Directive 2010/63/EU

Progress, challenges and future directions

Centro 3R, Genova
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Progress, challenges and future directions

- *Directive Review results*
- *Addressing recommendations - together*
- *Focus on the Three Rs*

Aims of the Directive

- ***Harmonisation of legislation*** *to obtain level playing field; promote competiveness and innovation*
- *Improve* ***animal welfare*** *standards and the* ***uptake of Three Rs*** *(Replacement, Reduction, Refinement)*
- *Improve* ***transparency***

Article 58 Review

*"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**"*

- *The **progress** towards Directive aims*
- *The continued **relevance** of the Directive*

Timing of the Review: 2016 (early 2017) information

- *Commission assessment of national legislation on-going*
- *Housing and care standards from Jan 2017*
- *First MS implementation reports 2018*
- *EU Implementation report (2019)*
- *First EU statistics (2019)*

➢ *MSs, user and stakeholder communities will have had **limited experience** of the Directive*

Aims of the Directive

1. *Harmonisation and level playing field*
2. *Animal welfare and uptake of the Three Rs - both existing and new alternatives*
3. *Transparency*

- Review Report COM/2017/0631 final: http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1510219889073&uri=COM:2017:631:FIN
- Staff Working Document SWD(2017) 353 final/2: http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=SWD:2017:353:REV1&from=EN

1. Harmonisation and level playing field

New tools and obligations

- *Enlarged, harmonised scope*
- *Systematic project evaluation and authorisation*
- *National committee*
- *Binding welfare standards (e.g., housing & care)*
- *E&T and competence requirements*

1. Results – Harmonisation

Positive:

- *Some progress especially in animal welfare standards*

Further work required:

- *Uniform understanding of terms and concepts*
- *Varied PE/PA processes: improve efficiency and consistency*
- *Role of National Committee in consistency*
- *Obstacles remain for staff to move within EU*

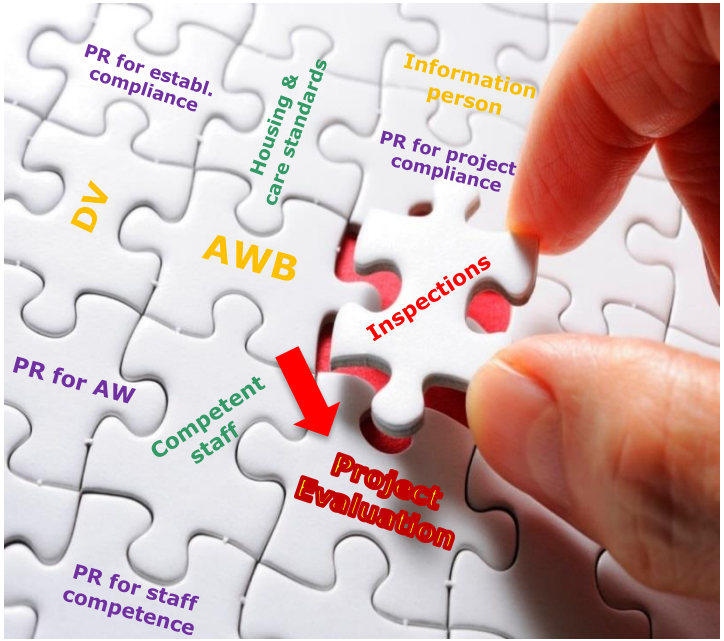
1. Results – Harmonisation: Uniform understanding

- *"Procedure"*
- *"Project"*
- *"Multiple generic project"*
- *"Simplified procedure"*
- *Amendments to authorisations*

➢ *Need more experience and working closely together!*

1. Results – Harmonisation: Duplication of processes

- ***Foundation, conditions***
- ***Internal support***
- ***Internal safety-net***
- ***Internal control***
- ***External control***



- ***If all parts function as designed, there is no need for duplication***
- ***Frees resources to focus on essential***

2. AW and Three Rs' uptake

New tools and obligations

- *Three Rs as a legal obligation*
- *Systematic project evaluation*
- *Animal Welfare Bodies*
- *National Committees*
- *Requirements on competence (beyond E&T)*
- *New structures for the development and validation of new alternative approaches*

2. Results – AW and Three Rs

Positive:

- *Raised AW standards & promotion of Culture of Care*
- *Animal Welfare Bodies already delivering*
- *Increased focus on Three Rs owing to PE and AWB*
- *Recognition of the link between AW and good science*

Further work required:

- ➢ *Consistency in project evaluation*
- ➢ *Access to and full application of the Three RS*

3. Transparency

New tools and obligations

- *Publication of operational processes*
- *Publication of* ***non-technical project summaries***
- *Comprehensively* ***revised statistical reporting*** *on animal use; national report published annually*

3. Results - Transparency

- *Timing of the review premature*

Positive:

- *Increase in transparency commented by user community and MSs – however, critisised by NGO community for AW*

Requiring further work:

- ***Access** to information on the use of animals*
- ***Quality** of information on the use of animals*

Review results – conclusions

- *Timing of the review premature*
- *Regulatory framework considered appropriate*
- *No significant gaps – remains fit for purpose*

- *No amendments proposed on the basis of the Directive Review results*

Staff Working Document

- *Detailed information on each area including breakdown and examples of different views*
- *Broken down by type of stakeholder groups*
- *An opportunity to bring real benefits to both animals and science:*

  ➢ *45 recommendations to move forward*

Progress, challenges and future directions

- *Directive Review results*
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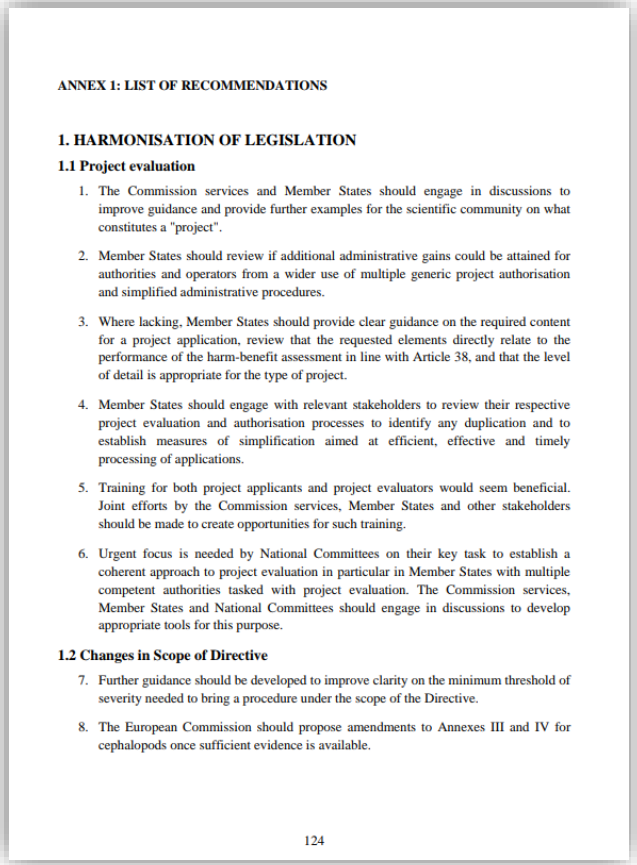
Addressing recommendations

- *Most recommendations require close **collaboration of all stakeholders***
- *Examples on ways to address recommendations*



ANNEX 1: LIST OF RECOMMENDATIONS

1. HARMONISATION OF LEGISLATION

1.1 Project evaluation

1. The Commission services and Member States should engage in discussions to improve guidance and provide further examples for the scientific community on what constitutes a "project".
2. Member States should review if additional administrative gains could be attained for authorities and operators from a wider use of multiple generic project authorisation and simplified administrative procedures.
3. Where lacking, Member States should provide clear guidance on the required content for a project application, review that the requested elements directly relate to the performance of the harm-benefit assessment in line with Article 38, and that the level of detail is appropriate for the type of project.
4. Member States should engage with relevant stakeholders to review their respective project evaluation and authorisation processes to identify any duplication and to establish measures of simplification aimed at efficient, effective and timely processing of applications.
5. Training for both project applicants and project evaluators would seem beneficial. Joint efforts by the Commission services, Member States and other stakeholders should be made to create opportunities for such training.
6. Urgent focus is needed by National Committees on their key task to establish a coherent approach to project evaluation in particular in Member States with multiple competent authorities tasked with project evaluation. The Commission services, Member States and National Committees should engage in discussions to develop appropriate tools for this purpose.

1.2 Changes in Scope of Directive

7. Further guidance should be developed to improve clarity on the minimum threshold of severity needed to bring a procedure under the scope of the Directive.
8. The European Commission should propose amendments to Annexes III and IV for cephalopods once sufficient evidence is available.

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Recommendations: Harmonisation

- *MS meetings twice/yr to tackle recommendations on clarity and administrative processes*
- *EU Guidance **with all stakeholders** to address the 'devil in the room' - understanding, definitions*
  - **agree on a common framework & recommend good practice**
  - **provide practical, illustrative examples to facilitate understanding**

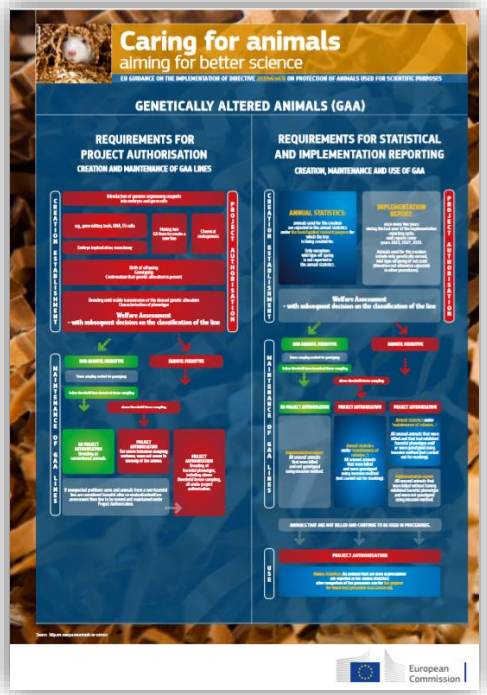
http://ec.europa.eu/animals-in-science

guidance in all EU laguages

How to deal with Genetically Altered Animals

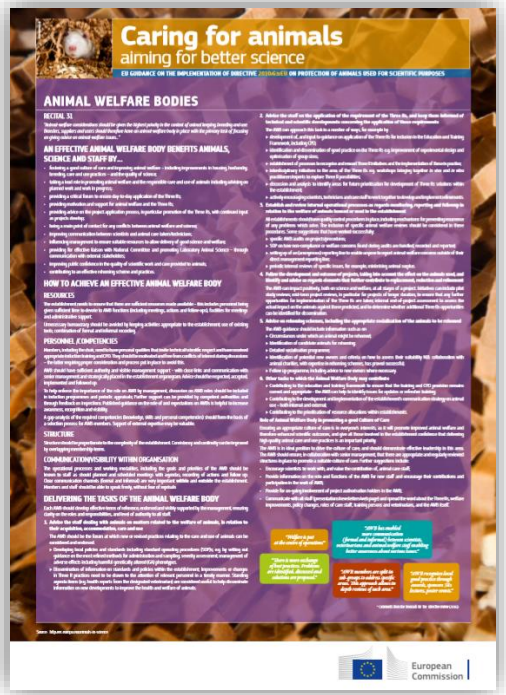
Followed by a consolidated guidance document on GA

Regular Severity Assessment Workshops around Europe



Recommendations: Animal Welfare and the Three Rs

- *Support the users and MS in promoting the work of Animal Welfare Bodies*
- *Next guidance document on Culture of Care?*



COM work on recommendations Animal Welfare & ethics

Recommendation on the use of non-human primates

*"With regard to **transgenic techniques** (e.g., CRISPR) SCHEER recommends that the European Commission form a working group to assess the scientific and **ethical implications of such research** to determine **if** it should be **allowed in the EU** and, if so, **within what constraints**."*

Non-human primates testing (update 2017)
Final Opinion

European Commission

Scientific Committee on Health Environmental and Emerging Risks
SCHEER

Final Opinion on
The need for non-human primates in biomedical research, production and testing of products and devices (update 2017)

Scientific Committees
on Consumer Safety
on Health, Environmental and Emerging Risks

The SCHEER adopted this final Opinion at its plenary meeting on 18 May 2017

COM work on recommendations
Animal welfare & ethics

European Group on Ethics in Science and New Technologies (EGE)

An independent, multi-disciplinary body which advises on all aspects of Commission policies where ethical, societal and fundamental rights issues intersect with the development of science and new technologies.

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What is the EGE?

The EGE provides the Commission with high quality, independent advice on ethical aspects of science and new technologies in relation to EU legislation or policies.

The EGE is an independent advisory body of the President of the European Commission. It was founded in 1991.

The group's legal mandate is enshrined in Commission Decision (2016/835).

The EGE reports to the president, and to the College of Commissioners as a whole. The group is under the direct responsibility of Commissioner for Research, Innovation and Science, Carlos Moedas.

The work of the EGE

The EGE is tasked with integrating ethics at

- international level
- at inter-institutional level with the European Parliament and the Council
- within the Commission itself

EGE members are appointed for their expertise in the fields of law, natural and social sciences, philosophy and ethics.

This ensures an independent, inter-disciplinary perspective on the ethical questions posed by scientific and technological innovation.

The EGE acts as a key reference point for the 28 National Ethics Councils in the EU and further afield within the international ethics framework.

Opinion on gene editing

A current focus for the work EGE is preparing an opinion on gene editing which will be completed by summer 2019.

The request for this opinion was made in a letter from Commissioner for Research, Innovation and Science, Carlos Moedas in July 2018.

COM work on recommendations Transparency

Recommendations

- Training for scientists (EU Education and Training Framework Module 11) should include training on requirements and expectations of non-technical project summaries.
- Member States should ensure that non-technical project summaries are published in a timely manner.
- Competent authorities, through the project evaluation and authorisation processes, should ensure that non-technical project summaries are accurate, fairly represent harms and be realistic about the expected benefits to improve the quality of non-technical project summaries.
- The Commission services, Member States and stakeholders should explore possibilities of a central repository of (or provide easy, searchable access to) all non-technical project summaries at EU level taking into account the legal requirements and linguistic limitations.

COM work on recommendations Transparency

On 22 May 2019 adoption of a new regulation on environmental reporting moving transparency to the next level:

- *Central, open access,* ***searchable EU Database*** *for the publication of* ***non-technical project summaries,*** *Jan 2021*
- *Central, open access,* ***searchable EU Database*** *for release of annual MS* ***statistics***

COM initiatives to address multiple recommendations

*EP Pilot project promoting Three Rs through **education, training** and **dissemination** activities:*

Targeting

- *Today's scientists*
- *Future scientists through educators*

➢ *to improve implementation of the Directive and the uptake of non-animal alternatives*

COM initiatives: EP Pilot to deliver by end 2020

- *6 open access, stand-alone, eModules:*
  - ***Searching for non-animal alternatives***
  - ***Project evaluator (25)***
  - ***Severity Assessment Framework***
  - ***Procedure/Project design, level 1 (10)***
  - ***Procedure/Project design, level 2 (11)***
  - ***Developing alternatives for reg.use (GIVIMP)***
- *Develop ETPLAS as the central E&T hub with **tools for LO** and **competence assessment**; **host eModules***
- ***Guidance** and **practical tools** for **educators** at high school, university and early career scientist level*

Progress, challenges and future directions

- *Directive Review results*
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Directive and the Three Rs

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

Focus on the Three Rs

1. *Implementation of **existing Three Rs** (Directive)*
2. *The development and validation of **new alternative approaches** (Directive)*
3. *The **role of 3Rs Centres** in the **Three Rs tool box** and **knowledge chain***

"Three Rs are not applicable in our work"

"We have been in business for 24 years and always complied"

"We already work to the highest standards"

"We have already Replaced, Reduced and Refined"

1. Implementing existing Three Rs

- ***Project planning*** *(scientists,* ***AWB****, DV)*
- ***Project evaluation*** *(****competent authorities****)*
- ***During*** *the life cycle of a project (all staff involved,* ***AWB****, inspectors)*
- ***Before****,* ***after*** *and* ***in between projects*** *(care staff,* ***AWB****, staff responsible for breeding)*

Animal Welfare Body

- *Promotes awareness of animal welfare*
- *Provides a forum for discussion and ethical reflection for all staff*
- ***Promotes the Three Rs and advises staff***
- *Promotes a "Culture of Care"*

Achieving an effective AWB

Obstacles include

- *Insufficient resources*
- *Insufficient expertise*
- *Insufficient management support*
- *Failing to take advice/enforce advice*
- *Empowerment*

1. Implementing existing Three Rs - AWBs

- ***Clarify of roles and responsibilities*** *especially where integration or overlap with project evaluation process*
- *Ensure that* ***all core tasks are being fulfilled***
- *Senior management should ensure that the AWB has* ***sufficient resources*** *and* ***empowerment***
- *Consider addition of a DV as a full member of the AWB*

Implementing existing Three Rs – Project Evaluation

Justification for the animal models?

How were alternatives searched?

Experimental design? Reduction of bias?

Use of humane end-points, observational strategy?

Origin of animals & training?

Refinement during procedures?

Dissemination of results?

Named person responsible for establishment compliance

Named person responsible for project compliance

Named person responsible for staff competence

Competent staff

- ✓ [illegible] relief, anaesthesia?
- ✓ AW and care [illegible] legal requirements?
- ✓ Properly educated [illegible] competent staff?
- ✓ Compliant housing, appropriate to the species?

1. Implementing existing Three Rs – Project Evaluation

- *Concentrate on **essential** elements, don't duplicate*
- *Improve efficiency and **consistency***
- *Provide **training for project evaluators***
- *Role of **National Committees** in consistency*

2. Focus on new Three Rs approaches

- *Directive obligations to the COM*
  - *Establishment of **EURL ECVAM***
  - ***Promotion** of alternatives at **international level***
- *Directive obligations to the MS*
  - ***Contribute** to the development and validation of alternative approaches*
  - ***Promotion** alternatives at **national level***

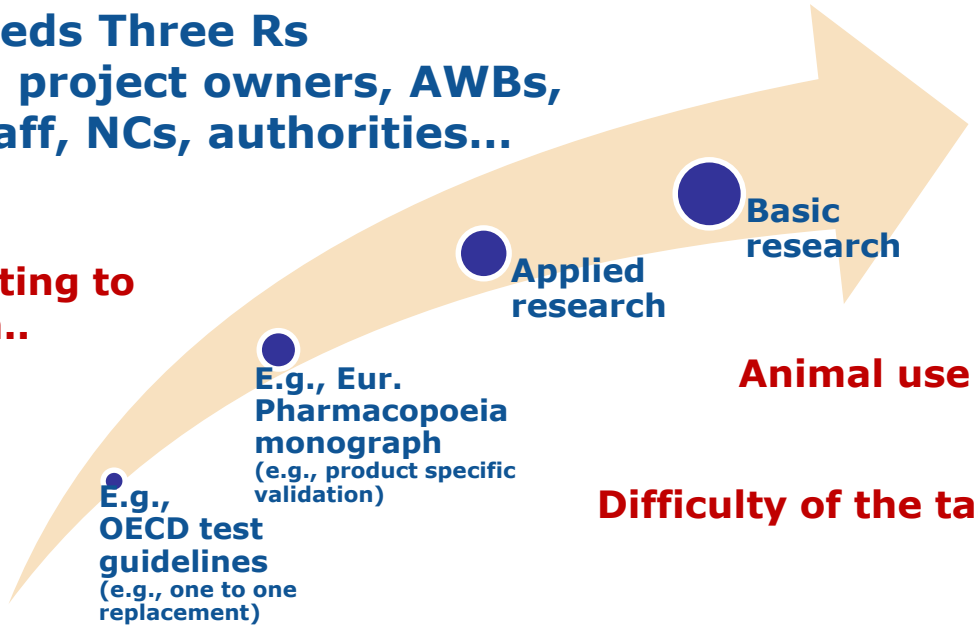
2. New structures for the Three Rs

- *MS shall identify and nominating **suitable specialised** and qualified **laboratories** to carry out validation studies, **EU-NETVAL***
- *MS shall appoint a single point of contact for **assessment of regulatory relevance, PARERE***
- *How can **more resources** be directed to assist these activities - **MS "contribution"** under Article 47?*

Finding the Three Rs

Everyone needs Three Rs information: project owners, AWBs, DVs, care staff, NCs, authorities…

From regulated testing to blue skies research..



Animal use volume

Difficulty of the task

3. The role of Three Rs centres

- *How can Three Rs Centres **become active members** in the Three Rs **knowledge chain**?*
- *Could a **network of Three Rs Centres of Excellence** be of wider benefit?*

3. Future of Three Rs centres' through strategic networking

- *Clear focus with efficient use of limited resources*
- *Join resources and increase areas of expertise*
- *Active drawing of new Three Rs innovation from the networks of NCs/AWBs*
- *Consistency of advice*
- *From national to EU wide dissemination and outreach*

3. Invest in Three Rs centres

- ***Voluntary – there is no legal obligation***
- *However, Article 47 requires MS to*
  - ***Contribute*** *to the development and validation of alternatives*
  - ***Promote*** *and disseminate information on the Three Rs*

➢ *MS support to Three Rs Centres can contribute towards these obligations*

Three Rs into the next level

- *Implementation of existing Three Rs*
  - ***Establishments need to resource and empower AWBs***
  - ***MS to ensure consistency and quality of project evaluation***
- *Development of new alternative approaches*
  - ***Continue efforts in R&D, validation, and E&T***
  - ***MS contribution under Article 47 – consideration for***
    - ***EU NETVAL member laboratories, PARERE***
    - ***Three Rs centres***

Final thoughts

"I can do STILL better!"

"We can aim EVEN higher!"

There are always opportunities for the Three Rs for those motivated and committed - for the benefit of science & animals

Thank you for your attention!

More information at:

http://ec.europa.eu/animals-in-science