

REVISION TO THE UK REGULATORY FRAMEWORK GOVERNING HUMAN AND ANIMAL PATHOGENS: WORKING PAPER SUBMITTED BY THE UNITED KINGDOM

Introduction

1. At the 2003 Meeting of Experts the UK presented a working paper whose annex explained the regulatory framework for facilities handling pathogens and toxins.¹ Events since then have had a significant bearing on this framework. This paper summarises the background to these events and their follow-up, and explains the changes that have already taken place and those that are envisaged. States Parties may find this experience of interest to their own regulatory systems, especially if they are contemplating any changes, or are setting up new systems. The immediate catalyst for change in the UK was an outbreak of foot and mouth disease (FMD) in Surrey, UK in August 2007.

Investigations and reviews

2. Preliminary investigations by the Department for Environment, Food and Rural Affairs (Defra) indicated that the virus may have originated from nearby facilities at Pirbright. This site houses an Institute for Animal Health (IAH) laboratory; Merial, a commercial animal vaccine manufacturer; and Stabilitech, a company that works with FMD virus in a small laboratory within the IAH facility. Subsequently, the government asked the Health and Safety Executive (HSE) to lead an investigation at Pirbright. The investigation concluded that it was possible for live virus to enter the site effluent drainage system, and judged it likely that waste water containing live virus, having entered the drainage pipework, then leaked out and contaminated the surrounding soil. The conclusion was supported by evidence of long term damage and leakage, including cracked pipes, tree roots breaching pipework, and unsealed manholes. Inspectors also believed that excessive rainfall in July may have increased the potential for virus release from the drain.² The HSE recommended that a review of the regulatory framework for animal pathogens should be undertaken. Other recommendations and comments were specific to the site operators and concerned issues such as: whether a high containment laboratory could be sealed for fumigation; the testing of filters; the need to investigate whether liquid waste could be effectively sterilised; and improvements to the effluent drainage system.³

3. A separate review at government request was conducted by Professor Brian Spratt, Imperial College London on the safety of facilities handling FMD virus.⁴ The Review Group noted a potential conflict of interest between the role of Defra as regulator, licensor and inspector of the Specified Animal Pathogens Order 1998 (SAPO) Category 4

¹ BWC/MSP.2003/MX/WP.7/Rev.1 15 July 2003 *The Design of National Mechanism to Maintain the Security and Oversight of Pathogenic Micro-organisms and Toxins* Prepared by the United Kingdom

² see *HSE Final report on potential breaches of biosecurity at the Pirbright site 2007*
<http://www.hse.gov.uk/news/archive/07aug/finalreport.pdf>

³ *HSE Final report on potential breaches of biosecurity at the Pirbright site 2007* pages 43-44 paragraphs 8, 9 and 13; page 45 paragraphs 26 and 28 for example.

⁴ Professor Spratt, *Independent review of the safety of UK facilities handling foot-and-mouth disease virus* (2007) http://www.defra.gov.uk/FootandMouth/investigations/pdf/spratt_final.pdf

facilities *and* as a major customer of animal pathogens research and diagnostics. The report recommended that there should be a review of systems for regulation, inspection and enforcement of biosecurity for work on animal and human pathogens at containment level 4.⁵ This should consider whether there should be a common regulatory inspection framework overseen by an arm's length body such as the HSE.⁶

4. Consequently, the Secretary of State for Environment, Food and Rural Affairs asked Sir Bill Callaghan to lead a review of the regulatory framework for handling animal pathogens and to make recommendations to the government for changes that would strengthen regulation of animal pathogens.⁷ Specifically, the review was tasked to make recommendations on:

- any changes needed to clarify and strengthen the regulatory framework for animal pathogens in the light of that for human pathogens;
- any steps needed to ensure independence and clarity on the separate roles and responsibilities of funders, regulators, customers and the institutions themselves; and,
- any steps needed to provide clear lines of accountability, inspection protocols and responses to non-compliance and breaches.

Recommendations of the Callaghan Review

5. Although the Review accepted that there is a need to recognise the different threats posed to animal or human health by different pathogens, it did not think it was helpful to have two separate regulatory systems, each dealing with a different aspect of what was essentially the same thing, i.e. the need to contain the pathogen and prevent its release such that it can cause harm.⁸ As a result of this conclusion the Review recommended that:

- Defra, Department of Health (DH), HSE and other interested parties work together to develop a **single regulatory framework** to govern work with human *and* animal pathogens (the Advisory Committee on Dangerous Pathogens (ACDP – See Annex for details) met on 5th February 2008 to begin work on a common set of containment measure to apply to animal and human pathogens);

⁵ The Spratt report defines biosecurity thus: “*Laboratory biosecurity describes the action taken to prevent unauthorised access, loss, theft, misuse, diversion, or intentional release of biological agents and toxins.*” It defines biosafety thus: “*Laboratory biosafety describes the action taken to prevent unintentional exposure to biological agents and toxins, or their accidental release.*” Annex 6 page 81

⁶ See Annex for summary of SAPO 1998 prior to changes described in this paper.

⁷ Sir Bill Callaghan was chair of the Health and Safety Commission from 1999 to September 2007 and was formerly the Chief Economist at the Trades Union Congress and member of the Low Pay Commission between 1997 and 2000. He is Chair of the British Occupational Health Research Foundation, Chair of the Policy Advisory Committee Centre for Risk and Regulation at the London School of Economics and Visiting Fellow at Nuffield College, Oxford.

⁸ A REVIEW OF THE REGULATORY FRAMEWORK FOR HANDLING ANIMAL PATHOGENS, Chaired by Sir Bill Callaghan, Presented to the Secretary of State for Environment, Food and Rural Affairs 13 December 2007 at <http://www.defra.gov.uk/animalh/diseases/fmd/pdf/callaghan-reviewreport071213.pdf>

- Defra, DH, HSE and other interested parties work immediately towards the introduction of **cost recovery in any new regulatory framework** (i.e. regulated bodies pay for licensing and inspection systems);
- **risk assessment should be a key element** of the single regulatory framework for handling human and animal pathogens, as it currently is for human pathogens and genetically modified organisms;
- the ACDP should be tasked with formulating a **common set of containment measures to apply to both animal and human pathogens** to complement the single regulatory framework when it is introduced.
- the regulator under the single regulatory framework should be given discretion to agree with operators **departures from the containment measures** drawn up by ACDP, **on the basis of risk assessments**.
- responsibility for inspection and enforcement functions in respect of animal pathogens should move from Defra to a body that is not subject to the same conflict of interest and which has access to the range of technical expertise needed to carry out the regulatory function fully.
- **HSE become the single regulatory body for both animal and human pathogens**, and that the powers of inspectors under the animal health act be extended to reflect the powers currently available to HSE inspectors under health and safety legislation. This would bring into play the ability to issue improvement notices and prohibition notices, which are not currently available under SAPO.

6. The review also observed that *The Management of Health and Safety at Work Regulations 1999* place clear duties on employers sharing a site to co-operate with each other in managing health and safety. These regulations apply to laboratories handling human pathogens. The review recommended that this duty to co-operate should apply in any new regulatory framework for handling dangerous pathogens. It would thus apply also to those in charge of facilities handling animal pathogens. In addition, where there are several separate organisations operating from the same site, as was the case at Pirbright, there must be complete clarity as to who is responsible for the site infrastructure and how biosecurity for the site as whole is managed.⁹

Timetable for changes

7. The Callaghan Review recommended a phased approach to these changes. In phase 1, Defra was to enter into immediate discussions with the HSE to formalise its support of

⁹ The Callaghan Review defined biosecurity as in the sense described in the HSE report on Pirbright: “to cover the implementation of a combination of containment measures and work practices, supplemented by management controls, to prevent the inadvertent exposure of susceptible species to biological agents and their distribution in the wider environment.” Page 4 paragraph 2.7.

SAPO inspections by 1 January 2008. The ACDP should begin work on drawing up guidance on a single set of containment requirements for human and animal pathogens. Under phase 2, changes should be made to SAPO to designate HSE as the inspection and enforcement body under the Order. And finally in phase 3, Defra, DH, HSE and other interested parties should begin work urgently to bring in the single regulatory framework by the end of 2008.

Purpose of changes

8. The fundamental aim was to encourage the development of a regulatory framework that is consistent, transparent, proportionate, and targeted on where the greatest risks are, and that includes a high level of accountability. Such a regime should encourage compliance, and emphasise that primary responsibility for the safe operation of laboratories rests with the laboratory operators, not with the regulator. An effective regulatory framework should require duty holders to take all reasonably practicable measures to protect others from harm and demonstrate this by preparing a thorough risk assessment identifying the measures needed to contain hazards. In turn, the regulator's role should be to consider the risk assessment and to take action as appropriate.

9. The process of changes outlined in the Review to the existing regulatory framework is designed to bring about a range of benefits, most importantly simplification of what is currently a complex system, and greater transparency in the relationship between the regulator and the regulated.

Progress and status: 1 July 2008

10. Ministers accepted the Callaghan recommendations in full. Phase 1 was implemented in January 2008. Phase 2 was completed by the end of April 2008. The SAPO was amended to provide a legal basis for the formal transfer of the inspection and enforcement role for this legislation from Defra, the Veterinary Laboratories Agency and local authorities to the Health and Safety Executive (HSE). The legislation came into effect on 28 April 2008.

11. The SAPO 2008 provides HSE inspectors that are appointed as inspectors under SAPO with certain powers that are equivalent to those which HSE inspectors currently have under the Health and Safety at Work Act 1974. These include: the ability to issue formal improvement and prohibition notices; allowing HSE to ask veterinary or other experts to accompany them on inspections as considered necessary on a case by case basis; and taking on to the premises equipment and other things necessary to carry out the inspection. The Containment Requirements for Laboratories to be Licensed to Handle Defra Category 4 Pathogens under the SAPO 1998 have also been amended. This was done in response to an HSE recommendation that the required standards of containment should be clearly documented to facilitate the regulatory process.

12. Responsibility for licensing premises under SAPO remains with Defra. Work is now underway to implement Phase 3 to create a single regulatory framework. This will be a

more complex project, involving amendments to the existing Control of Substances Hazardous to Health Regulations (COSHH), SAPO and the Genetic Modification (Contained Use) Regulations, and drafting a revised single guidance document. A working group is being established by the ACDP to commence work on producing a common set of containment measures as proposed by the Callaghan Review.¹⁰

13. Phase 3 has been split over six identified areas for action and positive progress has already been made in each area:

- development of a single regulatory framework for work with human and animal pathogens;
- development of a cost recovery regime;
- stakeholder engagement and a communications plan;
- production of a common set of containment measures to apply to both human and animal pathogens;
- development of an integrated notification system; and,
- engagement of the Administrations in Scotland, Wales and Northern Ireland.

14. Under Phase 3, the lead for implementing the Callaghan recommendations has transferred from Defra to HSE. It is envisaged that there will be full recovery of costs for the regulation of animal and human pathogens. Full regulatory responsibility for handling of animal pathogens will pass to HSE. This final phase will involve change in the way in which animal pathogens are regulated. However, it will simplify the overall approach to regulating work involving all pathogens, because the same principles and approach will apply to all types of pathogens. This is to reflect the Callaghan review recommendation that risk assessment be a key element of the single regulatory framework and that the regulator be given discretion to agree with operators departures from containment measures on the basis of a risk assessment, similar to the approach adopted in the Genetically Modified Organisms (Contained Use) Regulations.

15. The central issue revolves around developing a framework that is legally feasible and practicable; that is understood by facility personnel and that the regulations can be enforced by the regulator: the aim being to ensure that facility personnel have a clear understanding of what is required of them when seeking to work with biological agents. Phase 3 will be subject to a separate impact assessment as well as a public consultation later this year, with a view to the single regulatory framework being established sometime in 2009.

¹⁰ <http://www.hse.gov.uk/aboutus/meetings/acdp/100608/acdp89p5.pdf> ADVISORY COMMITTEE ON DANGEROUS PATHOGENS Callaghan review and the new regulatory framework for animal and Human pathogens, ACDP/89/P5

ANNEX

1. The **Specified Animal Pathogens Order 1998 (SAPO)** prohibits the possession or the introduction into any animal or bird of any of the animal pathogens listed in Part I of the Schedule to the Order and the possession of any carrier containing such a pathogen, except under licence. These are mainly agents that can cause serious exotic diseases of economic importance in farmed livestock and poultry, some of which can affect humans. No licence is required to possess the pathogen listed in Part II of the Schedule but its introduction into any animal or bird is prohibited except under licence. Restrictions are also placed on domestic transfers of specified animal pathogens or carriers through conditions in licences granted to those in possession of such material under SAPO.

2. Licences that authorise the possession of specified animal pathogens under SAPO are only issued where laboratories have the necessary operating procedures and facilities to ensure the safe containment, handling and disposal of the pathogens concerned. Licensing under SAPO is administered by the Department for Environment, Food and Rural Affairs in England, The Scottish Executive Environment and Rural Affairs Department in Scotland and by the Agriculture and Rural Affairs Department of the National Assembly for Wales in Wales.

3. The **Advisory Committee on Dangerous Pathogens (ACDP)** advises the Health and Safety Commission, the Health and Safety Executive, Health and Agriculture Ministers and their counterparts under devolution in Scotland, Wales and Northern Ireland, as required, on all aspects of hazards and risks to workers and others from exposure to pathogens. The ACDP is a non-statutory advisory non-Departmental Public Body. The Committee comprises a Chairman and 17 members. The membership is tripartite, including 9 scientific experts, 4 employer representatives and 4 employee representatives. ACDP is serviced by a joint secretariat (Health and Safety Executive, the Department for Environment, Food & Rural Affairs, and the Health Protection Agency).

4. The ACDP produces guidance on a range of dangerous pathogens-related subjects. Documents are available as a paper copy from The Stationery Office or HSE Books or online; a current list is at <http://www.advisorybodies.doh.gov.uk/acdp/index.htm>. The electronic documents can also be accessed from the HSE's website - <http://www.hse.gov.uk/aboutus/meetings/acdp/>.