Directive 2010/63/EU

Implementing the Directive - current status and next steps

Linz Alternatives Congress
11 October 2019

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Implementing the Directive - current status & next steps

- *Working together for the implementation*
- *2019, the year of even more milestones*
- *2020 and beyond*

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. *Improved* ***transparency***

Milestones until 2019

- *Directive adopted 2010*
- *National legislation in place for Directive to take effect from January 2013*
- *Housing and care standards from January 2017*
- *Directive Review November 2017*

Directive review

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

- 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

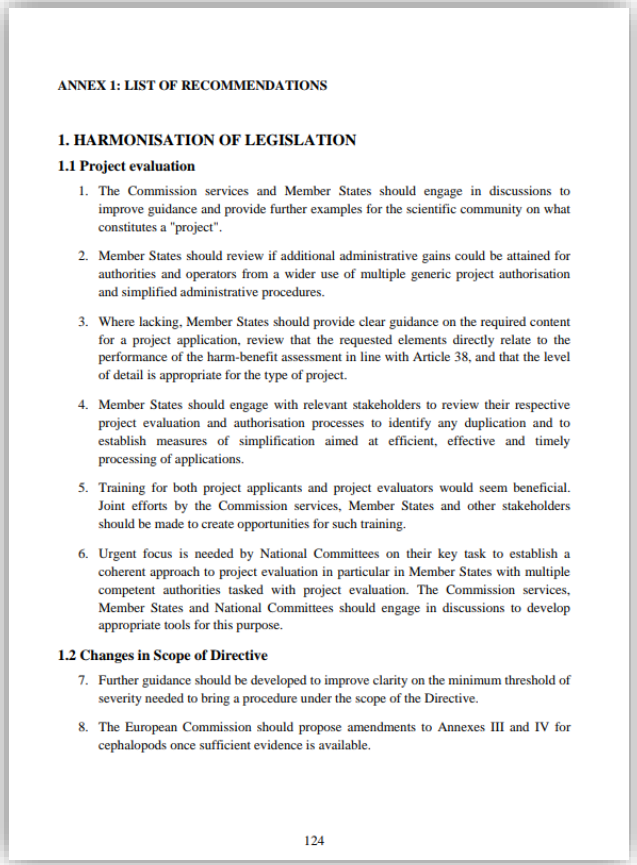
Staff Working Document

- *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*

Addressing recommendations

- *Most recommendations require close **collaboration of all stakeholders***
- *How recommendations are being addressed?*



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.

124

1. Results – Harmonisation

Further work required:

- *Uniform understanding of terms and concepts*
- *Varied PE/PA processes: improve efficiency and consistency*

Recommendations: Harmonisation

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

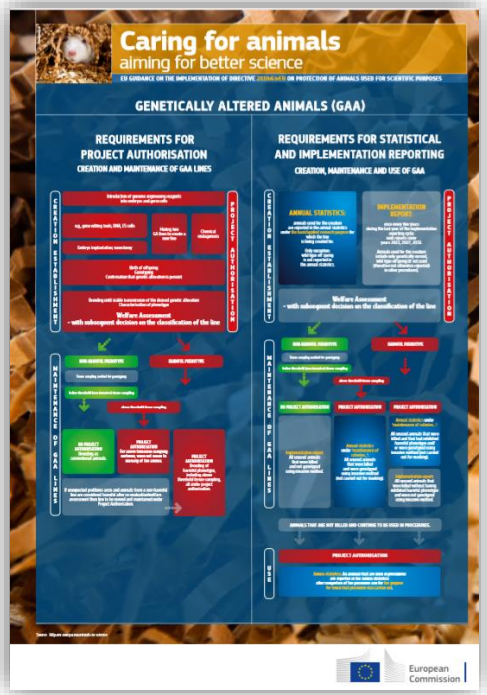
http://ec.europa.eu/animals-in-science

guidance in all EU laguages

How to deal with Genetically Altered Animals

Will be followed by a consolidated guidance document on GA

Regular Severity Assessment Workshops around Europe



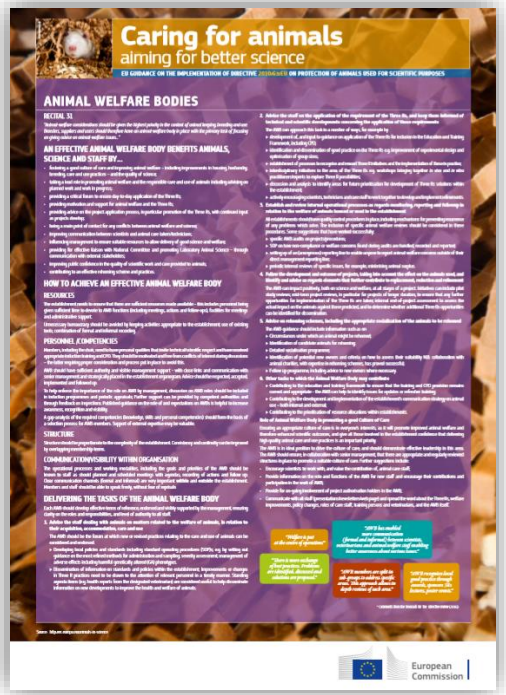
2. Results – AW and Three Rs

Further work required:

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

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?*



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?

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*

Session 12
Implementing Directive
Fri 9:40 at Hall 1

COM acting on Animal Welfare and the Three Rs

*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*

EP Pilot project

i. Develop open access ***eLearning tools***

ii. Facilitate ***mutual recognition*** *of, and* ***access to quality E&T*** *through* ***ETPLAS***

iii. Create practical ***teaching resources*** *on alternative approaches to support* ***Three Rs education***

i. Development of open access eLearning modules

*Focus on **all Three Rs** and **Directive implementation***

- *Design of procedures and projects (levels 1 and 2)*
- *Project evaluation*
- *Severity Assessment Framework*

*Focus on **Replacement***

- *Searching for non-animal alternatives*
- *Developing alternatives for regulatory application*

ii. ETPLAS for consistency and harmonisation of LAS E&T

- *Among others, tools for competence assessment*
- *Hosting of eLearning modules*

iii. Addressing future scientist

- *Targeting **educators***
- *Three Rs for **high school**, **university** and **early career scientist** levels*

Session 3.1
3Rs in education and academia
Fri 11:40 at Hall 1

3. Results – Transparency

Requiring further work:

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

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.

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- *Working together for the implementation*
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COM acting on Transparency

Regulation (EU) 2019/1010 adopted 5 June 2019 amending Directive 2010/63/EU for:

- *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***

Article 43 on non-technical project summaries

- *From 1 January 2021, **publication of NTS** within **six months** of authorisation*
- *Commission to establish a **central**, **open access, searchable database** for NTS*

Session 16.1
Reduction & refinement - I
Fri 15:30 at Hall 1

Article 54(2) on statistics

- *MS to submit annual statistical data to the Commission electronically*
- *Commission to establish a **central**, **open access, searchable database** for statistics*
- *Commission to provide annual EU summary*

COM acting on 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.

PAGE CONTENTS

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.

2019 milestones

- *Work on EP Pilot started*
- *Work EGE opinion started*
- *Directive amended in June 2019*
  - ***Preparatory work for the legal frame for databases***
- *First EU implementation report still expected*
- *First statistical report at EU level still expected*

2020 and beyond

- *New Commission Implementing Decision early 2020*
- *EGE opinion on gene-editing on NHP early 2020*
- *eLearning modules & other deliverables from EP Pilot by the end of 2020*
- *NTS publication via central EU database from July 2021*
- *EU database on statistics on animals use*

Growing evidence base for future policy decisions

- *Directive review from 2017*
- *EU report on MS implementation (2019)*
- *First statistical report at EU level followed by **annual publications** and **open access database***
- *NTS database*

Growing evidence base for future policy decisions

- *Directive written with a view to making itself obsolete*
- *Stepwise approach embedded as science advances*
- *World leading transparency measures will allow*

➢ ***Focusing implementation efforts***

➢ ***Targeting scientific work to replace and refine animal use with highest impact***

Thank you for your attention!

More information at:

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