



Home Office

# Session VI: Core Principles View from a European Regulator

Judy MacArthur Clark  
Chief Inspector, ASPI, Home Office

Kavli Royal Society International Centre, UK.  
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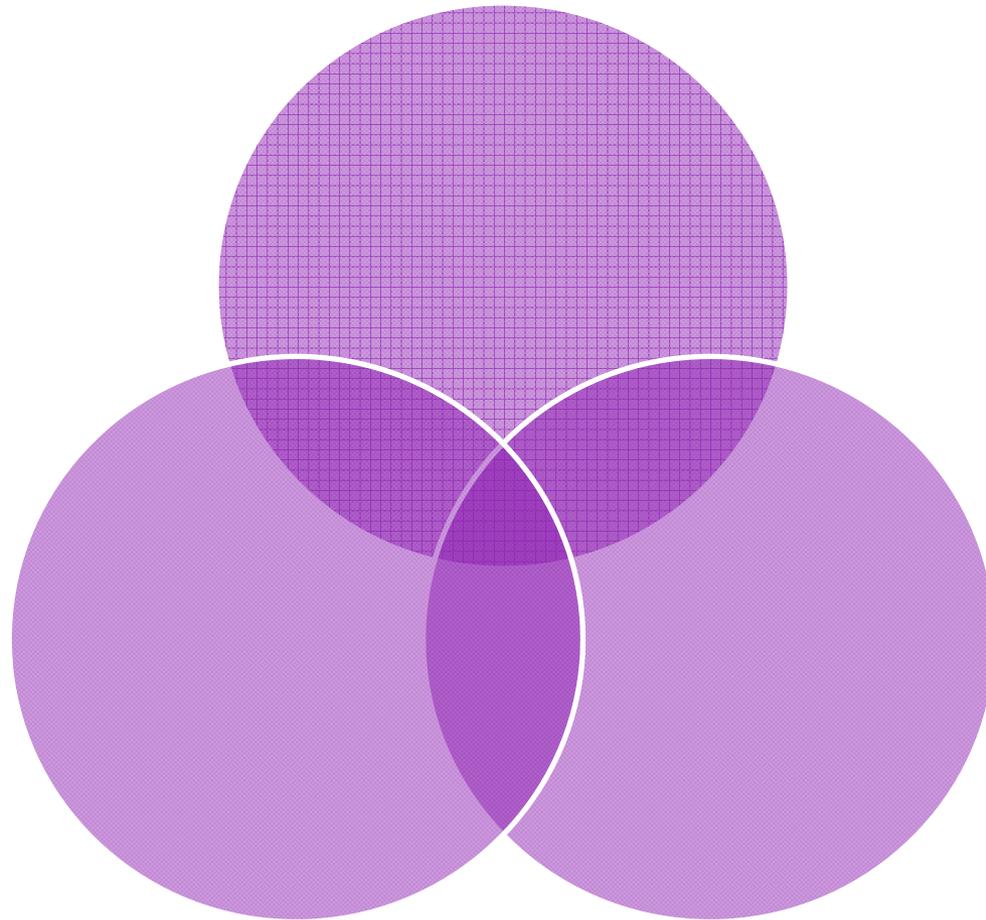
- Establish some core principles
- Project authorisation – avoiding bureaucracy
- Training, supervision & competence
- Harmonisation & consistency

# Who am I?

## ➤ My background

- Worked as licence holder under the UK 1876 Act
- Participated in the debates which led to UK 1986 Act (ASPA)
  - Based on EU Directive 86/609/EEC
- Early implementer of ASPA as both PI and NVS (AV) with project licences and 'ethical evaluation'
- Worked as Attending Veterinarian and subsequently Institutional Official in USA
- Last 3 years as regulator in UK
  - Initially focused on response to Better Regulation
  - Since November 2008, negotiating a new set of rules for the 27 EU Member States
    - EU Directive 2010/63/EU – key aims
      - Reduce disparities ... harmonisation of legislation (R 1&56)
      - Improve animal welfare by raising ... standards for their protection (R 6)
      - Facilitate and promote ... alternative approaches (R 10)

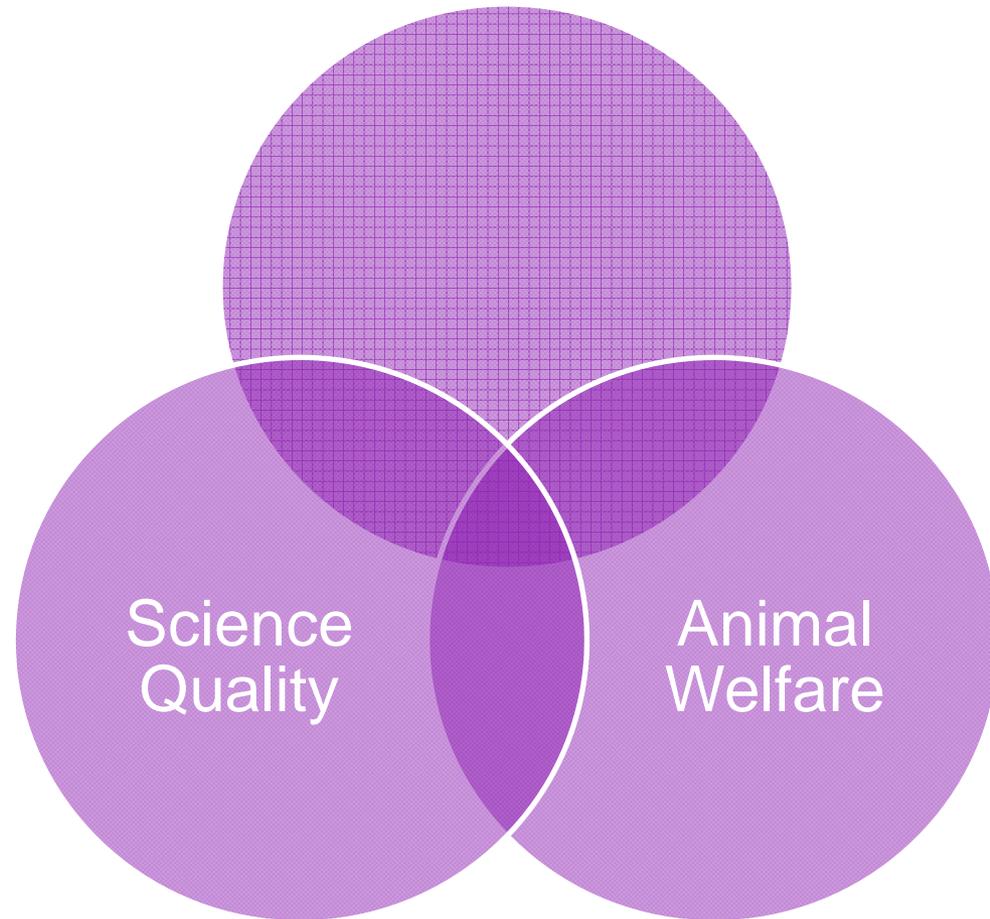
# The Regulatory Balance



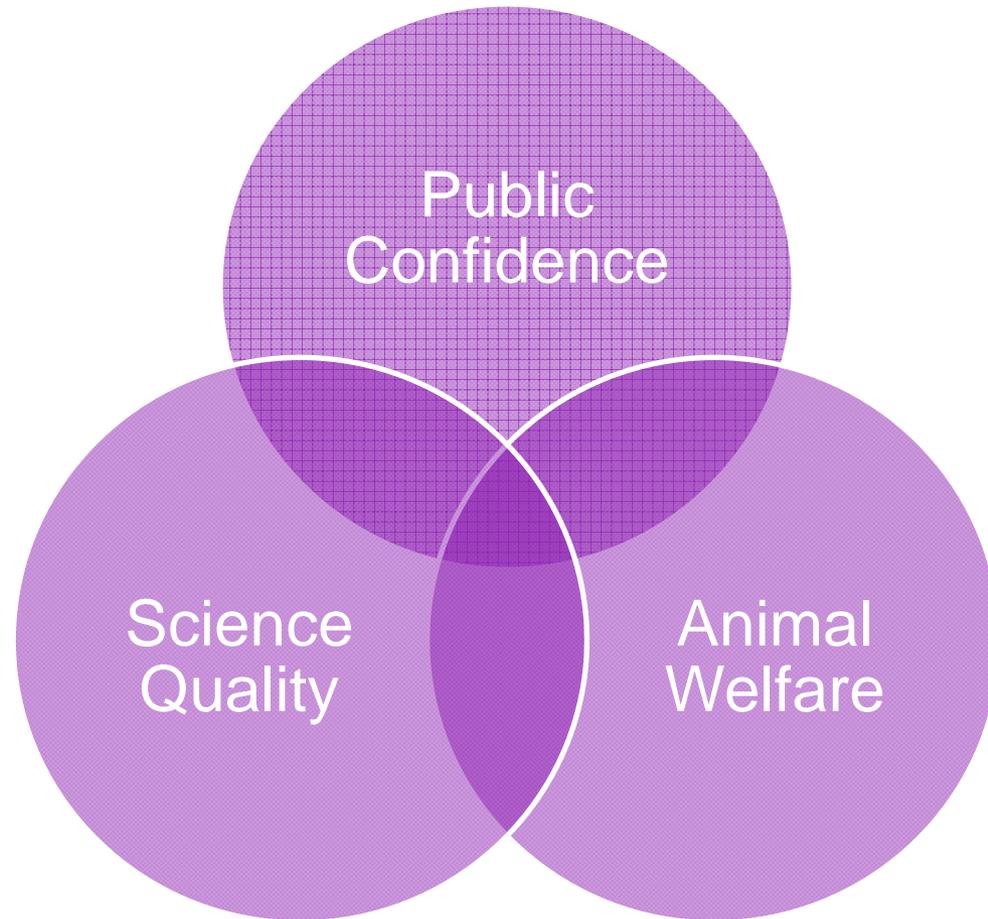
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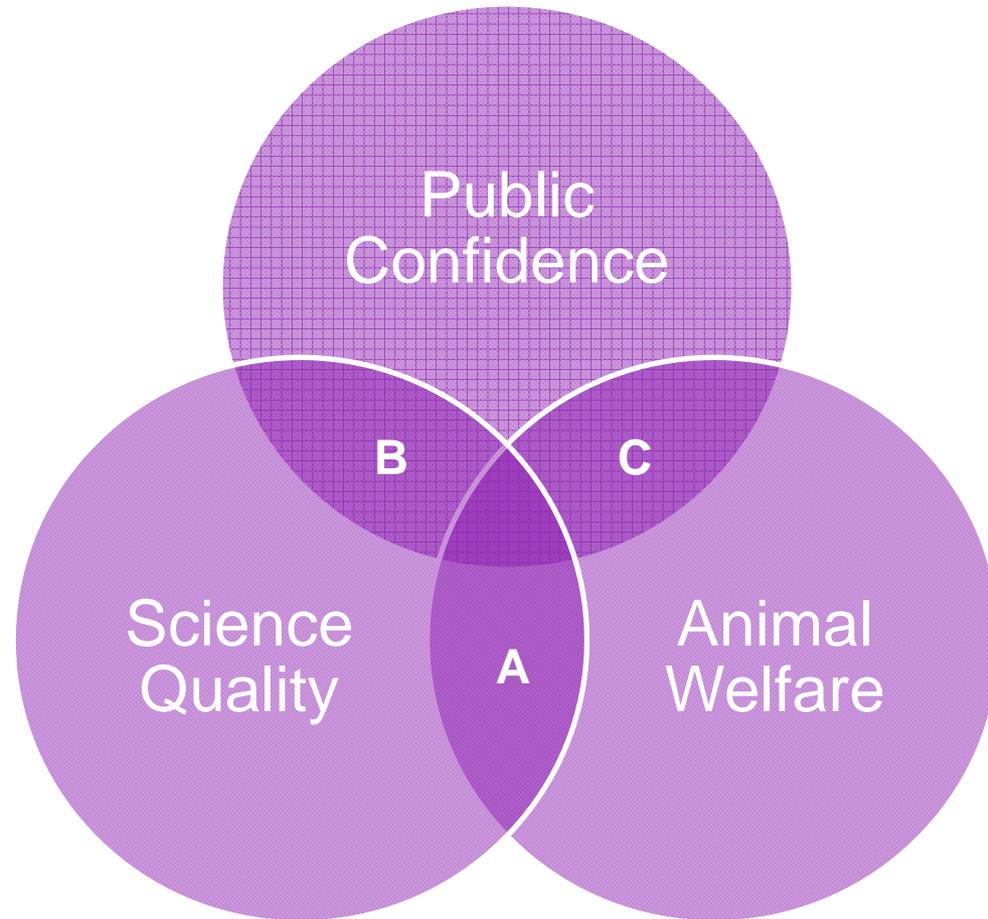
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# The Regulatory Balance



# Balance and the Directive

- EU Directive 2010/63/EU – key aims
  - Reduce disparities ... harmonisation of legislation (R 1&56)
  - Improve animal welfare by raising ... standards for their protection (R 6)
  - Facilitate and promote ... alternative approaches (R 10)
- **European public views of animal research considered**
- **Little mention of supporting high quality science in Europe**

# Core Principles?

- System of authorisation of places, people and projects
- System for ethical evaluation of projects
  - Impartiality and independence of those evaluating
  - Based upon balancing the costs (harms) to the animals against the benefits expected to accrue
- System for verifying compliance
  - Impartiality and independence of those verifying
  - Based upon some form of inspection
- Components of these systems – evidence we seek:
  - Implementation of 3Rs
  - Training and competence of individuals
    - ethical, legal, specific skills
  - Provision of veterinary care
  - Viable sources of animals and transport
  - Inspection of facilities
    - Physical environment, standards of care & husbandry, record keeping

# Consequences of Core Principles

- Some proposals may not be justifiable!
  - May involve long-lasting severe pain which cannot be alleviated
  - Cost-benefit assessment may simply not balance
    - Refinement can reduce the costs – but only so far
    - Benefits may be too insignificant or intangible – “marginal projects”
    - May simply be poor science
  - Exercise tough love!
- The nature of ethical evaluation of “marginal projects”:
  - The assessor/committee keeps asking more and more questions
    - “Paralysis of analysis”
  - until, worn down by the process, either:
    - The project finally gets approved; or
    - The applicant gives up!
  - If the project gets approved, it’s often on the basis that the work will be monitored constantly and in minute detail
    - Post-approval compliance monitoring
    - Persistent inspection
  - High level of bureaucracy with probably little welfare benefit

# Models of governance

- Self-regulation      USA      IACUC
- Central governance      Europe      Competent Authority

# Thin-slicing – how we decide

- Spontaneous decisions are often as good as - or even better than - carefully planned and considered ones.
  - Snap decisions often better than volumes of analysis
  - Avoid Paralysis of analysis
- Identify “marginal projects” as early as possible
  - Have a separate process to deal with these projects
  - Make prompt and early decisions
    - If reject, give reasons
    - If accept, build in milestones but not overly restrictive
  - Avoid drowning the science in bureaucracy – exercise trust
- Other projects
  - Clarity of thinking to address implementing the 3Rs
  - Aimed at reducing costs – project will be approved
  - Efficient processing supports science and welfare
- Compliance without bureaucracy

# Training & Competence

- EU Commission declared intention
  - free movement of staff throughout Europe
- Based on common training standards
- Training doesn't equate to competence
- Maintenance of competence important also
- Avoid lengthy training 'hurdle'
  - Core training – Legislation, Ethics and the 3Rs
  - Additional training – appropriate; modular; ?points based
  - Continuing training - relevant; maintaining skills; developing new skills

# Harmonisation & Consistency

- Harmonisation – key aim of EU Directive
  - Scope – types of animals protected
  - Minimum housing standards
  - Project authorisation & severity classification
  - Accountability for Training & Competence
  - Animal Welfare bodies & Designated Veterinarians
  - Inspections for compliance
  - Safeguard clauses – key to harmonisation (R 50)
  - Member States can apply higher standards – but not to affect market competitiveness
  
- Consistency might be a core principle
  - Will harmonisation bring consistency?

# Final thoughts

“..this Directive represents an important step towards achieving the final goal of full replacement of procedures on live animals for scientific and educational purposes as soon as it is scientifically possible to do so.”

Recital 10, EU Directive 2010/63

“Nothing will ever be attempted if all possible objections must first be overcome”

Samuel Johnson (1709-84)