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COMMISSION STAFF WORKING DOCUMENT

Accompanying the document

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

{COM(2020) 15 final}

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INTRODUCTION

This Staff Working Document is an annex to the main report[1] to the European Parliament and the Council on Member States' implementation of Directive 2010/63/EU on the protection of animals used for scientific purposes[2] ("the Directive").

Under Article 54(1), Member States are required to send the information on the implementation of the Directive and in particular Articles 10(1), 26, 28, 34, 38, 39, 43 and 46 to the Commission. The detailed content of Member State reporting requirements is laid out in Annex I of Commission Implementing Decision 2012/707/EU[3] ("the Annex").

In June 2019, the Directive was amended by Regulation (EU) 2019/1010[4] ("the Regulation"). In particular, Article 54(1) was amended to require the next Member State implementation reports to be submitted to the Commission through electronic transfer by 10 November 2023, and every five years thereafter. 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.

This Commission Staff Working Document presents the results of the examination of the reports by the Member States in greater detail than in the report to the European institutions, which focuses on the main elements. It describes how Member States have implemented the Directive, in line with the requirements of the Annex, and highlights any identified issues. It does not provide an exhaustive account of all national implementation measures.

i. Information from the Member States

Member States were requested to submit their national implementation reports using a tailored questionnaire. The deadline for the submission was 10 November 2018 in accordance with Article 54(1), as applicable at the relevant time. The questionnaire covered all the elements described in the Annex to Commission Implementing Decision 2012/707/EU. Furthermore, it contained some additional, voluntary, questions (marked with an asterisk) to provide wider context to the answers. In some cases, an element described in the Annex was broken down to sub-questions to aid comprehension of the reporting obligation.

22 Member States submitted their reports by the deadline. Of the six Member States that were late, the last submitted the report at the end of February 2019. When reviewing the content and the quality of the provided information, on the one hand several shortfalls were identified including unanswered compulsory questions, incorrect data due to misunderstanding of the reporting obligation, or the report containing conflicting information. On the other, some Member State reports gave very detailed information and often provided additional, voluntary information,

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

to aid understanding. Concerning the shortfalls, in some cases further clarity was obtained through bilateral communication, but in a number of cases it was not possible due to the tight deadline set for the publication of the EU report. The conclusions and tables included in this report are based on the original submissions and incorporate directly any later updates/corrections to these. The last Member State correction to the original submission was received as late as September 2019. Member State submissions can be found at https://ec.europa.eu/environment/chemicals/lab_animals/index_en.htm.

The inconsistent quality of reporting has made drawing of conclusions at EU level challenging. Some such areas will be highlighted in the report.

ii. Structure of the Report

The structure of the report will follow the format and order as set out in the Annex. In addition, to the legal reporting obligations, the questions from the questionnaire precede the analysis. In some cases, survey questions are grouped together when these are closely linked and would have otherwise resulted in repeated answers. Some comparative tables are presented but only drawing from elements that make part of compulsory Annex I reporting obligations, and for which the basis of the reporting is assumed to be similar.

A. GENERAL INFORMATION

Reporting obligation

"Changes made to national measures regarding the implementation of Directive 2010/63/EU since the previous report"

Analysis

Question in the questionnaire

A - 1 Describe main changes made to national legislative measures regarding the implementation of Directive 2010/63/EU. For the purposes of the first implementation report, the changes should reflect those made to the previous legislation (under Directive 86/609/EEC) as a result of the transposition of the Directive, and any subsequent amendments. "Description of main changes" should provide an understanding of the key elements that underwent legislative changes.

Ten Member States indicated that the national legislation had been changed to meet the provisions of the new Directive, but did not provide any information on what changes were required to the previous legislation.

Of the remaining responses, some Member States reported major changes to their legislative structure, for example with the introduction for the first time of project evaluation and authorisation processes, the publication of non-technical project summaries and the requirement to have Animal Welfare Bodies in each establishment.

Others reported fewer changes, for example, Member States where project authorisation systems had already been in place under Directive 86/609/EEC. However, the new requirements for severity classification and reporting, non-technical project summaries, retrospective assessment and timeliness of authorisation decisions necessitated changes to

legislation in all Member States. In addition, the following elements were reported by a majority of Member States as having resulted in significant changes:

- the extended scope to include foetal forms of mammals and also Cephalopods;
- the new requirements for accommodation and care and methods of killing;
- the risk-based approach to, and frequency of, inspections.

The focus on alternatives has also required many Member States to consider how best to meet the provisions in the Directive. A number of Member States have developed voluntary Three Rs centres to promote improved availability of information and development of alternatives.

National Committees were new to many Member States.

In summary, from the responses received, there were significant differences among Member States on the extent of changes required to existing legislation to meet the requirements of the new Directive.

B. STRUCTURES AND FRAMEWORK

B.1. Competent authorities (Article 59 of Directive 2010/63/EU)

Reporting obligation

"*information on the framework for competent authorities, including the numbers and types of authorities*"

Background

The Directive requires that the following tasks are performed by a competent authority

1) Authorisation of breeders, suppliers and users (Article 20(1))
2) Inspections (Article34(1))
3) Project evaluation (Article 36(2))
4) Project authorisation (Article 36(1))
5) Retrospective assessment of projects (Article 39(1))

A competent authority is usually a public authority. However, the Directive allows also bodies other than public authorities to be designated as competent authorities provided the conditions in Article 59(1) are met, namely, that the body

> *"(a) has the expertise and infrastructure required to carry out the tasks; and*
>
> *(b) is free of any conflict of interests as regards the performance of the tasks."*

Finally, in reference to the task of project evaluation, the Directive further requires in its Article 38(3) and (4):

> *"3. The competent authority carrying out the project evaluation shall consider expertise in particular in the following areas:*
>
> *(a) the areas of scientific use for which animals will be used including replacement, reduction and refinement in the respective areas;*
>
> *(b) experimental design, including statistics where appropriate;*

(c) veterinary practice in laboratory animal science or wildlife veterinary practice where appropriate;

(d) animal husbandry and care, in relation to the species that are intended to be used.

4. The project evaluation process shall be transparent.

Subject to safeguarding intellectual property and confidential information, the project evaluation shall be performed in an impartial manner and may integrate the opinion of independent parties. "

Analysis

Questions in the questionnaire

2 - Is the implementation of Directive 2010/63/EU a responsibility of one or more ministry/ministries

2.bis - Please provide the name of the ministry

2.tris - Please provide the name of the ministries involved and briefly describe the distribution of responsibilities

B - 1.1 Provide information on the framework for competent authorities. Where there is more than one competent authority, explain 1) how the tasks are divided between different authorities 2) how the authorities interact to ensure that the Directive is implemented effectively. If possible, please explain what measures are in place to ensure coherent approach and consistency of outcomes. Make sure to consider all five tasks requiring a competent authority i.e. authorisation of establishments, inspections, project evaluation, project authorisation and retrospective assessment.

** B - 1.1.bis An organogram or another explanatory document can be uploaded here.*

B – 1.2 There is only one public competent authority for the Member State, or for each region (where regional structure) who is tasked with all five tasks requiring competent authority (I.e., the same competent authority (national/regional) performs all tasks: authorisation of establishments, inspections, project evaluation, project authorisation and retrospective assessment of projects). Yes/No

B - 1.2.bis If your MS has a regional structure, how many regional authorities are there?

B - 1.3 Other than single national or regional authority: Please provide information on the numbers and types of authorities per task

B - 1.3.bis Please explain if "other" than national/regional authority and/or "non-public authority" was selected

Implementation of the Directive

In addition to requiring information on competent authorities assigned for the tasks in the Directive, the questionnaire also invited Member States to specify the ministry(/ies) responsible for the implementation of the Directive. Where the responsibility was shared, further clarification was requested on the distribution of responsibilities.

Is the implementation of Directive 2010/63/EU a responsibility of one or more ministry/ministries?	
Responsibility of a single ministry	21
Shared responsibility between two or more ministries	7
Total	**28**

Most ministries responsible for the implementation of the Directive are those responsible for agriculture and the environment, although some are responsible for health, education, science and innovation.

Competent authorities

It is challenging to draw EU level conclusions on the way in which tasks are assigned to competent authorities. Member States have highly different structures varying from central to regional and local structures. In addition, in some cases the designation of tasks between competent authorities may vary even between different regions within a single Member State. Member States have implemented the responsibilities for competent authorities in a number of different ways, to some extent reflecting the different national legislative frameworks and to some extent reflecting the numbers of animals used.

The analysis is further complicated by the fact that some Member States may seem to have misunderstood some of the questions, for example, reporting only one single public authority, however, having a regional structure with regional authorities.

Finally, it is not certain that the term 'competent authority' is understood in the same manner by all Member States. On one hand, some Member States have stated that only one competent authority is responsible for five tasks in the Directive. On the other, in written comments, reference is made for example to project evaluation which is delegated to 'ethics committees'.

Is there only one public competent authority for the Member State?	
Yes	15
No; there are two or more different types of competent authorities depending on the task	13
Total	**28**

If your Member State has a regional structure, how many regional authorities are there?	
Latvia	1
Luxembourg	0
Austria	10
United Kingdom	2
Total	**13**

Of the **15 Member States** who reported having **one public competent authority**, nine (Bulgaria, Ireland, Croatia, Cyprus, Latvia, Lithuania, Luxembourg, Portugal and Slovakia) indicated a single competent authority being responsible for all five tasks, namely

authorisation of establishments, inspections, project evaluation, project authorisation and retrospective assessment.

Two Member States (Austria and United Kingdom) stated that there were regional competent authorities (ten and two regional authorities respectively) but that one competent authority in each region is responsible for all five tasks.

Four Member States (Denmark, Italy, Romania and Slovenia) gave conflicting information:

- Denmark – indicated one competent authority – but in another instance reported **split responsibility** between Danish Experimentation Council and Animal Experiments Inspectorate;
- Italy – indicated one competent authority – but in another instance reported **split responsibility** for tasks and separate competent authorities for authorisation and inspection of breeders, suppliers and users;
- Romania - indicated one competent authority - but in another instance stated that the evaluation of the projects is carried out by **ethics committees established within the establishments of users;**
- Slovenia – indicated one competent authority – but in **another instance** reported ten regional offices;

13 Member States (Belgium, Czechia, Germany, Estonia, Greece, Spain, France, Hungary, Malta, Netherlands, Poland, Finland and Sweden) indicated **more than one competent authority.**

Other than single national or regional authority: Please provide information on the numbers and types of authorities per task.

N = National; R = Regional; O = Other ; P = Public authority; NP = Non-public authority

Member State	Number of CA for authorisation of establishments			Number of CA for inspections			Number of CA for project evaluation			Number of CA for project authorisation			Number of 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

A number of Member States have formal regional structures, for example Germany, Spain and Austria, where all five tasks are allocated to the regional governments who determine the allocation of tasks within their respective region.

In many Member States, the tasks are allocated to two, three or four different types of competent authorities, responsible for different tasks in the Directive.

Where there are two or more different types of competent authority depending on the task, numbers of these in five Member States suggest that there may be grouping of tasks such that authorisation of establishments and inspections may be done by the same authority, and project authorisation and retrospective assessment by a separate authority. In two additional Member States the same authority may perform project evaluation and retrospective assessment.

The more common division is a separation of inspection and authorisation of breeders, suppliers and users, from project evaluation and authorisation, and retrospective assessment.

In some Member States, for example Hungary and Netherlands, a single competent authority is responsible for authorisation of breeders, suppliers and users and inspections, but separate competent authority/(ies) have responsibility for project evaluation and authorisation, and retrospective assessment.

In contrast, for example, in Poland, although the division of functions is similar, they reported 305 competent authorities with responsibility for inspection and authorisation of breeders, suppliers and users. Inspection is often undertaken by Veterinary Authorities, and the competent authority role for this function is often undertaken at a local or regional level – for example Greece reported 71, Germany 285.

The structures for project evaluation and authorisation also differ significantly – from single committees (competent authorities) charged with evaluation and authorisation for all projects in the Member State, to regional structures (for example Germany (26), Austria (10) and Sweden (6)) to local ethics committees which evaluate only projects local to that area, or within a single establishment (for example Belgium (33), France (125)). Authorisation may be performed by another competent authority.

It has been acknowledged that the greater the number of competent authorities involved in the implementation of the Directive within a Member State, the greater the challenges are to ensure a common and consistent approach and outcomes.

Methods adopted to promote a consistent approach include training for project evaluators and inspectors, regular meetings of competent authorities, standardised project application and evaluation forms, standard checklists for authorisation and inspection of establishments.

The 2017 review of the Directive[5] identified difficulties for the scientific community due to variations in implementation within and between Member States. Given the significant variations in competent authority structures across Member States it is perhaps not surprising that concerns over inconsistencies were raised.

[5] https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1510219889073&uri=COM:2017:631:FIN

Five Member States submitted an organogram or another explanatory document (Belgium, Germany, Latvia, Netherlands and Slovakia). Three of these gave a pictorial representation, which appear to correlate with elements of written text. These are included in the detailed Member State summaries.

B.2. National committee (Article 49 of Directive 2010/63/EU)

Reporting obligation:

"*information on the structure and operation of the national committee*"

Background

Article 49

National committees for the protection of animals used for scientific purposes

1. Each Member State shall establish a national committee for the protection of animals used for scientific purposes. It shall advise the competent authorities and animal-welfare bodies on matters dealing with the acquisition, breeding, accommodation, care and use of animals in procedures and ensure sharing of best practice.

2. The national committees referred to in paragraph 1 shall exchange information on the operation of animal-welfare bodies and project evaluation and share best practice within the Union.

Analysis

A number of Member States already had in place similar committees advising on matters relating to the use of animals in research, whereas for others this was a new requirement. Although many Member States had a committee in place soon after transposition, in others it took some years to develop the necessary framework, and therefore experience of the various National Committee functions are varied.

The general view given is that as the role evolves, links between Animal Welfare Bodies and National Committees continue to strengthen, but their effectiveness is almost wholly dependent on suitable resourcing by the Member State.

2.1.Structure

Question in the questionnaire

B - 2.1 Provide information on the structure of your National Committee

National Committees vary in composition, but generally include members of differing scientific and welfare backgrounds and disciplines, with logistical support provided by the ministry(/ies)/authorities – depending on Member State structure. Some members are also members of Animal Welfare Bodies.

Membership is generally for a limited period, and appointments are endorsed by ministry(/ies)/authorities.

The frequency of meetings varies significantly, largely dependent on the size and complexity of scientific work conducted, and whether or not additional responsibilities, such as project evaluation, have been added to their remit. Meetings reported vary from annual to monthly.

Financial support varies, and this is reflected in the level of activities achieved.

A number of National Committees have bespoke web-sites[6], and publish their activities.

2.2.Advice to competent authorities, in particular with regard to project evaluation

Question in the questionnaire
B - 2.2 Provide information on the operation of your National Committee in relation to its task to advise competent authorities, including on how it aims to address coherent approach to project evaluation and review strategies at national level as provided in Recital 48

In a few Member States, the National Committee has also assumed the task of project evaluation for all projects in the Member State. In others, the competent authorities refer specified types of projects (for example those using non-human primates, or those presenting difficult or novel ethical challenges) to the National Committee or invite their view on requests for exemption, for example, to conduct of procedures outside establishments.

A number of National Committees have developed templates and guidance for project applications and evaluations to facilitate consistency. These have been found to be helpful where there are multiple competent authorities responsible for project evaluation. In a few Member States, the National Committee is involved in training of project evaluators. Standardised formats for submission of non-technical project summaries and retrospective assessment have also been developed by some. Several National Committees are involved in oversight and approval of education and training courses for personnel involved in animal use and care.

Competent authorities in many Member States have utilised the National Committee to address specific questions, but the level of consultation varies significantly, with one response indicating that the National Committee had received no requests from competent authorities. Other National Committees have been consulted by competent authorities, for example on appropriate accommodation and care practices for species without detailed requirements in Annex III. National Committees have also been invited to develop guidance on specific areas of scientific use and care, for example on staff responsibilities for animal use and care, on rehoming and, on advice to avoid duplication of procedures.

2.3.Advice to Animal Welfare Bodies

Question in the questionnaire
B - 2.3 Provide information on the operation of your National Committee in relation to its task to advise animal welfare bodies

In the majority of Member States, National Committees have developed effective communication channels with Animal Welfare Bodies to disseminate relevant information and have provided mechanisms for Q&A and sharing of best practice. In some Member States the ministry(/ies)/authorities remain a valuable source of information.

[6] https://ec.europa.eu/environment/chemicals/lab_animals/nc_en.htm

A few National Committees have invited contributions from Animal Welfare Bodies by means of questionnaires to inform and focus their future work programme.

Provision of up-to-date information on replacement (alternatives) has been requested of a few National Committees. One National Committee reported that no advice had been sought by Animal Welfare Bodies.

2.4.Sharing of best practice

Question in the questionnaire

B - 2.4 Provide information on the operation of your National Committee in relation to its task to share best practice

Some National Committees have organised meetings of Animal Welfare Bodies and arranged training sessions for Animal Welfare Body members, for example, a symposium on experimental design.

One Member State hosts an annual symposium to showcase best practice initiatives, and provides financial support to encourage further improvements.

Symposia are organised by some National Committees on relevant topics, for example neurological and psychiatric models, promoting consistency in statistical reporting, and procedural training for animals.

Good practice guidance has been developed on a number of topics, either at the request of the competent authority, feedback from Animal Welfare Bodies, or on their own initiative. Examples include guidelines on tumour models, blood sampling, recognising and alleviating pain, water and food restriction for scientific reasons.

Questions in the questionnaire *[voluntary question]*

** B - 2.5 Has the EU Guidance on Animal Welfare Bodies and National Committees been made available to the members of National Committee and establishment Animal Welfare Bodies?*

EU Guidance made available	
Yes	25
No	1
No response	2
Total	**28**

Question in the questionnaire *[voluntary question]*

** B - 2.6 Has additional official guidance for Animal Welfare Bodies and National Committee been developed to facilitate implementation?*

Additional guidance developed	
Yes	7
No	18

No response	3
Total	**28**

Question in the questionnaire *[voluntary question]*

** B - 2.6.bis If you consider this guidance helpful for other Member States to facilitate the implementation of the Directive, please provide web-address for the guidance, where available*

Some Member States have developed additional guidance and websites are provided in the detailed Member State summaries.

B.3. Education and training of personnel (Article 23 of Directive 2010/63/EU)

Reporting obligation

"*information on the minimum requirements referred to in Article 23(3) of Directive 2010/63/EU including any additional educational and training requirements for staff coming from another Member State."*

Background:

Directive provides, in its Article 23 that

> *"1. Member States shall ensure that each breeder, supplier and user has sufficient staff on site.*
>
> *2. The staff shall be adequately educated and trained before they perform any of the following functions:*
>
> > *(a) carrying out procedures on animals;*
> >
> > *(b) designing procedures and projects;*
> >
> > *(c) taking care of animals; or*
> >
> > *(d) killing animals.*
>
> *Persons carrying out the functions referred to in point (b) shall have received instruction in a scientific discipline relevant to the work being undertaken and shall have species-specific knowledge.*
>
> *Staff carrying out functions referred to in points (a), (c) or (d) shall be supervised in the performance of their tasks until they have demonstrated the requisite competence.*
>
> *Member States shall ensure, through authorisation or by other means, that the requirements laid down in this paragraph are fulfilled.*
>
> *3. Member States shall publish, on the basis of the elements set out in Annex V, minimum requirements with regard to education and training and the requirements for obtaining, maintaining and demonstrating requisite competence for the functions set out in paragraph 2.*

4. Non-binding guidelines at the level of the Union on the requirements laid down in paragraph 2 may be adopted in accordance with the advisory procedure referred to in Article 56(2).”

Analysis

Question in the questionnaire

B - 3.1 Provide information on the minimum requirements for education and training for functions in Article 23(2)

The level of detail and clarity in responses vary significantly, making it challenging to determine with certainty what the exact training requirements are across the EU. It is important to note in this context that education and training matters remain the competence of the Member States, although minimum requirements are listed in the Directive (see Annex V of the Directive).

The national legislation requires appropriate education and training for the personnel listed in Article 23(2). General requirements are included in national legislation, the majority of Member States have published the EU Guidance document on Education and Training Framework[7] and a minority have produced additional Member State guidance. Several Member States reported that recent improvements in training provision are underway.

Some Member States state that there are minimum educational requirements, including higher education degrees required for the role as project designer in several Member States.

From the information provided

Training courses are provided	Number of MS
Accredited and/or MS approved courses	6
Training course provided but not formally accredited/approved	4
Local/establishment level training	5
Unclear	10
None	3

Accredited/Member State approved courses seem to be available only in a minority of Member States. Training courses without reported quality assurance are provided by a few others. Local training and supervision occurs in some Member States, and what training, if any, is delivered in other Member States is unclear on the basis of the responses.

Some Member States define a syllabus for training courses and some determine a minimum duration of training, which can differ between Member States. Many training courses still relate to teaching hours, or numbers of lessons, but not attainment of specific Learning Outcomes – contrary to what is promoted in the EU Guidance document on Education and Training Framework endorsed by the Member States.

[7] https://ec.europa.eu/environment/chemicals/lab_animals/pdf/guidance/education_training/en.pdf

A small number, perhaps as many as nine, seem to have implemented the EU guidance document on Education and Training Framework. For others it is unclear how quality of training ensures that all necessary learning is acquired to an adequate standard.

In three cases, while training courses are required, they may be completed within the first 6-12 months of starting work. It was not clear from the responses, whether it is systematically required that these persons, when working with animals, work under supervision as obliged by the Directive, until such time training is completed and competence demonstrated.

From the responses provided (November 2018), there seem to be three Member States where no formal requirement for training have been adopted.

- Italy: "*With regard to the information on the minimum requirements for education and training of staff referred to in Article 23(2) of D.lgs. 26/2014, we should point out that no ministerial decree governing this matter has yet been issued"*

- Cyprus: "*So far there are general requirements for education and training for functions in Article 23(2) and these are fulfilled via authorization of the persons who carry out procedures on animals (personal license) and via evaluation of the competence of the persons designing procedures and projects during project evaluation. Moreover, in 2019 the National Committee schedules to start organizing training programs for all functions so that the education and training is more consistent and invariable"*

- Romania: "*There are no specific requirements other than those established by law. A specific legal order on training for functions in Art. 23(2) is currently being drafted;"*

Greece indicated that a ministerial decision regulating the procedures required in order to authorise training of scientific associations or other training bodies and training programs for all four functions is about to be issued.

There remain differing requirements among Member States for training of personnel under Article 23, in terms of course content, duration and minimum educational requirements, although there are now mechanisms in place in the majority of Member States to consider the suitability of training elsewhere when applications are submitted, to avoid unnecessary duplication of training, costs and delays to the personnel concerned.

Question in the questionnaire
B – 3.2 Provide information on the requirements for obtaining, maintaining and demonstrating requisite competence for functions in Article 23 (2) – that is carrying out procedures on animals, taking care of animals or killing animals

Information, often repetition from earlier question in the questionnaire, was provided on training courses, but little on attainment and maintenance of competence, which was a new obligation introduced by the Directive. It is not clear in many responses what systems are required to ensure attainment and maintenance of competence.

In some Member States, it is the responsibility of the establishment to train and ensure competence of the personnel, seemingly in the absence of formal training courses. Within the establishment, this is often effected by the person identified in Article 24(1)(c) – person

responsible for ensuring staff are adequately educated, supervised until competent, that competence is maintained and that they are continuously trained.

This is a new requirement for Member States and acknowledgement was made that in many Member States there are no formal systems for supervision and competence assessment. A few Member States noted that further guidance was in preparation, and some training providers are working on measures for consistent assessment of competence (for example DOPS – Direct Observation of Procedural/practical Skills).

Some Member States indicated that if staff had not been working with animals for a specified period of time, the individual would have to undergo re-training and/or a period of supervision.

One Member State noted that annual refresher training would be provided by the establishment, and that if there are extended breaks between carrying out any of the tasks, re-training would be required. A few (for example Spain, Luxembourg and Slovakia) noted formal requirements for maintaining standards (CPD – Continued Professional Development), and some professional organisations, for example for veterinarians and animal technologists, have published guidance.

Despite the diversity of training, there were no comments suggesting that lack of competence was an issue. It was often noted that implementation of education and training requirements, including attainment and maintenance of competence, is checked during inspections, suggesting that there is oversight of outcomes (at least in some Member States) and that if training were less than ideal, it could be identified and remedied.

A few responses giving examples of some different approaches to supervision and competence assessment are included below

- Spain: "*Maintenance of training:*

  1. The initial training shall be maintained through ongoing training activities.
  2. The ongoing training activities shall aim to ensure the improvement and updating of the skills and knowledge initially acquired and shall meet the following conditions

  a) *They shall include the delivery of or attendance at courses, seminars, lectures, workshops or scientific conferences; authorised stays in research centres or other similar activities which are specified by the competent bodies and are aimed at learning about new or updated techniques, methods or rules applicable to animal experiments.*
  b) *They shall be related to the learning outcomes of the modules corresponding to the function in question.*
  c) *As a whole, they shall have the minimum duration set out in Annex III for each function.*
  d) *They shall be accredited through diplomas or certificates of attendance in which reference is made to their content and duration.*
  e) *Their content shall enable the training for one or more functions to be maintained.*
  f) *They shall respect the conditions laid down for the use of live animals in training courses."*

- Luxembourg: *"The framework for obtaining the competence for carrying procedures, taking care of animals and performing euthanasia begins with the trainee initially observing the procedures/euthanasia/taking care of animals being carried out, he then carries out the procedures/euthanasia/taking care of animals under close supervision until competency is acquired. The supervision period and the time until competency is attained vary for each individual, the task being performed, technical complexity and the ability of the individual. Only after full competency has been attained the trainee is allowed to conduct the procedure/ euthanasia/ taking care of animals unsupervised. The demonstration and the assessment of requisite competence is performed by the designated veterinarian (Article 25) or/and the person responsible for education, competence and CPD (Article 24). The progress of obtaining requisite competence for functions listed in Article 23§2 must be documented in a record at the breeder/supplier/user establishment for each individual and for each procedure, function and task."*

- Netherlands: "*The person (responsible for training) checks that staff are trained in accordance with the requirements, both in theoretical subjects in order to maintain competence (additional and continuing development) and in practical subjects in order to maintain or obtain proficiency (skill). Although the Dutch authorities leave open the possibility of laying down more detailed requirements, there are at present no additional rules regarding the continuing development of staff who carry out procedures on animals or who design animal experiments"*

- Slovenia: "*The basic training for animal keepers and persons responsible for killing animals comprises at least 30 lessons, whereas the basic training for persons who perform procedures on animals comprises at least 40 lessons. After a person has successfully completed his or her basic training, he or she works under the supervision of a mentor for at least six months. The mentor is appointed by the animal welfare expert in the organisation where the above-mentioned persons work. When a person demonstrates the requisite professional competence, the animal welfare expert enters him or her in the register of qualified persons on the basis of the mentor's written opinion. The persons referred to in Article 23(2) (a), (c) and (d) of the Directive must maintain their professional competence through regular work, by keeping up to date and by refreshing their knowledge in their scientific or professional field, as demonstrated by scientific or expert publications or by participating in scientific or expert meetings within five years of the completion of basic training. The further training of animal keepers and persons responsible for killing animals must comprise at least four lessons, whereas the further training of persons who perform procedures must comprise at least eight lessons.*

- Finland: *"After the theoretical education & training, persons may get more practical training when necessary. They work under supervision until they have needed knowledge and skills. The demonstration and assessment for the official competency is not yet working. This is, however, under a joint development – the assessment, assessment forms and training of evaluators are planned in the working group of FinLAS. The goal is that this process will be working 2019."*

Questions in the questionnaire

B - 3.3 Are there any additional education and training requirements for staff coming from another Member State?

B - 3.3.bis Provide information on additional education and training requirements for staff coming from another Member State

The 2017 review of the Directive[8] suggested that there were still difficulties for staff and researchers in moving between Member States as education and training requirements differed and additional training was required, causing delays in being able to start work.

There was acknowledgement in some Member States of acceptability of training courses, which had been provided by other Member States or other external course accreditors, for example FELASA[9], such that persons coming from another Member State need not necessarily complete all within-Member State training. Details are generally checked by the competent authority during assessment of an application for authority to work with animals in scientific procedures.

Only eight Member States (Belgium, Denmark, Ireland, France, Netherlands, Poland, Portugal and United Kingdom) indicated that there were additional training requirements for personnel coming from another Member State.

Of these responses, six indicated that training in local legislation and practices would be required. In Denmark there is an e-learning module available.

The UK requires further additional training for project designers and applicants.

The competent authorities will assess the previous training of the applicant to determine whether any further additional training will be necessary. If training in another Member state has been completed and is determined to be equivalent, then the other Member State training is accepted.

There is evidence that training from other Member States is recognised by some others allowing exemption from repeated training in the new Member State.

Question in the questionnaire *[voluntary questions]*

** B - 3.4 Has the EU Guidance on Education and Training Framework been made available to those responsible for education, training and competence in establishments? See table below (3.5).*

** B - 3.5 Have specific training requirements been introduced by authorities for persons in Articles 24, 25 and 38 as recommended by the EU Guidance?*

** B - 3.6 Has additional official guidance on education, training and competence been developed to facilitate implementation?*

[8] https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1510219889073&uri=COM:2017:631:FIN

[9] Federation for Laboratory Animal Science Associations

** B - 3.6.bis If you consider this guidance helpful for other Member States to facilitate the implementation of the Directive, please provide web-address for the guidance, where available?*

	EU Guidance made available	MS Guidance produced	Training of named welfare and care persons	Training of named person responsible for information	Training of named person responsible for training	Training of DV	Training of project evaluators
Yes	**24**	**4**	**8**	**5**	**5**	**8**	**4**
No	4	19	12	15	15	11	16
Unclear						1	
Blank		5	8	8	8	8	8
Total No+Blank	**4**	**24**	**20**	**23**	**23**	**19**	**24**
Grand total	**28**	**28**	**28**	**28**	**28**	**28**	**28**

Specific training relevant to animal care is required for any person responsible for animal care and welfare in a number of Member States, with some but not all requiring degree level training. Few Member States have requirements for training of person responsible for information. In some cases, joint posts are held with the person responsible for care and welfare.

Designated Veterinarian (DV) training: Responding countries mentioned the requirement to be a trained / practising veterinarian. One Member State mentioned an option to appoint another relevant expert, with species specific knowledge and expertise as a requirement. Only one country (the UK) reported a specific training course for DV. Some countries have additional training requirements for DVs including attending modules for other functions. Some mentioned the importance of CPD.

These figures and statements show that many Member State have yet to develop training for the persons named in Article 24 of the Directive.

Five Member States reported that they had developed additional guidance and four of these have provided weblinks available in the detailed Member State summaries.

B.4. Project evaluation and authorisation (Articles 38 and 40 of Directive 2010/63/EU)

Reporting obligation:

"*description of the processes of project evaluation and authorisation and how the requirements of Articles 38 and 40 of Directive 2010/63/EU are met*"

Background:

The Directive provides the following in its Article 38 on project evaluation:

> *1. The project evaluation shall be performed with a degree of detail appropriate for the type of project and shall verify that the project meets the following criteria:*

(a) the project is justified from a scientific or educational point of view or required by law;

(b) the purposes of the project justify the use of animals; and

(c) the project is designed so as to enable procedures to be carried out in the most humane and environmentally sensitive manner possible.

2. The project evaluation shall consist in particular of the following:

(a) an evaluation of the objectives of the project, the predicted scientific benefits or educational value;

(b) an assessment of the compliance of the project with the requirement of replacement, reduction and refinement;

(c) an assessment and assignment of the classification of the severity of procedures;

(d) a harm-benefit analysis of the project, to assess whether the harm to the animals in terms of suffering, pain and distress is justified by the expected outcome taking into account ethical considerations, and may ultimately benefit human beings, animals or the environment;

(e) an assessment of any justification referred to in Articles 6 to 12, 14, 16 and 33; and

(f) a determination as to whether and when the project should be assessed retrospectively.

3. The competent authority carrying out the project evaluation shall consider expertise in particular in the following areas:

(a) the areas of scientific use for which animals will be used including replacement, reduction and refinement in the respective areas;

(b) experimental design, including statistics where appropriate;

(c) veterinary practice in laboratory animal science or wildlife veterinary practice where appropriate;

(d) animal husbandry and care, in relation to the species that are intended to be used.

4. The project evaluation process shall be transparent.

Subject to safeguarding intellectual property and confidential information, the project evaluation shall be performed in an impartial manner and may integrate the opinion of independent parties"

And on project authorisation in its Article 40 that:

"1. The project authorisation shall be limited to procedures which have been subject to:

(a) a project evaluation; and

(b) the severity classifications assigned to those procedures.

2. The project authorisation shall specify the following:

(a) the user who undertakes the project;

(b) the persons responsible for the overall implementation of the project and its compliance with the project authorisation;

(c) the establishments in which the project will be undertaken, where applicable; and

(d) any specific conditions following the project evaluation, including whether and when the project shall be assessed retrospectively.

3. Project authorisations shall be granted for a period not exceeding 5 years.

4. Member States may allow the authorisation of multiple generic projects carried out by the same user if such projects are to satisfy regulatory requirements or if such projects use animals for production or diagnostic purposes with established methods."

Analysis

Questions in the questionnaire
B - 4.1 Have the processes of project evaluation and authorisation been published as a means to implement the requirement of Article 38(4)?
B - 4.1.bis Please provide the web-address where these processes can be found [voluntary question]
B - 4.1.tris Please explain how the obligation for the project evaluation process to be transparent has been achieved?

22 Member States provided web-links to the published processes for project evaluation and authorisation. Of the remaining Member States two referred to templates provided for project application available for applicants on their web-site. Three (Malta, Slovakia and Slovenia) describe briefly their respective processes but not how the transparency of the process is ensured. Lithuania reported non-technical summary publication as the means for transparency.

Question in the questionnaire
B - 4.2 Explain the key steps of the project evaluation and authorisation processes including those for multiple generic projects and simplified administrative procedures in a Member State where these are allowed

A variable amount of information was provided by Member States, which has made it challenging to confirm that all the elements of project evaluation and authorisation processes have been adequately addressed.

Many Member States have a common structure for application to facilitate consistency and invite the correct information. Guidance on completion of application forms is available in many Member States. Other tools include training for project applicants which is provided in a few Member States, and the introduction of electronic application processes, which are reported to be speeding up the processing times.

Different evaluation processes have been developed, ranging from national to regional and local processes. Equally, there are variable sizes to committee structures – from very large to small groups or evaluations by individuals (with other support where necessary).

Some utilise local establishment processes through Animal Welfare Bodies or local ethical review groups to provide further information, a local perspective and/or opinion on the application to better inform the evaluation process.

Methods of decision making vary from simple majority, 2/3 majority to consensus.

Refusals tend to be relatively low as applications are generally revised and improved during the application and evaluation process, and also because the applicant may withdraw an application before it is formally refused.

Little feedback was provided on training of evaluators or what competencies are involved, equally only a few comments were received on the process of harm benefit assessment

Some Member States do not describe the steps in the process, rather providing only the legal framework with little information on how the process works in practice.

An appeals procedure was mentioned by a few - in other Member States no appeal against the project authorisation decision can be made.

It is clear that most Member States are making strenuous efforts to comply with the requirements of the Directive with respect to project evaluation and authorisation. There are multiple requirements in Article 38 and 40, and in most Member States, it cannot be concluded just from responses to question 4.2 that all requirements of these articles are complied with. However, much information on the process is provided by most Member States and links to websites provided (see 4.1), which may provide more evidence of full compliance.

Question in the questionnaire
B - 4.2.bis Where allowed, please explain what type of projects are accepted under simplified administrative procedure?

Not all Member States use the option of the simplified administrative procedure; 10 Member States report using it and a small number of others have it available, but have not yet used it. Not all Member States utilise the option of multiple generic projects.

Types of projects reported to be accepted under simplified administrative procedure, were largely as permitted in Article 42, that is projects

- necessary to satisfy regulatory requirements,
- which use animals for production or diagnostic purposes with established methods, and
- animal experiments carried out to produce, obtain, preserve or propagate substances, products or organisms using established methods.

And which

- contain only procedures classified as ‘non-recovery’, ‘mild’ or ‘moderate’, and
- are not using non-human primates.

Some Member States require reports of substances tested and harms to animals retrospectively, and one that if severe harms occur the project leader needs to submit a non-technical project summary, which is not required at the point of authorisation. Several do not require non-technical project summaries for this type of project.

Question in the questionnaire

B - 4.3 What is the maximum length (in years) for a project authorisation implementing the requirement under Article 40(3)?

All Member States reported maximum durations of five years except one, Greece, where only three years is permitted.

Question in the questionnaire

B - 4.4 Explain how the requirement for expertise for project evaluation in Article 38 (3) is considered.

There appeared to be some variation in how this article has been interpreted, leading to differences in responses. Contrary to the intention of the Directive, a significant number of Member States appear to have interpreted the requirement to be that project evaluation should determine whether these areas of expertise are available *for the project*, not the *evaluation process*.

Many Member State responses replicated the competencies set out in Article 38. Eight Member States specifically stated that the project evaluation process involves expertise in all four areas. Others responded how the required expertise set out in Article 38(3) would be considered as part of the evaluation process. However, very little information was provided on what competences were involved and whether training was provided for those tasked with project evaluation.

The importance of, as well as the difficulty of, getting expertise in experimental design and statistics was emphasised, as well as expertise in particular scientific areas, especially if dealing with projects in narrow fields with few experts.

A number of project evaluation systems retained the option of co-opting external expertise in specific subjects, where the main committee may not have sufficient knowledge to offer an opinion.

In a small number of Member States, the systems were still evolving.

Questions in the questionnaire

B - 4.5 Explain if and how the opinions of independent parties are integrated as provided in Article 38(4)

B - 4.7 When project evaluation is tasked to a non-public authority and/or within an establishment, please describe how the impartiality of the process is achieved, in line with Article 38(4)

The Directive allows the option to integrate independent parties in the process, but few Member States reported utilising them. Responses indicated that independent parties may be integrated within ethics committees or national committees providing advice on project evaluation, or may be called upon if required. In some cases, these independent members are from animal welfare organisations, medical doctors, patient group representatives, or members of staff within the establishment not involved in research.

15 Member States reported having a single competent authority performing project evaluation (based on responses provided to question B.1 on competent authorities). Whilst not specifically reported, it is assumed that these are public bodies and are therefore independent. Of the remaining 13 Member States, seven are public bodies for project evaluation, and 11 for project authorisation. When conducted by public authorities there should be no issues of impartiality.

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 department's work is being assessed. This is an issue in particular for project evaluation performed by local committees. Declarations are used to state impartiality/lack of conflict of interest.

In the case of local committees, in some cases there is reported oversight by an independent member of the government department which implements the Directive, or a second tier of review at national level.

A few Member States actively encourage independent involvement in the process. For example, in Poland 3/12 members of the local evaluation committees are representatives of organisations promoting animal welfare, and 1/12 must also represent an organisation whose statutory aims include the protection of patients' rights. Sweden requires half of the members in the ethics committees are laypersons who are included to represent society's point of view regarding benefit and necessity of research versus ethical justification of harm inflicted to the animals. Two of these laypersons represent animal welfare organisations. Another Member State encourages involvement of persons within the establishment who are not involved in the scientific programmes to provide a "lay" perspective.

Question in the questionnaire

B - 4.6 The decision within the project evaluation process is reached by

Decision reached by	
Consensus	9
Vote or simple majority	11
Other	8
Total	**28**

Where vote or simple majority or other were reported, these are mostly by simple majority with a chairman's casting vote following discussion. One Member State reported that members are given the opportunity to register dissent from the decision, which is included in the report on the evaluation. One Member State reported that there is variability between the

different competent authorities responsible for project evaluation on how decisions are reached.

> Question in the questionnaire *[voluntary question]*
>
> ** B - 4.8 Two key elements which impact on the project evaluation and authorisation processes are the definition of "a project" and the interpretation of "a complete and correct application please provide a short description of the types of "projects" authorised in your MS - e.g., are projects limited to single procedures of short duration or are more complex multi-species, multi-procedure projects of up to 5 years also authorised; how is a "complete and correct application" determined, and communicated to applicant; how are the interactions between applicant and competent authority accounted for in the authorisation deadlines as required in Article 41*

Background:

During the review of the Directive[10], a number of comments were raised over the apparent interpretation of the term "project", suggestive that there were Member States who had taken a very narrow interpretation, effectively only authorising single procedures as projects.

In the review responses, it was also reported that delays were being encountered and the timescales for project authorisation were not being met as the "time allowed" did not begin until an entirely correct application was received for evaluation.

Analysis

Eighteen Member States have included a response to these non-mandatory questions.

"**project"**

The majority of responses confirmed that projects vary in size and complexity, and can involve multiple procedures and species, and are issued for different periods up to a maximum of five years.

"a complete and correct application"

The responses confirmed that often the initial application for a project contains insufficient information to allow a full project evaluation to be undertaken.

Member States have different structures for conducting project evaluation, but in all circumstances reported, there is the possibility for interaction (and indeed this is regularly utilised) with the applicant to secure the necessary additional information to allow project evaluation to be undertaken.

Correction/improvement to the application seems the preferred solution, rather than outright rejection of an initial incomplete application.

Many Member States have issued a standard project application form together with guidance for completion, and a few provide training for applicants in the application requirements.

[10] https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1510219889073&uri=COM:2017:631:FIN

Question in the questionnaire *[voluntary question]*

** B - 4.9 - Are the processes for amendments to projects the same as for the initial project evaluation and authorisation (including the deadlines in Article 41)? If not, please describe the main differences. What changes to a project will require a request for an amendment?*

19 Member States responded to this non-mandatory question.

All indicated that any changes to a project which may negatively impact on animal welfare would require a further, proportionate, evaluation.

Many responses indicated that amendments would be required for changes to projects, not involving additional welfare costs, but that such amendments would be dealt with in a different, but proportionate manner, for example through Animal Welfare Bodies, and generally these would be dealt with more quickly, and in a few cases by a simple notification.

One Member State (Malta) indicated that a new application would be required on each occasion an amendment was required.

Question in the questionnaire *[voluntary question]*

** B - 4.10 Has the EU Guidance on Project Evaluation and Retrospective Assessment been made available to all project evaluators?*

EU Guidance made available	
Yes	24
No	1
No response	3
Total	**28**

Question in the questionnaire *[voluntary question]*

** B - 4.11 Has additional official guidance on project evaluation and retrospective assessment been developed to facilitate implementation?*

Additional guidance developed	
Yes	7
No	16
No response	5
Total	**28**

Question in the questionnaire *[voluntary question]*

** B - 4.11.bis If you consider this guidance helpful for other Member States to facilitate the implementation of the Directive, please provide web-address for the guidance, where available.*

Five Member States provided links to websites which may be helpful to others, available in the detailed Member State summaries.

C. OPERATION

C.1. Projects

C.1.i. Granting of project authorisation (Articles 40 and 41 of Directive 2010/63/EU)

Reporting obligation
"information on the annual number of projects authorised, and on the number and type authorised as 'multiple generic projects'; *information on the circumstances and proportion of total authorisations where the deadline of 40 days has been extended as permitted by Article 41(2) of Directive 2010/63/EU."*

Background:

The Directive provides the following in its Articles 40 and 41 on project authorisation:

"Article 40

Granting of project authorisation

1. The project authorisation shall be limited to procedures which have been subject to:

(a) a project evaluation; and

(b) the severity classifications assigned to those procedures.

2. The project authorisation shall specify the following:

(a) the user who undertakes the project;

(b) the persons responsible for the overall implementation of the project and its compliance with the project authorisation;

(c) the establishments in which the project will be undertaken, where applicable; and

(d) any specific conditions following the project evaluation, including whether and when the project shall be assessed retrospectively.

3. Project authorisations shall be granted for a period not exceeding 5 years.

4. Member States may allow the authorisation of multiple generic projects carried out by the same user if such projects are to satisfy regulatory requirements or if such projects use animals for production or diagnostic purposes with established methods.

Article 41

Authorisation decisions

1. Member States shall ensure that the decision regarding authorisation is taken and communicated to the applicant 40 working days at the latest from the receipt of the complete and correct application. This period shall include the project evaluation.

2. When justified by the complexity or the multi-disciplinary nature of the project, the competent authority may extend the period referred to in paragraph 1 once, by an additional

period not exceeding 15 working days. The extension and its duration shall be duly motivated and shall be notified to the applicant before the expiry of the period referred to in paragraph 1.

3. Competent authorities shall acknowledge to the applicant all applications for authorisations as quickly as possible, and shall indicate the period referred to in paragraph 1 within which the decision is to be taken.

4. In the case of an incomplete or incorrect application, the competent authority shall, as quickly as possible, inform the applicant of the need to supply any additional documentation and of any possible effects on the running of the applicable time period."

Analysis

Question in the questionnaire

C - 1.i.1 Granting of project authorisations (Articles 40 and 41)

Total EU projects

Year	Number of projects authorised	Total number of decisions (authorised and rejected)	total number rejected (calculated)	Number of decisions >40days	Proportions >40 days of all decisions
2013	6,063	6,119	56	945	15%
2014	11,210	11,226	16	4,140	37%
2015	15,044	15,401	357	5,289	34%
2016	15,246	15,849	603	6,144	39%
2017	16,708	17,230	522	6,951	40%

It is important to note in this context that the lower numbers during the first years reflects the fact that the Directive obligations had yet to be transposed in the national legislation in some Member States. The last Member State adopted national legislation only in the spring of 2015.

A comparison of numbers of authorised projects between Member States is less informative due to differences in interpretation of what constitutes a project (see question B.4.8).

However, to facilitate competitive EU research, the Directive introduced a 40-day deadline within which the decision has to be taken and communicated by the authorities. Only in cases justified by the complexity or the multi-disciplinary nature of the project, this deadline could be extended by 15 days. There are significant differences between Member States of the proportion of decisions taken beyond 40 days, varying from 0% to 100%. This is illustrated below with the data provided for 2017. Three Member states did not provide data on this.

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	73%
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	61%
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%

*) Numbers calculated from the data provided in the other columns

Question in the questionnaire

C - 1.i.1.bis Provide information of circumstances where the deadline of 40 days has been extended as provided in Article 41(2)

Circumstances for the deadline being extended included: projects of complex or of a multi-disciplinary nature, where large numbers of animals are to be used, where large amounts of information had been requested of applicants, or when there were controversial procedures being used. In some cases, it was reported that the deadline was exceeded because there were insufficient staff to process the applications.

Question in the questionnaire

C - 1.i.2 Number and type authorised as "multiple generic projects"

Total EU multiple generic projects						
Year	**Number of multiple generic projects authorised for regulatory purposes**	**Number of multiple generic projects authorised for routine production**	**Number of multiple generic projects authorised for diagnostic purposes**	**Total number of multiple generic projects authorised**	**Total number of projects authorised (from C1.i.1)**	**Proportion of multiple generic projects of all authorised projects**
2013	43	20	14	77	6,063	1%
2014	148	30	58	236	11,210	2%
2015	213	37	54	304	15,044	2%
2016	223	55	82	360	15,246	2%
2017	267	79	103	449	16,708	2%

C.1.ii. Retrospective assessment, non-technical project summaries (Articles 38, 39 and 43 of Directive 2010/63/EU)

Reporting obligation

"information on the operation of non-technical project summaries; how it is assured that the requirements under Article 43(1) of Directive 2010/63/EU are met and whether the non-technical project summaries will indicate projects chosen for retrospective review (Article 43 (2) of Directive 2010/63/EU);

information on the proportion and types of projects submitted for retrospective assessment under Article 38(2)(f) of Directive 2010/63/EU beyond those compulsory under Article 39(2) of that Directive."

Non-technical project summaries

Background

Directive provides in its Article 44 the following:

"1. Subject to safeguarding intellectual property and confidential information, the non-technical project summary shall provide the following:

(a) information on the objectives of the project, including the predicted harm and benefits and the number and types of animals to be used;

(b) a demonstration of compliance with the requirement of replacement, reduction and refinement.

The non-technical project summary shall be anonymous and shall not contain the names and addresses of the user and its personnel.

2. Member States may require the non-technical project summary to specify whether a project is to undergo a retrospective assessment and by what deadline. In such a case, Member States shall ensure that the non-technical project summary is updated with the results of any retrospective assessment.

3. Member States shall publish the non-technical project summaries of authorised projects and any updates thereto."

Analysis

Question in the questionnaire

C – 1.ii.1 Provide information on the operation of non-technical project summaries; and on how it is assured that the requirements under Article 43(1) are met. Requirements of Article 43(1): (a) information on the objectives of the project, including the predicted harm and benefits and the number and types of animals; (b) demonstration of compliance with the requirement of Replacement, Reduction and Refinement; (c) anonymity

The essential requirements for non-technical project summaries have been transposed in the national legislation of the Member States.

During the project evaluation process, the non-technical summaries should be checked for appropriateness of content, and that the summaries do not contain information of a confidential nature, or information which may compromise intellectual property rights.

All Member States have a template for non-technical project summaries included in the project application, with many using the EU template developed as guidance.

It was acknowledged in a few responses that although initially the quality of the content and the time to publication were a concern (for example Italy), the content has improved as experience developed, and time to publication has been reduced as systems have been put in place to host these non-technical project summaries.

One Member State (Denmark) reported that, subject to personal data and IP issues, the full contents of project applications are published, including the non-technical project summaries.

Question in the questionnaire

C - 1.ii.1.bis Based on the information on the operation the non-technical summaries during the first five years, what is the average time (in months) from authorisation to publication?

Average time (in months) from authorisation to publication?	
Belgium	18
Bulgaria	1
Czechia	1
Denmark	0
Germany	3
Estonia	2
Ireland	6
Greece	2
Spain	6
France	12
Croatia	12
Italy	24
Cyprus	2
Latvia	3
Lithuania	2
Luxembourg	2
Hungary	5
Malta	0
Netherlands	1
Austria	6
Poland	1
Portugal	12
Romania	3
Slovenia	1
Slovakia	6

Finland	6
Sweden	36
United Kingdom	12

In some cases Member States provided additional information on efforts made to improve the situation. As an example, Sweden stated that *"To date, only few non-technical summaries have been published. However, the Swedish Board of Agriculture has recently finalised a new improved publishing format. The delay in publishing is unfortunate, and has resulted in a long average time from authorisation to publication, but the Board now envisions a steady publication rate in a user-friendly format."*

Question in the questionnaire

C - 1.ii.2 Do the non-technical project summaries indicate projects chosen for retrospective assessment (Article 43(2))

NTS indicates projects selected for retrospective assessment	
Yes	13
No	15
Total	**28**

13 Member States have determined that they update the non-technical project summaries with the results of any retrospective assessment.

Question in the questionnaire

C - 1.ii.3 Please provide the web-address where non-technical project summaries are published

Links to Member State publications are now available on the Commission web-site at https://ec.europa.eu/environment/chemicals/lab_animals/nts_en.htm

Retrospective assessment of projects

Background

Directive provides in its Article 38(2)(f) the following:

"2. The project evaluation shall consist in particular of the following:

...

(f) a determination as to whether and when the project should be assessed retrospectively."

And in its Article 39 that:

1. Member States shall ensure that when determined in accordance with Article 38(2)(f), the retrospective assessment shall be carried out by the competent authority which shall, on the basis of the necessary documentation submitted by the user, evaluate the following:

(a) whether the objectives of the project were achieved;

(b) the harm inflicted on animals, including the numbers and species of animals used, and the severity of the procedures; and

(c) any elements that may contribute to the further implementation of the requirement of replacement, reduction and refinement.

2. All projects using non-human primates and projects involving procedures classified as 'severe', including those referred to in Article 15(2), shall undergo a retrospective assessment.

3. Without prejudice to paragraph 2 and by way of derogation from Article 38(2)(f), Member States may exempt projects involving only procedures classified as 'mild' or 'non- recovery' from the requirement for a retrospective assessment."

Analysis

Question in the questionnaire

C - 1.ii.4 Provide information on the proportion and types of projects submitted for retrospective assessment (RA) beyond those compulsory under Article 39(2)

Projects required to have Retrospective Assessment - all Member States

Year	Number of projects involving non-human primates (NHP)	Number of projects involving severe procedures	Number of projects involving NHP and severe procedures	Number of "other" projects (than those involving NHP/severe procedures) submitted for RA	Total number of projects submitted for RA (sum of previous four columns)	Proportion of "other" projects versus all authorised
2013	6	559	4	886	1,464	61%
2014	15	776	0	1,120	1,968	60%
2015	21	1,477	0	1,595	3,274	49%
2016	34	1,475	7	1,475	3,403	43%
2017	51	1,528	7	1,573	3,721	42%

It is important to note in this context that the lower numbers in the Member State submissions during the first years reflect the fact that the Directive obligations had yet to be transposed in the national legislation in some Member States. The last Member State adopted national legislation only in the spring of 2015.

Furthermore, it should be noted that some Member States (for example United Kingdom) had misunderstood this question to refer to completed retrospective assessments, instead of those

selected, during project evaluation (Article 38(2)(f) between 2013 and 2017, for future retrospective assessment after the completion of the project. In addition, Germany stated that roughly 10% (during years 2013-2017) is requested for retrospective assessment beyond those compulsory, without providing any numbers. France and Spain provided numbers for only those beyond compulsory but not of those required by law.

Due to the lack of exact numbers from Member States presenting some of the highest volumes of animal use in EU (Germany, Spain, France and United Kingdom) the accuracy of the total value of the above table is likely to be poor. Of the remaining Member States, the proportion called for retrospective assessment beyond those compulsory is relatively high, above 40%.

Question in the questionnaire

C - 1.ii.5 Provide reasons for other projects (beyond those compulsory) being submitted for retrospective assessment broken down by each reporting year

Many Member States applied a requirement for retrospective assessment for projects (beyond those compulsory) for a number of reasons. These reasons fell into a number of categories:

Refinement - examples included:

- to ensure suitability of severity scoring sheets;
- to review monitoring during procedures - potential cumulative suffering;
- to review impact of an extended duration of the procedure on the animals;
- to review the effectiveness of proposed humane endpoints;
- projects from which further insights might be gained on the actual functioning of refinement strategies;
- project where mortality rate of 20-30 % was expected;
- to review impact on animals being reused in oncological tests;
- to review fate of animals when being released or rehomed.

Reduction - examples included:

- uncertainty over the number of animals born and used during the experiment;
- projects involving large numbers of animals;
- uncertainties over proposed design or group sizes.

Uncertainty - examples included:

- complex pathway of experiments with multiple options making severity assessment challenging;
- project involving the use of complex technology and lengthy anaesthetic episodes;
- project involved a novel disease model with the potential to cause higher suffering than predicted;
- unknown effects of device implantation and possible rejection;
- multiple generic projects - useful to review the individual studies performed under generic authorisation;

- use of models not well established within that particular research group, within the establishment, or not well established in any location;
- newly authorised establishment and their first ever project.

Other – examples included:

- projects using animals for education purposes within the universities, especially to review the availability of alternatives;
- project using wild and / or endangered species.

C.2. Animals bred for use in procedures (Articles 10, 28 and 30)

C.2.i. Animal bred, killed and not used in procedures

Reporting obligation

"animals bred, killed and not used in procedures including genetically altered animals not covered in the annual statistics, covering the calendar year prior to that in which the 5-year report is submitted; the global figure shall differentiate those animals involved in GA creation and maintenance of established GA-lines (including wild-type offspring)"

Background

Directive provides in its Article 10(1) the following:

> *"1. Member States shall ensure that animals belonging to the species listed in Annex I may only be used in procedures where those animals have been bred for use in procedures. .."*

And in its Article 30 on animal records that:

> *"1. Member States shall ensure that all breeders, suppliers and users keep records of at least the following:*
>
> > *(a) the number and the species of animals bred, acquired, supplied, used in procedures, set-free or rehomed;*
> >
> > *...*
> >
> > *(f) the number and species of animals which died or were killed in each establishment…"*

Analysis

Question in the questionnaire

C - 2.i Animals bred, killed and not used in procedures including genetically altered (GA) animals not otherwise reported in the annual statistics. This section covers animals only from the last calendar year preceding submission of information for the 5-year implementation report, that is 2017.

Columns 3 and 4 exclude animals that were genotyped using invasive method as these have already been included in the annual statistics. Equally, any animal from a harmful

phenotype line that experienced adverse effects before being killed will already have been reported.

This element of the implementation report will provide complementary information to the annual statistical data reported by the Member States under Article 54(2) of the Directive. As part of the implementation report, Member States are required to provide information of *all other animals* not reported otherwise. Together, once every five years, the annual statistical report, and the information provided by the implementation report will give a comprehensive picture of all animals needed to support research, testing and education/training needs using animals in the EU in a given year:

- annual statistical report:
    - animals used in scientific procedures
    - animals used for the creation and maintenance of genetically altered animal lines (that have experienced harm during the process)
- implementation report once every five years:
    - animals bred, but not used in scientific procedures before being killed, including
        - conventional and
        - those not reported otherwise under creation and maintenance of genetically altered animal lines.

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. It is important to note that these numbers include also those bred and humanely killed for the purpose of providing organs and tissues, including to advance or be used in alternative (animal based) methods. These numbers will also include many breeding animals at the end of their breeding life.

To ensure that sufficient suitable animals are available to meet scientific demand, more animals are bred than used. Often, for example the age or sex of the animals will render them unsuitable for an intended scientific purpose. Other elements that impact on the size of a breeding stock include fecundity and gestation length. However, the most important factor is fluctuation in scientific demand. This can apply to both conventional (row 1 in table below) and genetically altered animals (row 3 in the table below).

Some of these animals may have been used in scientific studies (for example, observation of behaviour) which did not cause harm beyond the minimum threshold as provided in Article 3(1) of the directive, as these are not classified as procedures.

A number of ways exist aiming to reduce breeding surplus. These will be briefly discussed at the end of this section.

In reference to genetically altered animals, unless there is breeding of a homozygous genetically altered line, where all offspring will be genetically altered, crossing of heterozygotes will necessarily lead to some wild-type (conventional) animals being born (row 2 and row 3).

Row 3 also includes animals which are genetically altered, but which have suffered no harms as a consequence, and therefore were not reported in the annual statistical report.

Finally, these animals also include those that were intended to be used, but for example have fallen ill and killed humanely before being used. This would also include health status breakdowns, where a number of animals would need to be killed to protect the health and scientific integrity of the colony.

The total numbers of animals in 2017 for the three reported categories in the EU were as follows:

Types of animals	Numbers
Number of **conventional animals** bred, killed and not used in procedures (excluding those involved in the creation or maintenance of a genetically altered animal (GA) line)	**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 (GA) line***	**525,085**
Number of animals bred and killed for the **maintenance of an established genetically altered (GA) line**	**5,588,196**
Total number of animals bred, killed and not used in procedures and not covered in annual statistical reporting	**12,597,816**

* This category includes all animals (all GA and wild type offspring) bred and killed from both harmful and non-harmful phenotype lines, that were not otherwise reported in the annual statistics

The table below shows by species the total number of animals bred, killed and not used in procedures including genetically altered (GA) animals not otherwise reported in the annual statistics reported by Member States, combining all the categories discussed above.

Species	**Numbers**
Mice	10,496,190
Zebra fish	961,802
Rats	557,880
Other fish	320,230
Guinea-pigs	75,590
Rabbits	64,633
Domestic fowl	35,593
Pigs	21,588
Other rodents	18,842
Mongolian gerbil	15,046
Xenopus	10,470
Rana	5,248
Other birds	3,631
Other carnivores	3,021
Amphibians	2,181
Ferrets	1,937
Syrian Hamster	1,355

Cattle	1,303
Sheep	461
Other mammals	346
Dogs	230
Marmosets and tamarins	107
Rhesus monkey	48
Cynomolgus monkey	32
Goats	17
Horses, donkeys & cross-breeds (Equidae)	12
Prosimians	10
Reptiles	7
Cats	4
Cephalopods	2
Total	**12,597,816**

Other fish includes Oryzias latipes -Japanese rice fish, Onchorynchus mykiss- Rainbow trout, brown trout, Salmo salar salmon, Anguilla anguilla - European eel, Killifish, Oreochromis niloticus -tilapia, Whitefish

Other rodents includes hamsters including specified species Cricetus cricetus - European hamster, Phodopus sungorus - Winter white dwarf hamster, Myodes glareolus - bank vole.

Other carnivores includes: Vulpes lagopus – Bluefox, Neovison vison – mink, badger

Other mammals includes: Reindeer, Monodelphis domestica - short tailed opossum, Laboratory opossum

Two Member States reported no animals that were bred and killed without being used in procedures (Bulgaria and Malta). All other Member States reported such animals, which are shown below with Member State data reported in the different reporting categories.

Member State	Conventional animals	Creation of a new genetically altered animal line	GA maintenance	Total GA (creation and maintenance)	Total per Member State
AT	**146,925**	13,004	138,277	**151,281**	**298,206**
BE	**183,147**	9,088	283,534	**292,622**	**475,769**
BG	**0**			**0**	**0**
CY	**242**		997	**997**	**1,239**
CZ	**115,058**	7,463	49,779	**57,242**	**172,300**
DE	**1,410,300**	288,000	2,246,000	**2,534,000**	**3,944,300**
DK	**270,081**	11,946	266,917	**278,863**	**548,944**
EE	**11,006**	16	11,625	**11,641**	**22,647**
EL	**10,400**	2,800	25,000	**27,800**	**38,200**
ES	**148,367**	14,971	126,052	**141,023**	**289,390**
FI	**90,554**	1,532	59,246	**60,778**	**151,332**

FR	**1,452,168**	61,205	609,996	**671,201**	**2,123,369**
HR	**7,193**	328	2,608	**2,936**	**10,129**
HU	**50,272**	6,389	36,876	**43,265**	**93,537**
IE	**438,224**	311	91	**402**	**438,626**
IT	**92,981**	4,792	53,902	**58,694**	**151,675**
LT	**721**		14	**14**	**735**
LU	**2,679**	146	7,052	**7,198**	**9,877**
LV	**539**			**0**	**539**
MT	**0**			**0**	0
NL	**396,648**	32,542	72,081	**104,623**	**501,271**
PL	**17,708**	1,589	22,075	**23,664**	**41,372**
PT	**13,842**	1,000	7,172	**8,172**	**22,014**
RO	**1,936**	0	40	**40**	**1,976**
SE	**68,956**	13,463	112,586	**126,049**	**195,005**
SI	**4,855**	68	1,838	**1,906**	**6,761**
SK	**4,467**		547	**547**	**5,014**
UK	**1,545,266**	54,432	1,453,891	**1,508,323**	**3,053,589**
Total	**6,484,535**	**525,085**	**5,588,196**	**6,113,281**	**12,597,816**

It is important that there is good oversight of breeding programmes to minimize as far as is practicable surplus animals, but it is acknowledged 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.

Other avenues for their use should be considered, for example rodents as food for raptors or reptiles, and farm animals being returned for agricultural use.

Matching supply and demand of laboratory animals

The list below has been developed as part of an EU Expert Working Group focusing on the use of genetically altered animals. A number of the recommendations included in a draft report (still under preparation) are equally suitable in a conventional breeding environment.

- Ensure that exacting specific requirements made by scientists are necessary and justified – use of single sex; age/weight range.
- Efficiencies are generally found in large breeding colonies servicing multiple users (commercial breeders) or internal collaborations.
- Effective communication over availability of, and sharing of tissues.
- Ensure appropriate notification by scientists to colony managers of numbers required and when to allow lead in times to studies to facilitate optimum management of breeding colonies.
- Effective preventive and reactive disease control.
- Consider using ex-breeding animals.

With respect to breeding of genetically altered animals

- There are likely to be animals of the incorrect genetic make-up which make them unsuitable for the proposed scientific use.
- Method of generation of GA animals will influence number of animals unsuitable for scientific use. Efficient methodologies should be selected when available and where increased harms are outweighed by a significant reduction in numbers.

C.2.ii. Sourcing of non-human primates

Reporting obligation

"the sourcing of non-human primates and how the requirements of Articles 10 and 28 of Directive 2010/63/EU are met"

Background

The Directive provides in its Article 10 concerning animals bred for use in procedures the following:

"1.Member States shall ensure that animals belonging to the species listed in Annex I may only be used in procedures where those animals have been bred for use in procedures.

However, from the dates set out in Annex II, Member States shall ensure that non-human primates listed therein may be used in procedures only where they are the offspring of non-human primates which have been bred in captivity or where they are sourced from self-sustaining colonies.

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. .....

2. ……

3.Competent authorities may grant exemptions from paragraph 1 on the basis of scientific justification."

In Article 28 on breeding strategy for non-human primates:

"Member States shall ensure that breeders of non-human primates have a strategy in place for increasing the proportion of animals that are the offspring of non-human primates that have been bred in captivity."

Analysis

Questions in the questionnaire

C - 2.ii Do you have any authorised users, breeders or suppliers of non-human primates (NHP) in your Member State? Yes/No

C - 2.ii.bis Provide information on the sourcing of NHP and how the requirements of Article 10 are being met. For example, what measures have been taken to promote/require the use of F2 NHP or those sourced from self-sustaining colonies, including when sourcing from outside the EU?

C - 2.ii.tris Provide information on strategies in place to increase the proportion of animals of F2 (or higher) in line with Article 28

12 Member States reported that they had authorised establishments for the use, breeding and/or supplying no-human primates.

The objective of the provision in Article 28 is to facilitate the move towards second or higher generation purpose-bred (F2/F2+) breeding of non-human primates in the EU. However, on the basis of the implementation reports received from the Member States it can be concluded that this objective has already been achieved in the EU. All authorised breeding establishments in the EU are already today supplying only F2/F2+ animals, confirming the findings of the feasibility study[11] conducted under Article 10 and published in November 2017.

To further the aims of the Directive globally, in Member States where animals are sourced from overseas, Member States are making efforts to obtain only F2/F2+ animals, and although not within EU jurisdiction, are encouraging overseas breeders to increase the supply of F2/F2+ animals available.

C.3. Exemptions

Reporting obligation

"information on circumstances under which exemptions were granted in accordance with Articles 10(3), 12(1), 33(3) of Directive 2010/63/EU and in particular on the exceptional circumstances referred to in Article 16(2) of that Directive where a reuse of an animal after a procedure in which the actual suffering was assessed as severe was authorised during the reporting period"

It is important to note that no detailed, numerical data are required on exemptions. Instead, Member States are required to provide information on the *type of circumstances* under which such exemptions have been granted. However, in some instances Member States did provide voluntarily numerical, more detailed data.

Analysis

Article 10 - Animals bred for use in procedures

Directive provides:

"1. Member States shall ensure that animals belonging to the species listed in Annex I may only be used in procedures where those animals have been bred for use in procedures.

2. ....

3. Competent authorities may grant exemptions from paragraph 1 on the basis of scientific justification."

Question in the questionnaire

[11] https://ec.europa.eu/environment/chemicals/lab_animals/related_topics_en.htm

C - 3.1 Provide cumulative information covering years 2013-2017 on circumstances under which exemptions were granted to the requirement to use animals (listed in Annex I) purpose bred for scientific use; and/or to the use of marmosets that not of F2/F2+ generation (Article 10(3). Please remember to indicate the type of species involved in these exemptions. Where possible, provide an estimate of the relative frequency of such exemptions.

During the reporting period 2013-2017, 15 Member States reported authorising exemptions. Where numerical data were voluntarily provided, the numbers of exemptions varied significantly from one exemption in five years to more than one hundred per annum.

The main exemptions were for work in the wild (for example using mice or rats naturally bred in the wild) investigating for example wild populations or disease/zoonotic status, or work using pet dogs and cats in veterinary research to investigate clinical disease and novel treatments. Other examples included scientific need for breeds of dogs that develop naturally the disease of interest and which are not available from authorised breeders. Wild-caught frogs were also reported as having been used.

There were no reported exemptions given for the use of marmosets that were not of F2/F2+ generation.

Article 12 - Procedures

Directive provides:

"1.Member States shall ensure that procedures are carried out in a user's establishment.

The competent authority may grant an exemption from the first subparagraph on the basis of scientific justification."

Question in the questionnaire

C - 3.2 Provide cumulative information covering years 2013-2017 on circumstances (such as work on animals in the wild, work on animals in a commercial farm) under which exemptions were granted to the requirement to carry out a project in user's establishment (Article 12(1)). Where possible, provide an estimate of the relative frequency of such exemptions.

22 Member States authorised exemptions under Article 12 to enable work to be performed outside a user establishment.

Work in the wild is the most common exemption, used for investigating animals in their natural habitat, for example behavioural, population or health studies, although many exemptions are also authorised for research work under commercial conditions on farm animals. Work in veterinary practices has also been authorised. Authorisations have been given to enable work in hospitals with specialist equipment (for example CT scan) not available within the scientist's own establishment.

On the basis of additional voluntary data, the frequencies of such exemptions were estimated by a few Member States to be around 5% of projects.

Article 16 - Reuse

Directive provides:

"1. Member States shall ensure that an animal already used in one or more procedures, when a different animal on which no procedure has previously been carried out could also be used, may only be reused in a new procedure provided that the following conditions are met:

a) the actual severity of the previous procedures was 'mild' or 'moderate';
b) it is demonstrated that the animal's general state of health and well-being has been fully restored;
c) the further procedure is classified as 'mild', 'moderate' or 'non-recovery'; and
d) it is in accordance with veterinary advice, taking into account the lifetime experience of the animal.

2. In exceptional circumstances, by way of derogation from point (a) of paragraph 1 and after a veterinary examination of the animal, the competent authority may allow reuse of an animal, provided the animal has not been used more than once in a procedure entailing severe pain, distress or equivalent suffering.

Question in the questionnaire

C - 3.3 Provide cumulative information covering years 2013-2017 on the exceptional circumstances under which exemptions were granted for the reuse of an animal after a procedure in which the actual suffering was assessed as severe (Article 16(2)). Please remember to indicate the type of species involved in these exemptions. Where possible, provide an estimate of the relative frequency of such exemptions.

Two Member States stated that they have disallowed this option under their national legislation.

Only France reported that some derogation was permitted in certain projects without providing further information on the specific circumstances.

Article 33 - Care and accommodation

Directive provides:

"1. Member States shall, as far as the care and accommodation of animals is concerned, ensure that:

a) all animals are provided with accommodation, an environment, food, water and care which are appropriate to their health and well-being;
b) any restrictions on the extent to which an animal can satisfy its physiological and ethological needs are kept to a minimum;
c) the environmental conditions in which animals are bred, kept or used are checked daily;
d) arrangements are made to ensure that any defect or avoidable pain, suffering, distress or lasting harm discovered is eliminated as quickly as possible; and
e) animals are transported under appropriate conditions.

2. For the purposes of paragraph 1, Member States shall ensure that the care and accommodation standards set out in Annex III are applied from the dates provided for therein.

3.Member States may allow exemptions from the requirements of paragraph 1(a) or paragraph 2 for scientific, animal-welfare or animal-health reasons."

Question in the questionnaire

C - 3.4 Provide cumulative information covering years 2013-2017 on circumstances (reasons) under which exemptions (such as for single housing, restriction of food/water, restriction on enclosure sizes) were granted to the care and accommodation requirements (Article 33(3)). Please remember to indicate the type of species involved in these exemptions. Where possible, provide an estimate of the relative frequency of such exemptions.

18 Member States reported that exemptions were authorised from the care and accommodation standards. A number of responses merely indicated that exemptions had been given, whereas others provided detailed information on the reasons for such exemptions. A few Member States voluntarily provided numerical data.

The circumstances for exemptions included:

- Use of metabolic cages, whose dimensions were below those set out in Annex III was a common reason for exemption;
- Use of "commercial stocking densities" during certain research studies in agricultural animals into for example behaviour, mechanisms of spread of infectious disease;
- Single housing for scientific reasons, for example to measure behavioural responses to stimuli, food intake;
- Food / water control as a motivational tool in training animals to perform novel or learned tasks required for a research protocol;
- Disruption to "normal" environment and group housing as behavioural stressors;
- Feeding altered diets to investigate for example mineral deficiencies.

It is perhaps surprising, given the scale and breadth of exemptions for variations in the housing and care requirements to enable scientific projects to proceed, that 10 Member States had not reported any requests for exemptions from these requirements.

C.4. Animal Welfare Body (Articles 26 and 27 of Directive 2010/63/EU)

Reporting obligation

"information on the structure and functioning of animal welfare bodies"

Background:

The Directive states in its Articles 26 and 27 the following:

"Article 26 Animal-welfare body

1. *Member States shall ensure that each breeder, supplier and user sets up an animal-welfare body.*
2. *The animal-welfare body shall include at least the person or persons responsible for the welfare and care of the animals and, in the case of a user, a scientific*

member. The animal- welfare body shall also receive input from the designated veterinarian or the expert referred to in Article 25.

3. *Member States may allow small breeders, suppliers and users to fulfil the tasks laid down in Article 27(1) by other means.*

Article 27 Tasks of the animal-welfare body

1. *The animal-welfare body shall, as a minimum, carry out the following tasks:*
   a. *advise the staff dealing with animals on matters related to the welfare of animals, in relation to their acquisition, accommodation, care and use;*
   b. *advise the staff on the application of the requirement of replacement, reduction and refinement, and keep it informed of technical and scientific developments concerning the application of that requirement;*
   c. *establish and review internal operational processes as regards monitoring, reporting and follow-up in relation to the welfare of animals housed or used in the establishment;*
   d. *follow the development and outcome of projects, taking into account the effect on the animals used, and identify and advise as regards elements that further contribute to replacement, reduction and refinement; and*
   e. *advise on rehoming schemes, including the appropriate socialisation of the animals to be rehomed.*
2. *Member States shall ensure that the records of any advice given by the animal-welfare body and decisions taken regarding that advice are kept for at least 3 years.*

   The records shall be made available to the competent authority upon request."

Analysis

The inclusion of the requirement to have Animal Welfare Bodies in every establishment has been recognised as a very positive step to improve welfare and science. Their inputs at establishments have raised awareness of the importance of the application of 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.

Questions in the questionnaire

C - 4.1 Provide general information on the structure and functioning of animal welfare bodies

C - 4.2 In describing the structure of animal welfare bodies, does your MS require other persons to be permanent members beyond those listed in Article 26(2)?

C - 4.2.bis Please provide a description of the other persons required to be members of animal welfare bodies

C - 4.3 Does your MS allow achieving the tasks in Article 27(1) by other means than through establishment of an animal welfare body?

C - 4.3.bis Please describe what other means are used to achieve the tasks in Article 27(1). Where possible, please include the definition for a "small" breeder, users and/or supplier

Structure and functioning of Animal Welfare Bodies

Many Member States reported that the composition of Animal Welfare Bodies is broader than the minimum set out in the Directive. Almost one-third of the Member States 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 the addition of lay persons has been included by a few, as well as in one Member State a requirement for an ethologist for establishments using non-human primates.

There was general agreement that the composition is dictated by the size and complexity of the establishment. 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, and where it does occur often a number of small establishments pool resources into a single animal welfare forum. A further alternative strategy has been to require the “small” establishment fulfil all the functions of the Animal Welfare Body, and secure external input, as necessary, to ensure compliance. No Member States provided information on the criteria used for defining a "small" breeder, user and/or supplier.

Additional tasks

In a number of Member States, the Animal Welfare Body has been given additional tasks – generally relating to the oversight of project applications, ranging from providing local advice and input to applications, to full project evaluation, and reviewing reports of retrospective assessment, as, or before submitting to, the competent authority. Where this is happening, the composition of the Animal Welfare Body is amended to include as necessary other members to ensure the necessary expertise for project evaluation.

Some Member States have explicitly mentioned advice to manage surplus animals as part of their Three Rs remit. Other additional tasks include approval and co-ordination of training of scientific and care staff.

Question in the questionnaire [*voluntary question*]

** C - 4.4 If possible, based on experience obtained through inspections and through the work of the National Committee that shares best practice and interacts with animal welfare bodies, what aspects of the work of animal welfare bodies function well - please provide examples if possible?*

General view is that the majority of Animal Welfare Bodies are working well. Animal Welfare Bodies have improved openness and communication internally and externally on animal use; they encourage all to raise concerns, for example through the use of an anonymous mailbox.

Other reported benefits include:

- improved discussions on animal use before procedures begin;
- advising on resources required to maintain high standards of welfare and care;
- improved understanding/oversight of procedures enabling prompt interventions as necessary, open dialogue on problems occurring;
- development and championing a culture of care;
- conditions of accommodation and care have improved – better knowledge; application of enrichment programmes;
- improved education and training, and continued professional development opportunities;
- networking with other Animal Welfare Bodies to share experiences and promote the Three Rs;
- symposia/lectures on welfare and the Three Rs – either at local, regional or national level.

In some cases, Animal Welfare Bodies also consider scientific research on animals beyond the scope of the Directive (such as observation studies, or studies using species not falling within the scope of the Directive). Some also consider the appropriateness of scientific research using animals conducted by scientists from the establishment while working overseas.

Question in the questionnaire *[voluntary question]*

** C - 4.5 If possible, based on experience obtained through inspection and through the work of the National Committee that shares best practice and interacts with animal welfare bodies, what aspects of the work of animal welfare bodies could be improved - please provide examples if possible.*

Animal Welfare Bodies vary in their functioning, with some taking a lead role in the establishment, in promoting the Three Rs and a culture of care, with others more reactive to animal welfare issues and deal with adverse events as they arise.

There are still areas regarding communication that could be improved such as between

- Animal Welfare Bodies and some scientists: including a need for some awareness raising among scientific staff over the role and benefits of Animal Welfare Body;
- committees tasked with project evaluation and Animal Welfare Bodies - including clearer lines of responsibilities; minimising duplication of effort.

From the establishment perspective sufficient veterinary expertise and input (availability/costs), as well as other resources need to be assured. This also includes sufficient time and reward/acknowledgement for those involved, and empowerment of Animal Welfare Body within the establishment to ensure recommendations are accepted and implemented.

Local input to project applications could be improved to streamline and make more efficient the project evaluation/authorisation process. Other elements indicated include the need to:

- improve access to and dissemination of information on Three Rs, especially on replacement;
- further develop networks of communication among Animal Welfare Bodies and
- further development in openness and culture of care.

Other initiatives

In a few Member States direct communication channels among Animal Welfare Bodies have been developed either at national or regional level.

It was also reported that an informal trans-national network of Animal Welfare Bodies has been developed.

D. PRINCIPLES OF REPLACEMENT, REDUCTION AND REFINEMENT

D.1. Principle of replacement, reduction and refinement (Articles 4 and 13 of Directive 2010/63/EU)

Reporting obligation

"the general measures taken to ensure that the principle of replacement, reduction and refinement is satisfactorily addressed within authorised projects as well as during housing and care also in breeding and supplying establishments"

Background

Directive provides in its Articles 4 and 13 the following:

"*Article 4*

Principle of replacement, reduction and refinement

1. Member States shall ensure that, wherever possible, a scientifically satisfactory method or testing strategy, not entailing the use of live animals, shall be used instead of a procedure.

2. Member States shall ensure that the number of animals used in projects is reduced to a minimum without compromising the objectives of the project.

3. Member States shall ensure refinement of breeding, accommodation and care, and of methods used in procedures, eliminating or reducing to the minimum any possible pain, suffering, distress or lasting harm to the animals.

4. This Article shall, in the choice of methods, be implemented in accordance with Article 13."

"Article 13

Choice of methods

1.Without prejudice to national legislation prohibiting certain types of methods, Member States shall ensure that a procedure is not carried out if another method or testing strategy for obtaining the result sought, not entailing the use of a live animal, is recognised under the legislation of the Union.

2. In choosing between procedures, those which to the greatest extent meet the following requirements shall be selected:

(a) use the minimum number of animals;

(b) involve animals with the lowest capacity to experience pain, suffering, distress or lasting harm;

(c) cause the least pain, suffering, distress or lasting harm;

and are most likely to provide satisfactory results.

3. Death as the end-point of a procedure shall be avoided as far as possible and replaced by early and humane end-points. Where death as the end-point is unavoidable, the procedure shall be designed so as to:

(a) result in the deaths of as few animals as possible; and

(b) reduce the duration and intensity of suffering to the animal to the minimum possible and, as far as possible, ensure a painless death."

Analysis

15 Member States have voluntarily uploaded information to the EC website[12] on their activities in relation to the development, validation and promotion of alternative approaches at national level.

Key Points from Member State responses included

- Project application forms have specific sections on the Three Rs.
- In some Member States, Animal Welfare Bodies advise the project applicant on relevant Three Rs issues.
- Some Member States obligate literature reviews and searches on the Three Rs to be included with application.
- One Member State requires screenshots of searches to be included in application form.
- Experts challenge on the Three Rs during evaluation process, and confirm that application is compliant with the Three Rs.
- Three Rs are subject to continuous review and update during the course of the project. Animal Welfare Body provide input and update on the Three Rs.
- Compliance with the Three Rs is checked as part of the inspection process.

Questions in the questionnaire

D - 1.1 Provide information on general measures taken to ensure that the principle of Replacement, Reduction and Refinement is satisfactorily addressed within authorised projects.

D - 1.2 Provide information on general measures taken to ensure that the principle of Replacement, Reduction and Refinement is satisfactorily addressed during housing and care including in breeding and supplying establishments.

[12] https://ec.europa.eu/environment/chemicals/lab_animals/3r/advance_en.htm

Please note that the voluntary Article 47 report covers development, validation and promotion of alternative approaches, and dissemination of information thereon at national level with no specific focus on operational application of the Three Rs

Key Points from Member State responses cover

- Major benefits with introduction of Animal Welfare Bodies, whose remit covers accommodation and care, and implementation of the Three Rs for all animals in the establishment.
- Animal Welfare Bodies implement standardised practices throughout the establishment – for example improved, standardised handling practices.
- Importance of ensuring Animal Welfare Bodies are supported and effective.
- Increased input of care staff to refinement opportunities.
- Improved communication and dissemination of information by information person/ Animal Welfare Body.
- Input from Designated Veterinarian
- Inspections and advice on the Three Rs from Inspectors
- The compliance with application of the law as regards applying the Three Rs is checked during inspections in some Member States and this appears to be another key measure to ensure the Three Rs are applied
- In project applications, the applicant must describe the housing and care arrangements for the animals to be enrolled on the project - this should include social housing plus environmental enrichment, as well as monitoring of health and welfare.
- Environmental and social enrichment for the animals, as appropriate for the species.
- Training and ongoing continuous training of care staff.
- Some Member States have programmes of education and training of personnel (meetings/workshops/training days) including dissemination of experiences.
- In some Member States the National Committee has been active at improving communication between Animal Welfare Bodies and communicating information on Three Rs.
- Oversight of breeding practices to minimise surplus, to match supply and demand.
- Strategies in place to use surplus animals for organs and tissues.
- Use of refined methodologies in re-derivation programmes.

Question in the questionnaire *[voluntary question]*

** D - 1.3 Has the EU Guidance on Severity Assessment Framework been made available to establishments, project evaluators and inspectors? Yes/No*

EU Guidance made available	
Yes	26
No	1
(blank)	1
Total	**28**

Question in the questionnaire *[voluntary question]*

** D - 1.4 Has additional official guidance on Replacement, Refinement and Reduction been developed to facilitate implementation? Yes/No*

Additional guidance developed	
Yes	7
No	17
(blank)	4
Total	**28**

Question in the questionnaire *[voluntary question]*

** D - 1.4.bis If you consider this guidance helpful for other Member States to facilitate the implementation of the Directive, please provide web-address for the guidance, where available*

Provided links to websites are available in the detailed Member State summaries.

D.2. Avoidance of duplication (Article 46 of Directive 2010/63/EU)

Reporting obligation

"general description of measures taken to ensure that there is no duplication of procedures"

Background

Directive provides in its Articles 4 and 13 the following:

"*Article 4*

Principle of replacement, reduction and refinement

1. Member States shall ensure that, wherever possible, a scientifically satisfactory method or testing strategy, not entailing the use of live animals, shall be used instead of a procedure.

2. Member States shall ensure that the number of animals used in projects is reduced to a minimum without compromising the objectives of the project.

3. Member States shall ensure refinement of breeding, accommodation and care, and of methods used in procedures, eliminating or reducing to the minimum any possible pain, suffering, distress or lasting harm to the animals.

4.This Article shall, in the choice of methods, be implemented in accordance with Article 13."

Analysis

Question in the questionnaire

D – 2 Provide general description of measures taken to ensure that there is no duplication of procedures

Many Member States ask for information on database searches / declaration in project application to provide reassurances that no unnecessary duplication of procedures will occur.

Some competent authorities request a minimum number of references indicating the date on which the query was made and the key word(s) used in the search

Project evaluation process includes checks on information provided. If similar/related procedures found, additional enquiries made and justification required.

The responses also encouraged publication of studies with negative results to help avoid duplication.

Publication of non-technical project summaries may assist in preventing duplication of procedures.

D.3. Tissue sampling of genetically altered animals (Articles 4, 30 and 38 of Directive 2010/63/EU

Reporting obligation

"representative information on approximate numbers, species, types of methods and their related severities of tissue sampling for the purposes of genetic characterisation carried out with and without project authorisation covering the calendar year prior to that in which the 5-year report is submitted, and on efforts made to refine those methods"

Background:

Directive provides in its Articles 4 and 13 the following:

"Article 4

Principle of replacement, reduction and refinement

1. Member States shall ensure that, wherever possible, a scientifically satisfactory method or testing strategy, not entailing the use of live animals, shall be used instead of a procedure.

2. Member States shall ensure that the number of animals used in projects is reduced to a minimum without compromising the objectives of the project.

3. Member States shall ensure refinement of breeding, accommodation and care, and of methods used in procedures, eliminating or reducing to the minimum any possible pain, suffering, distress or lasting harm to the animals.

4. This Article shall, in the choice of methods, be implemented in accordance with Article 13."

Analysis

Question in the questionnaire

D - 3.1 Are genetically altered animals/animal lines (non-harmful and/or harmful phenotype) being created, bred and/or used in your MS? Yes/No

26 Member States reported that genetically altered animals/animal lines were being created, bred and/or used in their Member States. Bulgaria and Malta stated that no genetically altered animals are created/bred and/or used in their Member State.

Questions in the questionnaire

D - 3.2 Provide representative information on approximate numbers, species, types of methods and their related severities of tissue sampling for the purposes of genetic characterisation carried out with and without project authorisation.

D - 3.4 Please indicate the criteria for sampling to obtain representative information above (for example as a proportion of all establishments breeding GA animals and the period during which the sample was taken)

It is important to note in this context that the Member States were required to only provide **representative information** on methods used for tissue sampling. Therefore, the provided figures are **not comparable** between Member States, as the basis on which the sample has been given varies from one Member State to another. Nine Member States sampled all establishments over a whole year, two sampled all establishments over six months, others indicated a variety of differing systems, and no sampling information were provided from a few.

The purpose of the data was to understand the relative distribution of different types of methods and the related severities of methods authorised within projects.

However, it is not possible to provide quantitative EU level summary on the basis of the Member State data submissions. The information requirements were not understood correctly by all Member States, possibly partly due to insufficient precision in the formulation of the question. As a result, the data either lacked the related sub-categorisation, or provided an indication of sub-categories but without detailing the numbers or species involved in each. For example, tail biopsy and ear biopsy were included in the same entry, thus it was impossible to separate the numbers for each method.

Information was provided on sampling methods for around 5.9 million animals, 97% of these being mice, with fish accounting for 2%.

As the quality of the information varied so significantly, further analysis was carried out only on the data provided on mouse tissue sampling methods.

Data from only around 2 million animals (34%) of the total data submitted on mouse tissue sampling methods contained in the Member State reports could be used for further analysis and conclusions.

Qualitative analysis of the data that could be interpreted shows that, for mice, tail biopsy, ear biopsy and removal of part or all of a digit remain the most commonly used methods to provide tissue for genotyping in the EU, despite some more refined alternatives being used by some, such as hair bulb or observation under special lighting conditions. In some cases, genotyping can be performed post mortem, which does not increase the welfare impact on the animals.

Acquisition of surplus tissue from methods of identification accounted for just over half of all the mice sampled – of these methods ear punch/biopsy accounted for 89%, distal phalanx biopsy 10.9% - although it was reported in a few cases that surplus tissue from tail sampling is used for identification, tail sampling rarely can be used to identify animals: it provides only a binomial marking system – normal length tail or short tail.

If surplus tissue from an identification method can be used, then this is fully refined as no other technique need be applied. On the basis of the data that could be used for analysis, surplus tissue from 87% of ear marks form the biopsy tissue for genotyping. This falls to 59% for (partial) digit removal.

Blood sampling, skin sampling and post-mortem sampling are also unlikely to permit animal identification, and these submissions may be in error.

With regard to methods of tissue sampling under project authorisation, tail biopsy is the most commonly used (65%), followed by ear biopsy (20%), distal phalanx biopsy (13%) and blood sampling (2%).

Even for these common techniques, there is variability in the reporting of severity. This may be because of other techniques applied (including analgesia/anaesthesia) or phenotype effects of the genetic mutation. However, it may reflect inconsistencies in the reporting of the same technique.

The use of sampling methodologies considered non-invasive, not requiring a project authorisation accounted for less than 2% of all sampling, with use of post-mortem material accounting for the majority in this category, with a few using observation, exposure to specific lighting conditions or hair sampling.

Question in the questionnaire

D - 3.3 Provide information on efforts being made to refine tissue sampling techniques for genotyping

The replacement of tail biopsy by taking surplus tissue from identification is occurring in many Member States.

Other methods to reduce and refine the effects on the animal include avoidance of the need for tissue sampling/genotyping by use of particular breeding strategies, for example homozygous x homozygous, genotyping post mortem, tissue taken is as small as possible, reliable analysis methods which remove the need for second testing / sampling, saving part of tissue in case resample is required, tail / toe biopsy technique is performed before ossification and innervation is advanced (young animals), use of local and/or general anaesthesia, use of analgesia, use of fluorescent markers (non-invasive). Size of sample required is now much reduced due to the accuracy of analytical method.

For zebrafish rapid analyses reduces the time that fish must be kept single housed to one to two days, and genotyping of larvae means that surplus animals can be removed before independent feeding.

It is important that the obligation to refine tissue sampling methods, where possible, is systematically addressed to ensure uptake of more refined methods and compliance with the Directive. There are non-invasive methods becoming available and these should be taken up where technically possible. When invasive methods are used for identification, these should provide surplus tissue for genotyping. In the light of the fact that tail biopsy, ear biopsy and removal of part or all of a digit remain the most commonly used methods in EU, inspections

should systematically address whether the most refined methods of identification and tissue sampling are being used. Since tail biopsy does not allow identification, it is unlikely that this method will be the most refined.

Question in the questionnaire *[voluntary question]*

** D - 3.5 Has the Working Document on Genetically Altered animals been made available to establishments housing or using genetically altered animals? Yes/No*

EU Guidance made available	
Yes	20
No	
n/a	2
(blank)	6
Total	**28**

22 Member States answered this voluntary question. Of these, 20 Member States have made this available, and the two answering n/a do not use genetically altered animals.

Question in the questionnaire *[voluntary question]*

** D - 3.6 Has additional official guidance on genetically altered animals been developed to facilitate implementation?*

** D - 3.6.bis If you consider this guidance helpful for other Member States to facilitate the implementation of the Directive, please provide web-address for the guidance, where available*

Additional guidance developed	
Yes	4
No	16
n/a	2
(blank)	6
Total	**28**

Four Member States have created additional guidance and websites have been provided in the detailed Member State summaries.

E. ENFORCEMENT

E.1. Authorisation of breeders, suppliers and users (Articles 20 and 21 of Directive 2010/63/EU)

Reporting obligation

"number of active authorised breeders, suppliers and users; information on suspensions or withdrawals of authorisations of breeders, suppliers and users and the reasons therefore"

Background

Directive provides in its Articles 20 and 21 the following:

"*Article 20*

Authorisation of breeders, suppliers and users

1. Member States shall ensure that all breeders, suppliers and users are authorised by, and registered with, the competent authority. Such authorisation may be granted for a limited period.

Authorisation shall be granted only if the breeder, supplier or user and its establishment is in compliance with the requirements of this Directive.

2. The authorisation shall specify the person responsible for ensuring compliance with the provisions of this Directive and the person or persons referred to in Article 24(1) and in Article 25.

3. Renewal of the authorisation shall be required for any significant change to the structure or the function of an establishment of a breeder, supplier or user that could negatively affect animal welfare.

4. Member States shall ensure that the competent authority is notified of any changes of the person or persons referred to in paragraph 2.

Article 21

Suspension and withdrawal of authorisation

1. Where a breeder, supplier or user no longer complies with the requirements set out in this Directive, the competent authority shall take appropriate remedial action, or require such action to be taken, or suspend or withdraw its authorisation.

2. Member States shall ensure that, where the authorisation is suspended or withdrawn, the welfare of the animals housed in the establishment is not adversely affected."

Analysis

Questions in the questionnaire
E - 1.1 Provide number of active authorised breeders, suppliers and users. The numbers in this table indicate the total number of active establishments authorised and having bred, used and/or supplied animals in the reporting year (not only those newly authorised in a given year)
** E - 1.2 Provide number of active establishments keeping non-human primates*
[voluntary question – requested for the purposes of assessing compliance with requirements for inspections under section E-2]

It is important to note in this context that the lower numbers during the first years reflect the fact that the Directive obligations had yet to be transposed in the national legislation in some Member States. The last Member State adopted national legislation only in the spring of 2015.

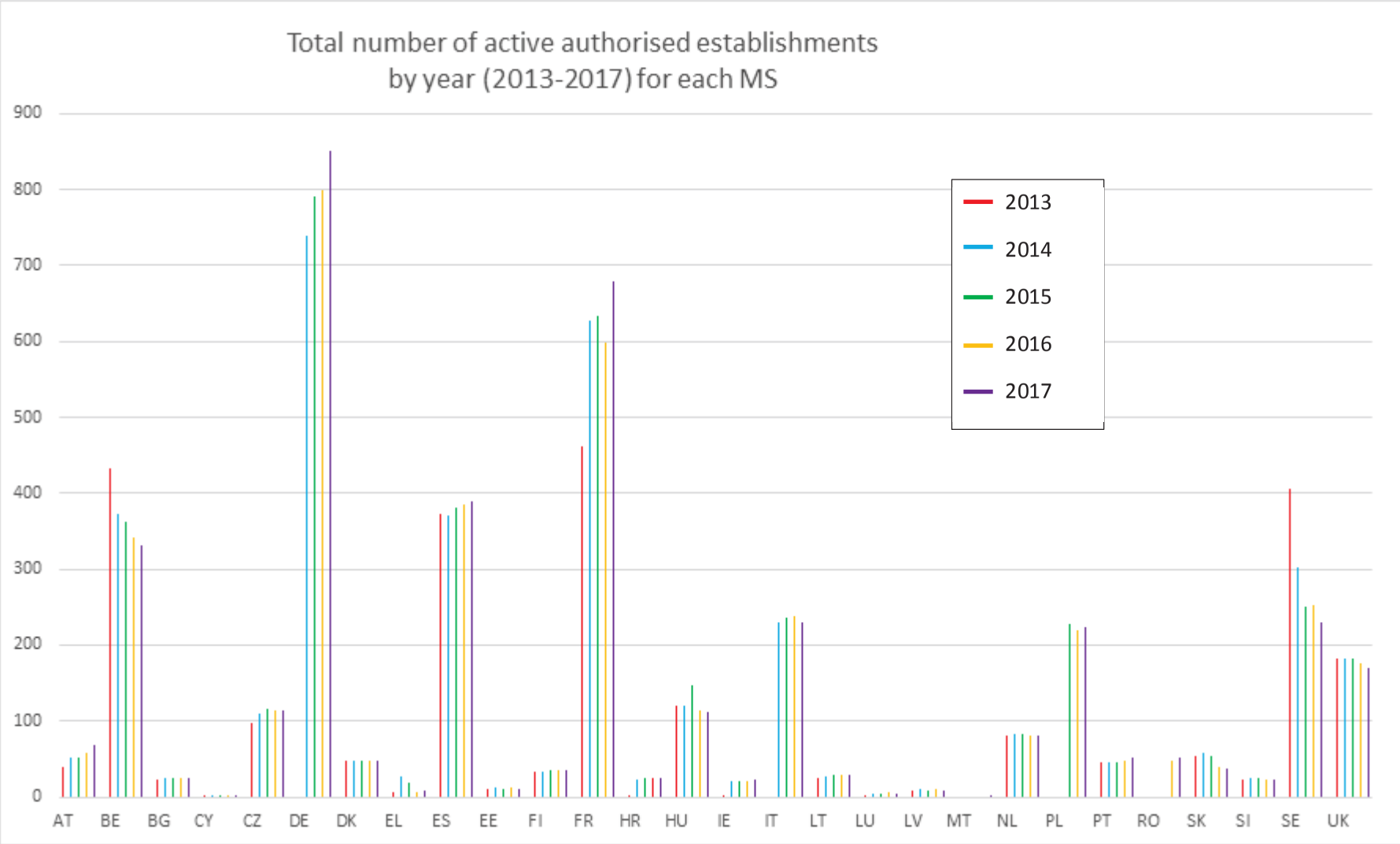
Not all Member States gave complete data for all columns, and some only the total numbers of breeders, suppliers and users combined.

Only half of the Member States using non-human primates answered the voluntary question on establishments housing non-human primates.

Total number of active breeders, suppliers and users authorised in the EU									
Year	1. Number of active breeding establishments (not using animals)	2. Number of active establishments authorised only to supply animals bred by others (not breeding /using animals)	3. Number of active establishments authorised to breed both and supply their own and those bred by others (not using animals)	4. Total number of breeders and/or suppliers (from columns 1 to 3)	5. Number of active establishments authorised to only use animals	6. Number of active establishments authorised to use and breed animals	7. Number of active establishments authorised to use and supply animal	8. Number of active establishments authorised to use, breed and supply animals	9. Total number of active establishments authorised to use animals (the total of columns 5 to 8)
2013	115	36	84	**696**	1,348	251	6	176	**1,781**
2014	180	40	97	**945**	1,354	1,035	7	205	**2,602**
2015	255	49	106	**1,044**	1,405	1,141	7	211	**2,772**
2016	257	51	104	**1,011**	1,354	1,156	10	220	**2,748**
2017	258	50	106	**1,093**	1,338	1,197	10	216	**2,769**

Total number of authorised breeders, suppliers and users in the EU (from columns 4 and 9)	
2013	2,477
2014	3,547
2015	3,816
2016	3,759
2017	3,862

Member State comparison of active authorised breeders, suppliers and users.



Withdrawals of breeders, suppliers and users

Question in the questionnaire

E - 1.3 Provide cumulative information covering years 2013-2017 on the suspensions or withdrawals of authorisation of breeders, suppliers and users and reasons thereof

21 Member States reported that no authorisations for breeders, suppliers or users had been withdrawn during the reporting period as a consequence of enforcement action.

A few reported that establishments had closed during this period but for reasons unrelated to compliance, such as lack of funding or loss of expertise. One Member States reported that a number of establishments closed due to their inability to meet the new requirements in Annex III on housing and care practices.

Two Member States reported that authorisations had been removed. In one Member State, one user was closed in 2014, one in 2016 and one in 2017, but no reasons were provided. In the other Member State, three authorisations were withdrawn, one due to water damage, one for failing to meet building requirements, and one where no application was received to continue.

Five Member States did not provide any information in response to this question.

E.2. Inspections (Article 34 of Directive 2010/63/EU)

Reporting obligation

"quantitative and qualitative operational information including criteria applied under Article 34(2) of Directive 2010/63/EU and proportion of unannounced inspections broken down by year"

Background

Directive provides in its Articles 4 and 13 the following:

> *"1. Member States shall ensure that the competent authorities carry out regular inspections of all breeders, suppliers and users, including their establishments, to verify compliance with the requirements of this Directive.*
>
> *2. The competent authority shall adapt the frequency of inspections on the basis of a risk analysis for each establishment, taking account of:*
>
> *(a) the number and species of animals housed;*
>
> *(b) the record of the breeder, supplier or user in complying with the requirements of this Directive;*
>
> *(c) the number and types of projects carried out by the user in question; and*
>
> *(d) any information that might indicate non-compliance.*
>
> *3. Inspections shall be carried out on at least one third of the users each year in accordance with the risk analysis referred to in paragraph 2. However, breeders, suppliers and users of non- human primates shall be inspected at least once a year.*
>
> *4. An appropriate proportion of the inspections shall be carried out without prior warning.*

5. Records of all inspections shall be kept for at least 5 years."

Analysis

Questions in the questionnaire
E - 2.1 Is the endorsed EU Inspection Risk Analysis Criteria used as the basis for risk assessment? Yes/No
E - 2.1.bis Please provide the criteria used for risk analysis in your MS (including web-address where the criteria can be found)

24 Member States confirmed using EU Inspection Risk Analysis Criteria as the basis for risk assessment. Three Member States gave other local criteria similar to the EU document, or with one stating that the system was in development.

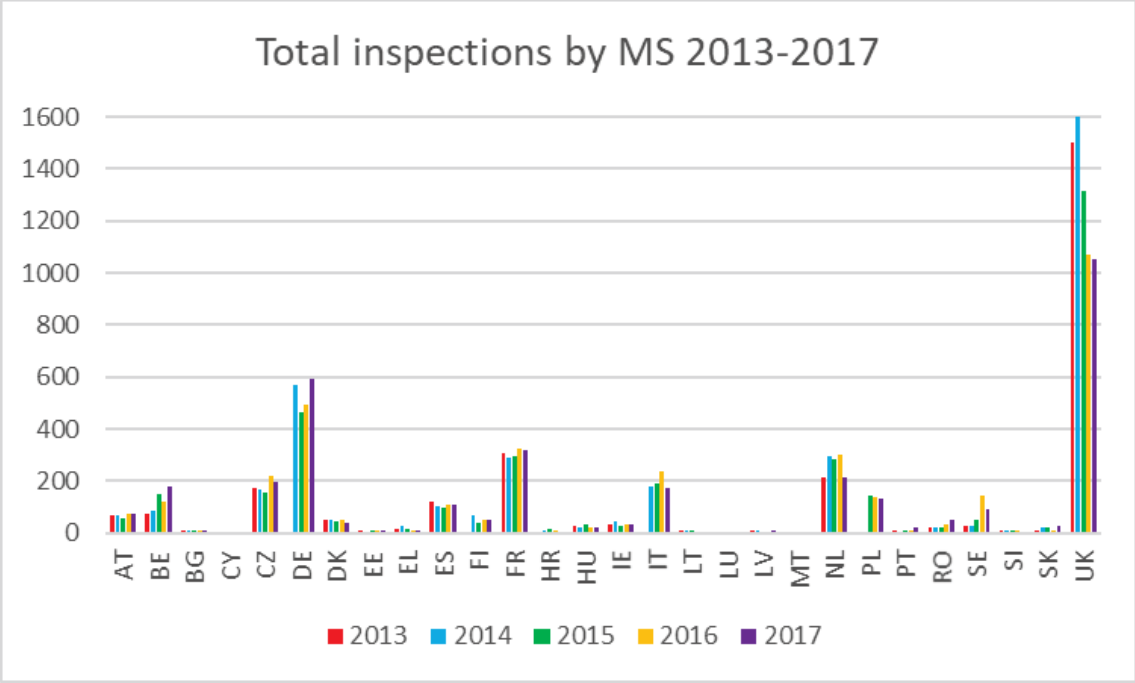
Several Member States made comment in other sections about the risk drivers for inspection including outcomes of previous inspections of the establishment; types of animals held especially use of special species, the number of animals kept and used, relating to that the severity, duration and frequency of the procedures carried out influence the inspection programme. Identification of any deficiencies, particularly if there is apparent resistance to change or any unwillingness to provide information requested are significant drivers for increased inspections.

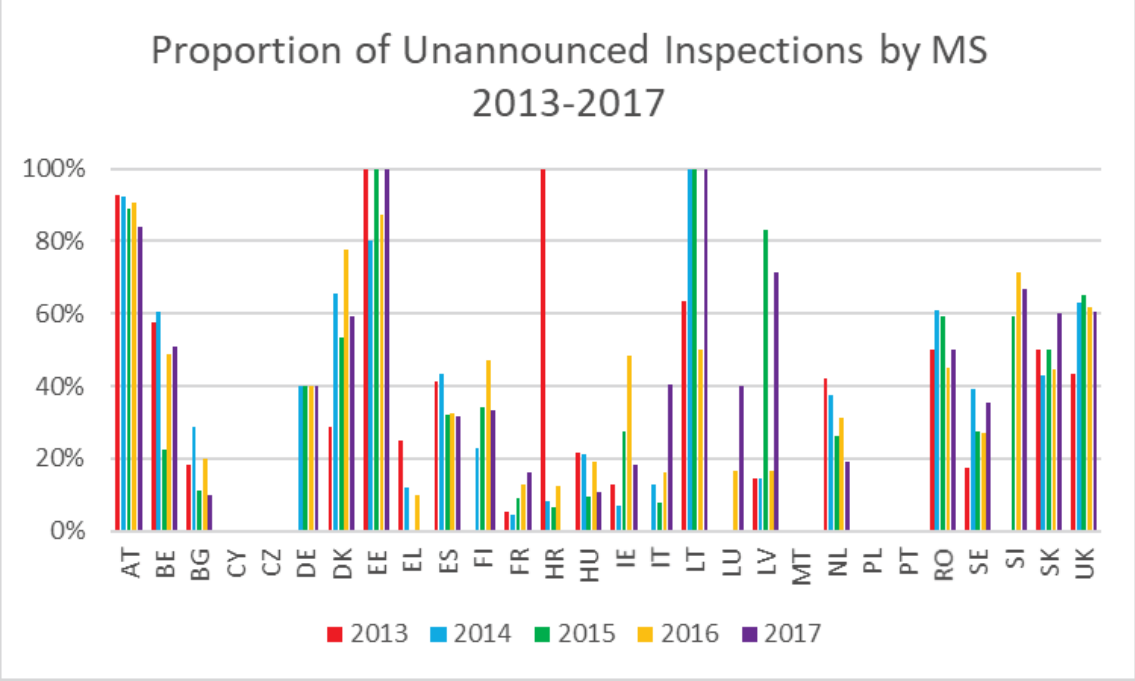
Questions in the questionnaire
E - 2.2 Are all new establishments inspected before an authorisation is granted? Yes/No
E - 2.2.bis Provide description on how the compliance with the provisions of the Directive is ensured as required in the second paragraph of Article 20(1)

27 Member States confirmed inspection of an establishment being necessary before granting an authorisation. Austria stated that in most cases this includes an on-site visit before authorisation is granted but not all new establishments were inspected before granting an authorisation.

Questions in the questionnaire
E - 2.3 Provide quantitative operational information on inspections including proportion of unannounced inspections broken down by reporting year
E - 2.4 Provide qualitative operational information on inspections carried out under Article 34. Qualitative operational information includes e.g. effectiveness in terms of impacts (such as declining trend in non-compliance); changes in risk profile of establishments; reduction in legal and administrative actions due to infringements. Explain unusual or outlying figures – in particular, if not meeting minimum requirements, make clear the actions being taken to meet these.
** E - 2.5 What information is made publicly available on inspection / enforcement? Please provide a web-address where any published material on inspections / enforcement may be found [voluntary information]*

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%





It is important to note in this context that the lower numbers during the first years reflects the fact that the Directive obligations had yet to be transposed in the national legislation in some Member States. The last Member State adopted national legislation only in the spring of 2015.

The Directive requires that one-third of user establishments should be inspected per year.

18 Member States have performed more inspections than on one-third of total number of user establishments for that Member State for all years since the transposition of the Directive. Other Member States appear not to have achieved this in some years. One Member States (Hungary) has performed fewer inspections than one-third of total number of user establishments for that Member State for all five years of this report.

All establishments breeding, supplying and/or using non-human primates must be inspected at least once per year. Member States which have non-human primates have performed more inspections each year than the number of establishments housing non-human primates. However, the reporting obligations do not allow for a conclusion to be made on whether there is compliance with this requirement specifically, that is to say, annual inspections in establishments housing non-human primates, even if total number of inspections was to exceed this.

Concerning unannounced inspections, five Member States have reported no unannounced inspections (Czechia, Cyprus, Malta, Poland and Portugal). Despite this, the total proportion of unannounced inspection in the EU since the Directive took effect seem to be relatively high, up to around 40%.

Inspections are carried out by a variety of persons, such as veterinarians, official experts. Several Member States made reference to the minimum numbers of inspections as stated in the Directive, that is to say one-third of all user establishments every year and all establishments housing non-human primates. One Member State also inspects all establishments using domestic carnivores annually.

The inspector is often accompanied by a representative of the establishment. In one Member State, all inspections are identified in order to give notice to this person, although most Member States did not report that this was necessary.

Several Member States stated aspects inspected including animal housing standards *inter alia* ventilation, temperature, lighting, noise, availability of feed and water, stocking densities, bedding, hygiene, enrichment, animal health and care, record keeping in projects, and whether procedures complied with authorisations of projects. The documents from the Animal Welfare Bodies, and the functioning of them were also included by some.

Several stated that the inspectors use a common check-list to ensure inspection of relevant issues.

Some communicated the result of the inspection back to the establishment and some included suggestions for improvement. One Member State has performed themed inspections aimed specifically at improving standards, and published summaries of common findings annually.

In cases where more serious issues were identified, Member States stated that administrative / legal procedures would be taken sometimes requiring improvement within a specified timeframe. Some Member States have identified a declining trend in non-compliance, as evidenced in their inspection reports.

One Member State has stated that centralising the duties of inspections has led to greater consistency and efficiency.

E.3. Withdrawals of project authorisation (Article 44 of Directive 2010/63/EU)

Reporting obligation

"information and reasons for the withdrawals of project authorisation during the reporting period"

It is important to note that no detailed, numerical data are required on withdrawals. Instead, Member States are required to provide information on reasons for withdrawals.

Background

Directive provides in its Article 44 the following:

> *"1. Member States shall ensure that amendment or renewal of the project authorisation is required for any change of the project that may have a negative impact on animal welfare.*
>
> *2. Any amendment or renewal of a project authorisation shall be subject to a further favourable outcome of the project evaluation.*
>
> *3. The competent authority may withdraw the project authorisation where the project is not carried out in accordance with the project authorisation.*
>
> *4. Where a project authorisation is withdrawn, the welfare of the animals used or intended to be used in the project must not be adversely affected.*
>
> *5. Member States shall establish and publish conditions for amendment and renewal of project authorisations."*

Analysis

Question in the questionnaire

E - 3 Provide cumulative information covering years 2013-2017 on the withdrawals of project authorisation, and reasons thereof

A few Member States commented in this section on refusals to grant authorities rather than removal of authorities after project authorisation. Other Member States commented on voluntary withdrawals by user or person responsible for project, for example when no funding is secured to conduct the work.

One Member State noted that projects were withdrawn as under the new legislation, projects were no longer required for killing and harvesting of tissues after death.

19 Member States reported that no project authorisations were withdrawn during the reporting period. In other Member States where numbers were provided (voluntarily), only a few (one to three) projects were withdrawn.

A variety of reasons were given:

- animal welfare concerns;
- poor experimental methodology/scientific design;
- use of higher numbers of animals than authorised;
- failing to provide statistical information on animal use;
- unsuitable facilities for the proposed animal work
- failure to provide the competent authority with reports on progress.

E.4. Penalties (Article 60 of Directive 2010/63/EU)

Reporting obligation

"information on the nature of infringements as well as legal and administrative actions resulting from those infringements during the reporting period"

It is important to note that no detailed, numerical data are required on penalties. Instead, Member States are required to provide **information on the nature of infringements**, including those leading to legal and/or administrative actions.

Question in the questionnaire *[voluntary question]*

** E - 4.1 Provide a general description of the main rules and steps governing penalties in your MS that will put into context the cumulative information provided below in section 4.2-4.4. Please note that administrative procedures may vary significantly between countries*

Although a non-mandatory question, 21 Member States provided some information on the structures under which breaches of the legislation are dealt with, and/or some indication of the penalties applied.

From the information provided, there is generally within the Member States a range of administrative and legal actions, which can be taken, and these are applied proportionately dependent on the nature of the infringement.

Typically, minor breaches will be dealt with administratively with timely, corrective action required by the transgressor.

Tariffs are escalated where there is reluctance or delays to the introduction of corrective measures, and, in particular, where avoidable animal suffering has occurred. In very severe cases, a number of Member States have the option of imprisonment as a sanction.

Analysis

Questions in the questionnaire

E – 4.2 Provide cumulative information covering years 2013-2017 on the nature of infringements

E – 4.3 Provide cumulative information covering years 2013-2017 on the nature of administrative action as a result of infringements

E – 4.4 Provide cumulative information covering years 2013-2017 on the nature of legal actions as a result of infringements

There were significant differences in the quantity and quality of information provided by Member States on infringements encountered, and administrative and/or legal actions imposed as a consequence of such infringements.

Three Member States (Estonia, Malta and Portugal) indicated that no infringements were recorded in the reporting period and two Member States (Italia and Latvia) indicated that there had been no cases severe enough to warrant administrative or legal action.

The remaining Member States provided information on the types of infringements that had been 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 (accommodation and care).

All reported a proportionate response was taken, dependent on the severity of the infringement.

The majority of infringements were dealt with by administrative means, requiring corrective measures be put in place to prevent recurrence. A number of Member States noted that follow up inspections were often made to ensure any 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 (United Kingdom) reported that (anonymised) information on infringements and actions were published annually.

Question in the questionnaire *[voluntary question]*

** E - 5 Has the EU Guidance on Inspections and Enforcement been made available to all inspectors? Yes/No*

EU Guidance made available	
Yes	25
No	1
n/a	2
(blank)	6
Total	**28**

Question in the questionnaire *[voluntary question]*

** E - 6 Has additional official guidance on Inspections and Enforcement been developed to facilitate implementation? Yes/No*

National guidance developed	
Yes	8
No	16
(blank)	6
Total	**28**

Question in the questionnaire *[voluntary question]*

** E - 6.bis If you consider this guidance helpful for other Member States to facilitate the implementation of the Directive, please provide web-address for the guidance, where available*

Provided links to websites are available in the detailed Member State summaries.

F. OTHER – ADDITIONAL VOLUNTARY QUESTIONS

Member States were invited to provide their views and comments on the implementation of the Directive, highlighting areas of difficulty, on well-functioning elements, on areas where further collaborative efforts could improve implementation.

Eighteen Member States provided comments for one or more of the questions.

F.1. Problematic areas for implementation of the Directive

Question in the questionnaire *[voluntary question]*

** F -1 Please provide here views on problematic areas for implementation of the Directive in your Member State*

Fifteen Member States responded to this question. Answers included:

- Ensuring sufficient expertise for Animal Welfare Bodies and other roles in small establishments.
- Provision for farm animal accommodation could be improved.
- Ensuring sufficient training for and trained staff for competent authority tasks, including for National Committee. This can lead to delays in meeting project authorisation deadlines.
- Availability of sufficient education and training courses can delay scientific work.
- Maintaining anonymity of non-technical project summaries in small Member States.
- The killing of animals for tissues and organs is not subject to authorisation, with only numbers reported in the five-year cycle.
- No common up-to-date database of available alternative methods.
- Where not in place under previous legislation, significant increase in costs and administrative burden to implement new requirements such as project authorisation

- Difficult to decide which animal has the lowest capacity to experience pain, suffering, distress or lasting harm (text replaced from Directive 86/609 "…involve animals with the lowest degree of neurophysiological sensitivity..").

F.2. Views on well-functioning elements of the Directive in your Member State

Question in the questionnaire *[voluntary question]*

** F - 2 Please provide here views on well-functioning elements of the Directive in your Member State*

Fifteen Member States responded to this question. Answers included:

- Inspection is easier due to defined standards and authorities.
- Project evaluation and authorisation – improved implementation of the Three Rs. Development of standardised project application and evaluation forms.
- Requirement for harmonised training and competence framework.
- Animal Welfare Bodies promoting and overseeing improved standards within establishment, including culture of care.
- Improved transparency – non-technical project summaries and annual statistical reporting.

F.3. Views on issues that would benefit from collaborative efforts to improve implementation of the Directive

Question in the questionnaire *[voluntary question]*

** F - 3 Please provide here views on issues that would benefit from collaborative efforts to improve implementation of the Directive*

Thirteen Member States responded to this question. Answers included:

- Continue to promote consistency in education and training requirements for all those with responsibilities under the Directive. Consider some sort of European certification of common standards. Central repository of "certified" training courses would be helpful.
- Guidance on good re-homing practices would be helpful.
- Provision of an easily searchable database for non-technical project summaries.
- Continue meetings of National Contact Points (Article 59) and National Committees (Article 49).
- Improved use of EC IT tools for sharing of Member States guidance material.
- Central, up-to-date database on alternative (Three Rs, in particular replacement) methods.
- Development of training courses for the competent authorities, evaluators, inspectors, etc. on their respective aspects and task (similar to DG SANTE's BTSF (*Better Training for Safer Food) programme)*.
- Promote consistency in requirements concerning genetically altered animals.

F.4. Any other additional comments concerning the implementation of the Directive

Question in the questionnaire *[voluntary question]*
** F - 4 Please provide here any other additional comments concerning the implementation of the Directive*

Eight Member States responded to this question. All of the responses are available in the Member State summaries.

- Nuances in transposition among Member States due to differing interpretations and an indication that interpretation of some of the terminology is not straightforward depending on local implementation. For example, in some Member States an establishment may have several 'user' authorisations, whereas in others one 'user' authorisation may include several facitilites.
- It was expressed that some time is needed without changes to the legislation, nor to its interpretation, to facilitate its correct application.
- A review of reporting of exemptions in the next five-year implementation report has been requested due to repetitive nature of exemptions and the likelihood of the reasons remaining the same from one reporting period to another.

G. COMMISSION ACTIVITIES TO FACILITATE THE IMPLEMENTATION OF THE DIRECTIVE

G.1. Transposition conformity checks

According to Article 61 of the Directive, the Member states were required to adopt and publish, by 10 November 2012, the laws, regulations and administrative provisions necessary to comply with the Directive.

A majority of Member states did not comply with this requirement and the Commission had, in 2013, to open infringements procedures (in accordance with Article 258 of the Treaty of the Functioning of the European Union) for non-communication of the transposition measures against 15 Member states[13]. Further to the subsequent adoption of the transposition measures, these procedures were closed and finally all Member States have transposed into their national law the Directive.

The Commission services carried out subsequently systematic, in-depth assessments of the conformity of the transposition measures in order to check whether these measures correctly transpose the provisions of the Directive. Since several instances of possible incorrect transpositions issues were identified, the Commission services entered into dialogue with all Member States in order to gather further explanations and information from them. The dialogue between the Commission services and the Member States gives a possibility to the Member States concerned to address identified shortcomings. Depending on the replies given by the Member States, the Commission has been able to successfully conclude the discussions with eight[14] Member States. Where the issues could not be addressed in the frame of this

[13] BG, DE, EL, ES, FR, IT, CY, HU, MT, NL, PL, PT, RO, SI and FI
[14] BE, IE, EL, HR, CY, LT, LU and MT

dialogue, the Commission decided to open several infringement procedures in accordance with Article 258 of the Treaty of the Functioning of the European Union.

By mid of October 2019, the Commission has opened 15[15] infringement procedures for non-conforming transposition of the Directive. Two[16] out of these 15 procedures could be successfully closed since the concerned Member States took the necessary measures. Further procedures may be launched against other Member States on the basis of the ongoing assessment of their replies.

G.2. Other activities to facilitate correct and comprehensive implementation of the Directive.

To achieve the aims of the Directive, a uniform understanding on the Directive's obligations and objectives across the EU is imperative. The European Commission has gone to great length to facilitate correct implementation of the Directive.

The European Commission hosts meetings of National Contact Points set up under Article 59 of the Directive twice a year to identify and discuss issues on implementation. These issues can be divided in three categories:

1. Questions related to correct interpretation of a legal term or requirement;
2. Questions related to concepts in the Directive.
3. Questions related to Member State administrative processes for implementing the Directive, including tools to reduce administrative burden;

For questions in the first category the Commission developed a Q&A document, which is published on the Commission web-site[17], and is being kept up to date.

Concerning questions related to concepts in the Directive, the Commission hosted several expert working groups, with experts nominated by Member States, science/academia, industry, animal welfare organisations and other specialist organisations (such as laboratory animal veterinarians, laboratory animal breeders, animal technologists). The objectives of these working groups were to develop EU guidance and common lines to topics of importance to harmonise their implementation.

The guidance documents, endorsed by the National Contacts Points of the Member States, are available in all community languages to make them accessible to widest possible audience. The current series of EU guidance consist of

- Project evaluation and retrospective assessment;
- Education and training framework;
- Severity assessment framework;
- Animal Welfare Bodies and National Committees;
- Inspections and enforcement.

[15] CZ, DK, DE, EE, ES, IT, LV, HU, AT, PL, PT, RO, SI, SK and FI
[16] EE and ES
[17] https://ec.europa.eu/environment/chemicals/lab_animals/interpretation_en.htm

Questions on administrative processes are discussed on a regular basis, encouraging sharing of good practice among Member States. Through discussions with Member States and other stakeholders, the Commission developed tools covering *inter alia*

- inspection risk analysis criteria and Aide Memoire;
- pre-formulated questions for building a project application template;
- recommended template for a non-technical project summary.

In addition, the European Commission together with Member States developed a common template for collecting and submitting statistical data under the Directive. This is to share resources and minimise the administrative burden.

The role of National Committees is important for the functioning of the Animal Welfare Bodies, and for advising competent authorities in matters dealing with the acquisition, breeding, care and use of animals. To aid their work, the Commission hosted two meetings of National Committees to explore areas of common interest and share good practice.

The review of the Directive, adopted in November 2017[18], identified problems in the quality and timeliness of the publication of non-technical project summaries of authorised projects. The Commission took the initiative to streamline and modernise reporting obligations resulting in adoption of amendments to the Directive through Regulation (EU) 2019/1010[19] in June 2019. These include setting up open access, searchable central EU databases for non-technical project summaries and statistical data, significantly improving transparency of animal use in the EU.

With additional funds provided by the European Parliament, the Commission was able to initiate an EP Pilot Project focusing on education, training and information sharing activities on the Three Rs. The project aims at expediting the development and validation of new alternatives, and the uptake of existing alternatives through better implementation of the Directive. This project will deliver six interactive eLearning training modules covering some of the key aspects of the Directive, such as on the severity assessment framework, project evaluation and how to search for non-animal alternatives.

Making these modules available to project applicants, project evaluators, inspectors and those working with animals, can have a significant impact in improving consistency of implementation of the Directive across the EU. The modules are expected to be finalised by the end of 2020.

Under the same project, funding was granted for the European Education and Training Platform for Laboratory Animal Science (ETPLAS), established on the basis of a recommendation in the EU Guidance on Education and Training Framework, to develop practical tools and criteria for the assessment of learning outcomes and competence of staff. The harmonised approach to competence assessment across the EU is expected to have a great impact on improving the competence of those working with the animals, in line with the aims of Directive obligations under Article 23.

[18] COM/2017/0631 final
[19] OJ L 170, 25.6.2019, p. 115–127