



European Federation of Pharmaceutical
Industries and Associations

Directive 2010/63

status of national transposition debates

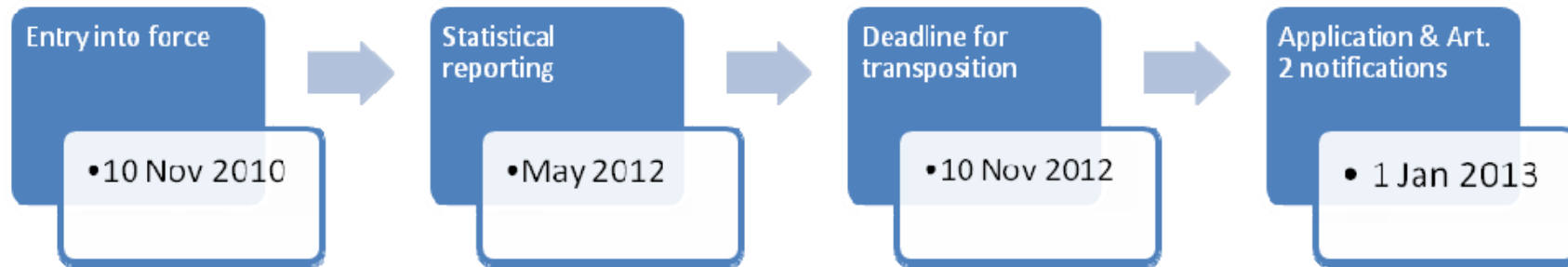
Nicolas Dudoignon, EFPIA Research and Animal Welfare WG
EP Intergroup on Animal Welfare, 24 May 2012

Contents of the presentation

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

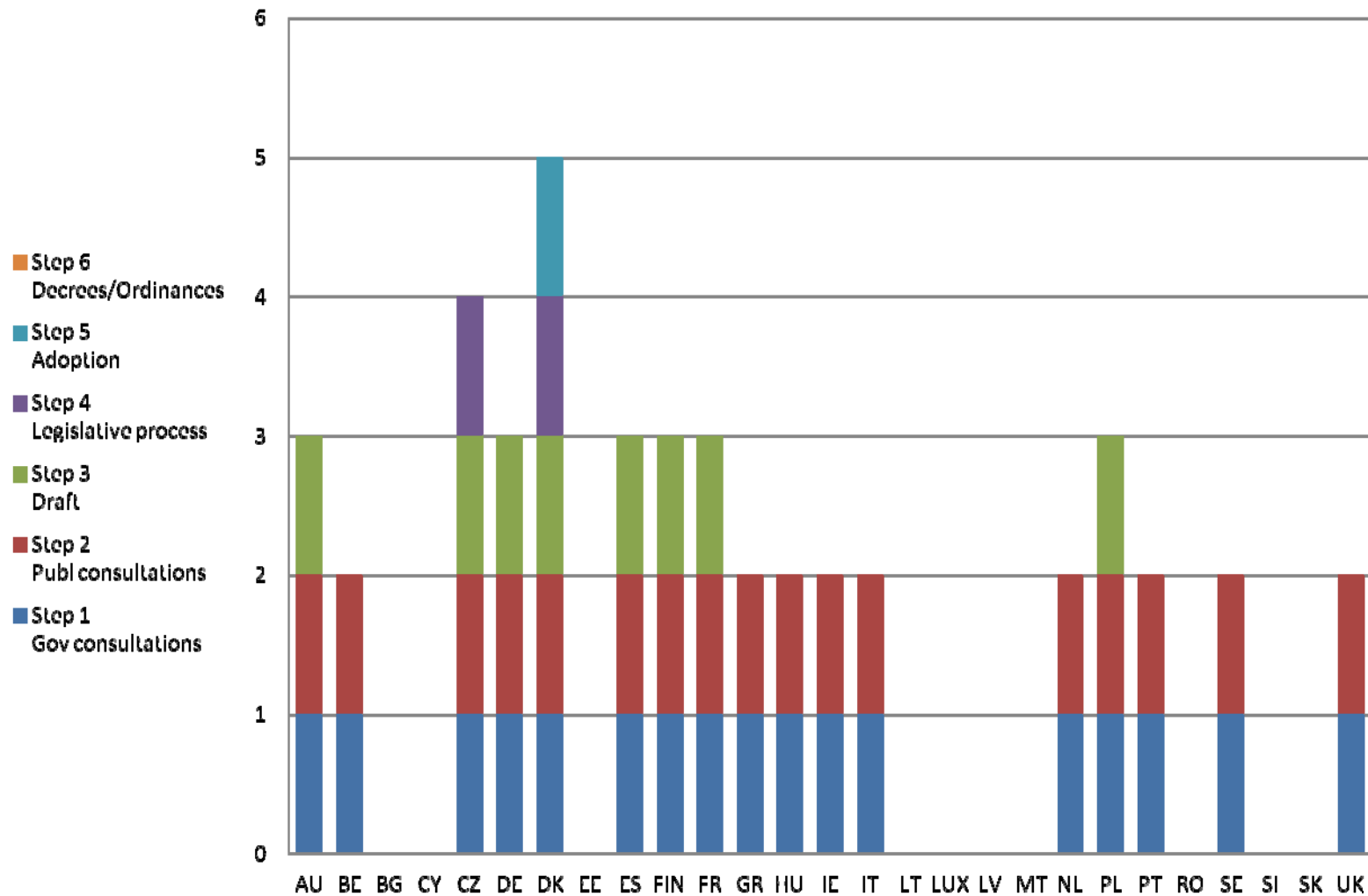
TIMELINES – PROGRESS – DEBATES

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

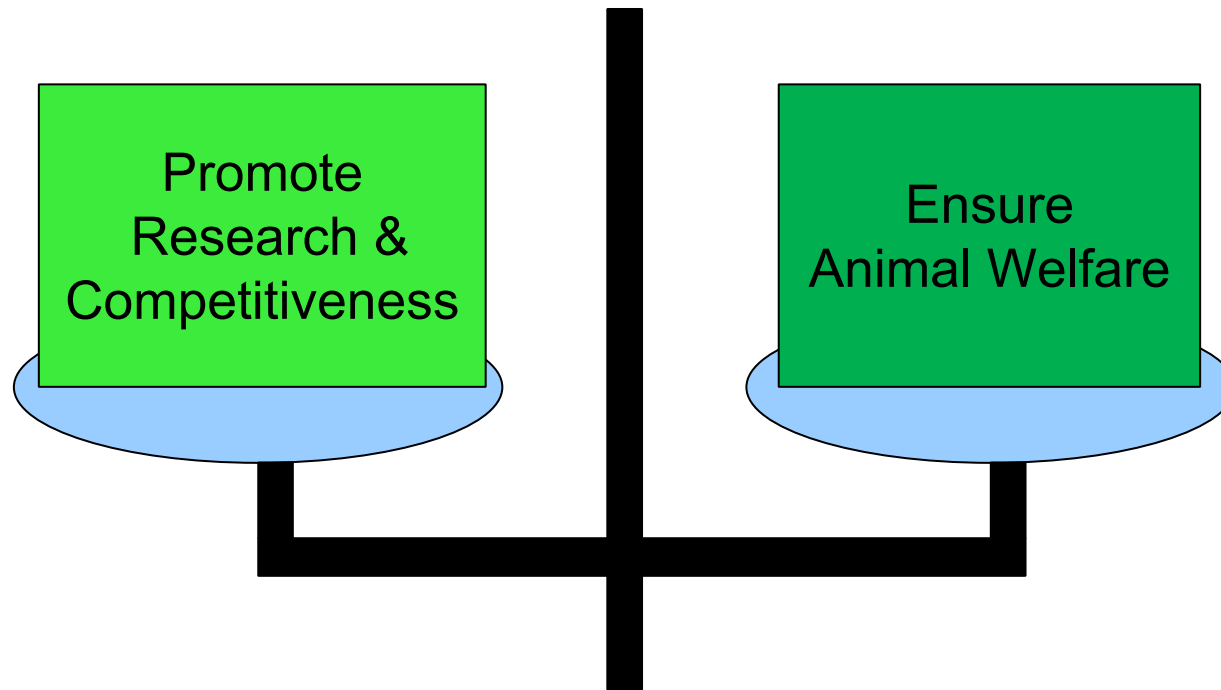
- Mandatory use and promotion of alternatives - 3Rs explicitly addressed/defined
- Housing, care and breeding of animals
- Internal animal welfare bodies
- Competence and continued education of personnel
- Inspections & controls of national inspection systems where there is cause for concern
- Designated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

The screenshot shows a web browser window displaying the European Commission Environment website. The URL is ec.europa.eu/environment/chemicals/lab_animals/interpretation_en.htm. The page features the European Commission logo and the title "European Commission Environment". The navigation menu includes "Home", "Who's who", "Policies", "Integration", "Funding", "Law", "Resources", and "News & Developments".

The main content area is titled "Interpretation and terminology of Directive 2010/63/EU". It includes a photograph of two white mice. The text states: "The following document is intended as guidance to assist Member States and others affected by this Directive to arrive at a common understanding of the provisions contained in the Directive. All comments should be considered only within the context of Directive 2010/63/EU on the protection of animals used for scientific purposes." It also notes: "Only the Court of Justice of the European Union is entitled to interpret EU law with legally binding authority."

A "Consensus document" section is highlighted, listing the following articles covered by the document of 6-7 October 2011:

- Article 1(5) Practices that are exempted from the scope of the Directive
- Article 3 Definitions for a procedure and project
- Article 16 Use, re-use and continued use
- Article 40 Multiple generic projects
- Article 41 Complex or multi-disciplinary projects

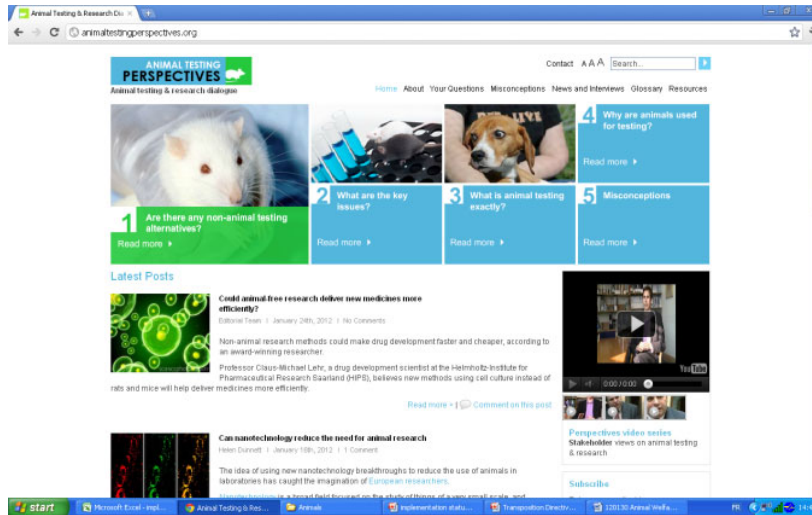
A sidebar menu on the left lists various topics under "Laboratory Animals":

- Legislation
- Statistics
- Opinions of European Commission Expert Committees
- Alternative methods
- Related topics
- Events
- Links
- Contact Us

Additional menu items visible in the sidebar include: "Legislation for the protection of animals used for scientific purposes", "Implementation of Directive 2010/63/EU", "Revision of Directive 86/609/EEC", "Stricter national measures", "Interpretation and terminology", "Member States", and "National contact points".

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