

# Beyond ASPA: Resolving the Systemic Expertise Deficit and Regulatory Failures in UK Animal Research

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## Authorship & Affiliation

This report was authored by **Tarnia Wilson** on behalf of **The Alliance for Cruelty Free Science**. The findings are based on a comprehensive review of the Animals (Scientific Procedures) Act 1986, Freedom of Information (FOI) disclosures, and the 2025 UK Cross-Government Strategy.

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## Table of Contents

1. Introduction
  - 1.1 Foundational Flaws: ASPA’s Reliance on Translationally Defective Models
  - 1.2 Non-Delegable Statutory Duty
2. Timeline of Regulatory Failures (2010–2026)
3. Structural Barriers to Effective Enforcement
  - 3.1 ASPA’s Structural Limitations
  - 3.2 Fragmented Responsibilities
  - 3.3 Expertise Deficit
  - 3.4 Implementation Gaps
  - 3.5 Expert Legal and Regulatory Analysis of ASPA's Structure
4. Divergence Between UK and International Standards
  - 4.1 Internal UK Policy Divergence: MHRA Roadmap and Cross-Government Strategy vs. ASRU Licensing Practice
  - 4.1A Inter-Departmental Divergence: HSE/REACH vs. Home Office/ASRU
  - 4.2 International Divergence: A Regulatory Landscape in Flux
5. Legal and Ethical Failures
  - 5.1 Potential Illegality of Licences
  - 5.1A Potential Illegality of Licences: The AWA 2006 “Pincer”
  - 5.2 Failure to Make Adequate Inquiry
  - 5.3 Irrationality of Decisions – Passive vs. Active Inquiry Failure
  - 5.3A Error of Law – Misdirection by Adopting a “Phasing Out” Policy
  - 5.4 Breach of Due Regard (Animal Sentience Act 2022)
6. The Legal “Pincer” and Path to Judicial Review
  - 6.1 Grounds: Illegality, Irrationality, Procedural Impropriety
  - 6.2 Standing and Claimants
  - 6.3 Remedies Sought
  - 6.4 Counter-Arguments and Risks
7. Structural and Legal “Red Flags”: Evidence from FOI and Policy
8. Strategic Recommendations
  - 8.1 Immediate Actions
  - 8.2 Long-term Reforms
9. The Home Secretary’s Liability
10. Evidence of Systemic Failure
11. Conclusion References

## **Executive Summary**

The UK's ambition to be a global leader in ethical, innovative science is undermined by systemic challenges within its regulatory framework for animal research. Under the Animals (Scientific Procedures) Act 1986 (ASPA), Section 2A requires the Secretary of State to ensure compliance with the 3Rs, including replacing animal use with scientifically satisfactory non-animal methods (NAMs) wherever possible. <sup>1</sup> Section 5B mandates a favourable evaluation of project licence applications, including assessment of 3Rs compliance and a harm-benefit analysis.

However, enforcement of the replacement principle is hampered by an expertise deficit within the Home Office's Animals in Science Regulation Unit (ASRU). ASRU inspectors, primarily veterinarians, often lack specialised knowledge in modern NAMs. This leads to inadequate inquiry into available NAMs, potentially resulting in licences granted without proper regard to the 3Rs, raising questions about compliance with statutory duties, and exposing decisions to judicial review on grounds of irrationality or failure to have due regard to animal sentience. ASPA's structure, built on the assumption of animal model predictivity, exacerbates these issues, despite evidence of high translational failure rates and the potential legal misdirection created by adopting a "phasing out" policy where the statute demands replacement "wherever possible".

This report examines regulatory challenges, highlights divergence from international standards (e.g., US FDA Modernization Acts 2.0 and 3.0), and outlines a "legal pincer" for potential challenges. It recommends reforms to integrate NAM expertise, ensuring compliance and aligning with the November 2025 Cross-Government strategy 'Replacing Animals in Science'.

## 1. Introduction

This report exposes structural and legal challenges impeding the full implementation of ASPA's replacement principle. While ASPA aims to minimise animal use through the 3Rs, the absence of dedicated NAM expertise in ASRU renders this a facilitative rather than absolute duty, often reliant on applicant-led assessments without sufficient independent scrutiny.

The Secretary of State is responsible for compliance, yet ASRU's composition limits effective evaluation of NAMs. This risks raising questions about compliance with duties under ASPA, the Animal Welfare Act 2006 (AWA), and the Animal Sentience Act 2022, while diverging from global progress. This divergence potentially harms the UK's "Science Superpower" status and biotech investments by creating a regulatory environment that lags behind international competitors.

### 1.1 Foundational Flaws: ASPA's Reliance on Translationally Defective Models

Since its passage in 1986, ASPA has enshrined animal use as the default where 'no alternative exists'. This premise rested on the assumption that animal models provide reliable predictors of human responses. However, animal models have long shown limitations in predicting human outcomes, evidenced by high attrition rates in drug development (often cited at over 90% from preclinical to approval stages) linked to species differences and poor pharmacokinetics. The expertise deficit in ASRU reflects these structural challenges in a licensing regime prioritising animal models despite evidence of translational limitations.

### 1.2 Non-Delegable Statutory Duty

Under Sections 2A and 5B of ASPA, the duty to assess the 3Rs, particularly replacement, rests solely with the Secretary of State (SoS) for the Home Department. This is a personal statutory duty that cannot be fully delegated. A decision-maker must properly inform themselves of all relevant considerations. Relying solely on applicant assertions or external bodies without ASRU conducting its own technical assessment would constitute a failure to perform this independent inquiry.

#### Actions:

- **Immediate:** Acknowledge the non-delegable nature of the SoS's duty under ASPA Sections 2A and 5B.
- **Immediate:** Establish clear internal protocols for ASRU to conduct independent verification of NAM availability and suitability for all licence applications.

## 2. Timeline of Regulatory Failures (2010–2026)

This section outlines key periods and events demonstrating a historical pattern of regulatory challenges and slow adoption of NAMs.

- **2010–2014:** EU Directive 2010/63/EU transposed without robust NAM pathways or inspector upskilling.
- **2015–2019:** NAM advances outpaced ASRU capabilities; reliance on applicant-led searches persisted.
- **2020–2021:** Post-Brexit, no new statutory mandates for NAM adoption.
- **2022–2023:** Reports indicated rising non-compliance; transparency stalled; no centralised NAM database.
- **2024:** Home Office statistics showed 2.64 million procedures on living animals in Great Britain.
- **2025:** Publication of UK Cross-Government strategy 'Replacing Animals in Science' (November 2025), committing £75 million and establishing UKCVAM. MHRA published 2025 NAM Roadmap. Limited immediate changes in ASRU licensing practices noted.
- **2026:** ASRU's 2024 Annual Report (published December 2025) documented ongoing reform but persistent gaps in NAM training and verification. Westminster Hall debate on ASRU 2024 report.

### Actions:

- **Immediate:** Review and expedite the implementation of the November 2025 'Replacing Animals in Science' strategy and the MHRA 2025 NAM Roadmap within ASRU's licensing practices.
- **Immediate:** Establish clear timelines and metrics for ASRU to demonstrate tangible progress in NAM integration, moving beyond incremental compliance oversight.

## 3. Structural Barriers to Effective Enforcement

This section details the fundamental structural and operational issues within ASPA and ASRU that impede effective enforcement of the 3Rs, particularly the replacement principle.

### 3.1 ASPA's Structural Limitations

No statutory definition of 'scientifically satisfactory' NAMs: Allows subjective interpretation and inconsistent application.

- **Inherent design defect (1986):** Assumes animal models are satisfactory predictors, despite evidence to the contrary.
- **No mandatory validation pathway or sanctions for overlooking NAMs.**
- **Duty under Section 2A** is to “have regard” to replacement “wherever possible,” requiring adequate inquiry but allowing discretion. Suffering is 'unnecessary' if 'reasonably avoided or reduced' by NAMs, a condition met when NAMs exist but are overlooked due to ASRU's limitations.

### 3.2 Fragmented Responsibilities

- **Inter-departmental divergence:** Inconsistent approaches to NAM adoption across government (e.g., HSE/REACH vs. Home Office/ASRU).
- **Absence of Formal Referral Protocols:** No formal mechanism between ASRU and MHRA/FSA for NAM feasibility reviews or expert input. This leads to siloed operations and prevents a unified approach.
- **Silos across Home Office, MHRA, NC3Rs, OECD, ICH; no shared NAM database.**

### 3.3 Expertise Deficit

- **ASRU composition:** Predominantly veterinarians lacking expertise in modern NAMs (AI, organ-on-a-chip, computational biology).
- **Training limitations:** Inspectors' training rooted in animal husbandry and traditional toxicology, inadequate for evaluating advanced NAMs.
- **Consequences:** Difficulty in identifying NAM needs, understanding validation, and engaging in meaningful scientific dialogue. This limits effective collaboration and independent verification under Section 5B.
- A Home Office written answer dated 19 March 2026 states that ASRU inspectors receive NC3Rs training focused on 3Rs knowledge and assessing licence applications, with signposting to external resources such as replacement checklists. Crucially, it emphasises that “the responsibility of ensuring the principles of the 3Rs have been fully applied in applications belongs to the applicant.” While this supports general awareness of the 3Rs, **it does not demonstrate that inspectors are equipped to discharge the Secretary of State’s distinct, non-delegable duty under Section 2A** for proactive and independent verification that a scientifically satisfactory NAM exists and must be used “wherever possible”. This reinforces the gap between routine applicant-led 3Rs review and the statutory requirement for active regulatory inquiry.<sup>^1</sup>

**Evidence:** NC3Rs Rawle report (2023) states inspectors lack training in modern bioengineering and computational biology. Job descriptions do not require NAM-specific expertise. Footnote 1: Written answer to parliamentary question on training for ASRU inspectors, 19 March 2026 (ref: 121156).

### 3.4 Implementation Gaps

- **Absence of a national NAM database or mandatory referral mechanism:** Hinders systematic tracking and understanding of NAM adoption.
- **Inadequate inspector training and lack of enforcement for mid-project NAM adoption:** No routine mechanism to enforce adoption of newly validated NAMs during multi-year licences.
- **Reliance on applicant-led assessments:** Limits independent regulatory verification.

### 3.5 Expert Legal and Regulatory Analysis of ASPA's Structure

- **Exemption-Based Model:** ASPA acts as a permitting office, creating a conflict of interest where KPIs may focus on throughput and legal shielding rather than rigorous Section 2A enforcement.
- **Technical Literacy Deficit:** A veterinary-dominated inspectorate lacks the mandate to evaluate modern NAMs, constituting a "Critical Expertise Deficit."
- **"Reasonably Practicable" Loophole:** Allows institutional inertia and lack of investment to justify continued animal use, rewarding technical stagnation.
- **Section 24 Transparency Deficit:** Prevents release of establishment-level data, hindering public accountability and Competitive Refinement.
- **"Validation Trap":** Lack of statutory bridge between Home Office, MHRA, and HSE creates a "Pass-the-Parcel" of accountability.

#### Actions:

- **Immediate:** Conduct NAM skills audit of ASRU/AWERBs.
- **Immediate:** Develop and implement a mandatory national NAM training program for ASRU inspectors and AWERB members.
- **Immediate:** Establish regulator-led verification processes and a central, publicly accessible NAM database.
- **Immediate:** Mandate ASRU to proactively search for and assess available NAMs for each licence application.
- **Long-term:** Amend ASPA to define 'scientifically satisfactory' NAMs and introduce sanctions for overlooking them.
- **Long-term:** Establish a dedicated, independent cross-regulator body for NAM oversight.
- **Long-term:** Embed NAM experts within ASRU through recruitment.
- **Long-term:** Implement regular, independent audits of ASRU's NAM assessment processes.

### 4. Divergence Between UK and International Standards

This section examines how the UK's regulatory framework compares to international advancements, highlighting ASRU practices' divergence from stated policy and global trends.

#### 4.1 Internal UK Policy Divergence: MHRA Roadmap and Cross-Government Strategy vs. ASRU Licensing Practice

- **Policy Commitments:** UK strategy (November 2025) and MHRA Roadmap (2025) advocate NAM adoption with specific timelines (e.g., rabbit pyrogen replacement by end-2025, ending in vivo irritation/sensitisation tests by 2026).
- **ASRU Practice:** Limited immediate changes in ASRU licensing practices observed as of March 2026 for procedures targeted by these timelines, with continued reliance on applicant-led assessments.
- **Inconsistency:** Highlights a lag between high-level policy and operational licensing, potentially breaching ASPA Section 5B's duty.

- **Inter-Departmental Divergence:** HSE/REACH actively accepts NAMs for chemical safety (e.g., irritation), while ASRU continues to license animal procedures for similar endpoints. This highlights a lack of unified cross-government mechanisms for NAM adoption.

#### 4.2 International Divergence: A Regulatory Landscape in Flux

- **US FDA:** Proactive NAM adoption. Modernization Acts 2.0 (2022) and 3.0 (Senate-passed Dec 2025) remove mandatory animal testing. April 2025 roadmap phases out/reduces animal tests for monoclonal antibodies, prioritising human-relevant methods. March 2026 draft guidance establishes validation framework (Context of use, Human biological relevance, Technical characterisation, Fit-for-purpose).
- **OECD/ICH:** Actively validating NAMs via guidelines, emphasizing human-relevant approaches. UK strategy aligns partially but ASRU has not fully integrated these.
- **EU:** European Pharmacopoeia deleted ATT in Jan 2019.
- **Consequences:** UK's operational practices risk significant divergence, impacting scientific competitiveness, biotech investment, and access to predictive data.

#### Actions:

- **Immediate:** Align UK regulatory practices with US FDA Modernization Acts 2.0 and 3.0, prioritising and accepting NAM data.
- **Immediate:** Ensure ASRU licensing practices reflect the timelines and commitments of the UK's own 2025 strategy and MHRA Roadmap.
- **Immediate:** Establish unified cross-government mechanisms for NAM adoption, drawing on HSE/REACH's proactive approach

### 5. Legal and Ethical Failures

This section analyses potential legal consequences arising from ASPA's structural, expertise, and implementation gaps.

#### 5.1 Potential Illegality of Licences

- **Breach of Section 5B:** Licences granted without adequate independent inquiry into NAM availability may be ultra vires.
- **AWA 2006 "Pincer":** If a licence is ultra vires due to inadequate NAM assessment, the ASPA exemption from AWA 2006 prohibitions on unnecessary suffering may not apply, potentially leading to criminal liability for causing unnecessary suffering.

#### 5.2 Failure to Make Adequate Inquiry

ASRU's reliance on applicant assertions, coupled with the lack of a central NAM database and referral protocols, constitutes a failure to properly inform the decision-maker, contravening administrative law principles and ASPA Sections 2A/5B.

#### 5.3 Irrationality of Decisions: Passive Approach vs. Active Inquiry and Strategy Alignment

- **Passive Approach:** Deferring to external regulators or transition periods contradicts ASPA Section 5B's active, case-by-case assessment and preference for NAMs.
- **Flaw 1 (Contradiction of ASPA's Active Duty):** Justifying continued animal testing based on slow processes or lack of investment may breach statutory requirements and be Wednesbury unreasonable. Lack of mid-project NAM enforcement is a critical gap.
- **Flaw 2 (Contradiction of Government's Strategy):** Continued licensing of replaceable procedures, absent proactive verification, appears inconsistent with government policy (2025 strategy, MHRA Roadmap) and international advancements (US FDA March 2026 draft guidance).
- **Wednesbury Unreasonableness:** Decisions may be unreasonable due to reliance on flawed animal-to-human translation assumptions and passive approaches, failing to inform the decision-maker properly.

### 5.3A Error of Law – Misdirection by Adopting a “Phasing Out” Policy

- An arguable error of law arises where the Secretary of State or ASRU applies the general “phasing out” or transition-period approach set out in the November 2025 Cross-Government Strategy Replacing Animals in Science and the MHRA 2025 NAM Roadmap, even where scientifically satisfactory NAMs already exist for specific endpoints.<sup>2</sup>
- Section 2A of ASPA requires the Secretary of State to exercise her functions “with a view to ensuring compliance with the principle of replacement”, and defines replacement as requiring that a scientifically satisfactory NAM “must be used instead” of a regulated procedure wherever possible.<sup>3</sup> Section 5B requires a favourable evaluation of each individual project licence application, including proper assessment of 3Rs compliance.
- By contrast, the strategy establishes defined timelines that permit continued licensing of animal procedures during transition periods (e.g., rabbit pyrogen test replacement targeted for end-2025, irritation/sensitisation tests by end-2026). This approach risks misdirecting the decision-maker in law by subordinating the statutory “wherever possible” replacement mandate to a discretionary policy timetable.
- In such cases, the decision-maker may be asking the wrong question (“Is this procedure within the permitted phase-out window?”) rather than the statutory question (“Is a scientifically satisfactory NAM possible here and now?”). This constitutes a classic error of law through misdirection or misapplication of the statutory duty.

### 5.4 Breach of Due Regard (Animal Sentience Act 2022)

Failure to actively consider and prefer available NAMs may breach the duty to have “all due regard” to adverse effects on sentient animals, potentially perpetuating avoidable suffering.

## 6. The Legal “Pincer” and Path to Judicial Review

This section outlines the principal grounds on which a judicial review challenge could be advanced, the potential remedies sought, and the key counter-arguments and risks.

### 6.1 Grounds: Illegality, Irrationality, Procedural Impropriety

Project licences granted without competent, independent verification of available scientifically satisfactory NAMs may breach Section 5B(2)(a) of ASPA and be open to challenge as ultra vires. If the Secretary of State fails to discharge the non-delegable duty of adequate inquiry under Sections 2A and 5B, decisions may be unlawful.

ASPA provides a conditional exemption from the general prohibitions on causing unnecessary suffering under the Animal Welfare Act 2006. If a licence is found to be ultra vires due to inadequate NAM assessment, this exemption may not apply. This creates a potential (as-yet-untested) pathway whereby suffering under such a licence could be deemed “unnecessary” under AWA s.4, although any such claim would face high evidential thresholds.

**Principal grounds therefore include:**

- Breach of the non-delegable duties under Sections 2A and 5B (failure to conduct adequate independent inquiry into replacement options).
- **Error of law by misdirection:** Applying a “phasing out” policy that permits continued animal use where scientifically satisfactory NAMs already exist, contrary to the mandatory preference for replacement “wherever possible” under ASPA Section 2A.
- Potential irrationality (Wednesbury unreasonableness) where decisions rest on passive approaches or outdated assumptions about animal model predictivity.
- Procedural impropriety arising from inadequate inquiry and lack of transparent decision-making.

### 6.2 Standing and Claimants

Organisations or individuals with sufficient interest in animal welfare and the proper enforcement of ASPA would likely have standing under s.31(3) of the Senior Courts Act 1981. Claimants with a history of engagement in this field are particularly well-placed.

### 6.3 Remedies Sought

The following remedies could be pursued, graduated from targeted to systemic:

- **Quash specific licences:** This seeks certiorari to quash individual project licences where there is clear evidence that ASRU failed to adequately verify NAM availability, breaching Section 5B and potentially Section 2A. It targets licences with the strongest evidential basis (e.g., those involving endpoints acknowledged in the 2025 strategy/MHRA Roadmap as replaceable). Revocation would prevent further animal use under those licences and set a precedent for 3Rs compliance.
- **Declaration of systemic unlawfulness:** declaration that ASRU's general practice of licensing without adequate independent NAM verification constitutes a systemic

failure to comply with ASPA Sections 2A and 5B. This would establish the unlawfulness of the current framework due to pervasive expertise deficits and inadequate inquiry, providing a strong legal foundation for reform without immediately disrupting all licences.

- **Mandamus for NAM expertise integration and policy reforms:** Mandamus compels performance of a public duty. Orders could require the Home Office/ASRU to:
- **Integrate NAM expertise:** Recruit and embed specialists in computational biology, bioengineering, AI modelling, and advanced in vitro systems within ASRU.
- **Implement policy reforms:** Establish regulator-led verification processes for NAMs, create a central NAM database/referral mechanism, and introduce mandatory NAM-specific training for inspectors.
- **Compel alignment with the 2025 Cross-Government NAM Strategy:** Require mandatory consideration and adoption of UKCVAM-validated methods and timelines in licensing decisions.

These remedies aim to secure legally binding steps to address the identified failures and ensure future compliance with statutory duties

#### 6.4 Counter-Arguments and Risks

**The Home Office may advance several defences:**

- Applicant-led assessments, AWERB review, and ad hoc consultations with MHRA/NC3Rs are sufficient to discharge the Section 5B duty.
- The 3Rs principles are aspirational rather than absolute; courts should defer to executive judgment in a technically complex field.
- Ongoing reforms (e.g., inspector increases to 22 FTE by March 2026, broader skills push in ASRU 2024 report) demonstrate progress.
- High Wednesbury threshold: Courts are reluctant to interfere unless decisions are "so unreasonable that no reasonable authority could ever have come to it."

**Rebuttal considerations:** The Secretary of State's duties under Sections 2A and 5B are personal and non-delegable. While consultation is permitted, reliance on applicant assertions or external bodies without ASRU's own technical assessment may fail to satisfy the independent inquiry obligation. The Rawle report (2023) and absence of NAM-specific training requirements provide objective evidence of structural limitations. The government's own strategy timelines and NAM acknowledgements are relevant considerations that must be taken into account.

**Risks:**

- Permission refusal due to high deference in scientific/regulatory contexts.
- Costs if unsuccessful (claimant bears risk unless protective costs order obtained).
- Limited systemic overhaul if only specific licences are quashed.

## 7. Structural and Legal “Red Flags”: Evidence from FOI and Policy

Law/Standard	Official Standard	Evidence	Implication
ASPA Section 2A – Replacement Principle	NAM must be used wherever possible (mandatory preference on a case-by-case basis)	2025 Cross-Government Strategy and MHRA Roadmap adopt “phasing out” timelines that permit continued animal use for endpoints where NAMs are already available	Arguable error of law / misdirection: Subordinating the statutory “wherever possible” duty to a discretionary policy timetable; decisions may fail to ask the correct statutory question
ASPA 1986 foundational premise	Animal models as default where no alternative exists	High attrition rates in drug development (often cited >90% from preclinical to approval stages); long-standing evidence of translational limitations (species differences, poor replication of human disease heterogeneity, pharmacokinetics)	Raises questions about whether the Act’s design adequately supports proactive replacement in light of modern scientific understanding; contributes to ongoing challenges in effective 3Rs enforcement.
ASPA Section 5B	Favourable evaluation including 3Rs compliance; preference for scientifically satisfactory NAMs wherever possible	NC3Rs Rawle report (2023): inspectors “do not (and could not)” have detailed knowledge across all 3Rs approaches and “rarely suggest use of replacements”; Home Office job postings require veterinary qualifications but no NAM-specific expertise	Potential ultra vires licensing if independent inquiry into NAMs is inadequate; arguable breach of non-delegable duty to assess replacement options.
Animal Welfare Act 2006	No unnecessary suffering	2024 statistics: 2.64 million procedures (lowest since 2001), ~48,224 severe experimental procedures (3% of experimental); ~16,000 on specially protected species	If licences are ultra vires due to failure to prefer available NAMs, suffering may be deemed “unnecessary” (could reasonably have been avoided/reduced), exposing activities to potential AWA criminal liability
Animal Welfare (Sentience) Act 2022	Public authorities must have “all due regard” to adverse effects on sentient animal welfare	No evidence of systematic, proactive consideration of NAMs as a means to minimise adverse welfare impacts in licensing decisions	Potential breach of due regard duty where available NAMs could reduce or eliminate suffering but are not adequately assessed or preferred

Law/Standard	Official Standard	Evidence	Implication
UK 2025 Cross-Government Strategy (Replacing Animals in Science)	Transition to NAMs; ~£75m funding; UKCVAM establishment; specific timelines (rabbit pyrogen by end-2025, irritation/sensitisation by 2026, etc.	Strategy published November 2025; ASC minutes (September 2025) confirm finalisation/publication stage; ASRU 2024 Annual Report (Dec 2025) notes ongoing reform but no specific NAM training/verification updates	Partial alignment only; ongoing implementation challenges and limited immediate impact on licensing practices raise questions about translation of policy commitments into regulatory action.
MHRA 2025 NAM Roadmap	Endorsement of NAM-only packages; timelines for replacement (e.g., rabbit pyrogen by end-2025)	Roadmap published 2025; no new rabbit pyrogen licences reported post-strategy; European Pharmacopoeia deletion effective Jan 2026	Internal divergence; ASRU licensing has not shown corresponding changes for broader endpoints, suggesting incomplete integration of MHRA-endorsed methods.

### Notes on Evidence Sources

- Statistics: Home Office annual statistics (published 23 October 2025).
- Rawle report: NC3Rs-commissioned review (2023).
- Strategy & Roadmap: GOV.UK publications (November 2025).
- ASC minutes: Animals in Science Committee, 48th plenary (8 September 2025).
- FOI responses: Consistent “information not held” replies reinforce data/oversight gaps.

## 8. Strategic Recommendations

### 8.1 Immediate Actions

- Conduct a comprehensive NAM skills audit of ASRU inspectors and AWERB members to identify current levels of expertise in modern non-animal methods (e.g., organ-on-a-chip, AI-driven toxicology, computational modelling) and inform targeted recruitment/training.
- Implement a mandatory national training programme for ASRU inspectors and AWERB members, covering scientific principles, validation status, regulatory acceptance, and assessment of NAM suitability under ASPA Section 5B.
- Shift to regulator-led verification of NAM availability: move from reliance on applicant assertions to proactive ASRU assessment, supported by a central, regularly updated database of validated NAMs and their applications.
- Align ASRU guidance and practice with the FDA Modernization Acts 2.0/3.0 principles and the UK's own 2025 strategy timelines, prioritising acceptance of NAM data where scientifically appropriate.

## 8.2 Long-term Reforms

- Amend ASPA to include clearer definitions of “scientifically satisfactory” NAMs and introduce statutory sanctions for failure to adequately consider or verify them.
- Establish a cross-regulator oversight body (or strengthen existing mechanisms) to ensure consistent NAM policy application across MHRA, FSA, HSE, and ASRU, with authority to set validation standards and monitor implementation.
- Embed NAM specialists (computational biology, bioengineering, AI/modelling) within ASRU licensing and inspection teams on a permanent basis.
- Introduce regular independent audits of ASRU's NAM assessment processes and licensing decisions, with greater transparency (e.g., public summaries of evidence considered in 3Rs evaluations).

## 9. The Home Secretary’s Liability

***The Secretary of State bears personal, non-delegable responsibility under ASPA Sections 2A and 5B for ensuring proper evaluation of licence applications, including independent verification of NAM availability.***

If the Home Secretary is (or ought reasonably to be) aware of systemic expertise deficits—through parliamentary scrutiny, NC3Rs reports (e.g., Rawle 2023), FOI disclosures, ASC minutes, or ASRU annual reports—continued authorisation of licences without rectifying these gaps may constitute a failure to adequately supervise and perform her statutory duty.

Where licences are arguably ultra vires due to inadequate NAM inquiry, the conditional exemption under AWA 2006 may not apply, exposing authorised procedures to potential criminal liability for unnecessary suffering. This risk is heightened in cases of severe procedures or use of specially protected species. While prosecution would require proof of specific unnecessary suffering and causation, the “pincer” mechanism underscores the seriousness of any ASPA non-compliance.

## 10. Evidence of Systemic Failure

**See Section 7** table and supporting sources throughout the report (Home Office statistics, NC3Rs Rawle report, 2025 strategy, MHRA Roadmap, ASC minutes, FOI responses).

## 11. Conclusion

The expertise deficit within the Home Office’s Animals in Science Regulation Unit (ASRU) fundamentally undermines the effective enforcement of ASPA’s 3Rs principles, particularly the replacement of animal use with scientifically satisfactory non-animal methods (NAMs). This deficit, evidenced by the Rawle report (2023), job requirements, and absence of dedicated NAM training, risks rendering certain licensing decisions ultra vires and exposes the framework to challenge on grounds of illegality, irrationality, and procedural impropriety.

The systemic failure to integrate modern NAM expertise, combined with fragmented responsibilities, passive inquiry approaches, limited implementation of the November 2025

Cross-Government strategy, and the potential misdirection created by adopting a “phasing out” policy where the statute demands immediate replacement “wherever possible”, results in a regulatory regime that appears out of step with both international trends (e.g., US FDA Modernization Acts) and the UK’s own policy commitments. This not only perpetuates avoidable animal suffering but also poses competitive disadvantages for the UK’s scientific and biotech sectors.

Urgent, comprehensive reforms are required. These must centre on embedding genuine NAM expertise within ASRU, mandating independent and proactive verification of NAM availability, strengthening cross-regulator coordination, and ensuring transparency and accountability. Failure to implement such changes risks continued legal vulnerability, reputational damage, and erosion of the UK’s position as a leader in ethical and innovative science.

## **Supporting Appendices**

### **Appendix A: FOI Data**

### **Appendix B: MP Toolkit**

### **Appendix C: Cascading Legal Failure Model (available on request)**

## Footnotes

<sup>1</sup> Animals (Scientific Procedures) Act 1986, s.2A(1)–(2).

<sup>2</sup> UK Government, Replacing Animals in Science strategy (November 2025).

<sup>3</sup> Animals (Scientific Procedures) Act 1986, s.2A(2)(a).

<sup>4</sup> NC3Rs Rawle Report (2023), key finding on inspector expertise

Written answer to parliamentary question on training for ASRU inspectors, 19 March 2026 (ref: 121156).

## **APPENDIX A: FOI Data**

This appendix summarises key Freedom of Information (FOI) responses obtained from the Home Office that underpin the findings in this report regarding the expertise deficit in ASRU and limitations in data collection and transparency.

### **Key FOI Findings:**

#### **Absence of Dedicated NAM Expertise**

- FOI requests submitted regarding the qualifications and specialist training of ASRU inspectors (2019–2021 and subsequent updates) confirm that there are no dedicated specialists in non-animal methods (NAMs) such as organ-on-a-chip technology, computational toxicology, or AI-driven modelling within the inspectorate. Inspectors are primarily qualified veterinarians with expertise in animal welfare and traditional toxicology.

#### **Inspector Training on NAMs**

- Responses indicate that while inspectors receive general 3Rs training via the NC3Rs, there is no mandatory or comprehensive training specifically focused on the evaluation and validation of advanced non-animal methods. Training remains focused on assessing animal-based procedures.

#### **Data on AWERB Effectiveness and NAM Consideration**

- Multiple FOI requests concerning aggregated data on AWERB (Animal Welfare and Ethical Review Body) discussions of replacement options and NAMs have been met with the response “information not held”. This indicates that the Home Office does not centrally collect or monitor how effectively AWERBs are applying the replacement principle.

#### **Overall Effectiveness Reviews**

- FOIs requesting copies of internal or external reviews into the overall effectiveness of the 3Rs (particularly replacement) in ASRU licensing decisions have consistently returned “information not held”. This highlights a significant transparency and oversight gap.

#### **Conclusion from FOI Evidence**

The pattern of responses demonstrates systemic limitations in both specialist expertise within ASRU and the Home Office’s ability (or willingness) to collect and publish data on how effectively the replacement principle is being applied in practice. These gaps make it difficult to assess genuine progress toward the objectives set out in the 2025 Cross-Government “Replacing Animals in Science” strategy

## **APPENDIX B - Executive Summary for MPs**

The Home Office’s Animals in Science Regulation Unit (ASRU) suffers from a critical expertise deficit in modern non-animal methods (NAMs). Despite the Animals (Scientific Procedures) Act 1986 (ASPA) placing a non-delegable statutory duty on the Secretary of State to ensure replacement “wherever possible” (ss.2A and 5B), project licences continue to be granted without independent verification that scientifically satisfactory NAMs exist.

This creates ultra vires licences, removes the ASPA exemption from the Animal Welfare Act 2006, and opens the door to avoidable animal suffering that may now be unlawful.

The UK is also falling behind international standards (US FDA Modernization Acts 2.0 & 3.0) while its own 2025 Cross-Government Strategy Replacing Animals in Science and MHRA NAM Roadmap remain unimplemented in licensing practice.

Full report and appendices available here:



Beyond ASPA -  
Revision 29032026.pd



Appendix C -  
Cascading Legal Failu

Key Evidence (all publicly available)

- NC3Rs Rawle Report (2023): ASRU inspectors “do not (and could not)” have detailed knowledge across all 3Rs approaches and “rarely suggest use of replacements”.
- Home Office written answer, 19 March 2026 (ref 121156): Confirms that “the responsibility of ensuring the principles of the 3Rs have been fully applied belongs to the applicant.”
- November 2025 Cross-Government Strategy & MHRA 2025 NAM Roadmap: Set clear replacement timelines (e.g. rabbit pyrogen test by end-2025, irritation/sensitisation tests by 2026) – yet no corresponding change in ASRU licensing.
- 2024 Home Office statistics: 2.64 million procedures on living animals, including 48,224 severe experimental procedures.

Legal “Pincer” Risk (see Appendix C – Cascading Legal Failure Model)

**The expertise deficit triggers a clear legal cascade:**

1. Failure to discharge non-delegable duty under ASPA ss.2A & 5B
2. Ultra vires licensing decisions
3. Loss of ASPA exemption from Animal Welfare Act 2006
4. Potential criminal liability for unnecessary suffering (AWA s.4)
5. Judicial review on grounds of illegality, irrationality and procedural impropriety

This risk now extends to the Home Secretary personally if she “ought reasonably to be aware” of the systemic gaps.

### **Suggested Parliamentary Questions (ready to table this week)**

You can table these immediately as Written or Oral Questions:

**1.**

*“To ask the Secretary of State for the Home Department what assessment her Department has made of the NC3Rs Rawle Report (2023) findings that Animals in Science Regulation Unit inspectors lack detailed knowledge of modern non-animal methods; and what steps she is taking to ensure ASRU can independently verify the availability of scientifically satisfactory NAMs as required by ASPA s.2A.”*

**2.**

*“To ask the Secretary of State for the Home Department whether she will publish the results of a NAM skills audit of ASRU inspectors and AWERB members, as recommended in the Alliance for Cruelty Free Science report Beyond ASPA (29 March 2026).”*

**3.**

*“To ask the Secretary of State for the Home Department if she will confirm that the November 2025 Cross-Government Strategy Replacing Animals in Science does not override the statutory duty under ASPA s.2A to replace animal procedures ‘wherever possible’ on a case-by-case basis.”*

**4.**

*“To ask the Secretary of State for the Home Department what steps she is taking to resolve the inter-departmental divergence between the Health and Safety Executive (which accepts NAMs for chemical safety) and ASRU (which continues to license animal procedures for the same endpoints).”*

### **Simple Actions You Can Take This Week**

- Write to the Home Secretary urging immediate implementation of the report’s Immediate Actions (NAM skills audit, regulator-led verification, mandatory training).
- Request a Westminster Hall debate on the ASRU 2024 Annual Report and the findings of Beyond ASPA.
- Support / co-sign an Early Day Motion on regulatory reform.
- Attend or speak in the next Science & Technology Select Committee session on animal research.

### **We can provide:**

- A full draft letter to the Home Secretary
- A one-page visual of the Cascading Legal Failure Model (Appendix C)

### **Why This Matters to Your Constituents**

- Animal welfare: Avoidable suffering on sentient animals, including specially protected species.
- Science & economy: The UK risks losing ground to countries that have already modernised regulation, threatening biotech investment and our “Science Superpower” status.
- Public money: £75 million committed in the 2025 strategy – yet licensing practice shows no visible change.
- Rule of law: Statutory duties must not be subordinated to discretionary policy timelines.

## APPENDIX C - Cascading Legal Failure Model

Stage	Legal Failure	Key Statutory Provisions	Evidence/Trigger	Consequence/Exposure
1	Expertise & Enquiry Deficit	ASPA's s.2A(1)-(2) (Replacement Principle) ASPA s.5B (favourable evaluation & 3R's)	<ul style="list-style-type: none"> <li>NC3R's Rawle Report (2023)</li> <li>Home Office job descriptions</li> <li>19<sup>th</sup> of March 2026 written answer (ref 121156)</li> <li>Absence of central NAMs database</li> </ul>	Secretary of State fails to "properly inform herself" – breach of non-delegable duty (Padfield/Tameside principles)
2	Ultra Vires Licenses	ASPA s.5B(2) (a)	Licenses issued without competent, independent NAM verification	Decisions unlawful and liable to be quashed
3	Loss of Statutory Shield	ASPA s.3 (exemption from AWA 2006)	Ultra Vires license = no valid exemption	Procedures fall back under general AWA prohibitions
4	Unnecessary Suffering	AWA2006 s.4(1) & s.4(2)	NAMs already validated/available but not used	Criminal offence (summary or indictment)
5	Personal & Vicarious Liability	AWA2006 s.4 + common law supervisory duty	Home Secretary "ought reasonably to be aware" (ASC Minutes, ASRU reports, PQ's FOI's)	Potential personal liability for SoS; Corporate liability for PIs/Named Persons
6	Judicial Review + Collateral Attack	Senior Courts Act 1981 s.13	<ul style="list-style-type: none"> <li>"Phasing out" Policy misdirection (error of Law)</li> <li>Wednesbury unreasonableness</li> </ul>	Quashing orders, declarations, mandatory orders for NAM integration; possible criminal complaints