



Resource Sheet Number 9 – The Law and Harm Benefits Analysis

In the UK, there is no explicit legal requirement to use animals for testing pharmaceuticals and chemicals. International guidelines do however include animal tests as the standard expectation. To use a non-animal method, it must be formally validated and accepted as a “replacement”. If no officially accepted non-animal method exists, the UK Home Office will automatically grant a licence for the animal testing to go ahead. In practice this means tests that use animals are **functionally** required by law even though there is **no explicit** legal requirement to use animals in this way. This is in direct conflict with Animals in Scientific Procedures Act (ASPA 1986, revised 2012) which states in section 2A:

*“...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.”*

Yet animal use per se has never been validated or approved and is certainly not scientifically satisfactory.

Since 2021 medicines are regulated independently under the [Human Medicines Regulations 2012](#) which does not mandate animal testing specifically. The latest version - [Schedule 8](#), states that the materials to accompany a UK marketing authorisation for new drugs must include:

“The results of the following in relation to the medicinal product and its constituent active substances -

- (a) Pharmaceutical (physico-chemical, biological or microbiological) tests;*
- (b) Pre-clinical (toxicological and pharmacological) tests; and*
- (c) Clinical trials.”*

The UK is part of the International Council for Harmonisation (ICH) of Technical Requirements for Pharmaceuticals for Human Use, which publishes guidelines and standards for testing, e.g., [Guidance M3\(R2\) on non-clinical safety studies](#). The latter lists all sorts of tests on animals for pharmacology and toxicity assessments. However, it also mentions that;

“This guidance should [...] reduce the use of animals in accordance with the 3R (reduce/refine/replace) principles [...]. Although not discussed in this guidance, consideration should be given to use of new in vitro alternative methods for safety evaluation. These methods, if validated and accepted by all ICH regulatory authorities, can be used to replace current standard methods.”



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The ICH guidelines are an expectation to enable smoother trade between the participating countries of UK, EU, USA and Japan. They are *not a legal requirement*.

For basic research carried out in universities, scientists are generally free to use entirely non-animal approaches, yet animals use is still widespread.

ASPA 1986 (Revised 2012)

<https://www.legislation.gov.uk/ukpga/1986/14/contents>

The Regulators are the Animals in Science Regulatory Unit (ASRU) which is part of the Home Office. In April 2022, the Animals in Science Regulation Policy Unit (ASRPU) was established within the Home Office, as a separate entity from the Animals in Science Regulation Unit (ASRU).

Harm/Benefit Analysis (HBA)

[The Harm–Benefit Analysis Process Advice Note 05 2015](#)

The harm that might be caused to protected animals in terms of pain, suffering, distress or lasting harm (PSDLH) must be justified by the expected benefits.

This is an analysis in which the likely adverse effects in a procedure within a project are weighed against the potential benefits of the project for people, animals or the environment.

The benefits considered are the specific, expected beneficial outcomes of the objectives of the project, and not the non-specific benefits of the area of research in general.

The harms must be considered beyond the severity classification and also the effect on the 'five freedoms' 1. Hunger/thirst, 2. Discomfort, 3. Pain/injury/disease, 4. Expression of normal behaviour, 5. Fear/distress.

From ASPA 1986 makes the HBA a legal requirement.

5B Determining an application: evaluation of the program of work

(3) In carrying out the evaluation of a programme of work the Secretary of State must—

(d) carry out a harm-benefit analysis of the programme of work to assess whether the harm that would be caused to protected animals in terms of suffering, pain and distress is justified



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by the expected outcome, taking into account ethical considerations and the expected benefit to human beings, animals or the environment.

On the 20th May 2025, Stephen Reed MP, then the Secretary of State for Environment, Food and Rural Affairs (DEFRA), stated the Environment, Food and Rural Affairs meeting that:

“I have spoken to a lot of the companies that are required to carry out testing on animals and, in many cases, they will tell you that they carry it out only because they are required to by regulation and legislation, not because it adds anything of value that they can use in developing better or safer products.”

<https://committees.parliament.uk/oralevidence/15951/pdf/> the full transcript is here but see specifically Q256 – Q258.

Although Mr. Reed refers to “by regulation and legislation” it has been previously confirmed that there is no United Kingdom legislation that mandates animal testing.

[Dept. of Health and Social Care written question answered 17.10.23](#)

Instead, there is for pharmaceuticals just the International Council of Harmonisation (ICH) guidelines or regulations for chemicals under REACH UK (Registration, Evaluation, Authorisation and Restriction of Chemicals).

There is no doubt that Stephen Reed, when referring to ‘a lot of the companies that are required to carry out testing on animals’ that these will be or at least include some of Labcorp, Charles River and Sequani – these are the contract research organisations (CRO’s) that do the testing for guidelines and regulations. These are also the same companies that the pups from MBR are sold to.

The harm/benefit analysis is a legal requirement. In order for a project licence to be granted potential benefits to humans must exceed actual harms to animals. If a company applying for a licence admits the results in many cases will have NO value, then it is obvious that benefits cannot outweigh harms. So, animal researchers should not be making the application (even to meet a regulator guideline as these do not overrule the law) if they admit a test does not have beneficial value. Furthermore, (Animal in Science Regulation Unit should not be approving licences where there is no beneficial value. We believe licences are being both applied for and approved illegally.



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We started asking questions via Freedom of Information Requests and with formal complaints. Some of these are below and prove that seemingly ASRU do not care and also do not understand their own guidance as to the permissible purposes for scientific procedures under ASPA. We have also written to Lord Hanson of Flint (Minister of State for the Home Office), Lady Susan Mary Hayman, Baroness Hayman of Ullock (the Parliamentary under-secretary for DEFRA) and of course to Stephen Reed MP who was in September 2025 shifted to be the Secretary of State for Housing, Communities and Local Government.

Stephen Reed constituency is Streatham and Croydon North. We urgently need residents to come forward who are prepared to meet with or at least write to him.

Letters addressed to all three individuals were all forwarded to ASPRU to respond to. We have gone back to the individuals again and made very clear we expect them to answer personally.

Some extracts of questions and responses (where questions have not been ignored) are below. **The responses are in red.**

Has there been a review or investigation of project licences which have been applied for, approved and then used to test on animals that in many cases had no value? This would be unlawful re the provisions of ASPA 1986 (section 5B in particular).

Has Stephen Reed MP met with ASRU to explain what companies he spoke to (likely the contract research organisations like Labcorp and Charles River) and how many thousands of animals they are using in tests which they have confirmed to have no value.?

Have any project licences been revoked or revised in the light of this public statement?

10 July 2025: there has not been a review, and no licenses have been revoked or revised. No discussions have been held with regard to any recent statements made.

Therefore, if a non-animal alternative is available for the scientific outcome sought then the Home Office will not authorise that testing to take place. Other parts of the response very much concentrated on ‘alternatives’ and the role of the Establishment, Animal Welfare and Ethical Review Body (AWERBS), this presumably was to avoid the actual questions about harm/benefit.

For the years 2020 – 2023, via FIOR, to all public bodies which are licenced establishments under ASPA 1986 we asked for information. For 2023 there were 85 replies and in response to how many project licences were rejected by AWERBS to continue to the Home Office it was 4 (all were rejected as the applicant did not make the wording changes requested or left the



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Establishment). In answer to how many individuals in AWERBS had in depth knowledge of NAMS this was zero.

Our findings were that animal researchers put forward a project licence, this is then reviewed by animal researcher AWERBS team and then passed on to ASRU to be approved by an Inspector who is an ex-animal researcher. AWERBS look at wording and ask the applicant to make changes to meet the 3Rs. For the 4 years, zero project licences were rejected by AWERBS because a NAMS alternative was found.

Further evidence is confirmed by the ASC AWERB Hub workshop

<https://assets.publishing.service.gov.uk/media/685e8320f85b4b993fd75363/AWERB+Hub+Workshop+Report+April+2025.pdf> - see the graph on page 5 .

Also, the damning Rawle Report was highly critical re consideration of or development of replacements. A massive problem is that throughout the application process there is not an advisory NAMS committee with expert knowledge.

Having been alerted to S Reed MP statement it is obvious you should have sought more information so that you, the Establishments and researchers can comply with the law.

The law also says that a procedure must be for a “qualifying purpose” if it is known in advance to have no value it cannot be for a qualifying purpose. Even if under a repeat dose toxicity licence there are some that are considered to have value (perhaps those for same species like dog to dog) then the many known not to have value should not be carried out.

[Animal Experiments: Primates 15.07.25](#) written answer, Lord Hanson of Flint:

“All project licence applications are reviewed by the Home Office Animals in Science Regulation Unit to ensure that any harm that may be caused to the animals is justified by the expected benefits for humans, animals or the environment.”

Going back to S Reed MP, Secretary of State for the Department of Environment, Food and Rural Affairs (DEFRA) statement that (“I have spoken to a lot of the companies that are required to carry out testing on animals and, in many cases, they will tell you that they carry it out only because they are required to by regulation and legislation, not because it adds anything of value that they can use in developing better or safer products.”) the applicant establishment acknowledge there are NO expected benefits for humans. Why are ASRU continuing to approve licences?



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23rd September 2025: Guidance from the Information Commissioner's Office (ICO) states that FOIA requests apply to "any recorded information held by a public authority" and that "There is no obligation for a public authority to create new information in order to respond to your request. You can find more information on the ICO website at: [ICO Link](#)

Asked was why are ASRU continuing to approve licences? Apparently, they would need to prepare new information to answer this.

So, we wrote back and referred to previous responses and information:

DECS Reference: TRO/1353672/25

"Further, it is a requirement of ASPA that the Home Office conducts a robust and rigorous harm benefit assessment which requires a detailed justification of the harms and which demonstrates the 3Rs (Replacement, Reduction and Refinement) have been fully considered." **Note: not interested in the 3Rs only the harm benefit assessment.**

FOI2025/07873

Applications are internally reviewed by an establishment's Animal Welfare and Ethical Review Body before being submitted to the regulator for assessment. Home Office Inspectors in the Regulator will only review applications from establishments that fulfil all requirements of the legislation.

[Lord Hanson of Flint](#) written answer on 15.07.2025 "All project licence applications are reviewed by the Home Office Animals in Science Regulation Unit to ensure that any harm that may be caused to the animals is justified by the expected benefits for humans, animals or the environment."

All our questions relate to Stephen Reed MP statement as, former Secretary of State for the Department of Environment, Food and Rural Affairs (DEFRA) states that: "I have spoken to a lot of the companies that are required to carry out testing on animals and, in many cases, they will tell you that they carry it out only because they are required to by regulation and legislation, not because it adds anything of value that they can use in developing better or safer products."

As the applicant establishment acknowledge there are in many cases NO expected benefits for humans. Why are ASRU continuing to approve licences? It is not good enough to say licences are approved because of international guideline – there must be a high bar set to harm benefit analysis. Guidelines do not have to be satisfied and most certainly do not justify a harm where data in many cases has no value.



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DECS Reference: TRO/1353672/2 stated that a regulator expectation is the benefit as opposed to any human relevant data, this is apparently a permissible purpose. I was directed to the Guidance on the operation of the Animals (Scientific Procedures) Act 1986 (ASPA) [Link](#) - that specifically allows for work to be conducted regarding regulation (Section 5.9 b) (ii)).

This clause says: **5.9 Permissible purposes** We cannot grant a project licence unless the programme of work is to be carried out entirely for one or more of the following purposes: **(ii) the assessment, detection, regulation or modification of physiological conditions in humans, animals or plants; or**

The word regulation here relates to the body regulatory functions like a heartbeat it has absolutely nothing to do with a regulator expectation being a permissible purpose. As this was such a horrendous mistake to make it was run by some legal ASPA 1986 experts and scientists who were 100% in agreement that this has been misinterpreted. Project licences for toxicity/safety are being illegally applied for and illegally approved because they knowingly by all parties fail the harm/benefit tests, a requirement of ASPA.

As at 28th November 2025 we are still waiting on a response.