

Directive 2010/63/EU

- **What's next**
- **EU Scientific Conference "Non-Animal Approaches – the way forward"**



European Citizens' Initiative

*"..we urge the European Commission to **abrogate Directive** 2010/63/EU and*

*to present a **new proposal** that does away with animal experimentation and instead makes compulsory the use... of data directly relevant for the human species."*



Commission's response

- *Ban and abrogation of Directive premature*
- *Directive obliges alternatives and provides protection*
- *New tools and structures needed to advance towards the final goal*



Commission's response

- *Scientific principles do not invalidate animal models*
 - **Both animal and non-animal approaches have their advantages as well as limitations**
- *Need intelligent combinations of all tools and in line with the Three Rs*

REPLACEMENT



REDUCTION



REFINEMENT



Three Rs in the Directive

- *Full **Replacement** is the ultimate goal*
- *Three Rs is **a legal obligation in all interaction with animals, also when not in a project***



Action 1 – new ways forward

*..analyse technologies, information sources and networks from **all relevant sectors***

*by end 2016 assess options to enhance **systematic knowledge sharing** through **communication, dissemination, education and training:***

***JRC** will present results from a **public consultation** and a **study** at the Dec 6-7 conference*



Action 2 - alternatives

*support the **development, validation and implementation** of alternative approaches*

*for regulatory and **research** use*

***close cooperation** between the Commission, Member States and international organisations*

*supported, as appropriate, by **EU programmes***

DG Research** will report about **key EU programmes** at **Dec 6-7 conference



Action 3 - compliance

***compliance** with the DIR and sector legislation
correct **enforcement** by all Member States
examination and alignment of relevant sector
legislation*

***DG ENV** will report about DIR **implementation**
and **alignment of sector legislation** at Dec 6-7
conference*

Compliance - Legislative process



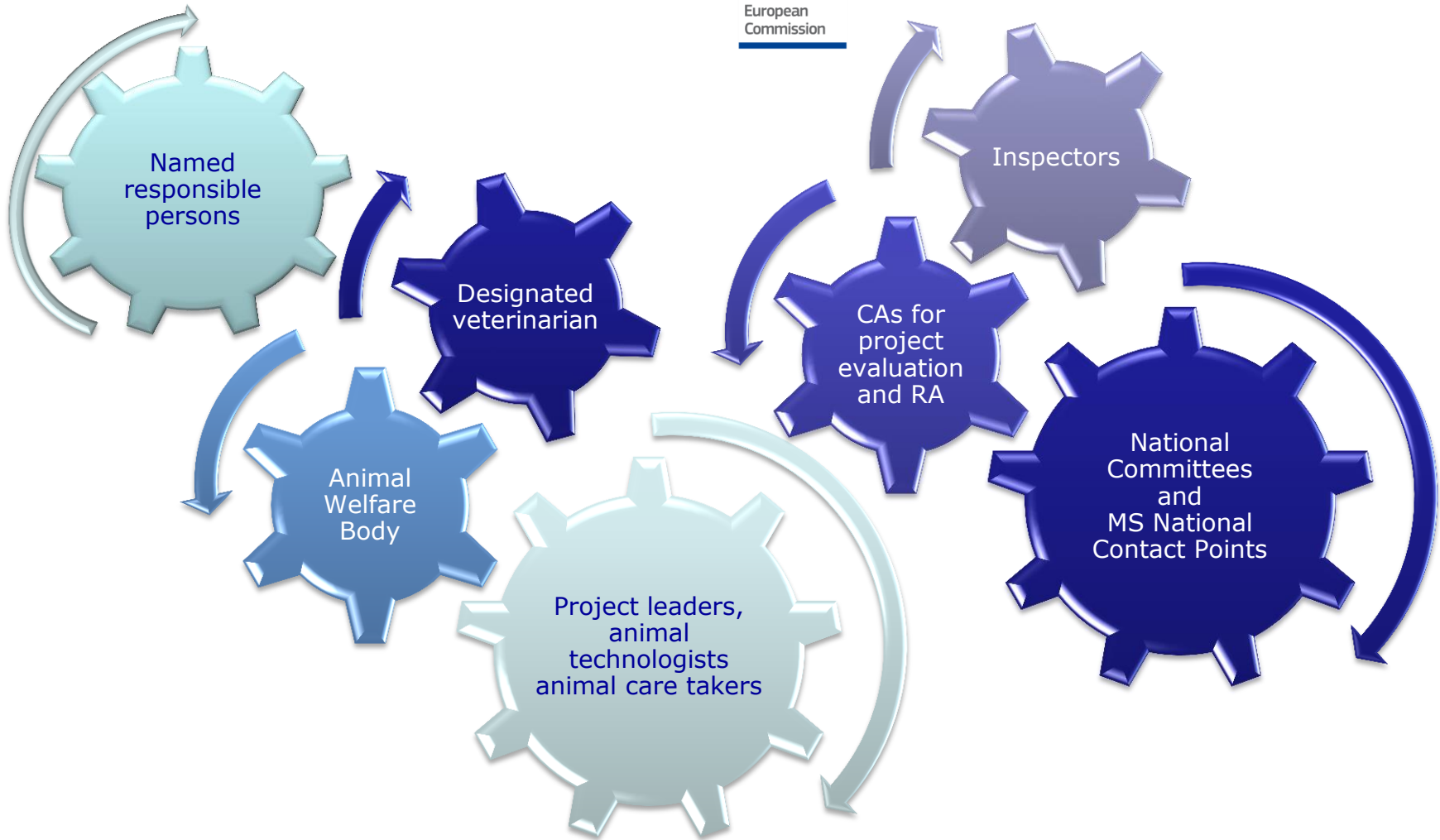
Legal framework



- *Transposition completed*
- *Conformity check ongoing*



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Education, training and competence

Legislation, codes of practice, guidance

Efficient COMMUNICATION



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Caring for animals

aiming for better science

DIRECTIVE 2010/63/EU
ON PROTECTION OF ANIMALS USED
FOR SCIENTIFIC PURPOSES

ANIMAL WELFARE BODIES AND NATIONAL COMMITTEES

Environment

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Caring for animals

aiming for better science

DIRECTIVE 2010/63/EU
ON PROTECTION OF ANIMALS USED
FOR SCIENTIFIC PURPOSES

SEVERITY ASSESSMENT FRAMEWORK

Environment

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Action 4 – scientific debate

*A conference to debate with the **scientific community** and **relevant stakeholders** how to exploit the advances in science for the development of scientifically valid non-animal approaches*

Scientific Conference: Non-Animal Approaches – The Way Forward

December 6-7, 2016, Brussels, Belgium

[Register here](http://www.euconf.eu/non-animal-approaches-the-way-forward/en/registration/index.html)

<http://www.euconf.eu/non-animal-approaches-the-way-forward/en/registration/index.html>



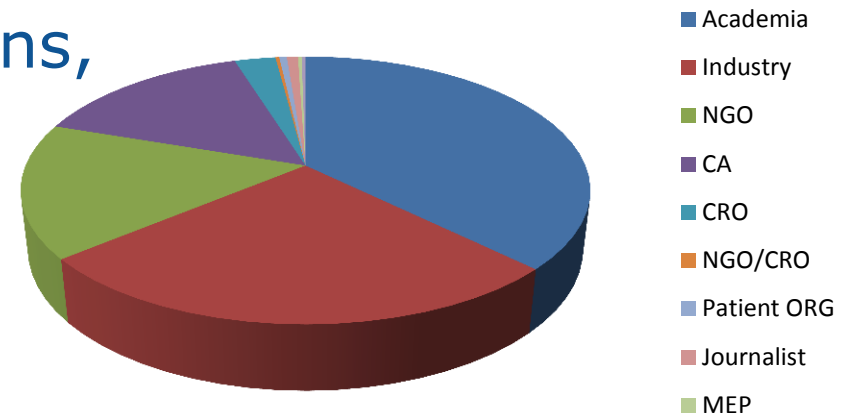


**400 participants,
80% scientists**

**Registration mandatory
Programme published:**

- moderated panel discussions,
involving audience
- follow via web-stream
- comment via Twitter
([#NonAnimalScience](#))
- **poster session only on
alternatives**

Count of Type of ORG





Conclusions

- *Directive is the most advanced legislation in the world*
- *Citizens' Initiative challenges Commission to find new ways to speed up the paradigm shift*
- *We need to work together at **all fronts**, and both **in interim** and **long term***

Thank you for your attention!

More information at:

**[http://ec.europa.eu/
animals-in-science](http://ec.europa.eu/animals-in-science)**





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Backup slides



Review of Directive

Article 58 – (extract)

*"The Commission shall review this Directive by 10 November 2017, taking into account advancements in the development of alternative methods not entailing the use of animals, in particular of non-human primates, and shall propose any amendments, **where appropriate**"*



Article 58 Review process

*Commission adoption **10 November 2017***

- ***Targeted stakeholder consultation Q2 2016***
- *Receipt of information by Q3 2016*
- *Analysis and additional requests by end Q1 2017*
- *Report to be completed by end Q2 2017*



Timing of Article 58 Review

- *Precedes MS implementation reports (due 2018)*
- *Precedes EU Implementation report (due 2019)*
- *Commission conformity checks on-going*
- *Housing and care standards from Jan 2017*
- *EU statistics by Nov 2019*
- *MSs and user community will have limited experience of pros and cons of the Directive*



Article 10

Feasibility study on NHP F2

- *Commission required to carry out a feasibility study on moving to second generation purposes bred non-human primates*
- *Deadline Nov 2017*
- *In consultation with MSs and stakeholders*
- *Propose amendments to Annex II where appropriate*