,

We are going well thanks.

We are happy to approve both methods. Please note AOAC 2019.03 is a screening method for E. coli O157:H7 and AOAC 2020.06 is a screening and confirmation method for all seven STEC (including O157).

I believe the lab has conducted verification test on both methods. I would appreciate if you please provide us with the verification results along with method SOPs (AOAC 2019.03 and AOAC 2020.06) for our review.

Apologies, the Approved Method document is an old version, we will update the document to include AOAC 2020.06 as STEC confirmation method.

Kind regards

s. 22(1)(a)(ii)

s. 22(1)(a)(ii)

Microbiologist | Residues and Microbiological Policy

Tel: + s. 22(1)(a)(ii) | Ext. s. 22(1)(a)(ii)

Department of Agriculture, Fisheries and Forestry

Export Standards Branch | Exports and Veterinary Services Division

70 Northbourne Ave, Canberra ACT 2601 Australia

GPO Box 858 Canberra ACT 2601 Australia

From: Melinda Skipper <s. 47F(1) @mxns.com>
Sent: Wednesday, 1 February 2023 3:02 PM
To: s. 22(1)(a)(ii) @awe.gov.au>; s. 22(1)(a)(ii) @awe.gov.au>
Cc: Lucy Evans <s. 47F(1) @mxns.com>; s. 47F(1)
<s. 47F(1) @mxns.com>
Subject: Request for change to list of Approved Tests for Silliker Melbourne Site [SEC=UNOFFICIAL]

Hi s. 22(1)(a)(ii) and s. 22(1)(a)(ii),

Hope you are both well.

We would like to request an addition to our list of approved methods for our Melbourne site if possible please, to include *E. coli* O157 by Gene-Up AOAC 2019.03 and STEC by Gene-Up AOAC 2020.06 for Meat and Meat Products.

We have recently received NATA accreditation for these tests under meat testing for Agribusiness and I have attached our NATA scope or your review.

I have also attached our current list of export meat approved tests for your reference.

Also, just a question regarding the confirmation of *E. coli* O157 and STEC organisms: the AOAC reference documents include confirmation of the organisms in question, but as in part of our preparation of this request, we noticed the following comments in your Approved Methods document:

***Escherichia coli* O157:H7**

- | | |
|--------------------------------|--|
| ➤ ISO 16654:2001 | Microbiology of food and animal feeding stuffs – Horizontal method for the detection of <i>Escherichia coli</i> O157

Note - when analysing frozen or chilled samples, the temperature of broth and samples must be at $41.5 \pm 1^\circ\text{C}$ for a minimum of 6 h and subsequently for a further 12 to 18 hours. |
| ➤ FSIS MLG 5 | Detection, isolation, and identification of <i>Escherichia coli</i> O157:H7 from meat products

Note the method has been updated changing the initial enrichment to mTSB and the definition of <i>E. coli</i> O157:H7. When analysing frozen or chilled samples, the temperature of broth and samples must be at $42 \pm 1^\circ\text{C}$ for a minimum of 15 hours. |
| ➤ FDA BAM Chapter 4A(K) | Diarrheagenic <i>Escherichia coli</i> - Enrichment and isolation of <i>E. coli</i> Serotype O157:H7 from Foods

With the following modification; must use the IMS option and a sample size of 325 g for ground beef, analysed as five separate 65 g portions |

Rapid methods

Where positive confirmation is required such confirmation must be by ISO 16654:2001, FDA BAM 4A(K) or FSIS MLG 5

Note all modifications/notes listed for each method must be followed

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

-
- **FSIS MLG 5B** Detection and isolation of non-O157 Shiga-toxin Producing *Escherichia coli* (STEC) from meat products
-

Rapid methods

Where positive confirmation is required such confirmation must be by FSIS MLG 5B

-
- **AOAC 071301** Assurance GDS® MPX Top 7 STEC for detection of top 7 pathogenic STEC in beef trim
- Samples (375 g) are diluted in 1.5 L of pre-warmed (42°C) mHEEC medium. Incubation is carried out for 10 h at 42°C. Note – temperature of broth and samples must be 42 ± 1°C for a minimum of 10 hours
-
- **AOAC 091301** DuPont Qualicon BAX® System Real-Time PCR Assays for detection of selected STEC in beef trim
- Samples (375 g) are diluted in 1.5 L pre-warmed (45-46°C) Bax® System MP enrichment broth. Samples are incubated at 39-42°C for 12-24 h. Note – temperature of broth and samples must be at 39-42°C for a minimum of 12 hours.
-
- **AOAC 0100701** IEH *E. coli* Test System for detection of non-O157 Shiga-toxin producing *E. coli* and *E. coli* O157 in raw ground beef
- Samples (375 g) are diluted in 750 mL of pre-warmed IEH enrichment medium.
-

Can you advise whether confirmation by the AOAC methods in question have been approved by your Department. I think we have received letters from Biomeriueux indicating that both Gene-Up methods have been approved by you for screening and confirmation, would this be correct?

Looking forward to hearing back from you.

Thanks and best regards,

Melinda.



Melinda Skipper

National Quality Assurance Manager





Mérieux NutriSciences

20 King Street, Blackburn, Victoria 3130, Australia

Phone: 1300 000 990

Direct: +s. 47F(1)

<http://www.merieuxnutrisciences.com/au>

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s. 22(1)(a)(ii)

From: s. 22(1)(a)(ii)
Sent: Monday, 13 February 2023 1:51 PM
To: s. 22(1)(a)(ii)
Subject: FW: Request for change to list of Approved Tests for Silliker Melbourne Site [SEC=UNOFFICIAL]
Attachments: M143 Detection of E.coli 0157 in Meat Samples using GENE UP Real-Time PCR.pdf; M142 Detection of Enterohemorrhagic Escherichia coli (EHEC) in Meat Samples using GENE-UP Real-Time PCR.pdf; Form 373 IV_2021_009 Verification of E.coli 0157H7 using GENE UP E.coli 0157H7 ECO 2.pdf; Form 373 Verification of EHEC GENE UP Melbourne.pdf; Silliker Melbourne 13 02 2023.docx

Hi ^{s. 22(1)(a)(ii)},

I have reviewed Silliker (Melbourne) GENE UP confirmation methods and validation study. They have conducted verification on both methods which I believe NATA accepted.

I have also identified some issues as below. Please let me know if you agree or if you identify any other issues. I also attached a draft approval letter.

S. 47C(1)

Kind regards
^{s. 22(1)(a)(ii)}

From: Melinda Skipper

Sent: Thursday, 2 February 2023 10:15 AM

To: s. 22(1)(a)(ii)

Cc: s. 22(1)(a)(ii) ; Lucy Evans ; s. 47F(1) ; s. 47F(1)

Subject: Re: Request for change to list of Approved Tests for Silliker Melbourne Site [SEC=UNOFFICIAL]

Hi s. 22(1)(a)(ii),

I have attached our internal test methods, which are based on AOAC 2019.03 and AOAC 2020.06 and also the verification data for both, as you requested.


Let me know if you need anything else.

Thanks and best regards,
Melinda.



Melinda Skipper
National Quality Assurance Manager



Mérieux NutriSciences
20 King Street, Blackburn, Victoria 3130, Australia
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On Wed, Feb 1, 2023 at 4:46 PM s. 22(1)(a)(ii)

[@aff.gov.au](#)> wrote:

Thanks for confirming.

Kind regards

s. 22(1)(a)(ii)

From: Melinda Skipper <s. 47F(1) @mxns.com>
Sent: Wednesday, 1 February 2023 4:43 PM
To: s. 22(1)(a)(ii) @aff.gov.au>
Cc: Lucy Evans <s. 47F(1)@mxns.com>; s. 47F(1) @mxns.com>; s. 22(1)(a)(ii) <s. 22(1)(a)(ii)@aff.gov.au>
Subject: Re: Request for change to list of Approved Tests for Silliker Melbourne Site [SEC=UNOFFICIAL]

Yes that's right s. 22(1)(a)(ii), NATA have assessed both screening and confirmation for these methods. I will get our relevant documents together tomorrow and send them to you.



Thanks and best regards,



Melinda Skipper
National Quality Assurance Manager



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s. 22(1)(a)(ii)

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Sent: Wednesday, 1 February 2023 4:03 PM

To: Melinda Skipper <s. 47F(1) @mxns.com>

Cc: Lucy Evans <s. 47F(1)@mxns.com>; s. 47F(1) @mxns.com>; s. 22(1)(a)(ii) <s. 22(1)(a)(ii)@aff.gov.au>

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Apologies, the Approved Method document is an old version, we will update the document to include AOAC 2020.06 as STEC confirmation method.

Kind regards

s. 22(1)(a)(ii)

s. 22(1)(a)(ii)

Microbiologist | Residues and Microbiological Policy

Tel: + s. 22(1)(a)(ii) | Ext. s. 22(1)(a)(ii)

Department of Agriculture, Fisheries and Forestry

Export Standards Branch | Exports and Veterinary Services Division

70 Northbourne Ave, Canberra ACT 2601 Australia

GPO Box 858 Canberra ACT 2601 Australia

From: Melinda Skipper <s. 47F(1) @mxns.com>
Sent: Wednesday, 1 February 2023 3:02 PM
To: s. 22(1)(a)(ii) @awe.gov.au>; s. 22(1)(a)(ii) @awe.gov.au>
Cc: Lucy Evans <s. 47F(1)@mxns.com>; s. 47F(1) @mxns.com>
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Escherichia coli O157:H7

- | | |
|--------------------------------|--|
| ➤ ISO 16654:2001 | Microbiology of food and animal feeding stuffs – Horizontal method for the detection of <i>Escherichia coli</i> O157

Note - when analysing frozen or chilled samples, the temperature of broth and samples must be at $41.5 \pm 1^\circ\text{C}$ for a minimum of 6 h and subsequently for a further 12 to 18 hours. |
| ➤ FSIS MLG 5 | Detection, isolation, and identification of <i>Escherichia coli</i> O157:H7 from meat products

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Rapid methods

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Note all modifications/notes listed for each method must be followed

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

- | | |
|----------------------|---|
| ➤ FSIS MLG 5B | Detection and isolation of non-O157 Shiga-toxin Producing <i>Escherichia coli</i> (STEC) from meat products |
|----------------------|---|

Rapid methods

Where positive confirmation is required such confirmation must be by FSIS MLG 5B

- | | |
|-----------------------|--|
| ➤ AOAC 071301 | Assurance GDS® MPX Top 7 STEC for detection of top 7 pathogenic STEC in beef trim

Samples (375 g) are diluted in 1.5 L of pre-warmed (42°C) mEHEC medium. Incubation is carried out for 10 h at 42°C . Note – temperature of broth and samples must be $42 \pm 1^\circ\text{C}$ for a minimum of 10 hours |
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Samples (375 g) are diluted in 1.5 L pre-warmed ($45\text{--}46^\circ\text{C}$) Bax® System MP enrichment broth. Samples are incubated at $39\text{--}42^\circ\text{C}$ for 12-24 h. Note – temperature of broth and samples must be at $39\text{--}42^\circ\text{C}$ for a minimum of 12 hours. |
| ➤ AOAC 0100701 | IEH <i>E. coli</i> Test System for detection of non-O157 Shiga-toxin producing <i>E. coli</i> and <i>E. coli</i> O157 in raw ground beef

Samples (375 g) are diluted in 750 mL of pre-warmed IEH enrichment medium. |

Can you advise whether confirmation by the AOAC methods in question have been approved by your Department. I think we have received letters from Biomeriux indicating that both Gene-Up methods have been approved by you for screening and confirmation, would this be correct?

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Melinda.



Melinda Skipper

National Quality Assurance Manager





Mérieux NutriSciences

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<http://www.merieuxnutrisciences.com/au>

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