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REPORT FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT AND THE COUNCIL

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

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1. Introduction

In June 2019, Directive 2010/63/EU on the protection of animals used for scientific purposes[1] ("the Directive") was amended by Regulation (EU) 2019/1010[2] ("the Regulation"), and in particular its Article 54(1) on Member State obligation to submit to the Commission a report on its implementation by 10 November 2018. Furthermore, the obligation for the Commission to submit a report on its implementation to the European Parliament and the Council by 10 November 2019 (Article 57(1)) was deleted.

As the Regulation was adopted after Member States had already submitted the information covering the first five years of the functioning of the Directive, i.e. the period 2013-2017, the European Commission considers it appropriate, especially given that improved transparency is one of the key objectives of the Directive, to provide a consolidated EU report on its implementation.

The report focuses on the key elements affecting the implementation, as defined in Annex I ("the Annex") of Commission Implementing Decision 2012/707/EU[3]. However, it is not an exhaustive account of all national implementation measures. The report is accompanied by the Commission Staff Working Document[4].

The content and quality of Member States' reports varied. All Member States submitted their report, 22 by the deadline of 10 November 2018, with the last report received in February 2019, and final corrections in early September 2019. Some Member States provided additional, voluntary information. Late submissions and inconsistent quality of reporting made the drawing of conclusions at EU level challenging.

This report does not prejudge the Commission's stance in any infringement procedure on the compatibility of national implementation measures with Union law.

2. Changes to national 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.

The new requirements for severity classification and reporting, non-technical project summaries, retrospective assessment and timeliness of authorisation decisions led to changes in all national legislations. In addition, most Member States reported having made major changes due to:

- the extended scope;
- new requirements for accommodation and care and methods of killing;
- the risk-based approach to, and frequency of, inspections.

[1] OJ L 276, 20.10.2010, p. 33–79
[2] OJ L 170, 25.6.2019, p. 115–127
[3] OJ L 320, 17.11.2012, p. 33–50
[4] SWD(2020)15 final

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[5] centres voluntarily to promote alternatives.

3. Key elements of the reporting on the Directive

3.1 Structures and framework of competent authorities

In 21 Member States, one ministry is responsible for implementing the Directive, mostly the ministry for agriculture and environment; sometimes the ministry for health, education, science and innovation. In Belgium, Germany, Greece, Spain, France, Poland and the United Kingdom it is a shared responsibility between two or more ministries.

A competent authority must carry out five tasks: authorisation and inspections of establishments, project evaluation, project authorisation and retrospective assessment. Under the Directive, a competent authority does not have to be a public body, provided it has the required expertise and infrastructure, and is free from any conflict of interests as regards the performance of the tasks.

Member States' structures vary greatly from central to regional and local. Sometimes the designation of tasks between competent authorities even varies between different regions within a Member State.

15 Member States reported having one public competent authority for all five tasks. Two of these have a regional structure with each region delivering all five tasks. 13 Member States indicated more than one competent authority.

The more common task division is that inspection and authorisation of breeders, suppliers and users are separate from project evaluation and authorisation, and retrospective assessment. Inspection is often done by veterinary authorities.

The structures for project evaluation and authorisation also differ greatly – from single committees (competent authorities) charged with evaluation and authorisation for all projects in the Member State, to regional structures (e.g. Germany (26), Austria (10) and Sweden (6)) to local ethics committees which evaluate only local projects, or within a single establishment (for example Belgium (33), France (125)). Romania indicated one competent authority, but in a separate instance stated that the project evaluation is carried out by ethics committees set up within the establishments of users.

[5] To Replace, Reduce and Refine the use of animals for scientific purposes

N = National; R = Regional; O = Other ; P = Public authority; NP = Non-public authority															
Member State	**CA for authorisation of establishments**			**CA for inspections**			**CA for project evaluation**			**CA for project authorisation**			**CA for retrospective assessment of projects**		
Belgium	3	R	P	3	R	P	33	O	NP	33	O	NP	33	O	NP
Czechia	1	N	P	14	R	P	8	O	P	8	O	P	8	O	P
Germany	26	R	P	285	R	P	26	R	P	26	R	P	26	R	P
Estonia	11	R		11	R		1	N		1	N		1	N	
Greece	13	R	P	71	R	P	57	R	P	13	R	P	57	R	P
Spain	17	R	P	17	R	P	89	N	P/NP	17	R	P	89	N	P/NP
France	1	N	P	1	N	P	125	O	NP	1	N	P	125	O	NP
Hungary				19	R		1	N	P	19	R		1	N	
Malta	1	N	P	1	N	P	2	N	P	2	N	P	1	N	P
Netherlands	1	N	P	1	N	P	17	R	NP	1	N	P	1	N	P
Poland	305	O	P	305	O	P	11	O	P	11	O	P	11	O	P
Finland	2	R	P	2	R	P	1	N	P	1	N	P	1	N	P
Sweden	1	N	P	21	R	P	6	R	P	6	R	P	1	N	P

Table 1. Number and type of competent authorities (CA) for the 13 Member States with more than one competent authority in 2017

It is acknowledged[6] that the more competent authorities are involved in implementing the Directive within a Member State, the greater the challenges are to ensure a consistent approach and outcome.

Methods to promote consistency include training, regular meetings of competent authorities, standardised project application and evaluation forms, standard checklists for authorisation and inspection of establishments.

Given the significant variations in competent authority structures across Member States it is not surprising that the 2017 review of the Directive[7] identified difficulties for the scientific community and raised concerns over inconsistencies.

3.2 National Committees

According to the Directive, each Member State must establish a National Committee for the protection of animals used for scientific purposes. It advises the competent authorities and Animal Welfare Bodies on matters dealing with the acquisition, breeding, accommodation, care and use of animals in procedures and ensures sharing of best practice.

Some Member States already had similar committees in place, whereas others had to establish one. Hence, the experience of the National Committees varies.

In most Member States, National Committees developed effective communication channels with Animal Welfare Bodies for sharing relevant information and best practice, including Q&A systems.

As the role of the National Committee evolves, links between Animal Welfare Bodies and National Committees are expected to get stronger, but their effectiveness greatly depends on appropriate resourcing by the Member State.

3.3 Education and Training

The Directive requires appropriate education and training for staff carrying out procedures, caring for animals, killing animals and designing procedures and projects. General requirements are included in national legislation, most Member States have published the EU Guidance document on Education and Training Framework[8] and some have produced additional guidance. Several Member States reported on-going activities to improve training provision.

Staff conducting procedures, caring for animals or killing animals must be supervised until their competence is assessed. This is a new requirement and many Member States do not yet have formal systems for supervision and competence assessment. A few Member States noted that further guidance was in preparation. Some training providers and ETPLAS[9] are developing tools for consistent competence assessment.

Despite the diversity of training, no comments suggested that a lack of competence was an issue. The education and training requirements, including attainment and maintenance of competence, are often checked during inspections, suggesting that there is oversight of outcomes and that if training were less than ideal, it could be identified and remedied.

[6] https://ec.europa.eu/environment/chemicals/lab_animals/pdf/guidance/project_evaluation/en.pdf
[7] COM/2017/0631 final
[8] https://ec.europa.eu/environment/chemicals/lab_animals/pdf/guidance/education_training/en.pdf
[9] Education and Training Platform for Laboratory Animal Science, https://www.etplas.eu

The 2017 review of the Directive suggested difficulties for staff and researchers in moving between Member States as education and training requirements differed, requiring additional training delaying the start of work.

Some Member States recognise training courses from other Member States or external course accreditors, for example FELASA[10], allowing persons from another Member State to skip some intra-Member State training.

Only eight Member States indicated having additional training requirements for personnel from another Member State.

3.4 Project evaluation and authorisation, and retrospective assessment of projects

During project evaluation, all applications to use animals must be carefully considered to ensure the animal use is justified, the Three Rs are applied and that a harm-benefit assessment is carried out. A project authorisation can only be granted if the competent authority gives a favourable project evaluation.

Many Member States have structures in place, mostly templates and guidance, to facilitate consistency of and correct information for the evaluation. A few Member States also include other tools such as training for project applicants and evaluators, and electronic application systems, which are reportedly speeding up processing times.

There are different evaluation processes, ranging from national to regional and local. Equally, committee structures vary in size – from very large to small groups or evaluations by individuals (with other support where necessary).

Some evaluators work with local Animal Welfare Bodies or local ethical review groups for a local perspective and/or opinion on the application to better inform the evaluation process.

Impartiality and lack of conflict of interest must be assured, especially when the project evaluation is tasked to a non-public authority. Most Member States reported that conflict of interest is addressed by requiring that committee members do not take part if their own work or that of a family member, or their department's work is being assessed. This is an issue in particular for project evaluation done by local committees. Declarations are used to state impartiality/lack of conflict of interest. In some cases, an independent member of the government department provides oversight, or a second tier of review is carried out at national level. A few Member States actively encourage independent involvement in the process.

Relatively few applications are refused, as they are generally revised and improved during the process. An application may also be withdrawn before it is formally refused.

Most Member States are making strenuous efforts to comply with the Directive's requirements on project evaluation and authorisation.

To facilitate competitive EU research, the Directive introduced a 40-day deadline for deciding on authorisation and informing the applicant. Only in justified cases, this deadline could be extended by 15 days. Circumstances for deadline extensions included projects of complex or multi-disciplinary nature with large numbers of animals and use of controversial procedures.

A comparison of numbers of authorised projects between Member States is not relevant due to differences in interpretation of what constitutes "a project". However, there are major differences among Member States regarding the proportion of decisions taken beyond 40 days. Three Member States did not provide data on this.

[10] Federation for Laboratory Animal Science Associations, www.felasa.eu

Member State	Number of projects authorised in 2017	Total number of decisions (authorised and rejected)	Number rejected (calculated)	Number of decisions >40 days	Proportions >40 days of all decisions
AT	717	721	4	10	1%
BE	1,605	1,621	16	146	9%
BG	23	23	0	9	39%
CY	6	6	0		
CZ	528*)	528	0*)	3	1%
DE	3,800	3,800	0	3,000	79%
DK	269	269	0	31	12%
EE	17	17	0	0	0%
EL	175	183	8	15	8%
ES	1,569	1,569*)	0*)	84	5%
FI	124	124	0	0	0%
FR	3,708	3,708	0	2,433	66%
HR	47	50	3	9	18%
HU	206	271	65	135	50%
IE	120	120	0	3	3%
IT	1,005	1,264	259	929	74%
LT	24	24	0	24	100%
LU	22	22	0	22	100%
LV	13	15	2		
MT	1	1	0	0	0%
NL	431	440	9	31	7%
PL	774	914	140		
PT	56	56	0	34	60%
RO	114	114	0	0	0%
SE	657	662	5	20	3%
SI	18	28	10	12	43%
SK	92	93*)	1*)	0	0%
UK	587	587	0	1	0%

Table 2. Project authorisation decisions per Member State in 2017
*) Numbers calculated from the data provided in the other columns

Projects involving severe procedures and/or non-human primates as well as those selected by competent authorities during the project evaluation, are subject to retrospective assessment by a competent authority to consider whether the objectives were achieved, to consider the harm inflicted on the animals, and to identify any elements that could lead to further implementation of the Three Rs. It is relatively early to assess the implementation of this requirement as the transitional measures for project authorisation covered projects until 31.12.2017. The main reasons given for selecting projects for a retrospective assessment (beyond those for which it is compulsory) were in relation to concerns on animal welfare due to use of complex or novel technology, new disease models, lengthy anaesthetic episodes, potential for cumulative suffering, large numbers of animals or uncertainties on proposed design or group sizes.

3.5 Non-technical project summaries

The Directive requires that non-technical summaries of authorised projects are published to inform the public on live animal use. All Member States use a template included in the project application, with many using the EU template as guidance.

Initially the quality of the content and the time to publication were a concern. However, 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[11].

3.6 Animals bred for use in procedures

Under the Directive, as part of the implementation report, Member States must now provide data once every five years, on all "other" animals: bred and killed, but not used. These animals are not reported in the annual statistics. 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.

Animals that are bred, but not used in procedures cover all animals that for one reason or another were not used or were unsuitable for scientific purposes. These include also those bred and humanely killed for their organs and tissues, for example to be used in alternative (animal tissue-based) methods. These numbers also include many breeding animals that arrived at the end of their breeding life. Finally, they include those that were intended for use, but for example, were ill and killed humanely before being used. Sometimes, animals may need to be killed on welfare grounds and in order to protect the health and scientific integrity of the colony.

Types of animals	Numbers
Number of **conventional animals** bred, killed and not used in procedures	**6,484,535**
Number of **genetically normal** animals (wild type offspring) produced, bred and killed as a result of **creation of a new genetically altered line**	**525,085**
Number of animals bred and killed for the **maintenance of an established genetically altered line** (those not covered by project authorisation and excluded from annual statistical reporting)	**5,588,196**
Total	**12,597,816**

Table 3. Numbers of animals bred, killed and not used in procedures in the EU in 2017

91% of the animals reported are mice (83%) and zebra fish (7%). Good oversight of breeding programmes is essential to minimise surplus animals as far as practicable, but given the fluctuations in supply and demand, and the specificity of requirements for certain studies, there will always be some animals which cannot be used for scientific studies.

[11] OJ L 170, 25.6.2019, p. 115–127; Article 6

3.7 Sourcing of non-human primates

The Directive promotes second or higher generation purpose-bred (F2/F2+) non-human primates in the EU. From the implementation reports, it can be concluded that all authorised breeding establishments in the EU are already supplying only F2/F2+ animals today.

To advance the aims of the Directive globally, where animals are sourced from non-EU countries, Member States strive to obtain only F2/F2+ animals, and are encouraging non-EU breeders, although they are not within EU jurisdiction, to increase the supply of F2/F2+ animals.

3.8 Exemptions from requirements within the Directive

The Directive allows exemptions to be granted in relation to species that must be purpose-bred, the place where procedures are carried out, the conditions on reuse of animals, and accommodation and care requirements.

15 Member States reported exemptions to use non purpose-bred animals, mainly to carry out work in the wild, or on pet dogs and cats in veterinary research to investigate clinical disease and novel treatments. 22 Member States authorised exemptions to allow work outside a user establishment. Work in the wild was the most common reason to investigate animals in their natural habitat, followed by research under commercial conditions on farm animals, and work in veterinary practices.

Reuse after the animal has experienced severe pain in the previous procedure may only be approved in exceptional circumstances. Only one Member State reported that some derogation was permitted in certain projects without providing information on the specific circumstances.

18 Member States reported that exemptions were authorised from the care and accommodation standards. The circumstances included use of metabolic cages, whose dimensions were below those set out in Annex III; "commercial stocking densities" during research studies in agricultural animals into for example mechanisms of spread of infectious disease; single housing, for example, to measure behavioural responses to stimuli; and food/water control as a motivational tool in training animals to perform novel or learned tasks.

It is noteworthy, given the scale and breadth of exemptions for variations in the housing and care requirements to enable scientific projects to proceed, that ten Member States had not reported any requests for exemptions from these requirements.

3.9 Animal Welfare Body

Each establishment which breeds, uses or supplies animals must have an Animal Welfare Body to advise staff on issues relating to the welfare and care of animals; on aspects of the Three Rs; to establish and review internal operational processes regarding the welfare of animals housed or used; to follow the development and outcome of projects and to advise on rehoming schemes.

In many Member States, the composition of Animal Welfare Bodies is broader than the minimum set out in the Directive. Almost one-third have mandated additional members in their national legislation, and others have encouraged a wider membership in administrative/guidance documents. The common mandated addition is inclusion of the Designated Veterinarian, although laypersons have been included by a few. In large establishments, the frequency of meetings was higher (up to once a month), and in some, the functions were divided up into sub-groups, to ensure all tasks were covered efficiently and effectively.

The Directive gives the option in small establishments for the tasks of Animal Welfare Bodies to be fulfilled by other means. Just under half of Member States include this option in their national legislation. In practice, however, this option is not used commonly.

Animal Welfare Bodies are recognised as a very positive step to improve welfare and science. Their inputs have raised awareness of the importance of applying the Three Rs for all animals, whether being used, bred or held in stock. Animal Welfare Bodies have improved communication between those conducting procedures and those caring for the animals.

3.10 Principles of replacement, reduction and refinement

The Directive requires a systematic application of the Three Rs in all interaction with animals. The responses to how the Three Rs are addressed satisfactorily within authorised projects and during housing and care included:

- Project application forms have specific sections on the Three Rs, requiring, for example, literature reviews and searches on the Three Rs;
- Animal Welfare Bodies advise project applicants on the Three Rs, and ensure implementation of the Three Rs is continuously reviewed and updated during the project;
- Experts' challenge on the Three Rs during project evaluation, and compliance with the Three Rs is checked as part of the inspection process.

3.11 Tissue sampling of genetically altered animals

Member States were required to submit representative data on the methods used for genotyping (genetic characterisation of an animal) during the creation, maintenance and use of genetically altered animals.

However, due to numerous errors in the reporting, it was difficult to draw conclusions hence only the data on mouse tissue sampling methods were analysed.

For over half the mice sampled, tissue coming from identification of the animal was used for genotyping, hence not adding further welfare harm to the animal. 89% of those samples came from ear clipping and 11% from toe clipping.

In terms of methods used under a project authorisation, tail biopsy, followed by ear biopsy are the most common. The reported severities differed (mild or moderate). The reasons for the differences are not reported but may be due to refinement techniques such as anaesthesia (local or general) and analgesia.

Less than 2% of methods reported are "non-invasive" (below threshold of minimum pain, suffering, distress or lasting harm requiring project authorisation). This concerns mostly the use of post-mortem material, or the use of observation, exposure to specific lighting conditions or hair sampling.

This information will serve as a baseline for future reports. The obligation to refine tissue sampling methods should be systematically addressed. When invasive methods are used for identification, these should provide surplus tissue for genotyping. As non-invasive methods become available, these should be taken up where technically possible.

3.12 Enforcement

3.12.1 Authorisation of breeders, suppliers and users

In the EU, in 2017, there were just under 4000 active authorised breeders, suppliers and/or users of animals carrying out procedures under around 16,500 authorised projects. A comparison of numbers between Member States is discouraged because the terms 'breeder/supplier/user' and 'project' may be regulated differently. For example, in one Member State a university may hold only one 'user' authorisation covering all of its animal facilities compared to another Member

State in which each animal facility (within the same university) is considered a separate legal person holding an individual user authorisation.

	Total number of authorised breeders, suppliers and users	Total number of authorised projects
2013	2,477	6,063
2014	3,547	11,210
2015	3,816	15,044
2016	3,759	15,246
2017	3,862	16,708

Table 4. Numbers of operators and authorised project in the EU, years 2013 - 2017

3.12.2 Withdrawals of project authorisation, and authorisations of breeders, suppliers and users

19 Member States stated that no project authorisations were withdrawn in the reporting period. The others gave a variety of reasons for withdrawing authorisations: animal welfare concerns; poor experimental methodology/scientific design; use of higher numbers of animals than authorised and failure to provide statistical information on animal use.

21 Member States stated that no authorisations for breeders, suppliers or users were withdrawn in the reporting period as a consequence of enforcement action. One Member State reported that some establishments closed due to their inability to meet the new requirements in Annex III on accommodation and care. Authorisations withdrawn were due to water damage, failure to meet building requirements, and one failure to renew the application. Five Member States did not provide any information in response to this question.

3.12.3 Infringements, administrative and legal actions, and penalties

Member States use a range of administrative and legal actions, dependent on the nature of the infringement. Typically, minor breaches are handled administratively requiring timely, corrective action by the transgressor.

Tariffs increase in case of inaction or delay in taking corrective measures, and, in particular, where avoidable animal suffering has occurred. For very severe cases, some Member States have the option of imprisonment as a sanction.

Three Member States recorded no infringements in the reporting period and two Member States stated that there were no cases severe enough to warrant administrative or legal action. All other Member States provided information on the types of infringements encountered and action taken.

Commonly reported infringements included performance of procedures without appropriate authorisation, inappropriate record keeping, inadequate training and failure to meet requirements of Annex III.

Most infringements were handled administratively, with corrective measures to be put in place preventing recurrence. Some Member States carry out follow-up inspections to ensure deficiencies had been resolved. Few reports of legal action were reported, with such action generally kept for the more severe cases, in particular those involving unnecessary animal suffering. One Member State reported that (anonymised) information on infringements and actions was published annually.

3.12.4 Inspections

Member States must ensure regular inspections by competent authorities of all breeders, suppliers and users and their establishments, to verify compliance with the Directive.

The competent authority must adapt the frequency of inspections based on a risk analysis, taking account of the number and species of animals housed, the previous history of compliance with the Directive, the number and types of projects carried out by the user in question and any information that might indicate non-compliance.

24 Member States confirmed using the EU Inspection Risk Analysis Criteria[12].

Inspections must be carried out on at least one third of the users each year. However, breeders, suppliers and users of non-human primates must be inspected at least once a year. An appropriate proportion of the inspections must be carried out without prior warning.

Year	Number of announced inspections	Number of unannounced inspections	Total inspections	Proportion unannounced
2013	1,717	978	2,695	36%
2014	2,046	1,646	3,692	45%
2015	2,080	1,388	3,468	40%
2016	2,143	1,353	3,496	39%
2017	2,045	1,367	3,412	40%

Table 5. Numbers of inspections in the EU, years 2013 - 2017

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%.

[12] https://ec.europa.eu/environment/chemicals/lab_animals/pdf/guidance/inspections/en.pdf

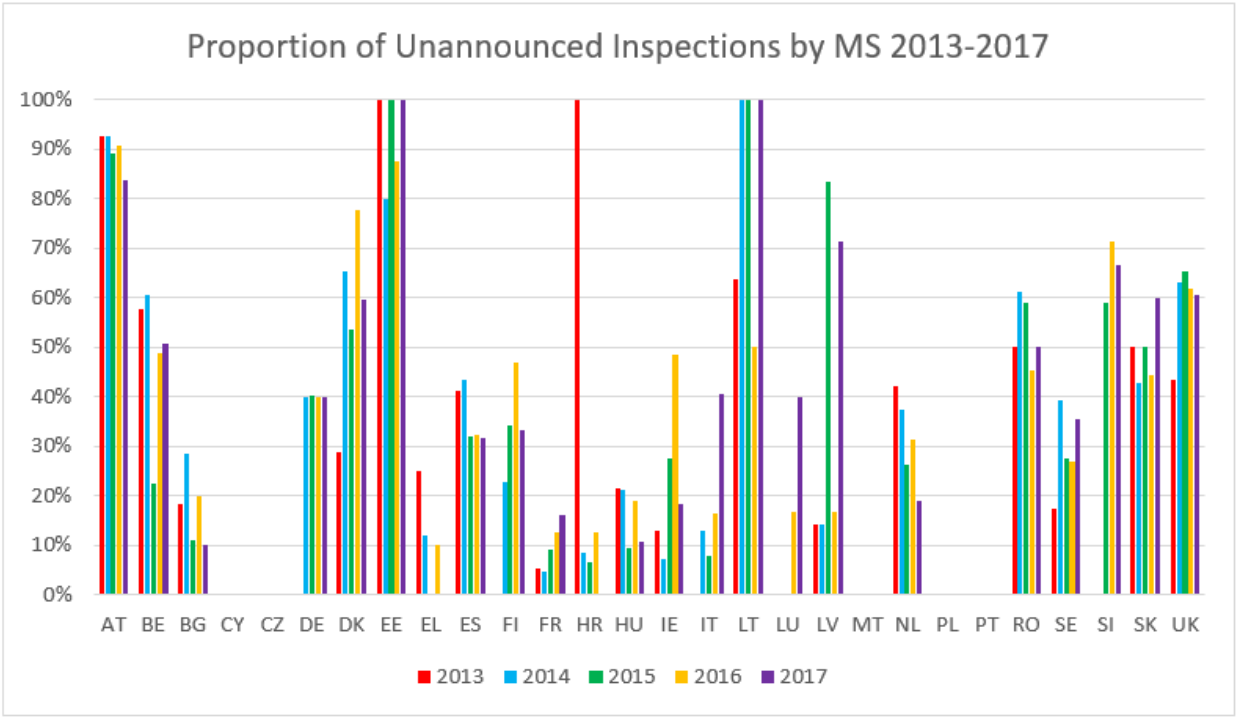

Table 6. Proportion of unannounced inspections by Member State, years 2013 - 2017

4. Conclusions

The implementation of the Directive rather varies between Member States. However, it is clear that most Member States are making determined efforts to comply with the Directive. Experience of the new legislative requirements is still at an early stage, in particular for those Member States whose transposition was slow.

Education and training requirements continue to differ between Member States even if some simplified processes have been installed to facilitate movement of scientists. 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.

The implementation of Animal Welfare Bodies and National Committees has been successful, although influenced by the available resources.

All Member States already achieved the first stage of the Directive's ambitious strategy, to produce, in the EU, only second or higher generation purpose bred non-human primates for research purposes.

Regular inspections take place, including on average 40% unannounced inspections. However, some Member States still do not reach the minimum level of inspections required by the Directive.

For the first time in the EU, the number of animals bred and killed without being used in procedures were provided for 2017. Together with the annual statistics, this indicates the total numbers of animals currently required to support EU research and testing, setting a baseline for measuring immediate and future efforts towards reducing the use of animals.

As guardian of the Treaties and in line with its commitment in response to the European Citizens Initiative "Stop Vivisection", the Commission is assessing the conformity of the transposition into national legislation assertively. This resulted in the Commission services opening EU Pilots with all Member States. While some EU Pilots led to successful results, others were followed up by a formal infringement procedure launched by the Commission. For yet other Member States,

the assessment of their replies is ongoing. If non-compliance is identified, the Commission may launch further infringement procedures.

The review of the Directive (November 2017[13]) showed problems in the publication of non-technical project summaries of authorised projects. The Commission then streamlined reporting obligations, amending the Directive through Regulation (EU) 2019/1010[14] in June 2019. These include setting up an open access, searchable central EU database for both non-technical project summaries and statistical data hence significantly improving transparency of animal use in the EU and reducing administrative burden.

In addition, the Commission has prioritised efforts to facilitate implementation. Together with stakeholders, the Commission developed guidance documents addressing key concepts in the Directive, available in all 23 Union languages. The Commission is committed to continuing this work. The Commission is also addressing future scientists through development of education and training tools focusing on alternatives to animal use.

[13] COM/2017/0631 final

[14] OJ L 170, 25.6.2019, p. 115–127