



RESOURCE SHEET NUMBER 8 – The Regulators – Animals in Science Regulation Unit (ASRU)

The Home Office stated purpose of the Animals in Science Regulation Unit (ASRU) is to protect animals in science by maintaining compliance with the Animals (Scientific Procedures) Act 1986 (ASPA). ASRU is a department of the Home Office. As the regulators it is only them that have right of access to Establishments licenced under ASPA 1986. Neither the RSPCA or even the police can enter or inspect Establishments without there being proof of illegal activity. The office address of ASRU is 14th Floor Lunar House 40 Wellesley Road, Croydon, CR9 2 BY.

<https://www.gov.uk/government/collections/animals-in-science-regulation-unit>

The Email address to send in Freedom of Information Requests is:

foirequests@homeoffice.gov.uk

To report non-compliance to ASRU use:

ASRUEnforcement@homeoffice.gov.uk

To make a complaint, mark FAO Will Reynolds, and use:

AnimalsinSciencePolicy@homeoffice.gov.uk

ASRU issue three types of licences

1. Establishment (PEL) or the place at which the work is carried out. Fee £915 in 2022
2. Project Licence (PPL) for the programme of work. No fee
3. Personal Licence (PIL) for each person carrying out procedures on animals. Fee £299 in 2022

There is no need to hold a project licence for the breeding of non GA (Genetically Altered) animals as this is not a regulated procedure. The facility though must hold an Establishment licence. MBR Acres does have a project licence for The Production of Laboratory Animal Bio-Products as this involves experimental or other scientific procedure applied to a protected animal which may cause pain, suffering, distress or lasting harm.

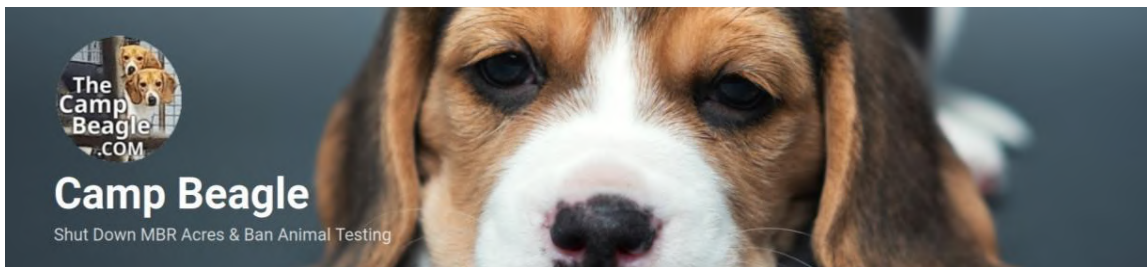
In 2022:

The ASRU Licensing Team comprised one full-time equivalent (FTE) senior leader, 9.34 FTE inspectors, three FTE executive officers and two FTE administration officers.

The compliance assurance team comprised It comprised one FTE senior leader, 5.75 FTE inspectors, one FTE senior executive officer and three FTE executive officers.

The business support function team comprised 2.5 FTE members of staff.

During 2021, there were 22.69, full time equivalent, Home Office inspectors.



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A graph of inspectorate staff shows for 2022: 19.70 and 2021: 22.70. It is not obvious to us where the 19.70 figure comes from bearing in mind the team summaries.

As for project licences granted per inspector it was 2022: 52.50 compared with 2021: 21.90 no wonder project licences are just approved with no consideration of non animal methods.

Licence applications and amendments, 2022

PIL: Granted 2319, Amended 696, in force at end of year 13,483

PEL: Granted 1, Amended 26, in force at end of year 135

PPL: Granted 490, Amended 987, in force at end of year 2300

Lack of regulatory oversight, combined with the sheer number of animals held in laboratories, means that shocking welfare violations occur. ASRU annual reports for 2019-2021 were not published until 26th October 22. Non-compliance cases showed a significant increase (2018–28 to 2021–61) despite inspections reducing from 470 in 2019 to 214 in 2021.

Looking at 2022 non compliance cases were 175, which in 163 cases effected 16,062 animals. Just 56 Establishments were audited in 2022 compared with 214 in 2021. Whilst the audit regime has changed they can still be remote or announced or not even include sight of animals, it is all very much a paper exercise with reliance upon self reporting of non compliance. In 2022 just 10 audits were unannounced and only 4 were full system audits.

Types of audit under the new change in working regime:

- Full systems audits: evaluating governance systems within an establishment or a project to understand how robust they are at maintaining compliance.
- Facilities audits: to record evidence of the effectiveness of the governance systems in place to maintain compliance with standard conditions of the establishment licence and Code of Practice for the Housing and Care of Animals Bred, Supplied or Used for Scientific Purposes, and to decide about any regulatory actions required to reduce the risk of non-compliance.



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- Facility assessment for establishment licence amendments: to assess new facilities and/or significant changes to existing facilities that cannot be confirmed remotely.
- For cause audits: for enforcement investigations when the cause of non-compliance cannot be confirmed and for other regulatory purposes such as investigation following a whistle-blowing report received by ASRU.

If a licenced establishment has specially protected species (dogs, cats, horses, non-human primates) then it will be expected to be audited once each calendar year, those without are audited every 4 calendar years. By way of example MBR Acres could be audited in Jan 24 then not until Dec 25 as it is by calendar year.

For non compliance, remedial action, in almost all cases, is a letter or inspectors advice. Non-compliance falls under systems relying on self-reported or whistleblower testimony, leading to a worrying lack of oversight by the regulatory authority. The reality is neither the Home Office Animals in Scientific Regulation Unit (ASRU) or the public know what is happening behind those closed doors. The self reported non-compliance cases will be just the tip of the iceberg.

Additionally, ASRU is fully funded by those it regulates leading to a conflict of interest and lack of independence.

Sadly, the cruel treatment of animals within laboratories continues under the falsehood that the ASRU regulation of ASPA, provides adequate protection for laboratory animals.

In February 22, Chris Sherwood, CEO of the RSPCA, resigned from the ASRU change programme steering committee, citing lack of confidence in this Regulator.

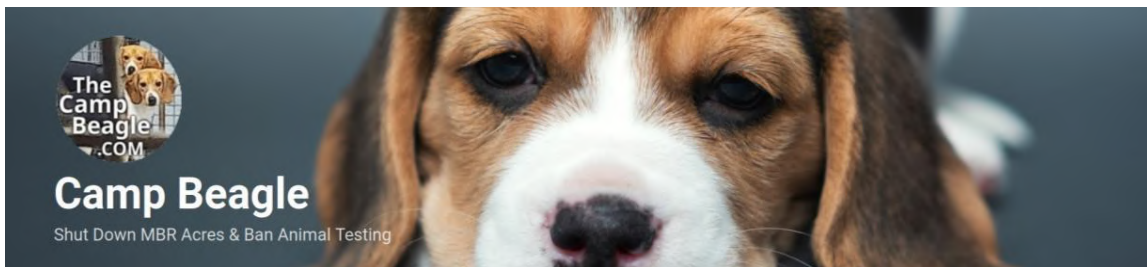
<https://www.vettimes.co.uk/news/rspca-chief-quits-group-after-losing-confidence-in-regulation-of-animal-testing>

The regulated community and wider stakeholders also have expressed concerns that there was inadequate consultation in the regulatory reform that was implemented in July 2021.

ASRU Annual Reports

<https://www.gov.uk/government/collections/animals-in-science-regulation-unit-annual-reports>

If you have time please do read these.



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Investigations into ASRU data integrity and as to if they are fit for purpose:

1. Statistics

<https://osr.statisticsauthority.gov.uk/correspondence/mark-pont-to-jon-simmons-annual-statistics-of-scientific-procedures-on-living-animals-great-britain/>

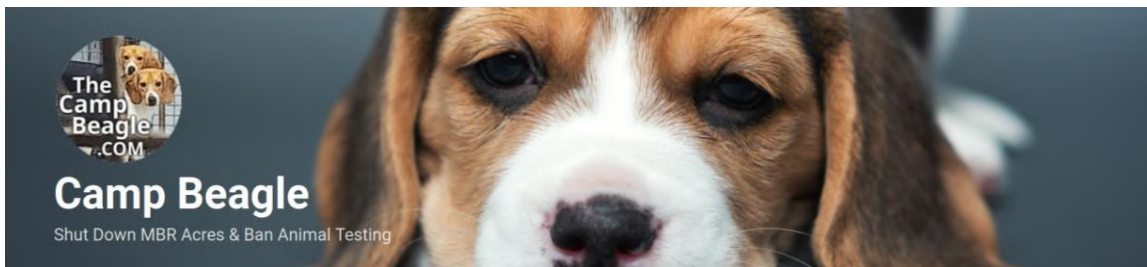
This compliance check by the Office of National Statistics (ONS) was instigated following a complaint by a member of the public in August 22. Over 5000 data errors were identified by someone who had access only to public records and freedom of information requests. The raw data of the publication 'Annual statistics of scientific procedures on living animals Great Britain' is not suitably audited, collected, reconciled or recorded by appropriately trained individuals. On the day of publication of the 2021 annual statistics, a number of errors were found in the accompanying data tables. At a later time 5 out of 20 universities either gave wrong data in FOI responses or published incorrect data on their website.

Up to another 2 million laboratory animal deaths are ignored in the annual statistics as they are not used in 'regulated' procedures. If a non genetically altered animal is bred, found to be surplus to requirements or its tissues/organs wanted and is then humanely killed then its life/death is not made public. These additional statistics were last published for 2017 and at that time was 1.81 million animals <https://www.gov.uk/government/statistics/additional-statistics-on-breeding-and-genotyping-of-animals-for-scientific-procedures-great-britain-2017>

Establishments were found to not perform stocktakes, audits or data reconciliations. Data collection was chaotic with no guidance issued. Researchers admitted to writing animals killed on a sheet of paper and filed in a drawer, laptops with no back up taken home, establishments using same data as project licence holders. None of the people involved are qualified data controllers or auditors.

The Home Office for the annual statistics rely on a project licence holder to tell them the number, species and birth place. Project Licence holders don't even have to be located at the site animals are kept.

No Government department will take responsibility for data integrity of the import of research animals and there are no reconciliations between departments. The reality is no one knows how many animals are being bought into the UK, where they come from or what was the purpose of movement (this is an optional field to complete).



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In 2021, the annual statistics document stated that 'use of dogs in procedures decreased by 3% in the last year, but have increased by 24% over the last 10 years.' Again it was left to a member of the public to dispute these percentages and the Home Office admitted that 'Due to a processing error, the 24% increase was incorrect. The correct figures show a 7% decrease in the use of dogs in experimental procedures over the last 10 years.'

2. Non technical summaries. Members of the public identified over 400 errors out of around 2000 documents – this was the result:

https://assets.publishing.service.gov.uk/media/662a65dfe8c75df17da7e577/2019-2021_annual_report_explanatory_note_final.pdf

Also out of 7 cosmetic project licences 3 non technical summaries were not published until they were pursued at end of 2023. 3 times incorrect information was given just for these 7 documents. We have requested a copy of the report of the independent auditors but this has been denied.

3. Retrospective assessments. An initial investigation indicates that around one third are missing. A ASRU FOI response in July 22 said: 'We are aware of some gaps in our database and are working to address these. Retrospective assessments are published as part of updated non-technical summaries once a project has expired. We are currently reviewing outstanding non-technical summaries and will publish them updated following retrospective assessments, where appropriate, by the end of 2022.'

Retrospective Assessments are a legal requirement. We chased an update to this situation in February 24 after seeing this document:

<https://www.gov.uk/government/publications/asru-operational-newsletter-february-2024/asru-operational-newsletter-february-2024>

see paragraph Overdue submission of retrospective assessments. The response was 'We are currently reviewing outstanding retrospective assessments and will publish them at the earliest opportunity.' The retrospective assessment we had requested sight of in July 22 remain unpublished.

We also asked for a copy of the MBR Acres licence for 'The Production of Laboratory Animal Bio-Products' for 2018. The response was 'the Retrospective Assessment is due to be carried out by 2 April 2024 and the information requested is not held. Please note that when the document is published it will be located with NTS's for projects granted in 2018 and not 2019. The NTS was incorrectly published in the 2019 volume and will be moved.' While writing in August 24 the document still has not been published.



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4. The Number of inspectors is insufficient, 1 visit annually if establishment has special species, 1 visit every 4 years if not. Even looking at the department as a whole the 2022 annual report said there were 19.70 full time equivalent staff. This cannot be adequate for 2.76 million regulated procedures and an additional 1.81 million animals killed in laboratories without regulated procedures (based on last published figure for 2017). Procedures will be slightly higher than actual animals as some are re-used but ignoring that and assuming they are the same we are looking at 4.57 million animals. The compliance assurance team in 2022 is just one FTE senior leader, 5.75 FTE inspectors, one FTE senior executive officer and three FTE executive officers, so 10.75 FTE staff. That equates to responsibility for the protection of 425,000 animals each.

We are aware of 3 first tier tribunals re FOIA 2000 exemptions, the respondents are the Information Commissioners Officers (ICO) and the Home Office. Three exemptions have been challenged, work towards these started in March 22, it is a very slow process. The exemptions used under the FOIA 2000 that have been appealed are:

S38 Health and Safety – this is for the names of Licenced Establishments that are public bodies.

S36 prejudice to the conduct of public affairs exemption – for the release of MBR Inspection reports for 2022 and 2023.

S44 disclosure is prohibited by other legislation specifically in this case to s24 ASPA 1986 (the secrecy clause) – re copies of project licences for safety and toxicity testing using dogs

We will let you know the outcomes when we can.

5. Non animal methods not considered at all throughout the project licence application process. ASPA 1986 says ‘the principle of replacement is the principle that, wherever possible, a **scientifically satisfactory** method or testing strategy not entailing the use of protected animals must be used instead of a regulated procedure.’ Further, the Government repeatedly states that animals are only used as a last resort principle and that their use is only permitted where no alternative exists. In practice a ‘scientifically satisfactory’ method is interpreted as one that has undergone regulatory approval and validation, thus creating an additional layer of compliance that is not explicitly required by the legislation. UK Law is routinely overridden by a global Regulator expectation (the FDA Modernization Act 2.0 should remove this). Even if Inspectors are consulted, most, if not all, come from an animal research background and thus are biased from the outset. Inevitably animal procedures will be approved where non-animal methods do exist. The last PPL application to be rejected was one in 2012, data is not held prior to 2011.



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6. In Oct 23 finally the Government agreed animal use not mandated in UK Law
<https://www.theyworkforyou.com/wrans/?id=2023-09-19.200502.h&s=Animal+testing#g200502.r0>
The Government response to our 2023 toxicity petition stated: ‘In the UK it is required by law that all new drugs are tested within two species’. This was never updated with a correction despite in October the response being ‘There is no United Kingdom legislation that mandates animal testing.’ The source for this conflicting information will have in both cases been the Home Office, likely consulting with ASRU. If a department does not know UK law, should it be regulating it?
8. S24 ASPA 1986 – the results of a consultation in June 14 remain unpublished. Please see separate resource sheet.
9. The code of practice for animal care and housing gives little to no protection for laboratory animals.
<https://www.gov.uk/government/publications/code-of-practice-for-the-housing-and-care-of-animals-bred-supplied-or-used-for-scientific-purposes>
For instance stating only that care staff should be relevant to species allows MBR acres to have 4-6 staff go in at a weekend for 4 hours for 1000-1500 dogs, for 20 hours there are no care staff on site only security who do not enter the sheds.
10. The Rawle Report was commissioned by the National Centre of 3Rs (NC3Rs)
<https://nc3rs.org.uk/sites/default/files/2023-02/Rawle%20project%20report.pdf>
This organisation is Government funded and included as being interviewed for it was Will Reynolds of ASRU.