

**Dr Mark Matfield**

**Director**

**European Biomedical Research Association**

**matfield@ebra.org**

**The Revision of Directive 86/609**

# Revising the EU Directive

- Three key documents:
- 2002: European Parliament ‘own initiative’ report
- 2004: European Commission: Technical Expert Working Group report
- 2005: European Commission: Impact assessment tender call - technical annex

# 2002 Own Initiative Report

- European Parliament
  - Easily influenced by antivivisection groups
  - Suspicious of European Commission proposals
- Own Initiative Report
  - Negative view of animal experimentation
  - Poorly informed
  - Very critical of current Directive
  - Several radical proposals

# 2004 Technical Expert Working Group Report

- Commission set out all the questions to be answered
- TEWG included
  - scientists and antivivisection campaigners
  - representatives from member states
  - representatives from candidate countries
  - European Commission officials

- Own Initiative Report

[http://www.europarl.eu.int/omk/sipade3?L=EN  
&OBJID=9735&LEVEL=4&MODE=SIP&NAV=X&LSTDOC=N](http://www.europarl.eu.int/omk/sipade3?L=EN&OBJID=9735&LEVEL=4&MODE=SIP&NAV=X&LSTDOC=N)

- TEWG Report

[http://europa.eu.int/comm/environment/chemicals/lab\\_animals/revision\\_en.htm](http://europa.eu.int/comm/environment/chemicals/lab_animals/revision_en.htm)

# What will the revised Directive say?

## *Almost Certain*

- Centred around the Three R's
- Ethical review process for all projects
- Licensing for all projects, based on Cost-Benefit
- Changes to projects will require licensing
- Regular inspection of institutions

# What will the revised Directive say?

## *Likely*

- Animals killed to provide tissues to be included
- Procedures classified on a severity scale
- Cephalopods and decapods included
- Foetal and embryonic forms included

# What will the revised Directive say?

## *Possible*

- Central EU database of alternatives
  - Have to check for all new licences
- Greater training requirements
  - FELASA standards likely
- Tighter definition of re-use
- Tighter controls on transportation

# What will the revised Directive say?

## *Unlikely*

- Central EU Inspectorate
- Restrictions on the use of primates
- Purpose-bred defined as F2
- Ban the use of animals in education & training
- Restrictions on the use of 'severe' TG animals

# Timescale

- 2004 - EU enlargement
- 2005 - Commission consulting with EFSA
- 2006 – impact assessment
- 2007 - public consultation
- European Parliament first reading in late 2007?
- From 1 year to 3 years for agreement
- Into national legislation 2009 to 2012