

# Directive 2010/63/EU



Animal Welfare Bodies –  
opportunities to make a  
difference

*Symposium on laboratory animals*  
27 March, 2023  
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# Animal Welfare Bodies – opportunity to make a difference



- *Animal Welfare Bodies – legislation and the key tasks*
- *Tools and resources for making a difference*
- *Bringing tools together for action*

# Why Animal Welfare Bodies



*Directive 2010/63/EU requires*

- *Animal welfare considerations to be given the highest priority*
  - *Advice on animal welfare matters as the primary task*
- ***To enhance the life-time experience of the animals***

# How to achieve these objectives



- *Providing tools for **the timely and practical implementation of latest scientific and technical developments on the Three Rs***
- *Following the developments and outcomes of projects*
- *Fostering the culture of care*

# The five tasks of an AWB



1. Advise the staff on **welfare of animals**
2. Advise the staff on **the application of the Three Rs, especially on new methods and approaches**
3. Review **internal operational processes**
4. Follow the **development and outcome of projects**
5. Advise on **re-homing schemes**



# Other suggested tasks beyond compulsory



- *EU Guidance on NTS: review **NTS content and accuracy***
- *EU Guidance on AWBs: **provide input in the project application, in particular on the Three Rs***

N.B. “Although the AWB may have input to the project application process, **the evaluation of projects is an entirely separate requirement under the Directive.**”

# Animal Welfare Bodies – opportunity to make a difference



- *Animal Welfare Bodies – legislation and the key tasks*
- *Tools and resources for making a difference*
- *Bringing tools together for action*

# The heart and soul of the Three Rs

*Supported by*

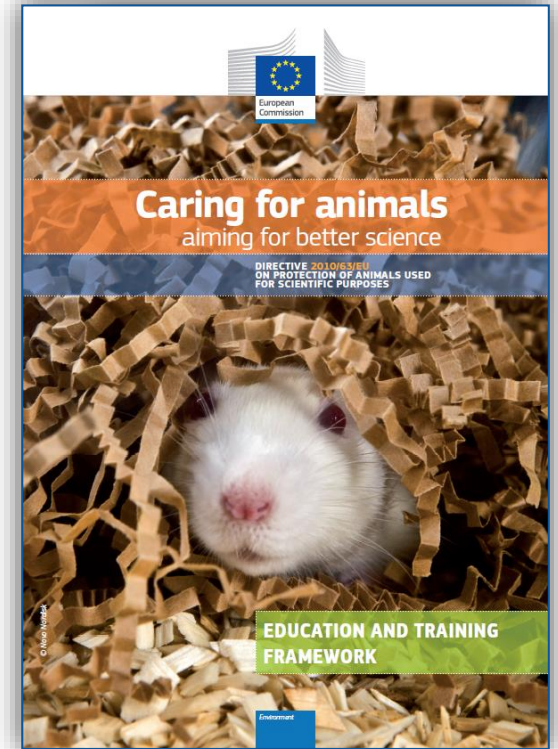
- *Individuals*
- *Its members*
- *Organisation at all levels*
- *External networks*





# Tools for making a difference: Training and CPD

- *Initial training*
- *Continued professional development to maintain competence*
- *Life-long learning*



## EU modules for Education and Training in Laboratory Animal Science and Alternatives to Animal Use



Search  search

The eModules were developed with a view to using them in a blended-learning approach that combines e-learning with face-to-face teaching. These can be integrated in existing courses or followed on need-basis. It is expected, however, that these additional tools would be complemented with further development of the material, either face-to-face or otherwise.



EU-10: Design of procedures and projects – level 1

Course Details



EU-11: Design of procedures and projects – level 2

Course Details



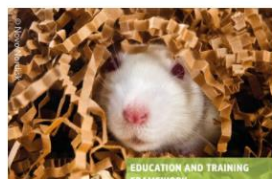
EU-12: The severity assessment framework

Course Details

➤ **Replacement**

➤ **Reduction**

➤ **Refinement**



EU-25: Project evaluation

Course Details



EU-52: Searching for (existing) non-animal alternatives

Course Details



EU-60: Developing in vitro methods and approaches for scientific and regulatory use

Course Details

# Members of Animal Welfare Bodies

*Freely available eModules as self-learning or part of a formal training*

➤ **Compulsory initial training for all AWB members**

➤ **As CPD**

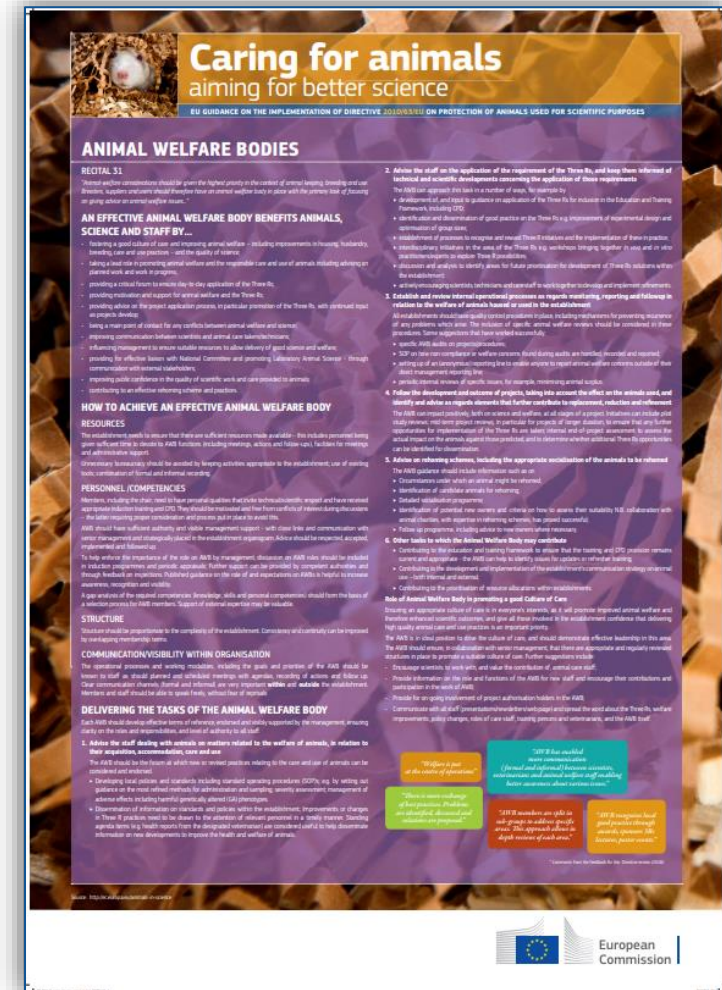
*13 new eModules under development e.g. recognition of pain, suffering and distress*

# Tools for making a difference: Guidance



➤ Guidance document

➤ Poster





# Guidance for Animal Welfare Bodies

*EU guidance document in all community languages - endorsed by Member State authorities*

<b>Animal Welfare Bodies.....</b>	<b>5</b>
<i>Benefits of an effective Animal Welfare Body .....</i>	<i>5</i>
<i>Structure, composition and competencies required of Animal Welfare Bodies .....</i>	<i>6</i>
<i>Meeting the Animal Welfare Body requirements in small breeders, users and suppliers .....</i>	<i>9</i>
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i. Advise the staff dealing with animals on matters related to the welfare of animals, in relation to their acquisition, accommodation, care and use

The AWB should be the forum at which new or revised practices relating to the use of animals can be considered. The AWB should take into account information such as new publications, attendance at conferences, and other events and contacts with other establishments.

• **Developing local policies (procedures)**

The AWB often reviews animal care and use and suggests improvements. For example, it can advise on administration and sampling procedures; management of (GA) phenotypes; environmental conditions; the use of animals in the wild.

The AWB may develop advice (e.g. any requirement for similar procedures) to assess the impact on the animals.

It may also consider elements of animal welfare, local establishment issues, local legislation by other pieces of legislation.

• **Dissemination of information**

The AWB has a significant role in ensuring access to information, ensuring that staff are informed of the establishment's policies, practices, and that such practices need to be drawn up and followed up to assess the impact.

Consideration may also be given to an advisory board that meets regularly to discuss practices and the effectiveness of the AWB.

Standing agenda items (e.g. animal welfare) should be considered useful to help discuss the health and welfare of animals.

Issues which may be considered include the health and welfare of surplus animals and promotion of animal welfare.

ii. Advise the staff on the application of the refinement, and keep them informed concerning the application of those requirements

The AWB can approach this task in a number of ways:

- development of, and input to guidance on the Education and Training Framework
- identification and dissemination of good practice, experimental design and optimisation of procedures
- establishment of processes to recognise and implement these in practice;
- interdisciplinary initiatives in the area of together *in vivo* and *in vitro* practitioners
- internal discussion and analysis to develop development of Three Rs solutions with scientists
- actively encouraging scientists, technicians and implement refinements;
- ensuring Reduction and Replacement – members with expertise in experience can provide effective contributions on the creation of a Three Rs culture within the establishment (example of how this may be approached)

iii. Establish and review internal operating procedures, reporting and follow-up in relation to the establishment

The mechanisms adopted to meet these requirements should take into account the size of the establishment and the nature of the work.

All breeders, suppliers and users should be recorded. These should include the definition of the establishment, and the related principles of recording, reporting, and managing relevant information. The inclusion of specific animal welfare reviews should be considered in these procedures (what/when/how/frequency/reporting and feedback need to be considered).

There may be other management practices in place focusing on operational processes independent from the AWB. However, AWBs should be aware of any that impact on the welfare, care and use of animals. They should ask to receive relevant reports from such processes and be encouraged to input to and provide feedback on them.

<sup>3</sup> National Centre for the Replacement, Refinement & Reduction of Animals in Research (UK)

<sup>4</sup> An institutional framework for the Three Rs <http://www.nc3rs.org.uk/institutional-framework-3rs>

iv. Follow the development and outcome of projects, taking into account the effect on the animals used, and identify and advise on elements that further contribute to replacement, reduction and refinement

The AWB can impact positively at all stages through the formal application process, monitoring progress, and up on project completion.

Input at the project planning and application stage can ensure the quality of applications, ensure that the TH is aware of whether or not there are suitable facilities within the establishment. Further information can be provided in a similar way to submissions for project approval.

It is helpful for the AWB to receive reports from project teams where there are some uncertainties over the project.

Mid-term project reviews, in particular for long-term projects, ensure that the work is on track and that the Three Rs are taken.

Internal end-of-project assessment/reports can provide an impact on the animals against those predicted. Opportunities can be identified for Evaluation and Retrospective Assessment.

Further approaches which can be utilised by the AWB include:

- The AWB can require a system for recording deaths, or where projected numbers are high
- AWBs in consultation with project holders for animals under-going procedures
- Severity Assessment Framework – reference to the frequency of monitoring procedures (defining specific criteria)

The inclusion of specific animal welfare reviews should be considered in these procedures (what/when/how/frequency/reporting and feedback need to be considered).

Other tasks to which the Animal Welfare Body may contribute

The central role of the AWB in an establishment coupled with the good overview it should have on matters relating to animal welfare, care and use provides a prime opportunity to assist in other related tasks for the benefit of both animal welfare and science should resources permit. Further tasks suggested where AWBs can usefully contribute to welfare and care practices within an establishment include:

- Contributing to the education and training framework and its content within the establishment; liaison with the person responsible for training (Article 24(1)(c)) to ensure that the training and appropriate - the AWB can help to identify issues on anaesthesia;
- Considering the implementation of related legislation and biosafety;
- Contributing to the development and implementation of a communication strategy on animal use – both internally and externally;
- Contributing to the prioritisation of resource allocation.

Fostering a Culture of Care

Ensuring an appropriate culture of care is in everyone's interest and therefore enhanced scientific outcomes. Establishing confidence that delivering high quality animal care is an important priority.

Simply having animal facilities and resources which meet the requirements will not ensure that appropriate animal welfare, care and use follow. All those involved in the care and use of animals should be trained in the Three Rs principles and demonstrate a caring and respectful attitude. Without an appropriate culture it is unlikely that welfare and scientific outcomes will be improved.

The key factors which blend together to foster the appropriate culture of care in an establishment include:

- Appropriate behaviour and attitude towards animals is of critical importance. Managing animal care and use issues with a commitment to standards; staff who work diligently, at all levels, and are willing to take the initiative. In summary, an attitude that is not just about the animal but on an individual's positive and animal welfare and humane science;



Challenges and possible solutions to achieving an effective AWB

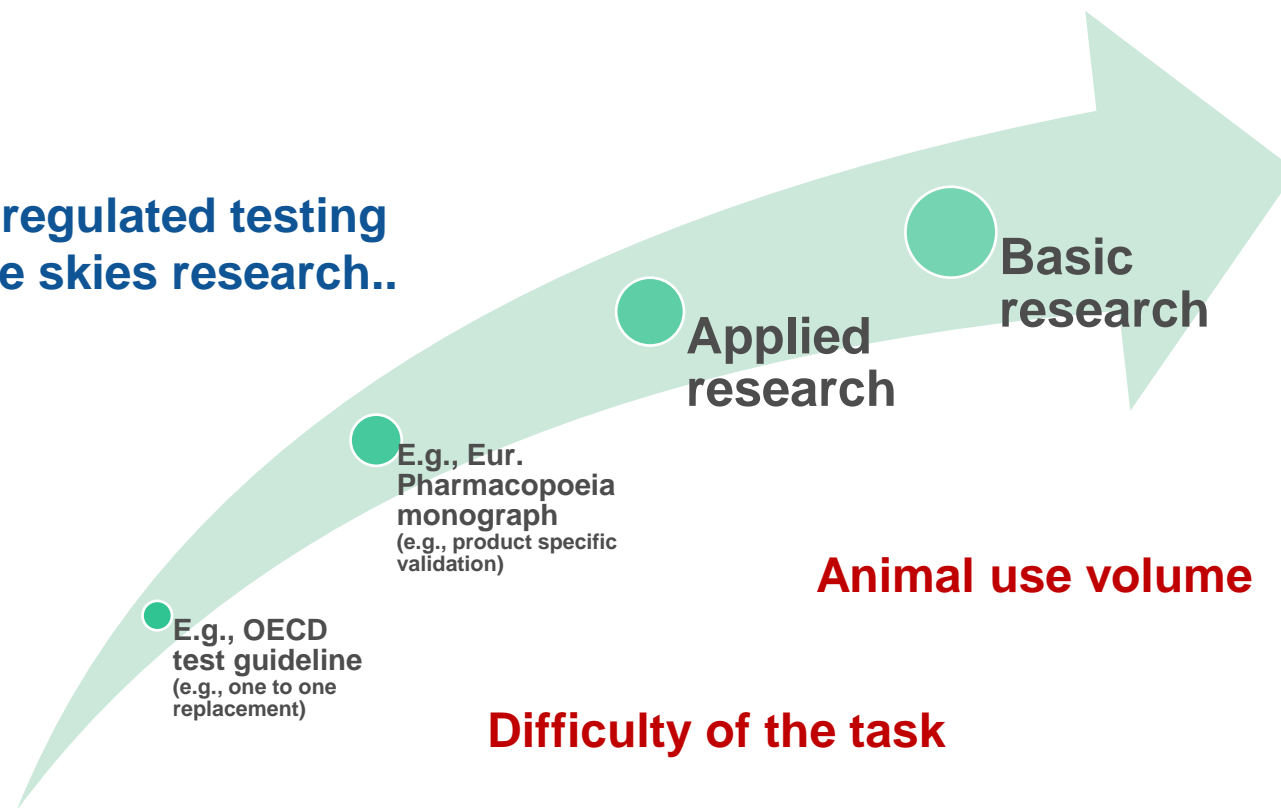
Challenges	Possible Solutions
Insufficient resource/authority/management support - with no effective authority to deal with non-co-operative individuals, or to have advice accepted, or inadequate resource to deliver recommendations.	A heightened awareness within senior management of the key roles and responsibilities of AWB can be conveyed through encouragement/support from competent authority  Through feedback on inspections (under Article 34) ; Published guidance on role/expectations of AWBs and Establishments e.g. Compliance; Good culture of care; Adequate composition and skills; Regular meetings; Effectively dealing with problems; Appropriate education and training
Lack of knowledge/understanding of role of AWB; Insufficient in-house expertise; Personnel reluctant to volunteer for AWB role; concerns over conflict of interest	Acknowledgement of importance of role on AWB by management; inclusion of discussion on AWB roles in induction programmes and periodic appraisals.  Training and CPD for members of AWB  Careful consideration of competencies needed (knowledge, skills and personal competencies) and a selection process for AWB members based on these.  Gap-analysis of skills required, and support to seek external expertise as necessary  Avoidance of conflict is essential: needs to be given proper consideration and process put in place to avoid this
Poor, unstructured communications from AWB	Support for effective information strategy; develop close links and support for person(s) responsible for information



# Access to Three Rs information



From regulated testing  
to blue skies research..



➤ **Replacement**

➤ *Reduction*

➤ *Refinement*

# Three Rs and AWBs - input to project applications

## **Replacement**

- *Does not seemed to be covered by AWBs*
- *Lacking sufficiently detailed knowledge*
- *Assume that researchers and funders already considered Replacement and animal use is necessary*

## **Reduction**

- *Closer attention to experimental design and statistics*
- *Shortage of people with necessary expertise*

## **Reduction**

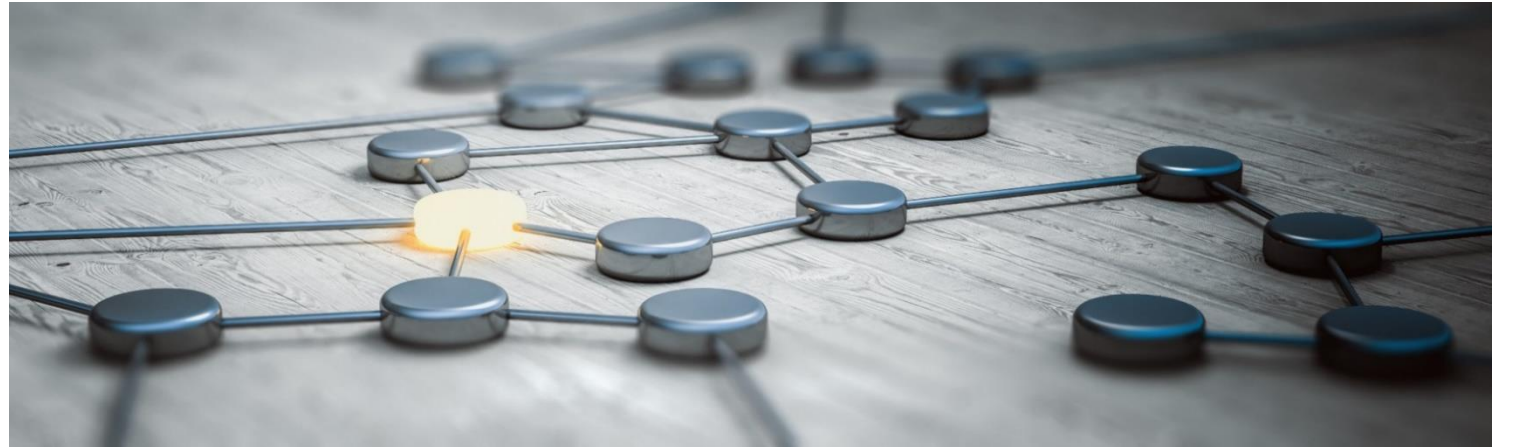
- *Most confident to challenge*
- *Feel that their input adds most value*



# Tools for making a difference: Access to Three Rs information



- *Training*
- *Resources*
- *Networking*
  - **within establishment**
  - **National Committee**
  - **regional / national**
  - **international**



# Three Rs information:

## Resources - EURL-ECVAM reports



Breast cancer



Neurodegenerative diseases



Immune oncology models



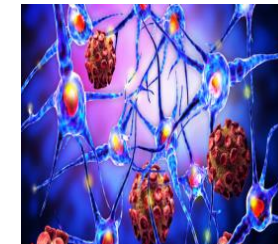
Cardiovascular diseases



Respiratory tract diseases



Immunogenicity testing for advanced therapy medicinal products



Autoimmune diseases





# Advanced Non-animal Models in Biomedical Research

## Respiratory Tract Diseases



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### Advanced Non-animal Models in Biomedical Research: Respiratory Tract Diseases

**Respiratory diseases** are a leading cause of death and disability worldwide. Research on human diseases relies extensively on animal models, however, effective **new therapies** for serious respiratory conditions are still lacking. The reason for this is that animal models often poorly represent human physiology and pathology. The European Commission's Joint Research Centre (JRC) has carried out an extensive review of advanced non-animal models being used for basic and applied research on respiratory tract diseases. Researchers characterised and catalogued almost **300 models** to make them more accessible for human relevant studies that avoid the use of animals.

"3 million people die from chronic obstructive pulmonary disease (COPD) each year, making it the third leading cause of death worldwide"  
Forum of International Respiratory Societies, 2017

#### RESPIRATORY TRACT DISEASES

Respiratory tract diseases, such as asthma, chronic obstructive pulmonary disease (COPD) and lung cancer, are one of the leading causes of **morbidity and mortality globally**. Animal models are extensively used in research although their scientific relevance is a matter of debate.

#### LEGISLATIVE FRAMEWORK

**Directive 2010/63/EU** on the protection of animals used for scientific purposes sets out clear legal requirements for the implementation of the Three R's: principles of **Replacement**, Reduction and Refinement of animal procedures. The final goal is that animal testing should be phased out and replaced by scientifically valid non-animal alternatives.

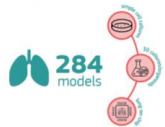
#### LACK OF EFFECTIVE NEW THERAPIES

According to the latest statistics, in 2017 the European Union used approximately 10 million animals in experimental procedures with about 70% of those being used for disease-related research. However, there is still a **lack of effective new therapies** for serious respiratory conditions. Over 50% of new drugs fail to progress to market due mainly to a lack of efficacy or unexplained toxicity.

This suggests that reliance on animal models is failing to identify novel therapies. In this context, the JRC's EU Reference Laboratory for alternatives to animal testing (EUR-ECVAM) carried out a study to produce a unique **knowledge base** that contains detailed descriptions of non-animal models being used for respiratory disease research.

#### KNOWLEDGE BASE OF ADVANCED NON-ANIMAL MODELS

About 21,000 scientific papers were screened for relevant human-based models of respiratory diseases and from those a total of **284 models** were identified as being the most representative and promising.



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# Advanced Non-animal Models in Biomedical Research

## Breast Cancer



### Advanced Non-animal Models in Biomedical Research: Breast Cancer

**Breast cancer** is the most common cancer among women in the European Union and worldwide. Preclinical breast cancer research currently relies on animal models, mostly rodents. However, animal models mimic **limited aspects** of human breast cancer. The European Commission's Joint Research Centre (JRC) has carried out an extensive review of the state-of-the-art of advanced non-animal models used for basic and applied research on breast cancer. Researchers characterised and catalogued about **935 models** to make them more accessible for human relevant studies that avoid the use of animals.

"Before reaching the age of 75, 1 in 22 women will be diagnosed with breast cancer and 1 in 73 women will die from breast cancer, worldwide"  
JARC Handbooks of Cancer Prevention Volume 15

#### BREAST CANCER AND ITS HETEROGENEITY

Breast cancer is the **most commonly occurring cancer in women** in the European Union and worldwide. The European Cancer Information System (ECIS) estimates that in 2020 over 555,000 women were diagnosed with breast cancer in the EU, accounting for 13.3% of all cancers diagnosed.

Despite advances in early detection and understanding of breast cancer biology, relapse and subsequent metastasis often occurs in bone, lung, liver and brain.

Human breast cancer is **highly heterogeneous**, even within the same tumour. To offer better treatment with increased efficiency, it is necessary to use therapies that match patient profiles and the clinical and molecular characteristics of the tumour. Breast cancer research currently relies heavily on animal models, which, however, have limitations in capturing important cancer traits.

For this reason, research is gradually moving towards the use of advanced non-animal models that more faithfully represent the characteristic heterogeneity peculiar to human breast cancer.

#### LEGISLATIVE FRAMEWORK

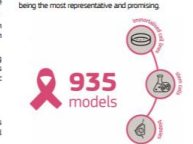
**Directive 2010/63/EU** on the protection of animals used for scientific purposes sets out clear legal

requirements for the implementation of the Three R's: principles of **Replacement**, Reduction and Refinement of animal procedures. The final goal is the phasing out of animal testing when scientifically valid non-animal alternatives are available.

To aid this transition, the JRC's EU Reference Laboratory for alternatives to animal testing (EUR-ECVAM) produced a unique **knowledge base** of detailed descriptions of non-animal models used for breast cancer research.

#### KNOWLEDGE BASE OF NON-ANIMAL MODELS

About 120,000 scientific papers were reviewed to identify relevant human-based models of breast cancer. From those, a total of **935 models** were selected as being the most representative and promising.



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# Advanced Non-animal Models in Biomedical Research

## Neurodegenerative Diseases



### Advanced Non-animal Models in Biomedical Research: Neurodegenerative Diseases

**Neurodegenerative diseases** are a common and growing cause of morbidity and mortality worldwide, particularly in the elderly. Research on human diseases relies extensively on animal models, however, effective **new therapies** for these serious diseases are still lacking. The reason for this is that animal models often poorly represent human physiology and pathology. In response, the European Commission's Joint Research Centre (JRC) has carried out an extensive review of advanced models being used for basic and applied research into neurodegenerative diseases. Researchers characterised and catalogued **568 models** to make them more accessible for human relevant studies that avoid the use of animals.

"Neurodegenerative diseases are one of the leading medical and societal challenges faced by EU society. It currently costs approximately €1.77 billion per year to care for people with dementia across Europe."  
World Alzheimer Report, 2016

#### NEURODEGENERATIVE DISEASES

Neurodegenerative diseases such as Alzheimer and Parkinson are untreatable conditions leading to dementia. Alzheimer's disease affects **over 10 million people in Europe**. Animal models are extensively used in research although their scientific relevance is a matter of debate.

#### LEGISLATIVE FRAMEWORK

**Directive 2010/63/EU** on the protection of animals used for scientific purposes sets out clear legal requirements for the implementation of the Three R's: principles of **Replacement**, Reduction and Refinement of animal procedures. The final goal is that animal testing should be phased out and replaced by scientifically valid non-animal alternatives.

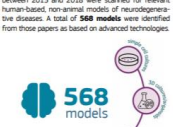
#### LACK OF EFFECTIVE NEW THERAPIES

According to the latest statistics, in 2017 almost 7 million animals were used for basic, applied and translational research in the European Union.

However, **existing treatments** for neurodegenerative diseases are **very limited** and only treat the symptoms. No new drug treatment for Alzheimer's disease has been approved since 2003 because of a

high rate of failure in drug development programs due mainly to lack of efficacy or unexplained toxicity. This suggests that reliance on animal models is failing to identify novel therapies. In this context, the JRC's EU Reference Laboratory for alternatives to animal testing (EUR-ECVAM) carried out a study to provide an **extensive review of non-animal models** currently in use for basic and applied research in the area of neurodegenerative diseases.

**ADVANCED MODELS IN BIOMEDICAL RESEARCH**  
The abstracts of 13,000 scientific papers published between 2013 and 2018 were screened for relevant human-based, non-animal models of neurodegenerative diseases. A total of **568 models** were identified from those papers as based on advanced technologies.



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EUR30334 EN

- Technical report
- Executive Summary
- Leaflets
- JRC Data catalogue



# Three Rs information: Resources - Refinement Wiki





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  - 2.2 Evidence base
  - 2.3 Would you like to contribute?
  - 2.4 Acknowledgements

**Introduction and aims**

Welcome to Norecopa's [Refinement Wiki](#).  
The aim of the Wiki is to provide a platform where methods for the refinement of animal experiments can be shared and discussed.

***Click here for a list of the pages created so far***


The Wiki aims to fill the gap between peer-reviewed scientific publications and more anecdotal information. We foresee a number of uses:

1. **Rapid dissemination of refinement techniques** where resources or interest in writing are lacking
2. **Identification of experts** on specific techniques
3. **As a hub to identify collaborators** when investigating the effects of a potential refinement method
4. **Creation of pages encouraging colleagues to share** experiences or develop new methods

We hope that this Wiki will help to accelerate the introduction of refinement methods. It is currently in its early stages.  
The administrative work is led by [Adrian Smith](#), Secretary of Norecopa.

**Using the Refinement Wiki**

Like most Wikis, the Refinement Wiki does not have a Table of Contents. Use the search box to find what you are looking for.  
Searches using the [main search engine](#) on Norecopa's website will retrieve hits from the Refinement Wiki.



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**All pages**

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(Main)

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- Acclimatisation
- Adrian Smith
- Alphaxalone
- Anaesthesia in neonates
- Analgesia
- Asepsis
- Blood sampling of hamsters
- Blood sampling of pigs
- Blood sampling of rainbow trout
- Breeding strategies for mice
- Clicker training
- Contingency plans
- Decapitation
- Dehydration
- Detecting early onset of clinical signs in the mouse model of Covid-19
- Detection of pain and distress in mice
- EMLA cream
- Embryo transfer

- Habituation training
- Health monitoring
- High-fat diets
- Hot Bead Sterilisers
- Housing nude mice
- Housing research fish
- Humane endpoints
- Hydrodynamic gene delivery
- Intra-ocular injections
- Intranasal administration
- Intraperitoneal injection
- Intraperitoneal pentobarbitone
- Irradiation for haematology studies
- Ketamine and alpha-2 agonist combinations
- Long-term anaesthesia in rodents
- Lumpfish
- Main Page
- Marble Burying Test

- Nest building material
- Non-invasive genetic sampling in wildlife research
- Oestrus suppression in ferrets
- Pneumocystis murina
- Recapping needles
- Refinement of oral gavage
- Rotarod Test
- Screening cell lines
- Sedation of cattle
- Splenectomy
- Sterilisation of instruments
- TTEAM and TTouch
- Tail vein injection
- Tamoxifen
- Tamoxifen information sheet V4.pdf
- The use of DMSO
- Tramadol
- Transport stress

# Tools for making a difference: ALURES Statistics

*To improve:*

- *Accuracy and objectivity of reporting*
- *Speed of publication*
- *Access to data*



SECTION 1	SECTION 2	SECTION 3
<b>Numbers of animals (conventional and genetically altered)</b> used for the first time for research, testing, routine production, and education and training	<b>All uses and reuses of animals</b> for research, testing, routine production, and education and training <b>Reason for use</b> (e.g. specific research area, type of testing)	<b>Numbers, uses and reuses of animals</b> for the creation and maintenance of <b>genetically altered animals</b> (mostly mice and fish)
<b>Species</b>	<b>Actual severity</b> (mild, moderate, severe) experienced by animals	
<b>Origins</b>	<b>Genetic status</b>	
	<b>Use of animals to meet legislative requirements</b>	

*Two open access central EU databases*

- **ALURES Statistical EU database**
- **ALURES NTS EU database**

# Three R's information: Resources - ALURES NTS

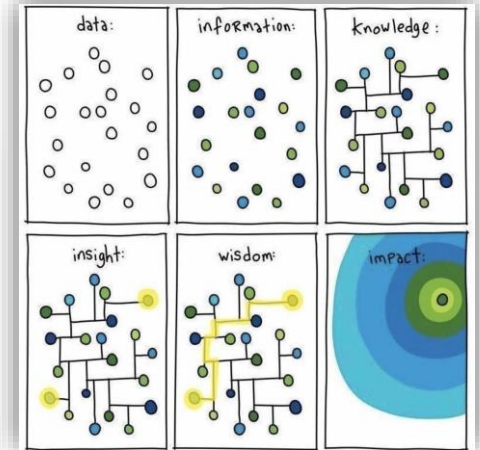
Objectives and predicted benefits of the project	
Describe the objectives of the project (for example, addressing certain scientific unknowns, or scientific or clinical needs).	
What are the potential benefits likely to derive from this project? Explain how science could be advanced, or humans, animals or environment may ultimately benefit from the project. Where applicable, differentiate between short-term benefits (within the duration of the project) and long-term benefits (which may accrue after the project is finished).	

Application of the Three Rs
<b>1. Replacement</b> State which non-animal alternatives are available in this field and why they cannot be used for the purposes of the project.
<b>2. Reduction</b> Explain how the numbers of animals for this project were determined. Describe steps that have been taken to reduce the number of animals to be used, and principles used to design studies. Where applicable, describe practices that will be used throughout the project to minimise the number of animals used consistent with scientific objectives. Those practices may include e.g. pilot studies, computer modelling, sharing of tissue and reuse.

**3. Refinement**  
 Give examples of the specific measures (e.g., increased monitoring, post-operative care, pain management, training of animals) to be taken, in relation to the procedures, to minimise welfare costs (harms) to the animals. Describe the mechanisms to take up emerging refinement techniques during the lifetime of the project.

Explain the choice of species and the related life stages.

Predicted harms
In what procedures will the animals typically be used (for example, injections, surgical procedures)? Indicate the number and duration of these procedures.
What are the expected impacts/adverse effects on the animals, for example pain, weight loss, inactivity/reduced mobility, stress, abnormal behaviour, and the duration of those effects?
What species and numbers of animals are expected to be used? What are the expected severities and the numbers of animals in each severity category (per species)?
What will happen to the animals kept alive at the end of the procedure? (7) (8)
Please provide reasons for the planned fate of the animals after the procedure.



# Tools for making a difference: Networking - ENAWB



- *European Network of Animal Welfare Bodies, ENAWB*
- *Initiated at FELASA 2022*
- *Initiators: Belgium, Denmark, France, Portugal, Spain, Switzerland, the Netherlands and the UK*
- *Presentation at the next Member State meeting in April*

Interested in knowing more?



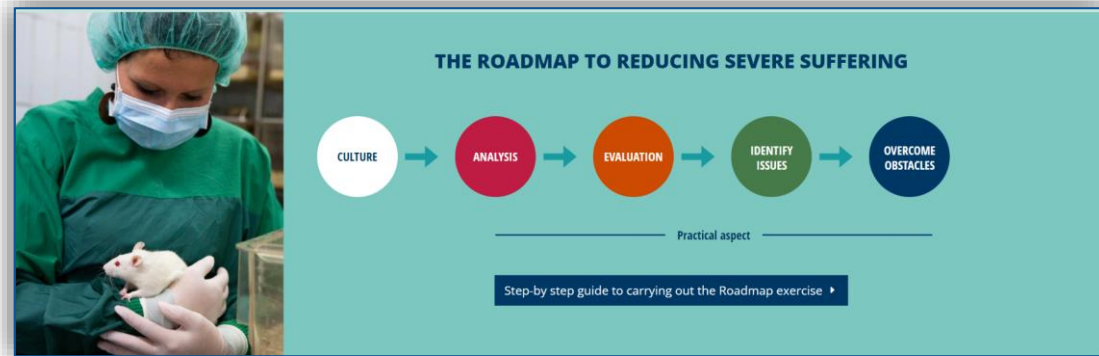
# Animal Welfare Bodies – opportunity to make a difference



- *Animal Welfare Bodies – legislation and the key tasks*
- *Tools and resources for making a difference*
- *Bringing tools together for action*

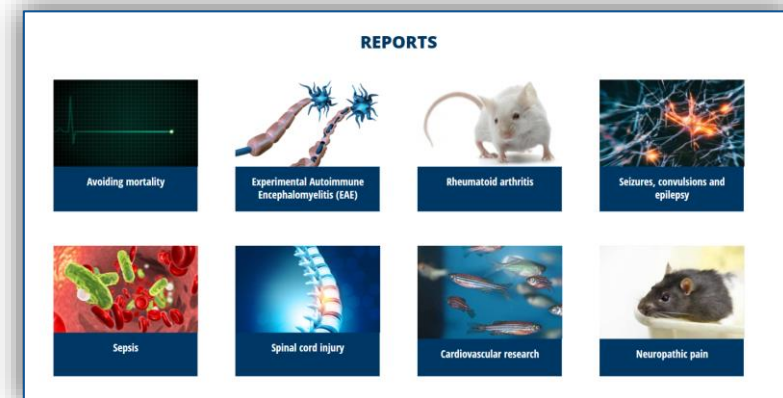


# Bringing tools together



*Initiate projects at establishment to tackle:*

- *high animal **volume** uses*
- *higher **severity** areas*
- *slow uptake of available **alternatives***
- *areas with specific **species***
- *animals bred, killed and not used*



# Bringing tools together



- *Participate in and draw from networks*
- *Develop a plan for **each of the Three Rs***
- *Develop a plan for **each of the five tasks***
- *Focus on Replacement*
  - *before the train leaves from the station*

# Conclusions



- *Legislation sets out five compulsory tasks - requires*
  - **Appropriate training, including CPD**
  - **Access to right tools**
  - **Sufficient resources**
- *Engage with management*
- *Become the centre of excellence*





# Thank you for your attention!

More information at:

<https://ec.europa.eu/animals-in-science>

All guidance documents in all Union languages available at the Publications Office of the EU

The views expressed in this presentation are solely those of the presenter and do not reflect the official view of the European Commission.

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