CEMHD8 Risk Ranking Inspection Report

OFFICIAL SENSITIVE
Section 1 – Summary

Dutyholder:	Agri-Food and Biosciences Institute	**IPSO Ref:**	[redacted]
Site address:	AFBI Stormont, [redacted]		
Containment Level:	CL2 ☒ CL3 ☒ CL4 ☐		
Facility(ies) Inspected	Containment Level 3 facilities inspected (Address): AFBI Stormont, [redacted] All facilities (Contingency facilities and Lamont facilities (Brucella and exotic Mycoplasma Labs)) inspected for Specified Animal Pathogens Order (SAPO) license renewal, not inspected in relation to work with ACDP Hazard Group 3 biological agents. Containment Level (CL) 2 facilities inspected in relation to outbreak BTV work.		
Inspected by:	[redacted]	**Date of inspection**	2nd to 4th December 2025
SAPO Licence Reference	N/A		

Other regulators in attendance	**Role / Responsibilities**
[redacted]	DAERA Veterinary officer ([redacted]
Person(s) met	
Director of Veterinary Sciences Division (AFBI)	
[redacted]	
[redacted]	
[redacted]	
[redacted]	
[redacted]	
[redacted]	
[redacted]	
[redacted]	
[redacted]	
[redacted]	

[redacted]

[redacted]

Visit summary

THIS REPORT SHOULD BE READ IN CONJUCTION WITH THE ASSOCIATED LETTER SENT TO DAERA BY HSE, Ref: [redacted]

Background

An inspection was undertaken of the facilities at Agri-Food and Biosciences Institute (AFBI) site (AFBI Stormont, [redacted] in relation to the renewal of the SAPO licence (issued by DAERA) for their work with [redacted]

In relation to this inspection, HSE were accompanying [redacted] during the licensing renewal inspection at AFBI, to provide advice on AFBIs compliance to the wider requirements as applied in Great Britain (GB) (under the Specified Animal Pathogens Order (2008)).

In particular the benchmark standard against which AFBI was assessed was the HSE document 'Guidance for licence holders on the containment and control of specified animal pathogens (HSG280)'. This was the benchmark standard requested and agreed by DAERA in advance of the inspection.

HSG280 sets out the containment and control measures and wider arrangements that are necessary (in GB) to control the risks associated with working with Specified Animal Pathogens (SAPs) and comply with SAPO.

Purpose

Assessment/verification of the adequacy of the facilities, safety management systems, and procedures in meeting the conditions set out in HSG280.

Focus and scope:

Sampling-based assessment of the continued application of appropriate standards of containment and control. In particular, confirmation of (i) the application of the appropriate principles of prevention and the specific containment measures required by HSG280 and (ii) the maintenance and verification of integrity and effective function of safety related plant and equipment. The intervention involved physical inspection of facilities, supplemented by viewing of documentation and discussion with personnel, as relevant.

The inspection was undertaken to provide advice to DAERA on AFBI's compliance with the conditions set out in HSG280 in order to allow DAERA to consider whether the SAPO licenses should be renewed. AFBIs licenses to hold SAPs issued by DAERA expired in December 2024, although HSE understands that these licenses were subsequently extended by DAERA to allow work to continue.

There are 2 CL3 facilities for work with SAPO3 biological agents at the AFBI Stormont site. Physical inspection of both facilities was undertaken.

Facilities:

- Contingency facility – 3 x CL3 laboratories, 1 x pass through autoclave unit located within the laboratory suite.
- Lamont facility – 2 x CL3 Laboratories for work with SAPO3 agents ([redacted] within a CL3 facility with a total of 9 Laboratories, 1 x autoclave within the CL3 facility.

The SAPO diagnostic work undertaken at AFBI Stormont is on behalf of DAERA and includes animal disease surveillance and investigation, and maintenance of an emergency response capability for known and emerging disease threats; [redacted]

The routine diagnostic service consists of taking blood and tissue samples from ruminant animals on farms and abattoirs, which are then screened for the SAPO2/3 biological agents.

Visit Summary:

Discussion led assessments of AFBI compliance against the conditions stated in HSG280 and physical inspection of Contingency and Lamont CL3 facilities.

Met with a number of AFBI staff including : Director of Veterinary Sciences Division, [redacted]

Details regarding SAPO compliance are in the technical assessment of this report (Appendix 1). Further detail and relevant information related to other topics are provided in the main body of the report. HSEs advice to DAERA has been provided in an accompanying letter (Ref: [redacted]) and are detailed in the main body of the report and the SAPO technical report.

[redacted]

BTV Testing at AFBI.

During the routine SAPO renewal inspection, HSE were made aware of an emerging BTV outbreak occurring in Northern Ireland. HSE were informed late on Wednesday 3rd December 2025, that this testing was being undertaken in Containment Level (CL) 2 laboratories which is used for the routine surveillance of samples for BTV on a regular basis. On receipt of this information, HSE additionally inspected the facilities where this work was being undertaken which included two CL2

areas, one where serology testing was undertaken and one where PCR testing was conducted. Both of these facilities operate at CL2 and are not compliant with the SAPO 3 requirement set out in HSG280 for work with SAPO Group 3 agents (and their carriers). Findings (where relevant) relating to this aspect are detailed in the report and in the accompanying letter (Ref: [redacted]

[redacted]

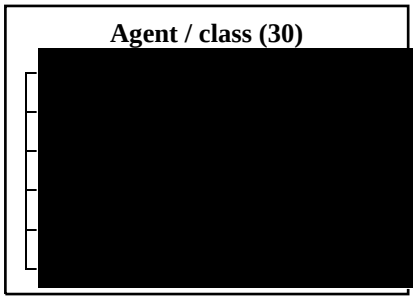
Avian Influenza/Newcastle Disease Surveillance Testing at AFBI.

During the inspection, we were advised by AFBI personnel that ongoing surveillance testing for both Highly Pathogenic Avian Influenza Virus (HPAIV), and Newcastle Disease Virus (NDV) was being conducted on the site, but that this was being undertaken at SAPO CL3 rather than at SAPO CL4 (the containment level that is required to control the risk of release of these agents). It should be noted that HPAIV is regularly detected in the samples tested at AFBI during surveillance activities, despite this work being undertaken at the inappropriate containment level. Furthermore, from the information and documentation provided to HSE during the course of the inspection, it would appear neither of these SAPO Group 4 agents are currently listed on AFBIs SAPO licence.

In relation to the current arrangements for HPAIV and NDV testing, HSEs advice to DAERA is therefore that the current arrangements for HPAIV and NDV testing at AFBI should stop immediately. HSE advice is that this work should only be undertaken within a fully compliant facility operating at SAPO CL4.

[redacted]

[redacted]

Hazard criteria	Hazard Information	Comments	Score
[redacted]		[redacted]	[redacted]
[redacted]		[redacted]	[redacted]

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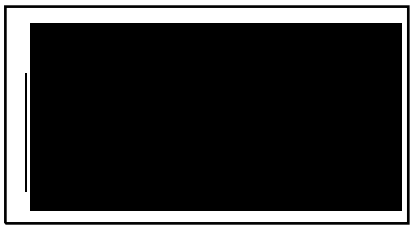
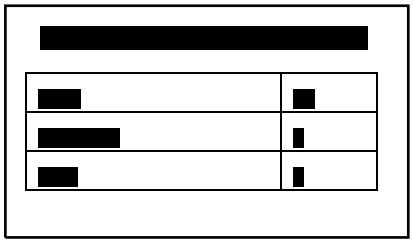
[redacted]		[redacted]	[redacted]
[redacted]		[redacted]	[redacted]

[redacted]

Section 3 – Performance assessment

Performance topic	Score (10-60)	Comments (for variation from score of 20)
Safety performance indicators • Strategic topic Delivery Guide	n/a	Not assessed
Competence management system • Strategic topic Delivery Guide	n/a	Not assessed
Safety leadership • Strategic topic Delivery Guide	n/a	Not assessed
Containment and control systems Assessment of the adequacy of the selection and application of appropriate standards of containment and control to contained use work with biological agents; including wild type organisms, genetically modified organisms, and specified animal pathogens. The topic includes in particular - assessment of the adequacy of the application of the appropriate principles of prevention and the specific containment measures required by containment tables of COSHH 2002 (Sched 3), GM (CU) 2014 (Sched 8), and SAPO 2008 (Licence conditions).	n/a	Management arrangements are detailed in the SAPO technical assessment (Appendix 1). A physical inspection of the laboratories was undertaken and the application of the measures detailed in the containment tables (HSG280 Appendix 2, Table 1) assessed. [redacted]

[redacted]

[redacted]

Performance topic	Score (10-60)	Comments (for variation from score of 20)
		[redacted]

[redacted]

Performance topic	Score (10-60)	Comments (for variation from score of 20)
		[redacted]

[redacted]

Performance topic	Score (10-60)	Comments (for variation from score of 20)
		[redacted]

[redacted]

Performance topic	Score (10-60)	Comments (for variation from score of 20)
		[redacted]

[redacted]

Performance topic	Score (10-60)	Comments (for variation from score of 20)
		[redacted]

[redacted]

Performance topic	Score (10-60)	Comments (for variation from score of 20)
		[redacted]

[redacted]

Performance topic	Score (10-60)	Comments (for variation from score of 20)
		[redacted]

[redacted]

[redacted]	[redacted]	[redacted]
		[redacted]
Operating procedures Assessment of the adequacy, implementation, and verification of procedures required to ensure the safe operation of plant, equipment and the undertaking of safety critical activities arising from or in connection with work with biological agents. Topic includes assessment of	n/a	[redacted]

[redacted]

Performance topic	Score (10-60)	Comments (for variation from score of 20)
the adequacy of consideration given to the nature of the work, and likelihood and consequences of unsafe practices being undertaken.		[redacted]
Maintenance procedures Assessment of the adequacy, implementation, and verification of arrangements to ensure safety-related facilities, plant and equipment are maintained in an efficient state, efficient working order, and good repair. Topic includes assessment of the scope, form, and frequency of planned pro-active, and reactive based maintenance, examination and testing. Extends in particular to - laboratory fabric (e.g. furniture, fittings, sealability); engineering controls (e. g. MSC, autoclaves, and air handling; and PPE (e.g. respirators), and includes alarms and monitoring devices.	n/a	[redacted]
Occupational health	n/a	Not assessed

Performance topic	Score (10-60)	Comments (for variation from score of 20)
Assessment of the adequacy, implementation, and verification of arrangements to ensure that suitable occupational health support is available to employees at risk of exposure to biological agents in the course of their work. Topic includes in particular - assessment of the adequacy of health surveillance (e.g. pre-employment and post-incident assessment and follow-up), immunisation provision, and the maintenance of records of exposure of employees.		
Management of contractors Assessment of the adequacy, implementation, and verification of arrangements for the selection and control of contractors who undertake work in (or associated with) facilities handling biological agents. Topic includes in particular - the management of cleaning and maintenance activities (e.g. MSC, LEV, autoclaves), room sealability checks, laboratory fumigation, and transport of biological agents undertaken by non-laboratory personnel. Considers both risks to contractors as well as the consequences of the work they undertake.	n/a	
Emergency response arrangements Assessment of the adequacy, implementation, and verification of arrangements for responding to accidents, incidents, and emergencies presenting serious or imminent danger arising from or in connection with the contained use of biological agents. Topic includes in particular - arrangements to deal with spillage of biological agents; equipment failure leading to loss of	n/a	[redacted]

Performance topic	Score (10-60)	Comments (for variation from score of 20)
containment; and extends to the suitability of warning and communication systems.		• [redacted]
Auditing and inspection Assessment of the adequacy, implementation, and verification of arrangements for the monitoring and review of the effectiveness of the measures employed to prevent and control exposure to biological agents. Topic includes in particular - assessment of the approach to selection of appropriate performance indicators, the scope, frequency and depth of inspection; the recording, communication, and analysis of findings; and the clearance of actions, giving due regard to the hazards posed by the work.	n/a	[redacted]

Performance topic	Score (10-60)	Comments (for variation from score of 20)
		[redacted]
Training and competence Assessment of the adequacy, implementation, and verification of arrangements for the securing of competence of personnel involved in the management and/or undertaking of work with biological agents as well as persons who may be at risk of incidental exposure. Topic extends to assessment of the adequacy of information, instruction, and training with regard to the extent and nature of risks associated with work and the measures to control these risks. Includes in particular – procedures for the operation of safety critical equipment (e.g. MSC's, autoclaves, RPE) and the measures to be taken in the event of adverse incident.	n/a	[redacted]

Performance topic	Score (10-60)	Comments (for variation from score of 20)
		[redacted]
Risk assessment Assessment of the adequacy, implementation, and verification of arrangements for the identification and assessment of risks arising from or in connection with work with biological agents. Topic extends to assessment of the suitability and sufficiency of the methodology employed in relation to nature of the work (e.g. Five steps; HAZOP at CL4).	n/a	[redacted]

Performance topic	Score (10-60)	Comments (for variation from score of 20)
		[redacted]
Waste management Assessment of the adequacy, implementation, and verification of arrangements for the handling, storage, transport, inactivation and disposal of waste contaminated with biological agents. Topic extends to - assessment of adequacy of the degree and method of inactivation and includes adequacy of validation of the inactivation process in the context of the risks to both human health and the environment (e.g. autoclave; chemical inactivation).	n/a	[redacted]
Specimen transport Assessment of the adequacy, implementation, and verification of arrangements for the transport of infectious substances or materials containing such substances. Topic extends to both on-site (e.g. lab to lab; building to building)	n/a	• [redacted]

Performance topic	Score (10-60)	Comments (for variation from score of 20)
and inter-site transport and includes in particular - assessment of the adequacy of transport containers, packaging, and labelling to minimise the risk of leakage in transit and to ensure that those involved are aware of the hazard presented by the contents.		
Storage Assessment of the adequacy, implementation, and verification of arrangements for the safe (and where required, secure) storage of biological agents. Topic includes in particular - assessment of the adequacy of storage location; access restriction; storage containers and equipment. Also extends to alarms; Contingency arrangements; and inventory, giving due regard to the characteristics and degree of hazard presented by the agents.	n/a	• [redacted]
Plant design Assessment of the adequacy, implementation, and verification of arrangements for the design, selection, and installation of facilities and safety-related equipment, to ensure that they meet the required standard and provide the appropriate level risk reduction in the context of the intended application. Topic includes in particular - assessment of the adequacy of consideration of the required hierarchy of risk control as well as consideration of the foreseeable health and	n/a	Not assessed

Performance topic	Score (10-60)	Comments (for variation from score of 20)
safety risks in subsequent operation, installation, cleaning, and maintenance.		
Plant commissioning Assessment of the adequacy, implementation, and verification of arrangements for the inspection and testing of facilities, safety-related equipment and procedures to ensure that they meet the required standards before being brought into operation. Topic extends to construction projects, the installation of new equipment, as well as modifications to existing facilities and equipment. Includes in particular - lab fabric (e.g. sealability); engineering controls (e. g. MSC, autoclaves, ETP, air handling, pressure gradients, HEPA Filters; and associated alarms and monitoring devices). Also extends to verification of effective of safety-related procedures (e.g. fumigation, evacuation).	n/a	Not assessed
Other Assessment of the adequacy, implementation, and verification of arrangements/activities not appropriate or sufficient for inclusion in other RCS topics. Examples could include – Good laboratory practice (e.g. housekeeping; cleaning), as well as matters and administrative arrangements (e.g. Advance / significant change Notifications).	n/a	Not assessed

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Section 4 – Administrative Action required

Comments for future inspection or portfolio holder:
• [redacted] N/A – this section is for internal HSE use in GB.

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Appendix 1 – SAPO licence information

TECHNICAL ASSESSMENT OF SAPO LICENCE APPLICATION

Specified Animal Pathogens Order 2008, Specified Animal Pathogens (Scotland) Order 2009, and Specified Animal Pathogens (Wales) Order 2009

COIN case number:	[redacted]	**Application reference:**	[redacted]
SAPO Licence reference	[redacted]		
Name of organisation :	[redacted]		
Containment Level:	[redacted]	[redacted]	**4**

Organisation details and proposed activity:

[redacted]

[redacted]

[redacted]

- [redacted]

- [redacted]

[redacted]

- [redacted]
- [redacted]
- [redacted]
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- [redacted]

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[redacted]

[redacted]

[redacted].

BTV Outbreak testing at AFBI.
On 30/11/25, 2 positive cases of BTV were detected from samples collected at an abattoir, and subsequent testing of the rest of the herd and sheep identified a further 42 cases from the cows, with all sheep testing negative. An exclusion zone of 20km was placed around the affected farm and further testing of farm animals within the exclusion zone was in process during this inspection. DAERA were expecting AFBI to receive 3000-4000 samples taken from approximately 20 farms within the exclusion zone.

We were informed on the afternoon of Wednesday 3rd December that this BTV diagnostic testing, including DNA extraction and PCR was being undertaken at CL2 and not in a CL3/SAPO3 laboratory. Following a decision to inspect this laboratory, during the morning of Thursday 4th December we were made aware that this testing was being undertaken in two separate areas at AFBI, one area for receipt and subsequent serology testing of blood samples and one area where DNA extraction and PCR was undertaken. **Both of these facilities operate at CL2 and are not compliant with the SAPO 3 requirements of HSG280.**

Avian Influenza/Newcastle Disease Surveillance Testing at AFBI.
During the routine SAPO licence renewal inspection we were advised that ongoing surveillance testing for both Highly Pathogenic Avian Influenza and Newcastle Disease Virus was being conducted, both of which are SAPO4 pathogens. AFBI does not currently have a SAPO4 compliant facility, and we were informed that this testing is taking place in one of the SAPO3 facilities despite the fact that Highly pathogenic Avian Influenza (HPAI) is regularly being detected in the samples examined. Furthermore, from the information and documentation provided to HSE in advance of and during the inspection, neither of these SAPO4 pathogens are currently listed on AFBIs SAPO licence. **This work is being undertaken within a SAPO3 facility which is not compliant with the SAPO 4 requirements of HSG280. Furthermore, these pathogens are not listed on AFBIs current SAPO licence.**

Management arrangements:

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted].

[redacted]

[redacted]

[redacted].

Containment and control measures:

At [redacted]

[redacted]

- [redacted]

- [redacted]

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[redacted]

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Consideration of whether it is appropriate for a particular containment measure to be derogated:
"Any derogation requested or deemed necessary? Confirm the acceptability of alternative arrangements." No derogations requested by AFBI.

Issues related to the application that should be taken forward:
Is there anything that should be raised with the Intervention Team Managers? "e.g. is this a novel hazard group 3 or 4 pathogen? Is an attenuated strain to be handled at a lower level?" "e.g. is there a risk of significant harm to animal or environment that would require a site visit?" N/A – this section is for internal HSE use in GB.
Action required:
[redacted]

1st reviewer:	[redacted]	**Date:**	[redacted]
2nd reviewer:	[redacted]	**Date:**	[redacted]

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TECHNICAL ASSESSMENT OF SAPO LICENCE APPLICATION ADDITIONAL INFORMATION			
Comments on response to additional information request:			
n/a			
Acceptability of any new derogations which are sought:			
n/a			
Further issues related to the activity that should be taken forward:			
n/a			
n/a			
1st reviewer:		**Date:**	
2nd reviewer:		**Date:**	

INFORMATION TO BE TRANSFERRED TO THE SAPO LICENCE	
SECTION A – The first three parts of this section must be completed for all SAPO licence reviews. This information should be entered with care as it will be transferred into the licence. The remaining parts of this section only need to be completed if the information on the licence application is incorrect, incomplete or misleading. Therefore, the relevant parts of the licence should be checked, but in most cases no further recording will be necessary. However, if you consider that support team will require clarification, please record the correct information in the appropriate box.	
Does the licence include ATCSA Schedule 5 agents?	**YES** ☐ **NO** ☐
Does the licence require the inclusion of the Crown Employer indemnity statement?	**YES** ☐ **NO** ☐
Does the licence require the inclusion of 'Section 11 – Containment of foot and mouth disease virus'?	**YES** ☐ **NO** ☐
Relevant SAPO legislation	**ENGLAND** ☐ **WALES** ☐ **SCOTLAND** ☐
Organisation name (legal entity)	
"Name of organisation should be verified from section 1 of application form, e.g. University of Oxford"	
Address of Organisation	
Registered address of the organisation verified from section 1 of application form"	
Address where specified animal pathogens will be stored or used	
"Address where the SAPs are to be stored or used, verified from section 1 or section 2 of application form"	
Specific information relating to the specified animal pathogen(s) to be included in Schedule 1 of the licence	

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"Licence requires the name of the pathogen(s), approved containment level and approved derogations from full containment to be listed. This information should be determined from section 3 of the application form and review of the risk assessment"

Specified animal pathogen	Approved containment level	Approved derogation(s)

Action on unit support :			
• *Inspector to confirm that tracking sheet details reflect information gathered during visit and provide revised details if appropriate.* • *Inspector to specify instructions on MBUST related to COIN, tracking sheet, or inspection files – e.g. change in duty holder; site details; significant change in scale or nature of the work – liaison with FOD as to action planned / taken.*			
Report written by:	[redacted]	**Date of Report:**	17/12/2025

Notes

1. The risk ranking delivery guide HID SI4 Risk Ranking Delivery Guide (CM9 2011/12554**)** and COIN work instructions (CM9 2011/103127) for MBU intervention plans have been issued. An updated annex containing the revised topic specific success criteria has been incorporated into the delivery guide. The MBU Intervention Strategy Document HID SI4 Guidelines for Intervention Programme (CM9: 2011/254457) has also been issued. These and the (references therein) are key documents that should be followed in organising, undertaking, and recording of inspections.

2. As detailed in the aforementioned Intervention strategy document, matters giving rise to scores of 40 or above, should be tracked on the Issues Tab in COIN, and formal enforcement action (i.e. Notices and / or prosecution) should be considered. As a minimum these issues must be conveyed to the employer by letter. Please indicate in Section 3 of your report the reasons for the action taken (in line with the enforcement management model and the enforcement policy statement). For any scores of 30, it is unlikely to be necessary to write to the employer (particularly if only one or two issues), however these may be picked up in the form of a reverse letter and should be recorded in the inspection report. Where there are significant numbers of topics (four or five) that score 30, consideration should be given as to the adequacy of the overall health and safety management arrangements, and whether enforcement action is necessary. Further work (through intervention team meetings) will continue on developing consistency on scoring across topics

3. It is important to note that inspectors should use the technical breaches observed to inform and address the wider underlying management failings of the organisation (e.g. failure to maintain sealability may be a symptom of a lack of an adequate management system for planned preventative maintenance or a programme of monitoring and reviewing of protective and preventative control measures). General guidance on this approach already exists that inspectors should be aware of. However, more specific guidance for inspectors is currently being drafted for issue in due course.