

MEMORANDUM OF UNDERSTANDING

Ref: PATH 90

**April 2008 to the end of Phase 2
Phase 2**

**Provision of HSE support for
Statutory Inspections of
SAPO laboratories**

On behalf of

Exotic Disease Policy (EDP)

**Department for
Environment,
Food and Rural Affairs
(Defra)**

24/04/2008

1. Introduction

1.1 This document forms a Memorandum of Understanding (MoU) made between Exotic Disease Policy (EDP) of the Department of Environment, Food and Rural Affairs (Defra), and the Health and Safety Executive (HSE).

1.2 The Specified Animal Pathogens Order 2008 No. 944 (SAPO) prohibits any person from having in their possession any specified animal pathogen listed in Part 1 of the Schedule to the Order or any carrier in which he knows such a pathogen is present unless they have a SAPO license. It also prohibits the unlicensed introduction into any animal or bird of any pathogen listed in the Schedule to the Order (Parts I and II).

1.3 The purpose of the Order is to prevent the introduction and spread into England of specified animal pathogens, which, if introduced, could cause serious disease and economic loss to animals and poultry industries.

1.4 SAPO licences stipulate the way in which the specified animal pathogens covered by the licence must be handled to ensure their safe containment and disposal, the areas of the laboratory in which various types of work may be done and the persons responsible for supervising the work. Licence holders are required to meet the relevant Defra containment and operating standards and the SAPO licensing process requires an inspection of the premises that are the subject of the application. Licences are usually valid for 5 years. Re-inspections of laboratories licensed under the Order may be carried out at any time to ensure full compliance with licence conditions.

2. The aims and objectives of the SAPO licensing Inspections

2.1 The licensing regime aims to provide Defra with assurance that those persons:

- issued with SAPO licences have the necessary trained staff, documented operating and management procedures and facilities to ensure the safe containment, handling and disposal of the specified animal pathogens for which the licence is given;
- licensed under SAPO continue to comply with the relevant containment and operating standards, and with the conditions on their SAPO licences while they remain licensed.

3. Objectives of the MoU

3.1 The purpose of this memorandum is to complement the Agency Agreement between Defra and HSE for the enforcement of the Specified Animal Pathogens Order 2008 and record the arrangements made between EDP and HSE for the provision of inspection and enforcement services as described below.

4. Scope of agreed work and services to be provided by the HSE

4.1 EDP, as the Defra policy area responsible for administering SAPO, will:

- in respect of current SAPO licensees, provide HSE's Biological Agents Unit (BAU) with a comprehensive list of currently licensed facilities, their inspection and enforcement history, when the next inspection is due and copies of existing licences to assist HSE in defining the inspection programme priorities;
- in respect of applicants for a new SAPO licence, an amendment or a renewal of a licence, request inspections of premises identified in the application and specify the relevant containment level to which the inspection should be carried out;
- in respect of all licensees/licence applicants, obtain and provide BAU with staff details, Standard Operating Procedures (SOP) and floor plans that show clearly the layout of the areas where the specified animal pathogen(s) are to be stored and forward them to HSE with the acknowledgement letter and a copy of the acknowledgement letter sent to the applicant about the laboratory inspection, the application form and any previous inspection reports or licenses;
- review inspection reports and comment on any licensing issues;
- provide expert veterinary advice into the inspection process as required;
- take the lead, with the Animal Health Agency, to deal with suspected or actual outbreaks of animal disease in accordance with Defra contingency plans, for example, cleansing and disinfection of premises, epidemiological investigations, etc.

4.2 HSE's BAU has a national remit for their inspection programme under HSWA in relation to biological agents. HSE may decide to brigade forthcoming SAPO inspections based at the same site with inspections to be carried out as part of their rolling inspection programme. However, HSE may decide not to carry out a SAPO inspection of the licence holder's premises if an inspection has recently been undertaken and HSE has full knowledge of the history of the laboratory. In either case, Defra will be informed of this decision and the rationale for it. A full report, with recommendations, will still be submitted to Defra within the agreed timescales. The HSE will:

- follow the HSE Enforcement Policy and apply the principles outlined in HSE operational procedures and the Enforcement Management Model in carrying out SAPO inspections:
<http://www.hse.gov.uk/pubns/hsc15.pdf>
<http://www.hse.gov.uk/foi/internalops/og/ogprocedures>
- appoint an inspector from the BAU within 10 working days of receipt of EDP notification;
- contact the applicant/SAPO licence holder in writing within 15 working days of receiving a request to undertake an inspection;
- confirm the date of the inspection to the applicant/SAPO licence holder in writing;
- complete the inspection within 30 working days of the inspector being appointed;

- undertake inspections for SAPO containment facilities at levels 2, 3 and 4. The inspections will comprise both routine re-inspections and new inspections;
- carry out physical inspections of the premises bio-security and bio-containment arrangements, review staffing and management, staff training arrangements and associated record keeping, documented procedures, compliance with relevant Defra containment standards at <http://www.defra.gov.uk/animalh/diseases/pathogens/category2.htm> and, where appropriate, licence conditions;
- give advice to resolve minor non-compliances and follow-up in writing;
- ensure an appropriate number of trained inspectors are available to undertake the work agreed by this MoU;
- maintain competence and expertise in conducting inspections of premises that are to hold specified animal pathogens;
- provide Defra with a record of the hours spent on inspections and the total number of inspections completed by containment level, their findings and provide a general overview of their issues, concerns and trends for discussion/forward planning at the 2nd quarter meeting;
- HSE's BAU have dedicated resource for dealing with technical queries on a daily basis under the Unit's Duty Inspector (DI) system, the DI will act as a contact point for applicant and licence holders for issues concerning specific inspections and containment requirements. Specific queries on licensing applications will be referred to Defra.

4.3 Within 10 working days of completion of the inspection the HSE will submit to Defra a complete inspection report with a recommendation that a SAPO licence be rejected, issued immediately, or issued after certain shortcomings have been addressed. The document should bring to Defra's attention anything that materially affects containment requirements being met and indicate on what information the recommendations are made. Copies of any relevant correspondence should also be included.

4.4 Subject to Defra's veterinary advisor resolving any issues that they may have regarding the content of the report, if the laboratory is compliant, and based on HSE's recommendation, Defra will arrange for a licence to be issued and a copy sent to HSE for their records.

4.5 Where licence holders are found to have minor non-compliances on inspection, HSE will:

- write to the applicant/licence holder within 10 working days of carrying out the inspection to specify corrective action required including action to be taken if not cleared within 20 working days and copy this to Defra;
- allow twenty working days for the non-compliances to be cleared;
- within 5 working days of the receipt of confirmation that the minor non-compliances have been rectified, HSE will write to Defra confirming whether they are content that they have been cleared and make recommendations about issuing a licence. Any documents that have been revised, e.g. SOPs or floor plans should also be copied to Defra;

- if, at the end of the 20 day period, confirmation of the correction of non-compliance has not been received, HSE will inform Defra of the action to be taken and make recommendations about licence issues, including suspension and withdrawal for existing licence holders.

4.6 Where licence holders are found to have a major non-compliance, HSE will:

- take action in line with HSC Enforcement Policy and the principles outlined in HSE's EMM and Operational Procedures;
- the initial notification, improvement notices (IN) and prohibition notices (PN) will be followed up in writing within 5 working days;
- notify Defra's Veterinary Exotic and Notifiable Disease Unit (VENDU) immediately by telephone and inform them of the proposed action/next steps.

If it becomes clear that it will not be possible to provide Defra with the information within the specified time, HSE will inform Defra as soon as possible (and at least within the timeframes above) and give reasons for the delay.

4.7 Representatives from Defra's SAPO administrative team and the HSE's BAU will:

- hold formal, quarterly liaison meetings to monitor progress of the MoU and the on-going inspection programme;
- agree arrangements if it is necessary to extend Phase 2 beyond 2008
- will work together to ensure that licence conditions meet the needs of effective containment and enforcement and which, in HSE's view, are workable and enforceable.

5. Definitions

5.1 Minor non-compliances

These are 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.

5.2 Major non-compliances

This may be either one single issue that, in the opinion of the inspector, by itself significantly compromises bio-security and/or bio-containment, or a number of minor non-compliances that when taken together would compromise bio-security.

5.3 Bio-security

The prevention of disease-causing agents entering or leaving a property and being spread. It involves a number of measures and protocols designed to prevent pathogens and disease being spread.

5.4 Persons

In practice, the 'person' will generally be either an individual or corporate body, licensed under SAPO to carry out work with animal pathogens.

6. Standards

6.1 This work will be conducted according to Defra and HSE desk instructions, Agency Agreement, the HSE Enforcement Policy, the principles of HSE's EMM and Operational Procedures and the SAPO 2008. Any changes to the desk instructions must be agreed between Defra and HSE.

7. Duration

7.1 This agreement shall be deemed to commence in April 2008 and end when Phase 3 comes into effect.

7.2 Both parties have the right to renegotiate this agreement if, at Ministerial direction, for example, as a result of a national or other emergency, HSE resources are diverted to other priorities, or additional resources are required to meet the emergency needs of the customer.

8. Price and payment

8.1 Defra agrees to pay £113,460.00 to HSE for 732 inspector hours for work at SAPO sites in England between 1 April and 31 December 2008. A review of the planned hours will take place at the 2nd quarter meeting and if, as a result of unexpected levels of reactive work or other unforeseen factors these hours prove insufficient to properly enforce SAPO then the agreement and the payment will be renegotiated in accordance with section 13 below.

8.2 Payment will be to HSE in one lump sum advance payment on receipt of an invoice from HSE. The invoice should detail the planned number of hours to be spent on visits and the planned number of hours to be spent on other reactive work. Defra will pay HSE within 30 days of receiving an invoice.

8.3 In the event of this agreement being terminated before the due date, HSE will submit a statement of the cost from the date of the last payment, if any, up to the termination date certified as an accurate statement of the costs properly incurred under this MoU. HSE may also claim costs that it is legally bound to pay after the termination date as a result of commitments properly incurred before the date of notice of termination, but shall not be entitled to any payment by way of compensation.

9. Contacts and management of the agreement

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

9.4 Where there is a difference of opinion between Defra and HSE on the interpretation of the Terms and Conditions of this MoU, or any matter arising out of this MoU, the matter will, in the first instance, be referred to the nominated contacts above. If they are unable to reach agreement, the matter will be referred to the signatories of this MoU and then to the Secretary of State who shall be the final arbiter.

10. Audit

10.1 HSE will keep and maintain cost records until two years after the completion of the agreed work. These will be available for scrutiny at HSE, by prior arrangement, to Defra auditors acting on their behalf.

11. Record keeping

11.1 Records of inspections and enforcement actions conducted under this agreement will be maintained at HSE for a period of two years and will be available for inspection, by prior arrangement, with Defra.

12. Publication and disclosure

12.1 Inspection reports are between HSE inspectors, the facility inspected and Defra. The reports, suitably redacted, may be issued under the Freedom of Information Act (FOI) or Environmental Information Regulations (EIR).

13. Variation

13.1 Variation may only be by consent of both parties. Either party may seek to vary the agreed scope of this MoU and work contained in it. However, each

party will give reasonable notice of any major changes it is seeking in order to enable the other party to respond as quickly as possible.

13.2 On receipt of a request to vary the agreement, the HSE will provide an estimate of the financial, human and other resources necessary to meet the request and give an estimated timetable. Any telephone requests concerning proposals for additional or changed services to be carried out by the HSE must be followed up with written confirmation within 5 working days.

14. Unlawful discrimination

14.1 HSE shall not unlawfully discriminate with the meaning and scope of the provisions of the Race Relations Act 1976, the Sex Discrimination Acts 1975 and 1986 or the Disability Discrimination Act 1995 or any statutory modification or re-enactment thereof relating to discrimination in employment.

I agree to and accept all the terms and conditions of the above agreement

Signed on behalf of Exotic Disease Policy, Defra

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Print Name [Redacted]

[Redacted]

Date.....

Signed on behalf of Health and Safety Executive

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Print Name: [Redacted]

[Redacted]

Date.....