efpia

European Federation of Pharmaceutical Industries and Associations

Directive 2010/63
EU research community views

Magda Chlebus, Director Science Policy

European Federation of Pharmaceutical Industries and Associations

PolLASA, Warsaw, 7 September 2011

Contents of the presentation

- Policy drivers
- EU research community principles and objectives
- Key (new) features
- Grey areas and challenges
- Resources/information

New legislation: EU rationale

- Directive 86/609 was poorly structured
- Key clauses of 86/609 are weak
- Lack of harmonisation
- To incorporate issues of common regulatory evolution
- Changes in public attitude

Research community guiding principles

- Keep balance between animal welfare, human and animal health and research needs
- No animal testing = no new medicines
- Good animal welfare = good science = good animal welfare
- Europe has highest standards of protection = we want to maintain research in Europe

New Directive: a political compromise

- No definitive ban on any type of research or species than Great Apes – but limitations beyond scientific needs
- Reliance on ethical evaluation for a case by case approach
- Reasonable scope: invertebrates limited to cephalopods, compromise on immature forms
- No duplication between authorisation and ethical review
- Reasonable euthanasia requirements
- Simple severity classification
- Optimal reuse provisions
- Protection of confidential information
- Security of staff and business confidentiality granted
- Transitional periods for adapting housing and care standards

Devil in the detail…

- Grey areas – research friendly interpretation is a must
  - Articles + recitals + transposition guidance
- Problems created by translation mistakes
  - In doubt - take the English version and use the guidance
- Main law but (legislative debate) and implementing decrees (often in hands of competent ministers)
  - Be cautious until the last act is adopted
- Other parties may have a different agenda
  - The processes do not need to be bureaucratic but efficient
  - Efficiency should not be measured in number of studies delayed or blocked by administrative procedures, but how these translate into better welfare/less negative impact

What's at stake?

- Impacts on ability to conduct research in your country
  - Fundamental and applied research in all sectors of activity - if not relevant today, may be relevant tomorrow (biotechs, medical research, chemicals)

- Political compromise - contains areas of legal uncertainty that
  - Could be turned into significant bureaucratic burden
  - Could limit/ban certain studies
  - Could create significant divergences of interpretation/implementation across Europe (harmonisation?)

- Risk for the debate to be monopolised by opponents
  - Responsibility of research community to step in the debate

- Important not to miss any consultation stage
  - Prevention better than cure – difficult to change problematic provisions once in the public domain

Main features of Directive 2010/63/EU

- Rules on the use of laboratory animals in Europe
- Rules on the origin, breeding, marking, care and accommodation of animals
- Authorization and supervision of establishments, incl. inspections
- Competence of personnel responsible for supervising or performing procedures, as well taking care of animals
- Authorization of projects, after prior ethical review (project evaluation)
- Promotion of alternative methods (3Rs)
- Transparency: publication of non-technical project summaries and statistical information

New provisions: scope and processes

- Mandatory project (ethical) evaluation
- Retrospective review of projects
- Severity classification & retrospective assessment
- Scope extended to immature forms and cephalopods
- Partially simplified authorization procedures

New provisions: focus on welfare

- Mandatory use and promotion of alternatives - 3Rs explicitly addressed/defined
- Housing, care and breeding of animals
- Advisory internal animal welfare bodies
- Competence and continued education of personnel
- Enhanced role of veterinarian?
- Inspections

New provisions: transparency

- Non technical summary of projects
  - Great opportunity to raise awareness of objectives of studies involving animals and show 3Rs and welfare efforts
- Retrospective reporting
  - Great opportunity to show real effect on animals (prospective evaluation overestimates severity)

Grey areas & challenges (1)

- Definitions/Interpretation:
  - Procedure vs. Project
  - Reuse vs continued use
  - Application of severity categories
- Limitations:
  - Ban of procedures that result in severe pain, suffering or distress, which is likely to be long-lasting & cannot be ameliorated
- Red tape:
  - Increased statistical reporting requirements
  - Possibility to apply simplified procedures, and use of local committees for authorisations and ethical review
- Competent authorities – delegation of powers at local level?
- Resources:
  - Financial - for upgrading facilities (caging)
  - Human - for various committees and responsibilities

Grey areas & challenges (2)

- Definition of “debilitating or life threatening clinical conditions” in relation to non-human primates (Obesity? Reproductive health? Biosimilar products?)

- Requirement to use only F2+ non human primates (second generation born in captivity)
  - Possible shortage problems of “fit for purpose” animals
  - F2 Feasibility study conducted by the European Commission

Other developments to watch out

- Freedom of Information
  - Need to balance with commercial confidentiality
- Data-sharing
- Numerical targets
- Questionable ethical judgements
- Administrative burden - cumulative effect
  - Opportunity to rationalise the processes with benefit to animal welfare
- Bans/phase-outs
  - cf Cosmetic directive

Article 2: Stricter national measures?

Member States may, while observing the general rules laid down in the TFEU, maintain provisions in force on **9 November 2010**, aimed at ensuring more extensive protection of animals falling within the scope of this Directive than those contained in this Directive.

When acting pursuant to paragraph 1, a Member State shall not prohibit or impede the supply or use of animals bred or kept in another Member State in accordance with this Directive, nor shall it prohibit or impede the placing on the market of products developed with the use of such animals in accordance with this Directive.

Guide for Transposition

Update 19 January 2010

Guidance on

Transposition of Directive 2010/63/EU on the protection of animals used for scientific purposes

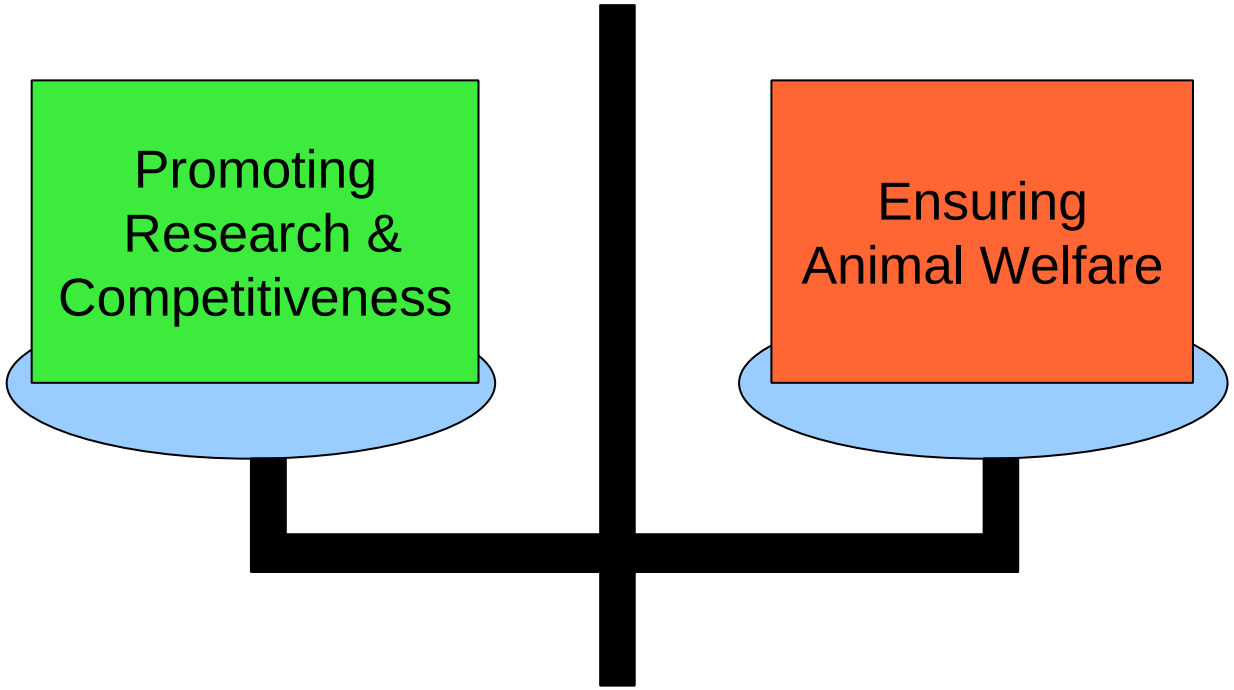
Developed by EFPIA[1], FELASA[2], ESLAV[3], ECLAM[4] and ESF[5]

Article	Recital	Annex	Title /Text	Issue/potential issue	Interpretation of the measure Proposed solutions Impact assessment of various scenarios
1	8, 9		Subject matter and scope	Is breeding a procedure?	Breeding is not a procedure unless it implies conditions of article 3.1.
				Is killing a procedure?	Killing is not a procedure if for the primary purpose of cells and tissues harvesting. Article 1.2 discriminates between animals used in procedures and animals supplying organs and tissues for scientific use. In consequence, killing animals for their tissues is not considered a procedure. This is consistent with article 3.1. Such animals are protected by the directive because there e are set requirements for breeding, housing and care (Articles 10 and 20) and methods of killing (Article 6) and competence of personnel (Art. 23). It is essential that these practices are regulated uniformly in EU countries to promote replacement alternatives to stimulate the use of animal materials rather than live animals (replacement alternative) as intended by article 4 (3Rs) and the application of article 18 (tissue sharing), also by breeding establishments. Any gold plating intending to define these practices as procedures would distort the intention of this directive and cause lack of unity in defining replacement alternatives. Furthermore, it would add to the bureaucratic burden in the absence of a justification, because it is morally contra-intuitive to regulate the use of animal materials after killing whereas killing in the absence of further use of animal materials for scientific purposes would not be regulated as a procedure. Killing would be considered part of the procedure when in the context of a project (see article 6)
				It is unclear how veterinary practice and animal husbandry are applied to typical laboratory species. The activities undertaken for colony health and the characterization of animals to be selected for breeding or procedures could	This would typically include practices for periodic health monitoring and testing for release from quarantine, as well as diagnostic procedures in case of intercurrent health problems. It should also include routine measures to prevent or eliminate micro-organisms that would

Conclusions

- All sectors and types of research are concerned
- Researchers responsibility to get involved
- Political compromise:
  - Grey areas – check initial intention (policy drivers)
  - Translations!!
- Key challenges:
  - Bureaucracy without welfare benefits – new legislation offers possibility to rationalise/simplify
  - Undue limitations
  - Human and financial resources
- Almost all questions have been addressed – transposition users' guidance

Objectives for revision of Transposition of Directive 2010/63/EU



… Striking the balance

Find out more

- Most questions have been addressed during the co-decision campaign – no need to reinvent the wheel – contact us
- Explaining health benefits
  - http://animaltestingperspectives.org/ (blog)
  - www.animalresearchforlife.eu
  - Publication « Making sense of animal research »
  - www.animalresearch.info