



# Directive 2010/63/EU

**EU legal framework – exploring all the  
tools for better science**



# Directive 2010/63/EU

- *A walk down memory lane*
- *Transparency for the service of science*
- *More tools for better science - drawing from the legislation*
- *Frame for the future*



# Once upon a time

- *Little communication and collaboration*
- *Prejudice and assumptions on one another's positions*
- *Lack of understanding of one another's needs*
- *Emotionally toned discussions at the level of moral principles*



## At the same time

- *Increased interest in ethical issues*
- *Increased knowledge on animal biology, sentience and behaviour*
- *Increased awareness of the areas in which animals are used*
- *Demand for more transparency*

# The road to a change of mindset



- *An **opportunity to participate** for those impacted*
- *Tackling even difficult topics with a **focus on practical problems**, seeking balanced solutions*
- *Agreement to **principles and approaches***
  - *Successful collaboration with tangible results increased understanding, mutual respect and future co-operation*

# Setting the new legal framework



- *2009, the Treaty on the Functioning of the EU:*  
*Article 13 obliges **full regard to be paid for animal welfare** when drafting **other community policies***
- *2010, adoption of **Directive 2010/63/EU***

# Setting the new legal framework



- *Animal welfare had become a **value of the Union***
- *Animals are **sentient creatures** with **intrinsic value***
- ***Ethical concerns** on the use of animals taken into account*
- *The **ultimate goal** is to **replace** the use of animals*
- *The **principles of the Three Rs** must govern all breeding, use and care of animals*

# Where are we today?





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# Today's issues of concern

- *Ethical concerns on the use of animals*
- *Extrapolation of data to the target species*
- *Insufficiently predictive research models and testing methods*
- *Noise*
- *Research reproducibility*

***Can a legal framework help improve science?***



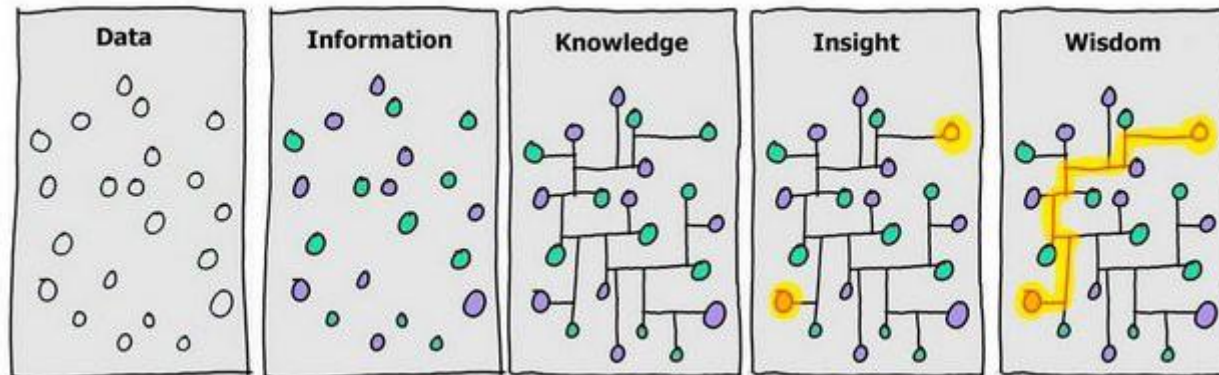
# Directive 2010/63/EU

- *World leader in transparency*
- *Gear shifted to an even higher level in 2019*
- *Speed of publication, accuracy and access to **Member State statistical data***
- *Speed of publication, quality and access to **Non-technical Project Summaries (NTS)***

# From data to information, information to knowledge...



- *Open access, searchable database for Member State statistical data on animal use*
- *Open access, searchable database for all NTS*





# Data: key changes in the statistical reporting

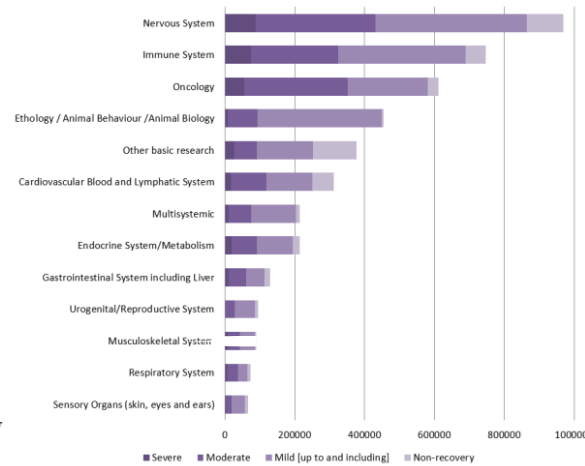
- ***The scope:*** extended to cover *cephalopods and GA creation and maintenance*
- ***Each use is counted and detailed:*** "animals" and "**uses**"; "first use" and any subsequent "re-use"
- ***The actual severity*** experienced by an animal

# Improved level of detail



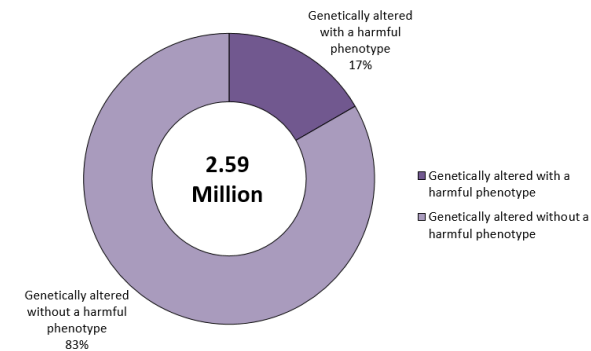
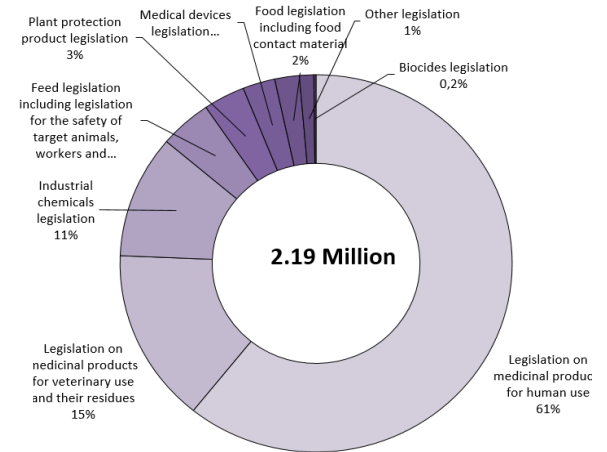
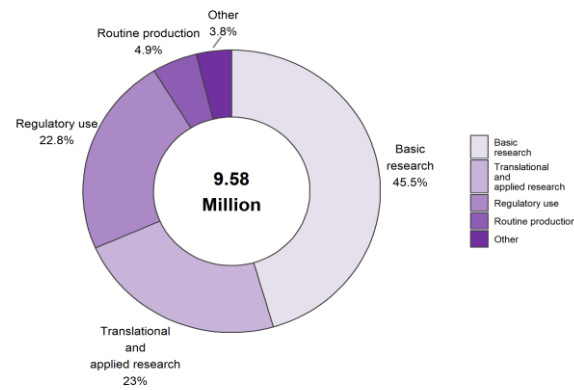
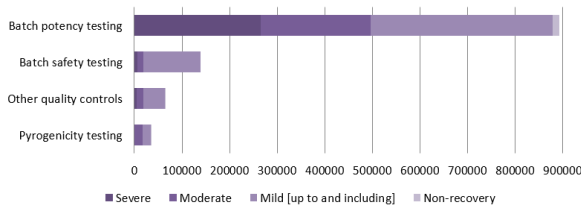
	2015	2016	2017
<b>Mice</b>	5,711,612	5,989,413	5,707,471
<b>Rats</b>	1,201,189	1,173,135	1,146,299
<b>Guinea-Pigs</b>	149,328	150,985	144,824
<b>Other rodents</b>	52,512	38,490	43,298
<b>Rabbits</b>	346,052	350,405	351,961
<b>Cats</b>	1,975	1,951	1,879
<b>Dogs</b>	14,501	15,691	13,688
<b>Other carnivores</b>	5,860	2,974	4,402
<b>Farm animals</b>	126,214	128,890	124,954
<b>Non-human primates</b>	7,136	7,239	8,235
<b>Other mammals</b>	9,535	3,637	26,335
<b>Total</b>	<b>7,625,914</b>	<b>7,862,810</b>	<b>7,573,346</b>

Table 1.3: Numbers of animals used for the first time in the Mammal category



	2015	2016	2017
<b>Self-sustaining colony</b>	39% (2,748)	31% (2,271)	30% (2,504)
<b>F2 or greater</b>	37% (2,614)	47% (3,435)	53% (4,368)
<b>F1</b>	25% (1,773)	21% (1,528)	17% (1,363)
<b>F0</b>	0% (1)	0% (5)	0% (0)
<b>Total</b>	<b>100% (7,136)</b>	<b>100% (7,239)</b>	<b>100% (8,235)</b>

Table 1.7: Generation of non-human primates in 2017





# Further improvements from 2021 data onwards

- *Gather information on NHP generation of animals obtained from self-sustaining colonies*
  - *Separation of higher education from the training of vocational skills*
  - *New categories to reduce the use of "other"*
    - Several new species (e.g., Sea bass, Salmon, Turkey)
    - New purpose categories (e.g., developmental biology, animal nutrition)
    - Further precision and clarity in instructions
- > Needs to be supported by on-going monitoring to improve accuracy



# Using data to inform science

*From statistical data into information to:*

- *set a base line*
- *identify use areas with highest volumes and severities, and the related trends*
- *assess differences between MS, uses, trends*

*Key tool for the prioritisation of activities and research*



# Indicative trends before and after the Directive adoption



Numbers of <u>animals</u> used in research, testing, routine production and E&T	2008*) (EU27)	2011*) (EU27)	2015 (EU28)	2016 (EU28)	2017 (EU28)
		12 001 022	11 481 521	9 590 379	9 817 946
Change from 2008		-4,3%	-20,1%	-18,2%	-21,8%

\*) **Data under the previous legislation, Directive 86/609/EEC** (differences in the scope and completion rules)

An estimate based on new data on animals (=first use) used in research, testing, routine production and in education and training to have near comparative data with previous reporting



European  
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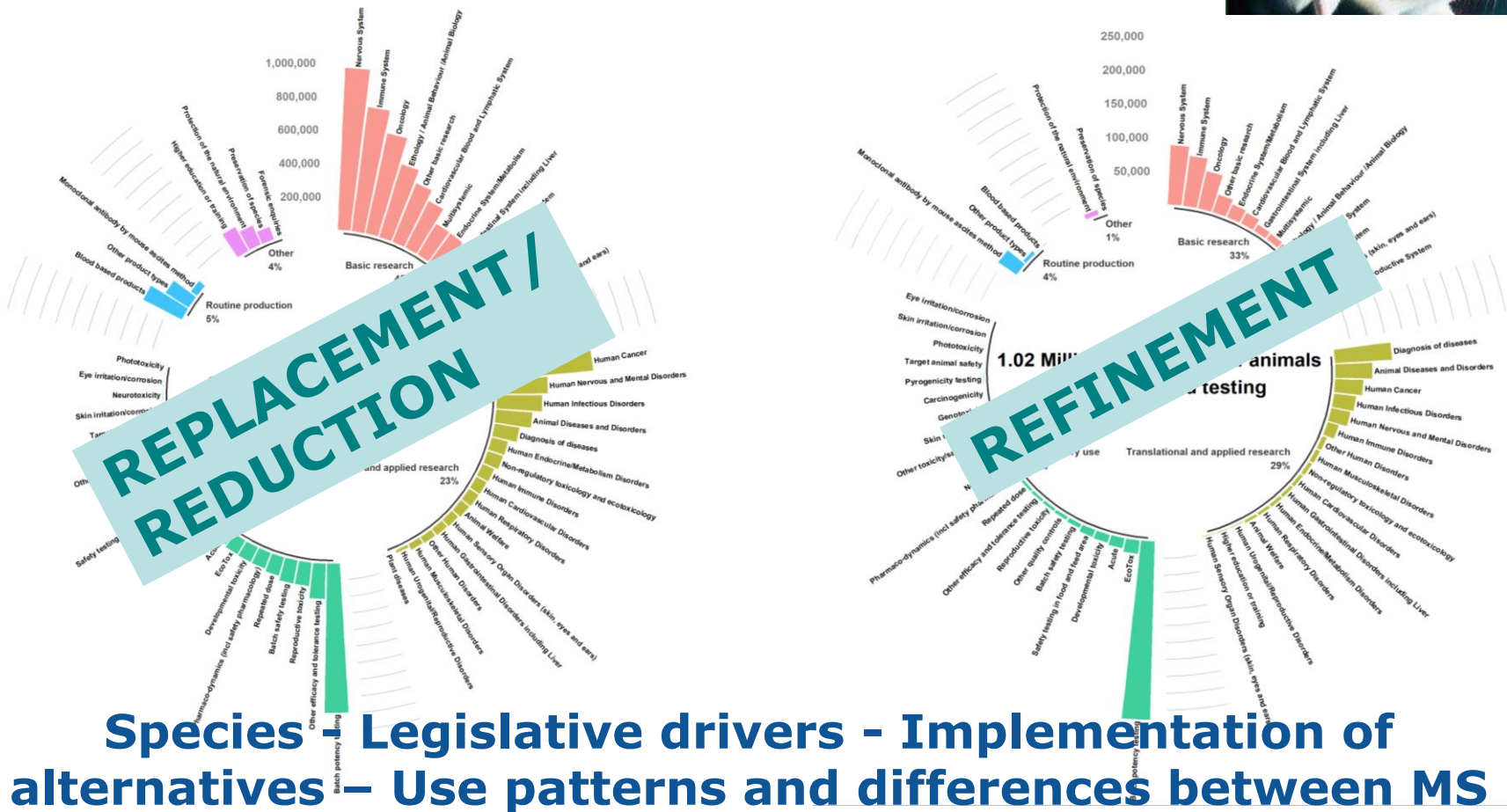
	EU27 2008	EU27 2011	EU28 2015	EU28 2016	EU28 2017		2008 versus 2017
Mice	7.122.188	6.999.312	5.711.612	5.989.413	5.707.471		-19,9%
Rats	2.121.727	1.602.969	1.201.189	1.173.135	1.146.299		-46,0%
Guinea-Pigs	220.985	171.584	149.328	150.985	144.824		-34,5%
Hamsters	32.739	25.251	20.225	19.133	12.887		-60,6%
Other rodents	39.506	28.465	32.287	19.357	30.411		-23,0%
Rabbits	333.213	358.213	346.052	350.405	351.961		5,6%
Cats	4.088	3.713	1.975	1.951	1.879		-54,0%
Dogs	21.315	17.896	14.501	15.691	13.688		-35,8%
Ferrets	3.208	2.540	2.212	1.530	2.016		-37,2%
Other carnivores	2.853	4.982	3.648	1.444	2.386		-16,4%
Horses, donkeys and cross-breeds	5.976	6.686	3.217	3.474	2.414		-59,6%

Pigs	92.813	77.280	73.895	80.029	71.522		-22,9%
Goats	3.840	2.907	2.233	1.365	1.563		-59,3%
Sheep	30.190	28.892	20.106	21.240	18.812		-37,7%
Cattle	33.952	30.914	26.763	22.782	30.643		-9,7%
Prosimians	1.261	83	169	44	98		-92,2%
Other species of New World Monkeys (Ceboidea)	904	700	442	293	476		-47,3%
Other species of Old World Monkeys (Cercopithecoidea)	7.404	5.312	6.525	6.902	7.661		3,5%
Other mammals	5.704	7.888	9.535	3.637	26.335		361,7%
Birds	764.111	675.065	635.211	595.724	563.963		-26,2%
Reptiles	4.101	3.824	2.414	3.240	2.937		-28,4%
Amphibians	61.789	29.583	35.911	42.551	27.707		-55,2%
Fish	1.087.155	1.397.462	1.275.067	1.304.737	1.219.695		12,2%

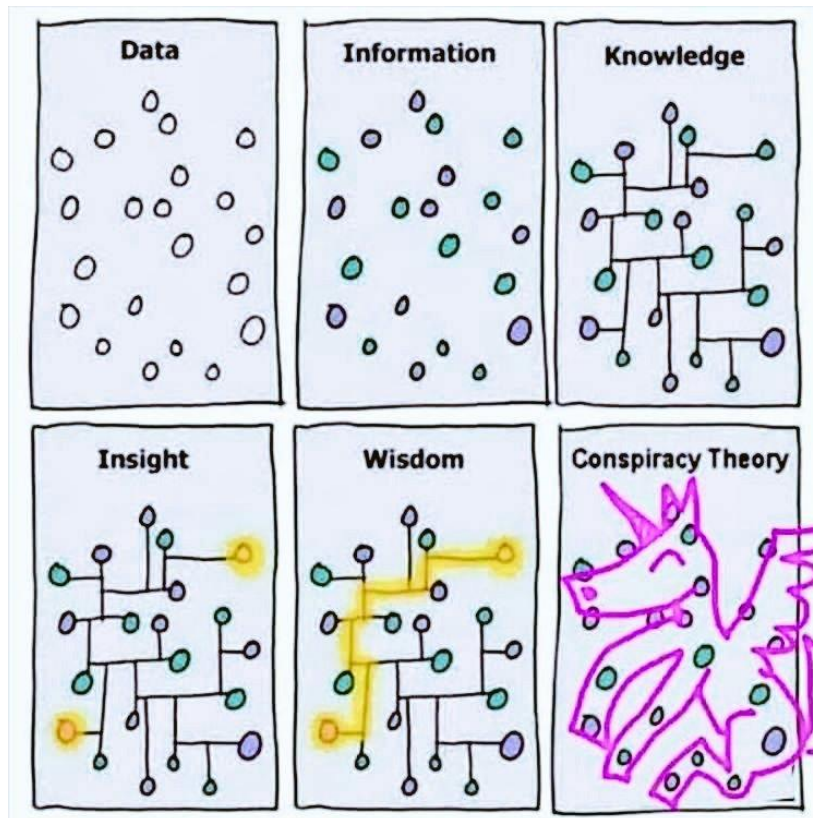
N.B. table excludes cephalopods



# Information as a key tool



# How to turn information into knowledge and insight



*...and avoid mis-  
presentation?*



# NTS/RA data mining: from information to knowledge

- *Better understanding of different animal use areas*
- *Gain insight into the areas of highest animal use and severities*
- *Assess Three Rs efforts already in use*
- *Identify new Three Rs opportunities through the results of retrospective assessments (RA)*



# From knowledge to insight and wisdom

## *Thematic reviews in Article 58*

“...The Commission shall, where appropriate, and in consultation with the Member States and stakeholders, conduct periodic thematic reviews of the **replacement, reduction and refinement** of the use of animals in procedures, paying specific attention to non-human primates, technological developments, and new scientific and animal-welfare knowledge.”

- *Timely tool for in-depth analysis of areas of concern*
- *Preliminary discussions started both internally and with MS and stakeholders*
- *Roadmaps and recommendations to improve*

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# Tools and activities to improve on-going work

## *Identifying key events and equipping key players*

- **Project application:** *experimental design, statistical design, procedures, impact from pain, suffering distress and its management, humane end-points, etc (scientists, AWB)*
- **Project evaluation** (competent authorities)
- **During the project** (scientists, animal technicians, AWB, veterinarians, inspectors )

# Equipping key players



**Commission supporting  
stakeholder efforts:  
Severity Assessment  
Workshops**

[http://ec.europa.eu/  
animals-in-science](http://ec.europa.eu/animals-in-science)  
guidance in all EU languages

# Support networks and tools

3Rs information  
sources, networks,  
dissemination  
platforms

Central platform for  
**LAS E&T**  
**ETPLAS**

Multi-disciplinary  
approach to cross-  
fertilise research  
tools

R&D on modern non-  
animal research  
tools

Regulatory  
application,  
incl. validation and  
acceptance

Tools for measuring  
progress

## Future scientist

**3Rs education** at  
schools, universities,  
and for early career  
scientists

**Tools and strategies**  
for educators on the  
integration of 3Rs in  
curricula

## Today's users

Practical **training**, CPD

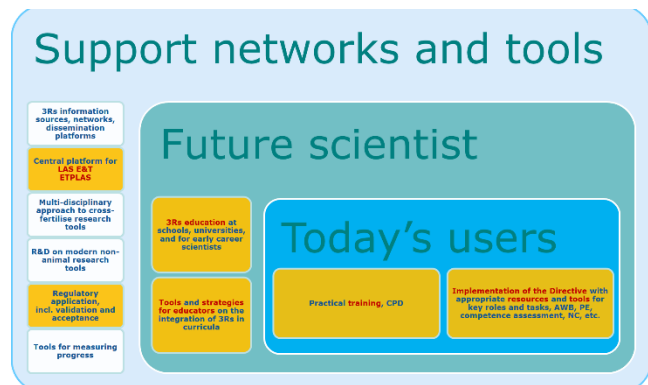
**Implementation of the Directive** with  
appropriate **resources and tools** for  
key roles and tasks, AWB, PE,  
competence assessment, NC, etc.



# EP Pilot on education and training

- *Open access, **interactive e-Learning** modules*
- *Create practical **teaching resources** to support **Three Rs education** at high schools, universities and for early career scientists*
- *Central repository at E&T Platform for Laboratory Animal Science, **ETPLAS***

# Interactive E-learning modules



*To promote consistent approach to Directive implementation*

- **focus on all Three Rs** and key processes for the **implementation** of the Directive
- **focus on non-animal alternatives**



# Implementing the Three Rs - improving scientific rigour

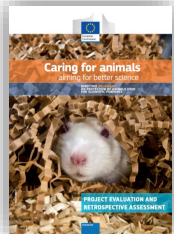


- "Design of procedures and projects" (levels 1 & 2)
- "Severity Assessment Framework"
- "Project evaluation"
- "Searching for non-animal alternatives"
- "Developing alternatives for regulatory application"





2021				2022				2023			
Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4



Publication of 2019 statistical data

Publication of 2020 statistical data

Access to 2021 MS statistical data via EU database

**Public access to NTS/RA EU database**  
[publication within 6 months from authorisation => 1.7.2021]

Access to first six EU eModules under the Directive

*“These courses are of extreme importance and should be obligatory before experimenting in animals. All researchers should do this!”*

*“Especially engaging and interesting!”*

[Another set of open access eModules planned]

Thematic reviews



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# Final goal of full replacement



*"...this Directive represents an important step towards achieving the **final goal of full replacement** of procedures on live animals for scientific and educational purposes as soon as it is scientifically possible to do so"*

# Final goal of full replacement

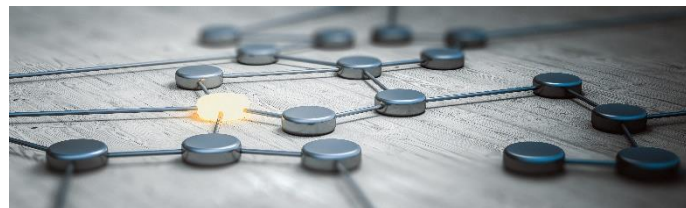


- *EU is in a unique position with a **phasing-out strategy** already firmly embedded in the legislation*
- *Scientifically satisfactory approaches **must replace animal use** as soon as these become available*



# Implementing the phasing-out strategy

- *Use transparency tools to analyse and prioritise efforts*
- *Equip players of today and future with knowledge, skills, tools and resources*
- *Monitor and enforce compliance*
- *Connect, collaborate and share*





# Implementing the phasing-out strategy

- *Strategic use of national and EU research funding programmes to develop scientifically sound and predictive research tools bridging across disciplines*
- *Continued integration of policy objectives in other Union activities*
- *Collaboration between DGs, Member States, regulatory authorities, agencies, stakeholders*
- *Engaging with international partners*



# Conclusions

- *EU has a unique legislative framework*
- *Global leader in transparency*
- *Transparency provides powerful tools to support science*
- *Further supported by new resources to equip all current and future players*
- *Progress is only possible with engagement and commitment by all – policy beyond borders*

# ***Thank you for your attention!***

***More information at:***

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

*The views expressed in this presentation are solely those of the presenter and do not reflect the official view of the European Commission.*

