

Foot and Mouth Disease

Government Statement in response to investigations into
the probable release of FMD virus from Pirbright

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Introduction

1. It is 35 days since Foot and Mouth Disease was confirmed in cattle in Surrey on 3 August 2007. In that time, the outbreak has been contained, the Protection Zone and national movement ban lifted and trade within the EU resumed outside of the surveillance zone on 25 August. We are also on the way to regaining international disease free status. This would not have been possible without the partnership between government (including the Devolved Administrations), farmers, food businesses and the local community.
2. Any outbreak of animal disease is serious and as a result of this outbreak farmers have incurred the loss of their animals and considerable disruption. This is why we must learn the lessons from any outbreak, as we did in 2001, and Iain Anderson will be carrying out a review of how these lessons were applied in handling this outbreak.
3. The Government commissioned two reviews when laboratory tests revealed that there was a possible link between the outbreak of Foot and Mouth Disease and the Pirbright site. The HSE was asked to investigate biosecurity at the public and private laboratory premises at Pirbright and Professor Brian Spratt to examine the biosecurity arrangements in place. We are publishing these today, as well as the correspondence referred to in the HSE and Spratt reports. The Government is accepting all the recommendations made by both reports. We are also publishing the latest report of the National Emergency Epidemiology Group.
4. This statement sets out the steps which the Government has already taken in relation to the issues addressed in the reports. It also outlines the further actions which will be taken to address the findings and the recommendations of both reports.
5. The Government would like to thank all those involved in the investigations and the resulting reports for their professionalism, thoroughness and speed of work. We would like to express particular gratitude to Professor Spratt and his colleagues for the expertise that they have put at the service of the public in carrying out their review. Finally, the Government would like to thank the farming and rural communities for their unrelenting vigilance, co-operation and forbearance throughout this difficult time.

Background

6. The reports published today indicate that the cause of the outbreak was almost certainly the escape of live virus from Pirbright – most probably in the period immediately following 20 July. The virus was in use by three parties on the Pirbright site at the time when the release occurred: the Institute for Animal Health (IAH), a research institute sponsored and grant-aided by the Biotechnology and Biological Sciences Research Council (an Non-Departmental Public Body, (NDPB) of the Department for Innovation, Universities and Science), which owns the land and buildings on the Pirbright site; Merial Animal Health Limited and Stabilitech Limited (both private companies). Stabilitech rents 300 square feet of laboratory space within the main IAH laboratory and comes under the conditions of the Specified Animal Pathogens Order (SAPO) licence issued to IAH. IAH is responsible for ensuring that the requirements of SAPO are implemented and this includes occupants of areas that may be subject to sub-letting arrangements. The reports are inconclusive as to which of these parties' operations may have been the origin of the release.

7. The precise means by which the escape occurred cannot be established beyond doubt – as Professor Spratt says: “identifying the source of an outbreak of this kind with any certainty is always likely to be inconclusive”. The Health and Safety Executive investigation and the epidemiological report find that the likeliest explanation is through accidental release from the drainage system, which was found to be no longer in good repair. The drainage system connects the vaccine production plant to the sodium hydroxide treatment tanks used for waste inactivation on another part of the Pirbright site. Localised flooding caused by the heavy rains on 20 July and further relatively high rainfall on 21/22 and 23/24 July may have resulted in effluent escaping from the system and gaining access to the surface soil. It is likely that soil contaminated by the escape was then transported on the wheels and wheel arches of construction vehicles which left the site and drove past the track leading to the first farm that became infected with the Foot and Mouth virus.

8. The HSE investigation provides a thorough assessment of the integrity of the drainage system and other facilities and control systems on the Pirbright site, as well as the management systems in place to assure the safe handling of pathogens. Professor Spratt’s report analyses the HSE’s evidence and makes a number of recommendations in relation both to Pirbright itself and the wider framework of pathogen regulation and control in laboratories.

9. In acting on these reports, the steps the Government has already taken and the further steps that we are announcing today have two main objectives. We have been determined, first, to ensure that action was taken immediately to address any further risk of virus escape from Pirbright and, secondly, to address any wider implications for biosecurity arrangements governing the use of animal viruses and pathogens and the manufacture of vaccines in the United Kingdom (UK).

Action taken in relation to Pirbright

10. A number of steps have already been taken. As soon as the virus strain was identified on 4 August, it became evident that Pirbright was a potential source of the outbreak. A single Protection Zone was created encompassing both the infected farm premises and the Pirbright site, within a single 10km radius Surveillance Zone. In addition, as an immediate safeguard, Defra and Merial agreed that the use of live virus would be voluntarily suspended by Merial, because of the large quantities involved. That suspension remains in place and has been formalised through a modification of Merial’s SAPO licence for the plant. In respect of IAH, the case for a similar suspension was considered on 4 August and has been kept under active review since then. Our judgement to date, has been that because of the relatively small volumes of live virus handled by IAH and the additional measures which IAH have now taken, as described below, suspension is not justified. That judgement has also been based on ongoing advice from the HSE as to the measures necessary to assure immediate safety of the activities at the facilities.

11. In commissioning the HSE to investigate the potential release, it was agreed that any urgent remedial measures identified by HSE would be brought to Defra’s attention for immediate action. On 8 August, the HSE, having published an initial report on 7 August, duly advised Defra that all construction work at Pirbright should be suspended as a potential biosecurity risk. This recommendation was immediately put into effect and remains in place, except for specific controlled derogations to permit the remedial drainage work described below and to allow essential roadway and steam-main works to proceed.

12. A second recommendation was received from HSE on 17 August. On this date, HSE informed Defra of the results of a survey of the Pirbright drainage system, which revealed that leaks could have occurred from the system. HSE also advised that access to the area potentially infected by such leaks should be restricted. On the same day, therefore, Defra contacted the IAH, which that afternoon put into effect a plan controlling access and strengthening biosecurity measures for movement of people and vehicles. This included strengthened disinfection procedures and increased autoclaving of liquid waste, to ensure that the risk of virus from the laboratories entering the drainage system was reduced to negligible levels. Work also began immediately on restoring the integrity of the drains and manholes concerned.

13. On the same day, Defra, as the body responsible for licensing both IAH and Merial for the use of pathogens under SAPO, commissioned a new SAPO inspection. This was carried out on 21/22 August, the purpose was to assess the work being undertaken to implement the above HSE recommendations and to advise on any further risk mitigation measures needed. The SAPO inspection formally presented its report on 24 August, recommending further biosecurity measures to prevent contamination from the area around the drains. The inspection also recommended that IAH and Merial adopt new protocols for the use of inactivation agents to treat waste and to clarify their respective areas of responsibility and it recommended that Merial test certain of the air filters used in their facility. Recommendations on a number of secondary matters were also addressed in the report of the inspection including clearer restrictions on the movement of objects between the restricted and administrative areas, clearer biosecurity roles and responsibilities and that all surfaces should be able to be easily cleaned.

14. On 24 August, IAH and Merial were instructed to implement the SAPO investigation recommendations and were informed that a further inspection would be carried out to ensure that all necessary measures were in place and all actions taken. That inspection was duly carried out on 5 September and the inspection confirmed that the work had been completed quickly and to a high standard.

15. As a result of the above steps and the advice received from the HSE about the risk of further virus release, the Government is satisfied that the necessary measures are now in place.

The HSE and Spratt Reports

16. The reports by the HSE and by Professor Spratt's team, that we are publishing today, make a number of recommendations in the light of their findings which include that human and vehicle movements at the site were not adequately controlled and that there were a number of breaches of biosecurity. They recommend a review of the full range of biosecurity measures and procedures at the Pirbright site and also consider the wider context of animal pathogen regulation in the UK. In the light of a number of detailed findings about the management of biosecurity at Pirbright, recommendations and observations are also made on the role of government in relation to Pirbright and other similar establishments.

17. The Government has accepted all of the recommendations of both reports which are directed at the Government. But, as this statement makes clear, we have decided to go beyond these recommendations in requiring sterilisation of all waste in a high containment area, by undertaking to carry out joint inspections with HSE of Pirbright and arranging an international audit; and by agreeing with IAH that they will carry out a more far reaching review than that recommended by Professor Spratt. Other recommendations are directed at other parties who have also given assurances that they will implement the actions required.

18. In particular, we agree that the way in which animal pathogens are regulated should be reviewed by an independent person to ensure that the reports of the HSE and Professor Spratt set the foundations for a simpler and stronger structure for controlling these substances in future. All the specific recommendations made by the reports about practices at Pirbright will be implemented through improvement plans for both IAH and Merial, which will involve inspections, including unannounced inspections. IAH will also be subject to an expert inspection team set up by the European Commission. We will also ensure that the findings of the reports are addressed by all other laboratories handling high security human and animal pathogens. We are therefore announcing the following steps today:

- I. we agree with the HSE that a **review of the regulatory framework for animal pathogens** should be undertaken. We have asked Sir Bill Callaghan to lead this review and to report by 14 December 2007. The review team will include representatives of Defra and the HSE. In view of the importance to the agriculture sector of animal pathogens regulation, a representative of the farming community will be asked to participate as a member of the review team. The team will also work with all other relevant regulatory and customer bodies;
- II. we agree with the recommendation of Professor Spratt that the **position of Defra as regulator, licenser and inspector of SAPO 4 regulation and as a major customer of animal pathogens research and diagnostics should also be reviewed**. Sir Bill Callaghan's review will therefore address this issue as well;

The terms of reference for the review will be as follows:

The review will take forward recommendations of the HSE's report on potential breaches of biosecurity at the Pirbright site 2007 and Professor Spratt's review of safety of UK facilities handling FMD virus, by making recommendations to Government no later than 14 December 2007 on:

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

- III. as part of the review, the **Advisory Committee on Dangerous Pathogens will be asked to advise the review team on technical matters**, with a view to the production of new guidance on managing animal pathogens in light of the review team's findings;
- IV. in addition to implementing the above recommendations, the HSE and Defra are today issuing a **safety alert advising all HSE hazard group 3 and 4 and SAPO category 3 and 4 laboratories of issues arising from their investigation which need wider dissemination and action**. This will require all such laboratories to satisfy themselves that their facilities and procedures address all the risk issues identified in the Pirbright investigation. HSE will also undertake a programme of inspection that will apply to all human pathogen level 4 laboratories and higher risk level 3 laboratories; all animal pathogen category 3 and 4 facilities in conjunction with Defra; and will carry out similar inspections in conjunction with the Devolved Administrations in relation to laboratories in Scotland and Wales.

Other recommendations by the HSE

19. The action we are taking in response to the other recommendations made to Government by the HSE is as follows:

- I. we agree with the HSE recommendation for a **review of arrangements for setting and monitoring safe operating practices where work is sub-contracted** under a single operating SAPO licence. We will ask the Advisory Committee on Dangerous Pathogens to advise on this matter as part of Sir Bill Callaghan's review of the regulatory framework;
- II. we agree with the HSE that the appropriateness of **chemical treatment for sterilising liquid waste containing Category 4 pathogens should be reviewed**. In particular we will require IAH and Merial to make arrangements which ensure that all such waste is sterilised within a high containment area and we shall not remove the existing licence restrictions until those arrangements are in place. IAH and Merial are cooperating with us to achieve this through additional heat treatment systems and other preventive measures;
- III. we agree that the HSE's concerns about the upper south wing of the IAH laboratory, the filter arrangements in the IAH/Stabilitech facility, the effluent drainage system and associated record keeping, maintenance and monitoring regimes and the control of vehicle and human movement on the IAH site must be addressed. We will immediately start work to prescribe an **Improvement Plan** which will set out the action which IAH must take on all of these issues. This will be subject to inspections which will include an HSE input. We have asked the European Commission to audit the plan and our inspection of it by arranging a visit to Pirbright by an expert inspection team.

Other recommendations by Professor Spratt

20. The action we are taking in response to the other recommendations made to Government by Professor Spratt is as follows:

- I. **Defra should require that actions are taken to ensure the effluent drainage system at Pirbright is fully contained.**
- II. **Merial should discuss with Defra how it plans to modify its procedures to minimise the possibility of release of infectious FMDV into the effluent pipe.**

We agree with both of these recommendations. As indicated above, IAH and Merial are cooperating with us to ensure that all waste potentially containing live virus is sterilised within a high containment area. IAH have already completed relining of the effluent pipes with a polyester lining, blocked off disused drain runs and sealed all manholes.

- III. **IAH should have a thorough review of the safety of all laboratory activities to ensure that procedures which could release infectious FMDV into the containment laboratories are eliminated.** We agree, and believe that IAH should carry out a more far-reaching review of the safety of management procedures for all pathogens. IAH will appoint an independent person to lead the review. The Biotechnology and Biological Sciences Research Council will work with IAH to assist in undertaking the review and applying any findings from it;
- IV. **Entry to any facility handling Category 4 pathogens should require all visitors to sign in, obtain a numbered visitor pass, be escorted into the building and handed over to their host.** We agree. Defra will ensure through revised guidance and licence conditions that this is a requirement for all SAPO 4 facilities and will test compliance as part of the SAPO 4 inspections;
- V. **Defra and the Veterinary Medicines Directorate should work together more closely and exchange information about inspections at Merial.** We agree. Defra and VMD will ensure that all reports and information about GMP and SAPO Inspections is shared. A key part of the review that we are announcing into the regulatory framework will focus on how SAPO inspections are undertaken and how they relate to other inspection regimes including those undertaken by VMD;
- VI. **Construction of the new high containment laboratories at IAH should go ahead as a matter of urgency.** We agree. Following reviews of the services provided by IAH, conducted in 2002 and 2003, the Government committed in 2005 to a new laboratory on the Pirbright site. This £121 million programme will be the biggest investment on the site since it was established in 1924. £31M of this investment has already been spent on a new isolation unit, an Insectary, demolition of some old buildings, upgrading utilities, new security fencing, and further site preparation for the main laboratory which is due to be completed in 2012.

VII. **The plans for future development of the Pirbright site should be reviewed to ensure that all safety critical issues have been addressed.**

VIII. **There should be a review of funding, governance and risk management at IAH Pirbright.** We agree with both of these recommendations, and at all stages of the design of the new laboratories at Pirbright biosecurity issues have been a priority. The Pirbright Site Redevelopment Programme Board which oversees the project (and which includes members from the IAH, the IAH Governing Body, VLA and the funders), will undertake a review of all aspects of the Pirbright site so as to ensure that all safety critical issues have been addressed. It will report its findings to a review body led by BBSRC, an NDPB of the Department for Innovation, Universities and Science, in conjunction with the IAH Governing Body and supported by Defra, and with a representative of the farming community. This review body will also assess and report on the funding, governance and risk management at Pirbright.

21. Finally, we note Professor Spratt's recommendation that "if identifying the source of the virus is considered a priority, an independent group consisting of international experts in the molecular epidemiology of FMD, and in RNA virus molecular evolution" should be convened. There is uncertainty as to whether any further work could conclusively identify the source of the virus. At present we do not believe that it would add to our understanding of the risk mitigation measures that need to be put in place as a result of the Pirbright escape, but that assessment will be kept under review in the light of findings from the other work that we are announcing in this statement.

22. Professor Spratt's report also includes a number of recommendations directed to IAH and Merial themselves. These are recommendations for regular meetings between IAH and Merial; fencing to separate the IAH and Merial premises; separation of the Merial Director and Biological Safety Officer roles; and other steps to clarify the responsibilities of IAH and Merial. These recommendations have been brought to the attention of IAH and Merial who have committed to implement all of them.

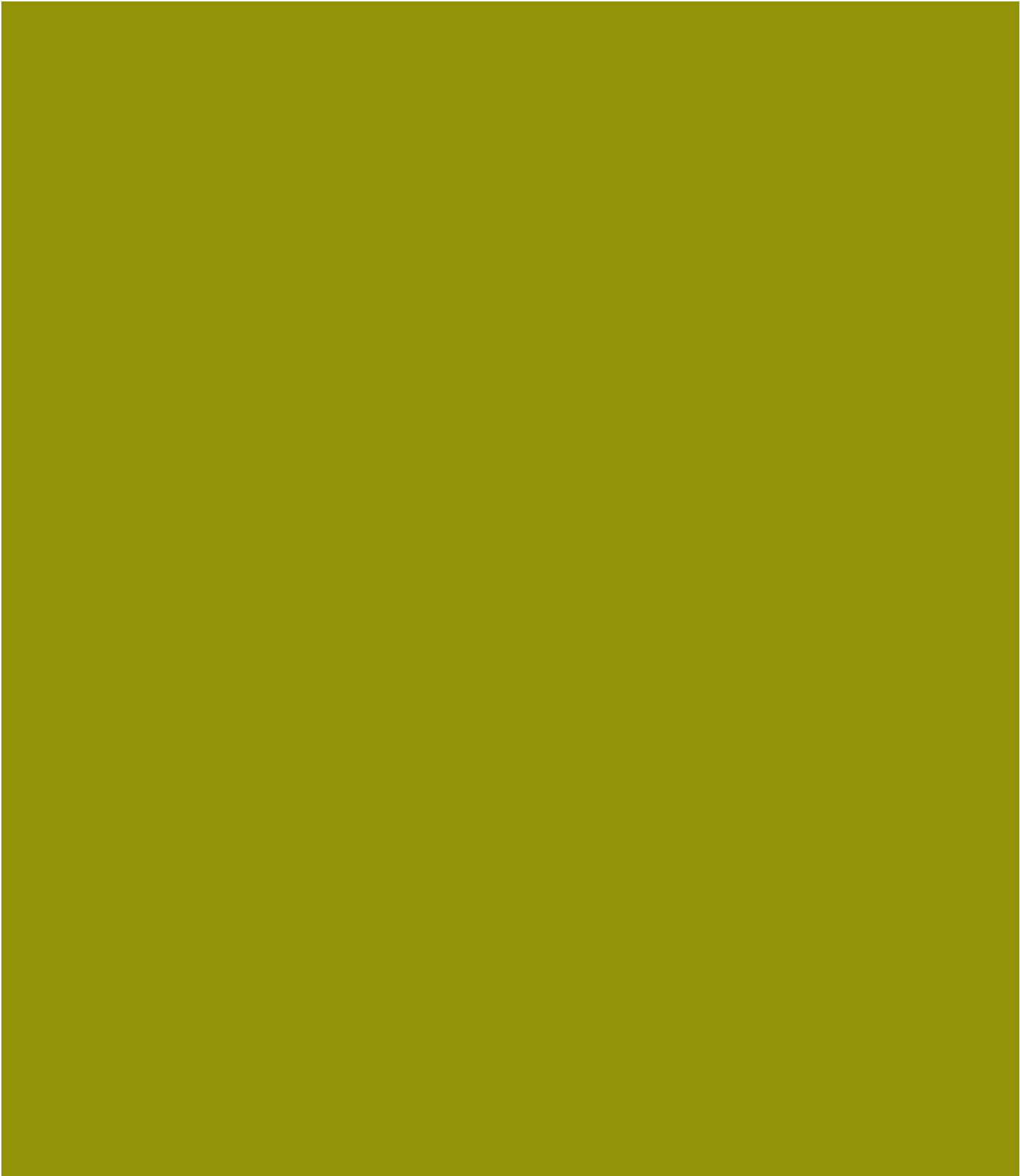
Conclusions

23. The reports that we are publishing identify a number of respects in which, on the assessment of the HSE, biosecurity at Pirbright was or may have been breached. This is clearly a matter of significant concern in relation to a laboratory licensed to handle high category pathogens. We have an enviable science base in the United Kingdom and we attach great importance to the work of our internationally recognised reference laboratories and the outstanding capability of our scientists at Pirbright and similar establishments. But in this case a series of events and combination of factors occurred which, it is likely, led to the release of virus, followed by infection on two livestock premises in Surrey.

24. This statement sets out the measures that the Government has already taken and will take to address the risk pathways that are believed to have been involved. Through the advice of the HSE and others, we have already put in place amendments to SAPO licence conditions, and an inspection procedure which safeguards against any immediate risk. Implementation of the programme of remedial work at Pirbright will be closely inspected and regulated as set out in this statement and the re-licensing of suspended activities at the site will be permitted only when the prescribed safeguards, controls and procedures are in place. Government will report to Parliament in due course on the progress of this programme of work.

25. The review of the regulatory framework that we have announced will provide the basis for a fuller and more considered response to the wider issues presented in today's reports. There are substantial public benefits to be drawn from research and diagnostic work involving the use of animal pathogens, but those benefits can be achieved only if there are practicable and fully effective safeguards in place to protect the public and the natural environment from accidental or malicious release. Those safeguards rely on very high levels of management practice, vigilance and rigorous adherence to documented operating procedures on the part of the institutions taking responsibility for handling the pathogens. The regulatory framework exists to ensure that clear guidance, standards and inspection procedures are in place to assure these practices.

26. The risk can never be zero, but in this case the existing arrangements did not prevent the release of virus. The review of the regulatory framework will identify lessons both for the operators of SAPO-licensed facilities and for Government on the steps that need to be taken to achieve better protection in future. We have asked for the review team's work to be taken forward as a matter of urgency. A further statement will be made after the report of the review is received.



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