An Roinn Talmhaíochta, Bia agus Mara Department of Agriculture, Food and the Marine



Ms. Denise Mc Andrew ALS Life Sciences t/a ALS Carrigreen Business Park Clonmel Co. Tipperary

5th December 2023

Re: Department of Agriculture, Food and the Marine Approval (DAFM) for microbiological testing

Dear Ms. Mc Andrew,

I wish to advise you that with effect from 5th December, 2023 and for a period of two years ALS Life Sciences t/a ALS, Carrigreen Business Park, Clonmel, Co. Tipperary has been re-approved by DAFM to carry out testing as per Table 1 Annex 1.

The Department of Agriculture, Food and the Marine's (DAFM) Laboratories (Backweston) undertake the National Reference Laboratory functions for *Salmonella*, *Campylobacter*, *Listeria monocytogenes*, *Staphylococcus aureus*, *E. coli*, Antimicrobial Resistance and Parasites in food, feed and animal health under Regulation (EU) 2017/625.

Approval of laboratories is on a programme by programme (i.e., *Trichinella*, Animal By-products, Poultry Regulations *Salmonella* controls), test by test (e.g., *Salmonella*, Shiga-toxin producing *E. coli* (STEC), *Enterobacteriaceae*) and matrix by matrix (e.g., pet food, or faeces) basis. In order to be approved, laboratories must confirm that they are currently in compliance with and will for the period for which they are approved, continue to comply with the criteria listed below. Laboratories may submit an application for approval at any time. DAFM reserves the right to revoke the approval of laboratories on the grounds of noncompliance with these criteria.

Approval criteria:

- 1. Be accredited to ISO 17025 for all relevant tests and matrices (Except *Trichinella* laboratories attached to slaughtering plants).
- 2. Inform DAFM Laboratories of any change in accreditation status as soon as practically possible (including any refusal of an application for accreditation), and any major non-compliances or concerns with the reliability of the laboratory's testing.
- 3. Utilise only those test methods approved by DAFM (see table 1).
- 4. Not re-test samples with positive / unsatisfactory test results to avoid reporting the original positive / unsatisfactory result.
- 5. Test samples individually and not to pool samples for analysis unless this is specifically allowed by the method (i.e., *Trichinella*) or approved previously by DAFM Laboratories.



- 6. Participate to the satisfaction of DAFM Laboratories in relevant proficiency testing and technical reviews as may be considered appropriate by DAFM (see Table 1) and provide the results of such proficiency testing to DAFM Laboratories upon completion or upon request by DAFM.
- 7. Facilitate such laboratory visits as may reasonably be requested by DAFM within specified deadlines.
- 8. Submit all recovered *Salmonella* and STEC isolates and *Trichinella* larvae for typing within one week of isolation and other zoonotic pathogens as directed by DAFM Laboratories.
- 9. Submitted isolates must be accompanied by the most up-to-date DAFM Laboratories submission form, identifying each isolate uniquely and containing all other relevant details requested in the form, including the source of the isolate. An electronic copy of the submission form must be submitted to SalmonellaNotifications@agriculture.gov.ie in addition to the hard copy sent with the isolates.
- 10. Only provide serotyping results to clients using the precise format of the DAFM Laboratories Backweston report, without paraphrasing or interpretation. Be aware that DAFM reports state "These results can only be reproduced in full".
- 11. Retain a record of all testing carried out in relation to the programmes for at least 3 years and furnish copies/extracts from time to time to DAFM Laboratories on request in such a manner as DAFM may require.
- 12. Report results and return summaries of results in such format as may be required by DAFM from time to
- 13. Give permission to the Accreditation Body to provide DAFM Laboratories with documents related to the accreditation process pertaining to the approved activities.

Yours sincerely,

Sarah Lawless

Milk and Meat Hygiene/ABP/TSE Division



Annex 1

Revised Table 1: Scope of DAFM Laboratories approval for microbiological testing for ALS Life Sciences t/a ALS.

DAFM Testing Programme	DAFM Testing requirement	Types of samples DAFM approved for this Laboratory	Laboratory method code	Laboratory method name	
Poultry Regulations (S.I. 706/2006, S.I. 247/2008, S.I. 64/2009, S.I. 99/2010, SI 565/2010)	Salmonella detection by ISO 6579-1:2017 using MSRV agar as the selective enrichment or certified alternative validated method	Boot swabs, Faeces and Dust	SP038 and SP178	SP038 Method for the detection of salmonella spp and SP178 Method for the confirmation of salmonella spp	
Animal by-products (Commission Regulation (EU) No 142/2011, implementing Regulation (EC) No 1069/2009)	Salmonella detection by ISO 6579-1:2017 or certified alternative validated method	Pet food, Processed Animal Proteins (PAP), Rendered Fats, Compost and digestates	SP038 and SP178	SP038 method for the detection of salmonella spp and SP178 method for the confirmation of salmonella spp	
Animal by-products (Commission Regulation (EU) No 142/2011, implementing Regulation (EC) No 1069/2009)	Salmonella detection by ISO 6579-1:2017 or certified alternative validated method	Pet food, Processed Animal Proteins (PAP), Rendered Fats, Compost and digestates	SP102	Detection of Salmonella spp by Solus Salmonella ELISA	
Animal by-products (Commission Regulation (EU) No 142/2011, implementing Regulation (EC) No 1069/2009)	Enterobacteriaceae enumeration by ISO 21528-2:2017 or certified alternative validated method	Pet food, Processed Animal Proteins (PAP), Rendered Fats	SP033	Enumeration of Enterobacteriaceae (Presumptive & Confirmed)	
Animal by-products (Commission Regulation (EU) No 142/2011, implementing Regulation (EC) No 1069/2009)	E. coli enumeration by ISO 16649 or certified alternative validated method	Compost and digestates	SP049	Enumeration of presumptive β- glucuronidase positive E. coli	
US trade requirements Certification requirements Shiga-toxin E. coli detection by USDA MLG 5 or method with a No- objection letter issued by FSIS		Carcass swabs and Pooled trimmed meat SP209 and SP210		SP209 Method for the real-time PCR detection of virulence genes in Shiga Toxin Producing E. coli (STEC) and of 7 major serogroups (O157, O111, O26, O103, O145, O45 and O121) AND SP210 Method for the isolation and confirmation of Shiga Toxin Producing E. coli (STEC) Serogroups (O157, O111, O26, O103, O145, O45 and O121) following PCR detection of virulence genes	
US trade requirements Certification requirements	E. coli O157 detection by ISO 16654, USDA MLG 5 or certified alternative validated method	Carcass swabs and Pooled trimmed meat	SP052 and SP041	SP052 Detection of E.coli O157:H7 by Neogen Reveal AND SP041 Detection of E.coli O157:H7 using the immunomagnetic separation technique	
US trade requirements Certification requirements	Salmonella detection by MLG 4 or by a method deemed equivalent by FSIS	Carcass swabs	SP102	Detection of Salmonella in food, animal feed and environmental samples by Solus Salmonella Optima ELISA kit	



Annex 2

Table 2 summarising the approval requirements

Programme	Legal basis	Parameters required	Types of samples	Approved methods	Specific Proficiency Testing requirements	Reporting requirements	
Poultry Regulations	S.I. 706/2006; S.I. 247/2008; S.I. 64/2009 and S.I. 99/2010	Salmonella detection	Dust, dust swabs, faeces, boot swabs	ISO 6579-1:2017 using MSRV agar as the selective enrichment or certified alternative validated method	http://apha.defra .gov.uk/ahvla- scientific/vetqas/ PTpriceList.html# micro Test code PT0088	Flock owner to be immediately informed of all positive results.	
Animal by- products im		Salmonella detection	Pet food, Processed Animal Proteins (PAP), tallow and greaves, compost, digestates	ISO 6579-1:2017 or certified alternative validated method			
	Commission Regulation (EU) No 142/2011 implementing Regulation (EC) No 1069/2009	Enterobacteri aceae enumeration	Pet food, Processed Animal Proteins (PAP), tallow and greaves	ISO 21528-2:2017 or certified alternative validated method			
		E. coli enumeration	Compost, digestates	ISO 16649 or certified alternative validated method			
		Clostridium perfringens detection	Processed Animal Proteins (PAP), tallow and greaves obtained during validation of new rendering processes	ISO 7937:2004 to plate 10 ml of 1/10 dilution instead of 1 ml			
Trichinella	Commission Regulation (EU) 2015/1375	Trichinella larvae counting	Pig and horse muscle	Reference digestion method described in Commission Regulation (EU) 2015/1375 or approved alternative method (none approved by NRL at present)	http://apha.defra .gov.uk/ahvla- scientific/vetqas/ PTpriceList.html# micro Test code PT0111	All test reports to be copied to Veterinary Officer in slaughterhouse	
US trade requirements	Certification requirements	Salmonella detection	Carcass swabs	USDA MLG 4 or FSIS approved alternative method			
		STEC detection	Carcass swabs, pooled trimmed meat	USDA MLG 5 or method with a No-objection letter issued by FSIS	https://www.lgcs tandards.com/ES/ en/Proficiency- Testing/Food- and-Feed- Schemes/Shiga Toxin-E-coli-STEC- /cat/268350	All test reports to be copied to Veterinary Officer in slaughterhouse	
		E. coli O157 detection	Carcass swabs, pooled trimmed meat	ISO 16654, USDA MLG 5 or FSIS approved alternative method			