



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.

Purpose and scope of the report:

This report provides a summary of investigations and conclusions made by the Animals in Science Regulation Unit, following a self-reported incident of non-compliance in July 2014 at an establishment licensed by the Home Office.

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.

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Nature of the incident:

An animal which had been taken from the wild for use in regulated procedures was found dead at an establishment.

The animal was taken from the wild on 26 June 2014. It was health checked both at the site of capture and under anaesthesia after transport to the establishment, on the same day.

The animal was housed with another animal of the same species and was cared for and monitored according to the local practices. Closed circuit television (CCTV) recording equipment was also available to aid monitoring.

The animal was found dead in a nest box on Monday 21 July 2014. The animal had last been seen by a member of the care staff on Saturday 19 July.

A post-mortem examination was performed on Tuesday 22 July by the Named Veterinary Surgeon (NVS). The post-mortem report stated that the animal had died through 'starvation' even though food had been present and available throughout its period of captivity.

As food had been provided and was being eaten (by the other animal), the 'starvation' was thought likely to be a result of a failure to eat. This was likely to have been secondary to another health or welfare problem.

Failure to eat was thought likely to have extended over a long period, as significant weight loss had occurred; between the date of arrival at the establishment and the post-mortem examination the animal lost 37% of its body weight. The local monitoring systems failed to identify that the animal was losing a significant amount of weight and not eating.

Discovery: How was the incident discovered?

The incident was self-reported by the licensed establishment's Home Office Liaison Contact.

Adverse animal welfare costs: The following unexpected adverse animal health or welfare costs arose as a result of the incident

The animal lost significant weight during its captivity, and died. The animal's loss of condition after arriving at the establishment was not detected before its death, so no action was taken to investigate or deal with its condition or any underlying problem while it was alive. It is likely that avoidable suffering occurred as a result.

Immediate action: The following actions were taken to prevent additional animal welfare costs

The major concern at the outset was that this animal appeared to have died due to failure to eat the food supplied over some period of time, suggesting that monitoring of its health and welfare had not been adequate. Further, the condition of the animal did not appear to have been checked daily, as is required by Standard Condition 4(5) of the Establishment Licence.

To ensure that no further animals were similarly affected, the ASRU inspector required that preventative measures were put in place that would be sufficient to (a) detect any further animals that showed any signs of illness or weight loss at a much earlier juncture; and (b) ensure that the checks referred to in establishment licence standard condition 4(5) would be carried out to an appropriate standard to promptly detect problems with health and well-being of all protected animals at the establishment.

The establishment revised their procedures, including daily monitoring regimes, regular weighing of recently received animals, enhanced monitoring (including by CCTV) to check that all individual animals were seen to be active and eating every day, and detailed plans for dealing with animals not seen eating.

An inquiry was instituted at the establishment, including discussion by the Animal Welfare and Ethical Review Body (AWERB).

Investigation:

Health of the animal at capture

It was confirmed that the animal had been health checked both at capture and again shortly afterwards (at the establishment) under general anaesthesia. The checks were carried out by the project licence holder and an assistant also holding a personal licence. The animal was assessed as “very old” and in fair to poor body condition with some healed injuries. Despite its condition it was not given specific treatment or enhanced monitoring, and specific veterinary advice was not sought.

The Named Veterinary Surgeon (NVS) was not present and had not personally examined the animal, but received the results of tests on blood samples (taken by a personal licence holder), which were described as unremarkable.

Animal care and checking

Records showed that the animal enclosures were checked daily, but it was found that individual animals that were not active and visible during the checks were not always physically seen. Animals could go 48 hours without being seen.

There was some reluctance to closely investigate animals that were not readily seen on inspection after they had been taken from the wild, in case the disturbance adversely affected them.

Staff considered that seasonal fluctuations in weight and eating / activity patterns for the species meant that the use of weight data was of limited value in determining health.

The animal's weight and other observations (including from the CCTV) such as activity, apparent appetite / approaches to food, and individual food consumption either were available or could have been obtained and used to assess the health and welfare of the animal. Co-ordinated collection of this information, consideration and action upon it, did not take place in this case.

Rodent control in the wild-caught animal accommodation was also found to be ineffective, which led to difficulty in establishing if food was being consumed by protected animals or by the rodents.

Training records & procedures

Training records showed that three of the care staff had received initial training in the care and management of the particular species of animal. Refresher training in the requirements had not been carried out since the initial training and the local procedures were not regularly reviewed and updated.

Project licence holder oversight

The project licence holder stated that they were unaware that the animals were not being checked daily and had thought they were being monitored more closely.

The results of the initial examination had not been personally communicated to the care staff, apart from leaving a copy of the health check sheet in the animal unit. The project licence holder assumed that the care staff would take appropriate care of the animal and did not return to check on the animals or care procedures personally.

The project licence holder felt that when the animal was captured and first examined, it had not been in exceptionally poor condition given the "normal" natural conditions seen in the species and their expected weight at that time of the year.

Conclusions

The health and wellbeing of the animal had not been effectively checked daily as required by the conditions attached to the establishment licence.

There were insufficient measures for detecting and dealing with animals that were ill, not eating or losing weight, if they were not acutely or visibly clinically sick.

The presence of wild rodents and another animal that was eating partially obscured the failure to eat.

Communication between licence holders, named persons with responsibility under ASPA, and care staff was very poor in this case, and this directly contributed to poor care for the animal. Had communication been better, care might have been given that would have detected and prevented the animal's deterioration.

It would reasonably be expected that linkage of the animal's weight and other observations (including from the CCTV) such as activity, apparent appetite (approaching food) and food consumption would be used to assess the health and welfare of the animals. Central collection of this information, consideration and action upon it, did not take place.

The practice of the project licence holder and personal licence holder in checking the health of animals on arrival, and only if deemed necessary involving the NVS, was not consistent with practices at other establishments where the NVS was always present at initial checks. Further, the greater / personal involvement of the NVS, including formal recording of health and body condition at each examination, would be good practice.

In summary, it was considered that there were failures to adequately check the health and well being of the animal properly, and failures of staff to communicate properly and this directly contributed to poor care for this animal.

Referral to the Crown Prosecution Service (CPS).

ASRU considered factors relevant to a range of sanctions available to the Secretary of State. The details of this incident were referred to the Crown Prosecution Service for consideration of prosecution action. The CPS declined to take action on the case.

Our decision to refer a case to the CPS is one that is infrequently taken and was an indication of the seriousness with which the Secretary of State viewed this matter.

Considerations for recommendation to the Secretary of State.

Mitigating circumstances

The incident was self-reported in a timely manner.

The establishment licence holder recognised that there had been failures in the quality of the care provided to this animal and took a number of immediate steps to address them.

Immediate Actions

The checking system for the animals was rapidly changed and animals were subsequently all checked daily. There was evidence that this was being performed at subsequent inspections conducted by the inspectorate. Pen and animal records in the unit showed that staff were now adequately and effectively checking the pens/cages.

Measures to strengthen and broaden care and welfare monitoring procedures were proposed and were the subject of further discussion with the AWERB and Home Office. Procedures were strengthened to a sufficient degree to give assurance that failure to eat and / or weight loss would be detected, assessed and appropriately

dealt with. Good practice from other establishments and external experts was obtained and taken into account.

Communication between scientists, named persons and care staff was recognised as having been inadequate and positive steps were taken to improve this.

Attitude of the people involved

The licence holders and named persons were supportive of reform to processes for care of protected animals.

No deliberate non-compliance or negligence was detected.

The establishment provided all details requested in support of the investigation, provided access to all personnel freely, and were open and co-operative in the course of the investigation. Action was swiftly taken to implement new monitoring practices compliant with ASPA and to address concerns around communication between staff at all levels.

Sanctions

Sanctions against the Establishment licence holder

The Secretary of State issued the establishment licence holder with a compliance notice.

By means of the compliance notice, the Secretary of State required the establishment licence holder to provide an immediate reassurance and to instigate a short-term response and longer term improvement in line with the five requirements set out below.

To review local management controls and review core husbandry practices for all animals, with particular reference to wild-caught animals whether on procedure or not, aimed at optimising procedures and practices to benefit animal health and welfare;

To ensure that checking of all animals and their environment was being appropriately carried out, in order to satisfy the requirements of standard condition 4 of the establishment licence;

To formally reassess and where necessary improve the competency, performance, management and training of all care staff and named persons, including the Named animal care and welfare officer (NACWO) and NVS, who are entrusted with the welfare, care and treatment of protected animals;

To ensure effective communication between all care staff and named persons including licensees involved in the conduct of live animal research, and those key people entrusted with the care of protected animals;

To take effective steps to monitor, prevent and where necessary control vermin /

rodent ingress, in compliance with the published ASPA Code of Practice.

In addition to these actions, the establishment licence holder was also required to deliver the following reports by the dates indicated:

A re-assurance by 31 Jan 2015, of how they were now providing appropriate day-to-day care and welfare of all animals.

A short-term response by 30 June 2015, addressing each of the five required actions and providing re-assurance in relation to the establishment's organisational restructuring plans.

A report by 30 June 2016 demonstrating how the establishment licence holder would embed sustained improvements into the establishment's culture in relation to all the five required actions.

Under ASPA there is no right to make representations against the issue of a compliance notice and if it appears to the Secretary of State that an establishment licence holder has failed to comply with the requirements of a compliance notice then, under section 11 of the Act, the Secretary of State may vary or revoke the establishment licence. There is a right to make representations under these circumstances.

Sanctions against the Project/Personal licence holder

The Secretary of State considered that the failure to properly monitor the health of the animal and the failure to seek veterinary advice meant that standard conditions 2 and 15 of the personal licence had not been met.

The Secretary of State also considered that the failure to minimise the suffering of an animal that was taken from the wild and found to be in poor health meant that standard condition 14(b) of the project licence had not been met. Furthermore, exceeding the severity controls of the project licence without notifying the Home Office was a breach of standard condition 18.

The Secretary of State informed the project/personal licence holder of her intention to vary both the personal and the project licences by adding a condition to each requiring retraining. The personal licence would be suspended until such time as module 1 retraining was successfully completed, and the project licence would be suspended until such time as module 5 retraining was successfully completed, both to the satisfaction of the Secretary of State.

The reason for requiring retraining was to improve the licence holders' understanding of ASPA and to ensure they were able to meet their responsibilities as specified in the licences. To that end, the Secretary of State had to be satisfied that the licence holder had not only improved their understanding but that they were also committed to ensuring they met their responsibilities and demonstrated a culture of care.

The Secretary of State also required the project licence to be amended to take account of the lessons learned from the incident, particularly in regard to the care

and husbandry of this particular wild animal. Revisions to the project licence would need to be considered and approved by the establishment's AWERB before submission to ASRU for consideration by the assigned inspector and recommendation.

Subsequent events

The establishment licence holder who was served with the compliance notice had not been in post on the date of the incident. However, as the new establishment licence holder with full responsibility for all ASPA issues at the establishment, it fell upon them to take responsibility for complying with the requirements in the compliance notice that were imposed by the Secretary of State.

The new establishment licence holder immediately commenced a review to identify future ways of working which would examine whether the standard operating procedures were fit for purpose.

They also reassessed and where necessary improved:

(i) the competency, performance, management and training of all those care staff and named persons entrusted with the welfare, care and treatment of protected animals, and;

(ii) implemented improvements to procedures around husbandry and monitoring with specific consideration around the culture of care, including processes for staff to feel safe to raise issues (informal as well as formal 'whistle blowing'), and how the animal technicians and ethical advisors were engaged in the project work.

There were improvements to clarity of responsibilities, standard operating procedures and management and communication methods in order to make recommendations on how the establishment could generally work better in the future.

Shortly after the issue of the sanction letters, the project licence holder, who also held a personal licence made an application to revoke their personal and project licences, and this was agreed.

A new project licence, which authorised continuation of the studies with appropriate additional measures to take account of the incident, was granted to a senior scientist not connected to the incident. This permitted the completion of regulated procedures on the animals concerned, and consequently no animals had to be euthanased as a result of licence revocation.

Following the issue of the compliance notice, significant work was undertaken at the facility housing the animals to upgrade remote monitoring systems for wild-caught animals, together with the provision of added environmental enrichment for the animals.

Revised procedures were also put in place to ensure regular health monitoring of the animals together with monitoring of sufficient food intake for each animal. In addition, the inspectorate was able to report a number of other positive steps in moving the establishment into an improved position with regard to compliance with ASPA since the appointment of the new establishment licence holder, and, it was apparent from

discussions with the holder that there was clear commitment to continue with these improvements.

Inspections undertaken throughout the period of the compliance notice reported a significant improvement in the culture of care and in the husbandry and care practices at the establishment. The pro-active actions taken by the establishment licence holder and co-operative behaviours that were demonstrated, coupled with a willingness to embrace change and learn from the incident, were considered to be major factors in resolving the historical issues that had been inherited by the new establishment licence holder.

The reports to the Secretary of State were required to demonstrate that the establishment licence holder had satisfactorily addressed all the requirements set out by the relevant dates, thereby complying with the terms of the compliance notice.

All of the required reports to the Secretary of State were submitted by the due dates. These reports satisfactorily addressing all of the requirements set out in the compliance notice, together with the results of the ongoing inspection programme, resulted in the Secretary of State considering that the establishment licence holder had fully discharged all of the actions required and real improvements had resulted.

Conclusion

Failures in basic animal care and inadequate communications between staff had serious animal welfare consequences in this case. The failings were regarded as serious non-compliance.

The establishment responded fully to the findings and sanctions imposed, which has led to further improvement in the care and welfare of protected animals held at the establishment.

Outcomes relevant to other establishments

Processes at licensed establishments must ensure that good levels of welfare are maintained. This includes appropriate daily checking of the health and well-being of all protected animals, good training and competence arrangements for those carrying out animal work, and availability of sufficient numbers of appropriately trained staff for basic animal care.

ASRU considers that strong and effective delivery of these basic processes is essential not only for animal welfare, but for the performance of high quality science.

Particular lessons arising from this incident:

1. Good communication needs to be in place at all levels to ensure animals are properly cared for. Where animals show signs of potential ill health or compromised welfare it is necessary that scientists, care staff and named persons communicate effectively to identify the likely reasons, in order to safeguard good welfare and scientific outcomes. This is essential to embed a good culture of care. The fostering of good communication is required by the

standard conditions of all establishment licences and is a key responsibility for establishment licence holders.

2. The specific needs of animals taken from the wild must be given a high level of consideration when developing standard procedures for housing, monitoring, husbandry and care. AWERBs and all staff involved in animal care must be proactive in identifying appropriate measures, and reviewing procedures in the light of experience. Advice from external experts is also likely to be useful.
3. Regardless of species-specific considerations, it is essential that effective daily checks are undertaken on all protected animals, in order to provide reassurance that animals are well and so that any health and/or welfare issues can be identified and acted upon as soon as possible. Where direct observation of animals is difficult due to their particular behavioural characteristics, establishment licence holders must still make sure that appropriate staffing, procedures and equipment is in place to ensure that effective monitoring takes place.
4. Where animals are taken from the wild, pre-existing health and welfare conditions should not be disregarded and must be assessed by a vet or other competent person in the same way as captive bred animals. Where necessary, veterinary advice on treatment and care should be sought and acted upon (unless specific authority not to take action has been given in a project licence for scientific reasons).