s. 42(1)

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>
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)

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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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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>
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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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 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>
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)

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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>
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> 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.

Ill send you a meeting invite as a reminder.

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:

> Thanks s. 22(1)(a)(ii),
>
> I'll call you now.

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:

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 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)

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s. 45(1),s. 47(1)(b)

s. 45(1),s. 47(1)(b)

s. 45(1),s. 47(1)(b)

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s. 45(1),s. 47(1)(b)

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

From: s. 22(1)(a)(ii)
Sent: Thursday, 16 February 2023 2:40 PM
To: s. 22(1)(a)(ii)
Subject: RE: Request for change to list of Approved Tests for Silliker Melbourne Site [SEC=UNOFFICIAL]

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

Yes, we need to add AOAC 2013.01 as well. Please see my comments below:

From: s. 22(1)(a)(ii)
Sent: Thursday, 16 February 2023 11:06 AM
To: s. 22(1)(a)(ii)
Subject: RE: Request for change to list of Approved Tests for Silliker Melbourne Site [SEC=UNOFFICIAL]

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

Thanks for reviewing these.

S. 47C(1)

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

s. 47C(1)

From: s. 22(1)(a)(ii) @aff.gov.au>
Sent: Monday, 13 February 2023 1:51 PM
To: s. 22(1)(a)(ii) @aff.gov.au>
Subject: FW: Request for change to list of Approved Tests for Silliker Melbourne Site [SEC=UNOFFICIAL]

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)

s. 47C(1)

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

From: Melinda Skipper <s. 47F(1) @mxns.com>
Sent: Thursday, 2 February 2023 10:15 AM
To: s. 22(1)(a)(ii) @aff.gov.au>
Cc: s. 22(1)(a)(ii) @aff.gov.au>; Lucy Evans <s. 47F(1)@mxns.com>; s. 47F(1) <s. 47F(1) @mxns.com>; s. 47F(1) @mxns.com>
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

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

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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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: 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]

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 anv 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>
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 *Escherichia coli* O157 Note - when analysing frozen or chilled samples, the temperature of broth and samples must be at 41.5 ± 1°C for a minimum of 6 h and subsequently for a further 12 to 18 hours.
➢ **FSIS MLG 5**	Detection, isolation, and identification of *Escherichia coli* O157:H7 from meat products Note the method has been updated changing the initial enrichment to mTSB and the definition of *E. coli* O157:H7. When analysing frozen or chilled samples, the temperature of broth and samples must be at 42 ± 1°C for a minimum of 15 hours.
➢ **FDA BAM Chapter 4A(K)**	Diarrheagenic *Escherichia coli* - Enrichment and isolation of *E. coli* 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) mEHEC 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 Biomeriuex 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

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Phone: 1300 000 990

Direct: +s. 47F(1)

http://www.merieuxnutrisciences.com/au

Follow us on:

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

From: s. 22(1)(a)(ii)
Sent: Thursday, 16 February 2023 11:06 AM
To: s. 22(1)(a)(ii)
Subject: RE: Request for change to list of Approved Tests for Silliker Melbourne Site [SEC=UNOFFICIAL]
Attachments: AOAC 2020.06 GENE-UP EHEC Detection Method 2020 2020_06.pdf; AOAC 2019.03-2019.pdf

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

Thanks for reviewing these.

s. 47C(1)

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

s. 47C(1)

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]

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)

s. 47C(1)

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

From: Melinda Skipper <s. 47F(1) @mxns.com>
Sent: Thursday, 2 February 2023 10:15 AM
To: s. 22(1)(a)(ii) @aff.gov.au>
Cc: s. 22(1)(a)(ii) @aff.gov.au>; Lucy Evans <s. 47F(1)@mxns.com>; s. 47F(1) <s. 47F(1) @mxns.com>; s. 47F(1) @mxns.com>
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

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Follow us on:

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: 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

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: 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]

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

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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 anv 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: s. 47F(1) @mxns.com>; s. 47F(1) @mxns.com>
Subject: Request for change to list of Approved Tests for Silliker Melbourne Site [SEC=UNOFFICIAL]

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We have recently received NATA accreditation for these tests under meat testing for Agribusiness and I have attached our NATA scope or your review.

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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:

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➢ **ISO 16654:2001**	Microbiology of food and animal feeding stuffs – Horizontal method for the detection of *Escherichia coli* O157 Note - when analysing frozen or chilled samples, the temperature of broth and samples must be at 41.5 ± 1°C for a minimum of 6 h and subsequently for a further 12 to 18 hours.
➢ **FSIS MLG 5**	Detection, isolation, and identification of *Escherichia coli* O157:H7 from meat products Note the method has been updated changing the initial enrichment to mTSB and the definition of *E. coli* O157:H7. When analysing frozen or chilled samples, the temperature of broth and samples must be at 42 ± 1°C for a minimum of 15 hours.
➢ **FDA BAM Chapter 4A(K)**	Diarrheagenic *Escherichia coli* - Enrichment and isolation of *E. coli* 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	

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➢ **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) mEHEC 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 Biomeriuex 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

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s. 45(1),s. 47(1)(b)

s. 45(1),s. 47(1)(b)

s. 45(1),s. 47(1)(b)

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s. 45(1),s. 47(1)(b)

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

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

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

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

From: s. 22(1)(a)(ii)
Sent: Friday, 17 February 2023 12:58 PM
To: s. 22(1)(a)(ii)
Subject: FW: Request for change to list of Approved Tests for Silliker Melbourne Site [SEC=UNOFFICIAL]
Attachments: Package_Insert_-_43-04330_-_D_-_en_-_GENE-UP_EHEC_Detection_Method.pdf

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

s. 47C(1)

Updated comments as below:
---

s. 47C(1)

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

From: s. 22(1)(a)(ii) @aff.gov.au>
Sent: Thursday, 16 February 2023 11:06 AM

To: 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 s. 22(1)(a)(ii),

Thanks for reviewing these.

s. 47C(1)

s. 47C(1)

From: s. 22(1)(a)(ii) @aff.gov.au>
Sent: Monday, 13 February 2023 1:51 PM
To: s. 22(1)(a)(ii) @aff.gov.au>
Subject: FW: Request for change to list of Approved Tests for Silliker Melbourne Site [SEC=UNOFFICIAL]

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)

s. 47C(1)

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

From: Melinda Skipper <s. 47F(1) @mxns.com>
Sent: Thursday, 2 February 2023 10:15 AM
To: s. 22(1)(a)(ii) @aff.gov.au>
Cc: s. 22(1)(a)(ii) @aff.gov.au>; Lucy Evans <s. 47F(1)@mxns.com>; s. 47F(1) <s. 47F(1) @mxns.com>; s. 47F(1) @mxns.com>
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

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About Mérieux Nutrisciences

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]

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National Quality Assurance Manager

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Hi Melinda,

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Kind regards

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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>
Subject: RE: Request for change to list of Approved Tests for Silliker Melbourne Site [SEC=UNOFFICIAL]

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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 anv 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>
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),

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Looking forward to hearing back from you.

Thanks and best regards,

Melinda.

Melinda Skipper

National Quality Assurance Manager

Mérieux NutriSciences

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s. 45(1),s. 47(1)(b)

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s. 45(1),s. 47(1)(b)

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s. 45(1),s. 47(1)(b)

s. 45(1),s. 47(1)(b)

s. 45(1),s. 47(1)(b)

s. 45(1),s. 47(1)(b)

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

From: s. 22(1)(a)(ii)
Sent: Friday, 17 February 2023 3:04 PM
To: Melinda Skipper
Cc: Lucy Evans; s. 22(1)(a)(ii)
Subject: FW: Request for change to list of Approved Tests for Silliker Melbourne Site [SEC=UNOFFICIAL]
Attachments: Silliker Melbourne 17 02 2023.pdf

Good afternoon Melinda,

Thanks for the documents for our review. Some minor comments:

M134 (Detection of E. coli O157:H7 using AOAC 2019.03)

Section 12: please note that the department approved this method for screening of O157:H7 only. Please add a note that all DAFF screen positive samples are to be confirmed by AOAC 2020.06 or other department approved confirmatory methods.

Section 15 (Appendix), flow diagram needs to be updated

M142 (Detection of Enterohaemorrhagic (EHEC) using AOAC 2020.06)

Section 11.1.3 (step 5): refers to 20µL, however, AOAC 2020.06 standard method requires that 10µL of sampled is added to the lysis tube.

Section 12.3
Confirmation of Positive Latex Test: Latex positive samples are to be confirmed by virulence gene PCR as well as serogroup specific PCR. This is the requirement of US FSIS, MLG 5C states “For a sample to identify as positive for STEC, the E. coli isolate must contain an stx gene, an eae gene; and genetically identify as one of more of the top seven serogroups”.

Page 18 (flow diagram) needs to be updated to reflect this. i.e. Latex > Serogroup PCR > stx/eae PCR

Please find attached updated approval letter. Please do not hesitate to contact us if you have any questions.

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 anv Veterinary Services Division
70 Northbourne Ave, Canberra ACT 2601 Australia
GPO Box 858 Canberra ACT 2601 Australia

From: s. 22(1)(a)(ii)
Sent: Tuesday, 7 February 2023 11:29 AM
To: Melinda Skipper
Cc: s. 22(1)(a)(ii) ; Lucy Evans
Subject: RE: Request for change to list of Approved Tests for Silliker Melbourne Site [SEC=UNOFFICIAL]

Hi Melinda,

We are reviewing your request, we will let you know if we need any other information.

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

From: Melinda Skipper <s. 47F(1) @mxns.com>
Sent: Tuesday, 7 February 2023 10:10 AM
To: s. 22(1)(a)(ii) @awe.gov.au>
Cc: s. 22(1)(a)(ii) @awe.gov.au>; Lucy Evans <s. 47F(1)@mxns.com>
Subject: Re: Request for change to list of Approved Tests for Silliker Melbourne Site [SEC=UNOFFICIAL]

Hi s. 22(1)(a)(ii),
Just following up on my email below, do you need anything else from us in regard to this request for addition to our list of approved tests?

Thanks and best regards,
Melinda.

Melinda Skipper
National Quality Assurance Manager

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Subject: Re: Request for change to list of Approved Tests for Silliker Melbourne Site [SEC=UNOFFICIAL]

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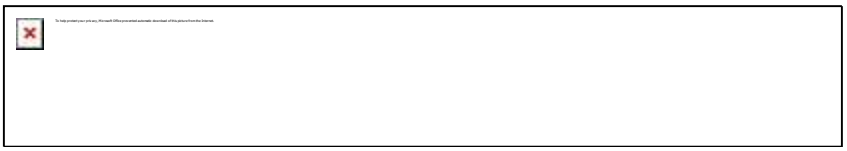
National Quality Assurance Manager



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

---

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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 anv Veterinary Services Division

70 Northbourne Ave, Canberra ACT 2601 Australia

GPO Box 858 Canberra ACT 2601 Australia

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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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➢ **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 ± 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 Biomeriuex 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

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Australian Government
Department of Agriculture, Fisheries and Forestry

Ms Melinda Skipper
National Quality Assurance Manager
Mérieux NutriSciences
20 King Street
BLACKBURN VIC 3130

Dear Ms Skipper,

Department of Agriculture, Fisheries and Forestry approval to test meat and meat products at Silliker Australia Pty Ltd – Melbourne Microbiology Laboratory, NATA Accreditation No: 2020, Site No: 2013

The Department of Agriculture, Fisheries and Forestry (DAFF) has issued a new approval based on the current NATA scope of accreditation for testing of exported meat surfaces and meat/meat products. Your laboratory has been granted department approval for the following tests:

	APC	*E. coli*/coliforms	*Salmonella*	*Listeria*	STEC
Meat Surfaces	AS 5013.5	AOAC 991.14 AOAC 998.08	AS 5013.10 AOAC 996.08 AOAC 2013.01	AS 5013.24.1 AOAC 999.06 AOAC 2004.06	
Meat & Meat Products	AS 5013.5	AOAC 991.14 AOAC 998.08	AS 5013.10 AOAC 996.08 AOAC 2013.01	AS 5013.24.1 AOAC 999.06 AOAC 2004.06	AOAC 2020.06 (screening & confirmation) AOAC 2019.03 (screening only)

It is a condition of approval that methodology used at your laboratory for the above tests is as detailed in the applicable standards. No in-house modifications of methods are allowed without written approval from the department. Conditions of approval can be reviewed in the *Microbiological Manual for Sampling and Testing of Export Meat and Meat Products* on the department's website.

If you have any questions regarding approval or DAFF approved methods, please contact me directly on s. 22(1)(a)(ii) .

Yours sincerely

s. 47F(1)

s. 22(1)(a)(ii)
Principal – Microbiology and Laboratory Oversight
Export Standards Branch – Exports and Veterinary Services Division
17 February 2023

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F +61 2 6272 5161
70 Northbourne Ave
Canberra City ACT 2601
GPO Box 858
Canberra ACT 2601
agricultue.gov.au
ABN 34 190 894 983

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

From: s. 22(1)(a)(ii)
Sent: Friday, 17 February 2023 10:14 AM
To: s. 22(1)(a)(ii)
Subject: RE: Request for change to list of Approved Tests for Silliker Melbourne Site [SEC=UNOFFICIAL]

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

Updated comments as below:
---

s. 47C(1)

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

From: s. 22(1)(a)(ii)
Sent: Thursday, 16 February 2023 11:06 AM

To: s. 22(1)(a)(ii)
Subject: RE: Request for change to list of Approved Tests for Silliker Melbourne Site [SEC=UNOFFICIAL]

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

Thanks for reviewing these.

s. 47C(1)

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

s. 47C(1)

From: s. 22(1)(a)(ii) @aff.gov.au>
Sent: Monday, 13 February 2023 1:51 PM
To: s. 22(1)(a)(ii) @aff.gov.au>
Subject: FW: Request for change to list of Approved Tests for Silliker Melbourne Site [SEC=UNOFFICIAL]

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)

s. 47C(1)

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

From: Melinda Skipper <s. 47F(1) @mxns.com>
Sent: Thursday, 2 February 2023 10:15 AM
To: s. 22(1)(a)(ii) @aff.gov.au>
Cc: s. 22(1)(a)(ii) @aff.gov.au>; Lucy Evans <s. 47F(1)@mxns.com>; Anupriya Moorkanath <s. 47F(1) @mxns.com>; s. 47F(1) @mxns.com>
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

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

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

Mérieux NutriSciences

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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: 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]

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 anv 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>
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 *Escherichia coli* O157 Note - when analysing frozen or chilled samples, the temperature of broth and samples must be at 41.5 ± 1°C for a minimum of 6 h and subsequently for a further 12 to 18 hours.
➢ **FSIS MLG 5**	Detection, isolation, and identification of *Escherichia coli* O157:H7 from meat products Note the method has been updated changing the initial enrichment to mTSB and the definition of *E. coli* O157:H7. When analysing frozen or chilled samples, the temperature of broth and samples must be at 42 ± 1°C for a minimum of 15 hours.
➢ **FDA BAM Chapter 4A(K)**	Diarrheagenic *Escherichia coli* - Enrichment and isolation of *E. coli* 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) mEHEC 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
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Can you advise whether confirmation by the AOAC methods in question have been approved by your Department. I think we have received letters from Biomeriuex 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

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http://www.merieuxnutrisciences.com/au

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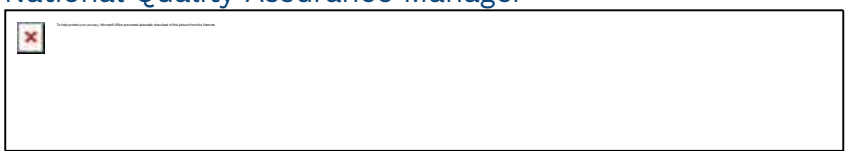
s. 22(1)(a)(ii)

From: Melinda Skipper <s. 47F(1) @mxns.com>
Sent: Friday, 17 February 2023 3:07 PM
To: s. 22(1)(a)(ii)
Cc: Lucy Evans; s. 22(1)(a)(ii)
Subject: Re: FW: Request for change to list of Approved Tests for Silliker Melbourne Site [SEC=UNOFFICIAL]

Thank-you very much s. 22(1)(a)(ii) for the approval letter and also the method comments, which we will review and take action immediately.

Very best regards,
Melinda.

Melinda Skipper
National Quality Assurance Manager

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On Fri, Feb 17, 2023 at 3:04 PM s. 22(1)(a)(ii) @aff.gov.au> wrote:

> Good afternoon Melinda,
>
> Thanks for the documents for our review. Some minor comments:
>
> **M134 (Detection of E. coli O157:H7 using AOAC 2019.03)**
>
> Section 12: please note that the department approved this method for screening of O157:H7 only. Please add a note that all DAFF screen positive samples are to be confirmed by AOAC 2020.06 or other department approved confirmatory methods.
>
> Section 15 (Appendix), flow diagram needs to be updated

M142 (Detection of Enterohaemorrhagic (EHEC) using AOAC 2020.06)

Section 11.1.3 (step 5): refers to 20µL, however, AOAC 2020.06 standard method requires that 10µL of sampled is added to the lysis tube.

Section 12.3

Confirmation of Positive Latex Test: Latex positive samples are to be confirmed by virulence gene PCR as well as serogroup specific PCR. This is the requirement of US FSIS, MLG 5C states “For a sample to identify as positive for STEC, the E. coli isolate must contain an stx gene, an eae gene; and genetically identify as one of more of the top seven serogroups”.

Page 18 (flow diagram) needs to be updated to reflect this. i.e. Latex > Serogroup PCR > stx/eae PCR

Please find attached updated approval letter. Please do not hesitate to contact us if you have any questions.

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 anv Veterinary Services Division

70 Northbourne Ave, Canberra ACT 2601 Australia

GPO Box 858 Canberra ACT 2601 Australia

From: s. 22(1)(a)(ii)
Sent: Tuesday, 7 February 2023 11:29 AM
To: Melinda Skipper <s. 47F(1) @mxns.com>
Cc: s. 22(1)(a)(ii) @awe.gov.au>; Lucy Evans <s. 47F(1) @mxns.com>
Subject: RE: Request for change to list of Approved Tests for Silliker Melbourne Site [SEC=UNOFFICIAL]

Hi Melinda,

We are reviewing your request, we will let you know if we need any other information.

Kind regards

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

From: Melinda Skipper <s. 47F(1) @mxns.com>
Sent: Tuesday, 7 February 2023 10:10 AM
To: s. 22(1)(a)(ii) @awe.gov.au>
Cc: s. 22(1)(a)(ii) @awe.gov.au>; Lucy Evans <s. 47F(1) @mxns.com>
Subject: Re: Request for change to list of Approved Tests for Silliker Melbourne Site [SEC=UNOFFICIAL]

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

Just following up on my email below, do you need anything else from us in regard to this request for addition to our list of approved tests?

Thanks and best regards,

Melinda.

Melinda Skipper

National Quality Assurance Manager

Mérieux NutriSciences

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http://www.merieuxnutrisciences.com/au

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On Thu, Feb 2, 2023 at 10:15 AM Melinda Skipper <s. 47F(1) @mxns.com> wrote:

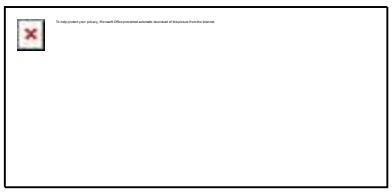
> Hi s. 22(1)(a)(ii),

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.

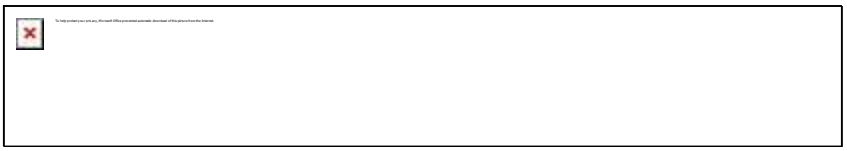
Thanks and best regards,

Melinda.



Melinda Skipper

National Quality Assurance Manager



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http://www.merieuxnutrisciences.com/au

Follow us on:

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) <s. 47F(1) @mxns.com>; s. 22(1)(a)(ii) @aff.gov.au>

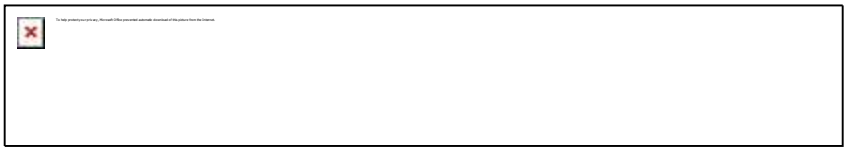
Subject: Re: Request for change to list of Approved Tests for Silliker Melbourne Site [SEC=UNOFFICIAL]

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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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: Lucy Evans <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]

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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 anv 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) <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),

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***Escherichia coli* O157:H7**

➢ **ISO 16654:2001**	Microbiology of food and animal feeding stuffs – Horizontal method for the detection of *Escherichia coli* O157 Note - when analysing frozen or chilled samples, the temperature of broth and samples must be at 41.5 ± 1°C for a minimum of 6 h and subsequently for a further 12 to 18 hours.
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➢ **FDA BAM Chapter 4A(K)**	Diarrheagenic *Escherichia coli* - Enrichment and isolation of *E. coli* 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) mEHEC 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
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Can you advise whether confirmation by the AOAC methods in question have been approved by your Department. I think we have received letters from Biomeriuex indicating that both Gene-Up methods have been approved by you for screening and confirmation, would this be correct?

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Thanks and best regards,

Melinda.

Melinda Skipper

National Quality Assurance Manager

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s. 47F(1) *@mxns.com and delete the message from your system.*

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

From: s. 22(1)(a)(ii)
Sent: Thursday, 13 March 2025 12:13 PM
To: s. 22(1)(a)(ii)
Subject: RE: Silliker verification report/Gene-Up methods [SEC=OFFICIAL]
Attachments: AOAC 2020.06 GENE-UP EHEC Detection Method 2020 2020_06.pdf; FW: AskUSDA Case #00417862 : STEC confirmation test methods [SEC=UNOFFICIAL]

OFFICIAL

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

We have the attached AOAC 2020.06 method in our J: drive. Also approval from FSIS.

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

OFFICIAL

From: s. 22(1)(a)(ii) @aff.gov.au>
Sent: Thursday, 13 March 2025 12:04 PM
To: s. 22(1)(a)(ii) @aff.gov.au>
Subject: RE: Silliker verification report/Gene-Up methods [SEC=OFFICIAL]

OFFICIAL

Thanks s. 22(1)(a)(ii). Do we have a copy of the AOAC validated method in addition to the lab method SOPs?

OFFICIAL

From: s. 22(1)(a)(ii) @aff.gov.au>
Sent: Thursday, 13 March 2025 11:23 AM
To: s. 22(1)(a)(ii) @aff.gov.au>
Subject: Silliker verification report/Gene-Up methods [SEC=OFFICIAL]

OFFICIAL

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

I have found Silliker verification report and GENE-UP STEC methods in our J: drive. The method could be an older version.

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

s. 45(1),s. 47(1)(b)

s. 45(1),s. 47(1)(b)

s. 45(1),s. 47(1)(b)

s. 45(1),s. 47(1)(b)

s. 45(1),s. 47(1)(b)

s. 45(1),s. 47(1)(b)

s. 45(1),s. 47(1)(b)

s. 45(1),s. 47(1)(b)

s. 45(1),s. 47(1)(b)

s. 45(1),s. 47(1)(b)

s. 45(1),s. 47(1)(b)

s. 45(1),s. 47(1)(b)

s. 45(1),s. 47(1)(b)

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)
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?


AOAC Official Method 2020.06
Enterohemorrhagic *E. coli* in Select F
GENE-UP® EHEC Detection Metho
First Action 2020

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

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

> Hi s. 22(1)(a)(ii),
>
> See Below:

AOAC RI Approved Protocols (No. 121	
Matrix	Prot
25 g of Raw Meat Products (Not Poultry)	• 25 g of sample • 225 mL of Buffered Peptone W • Mix using a paddle blender • Incubate at +42°C ± 1°C for 18
25 g of Raw Meat products (Not Poultry) – Short Enrichment Protocol	• 25 g of sample • 225 mL of prewarmed (+42°C ± (BPW) • Mix using a paddle blender • Incubate at +42°C ± 1°C for 8-2
Large sample size of Raw Meat Products (Not Poultry)	• 375 g of sample • 1125 mL of prewarmed (+42 ± (BPW)

Kind Regards

s. 47F(1)
Senior Technical Microbiologist

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

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:
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20 King Street Blackburn
VIC 3130 Australia
Phone: 1300 000 990
Direct: +613 8878 2128
E-mail: s. 47F(1) @mxns.com
https://www.linkedin.com/company/merieux-nutrisciences-australia

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?

Australian Government
Department of Agriculture and Water Resources

VIDAS *Salmonella* (SLM) Assay - AOAC 996.08

SCOPE

This method is applicable to:

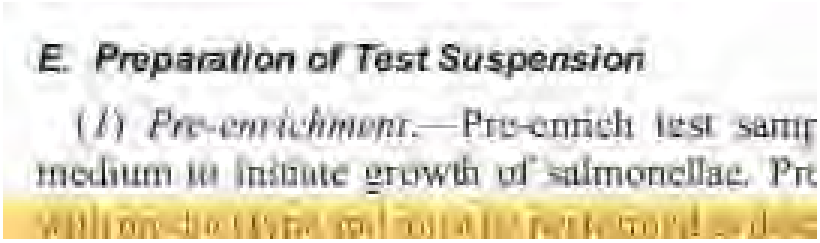
– Raw meats, meat products and carcass swabs.

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 VIDS 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 ± 1°C for large volumes) buffered peptone water and pre-enriched at 37 ± 1°C for 18 h ± 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 ± 1°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 ± 1°C, respectively, for 18 ± 2 h.
- **Post-enrichment**
  Selective enrichment broths are inoculated into M-broth and incubated for 6 h at 42 ± 1°C.

Extract from AOAC 996.08:



E. Preparation of Test Suspension

(1) Pre-enrichment.—Pre-enrich test samp
medium to initiate growth of salmonellae. Pr

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.

Another discrepancy I have located in the checklist relates to the incubation temperature for the *E.coli* 0157:H7 for AOAC 121805.

The AOAC and packet insert for the procedure requires enrichments to be incubated at

42C +/- C and not 41.5C +/- 1C as specified by the DAWE checklist.

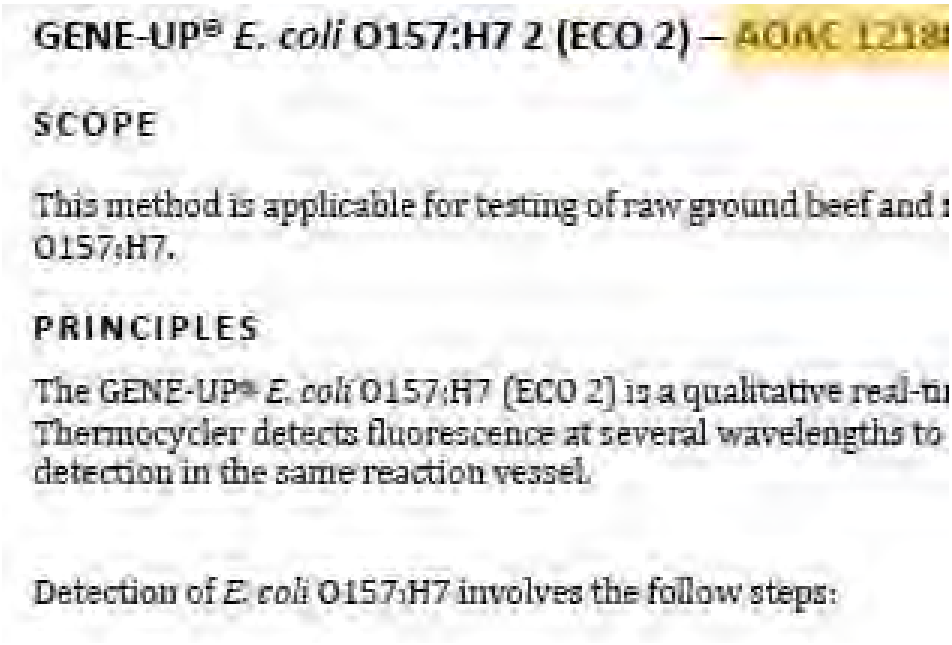
Packet Insert:

AOAC RI Approved Protocols (No. 121805)	
Matrix	**Protocol**
25 g of Raw Meat Products (Not Poultry)	• 25 g of sample. • 225 mL of Buffered Peptone Water (BPW). • Mix using a paddle blender. • Incubate at +42°C ± 1°C for 18-24 hours.
25 g of Raw Meat products (Not Poultry) – Short Enrichment Protocol	• 25 g of sample. • 225 mL of prewarmed (+42°C ± 1°C) Buffered Peptone Water (BPW). • Mix using a paddle blender. • Incubate at +42°C ± 1°C for 8-24 hours.
Large sample size of Raw Meat Products (Not Poultry)	• 375 g of sample. • 1125 mL of prewarmed (+42 ± 1°C) Buffered Peptone Water (BPW). • Mix manually. DO NOT use a blender. • Incubate at +42°C ± 1°C for 10-24 hours.
Produce or Vegetable	• 200 g of sample. • 800 mL of prewarmed (+42 ± 1°C) Buffered Peptone Water (BPW). • Mix manually. DO NOT use a blender. • Incubate at +42°C ± 1°C for 10-24 hours.

AOAC Official Method 20
***E. coli* O157:H7 in Select**
GENE-UP® *E. coli* O157:H7 2 (E
First Action 2019

[Applicable to detection of *E. coli* O157:H
beef (73% lean, 25 and 375 g), fresh spina
cheese (25 g), raw ground chicken (25 g), ra
375 g), raw ground pork (375 g), Romaine

Allow enrichment broths to reach 15–25°
thawed before analysis. To decrease occur
use a quick-thawing process. (This can be
at temperatures less than 45°C in a water
15 min. Agitate the sample continuously
containing filter.
(a) Fresh raw ground beef (25 g)—



GENE-UP® *E. coli* O157:H7 2 (ECO 2) – AOAC 121

SCOPE

This method is applicable for testing of raw ground beef and
O157:H7.

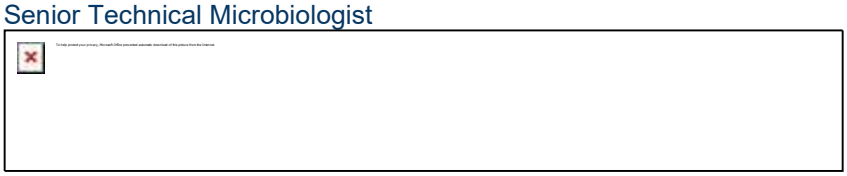
PRINCIPLES

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

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

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

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

From: s. 47F(1) @mxns.com>
Sent: Friday, 1 October 2021 9:47 AM
To: s. 22(1)(a)(ii)
Subject: Re: Checklist Enquiry [SEC=UNOFFICIAL]

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

We have implemented the GENE-UP in our Melbourne site and have NATA accreditation for *Salmonella, Listeria spp, Listeria monocytogenes* and *Cronobacter*.
We are in the process of verification for *E.coli* 0157 and EHEC and looking at implementing the confirmation for EHEC testing as specified in the AOAC 2020.6 / Biomerieux packet insert.

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.

Reference	Method
423105	GENE-UP® *Salmonella* 2
423106	GENE-UP® *Listeria* 2
423107	GENE-UP® *Listeria monocytogenes* 2 (including ALOA for confirmation)

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 20
***E. coli* O157:H7 in Select F**
GENE-UP® *E. coli* O157:H7 2 (EC
First Action 2019

[Applicable to detection of *E. coli* O157:H7 beef (73% lean; 25 and 375 g), fresh spinac cheese (25 g), raw ground chicken (25 g), ra 375 g), raw ground pork (375 g). Remains

D. Sample Enrichment

Allow enrichment broths to reach 15–25°C
cases, enrichment media should be prewarm
42 ± 1°C before adding to food samples. Froz
thawed before analysis. To decrease occurre
use a quick-thawing process. (This can be p
at temperatures less than 45°C in a water b
15 min. Agitate the sample continuously.)
containing filter.

(a) *Fresh raw ground beef (25 g).*—A
Homogenize and incubate at 42 ± 1°C for 18–

(b) *Fresh raw ground beef short protocol (*
prewarmed BPW. Homogenize and incubate a

(c) *Raw ground chicken (25 g).*—Add 225
or modified tryptic soy broth (mTSB). Homog
42 ± 1°C for 18–24 h.

(d) *Fresh spinach (200 g).*—Add 800 mL

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 be
O157:H7.

PRINCIPLES

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

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

- **Enrichment**
  Sample (375 g) is enriched in 1,125 mL of pre-warmed (to 41.5
  water (BPW). Sample and enrichment media are placed in a ste

Biomerieux package Insert:

REF 423108

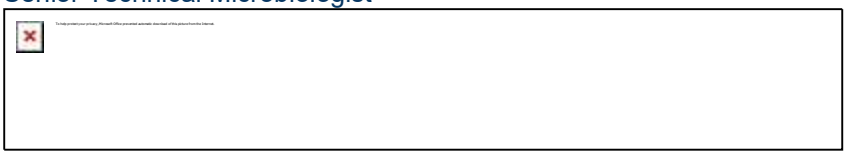
GENE-UP® *E. coli* O157:H7 2 (ECO 2)

AOAC RI Approved Protocols (No. 1218	
Matrix	**Proto**
25 g of Raw Meat Products (Not Poultry)	• 25 g of sample. • 225 mL of Buffered Peptone Wa • Mix using a paddle blender. • Incubate at +42°C ± 1°C for 18-
25 g of Raw Meat products (Not Poultry) – Short Enrichment Protocol	• 25 g of sample. • 225 mL of prewarmed (+42°C ± (BPW). • Mix using a paddle blender. • Incubate at +42°C ± 1°C for 8-2
Large sample size of Raw Meat Products (Not Poultry)	• 375 g of sample. • 1125 mL of prewarmed (+42 ± 1 (BPW). • Mix manually. DO NOT use a bl

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

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),

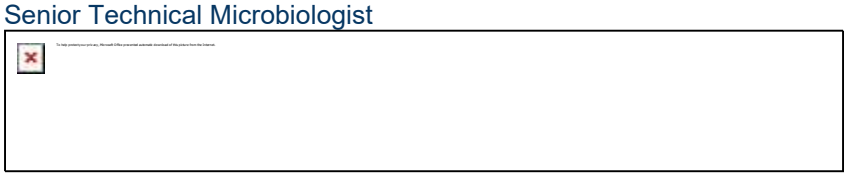
Hopefully this is the last you hear of me today.

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

AOAC Official Method 2020.06
Enterohemorrhagic *E. coli* in Select F
GENE-UP® EHEC Detection Metho
First Action 2020

(Applicable to detection of enterohemorrhagic *E. coli* (O26, O45, O10

Kind Regards
s. 47F(1)
Senior Technical Microbiologist



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Kind Regards

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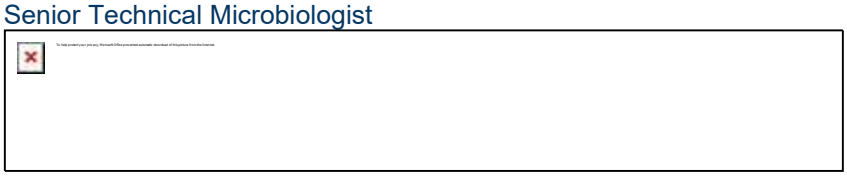
Senior Technical Microbiologist



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To: s. 22(1)(a)(ii) @awe.gov.au>
Subject: Re: Checklist Enquiry [SEC=UNOFFICIAL]

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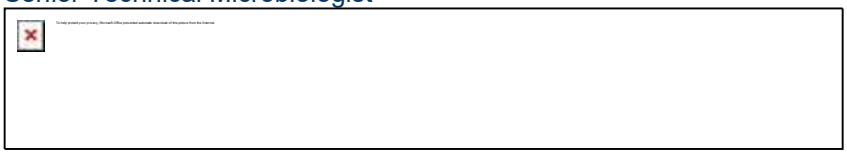
Senior Technical Microbiologist



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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]

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Australian Government
Department of Agriculture and Water Resources

VIDAS *Salmonella* (SLM) Assay - AOAC 996.08

SCOPE

This method is applicable to:

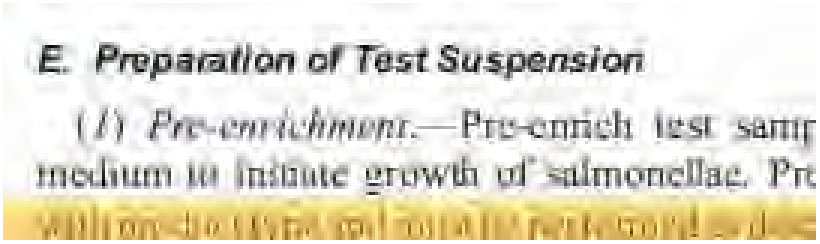
— Raw meats, meat products and carcass swabs.

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 VIDS 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 ± 1°C for large volumes) buffered peptone water and pre-enriched at 37 ± 1°C for 18 h ± 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 ± 1°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 ± 1°C, respectively, for 18 ± 2 h.
- **Post-enrichment**
  Selective enrichment broths are inoculated into M-broth and incubated for 6 h at 42 ± 1°C.

Extract from AOAC 996.08:



E. Preparation of Test Suspension

(1) Pre-enrichment.—Pre-enrich test samp
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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.

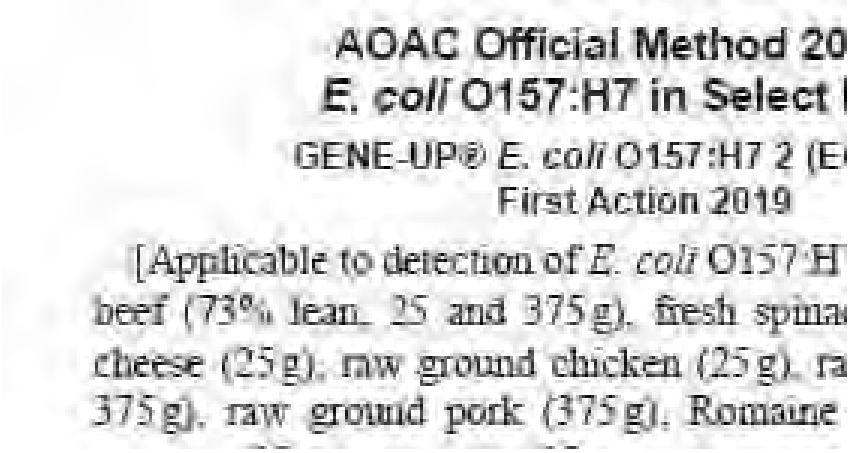
Another discrepancy I have located in the checklist relates to the incubation temperature for the *E.coli* 0157:H7 for AOAC 121805.

The AOAC and packet insert for the procedure requires enrichments to be incubated at

42C +/- C and not 41.5C +/- 1C as specified by the DAWE checklist.

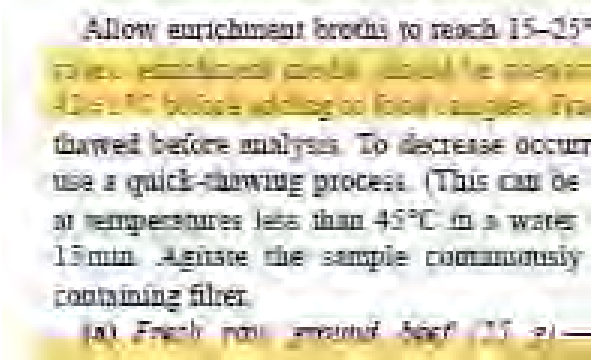
Packet Insert:

AOAC RI Approved Protocols (No. 121805)	
Matrix	**Protocol**
25 g of Raw Meat Products (Not Poultry)	• 25 g of sample • 225 mL of Buffered Peptone Water (BPW) • Mix using a paddle blender. • Incubate at +42°C ± 1°C for 18-24 hours.
25 g of Raw Meat products (Not Poultry) – Short Enrichment Protocol	• 25 g of sample • 225 mL of prewarmed (+42°C ± 1°C) Buffered Peptone Water (BPW). • Mix using a paddle blender. • Incubate at +42°C ± 1°C for 8-24 hours.
Large sample size of Raw Meat Products (Not Poultry)	• 375 g of sample. • 1125 mL of prewarmed (+42 ± 1°C) Buffered Peptone Water (BPW). • Mix manually. DO NOT use a blender • Incubate at +42°C ± 1°C for 10-24 hours.
Produce or Vegetable	• 200 g of sample. • 800 mL of prewarmed (+42 ± 1°C) Buffered Peptone Water (BPW). • Mix manually. DO NOT use a blender. • Incubate at +42°C ± 1°C for 10-24 hours.

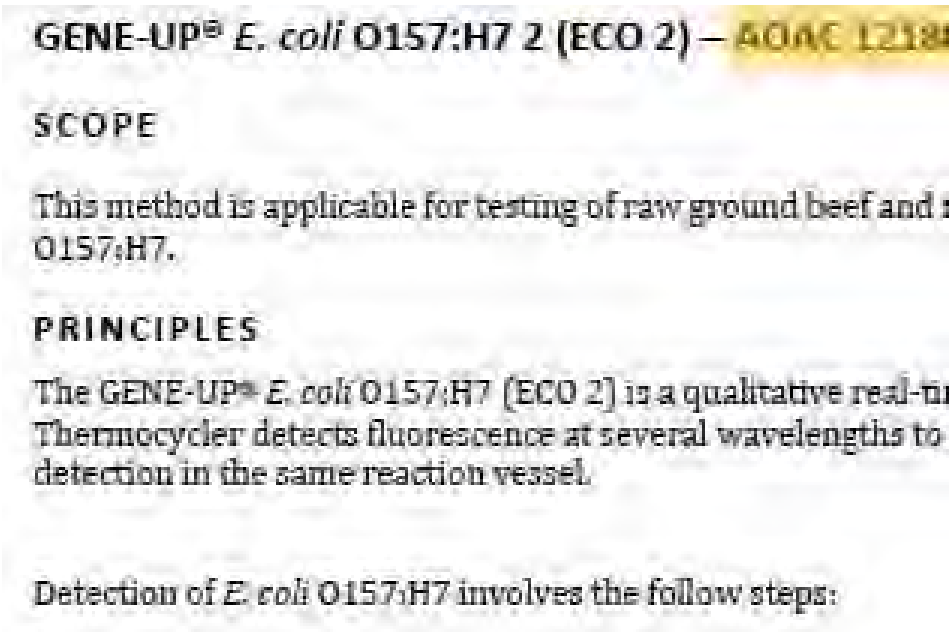


AOAC Official Method 20
E. coli O157:H7 in Select
GENE-UP® *E. coli* O157:H7 2 (E
First Action 2019

[Applicable to detection of *E. coli* O157:H
beef (73% lean, 25 and 375 g), fresh spina
cheese (25 g), raw ground chicken (25 g), ra
375 g), raw ground pork (375 g), Romaine



Allow enrichment broths to reach 15–25°
thawed before analysis. To decrease occur
use a quick-thawing process. (This can be
at temperatures less than 45°C in a water
15 min. Agitate the sample continuously
containing filter.



GENE-UP® *E. coli* O157:H7 2 (ECO 2) – AOAC 121

SCOPE

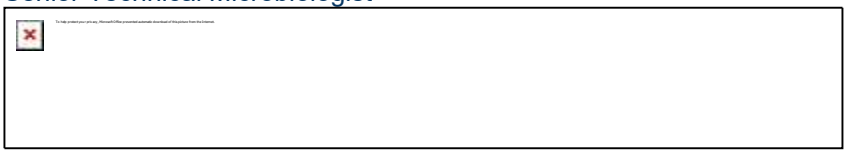
This method is applicable for testing of raw ground beef and
O157:H7.

PRINCIPLES

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

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

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

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

From: s. 22(1)(a)(ii)
Sent: Wednesday, 1 February 2023 3:27 PM
To: s. 22(1)(a)(ii)
Subject: RE: Request for change to list of Approved Tests for Silliker Melbourne Site [SEC=UNOFFICIAL]

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

Melinda is right about the highlighted text on our website – we'll need to amend that given our approval of Gene-up for confirmation.

Do you mind drafting an update for the webpage and responding to Melinda?

s. 47C(1)

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

From: Melinda Skipper
Sent: Wednesday, 1 February 2023 3:02 PM
To: s. 22(1)(a)(ii)
Cc: Lucy Evans ; s. 47F(1)
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 *Escherichia coli* O157 Note - when analysing frozen or chilled samples, the temperature of broth and samples must be at 41.5 ± 1°C for a minimum of 6 h and subsequently for a further 12 to 18 hours.
➢ **FSIS MLG 5**	Detection, isolation, and identification of *Escherichia coli* O157:H7 from meat products Note the method has been updated changing the initial enrichment to mTSB and the definition of *E. coli* O157:H7. When analysing frozen or chilled samples, the temperature of broth and samples must be at 42 ± 1°C for a minimum of 15 hours.
➢ **FDA BAM Chapter 4A(K)**	Diarrheagenic *Escherichia coli* - Enrichment and isolation of *E. coli* 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) mEHEC 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 Biomeriuex 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

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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: Wednesday, 1 February 2023 4:15 PM
To: s. 22(1)(a)(ii)
Subject: RE: Request for change to list of Approved Tests for Silliker Melbourne Site [SEC=UNOFFICIAL]

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

I'm presuming NATA didn't assess the confirmation component of AOAC 2020.06 at Silliker?

From: s. 22(1)(a)(ii)
Sent: Wednesday, 1 February 2023 4:03 PM
To: Melinda Skipper
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]

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 anv 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>
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 *Escherichia coli* O157 Note - when analysing frozen or chilled samples, the temperature of broth and samples must be at 41.5 ± 1°C for a minimum of 6 h and subsequently for a further 12 to 18 hours.
➢ **FSIS MLG 5**	Detection, isolation, and identification of *Escherichia coli* O157:H7 from meat products Note the method has been updated changing the initial enrichment to mTSB and the definition of *E. coli* O157:H7. When analysing frozen or chilled samples, the temperature of broth and samples must be at 42 ± 1°C for a minimum of 15 hours.
➢ **FDA BAM Chapter 4A(K)**	Diarrheagenic *Escherichia coli* - Enrichment and isolation of *E. coli* 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) mEHEC 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
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➢ **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 Biomeriuex 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
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Phone: 1300 000 990
Direct: +s. 47F(1)
http://www.merieuxnutrisciences.com/au
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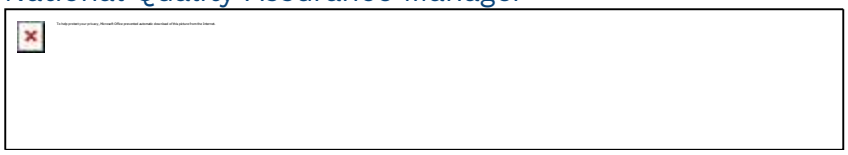
About Mérieux Nutrisciences

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)
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

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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: Lucy Evans <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,

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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 anv 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.

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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 *Escherichia coli* O157 Note - when analysing frozen or chilled samples, the temperature of broth and samples must be at 41.5 ± 1°C for a minimum of 6 h and subsequently for a further 12 to 18 hours.
➢ **FSIS MLG 5**	Detection, isolation, and identification of *Escherichia coli* O157:H7 from meat products Note the method has been updated changing the initial enrichment to mTSB and the definition of *E. coli* O157:H7. When analysing frozen or chilled samples, the temperature of broth and samples must be at 42 ± 1°C for a minimum of 15 hours.
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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) mEHEC 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
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Thanks and best regards,

Melinda.

Melinda Skipper

National Quality Assurance Manager

Mérieux NutriSciences

20 King Street, Blackburn, Victoria 3130, Australia

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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.*

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

From: Melinda Skipper <s. 47F(1) @mxns.com>
Sent: Wednesday, 1 February 2023 3:02 PM
To: s. 22(1)(a)(ii)
Cc: Lucy Evans; s. 47F(1)
Subject: Request for change to list of Approved Tests for Silliker Melbourne Site [SEC=UNOFFICIAL]
Attachments: DAWE Meat and Meat Products List of Approved Tests May 2021.pdf; NATA Accreditation Microbiology Scope Jan 2022.pdf

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

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Where positive confirmation is required such confirmation must be by ISO 16654:2001, FDA BAM 4A(K) or FSIS MLG 5	
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Shiga-toxin producing *E. coli* (STEC)

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Rapid methods	
Where positive confirmation is required such confirmation must be by FSIS MLG 5B	
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➢ **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.

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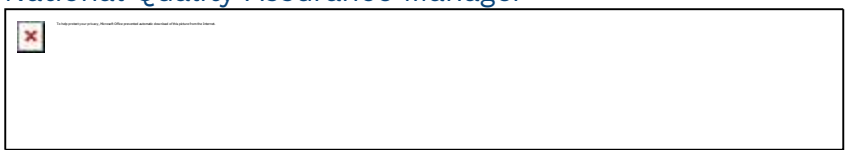
Looking forward to hearing back from you.

Thanks and best regards,
Melinda.

Melinda Skipper
National Quality Assurance Manager



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Direct: +s. 47F(1)
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National Association of Testing Authorities, Australia

Scope of Accreditation

Silliker Australia Pty Ltd

Site

Melbourne Microbiology Laboratory

Accreditation No.	Site No.	Date of Accreditation
2020	2013	28 Feb 1986

Address
20 King Street
Blackburn, VIC 3130
Australia

merieuxnutrisciences.com

Contact
Ms Anupriya Pavithran
P: +61 1300000990
anupriya.moorkanath@mxns.com

Availability
Services available to external clients

Melbourne Microbiology Laboratory

ISO/IEC 17025 (2017)

Agribusiness

SERVICE	PRODUCT	DETERMINANT	TECHNIQUE	PROCEDURE
Analysis for microorganisms	Bacterial isolates; Yeast isolates	Identification	MALDI-TOF	AOAC 2017.09; AOAC 2017.10 (in-house method M139)(MBT Compass Library Revision H, MBT 5442)
	Pet foods	*Salmonella spp.*	PCR - Real time	NF BIO 12/38-06/16 (in-house method M80.8)
Analysis for microorganisms in abattoirs	Meat	*Escherichia coli* non 0157 STEC serogroups 026, 045, 0103, 0111, 0121, 0145	PCR - Real time	AOAC 2020.06
		Escherichia coli 0157 H7	PCR - Real time	AOAC 2019.03
		Listeria monocytogenes	Qualitative selective enrichment	AS 5013.24.1
	Meat; Meat surfaces	Plate count	Pour plate	AS 5013.5

SERVICE	PRODUCT	DETERMINANT	TECHNIQUE	PROCEDURE
		Escherichia coli; Coliforms	Spread plate - Petrifilm	AOAC 991.14, AOAC 998.08
		Listeria monocytogenes	Enzyme linked immunosorbent assay (ELISA) - Automated (VIDAS)	AOAC 999.06, AOAC 2004.06
		Salmonella spp.	Qualitative selective enrichment	AS 5013.10
		Salmonella spp.	Enzyme linked immunosorbent assay (ELISA) - Automated (VIDAS)	AOAC 996.08
	Meat; Meat surfaces; Product contact surfaces	Plate count	Pour plate	AS 5013.5
		Listeria monocytogenes; *Salmonella spp.*	Enrichment; Enzyme linked immunosorbent assay (ELISA) - Automated (VIDAS)	AS 5013.24.1, AS 5013.10, AOAC 2013.01
		Escherichia coli; Coliforms	Spread plate - Petrifilm	AOAC 991.15, AOAC 998.08
		Listeria monocytogenes; *Salmonella spp.*	Enzyme immunoassay (EIA)	AOAC 999.06, AOAC 2004.06, AOAC 996.08

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Environment

SERVICE	PRODUCT	DETERMINANT	TECHNIQUE	PROCEDURE
Analysis for microorganisms	Air - Ambient; Air - Confined spaces; Air - Indoor	Plate count	Air sampler	in house methods M33, M34
	Air - Ambient; Air - Confined spaces; Air - Indoor; Product contact surfaces; Surfaces	*Salmonella spp.*	Qualitative selective enrichment	AS 5013.10
	Air - Ambient; Air - Confined spaces; Air - Indoor; Purified and	*Staphylococcus spp.* - Coagulase producing strains	Spread plate	AS 5013.12.1

SERVICE	PRODUCT	DETERMINANT	TECHNIQUE	PROCEDURE
	processed waters; Surfaces			
		Escherichia coli	Most probable number (MPN)	AS 5013.15 (in-house method M8.1)
		Enterococci; *Streptococcus* - Faecal	Membrane filter	AS 4276.9
		Clostridium perfringens	Spread plate - Aerobic and anaerobic	AS 5013.16
		Plate count	Pour plate	AS 5013.5 (in-house method M2.1)
		Listeria monocytogenes; *Listeria spp.*	Enzyme linked immunosorbent assay (ELISA) - Automated (VIDAS)	AOAC 999.06
		Listeria monocytogenes; *Listeria spp.*; *Salmonella spp.*	Qualitative selective enrichment	APHA 2001, AS 5013.24.1, AOAC 2004.02, AS 5013.10, AOAC RI Cert 020901 (in-house method M36.2_
		Coliforms - Thermotolerant and total	Most probable number (MPN)	AS 5013.3 (in-house methods M8.1, M8.2)
		Listeria monocytogenes; *Listeria spp.*	Spread plate	AS 5013.24.2
		Osmophilic yeasts; Yeasts and moulds	Pour plate	AS 5013,29
		Staphylococcus spp. - Coagulase producing strains	Most probable number (MPN) - Triplicate tube	AS 5013.12.3
		Enterobacteriaceae; *Escherichia coli*; *Staphylococcus spp.* - Coagulase producing strains; Coliforms; Coliforms - Thermotolerant	Most probable number (MPN)	AS 5013.3, AS 5013.15, AS 5013.12.3 (in house methods M8.1, M8.2, M40.1)

SERVICE	PRODUCT	DETERMINANT	TECHNIQUE	PROCEDURE
		Enterococci; *Streptococcus* - Faecal; Coliforms; Osmophilic yeasts; Plate count; Yeasts and moulds	Pour plate	AS 5013.5, AS 5013.4, ,AS 5013.29, APHA 2001 (in-house method M2.1)
		Bacillus cereus	Spread plate - Aerobic and anaerobic	AS 5013 2
		Listeria spp.	Enzyme linked immunosorbent assay (ELISA) - Automated (VIDAS)	AOAC 999.06
		Plate count	Spread plate - Petrifilm	AOAC 990.12
		Bacillus cereus; *Campylobacter spp.*; *Clostridium perfringens*; *Enterobacteriaceae*; *Escherichia coli*; *Listeria monocytogenes*; *Listeria spp.*; *Staphylococcus spp.* - Coagulase producing strains; Coliforms; Osmophilic yeasts; Plate count; Yeasts and moulds	Spread plate - Aerobic and anaerobic	AOAC 990.12, AS 5013.2, AS 5013.6, AS 5013.16, AOAC 991.14, AOAC 998.08, AOAC 2003.01, AS 5013.24.2, AS 5013.12.1, AS 5013.29
		Staphylococcus spp. - Coagulase producing strains	Spread plate	AS 5013 .12.1
		Enterococci; *Streptococcus* - Faecal; Osmophilic yeasts; Yeasts and moulds	Membrane filter	AS/NZS 4276.9, AS 5013.29
		Enterobacteriaceae	Spread plate - Petrifilm	AOAC 2003.01
		Osmophilic yeasts; Yeasts and moulds	Spread plate - Aerobic and anaerobic	AS 5013.29
		Coliforms	Pour plate	AS 5013.4
		Enterobacteriaceae	Pour plate	in-house method M40.1
		Listeria monocytogenes	Enzyme linked immunosorbent assay (ELISA) -	AOAC 2004.02

SERVICE	PRODUCT	DETERMINANT	TECHNIQUE	PROCEDURE
			Automated (VIDAS)	
		Listeria monocytogenes; *Listeria spp.*	Qualitative selective enrichment	APHA 2001, AS 5013.24.1 (in-house method M36.2)
		Escherichia coli; Coliforms	Spread plate - Petrifilm	AOAC 991.14 AOAC 998.08
		Campylobacter spp.	Spread plate - Aerobic and anaerobic	AS 5013.6
		Enterococci; *Streptococcus* - Faecal	Pour plate	APHA 2001
		Osmophilic yeasts; Yeasts and moulds	Membrane filter	AS 4276.29
	Air - Ambient; Air - Confined spaces; Air - Indoor; Surfaces	Plate count	Air sampler; Contact plates	CMME 2001 (in-house methods M33, M34)
	Bacterial isolates; Yeast isolates	Identification	MALDI-TOF	AOAC 2017.09; AOAC 2017.10 (in-house method M139) (MBT Compass Library Revision H, MBT 5442)
	Estuarine waters; Fresh waters; Industrial waters - Treated, recirculating; Marine waters; Purified and processed waters; Sewage; Trade wastes	Plate count	Spread plate - Aerobic and anaerobic	AS 4276.3.1
	Estuarine waters; Fresh waters; Industrial waters - Treated, recirculating; Marine waters; Sewage; Swimming pool and spa waters; Trade wastes	*Clostridium spp.* (including spores of sulfite reducing *Clostridia*); *Enterococci*; *Escherichia coli*; *Pseudomonas aeruginosa*; *Pseudomonas spp.*; *Streptococcus* - Faecal; Coliforms; Coliforms - Thermotolerant; Plate count	Membrane filter	AS/NZS 4276.3.1, AS/NZS 4276.17.1, AS/NZS 4276.5, AS/NZS 4276.7, AS/NZS 4276.9, AS/NZS 4276.11, AS/NZS 4276.13
		Pseudomonas aeruginosa; *Pseudomonas spp.*	Membrane filter	AS 4276.11, AS 4276.13

SERVICE	PRODUCT	DETERMINANT	TECHNIQUE	PROCEDURE
		Plate count	Membrane filter	AS 4276.3.1
		Heterotrophic colony count; Plate count	Pour plate	AS 4276.3.1, AS 4276.3.2
		Heterotrophic colony count; Plate count	Pour plate	AS/NZS 4276.3.1, AS/NZS 4276.3.2
		Escherichia coli; Coliforms; Coliforms - Thermotolerant	Membrane filter	AS 4276.5, AS 4276.7
		Enterococci; *Streptococcus* - Faecal	Membrane filter	AS 4276.9
		Salmonella spp.	Qualitative selective enrichment	AS/NZS 4276.14
		Clostridium perfringens (including spores of sulfite reducing *Clostridia*)	Qualitative selective enrichment	AS 4276.17.1
		Legionella pneumophila; *Legionella spp.*; Plate count	Spread plate - Aerobic and anaerobic	AS/NZS 4276.3.1, AS 3896
		Escherichia coli; Coliforms; Coliforms - Thermotolerant	Most probable number (MPN)	AS/NZS 4276.6
		Listeria monocytogenes; *Listeria spp.*	Cultural; Enzyme linked immunosorbent assay (ELISA) - Automated (VIDAS)	in-house methods M36.3, M36.8
		Legionella pneumophila; *Legionella spp.*	Spread plate - Aerobic and anaerobic	AS 3896
	Estuarine waters; Fresh waters; Industrial waters - Treated, recirculating; Product contact surfaces; Purified and processed waters; Recycled waters; Surfaces; Swimming pool and spa waters	*Salmonella spp.*	Enzyme linked immunosorbent assay (ELISA) - Automated (VIDAS)	AOAC 2013.01 (in-house method M80.6)
	Product contact surfaces	*Salmonella spp.*	Enzyme linked immunosorbent assay (ELISA) -	AOAC 2013.01

SERVICE	PRODUCT	DETERMINANT	TECHNIQUE	PROCEDURE
			Automated (VIDAS)	
		Listeria monocytogenes	Enzyme linked immunosorbent assay (ELISA) - Automated (VIDAS)	AOAC 2004.06
		Escherichia coli; Coliforms	Spread plate - Petrifilm	AOAC 991.14, AOAC 998.08
		Salmonella spp.	Enzyme linked immunosorbent assay (ELISA) - Automated (VIDAS)	AOAC 996.08
		Listeria monocytogenes	Qualitative selective enrichment	AS 5013.24.1
		Plate count	Pour plate	AS 5013.5
		Salmonella spp.	Qualitative selective enrichment	AS 5103.10
	Surfaces	*Cronobacter spp.*	PCR - Real time	NF BIO 12/42-03/18 (in-house method M140)
		Salmonella spp.	PCR - Real time	NF BIO 12/38-06/16 (in-house method M80.8)
		Listeria monocytogenes	PCR - Real time	NF BIO 12/40-11/16 (in-house method M36.11)
		Listeria spp.	PCR - Real time	NF BIO 12/39-09/16 (in-house method M36.10)
Sample collection	Air - Ambient; Air - Confined spaces; Air - Indoor; Surface waters	Not applicable	Settle plate	CMME 2001

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Food and Beverage

SERVICE	PRODUCT	DETERMINANT	TECHNIQUE	PROCEDURE
Analysis for microorganisms	Bacterial isolates; Yeast isolates	Identification	MALDI-TOF	AOAC 2017.09; AOAC 2017.10 (in-house method M139)
	Beverages; Cereal products; Cocoa and cocoa products; Coffee; Confectionery; Crustaceans; Dairy products; Eggs and egg products; Fish; Food additives; Fruit and fruit products; Gelatine and other gums; Heat-processed foods in hermetically sealed containers; Herbs and spices; Honey; Meat and meat products; Mixed foods; Molluscs (including shell); Nuts and nut products; Poultry and poultry products; Sugar products; Vegetables and vegetable products	Plate count	Spread plate - Petrifilm	AOAC 990.12
	Beverages; Cereal products; Cocoa and cocoa products; Confectionery; Crustaceans; Dairy products; Eggs and egg products; Fish; Food additives; Frozen foods; Fruit and fruit products; Gelatine and other gums; Heat-processed foods in hermetically sealed containers; Herbs and spices; Honey; Meat and meat products; Mixed foods; Molluscs (including shell); Nuts and nut products; Poultry and poultry products; Sugar products; Vegetables and vegetable products	*Bacillus cereus*	Spread plate - Aerobic and anaerobic	AS 5013.2
	Beverages; Cereal products; Cocoa and cocoa products; Confectionery; Crustaceans; Dairy products; Eggs and egg products; Fish; Food additives; Fruit and fruit products; Gelatine and other gums; Heat-processed foods in hermetically sealed	*Salmonella spp.*	PCR - Real time	NF BIO 12/38-06/16 (in-house method M80.8)

SERVICE	PRODUCT	DETERMINANT	TECHNIQUE	PROCEDURE
	containers; Herbs and spices; Honey; Infant formulas; Meat and meat products; Mixed foods; Molluscs (including shell); Nuts and nut products; Poultry and poultry products; Sugar products; Vegetables and vegetable products			
	Beverages; Cereal products; Cocoa and cocoa products; Confectionery; Crustaceans; Dairy products; Eggs and egg products; Fish; Food additives; Fruit and fruit products; Gelatine and other gums; Heat-processed foods in hermetically sealed containers; Herbs and spices; Honey; Meat and meat products; Mixed foods; Molluscs (including shell); Mould isolates; Nuts and nut products; Poultry and poultry products; Sugar products; Vegetables and vegetable products	*Salmonella spp.*	Enzyme linked immunosorbent assay (ELISA) - Automated (VIDAS)	AOAC 996.08
		Enterobacteriaceae	Pour plate	in-house method M40.1
		Escherichia coli; Coliforms	Spread plate - Petrifilm	AOAC 991.14
		Plate count	Spread plate - Aerobic and anaerobic	in-house method M2.2
	Beverages; Cereal products; Cocoa and cocoa products; Confectionery; Crustaceans; Dairy products; Eggs and egg products; Fish; Food additives; Fruit and fruit products; Gelatine and other gums; Heat-processed foods in hermetically sealed containers; Herbs and spices; Honey; Meat and meat products; Mixed foods; Molluscs (including shell); Nuts and nut	*Listeria spp.*	Enzyme linked immunosorbent assay (ELISA) - Automated (VIDAS)	AOAC 2013.10 (in-house method M36.8)

SERVICE	PRODUCT	DETERMINANT	TECHNIQUE	PROCEDURE
	products; Potable waters; Poultry and poultry products; Sugar products; Vegetables and vegetable products			
	Beverages; Cereal products; Cocoa and cocoa products; Confectionery; Crustaceans; Dairy products; Eggs and egg products; Fish; Food additives; Fruit and fruit products; Gelatine and other gums; Heat-processed foods in hermetically sealed containers; Herbs and spices; Honey; Meat and meat products; Mixed foods; Molluscs (including shell); Nuts and nut products; Poultry and poultry products; Prawns; Sugar products; Vegetables and vegetable products	*Clostridium spp.*	Pour plate	FDA BAM (in-house method M6.2)
	Beverages; Cereal products; Cocoa and cocoa products; Confectionery; Crustaceans; Dairy products; Eggs and egg products; Fish; Food additives; Fruit and fruit products; Gelatine and other gums; Heat-processed foods in hermetically sealed containers; Herbs and spices; Honey; Meat and meat products; Mixed foods; Molluscs (including shell); Nuts and nut products; Poultry and poultry products; Sugar products; Vegetables and vegetable products	*Campylobacter spp.*; *Clostridium spp.*; *Listeria monocytogenes*; *Listeria spp.*; *Salmonella spp.*; *Vibrio cholerae*; *Vibrio parahaemolyticus*; *Vibrio vulnificus*; Yeasts and moulds (including osmophilic and preservative resistant forms)	Enrichment	AS 5013.6, AS 5013.24.1, AS 5013.10, AOAC 2004.02, AOAC RI Cert 020901, AS 1766.2.9, APHA 2001, FDA BAM 2004 (in house methods M36.2, M57)
		Yeasts and moulds; Yeasts and moulds - Osmophilic	Spread plate - Petrifilm	AS 5013.29
		Listeria monocytogenes; *Listeria spp.*	Enrichment	APHA 2001, AS 5013.24.1 (in-house method M36.2)
		Bacillus cereus; *Enterobacteriaceae*;	Most probable number (MPN)	AS 5013.3, AS 5013.15, AOAC

SERVICE	PRODUCT	DETERMINANT	TECHNIQUE	PROCEDURE
		Escherichia coli; *Staphylococcus spp.* - Coagulase producing strains; *Vibrio cholerae*; *Vibrio parahaemolyticus*; *Vibrio spp.*; *Vibrio vulnificus*; Coliforms; Coliforms - Thermotolerant		2009.02, AS 5013.12.3, AS 1766.2.9, FDA BAM 2004 (in house methods M43.2, M8.1, M8.2, M40.1)
		Yeasts and moulds (including osmophilic and preservative resistant forms)	Enrichment	in-house method M57
		Enterobacteriaceae	Spread plate - Petrifilm	AOAC 2003.01
		Clostridium perfringens	Spread plate - Aerobic and anaerobic	AS 5013.16
		Campylobacter spp.	Enrichment	AS 5013.6
		Coliforms - Thermotolerant	Most probable number (MPN)	AS 5013.15 (in-house method M8.2)
		Thermoduric organisms; Thermoduric spores	Pour plate	AS 5013.28
		Vibrio cholerae; *Vibrio parahaemolyticus*; *Vibrio spp.*; *Vibrio vulnificus*	Enrichment	FDA BAM 2004
		Staphylococcus enterotoxins	Enzyme linked immunosorbent assay (ELISA) - Automated (VIDAS)	in-house method M79
		Listeria spp.	Enzyme linked immunosorbent assay (ELISA) - Automated (VIDAS)	AOAC 999.06, AOAC 2004.06
		Yeasts and moulds; Yeasts and moulds - Osmophilic	Pour plate	AS 5013.29
		Listeria spp.; *Salmonella spp.*; *Staphylococcus* enterotoxins	Enzyme immunoassay (EIA)	AOAC 999.06, AOAC 996.08, AOAC 2004.06 (in house method M79)

SERVICE	PRODUCT	DETERMINANT	TECHNIQUE	PROCEDURE
		Listeria monocytogenes	PCR - Real time	NF BIO 12/40-11/16 (in-house method M36.11)
		Plate count	Membrane filter	AS 5013.14.2
		Plate count; Yeasts and moulds - Osmophilic	Pour plate; Spread plate	AS 5013.14.2, AS 5013.29
		Listeria spp.	Enrichment	AOAC 2004.02
		Escherichia coli; Coliforms	Most probable number (MPN)	AS 5013.5 (in-house method M8.1)
		Lactic acid bacteria	Spread plate	APHA 2001
		Coliforms	Pour plate	AS 5013.4
		Enterococci; Lactic acid bacteria; Mesophilic aerobic spores; Rope spores; Thermophilic anaerobic spores	Pour plate	APHA 2001
		Listeria monocytogenes; *Listeria spp.*	Spread plate - Aerobic and anaerobic	AS 5013.24.2
		Salmonella spp.	Enzyme linked immunosorbent assay (ELISA) - Automated (VIDAS)	AOAC 2013.01 (in-house method M80.6)
		Listeria spp.	PCR - Real time	NF BIO 12/39-09/16 (in-house method M36.10)
		Staphylococcus spp. - Coagulase producing strains	Most probable number (MPN)	AS 5013.12.3
		Bacillus cereus; *Campylobacter spp.*; *Clostridium perfringens*; *Enterobacteriaceae*; *Escherichia coli*; *Listeria monocytogenes*; *Listeria spp.*; *Staphylococcus spp.* - Coagulase producing strains; Coliforms; Lactic acid bacteria; Plate count; Psychrotrophic microorganisms; Yeasts	Spread plate - Aerobic and anaerobic	AOAC 990.12, AS 5013.2, AS 5013.6, AS 5013.16, AOAC 991.14, APHA 2001, AS 5013.24.2, AS 5013.23, AS 5013.12.1, AS 5013.29, AOAC 998.08, AOAC 2003.01, AOAC 2003.07, AOAC 2003.08, AOAC

SERVICE	PRODUCT	DETERMINANT	TECHNIQUE	PROCEDURE
		and moulds; Yeasts and moulds - Osmophilic		2003.11 (in house method M2.2)
		Psychrotrophic microorganisms	Spread plate	AS 5013.23
		Clostridium spp.; *Enterobacteriaceae*; *Enterococci*; Coliforms; Lactic acid bacteria; Mesophilic aerobic spores; Plate count; Rope spores; Thermoduric organisms; Thermoduric spores; Thermophilic aerobic spores; Yeasts and moulds; Yeasts and moulds - Osmophilic	Pour plate	AS 5013.5, AS 5013.4, AS 5013.28, AS 5013.29, APHA 2001 (in house methods M2.1, M45)
		Campylobacter spp.	Spread plate - Aerobic and anaerobic	AS 5013.6
		Vibrio cholerae; *Vibrio parahaemolyticus*; *Vibrio spp.*; *Vibrio vulnificus*	Most probable number (MPN)	FDA BAM 2004
		Staphylococcus spp. (including coagulase producing strains)	Spread plate - Petrifilm	AS 5013.12.1, AOAC 2003.07, AOAC 2003.08, AOAC 2003.11
		Yeasts and moulds - Osmophilic	Spread plate	AS 5013.29
	Beverages; Cereal products; Cocoa and cocoa products; Confectionery; Crustaceans; Dairy products; Eggs and egg products; Fish; Food additives; Fruit and fruit products; Gelatine and other gums; Heat-processed foods in hermetically sealed containers; Herbs and spices; Honey; Meat and meat products; Mixed foods; Molluscs (including shell); Nuts and nut products; Poultry and poultry products; Sugar products; Vegetables and vegetable products; Yeast isolates	*Bacillus cereus*	Most probable number (MPN)	in-house method M43.2

SERVICE	PRODUCT	DETERMINANT	TECHNIQUE	PROCEDURE
		Clostridium spp.	Enrichment	AS 5013.10
	Beverages; Cereal products; Cocoa and cocoa products; Confectionery; Crustaceans; Dairy products; Eggs and egg products; Fish; Fruit and fruit products; Gelatine and other gums; Heat-processed foods in hermetically sealed containers; Herbs and spices; Honey; Meat and meat products; Mixed foods; Molluscs (including shell); Mould isolates; Nuts and nut products; Poultry and poultry products; Sugar products; Vegetables and vegetable products	*Enterobacteriaceae*	Most probable number (MPN)	in-house method M40.2
	Beverages; Cereal products; Cocoa and cocoa products; Confectionery; Crustaceans; Eggs and egg products; Fish; Food additives; Fruit and fruit products; Gelatine and other gums; Heat-processed foods in hermetically sealed containers; Herbs and spices; Honey; Meat and meat products; Mixed foods; Molluscs (including shell); Nuts and nut products; Poultry and poultry products; Sugar products; Vegetables and vegetable products	Plate count	Pour plate	AS 5013.5 (in-house method M2.1)
	Beverages; Cereal products; Cocoa and cocoa products; Confectionery; Dairy products; Eggs and egg products; Fish; Food additives; Fruit and fruit products; Gelatine and other gums; Heat-processed foods in hermetically sealed containers; Herbs and spices; Honey; Meat and meat products; Mixed foods; Molluscs (including shell); Nuts and nut	*Salmonella spp.*	Enrichment	AOAC RI Cert 020901

SERVICE	PRODUCT	DETERMINANT	TECHNIQUE	PROCEDURE
	products; Poultry and poultry products; Sugar products; Vegetables and vegetable products; Yeast isolates			
	Cereal products; Confectionery; Crustaceans; Dairy products; Edible fats and oils; Eggs and egg products; Fish; Food additives; Fruit and fruit products; Heat-processed foods in hermetically sealed containers; Herbs and spices; Honey; Meat and meat products; Mixed foods; Molluscs (including shell); Nuts and nut products; Poultry and poultry products; Sugar products; Vegetables and vegetable products	*Pseudomonas spp.*	Spread plate - Aerobic and anaerobic	in-house method M114.1
	Dairy products	*Escherichia coli*	Pour plate	ISO 16649-2 (in-house method M134)
	Dairy products; Infant cereal; Infant formulas	*Cronobacter spp.*	PCR - Real time	NF BIO 12/42-03/18 (in-house method M140)
	Dairy products; Meat and meat products	*Listeria monocytogenes*	PCR - Real time	AOAC 2019.11 (in-house method M36.11)
	Mixed foods	Coliforms - Thermotolerant	Spread plate - Petrifilm	AFNOR 3M 01/2-09/89C (in-house method M52)
	Potable waters	*Escherichia coli*; Coliforms; Coliforms - Thermotolerant	Most probable number (MPN)	AS/NZS 4276.6
		Salmonella spp.	Qualitative selective enrichment	AS/NZS 4276.14
		Pseudomonas aeruginosa; *Pseudomonas spp.*	Membrane filter	AS 4276.11, AS 4276.13
		Escherichia coli; *Streptococcus* - Faecal; Coliforms - Thermotolerant	Membrane filter	AS 4276.7
		Listeria monocytogenes; *Listeria spp.*	Cultural; Enzyme linked	in-house methods M36.3,

SERVICE	PRODUCT	DETERMINANT	TECHNIQUE	PROCEDURE
			immunosorbent assay (ELISA) - Automated (VIDAS)	M36.8
		Enterococci	Membrane filter	AS 4276.9
		Clostridium spp. (including spores of sulfite reducing *Clostridia*); *Enterococci*; *Escherichia coli*; *Pseudomonas aeruginosa*; *Pseudomonas spp.*; *Streptococcus* - Faecal; Coliforms; Coliforms - Thermotolerant; Plate count	Membrane filter	AS/NZS 4276.3.1, AS/NZS 4276.17.1, AS/NZS 4276.5, AS/NZS 4276.7, AS/NZS 4276.9, AS/NZS 4276.11, AS/NZS 4276.13
		Salmonella spp.	Enzyme linked immunosorbent assay (ELISA) - Automated (VIDAS)	AOAC 2013.01 (in-house method M80.6)
		Plate count	Membrane filter	AS 4276.3.1
		Coliforms	Membrane filter	AS 4276.5
		Legionella pneumophila; *Legionella spp.*; Plate count	Spread plate - Aerobic and anaerobic	AS/NZS 4276.3.1, AS 3896
		Heterotrophic colony count; Plate count	Pour plate	AS/NZS 4276.3.1, AS/NZS 4276.3.2
		Clostridium spp. (including spores of sulfite reducing *Clostridia*)	Membrane filter	AS 4276.17.1

ISO/IEC 17025 (2017)

Healthcare, Pharmaceutical and Media Products

SERVICE	PRODUCT	DETERMINANT	TECHNIQUE	PROCEDURE
Analysis for microorganisms	Bacterial isolates; Yeast isolates	Identification	MALDI-TOF	AOAC 2017.09; AOAC 2017.10 (in-house method M139)
Analysis for physical and chemical characteristics of cosmetics,	Cosmetic products; Essential oils; Perfumes	Bioburden	Classical	ANSI/AMMI/ISO 11737-1, BS EN 1174.1 (in-house method M38)

SERVICE	PRODUCT	DETERMINANT	TECHNIQUE	PROCEDURE
perfumes and essentials oils				
Analysis for physical and chemical characteristics of human and veterinary medicines including vaccines	Biological products; Pharmaceuticals	Bioburden	Classical	ANSI/AMMI/ISO 11737-1 BS EN 1174.1 (in-house method M38)
Biological analysis of cosmetics, perfumes and essentials oils	Cosmetic products; Essential oils; Perfumes	*Candida albicans*; *Clostridium perfringens*; *Clostridium spp.*; *Enterobacteriaceae*; *Escherichia coli*; *Pseudomonas aeruginosa*; *Pseudomonas spp.*; *Salmonella spp.*; *Staphylococcus aureus*; Aerobes; Aerobes - Total viable; Bile tolerant gram negative bacteria; Coliforms; Spores; Yeasts and moulds	Pour plate; Spread plate - Aerobic and anaerobic	British Pharmacopeia,British Pharmacopeia (Harmonised), CTMAA, FDA BAM, United States Pharmacopeia (in-house methods M21, M22, M24, M56)
Biological analysis of human and veterinary medicines including vaccines	Biological products	*Candida albicans*; *Clostridium perfringens*; *Clostridium spp.*; *Enterobacteriaceae*; *Escherichia coli*; *Pseudomonas aeruginosa*; *Pseudomonas spp.*; *Salmonella spp.*; *Staphylococcus aureus*; Aerobes - Total viable; Coliforms; Lactic acid bacteria; Yeasts and moulds		
	Biological products; Pharmaceuticals	*Candida albicans*; *Clostridium perfringens*; *Clostridium spp.*; *Enterobacteriaceae*; *Escherichia coli*; *Pseudomonas aeruginosa*; *Pseudomonas spp.*; *Salmonella spp.*; *Staphylococcus aureus*; Aerobes - Total viable; Bile tolerant gram negative bacteria; Coliforms; Lactic acid bacteria; Yeasts and moulds	Membrane filter; Pour plate; Spread plate - Aerobic and anaerobic	BP, CTMMS, FDA BAM, USP (in-house methods M21, M22, M56, M65.1)
Biological analysis of medical devices	Medical devices	*Clostridium perfringens*; *Clostridium spp.*; *Enterobacteriaceae*; *Escherichia coli*; *Pseudomonas aeruginosa*; *Pseudomonas spp.*; *Salmonella spp.*;	Pour plate	in-house methods M21, M22, M24

SERVICE	PRODUCT	DETERMINANT	TECHNIQUE	PROCEDURE
		Staphylococcus aureus; Aerobes; Coliforms; Spores; Yeasts and moulds		
Biological analysis of other healthcare or pharmaceutical products and accessories	Bandages; Surgical dressings and related products	Isolation of bacterial contaminants	Membrane filter; Plating	in-house methods M20.1, M20.2, M20.3
	Disinfectants	Efficacy	Pour plate	TGO 54 (in-house method M27)
		Pseudomonas aeruginosa; *Staphylococcus aureus*	Carrier test	AOAC 991.47, AOAC 991.48, AOAC 991.49 (in-house method M55)
	Pharmaceutical waters	Aerobes - Total viable	Membrane filter	BP Harmonised (in-house method M54)
	Tampons	Aerobes - Total viable; Yeasts and moulds	Membrane filter; Pour plate	AS 2869 (in-house method M21)

The only data displayed is that deemed relevant and necessary for the clear description of the activities and services covered by the scope of accreditation.

Grey text appearing in a SoA is additional freetext providing further refinement or information on the data in the preceding line entry.

Accreditation No.	Site No.	Print date
2020	2013	31 Jan 2023

END OF SCOPE

Australian Government
Department of Agriculture, Water and the Environment

Ms Melinda Skipper
National Quality Manager
Silliker Australia Pty Ltd
20 King Street
BLACKBURN VIC 3130

Dear Ms Skipper,

Department of Agriculture, Water and the Environment approval to test meat and meat products at Mérieux NutriSciences (Silliker Australia Pty Ltd) – Melbourne Microbiology Laboratory, NATA Accreditation No: 2020, Site No: 2013

The Department of Agriculture, Water and the Environment (the department) has issued a new approval based on the current NATA scope of accreditation for testing of exported meat surfaces and meat/meat products. Your laboratory has been granted department approval for the following tests:

	APC	*E. coli*/coliforms	*Salmonella*	*Listeria*
Meat Surfaces	AS 5013.5	AOAC 991.14 AOAC 998.08	AS 5013.10 AOAC 996.08	AS 5013.24.1 AOAC 999.06 AOAC 2004.06
Meat & Meat Products	AS 5013.5	AOAC 991.14 AOAC 998.08	AS 5013.10 AOAC 996.08	AS 5013.24.1 AOAC 999.06 AOAC 2004.06

It is a condition of approval that methodology used at your laboratory for the above tests is as detailed in the applicable standards. No in-house modifications of methods are allowed without written approval from the department. Conditions of approval can be reviewed in the *Microbiological Manual for Sampling and Testing of Export Meat and Meat Products* on the department's website.

If you have any questions regarding approval or department approved methods, please contact me directly on s. 22(1)(a)(ii) .

Yours sincerely

s. 47F(1)

s. 22(1)(a)(ii)
Principal – Microbiology and Laboratory Oversight
Export Standards Branch – Exports and Veterinary Services Division

26 May 2021

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F +61 2 6272 5161
18 Marcus Clarke Street
Canberra City ACT 2601
GPO Box 858
Canberra ACT 2601
awe.gov.au
ABN 34 190 894 983

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

From: Melinda Skipper <s. 47F(1) @mxns.com>
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)
Subject: Re: 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

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
Phone: 1300 000 990
Direct: +s. 47F(1)
http://www.merieuxnutrisciences.com/au
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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.
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> Kind regards
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Subject: Re: Request for change to list of Approved Tests for Silliker Melbourne Site [SEC=UNOFFICIAL]

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Thanks and best regards,

Melinda Skipper

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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 anv Veterinary Services Division

70 Northbourne Ave, Canberra ACT 2601 Australia

GPO Box 858 Canberra ACT 2601 Australia

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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 *Escherichia coli* O157 Note - when analysing frozen or chilled samples, the temperature of broth and samples must be at 41.5 ± 1°C for a minimum of 6 h and subsequently for a further 12 to 18 hours.
➢ **FSIS MLG 5**	Detection, isolation, and identification of *Escherichia coli* O157:H7 from meat products Note the method has been updated changing the initial enrichment to mTSB and the definition of *E. coli* O157:H7. When analysing frozen or chilled samples, the temperature of broth and samples must be at 42 ± 1°C for a minimum of 15 hours.
➢ **FDA BAM Chapter 4A(K)**	Diarrheagenic *Escherichia coli* - Enrichment and isolation of *E. coli* 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) mEHEC 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.
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Can you advise whether confirmation by the AOAC methods in question have been approved by your Department. I think we have received letters from Biomeriuex 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,

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National Quality Assurance Manager

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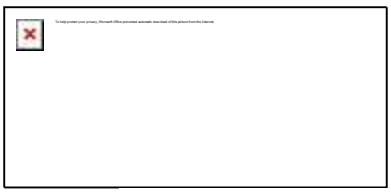
s. 22(1)(a)(ii)

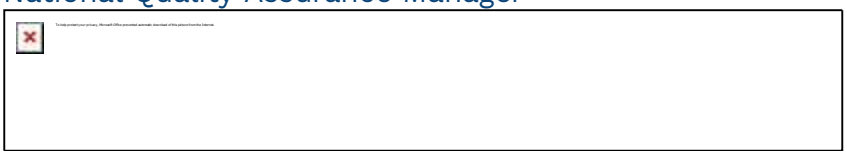
From: Melinda Skipper <s. 47F(1) @mxns.com>
Sent: Tuesday, 7 February 2023 11:40 AM
To: s. 22(1)(a)(ii)
Cc: s. 22(1)(a)(ii); Lucy Evans
Subject: Re: Request for change to list of Approved Tests for Silliker Melbourne Site [SEC=UNOFFICIAL]

Thanks s. 22(1)(a)(ii) - look forward to hearing back from you.

Best regards,



Melinda Skipper
National Quality Assurance Manager



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On Tue, Feb 7, 2023 at 11:28 AM s. 22(1)(a)(ii) @aff.gov.au> wrote:

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Sent: Tuesday, 7 February 2023 10:10 AM
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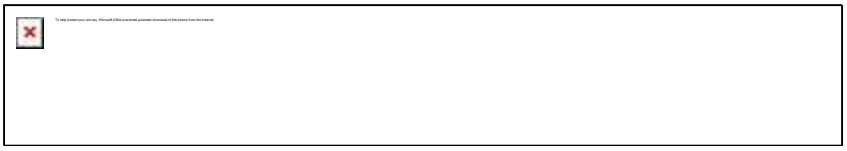

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Microbiologist | Residues and Microbiological Policy

Tel: + s. 22(1)(a)(ii) | Ext. s. 22(1)(a)(ii)

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Rapid methods

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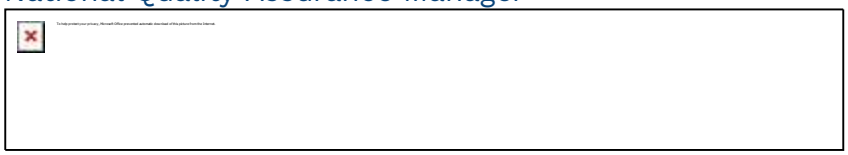
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Kind regards

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) <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]

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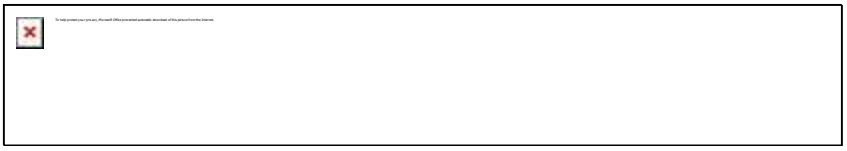
Thanks and best regards,

Melinda Skipper

National Quality Assurance Manager



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> **From:** s. 22(1)(a)(ii)
> **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) <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]
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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 anv 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>; Anupriya Moorkanath <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 *Escherichia coli* O157 Note - when analysing frozen or chilled samples, the temperature of broth and samples must be at 41.5 ± 1°C for a minimum of 6 h and subsequently for a further 12 to 18 hours.
➢ **FSIS MLG 5**	Detection, isolation, and identification of *Escherichia coli* O157:H7 from meat products Note the method has been updated changing the initial enrichment to mTSB and the definition of *E. coli* O157:H7. When analysing frozen or chilled samples, the temperature of broth and samples must be at 42 ± 1°C for a minimum of 15 hours.
➢ **FDA BAM Chapter 4A(K)**	Diarrheagenic *Escherichia coli* - Enrichment and isolation of *E. coli* 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
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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) mEHEC 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
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➢ **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 Biomeriuex 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,

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Melinda Skipper

National Quality Assurance Manager

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

From: s. 22(1)(a)(ii)
Sent: Friday, 17 February 2023 3:04 PM
To: Melinda Skipper
Cc: Lucy Evans; s. 22(1)(a)(ii)
Subject: FW: Request for change to list of Approved Tests for Silliker Melbourne Site [SEC=UNOFFICIAL]
Attachments: Silliker Melbourne 17 02 2023.pdf

Tracking:

Recipient	Read
Melinda Skipper	
Lucy Evans	
s. 22(1)(a)(ii)	Read: 17/02/2023 3:13 PM

Good afternoon Melinda,

Thanks for the documents for our review. Some minor comments:

M134 (Detection of E. coli O157:H7 using AOAC 2019.03)

Section 12: please note that the department approved this method for screening of O157:H7 only. Please add a note that all DAFF screen positive samples are to be confirmed by AOAC 2020.06 or other department approved confirmatory methods.

Section 15 (Appendix), flow diagram needs to be updated

M142 (Detection of Enterohaemorrhagic (EHEC) using AOAC 2020.06)

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Page 18 (flow diagram) needs to be updated to reflect this. i.e. Latex > Serogroup PCR > stx/eae PCR

Please find attached updated approval letter. Please do not hesitate to contact us if you have any questions.

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 anv Veterinary Services Division
70 Northbourne Ave, Canberra ACT 2601 Australia
GPO Box 858 Canberra ACT 2601 Australia

From: s. 22(1)(a)(ii)
Sent: Tuesday, 7 February 2023 11:29 AM
To: Melinda Skipper
Cc: s. 22(1)(a)(ii) ; Lucy Evans
Subject: RE: Request for change to list of Approved Tests for Silliker Melbourne Site [SEC=UNOFFICIAL]

Hi Melinda,

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

From: Melinda Skipper <s. 47F(1) @mxns.com>
Sent: Tuesday, 7 February 2023 10:10 AM
To: s. 22(1)(a)(ii) @awe.gov.au>
Cc: s. 22(1)(a)(ii) @awe.gov.au>; Lucy Evans <s. 47F(1)@mxns.com>
Subject: Re: Request for change to list of Approved Tests for Silliker Melbourne Site [SEC=UNOFFICIAL]

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Tel: + s. 22(1)(a)(ii) | Ext. s. 22(1)(a)(ii)

Department of Agriculture, Fisheries and Forestry

Export Standards Branch | Exports anv Veterinary Services Division

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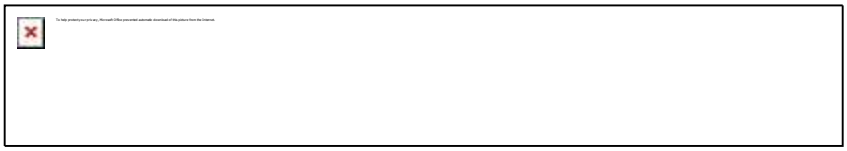

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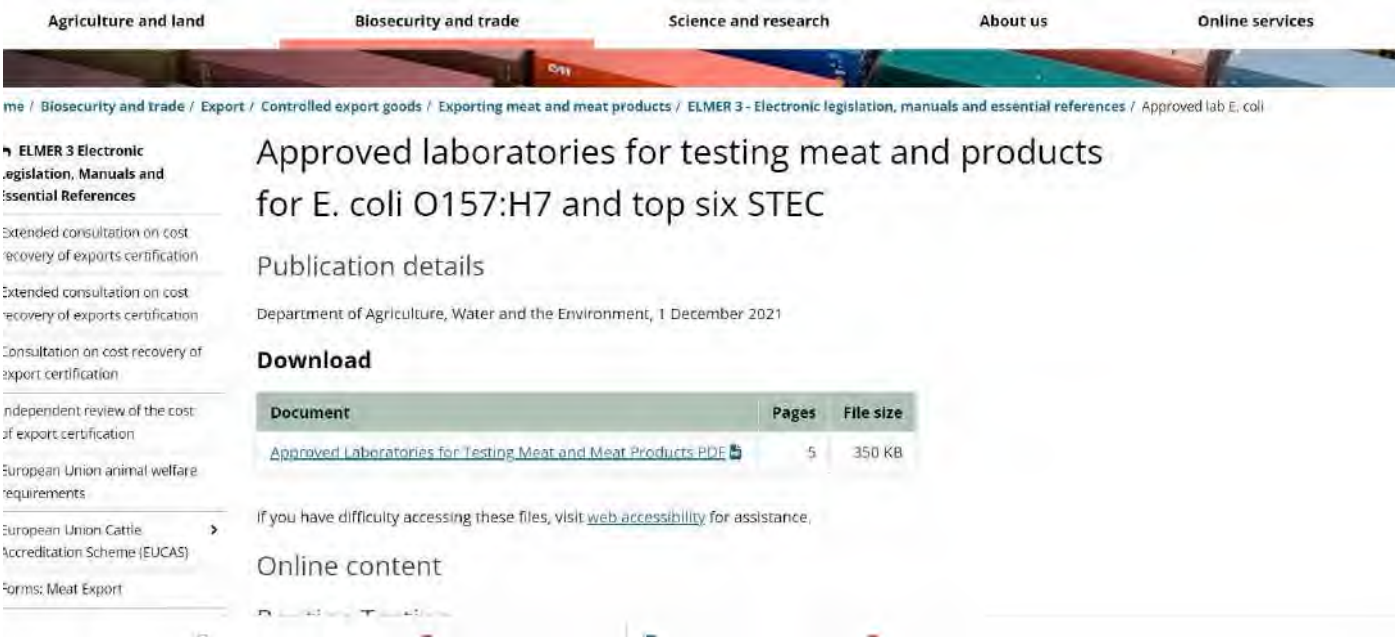
From: Melinda Skipper <s. 47F(1) @mxns.com>
Sent: Friday, 24 February 2023 1:05 PM
To: s. 22(1)(a)(ii)
Cc: Lucy Evans
Subject: Re: FW: Request for change to list of Approved Tests for Silliker Melbourne Site [SEC=UNOFFICIAL]

Hi s. 22(1)(a)(ii),
Are we now able to be added to your website under the list of approved laboratories, for Melbourne: E.coli O157 and STEC for Routine, Confirmatory & Verification Testing?



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Sent: Tuesday, 7 February 2023 10:10 AM
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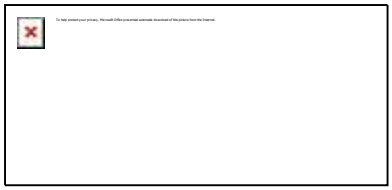

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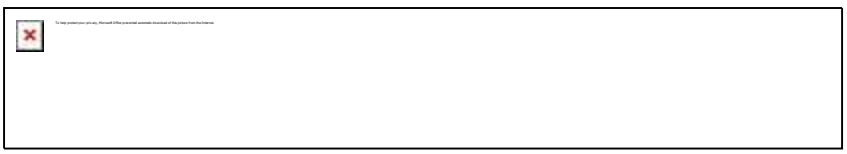
National Quality Assurance Manager



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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) <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 *Escherichia coli* O157 Note - when analysing frozen or chilled samples, the temperature of broth and samples must be at 41.5 ± 1°C for a minimum of 6 h and subsequently for a further 12 to 18 hours.
➢ **FSIS MLG 5**	Detection, isolation, and identification of *Escherichia coli* O157:H7 from meat products Note the method has been updated changing the initial enrichment to mTSB and the definition of *E. coli* O157:H7. When analysing frozen or chilled samples, the temperature of broth and samples must be at 42 ± 1°C for a minimum of 15 hours.
➢ **FDA BAM Chapter 4A(K)**	Diarrheagenic *Escherichia coli* - Enrichment and isolation of *E. coli* 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) mEHEC 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 Biomeriuex 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

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Phone: 1300 000 990

Direct: +s. 47F(1)

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

From: s. 22(1)(a)(ii)
Sent: Friday, 31 March 2023 3:34 PM
To: Melinda Skipper
Cc: s. 22(1)(a)(ii)
Subject: RE: FW: Request for change to list of Approved Tests for Silliker Melbourne Site [SEC=UNOFFICIAL]

Hi Melinda,

Verification samples need to be analysed by BAX methods only. But we are working on including GENE-UP (AOAC 2020.06) and other confirmatory methods in addition to BAX. We will update you once we finalize this.

We will update contact list in the next scheduled update.

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

---

s. 22(1)(a)(ii)
Microbiologist | Export Standards Branch | Exports & Veterinary Services Division
Tel: + s. 22(1)(a)(ii) | Fax: + 61 2 6272 4389

Department of Agriculture, Fisheries and Forestry
70 Northbourne Ave, CANBERRA ACT 2600
GPO Box 858 Canberra ACT 2601 Australia

From: Melinda Skipper
Sent: Friday, 31 March 2023 2:56 PM
To: s. 22(1)(a)(ii)
Subject: Fwd: FW: Request for change to list of Approved Tests for Silliker Melbourne Site [SEC=UNOFFICIAL]

Hi s. 22(1)(a)(ii),
I can see that your website has been updated to include E.coli O157 and STEC in our Melbourne site under Routine test and Confirmation - much appreciated!
I was just wondering about the Verification Category - are we not able to be listed under there too?

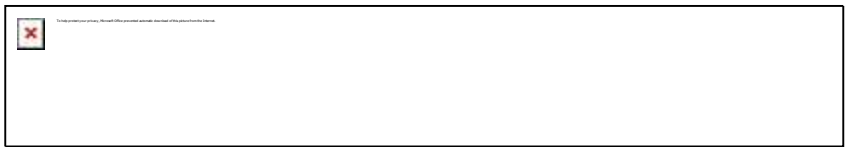
Also, the contact for Melbourne is listed as Elias Lye, when he has in fact now left our business. The correct contact for Melbourne now is as follow:

s. 47F(1)
Email address: s. 47F(1) @mxns.com
Phone: 1300 000 990

Is this able to be updated on the website?

Thanks and very best regards,
Melinda.

Melinda Skipper
National Quality Assurance Manager



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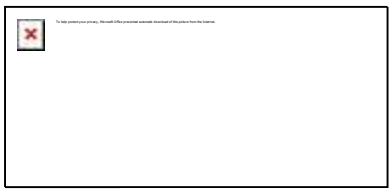
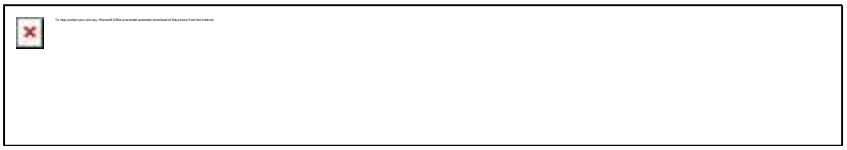
On Fri, 24 Feb 2023 at 13:40, Melinda Skipper <s. 47F(1) @mxns.com> wrote:

> Thank-you - much appreciated!
>
> Best regards,



Melinda Skipper
National Quality Assurance Manager



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s. 47F(1) *@mxns.com and delete the message from your system.*

On Fri, Feb 24, 2023 at 1:57 PM s. 22(1)(a)(ii) @aff.gov.au> wrote:

Hi Melinda,

We will update the department webpages in a couple of weeks. The lab can start doing confirmation testings.

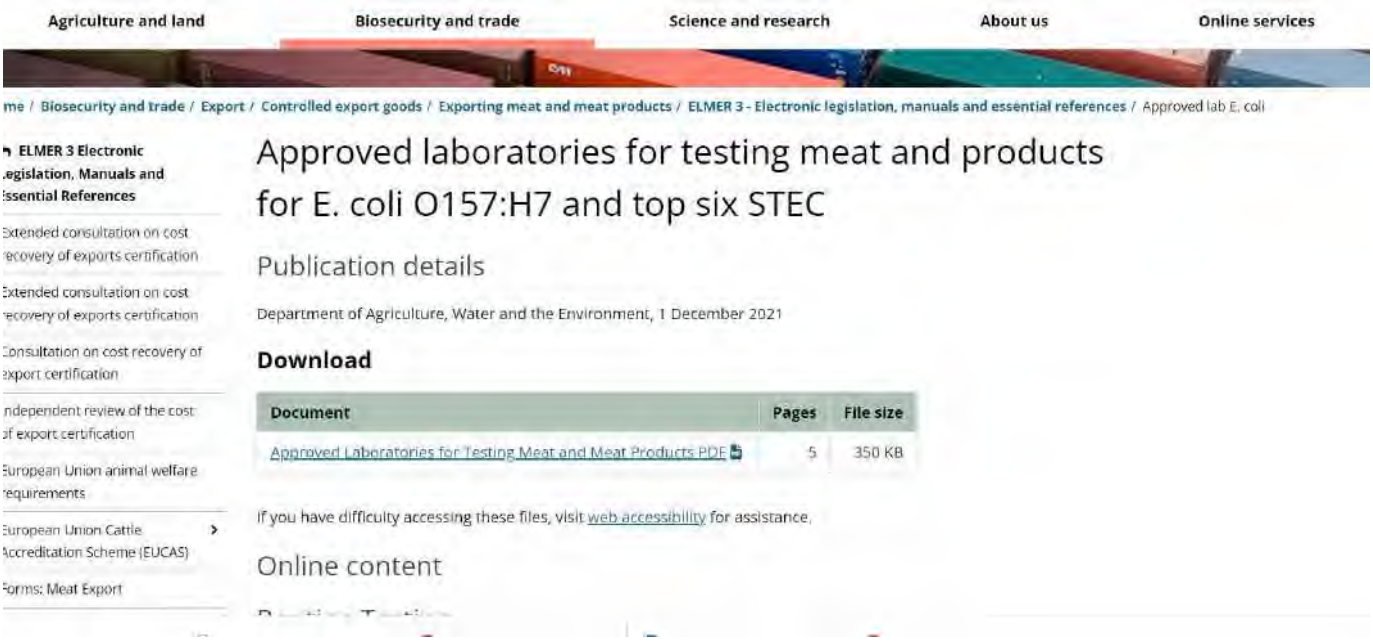
Kind regards

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

From: Melinda Skipper <s. 47F(1) r@mxns.com>
Sent: Friday, 24 February 2023 1:05 PM
To: s. 22(1)(a)(ii) @aff.gov.au>
Cc: Lucy Evans <s. 47F(1)@mxns.com>
Subject: Re: FW: Request for change to list of Approved Tests for Silliker Melbourne Site [SEC=UNOFFICIAL]

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

Are we now able to be added to your website under the list of approved laboratories, for Melbourne: E.coli O157 and STEC for Routine, Confirmatory & Verification Testing?



Thanks very much and best regards,

Melinda.

Melinda Skipper

National Quality Assurance Manager

Mérieux NutriSciences

20 King Street, Blackburn, Victoria 3130, Australia

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http://www.merieuxnutrisciences.com/au

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On Fri, Feb 17, 2023 at 3:04 PM s. 22(1)(a)(ii) @aff.gov.au> wrote:

Good afternoon Melinda,

Thanks for the documents for our review. Some minor comments:

M134 (Detection of E. coli O157:H7 using AOAC 2019.03)

Section 12: please note that the department approved this method for screening of O157:H7 only. Please add a note that all DAFF screen positive samples are to be confirmed by AOAC 2020.06 or other department approved confirmatory methods.

Section 15 (Appendix), flow diagram needs to be updated

M142 (Detection of Enterohaemorrhagic (EHEC) using AOAC 2020.06)

Section 11.1.3 (step 5): refers to 20µL, however, AOAC 2020.06 standard method requires that 10µL of sampled is added to the lysis tube.

Section 12.3

Confirmation of Positive Latex Test: Latex positive samples are to be confirmed by virulence gene PCR as well as serogroup specific PCR. This is the requirement of US FSIS, MLG 5C states “For a sample to identify as positive for STEC, the E. coli isolate must contain an stx gene, an eae gene; and genetically identify as one of more of the top seven serogroups”.

Page 18 (flow diagram) needs to be updated to reflect this. i.e. Latex > Serogroup PCR > stx/eae PCR

Please find attached updated approval letter. Please do not hesitate to contact us if you have any questions.

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 anv Veterinary Services Division

70 Northbourne Ave, Canberra ACT 2601 Australia

GPO Box 858 Canberra ACT 2601 Australia

From: s. 22(1)(a)(ii)
Sent: Tuesday, 7 February 2023 11:29 AM
To: Melinda Skipper <s. 47F(1) @mxns.com>
Cc: s. 22(1)(a)(ii) @awe.gov.au>; Lucy Evans <s. 47F(1)@mxns.com>
Subject: RE: Request for change to list of Approved Tests for Silliker Melbourne Site [SEC=UNOFFICIAL]

Hi Melinda,

We are reviewing your request, we will let you know if we need any other information.

Kind regards

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

From: Melinda Skipper <s. 47F(1) @mxns.com>
Sent: Tuesday, 7 February 2023 10:10 AM
To: s. 22(1)(a)(ii) @awe.gov.au>
Cc: s. 22(1)(a)(ii) @awe.gov.au>; Lucy Evans <s. 47F(1)@mxns.com>
Subject: Re: Request for change to list of Approved Tests for Silliker Melbourne Site [SEC=UNOFFICIAL]

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

Just following up on my email below, do you need anything else from us in regard to this request for addition to our list of approved tests?

Thanks and best regards,

Melinda.

Melinda Skipper
National Quality Assurance Manager

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20 King Street, Blackburn, Victoria 3130, Australia
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On Thu, Feb 2, 2023 at 10:15 AM Melinda Skipper <s. 47F(1) r@mxns.com> wrote:

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.

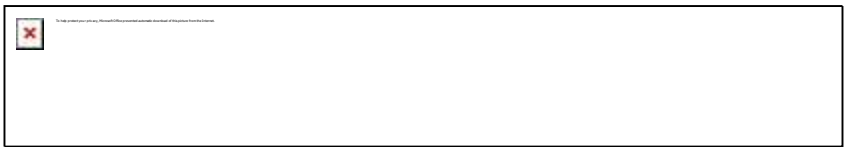
Let me know if you need anything else.

Thanks and best regards,

Melinda.

Melinda Skipper

National Quality Assurance Manager



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Follow us on:

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)

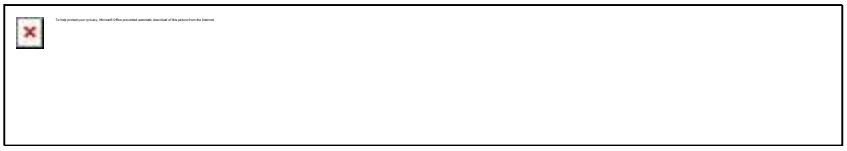
From: Melinda Skipper <s. 47F(1) @mxns.com>
Sent: Wednesday, 1 February 2023 4:43 PM
To: s. 22(1)(a)(ii) @aff.gov.au>
Cc: Lucy Evans <s. 47F(1)@mxns.com>; s. 47F(1) @mxns.com>; s. 22(1)(a)(ii)
s. 22(1)(a)(ii) @aff.gov.au>
Subject: Re: Request for change to list of Approved Tests for Silliker Melbourne 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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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: 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]

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 anv 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>
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 *Escherichia coli* O157 Note - when analysing frozen or chilled samples, the temperature of broth and samples must be at 41.5 ± 1°C for a minimum of 6 h and subsequently for a further 12 to 18 hours.
➢ **FSIS MLG 5**	Detection, isolation, and identification of *Escherichia coli* O157:H7 from meat products Note the method has been updated changing the initial enrichment to mTSB and the definition of *E. coli* O157:H7. When analysing frozen or chilled samples, the temperature of broth and samples must be at 42 ± 1°C for a minimum of 15 hours.
➢ **FDA BAM Chapter 4A(K)**	Diarrheagenic *Escherichia coli* - Enrichment and isolation of *E. coli* 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)

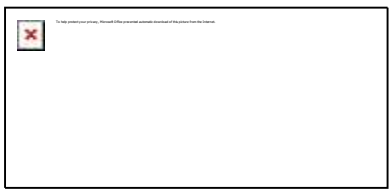
➢ **FSIS MLG 5B**	Detection and isolation of non-O157 Shiga-toxin Producing *Escherichia coli* (STEC) from meat products
Rapid methods	
Where positive confirmation is required such confirmation must be by FSIS MLG 5B	
➢ **AOAC 071301**	Assurance GDS® MPX Top 7 STEC for detection of top 7 pathogenic STEC in beef trim Samples (375 g) are diluted in 1.5 L of pre-warmed (42°C) mEHEC 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 Biomeriuex 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.

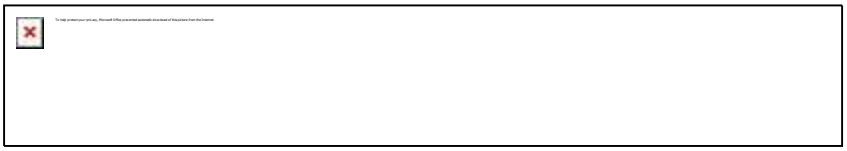
Thanks and best regards,

Melinda.



Melinda Skipper

National Quality Assurance Manager



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

From: s. 22(1)(a)(ii)
Sent: Wednesday, 31 January 2024 1:47 PM
To: s. 22(1)(a)(ii)
Subject: FW: GENE-UP® EHEC Detection Method – AOAC 2020.06 document amendment request [SEC=OFFICIAL]
Attachments: geneup-ehec-aoac-121806.pdf; AOAC Official Method 2020.06 Enterohemorrhagic E. coli in Select Foods GENE-UP® EHEC Detection Method First Action 2020 2020_06.pdf

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

Would you mind looking into this one. Do we need to amend our checklist? I can't recall if we discussed when s. 47F(1) sent the original request in October.

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

From: s. 47F(1)
Sent: Wednesday, January 31, 2024 1:37 PM
To: s. 22(1)(a)(ii)
Subject: FW: GENE-UP® EHEC Detection Method – AOAC 2020.06 document amendment request

> You don't often get email from s. 47F(1) @biomerieux.com. Learn why this is important

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

Hope you are well. Is there any updates on the email below? Thank you

Regards

s. 47F(1)
bioMérieux | Customer Support Manager ANZ
Industrial Applications
s. 47F(1) @biomerieux.com
HelpDesk: 1800 333 421 | Mobile: +s. 47F(1)
www.biomerieux.com

From: s. 47F(1)
Sent: Friday, 27 October 2023 3:57 PM
To: s. 22(1)(a)(ii)@aff.gov.au
Subject: GENE-UP® EHEC Detection Method – AOAC 2020.06 document amendment request

Good afternoon s. 22(1)(a)(ii),

Hope this email finds you well. I received your contact from a colleague of mine, s. 47F(1) whom you have had previous correspondence with.

I email today as I want to request an amendment to the GENE-UP® EHEC Detection Method – AOAC 2020.06 document published online with rationale mentioned below:

In the DAFF document, there is reference to both VIDAS ESPT and bead beating with the GENE-UP Lysis Kit as Immunoconcentration options. However only the VIDAS ESPT is an immunoconcentration step. The request would be to amend the document to outline the options and state one method of sample preparation involves immunoconcentration of targeted cells (VIDAS ESPT) and one uses a Bead Beating mechanical lysis step (Lysis kit). The AOAC Official method 2020.06 documentation also supports this differentiation.

- **Immuno-concentration[1]**
  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.

Queries from customers and concern over immunoconcentration protocol is what has triggered further review into this document. If you are unable to assist, can you please point me in the right direction for further discussion. Thank you.

Regards

s. 47F(1)
bioMérieux | Customer Support Manager ANZ
Industrial Applications
s. 47F(1) @biomerieux.com
HelpDesk: 1800 333 421 | Mobile: +s. 47F(1)
www.biomerieux.com

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

From: Lucy Evans <s. 47F(1)@mxns.com>
Sent: Tuesday, 18 March 2025 3:52 PM
To: s. 22(1)(a)(ii)
Cc: s. 22(1)(a)(ii) ; Melinda Skipper; s. 47F(1)
Subject: Re: FW: Merieux NutriSciences COA Tongala 8/03/2025 (MELBOURNE) [SEC=OFFICIAL]
Attachments: 24MX2_SillikerAustralia-PerthLaboratory.pdf

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

Below is an outline of our protocol for handling potential positive broths received from screening laboratories:

- A portion of the potential positive broth (500ml) from a BAX screen is sent to the Melbourne lab overnight.
- Upon receipt, the lab tests a 25ml aliquot of the broth.
- This aliquot is diluted by adding 225ml of BPW (1/10 dilution) and then incubated at 41.5°C for minimum 8 hrs.
- The sample is subsequently processed following method 142.

We will be updating our methods to reflect these details for better clarity.

Attached, is the most recent proficiency study which utilised this process of testing, with BAX screening initially and then confirmation through GeneUp(M142). We have performed other trials and will continue to utilise the proficiency programs to verify this procedure. The Melbourne lab has participated in proficiency testing using M142 twice per year since NATA accreditation was approved.

If you need any further information please let me know.

Kind Regards,

Lucy Evans
Operations Director

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

Better Food. Better Health. Better World.

Mérieux NutriSciences recognises and acknowledges the Wadjuk-Noongar People, the traditional custodians of the boodja (land)on which we live, work and kaartdijin (learn) together and pay our respect to the Elders past, present and emerging.

On Fri, 14 Mar 2025 at 13:35, s. 22(1)(a)(ii) @aff.gov.au> wrote:

OFFICIAL

Hi Lucy,

Thanks for the discussion earlier today.

As raised, I would really appreciate additional information on your protocol for receival of potential positive broths from screening laboratories, how these are sampled, incubated with BPW and introduced into the GENE-UP procedure, and any supporting verification studies for this part of your method.

Regards,

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

OFFICIAL

From: Lucy Evans <s. 47F(1)@mxns.com>
Sent: Thursday, 13 March 2025 7:04 PM
To: s. 22(1)(a)(ii) @aff.gov.au>
Cc: s. 22(1)(a)(ii) @aff.gov.au>; Melinda Skipper <s. 47F(1) @mxns.com>; s. 47F(1) s. 47F(1) @mxns.com>; s. 47F(1) @mxns.com>; Di Shen <s. 47F(1)@mxns.com>
Subject: Re: FW: Merieux NutriSciences COA Tongala 8/03/2025 (MELBOURNE) [SEC=OFFICIAL]

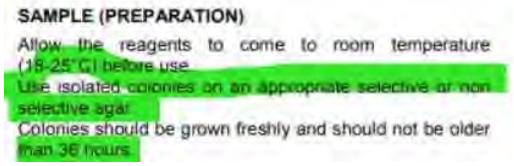
Hi s. 22(1)(a)(ii)

Please find our method attached as requested (*confidential information*). Our method is based on AOAC 2020.06, which was approved by the department as a confirmation and screening methodology prior to our implementation (and accreditation/approvals).

Additionally, please see the information below to address the issues raised.

1. Our methodology follows the AOAC 2020.06 reference method, which applies to the entire testing process. As per this methodology, samples were tested using the full protocol.

2. SLIDEX Latex Test on Selective Agars - According to the SLIDEX user manual, colonies may be picked from selective agar for testing, provided they are well-isolated and fresh (see screenshot for reference). This step is performed after an O-type PCR and is followed by EHEC gene-specific PCR (GENE-UP® STEC-stx & eae 2). The process complies with the GENE-UP® EHEC Detection Method.



SAMPLE (PREPARATION)

Allow the reagents to come to room temperature (18-25°C) before use.
Use isolated colonies on an appropriate selective or non selective agar.
Colonies should be grown freshly and should not be older than 36 hours.

3. According to the method, the workflow consists of the following steps:

=> Sample preparation

=> VIDAS ® ESPT

=> GENE-UP® STEC – stx & eae

=> GENE-UP® E. coli O157:H7 (ECO 2) and GENE-UP® STEC Top 6 (EH2)

=> Confirmation via VIDAS® ESPT2 to CHROMID® EHEC agar, SMAC CT agar, and CHROMID® Coli agar

=> Serogroup Identification using LATEX **OR** serogroup specific PCR (GENE-UP® STEC Top 6 and/or GENE-UP® E. coli O157:H7 2)--- in this case we choose SLIDEX, so serogroup PCR is not necessary.

=> EHEC gene specific PCR (GENE-UP® STEC-stx & eae 2).

GENE-UP® STEC-stx & eae 2 is sufficient to confirm colonies from LATEX, as per the method.

4. The Lysis Gene-UP step in this context refers to the preparation of a colony that has already been confirmed with SLIDEX, before proceeding to GENE-UP® STEC-stx & eae 2, not the initial PCR step from the enrichment phase. This step can be performed using either Lysis Gene-UP or VIDAS® ESPT, depending on the workflow.

5. This step follows the GENE-UP® EHEC Detection method workflow. It may appear repetitive, but it aligns with the required protocol to ensure confirmation at the appropriate stage.

If you need anything else, please let us know.

Thanks

Kind Regards,

Lucy Evans

Operations Director

Direct: +s. 47F(1)

Mobile: +s. 47F(1)

Better Food. Better Health. Better World.

Mérieux NutriSciences recognises and acknowledges the Wadjuk-Noongar People, the traditional custodians of the boodja (land)on which we live, work and kaartdijin (learn) together and pay our respect to the Elders past, present and emerging.

---------- Forwarded message ---------
From: s. 22(1)(a)(ii) @aff.gov.au>
Date: Thu, 13 Mar 2025 at 04:52
Subject: RE: FW: Merieux NutriSciences COA Tongala 8/03/2025 (MELBOURNE) [SEC=OFFICIAL]
To: Lucy Evans <s. 47F(1) @mxns.com>
Cc: s. 47F(1) @mxns.com>, s. 22(1)(a)(ii) @aff.gov.au>, Melinda Skipper <s. 47F(1) @mxns.com>s. 47F(1) <s. 47F(1) @mxns.com>, s. 47F(1) @mxns.com>, s. 47F(1) s. 47F(1) @mxns.com>, s. 47F(1) @mxns.com>, s. 47F(1) <s. 47F(1) @mxns.com>

OFFICIAL

Hi Lucy,

Thanks again for providing the investigation report.

I've been talking to Bob Barlow at CSIRO about your confirmation method. Please see below the issues he has raised. Can you please respond to these questions and provide me with your current method SOP?

Thanks,

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

- 1. Starting with broth, I assume this is a potential positive broth sent from the abattoir to the lab? If so, then why is it being enriched? I don't believe re-enrichment is part of the approved method. There is also an assumption that this will benefit E. coli/STEC concentrations in the sample but it may cause the opposite effect, especially when E.coli are low in concentration compared to the overall broth.
- STEC confirmation:
    - 2. Slidex latex test off selective agars – this is inline with the approved method, however there can be challenges doing agglutination tests off selective agars. I'm also noting this is the only confirmation of O serogroup. If that's the case then I would advise against it. Latex enables the calling of presumptive positives and should be backed up by confirmation of the O type by PCR
    - 3. Perform gene-up STEX for eae and stx (EH 1 2): this is confusing. It appears just a PCR for eae and stx. However this would be EH1 and not EH 1 2. EH2 is the big6 PCR. It's possible this step is talking to PCRs for stx, eae and big 6 O serogroups but is unclear. NB there is no PCR confirmation of O157 in this step, or at least it appears that way.
    - 4. Lysis Gene-up: don't understand this step. There is a bead beating protocol using a lysis kit but this would be used instead of ESPT2
    - 5. Perform PCR gene-up STEC stx and eae (EH 1 2) – appears to repeat two steps above. I'm unsure why.

Clarification required – what are the PCRs used following slidex and what targets do they test for?

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

A/g Director – Residues and Microbiology 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)@aff.gov.au

Department of Agriculture, Fisheries and Forestry

Postal address: PO Box 858 Canberra City ACT 2601

OFFICIAL

From: s. 47F(1) @mxns.com>
Sent: Wednesday, 12 March 2025 4:16 PM
To: s. 22(1)(a)(ii) @aff.gov.au>
Cc: s. 47F(1) @mxns.com>; s. 22(1)(a)(ii) @aff.gov.au>; Melinda Skipper <s. 47F(1) @mxns.com>; s. 47F(1) @mxns.com>; s. 47F(1) <s. 47F(1) @mxns.com>; s. 47F(1) @mxns.com>; s. 47F(1) @mxns.com>; s. 47F(1) @mxns.com>
Subject: Re: FW: Merieux NutriSciences COA Tongala 8/03/2025 (MELBOURNE) [SEC=OFFICIAL]

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

Please find attached the summary report of our investigation into the testing process for the Greenham samples.

If you need any further details or have any questions please do not hesitate to contact us.

Thanks

Kind Regards,

Lucy Evans

Operations Director

Direct: +s. 47F(1)

Mobile: +s. 47F(1)

Better Food. Better Health. Better World.

Mérieux NutriSciences recognises and acknowledges the Wadjuk-Noongar People, the traditional custodians of the boodja (land)on which we live, work and kaartdijin (learn) together and pay our respect to the Elders past, present and emerging.

On Tue, 11 Mar 2025 at 11:45, s. 22(1)(a)(ii) @aff.gov.au> wrote:

OFFICIAL

Thanks s. 47F(1), I appreciate the update. Looking forward to some further information.

Kind regards,

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

OFFICIAL

From: s. 47F(1) @mxns.com>
Sent: Tuesday, 11 March 2025 1:56 PM
To: s. 22(1)(a)(ii) @aff.gov.au>
Cc: s. 22(1)(a)(ii) @aff.gov.au>; s. 47F(1) @mxns.com>; Melinda Skipper <s. 47F(1) @mxns.com>; Lucy Evans <s. 47F(1)@mxns.com>; s. 47F(1) <s. 47F(1) @mxns.com>; s. 47F(1) @mxns.com>; s. 47F(1) <s. 47F(1) @mxns.com>; s. 47F(1) @mxns.com>
Subject: Re: FW: Merieux NutriSciences COA Tongala 8/03/2025 (MELBOURNE) [SEC=OFFICIAL]

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

Acknowledging your email has been received.

I have shared your email with the Merieux team Cc in this email and will have an update for you soon.

Merieux has responded to Greenham's email yesterday at 1:51pm, and attempted to call Abhi to discuss and clarify the testing process.

I dont believe the department was part of the email response chain.

In our response to Greenham Merieux confirmed that all internal quality and testing parameters have confirmed the reporting to be accurate.

Kind regards

s. 47F(1)

Mérieux NutriSciences

Unit C2, 391 Park Road, Regents Park NSW 2143

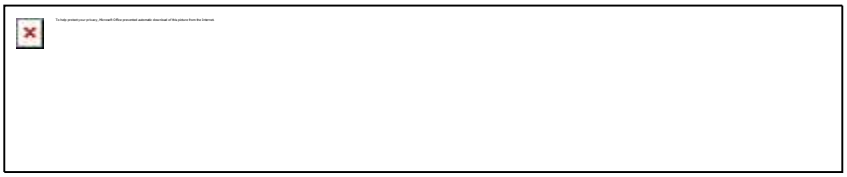
Phone: 1300 000 990

Direct: +s. 47F(1)

Mobile: +s. 47F(1)

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

www.merieuxnutrisciences.com/au/



On Mon, Mar 10, 2025 at 8:55 PM s. 22(1)(a)(ii) @aff.gov.au> wrote:

OFFICIAL

Hi s. 47F(1),

Letting you know that DAFF hasn't provided any advice to Greenham with respect to alternative testing.

As you will have seen, Greenham recently advised four confirmed Top 7 STEC positive samples from Establishment 234 and two from Est 716 . In two of the positive samples at each establishment, two different serotypes were confirmed to be present.

Given this is an unusual result for the company and Mérieux NutriSciences has only analysed a small number of Greenham samples, are you able to investigate and provide me with some additional information to support the results, i.e. ruling out cross-contamination, operator error, etc?

Also, Greenham's laboratory manager advised that Mérieux screens BAX MP media broth samples prior to confirmation procedures. If any additional serogroups are detected during their screen test, they will include them in their confirmation testing, along with those we requested. The reasoning behind this is that the Gene-Up method uses BPW, which differs from the BAX method. The lab manager's view was that this could lead to contradictory results and inconsistencies between methods.

In addition to the request information, can you comment on Greenham's observation?

Kind regards,
s. 22(1)(a)(ii)

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

A/g Director – Residues and Microbiology 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)@aff.gov.au

Department of Agriculture, Fisheries and Forestry

Postal address: PO Box 858 Canberra City ACT 2601

OFFICIAL

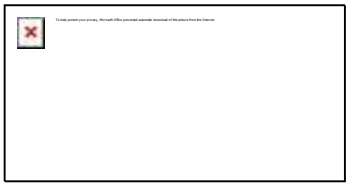
From: s. 47F(1) @mxns.com>
Sent: Monday, 10 March 2025 9:40 AM
To: s. 47F(1) @greenham.com.au>
Cc: s. 47F(1) @mxns.com>; gka.australia@mxns.com; s. 47F(1) <s. 47F(1)@greenham.com.au>; s. 22(1)(a)(ii) @aff.gov.au>; s. 22(1)(a)(ii) s. 22(1)(a)(ii) @aff.gov.au>; s. 47F(1) @mxns.com>; s. 47F(1) <s. 47F(1) @mxns.com>; Lucy Evans <s. 47F(1)@mxns.com>
Subject: Re: FW: Merieux NutriSciences COA Tongala 8/03/2025 (MELBOURNE)

Hello s. 47F(1),

Has this been approved by the department for further testing?

What are you trying to achieve by performing further testing?

Kind regards



s. 47F(1)

Mérieux NutriSciences

Unit C2, 391 Park Road, Regents Park NSW 2143

Phone: 1300 000 990

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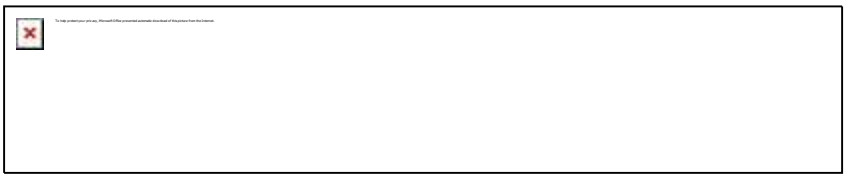
www.merieuxnutrisciences.com/au/



On Sat, Mar 8, 2025 at 6:36 PM 's. 47F(1) ' via AU-DPT-GKA-Australia <gka.australia@mxns.com> wrote:

Hi s. 47F(1),

As mentioned in our phone conversation, I have discussed today's STEC test results with our senior management. We would like to proceed with additional testing to confirm the results.

Based on the current data and knowledge we have, it is unlikely that we have a true STEC positive (Top-6 STEC). Please retain the original sample we submitted, along with all the culture isolates associated with the relevant sample for future testing. We are most likely to use BVAQ's services for further testing and will opt to confirm using the DAFF-approved MLG-5C method.

Your cooperation and support in this matter would be greatly appreciated.

Kind regards,

s. 47F(1)
Lab Manager
Tongala Plant

M
T 03 5859 0912
E s. 47F(1) @greenham.com.au

HW GREENHAM & SONS PTY LTD
www.greenham.com.au

From: coa.au@aus.mxns.com <coa.au@aus.mxns.com>
Sent: Saturday, 8 March 2025 12:17 PM
To: s. 47F(1) @greenham.com.au>
Subject: Merieux NutriSciences COA Tongala 8/03/2025 (MELBOURNE)

Kind Regards,

Merieux NutriSciences

If you have any queries with the attached please contact our Customer Care Department at csrsupport.au@aus.mxns.com

www.merieuxnutrisciences.com/au/

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 Commonwealth 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. 45(1),s. 47(1)(b)

s. 45(1),s. 47(1)(b)

s. 45(1),s. 47(1)(b)

Deed of confidentiality

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

Merieux NutriSciences Australia

Organisation

Contents

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**

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:

Print name of delegate

Signature

in the presence of:

Print name of witness

Signature of witness

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

Annexure A - Confidential Information

Document: MLA Gene UP trial July 2022.docx