

Final report on potential breaches of biosecurity at the Pirbright site 2007

Erratum

Paragraph 142 in this report is incorrect.

The full text of paragraph 142 should read:

142 Our investigations in the laboratory used by Stabilitech identified some issues relating to records of when stocks of chemicals had been made up. The issues related to the standardised method of preparation and higher concentrations than necessary being used. While this was not regarded as good practice, this was not considered significant.

Amended 20 December 2007

Contents

Foreword	1
Statement of key conclusions and recommendations	2
Background	6
Introduction	7
Activities involving the O1 BFS strain	15
Identifying the origin of the outbreak strain	16
Potential for release of the O1 BFS strain via the airborne route	20
Potential for release of the O1 BFS strain via the waste route	24
Potential for release of the O1 BFS strain via the human route	34
Summary of conclusions and recommendations	43
Annex: Assessment of the condition of the drainage systems at Pirbright and the implications for containment of effluent	47
Glossan	75

Foreword

HSE is now pleased to present to the government a final report on potential breaches to biosecurity at the Pirbright site. We have addressed the questions posed to us by our terms of reference and, as a result of our investigations, have been able to develop an explanation of how the foot and mouth disease virus used at the Pirbright site can be linked to the first farm infected.

This has been a complex investigation and the report is the product of careful work by a large group of technical experts. While HSE has led the team and contributed specialists across its own areas of expertise, vital contributions have been made by staff from a range of distinguished organisations. HSE is grateful to thank everyone involved for making their skills and knowledge so readily available. In particular, I would like to thank Defra, the Veterinary Medicines Directorate, the Health Protection Agency and the Environment Agency for the staff they provided to the investigation team. I would also like to record my appreciation of the work done in support of our inquiries by Surrey Police, the Central Science Laboratory, the Meteorological Office and the Health and Safety Laboratory.

My colleagues in HSE have been a tremendous support. Their professionalism and willingness to go the extra mile has made it possible for the work to be done thoroughly and for this report to be completed within four weeks of the start of the investigation. I would like to pay tribute to them – they deserve the thanks of everyone with an interest in this issue.

I would like to record that the investigation has been carried out with the support and co-operation of the management and staff from the Institute for Animal Health, Stabilitech Ltd, and Merial Animal Health Ltd.

Dr Paul Logan

Pirbright Lead Investigator

Paul hog

Statement of key conclusions and recommendations

- 1 Following the outbreak of foot and mouth disease (FMD) in Surrey on 3 August, the government asked the Health and Safety Executive (HSE) to lead an investigation into biosecurity issues at the Pirbright facility a site occupied by the Institute of Animal Health (IAH) and also by two private companies called Merial Animal Health Ltd (Merial) and Stabilitech Ltd (Stabilitech). The Department of the Environment, Food and Rural Affairs (Defra) had established that the virus strain causing FMD in the first infected herd of cattle at a farm in Normandy, Surrey was O1 BFS67 (also known as 01 BFS1860 and hereafter referred to as O1 BFS). This is a laboratory strain not naturally found in the environment and was one upon which work was being carried out by all three occupants of the Pirbright site ahead of the first outbreak. HSE's job was to lead a team to investigate:
- potential breaches of biosecurity at the Pirbright site;
- whether such breaches may have led to a release of any specified animal pathogen;
- whether any such breaches had been rectified to prevent future incidents.
- 2 The period covered by our investigation was 7–26 July following advice from Defra epidemiologists.
- 3 The team started work at the site on 5 August. Within two days, we established and prioritised our main inquiry lines and set these down in an initial report submitted on 7 August. Within a month of the first outbreak, the team has completed the investigation and our conclusions and recommendations are summarised below, according to the questions we were asked to address in our commission from the government. Our report in full follows.

O1 BFS virus strain

4 We conclude first that this virus strain, found in the first infected animal herd in Normandy, is highly likely to have originated from the Pirbright site. We conclude this from the results of nucleotide sequencing tests of the virus strain in question, which we commissioned as part of the investigation. However, due to very small differences in the strains used at all three organisations at Pirbright, it has not been possible to pinpoint precisely through sequencing the exact origin of virus found in the infected animals at Normandy.

Breaches of biosecurity at Pirbright

5 We looked at biosecurity controls in four areas where we judged it possible for the virus to escape containment arrangements at Pirbright, namely solid waste disposal, airborne routes through the fabric of site buildings or faults in filtration systems, liquid waste disposal, and human movements.

Solid waste

6 We found no evidence of any breakdown in the containment systems for solid waste disposal at the Pirbright site overall.

Airborne release

7 We found no evidence of a biosecurity failure that could have led to the virus being released from the site into the atmosphere. The appropriate bio control systems were functioning properly at Merial. The same was true at IAH and Stabilitech, although we did find some weaknesses in the physical integrity of their premises and in their filter testing regimes.

Liquid waste disposal

- 8 IAH and Stabilitech work on experiments with only small amounts of live FMD virus. Waste from those experiments can include the live virus that passes through a chemical effluent inactivation process before entering the Pirbright site drainage system. That process does not achieve complete inactivation; a final effluent treatment process on the site is designed to achieve that before the waste passes into the public sewer. Waste water from human showers, which could also contain some live virus, enters the site drainage system direct. It was therefore possible for small quantities of live virus from IAH and Stabilitech to have entered the site drainage system at this point in the system. However, because this was in accordance with Defra's requirements, we conclude there was no breach of biosecurity in this respect.
- 9 We take the same view in relation to Merial. During the period covered by our investigation, Merial were engaged in large-scale FMD vaccine production and we established that the resulting waste containing the live FMD virus O1 BFS was flushed into the company's effluent sump and then passed into the site drainage system. The quantities involved were much larger than those for IAH and Stabilitech. However, this act of discharge was permitted by Defra, hence we conclude there was no breach of biosecurity at this juncture by Merial.
- 10 However, such was the condition in which we found the site drainage system that we conclude that the requirements for Containment Level 4 were not met, thus constituting a breach of biosecurity for the Pirbright site as a whole. Our conclusion is supported by the evidence we found of long-term damage and leakage, including cracked pipes, unsealed manholes and tree root ingress. We have investigated ownership of the drainage system, which rests with IAH. However, we are aware of a difference of opinion between IAH and Merial over responsibility for maintenance of a key section of pipe relevant to this investigation.
- 11 The arrangements for discharge from the Merial sump into manhole FM1 (see later) leaves the potential for overflowing of the manhole and release of material from the effluent sump. If this were to contain live pathogens, in our view this would constitute a breach in biosecurity. Moreover, we judge the practice employed by IAH of using bowsers and hoses in the intermediate site effluent drains to clear blockages without a standard operating procedure (SOP) to be a breach of biosecurity.

Human movements

- 12 We established that, in the period covered by our investigation, not all human and vehicle movements via the IAH gatehouse to the site were recorded, in particular traffic associated with construction work going on at the site at the time. We conclude these failures to keep complete records were not in line with accepted biosecurity practice and represent a breach in biosecurity at the IAH site.
- 13 We also found evidence of poor monitoring and control of access to restricted areas within IAH facilities. We conclude that this too constitutes a breach in biosecurity.

Whether such breaches may have led to a release of any specified animal pathogen

14 Given what we say above, it is our conclusion that the breaches we have identified in the biosecurity arrangements for handling liquid waste are likely to have occasioned a breach of containment and release of FMD strain O1 BFS onto the Pirbright site. We judge it likely that waste water containing the live virus strain, having entered the drainage pipework, then leaked out and contaminated the surrounding soil. We also believe that excessive rainfall may have exacerbated the potential release from the drain.

Transfer of the released O1 BFS virus strain beyond Pirbright

- 15 We have said that in the period covered by our investigation, human and vehicle movements at Pirbright were not adequately controlled. Indeed, in relation to the construction traffic, we conclude that the vehicles involved were likely to have had unrestricted access to the site. In our opinion, the construction activities on site above the vicinity of the intermediate section of the effluent drainage system are likely to have caused disturbance and movement of soil in a way that contaminated some of the vehicles with live FMDV O1 BFS. We conclude it likely that those vehicles, having driven over this part of the site, carried off out of the site materials containing the live virus in the form of mud on tyres and vehicle underbodies. This is likely to have been exacerbated by the very heavy rainfall at the time, resulting in significant amounts of mud and slurry at the site as well as drainage problems.
- 16 We have further established that some of the vehicles thus contaminated drove from the site and along Westwood Lane, Normandy as part of their journey to their destinations. Westwood Lane passes the first infected farm. It is our conclusion that this combination of events is the likely link between the release of the live virus from the Pirbright site and the first outbreak of FMD.

Whether any such breaches have been rectified

17 We have drawn our concerns about potential breaches of biosecurity, together with the recommendation listed below, to the attention of the Pirbright site regulator (Defra) so that they can be rectified.

Recommendations

18 We make the following key recommendations in the light of our investigation:

- We recommend that the required standards of containment for animal pathogens should be clearly documented to facilitate the regulatory process and that a review is completed to contrast the actual regulatory position for animal pathogens with human pathogens to make sure the position is justified.
- We recommend review of arrangements for setting and monitoring safe operating practices where work is subcontracted under a single licence operating under the Specified Animal Pathogens Order (SAPO) with responsibilities clearly defined between the licence holder and the subcontractor.
- We have concerns about the suitability of continued use of the upper south wing of the IAH laboratory, which is also used by Stabilitech for high containment work. In our view, it does not meet the requirement for SAPO 4 and we recommend that remedial work be carried out at the facility.
- We have concerns about filter arrangements throughout the IAH/Stabilitech facility where banks of HEPA filters are tested as a single unit leading to possible undetected failures. We recommend consideration given be to changing the siting and testing arrangements.
- We recommend review of the appropriateness of chemical treatment for sterilising liquid waste containing SAPO Category 4 pathogens. It is our experience that chemical treatments, while reducing the amount of pathogen in the liquid, may not render the liquid completely pathogen-free.
- We recommend the effluent drainage system on the Pirbright site is improved to ensure high level SAPO requirements are met. In addition we also recommend better record keeping, maintenance and monitoring regimes in relation to the effluent drainage system.
- We recommend tighter controls of vehicle and human movement on the IAH site.

Background

- 19 An outbreak of FMD was confirmed at a farm in Surrey, UK on 3 August 2007.
- 20 Preliminary investigations by Defra indicated that the virus may have originated from nearby laboratory or manufacturing facilities at Pirbright, at which two main organisations are based: the Institute of Animal Health (IAH) and Merial Animal Health Ltd (Merial). In addition, Stabilitech Ltd (Stabilitech), a small, private company, operates in a laboratory on IAH premises.
- 21 A multidisciplinary cross-government team led by HSE and including representatives from Defra, VMD and the Environment Agency, started on-site investigations on 5 August 2007. The team was subsequently joined by representatives from HPA and received additional support from Surrey Police, the Health and Safety Laboratory (HSL) and the Central Science Laboratory (CSL).
- 22 An initial report was submitted to government and published on 7 August 2007.
- 23 This final report is being submitted four weeks after confirmation of the first outbreak and documents the findings, conclusions and recommendations of the team in relation to biosecurity arrangements at the Pirbright site.

Introduction

Foot and mouth disease: An overview

24 Foot and mouth disease (FMD) is a severe, highly communicable viral disease of cloven-hoofed animals (cattle, swine, sheep and goats) and can also affect a variety of wild animals, including deer. It presents a serious risk to UK farm livestock and is subject to statutory control measures, which include emergency procedures to contain and eradicate the disease.

25 It is caused by a virus of the genus *Aphthovirus*, family *Picornaviridae*. There are seven serotypes of FMDV, namely O, A, C, SAT 1, SAT 2, SAT 3 and Asia 1.

26 FMDV can infect in small doses, with a rapid rate of disease progression and can be present to a high level in all secretions and excretions of acutely infected animals, including in their breath. The most common route for transmission, however, is through direct contact between infected and susceptible animals with as few as 10 infectious virus particles enough to infect a cow. The incubation period between exposure to the virus and visible signs of infection is typically 2–14 days.

27 Under humid conditions, the virus survives well in the atmosphere and this makes the wind an important mechanism for FMDV transmission, particularly in Northern Europe. Humans are considered accidental hosts for the virus and rarely become infected or develop clinical disease. However, humans have been shown to carry the virus in their throats and nose for up to three days after they have been exposed to infected animals, making them potential carriers of the virus. In addition, the clothing, footwear and vehicles of humans have been implicated for transmission of FMDV during previous outbreaks.

The 2007 outbreak

28 On 3 August 2007, FMD was confirmed by Defra at a farm near Normandy in Surrey, UK. The first infected premises (IP1) was a small, family-run beef-finishing enterprise with a total of 64 cattle kept across three sites. Diagnosis of the infected cattle showed that FMD lesions were likely to have first appeared around 26 July 2007. As a result, epidemiologists from Defra's National Epidemiology Expert Group (NEEG) advised that the most likely period when the cattle were exposed to the virus was 14–26 July 2007. This period, together with the preceding week, became the period covered by our investigation, ie 7–26 July 2007.

29 On 6 August 2007, FMD was confirmed on a second, separate farm near IP1. This second infected premises (IP2) has a beef suckler herd run over approximately 300 acres. Diagnosis of the infected cattle showed that lesions were likely to have first appeared on 31 July 2007. It has subsequently been confirmed by NEEG that,

following further sequence analysis and clinical investigations, it is their view that IP2 was infected by IP1.

- 30 Defra identified the strain of FMDV involved in the outbreak as Type O1 BFS67, which is the strain recovered from the 1967 FMD epidemic in Great Britain. This strain is used in FMD reference laboratories and pharmaceutical manufacturing plants and is not known to be currently in circulation anywhere in the world. Hereafter this will be referred to as the O1 BFS strain.
- 31 In the UK, the only known location where the O1 BFS strain is held is at laboratories and manufacturing facilities at the Pirbright site in Surrey, some 4.6 km from IP1 and 2.9 km from IP2. The relationship between the Pirbright site and the two infected premises is shown in Figure 1.

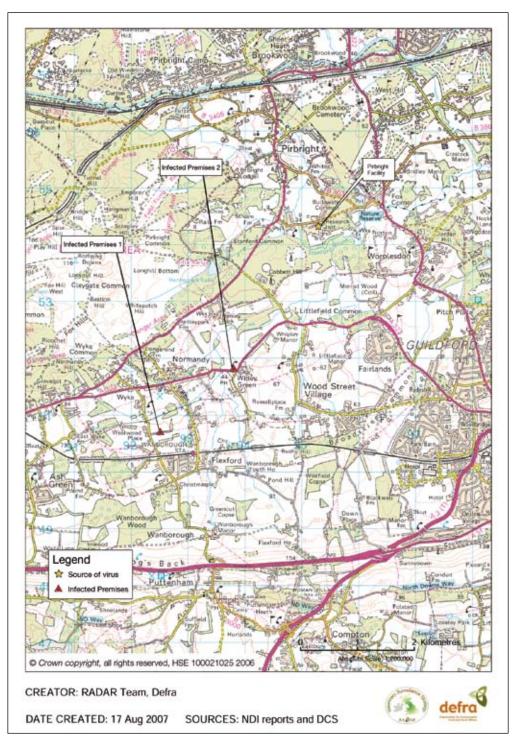


Figure 1 The relationship between the Pirbright site and the two infected premises

The Pirbright site

32 There are two main organisations that work with FMDV at the Pirbright site: IAH and Merial. In addition, a small company called Stabilitech works with FMDV in a small laboratory within the IAH facility. An overview of the site is shown in Figure 2.



Figure 2 Aerial view of the site with IAH and Merial facilities marked (Photo courtesy of Surrey Police)

- 33 We understand that the Pirbright site is owned by the Biotechnology and Biological Sciences Research Council (BBSRC) and that the Merial site is leased from them. We further understand that Stabilitech rent laboratory space from IAH.
- 34 IAH is a publicly-funded research organisation with laboratories at both Pirbright and Compton, Berkshire undertaking work on animal diseases. It is sponsored by BBSRC with Defra part-funding a number of research projects. It has had a presence on the Pirbright site since the 1960s. Approximately 140 staff are employed at the facility.
- 35 Merial is a global, commercial pharmaceutical company with headquarters in France. Its operations at Pirbright are primarily restricted to manufacturing vaccines to be used in veterinary medicines for a range of different animal diseases. There has been a vaccine production facility on the Pirbright site for many years, with a number of predecessors to Merial. Approximately 80 staff are employed at the facility.
- 36 Stabilitech is a company formed by a former employee of IAH. It is developing technologies to enable the stable and effective storage of vaccines and other biological materials in a dry state at ambient temperature. Four staff are employed at the facility.

Biosecurity

37 There is no accepted definition of 'biosecurity'. For the purposes of this report, the term will cover the implementation of a combination of containment measures and working practices, supplemented by management controls, to prevent the inadvertent exposure of susceptible species to biological agents and their distribution in the wider

environment. In practice, this requires a comprehensive system of both physical and procedural controls to minimise potential release of a pathogen along with suitable arrangements to minimise its subsequent spread.

The regulatory position

Specified Animal Pathogens Order 1998

- 38 FMDV is not normally present in the UK. Consequently, strict measures are adopted to ensure that the UK maintains its disease-free status. This includes regulating those wishing to work with the virus. Anyone undertaking such work is required to obtain a licence from Defra under the Specified Animal Pathogens Order 1998 (SAPO). The purpose of SAPO is to prevent the introduction and spread of specified animal pathogens that could cause serious disease and economic loss to the British livestock and poultry industries.
- 39 The SAPO regime includes Defra assigning animal pathogens into one of four categories of containment, Containment Levels 1–4. SAPO Containment Level 4 is required for facilities working with FMDV. This is the highest Containment Level available for use with animal pathogens, and is highly specialised, requiring stringent biosecurity measures.
- 40 Accordingly anyone wishing to work with FMDV must apply to Defra for a licence before commencing activities. Before any licence is issued, Defra inspectors will normally inspect the facility where the work is intended to be done and the licence will not be granted until and unless inspectors are satisfied that the management, facilities and documented operating procedures comply fully with the standards for the safe containment of the pathogen concerned.
- 41 SAPO licences are usually valid for five years and stipulate how the pathogens must be handled, covering:
- safe containment and disposal;
- the areas of the laboratory in which various types of work may be done; and
- the people responsible for the work.
- 42 Both the IAH and Merial facilities hold SAPO licences to work with FMDV. Defra has explained that Stabilitech does not operate under its own separate licence but that its work is carried out in accordance with the licence granted to IAH. This involves the individual (or the individuals) named as the supervisor in the IAH licence ensuring that everyone who performs work in the laboratory (including non-IAH staff) complies with the conditions of the licence. Defra further states that everyone who works in the laboratory is given training in the necessary biosecurity procedures by IAH's Biosecurity Officer. They are also taken through the agreed documented procedures that form part of the licence conditions. We have examined the 'Rental Agreement' under which Stabilitech occupies IAH's premises. This states that Stabilitech are responsible for training their own staff in good laboratory practices, the handling of specified animal pathogens and for the production of their own Standard Operating Procedures (SOPs).
- 43 Details of the SAPO licensing system can be found on the Defra website at: www.defra.gov.uk/animalh/diseases/pathogens.
- 44 The guidance describes the physical features and operating conditions that would

be required by Defra of any laboratory to be licensed to hold or work with Category 4 pathogens. It is concerned with preventing the escape of pathogens from the laboratory and not primarily with ensuring the safety of the workers.

45 The guidance states that the containment requirements are based on those published by the Advisory Committee on Dangerous Pathogens (ACDP) as being suitable for work with ACDP Category 4 human pathogens (see *The management, design and operation of microbiological containment laboratories* (HSE Books 2001 ISBN 978 0 7176 2034 0)). This is then qualified by the following statement:

'However, it should be noted that the Defra categorisation of pathogens and conditions of containment differ in points of detail from those published by ACDP. The reason for this is that ACDP is concerned with protection of workers in the workplace, whereas Defra is concerned with protection of livestock and the environment. Laboratories must meet Defra containment requirements to be considered for licensing under the Specified Animal Pathogens Order 1998 (SAPO). In addition, the relevant ACDP requirements apply.'

46 It is our opinion that this statement can cause confusion as to the standards required. Although the guidance states that the containment is based on ACDP Level 4, the practical reality is quite different. This may be because the organisms being used are exclusively animal pathogens, and controlling worker exposure is not considered a priority. For example, in animal houses workers are routinely exposed to infected animals, without the use of respiratory protective equipment. In ACDP Level 4 facilities, work with virus or materials/animals infected with virus must always be undertaken in a way that prevents human exposure. At IAH Pirbright, the culture is quite different from that observed in ACDP Containment Level 3 or 4 laboratories. For example, doors were observed left open during work, and there is open access to virus storage areas. The practical application of physical and procedural approaches to containment varied considerably between the Defra (SAPO) and ACDP standards. While this may be acceptable in some areas, these need to be carefully identified and justified to avoid confusion by both the regulator and those being regulated.

47 It is recommended that the required standards of containment should be clearly documented to facilitate the regulatory process.

48 In addition, a review should be completed to contrast the actual regulatory position for animal pathogens with human pathogens to make sure the position is justified.

49 We recommend review of arrangements for setting and monitoring safe operating practices where work is subcontracted under a single operating SAPO licence with responsibilities clearly defined between the licence holder and the subcontractor.

Veterinary Medicines Regulations 2006 (VMR)

50 Merial is involved in the manufacture and marketing of veterinary medicinal products in the UK. As well as a SAPO licence they must also obtain a Manufacturing Authorisation (ManA) from VMD. There is a legal requirement for a holder of a ManA to manufacture products in accordance with the principles for good manufacturing practice (GMP). The current legal basis for GMP for the manufacture of veterinary medicinal products are the Veterinary Medicines Regulations (VMR). EU Directive 91/412/EEC lays down the principles and guidelines of GMP for veterinary medicinal products and these have been transposed into UK legislation within the VMR.

51 VMD is the body (the 'Competent Authority') with responsibility for ensuring the manufacturers of veterinary immunological products comply with the requirements of GMP. GMP inspectors from VMD inspect manufacturers every two years in accordance with the Directive and, following a satisfactory audit, will issue a GMP Certificate to demonstrate that the manufacturer meets the required standard.

HSE involvement

52 The government asked HSE to lead a team to investigate any potential breaches of biosecurity at the Pirbright site. The team had a core of specialist inspectors from HSE's Hazardous Installations Directorate who have extensive experience of inspecting and regulating high containment facilities used for handling human pathogens and genetically modified organisms (GMOs) that pose a serious risk to human health. The team was led by a principal specialist inspector from this Directorate. Additional on-site support was provided by inspectors from HSE's Field Operations Directorate, who have extensive experience of inspecting, collecting and managing evidence across a wide variety of industries, and by an inspector from HSE's Nuclear Directorate with expertise in high containment nuclear facilities.

53 HSE was asked to lead this investigation due to its experience in regulating containment facilities handling human pathogens and expertise in carrying out complex investigations. Defra officials and VMD inspectors were part of the investigation team and were available to advise and act on issues relating to SAPO and GMP respectively.

Team set-up and support

54 The team was supported by Defra veterinarians and epidemiologists, who provided input on the epidemiology of FMD, updates on the outbreak and followed up potential links from the Pirbright site to the infected premises. Officials from the Central Science Laboratory (CSL) liaised with the Environment Agency to advise on soil sampling and testing strategies. The Environment Agency also advised on drainage and water issues and the wider movement of materials. Biosafety experts from the Health Protection Agency (HPA) also joined the team to review the ventilation systems at both IAH and Merial. Officers from Surrey Police provided support in tracing vehicle movements. Further technical expertise and support was provided by the Health and Safety Laboratory (HSL), Dyno-Rod Ltd and Biosafe Safety Solutions.

The Spratt review

55 In addition to the HSE-led investigation, an independent review was undertaken by Professor Brian Spratt of Imperial College, London. The Spratt review team comprised a group of experts in the fields of FMDV, molecular biology, laboratory management, biosecurity and containment issues. They were asked to provide an independent view and recommendations on overall biosecurity arrangements at the Pirbright site, and to examine the underlying science and plausibility of routes of possible release of FMDV. While they have carried out their own inspections at the site, the detailed investigations from this HSE report have provided evidence for the Spratt review.

Approach to the investigation

- 56 The terms of reference for the HSE investigation were as follows:
- to investigate any potential breaches of biosecurity at the Pirbright site;
- to investigate whether such breaches may have led to a release of any specified animal pathogen;
- to investigate whether any such breaches had been rectified to prevent future incidents.
- 57 As a team we concentrated our investigations on biosecurity issues associated with FMDV strain O1 BFS.
- 58 We concentrated our investigations on the time period 7–26 July as this included the timeframe advised by Defra when the cows were likely to have been exposed to the virus at the first affected farm.
- 59 We established the precise nature of work ongoing with the O1 BFS strain during this period at the IAH and Stabilitech and Merial facilities.
- 60 We investigated whether or not there had been any lapses in control measures which could have led to a release of the O1 BFS strain from any of these facilities in the period covered by our investigation.
- 61 We investigated whether there were any transfer mechanisms that could link any such releases to the first affected farm.
- 62 Our initial report was submitted after two days on site (www.hse.gov.uk/news/archive/07aug/pirbright.htm). This gave preliminary details on the five lines of inquiry we investigated.
- activities involving the O1 BFS strain;
- identifying the origin of the outbreak strain;
- potential for release of the O1 BFS strain via the airborne route;
- potential for release of the O1 BFS strain via the waste route;
- potential for release of the O1 BFS strain via the human route.
- 63 This final report is submitted a month after the confirmation of the first outbreak. It expands upon and gives conclusions for each of the five lines listed above.

Activities involving the O1 BFS strain

64 We established that the following activities involving the O1 BFS strain of FMDV were undertaken at the Pirbright site during the period covered by our investigation.

IAH

- 65 Activities involving hazardous animal pathogens at IAH can be divided into two broad strands: research activities to better understand the pathogen and its effects and diagnostic work associated with identifying strains involved in outbreaks. IAH is also the World Reference Laboratory for FMDV.
- 66 During the period covered by our investigation, activities involving the O1 BFS strain were limited to two researchers undertaking laboratory activities. Both were small-scale experiments: one involved monitoring infectivity in cell cultures while the other used the strain as a positive control for developing tests for a separate animal pathogen. While additional stocks of the strain were held elsewhere in the research facility as well as in the World Reference Laboratory, we found no evidence that these had been removed or worked on in the period in question.
- 67 In addition, we established that there was no work with animals infected with the O1 BFS strain during the period covered by our investigation of infection, and none had been carried out in the three months before the outbreak.

Stabilitech

68 Stabilitech is involved in developing methods to better preserve biological materials in a dry state at ambient temperature. During the period covered by our investigation, two researchers in the Stabilitech laboratory were involved in freeze-drying cultures of the O1 BFS strain on a number of different days.

Merial

- 69 Merial produces vaccines against a variety of animal diseases, including FMDV.
- 70 During the period covered by our investigation, Merial was growing up the O1 BFS strain in volumes of up to five litres in its laboratory facility and in volumes of up to 6000 litres in its production facility for subsequent vaccine production.
- 71 We conclude that activities involving the FMDV O1 BFS strain were carried out at the IAH, Stabilitech and Merial facilities during the period covered by our investigation.

Identifying the origin of the outbreak strain

72 The initial confirmation of the FMDV strain responsible for the 2007 outbreak was made by IAH. The first step was to identify to which antigen group the virus belonged. Antigen ELISA (Enzyme-Linked ImmunoSorbent Assay) testing indicated that the virus was an 'O' antigen strain. Subsequently, a more detailed analysis was carried out by IAH, which involved sequencing the VP1 gene of the virus. This method is commonly used to identify individual FMDV strains, and involves determining the 694-nucleotide sequence of VP1. The results of this test confirmed that the viral sequence gave a 99.67% match to the strain O1 BFS.

73 As we had established that this virus was in use at both laboratories during and before the infection period, we questioned whether a comparison of the complete sequence of the virus isolated from cattle infected during the outbreak, and those in use at IAH, Stabilitech and Merial, might be able to pinpoint the source of the virus. This was on the basis that the different passage history of the viruses might have resulted in small sequence changes, which could help to identify its origins.

74 Samples of O1 BFS strains held by Merial, IAH and Stabilitech were taken under the supervision of an independent observer (an HSE inspection team member) and sent for molecular analysis at IAH and at an independent laboratory in Denmark. The sequencing had to be undertaken at IAH, as the virus can only be used at the Pirbright site, and Merial does not have sequencing capacity on site. To rule out any bias, the samples were given a code by the HSE observer, and neither IAH nor the Danish laboratory were aware of the origins of each virus. A sample containing the virus from the 2007 outbreak was included in the test. In total four viruses were sequenced; two from IAH/Stabilitech, one from Merial, and one field isolate. These viruses were designated A, B, C and D. Table 1 gives details of the code used.

Sample code	Virus sample with origin of the virus
А	Merial vaccine production strain
В	Field sample – epithelial cells taken from lesion on infected cow on IP1
С	IAH immunology sample – used in research activities by IAH and used in freeze-drying experiments by Stabilitech
D	IAH biosecurity sample – used in disinfection studies by the IAH biosecurity team

Table 1 Code used for samples sequenced by IAH and the Danish laboratory, and for analysis by Professor Spratt's team

75 The IAH sequencing results showed that the field isolate (sample B) matched very closely to the sequence of the original isolate from the 2007 outbreak. Both these samples came from separate animals from the same herd. This provided confidence in

the sequencing methodology. Sample D matched closely to published sequences of other O1 BFS strains. These sequences are available on GENBANK, a publicly available database. This sequence was furthest away from that of the field isolate, making it unlikely to have been the cause of the outbreak. Samples A and C were both close to the sequence of the field isolate, and IAH concluded that one of these two viruses was likely to have caused the outbreak. There was a single nucleotide difference between the two viruses. The field isolate (sample B) had five nucleotide changes compared with sample A, and six changes compared with sample C.

76 The independent sequence data from the Danish group confirmed the results generated by IAH. The virus from Merial, and that used at IAH/Stabilitech, differed from the outbreak virus at five and six nucleotides, respectively.

77 The results show that the virus that caused the outbreak was a laboratory-adapted strain, of the type used by IAH, Merial and Stabilitech. This is confirmed by the presence of changes that are known to be associated with the adaptation of wild-type FMD viruses for growth in cell cultures. This change is primarily the switch from the normal cellular receptor found in cattle (an integrin molecule) to a heparan sulphate molecule found in cell culture. Both samples A and C had the distinctive molecular changes associated with adaptation to cell culture, indicating that they arose from a laboratory rather than from an animal source.

78 The results confirm that it is highly likely that the FMDV strain involved in the first farm outbreak originated from an organisation based at the Pirbright site.

79 Both IAH and Merial were invited to comment on the blinded results, as were experts from Professor Spratt's group. Subsequently, the samples were unblinded for Professor Spratt and his team. The following comments were made on the basis of the data provided, and, other than Professor Spratt, none of those commenting was aware of the origins of each virus.

80 Professor Spratt stated:

'The independent sequences from the Danish group showed that the virus from Merial, and that used at IAH for both molecular biology/immunology research and by Stabilitech, differed from the outbreak virus at 5 and 6 nucleotides, respectively. Although the Merial virus is more similar by one nucleotide, this should not be taken to mean that it is necessarily the source of the outbreak.'

81 IAH concluded on the basis of their own analysis and the Danish results:

'The relationships between the O1 BFS 1860 viruses have been evaluated based on their overall sequence similarity (ie number of nucleotide differences) and their possession of three different sequence motifs known to be associated with adaptation of wild type foot-and-mouth disease (FMD) viruses for growth in cell cultures (via binding to heparan sulphate receptors on cells grown in cultures). Assuming that sample "B" is the Surrey outbreak virus, then based on sequence similarity, either sample "A" or "C" which differed from one another by only one nucleotide, is most likely to have been the origin for the outbreak. The number of sequence differences between either "A" or "C" and "B" are within the range previously observed for viruses isolated from consecutive FMD outbreaks. Both "A" and "C" have five identical nucleotide differences from sample "B", as well as a heparan sulphate binding sequence motif (at

VP3⁵⁶) characteristic of cell culture-adapted viruses and not present in the outbreak virus. However, it is known that there is a strong selection pressure to revert this motif back to that of the "wild type" when FMD virus goes back into animals. Sample "C" has an additional nucleotide change that is not seen in "A" or "B", or any of the other viruses studied. This nucleotide change encodes an amino acid change in the leader protein of the virus, the significance of which is not known. In order for sample "C" to have been the progenitor of the Surrey outbreak, this acquired mutation would need to have reverted back to its original form, a very unlikely event to happen by chance, unless there is some selective pressure to favour this when the virus goes back into animals. Sample "D" is less likely than "A" or "C" to be the origin of the Surrey outbreak, based on both a higher number of nucleotide differences from the outbreak virus and the lack of another heparan sulphate binding motif present in the outbreak virus (at VP3⁶⁰) in both "A" and "C".'

82 Merial was also invited to comment on the results. The company concluded:

'The gene sequence data do not support a science-based conclusion that any of the blinded sample viruses is the source of the virus isolated in the field. There are several reasons for this. The virus samples have within-sample genetic diversity. Both laboratories used "consensus sequence techniques" that do not detect minorities representing less than ~30% of the population of each sample. The consensus technique thus masks the possibility that the different samples might actually contain identical minority subpopulations. The possible presence of minority subpopulations prevents a science-based conclusion ruling out "A", "C", or "D" as the source. Even if there were no within-sample diversity, which is not the case, samples "A" and "C" are so close to each other that there is no scientific basis to conclude one is a more likely source than the other. The consensus sequences of these two samples are virtual clones, differing at only one or two bases out of over 8000."

83 The Danish group that independently sequenced the viruses had the outbreak strain (sample B) unblinded and concluded:

'The outbreak isolate, labeled as isolate B, originated with high probability from isolate A or isolate C while an origin from strain D is unlikely. We cannot conclude with high certainty whether the origin of isolate B is in fact isolate A or isolate C, however, based on the number of differences, isolate A may be slightly more likely than isolate C, but this can not be assessed with any statistical significance as there is only a single difference between isolate A and C.'

84 This is confirmed by the presence of changes that are known to be associated with the adaptation of wild-type FMD viruses for growth in cell cultures. This change is primarily the switch from the normal cellular receptor found in cattle (integrin) to a heparin sulphate molecule found in cell culture. Both samples A and C had the distinctive molecular changes associated with adaptation to cell culture. Sample B (the outbreak strain) also had a distinctive change in the VP3 gene which suggests it has been adapted to tissue culture. Such a sequence change would not be expected if the virus had arisen from an animal origin.

85 The fact that there is only a single nucleotide change between A and C makes it difficult to identify which was the source of the virus. Scientists at IAH believe that

the change may be significant. However, they accept that without further studies, the significance of the change cannot be assessed. The Danish group concede that there is no statistically significant difference between the viruses, even though A has one less change than C.

- 86 Merial raised a number of technical questions about the ability of the sequencing methodology used to accurately differentiate between the viruses. It is their view that the sequence data do not support a science-based interpretation as to which virus caused the outbreak.
- 87 Notwithstanding Merial's view, we believe that the virus that caused the outbreak was a laboratory-adapted strain, of the type used by IAH, Merial and Stabilitech.
- 88 We conclude that there is a high likelihood that the virus that caused the 2007 outbreak at Normandy originated from the Pirbright site.
- 89 We also conclude that the close similarity between the outbreak strain, and the O1 BFS strains worked with at IAH, Stabilitech and Merial makes it difficult to precisely pinpoint its origin, as the single nucleotide difference may not be statistically significant.

Potential for release of the O1 BFS strain via the airborne route

90 We investigated:

- whether there could have been any breakdown in control measures which may have resulted in release of the O1 BFS strain from the facilities via the airborne route; and
- whether there were any airborne transfer mechanisms which linked the Pirbright site and the first affected farm.

Potential for release from the facilities

91 The following summary measures are required by Defra to prevent the release of a Category 4 animal pathogen via the airborne route. Full details are given at: www.defra. gov.uk/animalh/diseases/pathogens/category4.htm#labfacilities:

- all laboratory manipulations with live pathogens should be carried out in a microbiological safety cabinet (MSC) or other equally contained system;
- the laboratory should be maintained at a differential negative pressure of 75 Pascals (Pa) to ambient;
- the exhaust air must be filtered before discharge through two HEPA filters. The system must include a device to prevent back flow through the filters. The air intake should be protected by a single HEPA filter in case of power failure;
- the laboratory must be sealable to permit fumigation.

92 These measures, in combination with highly competent staff and adherence to rigorous working procedures, should provide a sufficient series of containment barriers to minimise the likelihood of accidental releases into the working environment, and, should this occur, prevent subsequent release outside the facilities.

93 We needed to establish whether there had been any incidents in which the working environment in all organisations may have been exposed to the O1 BFS strain during the period covered by our investigation and/or whether any of the control measures had broken down.

94 We interviewed staff, examined local operating procedures, workbooks and records. We inspected and examined all MSCs, ventilation systems and filters on both sites. We examined their most recent maintenance and testing regimes and requested that retesting of all filters be undertaken by external contractors. We used investigators from VMD to examine the arrangements at Merial and supported this with additional technical input from experts from HPA. We used the HPA experts to comment on the IAH facility and commissioned a second independent report from a company with expertise in determining laboratory configurations, air pressures and sealability issues (Biosafe Safety Services).

95 The only areas covered were those where the O1 BFS strain was being worked on during the period covered by our investigation. Our main findings are summarised below:

IAH and Stabilitech

- 96 Two IAH researchers were using the O1 BFS strain during the period covered by our investigation. Both were small-scale experiments conducted in the main laboratory facility, which is a two-storey building consisting of two wings (north and south), each containing a number of smaller laboratories.
- 97 Our investigations did not reveal any accidents or unusual incidents, or any activities which may have resulted in the laboratories used by IAH staff being exposed to the O1 BFS strain.
- 98 Two Stabilitech researchers were involved in freeze-drying cultures of the O1 BFS strain in a laboratory within the main IAH facility. Freeze-driers are a known source of aerosol, and we inspected the arrangements. The equipment did not have an in-line filter for vented gases, however, the line did pass through an oil sump before discharge into the room. We consider release of live virus of the O1 BFS strain into the laboratory as being of a low likelihood.
- 99 All work (excluding the freeze-drying process) was undertaken in MSCs: these were examined and found to be operating and tested properly.
- 100 Our investigations did not reveal any accidents or unusual incidents which may have resulted in the laboratories used by Stabilitech staff being contaminated with the O1 BFS strain. However, our investigation revealed that Stabilitech did not have a written SOP for some procedures carried out in their laboratories which relate to biosecurity-critical areas during the period covered by our investigation. Furthermore, records of staff training were poor. We recommend review of arrangements for setting and monitoring safe operating practices where work is subcontracted under a single operating SAPO licence with responsibilities clearly defined between the licence holder and the subcontractor.
- 101 The whole building housing the main laboratory in which both the IAH and Stabilitech researchers were working was ventilated by one common air extraction system, and one air supply air handling unit. The control was via a computerised building management system. One pressure sensor was located within each zone, at strategic points in the corridors; these were used to maintain a constant negative pressure of around -65 Pa with respect to the outside.
- 102 Our investigations revealed that some individual laboratories could become positively pressurised when the doors were closed and there was leakage of air between laboratories through unsealed pipe ducting. When laboratory doors were left open (as we observed when laboratory work was in progress) the pressure in the laboratories would effectively become the same as in the corridor, ie -65 Pa. This does not meet the recommended SAPO Level 4 standard of -75 Pa for laboratory work.
- 103 Control of the differential pressure was achieved by inverter speed controls on the fan motors, which would speed up or down as appropriate. All fan units were equipped with 'back-up' motors, which would automatically operate in the event of failure of the 'in-use' fan.

104 All ductwork was in galvanised steel, although some joints did not appear to be completely sealed. The extracted air passed through a double HEPA filtration system consisting of banked HEPA filters, before discharge to the outside air. The filters were located within a plant room, which was outside the official containment zone, but within an authorised area. It was not possible for each filter to be tested independently, thus leak testing was for the entire bank of filters. It is therefore possible for one or more of the filters in each bank to be leaking, but the overall leak test to indicate 'satisfactory'. This was confirmed by two sets of ventilation experts. The fabric of the building was poor, with visible cracks in the walls and ceilings, and leak points around some windows.

105 Despite the factors outlined above, there is no indication that the building lost negative pressure during the period covered by our investigation and/or that there was a failure in the air filtering system. In addition, our investigations did not reveal any incidents where the laboratory may have been contaminated with the O1 BFS strain.

106 We conclude that there is a low likelihood that the O1 BFS strain was released via the airborne route from laboratories used by either IAH or Stabilitech during the period covered by our investigation.

107 We have concerns about the suitability of continuing to use the upper south wing of the research laboratory for high containment. Unless it can be demonstrated that the facility is sealable for fumigation and that the laboratories can meet the required pressure regime, it is our view that this does not meet Defra's published standards for Category 4 pathogens. We recommend that this is investigated.

108 We have concerns about the filter arrangements throughout the main laboratory. In our view, this does not meet the requirement for SAPO Category 4 pathogens in that it does not allow both filters to be tested independently: therefore it cannot be guaranteed that both filters are working at any one time. We recommend that this is investigated.

Merial

- 109 The Merial facility is modern with a high degree of engineering controls. Our investigations revealed that the required SAPO Level 4 standards are achieved and regularly monitored. The filters are arranged in an appropriate fashion and could be tested according to agreed standards. All air discharged to atmosphere from the working environment is passed through a minimum of two HEPA filters. The most recent filter tests were scrutinised and no problems were identified; the repeat filter testing which was commissioned also raised no concerns.
- 110 We identified the key areas where aerosols could be generated and examined the measures in place to prevent their dissemination. We considered that the highest risk areas were in the production areas, and included air passed through the bioreactor, and the disc-stack centrifuge and inspected these.
- 111 The bioreactors are modern, highly engineered stainless steel vessels, which are pressure tested for leaks before use. Exhaust air from the bioreactors passes through double HEPA filter cartridges before discharge into the negative pressured working environment. These filters are replaced annually as part of the GMP regime.

- 112 Once the virus has been grown for the prescribed period, the bioreactor is discharged through a disc-stack centrifuge, which separates out the cell debris from medium containing virus. Such centrifuges have in the past been a source of aerosols, so the system was thoroughly examined to ensure that no leakages could have occurred. The design of the centrifuge in use was such that release of aerosol was prevented, and could only occur through catastrophic failure. There was no evidence that the centrifuge had failed, or had been the source of aerosol release into the workplace. In addition, air is extracted from the working environment at Merial through a further three HEPA filters before finally being discharged to atmosphere.
- 113 We found no evidence of any working practices or incidents such as laboratory spillages or leakages from plant or equipment which could have led to a release of the O1 BFS strain within the contained working environment at Merial. Even if this had been an unusual, unobserved incident, we are confident that the engineering control systems will have prevented any further release to the atmosphere.
- 114 We conclude that there is a negligible likelihood that the O1 BFS strain was released via the airborne route from the Merial facility during the period covered by our investigation.

Potential for transfer from the Pirbright site

- 115 We worked closely with Defra epidemiologists and staff from the Meteorological Office to establish the most likely dates during the period covered by our investigation when the local wind and other environmental conditions may have provided a direct, airborne link between the Pirbright site and the first affected farm.
- 116 These conditions were only likely to have occurred for a sustained period on the 23 July, although there were transitory periods on the 15, 19 and 20 July. We specifically examined records of all activities at all sites for these days and found no evidence of procedures that could have led to a failure in containment within the facility, or accidental discharge to atmosphere. On this basis we considered it was reasonable not to follow this line of inquiry further.
- 117 We specifically looked at whether there could have been an airborne release from the effluent drainage system on the site and consider this unlikely: this is covered in more detail in the next section of the report.
- 118 We conclude that there is a negligible likelihood of an airborne release of virus from the contained facilities of the Pirbright site having caused the outbreak of FMD.

Potential for release of the O1 BFS strain via the waste route

119 Supporting evidence for this section is provided separately in the Annex.

120 We investigated:

- whether there could have been any breakdown in control measures which resulted in release of the O1 BFS strain from the facilities via the waste route; and
- whether there were any transfer mechanisms which linked the Pirbright site and the first affected farm.

Potential for release from the facilities

- 121 The following summary measures are required by Defra to prevent the release of a Category 4 animal pathogen via the waste route (full details are given at: www.defra. gov.uk/animalh/diseases/pathogens/category4.htm#labfacilities):
- solid waste must be sterilised before removal from the laboratory. Each laboratory should have direct access to an autoclave;
- all autoclaved waste should be subsequently incinerated;
- liquid waste (effluent) should be sterilised by a procedure known to kill the relevant pathogens. This procedure must be confirmed as having operated satisfactorily before the effluent is discharged to the public sewer.
- 122 These measures, in combination with highly competent staff and adherence to rigorous working procedures, are expected to provide a sufficient series of containment barriers to minimise the likelihood of accidental releases via the waste route.
- 123 We needed to establish what measures and procedures for controlling waste were in place at Pirbright and whether any of these had broken down during the period covered by our investigation.
- 124 We interviewed staff, examined local operating procedures and arrangements and inspected the infrastructure for dealing with solid and liquid waste. We inspected and examined all autoclaves and chemical treatment measures for liquid waste on both sites. We examined their most recent validation, maintenance and testing regimes.
- 125 We used an HSE inspector to examine the process implications of liquid waste at Merial and another HSE inspector, with expertise in containment drainage, to comment on the site-wide effluent drainage system.
- 126 We had additional technical input from the Environment Agency and scientists from CSL to comment on flooding issues and to undertake sampling and analysis studies to determine whether the virus could be detected outside of containment.

127 Our main findings are summarised below.

Solid waste

- 128 Solid waste from IAH, Stabilitech and Merial is heat treated within the restricted areas, using autoclaves. These are run at 121 °C for 21 minutes, with all autoclaved waste being collected by an external waste contractor for off-site incineration. Staff were questioned and the service and maintenance records for all autoclaves were examined, along with records of sample runs.
- 129 We did raise concerns about the procedures in use at the IAH and Stabilitech laboratories: in all the laboratories inspected, the waste bins were overfilled and little or no segregation of waste occurred. The autoclave bags are placed into metal tins with lids attached by clasps. The bins are not opened at the autoclave in the main laboratory and are autoclaved with the lids on. This is not considered to be good practice when treating waste containing human pathogens and we raised concerns about the ability for steam to penetrate each load. However, the autoclave technician was able to demonstrate that typical loads are regularly tested and demonstrated to us that sufficient levels of kill were obtained.
- 130 Most of the autoclaves at IAH are serviced four times a year and a 12-point thermocouple test is carried out annually. No problems were identified. The autoclave in the epidemiology building uses chemical indicators and had been tested with typical loads to show a sufficient kill was being obtained.
- 131 Although we consider that procedures at IAH/Stabilitech could be improved, we were satisfied that the autoclaving processes carried out during the period covered by our investigation inactivated animal pathogens present in the solid waste.
- 132 We had no concerns about the procedures for autoclaving solid waste in place at Merial.
- 133 As a result, we did not consider it necessary to investigate the off-site incineration aspects.
- 134 We conclude that there is a negligible likelihood that the O1 BFS strain was released via the solid waste route from laboratories used by IAH, Stabilitech or Merial during the period covered by our investigation.
- 135 However, we do not consider some of the procedures observed at IAH and Stabilitech represent good practice and recommend that these be reviewed.

Liquid waste

136 The general procedure for treating liquid effluent waste at both Merial and IAH has been approved by Defra. The waste is subject to a two-stage chemical treatment process; the first being undertaken within each respective facility before discharge to the site's effluent drainage system and the second at the site's effluent treatment plant. Only when both chemical treatments have been undertaken is the waste considered suitable for discharge to the sewer.

137 We have concerns as to whether a system of chemical treatments could ever be considered to sterilise liquid waste as required for SAPO Category 4 pathogens. It is our experience that chemical treatments, while reducing the amount of pathogen in the liquid, may not render the liquid completely pathogen-free. Unless this system can be validated to demonstrate sterilisation, it is our view, that this does not meet the requirements for SAPO Category 4 pathogens. We recommend that this is investigated.

138 We have investigated ownership of the drainage system, which rests with IAH. However we are aware of a difference of opinion between IAH and Merial over responsibility for maintenance of a key section of pipe relevant to this investigation.

Preliminary chemical treatment by IAH and Stabilitech

- 139 The arrangements outlined below have been in place for a considerable period of time with the full knowledge of Defra. However, we are aware that the long-term aim at Pirbright has been to move towards heat inactivation for liquid waste.
- 140 For most of the activities involving FMDV within the IAH and Stabilitech laboratories, liquid waste is subject to a preliminary chemical treatment of either 0.4% citric acid or 1:240 dilution of FAM (a general purpose, iodophore-based disinfectant). Both were used at twice the concentrations recommended for FMDV. Liquid effluent from the other parts of the restricted area (showers, toilets etc) is not required to undergo a preliminary chemical treatment and is discharged directly to the effluent drains.
- 141 For activities involving cell cultures infected with FMDV, heat inactivation by autoclaving is used instead of chemical treatment. This is because IAH had identified that the presence of organic material in this waste may compromise any chemical treatments and used autoclaving to give a more consistent degree of inactivation. As outlined above, we had no concerns that the autoclaving arrangements in place at IAH would not inactivate any FMDV in the liquid waste.
- 142 Our investigations in the laboratory used by Stabilitech identified some issues relating to when stocks of the chemicals had been made up and the working dilutions required. The issues related to the standardised method of preparation, concentration used and expiry dates. While this was not regarded as good practice, this was not considered to be a significant issue as we concluded that the chemicals were still likely to be effective against the virus.

This paragraph is incorrect. See erratum on page ii

- 143 We found no evidence that the procedures and processes for undertaking preliminary chemical treatment at IAH were not undertaken according to Defra requirements.
- 144 Given that the overall chemical treatment required to inactivate SAPO pathogens involves both the preliminary and final treatments, Defra informed us that both they and the management of IAH accept that live pathogens may, on occasion, enter the site's effluent drainage system. While two researchers at IAH and a further two at Stabilitech undertook laboratory experiments involving the O1 BFS strain during the period covered by our investigation, these were only small-scale and we have no reason to believe that they did not follow the procedures for chemical treatment outlined above.

145 Accordingly we conclude that there is a negligible likelihood that live virus of the O1 BFS strain entered the effluent drainage system from the IAH or Stabilitech laboratories during the period covered by our investigation.

Preliminary treatment of liquid waste from Merial

- 146 All liquid waste from the restricted areas of Merial enters the effluent drainage system it shares with IAH via Merial's effluent sump. Cell and virus debris from a centrifugation stage of the process is held in a discard tank for treatment with 0.4% citric acid for a minimum of 48 hours before discharge to the sump. The empty vessels are treated with 0.8% citric acid followed by neutralisation with sodium hydroxide and discharge to the effluent sump. Liquid waste from the other parts of the restricted area (showers, toilets etc) is not required to undergo a preliminary chemical treatment and is discharged directly to the effluent sump.
- 147 This system is approved by Defra and uses citric acid concentrations and hold times greater than those recommended for FMDV. We found no evidence that the procedures and processes for undertaking preliminary chemical treatment at Merial were not undertaken according to Defra requirements.
- 148 Given that the overall chemical treatment required to inactivate SAPO pathogens involves both the preliminary and final treatments, Defra informed us that both they and the management of Merial accept that live pathogens may, on occasion, enter the Merial effluent sump and get from there into the site's effluent drainage system. We feel that this is more relevant for the Merial process, given the amounts of organic matter and cellular debris generated by centrifuging the contents of their 6000 litre bioreactors. Although this debris is diluted in 200 litres of 0.4% citric acid and held for 48 hours, there remains the possibility that the organic matter may reduce the efficacy of the chemical treatment.
- 149 Merial's effluent sump is located within a biosecure building within their restricted area. This building contains a number of key containment measures, such as negative pressure gradients, double HEPA filters on the extract air and showering-out arrangements. We inspected these and found no evidence that they were not operating to the standards required.
- 150 We conclude that it is likely that live virus of the O1 BFS strain entered the effluent drainage system from the Merial facilities during the period covered by our investigation.
- 151 This process was fully in compliance with their SAPO requirements. We feel it would be better practice for Defra to require a higher degree of inactivation before the centrifuge waste enters the effluent sump. We recommend that Defra and Merial work closely together to establish how best this could be done.

Secondary/final chemical treatment

152 Prior-treated liquid waste from both the IAH and Merial facilities is subject to a secondary and final chemical treatment stage at the site's effluent treatment plant. This is operated and managed by IAH. Here, caustic soda is added to the waste to raise its alkalinity to pH 12 and, after a mixing period, this is transferred to nearby storage

tanks to be held for 24 hours. The pH in these tanks is recorded and the contents are discharged to the sewer at around pH 12. This sometimes requires the addition of extra caustic soda directly to the tanks. We inspected the logs of the discharges made during the period covered by our investigation and found no evidence that these were not as required. We have no reason to suspect that the final discharges to sewer were not as required. Once discharged, the waste is further treated at the nearby Hockford sewage treatment works. Key features of the sites effluent drainage system are shown in Figures 3 and 4.

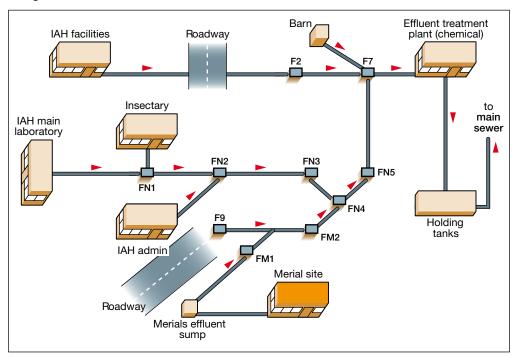


Figure 3 A schematic of the site's effluent drainage system

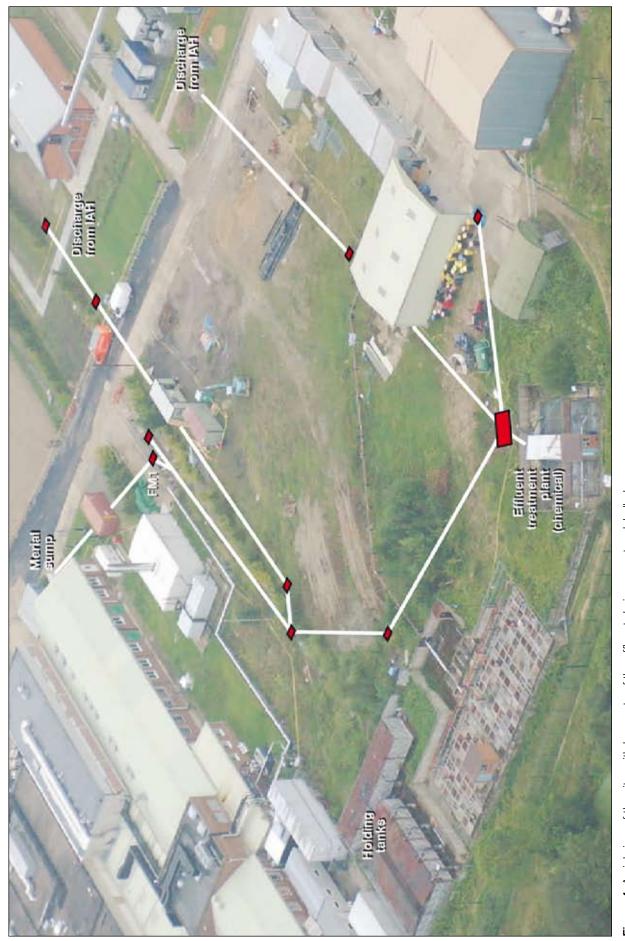


Figure 4 Aerial view of the site, with key parts of the effluent drainage system labelled (Photo courtesy of Surrey Police)

Assessment of site drainage system

- 153 The site effluent treatment plant is located approximately 100 m from both the IAH and Merial facilities. Liquid waste that has undergone preliminary treatment at either IAH, Stabilitech or Merial is transferred to this plant via a network of underground drainage pipes.
- 154 An assessment of the condition of these pipes was carried out. Dyno-Rod, working with HSL undertook a CCTV survey which was interpreted by experts from Dyno-Rod, the Environment Agency and an HSE inspector who has expertise in containment drainage systems. In addition, physical inspections were carried out, drawings were reviewed and effluent flows analysed.
- 155 Weaknesses were identified in the containment standard of the effluent drains across the Pirbright site. These included displaced joints, cracks, debris build-up and tree root ingress. For a biosecurity-critical system, record keeping, maintenance and inspection regimes were considered inadequate.
- 156 Our investigations revealed that blockages in the drainage system had been experienced in the past and that IAH had managed this using two different approaches: either their own staff would use a water bowser and hoses to flush through the system or external contractors would be hired. While strict supervision and biosecurity arrangements appear to have been put in place for the external contractor (rigorously treating the equipment and areas surrounding the manholes with chemical disinfectants), the biosecurity arrangements in place for IAH staff appeared less robust. We found no standard operating procedures to be in place for this process, particularly regarding the chemical treatment of both the hoses and the bowser after they had been used. We consider this lack of standard operating procedures to represent a breach to the biosecurity arrangements at IAH.
- 157 However, we found no evidence that either approach was used during the period covered by our investigation and conclude that this did not result in release of the O1 BFS strain.
- 158 The first report in the Annex was written by the HSE containment drains specialist, taking account of the reports from both Dyno-Rod and the Environment Agency. Some of our key findings in relation to the suitability of the effluent drainage system in the containment of animal pathogens are listed below.
- 159 Neither the existing effluent drainage system in use across the Pirbright site nor the record keeping, maintenance and monitoring regimes in place for it are considered to meet the standards required for SAPO Level 4.
- 160 We do not consider the current effluent drainage system provides adequate containment against the release of SAPO Category 4 pathogens.
- 161 We conclude that there may have been release of SAPO Category 4 pathogens from the buried pipework into the surrounding ground on the Pirbright site over an undefined period of time prior to our investigation.
- 162 We conclude that this represents a breach of the site's biosecurity arrangements.

163 We consider the lack of a written standard operating procedure to deal with blockages in the effluent drainage system to be a breach of the biosecurity arrangements at IAH.

Specific events during the period of investigation

164 We established that on 20 July 2007, the Pirbright site experienced extreme wet weather, with very heavy rainfall (up to 62 mm) and localised flooding. Areas of standing water and high groundwater levels were observed over the weekend and through to at least 23 July 2007 and perhaps longer.

165 During a portion of 20 July, excess surface and ground water was known to have entered the site's final treatment plant, increasing the volume of liquid present. This situation was closely monitored by IAH staff and there is no evidence that this plant was overwhelmed by water. However, to minimise the amount of water entering the treatment plant, IAH, Stabilitech and Merial reduced the amount of liquid waste they discharged to the system. We investigated the practices and procedures used in the laboratories at this time and found no evidence that biosecurity arrangements in relation to the primary treatment of effluent may have been compromised. We also found no evidence that the secondary chemical treatment stage was compromised or working outside the required parameters during this period or at any other time during our period of investigation.

166 We commissioned a survey of the site's effluent system by flood defence engineers from the Environment Agency (see report 2: Annex), who observed that the system has a series of poorly fitting manhole covers. In their experience of conventional drainage systems, this is likely to have led to surface water entering the drainage system via the manhole covers at some point on 20 July 2007. In addition, they observed that, during periods of high water levels, it is common for groundwater to enter drainage systems through cracks and misalignments in the pipework due to the high pressures exerted.

167 We have already concluded there to be a negligible likelihood that the O1 BFS strain entered the effluent drainage system from the IAH or Stabilitech facilities during the period covered by our investigation. However, it is likely that the O1 BFS strain entered the effluent drainage system from the Merial facilities during the period covered by our investigation. We needed to establish the amount of the O1 BFS strain likely to be in the drainage system over this period of heavy rainfall and localised flooding.

168 We focused on the liquid waste produced by Merial. We conclude that on 20 July 2007, the O1 BFS strain from the Merial plant may have been in the system, but only from the cleaning of the empty vessels with 0.8% citric acid and sodium hydroxide. Treated centrifuge waste from the first batch of O1 BFS production entered the effluent drainage system some time around 22–23 July 2007 and from the second batch around 25–26 July 2007. As outlined above, we consider it likely that this contained live virus of the O1 BFS strain.

169 Given our concerns regarding the lack of containment offered by the effluent drainage system, we conclude that it is likely that the O1 BFS strain from the Merial facility was released from the site's effluent drainage system between 22 and 26 July 2007.

Additional investigations undertaken on the discharge of liquid waste from Merial's effluent sump

170 Unlike the system at IAH where all liquid waste enters the main system through gravity flow, liquid waste from the Merial sump is actively pumped through a 4-inch cast iron pipe, joining the main system under manhole FM1 (See Figure 3). There are two pumps in the sump, each capable of pumping a volume of 25 000 litres an hour. Under certain circumstances they may both activate at the same time, resulting in a potential discharge rate of 50 000 litres an hour under a maximum pressure of 10 bar. Manhole FM1 is very shallow and, at 300 mm, is the shallowest on site. This had a poorly fitting cover with gaps around the edges. We commissioned experts from HSL to model the likely fluid movements in the drainage system around the discharge point from the Merial's effluent sump.

171 HSL's work is summarised in the body of the first report in the Annex, with the key finding summarised below.

172 The arrangements for discharge from the Merial sump into manhole FM1 leaves the potential for overflowing of the manhole and release of material from the effluent sump. If this were to contain live pathogens, in our view this would constitute a breach in biosecurity. We recommend that this is investigated.

173 The likelihood of manhole FM1 overflowing is shown by modelling to increase if both pumps are operating at the same time and particularly if there is a blockage in the discharge line from the Merial sump. From our CCTV survey we knew there to be significant ingress of tree roots at a point in this discharge line. Given the previous history of blockages in the system and the fact that on 20 July there was likely to be surface water entering the drainage system, we conclude that this may have exacerbated the existing blockages or created additional ones through bringing additional debris into the system or disturbing existing material. If specific, additional problems with blockages were to have occurred over this period, this will have coincided with waste from Merial with a medium likelihood of containing live virus of the O1 BFS strain being pumped into the site's main effluent system.

174 We worked with the Environment Agency to devise a strategy for taking soil samples from around manhole covers around the effluent drainage system and commissioned scientists from CSL to undertake testing to see whether traces of FMDV could be detected in the soil samples. This involved extracting the total RNA from the soil, and looking for the presence of FMDV sequences. The work was carried out in a laboratory at IAH. The results were inconclusive due to a high level of background laboratory contamination. Scientifically this was a difficult experiment to conduct. New methods had to be developed to extract virus from soil, and even if the results had been negative, this might not have been a conclusive result, as any virus may have degraded, or been washed away by rain.

175 Given the evidence we had by then accumulated on the general poor level of containment offered by the drains, we did not consider it necessary to repeat these experiments.

176 We have no direct evidence that there was an overflow from manhole FM1 releasing the O1 BFS strain over the period covered by our investigation. However, we conclude it likely that the extreme wet weather conditions experienced 20–23 July

exacerbated existing problems with the sites effluent drainage system and further compromised the already inadequate level of containment.

- 177 We consider it unlikely that aerosols containing the O1 BFS strain were released from the site's effluent drainage system during the period covered by our investigation.
- 178 Nevertheless, if this were to have occurred, the most likely time period will have been between 22–26 July when the centrifuge waste from both O1 BFS batches was discharged into the system. 23 July had already been identified as the most likely date when the wind direction linked the Pirbright site to the first affected farm for a sustained period.
- 179 Through discussions with NEEG, we conclude that it is it unlikely that the FMD outbreak resulted from release of aerosols from the site's effluent drainage system.

Potential for wider transfer off the Pirbright site

- 180 We sought advice from the Environment Agency on the possibility of whether water flooding the Pirbright site could have reached the first affected farm, taking material potentially contaminated with live animal pathogens with it. Their conclusion (report 2; Annex) was that this was 'practically impossible' due to the distance, topography and direction of flows involved.
- 181 In addition, it was considered a negligible likelihood that material potentially contaminated with live animal pathogens could also have reached the affected farm through the normal sewage system, should this have been contaminated around the Pirbright site.
- 182 We conclude that there was no direct, water-borne route by which potentially infected material moved from the Pirbright site to the first affected farm.
- 183 Other off-site routes for the movement of potentially contaminated materials are explored in more detail in the next section.
- 184 We conclude that it is likely that live virus of the O1 BFS strain worked with by Merial was released from the Pirbright site's effluent drainage system into the surrounding soil 20–26 July 2007. This mechanism is likely to have been either through overflowing of manhole FM1 or general leakage around the drainage pipes elsewhere in the system or both.
- 185 We conclude that during this period the Pirbright site may have become contaminated with live virus of the O1 BFS strain.
- 186 We conclude that the inadequate levels of containment offered by the effluent drainage system represent a breach to the biosecurity arrangements at the Pirbright site.

Potential for release of the O1 BFS strain via the human route

187 We investigated whether there could have been any breakdown in control measures which may have resulted in release of the O1 BFS strain from the facilities via the human route and whether there were any transfer mechanisms which linked the Pirbright site and the first affected farm.

Potential for release from the facilities

- 188 Many of the containment measures specified for work with SAPO Category 4 pathogens require well-trained, highly competent staff who adhere strictly to working procedures (standard operating procedures). In addition, there needs to be strict supervision of visitors and contractors. The activities of humans across both sites are critical to the success of the biosecurity arrangements.
- 189 We needed to establish whether any biosecurity measures and procedures involving human activities could have broken down.
- 190 We interviewed staff and followed up HR issues to determine whether any held grievances against their employers.
- 191 Although this was not a major focus of our investigation, we found no evidence that biosecurity arrangements were breached through the malicious intent of staff.

Staff links with the first affected farm

- 192 IAH, Stabilitech and Merial identified staff who were working with the O1 BFS strain during the period covered by our investigation. In addition, they identified all staff who might have accessed the Normandy area during this period.
- 193 All staff who were identified were interviewed as part of our investigation.
- 194 In addition, we identified that approximately 70 plastic containers had been transferred from the Merial facility to allotments adjacent to the first affected farm for use as water butts and planters. These had been brought to site over a number of years and had previously been held in the non-restricted areas of the Merial premises. These containers were classed as general waste and destined for disposal to landfill; Merial staff had been given permission to use these containers by senior management. We have no reason to believe that these containers were linked to the outbreak.
- 195 We found no evidence linking the activities of any members of staff at either IAH, Stabilitech or Merial directly with the first affected farm during the period covered by our investigation.

Access to restricted areas of the facilities

IAH and Stabilitech

196 The IAH restricted area contains the laboratories and support facilities. Access to the whole of the area is via the main bathrooms (which contain shower facilities), which lead to an open area within the main restricted zone. This area is exposed to the elements, is grassed and has footpaths running to the main laboratory buildings, canteen and laundry. A separate building is also provided for staff welfare.

197 The canteen is operated by an external contractor whose staff work in the clean kitchen area. Canteen staff can pass food to the main restricted area of the laboratory through one hatch and through another hatch to the outside clean area. Strict procedural controls need to be maintained between the kitchen and the main restricted area to minimise items touched by an individual in the restricted area passing through to the kitchen.

198 This system is very unusual in high containment facilities and is accepted by both Defra and IAH management as not being ideal.

199 We conclude that the current layout of buildings in the IAH restricted area is a weakness in the biosecurity arrangements at IAH. However, we have no reason to believe that this resulted in the FMD outbreak.

200 Access to the main restricted area is through a single self-closing door, which is protected by digital lock entry. The digital code has not been changed in recent years and managers were unsure as to the exact number of staff who had access to the numerical code, although the accepted figure is between 30 and 40. No log is kept on a day-to-day basis of who has entered the high containment facility although some guide may be achieved by challenging the records of entry to the main outer building, which is also digital keypad controlled. However, it is common for staff to hold the door open for colleagues and as such these records may not be reliable.

201 We conclude that the failure to properly control access to the main restricted area is a breach in IAH's biosecurity arrangements. However, we have no reason to believe that this resulted in the release of the O1 BFS strain during the period covered by our investigation.

Merial

202 At Merial, access to the restricted area is granted to a small number of staff and is controlled by electronic swipe cards, which record an individual's movements. In addition, all people entering the restricted area are recorded in a day diary.

203 We have no reason to believe there was any breakdown in Merial's biosecurity arrangements relating to entry to the restricted area.

Management of visitors to the Pirbright site

Access to sites

IAH and Stabilitech

204 Access to the IAH site is controlled by a gatehouse with barriers for vehicles and pedestrians. There is a gatehouse log for recording visitors and vehicles entering and

leaving the site. All visitors to the site are confirmed to the gatehouse in writing or by e-mail from the host department. Visitors are issued with a visitor badge and are directed to their destination on the site. Vehicles visiting the site to collect or deliver goods are recorded in the gatehouse log. While most of the fence line of the site is covered by CCTV, there is no camera or automatic number plate recognition equipment to record vehicle movements onto site.

205 During the period relevant to our investigation and while our investigation team were on site, a major building project was underway involving the redevelopment of the IAH site. Consequently, numerous large vehicles as well as other contractors' vehicles and equipment entered and left the site.

206 The IAH gatehouse log was analysed and we identified that, during the period covered by our investigation, most vehicle movements onto the site were cars, carderived vans and panel vans. Only a few heavy good vehicles are recorded on the gatehouse log. However, we did identify that large vehicles operated by a number of site contractors were not recorded within the log and additionally a significant number of entries in the log were not legible. As a result there is an incomplete record of visitor and vehicle movements onto site during the period covered by our investigation.

207 We conclude that the failure to properly record the transit of large vehicles to and from the site is a breach of the biosecurity arrangements at IAH.

Merial

208 Access to the Merial site is controlled by a remotely operated gate with an intercom. All visitors report to reception via the intercom and are then let into the car park of the facility – and told to report to reception. At reception all visitors entering the site are asked to complete a visitor's log book and are provided with a visitor's badge.

209 We found no evidence that the practices at Merial for accepting visitors onto site were outside their biosecurity arrangements.

Access to restricted areas

210 Both sites operate rigorous control measures when external contractors enter the facilities, eg to carry out maintenance or to test equipment. They must sign biosecurity declarations and complete a questionnaire and are interviewed by biosecurity managers. Work activities in the facilities they are visiting are made safe and they are accompanied by a member of staff at all times.

211 There was no evidence that access by visitors to the restricted area facilities of IAH, Stabilitech or Merial was not properly controlled during the period covered by our investigation.

212 However, our investigations revealed that control of IAH contractors to the rest of the IAH site, and particularly around the effluent drainage system described previously, does not appear to have been satisfactory.

213 We identified that three main contractors were on site during the period covered by our investigation, all of whom were under the control of IAH. These were engaged in the construction of a new roadway, the building of a new animal unit and improvement works on the effluent drainage system. IAH appointed a project management company to oversee the redevelopment works undertaken on the roadway and the drainage.

214 A separate company was appointed to project manage the construction of the new animal unit. These activities took place in a segregated area away from other activities at the IAH site. We investigated these and concluded that they were unlikely to been working in areas where the O1 BFS strain may have been present. Therefore they were eliminated from our inquiries.

215 Our investigations focused on the activities associated with (a) the drainage works and (b) the new roadway. Our findings over the period covered by our investigation are listed below.

Drainage

216 The works involved investigation and surveying of the site for a new effluent drainage system coupled with the digging and preparation of new manholes. This work commenced on 11 July and continued throughout the period covered by our investigation. Between 14 and 25 July, five excavations were started with a further three excavations commencing after this period. On 20 and 23 July no work was undertaken due to the extreme wet weather experienced as previously described.

217 On either 25 or 26 July an excavation was undertaken around the main discharge pipe from the Merial effluent sump, described in the previous section.





Figure 5 Main effluent pipe from Merial sump, exposed by IAH-appointed contractors on 25–26 July 2007

219 Following a basic inspection, this work did not appear to have damaged the pipe. However, a full examination was not possible as the pipe is encased in concrete and remains buried. The CCTV drainage survey did not cover this stretch of pipe as it contained liquid effluent, preventing access to the camera equipment.

220 The material excavated from this area was transferred to a spoil heap on site in a designated area allocated by IAH. Although contractors involved in the excavations were given verbal instructions, there is no evidence that there were any permits-to-work or written standard operating procedures in relation to either the excavation or movement of potentially contaminated soil. Figure 6 shows the heaps of potentially contaminated soil with vehicle tracks over them, indicating lack of access controls.

Roadway

221 Throughout the period under investigation, work was undertaken to remove soil and subsoil from the new roadway and lay a new surface. Some of the material was removed from site to a number of locations in the local area. Other material was used elsewhere on site. The roadway was widened in the area around Merial's effluent sump, passed close to where the excavation shown in Figure 5 was located and crossed the effluent drains leading from the IAH facility. This is shown in Figure 6. On 20 July work on the roadway was affected by the heavy rainfall: a small trench was dug at this time to try and divert water away from the portacabin facility used by the contractors in the vicinity of the road.



Figure 6 Key contractor activities around the effluent drainage system (*Photo courtesy of Surrey police*)

Biosecurity implications of this work

- 222 We identified that although some arrangements had been made for IAH to accompany construction workers at certain times and instructions had been given on the method of retaining potentially contaminated soil in a quarantine area at the site, these were not documented. In addition, the photograph of the spoil heaps in Figure 6 shows vehicle tracks over spoil indicating that access to this area was not restricted. There was no evidence of wheel washes or basic cleaning of vehicles involved in these activities.
- 223 There was no evidence of a permit-to-work system for the excavation around the discharge pipe from Merial's sump and this took place around the time period when we established that there was a medium likelihood that live virus of the O1 BFS strain was in the effluent system, with a low likelihood of it leaking into the surrounding soil.
- 224 Both the drainage work and work on the roadway was continuing during the start of our on-site investigation. On 8 August, when we began to have concerns about the containment level offered by the effluent drainage system, we raised our concerns with IAH senior management and Defra. As a result the access to the area around the effluent drainage system and all construction activities were suspended at the IAH site on 8 August.
- 225 We conclude that the construction activities around the effluent drainage system will have involved the disturbance and movement of soil during the period covered by our investigation. We conclude that it is likely that this soil was contaminated with live virus of the O1 BFS strain.
- 226 We conclude that the failure to properly manage contractors working around the effluent drainage system represents a breach of the biosecurity arrangements at IAH.
- 227 We conclude that this biosecurity breach was likely to have continued until 8 August 2007, when access to the area around drains was restricted and construction work was halted.

Potential for wider transfer from the Pirbright site

- 228 Our investigations focused on identifying and prioritising those vehicles that may have come into contact with the potentially contaminated soil and establishing whether these could provide a direct link between the Pirbright site and the first affected farm.
- 229 We established that approximately 1000 vehicles visited the IAH site alone between 14 and 26 July.
- 230 We interviewed the contractors responsible for the drainage and roadway work, examined CCTV footage of the site and collated anecdotal information from people who had observed the construction work.
- 231 We arranged for Surrey Police to examine the gatehouse log from IAH to identify further information about visitors to the site.

- 232 We prioritised the vehicles that were known to have been on the IAH site during the period covered by our investigation into the following categories:
- Category 1 Vehicles likely to have had soft soil contact (eg were transporting soil, had left the roadway onto soil or were working in the area around the effluent drainage system where soil debris may be present).
- Category 2 Other large vehicles with no reason to have left the hardstanding areas.
- Category 3 Vehicles parked or accessing flooded areas of hardstanding on 20 July.
- Category 4 All other vehicles accessing the site.
- Category 5 Pedestrian-only movements to and from the site (including arrivals in vehicles parked in the off-site car park).
- 233 Given the large numbers of vehicles and pedestrians involved, we focused on vehicles in category 1 above. However, it is important to note that many of the vehicles are registered to lease companies, numerous vehicles could not be traced because the gate log entry was not readable, and not all visitors to the site were recorded in the gate log. Of those we could identify, interviews were undertaken with the drivers to establish where they went on site, their route after leaving the Pirbright site and whether the drivers themselves had visited the Normandy area after leaving the site.
- 234 Our investigations revealed that most category 1 vehicles travelled on main roads in directions other than to Normandy.
- 235 We did identify that on 20 July and 25 July, soil and subsoil was removed from the Pirbright site and taken to three locations:
- a landfill site at Compton near Guildford;
- a topsoil grading company at Wrecclesham; and
- a construction site in Basingstoke.
- 236 We identified that the route taken to Compton from the Pirbright site included Westwood Lane in Normandy, close to the first affected farm and known to be used by the farmer and visitors. This route is shown in Figure 7.
- 237 We established that on 20 July, four 32-tonne trucks (believed to be 4-axle vehicles) transported 15-tonne loads of uncovered subsoil from the Pirbright site to Compton using this route. During this time both the Pirbright site and roads en-route were subject to flooding.
- 238 We established that on 25 July, two 32-tonne trucks transported 15-tonne loads of subsoil by the same route. The road conditions on this day were dry.
- 239 In addition to these category 1 vehicles, we also investigated the routes used on site by a number of vehicles visiting both the IAH and Merial sites. This included a feed lorry, a cattle trailer and a large goods vehicle parked in floodwater on 20 July.
- 240 We also investigated whether a vehicle wash facility in the Normandy area had been used to wash any plant used at the Pirbright site.
- 241 We found no further evidence of category 1 vehicle movements that provided a link between Pirbright and Normandy during the period covered by our investigation.

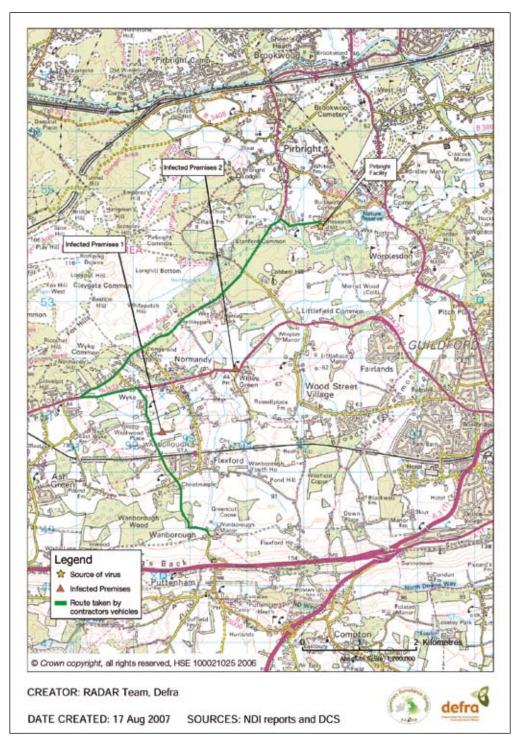


Figure 7 OS map showing route passed IP1

- 242 We believe that the movement of material contaminated with live FMDV virus O1 BFS along Westwood Lane provides a credible link between the Pirbright site and the first affected farm.
- 243 We conclude that it is likely that soil and/or materials contaminated with live FMDV strain O1 BFS was removed from the Pirbright site between 20 and 25 July 2007.
- 244 We conclude that this represents a breach to the biosecurity arrangements at the IAH site.
- 245 We conclude that it is likely that vehicles contaminated with this soil passed down Westwood Lane close to the first affected farm
- 246 We conclude that this occurred within the time period advised by Defra as being the most likely period of initial exposure of cows at the first affected farm to FMDV strain O1 BFS.
- 247 Considering all the other evidence we obtained during our investigation, we conclude that this is the most likely mechanism by which the first affected farm became infected with FMD.

Summary of conclusions and recommendations

- It is recommended that the required standards of containment should be clearly documented to facilitate the regulatory process.
- 2 In addition, a review should be completed to contrast the actual regulatory position for animal pathogens with human pathogens to make sure the position is justified.
- We recommend review of arrangements for setting and monitoring safe operating practices where work is subcontracted under a single operating SAPO licence with responsibilities clearly defined between the licence holder and the subcontractor.

Activities involving the O1 BFS strain

We conclude that activities involving the FMDV O1 BFS strain were carried out at the IAH, Stabilitech and Merial facilities during the period covered by our investigation.

Identifying the origin of the outbreak strain

- We conclude that there is a high likelihood that the virus that caused the 2007 outbreak at Normandy originated from the Pirbright site.
- We conclude that the close similarity between the outbreak strain, and the O1 BFS strains worked with at IAH, Stabilitech and Merial makes it difficult to precisely pinpoint its origin as the single nucleotide difference may not be statistically significant.

Potential for release of the O1 BFS strain via the airborne route

- We conclude that there is a low likelihood that the O1 BFS strain was released via the airborne route from laboratories used by either IAH or Stabilitech during the period covered by our investigation.
- We have concerns about the suitability of continuing to use the upper south wing of the research laboratory for high containment. Unless it can be demonstrated that the facility is sealable for fumigation and that the laboratories can meet the required pressure regime, it is our view that this does not meet Defra's published standards for Category 4 pathogens. We recommend that this is investigated.

- We have concerns about the filter arrangements throughout the main laboratory. In our view, this does not meet the requirement for SAPO Category 4 pathogens in that it does not allow both filters to be tested independently: therefore it cannot be guaranteed that both filters are working at any one time. We recommend that this is investigated.
- 10 We conclude that there is a negligible likelihood that the O1 BFS strain was released via the airborne route from the Merial facility during the period covered by our investigation.
- 11 We conclude that there is a negligible likelihood of an airborne release of virus from the contained facilities of the Pirbright site having caused the outbreak of FMD.

Potential for release of the O1 BFS strain via the waste route

- 12 We conclude that there is a negligible likelihood that the O1 BFS strain was released via the solid waste route from laboratories used by IAH, Stabilitech or Merial during the period covered by our investigation. However, we do not consider some of the procedures observed at IAH/Stabilitech represent good practice and recommend that these be reviewed.
- We have concerns as to whether a system of chemical treatments could ever be considered to sterilise liquid waste as required for SAPO Category 4 pathogens. It is our experience that chemical treatments, while reducing the amount of pathogen in the liquid, may not render the liquid completely pathogen-free. Unless this system can be validated to demonstrate sterilisation, it is our view, that this does not meet the requirements for SAPO Category 4 pathogens. We recommend that this is investigated.
- 14 We conclude that there is a negligible likelihood that live virus of the O1 BFS strain entered the effluent drainage system from the IAH or Stabilitech laboratories during the period covered by our investigation.
- We conclude that it is likely that live virus of the O1 BFS strain entered the effluent drainage system from the Merial facilities during the period covered by our investigation.
- 16 This process was fully in compliance with their SAPO requirements. We feel it would be better practice for Defra to require a higher degree of inactivation before the centrifuge waste enters the effluent sump. We recommend that Defra and Merial work closely together to establish how best this could be done.
- 17 Neither the existing effluent drainage system in use across the Pirbright site nor the record keeping, maintenance and monitoring regimes in place for it are considered to meet the standards required for SAPO Level 4.
- We do not consider the current effluent drainage system provides adequate containment against the release of SAPO Category 4 pathogens.

- 19 We conclude that there may have been release of SAPO Category 4 pathogens from the buried pipework into the surrounding ground on the Pirbright site over an undefined period of time prior to our investigation.
- 20 We conclude that this represents a breach to the site's biosecurity arrangements.
- 21 We consider the lack of a written standard operating procedure to deal with blockages in the effluent drainage system to be a breach in the biosecurity arrangements at IAH.
- We conclude that it is likely that the O1 BFS strain from the Merial facility was released from the site's effluent drainage system between 22 and 26 July 2007.
- 23 The arrangements for discharge from the Merial sump into manhole FM1 leave the potential for overflowing from the manhole and release of material from the effluent sump. If this were to contain live pathogens, in our view this would constitute a breach in biosecurity. We recommend that this is investigated.
- We have no direct evidence that there was an overflow from manhole FM1 releasing the O1 BFS strain over the period covered by our investigation. However, we do conclude it is likely that the extreme wet weather conditions experienced 20–23 July exacerbated existing problems with the site's effluent drainage system and further compromised the already inadequate level of containment.
- We conclude that there was no direct, water-borne route by which potentially infected material moved from the Pirbright site to the first affected farm.
- We conclude that it is likely that live virus of the O1 BFS strain worked with by Merial was released from the Pirbright site's effluent drainage system into the surrounding soil between 20 and 26 July 2007. This mechanism is likely to have been either through overflowing of manhole FM1 or general leakage around the drainage pipes elsewhere in the system or both.
- We conclude that during this period the Pirbright site may have become contaminated with live virus of the O1 BFS strain.
- We conclude that the inadequate levels of containment offered by the effluent drainage system represent a breach to the biosecurity arrangements at the Pirbright site.

Potential for release of the O1 BFS strain via the human route

- We conclude that the current layout of buildings in the IAH restricted area is a weakness in the biosecurity arrangements at IAH. However, we have no reason to believe that this resulted in the FMD outbreak.
- 30 We conclude that the failure to properly control access to the main restricted area is a breach of IAH's biosecurity arrangements. However, we have no reason to believe that this resulted in the release of the O1 BFS strain during the period covered by our investigation.

- We conclude that the failure to properly record the transit of large vehicles to and from the site is a breach of the biosecurity arrangements at IAH.
- 32 We conclude that the construction activities around the effluent drainage system will have involved the disturbance and movement of soil during the period covered by our investigation. We conclude that it is likely that this soil was contaminated with live virus of the O1 BFS strain.
- We conclude that the failure to properly manage contractors working around the effluent drainage system represents a breach of the biosecurity arrangements at IAH.
- We conclude that this biosecurity breach was likely to have continued until 8 August 2007, when access to the area around drains was restricted and construction work was halted.
- We conclude that it is likely that soil and/or materials contaminated with live FMDV strain O1 BFS was removed from the Pirbright site between 20 and 25 July 2007.
- We conclude that this represents a breach to the biosecurity arrangements at the IAH site.
- We conclude that it is likely that vehicles contaminated with this soil passed down Westwood Lane close to the first affected farm.
- We conclude that this occurred within the time period advised by Defra as being the most likely period of initial exposure of cows at the first affected farm to FMDV strain O1 BFS.
- 39 Considering all the other evidence we obtained during our investigation, we conclude that this is the most likely mechanism by which the first affected farm became infected with FMD.

Annex

Assessment of the condition of the drainage systems at Pirbright and the implications for containment of effluent

Introduction

This Annex details the findings from an investigation into the condition of the drainage pipework at the Pirbright site. This is based on the following information:

- the CCTV survey conducted by Dyno-Rod on 11–12 August 2007;
- a series of visual inspections undertaken on the IAH and Merial sites including some lifting of manhole covers on 15–17 August 2007;
- review of available documentation and plans of the site;
- discussions with the engineering managers of both the IAH and Merial sites.

Background

- An outbreak of FMDV was confirmed at a farm in Surrey on 3 August 2007.
- Preliminary Defra investigations indicated that the virus may have originated from the Pirbright site at which three separate organisations are based: IAH, Stabilitech and Merial Animal Health Ltd (Merial).
- A multidisciplinary cross-government team with representatives from HSE, Defra, VMD and the Environment Agency, supported by others, conducted on-site investigations.
- An initial report published by HSE outlined the investigation's key lines of inquiry and the next steps.
- One of the steps is a further investigation of leak paths from the site through the effluent drainage system. This report supports that portion of the investigation.

Overview of drainage system

The drainage systems on the site have developed over the site's history, since its formation in the 1930s, and developments in the intervening years. It is clear that management of the drains has not followed a clear protocol, rather individual projects have developed according to their own needs and connected into the extant system. In addition, when facilities have been decommissioned, there is evidence that remaining 'dead legs' have not been routinely isolated and so remain in place.

Effluent drains

Merial site

Figure 8 shows a simple schematic of the drainage system. The discharges from the Merial site all originate from a single effluent sump, which is then discharged into the broader IAH drainage system via manhole FM1. The sump receives effluent from all controlled areas.

The effluent sump was constructed in about 1971, and is a reinforced concrete sump arrangement with an invert level of around 3.5 m below ground level. Figure 9 shows a section through the sump. The design standards for the sump are not known, and are not detailed on the available drawings. It should be noted that the lower sump level was coated with a 1-inch Sika plaster lining with the intention of providing an additional barrier to water egress. The inlet line into the sump is a 6-inch diameter salt-glazed clay line with a 6-inch concrete surround. The details of the various connections into the inlet line have not been reviewed. They originate beneath the production buildings and at the time of inspection were in use discharging small volumes of condensate and foul drainage from showers and toilets.

The level of effluent in the sump is monitored by a series of float switches, which control, through a simple logic circuit, the operation of the discharge pumps. Under normal circumstances, a single pump with a duty of 25 000 litres/hour is used, however, if the level continues to rise, a second (identical) pump is started. Under normal circumstances, the pump(s) will run for a few minutes at a time. During a normal production day, an average of 20 m³ per day is discharged. This is monitored for charging purposes. Figure 10 shows the discharge history from mid-late July.

The discharge line is a 4-inch cast iron pipe, which has a 6-inch concrete surround. This has been exposed as part of an excavation immediately adjacent to the effluent sump (see Figure 13). This line has not been internally inspected by CCTV. The line rises in elevation from the sump up to manhole FM1 (see Figure 14). A short length of pipe (about 1.1 m) then taps into the IAH drainage run from FN9 to FM2. This run takes an unusual path and drops almost vertically into the crown of the existing line (see Figure 11 and Figure 15).

IAH site

Figure 8 shows that there are two primary routes on the IAH site, designated north and south. These lines pick up assorted facilities along their route but both terminate in manhole F7. F7 is a deep circular manhole with a weir arrangement to allow sludge to drop out. From beyond F7, the effluent runs into the effluent treatment plant (chemical), where caustic soda is added via a mechanical bucket arrangement, before entering a stilling basin. From the stilling basin, the effluent is pumped up to a series of Braithwaite tanks, where it is held for a minimum of 24 hours. The effluent is then tested for pH and soda content before sanction to discharge is given. The Environment Agency discharge consent has a limit of pH 11.

Surface water drains

The surface water drains and non-contaminated foul water drains for the Merial site are gathered and discharged into a public sewer, which runs along the road to the front of the premises.

For the IAH site, which occupies a much larger surface area, the drainage is fed towards the surface water unit, which is a series of buried open-topped concrete tanks. Should this become full, it overflows into a small lagoon. This allows water to be held up before discharge into the Stanford Brook. This system has been in place since the 1950s when there was a greater focus on the waterborne transfer of virus.

Construction details

Construction drawings

There are some original construction drawings available, which provide an insight into the nature of the construction used. The site has been in existence since the 1930s, however, the earliest drawings observed date from 1954 and the latest from 1985. There are not, however, a full set of coordinated services drawings available. The general findings from those drawings available can be summarised below.

1954

Under buildings, cast iron was used, and elsewhere salt-glazed stoneware. The stoneware pipes would be jointed using hemp rope and tar with buttered mortar into socket and sleeve type connections. The specification would almost certainly have come from the 'Ministry of Public Works', which allowed for bedding on single-sized pea gravel.

1967

Under buildings, cast iron was used, and elsewhere salt-glazed stoneware.

1985

Hepworth supersleeve was specified and hepsleeve connectors. The bedding was specified as 150 mm thick under the pipe, 300 mm cover, size 10 or 14 to BS 882 Class 2 with a Terram (geotextile) wrap where the pipework ran under buildings.

In 2005, the connections to the new insectory were laid. This is in 150 mm UPVC as evidenced from the CCTV footage.

The precise sequencing of the pipework is not clear, however, the dates given in Table 3 are the best estimate that can be made.

The Merial sump was constructed in 1970/71, however, the lagoons and effluent treatment plant are believed to have been constructed in the 1950s.

Drainage technical specifications

Over the period of the site, the technology for drainage has changed. The following gives a brief overview of the likely types of drainage used in each of the main periods of development.

1950s

The drainage would have been salt-glazed clay pipes, with spigot and socket connections. The connections are sealed with hemp rope and tar initially, and finally by cement mortar. The joints can be made waterproof, but damage can occur reasonably easily as a result of the lack of ductility in the connection. It is likely that the standards of construction would have been via a 'Ministry of Public Works' specification. These are generally viewed as a good quality type of installation.

1960s

The 1960s saw the introduction of vitrous clay, and the start of the use of plastic couplers, with Hepworth being the leaders in this field. The early connectors were provided ready fixed to pipework sections. Complex or non-standard connections would still have been made using mortar-style joints with concrete backing as judged necessary. Pipework installed in this period is likely to be a mixture of types.

1980s

Both vitrous clay and PVC pipework drainage is now available, with connection made by plastic sleeve couplers. The following summarises the typical details:

- pipe lengths are typically, 1.6 m for 100 mm diameter, and 1.75 m for 150 mm diameter;
- joints are affected by push-fit plastic couplers. They can accommodate a degree of out of alignment, typically of up to 5 degrees;
- the clay pipework is generally resistant to attack from most industrial chemicals;
- the pipework is manufactured to meet the demands of BS EN 295:1991¹ for leak tightness, which includes the following requirements:
 - air test: The pipes, bends and junctions are subjected to an initial air pressure of 100 mm water gauge, which may not drop below 75 mm water gauge in 5 minutes;
 - water test: the pipes, bends and junctions are required to withstand an internal water pressure of 50 kPa (0.5 bar) for 15 minutes without leakage.

The basic arrangements for pipework bedding have not changed markedly over the past 50 years, with the following being standard practice:

- the pipework should be bedded on a granular material, usually 10 or 20 mm single-sized gravel, and backfilled either with further granular material or selected backfill. This is dependent on the soil type within which the pipework is to be laid;
- where pipework passes under roads or other heavily trafficked areas, special precautions may be needed, including bedding/surrounding in concrete if the depth to the crown of the pipe is relatively small.

There are relevant current standards for construction and testing of this type of pipework.^{2,3}

The standards for construction of manholes have changed little over time, other than that the availability of pre-cast items has made effecting joints easier. The range of manhole covers available over the years has changed markedly, with a wide range of examples seen across the site.

Maintenance and testing

A discussion with the site representatives confirmed that there were no routine maintenance instructions or testing undertaken within either the effluent or surface drainage system. Any maintenance is undertaken on a reactive basis.

The Merial sump has not had, as far as is known, a formal inspection of its integrity since construction. The sump was drained within the past three years, and de-sludged, and no gross defects reported, however, a formal inspection by a competent person was not undertaken.

There is no evidence that there is any routine maintenance or inspection of the surface water collection tanks or the effluent treatment plant.

Investigation technique

A series of CCTV inspections of sections of the site effluent pipework was undertaken by Dyno-Rod on 11–12 August 2007.⁴

Table 2 Summary of inspections undertaken

Section No	From	То	Material	Diameter (mm)	Construction date
1	Approx RA wall	FW Insectory	Vitrous clay	150	1967
2	Insectory sump	FW Insectory	Plastic	150	2005
3	Downstream through Hall Road crossing north	FW Insectory	Vitrous clay	150	1967
4	Upstream towards FN2 Hall Road crossing	FN3	Vitrous clay	150	1967
5	FN4	FN3	Vitrous clay	150	1967
6	FN1	FN4	Vitrous clay	100	1967
7	Weir through Fn5	FN3	Vitrous clay	150	
8	Junction	FN1	Vitrous clay	100	Pre-1993
9	From upstream to F2	Downstream	Vitrous clay	150	1985
10	Upstream	F2			1985
11	ETP valve	Weir	Vitrous clay	150	1985
12	Weir	A barn from manhole	Vitrous clay	150	Abandoned

^{*} The dates given are best estimates from the limited information available

Some visual inspections of manholes FM1, FM2, FN4 and FN9 were undertaken. An excavation that exposed the cast iron discharge pipe from the Merial sump was also inspected. No pressure testing of the pipework has been done.

Findings

The findings below are based on the inspections identified in 'Investigation technique'.

General condition

Pipework

The condition is highly variable across the different sections. Few of the runs are completely clean, and a number have heavy deposits on the pipework, and also lumps of debris/accretion in the invert of the pipe run. The nature of the deposits is unclear. There is the use of detergents and soaps in the facilities, which could account for some of the deposits that have a fatty appearance. Some also look like a limescale-type deposit. Without sampling it is difficult to be certain over their origin.

On many pipes, there is evidence of the build-up of deposits at the joint locations, particularly and longitudinally at the primary waterline. In some cases, the deposits appear to be linked to water ingress at the crown of the pipe.

In many pipes there appears to be a permanent level of water in the pipework, which would exacerbate the build-up of deposits.

There are some sections of pipework that have not been inspected internally. Principal among these is the cast iron run from the Merial effluent sump up to manhole FM1. This run passes uphill and is permanently full of water, and access can only be gained via a complex draining operation, which was not possible with residual operations ongoing at the Merial site. A section of the pipe has been exposed externally (see Figure 13), and shown to be in good condition beneath its concrete casing. Internally, the permanent submersion under water will have limited corrosion, and the nature of the contents is such that aggravated degradation would be minor. Thus, while it is not possible to be categoric that this line is fully intact, it is seen at a lower risk of leakage than the vitrous clay lines.

Manholes

The majority of manholes have poorly fitting lids. Those that were originally intended to be gas tight are clearly not performing that function currently. Those manholes that were inspected were in a reasonable condition structurally, with no gross defects, with the side walls and benching generally intact. In some areas however, there was missing mortar from brickwork joints (see Figure 16) and evidence of washout of material at some junctions (see Figure 17).

Manhole covers on site are not coded or marked consistently to identify different drainage runs. The Environment Agency members of the investigation team noted that one manhole cover was marked as being on the surface water system but proved to be on the foul drainage (biosecure) system.

Merial sump

Access to the inside of the sump is by special arrangement, as a result of the effluent within it and the confined space aspects. A review of the drawings has shown it to extend to 12 inches below ground level (see Figure 9), with walls and base of 12-inch thickness. The most likely design standard would have been BS CP 2010-2:1970.5 The drawings note that 'Waterproof concrete to engineer's details' is to be used. The drawings also indicate a 1-inch lining of waterproof plaster (by SIKA) is to be applied. It is not known if any water bar was used in the construction of the sump.

There is limited evidence available from an external inspection, however, there was no distress noted. Equally, the details from the recent sludge removal suggest that no gross defects were present, however, a formal inspection of the structures was not undertaken.

Surface water lagoon

The surface water lagoon was believed to be constructed at some time in the 1950s, presumably to extant Ministry of Public Works standards. The structures appear from an external inspection to be sound, however, the bund walling around the tanks is showing some distress. In addition, the paving slabs around the tanks are showing considerable disruption, possibly as a result of water movements below from leakage, although it is not possible to be definitive on this without much more detailed invasive investigation.

During the inspection, a pile of material was noted at ground level, adjacent to the lagoon, having presumably been removed from it at some point. It was noted that a large tomato plant was growing from it, and there were a number of shaving blades present. This suggests that some foul drainage may have emerged into the surface lagoon, however, definitive proof is difficult.

In addition, there was an assortment of material, including polystyrene, polythene and a small glass bottle, observed floating in the lagoon. This may have been the result of recent heavy rain bringing material into the sump.

Effluent treatment plant

The effluent water treatment plant was believed to be constructed some time in the 1950s, presumably to Ministry of Public Works standards. The structures appear from an external inspection to be basically sound, however, the external covering structures are showing their age. Effluent is pumped from the concrete tanks after dosing to a series of 'Braithwaite' tanks via a Hepworth rigid plastic pipeline with sections of braided stainless steel at key intersections (see Figure 18). The Braithwaite tanks are in a reasonable condition.

Identified defects

Pipework

There are no gross defects identified such as collapsed sections, major open cracks in the pipes or gross misalignment. However, the footage in some areas is indistinct, and where there is a greater depth of water and pipe coating, definitive statements cannot be made.

There are a number of defects identified that are spread across each of the sections (Table 4 provides full details), which are listed below.

- some pipe misalignment at joints, possibly due to poor installation, or longer-term settlement (see Figure 19);
- the presence of tree roots in the pipe, ranging from small single roots through to larger clusters (see Figures 20, 21). The section most affected by this runs from manhole FM2 to F7. Although the larger clusters are at the crown of the pipe, there is concern that the joint may have been sufficiently disrupted to cause a leak path at the invert. An inspection of the area around the pipe sections most affected has shown that there is a young beech hedge or small tree plantation planted within 2 m of the pipe route (known to have been planted since 1998).

In addition, at that point, the pipe is relatively shallow (less than 800 mm to the crown). It is considered that the roots originate from these trees;

- what appears to be a displaced rubber seal, now discoloured by limescale;
- there is heavy corrosion on the cast iron/steel section adjacent to the ETP valve (see Figure 22);
- some areas where very sharp turns appear to have been made without the use of bends, but by displacing pipework at an offset;
- what appear to be small stalactites formed from the crown of the pipe, which may be indicative of water ingress from outside the pipe;
- poor connection details. The connection from manhole FM1 into the IAH discharge line is somewhat unusual, and has been eroded during its life as a result of the high volume flow rates into it (see Figure 15);
- there are a number of connections into the lines, which appear to be now defunct dead legs, the condition and termination points of which are unknown.

Table 3 provides an indication of the presence of each of the defects in each pipe run. This shows that runs 1, 6, 7, 9 and 12 are in the worst condition on the CCTV footage.

The connection arrangements for the discharge from manhole FM1 into the downstream leg are somewhat non-standard. The pipe drops very sharply, before joining the downstream leg almost vertically. Given that the connection arrangements are somewhat unusual, there is a concern that there could be backing up of material into the manholes, and potential overtopping. This has been considered in more detail, and is discussed in 'Implications for containment'.

Manholes

The manholes inspected have varying degrees of imperfection, either from small apertures around pipes at junctions (see Figure 17), or from damaged brickwork which forms the manhole structure (Figure 16). The lids are in varying condition, however, they cannot generally be considered to be gas tight, and in a number of cases are not insect proof, although they should be able to keep mammalian vermin out.

Implications for containment

While the defects identified above are relatively minor, their presence is not seen as compatible with the pipework being classed as a high-integrity containment. While it is not definitive that the defects above would lead to leakage at a high rate, it is equally not possible to claim that the pipe is leak free. The section of pipe of the greatest concern is that which connects manhole FM1 through to F7a, which carries the effluent from the Merial site. All of the defect types in the pipework or manholes are found in this length. It is perhaps coincidentally the length of pipework which also carries the greatest volume of effluent to the treatment plant.

If the pipe is bedded onto a granular material, leakage into that material could then readily spread along the axis of the pipe run due to its porous and free draining nature. The extent to which the leakage may spread is difficult to predict without a much greater understanding of the material below and around the pipe.

The manner in which leaked material may transport vertically to the surface is dependent on the prevailing hydrogeological conditions. It could be foreseen that post-leak flooding may cause some vertical transportation, however, without substantial further physical investigation, modelling and experimental work it is difficult to be more definitive.

In constructing high-integrity containment arguments, it is common to use a multilegged approach. The various legs that are generally used are detailed below:

- design;
- manufacture, construction and commissioning (original and modifications);
- condition assessment:
- damage tolerance assessment;
- monitoring; and
- examination and test.

At present, little is definitively known on the design and manufacturing aspects of the earlier phases of development, although it is likely that standard details and practices would have been employed. A condition assessment has been undertaken, but gives concerns in a number of areas. Monitoring of the pipework has not taken place other than reactively. Examination and testing have not been undertaken as a regular process through the lifetime of the facilities.

It can be seen that there are few credible legs that support the view that this pipework system can be considered to be an engineered containment.

Overflowing of manholes

There has been a concern that overflowing of manholes could cause a direct release of non-sterile effluent either waterborne or aerosol. The potential for this has been investigated further. In almost all of the manholes there is evidence of levels of water spreading up the benching, indicating a history of backing up of the system. In some areas this may lead to the possibility of leakage though the brickwork structure of the manholes, which have been observed to have questionable leak tightness (see Figure 16). Of more concern, however, are the rather peculiar arrangements around the Merial discharge line connection into the IAH drainage system.

The discharge line from Merial rises on a steady gradient, before entering manhole FM1. This manhole is very shallow, around 300 mm deep. From FM1, there is a short, near vertical drop into the line from manhole F10 to FM2. The discharge rate from single pump operation from the Merial sump is 25 000 litres/hour, or 7 litres/second. This is a considerable volume for foul drainage of 100 mm diameter. We have undertaken some CFD analysis of the arrangement to try and understand the likely behaviour, both in normal and fault conditions, eg with pre-existing water and/or a partial blockage. The findings from the studies undertaken follow.

Flow rate 25 000 litres/hr

- At this pumping rate, the manhole FM1 is not predicted to overflow if the drainage system is initially empty when the pump is started.
- The surface roughness of the pipe walls does not seem to have much effect on the flow behaviour. Similarly, predictions were obtained with the internal surfaces of pipes having a roughness of 0.25 mm or 1.0 mm, equivalent to cast iron or concrete surfaces respectively.
- The manhole FM1 is also not predicted to overflow even if there is a significant level of water initially within the drainage system when the pump is started. An initial water level up to 200 mm below the manhole cover did not produce any overflow.
- The manhole will overflow if there is no significant flow allowed through the drainage system, eg if the flow is blocked so that there is standing water within the sewers and the system acts like a very large manometer.

Flow rate 50 000 litres/hr

- The manhole FM1 will overflow at this higher pumping rate even if the drainage system is initially empty.
- The time taken for it to overflow is reduced if there is initially some level of water within the system.
- For an initially empty system, the manhole was predicted to start overflowing after around two and a half minutes; for a system with an initial level of water up to 400 mm below the manhole cover, it was predicted to overflow in less than one and a half minutes.
- The second, deeper manhole (F10), which is connected to the main sewer pipe, was not predicted to overflow in either case.

The predictions for the lower flow rate accord with anecdotal information from discussions with site personnel who confirmed that during normal pumping operations, there is some back-up into manhole FM1, however, there is no overflowing. Clearly, the above are theoretical predictions and to gain full confidence a physical simulation would be needed, however, it gives a strong indication that the arrangement is a poorly thought out detail.

Production of aerosols

To produce aerosols, there needs to be a process where droplets of liquid are created, small enough to be readily airborne. For example, where a pinhole is created in a pressurised system the flow regime at the nozzle initiates the formation of fine droplets.

Considering the situation in manhole FM1, the driving force is the impulse provided by the Merial sump pumps. Simple calculations suggest that the water will be entering the manhole with a velocity of around 1 m/sec, where due to the sudden presence of a phreatic surface, there will be some departure from essentially lamellar flow and turbulence will ensue. In a non-technical sense, this could be viewed as splashing and sloshing around in the manhole. After the initial impulse, some backing up will occur, and the inlet to FM1 will become submerged, resulting in a relatively stable surface demonstrating a churning type motion.

Any droplets formed in these processes are likely to have been relatively large, probably a few hundreds of microns to a few millimetres in diameter. Since the atmosphere within the sewer system was humid, evaporation is unlikely to have reduced the size of the droplets substantially. Other aerodynamic forces on the droplets that might have caused them to break up were also relatively insignificant. Droplets of a few hundred microns would not have stayed suspended in the air for long periods and would have fallen out of the air relatively quickly.

The mechanics of sprays are complex and at this stage it cannot be established beyond doubt that an aerosol of finer droplets did not form. The presence of surfactants in the effluent, for example, could have led to a reduction in the size of the droplets. To determine whether an aerosol could form in the sewer system it would be necessary to undertake some experiments using a physical mock-up of the system.

Buried sumps

A review of the buried water retaining structures has shown that there is currently little confidence that they are fully watertight structures. However, structures such as these are more prone to leakage with depth, and may not have the same levels of transmissible materials around their perimeters. In addition, the development of small-scale cracking in structures which passes water can self heal through autogenously healing. Under some circumstances, the hairline cracks that develop in concrete can repair themselves through reactions with constituents in the water. If the chemistry is favourable, the cracks fill with deposits, preventing access of water.

Given the evidence to date, it is considered that the risk of release of contaminated effluent from pipework is much more of a concern than that from the buried sumps.

Comparison with standards

Defra have commented that the drainage systems should be compatible with their own guidance – Containment requirements for laboratories to be licensed to handle Defra Category 4 pathogens under the Specified Animal Pathogens Order 1998.⁶ The key section is 'Laboratory siting and structure', which is repeated below:

- 1 Whereas the laboratory need not be physically separated from other laboratories it should not be sited next to a known fire hazard (eg the solvent store) or be in danger of flooding.
- The laboratory should be isolated by an air lock and provided with a suitably placed shower. Air locks and rooms must be ventilated by an exhaust air system. The air pressure in the laboratory should be monitored and displayed both within and immediately outside the laboratory. The laboratory should be maintained at a differential negative pressure of 75 Pascals (Pa) (0.3 inches or 7.6 mm water pressure) to ambient. An alarm should sound if the air pressure falls below this.
- 3 The exhaust air must be filtered before discharge through two HEPA filters. The system must include a device to prevent back flow through the filters. The air intake should be protected by a single HEPA filter in case of power failure.
- 4 The laboratory must be sealable so as to permit fumigation.
- The laboratory must be proofed against entry or exit of animals or insects. This is particularly important in the case of diseases which can be spread by insect vectors.
- 6 Effluent should be sterilised by a procedure known to kill the relevant pathogens. This procedure must be confirmed as having operated satisfactorily before the effluent is discharged to the public sewer, eg if heat sterilisation is to be used, temperature recording facilities should be provided to monitor the process. Since sterilisation and tests may take some time, it may be necessary to have more than one standing tank if work is to be carried out continuously. The standing tank(s) and recording equipment form parts of the facilities of the laboratory, so the Safety Officer is responsible for ensuring their proper functioning.

To apply this to drainage, some interpretation needs to be applied. However, it is clear that the pipework at the Pirbright site does not comply with these requirements for the following key reasons because the system is not:

- demonstrably leak proof;
- airtight, or negatively pressured;

- proofed against ingress and egress of insects, as evidenced by the large volume of spiders' webs in the pipework; or
- isolated from flooding.

The condition of the pipework does not meet the standards of installation that would be expected of current British Standards for workmanship (BS 8000-14:1989).³ The standard is intended for foul drainage and not specifically for fully contained drainage. In addition, it is considered that the pipework would fail the standard pipeline soundness testing identified in the above standard and in BS EN 1610.²

Site drainage characteristics

Site setting

The site is located in a broad valley bottom area at an elevation of between 35 m and 40 m AOD. The site is relatively flat in nature with a gentle slope from east to west. The site is bounded to the west and south by a small stream (the Stanford Brook) which runs in a southerly direction, before turning east and heading towards the sewage works located between Bullswater Common and Merrist Hill (see Figure 12).

Site geology

The site is underlain by the Lower Bagshot beds, which are a series of sands and clays of shallow-water origin, some being fresh water, some marine. They belong to the upper Eocene formation of the London and Hampshire basin. The lower division consists of pale yellow, current-bedded sand and loam, with layers of pipe clay and occasional beds of flint pebbles. During the site inspection, material which had been excavated on site was examined and found to be consistent with this description.

Drainage paths

The primary run off from paved areas on the site enters surface water drains, which either discharge into the public sewer (Merial site), or into the surface water facility on the IAH site. Groundwater will tend to migrate naturally towards the Stanford Brook, which forms the western and southern boundary of the site, through natural percolation and run off, dependent on the levels of extant saturation when rainfall occurs.

When inspecting the site, it was observed that there was pooling around various areas of the site, and it was three to four days since it had rained. In addition, there are a series of excavations on site which showed varying levels of water within them. This is consistent with the expected behaviour of material that contains elements with highly variable permeability.

It should also be noted that the presence of gravel bedding around engineered effluent or surface water drains will act as a conduit for ground water by virtue of its greater porosity. This may lead to the drainage routes acting as inadvertent land drainage.

Flooding history

The Environment Agency has undertaken some flood risk studies and has published them on their website. Figure 12 shows their predictions for flooding in an approximate 1 in 75 year event. This shows lower sections of the site potentially inundated as a result of the Stanford Brook levels rising, however, the inundation is limited in inactive areas of the site.

During extreme rainfall, eg on 20 August 2007, there was some localised site flooding, for example, on the Merial yard, where the failure of the surface water drains to cope led to depths estimated at up to 100 mm on a concrete yard area. There is no evidence of flooding affecting contained facilities.

Off-site discharge

The issue of a direct path from the Stanford Brook to the first infected premises (IP1) has been extensively debated. It is clear that from a drainage perspective, the normal routes away from the site run easterly, and not southerly. In addition, there is a 5–10 m difference in elevation between the Pirbright sight and IP1. These two individual factors essentially rule out this possibility, but collectively confirm it as a non-viable theory.

Conclusions

A brief study has been undertaken of key aspects of the effluent drainage systems at Pirbright and their potential to act as containment against the release of animal pathogens. This study has been a mixture of physical inspections, review of drawings, discussions with dutyholders and analysis of effluent flows. The key conclusions are:

- The existing effluent drainage system is not considered adequate as a containment against the release of animal pathogens.
- The existing effluent drainage system does not meet the requirements for Defra Level 4 containment.
- There is a strong possibility that contaminated material has leaked from the buried pipework, and into the surrounding ground. The subsequent transmission of this material may have been exacerbated by the porous nature of the surrounding medium.
- The arrangements for discharge of the Merial sump into manhole FM1 leave the potential for overtopping of the manhole and release of material, dependant on the extant flow rate in the discharge line, and the number of pumps operating.
- There is some evidence that some foul drainage may be discharging into the surface water lagoon, and this should be further investigated.

References

- 1 BS EN 295-3:1991 Vitrified clay pipes and fittings and pipe joints for drains and sewers. Test methods British Standards Institution
- 2 BS EN 1610:1998 Construction and testing of drains and sewers British Standards Institution
- 3 BS 8000-14:1989 Workmanship on building sites. Code of practice for below ground drainage British Standards Institution
- 4 HSL DVD of CCTV drain survey
- 5 BS CP 2010-2:1970 Code of practice for pipelines. Design and construction of steel pipelines in land British Standards Institution
- 6 Containment requirements for laboratories to be licensed to handle Defra Category 4 pathogens under the Specified Animal Pathogens Order 1998 DEFRA www.defra.gov.uk/animalh/diseases/pathogens/category4.htm

Corrosion 7 Root penetration | Water ingress 7 7 7 7 7 7 7 7 Diameter (mm) | Joint misalignment | 7 7 7 7 7 7 7 7 7 7 7 7 150 150 150 150 150 100 150 100 150 150 150 Vitrous clay/Cl Vitrous clay Material Plastic FW insectory FW insectory FW insectory Downstream A barn from manhole Weir FN3 FN3 FN4 FN3 Ę Z F2 မ Weir through FN5 through Hall Road towards FN2 Hall Insectory sump Approx RA wall From upstream crossing North Road crossing Downstream Upstream ETP valve Upstream Junction to F2 Section No | From FN4 Weir FZ FZ 9 7 = က 0 \sim 2 9 ∞ 4

 Table 2
 Summary of features found in CCTV survey

Table 3 Detailed comments on CCTV footage

Section	Distance (m)	Feature	Comments
1	General	Deposits on pipe of limestone/fat, varying from minor to almost complete and standing water	Suggests low flow rates and/ or pipework was laid to low gradients, or stagnation of water has occurred in past
1	1.1 6.6	White feature penetrating roof	May be a limescale deposit, possibly indicative of leakage into pipe
1	9.9	What appears to be some gelatinous material at a pipe joint	Origin unclear, may be some sealing compound leaking into pipe
1	15.1	Possible joint misalignment	Appears to be a pipe joint set at an angle
2	General	Dry, and light staining	Plastic pipe is more difficult for limescale to gain a purchase onto, hence better appearance
2	13.2	Intersection of pipes is heavily stained and marked by limescale/fat	
3	General	There is c 20 mm of stagnant water in the pipe. Deposits and discolouration vary along pipe from mild to extensive. In some placed yellow nuggets are found c 20 mm in size	Suggests low flow rates and/ or pipework was laid to low gradients, or stagnation of water has occurred in past
3	21	Possible joint misalignment	Appears to be vertical disruption at joint
3	38	Transect shows heavy limescale build up	
3	47	Yellow/white deposits on crown of pipe	Difficult to interpret, could be calcified tree roots
3	48	Limescale/fat on roof	May indicate leakage into crown of pipe of local groundwater and deposition of limescale
4	General	Generally good condition, minor limescale build up. Low levels of stagnant water	
4	9.9	Possible joint misalignment	Appears to be a pipe joint set at an angle
5	General	Images are difficult to see. There appears to be some discolouration and limescale, and a fair degree of stagnant water	Difficult to see the condition of joints in detail, but no gross distortions or collapses

Table 3 Detailed comments on CCTV footage

Section	Distance (m)	Feature	Comments
6	General	Thick, black sludgy deposits on base of pipe at start for 2–3 m, and stagnant water. Thereafter generally clean	
6	1.7	Possible joint misalignment and crack	Appears to be a pipe joint set at an angle
6	2.1	Possible joint misalignment	Appears to be a pipe joint set at an angle
6	13.5	Possible joint misalignment	Appears to be a pipe joint set at an angle
6	31.5	Apparent root penetration at crown	Relatively low-level penetration
6	45.6	Root penetration and joint displacement	C half of pipe circumference shows root penetration
6	48	Root penetration	C half of pipe circumference shows root penetration
6	51	Root penetration and joint displacement	Heavy root penetration extending 500 mm down pipe
6	51.7	Apparent joint damage as bend section joins straight	Difficult to be absolute, but looks like a joint which has been set wide, and is now filled with limescale
7	General	Pipe is heavily discoloured, and has extensive limescale/ fat deposits on the crown which are worse adjacent to pipe joints over first 15 m. Then onwards, relatively clear	It appears that ingress of water from outside sources may have caused limescale build up on the crown of the pipe
7	0.7	Pipe deviates in direction vertically, joint displaced	This is a poor construction detail
7	40	Possible joint misalignment	Appears to be a pipe joint set at an angle
7	41.3–41.7	On crown of pipe, white lines, which may be limescale /fat which has developed in cracks in pipe	Difficult to be absolute, but appears to indicate cracks in pipe
7	42	Green vegetation in pipe	Unsure of origin, but looks as if it has been dragged into pipe or dropped in.
7	43.3	Apparent root penetration at crown	Relatively low-level penetration
7	43.9	On crown of pipe, white lines, which may be limescale /fat which has developed in cracks in pipe	Difficult to be absolute, but appears to indicate cracks in pipe

Table 3 Detailed comments on CCTV footage

Section	Distance (m)	Feature	Comments
7	45	Evidence of tree roots	Origin unclear
8	General	Generally clean condition	
8	0.4	Poorly aligned joint	Very short length of pipe inspected in this section
9	General	Clean and good condition	
9	23.3	Lip at pipe joint	Minor vertical misalignment
9	28.7	Lip at pipe joint	Minor vertical misalignment
10	General	Initially clean and good condition, then further down line, grit and pebbles within the pipework	Origin of grit and pebbles unknown
10	0.9	White thin strip material protruding from base of pipe	Unclear, but this may be a displaced seal from the joint which has become covered in limescale
11	General	Difficult to interpret until layout better understood, however there are steel or iron sections with a fair degree of surface corrosion and pitting section	Level of pitting and remnant integrity of pipework difficult to gauge from camera footage
12	General	Discoloured pipework, and detritus present, lumps up to 20 mm observed. Images partially obscured when camera is underwater	
12	1.8	Possible joint misalignment	Appears to be a pipe joint set at an angle
12	9.3	Very sharp turn in pipe, not achieved by use of a bend	Poor detailing of pipe layout
12	10.1	Joint misalignment	Pronounced joint misalignment
12	11.3,24.3	Possible circumferential crack	
12	31.5	Joint misalignment	Appears to be a lateral offset

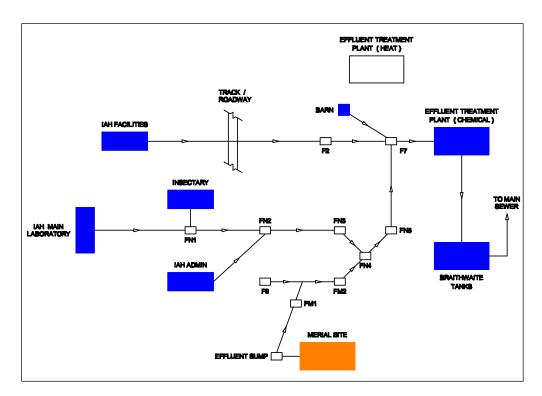


Figure 8 Schematic of effluent drainage system

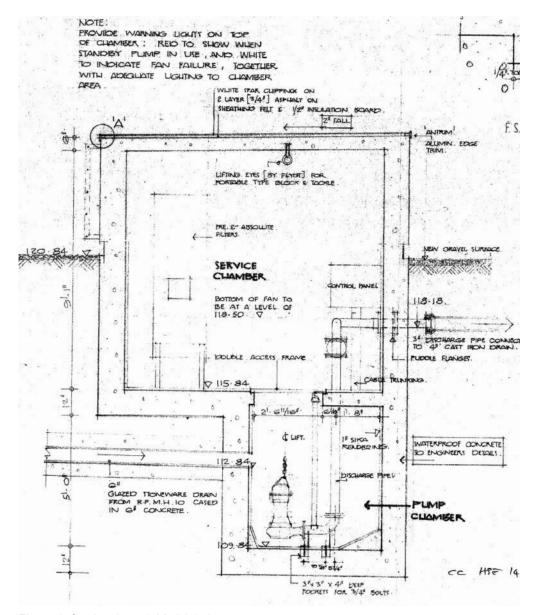


Figure 9 Section through Merial drainage sump

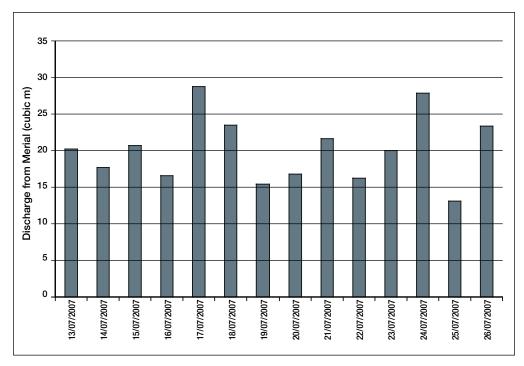
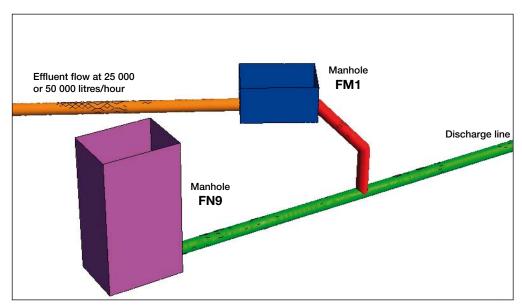


Figure 10 Discharge volumes from the Merial sump



 $\begin{tabular}{ll} \textbf{Figure 11} & \textbf{CFD} & \textbf{model of Merial discharge line connection to manhole FM1 and downstream connection} \end{tabular}$

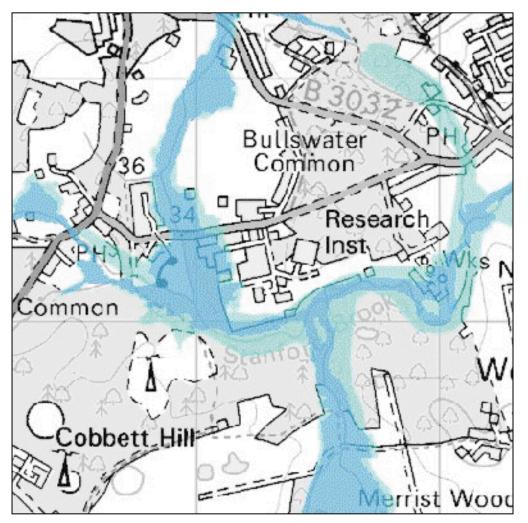


Figure 12 Environment Agency flood map showing extreme levels of flood



Figure 13 Cast iron discharge main from Merial sump

(a)

(b)



Figure 14 Manhole FM1





Figure 15 Connection point of discharge line from FM1 to main IAH northern line (a) view from main line (b) view from FM1



Figure 16 Manhole FM2 showing damaged mortar joints



Figure 17 Manhole FN4 showing damage around invert opposite Merial feed



Figure 18 Discharge line from effluent treatment plant to Braithwaite tanks



Figure 19 Typical pipe misalignment at a joint and crack damage



Figure 20 Root penetration into pipe-displacement of joint and cracking of rear pipe also visible



Figure 21 Heavy root penetration into pipe

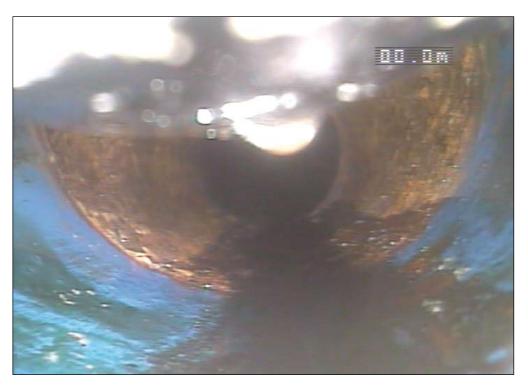


Figure 22 Heavy corrosion on the cast iron section adjacent to the ETP valve

Observations during the site inspection of the Institute for Animal Health, Pirbright Laboratory, Pirbright, Surrey by the Environment Agency on the 6 August 2007 based on discussion with the site engineering and maintenance staff (E&M) and site inspection

The site foul water system is separate from the surface water system on site. A trade effluent foul outlet pipe runs from the Merial block and connects into the foul system that runs from the Institute for Animal Health (IAH) block to the treatment installation on site. From there it flows to holding tanks for a 24 hour period before being sent to the pipe that conducts treated water to the Hockford, Thames Water Sewage Treatment Works. The foul system appears mainly to consist of small diameter cast iron pipework of 4" in diameter leading to 7" diameter and in places is encased in concrete. The drainage system or part of it appears to have been CCTV surveyed in 2002. In discussion with the engineering and maintenance (E&M) staff they stated that they could not absolutely guarantee the integrity of the pipework against joint leakage or hairline fracture, nor could they guarantee that there may be unplugged historic connections to now demolished buildings.

A significant concern on site during inspection was the presence of lightweight unsealed manhole covers on the trade effluent foul drainage system prior to the trade effluent treatment installation. In discussion the E&M staff stated that there was significant surface water on the site and in the area of these manhole covers on the 20 July 2007 and for the following 24 hours. This surface water is likely to have entered the trade effluent foul drainage system. The E&M staff stated that the trade effluent foul water system was in danger of becoming overloaded, so they asked Merial and their laboratories on site to cease flow into the trade effluent foul system. On the likelihood that surface water did enter the trade effluent foul system at these manholes or other points then it could be the case that contaminated water escaped at these points also. It is recommended that the area of land surrounding the trade effluent pipe before the treatment plant and where the trade effluent cast iron pipe runs through the open excavation adjacent to the Merial building, be checked for contamination.

It is highly unlikely and probably impossible that contaminated water was conveyed by the flood water from the IAH directly to the infected area at Normandy.

The disposal of waste soil and spoils arising from recent construction work on site was investigated. The waste transfer notes from a contractor responsible for works on the roads and car-parking at site were obtained: these related to five loads of topsoil removed from site on 26 July 2007. The contractor that removed this material confirmed that these loads were taken to recycling facilities in Compton (near Guildford) and Farnham. Another contractor carrying out work on the site's drainage did not remove any material from site, either stockpiling it or directly re-using it elsewhere.

A licensed soil screener on Glaziers Lane, Normandy was checked. They have not received any material recently, concentrating instead on processing materials already on-site.

Glossary

Advisory Committee on Dangerous Pathogens (ACDP) 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

aerosol A suspension or dispersion of fine particles of a solid or liquid in a gas. In this context an aerosol will contain viruses

airborne transmission Microorganisms showing the ability to be transmitted through aerosols are considered to be airborne

amino acid change Amino acids are the building blocks of proteins, which are defined by their unique sequence of amino acid residues. There are 20 amino acid residues. The substitution (change) of one amino acid for another in a protein can affect the protein's structure and function

animal pathogen Any organism which may cause disease in animals or poultry

autoclave A machine used to sterilise equipment or other objects by a combination of steam and pressure. This means that all bacteria, viruses, fungi and spores are killed

biosecurity The implementation of a combination of containment measures and working practices, supplemented by management controls, to prevent the inadvertent exposure of susceptible species to biological agents and their distribution in the wider environment

Biotechnology and Biological Sciences Research Council (BBSRC) BBSRC is the UK's leading funding agency for academic research and training in the non-clinical life sciences

CSL Central Science Laboratory. A public sector science organisation providing research and information services to governments and industry

Defra Department for Environment, Food and Rural Affairs. Defra is responsible for environmental protection, food production and standards, agriculture, fisheries and rural communities in England and Wales

disc stack centrifuge The disc bowl type centrifuge is designed to separate either a solid/liquid, liquid/liquid or liquid/liquid/solid suspension on a continuous basis. Solids settle on the wall of the bowl and are discharged by intermittent opening of the bowl. The disc stack greatly increases the effective settling/clarification area, and the liquid and solid phases travel up or down the disc surfaces. The liquid discharges through one or more paring discs

disinfection A process of reducing the number of viable microorganisms by various physical and chemical means

enzyme-linked immunosorbent assay (ELISA) Biochemical technique used mainly in immunology to detect the presence of an antibody or an antigen in a sample. ELISAs are used as a diagnostic tool in medicine

Environment Agency The leading public body for protecting and improving the environment in England and Wales. The Environment Agency carries out government policy, inspecting and regulating businesses, and reacts when there is an emergency such as a flood or pollution incident

epidemiology The study of factors affecting the health and illness of populations. The work of communicable and non-communicable disease epidemiologists ranges from outbreak investigation, to study design, data collection and analysis

EU Directive 91/412/EEC Directive laying down the principles and guidelines of good manufacturing practice for veterinary medicinal products whose manufacture requires the authorization referred to in Article 24 of Directive 81/851/EEC (concerning veterinary medicinal products)

GENBANK The US National Institute of Health (NIH) genetic sequence database, an annotated collection of all publicly available sequences produced at the US National Center for Biotechnology Information (NCBI) as part of the International Nucleotide Sequence Database

Health Protection Agency (HPA) HPA provides an integrated approach to protecting UK public health through the provision of support and advice to the NHS, local authorities, emergency services, the Department of Health and the devolved administrations

HEPA filter High efficiency particulate absorption filter. Filter efficiency required for biological containment systems is >99.997%, eg a H14 filter as defined in BS EN 1822-1:1998

HSE Health and Safety Executive. The Health and Safety Commission is responsible for health and safety regulation in Great Britain. The Health and Safety Executive and local government are the enforcing authorities who work in support of the Commission

HSL Health and Safety Laboratory. HSL is an executive agency of the Health and Safety Executive, providing operational support to HSE through its involvement in incident investigations and studies of workplace situations

Institute for Animal Health (IAH) IAH is the major centre in the UK for research on infectious diseases of livestock. IAH carries out basic, strategic and applied research into infectious diseases of large animals and poultry

microbiological safety cabinet A ventilated enclosure intended to offer protection to the user and the environment from aerosols generated when handling biological agents

Inactivation Living microorganisms are rendered non-viable/non-living

negative pressure (related to containment) A requirement to maintain a negative pressure relative to atmosphere. Atmosphere in this context may be taken to mean the external air and/or other parts of the laboratory. Requires engineering controls such that there is a continuous inward airflow into the laboratory, measured in Pascals

nucleotide Structural units of DNA and RNA

RNA Ribonucleic acid or RNA consists of nucleotide monomers that play several important roles in the processes that translate genetic information from deoxyribonucleic acid (DNA) into protein products. RNA acts as a messenger between DNA and the protein synthesis complexes and acts as an essential carrier molecule for amino acids to be used in protein synthesis

SAPO Specified Animal Pathogens Order 1998. Licences under SAPO 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 people responsible for supervising the work. Specified animal pathogens are classified into four categories by Defra. Category 4 pathogens are subject to particularly stringent controls

sequencing DNA sequencing is the process of determining the nucleotide order of a given DNA fragment

sterilisation A process which renders an item free from all living organisms

sterile A state of being free from viable (living) microorganisms

sump A low space that collects an often-undesirable liquid(s), such as water or chemicals

VMD Veterinary Medicines Directorate (Defra Executive Agency). VMD aims to protect public health, animal health, the environment and promote animal welfare by assuring the safety, quality and efficacy of veterinary medicines

VP1 gene Encodes Viral Protein 1, a FMD virus surface coat protein. Antibodies against VP1 can be detected in infected animals

VP3 gene Encodes Viral Protein 3, a FMD virus surface coat protein. Antibodies against VP3 can be detected in infected animals

water bowser (Usually mobile) water tanks used to distribute water. Usually used where the normal system of piped distribution has broken down or is insufficient