

## PARLIAMENT PULSE

### THE SCIENTIFIC CASE AGAINST ANIMAL TESTING: Why Harm–Benefit Assessments Must Be Transparent

#### The Science of the LD50 Test

The LD50 (Lethal Dose 50) determines the dose of a substance required to kill 50% of test animals. Criticised for decades as causing severe suffering while providing limited human-relevant data due to fundamental species differences in metabolism and physiology. In November 1981, a House of Commons speech already described the LD50 as scientifically “obsolete.” The classical OECD TG 401 was deleted in 2002, yet refined lethal-dose methods and legacy data persist in 2026 under the shadow of regulatory caution.

#### The Core Problem: Secrecy Around Harm–Benefit Decisions

Before any animal experiment is licensed, the Animals in Science Regulation Unit (ASRU) must conduct a “harm–benefit analysis.” Because of Section 24 of the Animals (Scientific Procedures) Act 1986, no one outside the licensing room can see how this decision is made—or whether modern non-animal methods (NAMs) were properly considered. This secrecy is especially acute for acute toxicity endpoints where validated alternatives (in silico QSAR/ML, in vitro human cell assays such as 3T3 NRU, and Weight-of-Evidence approaches) already exist and are accepted by ECHA, EPA and increasingly by MHRA/EMA.

#### TARGETED PARLIAMENTARY QUESTION

##### *For the Home Secretary:*

“To ask His Majesty’s Government what specific, auditable criteria the Animals in Science Regulation Unit uses to determine that a non-animal method is not ‘scientifically satisfactory’ before granting an animal project licence under ASPA 1986—particularly for acute toxicity endpoints where validated NAMs already exist; and whether these individual assessments can be made available to independent scientific scrutiny without violating Section 24?”

#### Strong Points for Challenge

1. The “obsolete” label applied to the LD50 in Parliament since 1981 has still not produced full regulatory phase-out. Implementation lags behind both the science and the available alternatives.
2. Once validated non-animal methods exist, continued reliance on animal lethal-dose data is an ethical choice about unnecessary suffering, not scientific necessity.
3. The Government’s own long-term strategy aims to eliminate animal testing except in exceptional circumstances. Progress cannot be measured if the evidence used to grant licences remains a criminal offence to disclose under Section 24.
4. Greater transparency is needed on the actual criteria used by ASRU when deciding that animal acute toxicity data is still required versus accepting modern NAMs.

#### ACTION FOR MPs

Table the question above. Follow up any Section 24 defence with: “If the Government is legally committed to a strategy of elimination, how can Parliament measure progress if the evidence used to grant these licences is a criminal offence to disclose?” Demand a clear timeline for full IATA/NAMs implementation for acute toxicity endpoints.

#### Key Evidence Frameworks

- OECD Test Guidelines — TG 401 (classical LD50) deleted 2002; current TGs 420/423/425 emphasise reduction/refinement and support Integrated Approaches to Testing and Assessment (IATA).
- UK Parliament Hansard (24 Nov 1981) — early recognition of the LD50 as both scientifically flawed and ethically unacceptable.
- Modern IATA & NAMs — Validated in silico, in vitro and Weight-of-Evidence approaches accepted by ECHA, EPA and increasingly by MHRA/EMA.