Maastricht University

CAPHRI
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animpact
European legislation
Impact on the scientific use of animals

Questions for and from the transposition of the Directive to Member States' Law

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- Central and continuing issue: 'cultural bandwidth' in relation to the treatment of animals in science and the satisfactory regulatory response (in the EU)
- What does the Directive give us as a regulatory architecture within which to work? What is the state of play?
- Observations about the Directive and the trajectory of its development
- Transposition into Member States' Law
- (Literature/ socio-legal desk-based analysis)

- Development to 2010/63/EU
  - From 1980s, from Council of Europe and EEC
  - positives:
    - presence of 3Rs in CofE
  - problems:
    - Council of Europe Convention had broad scope, but as a Treaty, limited take up and teeth
    - Directive 86/609/EEC binding on EEC, but limited scope - not animal welfare but commercial use, so not academic science use (because of legal competence)
    - of their time and cultures - criticisms: lack of harmonisation; lack of keeping pace with scientific understanding

- Legal basis of 2010/63/EU
  - Harmonisation and Competence
    - Single market: Treaty on Functioning of EU Art. 114
      - European Research Area - "level playing field" - (continued availability of animal use in science)
    - Animal welfare
      - TFEU Article 13

"In formulating and implementing the Union's agriculture, fisheries, transport, internal market, research and technological development and space policies, the Union and the Member States shall, since animals are sentient beings, pay full regard to the welfare requirements of animals, while respecting the legislative or administrative provisions and customs of the Member States relating in particular to religious rites, cultural traditions and regional heritage."

- Is 2010/63/EU set up in a way that will meet the criticisms of the previous Law?
  - Coverage: all scientific uses of animals, not just commercial
  - Centrality of 3Rs - commitment to 3Rs
    - But new "Harm/Benefit" balancing
  - Harmonisation? a Directive - requires transposition
    - explicit discretion
    - implicit discretion - interpretation
      - how much room for manoeuvre are MS given?

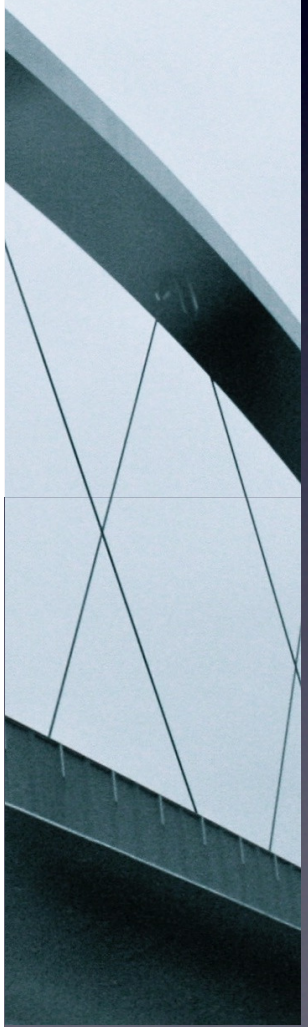
- 2010/63/EU responding to scientific understanding and animal welfare per se, minimising regional variation: positives
  - Coverage - all scientific use; increased range of species.
  - Procedural integrity of the Directive - breeders, facilities, researchers, projects - licensing;
  - Competent authority and National Committee
  - Directive embraces 3Rs as the underpinning concept
  - Most successful is welfare - where there is a degree of prescription because minimum standards relating to space, etc., can be and are defined - least conceptually dependent - Annex III
  - likewise, euthanasia techniques - (at least it's a list) Annex IV

- 2010/63/EU responding to scientific understanding and animal welfare per se, minimising regional variation: negatives
  - Lack of procedural detail on the required licensing procedures - Articles 36–38
  - Competent Authorities up to the MS
  - Conceptually contested nature of 3Rs
    - Explicit exemptions - explicit derogations from strong conceptual positions.
      - varies in the way that this appears in the Directive
      - but the wording of the derogations/ exemptions are open textured - will this lead to regional variation?
    - linguistic vagueness - linguistic uncertainty

- Nature of the exemptions
  - Article 33, exemption to Annex III - "scientific, animal-welfare or animal-health reasons"
  - Great Apes (Article 8.3) - tight range, based on the perception of the MS in face of species of human danger if no species alternative.
  - Endangered Species (Article 7) - species preservation, human, animal or plant health research or product/ substance testing where "scientific justification" that there is no species alternative
  - Nonhuman primates (Article 8.1) as Article 7, but also for "basic research" again where "scientific justification" that there is no species alternative

- Nature of the exemptions
  - Animal welfare v. ? (other interests)
  - according to hierarchies:
    - between species
      - Great apes, endangered species, > downwards
    - between purposes
      - health - animal, human, plant > scientific need
  - Is there a greater scientific consensus than cultural divergence around the meaning of the terms in the exemptions?
    - how far is "scientific justification" universal or domestic? Which tribunal will judge this claim? - competent authority - local view; or international? (role of journals and peer review?)

- Interpretative assistance?
  - Recitals (within Directive) - small indication of ideas, but essentially same gaps as Articles.
  - EU Expert Working Papers
    - nine papers - 2002–2009 - aspects of the Directive
    - how much detail do they give to make practical differences in the interpretation of the gaps?
    - what presumptions are found there about the compromise between the different approaches in 3Rs?
      - e.g. is there a presumption towards animal use in the way that replacement is framed?
      - how far is compromise possible?



- MS implementation experience?
  - Germany, NL, Belgium, UK, Ireland, Spain, and Sweden
  - Transposition generally close to the Directive - more or less explicitly (with detail - towards self-regulation - in codes of guidance)
  - But the Directive is open textured on key issues, giving space for operational differences in interpretation.

- What do we learn from all this?
  - Could the Directive do anything more (at this point)?
  - Is the solution in the hands of the international science community?
    - i.e. understandings about suffering, about necessity, about the seriousness of human, animal, environmental problems, about the potential to use other species?; about the framing of experiments and approaches to answering scientific question?; how far is the interpretation of the Directive also about lab culture?
  - Or in the hands of the MS Competent Authorities, National Committees and ECom Committee?
    - cf. Data Protection
  - Remembering that this is a point on a still-developing journey.