Review of Directive 2010/63/EU on the protection of animals used for scientific purposes

Questionnaire for **stakeholder organisations** intereste d in the care and use of animals for scientific purposes

Fields marked with * are mandatory.

Introduction to the Review of Directive 2010/63/EU

Directive 2010/63/EU 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 for such purposes.

Like all recent EU legislation, Directive 2010/63/EU includes a requirement for a review – in this case due by November 2017 (Article 58). Due to the relatively early timing of the review and its partly delayed transposition into certain national legislations, there will be only limited experience of the Directive. Morever, the implementation of one of the key elements of the Directive, namely binding housing and care standards, will only become compulsory in 2017. It is thus unlikely that the Directive's projected benefits, especially in terms of improved welfare and science, will have fully materialised.

The focus of the review is therefore to assess the impacts of the Directive on the basis of **preliminary findings** in **selected targeted areas**.

The purpose of this questionnaire is to **invite views on progress towards the main objectives of the Directive,** namely to ensure appropriate standards of welfare in line with Article 13 of TFEU[1] through effective application of the Three Rs in the use, care and breeding of animals, and to improve the transparency to the general public.

The responses will be analysed and summarised in the draft Commission Review report. There will be a further possibility for stakeholder input before the Commission Review report is finalised.

In addition to this Review, the Directive also requires an Implementation Report by 10 November 2019 on the basis of the reports from Member States due the previous year, in line with Articles 54(1) and 57(1). Therefore, this initial review will be followed by a more comprehensive evaluation as part of the Commission Better Regulation programme. At that time there will be further opportunities for input.

Further information on the review can be found on the right hand side of this page under heading "Background Documents".

[1] Treaty on the Functioning of the European Union

Objectives of the Directive

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 and for the competitiveness of EU research and industry;
- to ensure appropriate standards of welfare in line with Article 13 of TFEU through effective application of the Three Rs in the use, care and breeding of animals, and
- to improve the transparency to the general public.

The Directive contains 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, inspections 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:

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

Instructions and privacy statement

To facilitate an easy completion of the questionnaire, it is recommended to download the questionnaire (click on "Download PDF version" on the right hand side of this page; it is a two-step process: the first click will create the file and the second will download it) and **prepare the responses in advance**. This will speed up the input into the on-line questionnaire.

Once you have entered your responses, you can save the completed questionnaire as a draft, and if needed, amend them later. Once the completed questionnaire is submitted, it is no longer possible to change your responses.

Please submit the completed questionnaire at the latest by 31 August 2016.

Download here the privacy statement

Privacy_statement_consultations-final.pdf

Please tell us something about yourself and the organisation you represent

*

What is the name of your organisation?

100 character(s) maximum

Irish Anti-Vivisection Society

*My organisation represents

- ○ Science and academia
- ○ Industry
- ◉ Animal welfare / Animal protection
- ○ Patients
- ○ Veterinarians
- ○ LAS
- ○ Education & training
- ○ Accreditation
- ○ Other

*

My organisation operates in

Multiple choices are possible

☐ Austria	☐ Belgium	☐ Bulgaria	☐ Croatia
☐ Cyprus	☐ Czech Republic	☐ Denmark	☐ Estonia
☐ Finland	☐ France	☐ Germany	☐ Greece
☐ Hungary	☑ Ireland	☐ Italy	☐ Latvia
☐ Lithuania	☐ Luxembourg	☐ Malta	☐ Netherlands
☐ Poland	☐ Portugal	☐ Romania	☐ Slovak Republic
☐ Slovenia	☐ Spain	☐ Sweden	☐ United Kingdom
☐ Other country	☐ EU wide	☐ International	

*Please enter your full name for further contact, if necessary

Yvonne Smalley

*

Please enter your e-mail address for further contact, if necessary

info@irishantivivisection.org

Questions on the Directive

***1. The adoption and implementation of the Directive and the related national legislation has improved the standards of animal welfare, care and use in my country/region.**

- ○ Strongly agree
- ○ Agree
- ○ Neither agree nor disagree
- ◉ Disagree
- ○ Strongly disagree
- ○ No opinion or not applicable
- ○ Too early to provide an opinion

1bis Please comment on reasons with examples. Where appropriate, describe the elements that have impacted the most and why.

500 character(s) maximum

Official statistics indicate no discernible downward trend in the number of animals used or harm levels since the Directive's transposition. Still a high proportion of severe experiments, often for trivial/speculative goals. Lack of definition and openness about the harm-benefit assessments means animal welfare still disregarded relative to research goals. The Irish CA still effectively relies on ethical approval at institutional-level to avoid carrying out its own analysis.

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1.1 Project evaluation is a new element of the Directive. Article 38 of the Directive requires a systematic project evaluation of all projects using live animals irrespective of the purpose. The project evaluation has to be performed by a competent authority and it has to be impartial. Project evaluation needs to ensure that the project is justified from a scientific or educational point of view, or required by law, and that the harms to the animals are justified by the expected outcomes taking into account ethical considerations. Furthermore, the project evaluation is required to ensure the compliance with the Three Rs (that no animal is used if a scientifically satisfactory method or testing strategy to avoid the use of a live animal is available; the number of animals is reduced to the minimum necessary and that the harms to the animals are minimised).

Systematic project evaluation and project authorisation has improved the implementation of the Three Rs and welfare of animals in my country/region.

- ○ Strongly agree
- ○ Agree
- ○ Neither agree nor disagree
- ○ Disagree
- ◉ Strongly disagree
- ○ No opinion or not applicable
- ○ Too early to provide an opinion

1.1bis Please comment on reasons with examples. Where appropriate, describe the elements that have impacted the most and why.

500 character(s) maximum

In reality there is no systematic impartial project evaluation. Moreover, there is a lack of transparency about how the Irish CA carries out the hba. The CA aims to facilitate animal procedures rather than act as a neutral arbiter. NTPS V012/2013Q3 is one example, involving dosing pregnant rats with amphetamine and then subjecting them to the severe forced swim behavioural despair test. It is not clear that any ethical evaluation at all takes place in regulatory testing.

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1.2 Articles 26 and 27 require each establishment (whether animal user, breeder or supplier) to have an **Animal Welfare Body** to ensure that animal welfare considerations are given the highest priority. The Animal Welfare Bodies' primary task is to advise on animal welfare matters. They should also follow the development and outcome of projects to provide tools for timely implementation of new Three Rs opportunities in order to enhance the life-time experience of the animals.

Animal Welfare Bodies have improved the implementation of the Three Rs and welfare of animals in my country/region.

- ○ Strongly agree
- ○ Agree
- ○ Neither agree nor disagree
- ◉ Disagree
- ○ Strongly disagree
- ○ No opinion or not applicable
- ○ Too early to provide an opinion

1.2bis Please comment on reasons with examples. Where appropriate, describe the elements that have impacted the most and why.

500 character(s) maximum

There is no publicly-available data regarding how AWBs are working in practice and whether they have facilitated greater consideration of animal welfare. The statistics suggest there has been no tangible difference in welfare outcomes yet. The rules governing AWB composition are far too vague and fail to ensure sufficient independence, public accountability and ethical expertise.

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1.3 National Committees for the protection of animals used for scientifc purposes are required by Article 49 of the Directive to ensure a coherent approact to project evaluation. National Committees should advise the competent authroties and animal welfare bodies to promote the Three Rs principles and to exhancge best practice at the level of the EU.

National Committees have helped establishments to improve the implementation of the Three Rs and animal welfare in my country/region.

- ○ Strongly agree
- ○ Agree
- ◉ Neither agree nor disagree
- ○ Disagree
- ○ Strongly disagree
- ○ No opinion or not applicable
- ○ Too early to provide an opinion

1.3bis Please comment on reasons with examples. Where appropriate, describe the elements that have impacted the most and why.

500 character(s) maximum

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The Irish National Committee has organised a questionnaire and training
workshop for AWBs. This is positive but there is no evidence yet that it has
actually resulted in improvements in 3Rs implementation and animal welfare.
The NC doesn't meet frequently enough to develop policy effectively.
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***2. Alternative approaches** are promoted in a number of provisions in the Directive. In addition to making a firm legal obligation to use them, the Directvie requires both the Commission and the Member States to contribute to their development and validation (Article 47), to provide new resources through appointment of laboratories for the validation work (EU NETVAL) and have a single point of contact to assess regulatory relevance of new methods proposed for validation (PARERE). Finally, it established a legal base for the European Union Reference Laboratory for Alternatives to Animal Testing, EURL ECVAM, to coordinate the validation of alternative approaches in the aresa of basic and applied research and regulatory testing in the EU.

The Directive has increased the focus, activities and resources aimed at the development, validation and uptake of alternative approaches.

- ○ Strongly agree
- ◉ Agree
- ○ Neither agree nor disagree
- ○ Disagree
- ○ Strongly disagree
- ○ No opinion or not applicable
- ○ Too early to provide an opinion

2bis Please comment on reasons with examples. Where appropriate, describe the elements that have impacted the most and why.

500 character(s) maximum

An Irish Parere contact now exists, but we still have no EU-NETVAL member. This year the Govt through Science Foundation Ireland made the first explicit call for 3Rs project grant applications. However, the Govt has made no real effort to facilitate the sharing of new technology for non-animal testing of Allergan's Botox with other botulinum toxin makers, signifying a distressing lack of concern in relation to extremely severe LD50 testing for trivial purposes and the weakness of Article 13.

*3. **Transparency** is essential to inform the general public and policy makers on why and how animals are used for scientific purposes. Article 54 of the Directive and the related Commission Implementing Decision 2012/707/EU provides entirely revised reporting aiming at improving transparency. The new statistical data contains new elements such as genetic status of animals, more detailed use categories and details on the actual severities experienced by the animals. In addition, Article 43 requires Member States to publish non-technical project summaries to assist public information on the use of live animals.

The Directive has improved the transparency of animal use for scientific purposes in my country/region.

- ○ Strongly agree
- ◉ Agree
- ○ Neither agree nor disagree
- ○ Disagree
- ○ Strongly disagree
- ○ No opinion or not applicable
- ○ Too early to provide an opinion

3bis Please comment on reasons with examples. Where appropriate, describe the elements that have impacted the most and why.

500 character(s) maximum

Starting from a very low base, the NTPS are a useful insight into animal experimentation, although some of them fail to include relevant information. For example, V017/2013Q3 on Bcc infection in mice/ vaccine development doesn't state severity of Bcc infection or endpoints. Similarly the adverse effects section of V018/2013Q4 is not very informative. Irish statistics breach Decision 2012/707/EU by omitting a number of tables, including the purpose of animal toxicity tests.

*4. **The quality of science** should improve through *inter alia* the work of Animal Welfare Bodies (Article 26), Designated Veterinarians (Article 25), staff training and competence (Article 24), and systematic project evaluation (Article 38) focusing on elements such as experimental design, implementation of the Three Rs and harm-benefit assessment.

The Directive has improved the quality of science in my country/region through the application of new elements such as Animal Welfare Bodies, Designated Veterinarians and a systematic project evaluation including harm-benefit assessment.

- ○ Strongly agree
- ○ Agree
- ○ Neither agree nor disagree
- ◉ Disagree
- ○ Strongly disagree
- ○ No opinion or not applicable
- ○ Too early to provide an opinion

4bis Please comment on reasons with examples. Where appropriate, describe the elements that have impacted the most and why.

500 character(s) maximum

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Not seen any evidence of meaningful impact of AWBs and project evaluation,
still too much of a rubber-stamping exercise rather than challenging
applicants.
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*5. The development of a **level playing field for operators** is promoted through harmonised requirements on project evaluation and authorisation as well the establishment of deadlines for administrative processes such as through Articles 40-42. Equally, the Directive has harmonised the requirements on housing and care standards (Annex III) and requirements on personnel (Article 24).

The Directive has created a level playing field by providing similar conditions for operators, irrespective of their region or country.

- ○ Strongly agree
- ○ Agree
- ○ Neither agree nor disagree
- ○ Disagree
- ◉ Strongly disagree
- ○ No opinion or not applicable
- ○ Too early to provide an opinion

5bis Please comment on reasons with examples. Where appropriate, describe the elements that have impacted the most and why.

500 character(s) maximum

The cornerstone of the regulatory system, the harm-benefit assessment, is, in the absence of useful EU law setting its operational parameters, a highly discretionary exercise on a complex issue. It is astonishing that the EC believes that a level-playing field could be created in these circumstances. In any case, for ethical and democratic reasons MSs should be able to go as far as they like ahead of the Directive in terms of animal protection measures.

*6. **Research in the EU** using animals is permitted only where no alternative exists with reassurances on the adherence to high animal welfare standards and through authorisation of only ethically justified animal use by means of a combination of *inter alia* systematic project evaluation, improved enforcement and risk based inspections.

The Directive allows continued high quality research using animals, where still necessary, in my country/region.

- ○ Strongly agree
- ○ Agree
- ○ Neither agree or disagree
- ○ Disagree
- ○ Strongly disagree
- ◉ No opnion or not applicable
- ○ Too early to provide an opinion

6bis Please comment on reasons with examples. Where appropriate, describe the elements that have impacted the most and why.

500 character(s) maximum

Given the translational problems with research on nonhumans, your rhetorical construction of 'high-quality research' using animals is dogmatic and highly dubious. The Directive certainly facilitates egregiously poor quality animal research given most of it is not considered useful enough to publish.

*7. **EU Guidance** has been developed in collaboration with Member States and key stakeholders for a number of elements in the Directive to facilitate and guide the implementation. Today the guidance covers the following topics: "Education and Training Framework", "Severity Assessment Framework", "Project Evaluation and Retrospective Assessment", "Animal Welfare Bodies and National Committees", and "Inspections and Enforcement".

Are you aware of the guidance* developed in the EU by Member States and stakeholders to facilitate the common understanding and implementation of the Directive?

*See link to the guidance on the right hand side of this page under heading "Useful links"

- (●) Yes
- ( ) No

8. Please provide any other comments which you feel are relevant for the review of the Directive. Please provide examples/evidence to support your views.

1500 character(s) maximum

The Directive fails to institutionalise meaningful consideration of animal welfare. That is why it is failing to make a significant difference and certainly not fulfilling the requirement of Article 13 of TFEU to pay 'full regard' to animal welfare. Most animal research stakeholders have much greater political access than the general public and animal advocacy groups, and the outcomes reflect that power imbalance rather than the will of the people or the ethical imperatives to avoid animal harm. Even this consultation organises animal welfare out of serious consideration: the stated objectives of the Directive contain no effective animal welfare goals ('appropriate standards of welfare' is a meaningless phrase dictated by whoever has the power to define that). The aims of Recital 10 – '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' – have been neglected by this consultation's description of the Directive's aims. If the public's concern (and the stated aims of the Directive itself and the TFEU) for animal welfare are to be reflected then legally-binding targets are necessary for the reduction and elimination of pain and suffering in animal experimentation. At the moment, animal welfare is not taken seriously at all, only paid lip-service to, so that the public are fooled into thinking it is protected.

8bis If required, an additional reference document can be uploaded. The maximum acceptable file size is 1MB.

Useful links

Directive 2010/63/EU (http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32010L0063)

Commission Implementing Decision 2012/707/EU (http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:02012D0707-20140115)

Guidance for the implementation of the Directive 2010/63/EU (http://ec.europa.eu/environment/chemicals/lab_animals/pubs_guidance_en.htm)

More information on Better Regulation (http://ec.europa.eu/smart-regulation/better_regulation/key_docs_en.htm)

Background Documents

Background to Article 58 Review of the Directive (/eusurvey/files/1ec1b78f-57da-47c0-b88b-860adc2bffb7)

Contact

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