European Federation of Pharmaceutical Industries and Associations

Directive 2010/63
status of national transposition debates

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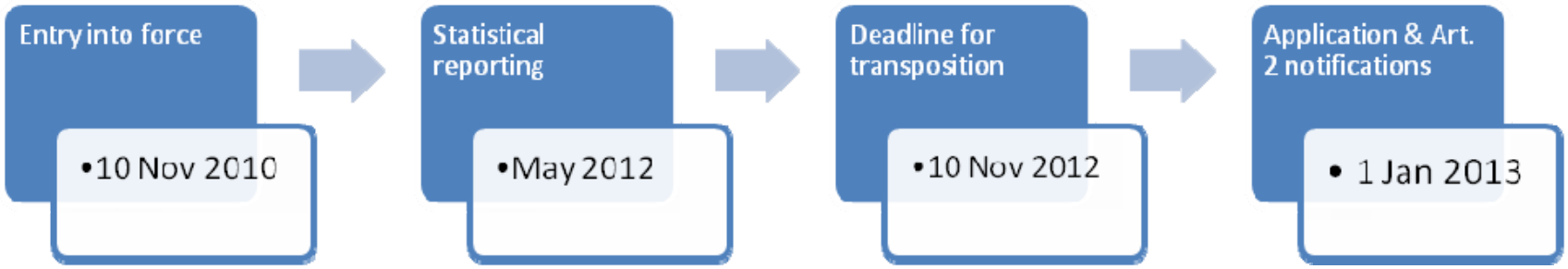
Contents of the presentation

- Timelines, progress, debates
- Key provisions
- Challenges and opportunities
- Resources/information

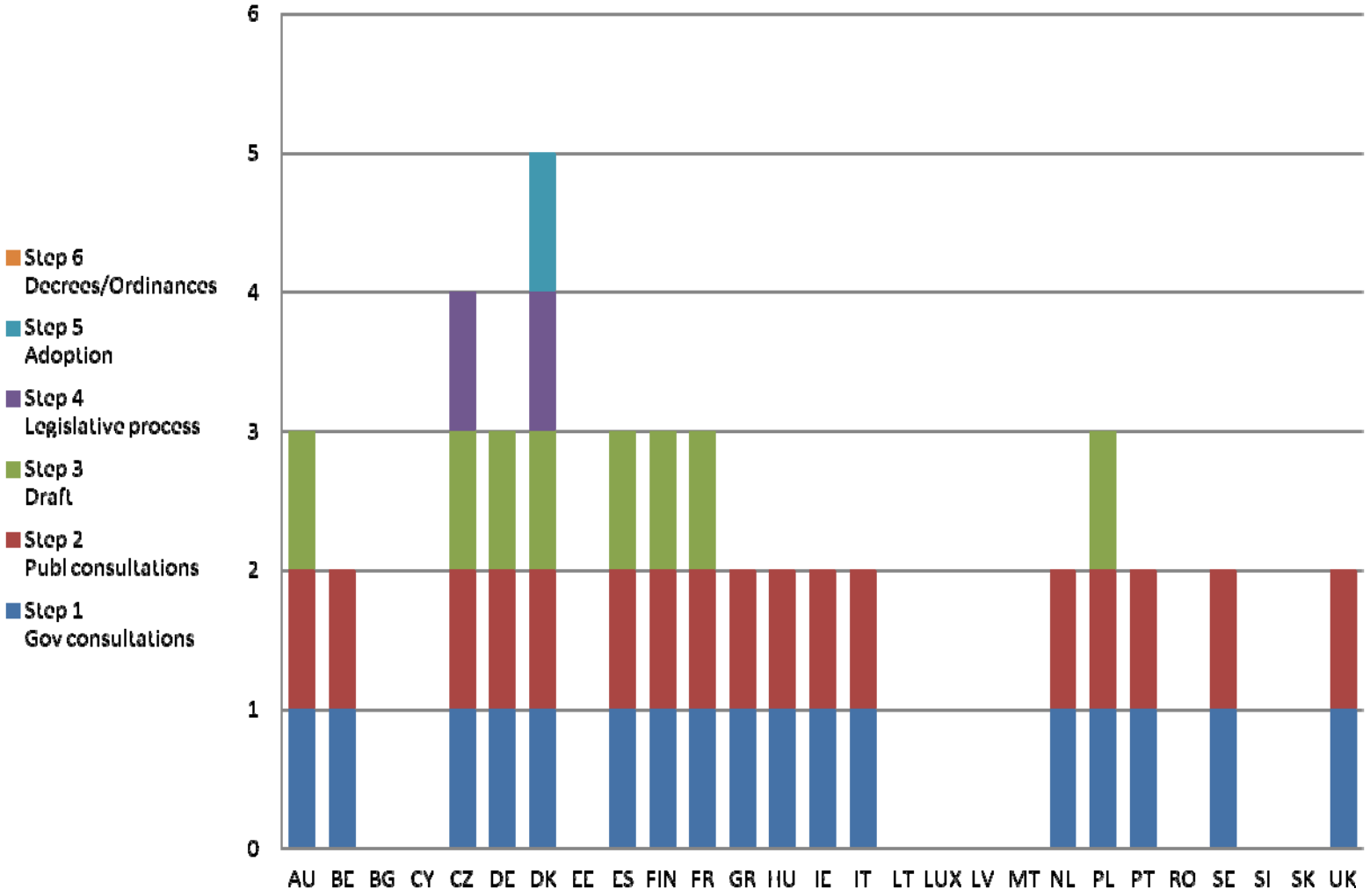
TIMELINES – PROGRESS – DEBATES

Timelines



- Other provisions/timelines
  - Statistics: New format by the 10 May 2012. Submission to the Commission by Nov 2015
  - Primate (Art 10, App II): outcomes of the feasibility study not later than 10 Nov 2017
  - Requirements for the care and accommodation of animals (Art 33, app III): 1 Jan 2017
  - Additional guidance: education & training; non technical summaries, Retrospective severity classification
  - Review of this Directive (Art 58): not later than 10 Nov 2017
  - Thematic reviews

Status of national implementation – April 2012



National transposition – issues debated

- Delegation of powers
- Use of dogs, cats and non human primates
- Severity classification and cumulative severity
- Alternative methods
- Timelines and process for staff authorizations
- Housing standards

Issues awaiting additional EU guidance

- Statistical reporting : new reporting forms to be adopted in May
- Retrospective severity evaluation and reporting : expert discussions started in March 2012
- Education and training/staff competence : expert discussions started in Feb 2012
- Non technical summaries : guidance expected later in 2012

KEY PROVISIONS

New provisions: scope and processes

- Mandatory project (ethical) evaluation and authorisation
- Retrospective review of projects
- Severity classification & retrospective assessment
- Scope extended to immature forms of mammalian species and cephalopods

New provisions: focus on welfare

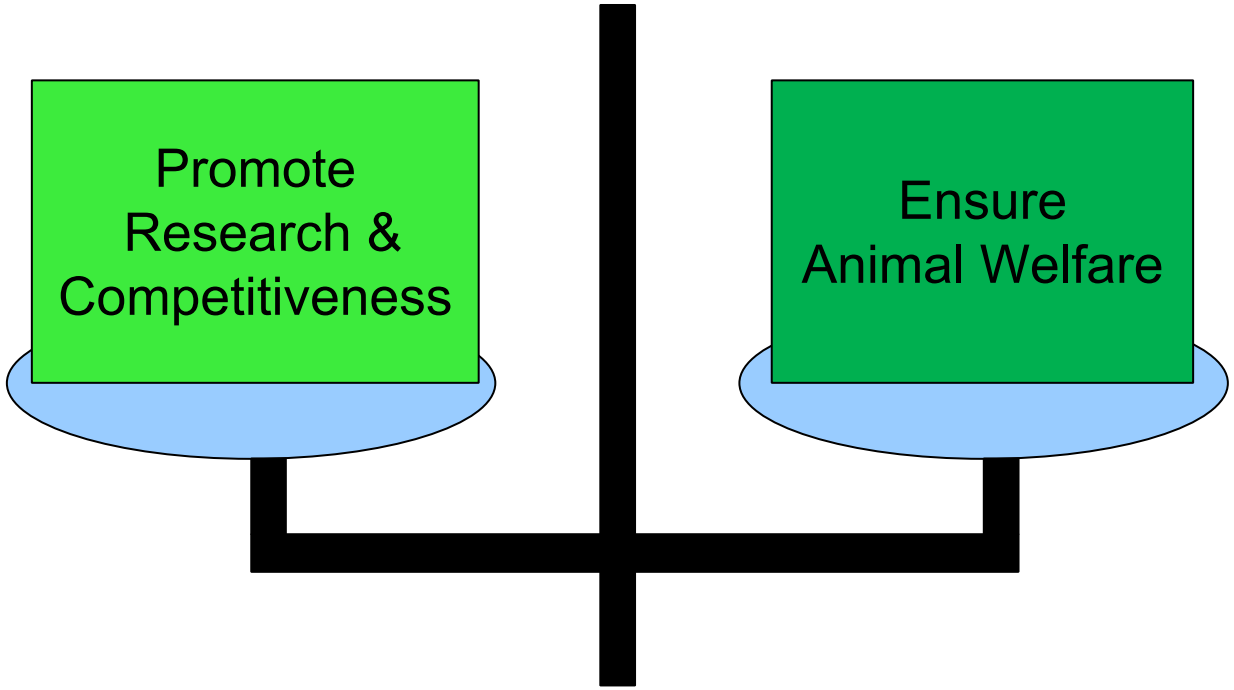
- Mandatory use and promotion of alternatives - 3Rs explicitly addressed/defined
- Housing, care and breeding of animals
- Internal animal welfare bodies
- Competence and continued education of personnel
- Inspections & controls of national inspection systems where there is cause for concern
- Designated vet

New provisions: transparency

- Non technical summary of projects
  - Great opportunity to explain objectives of studies involving animals and demonstrate 3Rs and welfare efforts
- Retrospective statistical reporting
  - Great opportunity to show real effect on animals
- 5-year MS report on implementation and application

GREY AREAS AND CHALLENGES

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



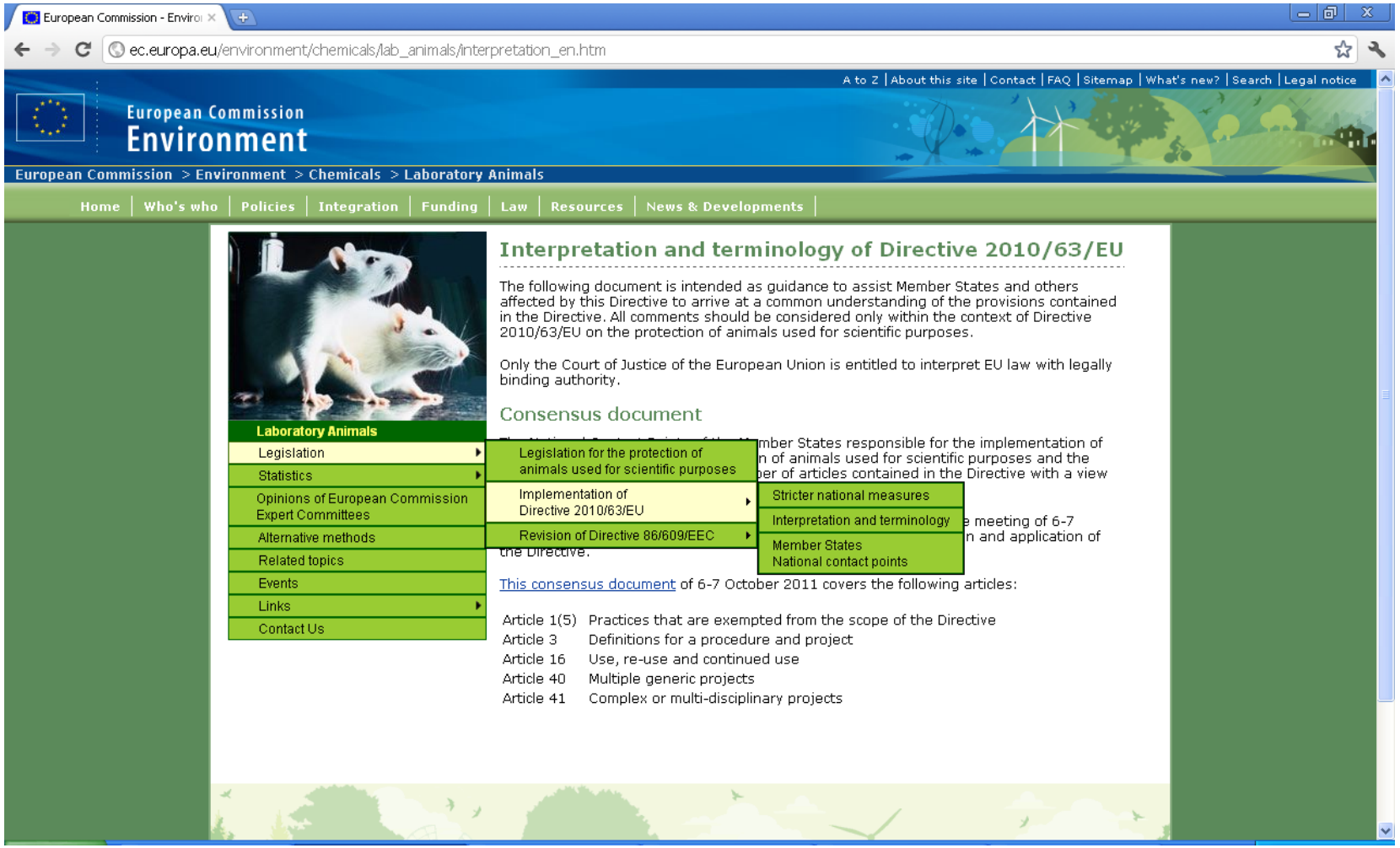
… Striking the balance

Grey areas

- Challenges:
  - Definitions/Interpretation: Procedure vs. Project; Reuse vs. continued use; severity procedures
  - Resources: Financial - for upgrading facilities (housing); Human - for various committees and responsibilities
  - Red tape: Increased statistical reporting requirements ; administrative processes ; delegation of powers
  - Stricter national measures in light of Art. 2
- Opportunities:
  - Rationalise and simplify administrative processes with benefit to animal welfare
  - Network of competent authorities – platform for exchange of experience and creating level playing field

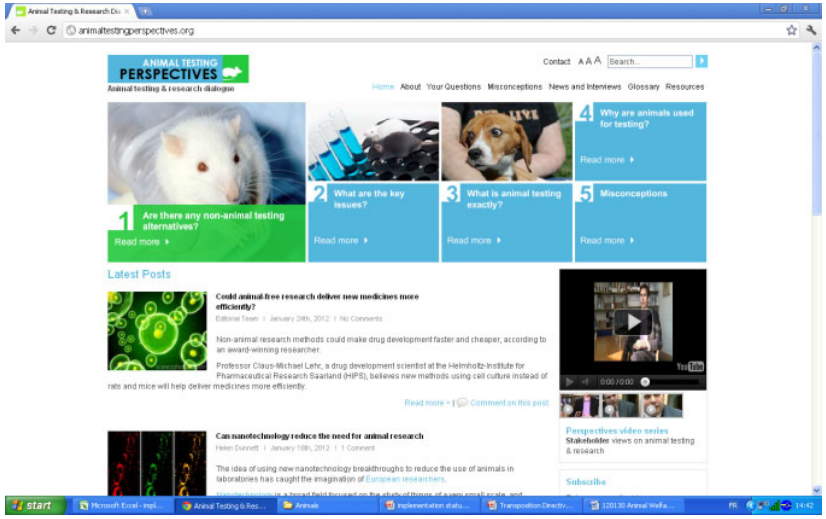
RESOURCES & INFORMATION

DG Environment dedicated site



Find out more

http://animaltestingperspectives.org/



http://www.animalresearchforlife.eu/

http://www.animalresearch.info/

Conclusions

- Keep balance between animal welfare, human and animal health and research needs – as does the compromise text
- Today: no animal research and testing = no new medicines
- Virtuous cycle: good animal welfare = good science = good animal welfare
- Europe has highest standards of protection = we want to maintain research in Europe
- Key challenges:
  - Bureaucracy without welfare benefits – new legislation offers possibility to rationalise/simplify
  - Human and financial resources