



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.

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Purpose and scope of the summary report:

This report summarises the investigations and evaluations made by the Animals in Science Regulation Unit (ASRU) Inspectorate in following up allegations made by an animal protection organisation regarding the conduct of a commercial establishment holding an establishment licence under the Animals (Scientific Procedures) Act 1986 (ASPA) and against ASRU. Specific allegations were made in a report provided to the Home Office based on material and video material covertly gathered by an investigator working as a junior animal technician.

Detailed investigations were made into studies at the relevant site during the period covered by the organisation's allegations.

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Section 1
EXECUTIVE SUMMARY

1. Purpose of licensed work

- The company develops and produces vaccines to protect animals from diseases that would cause them harm or to protect humans. Research & development work needs to be undertaken to:
 - Improve the safety or efficacy of current vaccines
 - Provide protection to a wider range of animals (e.g. different age range or a different species)
 - Develop new vaccines where there are none
- Studies need to be undertaken in the target species or other species to demonstrate safety and efficacy, that a live vaccine will not revert to virulence or spread to other animals and to determine the duration of protection. Also vaccines are often given in combination (to reduce the number of administrations) so studies are needed to demonstrate that the combination of vaccines is safe and efficacious. Specific studies are required to meet regulatory requirements before the vaccine can be marketed
- Where there is an apparent failure of a vaccine, studies may need to be undertaken to understand if there is a problem with the vaccine or if the field strain of the disease has changed

2. General procedures

- Some animals will need to be infected with the pathogen against which the vaccine is designed to protect in order to show that the vaccine is efficacious. In order to prove that the vaccine is protective, some unvaccinated animals need to show distinctive signs of disease to be sure that the challenge with the pathogen is a suitable model of the natural disease in the field
- The vaccine or novel vaccine will need to be given to test its effect
- Repeated blood sampling is often required to monitor how the immune system is reacting to the vaccination and/or to monitor how the disease is progressing
- Swabbing of body surfaces/cavities may be required to monitor the spread or excretion of the pathogen
- Post mortem samples may be required, for example to show how well the animal has been protected by the vaccine or how the pathogen has spread to or affected different tissues

3. General benefits

The benefits of new or improved vaccines for companion and farm animals accrue from the protection provided to animals from the use of safe, efficacious vaccines.

- Animals will suffer less disease (better welfare)

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- Food-producing animals will grow better and be healthy therefore be more economic for farmers and require fewer veterinary treatments, including antibiotic treatments
- Some vaccines are to prevent disease in humans, for example to prevent chickens from harbouring pathogens that cause food poisoning in humans

4. Outcomes of Assessment & Inspections

All licensed work has been assessed by an Inspector appointed under ASPA who has carried out a harm:benefit assessment as well as determined that the proposed programmes of work adequately address the 3Rs (Reduction, Refinement, Replacement). All studies carried out during the period in question were part of a licensed programme of work.

Specific justification is required to use dogs and cats in regulated procedures. The test applied for such programmes of work was that the purpose could only be achieved by the use of dogs or cats, not other species.

The Inspectorate is satisfied that the use of animals, and specifically the use of young dogs and cats and animals separated from their dam at an earlier than usual time, was justified.

Inspectors carry out a programme of inspections to determine if licence authorities are being complied with, including conditions which require an ongoing attention to the 3Rs. Inspection visits provide an opportunity for discussion of study- and welfare-related issues face to face or may be followed up subsequently via telephone contact or written advice. The site was visited in accordance with the planned risk-based inspection programme and ongoing advice to improve housing, husbandry or procedures was provided as required by the Act.

5. Investigation of assertions

Detailed investigation of the assertions made was undertaken by the Inspectorate. The local Inspector and Chief Inspector visited the premises to inspect the facilities and discuss work with scientists and animal technicians.

Detailed reports were provided on each study carried out during the period at the site in question. The reports provided specific information on:

- a. The scientific rationale for the study
- b. Justification for:
 - i. the species
 - ii. the age of animal used
 - iii. the source of the animal, in particular for Schedule 2 species obtained from non-licensed establishments
 - iv. (where applicable) separation from the dam earlier than recommended practice
 - v. rationale for administering analgesia (or not)

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- vi. humane endpoints used for the study
- vii. killing at the end of the study
- c. The expected and unexpected adverse effects seen
- d. Monitoring regime and humane endpoints applied.
- e. Fate of the animals, including explanation for not keeping alive and re-homing

Details provided were scrutinised and compared with the programmes of work licensed by the Secretary of State. Study records from selected studies were scrutinised in detail. Further detailed information has been sought relating to specific assertions in the report. No non-compliance with authorised programmes of work was detected apart from two minor issues¹ with no welfare implications.

The site was visited on a separate occasion by the local Inspector and the executive Head of the Compliance Team. No further issues of non-compliance were identified.

¹ A personal licensee was found to be competently slaughtering calves using a humane method under the assumption that this was a Schedule 1 method. As they were not a veterinary surgeon or a holder of a current licence granted under the Welfare of Animals (Slaughter or Killing) Regulations 1995, the killing was technically a regulated procedure for which there was neither project nor personal licence authority. The killing was carried out competently and with the knowledge and oversight of a veterinary surgeon. No welfare issues were identified. Action has been taken to address this technical non-compliance. A second technical issue was identified relating to use of pens smaller than ASPA Code of Practice during the period of sampling without express project licence authority. Calves remained under the care of two veterinary surgeons. This practice has been accepted by the Home Office on health and welfare grounds to protect wellbeing during the short period where breathing is compromised and to facilitate close examination. No welfare issues identified. Steps are being taken to regularise this practice.

Section 2 ISSUES

1. Application of the harm:benefit test

It is a requirement of the ASPA that all project licence applications must specify the required regulated procedures for the programme of work, the likely adverse effects that may occur as a result of those procedures, and the humane end-points that will be applied. Applicants must also explain what benefits are likely to accrue as a result of their project. The Inspectorate uses this information to undertake a harm-benefit analysis as part of the project evaluation process. As part of assessing and minimising the harms, inspectors evaluate the extent to which the 3Rs have been applied.

Only once the harms and benefits (including both impact and likelihood of delivery) have been fully explored a judgement is made as to whether the likely harms are justified by the likely benefits.

The programmes of work licensed by the Secretary of State lay out the specific benefits to be gained from developing new or modified (improved) vaccines for farm and companion animals and a harm:benefit assessment is made each time a project licence is granted or amended.

The project licence dealing with dogs and cats was amended on a number of occasions and on each occasion an Inspector performed a further harm-benefit analysis. Following the allegations, a Principal Inspector performed an independent harm-benefit analysis of this project licence. They reached the same conclusion that the work was justified.

Vaccination of companion animals is recommended by the Veterinary Medicines Directorate (VMD). The VMD has published a summary of the regulatory requirements for dog and cat vaccines which includes recommendations and benefits:

https://www.vmd.defra.gov.uk/pdf/leaflet_vaccinesVets.pdf

The British Veterinary Association

http://www.bva.co.uk/public/documents/vaccination_the_facts.pdf

the Kennel Club and Dogs Trust all recommend vaccination of companion animals.

Upon review, ASRU remain satisfied that the Inspectorate performed harm-benefit analyses as required by ASPA and gave defensible and correct advice to the Secretary of State.

2. Failure to consider non-animal strategies

In-vitro studies are always first used to identify vaccines that are not likely to work in animals and therefore halt further development work. As the intact and functioning

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immune system is needed to confirm what happens in an animal when it is vaccinated, then living animals need to be used at a later stage in the vaccine development process. Studies to demonstrate safety, efficacy and duration of immunity can only be carried out, currently, in the types of animal that the vaccines are intended to protect.

Regulatory authorities (the Veterinary Medicines Directorate in the UK) require evidence from studies carried out in the target species that the vaccines are safe and efficacious before allowing the vaccine to be marketed to the public.

The Home Office has licensed work using animals following an assessment that the proposed work cannot currently be undertaken using non-protected animal or non-animal alternatives. The suggestion was made that some of the studies, with adjustment, should be carried out in the target population and that insufficient attempts are being made, by either the company or the Home Office, to assess this on a case by case basis. We consider this demonstrates a lack of understanding of scientific method. Studies need to be carried out under specific and controlled conditions to ensure a robust scientific result is obtained. Experimental vaccines cannot be used in the target population without first being registered with the VMD.

3. Failure to keep suffering to a minimum

i. Severity limits exceeded and inappropriate endpoints

Some studies require that unvaccinated animals show unequivocal signs of disease in order to demonstrate the efficacy of the test vaccines. Most of the diseases against which the vaccines are designed to protect are serious, therefore unequivocal signs of disease are also likely to be serious. In some cases it can be important to determine if animals can recover from clinical signs of disease.

a. Rabbits

From the information supplied by the establishment, the harms to rabbits on study do not appear to have exceeded the severity limit (severe) in the project licence protocol. The purpose of the study was to determine if the vaccine virus could be carried around the body and shed if animals were infected close to the time of vaccination; a severe limit was appropriate for this study, given the seriousness of the disease. Some rabbits were retrospectively assessed as having suffered severely, others to mild or moderate levels.

A specific allegation was made about one rabbit. A note in the day book suggested that it had reached the endpoint on the evening before it was euthanased. The clinical condition of this rabbit was discussed with the experienced technician who had made the clinical assessment in the evening. They reported that the breathing difficulties noted were only apparent when the rabbit was disturbed and their assessment was that the rabbit had not reached the humane endpoint, nor was suffering of a degree that required immediate euthanasia. If this was the case then there is no reason to suppose that the humane endpoint had been exceeded.

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b. Cats

Records show that cats on an efficacy study showed signs at the limit of that allowed by the licence authority. The Home Office accepts the need to use cats (the target species). Severe (though transient) suffering was necessary in order that the animals had time to produce significant quantities of antibodies necessary for subsequent *in vitro* screening. Records show that cats that had been infected were treated with a long-acting analgesic on two occasions during the course of infection to mitigate the severity of the adverse effects. Repeated administration of the product used is contraindicated for use in cats in standard veterinary practice.

c. Calves

Records show that two of 45 calves were euthanased, one 6 days and one 8 days after arrival, as they failed to thrive or respond to veterinary treatment.

One calf was not considered suitable for production due to high antibody levels to infectious bovine rhinotracheitis and was released into the care of the Named Veterinary Surgeon. It was subsequently found dead; death reported to have been due to bloat.

From our enquiries and the records reviewed, we cannot reconcile the assertion that previous illness had made calves 'really poorly for two weeks'.

ii. Inadequate monitoring and care

We have been provided with reassurances that all animals are checked daily (as required by ASPA) and that in addition clinical monitoring is carried out on all necessary days. The records that we examined support this.

a. Competence of the investigator

The training and competence records of the investigator show that they was competent to clean out dogs and cats, to complete animal day books, to dispose of clinical waste and to use fire extinguishers. They had started training in data entry, routine animal handling and husbandry for cats and dogs and poultry. They had no training in clinical examination or monitoring.

Stock animals, or those not considered to require clinical monitoring, were inspected at least once a day. We have been assured that the investigator was never without support on site, even at weekends, and that a competent member of staff would follow them round the units to check the animals, including any necessary clinical monitoring.

b. Whelping bitches

Records show that several pups died at birth in one litter. Monitoring was more frequent after this with additional checks on whelping bitches in the evening, at midnight and early morning as well as during the course of the working day.

c. Cats

Cats were infected on two occasions on a Friday on the basis that it is expected that clinical signs following challenge will be seen at days 2-7 post-infection. By infecting on Friday the critical period coincided with the working week when more staff were on site. Records show that the cats showed no clinical signs on Sunday after the first inoculation, as predicted.

The company refutes the suggestion that a kitten with signs of cystitis was not treated on the basis that it could affect the study. The Named Veterinary Surgeon (NVS) reported that he examined the kitten in the presence of the investigator and diagnosed very mild, intermittent cystitis. The records suggest that clinical signs had resolved the next day. Mild signs of cystitis appeared 2 days later and a course of antibiotics was administered on the advice of the NVS.

An incident of 'flooding' of a kitten room describes the room as being 'under several inches of water and the food bowls floating'. There is no record of this in the day book; this could be interpreted as either that the incident was not considered of importance or that there was a serious incident which was covered up. The description of the conditions in the investigator's report is hard to reconcile with the design of room which has a central drain and potential for standing water to flow off down the corridor. Staff report that one drinker in a cat room was found to be dripping and a puddle had formed on the floor. The drinker was repaired and modified to make it more kitten proof. The truth of this incident cannot be determined but it is unlikely that the whole floor was covered in several inches of water as this is not possible due to the floor design.

An incident in the investigation report where a kitten was 'dropped onto her side' when having a blood sample taken cannot be corroborated. It is recognised that blood sampling can cause pain, suffering or distress; such a procedure can therefore only be conducted under ASPA for a licensed scientific purpose by trained and licensed staff who are competent or appropriately supervised.

Distress from other regulated procedures is also reported. Recognising the potential for pain, suffering, distress or lasting harm, such procedures are permitted only when carried out by trained and licensed staff who are competent or appropriately supervised and in accordance with a licensed programme of work.

d. Calves

A technical issue was identified relating to use of pens smaller than ASPA Code of Practice for calves during a limited period of sampling without express project licence authority. Calves remained under the care of two veterinary surgeons. This practice has been accepted by the Home Office on health and welfare grounds to protect wellbeing during the short period where breathing is compromised and to facilitate close examination and veterinary treatment.

4. Absence of outside runs

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The nature of the work requires that animals need to be protected from pathogens in the environment and the environment needs to be protected from pathogens or novel vaccines that may have been given to the animals.

Most studies require animals to be sero-negative for the viral or bacterial agent under test and animals are therefore obtained from unvaccinated or specific pathogen free breeding colonies. Many of the pathogens in question are carried by wildlife so it is possible that pregnant animals in outside runs could become infected.

It would, therefore, compromise the value of the science and pose a risk to the environment to provide outside runs for dogs being used on these studies, including pregnant bitches.

5. Early separation of animals from their mothers and use of very young animals

i. Early separation from the dam

Early separation from the dam was licensed via the project licence for defined scenarios; this was considered to be a regulated procedure, recognising the potential for distress or lasting harm.

Early separation was specifically authorised in the project licence for a number of scientific reasons:

- Young mammals being suckled derive a level of immunity through their mother's milk or previously via the placenta. These antibodies (MDA) can interfere with the response to a vaccine. To develop vaccines that are effective at an early age, and therefore protect young animals, young animals with the appropriate age-related physiology need to be used
- Some studies needed puppies with a high level of maternally derived immunity and some required a low level of maternally derived immunity – depending upon the scientific question being addressed
- Some studies required puppies that were free from infection with a specific common pathogen that can lie dormant and be excreted again at times of stress, such as transportation. Infection of the puppies would have compromised the scientific objectives of the study
- Some puppies were removed from the dam at an early age to increase the chance that they would remain pathogen free and so could be used in such studies

After separation the puppies need to be screened to ensure that they are not infected and are serologically negative, hence the need for swabbing and blood sampling at an early age before the start of the main study procedures.

In order to make best use of puppies, and to minimise the numbers of whelping bitches brought in, a number of different studies were performed on puppies taken from a number of litters. Mixing of animals from different litters also makes scientific sense. For husbandry and GLP reasons, where a single puppy was to be used in a study along with 6 pups from another litter, all pups were separated at the same time so that a single puppy was not kept in isolation. Separation of the bitch and her litter

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in this case allowed the bitch to be re-homed as it was not exposed to potential shedding of a live vaccine from the vaccinated pups.

The growth records suggest that there were no adverse effects on growth of the puppies and that all puppies separated earlier than recommended in standard texts thrived.

ii. Use of young animals

The investigation report notes that studies used very young animals. Specific project licence authority was in place to conduct regulated procedures on unweaned dogs and cats and to separate animals from their dam earlier than standard husbandry when scientifically justified. The Inspectorate has found no evidence that procedures on dogs and cats were carried out other than in accordance with licence authorities.

Safety studies must be carried out in the most susceptible type of animal. MDA negative puppies can be obtained from non-vaccinated dog colonies; there are no such colonies in the UK. UK transport regulations prohibit the movement of puppies of less than 8 weeks of age without the dam. For most studies bitches were imported and whelped on site. For one study a bitch with her was imported with her puppies. Some studies were started while animals were still with their mothers for sound scientific reasons.

Reversion to virulence studies require the collection of faeces from young pups. The natural behaviour of the dam is to clear up after the offspring have defecated therefore such puppies needed to be separated for the dam to obtain the necessary material.

6. Socialisation of puppies

We do not disagree that familiarising animals to being handled reduces the stress to animals. We note that staff do spend time with animals, although this seems to be on an *ad hoc* basis rather than regularly scheduled. This is an area where we expect improvement in the future.

Apart from the two bitches who were nervous soon after arrival, the Inspector has not noted lack of acclimatisation to humans to be a general problem at this establishment.

7. Poor sourcing of animals

a. Rabbits

Records show that some rabbits were found dead. These rabbits had been sourced from a non-licensed supplier in the UK with the express authority of the Secretary of State. Three rabbits of 30 died 2 days after arrival with a post-mortem diagnosis of heart failure/mucoid enteropathy. A further four animals died as a result of

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enterotoxaemia; two of these died before the first vaccination. No rabbits died from non-study-related causes after challenge as part of a licensed study.

Project licence conditions require that rabbits are bred for use in procedures unless there is authority from the Secretary of State to source elsewhere. It is expected that rabbits from licensed breeders or suppliers are of a suitably high health status. A particular study required non-purpose bred rabbits with a health status representative of the pet trade –likely to be lower than purpose bred standards

b. Cats

It is asserted in the investigation report that one batch of kittens ‘were wild’ and had to be sedated to take blood samples. These kittens were seen by the Inspector a few days after arrival and no temperament issues were raised or noted.

c. Chickens

It is asserted that chickens were transported in overstocked crates and had a feather pecking problem. Records show that birds were transported. The journey took approximately 45 minutes. 15 or 16 birds per crate of the size used is well within national transport regulations. The condition regarding fouling and feather pecking on arrival was not recorded. One bird was found dead the next day and the remainder remained in good health. Feather pecking is an intermittent issue at this establishment, as in commercial premises, and is treated and minimised by low light levels and topical sprays as required.

Losses of chicks within the first week of life are expected to be 3-5%. Where there is a poor hatching resulting in a high rate of first week loss, which does happen occasionally, the batch is not used for regulated procedures as the poor quality may compromise the scientific outcome.

d. Calves

It is asserted that three calves arrived with pneumonia – records show two calves were euthanased within a few days of arrival but there is no record of ‘pneumonia’ in their individual health records. A total of five calves, including these two, were treated soon after arrival for mild signs such as ‘slow to drink’.

8. Suffering associated with euthanasia

Dogs or cats being euthanased in some of the buildings at this site are euthanased in a procedure room adjoining the main holding room. Euthanasia of these species is undertaken by intravenous injection of an overdose of an anaesthetic (the same as animals being ‘put to sleep’ by a veterinary surgeon). Animals can become distressed when given an intravenous injection, even when competently undertaken. This is why such procedures are regulated under the Act.

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The technician is required to ensure that the animal is dead before starting the post mortem. In the video material we can see the technician check for permanent cessation of the circulation.

The Home Office requires that animals are not subjected to surgical procedures or post-mortem within sight, sound or smell of conscious animals. This was the advice provided in discussion between the Home Office Inspector and animal technicians during a visit on 22/8/13. The Inspector witnessed several anaesthetised cats in the holding area with the door open to the holding area during terminal procedures (cardiac puncture). She did not consider this unacceptable as all animals within sight, sound and smell were anaesthetised.

On the same day the Inspector witnessed post-mortem of two cats in a procedure room, both of whom were dead before post mortems were started.

There is no evidence of inappropriate practice and advice has been provided by the Inspectorate in this respect.

9. Re-homing animals

The establishment has a re-homing policy.

Note: most animals need to be euthanased at the end of studies:

- Section 15 of ASPA requires that if animals have been subjected to regulated procedures and are suffering or likely to suffer as a result of those regulated procedures at the conclusion of the study they are humanely euthanased
- Some animals will show signs of disease. Where these are severe or persisting then animals must be euthanased for humane reasons or to protect other animals, humans or the environment
- Some apparently recovered animals may have been infected with pathogens that can lie dormant in the animal with the potential to be reactivated in the future. Such animals would not pass the Section 15 test for being kept alive.
- Post-mortem samples are required in some studies e.g. to show how pathogenic organisms have spread around the body
- Where animals have been given a live, as yet unlicensed vaccine, they cannot be released from the establishment as the vaccine has not yet been accepted as safe
- Where puppies still with their mother are given live, unlicensed vaccines, there is the possibility of spread to the mother. This means that the mother cannot be re-homed either

Arrangements have been made to return animals from a UK breeder back to the breeding colony where practicable and where the returning animals will not pose a health risk to the rest of the breeding colony. Some of the breeding females provided were the last of a particular strain and would have been culled by the breeder in any case. It is not possible to return unvaccinated dogs to the overseas breeding colony as this would jeopardise the health of the whole colony.

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The Home Office supports the responsible re-homing of dogs where this is legal, practical and in the interests of the dogs. Some breeding animals will be of unsuitable temperament to settle well into a domestic environment. Older animals are less popular with adoptees than young animals.

Of the puppies used in 2013 and in related studies in 2012, 10 were considered to be suitable for re-homing and, of these, the establishment was able to re-home three.

Some adult ex-breeding dogs can be (and were) re-homed as were chickens. Cats that are suitable, and where it is legal to do so, are generally all re-homed.

10. Inadequate performance by the Named Veterinary Surgeon

The performance of the NVS is the responsibility of the Establishment Licence Holder. Through extensive review of project licence, health and animal care records, together with our own inspection records, we found no indication of inadequate performance by the NVSs.

Section 3
CONCLUSIONS

Our detailed investigations and review of available records and other evidence, does not support the allegations in the investigation report.

Our findings confirm that the site is well managed with staff at all levels committed to the provision of appropriate standards of welfare and care, within the constraints of the scientific requirements of the research. The site has been visited by the Inspectorate in accordance with the risk rating, which is reviewed periodically by the Chief Inspector. Advice has been provided on a number of occasions to continue to improve standards but no welfare issues have been reported.

The risk rating of the site is high as they use 'special species' (dogs and cats) and undertake work with a high severity rating. Inspectorate visits are therefore more frequent than at 'lower risk' sites.

We recognise the public concern, particularly about the use of young animals such as puppies and kittens, as well as the need for induction of potentially distressing clinical disease in the animals used at and the necessity for killing animals at the end of studies. However, we are satisfied that this work is properly justified under the terms of the Animals (Scientific Procedures) Act 1986, and that it is, thereby, lawful.

The issues which we will follow up relate to formalising the use of calf pens smaller than Code of Practice size when justified on welfare grounds and continuing to monitor the application of humane endpoints and controls, as we would do in any case. None of these give us cause for concern either with regard to compliance with the requirements of the legislation, nor animals being subjected to avoidable suffering, given the necessity of their use in scientific procedures.

As a result of these particular in-depth investigations we also identified a technical non-compliance, (competent and humane euthanasia of calves) which has been remedied.

Whilst we conclude that there need be no change to our current risk rating for this establishment, as a result of the investigations flowing from this investigation report, we are continuing to monitor progress on the provision of larger calf pens, and this will be carefully monitored to ensure no welfare compromise.