

Understanding Animal Research



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Background to the EU Directive and its current status

Principles

- **The revision of EU 86/609 is a political process**
- **The decisions are not themselves scientific**
- **Some decisions might be based on science**
- **Consultation is good practice**
- **But the European political institutions (Commission, Parliament and Council) can ignore the views of individuals and organisations**

Status

- **We have now reached political agreement**
- **First readings have been finalised**
- **Second readings are time-limited**
- **The text is agreed**
- **Member states are preparing for implementation**
- **There are two years allowed**

Background

- **Harmonisation**
- **Animal welfare**

Harmonisation

- **The EC Treaty is concerned with functioning of the internal market**
- **This means a level playing field, and therefore a common market**
- **But animal studies and scientific projects are not tradeable goods**
- **Benefits of harmonisation are small**

Competitiveness

- **Concern of EU is internal market**
- **Pharmaceutical companies operate in a global market**
- **Harmonisation can mean a high level of regulatory burden, with increased costs for the EU, and inability to carry out research (restrictions)**

Animal welfare

- **EU has a strong animal welfare agenda**
- **Animal welfare groups are powerful in the European Parliament**

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- **The aim of the revision of Directive 86/609/EEC is to address the current problems of the uneven playing field, to fully incorporate the principle of the "Three Rs", including the promotion of the alternatives to animal testing, and to improve significantly the welfare of the animals .**

- Commission letter June 2010

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- **...The EP's first reading report put a lot of emphasis on the reduction of administrative burden and the continuity and viability of European research and industry relying still on the use of animals.**
 - Commission letter June 2010

Frustrating?

- **...ever since the trialogue process started, the Coalition and other animal protection groups have been met at every turn with secrecy and unwillingness on the part of all three institutions to engage in discussion. There has been a refusal to disclose documents. Letters and email go unanswered. Public claims by officials do not reflect what is actually in the trialogue text...**
- Letter to Commission from European Coalition to End Animal Experiments (ECEAE)

Implementation

- **The final result is an acceptable compromise**
- **Interpretation is everything**

Article 8

- **Applied research or testing on NHPs must be... undertaken with a view to the avoidance, prevention, diagnosis or treatment of debilitating or potentially life-threatening clinical conditions in human beings**
- **... shall mean a reduction of a person's normal physical or psychological ability to function.**
- **Recital 17 “*having a substantial impact on a person's day-to-day functioning*”**
- **What does this mean? How is it translated?**

Article 15

- **Member States shall ensure that a procedure is not performed if it involves severe pain, suffering or distress that is likely to be long-lasting and cannot be ameliorated.**
- **What does this mean? What is meant by long-lasting?**
- **Why do we need the safeguard clause?**

Conclusion

- **The use of animals in research remains controversial in many European countries**
- **The EU now determines national laws**
- **The revision of EU 86 was a wake-up call**
- **We must work together across Europe**
- **We must explain to the public and to the politicians how and why we use animals**