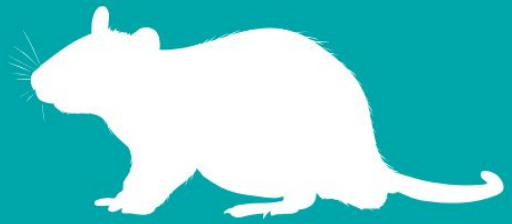
FOCUS ON SEVERE SUFFERING



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RSPCA

ANIMALS IN SCIENCE DEPARTMENT

Within the UK and the European Union, ‘severe’ procedures are those where animals used in science are likely to experience:

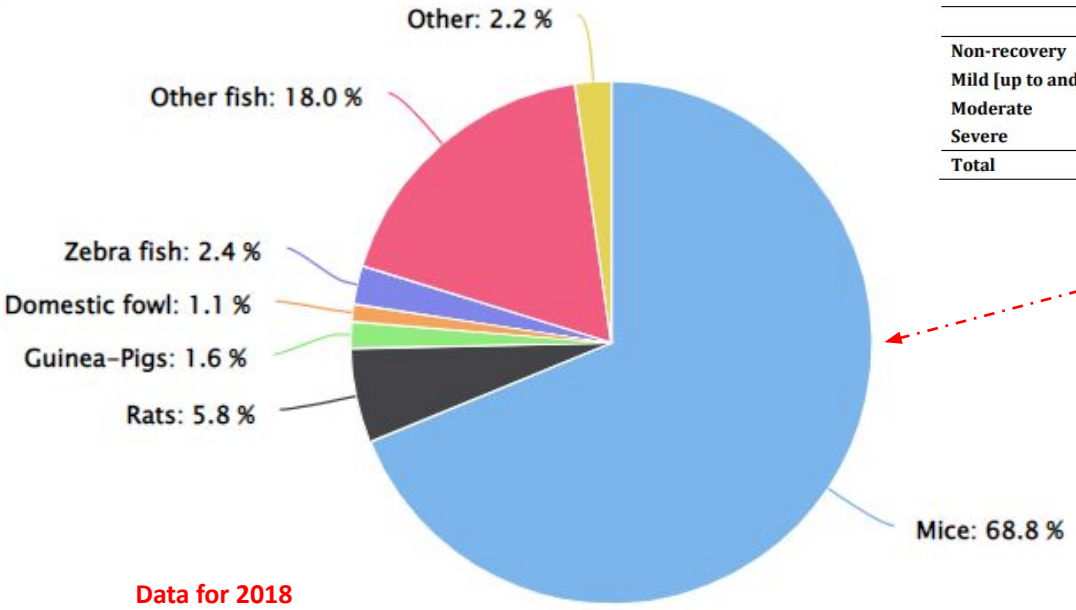
- severe pain, suffering or distress
- long-lasting moderate pain, suffering or distress, or
- severe impairment to their wellbeing or general condition

e.g. Annex VIII of EU Directive 2010/63

Causes of severe suffering

THREE MAIN REASONS

- Animals may be used in studies of **diseases or conditions** that by their nature can cause severe suffering
- A **combination** or series of less severe factors can combine to lead to an increase in overall suffering
- Where animals **die unexpectedly**, or where the **death** of an animal is used an **‘endpoint’** of the study



Data for 2018

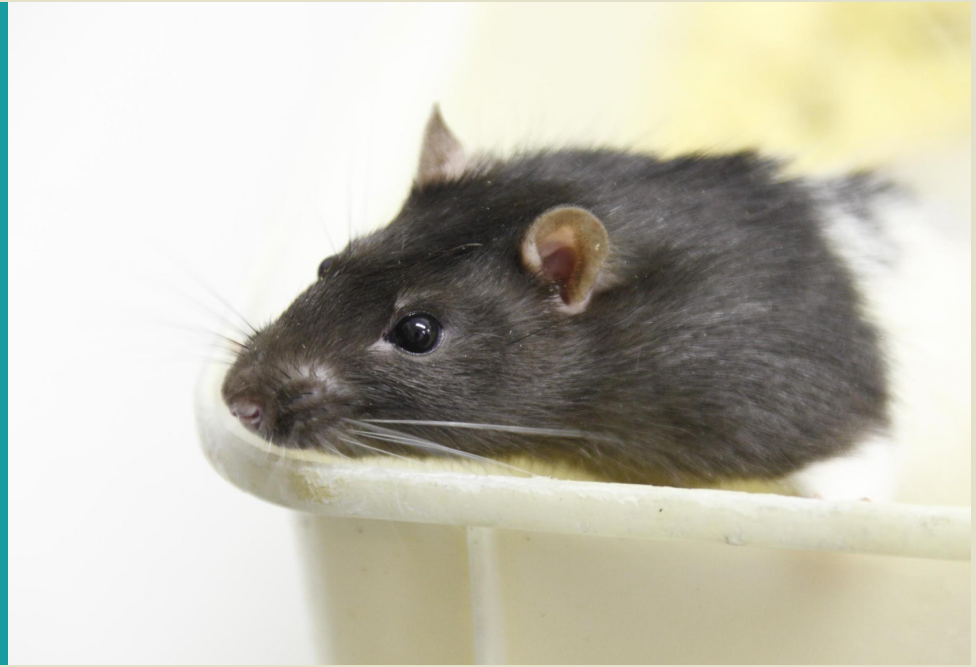
	2017	2018 (EU)	2018 (EU-28 incl. NO)
Non-recovery	6% (621,054)	6% (534,999)	6% (612,094)
Mild [up to and including]	51% (4,865,721)	49% (4,522,747)	50% (5,469,214)
Moderate	32% (3,071,828)	34% (3,096,460)	34% (3,658,621)
Severe	11% (1,023,138)	11% (983,237)	10% (1,064,925)
Total	**100% (9,581,741)**	**100% (9,137,443)**	**100% (10,804,854)**

https://ec.europa.eu/environment/chemicals/lab_animals/reports_en.htm

10M

animals across the world experience severe suffering each year

*estimate



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All laboratory animal suffering is a concern, but reducing and avoiding ‘severe’ suffering should be a top priority

- ✔ **Ethical** and animal welfare benefits
- ✔ **Legal** requirements to minimise suffering
- ✔ **Societal** concerns about harms to animals
- ✔ **Scientific** benefits - better welfare means better science

FOCUS ON SEVERE SUFFERING

Our initiative

Since 2012, the RSPCA has been **working collaboratively** with the scientific community in the UK, EU and internationally, to initiate and promote a range of activities aimed at identifying and promoting **practical steps** which will help people to **reduce** or, ideally, **avoid** 'severe' suffering.

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61% reduction

in experimental procedures causing severe suffering in the **UK** since 2014

NEW DATA PUBLISHED ON 'SEVERE' SUFFERING IN THE UK AND EU

15th July 2021

The most up-to-date data currently available on the use of animals in research and testing in the UK, and the EU, was published on 15 July 2021. This information is important for openness and transparency and can also help to focus 3Rs efforts more effectively. Below is a summary of the data relating to the number of animals reported to have experienced 'severe' suffering, and in which areas of science.

The mouse is the species most likely to experience 'severe' pain, suffering, distress or lasting harm. In both the UK and EU, batch potency testing of vaccines and other substances (such as botulinum toxin) for quality control purposes is the category responsible for the most uses of animals reported as 'severe'.

UK

Data for 2020
Source: Home Office. See Tables 3.1 and 3.2 of the Data Tables associated with the Statistics of scientific procedures on living animals, Great Britain 2020 – published 15 July 2021.

Summary

58,499 experimental procedures using animals (4% of the total) were reported as causing 'severe' pain, suffering, distress or lasting harm.

44,093 – for regulatory purposes *(9% of all use for regulatory purposes was 'severe')*
10,867 – in basic research
3,511 – in applied research

Main categories of research and testing involving severe suffering
(data shown represent the number of 'procedures' undertaken that were reported as causing 'severe' suffering)

35,997 – Batch potency testing *(represents 61.5% of all experimental procedures involving animals that were 'severe')*
2,592 – Nervous system
2,567 – Immune system
1,512 – Human infectious disorders
1,479 – Batch safety testing
1,303 – Oncology

Which animals experienced the most 'severe' suffering?
(data shown represent the number of 'procedures' undertaken involving those animals)

EXAMPLES OF POTENTIALLY 'SEVERE' PROCEDURES

Batch potency testing of vaccines (where control animals experience 'severe' disease symptoms) **and other biologics** e.g. botulinum toxin, for regulatory purposes

Studies involving infectious disease models, including the development of vaccines or other treatments, where animals may experience 'severe' disease symptoms

Various tests involved in regulatory toxicology, including ecotoxicology, especially where animals may become moribund or die

Monoclonal antibody production using the mouse ascites method – NB this method has not been used in the UK since 2012 but is still used elsewhere in the world

Some cancer models – involving large tumours, resection, bone metastasis, brain tumours, pancreatic tumours

Some heart disease models – myocardial infarction induction; monocrotaline (MCT)-induced pulmonary arterial hypertension; transverse aortic constriction/banding

Multi-organ failure models

Demyelination of the central nervous system (CNS)

Models of motor neurone disease (MND)

Spinal cord injury models

Neuroscience studies using non-human primates, involving the cumulative effects of numerous surgeries, regular and long periods of restraint, and/or fluid or food control

Tamoxifen as an inducer of gene function

Irradiation with reconstitution of bone marrow

Cerebral malaria in rodents

Pancreatitis models

Expert Working Groups

- Seizures, convulsions and epilepsy
- Experimental autoimmune encephalomyelitis (EAE)
- Rheumatoid arthritis
- Sepsis
- Spinal cord injury
- Bone marrow ablation and reconstitution

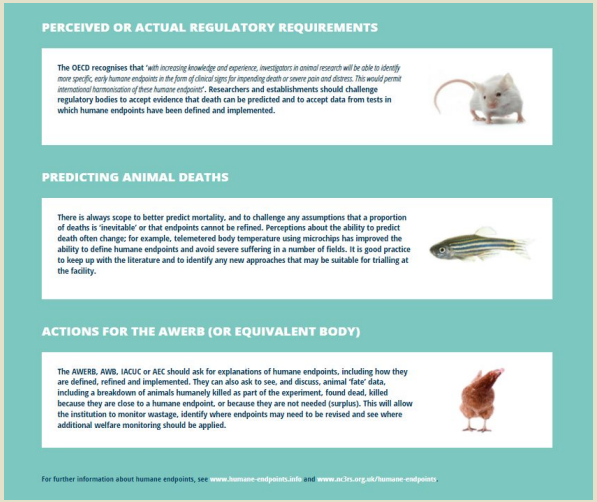
- Avoiding mortality

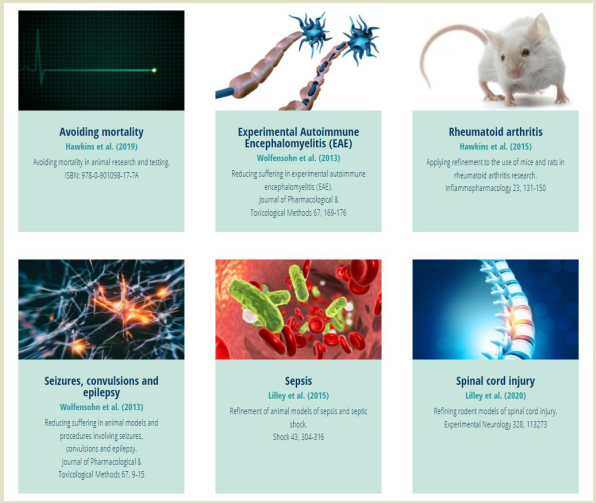
Events

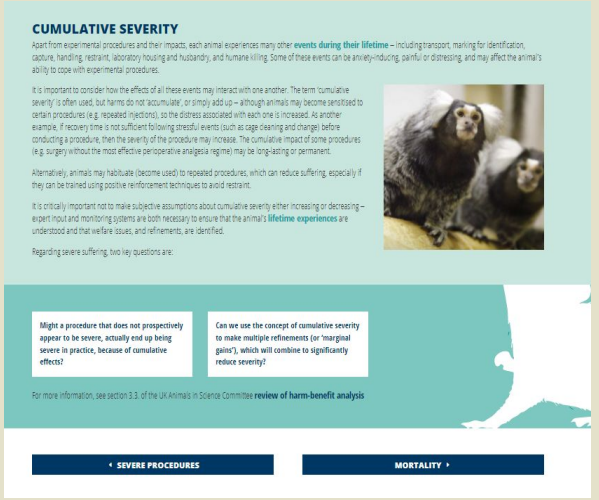
- **Brussels**, Belgium - 2016
- **Berlin**, Germany - 2017
- **Stevenage**, UK - 2019
- **Athens**, Greece - 2019
- **Manchester**, UK - 2022
- **Stockholm**, Sweden - August 2022

100s of participants: regulators, scientists, veterinarians, animal technologists and care staff, members of Animal Welfare Bodies and National Committees etc.

Website







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RSPCA · lasa Laboratory Animal Science Association · Laboratory Animals Veterinary Association · iat


Breeding ›


Capture from the wild ›


Transport ›


Marking for identification ›


Genotyping ›

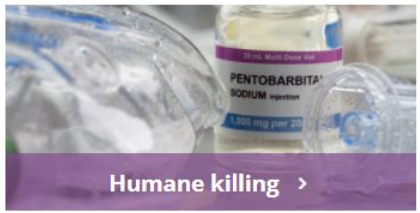

Housing ›


Husbandry procedures ›


Handling and restraint ›


Scientific procedures ›

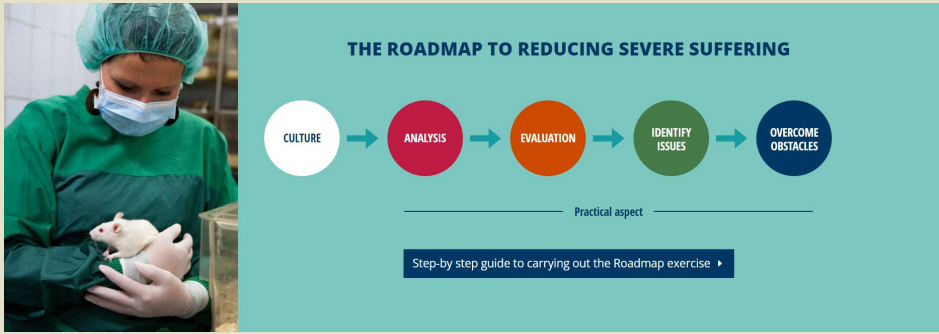

Effects of procedures ›


Humane killing ›

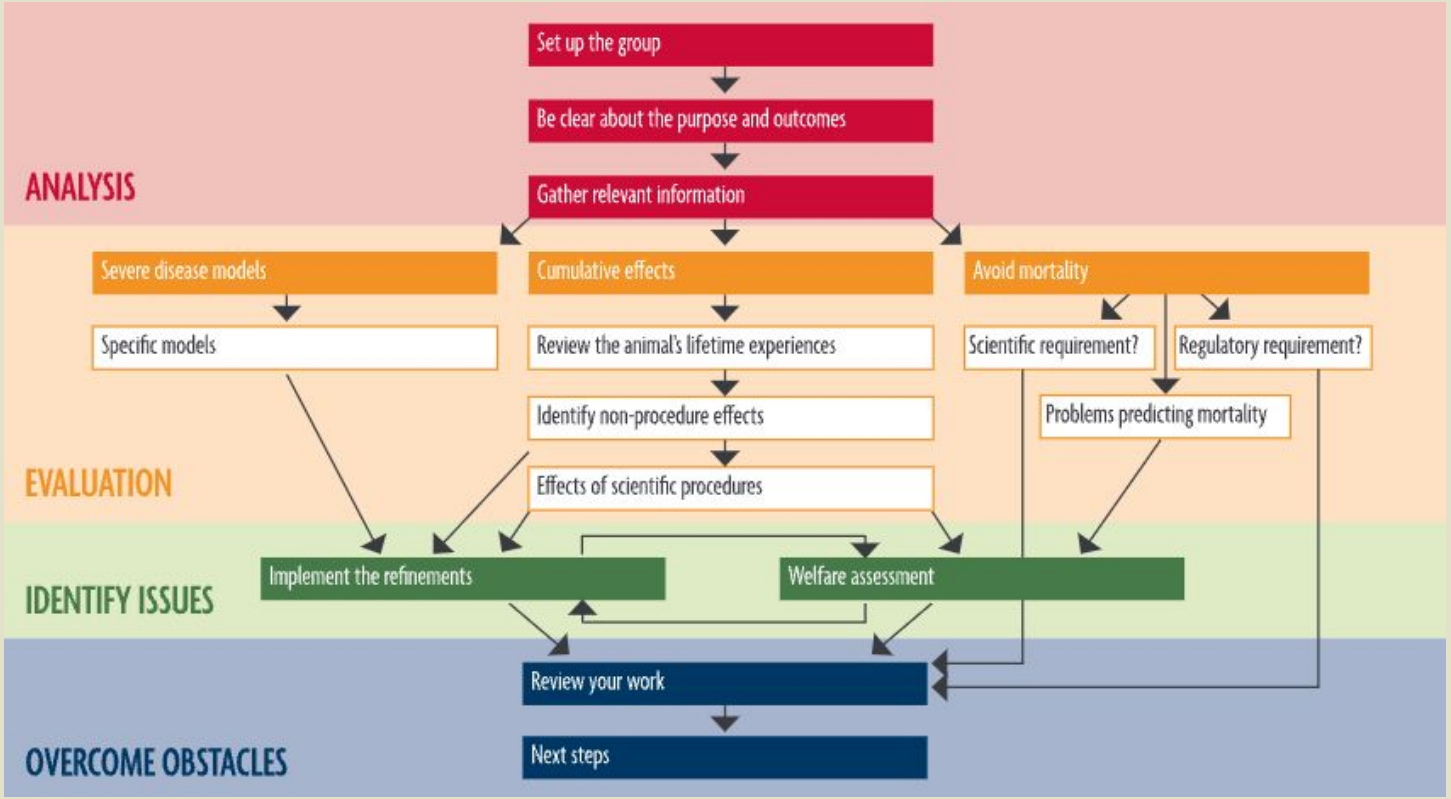

Rehoming or release ›

A commitment to address severe suffering

- Agreement as a priority area for attention and action
- Institutional strategy and responsibilities
- Setting of clear objectives



Consider as part of the 'Culture of Care'


ANALYSIS
Set up the group
Be clear about the purpose and outcomes
Gather relevant information
Severe disease models
Cumulative effects
Avoid mortality
Specific models
Review the animal's lifetime experiences
Scientific requirement?
Regulatory requirement?
Identify non-procedure effects
Problems predicting mortality
EVALUATION
Effects of scientific procedures
IDENTIFY ISSUES
Implement the refinements
Welfare assessment
Review your work
OVERCOME OBSTACLES
Next steps

Examples of questions to consider

- Why is severe suffering needed? Is there a robust scientific justification?
- Is the ‘model’ translatable? How significant are the proposed benefits of the work?
- Could the protocol be run with a moderate severity limit?
- Is there a regulatory requirement for the experimental design and ‘endpoint’? Can this be challenged?
- Are welfare assessment and monitoring protocols optimised?
- What more could be done to mitigate impacts on animals?

Refining severe disease models and procedures

24-25 August 2022

Stockholm, Sweden

Karolinska Institutet

RSPCA

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