



# JSAAE symposium

**Revision of the European Council  
Directive 86/609/EEC on the protection of  
animals used for scientific purposes**

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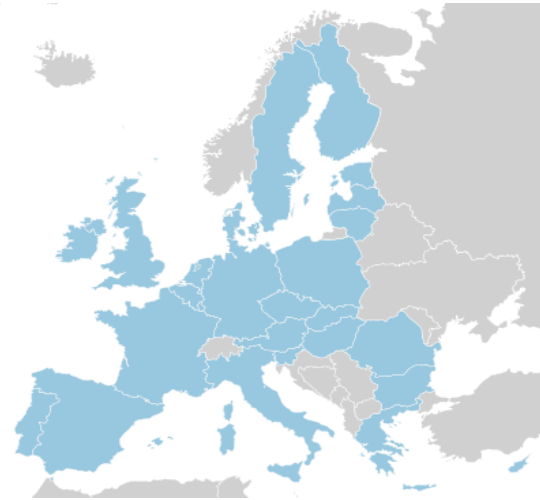
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# Revision of Council Directive 86/609/EEC: outline

## outline

- ❑ Historical context
- ❑ Revision Process
- ❑ Major proposed revisions
- ❑ Current status of revision process
- ❑ Conclusions

European Union



- 27 Member States (population: 495 million)
- economic and political union, common policies
- **Council Directive 86/609/EEC on the approximation of laws...regarding the protection of animals used for experimental purposes (1986)**
- legislation is meant to avoid affecting the common market

# Revision of Council Directive 86/609/EEC

## Background information



**Current situation in EU: number of Member States (MS) have established considerable more far-reaching measures in national implementation whereas other MS apply only minimal rules**

### Driving forces for the revision

- ❑ Directive dating back to 1986
- ❑ Directive's text containing inappropriate legal provisions, omissions language and inconsistencies
- ❑ Increasing consideration for animal welfare and ethical aspects in general
- ❑ Acceptance of the Three Rs as the basis for improved animal welfare and good science

# Revision of Council Directive 86/609/EEC: Aims and objectives

## Aims of revision



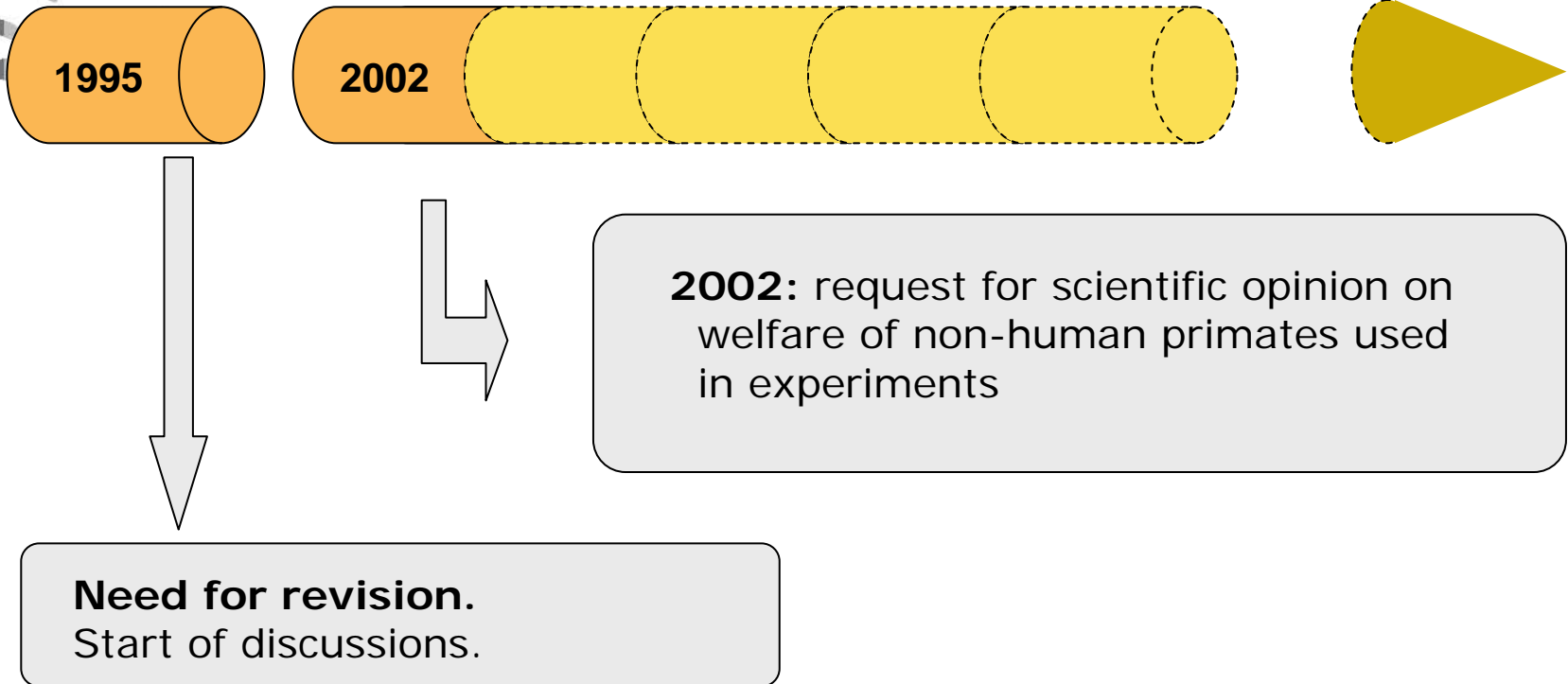
*ensuring a level playing field throughout EU, for research community and industry, at the same time strengthening the protection of animals still used in scientific procedures in line with the EC Treaty's Protocol on Animal Welfare<sup>1</sup>*

1 Treaty of Amsterdam (1999): recognising animals as sentient beings

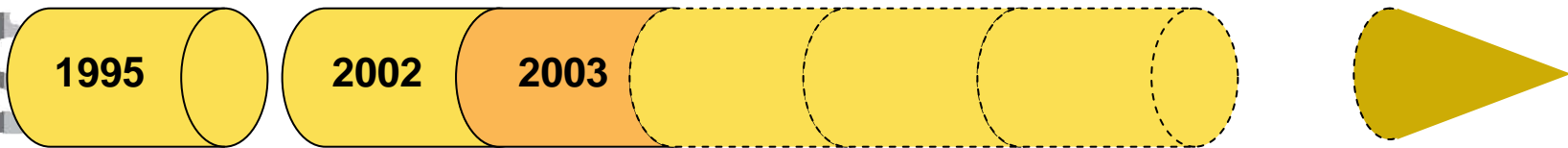
# The revision process

Only major steps in revision process are given

# Revision of Council Directive 86/609/EEC: steps in the process (1)



## Revision of Council Directive 86/609/EEC: steps in the process (2)



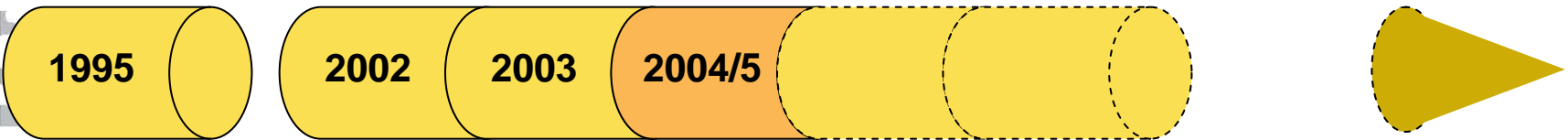
**2003:** set up of Technical Expert Working Group including stake-holder organizations

**Aim:** collect scientific and technical background information for the revision

### 4 sub-areas:

- Scope & definitions,
- Authorization,
- Ethical Review
- Cost-benefit analysis and severity classification

# Revision of Council Directive 86/609/EEC: steps in the process (3)

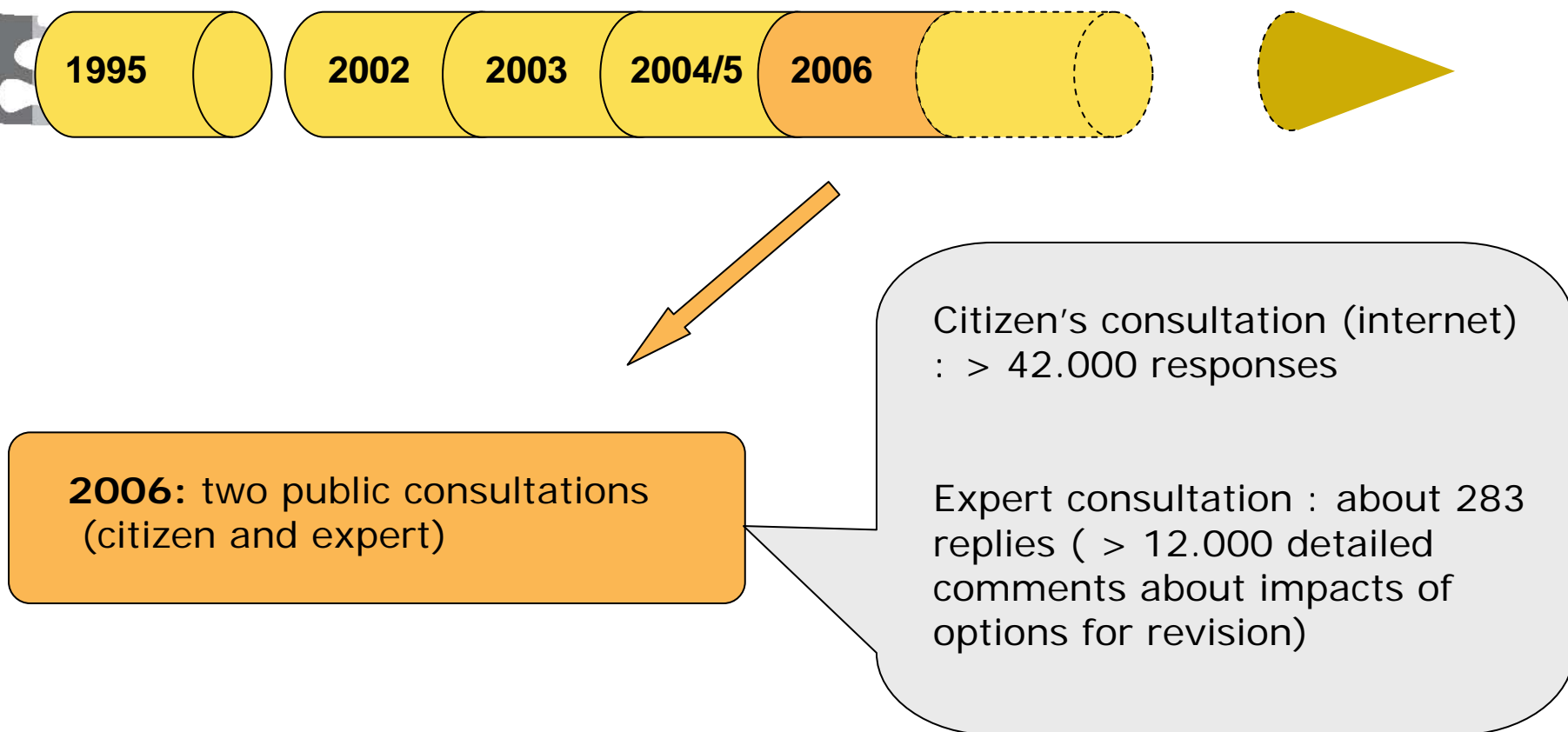


**2004-2005:** request for opinion to EFSA's Panel on Animal Health and Animal Welfare (AHAW) about critical scientific issues

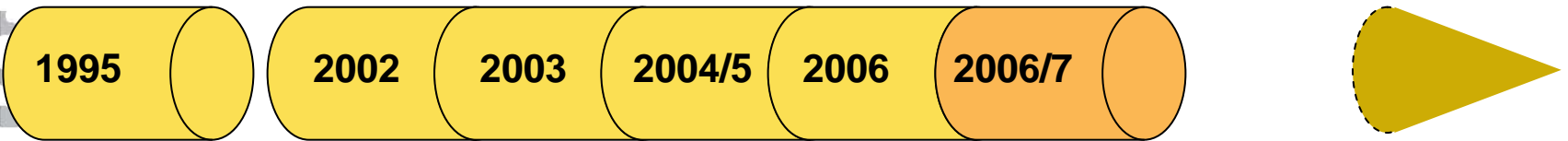
Request European Food Safety Agency (EFSA)

- Pain & Suffering
- Use of invertebrates
- Foetal & embryonic forms
- Purpose bred animals
- Euthanasia

## Revision of Council Directive 86/609/EEC: steps in the process (4)



# Revision of Council Directive 86/609/EEC: steps in the process (5)



**2006-2007:** impact assessments  
(socioeconomic and animal welfare)

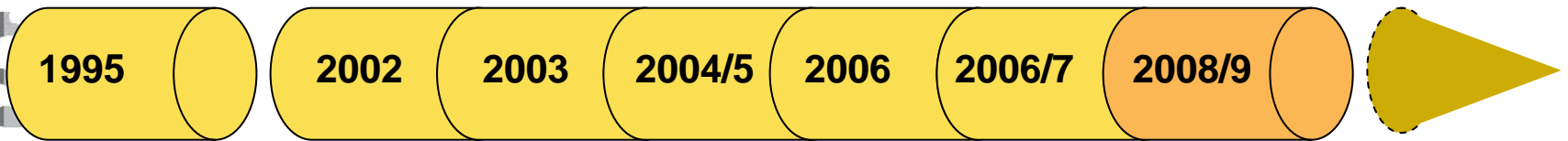
**Based on:** \* consultancy (Prognost)  
\* information stakeholders  
\* case studies

e.g. ethical review

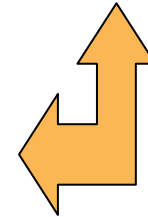
**+**  
Animal welfare  
Transparency  
Awarenes & work  
satisfaction res.  
Reduction no.  
animals  
Quality science  
Social impacts

**-**  
Admin. Costs  
Competitiveness  
Delay projects

## Revision of Council Directive 86/609/EEC: steps in the process (6)



- ❖ Draft revision produced by European Commission
- ❖ Send to European Parliament for reading
- ❖ 161 amendments made in revised document



# Revision of Council Directive 86/609/EEC: facts and misconceptions

## The revision of EU Directive is all about:

- Harmonising laboratory animal standards in Europe
- Extending the scope of animal protection to the whole life cycle of a laboratory animal
- Boosting activities on 3Rs
- Improving competence levels of all involved in animal experimentation
- Monitoring and guaranteeing good animal care throughout the life cycle of an animal

## The revision of EU Directive is NOT:

- Making animal research to an administrative battlefield
- Obstructing animal research and testing in Europe
- Banning all research on Non Human Primates.
- Accepting non-validated 3R alternatives
- Disrespecting intellectual property and confidential information



# Proposed revisions

Only major revisions are given

# Proposed major revisions: application

## The Directive applies to animals:

- a) Animals at breeders, suppliers and users
- a) Used in procedures
- b) Bred specifically for their tissues

## The Directive applies to:

- I. Live non-human vertebrates
- II. Some groups of live invertebrates

## Further details

### Live non-human vertebrates

including:

- independently feeding larval forms
- foetal forms of mammals as from last third of development

### Groups of live invertebrates

- Cephalopods
- Decapod crustaceans of infraorder Brachyura and Astacidea

# Proposed major revisions: Procedures

## Definition:

any use, invasive or non-invasive, of an animal for experimental or other scientific purposes, with known or unknown outcome, or educational purposes, which may cause the animal a level of pain, suffering, distress or lasting harm equivalent to, or higher, than that caused by the introduction of a needle. This excludes the killing of an animal solely for the use of their organs or tissues

**Classification categories for severity :  
mild, moderate, severe and non-recovery**

# Proposed major revisions: Authorization

## Education/Training

- ❖ Staff shall be adequately trained
- ❖ Use of minimum requirements for education/training and for maintaining competence
- ❖ Staff has to be authorised

## Specific expertises (required at each breeder, supplier and user establishment)

- ❖ Person responsible for animal welfare
- ❖ Designated veterinarian (or suitably-qualified expert)

# Proposed major revisions: Animal Care and Welfare

- ❖ Each breeder, supplier and user establishment sets up an animal welfare body
- ❖ Animal re-use allowed only when specific conditions are met
- ❖ Death as the endpoint should be avoided (Humane endpoints)

## Animal Welfare Body:

### Composition (at least)

- ✓ Person responsible animal welfare
- ✓ Scientific member
- ✓ Input from designated vet

### Tasks (as a minimum)

- ✓ Advice to staff on accommodation, care, etc)
- ✓ Advice to staff on 3R methods/approaches
- ✓ Establish & review internal operational procedures
- ✓ Follow development and outcome projects

# Proposed major revisions: 3Rs

## Additional 3R activities

- ❖ (General wording on 3Rs; 3Rs have to be used if available)
- ❖ Establish programmes for sharing of organs and tissues of animals killed
- ❖ Nominate qualified laboratories for validation studies
- ❖ EU-MS shall nominate contactpoint on 3Rs
- ❖ EU-MS shall establish a national committee for the protection of animals used for scientific purposes

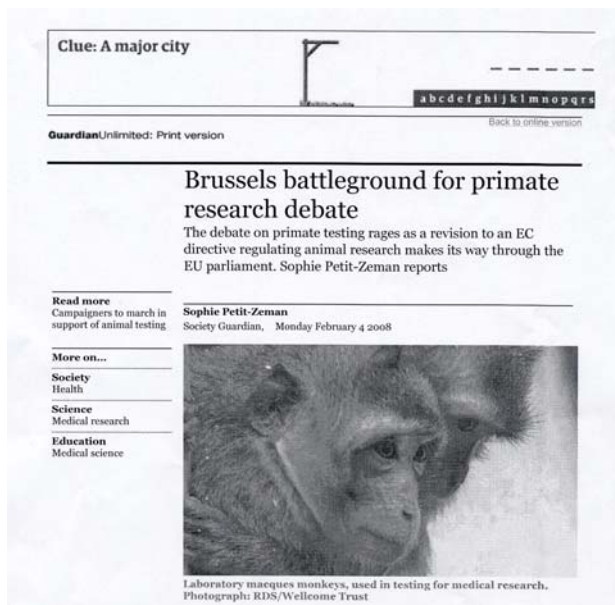
# Proposed major revisions: project authorisation

Projects require authorisation by a competent authority

Application shall include : the project proposal, a non-technical project summary and relevant project details (e.g. 3Rs, housing/care, experimental design, statistical analysis, humane endpoints,

Competent authority shall consider expertise in areas of animal use (+3Rs). statistics/experimental design, veterinary practice, animal husbandry/care

Retrospective analysis by competent authority : all projects classified as 'severe' and all projects using NHPs



## Written declaration European Parliament (09/25/07)

- Refers to public consultation: 80% respondents not acceptable
- advanced technologies available to replace animal use.
- make ending use of apes and wild-caught monkeys in experiments
- establish a time-table for replacing use of all primates in scientific experiments with alternatives

## Response of European Commission (01/08)

- 67% of NHPs are used in safety and efficacy regulatory studies
- The Commission is examining the possibility to ban the use of Great Apes and wild-caught animals with scientifically justified exceptions.
- Today, NHP use is unavoidable in several vital research areas.
- The current scientific knowledge does not allow for full replacement of NHPs today, nor in the near future.

# Proposed major revisions: NHPs

- ❖ **Use only for : -- basic research  
-- research aimed at preservation species  
-- debilitating or potentially life threatening human diseases**
- ❖ **Use only offspring of NHPs bred in captivity**
- ❖ **All projects using NHPs shall undergo retrospective assessment**



# Current status revision

# Revision of Council Directive 86/609/EEC: current status

1995

2002

2003

2004/5

2006

2006/7

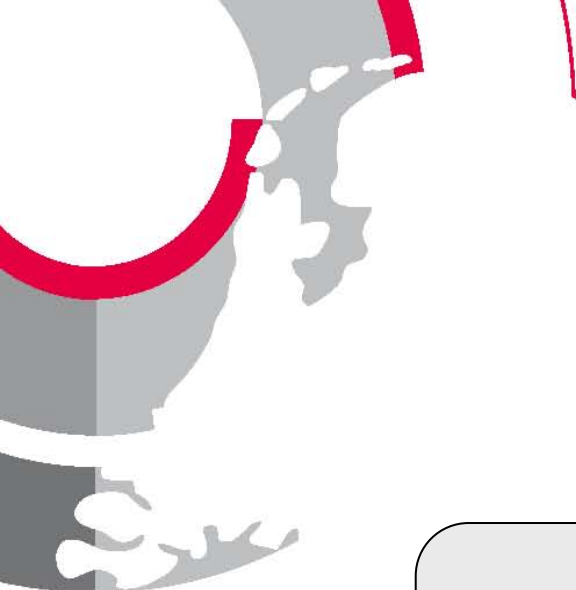
2008/9

2010??

- ❖ Draft revision produced by European Commission
- ❖ Send to European Parliament for reading
- ❖ 161 amendments made in revised document
- ❖ **Co-decision procedure Parliament and Council**
- ❖ **Adoption by Council of Ministers**

# Conclusions

- I Although not yet adopted, there is a strong commitment at Commission level to finalise the revision
- II. The proposed Directive has been successful in strengthening animal welfare while still allowing animal research/testing
- III The proposed Directive reflects the increased awareness on 3R alternatives. Furthermore it includes mechanisms to foster and boost 3R activities
- IV **The proposed Directive is implicit to improving animal welfare/care as well as to enhance the level of quality of research**



Thanks for your attention