

Protection of animals used for scientific purposes

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The Commission presented a report on the implementation of Directive 2010/63/EU on the protection of animals used for scientific purposes in the Member States of the European Union. The report is based on the reports submitted by the Member States. Its main conclusions are as follows:

Implementation of the legislation

All Member States made changes to their national legislation to transpose the Directive, but the extent of these varied significantly, dependent also on how the previous Directive (86/609/EEC) had been implemented.

Experience with the new legislative requirements is still limited, particularly for those Member States whose transposition has been slow. However, it is clear that most Member States are committed to meeting the requirements of the Directive. For example, most Member States have indicated that they have made major changes due to: (i) the extended scope; (ii) the new requirements on accommodation and care for animals and on killing methods; (iii) the risk-based approach and the frequency of inspections.

In addition, the focus on alternative approaches caused many Member States to consider how to best meet the provisions in the Directive. Some set up 'three Rs' (replacement, reduction and refinement) centres voluntarily to promote alternatives.

Structures and framework of competent authorities

In 21 Member States, one ministry is responsible for the implementation of the Directive. The structures for project evaluation and authorisation vary considerably - from single committees (competent authorities) responsible for the evaluation and authorisation of all projects in the Member State to regional structures, to local ethics committees which assess only local projects, or within a single establishment.

The implementation of animal welfare structures and national committees for the protection of animals used for scientific purposes has been successful, although it depends on the resources available.

Animal welfare bodies are recognised as a very positive step towards improving animal welfare and science. Their inputs have highlighted the importance of applying the Three Rs to all animals, whether used, bred or held in stock. Animal welfare bodies have improved communication between those conducting procedures and those caring for the animals.

Education and training requirements continue to differ between Member States even if some simplified processes have been installed to facilitate movement of scientists. Several Member States reported that they are currently carrying out activities to improve the provision of training. Despite the diversity of training, no observations suggested that lack of skills was a problem.

Differences in project application and evaluation processes and authorisation times continue to impact negatively on the objective of achieving a level playing field for scientists across the EU

Sourcing of non-human primates

The Directive promotes second or higher generation purpose-bred non-human primates in the EU. The implementation reports show that authorised breeding establishments in the EU already offer non-human primates today.

Inspections

The report notes that 18 Member States performed more inspections (covering users, breeders and suppliers) than one third of the number of authorised users in their Member State per year. Nine Member States appear not to have achieved one third in some years. One Member States has performed fewer inspections in all five years.

Five Member States reported no unannounced inspections. Despite this, the total proportion of unannounced inspections in the EU since the Directive took effect seems to be relatively high, around 40%.

Animals bred for use in procedures

For the first time in the EU, the number of animals bred and killed without being used in procedures was reported for the year 2017 (12 597 816 animals in total). Together, the annual statistical report and the implementation report give a comprehensive picture of all animals needed to support research, testing and education/training in the EU in a given year.

Non-technical project summaries

The Directive requires that non-technical summaries of authorised projects are published to inform the public on live animal use. As experience grew, the content improved, and the time to publication was reduced, thanks to IT systems to host these non-technical project summaries. From 2021 onwards, the publication of non-technical project summaries will be required through a central EU database and within six months of the authorisation of the project.

Together with stakeholders, the Commission developed guidance documents addressing key concepts in the Directive, available in all 23 Union languages. It is also addressing future scientists through development of education and training tools focusing on alternatives to animal use.

Monitoring transposition

As guardian of the Treaties and in line with its commitment in response to the European Citizens' Initiative "Stop Vivisection", the Commission is examining the conformity of the transposition into national legislation. As a result, structured dialogues (EU Pilot) have been launched with all Member States. If cases of non-compliance are identified, the Commission may launch new infringement procedures.