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

- National legislation
- Operational structures
- Implementation - tools and guidance
- Application, enforcement, reporting
- Experience and review
Legal framework

- Transposition completed
- Conformity check ongoing
Project leaders, animal technologists, animal care takers, Designated veterinarian, CAs for project evaluation and RA, Inspectors, National Committees and MS National Contact Points, Animal Welfare Body, Named responsible persons, Legislation, codes of practice, guidance, Efficient COMMUNICATION.
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
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
- Academia
- Industry
- NGO
- CA
- CRO
- NGO/CRO
- Patient ORG
- Journalist
- MEP
Focussing on scientific dialogue to advance alternatives:

<table>
<thead>
<tr>
<th>Session</th>
<th>Topic</th>
</tr>
</thead>
<tbody>
<tr>
<td>Session 1</td>
<td>Animal Testing Today</td>
</tr>
<tr>
<td>Session 2</td>
<td>Biomedical research: strengths &amp; limitations of non-animal Alternatives</td>
</tr>
<tr>
<td>Session 3</td>
<td>Regulatory testing: strengths &amp; limitations of non-animal Alternatives</td>
</tr>
<tr>
<td>Session 4</td>
<td>Reporting on Commission actions 1 – 3</td>
</tr>
<tr>
<td>Session 5</td>
<td>Responsible Research</td>
</tr>
<tr>
<td>Session 6</td>
<td>The Future: the way forward</td>
</tr>
</tbody>
</table>
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
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