HSE

Health and Safety Executive

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[redacted]

[redacted]

Reference: [redacted]

Date: 18th December 2025

For the attention of [redacted] Animal Health and Welfare Policy Division

SPECIFIED ANIMAL PATHOGENS ORDER (NORTERN IRELAND) 2008

Dear Sir

Background and approach

1. I am writing following the inspection of Agri-Food and Biosciences Institute (AFBI), [redacted] between 2nd and 4th December 2025 by myself and a colleague [redacted] The facilities inspected are used to handle biological agents covered under the Specified Animal Pathogens Order (Northern Ireland) 2008.

2. In Northern Ireland (NI) licenses to work with Specified Animal Pathogens (SAPs) are issued by the Department of Agriculture, Environment and Rural Affairs (DAERA). Great Britain's Health and Safety Executive (HSE) supports DAERA in NI by providing technical support and advisory services in the licensing of facilities and enforcement under the requirements of the Specified Animal Pathogens Order (Northern Ireland) 2008, and as detailed in the relevant Memorandum of Understanding (MoU). Under that MoU, HSE's role is to accompany a DAERA inspector on physical inspections of a premises bio-security and bio-containment arrangements, and advise on compliance with the SAPO licensing conditions and requirements.

3. 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.

4. In relation to this inspection, we were accompanying [redacted] DAERA inspector) to provide him with advice on AFBIs compliance to the wider requirements as applied in GB (under the Specified Animal Pathogens Order 2008; SAPO). 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 [redacted] DAERA) and colleagues 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 SAPs and comply with SAPO.

5. Due to an emerging Bluetongue Virus (BTV) outbreak in NI at the time of the inspection, [redacted] was only present for part of the discussions and physical inspections, however HSE's recommendations and advice in relation to remedial actions and potential enforcement were provided in full to [redacted] during the inspection, prior to HSE providing feedback to AFBI.

6. Non-compliance, as defined in the MoU, can be either minor (issues of a minor nature that, in the opinion of the inspector, by themselves do not significantly compromise bio-security and/or bio-containment of the pathogen) or major (either one single issue that, in the opinion of the inspector, by themselves significantly compromises bio-security and/or bio-containment, or a number of minor non-compliances that when taken together would compromise bio-security).

7. HSE inspectors have no legal vires or enforcement powers in NI. HSE's role with respect to SAPO (as set out in the MoU) is to offer advice to DAERA on whether compliance has been achieved. Where licence holders are found to have a major non-compliance, HSE will inform DAERA and provide expert advice in relation to the content of Improvement Notices (IN) and Prohibition Notices (PN) if requested. DAERA has responsibility for issuing SAPO licenses in NI and any enforcement in relation to SAPO.

8. The purpose of SAPO is to prevent the introduction and spread of SAPs, which are not endemic and which, if introduced, would cause serious disease and/or economic loss to the livestock industry. Some SAPs are also zoonotic pathogens capable of causing disease in humans.

9. For dutyholders working with SAPs, appropriate containment and control measures must be applied to ensure that activities involving SAPs will be adequately contained, thereby reducing or eliminating the likelihood of exposure of susceptible animals, laboratory workers, other people, and the outside environment.

10. These containment and control measures may be a combination of design specification, engineering systems/devices, physical integrity, chemical/biological controls, appropriate equipment, staff training, procedural and management arrangements, and will include a combination of primary (e.g measures to protect or avoid contamination of the worker and immediate vicinity) and secondary (e.g measures to protect susceptible animals, people and the environment outside the laboratory) containment measures and preventive or mitigation barriers. These measures and arrangements are all set out within HSG280 to provide guidance on how compliance with the various license conditions of SAPO can be achieved.

Inspection Findings

11. During the inspection we met with a number of AFBI personnel, including the Director of Veterinary Science Division, [redacted] Laboratory and Technical Managers and other scientific and technical staff.

12. We reviewed documentation provided by AFBI in advance of, and during the inspection, and inspected the facilities currently in use for work with SAPs. There were a number of issues identified that were not in compliance with the conditions detailed in HSG280. [redacted] This principle is the basis of HSE's advice on this matter to DAERA. Details and examples of these non-compliances are detailed below, with reference to the relevant licensing Condition from HSG280.

Condition 1 : Management Arrangements.

13. Condition 1(2)(c) includes the requirement for the licence holder to measure and review performance through proactive monitoring, and Condition 1(2)(d) requires the licence holder to implement the findings from performance measurements and reviews undertaken in accordance with 1(2)(c). Proactive monitoring should include physical inspection of control measures to ensure they are providing adequate control of risks and operating as intended, the assessment of procedural and administrative controls such as risk assessments and training records and the appropriate review of service, calibration, validation and maintenance reports (as relevant) to provide assurance that equipment/facilities are fit for purpose and safe to use.

14. [redacted]

15. HSEs advice to DAERA is that to comply with this condition:

- [redacted]

- [redacted]

use. This information should be adequately communicated to those staff with responsibilities for the operation of the facility and those who undertake work within.

16. [redacted].

17. [redacted]

18. [redacted]

- [redacted]

Condition 2. Training and Competency.

19. Condition 2(1) requires the licence holder to provide all users of SAPs with suitable and sufficient information, instruction and training for the prevention of the loss of containment of SAPs. This is to ensure all users are competent to use SAPs in a contained manner. Roles should have a core set of competencies assigned that details the required capabilities, knowledge and experience. All users (including those not directly involved in handling SAPs such as autoclave operators, maintenance staff etc.) should have an awareness of the risks associated with working with SAPs, whilst those working in containment and directly handling the SAPs, should have an advanced or expert level of competency.

20. Information, instruction and training should focus on critical aspects to prevent a loss of containment. As a minimum, it should include:

    a) the significant findings of the risk assessment, including information on the inherent hazards of the SAP and the consequences of a loss of containment;

    b) the selection of appropriate preventive and protective measures required to ensure containment, and how and when to correctly use these measures;

    c) the management arrangements implemented to ensure the risks associated with work with SAP are being controlled;

    d) safe work practices, including use of equipment, handling, storage and disposal of material and waste contaminated with SAP;

    e) correct use, including the dressing, removal and disposal of contaminated personal protective equipment (PPE), so as not to result in a loss of containment;

f) the procedures to be implemented following a loss of containment both within and outside the facility (emergency arrangements).

21. Additionally, users should undergo competency assessment to assess the understanding of the information, instruction and training provided. Both training and competency assessment should be periodically repeated as appropriate.

22. [redacted]

23. [redacted]

24. [redacted]

- [redacted]

- [redacted]

- [redacted]

Condition 3. Risk Assessment.

25. Condition 3(1) requires the licence holder to make a suitable and sufficient assessment of the risks from the loss of containment of SAPs, including the assessment of the risks arising from

the work being undertaken involving SAPs. This should include storage, handling, transport, decontamination, inactivation, disposal and waste management and biosecurity risk.

26. [redacted]

27. [redacted]

Condition 4. Application of Containment and Control Measures.

28. Condition 4(1) requires license holders to apply the appropriate containment measures from the applicable containment tables in Schedule 2 of the license. These tables are reproduced in Table 1 of Appendix 2 of HSG280 and set out measures for activities considered 'laboratory type' in terms of scale and nature, and includes the following containment measures:

- *Laboratory sealable to permit fumigation (Table 1, measure 2)*. This is required at SAPO CL3 and SAPO CL4 to reflect the greater hazards associated with SAPO Group 3 and SAPO Group 4 agents and the consequences of release from containment. This measure provides an effective means of decontaminating the laboratory using a gaseous/vaporised disinfectant, which can effectively make contact with all exposed surfaces. The requirement for laboratory sealability is to ensure that the fumigant is retained within the laboratory at sufficient concentration for the required contact time to effectively decontaminate the surfaces, and to ensure that the gaseous fumigant, which may be harmful to humans, is not released from the laboratory in an uncontrolled manner.

- *Shower before exit (Table 1, measure 11)*. At SAPO CL3, the requirement for showering before leaving the facility is determined by RA. Where applicable, additional information for the user (e.g minimum time to spend in the shower) should be included in relevant operating systems, documentation and training.

- *Efficient control of disease vectors which could disseminate animal pathogens (Table 1, measure 14)*. This is required at all containment levels, where there is a risk of disease vectors being able to disseminate the SAP out of the laboratory. This is relevant when working with SAPs that can infect rodents or be transmitted by insects, or that can be mechanically transferred to susceptible species by vectors.

- *Inactivation of SAPs in contaminated material and waste (Table 1, measure 16)*. Waste material containing viable SAPs must be inactivated by a validated means before disposal.

- *An observation window or alternative is to be present so that occupants can be seen (Table 1, measure 18)*. This is applicable at SAPO CL2 and SAPO CL3 where the SAP also presents a risk to human health.

29. [redacted]

    - [redacted]

    - [redacted].

    - [redacted]

    - [redacted]

- [redacted]

[redacted]

- [redacted]

Condition 6. Waste Management.

31. Condition 6(1) requires the licence holder to prepare and implement suitable and sufficient arrangements to ensure that all waste contaminated with SAPs is inactivated by a validated means. The method used to inactivate SAPs and contaminated waste must be validated to demonstrate that it can achieve the appropriate parameters to inactivate the agents, taking account of the nature of the waste (i.e. form, amount, density).

32. [redacted]

[redacted]

- [redacted]

Condition 8. Emergency Arrangements.

34. Condition 8(1) requires the licence holder to ensure that suitable and sufficient procedures and systems have been prepared which can be put into effect in the event of an accident or dangerous occurrence or emergency related to the presence of SAPs. The emergency procedures and scenarios should identify relevant and credible scenarios that could result in the release of a SAP and include response measures to limit the consequences that may arise. These emergency procedures should be appropriately and effectively communicated to all relevant employees and others. Training must be provided for those with responsibility for implementing the emergency procedures/systems and the training should be tested to ensure those personnel demonstrate knowledge of their application and importance.

35. [redacted]

- [redacted]

- [redacted]

- [redacted]

- [redacted]

- [redacted]

[redacted]

- [redacted]

- [redacted]

- [redacted]

Condition 9. Notification Requirements.

37. Condition 9 requires the licence holder to notify the licencing authority immediately in the event of (a) an accident or dangerous occurrence involving a SAP, or (b) the loss of a SAP during transportation.

38. [redacted]

[redacted]

- [redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

ADDITIONAL ISSUES IDENTIFIED AT AFBI

Testing for BTV at AFBI.

42. BTV is a SAPO Group 3 pathogen that causes an insect-borne viral disease primarily affecting cattle, sheep, goats, deer, llamas and alpacas. BTV is transmitted by biting midges (*Culicoides* spp) which are present in NI. SAPO Group 3 agents are disease-producing organisms which are either exotic or produce notifiable disease, have a moderate risk of spread from the laboratory, and require CL3 to work safely. These containment requirements also extend to surveillance and diagnostic activities with 'carriers' of SAPO agents, which are defined as any living creature, except man, which may carry or transmit a SAP or the tissue, cell culture, body fluid, excreta, carcase or part of a carcase of such creature by or by means of which a SAP may be transmitted.

43. During the inspection we were made aware of an emerging BTV outbreak in NI. We were informed late on Wednesday 3rd December 2025 that BTV testing at AFBI was being undertaken in CL2 laboratories which were also used for the routine surveillance of samples for BTV on a regular basis. On receipt of this information, we inspected the facilities where this work was being undertaken which included two areas; one where serology testing was undertaken and one where PCR testing was conducted. Despite CL3 facilities being present at AFBI, both of these facilities operate at CL2 and are not compliant with the CL3 requirements set out in HSG280 for work with SAPO Group 3 agents (and their carriers) such as BTV. [redacted]

- [redacted]

- [redacted]

- [redacted]

- [redacted]

- [redacted]

- [redacted]

- [redacted]

- [redacted]

- [redacted]

- [redacted]

44. HSE is aware of the developing environmental situation with BTV in NI. Nevertheless, significant issues were identified with the current arrangements and facilities used for BTV testing at AFBI in the response to this outbreak, and in HSE's opinion, the current operations have the potential to lead to the loss of containment of BTV from the facility and the potential release of this virus to the environment.

45. [redacted]

[redacted]

Avian Influenza/Newcastle Disease Surveillance Testing at AFBI.

47. Both Highly Pathogenic Avian Influenza Viruses (HPAIV) and Newcastle Disease Virus (NDV) are classified under SAPO as Group 4 pathogens, requiring work involving these viruses (including carriers thereof) to be undertaken at SAPO CL4. SAPO Group 4 agents are disease-producing organisms which are either exotic or produce notifiable disease and have a high risk of spread from the laboratory. HPAI is a severe form of Avian Influenza which primarily affects birds, particularly poultry, and is associated with high mortality rates and rapid transmission within flocks. NDV is similarly a highly contagious viral disease which again predominantly impacts domestic poultry, but can also affect a wide range of avian species including wild birds. Both HPAIV and NDV are also zoonotic pathogens with the ability to cause disease in humans.

48. Where the presence of such agents is known or suspected, all work must be conducted within a facility of the appropriate containment level to protect both those undertaking the work and to prevent environmental release. From a SAPO perspective, work with these viruses (and their carriers) must be undertaken at SAPO CL4 to ensure that the work can be undertaken safely and that the risks to the environment and human health are adequately controlled.

49. [redacted].

50. [redacted]

51. If you have any questions on any of the above, please do not hesitate to contact me.

52. Additional recommendations and advice, unrelated to compliance with SAPO and HSG280 are highlighted in the associated inspection report.

Yours faithfully

[redacted]

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