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Home Office

Report of ASRU Investigation into Compliance

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In the 2013 Animals in Science Regulation Unit Annual Report, ASRU set out details of plans to start publishing anonymised reports of substantial investigations upon their completion.

The publication of such investigations may be triggered by a number of factors including, but not limited to:

- an exposé making allegations in the public domain;
- a cluster of non-compliances or 'near misses' triaged by an Inspector to ASRU management;
- a non-compliance apparently involving significant animal harm;
- a published paper that appears to describe unjustified pain, suffering or distress; and,
- concern raised by Inspectors or others that a particular procedure may not optimally implement the 3Rs.

Such publication would be over and above the reporting of summary details of all cases of non-compliance in the ASRU Annual Report. This has routinely taken place for several years and will continue.

We believe such early publication of these investigations is in the interests of transparency and openness. We believe that this will also help ensure that all stakeholders can learn from the outcomes of these investigations as early as possible and enable them to address any potential weaknesses in their own management systems, creating a cycle of continuous improvement. These reports will also provide the public with an insight into this important aspect of ASRU's work.

ASRU Report on ASPA Compliance

Purpose and scope of the report:

This report sets out for Ministers the investigations and evaluations made by the Animals in Science Regulation Unit (ASRU) following allegations made by an animal rights organisation submitted to the Home Office in June 2014.

The scope of this report is bounded by the legal framework for the protection of animals used in experimental or other scientific procedures, under the terms of the Animals (Scientific Procedures) Act 1986 (ASPA). The legislation requires Inspectors to report on compliance with the provisions and conditions of licenses issued under the legislation and to advise on the action to be taken by the Secretary of State in the case of non-compliance.

The Establishment also commissioned its own investigative team made up from members of its AWERB to look into all the allegations raised by the animal rights organisation and this is now complete. They have shared their report with the Home Office.

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SECTION 1. Executive Summary

1.1 Introduction

In June 2014, an animal rights organisation made allegations against a licensed research establishment that animals, specifically sheep, being used under the authority of a granted project licence, had been suffering greatly at the Establishment. This followed their undercover investigation between January and March 2013. They also alleged inadequate care of animals.

In addition, they alleged that the Home Office had regulated unlawfully (including conducting an inappropriate harm-benefit analysis) and that there was inadequate enforcement by the Inspectorate.

An extensive and thorough investigation by the Animals in Science Regulation Unit (ASRU) has not substantiated the allegations in relation to the Animals (Scientific Procedures) Act 1986 (ASPA). There was one non-ASPA related allegation involving the euthanasia of a single sheep and this is described in more detail in pages 6, 14 and 19.

1.2 Background

The Animals (Scientific Procedures) Act 1986 (ASPA) permits the application of procedures which may cause pain, suffering, distress or lasting harm to animals, within the context of the justification for likely valuable benefit to man, animals or the environment.

The Establishment is licensed under the terms of ASPA and subject to appropriate inspection and scrutiny according to the level of risk perceived by the Inspectorate.

The complainant is an organisation which is committed to ending animal experiments.

1.3 The principal allegations

In June 2014, the animal rights organisation alleged that there was evidence of *"...distressing animal suffering, unlawful regulation by the Home Office (including the key harm-benefit test), inadequate care of animals and inadequate enforcement by the inspectorate..."* arising from an undercover investigation between January and March 2013. They stated that the issues raised by their report needed to be investigated by the Home Office as a matter of priority.

1.4 Immediate actions

Immediately prior to publication of the report, while making a visit to the Establishment, the assigned Inspector was notified of the impending report resulting from the infiltration and provided with an outline of the allegations. The Inspector discussed these at that time with the Establishment licence holder, Named Veterinary Surgeon (NVS), Named Animal Care and Welfare Officer (NACWO) and Project Licence holder, and subsequently examined the relevant animals.

As soon as the 32 page report was delivered to the Home Office and the video footage became publicly available, these were both reviewed in detail. A meeting with the Establishment Licence holder followed promptly together with a further inspection of the facility. Nothing was identified to suggest that either referral for prosecution or immediate suspension of licences on welfare grounds was merited. All the sheep were viewed and were found to be in a satisfactory condition with no housing or husbandry issues detected. One sheep was identified with an eye condition known as “pink eye” – this animal was already undergoing veterinary treatment for this condition.

1.5 Investigations of potential non-compliance

The Chief Inspector instructed the assigned Inspector to further investigate whether there was any potential non-compliance and to deliver the findings for preparation of a full investigation report.

The investigation included interviews, inspections, meetings, examination of records, review of inspection visit reports and of the project licence authority on which the allegations were based.

ASRU officials also wrote to the animal rights organisation to request any further documentation or video footage they might be holding to ensure that all key issues could be followed up. The organisation replied to say that, at that time, there was nothing further they wished to share with ASRU.

1.6 Project licence authority

The relevant project licence was reviewed to ensure it covered all the work in question and that the harm-benefit analysis was appropriate.

1.7 Conclusions

The allegations of cruelty at the Establishment have not been substantiated. Early in the investigation it was concluded that there was no case for the immediate suspension of any licence authorities in order to safeguard animal welfare. Subsequently during the extensive and thorough investigation, no cases of non-compliance with the requirements of ASPA were identified in relation to any of the allegations.

Specifically, in regard to the detailed Home Office investigation:

- ASRU found no breach of ASPA by the Project Licence holder, or any Personal Licence holder, or of the terms and conditions of their licences.
- ASRU found no breach of ASPA by the Establishment Licence holder or of the terms and conditions of their Establishment licence.

We acknowledge that a sheep did suffer from a fracture to its leg. However, this incident was out-with the remit of ASPA; personnel on site took immediate and appropriate action at the time in order to minimise animal suffering, and the individual involved in the incident was dealt with via the Establishment's internal HR disciplinary processes (see pages 14 & 15).

The Establishment is one of ASRU's larger licensed establishments. The size of the establishment, its multiple animal facilities, species housed, number of project licences, severity of authorised procedures being conducted, diversity of research work and history of non-compliance are all considered in determining its risk of non-compliance. Based on these criteria, the Establishment is considered to be towards the upper end of the risk scale. The extensive investigation, interviews, inspection visits and meetings with staff during 2014 have confirmed this assessment but not further elevated the Establishment's risk rating.

SECTION 2. Background

2.1 Main allegations by the animal rights organisation

On Friday 6 June 2014, ASRU was alerted by the Home Office Press Office that the Sunday Mirror was intending to publish an article on Sunday 8 June 2014, following material that had been supplied to it by an animal rights organisation. The article would allege the unlawful suffering of sheep kept at the Establishment for the purposes of scientific research. At the same time, the assigned Inspector, while

visiting the Establishment, was notified by staff of the impending report following from the infiltration.

On Sunday 8 June 2014, the animal rights organisation provided a 32 page report to the Home Office. The source for the allegations contained in the report was an under-cover infiltrator placed at the Establishment between January and March 2013. The animal rights organisation's report alleged distressing animal suffering, unlawful regulation by the Home Office (including the key harm-benefit analysis), inadequate care of animals and inadequate enforcement by the Inspectorate (*sic*).

The animal rights organisation also published a short video (4 mins, 21 secs) on YouTube purporting to be footage material recorded during their investigation period. The story featured in the Sunday Mirror on the 8th June 2014. The main allegations made are listed in **Annex A** to this report.

The Animal Rights Organisation's Report

The written report made numerous allegations relating to the use of animals under ASPA. All the allegations have been considered in Section Three of this report, including the allegation that the harm-benefit analysis for this Project Licence was unlawful.

Video Material

The publically available YouTube video purporting to have been filmed at the Establishment was not submitted formally to the Home Office as evidence. Nevertheless, we have fully considered this in the context of the animal rights organisation's report. All alleged identifiable cases of non-compliance in the video have been considered by the Inspectorate investigation.

2.2 The animal rights organisation's key requested outcomes

Through their report, the organisation called for:

- An investigation of the issues raised by their report
- A review of the harm-benefit assessment of the project licence
- A review of procedures and working practices of local Home Office Inspectors

This investigation report addresses each of these requests.

2.3 The Animals (Scientific Procedures) Act 1986

ASPA provides a framework of a three-tier licensing system for the protection of animals used in scientific procedures which may cause pain, suffering, distress or lasting harm. This is permissive legislation allowing the conduct of procedures on animals for a scientific purpose which might otherwise be deemed under other

animal welfare legislation to cause unnecessary suffering. Licences impose responsibilities on the holders, among others, to ensure that the 3Rs (replacement, reduction, refinement), humane endpoints and avoidance of unnecessary suffering are applied throughout the term of the licences. The provision of a licence to an individual not only entrusts them to uphold their legal obligations but also to behave in ways which ensure high standards of animal care and welfare at all times.

Licences

Each establishment using animals in regulated procedures must have an Establishment Licence to do so. The attached conditions clarify the responsibilities of the licence holder under ASPA, including an obligation to apply the principles of the 3Rs. A Project Licence is required to specify a programme of work using protected animals. Such licences may only be granted if the 3Rs have been rigorously applied and a satisfactory harm-benefit analysis has been made, reflecting the scale and significance of the proposed harms and likely or potential benefits. Each individual carrying out regulated procedures on animals must hold a Personal License providing authorisation.

Inspection

All establishments which carry out procedures on animals are subject to scrutiny by Home Office Inspectors, who play a key role in the implementation of ASPA. Inspectors follow a risk-based approach to inspection. This takes account of objective criteria including the number and species of animals held, the number of regulated procedures undertaken, the prospective severity of those procedures and the compliance history of the particular establishment. In addition, subjective criteria are considered including: the effectiveness of the Establishment Licence holder; the effectiveness of the local Animal Welfare and Ethical Review Body; the involvement and effective performance of Named Persons; the quality of training, supervision and competency checks and records; adequacy of staffing levels; the maintenance of facilities in good order; and the provision of environmental enrichment and other indicators of good quality animal care.

Visits by Inspectors to licensed establishments are an important aspect of determining compliance with ASPA; in 2013, 70% of inspection visits made to animal units were unannounced. An additional key role of Inspectors is to advise those working under ASPA on matters relating to compliance and encourage best practice with respect to the 3Rs. Inspectors have a sole right of entry to licensed establishments at all reasonable times and ready access to all records. By law, they are required to report on non-compliance and to provide advice on the action to be taken. Investigations into allegations such as those made by the animal rights organisation against the Establishment are therefore led by Inspectors in order to provide advice to the Secretary of State.

2.4 Initial actions taken by ASRU

The immediate actions taken by ASRU and its Inspectors are described in Section 1.4. The Chief Inspector commissioned the investigation and, as soon as the initial evidence had been collected, a meeting was held involving the Chief Inspector together with the Head of ASRU, the assigned Inspector, the Head of ASRU Policy and the Head of the ASRU Compliance Team. This was to review the early evidence and to agree a plan for the investigation. The following day, the Project Licence holder voluntarily attended an interview at the Home Office.

In addition to the Project Licence holder attending for interview with ASRU, the Establishment immediately instigated its own internal review into the allegations. A copy of their report was sent to the Home Office two weeks later. The Establishment also took the step of posting their report on their website.

2.5 The Establishment

The Establishment is in the top quartile of licensed establishments based on size and is considered to be towards the upper end of risk of non-compliance. This is due not only to the size of the establishment, but also to its multiple animal facilities, number of project licences, the severity of authorised procedures being conducted and the diversity of research work as well as their recent history of non-compliance. The extensive investigation, interviews, inspection visits and meetings with staff during 2014 have confirmed this view but not further elevated the Establishment's risk rating.

During the period, January to December 2013, compliance advice was provided on ten occasions. Typically, compliance advice may be given verbally by an Inspector upon discovery of a trivial breach of licence conditions. The outcome of compliance advice will be to note and record details of the advice in the Inspector's visit report, with further action taken by the relevant licensee as required and follow up action by the Inspector to ensure the breach has been appropriately remedied.

In addition, seven cases of non-compliance were dealt with in 2013 none of which involved serious animal welfare issues and all of which resulted in written reprimands being sent to those being sanctioned. Six of these cases were self-reported and one was discovered by an Inspector. This was a small increase in the numbers of non-compliance cases compared with previous years. For example, in 2012 there were three cases of non-compliance, all of which were self-reported. It could therefore be that the 2013 increase is due, at least partly, to increased attention to self-reporting. Over the five year period from January 2010 to June 2014, there were 17 events at this establishment which led to formal non-compliance action being taken.

It is notable that none of these non-compliances, nor any compliance advice given, was directly related to this Project Licence holder or to their research team.

The Establishment has a number of separate animal units each headed up by Principal NACWOs, who are, in effect, senior managers for their separate sections. Below the Principle NACWOs are a number of unit NACWOs with delegated responsibility for the day to day care and welfare of the animals in their unit.

2.6 The Project Licence holder and Research group

The area of research being studied (Huntington's Disease and Batten's Disease) is briefly described at **Annex B**. The Project Licence holder commenced research on sheep eight years ago overseas, working collaboratively with other scientists who were producing a transgenic sheep model for Huntington's disease. Developing and refining the behavioural tests in the United Kingdom on normal sheep has so far taken around five years. Neither the Project Licence holder, nor any of the members of the research team, who feature in the allegations has been the subject of compliance action in the last five years.

The Project Licence holder's main area of research is Huntington's disease (HD). In the UK work on HD undertaken by this research group is undertaken in mice, although this will change if the sheep HD model and behavioural tests, electrophysiological and imaging methods are perfected. The Project Licence holder also has access overseas, through a collaboration, to genetically altered sheep with the HD mutation. The relevant Project Licence was granted principally to authorise the licensee to develop electrophysiological, behavioural and cognitive tests for sheep, with imaging, which could be used to assess disease progression and ultimately gene treatment in a transgenic HD sheep model.

The development of HD in sheep (as in man) takes years. Preliminary Magnetic Resonance Imaging (MRI) data in HD sheep at five years of age triggered the idea that a faster progressing neurodegenerative disease model should be used to validate the testing methods being developed in normal sheep. The Project Licence holder became aware of two flocks of Batten's disease (BD) sheep which would be suitable, and so sought an amendment to the Project Licence to use BD sheep as a positive control. This amendment was granted in May 2012.

The BD sheep carry a natural mutation that gives them their disease. To otherwise create a BD sheep would have taken many years and significant investment. The Project Licence holder has advised the Home Office that using this naturally occurring animal model of the human disease, particularly with many similar clinical signs and similar pathology to that seen in people, is likely to give better insight than

transgenic models. The sheep were imported from overseas where a flock of affected sheep is maintained for research. The sheep from overseas originally came from the UK, and so there may be sheep carrying a similar mutation in the UK but none has yet been identified.

BD sheep develop the same brain pathology as BD patients, and many of their clinical signs are similar. The sheep under study do not develop epilepsy, but they do develop visual deficits and their brains deteriorate so they show overt signs of dementia. They become confused, anxious when they are confronted by novelty, and respond abnormally to strangers. The Project Licence holder believes that BD is theoretically curable as it is a recessively inherited genetic disease and therefore potentially amenable to gene therapy.

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SECTION 3 The Allegations

3.1 ASRU Investigation Team

The Chief Inspector instructed the assigned Inspector, assisted by the ASRU Compliance Team (CT), to investigate the allegations of potential non-compliances and to deliver their findings for preparation of a full investigation report. The CT consists of a Principal Inspector, responsible for consistency of non-compliance investigations and advice from the Inspectorate, and the Senior Compliance Manager, a senior member of the ASRU administrative team, both aided with administrative support. The investigation was taken forward principally by the assigned Inspector. Until March 2013 the Establishment had been inspected by two assigned Inspectors. When one of those Inspectors retired in March 2013, the remaining Inspector took over responsibility for the whole of the Establishment which included the facility where the Project Licence holder's sheep were housed. An appropriate adjustment was made to the Inspector's workload to ensure sufficient time was available for inspection by one Inspector.

3.2 Investigation Interviews

A lengthy meeting was held at the Home Office with the Project Licence holder within two days of the allegations being published (see paragraph 2.4). A number of further interviews were conducted at the Establishment with the Establishment Licence holder, other senior staff, research staff and animal care staff.

3.3 Specific allegations made by the animal rights organisation

The allegations are listed in summary at **Annex A**. The numbers at the end of each allegation refer to the relevant paragraph(s) in the animal rights organisation's report.

3.3.1 The need to euthanase a sheep on arrival at the airport in the UK (para 55, 70).

One of the animals that arrived at Heathrow airport was described as being disorientated on arrival but it was transported to the Establishment where it appeared fully normal on arrival and therefore entered the experimental flock and was used for research purposes.

The journey from overseas to the UK took about 60 hours. The animals initially travelled by truck to the airport. They were then air-transported in facilities normally used for racehorse transport. There was a stopover when the sheep were off-loaded for about 90 minutes and fed and watered. The sheep were then flown on to Heathrow Airport and were transported to the Establishment by truck. On arrival at the Establishment the animals were thoroughly checked by the Project Licence holder.

The following day they were checked by the Named Veterinary Surgeon (NVS). Photographic evidence of their condition and behaviour on arrival was reviewed as part of this investigation and illustrates that the sheep appeared to have travelled well. Video footage taken at the time of arrival has also been assessed as part of this investigation.

In summary, we conclude that this allegation is simply untrue in relation to the sheep imported for the Project Licence holder's research. No animals required euthanasia or were found dead on arrival at Heathrow Airport.

3.3.2. Distressing animal suffering (para 6, 83).

The video footage does show one animal apparently in a pen on its own and looking disorientated. This reaction is often seen in BD sheep when they are single housed and, for this reason, a clear staff instruction exists that BD sheep should only be singly housed when absolutely necessary. One explanation therefore may be that someone, possibly the animal rights organisation's infiltrator, had moved this sheep against instructions to a position in the pen where it was separate from the other sheep. The sheep would then naturally start to show signs of disorientation.

The Establishment has mechanisms in place for whistle-blowing, and it is of note that no animal welfare concerns had been raised by any staff at the Establishment, including the animal rights organisation's infiltrator, during the time period covered by the report, with the exception of an incident where a sheep's leg was broken on entering a weighing crate (see para 3.3.4).

In summary, we conclude this allegation is unfounded. No substantive evidence has been provided by the animal rights organisation of distressing animal suffering being deliberately caused to the BD sheep. Indeed the staff instruction would imply the opposite – that these animals are well cared for with sensitivity to their special needs.

3.3.3. Inadequate care of animals by the Establishment staff (para 6, 37).

There is a paucity of specific evidence from the animal rights organisation for this wide ranging and general assertion.

Nevertheless, it is noteworthy that, in early 2014, following consideration of the recent compliance history of the Establishment, the Chief Inspector determined that relevant management factors at the Establishment should be reviewed in greater detail. In April 2014, two Principal Inspectors joined the assigned Inspector to conduct a thorough and co-ordinated Team Inspection. This involved interviews with a number of staff as well as joint inspections on several dates. The issue of unit staffing was discussed with the Establishment Licence holder. The Team did not find evidence of a breach of licence conditions relating to the appropriate staffing of

the units intended to ensure the well-being of protected animals. The Establishment Licence holder acknowledged that there had been significant staff turnover which had involved a range of grades of animal care staff, and confirmed that these were being promptly filled with a mix of agency and permanently employed staff.

In summary, we have concluded that no evidence has been found for inadequate care of the animals and no evidence of inadequate adherence to controls.

3.3.4. A sheep would not go into a 'crush cage' for weighing. A staff member became "impatient and rammed her in". The sheep's leg became stuck and broke. The animal had to be euthanased (para 41, 70).

On the day that this sheep suffered a broken leg, new weighing equipment was being used and the sheep were therefore unfamiliar with this equipment. Where sheep would normally enter the weighing equipment voluntarily, this sheep did not. Instead the animal lent back on its back legs and one of its front legs slipped under the bar at the bottom of the weighing equipment. When pushed into the equipment the sheep's leg was broken.

The sheep was not one of the Project Licence holder's sheep. It was being weighed for routine husbandry purposes and was not undergoing any regulated procedures. There was therefore no requirement on the Project Licence holder to report the incident to the Home Office.

The Establishment management investigated this matter at the time and the Establishment Licence holder acknowledged that the animal should have been more carefully handled. The individual involved had been working with animals for 23 years without any record of poor handling. However, immediately following this incident, the individual was subjected to an internal disciplinary process. As a consequence, the individual was allowed to work with sheep only when supervised, and retraining and further monitoring was put in place to ensure that good practice in handling was maintained. The individual retired six months later.

The term "crush cage" is perhaps misleading. It is the term used by the animal rights organisation to describe standard equipment used to restrain animals for certain procedures, e.g. weighing, taking blood samples and checking visual responses. Sheep are also routinely transported around the site in similar equipment. The sheep are not "crushed". They become habituated to this equipment after a very short period of time and will typically enter without difficulty.

In summary, we have concluded that, whilst the description used by the animal rights organisation of the actions of the individual may have been at least partially accurate, there was no breach of ASPA involved and from an animal welfare

perspective, the matter had already been appropriately dealt with by the Establishment Licence holder and management.

3.3.5. A sheep was “starved” and then killed because it had a faulty brain implant (electrodes) (para 63, 70).

Under the Project Licence authority, EEG electrodes may be implanted on the skull of some of the sheep under the skin and muscle which covers the skull. Superficially mounted skin electrodes will not work in sheep due the significant muscle mass on the head in this species. The initial wound created may appear large but sheep do not appear to be uncomfortable following the surgery. Healing is relatively quick and, as with human surgery, post-operative analgesia is given to relieve any pain relating to the wound. The sheep are not “starved” for 24 hours before surgery but food is removed the afternoon prior to the day of planned surgery in order to give the ‘overnight fast’ that is standard veterinary surgical practice before a general anaesthetic is given. In sheep this reduces the risk of surgical complications which may arise from regurgitation of ruminal contents.

The sheep referred to as having been killed was called “Jane”, and was a normal Welsh Mountain sheep which had EEG electrodes implanted in July 2011. In 2012, Jane was re-anaesthetised and the wires connected to the electrodes were repaired because they had been nibbled by another sheep. On 14 February 2013, Jane was euthanased because the wires had again been nibbled by another sheep, but this time they could not be repaired. Jane was euthanased because it was felt that the stress of surgery would be disproportionate to the benefits, since a large amount of useful data had already been collected and she was nearing the end of the study.

The Project Licence holder’s sheep are housed in groups because sheep are social animals. While there is a risk that as a result of group housing sheep can cause damage to one another’s wires/devices, in practice, this has proved to be rare since the groups are kept stable as far as possible. The benefits to animal welfare from group housing have been deemed to outweigh the risks.

In summary, we have concluded that this allegation is unfounded.

3.3.6. A sheep, “Janet”, suffered severe weight loss and became virtually blind. Though eventually killed because of suffering, she was “inexplicably” left for several days in a “pitiful state”, even though it was acknowledged she would have to be killed.” (para 38, 57).

BD sheep tend to defecate where they lie during the night so it is not unusual for faecal material to accumulate in close proximity to the animals. This is checked for, and cleared, as part of morning checks by the care staff, and all the animals including those unaffected by BD are routinely checked every day, including at weekends.

The Project Licence holder's team have identified a sheep named "Janet". She was an unaffected heterozygous carrier of the BD gene so would not have developed clinical signs of BD and she did not undergo any surgical interventions (i.e. no CNS implant or electrodes). When she arrived from overseas, her body weight was 27.4kg compared with the weight range for the other sheep in the batch was 25 to 37kg. Janet's weight increased to 31kgs and then remained around this level whilst the other sheep in the group ranged between 30 and 60kgs. Therefore her start weight was not 62kg as stated in the animal rights organisation's report. When it became apparent that she was failing to grow and thrive, she was euthanased. She weighed 27kg at that time and her brain was used as a normal control specimen.

In summary, we have concluded that these allegations are unfounded.

3.3.7. Animals were found dead in the morning and would have suffered unnecessarily, in breach of ASPA (para 36).

During the period when the animal rights organisation's infiltrator was working at the Establishment, there were no records of any animals being found dead in the morning which would have suffered unnecessarily and in breach of ASPA. At other times, there have been two unexpected deaths recorded in the Project Licence holder's flock of sheep.

"Livingstone" developed facial nerve paralysis immediately after surgery (a CNS electrode implant in May 2013) which made it difficult for the sheep to eat. This sheep was referred to one of the Establishment's large animal veterinary surgeons for treatment. On veterinary advice, the sheep was fed by gastric tube for a period of time to ascertain if the nerve damage was temporary. The sheep became diarrhoeic and lost weight and the Project Licence holder took the decision to euthanase this animal if it did not soon regain nerve function. Shortly after, the animal was found dead. No post-mortem was undertaken because the animal had been under veterinary care and the cause of death was known. A second sheep, "Frances", was a BD sheep. This sheep had undergone cranial implants for EEG recording in February 2013 and was treated with antibiotics at that time. Subsequently, she was unexpectedly found dead in May 2013.

In summary, we have concluded that this allegation is unfounded. None of the Project Licence holder's sheep were found dead while the animal rights organisation's infiltrator was working at the Establishment. One animal died at later times from known causes, and had received appropriate veterinary care prior to death. One died unexpectedly without known cause.

3.3.8. *Concern about how the Home Office applies the key harm-benefit test (para 6, 30).*

Appendix I of the Home Office Guidance on the Operation of the Animals (Scientific Procedures) Act 1986 (published March 2014) describes the harm-benefit analysis and the relevant section entitled “What is a harm-benefit analysis” (pp 125-126) is reproduced at **Annex C**.

Upon receipt of the application to the Home Office, and before the decision was taken whether or not to recommend the grant of this project licence, the assigned Inspector made an assessment of the likely harm to the animals after taking into consideration the effective implementation of the 3R's. These were then balanced against the benefits that were likely to be gained from the work. The Inspector's duty is to make a judgement as to whether the likely harms are justified by the likely benefits, and to provide advice and a recommendation to the Secretary of State.

In the Inspector's assessment, the nature of the harms to the animals was described as follows: *“animals implanted with electrodes and/or CNS cannulae should make rapid recoveries. Implantation of microchips and telemetry devices should cause no more than transient discomfort. Behavioural tests are expected to cause little distress. The drugs and dosages used are not expected to cause more than moderate effects. The lentiviral vectors used for delivering mutant genes are in common use. They are known to cause little or no adverse effects. Effects of the mutant genes likewise are expected to be mild to moderate”*.

The benefits expected from the project were described as follows: *“this project should help to develop sheep as a suitable large animal for behavioural studies in normal and disease. Using non-regulated training, the applicant has demonstrated that sheep, contrary to common belief, have potential cognitive behaviours that can be exploited. The work should help to establish the foundation for investigating and developing potential therapies for a range of neurological diseases”*

The summary of the harm-benefit assessment (analysis) stated: *“given the advances of fundamental knowledge that are likely to accrue from this programme of work, the mild to moderate suffering in 100 sheep are justified”*.

The decision to recommend the grant of a licence to conduct this work was made by the Inspector on 19 October 2010. The Project Licence was subsequently granted by the Secretary of State with an overall severity band of Moderate. Between October 2010 and June 2014, four applications for minor amendments were made and each was subjected to a further harm-benefit analysis. All were granted.

3.3.9. Inadequate enforcement by the Inspectorate (para 6).

Under ASPA, the Inspectors' role is to monitor compliance and report on cases of non-compliance. Whilst they may offer advice to licensees working under ASPA, responsibility for compliance with the legislation lies with those licensees.

Inspectors gather information from inspection visits and their interaction with all levels of personnel at an establishment. In addition, assessment of Project Licence applications provides valuable background with regard to the applicant's scientific knowledge and standing as well as insight into their commitment to the application of the 3Rs and compliance with all aspects of the legislation. All of this information is integrated by the Inspector to inform their professional opinion on the risks and realities of potential non-compliance and how this might be minimised through providing advice to personnel at an establishment.

The inspection history at the Establishment from January to December 2013 was reviewed by the Chief Inspector. During the period to end March while the infiltrator was present, there had been 21 inspections representing 35.75 hours in total spent at the Establishment. During the entire period from January to December 2013, there had been 75 visits involving just over 230 hours spent at the Establishment. Whilst the inspection reports identified some issues and a few irregularities, these had all been appropriately followed up and no serious issues requiring urgent action had been identified.

Examination of inspection records also showed that the Establishment was inspected on a regular basis for the twelve months prior to the animal rights organisation's infiltration. The reports of these inspections for 2012 included three self-reported cases of non-compliance where formal action was taken. None of these cases of non-compliance action, nor examples of compliance advice given, involved the people who have featured in the allegations made by the animal rights organisation and who were subsequently investigated.

In addition, the apparent increase in the number of non-compliances in 2013 (see paragraph 2.5) led to the Chief Inspector putting in place a co-ordinated Team Inspection of this Establishment in early 2014, prior to any of these allegations being made. This Team Inspection particularly investigated relevant management factors including the standards of animal care in the Establishment and is therefore described in paragraph 3.3.4 of this report. This provides further evidence of the overall thoroughness of enforcement by the Inspectorate.

In summary, the level of inspection of the Establishment, together with the provision of compliance advice and investigation of non-compliance are supportive evidence that enforcement by the Inspectorate at this Establishment was effective. The animal rights organisation has provided no evidence on which to base their allegation of

inadequate enforcement. Therefore, we have concluded there are no grounds to support this allegation.

SECTION 4 Other considerations

The animal rights organisation's infiltrator had been employed by the Establishment through an employment agency to work as a research assistant in the Project Licence holder's group. The Establishment has provided the name of the animal rights organisation's infiltrator in confidence to ASRU. The animal rights organisation states that the infiltrator was recruited as a "*research assistant and the duties primarily involved training sheep to do particular tasks and analysing data*". The employment agency operates a rigorous clearance procedure as well as staff training and management practices to ensure the suitability of their staff for the planned employment.

Agency records indicated regular contact had taken place between the agency line manager and the animal rights organisation's infiltrator. This is, in part, designed to facilitate the relaying of any problems or concerns by agency staff to the agency management. There were no records of any concerns about animal welfare at the Establishment being raised by the animal rights organisation's infiltrator with the agency management. Similarly, the animal rights organisation's infiltrator failed to raise any concerns through the recognised whistle-blowing mechanism in place at the Establishment.

SECTION 5 Conclusions

Our detailed investigations, and review of available records and other evidence, do not support any of the allegations made by the animal rights organisation

All the issues raised have been thoroughly investigated. Allegations have been followed up through rigorous scrutiny of records, both at the Establishment and in ASRU. In addition, numerous interviews with senior staff, research staff, and named animal care staff have been conducted. None of these allegations has been substantiated nor has any allegation given us any further cause for concern with regard to compliance with the requirements of the legislation at this Establishment.

We found no evidence of animals being subjected to avoidable suffering. We recognise that there was one incident in which a sheep suffered a broken leg and had to be euthanased. The circumstances of this are set out at paragraph 3.3.4 of this report and we are satisfied that the matter, whilst unfortunate, was dealt with

promptly and appropriately by the Establishment management to ensure no repetition. The incident occurred out with the remit of ASPA.

A small number of the allegations were based on hearsay evidence and we can neither confirm nor deny these. However given the overall lack of substance where relevant evidence was to be found, we do not consider it likely that any of these other allegations would be substantiated.

We conclude there are no grounds for sanctioning any individuals in relation to these allegations, nor for raising our perception of the risk of non-compliance at this Establishment.

The allegations

The following list summarises the principal allegations made in the report submitted to the Home Office, as well as points identified in the YouTube video evidence.

1. The need to euthanase a sheep on arrival at the airport in the UK
2. Distressing animal suffering
3. Inadequate care of animals by Establishment staff
4. A sheep would not go into a 'crush cage' for weighing. A staff member became "*impatient and rammed her in*". The sheep's leg became stuck and broke. The animal had to be euthanased.
5. A sheep was killed because it had a faulty brain implant (electrodes).
6. A sheep suffered severe weight loss and became virtually blind. Though eventually killed because of suffering it was "*inexplicably*" left for several days in a "*pitiful state*", even though it was acknowledged it would have to be killed."
7. Animals were found dead in the morning and would have suffered unnecessarily.
8. Unlawful regulation by the Home Office, including the key harm-benefit test.
9. Inadequate enforcement by the Inspectorate.

The area of research relevant to this investigation***Huntington's disease***

1. Huntington's disease (HD) results from genetically programmed degeneration of brain cells, called neurons, in certain areas of the brain. This degeneration causes uncontrolled movements, loss of intellectual faculties, and emotional disturbance. HD is a familial disease, passed from parent to child through a mutation in the normal gene. Some early symptoms of HD are mood swings, depression, irritability or trouble driving, learning new things, remembering a fact, or making a decision. As the disease progresses, concentration on intellectual tasks becomes increasingly difficult and the patient may have difficulty feeding themselves and swallowing. The rate of disease progression and the age of onset vary from person to person. There is currently only one treatment that helps control the emotional and movement problems associated with HD, but there is currently no cure for the disease. Also, there is no treatment that has been found to delay the onset or to delay the progression of symptoms.
2. HD is a condition that slowly progresses so that the patient gradually develops more, and worsening, symptoms. In the later stages of HD, the patient will become totally dependent on other people and require full nursing care. HD leads to considerable disability and, at present, will eventually lead to death. At present, most people live from between 10 to 25 years after they first develop the symptoms of HD. The most common cause of death for someone with HD is usually an infection such as pneumonia.

Batten's disease

3. Batten's disease (BD) is an inherited disorder of the nervous system that usually manifests itself in childhood. Early symptoms of BD are confusing and not easily recognised even by medical personnel. Symptoms of BD usually appear in childhood when parents or doctors may notice a child begin to develop vision problems or seizures. In some cases the early signs are subtle, taking the form of personality and behaviour changes, delayed speech, slow learning, clumsiness or stumbling. Over time, affected children suffer mental impairment, worsening seizures, and progressive loss of sight and motor skills. Children become totally disabled and eventually die before reaching adulthood. The incidence of BD in the UK is around 1 of every 30,000 - 40,000 births.

Excerpt from the Home Office Guidance on the Operation of the Animals (Scientific Procedures) Act 1986, March 2014. Appendix I - Guidance on the Harm-Benefit analysis of project licence applications.

What is a harm-benefit analysis?

- The likely harms that the animals will experience as a consequence of the project are assessed by analysing the information you provide in the project licence application. The extent to which you have applied the 3Rs (replacement, reduction and refinement) will be evaluated in considering whether the proposed harms are minimised in relation to the particular purpose of the requested animal use. We will advise you if we consider you have not adequately explained how the proposed harms are minimised as much as possible.
- Inspectors may also use additional information to assess the likely harms such as evidence from inspection of your work or that of others, the scientific literature and their own specialist knowledge of science, animal welfare, veterinary and human medicine. During this process the Inspector will also confirm the severity categories of each of your protocols by using the descriptors in Annex 8 of 2010/63/EU (see Appendix G), other relevant guidance, literature evidence, knowledge of similar work authorised under ASPA and their own professional judgement.
- The benefits that may result and the likelihood of their delivery are also assessed from the information you provide in the application. Inspectors may seek further information either from you, from the scientific literature or from specialist knowledge within the Inspectorate to understand the context and the value of those benefits.
- Once the benefits have been clearly defined and understood, the likelihood of delivery of those benefits is considered. Inspectors use criteria such as the proposed scientific methodology, the resources available to you and your track record with regard to publications and animal use, to determine how likely the benefits are to be delivered.
- Only once the harms, benefits and likelihood of delivery have been fully explored by the Inspector, including the extent to which the effective implementation of the

3Rs has been addressed, is a judgement made as to whether the likely harms are justified by the likely benefits. This judgement is fundamental to the recommendation provided to the Secretary of State with regard to granting or rejection of the application and reflects the scale and significance of the proposed harms and benefits.

- The balance between harm and benefit may be further analysed throughout the life of the project for a number of reasons, and should be considered to be a continuous process. For example, unexpected adverse effects may increase the level of suffering during a project, and the Inspectorate will need to reconsider the analysis.
- On 1 January 2013, the recording of actual severity experienced by each animal became a legal requirement. This will facilitate continuous analysis of actual harm throughout and at the end of the project, providing a mechanism to review the predictions made at the beginning of the project. In addition, some categories of applications are subject to retrospective assessment, which in part involves reconsideration of actual harms and benefits. This will facilitate regular harm–benefit review which will inform our decisions regarding whether ongoing project authorities are still appropriate and whether new project applications have predicted harm appropriately.