

How is review and authorization of animal research organized across the EU?

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ANIMPACT final conference 8 December 2016



This talk

- Results of the mapping of project review systems in EU-28 carried out for ANIMPACT WP3
 - data retrieved from websites and expert informants and confirmed with competent authorities
- Discussion of these results in the context of creating a level playing field for research



Project review and authorization

- The Directive requires that projects/experiments with animals are reviewed for authorization prior to the start
- This is based on the understanding that
 - legislation can't regulate in detail which experiments are to be authorized
 - animal experiments need to be evaluated on a case-by-case basis



Project review and authorization

- Directive 86/609/EEC required that experiments were authorized but left it up to individual Member States to decide how to organize the authorization process
- This resulted in wide variation across Europe in what is required and how the review is done

Project review and authorization



- First comprehensive picture through FELASA working group report (2005)
- 20 countries



PRINCIPLES AND PRACTICE IN ETHICAL REVIEW OF ANIMAL EXPERIMENTS ACROSS EUROPE

**A report prepared by the FELASA Working Group on
Ethical Evaluation of Animal Experiments**



A harmonized process?

- An important objective in the revision => Directive 2010/63/EU
- Limits to the harmonization of the ethics review process:
 - Inherent to the transposition concept - Member State freedom in how to transpose
 - Specifically for this part: The majority of Member States had already functioning review systems in place



Room for variation under the Directive

- Detailed guidelines as to *what is to be covered* in the review but not to *how* the review is to be undertaken, e g *who is to review* and on *what level* review is to take place
- In practice, these requirements for the review can be met through a variety of approaches



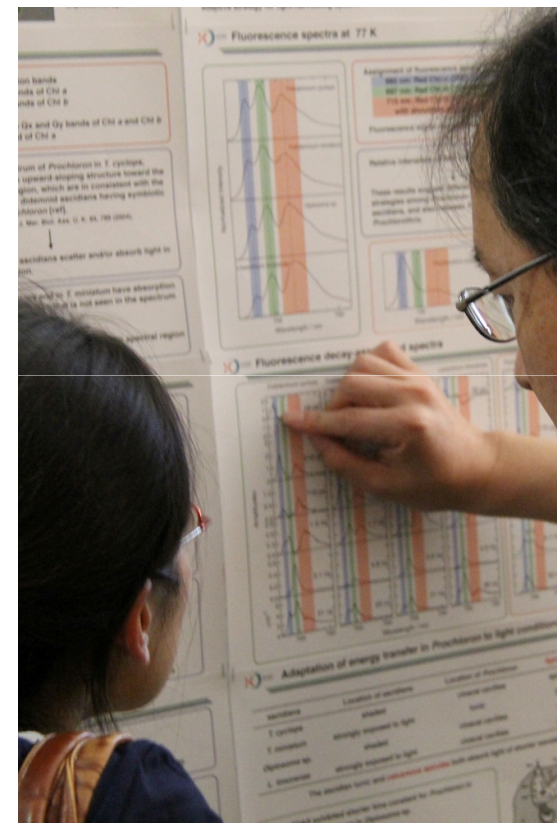
- Our mapping of the project review systems in EU28 confirms this variation





Key differences in review systems

- Geographical level
- (Review by committees or individual experts)
- Expertise and representation



- National
- Regional/local
- Institutional
- Combined
 - national authorization following advice from institutional committees
 - national committee with regional divisions





Geographical level

- Difference in proximity between review and research present different challenges:
 - Proximity – dialogue, knowledge exchange
 - Distance – authority, independence, uniformity



Committee or individual review?

- Committee review is the predominant system
- A few countries have traditionally had review by individual experts
- This is being replaced by a combined approach:
 - Institutional committee (typically the Animal Welfare Body) review before national competent authority review and authorization



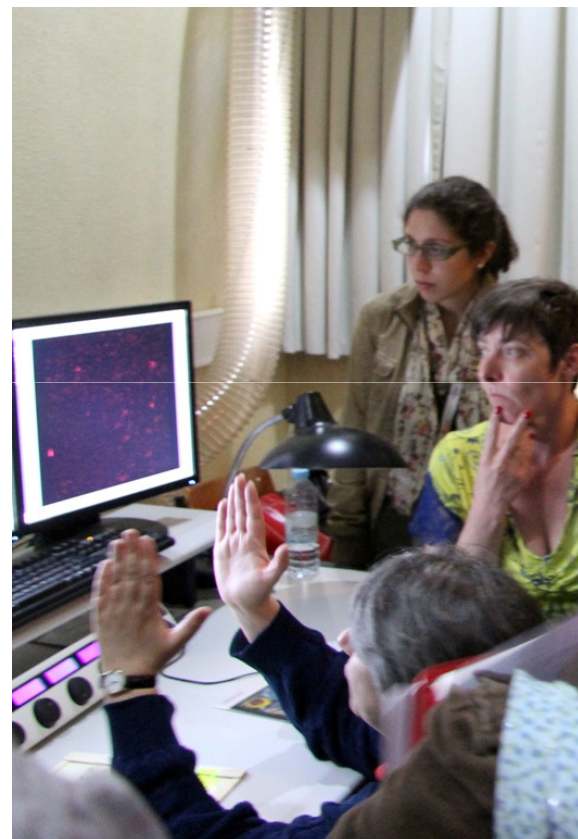
Committee or individual review?

- Single-person review may also happen in committees
- Review made by a single person
 - Makes it more difficult to consider different perspectives (nobody is neutral)
 - Completely misses out on the importance of dialogue in review and decision-making



Committee composition

- Areas of expertise represented
- Technical expertise only or combined with representatives of society and of special interest groups
- Balance between different interests / expertise





Mapping EU review committee composition in terms of...

Areas of expertise represented

- Scientific
 - In all countries
- Veterinary / animal welfare
 - In all countries
- Legal
 - DK, SE, FI, EE, PL
- Ethics
 - BE, FI, DK, SL, NL, PO
- Alternatives to animal experiments
 - BE, EE, LV

Representation of interests / society

- Representing special interests
 - Animal protection: DK, DE, SE, FI, EE, NL, PL, SL
 - Patients: DK
- Representing society
 - Lay members: SE, IE, UK



Balance in committee composition

- There are many possible approaches to balancing expertise and interests
- One is between *research* and *animal welfare*
- In many countries, committee composition seems to be based on a perceived need to balance these interests
- Another is between representation internal and external to the research community



Technocratic versus inclusive approaches

Technocratic

- Fully (experts only)
 - Most member states
- Mainly (non-research optional)
 - PT

Inclusive

- Fully (balanced research/non-research)
 - SE
- Somewhat (non-research in minority)
 - DE, FI, DK, EE, IR, NL, PL, SL, UK



- Technocratic approaches predominate
- Project evaluation as required by Directive 2010/63/EU implies
 - Considering predominantly technical/scientific issues (*compliance with 3Rs, scientific merit*)
 - Considerations which seem to involve more than strict technical expertise (*purpose justifying the use of animals, harms justified by expected benefits, ethical considerations*)



Summary

- Most of the previously existing differences between MS in ethics review systems remain after the transposition of Directive 2010/63/EU
- The most significant differences are
 - Geographical level of review
 - Balance in committee composition



Summary

- There are different challenges for committees operating on different levels:
 - Institutional: close to research but difficulties with expertise and impartiality
 - National: no direct contact with research; wide expertise and impartiality
- Will committees with different types of composition and balance review research differently?



Further work

- To answer the question how different committees and different individuals review similar projects, we are presently analyzing interview data
 - 23 committee members in 5 EU countries + Switzerland
 - 4 selected cases of different combinations of harm and benefit, species and purposes



From process to outcome

- This study has addressed how project review is organized – not the outcome that this produces
- We have shown that there is great variety of mechanisms for peer review and a huge number of committees (>100)
- Considering the decisive effect these committees will have on what research is being authorized, the variation in evaluation an outcome will be an important issue to address



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ANIMPACT

ANIMPACT is an ethical, legal and practical perspective on the impact of a new regulatory framework for the scientific use of animals on research and innovation in the European Union.

- Complete map of ethics review systems in EU28 (as of Sept 2015 – under update)

Thanks to informants and
competent authorities!

