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

Ms. Margaret Buggy
ALS Life Sciences t/a ALS
Carrigreen Business Park
Clonmel
Co. Tipperary

19 February 2020

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

Dear Ms. Buggy,

I refer to our letter dated 5th December, 2019 and with effect from that date for a period of two years ALS Life Sciences t/a ALS, Carrigreen Business Park, Clonmel, Co. Tipperary has DAFM approval for testing as per **revised Table 1 Annex 1 and Table 2 Annex 2.**

This approval is subject to the approved laboratory continuing to adhere to all the revised conditions of approval which are listed below.

Approval criteria:

1. Be accredited to ISO 17025 for all relevant tests and matrices (Except *Trichinella* laboratories attached to slaughtering plants).
2. In the event that the laboratory is not accredited to ISO 17025, to have made an application to a National Accreditation body by 1st November 2019 for such designation and to have achieved accreditation to ISO 17025 by 1st June 2020.
3. 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.
4. Utilise only those test methods approved by DAFM (See Table 2 Annex 2).
5. Not re-test samples with positive / unsatisfactory test results to avoid reporting the original positive / unsatisfactory result.
6. 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.
7. Participate to the satisfaction of DAFM Laboratories in such relevant proficiency testing and technical reviews as may be considered appropriate by DAFM (See Table 2 Annex 2) and provide the results of such proficiency testing to DAFM Laboratories upon completion or upon request by DAFM.
8. Facilitate such laboratory visits as may reasonably be requested by DAFM within specified deadlines.

9. 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. Isolates must be accompanied with the relevant DAFM Laboratories submission form that must identify each isolate uniquely and be completed with all other relevant details requested in the form.
10. Notify DAFM of the source of any pathogen if requested.
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 the format required by DAFM (See Table 2 Annex 2).

DAFM Laboratories reserves the right to revoke the approval of laboratories on the grounds of noncompliance with these criteria.

Yours sincerely,

Mairead Broderick

Mairead Broderick
Milk and Meat Hygiene/ABP/TSE Division
Department of Agriculture, Food and the Marine
Grattan Business Park, Portlaoise, Co. Laois R32 RY6V

Annex 1

Revised Table 1: Scope of DAFM Laboratory 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, 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, 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, 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/Canada 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/Canada 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/Canada 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

Revised Table 2: Summary of DAFM approval requirements.

Programme	Legal basis	Parameters required	Types of samples	Approved methods	Specific Proficiency Testing requirements	Reporting requirements / Disclosure of information
Poultry Regulations	S.I. 706/2006; S.I. 247/2008; S.I. 64/2009 and S.I. 99/2010	*Salmonella* detection	Dust, faeces, boot swabs	ISO 6579-1:2017 using MSRV agar as the selective enrichment or certified alternative validated method	https://science.vla.gov.uk/Tests/Default.aspx?SiteName=CDT Test code PT0088	*FBO and Flock No to be disclosed for positive Salmonella Enteritidis, S. Typhimurium, S. Hadar, S. Infantis and S. Virchow*
Animal by-products	Commission Regulation (EU) No 142/2011 implementing Regulation (EC) No 1069/2009	*Salmonella* detection	Pet food, Processed Animal Proteins (PAP), tallow and greaves, compost, digestates	ISO 6579-1:2017 or certified alternative validated method		
		Enterobacteriaceae enumeration	Pet food, 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	PAP, tallow and greaves obtained during validation of new rendering processes	ISO 7937:2004 to plate 10 ml of 1/10 dilution instead than 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)	https://science.vla.gov.uk/Tests/Default.aspx?SiteName=CDT Test code PT0111	All test reports to be made available to Veterinary Officer in slaughterhouse
US/Canada trade requirements	Certification requirements	*Salmonella* detection	Carcass swabs	USDA MLG 4 or FSIS approved alternative method		All test reports to be copied to Veterinary Officer in slaughterhouse
		STEC detection	Carcass swabs, pooled trimmed meat	USDA MLG 5 or method with a No-objection letter issued by FSIS	https://www.lgcstandards.com/ES/en/Proficiency-Testing/Food-and-Feed-Schemes/Shiga-Toxin-E-coli-STEC-/cat/268350	
		E. coli O157 detection	Carcass swabs, pooled trimmed meat	ISO 16654, USDA MLG 5 or FSIS approved alternative method		