Background to the stakeholder consultation gathering information for Article 58 Review of Directive 2010/63/EU

Introduction

The Directive regulates the care and use of animals for scientific purposes, and firmly embeds the principles of the Three Rs, to replace, reduce and refine the use of animals used for such purposes.

This Directive replaced Directive 86/609/EEC in 2010 and introduced a number of new provisions to promote common implementation, improved protection for animals used in scientific procedures and greater transparency in their use.

The basis for the review is in the Directive's Article 58:

> *"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 amendments, where appropriate….."*

The Directive also requires an Implementation Report by 10 November 2019 on the basis of the reports from Member States (MS) due the previous year, in line with Articles 54(1) and 57(1).

In practical terms, the sequencing is therefore: the Commission will publish its initial review under Article 58 based *inter alia* on the responses to the questionnaires by 10 November 2017. In 2018, a more systematic evaluation process will begin, as part of the Commission Better Regulation programme[1], with MS providing reports on their implementation as set out in Article 54 and the Commission Implementing Decision 2012/707/EU. At that time there will be further opportunities for input. The Commission will take all this further information into account and provide an evaluation by 10 November 2019 that incorporates and meets the legal requirement for an implementation report.

The objectives and the scope of the reports on the 2017 review and the 2019 evaluation differ:

- **The review is focused on emerging issues and preliminary findings and reflects the ongoing implementation process**.
- **The objective of an evaluation is to evaluate how the Directive is implemented** looking at elements such as administrative structures (e.g. role of competent authorities), evaluation and authorisation procedures, and compliance with the provisions of the Directive. The evaluation can be seen as meeting and going beyond the requirements for an implementation report. All Commission evaluations must contain an assessment of the relevance, effectiveness, efficiency, coherence and EU added value of the initiative.

[1] http://ec.europa.eu/smart-regulation/better_regulation/key_docs_en.htm

The transposition of the Directive into national legislation was delayed in a number of Member States with the last transposition completed as late as May 2015. In addition, one of the key elements of the Directive, namely binding housing and care standards, relating in particular to enclosure dimensions and space allowances, will only become compulsory in 2017.

It follows from the above that as MS will have limited experience of the Directive, it is very unlikely that the projected benefits of the new Directive, especially in terms of improved welfare and science, will yet have fully materialised. These should become more apparent after the deadline for the 2017 review. From the user community perspective, the same applies; since implementation is still in progress, there will be ongoing changes necessary (with associated costs) to meet the new requirements, without experiencing all the expected benefits. Furthermore, to allow for an objective review, factual data are needed in a number of areas, which in this case will only be forthcoming with the MS implementation reports, which are only due after the deadline for the review.

Therefore, the review will focus on assessing the impacts of the Directive on the basis of preliminary findings in selected targeted areas. Dependent on the responses received, the report will include some initial considerations on relevance, effectiveness and efficiency, to determine, for example, whether or not there are emerging problems for the user community or MS with application of the provisions. It is important to note that the impact of the Directive should be measured against the national legislation in place before the current Directive was implemented.

To recall, the main objectives of the Directive are to

- harmonise the legislation on the care and use of animals for scientific purposes to ensure a "level playing field" for all those impacted (MS, user community) and for the competitiveness of EU research and industry;
- to ensure appropriate standards of welfare in line with Article 13 of TFEU[2] through effective application of the Three Rs in the use, care and breeding of animals, and
- to improve transparency to the general public.

The Directive includes a number of mechanisms to progress these objectives, for example, systematic project evaluation and authorisation, establishment of animal welfare bodies, standards for accommodation and care, inspection of establishments, publication of statistics, non-technical summaries and the introduction of National Committees.

For the review, preliminary views are sought in the following key areas:

i. To what extent has the harmonisation of the legislation throughout the EU provided a level playing field for those involved in the care and use of animals in scientific procedures;
ii. The impact of the Directive on the promotion and implementation of the Three Rs;
iii. The impact of the Directive on the welfare of animals bred, held for use or used in scientific procedures;
iv. The impact of the Directive on science;

[2] Treaty on the Functioning of the European Union

v. Improved transparency on use of animals in scientific procedures.

The review process

i. As the first step of the process, the Commission carries out targeted stakeholder consultations on specific elements of the Directive between 27 May – 31 August 2016. The target audience for these consultations are

- User community (establishments using, breeding or supplying animals),
- Member State authorities and
- Other stakeholder EU level organisations.

To promote a balanced response, national animal welfare organisations have also been invited to contribute in addition to respondents from the user community, both at the establishment as well as at EU level.

The Commission has sought to reach out to all relevant stakeholder organisations at EU level, however, should another important EU-level organisation be identified, please send an e-mail to ENV-LABORATORY-ANIMALS@ec.europa.eu to request an invitation to contribute.

The questionnaires have been adjusted to correspond to the respective areas of knowledge and expertise of the different stakeholder groups.

ii. Article 58 requires taking into account the advancements in the development of alternative methods not entailing the use of animals, **in particular of non-human primates.** During the negotiation of the Directive, the Scientific Committee on Health and Environmental Risks, SCHER, prepared an opinion on the use of non-human primates and Three Rs opportunities on the use of non-human primates for scientific purposes in the EU[3].

To ensure that the most up-to-date information is available to inform the review, an update to this report has been requested. The full mandate and further information can be found on the website of the Scientific Committee on Health, Environmental and Emerging Risks, SCHEER[4].

iii. Additional information sources will be used to assess more generally the advancements of the development of alternative methods and approaches, such as EURL ECVAM reports[5].

iv. The Draft Review report should be available during Q2 2017.

[3] http://ec.europa.eu/environment/chemicals/lab_animals/pdf/scher_o_110.pdf
[4] http://ec.europa.eu/health/scientific_committees/scheer/requests/index_en.htm
[5] https://eurl-ecvam.jrc.ec.europa.eu/eurl-ecvam-status-reports