Directive 2010/63/EU

Animal Welfare Bodies – opportunities to make a difference

Symposium on laboratory animals
27 March, 2023
Susanna Louhimies

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.”

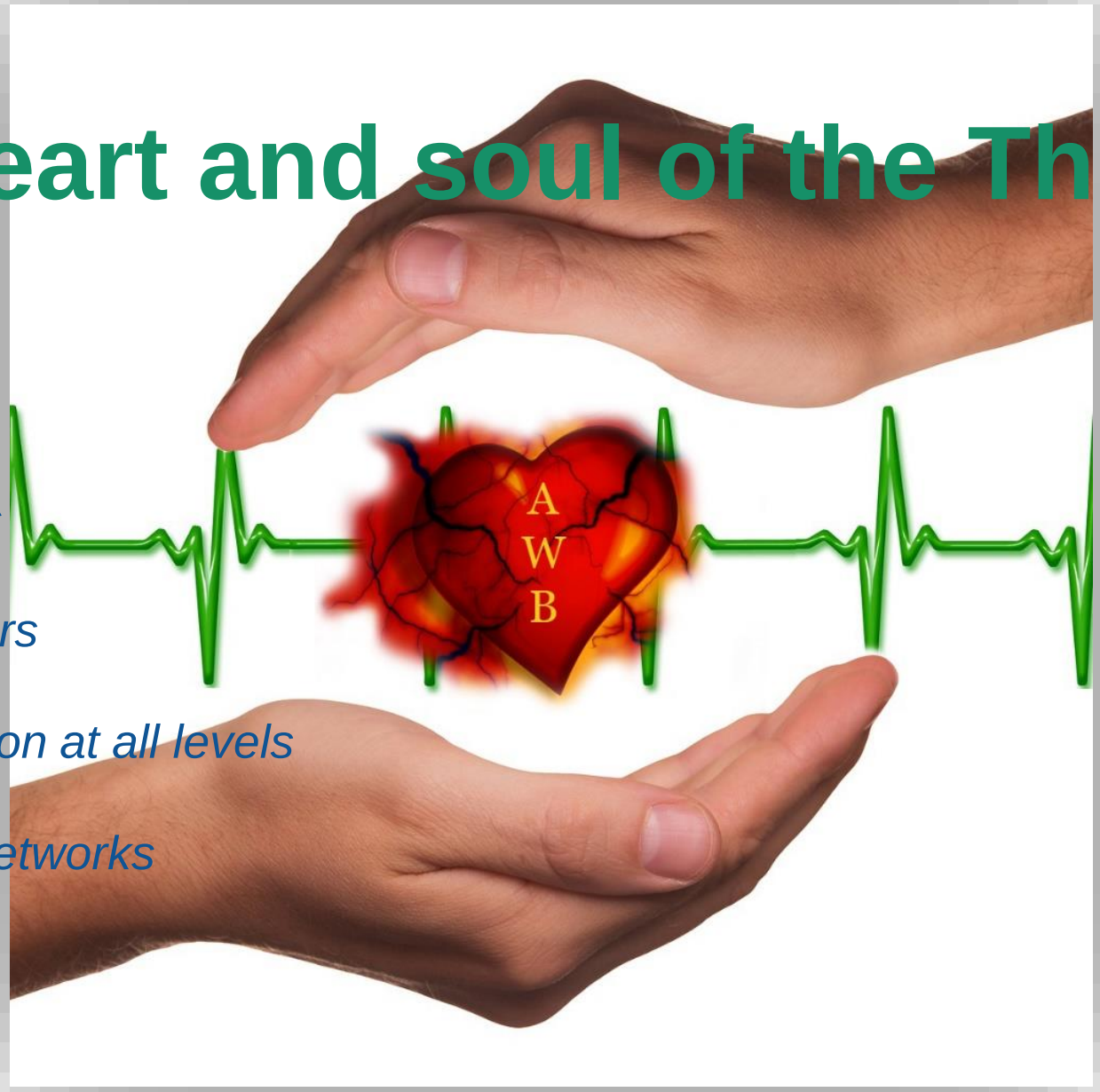
Animal Welfare Bodies – opportunity to make a difference

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

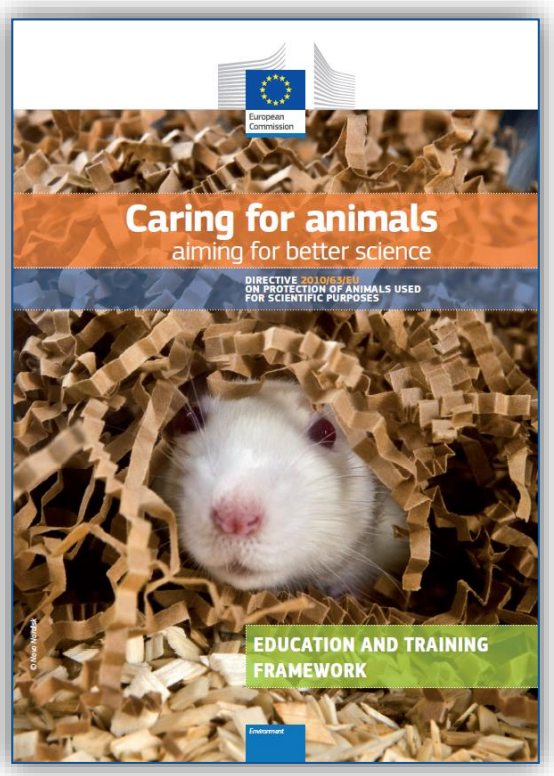
The heart and soul of the Three Rs

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*

Members of Animal Welfare Bodies

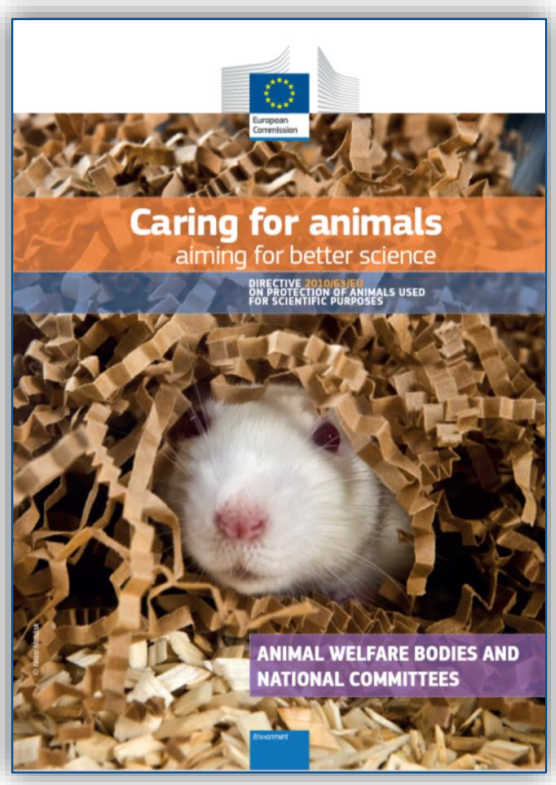
Freely available eModules as self-learning or part of a formal training

- ***Replacement***
- ***Reduction***
- ***Refinement***

- ***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*

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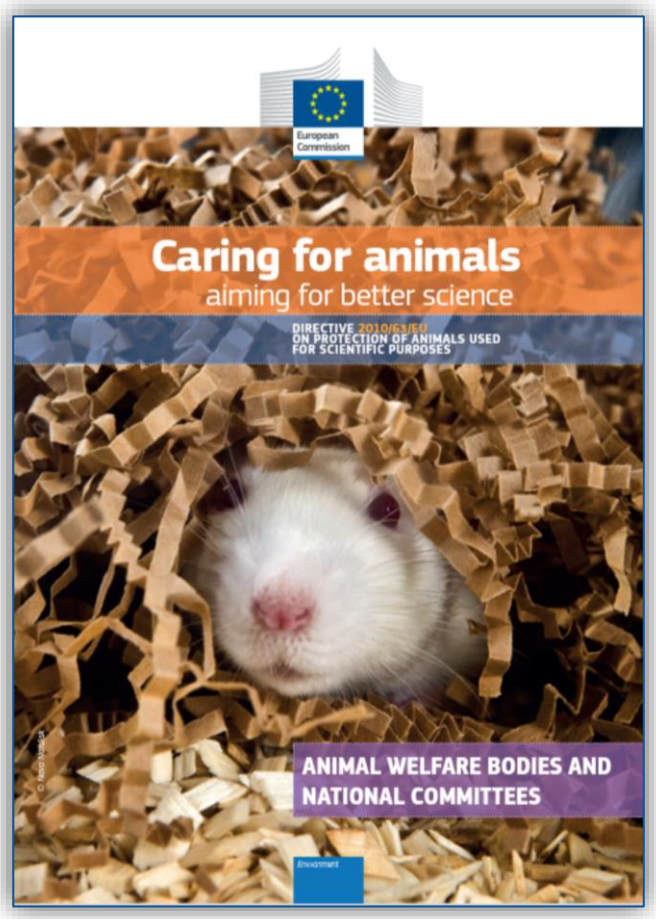
Guidance for Animal Welfare Bodies

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



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 in-house taking into account inf such as new publications, atte events and contacts with other s

- **Developing local policies procedures)**

The AWB often reviews an care and use and suggests u available. For example, it administration and samplin assessment; management o (GA) phenotypes; environm the use of animals in the wil

The AWB may develop adv (e.g. any requirement for si up to assess the impact on th

It may also consider eleme climate issues, local establis by other pieces of legislation

- **Dissemination of informati**

The AWB has a significant ensuring access to informat informed of the establish practices, and that such prac R practices need to be drawn and followed up to assess th

Consideration may also be advisory board that meets practices and the effectiven

Standing agenda items (e.g considered useful to help di the health and welfare of ani

Issues which may be consid of surplus animals and prom

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

The AWB can approach this task in a num

- development of, and input to guidance the Education and Training Framework
- identification and dissemination of goo experimental design and optimisation
- establishment of processes to recog implementation of these in practice;
- interdisciplinary initiatives in the ar together *in vivo* and *in vitro* practitione
- internal discussion and analysis to development of Three Rs solutions wit
- actively encouraging scientists, techni and implement refinements;
- ensuring Reduction and Replacement – members with expertise in experim can provide effective contributions on
- creation of a Three Rs culture within example of how this may be approache

iii. **Establish and review internal oper reporting and follow-up in relation to t establishment**

The mechanisms adopted to meet these re the size of the establishment and the nature

All breeders, suppliers and users should recorded. These should include the defini establishment, and the related princip recording, reporting, and managing releva recurrence of any problems which arise. 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.

[3] National Centre for the Replacement, Refinement & Reduction of Animals in Research (UK)
[4] 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 as regards elements that further contribute to replacement, reduction and**

The AWB can impact positively at all through the formal application process, mo up on project completion.

Input at the project planning and applicatio quality of applications, ensure that the Th whether or not there are suitable facilitie within the establishment. Further informat Principles on Good Practice for Ethical Re a similar way to submissions for project an

It is helpful for the AWB to receive repo where there are some uncertainties over the

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

Internal end-of-project assessment/reports impact on the animals against those predict Rs opportunities can be identified for Evaluation and Retrospective Assessment[7].

Further approaches which can be utilised by

- The AWB can require a system for re deaths, or where projected numbers are
- AWBs in consultation with project ho for animals under-going procedures Severity Assessment Framework – refe
  - the frequency of monitoring procedures (defining specific cri

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 respons (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 legisla and biosafety;
- Contributing to the development and imple communication strategy on animal use – both inte
- Contributing to the prioritisation of resource alloc

Fostering a Culture of Care

Ensuring an appropriate culture of care is in everyone's i animal welfare and therefore enhanced scientific outcom establishment confidence that delivering high quality a important priority.

Simply having animal facilities and resources which mee will not ensure that appropriate animal welfare, care a follow. All those involved in the care and use of animal Rs principles and demonstrate a caring and respectful a used for scientific procedures. Without an appropriate cul it is unlikely that welfare and scientific outcomes will be

The key factors which blend together to foster the ap establishment include:

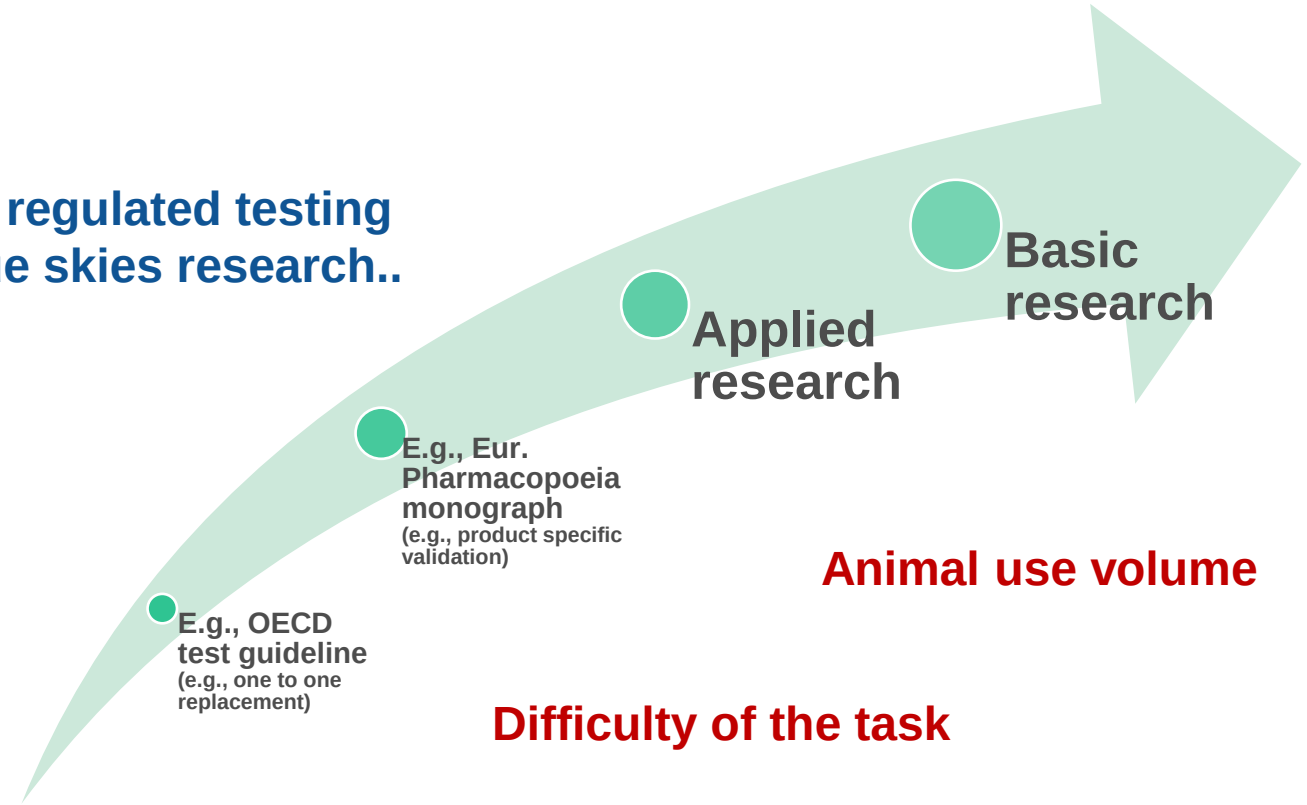
- Appropriate behaviour and attitude towa personnel is of critical importance. Manag animal care and use issues with a commit standards; staff who work diligently, acc levels, and are willing to take the initiati arise. In summary, an attitude that is not alone but on an individual's positive and animal 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*

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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*

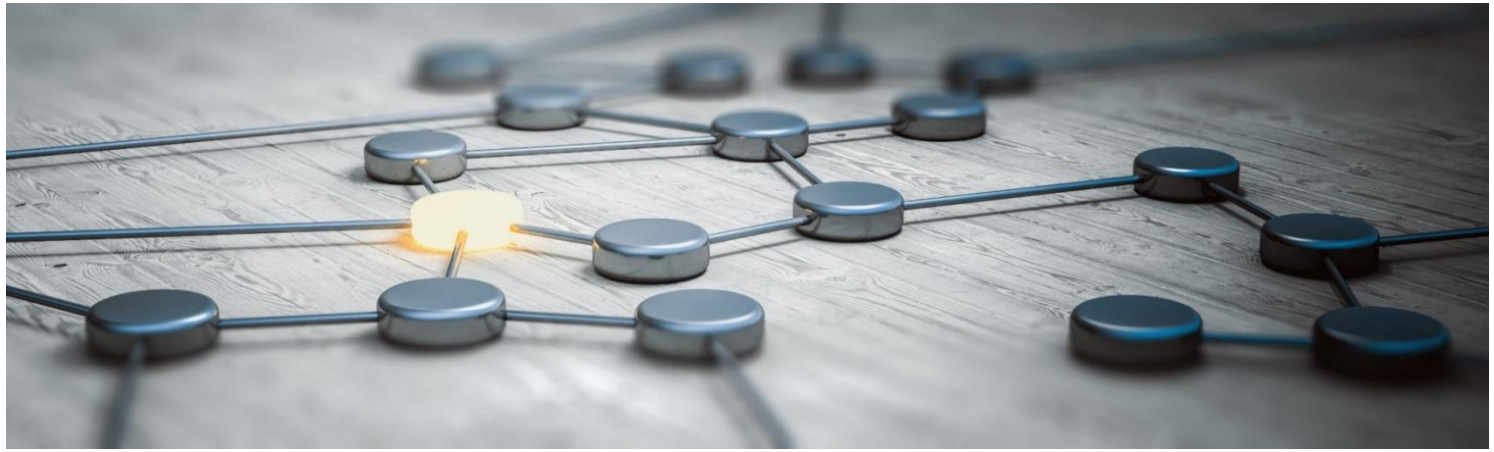
Reduction

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

https://www.nc3rs.org.uk/news/new-report-3rs-animal-research

Tools for making a difference: Access to Three Rs information

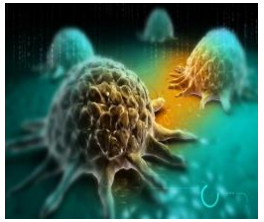
- *Training*
- *Resources*
- *Networking*
  - **within establishment**
  - **National Committee**
  - **regional / national**
  - **international**



Three Rs information:
Resources - EURL-ECVAM reports

Breast cancer

Neurodegenerative diseases

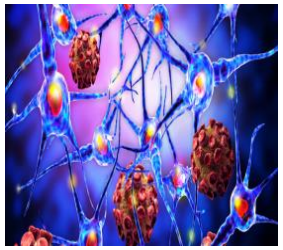


Immune oncology models

Cardiovascular diseases

Respiratory tract diseases

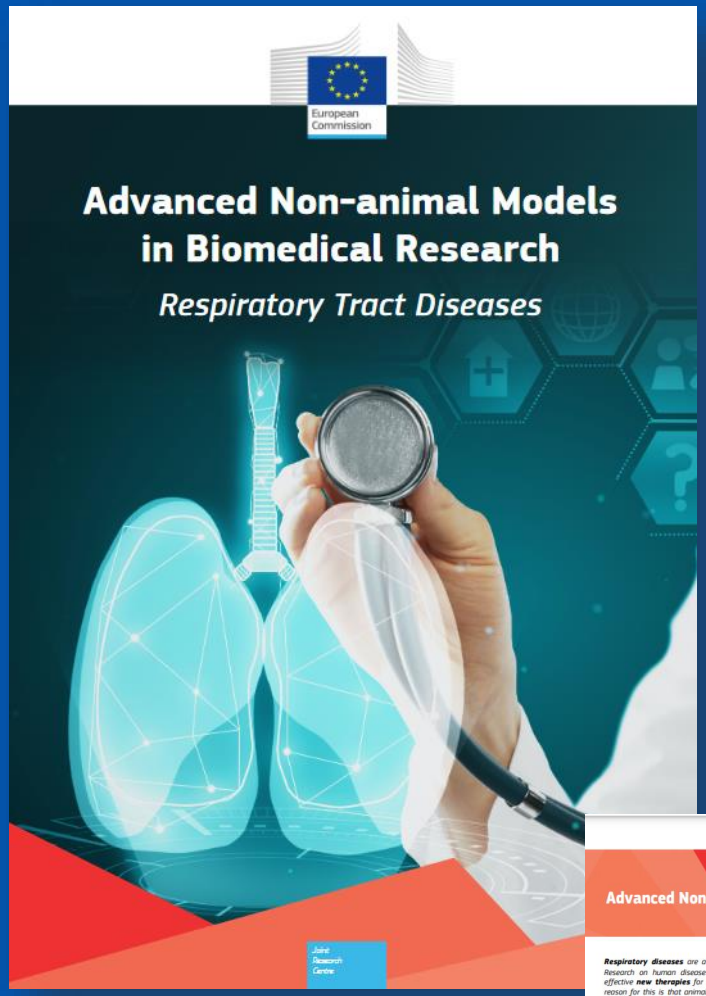
Immunogenicity testing for advanced therapy medicinal products

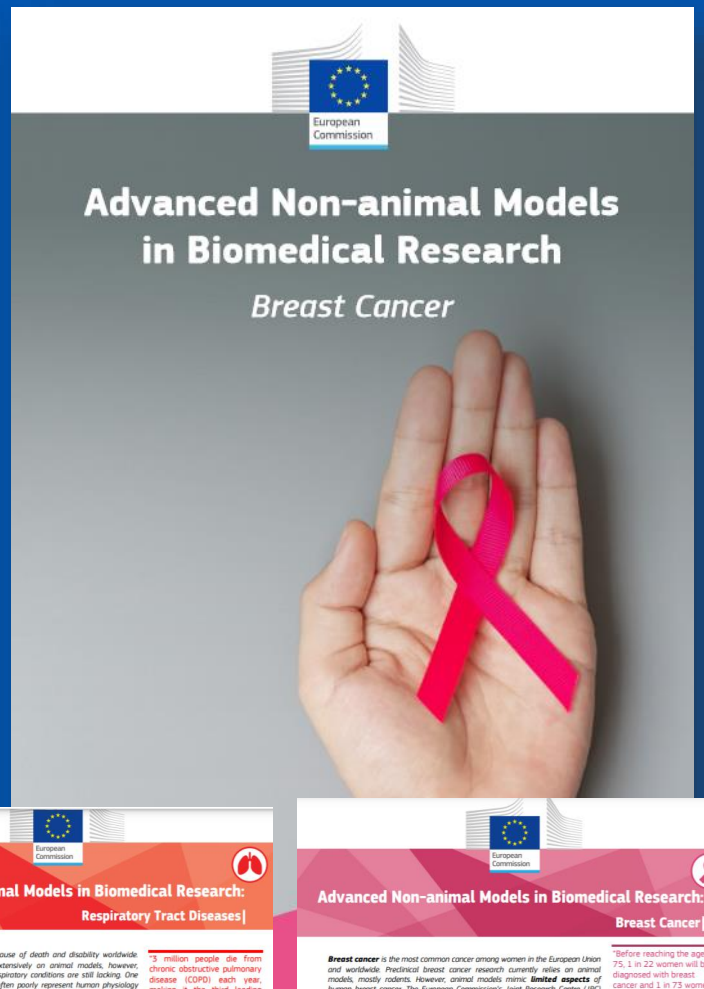


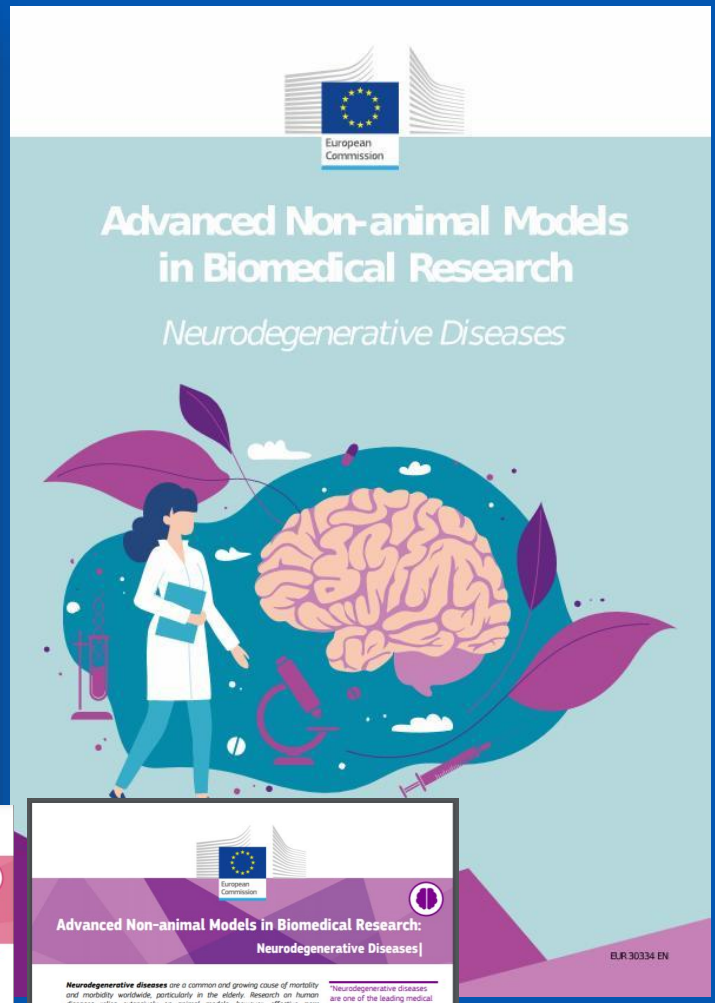
Autoimmune diseases

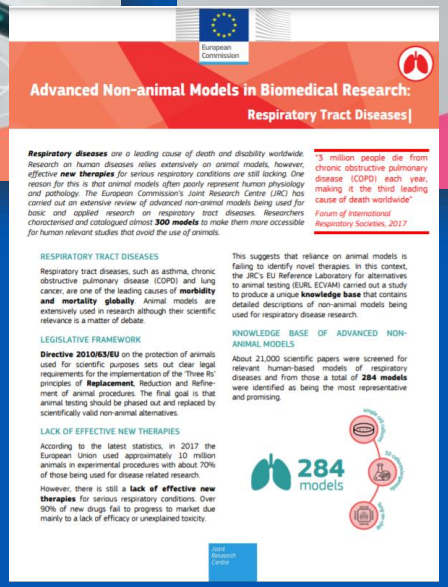
EURL ECVAM
European Union Reference Laboratory for Alternatives to Animal Testing

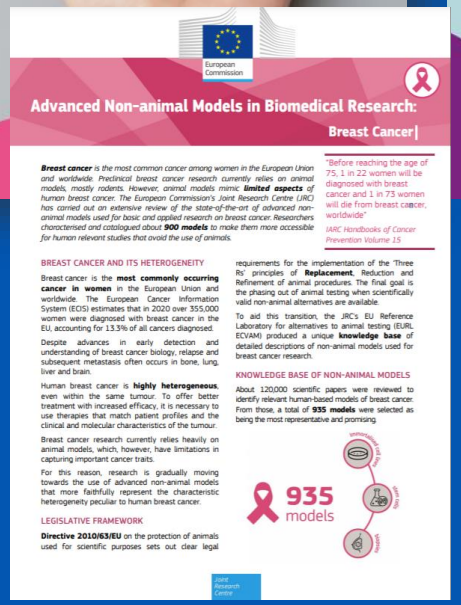
https://joint-research-centre.ec.europa.eu/eu-reference-laboratory-alternatives-animal-testing-eurl-ecvam/biomedical-research_en











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

European Commission

Three Rs information:
Resources - Refinement Wiki

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Main Page

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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 e

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 anec

We foresee a number of uses:

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

We hope that this Wiki will help to accelerate the introduction of refinement methods. It is

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

Searches using the main search engine on Norecopa's website will retrieve hits from th

Special page | Search Norecopa Wiki

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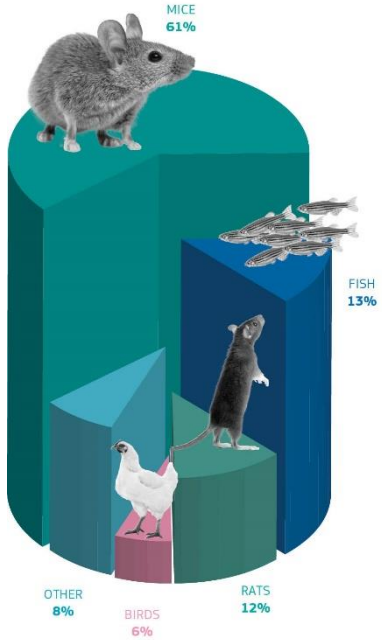
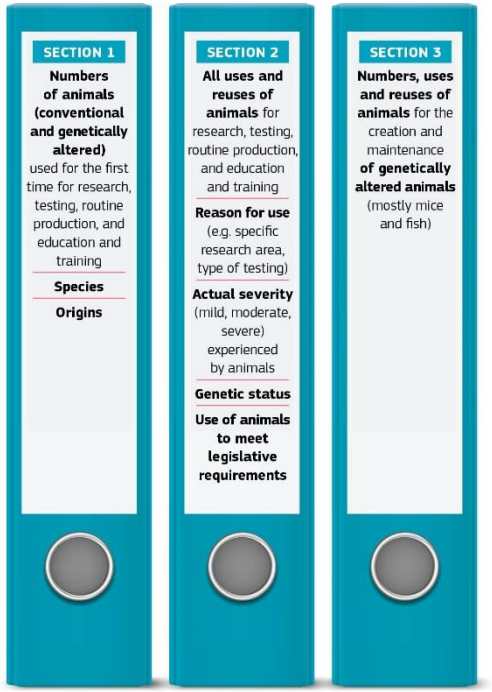
- Tail vein injection
- Tamoxifen
- Tamoxifen information sheet V4.pdf
- The use of DMSO
- Tramadol
- Transport stress

Tools for making a difference: ALURES Statistics

To improve:

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





Two open access central EU databases

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

https://ec.europa.eu/environment/chemicals/lab_animals/alures_en.htm
https://ec.europa.eu/environment/chemicals/lab_animals/alures_nts_en.htm

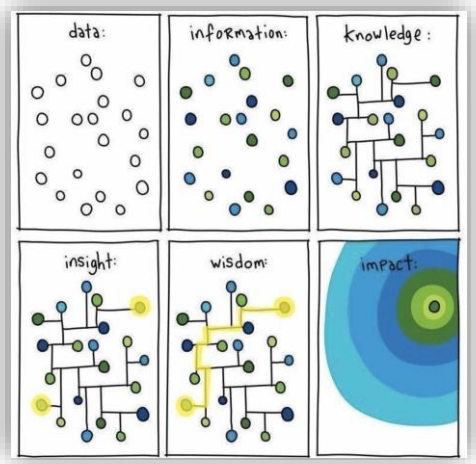
Three R's information: Resources - ALURES NTS

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
1. Replacement State which non-animal alternatives are available in this field and why they cannot be used for the purposes of the project.
2. Reduction 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? (5) (6)
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?

Piet Dierckx - PDIERCK2@its.jnj.com

Animal Welfare Bodies – opportunity to make a difference

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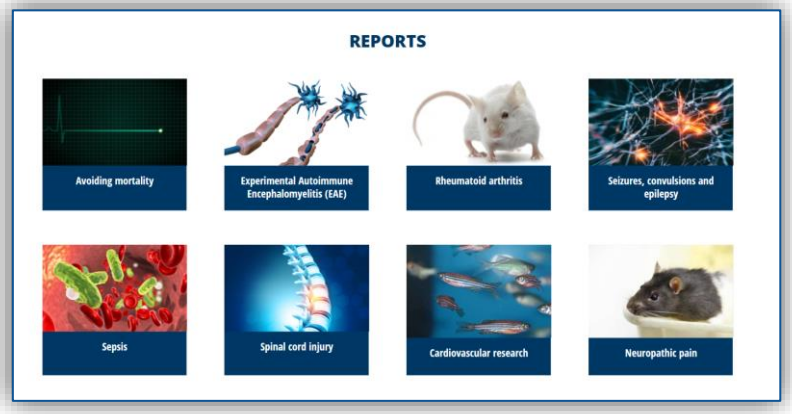
Bringing tools together

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*



https://focusonseveresuffering.co.uk/

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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