Directive 2010/63/EU

Report from the Commission in accordance with Article 58 of Directive 2010/63/EU on the protection of animals used for scientific purposes

Alliance for Biomedical Research in Europe
Annual Meeting
8 November, 2017

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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

- Information collection and analysis from Q2 2016 until end 2016
- Preliminary results and request for further information where necessary Q1 2017
- Public consultation on draft findings in March 2017
- Finalisation and Commission adoption by **10 November 2017**

Consultation process

Targeted stakeholder consultations (May – Aug 2016):

- user community (breeders, suppliers & users) (900 responses)

- Member State authorities (28 responses)

- EU-level stakeholder organisations (52 responses)

Open consultation meeting in Brussels in March 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 only from Jan 2017
- EU statistics by Nov 2019
- Transitional measures for existing authorisations until Jan 2018
- MSs and user community have limited experience of pros and cons of the Directive

Timing of Article 58 Review

→ **The review can only provide preliminary indications of progress, problem areas and good practice.**

The focus of the review was

- to evaluate if the measures in the Directive are fit for purpose, based on early user and stakeholder feedback.

… it was not intended to

- measure development or uptake of alternatives
- carry out a comprehensive evaluation of the DIR provisions due to lack of experience and data on implementation

Review Report

- Commission Review report covering main policy conclusions (publication imminent)
- Accompanied by Staff Working Document
  - More details on the findings
  - Recommendations to improve implementation – to be taken up as appropriate

Review conclusions

- Directive relevant and necessary for
  - **a level playing field and**
  - **achieving the animal welfare objectives**

- No amendments proposed at this stage

Directive starting to deliver

- **Animal Welfare Bodies** help improving animal use and care practices
- **Standards raised** in care, accommodation & research practices
- Increased **Three Rs awareness**

...

Directive starting to deliver

- Promotion of **Culture of Care**
- Recognition of good **animal welfare = good science**
- Improved **transparency** (non-technical summaries, statistics) - work in progress due to early timing

More attention needed

- **Efficiency** and **consistency** of project **evaluation** and **authorisation**
- **National Committees** not yet fully established and operational in all MS
- **Access** to and **quality** of **information** on animals use

Project Evaluation/Authorisation

- Some MS had processes in place, new for others
- Different operational structures – national CA vs regional committees vs bodies in user establishments

  → Impartiality – Proportionality – Consistency
- **Role of National Committees in ensuring consistency**
- Claimed delays in authorisation decisions beyond 40 / 55 day deadlines
- Requirements for project application going beyond necessary for harm-benefit assessment
- Simplified procedure not applied well yet

Alternatives and the use of non-human primates

Review informed by

- Additional survey among organisations with focus on **alternatives** (esp. basic/applied research and education/training)
- EURL ECVAM reports
- Updated scientific opinion on **non-human primate use** and alternatives by SCHEER

Development of new alternatives

New resources, however, at an early stage:

- Enlarged remit for EURL ECVAM to cover basic and applied research
- **EU-NETVAL**: MS appointed labs for validation
- **PARERE** network accelerating regulatory uptake
- Increasing voluntary MS activities and funding to promote alternatives

Update to SCHEER opinion

- The areas of research and testing in which non-human primates **continue to be used today**
- The available **possibilities to replace** their use now and in the foreseeable future
- The opportunities for **the reduction and refinement** of their use in areas where no replacement can be foreseen in medium or long term

Conclusions for non-human primates

- No phasing-out timetable for the use of non-human primates proposed

- Regular updates to the SCHEER opinion to monitor progress

Article 10 feasibility study

- Majority of non-human primate species (in EU) already F2/F2+
- For main species (C.macaques) global supply of F2/F2+ animals already supersedes EU demand
- Annex II deadline of Nov 2022 maintained

Minor amendments to be considered

- **Reporting categories** in Commission Implementing Decision **2012/707/EU** to require systematic reporting of the generation of non-human primates used, including when acquired from self-sustaining colonies.

Once sufficient scientific evidence available:

- **Annex III** (care & accommodation) to incorporate standards for cephalopods and to provide more details for some groups of species.
- **Annex IV** to add appropriate killing methods for cephalopods, and to align all methods with latest scientific knowledge.

Conclusions

- Communicate issues
- Collaborate to help find solutions at EU level
- Engage with MS CA for any issues
- Check Staff Working Document recommendations

Thank you for your attention!

More information at:

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

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