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**REPORT FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT, THE
COUNCIL, THE EUROPEAN ECONOMIC AND SOCIAL COMMITTEE AND THE
COMMITTEE OF THE REGIONS**

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

{SWD(2017) 353 final}

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1. Introduction

In 2010, the EU adopted Directive 2010/63/EU on the protection of animals used for scientific purposes ("the Directive") updating and replacing the 1986 legislation. All uses of live animals for research or education, and testing must be carried out in compliance with this Directive. This report is in response to the Directive's Article 58 that requires a review of the Directive by 10 November 2017.

1.1 Policy Objectives and Purpose

The Directive has three key objectives:

- Ensure efficient functioning of the EU internal market and enhance competitiveness and innovation of the EU research industry through the creation of a level playing field.
- Ensure high standards of welfare for animals used for scientific purposes.
- Improve transparency to the general public of the performance of research establishments in terms of animal use and welfare.

Critical to enhancing the welfare of animals is the effective application of the 'Three Rs': Replace, Reduce and Refine the use and care of animals used for scientific purposes.

The Directive sets out requirements on:

- The replacement and reduction of the use of animals in procedures and the refinement of the breeding, accommodation, care and use of those animals.
- The origin, breeding and marking of animals.
- The operations of breeders, suppliers and users.
- The evaluation and authorisation of projects involving the use of animals in procedures.

1.2 Scope and Timing of the Review Report

This review aims to assess how well the Directive's objectives are achieved and whether it is fit for purpose or needs updating given the latest scientific and ethical developments. The review takes into account advances in the development of non-animal alternatives - in particular those replacing non-human primates. It incorporates conclusions from a feasibility study on the progress towards using second and/or higher generation non-human primates, as required under Article 10.

The Directive took effect on 1 January 2013, however, the last national legislation was adopted only in 2015. Also, the common standards for animal accommodation and care only

entered into force on January 2017. At the time of this review, European Commission conformity checks were still ongoing, including a number of enquiries and infringement cases in progress, possibly leading to changes to some national legislation.

Factual information on practical implementation of the Directive by Member States is not due until 2018. National statistical data were published for the first time in 2015, but trends of animal use at EU level will not be known before 2019. Information on retrospective assessments of projects will become available from 2019. Therefore, a full REFIT evaluation of the Directive will be undertaken after 2019 when better information is available and sufficient time has lapsed for the Directive's implementation to enable an assessment of any changes in welfare and use practices.

For all these reasons, the legally required completion date of this review comes quite early. Therefore the report can only give preliminary indications of progress, problem areas and good practice.

The consultation methodology, analysed results and recommendations on improving the implementation and application of the Directive are found in the accompanying staff working document (SWD)¹.

3. Key issues found

The Directive's framework is generally considered to be a sound foundation for the regulation of animals used for scientific purposes.

The preliminary indications are that the impact of the Directive varies among Member States. This is to a great extent influenced by national legislations in place prior to the Directive. For those with existing, mature project evaluation and authorisation processes, the Directive's transposition into national legislation required relatively few adjustments. However, for those with no previous requirements or formal structures for project evaluation the implementation has been more challenging.

Yet there are some preliminary indications that the Directive's implementation will deliver some of the changes and results as envisaged. For example, stakeholders consider the creation of Animal Welfare Bodies (AWB) an effective requirement that is already contributing positively to improving animal use and care practices. Other positive effects reported include raised standards in care, accommodation and research practices, enhanced Three Rs awareness, promotion of a culture of care, growing recognition within the research community of the link between animal welfare and good science, and increasing transparency.

Areas identified by stakeholders as needing further attention and progress include the efficiency and consistency of project evaluation and authorisation processes as well as access to, and quality and transparency of information on the use of animals.

The sections below describe the key findings in view of the Directive's three main aims.

¹ SWD(2017) 353

Section 1 - Harmonisation of legislation within the EU

About one third of the user respondents thought that the Directive had started harmonising some important aspects, thereby already creating a more level playing field, particularly with respect to the harmonisation of animal care and accommodation practices.

However, in some Member States the requirements for project evaluation and authorisation led to concerns over additional bureaucracy, costs and delays. Unlike regulations, EU directives do not specify operational processes. There are concerns that the differences in structures and financial resourcing, in particular for project evaluation and authorisation, may become limitations to achieving the harmonisation objectives.

Project evaluation and authorisation

Consistency and efficiency in the project evaluation and authorisation process, and outcomes in and between Member States are essential for achieving a level playing field for the scientific community, along with the desired welfare and scientific benefits. In many Member States, similar processes were in place before the Directive, so no major changes or improvements were reported. However, many scientists have yet to submit a project application under the new system and are still using authorisations issued under previous legislation. Transitional measures for existing authorisations run until January 2018.

Member States developed differing structures to meet the Directive's requirements. In some, single national authorities deal with all applications in the country. In others, there are regional committees, or committees within user establishments, often integrated with the AWB.

Despite variations in structures, approx. half the users considered the project evaluation and authorisation processes to be effective and efficient. Some stakeholders raised concerns about the implications of these different structures, in particular with respect to achieving impartiality and proportionality. Some users expressed frustration and confusion about bureaucracy and duplications involved in project applications in some Member States.

Other issues raised include:

- Inconsistent approaches between Member States on how projects of different sizes, nature and complexity are categorised and handled.
- Delays in communicating authorisation decisions beyond the 40 or 55 day deadlines despite financial fees in some Member States for the project application.
- Additional bureaucracy due to information requirements that are in excess of those required in the Directive for harm-benefit assessments.
- More efficiency needed in dealing with amendments to authorised projects.
- Limited progress on the implementation and use of multiple generic projects and the simplified administrative procedure.

The EU guidance² on project evaluation to assist these processes was well distributed by most Member States.

One of the main roles of the National Committee is to ensure a harmonised approach to project evaluation. Less than 25% of the users considered that the National Committee had

² http://ec.europa.eu/environment/chemicals/lab_animals/pdf/guidance/project_evaluation/en.pdf

been effective in promoting a coherent approach partly reflecting the fact that many committees are still not well established.

Scope of the Directive

The Directive's scope had been extended to include:

- New species and life forms (e.g. cephalopods, foetal forms).
- Use of animals in basic research, education and training.
- Use of animals in routine production.

Many Member States already covered some or all of these under their previous legislation. No major issues were raised on the scope, apart from a few instances of additional administrative burden.

Education and training

Free movement of personnel in the sector within the EU is one of Directive's aims. However, education and training remain Member State competence. The users' majority view was that ensuring and maintaining staff competence was addressed satisfactorily. Some differences in expectations of training requirements between Member States were reported, hence duplication of training is sometimes still required. To facilitate a more harmonised approach, the European Commission developed an EU Framework guidance³ for education and training, and a voluntary EU-wide Education and Training Platform in Laboratory Animal Science (ETPLAS) was established.

Harmonisation of welfare standards

Many stakeholders stated that the Directive was beginning to harmonise standards of animal care and accommodation. The costs of complying with the new standards, noted as a potential issue in the Directive's ex-ante Impact Assessment, raised few concerns so far.

The lack of standards for cephalopods and certain fish species, including appropriate methods of killing (cephalopods) were identified as omissions.

The level playing field intention of Article 2 was seen by some stakeholders as a potential barrier to improving animal welfare standards. However, the Directive allows for technical adaptation to progress via delegated powers, ensuring that any improvements to animal welfare standards identified can, if well-founded, be adopted and applied EU-wide.

Section 2 - Animal Welfare and the Three Rs; application and development of alternatives approaches

Measures to improve animal welfare and the application of the Three Rs form the core of the Directive. The benefits of high welfare standards to animals and to the quality of science are widely recognised.

There are already significant positive indicators of the benefits, in particular the higher awareness within establishments of animals' welfare needs, with AWB playing a key role. Users and other stakeholders both reported benefits. Over half the users considered that animal welfare had been improved by applying the new housing and care practices, including e.g. enrichment and better trained and competent care staff.

³ http://ec.europa.eu/environment/chemicals/lab_animals/pdf/guidance/education_training/en.pdf

Responsibility for ensuring that alternative approaches are applied lies with researchers and care staff, supported by AWB and Designated Veterinarian, and those carrying out project evaluation. Almost half of the users agreed that project evaluation had improved the implementation of the Three Rs and animal welfare. However, views were divided among stakeholders and depending on whether measures were in place prior the Directive.

Crucial elements include provision of appropriate education and training, the role and tasks of AWB, and the tools available for obtaining up-to-date and relevant Three Rs information. Inspections are important in maintaining animal welfare standards.

The review report has taken into account progress with alternatives but it is not intended to measure the development, validation or uptake of alternative approaches. It evaluates whether the measures contained in the Directive are fit-for-purpose. Given the early stages of implementation of the Directive's requirements on the development and validation of alternative approaches, more time will be needed for their evaluation.

Animal Welfare Bodies, AWB

The Directive requires each establishment to have an AWB with the main objective to facilitate continuous day-to-day application of the Three Rs. In general, Member States, users and stakeholder organisations all welcomed this requirement. The interactions among scientists, care staff and veterinarians are viewed very positively, and the AWB is recognised as the promoter of a good culture of care. Of particular value is the inclusion of a Designated Veterinarian and the expertise on experimental design.

In some Member States, however, users reported that the role of AWB is unclear when also involved in the preliminary evaluation of projects. As the tasks for AWB and project evaluation differ, it is critical that there is awareness of the specific requirements, and that the competencies are appropriate for these separate processes. In such cases it is vital that all the core tasks, as required by the Directive, are addressed.

National Committees

National Committees should facilitate a coherent approach to project evaluation, promote good animal welfare and exchange good practice within the Member States and at EU level. In general, expectations are not yet met with a number of National Committees not yet fully established. Nevertheless, some committees are already active, developing guidance material, networks, and sharing best practices.

Training and education, and requirement for named responsible persons

In those Member States that previously lacked formal high quality training and education programmes, substantial benefits were reported thanks to meeting the Directive's requirements – including the appointment of a person formally responsible for overseeing training and competence. Benefits included better animal welfare, better recognition of pain, distress and suffering, and better understanding of animal behaviours and needs. However, between Member States considerable variability remains in the training required before animal procedures can be started.

Many users remain unaware of the EU guidance on training⁴ and other guidance documents by Member States or National Committees so there is clearly room for improved

⁴ http://ec.europa.eu/environment/chemicals/lab_animals/pdf/guidance/education_training/en.pdf

communication on these. There also appear to be some challenges with the recognition and implementation of the role for a "person responsible for the provision of species-specific information", in particular with their input into accessing information relating to the Three Rs in the relevant area of science. Additional guidance for this role could be valuable. The requirement for a Designated Veterinarian was welcomed and contributed to better practices in surgery, anaesthesia, analgesia and euthanasia.

Inspections by Member States

Quantitative data on inspections will not be available from Member States before late 2018. However, a few stakeholder responses suggested that the revised inspection requirements are helping to change the attitudes of scientists and technicians, leading to improved animal welfare and awareness of the Three Rs. This includes improvements in experimental protocols, better monitoring the animals and severity assessments, improved environmental enrichment and health monitoring.

Application of existing alternatives

The term 'alternatives' in the context of the Directive includes any tools or strategies implementing the "Three Rs" which:

- Obtain the required information without the use of live animals.
- Use fewer animals whilst obtaining the same level of information.
- Improve the way procedures are carried out so as to cause less pain, distress or suffering, or improve welfare.

Animals may only be used when there are no non-animal alternatives available to achieve the scientific objective. At this stage of the Directive's implementation, it is too early to assess its impact on the promotion and uptake of alternatives. Nevertheless, stakeholders confirmed some positive developments:

- The important influence of AWB, project evaluators and competent authorities in challenging the need of the proposed use of animals.
- The importance of inspection programmes to check compliance with the Three Rs and continued application of new alternatives throughout the life of the project.
- The formal establishment of the European Union Reference Laboratory for Alternatives to Animal Testing (EURL ECVAM) which plays a valuable role in co-ordinating validation of alternative approaches as well as in maintaining databases of information on alternatives.

However, responses identified four key issues hindering a more rapid uptake of alternatives: lack of knowledge; insufficient communication/spreading of information; acceptability, and cost. Organisations pointed to shortcomings in training on, and searching for, alternatives. Some AWB have not yet developed suitable information strategies for alternatives.

Users indicated that studies on some aspects of biology continue to need *in vivo* experimentation and alternative methods are unlikely to be available in the foreseeable future. Many stakeholders felt, however, that there is significant scope for the replacement of animals used for educational purposes where many alternatives are already available, but not always taken up. Further separation of educational purposes within the statistics would be helpful.

Development and validation of new alternatives

Welfare organisations expressed frustration at the slow progress towards validation and acceptance of new alternative methods. Validation and regulatory acceptance processes vary between different regulatory areas, which are not directly regulated by this Directive. Nevertheless, there is evidence of investment and activity advancing this field. The Directive contributes towards these objectives through obligations on Member States and the European Commission.

For validation, Member States have appointed laboratories for carrying out validation studies (European Union Network of Laboratories for the Validation of Alternative Methods, EU-NETVAL). Some Member States provide funds for the work but more is needed. For regulatory input, Member States have nominated single contact points for giving advice on the regulatory relevance and suitability of new alternative approaches proposed for validation (Preliminary Assessment of Regulatory Relevance PARERE Network) to accelerate validation and uptake in the regulatory field.

Many Member States have increased their activities in promoting alternatives, e.g., increasing research funding, voluntary development of Three Rs centres, supporting educational events and other information dissemination efforts. Half of the Member States have submitted voluntary reports detailing the actions taken towards the development, validation and promotion of alternative methods⁵.

The remit of EURL ECVAM was enlarged to include basic and applied research. Users requested EURL ECVAM to continue broadening its activities from being mainly regulatory toxicology to other areas of science. The EURL ECVAM report⁶ describes the current structures and progress supporting development, validation, regulatory uptake and promotion of alternatives.

Section 3 - Improved transparency

The Directive introduced elements aimed at improving transparency and in particular, requirements for non-technical project summaries, project evaluations process and statistical information.

Most Member States, users and scientific stakeholders thought that the requirements for publication of non-technical project summaries and revised annual statistical data contributed towards improving transparency, although the full impact has yet to materialise. However, an important proportion of the animal protection organisations expressed reservations about the impact, so far, of the Directive on improving transparency. This reflects, in part, the early stage of the Directive's implementation at the time of the review.

Non-technical project summaries

Non-technical project summaries must report information on the objectives and benefits of the project, numbers and types of animals to be used, the predicted harm to the animals as a result of the procedures applied, and compliance with the Three Rs. Most Member States stated that publication of the summaries is helping to improve transparency although some reservations were expressed by animal protection groups who pointed to significant

⁵ http://ec.europa.eu/environment/chemicals/lab_animals/3r/advance_en.htm

⁶ Annex II to Staff Working Document SWD(2017) 353

differences in quality and a lack of appropriate balance, e.g. too much emphasis put on generic, sometimes unrealistic benefits and insufficient information on harm.

Project Evaluation

Only a few Member States have, so far, published their project evaluation processes. It is expected that Member State information will be available at the time of the Commission implementation report in 2019.

Statistical information

Member States published statistical data on the use of animals for scientific purposes for the first time in 2015, however, very few did so with the level of detail required by the Commission Implementing Decision 2012/707/EU.

It is too early to determine the impact of the new reporting requirements on improving transparency, but for the first time information is provided *inter alia* on the genetic status of the animals, the actual experienced severity, and origin and species of non-human primates.

Section 4 – Results of the feasibility study on the progress to using second and/or higher generation purpose-bred non-human primates

With the aim of ending capture of non-human primates from the wild for both scientific and breeding purposes, the Directive allows, after an appropriate transition period, the use only of non-human primates that are the offspring of animals which have been bred in captivity (F2/F2+), or that are sourced from self-sustaining colonies⁷. The understanding of self-sustaining colony is that once closed, the colony no longer can be reopened. It is also implicit from the intentions of the legislators that "other colonies" from which animals can be sourced, must be considered to be also self-sustaining captive-bred colonies, and from which no wild-caught animals can be obtained as breeders.

The current deadline in the Directive Annex II is set at November 2022, apart from Marmosets which have been required to be F2/F2+ since January 2013. Article 10 requires a feasibility study to assess the appropriateness of Annex II deadlines, and to propose amendments, where appropriate. The key findings and conclusions of the feasibility study are presented below.

The majority of the species used within EU are already available as F2/F2+.

The main species of concern is the *Cynomolgus* macaque whose global supply of F2/F2+ animals already now comfortably exceeds the current and projected EU demand. However, the additional five years (2017-2022) are needed to complete the transition, including Herpes B-virus-free animals from suppliers in Mauritius who are not yet able to fulfil the scientific demand with F2/F2+ animals.

Considering the current and projected EU demand of the relevant species and their supply from EU and non-EU countries, the impacts of the transition on science, animal welfare and

⁷ Article 10 of Directive 2010/63/EU: .."For the purposes of this Article a 'self-sustaining colony' means a colony in which animals are bred only within the colony or sourced from other colonies but not taken from the wild, and where the animals are kept in a way that ensures that they are accustomed to humans."..

health, the feasibility study does not support altering the dates set out in Annex II of the Directive.

However, to facilitate accurate reporting that allows measuring the progress towards the Directive goals, Commission Implementing Decision 2012/707/EU should be adjusted to obtain annual information on the generation of non-human primates supplied also from self-sustaining colonies.

5. Conclusions

The timing of this review in the early stages of the Directive's implementation makes it premature to assess many aspects of its performance against policy objectives. However, it is clear that the majority of stakeholders consulted for this review consider the Directive to be relevant and necessary for creating a level playing field within the EU and achieving the animal welfare objectives and standards. Therefore no amendments to the Directive are proposed at this stage. Furthermore, and drawing from the conclusions of the SCHEER⁸ report⁹, no phasing-out timetable for the use of non-human primates is proposed, however, the European Commission will request regular updates to the SCHEER opinion to closely monitor progress.

On the basis of the Article 10 feasibility study, there is no justification to prolong the transitional period set out in Annex II for the use of second and/or higher generation purpose-bred non-human primates. However, the reporting categories in Commission Implementing Decision 2012/707/EU will be amended to require *inter alia* systematic reporting of the generation of non-human primates used, including when acquired from self-sustaining colonies.

Finally, once sufficient scientific evidence is available, Annex III on care and accommodation will need to be amended to incorporate standards for cephalopods and to provide more details for some groups of species. Annex IV should be amended to provide appropriate killing methods in for cephalopods, and to align existing methods with latest the scientific knowledge on the basis of annual reports by Member States, where appropriate.

⁸ Scientific Committee on Health, Environment and Emerging Risks

⁹ https://ec.europa.eu/health/sites/health/files/scientific_committees/scheer/docs/scheer_o_004.pdf