

# **Initial report on potential breaches of biosecurity at the Pirbright site 2007**

**Health and Safety Executive**

## **Background**

- An outbreak of foot and mouth disease virus (FMDV) was confirmed at a farm in Surrey on 03/08/07.
- Preliminary Defra investigations indicated that the virus may have originated from the Pirbright site at which two separate organisations are based: the Institute for Animal Health (IAH) & Merial Animal Health Ltd (Merial).
- A multidisciplinary cross-government team with representatives from HSE, Defra, the Veterinary Medicines Directorate (VMD) and the Environment Agency (EA) supported by others, conducted on-site investigations on 05/08/07, 06/08/07 & 07/08/07.
- This initial report outlines the investigation's key lines of inquiry and the next steps planned as of 07/08/07.

## **Purpose of the investigation**

The Health and Safety Executive (HSE) was asked by the Government to lead a team to investigate any potential breaches of biosecurity at the IAH and Merial sites; whether such breaches may have led to a release of any specified animal pathogen and whether any such breaches had been rectified to prevent future incidents. A multidisciplinary team was assembled with expertise in a wide range of relevant areas, including in investigation; in working with highly infectious viruses; in engineering control systems relevant to containment; in veterinary medicine production; and in management systems for controlling risk and environmental protection issues.

## **The legal position**

The primary legal requirement applying to the site is the Specified Animal Pathogens Order 1998, enforced by Defra, which requires licensing of work with FMDV. HSE's primary remit is to regulate the health and safety of staff at IAH and the Merial sites and to regulate (jointly with Defra) human health and environmental risks from work involving genetically modified organisms (GMOs) at the IAH.

## **What we did**

- We concentrated on biosecurity issues associated with FMDV strain O1BFS67 as this was the strain associated with the outbreak
- We concentrated on the timeframe between 14 and 25 July 2007 as this was advised by Defra to be the most likely period of infection
- We investigated whether or not this strain was in use at the IAH and Merial sites in that timeframe and the precise nature of any activities undertaken
- We investigated whether or not there had been any lapses in control measures which could have led to a breach in biosecurity and whether these could be linked to the outbreak.

To do this we carried out inspections of all facilities of both the IAH and Merial sites where the FMDV strain is handled. This involved checking key biosecurity measures including engineering controls, management systems, working practices and a review of the record logs. We reviewed documents, interviewed staff and visually inspected all the facilities.

### **What we found**

The following key lines of inquiry were investigated:

#### Identifying the virus strain

- We confirmed that the FMDV strain found at the outbreak farm was being worked on at both organisations at both the IAH and Merial sites during the period between 14 and 25 July 2007. This involved large scale production at the Merial site (10,000 litres) and a series of small scale experiments (less than 10 millilitres in each case) at the IAH site.
- We have initiated further studies intended to provide additional molecular information on the virus types in use at both organisations. This requires detailed technical analysis and the results are not available for inclusion in this report but are expected within a week.

**Subject to the ongoing work detailed above, the indications are that there is a strong probability that the FMDV strain involved in the farm outbreak originated from the IAH or the Merial sites.**

#### Potential for airborne release from the site

- 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 FMDV strain within the contained working environment at either organisation.
- We confirmed that all air being discharged to atmosphere from the contained working environments is first passed through a minimum of two High Efficiency Particulate Arrestance (HEPA) air filters.
- We confirmed that there is continuous monitoring of the pressures of the ventilation systems of the facility and that the HEPA filters are routinely integrity tested in line with regulatory requirements.
- Examination of local wind conditions for the period indicates that there was only a very limited period during which the wind could have acted as a transmission link. This would have had to coincide with a release of virus through the ventilation system. We found no evidence of such a release.

**We are further exploring the meteorological data, but at this stage, we consider there to be a negligible combined likelihood that there was an airborne release from the IAH**

**or the Merial sites which was subsequently transferred to the first affected farm between the 14 and 25 July 2007.**

Potential for waterborne release from the site

- We established that two separate effluent treatment systems exist on Pirbright site: one that services the animal isolation unit at the IAH; the second services both the remainder of the IAH site together with the Merial site.
- We established that the effluent treatment system servicing the IAH animal isolation unit employs a thermal inactivation process. There was no evidence of it operating unsatisfactorily between the 14 and 25 July 2007.
- We established that the effluent treatment system servicing the remainder of the IAH site together with the Merial site employs a chemical inactivation process. Whilst control measures are in place at both premises to require chemical treatment of liquid effluent before it enters the system, a number of biosecurity issues have arisen which are subject to ongoing investigation.
- These include:
  - the integrity of the system and all associated pipework;
  - the potential for the FMD Virus to have entered this system during the specified time period;
  - whether heavy rain and flooding during the period may have overwhelmed this system;
  - whether any contaminated material could have been transferred between the IAH and Merial sites and the first affected farm.
- For virus to have escaped from the effluent pipe, this would have required a failure in the intermediate inactivation process either at the Merial or IAH site and this would have had to coincide with the flooding.

**Waterborne release onto the site remains a possibility. But preliminary investigations into the possibility of whether surface water from flooding from the site could have reached and contaminated the affected farm have indicated that this was negligible due to the distance, topography and direction of flow. These issues are being investigated further.**

Potential for release from the site by human movements

There are various potential routes for accidental or deliberate transfer of material from the site. We have investigated site management systems and records and spoken to a number of employees. As a result we are pursuing lines of inquiry.

**Release by human movement must be considered a real possibility. Further investigation of the above issues is required and is being urgently pursued.**

**The next steps**

We will continue with our work and report further as necessary. This report also provides a basis for the independent review of biosecurity arrangements to be led by Professor Spratt of Imperial College. We are briefing Professor Spratt and his team and will also offer him continuing support.